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LIGHTSheer™

Diode Laser System

A Practical Guide for Success

2002 – 2003

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Lumenis™ assumes no responsibility for parameters, techniques, methods or results in the use of high-power, solid state diode lasers for hair removal, pseudofolliculitis barbae, leg veins or benign pigmented lesion treatment. Operators must use their own clinical judgment and professionalism in determining all aspects of treatment,including: preoperative preparations, safety, treatment technique, proper settings, treatment intervals and post-treatment care.

Lumenis hereby advises that purchaser(s) are considered sophisticated customers and practitioners with the ability to fully and independently determine the suitability of the LightSheer™ system for their practice. Further, Lumenis assumes no responsibility for any representations by Lumenis' employees or representatives with regard to the performance of the LightSheer system or the suitability of the LightSheer system for Purchaser's practice and intended use, other than the written representations and warranties accompanying the LightSheer system.

LightSheer™ Practical Guide for Success: An Overview

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This clinical manual is designed to provide you with the critical background information necessary to use the system safely and effectively. Although the information provided here is comprehensive, it is intended to supplement, not replace, a formal training program in the clinical use of this device. It is not meant to replace good clinical judgment, experience or common sense when treating patients with unwanted hair, pseudofolliculitis barbae, superficial leg veins and/or benign pigmented lesions.

This manual contains the following sections:

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INTRODUCTION TO THE LIGHTSHEER FAMILY OF SYSTEMS

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The LightSheer Diode Laser System is indicated for the permanent reduction of unwanted hair (in all skin types – Fitzpatrick I-VI and tanned skin) and for the treatment of pseudofolliculitis barbae, superficial leg veins, and benign pigmented lesions. It was developed based on clinical trials performed at the Wellman Laboratories of Photomedicine at the Massachusetts General Hospital and the Laser and Skin Surgery Center of New York, under the direction of R. Rox Anderson, M.D. of Harvard Medical School.

Designed Specifically for Hair Removal

Developed as a hair removal system from the ground up, the near-infrared laser energy produced by the LightSheer system is selectively absorbed by melanin in the hair shaft as well as in the surrounding follicle, causing thermal destruction of several key anatomic sites, which retards or eliminates hair growth. During our research and development process, we discovered that there were five key specifications for hair removal that any system must address: wavelength, pulse width, spot size, continuous contact cooling and compression. LightSheer has been designed for optimal performance with each of these specifications, as described in the following table.

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SECTION 1. INTRODUCTION TO THE LIGHTSHEER FAMILY OF SYSTEMS

Specification	Explanation
Wavelength	The LightSheer wavelength has been optimally chosen at 800 nm to be long enough to penetrate deeply to the follicle to provide permanent effects in all skin types (including tanned skin), while avoiding unwanted heating of the epidermal melanin. Shorter wavelengths have difficulties providing epidermal protection in darker skin due to the higher absorption by melanin. Longer wavelengths have a lower melanin absorption and thus require much higher fluences to have similar effects to the LightSheer.
Pulse Width	The optimal pulse duration is approximately equal to the thermal relaxation time (TRT) of the hair follicle. For human terminal hair, TRT varies from about 10 to 100 milliseconds. Laser pulses much shorter than the TRT can cause explosive damage to the hair follicle and/or insufficient heating of the target structures (bulb and papilla) surrounding the hair shaft. Pulses much longer than the TRT may result in insufficient heating of the target. The LightSheer has been designed for a range of 5-100 milliseconds.
Spot Size	The spot size needs to be large enough so that after the light is scattered in skin tissue, a sufficient percentage of the energy still reaches the hair follicle. Spot sizes smaller than 7 mm diffuse rapidly and thus are unable to deliver effective fluences for permanent hair reduction. Depending on the LightSheer model, spot sizes will be either 9 mm or 12 mm.
Continuous Contact Cooling	Cooling protects the epidermis, provides an anesthetic affect, and permits the use of higher fluences for more effective treatments. The LightSheer uses the patented ChillTip™ sapphire tip to provide contact cooling prior to the pulse, as well as removing heat generated in the epidermis during the laser pulse. It consists of a cold sapphire crystal through which the laser energy is focused. Its cooling action protects the epidermis from thermal damage, while the lens itself converges the laser light to deliver a high dose of energy deep into the targeted tissue. The ChillTip system also provides a more consistent cooling protection than disposable solutions such as gel or cryogen spray because it provides cooling before, during, and after the pulse of laser light.
Compression	Compressing the skin as it is treated brings the hair follicle closer to the surface of the skin. Compression also squeezes blood out of small vessels in the superficial dermis, removing oxyhemoglobin which can compete for light energy with the melanin target in hair. The LightSheer ChillTip is uniquely shaped to specifically take advantage of compression.

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INTRODUCTION TO THE LIGHTSHEER FAMILY OF SYSTEMS

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A Family of Systems

The LightSheer family currently consists of three models:

- The LightSheer XC is the top-of-the-line system. With its 2 Hz repetition rate, 12 X 12 mm spot size, and 60 J/cm^2 maximum fluence, it provides the fastest coverage of any laser in the market for quick patient turnaround.
- The LightSheer ET is equipped with a 2 Hz repetition rate and 60 J/cm^2 maximum fluence.
- The LightSheer ST is the standard model, with a maximum repetition rate of 1 Hz and a maximum fluence of 40 J/cm^2. Both the ET and ST models are equipped with a 9 X 9 spot size and are compact and portable to facilitate sharing among offices.

Other models of the LightSheer have been purchased in the past. Their characteristics are identified below:

LightSheer Model	System Characteristics
XC	2 Hz, 60 J/cm^2, 12x12 mm spot size
ET	2 Hz, 60 J/cm^2, 9x9 mm spot size, Tabletop Console
ST	1 Hz, 40 J/cm^2, 9x9 mm spot size, Tabletop Console
EC	2 Hz, 60 J/cm^2, 9x9 mm spot size, Single Piece Console
SC	1 Hz, 40 J/cm^2, 9x9 mm spot size, Single Piece Console
EP	2 Hz, 60 J/cm^2, 9x9 mm spot size, Portable Separable Consoles
SP	1 Hz, 40 J/cm^2, 9x9 mm spot size, Portable Separable Consoles

Section 1.
Introduction to the LightSheer Family of Systems

SECTION 2.
LASERS AND LASER ENERGY

The word ***LASER*** is an acronym that stands for ***L***ight ***A***mplification by the ***S***timulated ***E***mission of ***R***adiation. In order to understand how lasers work and how they are used medically, it is important to have a basic understanding of light, how it is produced, and how it behaves. This section provides a basic introduction to these topics.

SECTION 2.
LASERS AND LASER ENERGY

Light

Light is a form of electromagnetic radiation (not nuclear radiation; just light). It is produced when electrons emit (lose) energy. Whether the source is the sun, an incandescent bulb or a diode laser, light is generated when electrons emit energy in small packets known as **photons**.

Although photons are usually considered to be discrete particles, they travel through space as electromagnetic waves, and the amount of energy they carry corresponds to their wavelength. The shorter the wavelength of a photon the higher its energy.

The color of visible light is determined by its wavelength. For example, red light has a wavelength around 700 nanometers, while violet light has a wavelength around 400 nm. White light consists of a mixture of all of the other colors.

Visible light comprises only a small part of the entire electromagnetic energy spectrum (Fig. 2-1), and some medically important lasers produce invisible light. For example, the carbon dioxide laser, widely used in dermatology, produces light in the infrared portion of the spectrum and is typically coupled with a low-powered, visible laser for proper aiming.

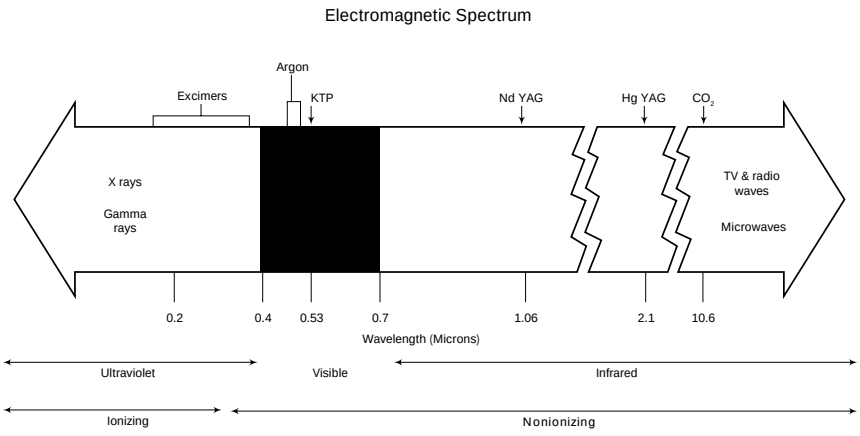

Figure 2-1. The Electromagnetic Spectrum. Visible light is roughly in the center of the spectrum. X-rays and gamma rays are of very high energy and short wavelength. Radio waves and microwaves are of low energy and long wavelength.

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Atomic Energy Levels and Spontaneous Emission

Atoms consist of a small, dense, positively charged nucleus orbited by one or more electrons. Each electron carries a certain amount of energy, and can be said to reside in a particular energy level. The electrons in the levels closest to the nucleus have the lowest energies, and electrons farther away have higher energies (Fig. 2-2).

Electrons normally occupy the lowest available levels. In such a case, the atom is said to be in the **ground state**. If an electron absorbs energy (from light or radio waves, for example) it will move to a higher energy level and is said to be in an **excited state**.

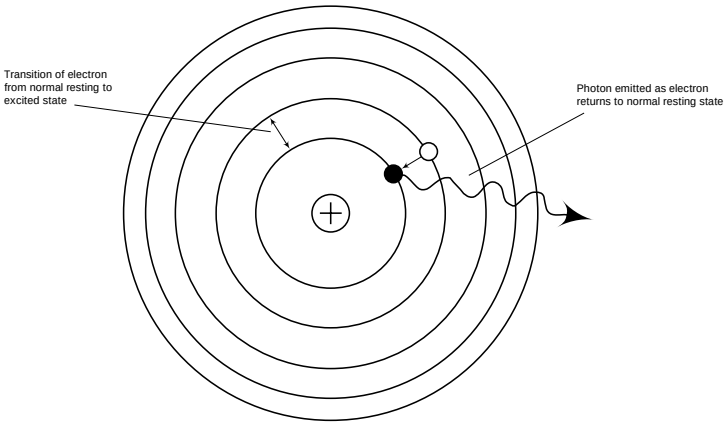

Figure 2-2. Atomic Energy Levels and Spontaneous Emission of Light. Electrons move from normal to excited states when they absorb energy. The electron may then emit a photon to return to its normal state.

An important characteristic of all matter is that it tends to move to the lowest energy state possible. Water runs downhill; electricity runs to ground. Thus electrons in excited states quickly lose their additional energy to return to their resting levels. The energy can be converted to heat or released as a photon. Release of such a photon is called **spontaneous emission**.

Spontaneous emission is the process by which fluorescent lights and neon signs work. An electrical current is used to stimulate electrons in the gas to jump to higher energy levels, and light is produced when the electrons return to lower levels.

Another characteristic of matter that makes lasers possible is that only certain, discrete energy levels are allowed in atoms. To move to a higher level, the electron must absorb the precise amount of energy

corresponding to the difference between two allowable levels. If light is being used to excite the electrons, only photons with the exact amount of energy necessary will be absorbed. If the photons have too little or too much energy, they will simply pass through or bounce off the atom.

Stimulated Emission

In 1917, Albert Einstein published a paper on the interaction between light and matter that provided the theoretical basis for lasers (and later won him a Nobel Prize). In the paper, Einstein theorized that a photon released from an electron in an excited state could stimulate another electron in a similarly excited state to release an identical photon.

For example, if you have a population of atoms in a ruby crystal, the majority of the atoms will normally be in the ground state. But they can be excited using a high-intensity white light like that produced by a xenon flash-lamp. With the right amount of external stimulation, more of the atoms will be in an excited state than the ground state, a condition known as a **population inversion**.

While in this state, one of the atoms in the crystal spontaneously emits a photon as its electron returns to a lower energy level. Traveling in a random direction, this photon interacts with another excited atom. Because the two atoms have the same allowable energy levels, the photon triggers the second atom to release another photon, while it continues on its way unchanged. The two photons are the same wavelength (color) because both photons have exactly the same amount of energy. They also have the same direction and phase (their waves line up). In essence, one photon has become two. This process is called **stimulated emission** (Fig. 2-3).

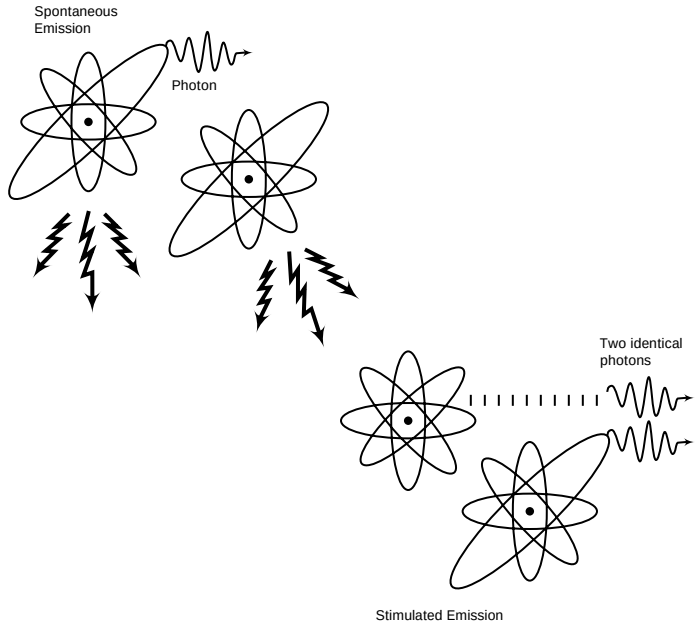

Figure 2-3. Spontaneous vs. Stimulated Emission. In spontaneous emission, photons are emitted in random directions from excited atoms. In stimulated emission, the excited atom emits a photon of the exact same wavelength, direction, and phase as the triggering photon.

Light Amplification by Stimulated Emission

Stimulated emission is the engine for producing laser energy, but by itself it is not sufficient. In the model described above, the amplified photons travel in random directions depending on the direction of the triggering photon, and more importantly, the amplification stops when the photons leave the crystal (Fig. 2-4a). Both problems are solved by placing mirrors on the ends of the long axis of the crystal (Fig. 2-4b). Photons traveling along the axis are reflected back into the crystal, continuing the chain reaction, while photons traveling in other directions leave the crystal without further amplification. One of the two mirrors is made to allow a small percentage of the light to leak out, and the resulting beam is focused with lenses and is emitted from the laser.

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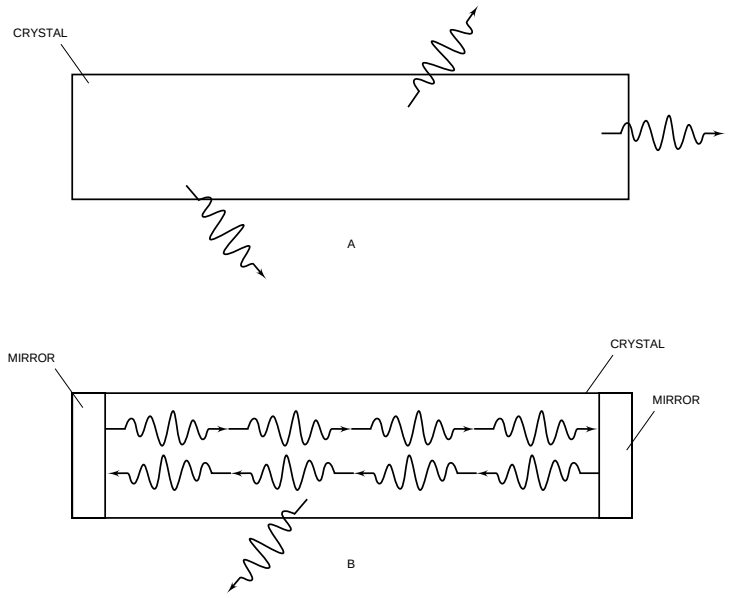

Figure 2-4. Amplification of Stimulated Emission. a) Amplification stops as photons leave the crystal in random directions. b) Amplification along the long axis continues when mirrors are placed at both ends of the crystal.

Characteristics of Laser Light

Laser light has three unique characteristics that are important to its use. Laser light is:

- monochromatic.
- collimated.
- coherent.

The light produced by a laser is **monochromatic**; that is, it consists of photons of a single wavelength (or a very narrow band of wavelengths). This characteristic gives a laser its medical specificity. For example, the LightSheer Diode Laser produces light with a discrete wavelength around 800 nm. This color of light is well absorbed by the pigment melanin in the skin and hair follicles, and significantly less so by cells without melanin. Because the light produced by the laser is monochromatic, it allows the operator to specifically target the laser energy to melanin-containing cells, reducing collateral damage to nearby, non-pigmented cells.

A second important characteristic of laser light is that it is **collimated**, that is, all of the rays are traveling parallel to each other in a single direction, with very little divergence even over long distances.

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Light produced by a point source such as an incandescent bulb radiates out in every direction three-dimensionally. Because of such rapid divergence, the light's intensity falls off rapidly, even over short distances. Collimation of laser light allows its energy to be focused into intense beams that cannot be produced any other way. Although the light emitted by a laser diode is more divergent than that emitted by some other lasers, it is still much more collimated than incandescent light.

The final important characteristic of laser light is its **coherence**; that is, its light waves are all in phase in both time and space. This characteristic allows laser light to carry information (e.g., fiber optic transmission of computer or voice data) and to produce three dimensional images (holograms).

Components of a Laser

A typical laser has three components: an active medium (the substance that actually lases), a "pumping" system that provides the energy to excite the atoms and an optical (or resonating) cavity bounded by the mirrors that contain the chain reaction of stimulated emission (Fig. 2-5).

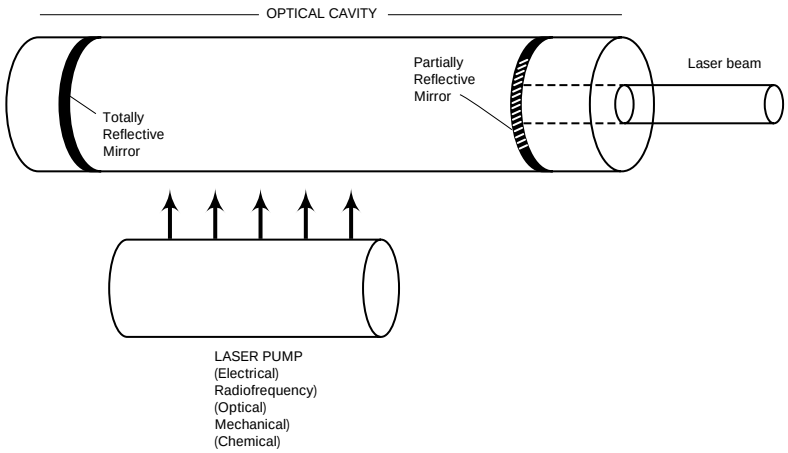

Figure 2-5. Components of a Typical Laser. The pumping system provides energy to stimulate the electrons in the active media and the optical cavity, bounded by parallel mirrors, contains the light amplifying chain reaction.

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Many different substances can be made to undergo stimulated emission to produce laser light. They include solids (e.g., crystals, semiconductors), liquids (e.g., organic dyes), or gases (e.g., carbon dioxide). To be effective as a lasing medium, a substance must not significantly absorb the wavelength of light being produced, and the atoms in the medium must have a **metastable state**, a state in which an electron can remain in an elevated energy level for a short period of time before destabilizing and emitting a photon. A metastable state is important because the excited electron needs time to interact with the triggering photon before decaying.

Technological advancements have made the diode laser systems the preferred laser technology for commercial use. Diode laser technology offers several advantages over older laser technologies. Diode lasers are more rugged and reliable (they are designed to be durable and require minimal maintenance). For example, with the LightSheer's design, the mirrors rarely get misaligned, a common disadvantage with many older laser technologies.

Diode laser technology also allows laser hair removal systems to be more compact and efficient that older laser technologies. For example, the LightSheer ET and ST models are quite portable because of their compact size and weight. Yet, they are efficient units that are able to convert 30-50 percent of the electrical power into laser light, compared to older laser technologies that can only covert 2-10 percent of electricity into laser light.

In addition to medical applications, diode lasers can be found in common products such as laser printers, CD-ROM drives, DVD players, barcode scanners and laser pointers, just to name a few.

The wavelength of the laser light depends on the characteristics of the active medium and, by choosing an appropriate medium, lasers can be built to emit over a wide range of the electromagnetic spectrum. For example, a carbon dioxide laser emits in the infrared, argon lasers emit in the blue-green portion of the visible spectrum, and excimer lasers (containing mixtures of gases) emit in the ultraviolet (Fig. 2-6).

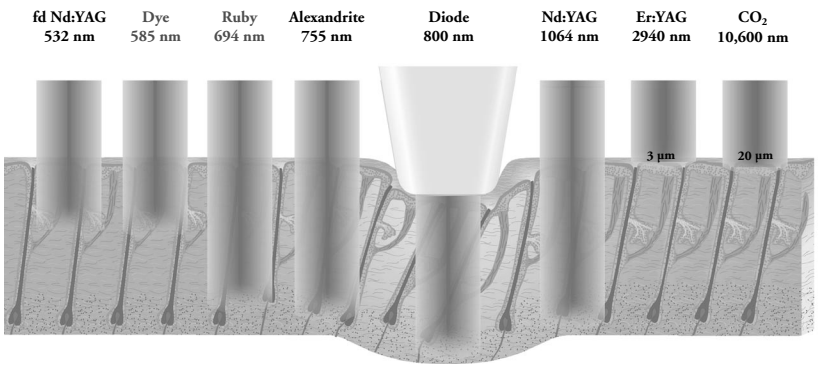

Figure 2-6. Wavelengths of Light Emitted by Common Lasers. The laser in the LightSheer Diode Laser System emits radiation at approximately 800 nm into the tissue.

The pumping system of a laser can use high voltage electricity, high intensity light, radio waves, or one of several other sources. Optical pumping uses photons to transfer energy to the active medium. In this case the optical source must provide photons which correspond to the allowed energy levels in the atoms of the lasing material.

As described earlier, the optical cavity plays a critical role in allowing amplification of light to occur after stimulated emission. The mirrors on either side of the cavity must be precisely aligned for the light beams to move parallel to the long axis and remain in the cavity.

Semiconductor Diode Lasers

The energy emitted by the LightSheer System is produced by multiple arrays of semiconductor diodes. Diodes are essentially one-way valves for electricity. That is, they let electrical current flow through a circuit in one direction, but stop current from flowing in the opposite direction. Diodes were first made from vacuum tubes and later from semiconductor materials such as silicon and gallium.

When an electron flows through a semiconductor laser, it emits energy in the form of a photon. Just as with other solid-state lasers, that photon in turn can stimulate another excited electron to release an identical photon, starting the process of stimulated emission. Mirrors on the ends of the optical cavity keep the chain reaction going.

Diode lasers are usually pumped by an external current that

stimulates the electrons in a semiconductor into an excited energy state (Fig. 2-7). The active region of the laser is the junction between an electron-rich (n-type) semiconductor and an electron-poor (p-type) semiconductor. The mirrors are formed by either the cleaved surfaces of the semiconductor crystal, or these surfaces may be optically ground, polished and coated. These mirrored surfaces are part of the diode and do not extend like the lasers described earlier.

The LightSheer System contains laser diode bars cleaved from a wafer of aluminum gallium arsenide (Fig. 2-8). The bars are typically 1 cm in width, have a gain length of typically 1 mm and a thickness of about 0.1 mm. Each bar has from 19 to 25 individual emitters.

Because each individual diode produces a relatively small amount of laser energy, they are often coupled into arrays. For example, every LightSheer handpiece contains five arrays, each typically containing 14 or 20 bars, which together generate at least 1,600 watts of peak power to the tissue.

In the LightSheer handpiece, the output of each of these individual diode lasers is combined into a single beam using a prism assembly that feeds into the sapphire tip. This condenser concentrates the energy from the arrays into a smaller area, permitting the LightSheer to achieve high fluences, and it produces a very uniform energy intensity beam at the output surface.

Sapphire is used for the tip because it has outstanding thermal conductivity (it removes heat from the skin very efficiently both before and during a laser pulse) and its hardness (second only to diamond) makes it nearly impossible to scratch.

Diode lasers are attractive also because they are compact and portable, they do not require special electrical supplies (i.e., they run on standard electrical current), and they do not require elaborate cooling or ventilation systems.

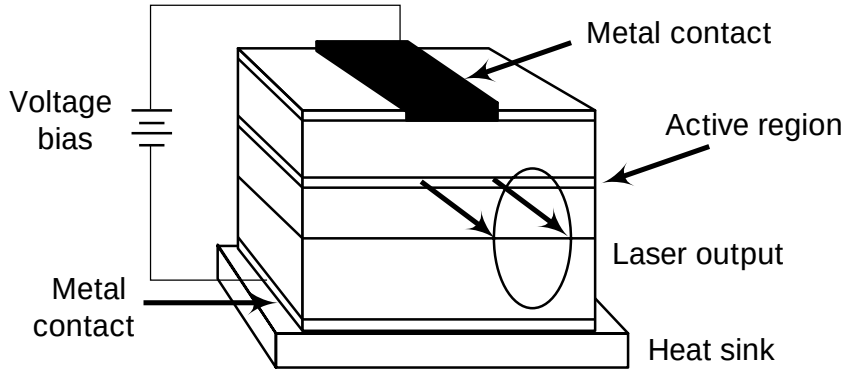

Figure 2-7. Semiconductor Diode Laser Schematic. An external current is used to create a voltage bias across the semiconductor. Electrons jump from the n-type semiconductor to the p-type semiconductor, emitting a photon. These photons drive the chain reaction that causes light amplification and production of the laser beam.

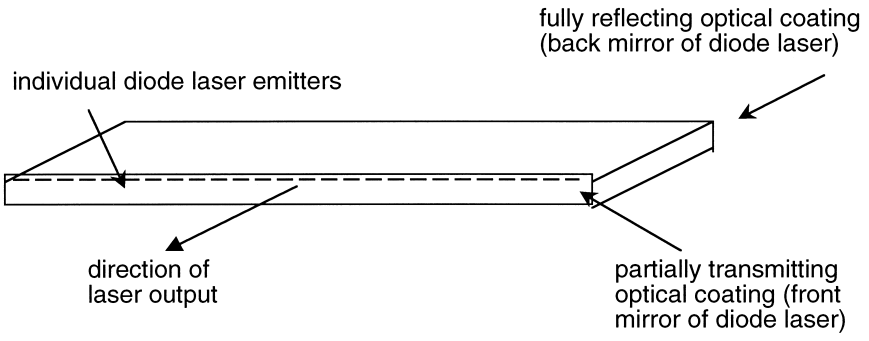

Figure 2-8. Structure of a Laser Diode Bar. Individual laser emitters are grown on a silicon wafer similar to the production of integrated circuits and computer microprocessors. The bars are coupled into laser arrays, and the individual emissions are focused through a prism assembly to produce a uniform beam.

SECTION 2.
LASERS AND LASER ENERGY

Modes of Laser Operation

Lasers can be designed to operate in different time modes, based on the rate at which energy is delivered.

- **Continuous wave** lasers produce a continuous beam of energy.
- **Pulsed** or normal mode lasers generally have pulse durations of a few hundred microseconds to tens of milliseconds.
- **Q-switched lasers** have a built-in delay that allows the active medium to store potential energy that is released in a massive burst on the order of a few nanoseconds long. As a result, Q-switched lasers have very high peak power output.

A laser's mode is chosen based on the anticipated use of the laser and the peak energy requirements. Some lasers can be operated in more than one mode.

SECTION 3.
INTERACTION OF LASER ENERGY WITH TISSUE

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Lasers are medically useful, because laser energy interacts with tissue in specific ways depending on the nature of the laser light and the characteristics of the target tissue. This section addresses these interactions, with special focus on how the interaction of laser energy and its target tissue are exploited for the treatment of unwanted hair, superficial leg veins and benign pigmented lesions. (For more information on these topics see the reprint following this section entitled: Illumination Geometry: *The Importance of Laser Beam Spatial Characteristics.*)

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SECTION 3. INTERACTION OF LASER ENERGY WITH TISSUE

Selective Photothermolysis

The LightSheer Diode Laser System is designed to remove unwanted hair and treat leg veins through **selective photothermolysis**. The process involves production of intense light pulses at wavelengths, pulse energies and pulse durations that cause the desired targets (hair follicles or oxyhemoglobin in the blood) to heat up sufficiently to destroy them without unnecessary damage to surrounding tissue. The theory of selective photothermolysis was developed and confirmed by clinical research done in the 1980s, in large part by Dr. Anderson and Dr. Parrish at the Wellman Laboratories at Harvard Medical School.

Selective photothermolysis is a balancing act. In treatment of unwanted hair, superficial leg veins and benign pigmented lesions, the structure that initially absorbs the laser energy is not necessarily the tissue targeted to be destroyed. The hair shaft absorbs most of the laser energy in treating unwanted hair, but that heat must be transferred to the follicle to prevent regrowth. Similarly, blood within superficial veins absorbs most of the laser energy, but it is the epithelial lining of the blood vessels that must be destroyed to clear the veins. And with benign pigmented lesions, we are targeting the melanin-producing cells of varying sizes. So, for treatment to be effective, heat transfer must take place, but allowing too much heat transfer can cause unwanted damage to adjacent tissues.

The theory of selective photothermolysis predicts that thermal injury can be confined to a given target if it is treated with the proper wavelength of light, proper pulse energy, and proper pulse duration.

Wavelength is especially important when the target structures and the surrounding tissues absorb light energy of different wavelengths. In terms of treating unwanted hair, the hair shaft as well as key structures within the follicle contain melanin, while surrounding cells in the dermis do not. So a wavelength of light energy absorbed by melanin but not by water (e.g., the 800 nm energy produced by the LightSheer System) will heat the hair shaft and follicle while not appreciably heating other cells in the dermis.

Of course, the epidermis does contain melanin, and it will be heated by laser energy used to heat melanin-containing cells in the hair shaft and follicle. In this case, the **pulse duration** (pulse width) is the key factor in being able to destroy the follicle without excessive damage

to the epidermis. Because the epidermis has a higher surface area-to-volume ratio than the follicle, it cools off much more quickly. In other words, its thermal relaxation time (TRT) is much shorter. The TRT of the epidermis is on the order of a few milliseconds (ms), compared to 10-100 ms for the hair follicle. Using a pulse duration longer than the TRT of the epidermis, say on the order of 20-30 ms in fair colored skin, allows heat to dissipate from the epidermis while it is still building up within the hair shaft and follicle. Longer pulse widths (as well as active cooling discussed below) are especially important with darker skin types. Clinical studies have shown that a 100 ms pulse width is effective at safely treating people with darker skin types despite the large amount of melanin in the skin. With a pulse duration and energy chosen properly for a particular skin type, the follicle can be destroyed with minimal heat damage to the epidermis.

Pulse duration is also a key parameter in maximizing the effectiveness of hair removal. The optimum pulse duration is approximately equal to the TRT of the hair follicle. Laser pulses much shorter than the TRT of the follicle cause insufficient heating of the target structures surrounding the hair shaft. Pulse widths much longer than the TRT may cause non-selective damage to the surrounding tissue.

To further reduce the risk of heat damage to the epidermis, the LightSheer System employs an **active cooling** system. The ChillTip handpiece contains an actively cooled sapphire lens that removes heat from the epidermis before and during the laser pulse. It is also designed to allow compression of the skin during treatment. Compression helps to displace blood from the tissue, reducing the amount of the chromophore oxyhemoglobin present. Longer pulse durations in combination with the active cooling and compression provided by the LightSheer System represent the state-of-the-art in epidermal preservation.

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SECTION 3. INTERACTION OF LASER ENERGY WITH TISSUE

Types of Interactions

When laser light is focused on human tissue, the energy can be reflected, scattered, absorbed or transmitted through the tissue (Fig. 3-1).

Reflection

As the skin is illuminated, a small fraction of the light is reflected from the skin. Reflection has little practical importance except as a safety concern. Because near-infrared laser energy can pass through the cornea and vitreous fluid of the eye, it can reach the retina and cause ocular injury. (Safety issues with laser use are covered in detail later in this guide.)

Transmission

Similarly, transmission of laser energy through the skin is generally not an important concern when using near-infrared laser light, because most of the light is absorbed before it can penetrate to sensitive underlying structures.

Scattering

After taking into account reflection and transmission, about 93% to 96% of energy shined on the skin is scattered or absorbed. Scattering is a process that reduces the amount of laser energy that can be directed at the target tissue and increases the amount of collateral tissue that receives unintended radiant energy. The penetration of laser light of the wavelengths used routinely for hair removal , leg vein treatment and benign pigmented lesions is determined primarily by the amount of scattering that occurs in the tissue.

Several factors affect the amount of scattering involved in a laser–tissue interaction, including the diameter (spot size) of the laser beam, the type and amount of laser energy applied and characteristics of the target tissue.

Absorption

Absorption of radiant energy is the key interaction between laser light and tissue that makes laser treatment work. Through absorption, laser energy is converted to heat, which then causes thermal destruction of the targeted structures within a tissue. The amount of radiant energy that will be absorbed by a tissue depends on characteristics of both the

laser and the tissue. Because of the importance of absorption in the clinical use of the LightSheer Diode Laser System, we will cover these factors in some detail here.

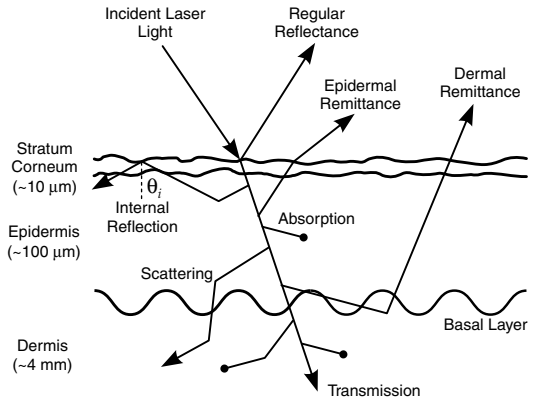

Figure 3-1. A Schematic Representation of Laser-Tissue Interactions.

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SECTION 3
INTERACTION OF LASER ENERGY WITH TISSUE

Characteristics of Laser Energy that Affect Absorption

The amount of radiant energy that will be absorbed by a tissue depends in part on characteristics of the laser, specifically wavelength of the light, the power density of the laser pulses, the energy distribution of the laser beam and the duration of each pulse.

Wavelength

The wavelength of the laser energy is a key parameter that affects the interaction between the laser and the tissue. For example, carbon dioxide lasers produce infrared light energy that is highly absorbed by water. Because tissues in the body consist mostly of water, the laser energy produced by the CO_2 laser is non-specifically absorbed by most tissues and is effective at vaporizing and cutting through whatever tissue with which it comes in contact. In contrast, KTP lasers produce a green light that is not well absorbed by water but is well absorbed by oxygenated hemoglobin in the blood. Consequently, the KTP laser is effective at treating vascularized lesions (e.g., hemangiomas) but is not effective for resurfacing or other conditions for which the CO_2 laser is indicated. This specificity between the absorptive characteristics of the target tissue (discussed in more detail below) and an appropriate wavelength of laser light provides the basis for the balance between efficacy and safety of laser treatment.

Energy Density

In addition to wavelength, the energy of the laser and the diameter of the beam also influence amount of laser energy absorbed by the tissue. The **energy density** (also known as fluence) of a laser is measured in Joules/cm^2.

Skin is considered a predominantly scattering medium. In other words, photons penetrating the skin will most likely be scattered multiple times before being absorbed. Both the loss of scattered photons and the spreading of the beam reduce the intensity of the radiation as it penetrates into the tissue. Conversely, internal reflection of photons at the skin surface may increase the intensity of radiation in the skin. In general, absorption of laser energy increases with higher applied energy densities.

The laser beam spot size can also affect the depth of penetration of the light energy. In a highly scattering medium such as skin, light

diffusion at the edges of the beam causes spreading of the energy as it penetrates into the tissue. As a consequence, a larger spot size (incident beam) results in a higher energy density at a given depth. This effect is illustrated schematically in Fig. 3-2, where the shaded region indicates the extent of the higher fluence area as indicated by the higher density of light. Fig. 3-3 shows actual calculated fluence profiles for flat 3-mm and 10-mm diameter beams of equal fluence using typical skin parameters for wavelengths of 650-1100 nm. As shown in the figure, there is considerable spreading of the smaller, 3-mm beam weakening the beam and limiting its penetration. With the larger beam, the probability of scattering is somewhat lower. Thus the concentration of light along the beam path of a relatively large size beam will remain relatively high resulting in deeper penetration into the tissue (Fig. 3-4).

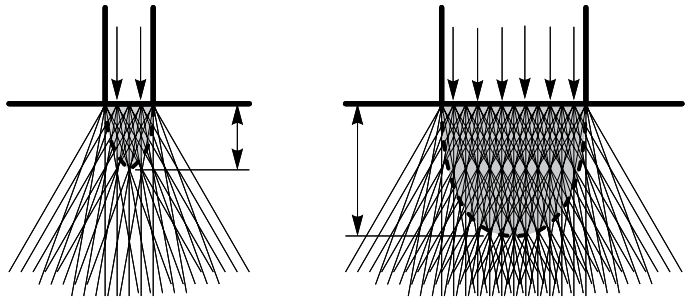

Figure 3-2. Spot Size Depth and Penetration. Because of increased internal scattering, a laser with a larger effective spot size will penetrate deeper than a laser with a smaller spot size.

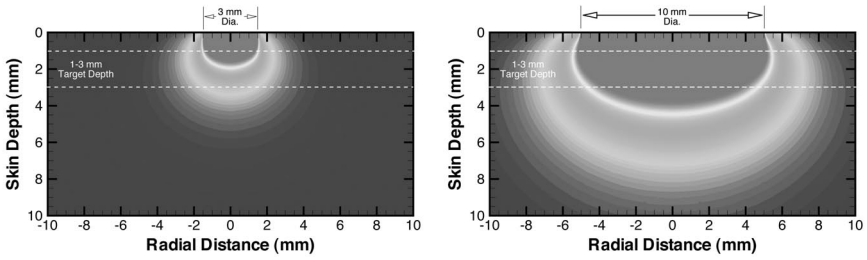

Figure 3-3. Calculated Penetration for 3- and 10-mm Spot Sizes. Calculated penetration of laser energy in the range of 650-1100 nm using typical skin parameters.

SECTION 3
INTERACTION OF LASER ENERGY WITH TISSUE

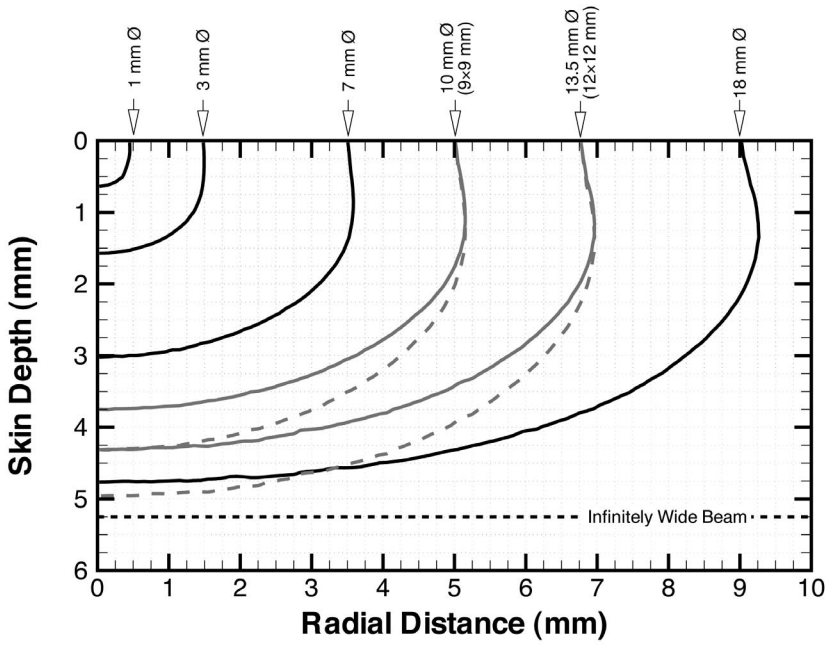

Figure 3-4. Effect of Laser Beam Diameter (spot size) on Penetration. The dashed lines indicate the estimated increase in the effective depth of penetration as a result of compression.

Energy Distribution

As one might expect, the energy profile within the laser beam also affects the penetration into the skin. Hair removal laser beams have energy distribution profiles that differ dramatically. Some lasers (e.g., LightSheer) produce flat beams in which the energy is evenly distributed over its entire area. Some other lasers produce energy that is more intense in the center of the beam than at the edges. This type of energy profile is called a gaussian profile (Fig. 3-5).

In general, a flat beam profile produces more uniform heating than a gaussian profile. In other words, a flat beam is less likely to produce "hot spots" within the beam than a gaussian beam (Fig. 3-6). Such hot spots considerably increase the risk of epidermal damage and limit the amount of energy that can be safely applied to the tissue. For this reason, a laser system with a predominantly flat beam profile will be more effective and induce fewer complications than a laser with a largely gaussian profile.

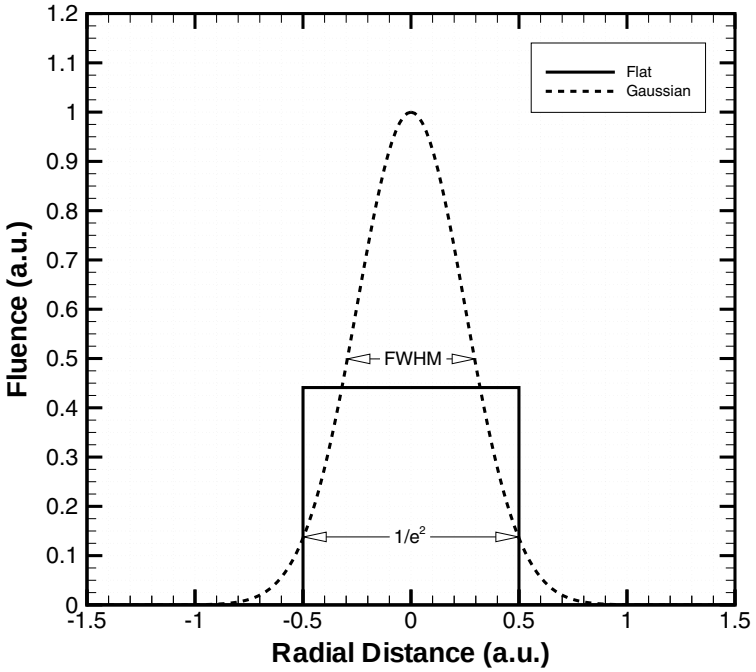

Figure 3-5. Cross Sections of the Relative Energy Distribution Profiles for Flat and Gaussian Beams of Equal Diameter and Fluence.

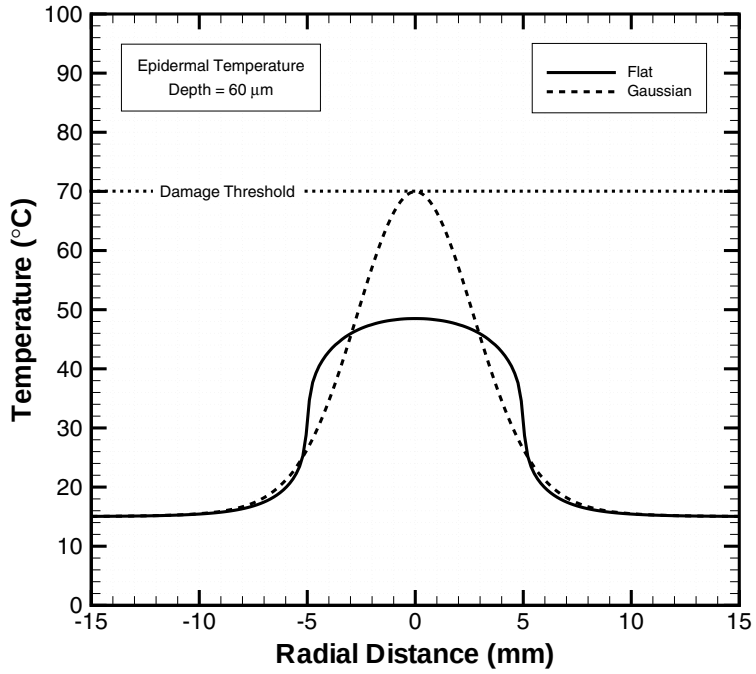

Figure 3-6. Calculated Epidermal Temperature Profiles at a Basal Layer Depth of 60 mm Resulting from the Illumination of the Skin by 10-mm Diameter Flat and Gaussian Beams of Equal Incident Fluence.

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Pulse Duration and Energy Fluence

The total amount of energy applied to a tissue in a single pulse is determined by the power density of the beam multiplied by the duration of the pulse. This total energy value, measured in Joules per square centimeter (J/cm^2), is known as the **energy fluence** of the pulse, and is a key parameter in the clinical use of medical lasers. The higher the fluence, the more energy per pulse the laser is capable of delivering to the target structure.

It is important to remember, however, that fluence by itself does not determine how the energy will be absorbed by the target tissue. The wavelength of the energy and characteristics of the tissue are key factors as well. This is especially important to remember when making comparisons between lasers. For example, a diode laser that produces a fluence of 60 J/cm^2 at 800 nm can be expected to produce more thermal destruction than a diode laser that produces 40 J/cm^2 at the same wavelength. But the same logic does not apply when comparing different types of lasers. A ruby laser that produces a fluence of 40 J/cm^2 at 694 nm will not necessarily cause the same physiological effect as a diode laser producing 40 J/cm^2 at 800 nm. The different wavelengths are absorbed differently by the tissue, and this difference has a major impact on the effectiveness of treatment.

For the LightSheer System, fluence is controlled by setting the desired level on the control panel. However, the system also allows the operator to control the pulse width. Three options are available. In the "auto" (OptiPulse) mode, the system calculates the pulse width based on the desired fluence. In the "30 ms" mode, the desired fluence is delivered during a pulse of 30 milliseconds (ms). In the "100 ms" mode, the desired fluence is delivered during a pulse of 100 ms.

The pulse duration is not only important in determining energy fluence; it is also important in the selective destruction of target tissues. For example, as will be discussed in more detail below, the pulse duration is a key parameter in destroying melanin-containing hair follicles without damaging melanin-containing skin cells in the epidermis, especially when combined with skin cooling.

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Characteristics of Target Tissues that Affect Absorption

In addition to the nature of the laser light, the amount of radiant energy that will be absorbed and retained by a tissue depends on characteristics of the tissue, specifically the type of chromophores in the tissue and the tissue's thermal relaxation time.

Tissue Chromophores

Chromophores are colored bodies that preferentially absorb light of particular wavelengths. The presence of chromophores in a tissue determine, in large part, the **absorption coefficient** of that tissue (Fig. 3-7). The absorption coefficient is a measure of how well light of specific wavelengths is absorbed by a tissue. The higher the number, the more complete the absorption. Whereas the fluence of a laser determines the amount of energy ***transmitted*** into the tissue, the product of the fluence and the absorption coefficient determines the total amount of energy ***absorbed*** by the tissue.

In tissues, the two most important chromophores are melanin and oxyhemoglobin (oxygenated hemoglobin). Melanin is found in cells of the epidermis as well as in the hair shaft, follicle and bulb. Oxyhemoglobin is found in all vascularized tissues, but in large amounts primarily in blood vessels. The absorption spectrum of both chromophores is shown in Fig. 3-6. Light emitted by the LightSheer Diode Laser System (800 nm) is absorbed preferentially by melanin and less by oxyhemoglobin. Although not shown in the figure, 800 nm light is not absorbed by water, the major component of tissue. This specificity for melanin (and less for oxyhemoglobin) allows destruction of hair follicles (or unwanted superficial leg veins and benign pigmented lesions) with little or no damage to surrounding non-pigmented cells and tissues.

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INTERACTION OF LASER ENERGY WITH TISSUE

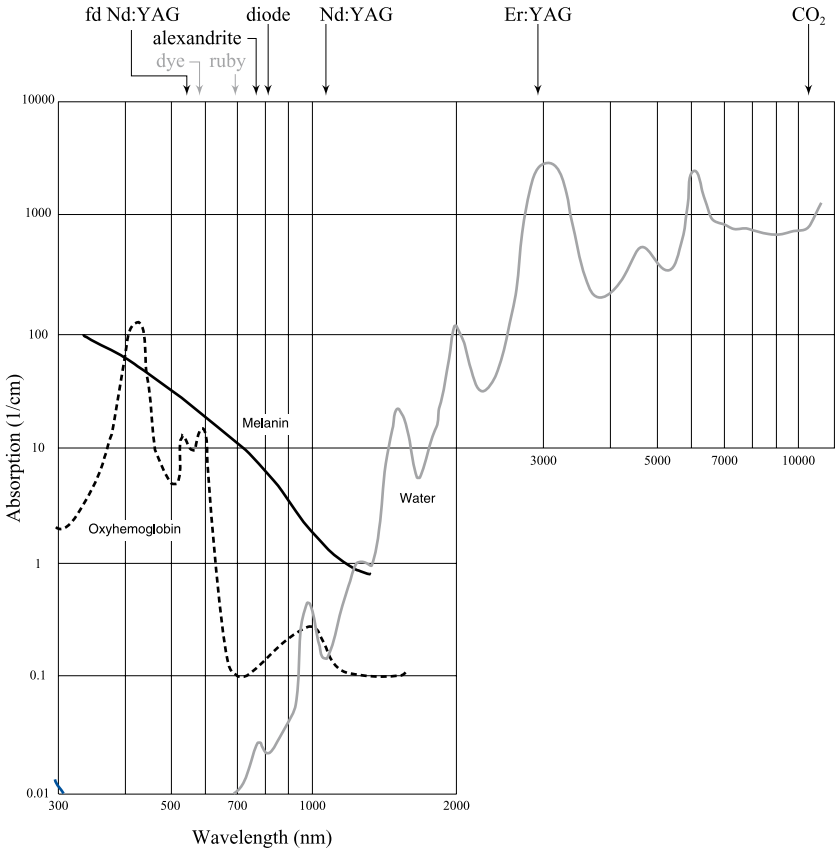

Figure 3-7. Absorption Spectrum of Melanin and Oxyhemoglobin. The LightSheer diode laser which emits light at approximately 800 nm is preferentially absorbed by melanin, and to a lesser extent, oxyhemoglobin. The absorption coefficient is a measure of how strongly light is absorbed in a particular material. A large number indicates strong absorption.

Thermal Relaxation Time

As described earlier, when a tissue absorbs laser light, the energy is converted to heat, and it is this heating that produces the laser's physiological effects. In addition to the amount of energy absorbed, the rate at which the tissue loses (conducts) heat also determines which structures will be heated sufficiently to destroy them.

The process of heat loss from a tissue is called thermal relaxation, and the **thermal relaxation time** (TRT) is defined as the time required for an object to cool to 50% of the temperature achieved immediately following laser exposure. The concept is important because it can be used to help restrict the effect of laser treatment to the target tissue, minimizing unintended damage to surrounding structures.

Two key factors determine the TRT of a tissue. The first is the tissue's composition. Different materials conduct heat at different rates. For example, a metal pan will lose heat much more quickly than one made of glass. In a similar way, a hair shaft made of the densely packed protein keratin will lose heat at a different rate than the surrounding tissue that consists mostly of water.

The second factor that determines how quickly a target tissue will lose heat is its **surface area to volume ratio**. Tissues that have a high surface area to volume ratio, like the epidermis of the skin, cool off much more quickly than structures that have a low surface area to volume ratio, such as the bulb of a hair follicle. The situation is analogous to a cup of coffee in a ceramic cup. In the cup, the coffee will stay warm far longer than if the same volume is spread out over a wide area on a ceramic counter. Differences in TRT are a key factor in being able to use laser energy to destroy hair follicles without excessive damage to the epidermis, even though both tissues contain the same chromophore, melanin.

Compression

While not a true characteristic of the tissue itself, the amount the tissue is compressed during treatment has a major effect on the amount of laser energy absorbed. Compression of the skin squeezes out the blood, eliminating oxyhemoglobin from the treatment area and forces the hair follicles to lie down, bringing the roots closer to the surface. As a result, the effective penetration of laser energy is improved significantly.

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Additional Resources

The following reprints have been inserted at the end of this section to provide you with additional information on the technical aspects of the use of the LightSheer Diode Laser System.

- Klavuhn K. *Illumination Geometry: The Importance of Laser Beam Spatial Characteristics*
- Klavuhn K. *Epidermal Protection–A Comparative Analysis of Sapphire Contact and Cryogen Spray Cooling*
- Klavuhn K. *Coverage Rate: The Influence of Laser Parameters on Treatment Time*

SECTION 4.
LASER SAFETY

The LightSheer Diode Laser System is a precision medical instrument that has undergone extensive testing. With proper handling, it is a safe and reliable instrument. To protect operating personnel, this safety section should be read thoroughly after system installation and reviewed before operation.

Lumenis does not make recommendations regarding the practice of medicine. The following precautions are extensive but may not be complete. Laser users are advised to supplement this information with that of technological advances in surgical products and techniques as they become available to the medical laser user community through the medical literature. Before using the LightSheer Diode Laser System, it is also important for clinical personnel to read the American National Standard (ANSI) publications ANSI Z136.3-1996 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1-1993 "American National Standard for the Safe Use of Lasers." Internationally, both the ANSI guidelines and the European standards (document EN207) have the most recent recommendations for safe use of lasers in health care facilities.

SECTION 4.
LASER SAFETY

Characteristics of the Light Produced by the LightSheer Diode Laser System

The energy produced by the LightSheer Diode Laser System classified it as a Class IV laser by the Center for Devices and Radiological Health. Class IV represents the highest power lasers; for this reason, the user must take precautions to prevent unintended exposure of laser energy to the eye and skin from either direct or diffusely reflected laser beams.

The wavelength of light emitted by the LightSheer Diode Laser is approximately 800 nm, in the near-infrared portion of the electromagnetic spectrum. It is highly absorbed by melanin in the skin and hair follicles, but less so by skin cells without melanin. This laser light is not readily absorbed by water or glass and may pass through windows. It can also be reflected off of smooth metallic surfaces.

Ocular Protection

Because the LightSheer Diode Laser produces a high-intensity beam of energy, it has the potential to cause ocular injury to the operator, treatment room personnel and the patient. The retina, especially, will absorb energy near 800 nm and can be severely damaged by accidental exposure. Consequently, no one should look directly into the laser light source or at scattered laser light from reflective surfaces.

In addition, special protective eyewear must be worn by all persons potentially subject to exposure. Each pair of laser glasses are stamped with the optical density provided by the eyewear and the particular wavelengths of laser light for which the protection is intended. All of the people in the operating room must use eyewear appropriate to the particular laser being used. For the LightSheer Diode Laser System, all persons subject to exposure must wear protective goggles or eyewear of optical density 5 or greater over a wavelength of 790-830 nm. For users outside the US, the appropriate standard may be EN207, in which case the safety eyewear must have a protection class of L5 (Fig. 4-1). In general, anyone within a nominal hazard zone of 50 meters must wear the appropriate protective eyewear.

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Figure 4-1. Protective Eyewear for Ocular Protection. When using the LightSheer Diode Laser System, all persons subject to exposure must wear protective goggles or eyewear of optical density 5 or greater over a wavelength of 790-830 nm.

Minimizing the Risk of Skin Burns

To ensure that all of the people entering the treatment room know which laser is being used, appropriate warning signs indicating the type of laser and its wavelength must be prominently displayed on the outside of the operating room door.

During treatment, the door of the room should be kept closed. An interlock is provided with the system that can be set to disable the laser when the door is opened inadvertently. Because the laser light can pass through glass, all of the windows in the treatment room must be covered with opaque covers.

Smooth objects can reflect the laser beam. Reflection hazards can exist several feet beyond the laser beam aperture. The operator should avoid directing the laser beam at unintended objects. Regardless of the color of a surface, reflection is a potential hazard when the laser strikes a non-absorbing surface such as a metallic surgical instrument. Whenever possible, low or non-reflecting instruments should be used.

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LASER SAFETY

The LightSheer Diode Laser System employs a cold, convergent sapphire lens (the ChillTip) that is held in direct contact with skin during laser treatment to focus the light and protect the epidermis from thermal damage. When used properly, this type of delivery system also helps minimize the potential risk of reflected laser light, and the laser should only be fired when the delivery system is placed against the patient's skin.

Minimizing the Risk of Electrical Hazards

The covers enclosing the active components of the laser should not be removed except by certified service engineers. The area around the laser should be kept dry, and the laser should never be operated if any fluid is leaking from the ChillTip handpiece (as opposed to collection of moisture due to condensation). The laser should not be operated if the power cable is faulty or frayed. Finally, the laser should be inspected regularly and serviced, and a written record of both service and maintenance should be kept.

Minimizing the Risk of Fire Hazards

The 800 nm laser energy produced by the LightSheer Diode Laser System has a relatively low risk of igniting surgical drapes, gowns or other potentially flammable materials in the operating room. However, to minimize the risk of fire hazards, the following precautions should be observed:

- Flammable skin preparation agents (e.g., alcohol) should either not be used in the treatment room or should be allowed to dry completely before beginning the procedure.
- Anesthetics administered topically or by inhalation must be approved as non-flammable.
- Particular care must be taken when oxygen is used in the room. Oxygen can accelerate the combustion of any flammable material.
- Use of combustible materials, such as gauze and drapes, should be avoided in the treatment area. When required, these materials may be made more fire resistant by keeping them moist with water. Clothing should be kept well away from the area of treatment.
- The laser should not be operated with any cover or drape over the laser.
- An appropriate fire extinguisher should always be available inside the room or just outside the door.

The Laser Plume

In some procedures performed with lasers, a plume of smoke and steam is produced that may contain viral fragments. In addition, a harmless, but malodorous gas, hydrogen sulfide, may be produced when the laser beam interacts with surface hair. To reduce any potential complication of a laser plume, a smoke evacuator with an appropriate filter may be used to reduce the level of hydrogen sulfide or other airborne particles in the treatment area.

Safety Features

The LightSheer Diode Laser has been designed for safety. The most important safety-related features are described below. Additional safety information can be found in the User Manual for each system.

- **Keyswitch**. The keyswitch prevents unauthorized used. The key should be removed when the system is not in use.
- **Safety interlocks**. The LightSheer System has several interlocks to protect the user and the patient. A remote interlock is available to disable the laser when the treatment room door is opened. The laser also has energy and temperature interlocks to disable system operation if the temperature or energy output goes outside operating parameters.
- **Footswitch and handpiece triggering**. To help prevent unintended emission, laser output occurs only if both the footswitch and the handpiece trigger are depressed.
- **Audible emission indicator**. For operator feedback and safety, each laser pulse is accompanied by an audible beep.
- **Electronic shutter**. As an extra backup safety feature, the laser includes an electronic shutter independent of the laser's main electrical system. This shutter prevents emission of laser energy unless the footswitch is depressed. It is a redundant system to the footswitch and handpiece triggering described above.
- **Emergency stop switch**. In the event of an emergency, the laser can be shut down immediately by pushing the emergency stop button located near the keyswitch on the console.

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Preventing Unintended Exposure

To prevent unintended exposure, the system should always be in Standby mode except during the actual treatment. Maintaining the system in this state prevents the laser from firing if the footswitch is accidentally depressed.

Similarly, all personnel who use the laser should have laser safety training, but only the person actually operating the laser should have access to the footswitch. To prevent accidental laser discharge, the system should always be turned off before moving it. The laser should be stored in a safe place, and the key should be removed to prevent unauthorized use of the instrument.

In the event of an emergency, the LightSheer Diode should be shut down immediately by either releasing the foot and hand switches or by depressing the emergency off button.

SECTION 5.
LASERS IN HAIR REMOVAL

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This section provides a detailed description of the theory and practice of laser hair removal. Specific instructions on the use of the LightSheer for the removal of unwanted hair are covered in Section 6.

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SECTION 5.
LASERS IN HAIR REMOVAL

The LightSheer Diode Laser System

The LightSheer System is a diode laser that produces pulsed, near-infrared light intended for hair removal and the treatment of pseudofolliculitis barbae, leg veins, and benign pigmented lesions. Three different versions of the system are available, differing in terms of repetition rate, maximum fluence, pulse width and portability.

The LightSheer ST and ET systems have a compact, table-top design that facilitates transport between multiple offices, enhancing the return on the initial investment. The LightSheer ST is the standard system with a 1 Hz repetition rate and fluence up to 40 J/cm^2. The LightSheer ET has a 2 Hz repetition rate and fluence up to 60 J/cm^2. The LightSheer XC has a larger spot size (12 x 12 mm), a 2 Hz repetition rate and fluence up to 60 J/ cm^2.

LightSheer Diode Laser System Specifications

Model	ST	ET	XC
Repetition Rate (max.)	1 Hz	2 Hz	2 Hz
Fluence	10-40 J/cm^2	10-60 J/cm^2	10-60 J/cm^2
Portability Between Office Sites	Yes	Yes	No
Spot Size	9 x 9 mm	9 x 9 mm	12 x 12 mm

Each laser system consists of a console, a footswitch and a handpiece connected to the console with an umbilical (Fig. 5-1). In addition, the LightSheer ST and ET models have an optional cart available for the unit to rest on. Laser light is generated in the handpiece by the laser diode arrays and exits at the sapphire tip that also serves as a skin cooler (Fig. 5-2). A microprocessor monitors the system, providing fault checking and controlling the laser operation.

SECTION 5.
LASERS IN HAIR REMOVAL

Figure 5-1. The LightSheer Family of Diode Laser Systems.

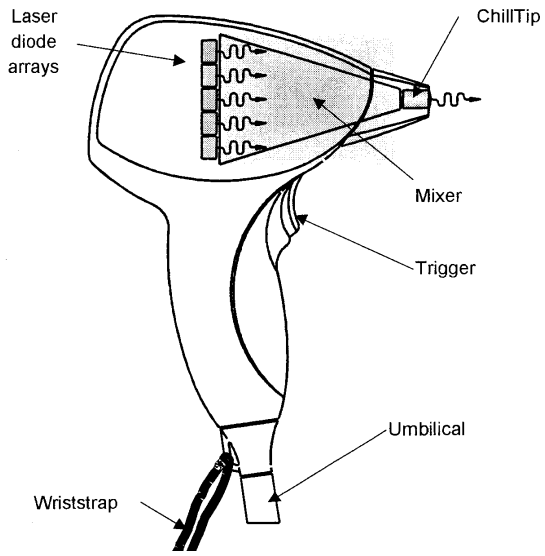

Figure 5-2. The LightSheer Diode Laser Handpiece and ChillTip.

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SECTION 5.
LASERS IN HAIR REMOVAL

For hair removal or the treatment of superficial leg veins and benign pigmented lesions, the two key parameters that can be set by the operator are energy fluence and pulse width, both of which are set using the touch-screen display on the front of the console (Fig. 5-3).

Fluence

The fluence setting in Joules/cm^2 is displayed on a digital indicator near the center of the screen. To adjust the fluence, the adjacent up and down arrows can be pressed to increase or decrease the setting. The default fluence is the value last used for treatment. Be sure the setting chosen is displayed before starting treatment.

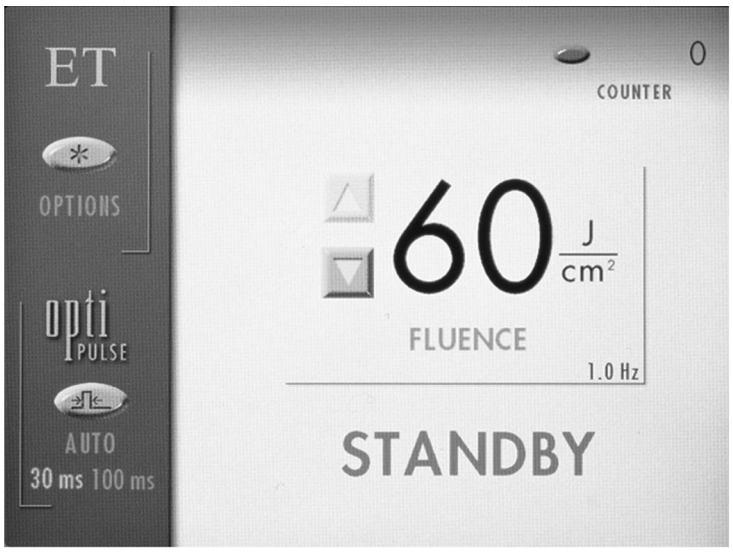

Figure 5-3. The LightSheer Treatment Screen.

OptiPulse

The OptiPulse button controls the laser's pulse width. OptiPulse has three user-selectable modes: "Auto," "30 ms, " and "100 ms". In "Auto" mode, the pulse width is half the fluence, which is the optimal setting for most treatments (see table). In "30 ms" mode, the pulse width is fixed at 30 ms, independent of the fluence setting. Similarly, in "100 ms" mode, the pulse width is fixed at 100 ms.

OptiPulse "Auto" Mode Pulse width and Fluence Combinations

Fluence (J/cm²)	Pulse width (ms)
10	5
15	7.5
20	10
25	12.5
30	15
35	17.5
40	20
45	22.5
50	25
55	27.5
60	30

Repetition Rate and ChillTip

The repetition rate for each LightSheer System is set in the options screen (Fig. 5-4). The pulse rate for the ET and XC systems can be set as high as 2 Hz. The pulse rate for the ST system can be set as high as 1 Hz.

When first turned on, the ChillTip requires approximately 30 seconds to cool to its operating temperature, during which time a "Cooling" message is displayed on the treatment screen. During this time the laser cannot be fired. When the ChillTip reaches its operating temperature, the screen message changes to "Ready."

The ChillTip helps protect the epidermis from thermal injury. The options screen allows the user to toggle the ChillTip off or on, but except in rare circumstances, the system should always be operated with the ChillTip on.

Other Controls

For additional information on set-up, calibration, operation and maintenance of the LightSheer System, see the User Manual provided with the system.

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SECTION 5.
LASERS IN HAIR REMOVAL

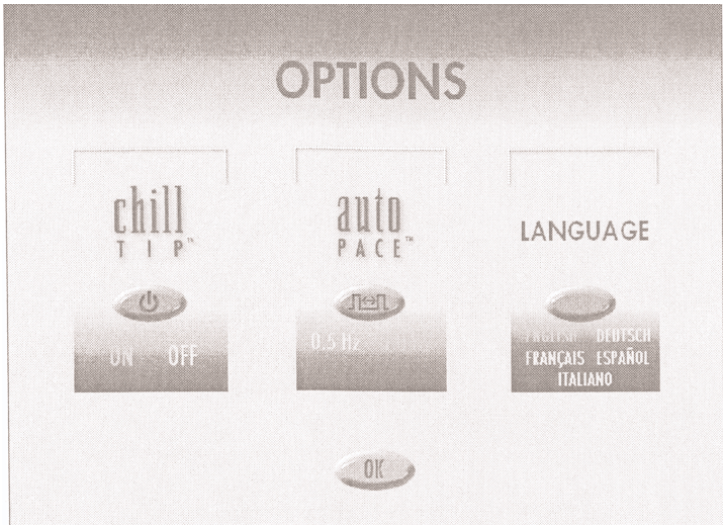

Figure 5-4. The Options Screen.

Hair Anatomy and Development

The LightSheer Diode Laser System was designed from the ground up for permanent reduction of unwanted hair. The pulse width, fluence and active cooling system are integral parts of the system. This section contains a brief introduction into hair anatomy and development, indications for hair removal, traditional treatments to remove unwanted hair, the theoretical basis and practical application of laser hair removal and a summary of the clinical results using the LightSheer Diode Laser System.

Although human hair is most often thought to be only of cosmetic importance, it also functions as a sensory organ, reduces friction at certain anatomic sites, provides thermal insulation, aids in pheromone dissemination and plays both social and sexual roles. Patients experiencing either the abnormal loss of hair or the development of unwanted or excess hair often experience tremendous psychological stress and may seek medical treatment.

The Skin

Hair is found in the skin, and the anatomy of the skin plays an important part in designing a system for effective hair removal. It is important then, to have a basic understanding of skin structure and anatomy.

The skin is composed of two discrete layers which overlay

subcutaneous tissue (Fig. 5-5). The **epidermis** is the thin, outer epithelial layer which ranges in thickness from 0.07 to 0.12 mm over much of the body.

Under the epidermis is the **dermis**, a 3-7 mm thick layer composed primarily of dense connective tissue within which are embedded sweat (eccrine) glands, secretory (apocrine) glands, hair follicles, blood vessels and nerves.

Under the dermis, the connective tissue becomes more fatty (adipose) in nature. This fatty layer is called the subcutaneous tissue. It's functions include heat insulation, mechanical protection and energy storage.

Epidermis

The epidermis is a stratified, flat epithelium which consists of 30-50 cell layers that are arranged in five distinct sublayers. No thicker than a sheet of paper, the epidermis forms a water-tight envelope that helps protect underlying body tissues. Many of the properties of the skin, including resistance to chemical corrosion, prevention of invasion of microorganisms into the body and temperature regulation can be directly attributed to the characteristics of the epidermal tissue.

Dermis

The dermis lies directly under the epidermis and contains the nerves, blood vessels and lymph channels that supply the epidermis. The dermis contains cells, fibers and ground substance. The cells of the dermis include fibroblasts, histiocytes (connective tissue macrophages that engulf and digest cellular debris) and mast cells (cells of the immune system that contain granules that regulate inflammation). The fibers of the dermis include collagen and elastin. The collagen fibers lend tensile strength to skin, while the elastin fibers impart flexibility. The ground substance is the medium in which the cells and fibers are embedded, and it contains the fluid that bathes these structures. The ground substance is important structurally–the matrix in which everything is imbedded – and in exchange of materials in and out of the connective tissue. Also scattered throughout the dermis are hair follicles, sebaceous glands, eccrine (sweat) glands and apocrine (secretory) glands.

The dermis is usually 3 mm thick but varies in texture and

thickness with location on the body. On the back where it is thickest, broad collagen bundles help withstand the stress of upright posture. The thinnest dermis is found in the eyelids where distensibility and rapid movement are essential for eye protection. Like other tissues, the dermis becomes thinner with advancing age.

Subcutaneous Tissue

At the bottom of the dermis, the connective tissue contains a greater number of adipose (fat containing) cells. There is no distinct line that separates the dermis from the subcutaneous layer. The thickness of the fatty layer varies with anatomical location, age and gender. This layer and the tissue it contains provides heat insulation and energy storage as well as acting as a shock absorber that facilitates the skin's mobility over underlying structures.

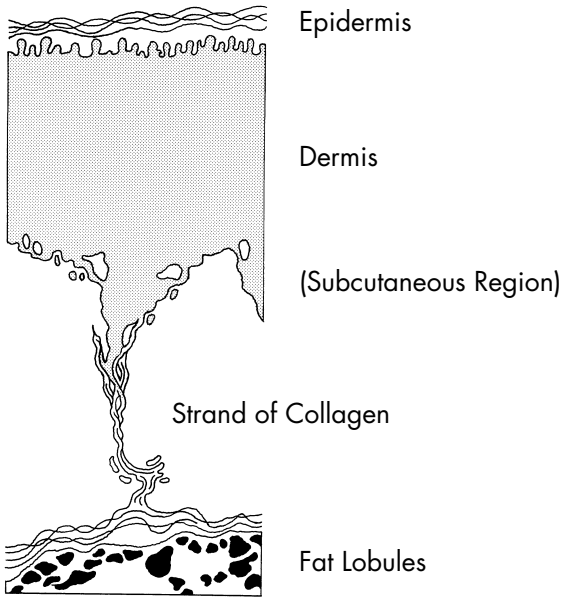

Figure 5-5. Structure of the Skin. The skin consists of two primary layers–the epidermis and the dermis–formed above subcutaneous tissue.

Hair Anatomy

Hair is composed of keratinous fibers that grow from epithelial follicles over the entire skin surface except in certain areas such as the palms of the hands and the soles of the feet. A person's total endowment of follicles is determined during his or her embryonic development. No new follicles are produced after birth.

Hair can be classified into two major types. **Terminal hairs** are

thick, pigmented with melani, and long. They are normally found on the scalp, the eyebrows, the underarms, and the genital areas as well as on the arms, chest, face, legs, and back. **Vellus hairs** are small in diameter, short and non-pigmented.

Hair occurs in a variety of natural colors. Hair color is produced by melanocytes (pigment-producing cells) located at the base of the hair follicle. The greater the amount of melanin produced, the darker the hair. Grey and white color hair result from non-functioning melanocytes.

Hair Follicle Bulb

The structure of a typical hair is shown in Fig. 5-6. The lower end of the hair follicle is expanded and is known as the hair follicle bulb. The hair grows from the bulb, which consists of the **dermal papilla** and the **hair matrix**. The papilla is composed of highly vascularized connective tissue and provides nutrients for the rapidly dividing cells of the matrix, which produces the hair. During active growth, the cells of the matrix divide every 23-72 hours, migrating upward to become keratinized, hardened and tightly packed into layers that become the hair shaft.

The matrix cells also produce the inner (internal) root sheath and outer (external) root sheath. The inner root sheath grows up the inside of the hair follicle with the hair shaft, guiding the shaft through the follicle canal. The outer root sheath supports the follicle (Fig. 5-7).

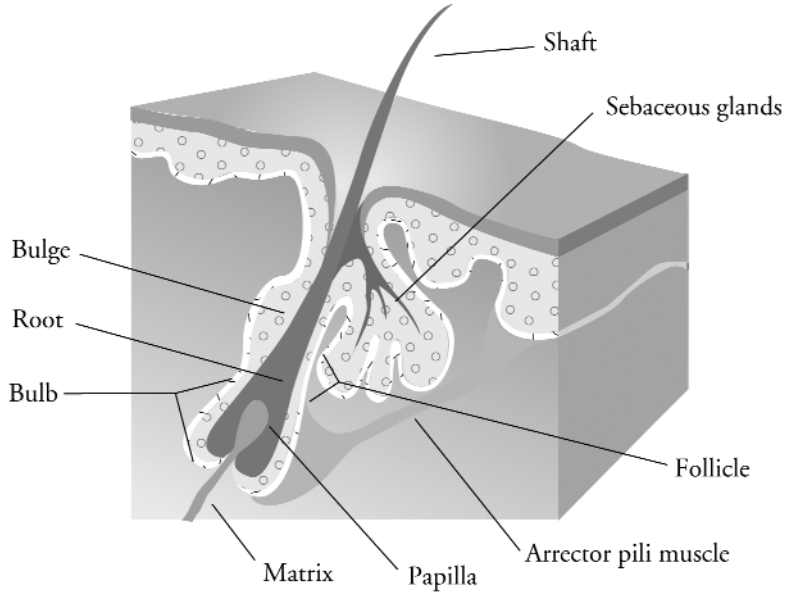

Figure 5-6. Basic Anatomy of a Terminal Hair. The hair shaft grows from the bulb as the cells of the matrix rapidly divide during the active phase of hair growth (anagen).

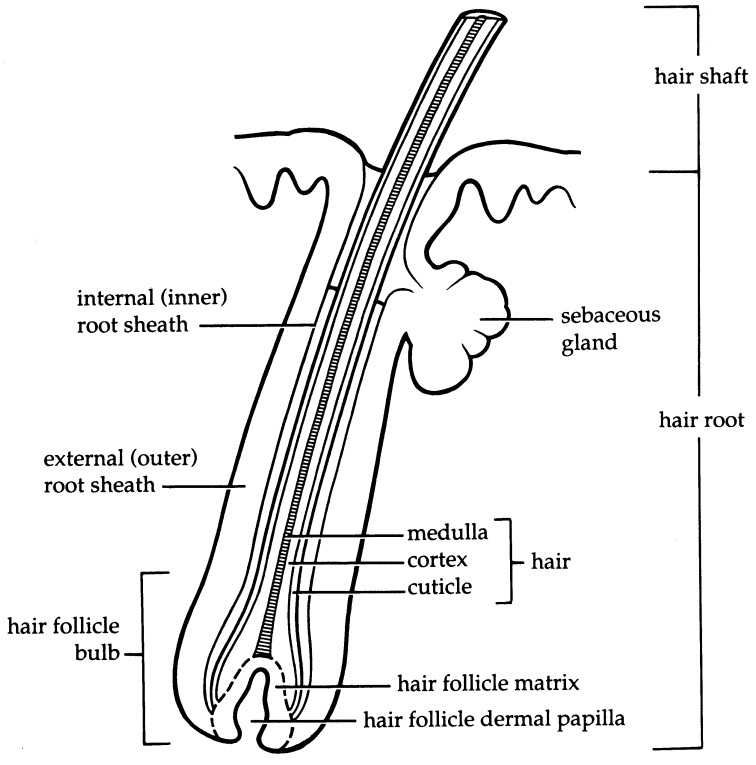

Figure 5-7. Detailed Anatomy of the Bulb and Shaft of a Terminal Hair.

Traditionally, it has been assumed that the papilla in the hair bulb directed all aspects of hair growth, but recent experiments suggest that a "bulge" of cells in the follicular epithelium (near the attachment point of the arrector pili muscle) plays an important role as well. Consequently, the two primary targets for permanent hair destruction appear to be the regions of the bulge and the papilla. The bulge is approximately 1.5 mm below the epidermis, while the papilla is deep in the dermis (typically 3-7 mm from the surface of the skin).

Hair Shaft

The hair shaft itself is composed of three different layers: the medulla (inner layer), the cortex (middle layer) and the cuticle (outer layer).

- **Medulla**. In scalp hair, the medulla is a single cell layer thick and is absent in places. Much of the medulla is air. It is only formed in terminal hairs.
- **Cortex**. The cortex is the main body of the hair shaft in humans.
- **Cuticle**. The cuticle consists of a single layer of overlapping, flattened, cuticle cells.

Hair Development

Growth Phases

Hair grows in recurring cycles through three phases: anagen, catagen, and telogen (Fig. 5-8).

- **Anagen** is the phase of active hair growth. It is quite variable depending on the location of the hair and can last up to 5-7 years in scalp follicles, although it is generally shorter in other locations. During anagen the dermal papilla is enclosed by the hair matrix, and cell division occurs rapidly. The hair shaft contains an abundance of melanin, and the hair follicle is at its maximum depth.
- **Catagen** is a brief transitional phase, during which cell division ceases, and the lower part of the follicle starts to be reabsorbed. Catagen lasts from a few days to a few weeks.
- **Telogen** is a resting phase, during which the follicle shortens, the old hair falls out in preparation for development of a new hair, and the lower end of the hair root begins to look like a club, and the hair is often referred to as a "club hair" at this stage. During telogen, the hair follicle is about one-third the size of the full-size anagen follicle and little or no melanin remains. The telogen phase typically lasts on the order of three months.

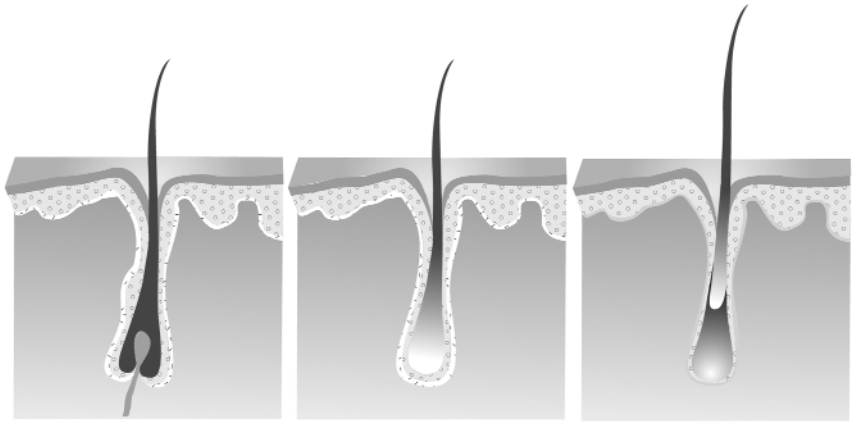

Figure 5-8. Recurring Cycles of Hair Growth. Anagen is the active growth phase. Catagen is a phase of regression. Telogen is a resting phase.

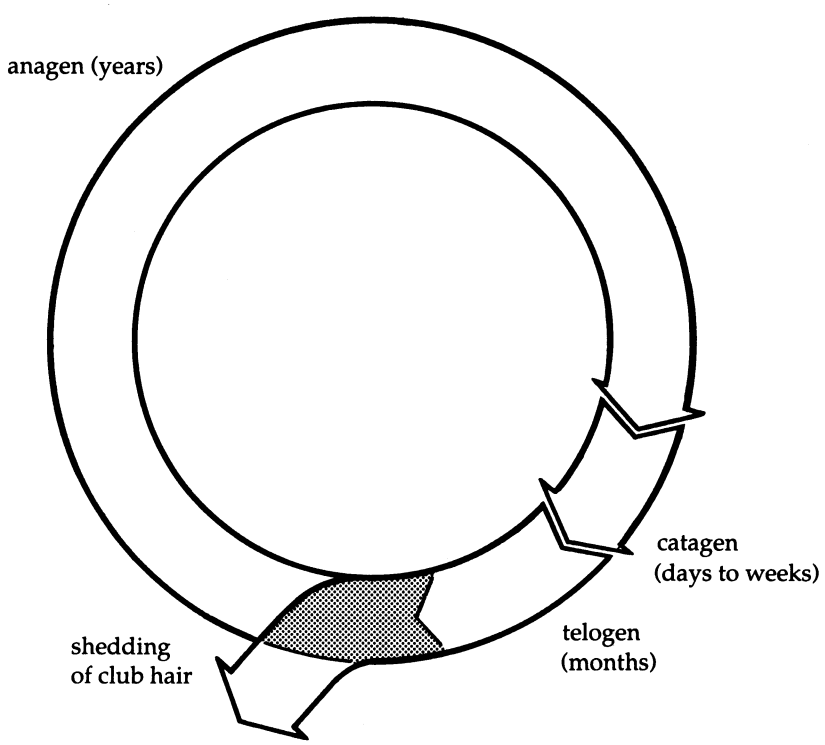

Figure 5-9. Relative Duration of Hair Growth Stages.

Table 5-1 lists the duration of anagen and telogen of hairs located on several different areas of the body.

Table 5-1: Duration of Hair Growth Cycles*

Location	Telogen	Anagen
Scalp	3-4 mo	2-6 yr
Eyebrows	3 mo	4-8 wk
Ear	3 mo	4-8 wk
Beard (chin)	10 wk	1 yr
Mustache	6 wk	16 wk
Axillae	3 mo	4 mo
Arms	18 wk	13 wk
Legs & Thighs	24 wk	16 wk

* From Richards RN and Meharg GE, *Cosmetic and Medical Electrolysis & Temporary Hair Removal*. Medrick Ltd:Toronto, 1997.

Synchronization of Hair Growth Cycles

Each follicle in human skin maintains an independent growth rhythm from the other follicles. At any given time, the majority of hair follicles (80-85%) are at some point in anagen. The remaining follicles are either in the catagen phase (2%) or the telogen phase (10-15%). The average scalp hair grows at a rate of approximately 37 mm per month while hairs at other anatomic sites generally grow more slowly.

Just as the anatomic target for laser hair removal is the bulge and papilla, the temporal target is the anagen phase. Hairs in the resting or regression phases appear to be less susceptible to the effects of laser light. However, after initial treatment with the LightSheer Diode Laser System, the hairs that regrow appear to be synchronized in the early anagen phase, where they are most vulnerable to treatment with laser light. For this reason, any necessary retreatment is usually performed as soon as possible after the hairs begin to regrow. While this approach works for most patients, research is currently being performed to identify the best time for retreatment.

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Indications for Hair Removal

People have their hair removed for either cosmetic or medical reasons.

Cosmetic Reasons

The most common reason people seek hair removal is to improve their cosmetic appearance. Some degree of cosmetic hair removal has been accepted in virtually all cultures, but the specific areas where body hair is considered undesirable varies widely from culture to culture.

In the US, men most frequently seek removal of their facial hair, nasal hair, back hair or ear hair. Women most frequently seek hair removal from their face (especially the upper lip), underarms, legs, abdomen and inner thighs, breasts, and eyebrows.

Medical Reasons

Hair removal may be desired for a variety of medical conditions that result in excess hair. There are two major types of excessive hair disorders. **Hypertrichosis** is an increase in the amount of hair in regions that do not respond to male hormones (androgens) while **hirsutism** is an increased amount of hair in androgen-dependent areas only. Hypertrichosis may be localized to a single area or generalized over large areas of the body and it can occur in both men and women. In hirsutism, women develop male hair patterns, such as facial hair. In general, fine vellus hairs become course terminal hairs in women who have the condition.

The development of unwanted, excess hair may be genetically determined as a normal familial trait. It may also occur in association with one of several inherited disorders, or it may occur as a complication of tumors of the ovaries or adrenal glands. Finally, certain medications, especially androgens, can cause development of unwanted hair (see Table 5-2).

Table 5-2: Causes of Hirsutism and Hypertrichosis

Virilizing tumors **Adrenal gland** Adrenal carcinoma Adrenal virilizing adenoma Congenital adrenal hyperplasia **Ovary** Arrhenoblastoma Granulosa-stromal tumor Lipoid cell tumor Hilus cell tumor	**Medications** Androgens Birth control pills Minoxidil Phenytoin Penicillamine Diazoxide Cyclosporine Corticosteroids
Syndromes Polycystic ovary **Hereditary** - normal variant **Idiopathic hirsutism** **Endocrine disorders** Cushing's disease	**Malnutrition** **Orphyria** **Anorexia nervosa** **Hypothyroidism (children)** **Dermatomyositis**

Traditional Treatments to Remove Unwanted Hair

A variety of techniques have been used traditionally to remove unwanted hair. The most common include:

- Shaving
- Waxing or Sugaring
- Tweezing
- Mechanical epilating devices
- Chemical depilatories
- Electrolysis/Electrothermolysis

While all of these methods are effective over the short term, they are, in turn, inconvenient, messy, painful or associated with significant risks such as infection or scarring. Of all of them, only the electricity-based methods have been shown to provide permanent removal of unwanted hair.

The two types of electricity-based removal of hair are called **electrolysis** and **electrothermolysis** (or thermolysis for short). In electrolysis, a weak DC current is passed into the deep portion of follicles between two electrodes. The procedure works by generating hydrogen gas and reactive hydrogen ions that chemically destroy the adjacent hair follicle. In electrothermolysis, a high frequency alternating current at low voltage and low current is used to generate heat and

thermally destroy hair follicles. Electrolysis is safe, less painful, and less likely to cause scarring than electrothermolysis, but the tradeoff is very slow treatment times, especially when large areas are epilated. Devices that blend both electrolysis and electrothermolysis are common.

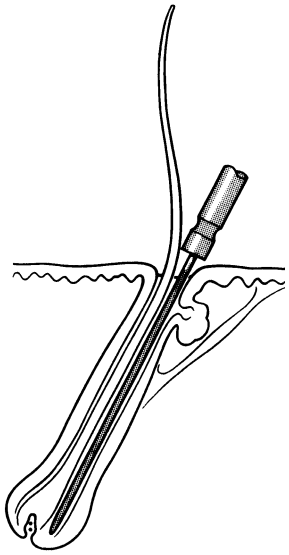

Figure 5-10. Electrolysis.

Laser Hair Removal Through Selective Photothermolysis

As described earlier, the LightSheer Diode Laser System is designed to remove unwanted hair through selective photothermolysis. The process involves local selective absorption of an intense light pulse at wavelengths that are absorbed by the desired targets (hair follicles) but not by the surrounding tissue. Like electrothermolysis, photothermolysis destroys hair follicles through thermal damage. Unlike electrothermolysis, the skin is not breached (which reduces the risk of infection), and many follicles can be treated simultaneously.

To review, the theory of selective photothermolysis predicts that thermal injury can be confined to a given target if it is treated with the proper wavelength of light, proper pulse energy, and a pulse duration that is equal to or less than the thermal relaxation time (TRT) of the target tissue. In human skin, 800 nm laser energy is absorbed by melanin. Melanin is found interspersed between the matrix cells in the hair bulb and is also transferred to the structural elements of the hair shaft during its development. Light is absorbed by the shaft and causes heating,

which is then transmitted to other areas. The absorbed energy, converted to heat, causes thermal destruction of several key anatomic sites. The hair's growth is significantly impeded or eliminated. Damage to adjacent tissues in the **dermis** is minimized, because the wavelength used is not absorbed significantly by non-melanin-containing cells. Damage to the **epidermis** (caused by absorption by the epidermal melanin) is minimized by using a pulse duration longer than the TRT of the epidermis and by the aggressive cooling provided by the ChillTip lens.

The ChillTip handpiece has three purposes (Fig. 5-11). First, it cools the epidermis to help prevent thermal damage and provide an anesthetic effect. Second, it focuses the laser light to maximize dose penetration to deep hair follicles. Finally, its convex shape allows compression of the skin during treatment which temporarily collapses the blood vessels, brings the root of the hair closer to the laser energy, and increases transmission through dermal collagen by as much as 40%.

When the ChillTip is placed against the skin, the sapphire window creates good contact while squeezing out the blood and bringing the hair follicles closer to the skin surface (Fig. 5-11). Because the sapphire window is above freezing, there is no risk of skin damage as a result of overcooling.

Results from a simple heat transfer analysis of sapphire contact cooling is shown in Fig. 5-12. The results indicate that the surface of the epidermis is cooled to approximately 9°C during the initial 250 ms of contact, while the more vulnerable basal layer at a depth of approximately 60-80 μm is cooled to 13-15°C. The temperatures of the important targets at depth of greater than 1 mm remain essentially unchanged even for contact times in excess of one second. And though in practice it is difficult to precisely judge a contact time of 250 ms, Fig. 30 shows that for the depths of interest, little variation in the skin temperature results for contact periods as short as 0.1 second (100 ms) or as long as 1 second. In fact, extended cooling time has no impact on the deeper structures, but it does give patients a greater anesthetic effect.

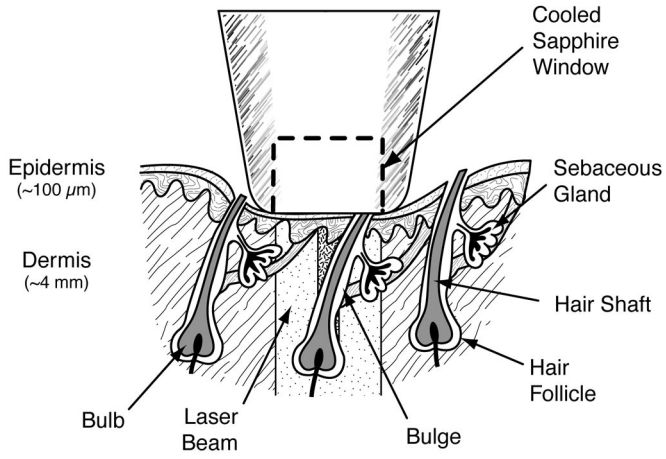

Figure 5-11. The ChillTip Handpiece Cools the Epidermis, Focuses the Laser Light to Maximize Dose Penetration to Deep Hair Follicles and Provides Compression.

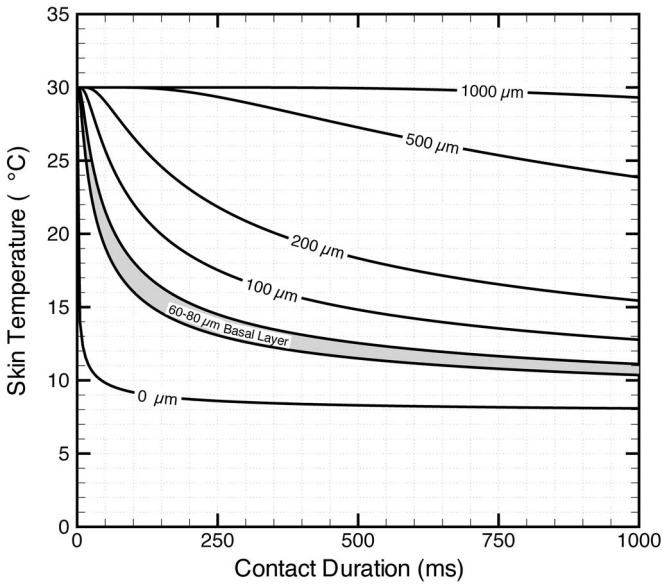

Figure 5-12. Skin temperature at Different Skin Levels After Contact Cooling with the ChillTip. Within 0.1 s (100 ms) the skin is sufficiently cooled to a depth of 60-80 μm for effective epidermal preservation. In contrast, the temperature of key targets for laser hair removal at depths of 1000 μm (1 mm) is essentially unchanged even at contact times in excess of 1 second.

SECTION 5.
LASERS IN HAIR REMOVAL

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The Importance of Skin Type in Laser Hair Removal

For safety reasons, skin type is an important factor to consider when choosing treatment parameters for laser hair removal. Several different skin classification systems have been developed. The Fitzpatrick Classification System is one of the most commonly used and is based on pigmentation, tanning and burning (see table). The lower the number of the skin type, the less melanin in the skin and the less risk of epidermal injury during laser hair removal.

Fitzpatrick Classification of Skin Types

Skin Type	Description
I	Always burns, never tans
II	Always burns, sometimes tans
III	Sometimes burns, always tans
IV	Rarely burns, always tans
V	Moderately pigmented
VI	Black skin

Because melanin in the skin will absorb laser energy intended for the hair shaft and follicle, the risk of unintended epidermal damage increases with darker skin. Early in the history of laser hair removal, people with darker skin (skin types IV, V, and VI) were often excluded from treatment because of safety concerns. As operators have gained experience and laser parameters have been optimized, it is now possible to safely treat patients with darker skin.

As patients with darker skin have been treated, it has become increasingly clear that the Fitzpatrick classification system has some important limitations. Because the categories are so broad, individuals with medium brown skin, for example, have variously been categorized as Fitzpatrick type IV, V, or VI. As a result, Dr. Elliot Battle and Dr. Rox Anderson from the Wellman Laboratories at Harvard Medical School proposed a new classification system, the Skin Ethnic Color Type (ECT), based on skin color and ethnicity. This new classification scale (see table) is believed to be significantly more useful in determining appropriate parameters for laser hair removal. (For more information on Skin Ethnic Color Types, see the reprint in the Clinical Information – Hair Removal section entitled: *Study of Very Long-Pulsed (100 ms) High-Powered Diode Laser for Hair Reduction in All Skin Types.*)

Skin Ethnic Color Types (ECT)

Skin Type	Description
I	Light White plus ethnic origin
II	Medium White plus ethnic origin
III	Dark White plus ethnic origin
IV	Light Brown plus ethnic origin
V	Medium Brown plus ethnic origin
VI	Dark Brown plus ethnic origin

Summary of Clinical Results Using the LightSheer Diode Laser System

The LightSheer Diode Laser System has been studied extensively for hair removal. The results from two key studies are presented here. The first study demonstrates that treatment with the LightSheer System results in permanent hair reduction. The second shows that the LightSheer System can be used safely and effectively in patients with darker skin types.

Long-Term Hair Reduction Study

The LightSheer has been studied extensively for permanence at the Massachusetts General Hospital and the Laser and Skin Surgery Center of New York. A reprint of the pivotal study is provided in the Clinical Information – Hair Removal section (Dierickx CC, et al. *Effective, Permanent Hair Reduction Using a Pulsed, High-Power Diode Laser*) and is summarized here.

In this study, large test sites on the back or thighs of 92 patients with skin types I-VI (fair to dark-skinned) and any hair color, were shaved and treated with a range of 15-40 J/cm^2 fluence and pulse duration from 5-20 ms using the LightSheer. All patients were treated and examined at 0, 1, 3, 6, and 9 months, and a large percentage were also examined at 12 months.

The endpoints examined were **hair growth delay** and **long-term hair reduction**. Long term hair reduction is defined as a significant reduction in the number of terminal hairs after treatment, which is stable for a longer period than the complete growth cycle of follicles at the body site tested.

Before each treatment, 8 test sites were positioned on a patient's thigh or back with two micro tattoos or other anatomic landmarks to ensure exact location of the test sites at follow-up visits. Hairs at each site were trimmed to a uniform length using clippers, and the skin was cleaned with isopropanol. Digital images of the treatment sites were taken at each visit, and the number of hairs was counted blindly in each test area before treatment and at each follow-up visit.

The key results were as follows:

- 100% of the patients had complete, or nearly complete, hair loss for 1-3 months after each treatment at all laser fluences.
- After two treatments at 40 J/cm^2 (20 ms pulse duration), the average long-term hair reduction was 46%.
- 89% of patients exhibited significant long-term hair reduction at all energy/pulse duration configurations.
- In addition to statistically significant hair reduction, treatment with the laser also showed reduction in hair diameter and reduction in color of regrowing hairs.
- Side effects were fluence and skin-type dependent. Hyper or hypopigmentation was minimal in fair skin and increased with fluence and with darker skin type.

The degree of long-term hair reduction was determined by the energy fluence and the number of treatments (see table below). The higher the energy delivered to the hair follicles, the greater the degree of long-term reduction. Similarly, patients who received two treatments had greater hair reduction than those who received only a single treatment.

Hair Reduction Results

Fluence	Number of Treatments	Percentage Hair Reduction				
		1 mo.	2 mo.	3 mo.	9 mo.	12 mo.
5 ms, 15 J/cm^2	1	65.4	21.5	17.9*	15.5*	26.6
10 ms, 20 J/cm^2	1	66.7	21.0	22.2	20.7	25.9
15 ms, 30 J/cm^2	1	70.8	30.2	28.7	30.6	29.4
20 ms, 40 J/cm^2	1	70.2	26.8	29.8	32.5	32.5
20 ms, 40 J/cm^2	2	69.3	51.5	37.1	42.3	46.6
20 ms, 40 J/cm^2, 3X	2	71.1	51.9	36.8	41.4	46.2
20 ms, 40 J/cm^2, 3X	1	68.9	30.8	32.3	32.4	38.5
Control	0	17.3	10.5	10.8	6.3	5.5

* Percentage is not statistically significant compared to control.

No serious complications occurred during the study. The most common side effect was transient hyper- or hypopigmentation that resolved between one and three months after treatment. Other side effects included pain, erythema, edema and blistering. These side effects generally resolved within a few days of treatment. No scarring was observed during the studies.

Note that in clinical practice, fluence and pulse width would be adjusted for skin type. At one clinical location, over 1,000 clinical treatments were performed with this device, in which fluence and skin type were matched to optimize the efficacy and safety of treatment. When this was done, the incidence of side effects was less than one percent and was limited to transient changes in skin pigmentation.

Study of Long-Pulsed Laser Treatment for Hair Reduction on All Skin Types

Long-pulsed laser treatment for all skin types was studied at the Massachusetts General Hospital. A reprint of the study is provided in the Clinical Information – Hair Removal section (Battle EF and Anderson RR. *Study of Very Long-Pulsed (100 ms) High-Powered Diode Laser for Hair Reduction on All Skin Types*) and is summarized here.

In this study, a very long pulse width, 100 ms, was used to treat medium-to-coarse pigmented hair for darker skinned patients. Forty patients (25 women, 15 men) with coarse, dark hair on their thighs and backs were treated with the LightSheer over a range of fluences (15-60 J/cm^2) and two pulse widths (30 or 100 ms). All patients were treated and examined at 0, 1, 3, and 6 months following treatment.

The endpoints examined were skin response (including hypopigmentation, hyperpigmentation, erythema and edema) and hair regrowth. Digital images of the treatment sites were taken at each visit, and the number of hairs and hair shaft diameter was determined in each test area before treatment and at each follow-up visit.

The key results were:

- Long-term hair loss after laser treatment was strongly correlated with fluence levels.
- A pulse duration of 100 ms and a fluence of 30 J/cm^2 could be safely used on all patients, except for patients with ECT Skin Type VI.

- Side effects increased with higher fluences, but at any given fluence, the side effects were significantly reduced with longer pulse durations.
- The tolerated fluences for the 100 ms pulse width in the study is shown in the following table.

Skin Ethnic Color Type (ECT)	Skin Color	Tolerated Fluences
I	Light white	15-60 J/cm^2
II	Medium white	15-60 J/cm^2
III	Dark white	15-45 J/cm^2
IV	Light brown	15-40 J/cm^2
V	Medium brown	10-35 J/cm^2
VI	Dark brown	Start with a 10 J/cm^2 test spot

Tolerated Fluences at 100 ms Pulse Width

- Very dark-skinned patients (Skin ECT VI) can still get epidermal damage (blistering) even at the lowest fluence tested (15 J/cm^2). Therefore the authors recommend caution when treating patients with very dark skin types and preceding treatment with 100 ms 10 J/cm^2 test spots.

The authors concluded that the long-pulsed diode laser is effective for darker-skinned subjects (up to and including Skin ECT V), because the higher fluences can be used safely with the 100 ms pulse width.

Additional Studies Using the LightSheer System

In addition to the studies described in detail above, several other studies have been performed to evaluate the safety, efficacy and duration of LightSheer hair removal in a wide variety of patients. Three of these key studies with their conclusions are listed below.

SECTION 5.
LASERS IN HAIR REMOVAL

Author(s)	Title	Conclusion
Adrian RM and Shay KP	800 nanometer diode laser hair removal in African American patients: A clinical and histologic study.	The LightSheer Diode Laser System, operating at pulse widths of 30 ms and 100 ms, can be used safely and effectively in African-American patients.
Kono T	Diode laser-assisted hair removal in Asians: A study of 101 Japanese patients.	In this retrospective study, the investigators were able to achieve temporary hair removal in all patients with a single laser treatment. In terms of longer-lasting results, 50% of all patients achieved 60% or greater permanent hair reduction. Complications were mild and transient.
Lou WW, et al	Prospective study of hair reduction by diode laser (800nm) with long-term follow-up.	In follow-up lasting an average of 20 months, the LightSheer Diode Laser System was safe and effective for long-term hair reduction in individuals with skin types II and III.

SECTION 6.
CLINICAL INFORMATION – HAIR REMOVAL

Successful use of the LightSheer Diode Laser System requires proper patient selection, patient compliance with instructions prior to treatment, pre-treatment testing, appropriate treatment, and follow-up. These topics are covered in this section. The information is meant to provide general guidance. It is not meant to be a protocol or an absolute guide to clinical practice. As always, operators should be guided by their clinical experience and professional judgment when using the LightSheer Diode Laser System.

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SECTION 6. CLINICAL INFORMATION – HAIR REMOVAL

Indications for Use

The LightSheer Diode Laser System is indicated for permanent hair reduction through selective targeting of melanin in the hair follicles. It is also indicated for the treatment of superficial leg veins based on selective photothermolysis of blood vessels, as well as the treatment of benign pigmented lesions and pseudofolliculitis barbae.

Contraindications

Patients who have had prior problems with laser therapy, should be carefully screened before treatment. Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser treatment. Laser hair removal, treatment of leg veins, or treatment of benign pigmented lesions should not be attempted in patients with active infections in the treatment site. For hair removal or treatment of pseudofolliculitis barbae, caution is advised in treating patients with any of the following relative contraindications:

- A history of keloid scarring.
- Active infection or a history of herpes simplex in the treatment area.
- Use of depilatories or other hair removal treatments, such as waxing, plucking, or electrolysis, within the preceding 6 weeks.
- Hypersensitivity to hydroquinone or other bleaching agents, if applicable.
- Use of oral Accutane (Isotretinoin) within the preceding 6 months. For leg veins, caution is advised in treating patients with any of the following relative contraindications:
- A history of keloid scarring.
- Active infection or a history of herpes simplex in the treatment area.
- Use of anticoagulants within the preceding 6 months.
- Presence of refluxing varicose veins feeding the telangiectases.
- A history of bleeding disorders.
- Use of oral Accutane (Isotretinoin) within the preceding 6 months.

For benign pigmented lesions, caution is advised in treating patients with any of the following relative contraindications:

- History of poor wound healing, keloid formation, or bleeding disorders.
- Active infection or a history of herpes simplex in the treatment area.
- Hypersensitivity to hydroquinone or other bleaching agents, if applicable.
- Use of oral Accutane (Isotretinoin) within the preceding 6 months.
- Personal or family history of melanoma.
- Dysplastic nevi.
- Inability or unwillingness to follow the treatment schedule.

Warnings

Darker skin types and individuals with a suntan are at a higher risk for pigmentary changes in the treatment area. These patients should be treated with lower fluences and/or longer pulse durations than similar skin types that are untanned. Sun exposure to the treatment area imme-diately after treatment and for one month following may also increase the risk of pigmentary changes in the treatment area.

Precautions

The physician should only attempt laser treatment after adequate training and familiarity with laser safety and with the device.

The laser can cause epidermal injury. The risk increases with greater laser fluence and skin pigmentation.

In general, both treatment effectiveness and inflammatory response to skin injury are fluence related. Higher fluence levels result in greater effectiveness and also higher inflammatory response and increased likelihood of epidermal damage. Begin treatment with a conservative exposure dose and increase the fluence gradually until the desired effect is observed.

Complications and Adverse Effects

In clinical studies of the LightSheer Diode Laser, the following minor complications were observed in some patients:

- **Superficial** erosions of the treated area.

- **Hypopigmentation** or **hyperpigmentation**. These complications have been rated as both transient and minor and typically resolve spontaneously over several months.
- **Mild pain**. Use of topical anesthetic creams may be helpful, but local anesthesia is generally not required.
- **Purpura**, confined to the exposure area, may be evident for 1-3 days following treatment.
- **Erythema** and **edema** may occur immediately following treatment but generally resolve after several hours.

Treatment Guidelines for Hair Removal

Patient Selection

Patient selection is a key aspect of the effective use of the LightSheer Diode Laser System. Hair color and skin type are the two most important factors in predicting success of treatment. Temporary hair loss almost always occurs regardless of hair color. Permanent hair reduction, however, is correlated with hair color. Black or brown hair, indicating a high concentration of melanin in the follicles, is ideal. Blond, white or gray hair is not treated as effectively. Hair loss in these patients can be maintained, if desired, by retreating when hair starts to regrow (anagen phase) in the treated area, which varies depending on the body area.

In the experience of the investigators who initially tested the LightSheer Diode Laser System, people with FItzpatrick Skin Types I-III are most easily treated. People with skin Types IV-VI may require reduced fluences, longer pulse widths and/or pre-treatment with bleaching creams to reduce the amount of melanin in the epidermis. As described earlier in the discussion of the Battle and Anderson study, people with dark skin can be safely and effectively treated with a 100 ms pulse width and lower fluences. People with the darkest black skin are at risk for blistering even with these treatment modifications and should be treated only with great caution and pre-testing.

For safety reasons, patients showing any evidence of a recently severe or lengthy tanned exposure at the intended treatment site should have their treatment postponed for at least a week and then reevaluated. Bleaching agents may be utilized if the treatment provider desires. Alternatively, the treatment provider may want to consider the

new treatment guidelines for darker skinned individuals (see chart titled *Typical Fluences for Treatment with the LightSheer Diode Laser System Using the 9 x 9 mm Spot Size* later in this section).

Patient Consultation

Prior to treatment, the physician or other user should conduct a patient consultation. The consultation has five purposes:

1) To inform the patient of the treatment options, procedures, costs, risks, benefits and possible complications.
2) To take a medical history to identify any pre-existing conditions or use of medications that may affect treatment.
3) To help set realistic patient expectations for treatment outcome.
4) To obtain informed consent for treatment.
5) To provide pre-treatment instructions for the patient.

Information and History

The better informed the patient is regarding the treatment and its probable results, the more likely the patient will be satisfied with treatment. Of course, before treatment a full history should be taken to identify possible endocrine disorders (related to hirsutism), allergies, current medications, local infections in areas to be treated (e.g., herpes simplex), previous scarring, history of keloid development, etc. A sample consultation form is provided in the Forms & Protocols section. It can be modified as necessary.

Patient Expectations

Setting realistic patient expectations is a critical part of the initial consultation. At a minimum, the patient should understand that:

- Short-term hair loss will occur in most patients, but the degree of long-term or permanent hair reduction will vary among patients.
- Permanent hair reduction is the long-term, stable reduction in the number of hairs regrowing after treatment. In practical terms, patients can expect to have fewer hairs regrow after treatment, and many of the hairs that do grow back will be lighter in color and have a smaller diameter. It is essential, however, that the patient understand that permanent hair reduction does not mean complete and permanent removal of every hair in the treated area.
- The extent of permanent hair reduction is related to hair color. Patients with red, gray, or blond hair should be advised not to expect significant long-term hair reduction.

- Multiple treatments will be necessary for permanent hair reduction. Three to six treatments are typically necessary.
- Within a few days to a week, the destroyed hair within the shaft will work its way out of the follicle and may appear to be a growing hair when in fact it is not. It is important that patients expect this phenomenon to occur so they do not mistakenly think that the laser treatment didn't work.
- Mild pain may occur during treatment. The amount of pain is often related to the site of treatment. For example, the area above a women's lip or a man's frontal neck may be sensitive to some patients. Topical anesthetic creams may be helpful. Local anesthesia, however, is generally not required.
- Redness and swelling occur commonly immediately following treatment, but generally resolve after several hours.
- Other complications, such as changes in skin pigmentation, may occur, but generally they are minor and transient.

Informed Consent

After discussing the treatment and expectations, the next step in the consultation is to obtain informed consent. The consent form should cover the information already discussed, especially regarding treatment outcomes and possible complications. In addition, many practitioners find it convenient to add a photo release to the form. An example of a consent form is provided in the Forms & Protocols section.

Pre-Treatment Instructions

Once a patient has agreed to treatment, he or she should be given the appropriate pre-treatment instructions, including the following:

- Patients should be advised to avoid prolonged tanning for at least one week prior to therapy and to use a sunscreen (SPF 15-30) on exposed areas for 1-2 weeks before treatment. Some treatment providers recommend pre-treatment with a bleaching cream – 4% hydroquinone twice daily for at least six weeks prior to treatment. The efficacy of this bleaching cream can be enhanced by combining its use with topical application of retinoic acid cream 0.025% twice daily for four weeks. Use of hydroquinone and retinoic acid should be stopped prior to treatment.
- All patients should be advised to avoid waxing, plucking or electrolysis for at least six weeks prior to treatment. For the treatment to be most effective, the hair shaft must be in the follicle. Patients may continue to shave for up to two weeks prior to the test treatment. For assessment

and documentation photos, however, full hair growth is required. After the initial assessment, the patient may continue to shave throughout treatment.

- Patients should be instructed to discontinue using any skin irritants (glycolics, Retin A, astringents, etc.) three days prior to treatment to avoid unnecessary irritation.
- Patients with a history of herpes simplex virus infection in the area to be treated should be instructed to use an antiviral medication (e.g., Zovirax or Famvir) for at least three days before treatment. This instruction is important because reactivation of herpes simplex has been reported after laser treatment. Of course, patients with an active infection should not be treated until it resolves.
- Patients taking oral isotretinoin (Accutane) should be advised to stop the drug before treatment. It is generally recommended that oral isotretinoin should be stopped for six months before laser hair removal.

Pre-Treatment

Before treatment, photographs should be taken of the treatment area, both to compile a record of treatment and to help show the patient the dramatic difference that results from treatment. After photographing the treatment site, it is important to shave the area and remove all cut hair from the skin by gently washing. If the external hair shaft is present, the laser will burn it, in turn possibly burning the skin.

If the treatment site is in a sensitive area or if the patient has a low pain threshold, a topical anesthetic like ELA-Max (lidocaine 4.0%, Ferndale Labs) or EMLA cream (lidocaine 2.5% and prilocaine 2.5%, Astra USA) may be applied with occlusion for 60-90 minutes prior to treatment. In order to provide the maximal degree of pain reduction with the topical cream, the skin must be vigorously cleaned with soap, water and an oil remover, like isopropyl alcohol or methanol, prior to application of the active agent. Intradermal local anesthetics or nerve blocks may also be used but are generally unnecessary.

Testing to Determine Appropriate Fluence

Treatment should be performed with the highest fluence the skin can tolerate. Studies have shown that the permanence of hair loss is fluence-dependent, with higher percentages at higher fluences.

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Every area to be treated should be tested with two or three different fluences to accurately determine the proper energy fluence and pulse width that will be required to obtain the best results. Starting fluences may range from 10 J/cm^2 for darkly pigmented individuals up to 40 J/cm^2 for fair-skinned patients. As a consequence, the ideal treatment parameters to use for each patient must be based on clinical experience and professional judgment.

The selection of the proper fluence to be used is done by beginning the test procedure at a fluence appropriate for the skin type (see chart below) and gradually increasing the energy fluence until the skin shows slight edema following laser exposure of the treatment site. The optimal fluence is that level just below the level at which epidermal injury (separation) would occur.

After the initial test pulses, wait 15-30 minutes for a reaction to develop. With darker skin types, a significantly longer waiting period may be appropriate (see following chart titled T*ypical Fluences for Treatment with the LightSheer Diode Laser System Using the 9 x 9 mm Spot Size*).

Note: Due to potential variations between individual units, it is of vital importance that the same laser be used for both test pulses and treatments.

The desired end point is an urticarial response or perifollicular swelling and redness (Fig. 6-1). This clinical endpoint, although often observed, is not always present in Skin ECT Types V-VI.

Very dark-skinned patients (Skin ECT VI) can still get blistering at 15 J/cm^2. Therefore, it is recommended, even at the 100 ms pulse width, to be very cautious with Skin ECT VI and to do 100 ms test spots starting at 10 J/cm^2 before attempting to treat their elective sites.

Hair color and skin type are the primary factors in choosing the appropriate fluence. The following initial treatment parameters–meant only as a guide–were provided by Eliot Battle, Jr., MD and R. Rox Anderson, MD.

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Typical Fluences for Treatment with the LightSheer Diode Laser System Using the 9 x 9 mm Spot Size[1]

Fitzpatrick Skin Type	Description	Starting Fluences[2] (Test Spots)	Tolerated Fluences[3]	Pulse Duration
I	light white skin always burns, never tans	40 J/cm^2 Wait at least 15-30 minutes. Observe epidermal response, increase or decrease by 2-5 J/cm^2.	15-60 J/cm^2	Auto 30 ms - high hair density areas
II	light white skin always burns sometimes tans	35 J/cm^2 Wait at least 15-30 minutes. Observe epidermal response, increase or decrease by 2-5 J/cm^2.	15-60 J/cm^2	Auto 30 ms – high hair density areas
III	medium white skin sometimes burns always tans	30 J/cm^2 Wait at least 15-30 minutes. Observe epidermal response, increase or decrease by 2-5 J/cm^2.	10-45 J/cm^2	Auto – finer hair 30 ms – coarser hair or high hair density areas
IV	dark/olive white and Asian skin rarely burns always tans	20-25 J/cm^2 Wait at least 15-30 minutes Observe epidermal response, increase or decrease by 2-3 J/cm^2.	10-40 J/cm^2	30 ms – finer hair 100 ms – coarser hair or high hair density areas
V	light brown skin	15-20 J/cm^2 Wait at least 48-72 hours. Observe epidermal response, increase or decrease by 2-3 J/cm^2.	10-35 J/cm^2	100 ms
VI	medium to dark brown, African and African-American skin	10-15 J/cm^2 Wait at least 48-72 hours. Observe epidermal response, increase or decrease by 1-2 J/cm^2.	10-30 J/cm^2	100 ms
All Skin Types	tanned skin	• Use low range of fluences recommended for one skin type darker than patient's skin type with no tan (e.g. treat tanned skin type III as skin type IV) • Perform test spots on areas with same degree of tan as area to be treated.		100 ms

1. Treatment fluences with 12 x 12 mm spot size should be reduced by approximately 15-20%.
2. Recommended by Eliot Battle, Jr. MD.
3. From: Study of very long-pulsed (100 ms) high-powered diode laser for hair reduction on all skin types, 2000, Eliot Battle, Jr., MD, R. Rox Anderson, MD.

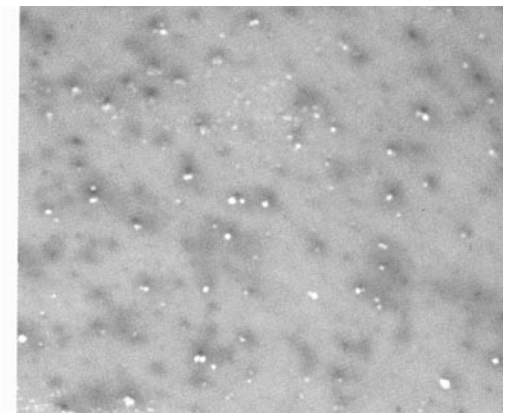

Figure 6-1. Follicular Swelling and Redness Immediately After Laser Exposure.

SECTION 6. CLINICAL INFORMATION – HAIR REMOVAL

Appropriate Pulse Widths for Treatment

Using the testing procedure outlined above, even patients with darker skin types (Fitzpatrick Types IV-VI) can be safely and effectively treated with the LightSheer System. In addition to determining the appropriate fluence, adjustments to pulse width will often be necessary.

The most appropriate pulse width is influenced not only by skin type, but also by hair color, coarseness, and density as well. In general, as described in the chart below, longer pulse widths are more appropriate for darker skin types.

Typical Pulse Widths for Treatment with the LightSheer Diode Laser System[1]

Hair	Fitzpatrick Skin Type	Hair Density	Pulse Duration
Light to medium brown, fine to medium diameter	I-III	Lower density areas: axilla, trunk, pubic, leg	Auto
Light to medium brown, fine to medium diameter	I-III	Higher density areas: cheeks, upper lip, beard, chin	Auto or 30 ms[2]
Dark brown to black, fine to medium diameter	I-III	Low and high density areas	Auto or 30 ms[2]
Dark brown to black, fine to medium diameter	I-III	Low and high density areas	Auto or 30 ms[2]
Dark brown to black, fine to medium diameter	IV	Low and high density areas	30 ms
Dark brown to black, medium to large diameter	IV	Low and high density areas	30 ms or 100 ms
Light to dark brown, medium to large diameter	V-VI	Low and high density areas	100 ms
Light to dark brown medium to large diameter	tanned	Low and high density areas	100 ms

1. Recommended by Eliot Battle, Jr. MD.
2. With multiple treatments, if hair becomes less dense and/or finer, Auto mode may be more efficacious.

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Treatment

Treatment should be performed with the highest fluence the skin can tolerate. Studies have shown that the permanence of hair loss is fluence-dependent, with higher percentages at higher fluences.

The ChillTip handpiece has been designed to protect the epidermis by providing aggressive cooling. The sapphire lens at the end of the handpiece should be held briefly in firm, direct contact with the treatment site just immediately prior to the delivery of each laser pulse. For effective cooling, the contact time can be as short as 0.1 second.

During treatment:

- The ChillTip can be placed one spot at a time or can be moved slowly and continuously. For the latter technique, coating the skin with a very thin layer of a clear, colorless, water soluble gel is recommended.
- The ChillTip should be placed flat on the surface of the skin.
- The operator can keep the skin surface flat and tight by stretching it between his or her fingers of the hand not holding the handpiece.
- The edge of the ChillTip leaves a brief indentation that can be used to align subsequent pulses. When gel is used, the path of the ChillTip through the gel can also be helpful for alignment.

Residue from hair shafts that have been destroyed and ejected from the hair follicle during exposure to the laser light may accumulate on the surface of the lens during treatment. This debris may interfere with the effectiveness of the treatment. The debris can also result in localized heating on the ChillTip and cause unwanted injury to the skin surface if it is not wiped off frequently. When treating areas with dense, course hair, the tip should be visually checked frequently and cleaned when necessary. The ChillTip should also be checked if the odor of burning hair is detected, or if the colorless gel becomes tinged with a brown color.

Gauze pads dampened with water and/or alcohol can be used for cleaning. Very abrasive scrubbing tools can be used on the sapphire tip, as sapphire is extremely hard and can only be scratched by a diamond.

In order to optimize laser treatment for each patient, it is recommended that the clinical response of each patient be evaluated three weeks after initial treatment.

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Post-Operative Care

In most cases, treatment will result in a mild sunburn-like sensation that typically disappears without treatment in 2-3 hours. Some mild redness and minor swelling may persist for 2-3 days following treatment, but dressings are usually not required. Following treatment:

- The treated site should be washed gently twice a day with soap and water.
- Any crusted areas should be treated twice daily with the application of a topical antibiotic ointment.
- Sunlight should always be avoided after treatment, and sunscreens should be applied daily.
- Cool compresses may be applied.
- Avoid deodorants until area is no longer irritated.

Retreatment

If hair starts to regrow in the treated area, it is generally best to perform retreatments. This regrowth or early anagen growth phase typically occurs between one and six months following the initial treatment. There is no known advantage to retreatment prior to hair regrowth, since there is no hair shaft for the laser light to be absorbed.

Treatment of Specific Anatomic Areas

Specific anatomic areas have specific requirements for most effective treatment. The following practical tips, provided by Judy Fahey, R.N, are based on a great deal of experience and provide guidelines for pre-treatment, treatment and post-treatment care based on the anatomic area treated. As with all treatment decisions, however, physicians or other users should be guided by their own clinical judgment and experience.

Legs

Pre-treatment:

- Use a white eye makeup pencil to physically outline the treatment areas. Have your patient do the same. It will eliminate any confusion about the exact area being treated and how much the treatment will cost.
- Always shave the treatment area first.

During treatment:

- Remember that bony areas such as the knees, ankles and shins require lower fluences (by at least 2 J/cm^2).
- Certain areas that have more coarse hairs (backs of thighs, inner thighs) may be uncomfortable for the patient. Go more slowly and consider a topical anesthetic.
- Keep the ChillTip handpiece flat on the skin surface of the leg.

Post-treatment:

- Cool the skin by washing the legs with cold water and a gentle soap.
- Counsel patient to:
  - Avoid hot baths or showers for several days after treatment. Tepid water is best.
  - Keep treated areas moist with 1% cortisone (OTC) or body lotion.
  - Avoid tight-fitting clothing for several days after treatment.
  - Avoid any sun exposure until all treatments are finished.

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Axillae

Pre-treatment:

- Wash the axilla with antibacterial soap. Gentle soaps will not remove the waxes found in deodorant.
- Outline the treatment boundaries with a white eye makeup pencil. Careful attention to the boundaries will help prevent treatment of a tanned edge.
- Always shave the treatment area before beginning.

During treatment:

- Have the patient lie on their side with their arm extended up and behind the head. Alternatively, the patient can lie on his or her back with their hand behind head, using the other hand to pull the breast slightly to the opposite side. This creates a flatter surface area.
- Be aware that the center area of the axilla is very tender and the patient might have some discomfort. Go slowly.
- To further reduce discomfort, move the ChillTip handpiece across the axilla in an up-and-down pattern, rather than back and forth.

Post-treatment:

- Offer the patient an ice bag as soon as a treatment is finished.
- Continue the cooling process by washing the treatment site with cold water and a gentle soap.
- Remind the patient to avoid deodorants until area is no longer irritated.
- Schedule the next treatment for 5 or 6 weeks.

Nasal Area

Pre-treatment:

- Carefully note any nevi, solar keratoses or lentigos. These can cause pigmentation problems and should be avoided.
- Wash the nose with warm water and a gentle soap.
- Shave the top and side of the nose and edges of the nostrils.
- Have the patient sit up and blow his or her nose before starting treatment, because the treatment will usually cause the patient to sneeze.

During treatment:

- Have the patient put on total block-out glasses and lie flat.
- If treating close to edge of nostrils/nares, consider packing nostril with wet gauze.
- Work from behind the patient.
- The ChillTip handpiece must be flat and in firm contact with the skin at all times. Do not touch the handpiece to the mucous membrane.

- **Do not fire the laser up the nose!**
- Expect the patient to sneeze and blow his or her nose several times during treatment.

Post-treatment:

- Wash the nose with cold water and a gentle soap.
- Counsel the patient to avoid all sun exposure after treatment.
- Remind the patient to expect to see fallen hairs when he or she blows their nose at 7-10 days after treatment.

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Bikini

Pre-treatment:

- A thorough consultation is essential.
  - Establish the treatment areas (bikini, abdomen, inner thighs, or all three) with the patient. Done beforehand, this consultation will reduce confusion about the treatment and the cost.
  - If the patient has ingrown hairs or folliculitis, use a topical antibiotic cream for at least 10 days prior to treatment.
  - If the patient has herpes simplex virus, treat with antiviral medication for at least three days prior to treatment.
- Ask the patient to bring her bathing suit to the treatment so that the appropriate areas will be treated.

During treatment:

- Be aware that skin tone varies and becomes darker as you treat the inner groin.
- Expect to change energy 2-4 times as you treat to compensate for different skin tones.
- Always keep the ChillTip handpiece flat on the skin surface.

Post-treatment:

- Offer patient an ice bag immediately after treating each side.
- Cool the skin by washing the treatment site with cold water and a gentle soap.
- Counsel patient to:
  - Avoid hot baths or showers for several days after treatment. Tepid water is best.
  - Keep treated areas moist with 1% cortisone (OTC), aloe vera gel or body lotion.
  - Avoid tight-fitting clothing for several days after treatment.
  - Avoid any sun exposure until after all treatments are finished.

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Treatment Guidelines for Pseudofolliculitis Barbae

Problematic and excessive hair growth are seen more commonly in many ethnic populations, including South American, African, Asian-Pacific, Middle Eastern, Mediterranean and African-American subjects. Pseudofolliculitis barbae (PFB), more commonly known as "beard bumps", is common in African-American, African-Caribbean and African subjects with tightly curled or coiled facial hair.

In PFB, curved hairs emerge from curved follicles at an acute angle and penetrate the nearby skin causing a reaction that is characterized by papules, pustules or small nodules at the point of reentry (Fig. 6-2).

Current treatments (including plucking, waxing, depilatories and electrolysis) are associated with increased incidence of unwanted side effects (hyperpigmentation and scarring) in this group of patients and are not effective. Elliot Battle and Robert Adrian (See end of Clinical Information–Hair Removal section) have studied numerous men and women with skin Types IV-VI with PFB.

Most of the treatment guidelines for PFB are similar in scope to those for hair removal. For example, a patient consultation, exam and history should be performed in both situations before treatment begins. Treating pseudofolliculitis barbae assumes that the reader has a good understanding of the treatment guidelines already presented for hair removal, especially the treatment guidelines for patients with darker skin. The majority of patients presented with PFB will be patients (especially men) with darker skin types.

When treating PFB occurring around the male beard area using lower fluences, temporary rather than permanent hair reduction is often the goal. A delay of regrowth will often allow the condition to improve without permanently reducing hair on the face. For men's necks and the female beard area, permanent hair reduction to treat PFB can be an appropriate goal.

Section 6. Clinical Information – Hair Removal

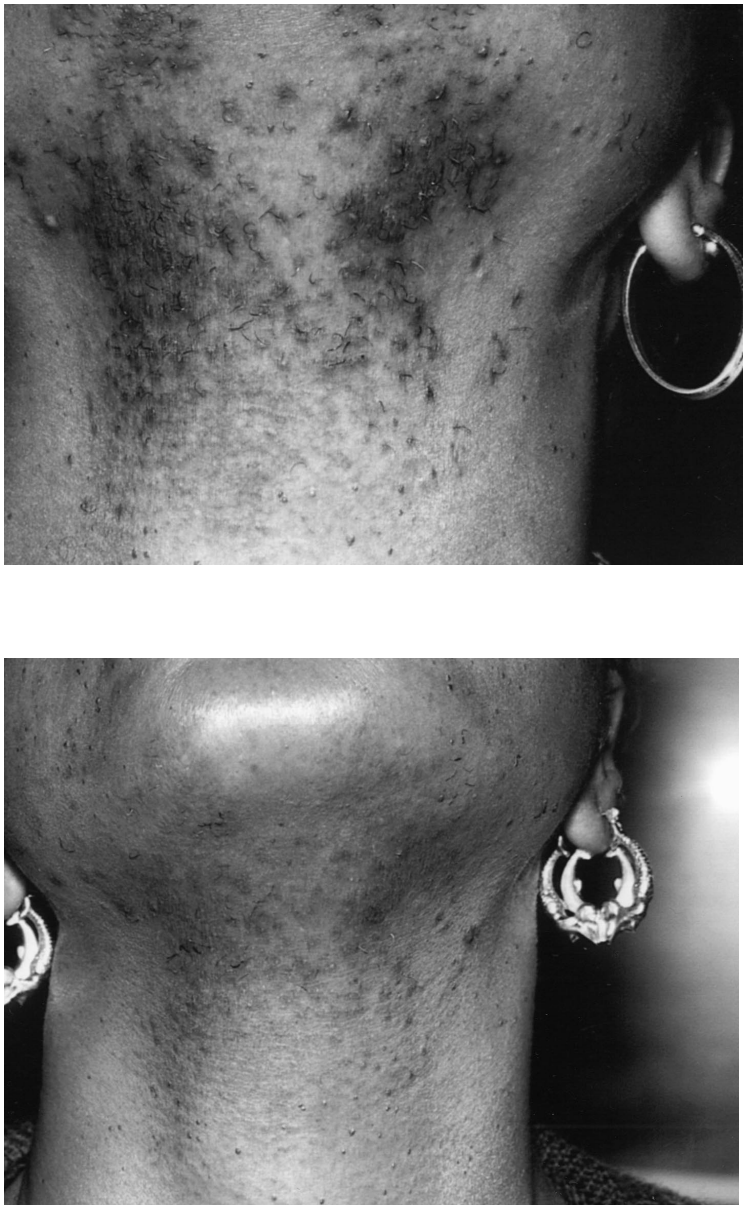

Figure 6-2. Pseudofolliculitis Barbae, also known as "beard bumps." Female patient with skin type V before treatment, and after 3 treatments with the LightSheer Diode Laser System.

Photo provided courtesy of Robert M. Adrian, M.D.

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Additional Resources

The following reprints have been inserted at the end of this section to provide you with additional information on hair removal with the LightSheer Diode Laser System.

- Dierickx–*Laser Hair Removal: Scientific Principles and Practices*
- Battle, et al–*Study of Very Long-Pulsed (100ms) High-Powered Diode Laser for Hair Reduction on All Skin Types*
- Pardo, et al–*Use of the LightSheer Diode Laser System for Hair Reduction: Safety and Efficacy in a Large Series of Treatments*
- Adrian–*LightSheer™ 800 nm Pulsed, High-Power Diode Laser Hair Removal System*
- Campos–*Safe and Effective Long Term Hair Reduction in Tanned Patients using an 800 nm Diode Laser*

SECTION 6.
CLINICAL INFORMATION – HAIR REMOVAL

Section 7.
Clinical Information – Treatment of Superficial Leg Veins

Successful use of the LightSheer Diode Laser System for superficial leg veins requires proper patient selection, patient compliance with instructions prior to treatment, pre-treatment testing, appropriate treatment and follow-up. The following information is meant to provide general guidance. It is not meant to be a protocol or an absolute guide to clinical practice. As always, operators should be guided by their clinical experience and professional judgment when using the LightSheer Diode Laser System.

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SECTION 7. CLINICAL INFORMATION – TREATMENT OF SUPERFICIAL LEG VEINS

Indications for Use

The LightSheer Diode Laser System is indicated for the long-term, or permanent, hair reduction through selective targeting of melanin in the hair follicles. It is also indicated for the treatment of superficial leg veins based on selective photothermolysis of blood vessels, as well as the treatment of benign pigmented lesions and pseudofolliculitis barbae.

Contraindications

There are no known contraindications to treatment with the LightSheer Diode Laser System. Patients who have had prior problems with laser therapy, however, should be carefully screened before treatment. Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser treatment.

For leg vein treatment, caution is advised in treating patients with any of the following conditions:

- A history of keloid scarring.
- Active infection or a history of herpes simplex in the treatment area.
- Use of anticoagulants within the preceding six months.
- Presence of refluxing varicose veins feeding the telangiectasias.
- A history of bleeding disorders.
- Use of oral isotretinoin (Accutane) within the preceding six months.

Laser Treatment of Superficial Leg Veins

Superficial leg veins, also known as spider veins or more technically as **telangiectasias**, are small, thin veins that lie close to the surface of the skin (Fig. 7-1). Although these veins are connected with the larger vascular system, they are not an essential part of it. Spider veins are usually not a serious medical condition; most often treatment is desired for cosmetic reasons.

Millions of women–some estimates put the number as high as 80 million–are affected by this common cosmetic problem. Although the actual cause of spider veins is not well understood, several factors contribute to their development, including heredity, pregnancy, hormonal shifts, weight gain, activities that require prolonged sitting or standing and the use of certain medications.

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Clinical Information – Treatment of Superficial Leg Veins

Figure 7-1. Typical Appearance of Spider Veins.* Spider veins usually take on one of three patterns: the branching pattern seen here, a linear pattern of parallel lines, or a true spider shape in which the veins radiate from a dark central point. *Copyright 1999 ASPS.

Traditional Treatment of Spider Veins

Traditional treatments of spider veins include **sclerotherapy** and surgery. In sclerotherapy, small and medium-sized veins are injected with a solution that damages the vascular epithelium, in turn scarring the affected veins, eventually closing them (Fig. 7-2). The treatment forces the blood to be rerouted to healthier veins.

When performed properly, serious complications rarely occur from sclerotherapy. However, because it is an invasive procedure, it does carry some important risks. They include:

- Infection
- Formation of blood clots in the veins
- Severe inflammation
- Allergic reactions to the sclerosing solution
- Transient changes in pigmentation
- Skin injuries that may cause permanent scarring
- **Telegiectatic matting**, a condition in which fine blood vessels appear around the treated area, requiring further injections.

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If sclerotherapy is ineffective, a physician may opt to use surgical methods of treatment. The most common approach is **ambulatory phlebectomy**, a procedure in which smaller veins are removed through a series of tiny skin punctures. In more serious cases, such as varicose veins, vein stripping and endoscopic vein surgery may be used.

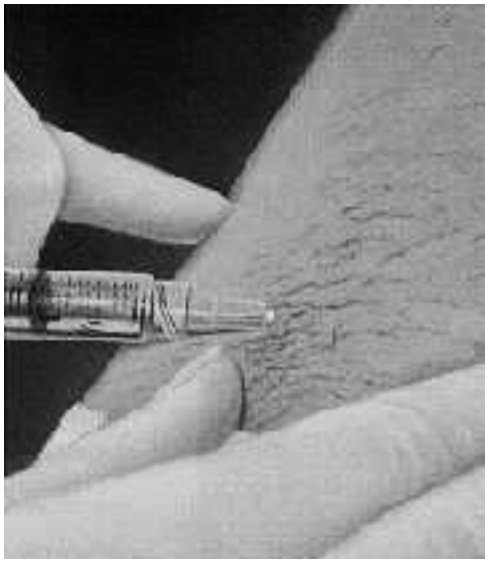

Figure 7-2. Injection of Sclerosing Solution into Superficial Leg Veins.
***Copyright 1999 ASPS.**

Laser Treatment of Spider Veins

Lasers are a relatively new option for the treatment of leg veins. In leg vein treatment the chromophore is oxyhemoglobin in the blood, which absorbs the laser energy, transferring heat to the vascular epithelium, thus denaturing the vessel wall. As with sclerotherapy, this damage causes the blood to be rerouted to healthier vessels, and the spider veins are eventually absorbed back into the body.

Several different types of lasers have been used for leg vein treatment. They include frequency-doubled Nd:YAG lasers, pulsed dye lasers and alexandrite lasers. In addition, filtered xenon flashlamps have also been used to treat leg veins.

The major advantages of laser treatment of leg veins over more traditional treatments such as sclerotherapy include the following:

- Because the treatment is not invasive, the risk of infection is greatly reduced.

- Because sclerosing solutions are not used, there is no risk of allergic reactions to treatment.
- Because no needles are used, even tiny veins can be treated.
- Laser treatment is simpler and faster than sclerotherapy.
- Laser treatment can be preferred by needle-phobic patients.

The LightSheer Diode Laser System offers additional advantages in clearing leg veins when compared to other laser sources. First, the 800 nm wavelength is less well absorbed by the competing chromophore melanin than when shorter wavelength light is used, potentially reducing side effects. In addition, the longer 800 nm wavelength penetrates deeper into the skin than other lasers emitting shorter wavelengths of light and thus may be more effective at reaching the target area.

Clinical Results in the Use of the LightSheer System for Spider Veins

Investigators at the Wellman Laboratories of Photomedicine at Harvard Medical School have studied the LightSheer Diode Laser System as a treatment for superficial leg veins. A reprint of the study is provided at the end of this section (Campos VB, et al. *Use of an 800 nm High Power Diode Laser for the Treatment of Leg Vein Telangiectasia*) and is summarized here.

In the study, twenty-five patients with superficial varicosities (1 mm or less in diameter) on the upper or lower legs were treated with a range of fluences of 15-40 J/cm^2. Treatment was repeated up to three times. Laser pulses were delivered with gentle pressure to allow skin surface cooling, but without compression of the veins being treated. The primary measure of efficacy was a blinded visual grading by the investigators of vessel clearance.

The key results were as follows:

- Based on leg vein clearance as measured in digital photographs, the optimal treatment for the small vessels (<0.4 mm diameter) is 20 ms pulse width and a 40 J/cm^2 fluence. For larger vessels (between 0.4 mm and 1 mm in diameter), the optimum treatment parameters were a 30 ms pulse width and a 40 J/cm^2 fluence.
- The clearance rate improved each month after treatment. In all cases, multiple treatments were more effective than a single treatment.
- The larger vessels (0.4 mm to 1 mm in diameter) responded better than those smaller than 0.4 mm in diameter, with 100% of the patients having greater than 50% clearance after three treatments. In contrast, 70% of patients with treated, smaller vessels had greater than 50% clearance after three treatments.

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The authors concluded that patients with blue or purple leg vein telangiectasias between 0.4 mm and 1 mm in diameter can be effectively treated with the LightSheer Diode Laser System. Based on the results, the treatment parameters for these vessels are optimally treated with a 30 ms pulse width and a 40 J/cm^2 fluence.

During the study, the clearance rate improved each month after treatment. The percentage of patients who had greater than 50% clearance increased over time. In all cases, multiple treatments were more effective than a single treatment. Size 2 vessels responded better than size 1 vessels, with 100% of the patients having greater than 50% clearance of the size 2 vessels after three treatments.

For more information, please refer to the clinical reprint *Use of an 800 nm High Power Diode Laser for the Treatment of Leg Vein Telangiectasia* at the end of this section.

LightSheer Treatment Guidelines

Most of the treatment guidelines for leg veins are similar in scope to those for hair removal. For example, a patient consultation, exam and history should be performed in both situations before treatment begins. This section contains information specific to the treatment of leg veins and assumes the reader has a good understanding of the treatment guidelines already presented for hair removal.

Patient Selection and Expectations

As with hair removal, patient selection is a key aspect of the effective use of the LightSheer Diode Laser System for treatment of superficial leg veins. Clinical studies and more recent clinical observations have shown that treatment is most effective for patients with blue or purple leg vein telangiectasias between 0.4 mm and 1.5 mm in diameter. Patients with smaller leg veins can be treated, but the treatment is likely to be somewhat less effective for them. Similarly, patients with red vessels can be treated, but because their telangiectasias contain less of the oxyhemoglobin chromophore, the effectiveness of treatment is likely to be lower.

Patients should be counseled that at least two treatments, and more likely three, will be required for maximum result. Patients should also be counseled that they may experience hair removal in the areas treated.

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Pre-treatment Instructions

Patients should be instructed to avoid sun exposure (by using sunscreen) for six weeks prior to treatment. Patients with tans or who use self-tanning creams should delay their treatment for at least a month. If a patient does not want to wait, a bleaching cream can be used to reduce the tan.

Testing and Treatment

As is the case with hair removal, the hair in the treatment area should be shaved before treatment to avoid the hair shaft from burning and causing epidermal damage. Sensitive patients may require a topical anesthetic; however, topical anesthetics are not recommended unless necessary, as they may cause vasoconstriction that can reduce the effectiveness of treatment.

Unlike hair removal, compression should not be used when treating leg veins. The handpiece should gently touch the skin to cool the epidermis, but no pressure should be applied. Pressure can force blood out of the target vessel, thus reducing the amount of oxyhemoglobin present to absorb the laser energy.

Some practitioners like to slide the handpiece across the skin. In this case, a very light layer of gel can help the handpiece move smoothly. About 10% overlap between pulses is recommended.

A few sites should be tested with different laser exposures before beginning the actual treatment. Patients with Fitzpatrick Skin Types I-III should be tested with a fluence of 40 J/cm^2. Darker skinned patients (Fitzpatrick Types IV-VI) should be tested with a lower fluence (20 J/cm^2). It is best to wait at least 24 hours after the test pulses before checking for epidermal damage. With darker skinned patients, wait one week before checking. The desired endpoint is thrombosis, erythema and perivascular edema. They should resolve within 24 hours of treatment.

In the pivotal clinical trial for the LightSheer in leg vein clearance, the optimal treatment parameters were determined as shown in the following table. They should be used as a guideline for treatment, assuming that testing demonstrates that the patient can be safely treated with these fluences.

SECTION 7. CLINICAL INFORMATION – TREATMENT OF SUPERFICIAL LEG VEINS

Optimal Fluences and Pulse Widths for Leg Vein Treatment

Vessel Size	Recommended Fluence and Pulse Width
<0.4 mm	40 J/cm^2 20 ms
0.4 mm–1 mm	20 J/cm^2 30 ms

Double or triple pulsing can be effective with darker skin patients. In double or triple pulsing, pulses are delivered to the exact same area two seconds apart. Multiple pulsing is recommended over multiple passes over the patient, as it is easier to know which area has been treated. Multiple pulsing has, however, also been shown to increase the incidence of side effects.

Postoperative Care

In most cases, treatment will result in a mild sunburn-like sensation that typically disappears without treatment in 2-3 hours. Some mild redness and minor swelling may persist for 2-3 days following treatment, but dressings are usually not required. Following treatment, the treated site should be washed gently twice a day with soap and water. Any crusted areas should be treated twice daily with the application of a topical antibiotic ointment. Sunlight should always be avoided after treatment, and sunscreens should be applied daily.

Some investigators have reported that treatment outcomes improve when stockings or support hose are worn for at least three days after treatment. Patients should be counseled to expect that clearance will increase over time, with the best results seen six months after the last treatment.

Section 7.
Clinical Information – Treatment of Superficial Leg Veins

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Additional Resources

The following reprint has been inserted at the end of this section to provide you with additional information on use of the LightSheer Diode Laser System for the treatment of superficial leg veins.

- Campos, et al–*Use of an 800 nm High-Power Diode Laser for the Treatment of Leg Vein Telangiectasia*

Section 7.
Clinical Information – Treatment of Superficial Leg Veins

Section 8.
Clinical Information – Treatment of Benign Pigmented Lesions

Benign pigmented skin lesions are a common dermatological problem. It is estimated that in the US population alone, these lesions number in excess of 10 billion. Patients consider a number of these lesions cosmetically undesirable because of their location, color, size or other clinical features. This section covers the use of the LightSheer Diode Laser System for the treatment of these lesions.

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SECTION 8. CLINICAL INFORMATION – TREATMENT OF BENIGN PIGMENTED LESIONS

Background

Pigmented lesions may be divided into three types according to the location of the pigment within them:

- E**pidermal pigmented lesions** include benign melanocytic lesions such as lentigo solaris, speckled letiginous nevus (nevus spilus), café-au-lait macules, sebhorrheic keratoses, and ephelides (freckles) and benign junctional nevi.
- **Epidermal-dermal pigmented lesions** with both an epidermal and dermal component include compound nevi, Becker's nevi, disorders such as melasma and post-inflammatory hyperpigmentation.
- **Dermal pigmented lesions** include blue nevi, nevi of Ota or Ito and nevomelanocytic nevi (acquired and congenital).

Dermal lesions have not usually been amenable to treatment except by surgical excision. For other lesions, chemical depigmenting agents, such as topical hydroquinone or tretinoin, have been used. Epidermal lesions, in particular, have been successfully treated using a destructive modality to remove the epidermis containing the lesion. Destructive modalities have included cryotherapy, dermabrasion, electrodessication and chemical peeling. Because such methods are essentially nonspecific in their destruction of the epidermis, however, side effects such as permanent hypopigmentation, atrophy, scarring and skin surface textural changes may result. Therefore, treatment of pigmented lesions by selectively targeting the pigment-containing cells is preferable. Recent advances in laser technology have provided a safe and effective alternative for the treatment of many types of benign pigmented skin lesions. Selective destruction of pigmented lesions has been best achieved via selective photothermolysis. Through prudent selection of laser parameters (e.g., wavelength, pulse duration, fluence and spot size), benign pigmented lesions can be destroyed while preserving surrounding normal skin and minimizing cosmetically unacceptable side effects.

Section 8.
Clinical Information – Treatment of Benign Pigmented Lesions

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Clinical Evidence Demonstrating the Safety and Efficacy of the LightSheer for Benign Pigmented Lesions

Dr. Suzanne Kilmer and her colleagues at the Laser and Skin Surgery Center of Northern California have studied the LightSheer Diode Laser System as a treatment for benign pigmented lesions. A reprint of the study is provided at the end of this section (Kilmer S, et al. *Use of the LightSheer Diode Laser System for the Treatment of Benign Pigmented Lesions*) and is summarized here.

Study Design

In the study, twenty-four patients with FItzpatrick Skin Types I-IV were treated. A total of 69 nevi, located on various regions of the body and with diameters less than 6 mm, were treated. Patients with a personal or family history of melanoma were excluded, and no dysplastic nevi were treated.

Patients were treated with the LightSheer equipped with a 9 x 9 mm spot. Initial treatments were conducted at fluences of 30-40 J/cm^2, 15-30 ms pulse durations and a double pulse. Pulse durations of 30 ms were used for patients with darker skin, and fluences up to a maximum of 60 J/cm^2 were used later in the study when higher fluences became available.

The clinical endpoint to treatment was a darkening of the nevus. Adequate treatment was also indicated by mild-to-moderate erythema and edema immediately surrounding the nevus appearing several minutes following the treatment.

Each patient underwent 2 treatments at 4-6 week intervals. If the patient's response was satisfactory, the fluence was increased to the maximum, and the number of pulses increased to 3 at subsequent treatments.

Key Results

Efficacy

- Treatment was effective in clearing nevi. Specifically, after one treatment, 67% of the lesions were less than 50% clear, but 26 were more than 75% clear, including 12% that were more than 95% clear.

- One month after the second treatment, only 32% of the nevi were less than 50% clear, but 57% were more than 75% clear, including 17% that were more than 95% clear.
- Preliminary results indicated that clearance of most nevi continued to improve after an additional treatment or 3 months after two treatments.

Safety

- The overall safety profile of treatment was excellent. Immediately after treatment, whitening to graying or darkening of the lesions occurred. Edema and sometimes erythema developed over the first three minutes.
- Side effects included temporary hypopigmentation surrounding 5 treated nevi that cleared within 2 months, and mild hyperpigmentation that occurred in 3 patients, which cleared with hydroquinone and sunscreen treatment.

Conclusion

The authors concluded that the LightSheer Laser Diode System is both safe and effective for the treatment of benign pigmented lesions.

Treatment Guidelines for Benign Pigmented Lesions

Most of the treatment guidelines for benign pigmented lesions are similar in scope to those for hair removal. For example, a patient consultation, exam and history should be performed in both situations before treatment begins. This section contains information specific to the treatment of benign pigmented lesions and assumes the reader has a good understanding of the treatment guidelines already presented for hair removal.

Types of Lesions Appropriate for Treatment

- Laser treatment of benign pigmented lesions has been most successful for moderately pigmented nevi.
- Very lightly pigmented nevi can be treated, but it may be difficult to achieve significant lightening. The low density of pigment in these nevi makes treatment by longer pulses less effective.
- Very dark and dense nevi can be treated but should be treated cautiously.

- Treatment of congenital melanocytic nevi is somewhat controversial because of the increased risk of melanoma. However, laser treatment has been performed for congenital nevi that are clinically benign and/or that are located in an area where surgical excision is unsuitable. Patients should be cautioned that congenital nevi can recur.
- Dysplastic nevi should not be treated.

Patient Selection

The LightSheer is suitable for the treatment of benign pigmented lesions in adults and children with all skin types except very dark skin. Persons with a personal or family history of melanoma should not undergo laser treatment for skin lesions.

Pre-Treatment Instructions

- Patients should remove all makeup and sunscreen from the area to be treated.
- The area around the nevus should be shaved prior to treatment to prevent unwanted thermal damage caused by absorption of the laser energy by the hair.
- Patients should be informed that they might experience long-lasting or permanent hair reduction in the area exposed to the laser energy.
- A thin layer of ultrasound gel can be applied to the skin before treatment.
- If a marker is used to annotate that patient's skin near the nevus, dark or black ink should not be used because it will absorb the laser light and heat the epidermis. Red ink or a white makeup pencil can be used instead.

Treatment Technique and Parameters

Suggested parameters for initial follow-up and treatment are shown in the table below. The parameters are based on the clinical experience of physicians who have used the LightSheer for benign pigmented lesions. But as with all laser techniques, operators should use their clinical knowledge and experience when determining treatment parameters. The exact parameters may need to be adjusted depending on:

- The type of lesion (e.g., dark, dense lesions may need to be treated with lower fluences).
- The patient's skin type or presence of tanning (e.g., longer pulse widths are appropriate for darker or tanned skin).

- Observations of clinical endpoints during and immediately after treatment with laser pulses.

Suggested Parameters for Use of the LightSheer for Pigmented Skin Lesions[a,d]

Fitzpatrick Skin Type	Fluence (J/cm^2)	Pulse Duration (ms)	No. of Pulses
Initial Treatment			
I-III	40	20-30	2
IV-V	30-40	30	2
Follow-up Treatments[b]			
I-III	Up to 60	30	3
IV-V	Up to 60[c]	30	3

a. Parameters for the 800-nm laser with a 9 x 9 mm chilled sapphire tip.
b. Exact parameters for follow-up treatments will depend on how the patient responds to the initial treatment.
c. With darker skin types, higher fluence levels should be approached with caution (e.g., increments of 2-3 J/cm^2).
d. Parameters based on the study *Use of the LightSheer Diode Laser System for the Treatment of Benign Pigmented Lesions* by Suzanne Kilmer, MD, Vera A. Chotzen, MD, and Marla McClaren, MD.

The most effective treatment technique is to:

- Place the laser tip on the area to be treated.
- Apply the pulse or pulses.
- Pick up the ChillTip and wipe it off.

The same technique can be used for all sizes of nevi, but larger nevi usually require multiple tip placements and treatments. Use of a sliding technique is not recommended, since debris may accumulate on the tip.

Post-Treatment Care

- Post-treatment stinging can be alleviated by application of ice packs, gauze soaked in cold water or an occlusive dressing.
- The treated area should be gently washed at least twice daily with soap and water.
- In the event the epidermis has been removed, an ointment, such as Aquaphor or aloe vera gel, can be applied with an occlusive dressing.
- Patients should be instructed to avoid excessive sun exposure and to use a zinc-oxide-based sunscreen with SPF 20 or higher for several months after treatment to avoid the chance of hyperpigmentation.

Section 8.
Clinical Information – Treatment of Benign Pigmented Lesions

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Additional Resources

The following reprint has been inserted at the end of this section to provide you with additional information on use of the LightSheer Diode Laser System for the treatment of benign pigmented lesions.

- Kilmer, et al–*Use of the LightSheer Diode Laser System for the Treatment of Benign Pigmented Lesions.*

Section 8.
Clinical Information – Treatment of Benign Pigmented Lesions

SECTION 9.
FORMS AND PROTOCOLS

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As a service to LightSheer users, we've included several forms and protocols used in laser hair removal practices. They are meant to provide general guidance only. Each physician or other user is encouraged to develop forms and protocols that reflect the needs and circumstances of each of their practices.

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SECTION 9.
FORMS AND PROTOCOLS

Explanation of Pre-Treatment Questions

There are important questions specific to laser hair removal that treatment providers should ask patients to ensure a successful treatment regimen. The table below identifies some of these questions (which have been incorporated in the sample pre-treatment consultation form), and why it is important to address these questions with the patient.

Pre-Treatment Questions

Question	Purpose Of Question	How Information Is Used
How do you tan?	Establish Fitzpatrick Skin Type.	Selection of parameters for test spots and treatments.
What is your race?	Establish ethnicity.	Selection of parameters for test spots and treatments.
What is your eye color?	Helps with skin typing and ethnicity.	Selection of parameters for test spots and treatments.
What is your hair color?	To determine if hair color is suitable for treatment.	Selection of parameters for test spots and treatments.
What is your skin color?	Helps with skin typing and ethnicity.	Selection of parameters for test spots and treatments.
When did you last expose yourself to the sun or sunlamp/bed?	To check for presence of tanned skin.	Selection of parameters for test spots and treatments (100 ms for tanned patients) or possible delay of laser treatment.
How long do you expose yourself to the sun or sunlamp/bed?	To check for presence of tanned skin.	Selection of parameters for test spots and treatments (100 ms for tanned patients) or possible delay of laser treatment.
What is your current form of hair removal?	May need to delay treatment depending on method used.	Patient should not be waxing, plucking or using electrolysis for at least 6 weeks before laser treatment.
Have you had any previous laser procedures, electrolysis, chemical peels or botox/ collagen injections?	To determine reaction to previous treatments, especially if it relates to the same areas of the body where laser treatment is being considered.	If yes, ask follow-up question regarding any side effects. Delay treatment if patient has had a chemical peel in same area for 1-3 weeks, or botox/collagen injections for at least 1 week.

Pre-Treatment Questions (cont.)

Question	Purpose Of Question	How Information Is Used
Do you use any skin care products that contain Retin-A, alpha/beta hydroxy acids or glycolic acid? If so, what is the last date of their use?	Patient may be more sensitive to laser treatment.	Ensure use is discontinued at least 3 days before laser treatment.
Have you ever taken Accutane? If so, when? Dosage and date discontinued?	Patient may not heal properly if treatment is prior to 6 months.	Ensure use is discontinued at least 6 months before laser treatment.
Do you have any history of abnormal or keloid scarring?	Assessment of potential for adverse complications or side effects.	Medical history.
Have you ever had any skin pigmentation during or following pregnancy or medications used?	Assessment of potential for adverse complications or side effects.	Treatment parameters and pulse duration in certain cases.
Do you have recurrent folliculitis?	Laser treatment can help treat folliculitis.	Efficacy of treatment.
Do you have herpes or cold sores?	Treatment scheduling, or need for precautions.	Treat with antiviral medication for 3 days prior to treatment (if treatment is in or near infected area). Postpone treatment until there are no active sores. Take extra care to disinfect ChillTip (with Virex and Cavicide) before treating another patient.
Have you ever had any gold therapy?	Photosensitivity issues.	Counseling regarding effectiveness of treatment.
Have you ever had any shingles?	May be a sign of herpes.	Possibly pre-medicate area prior to treatment.
Do you have any cosmetic or professional tattoos?	Treatment with LightSheer can change tattoo color.	Avoid treating patients who have cosmetic tattoos on upper lip.
Are you pregnant?	Safety issues.	Recommend delaying treatment until term.
Are you post- or peri-menopausal?	Hair growth changes at this time.	Counseling regarding effectiveness of treatment.
Have you ever had a blood hormonal workup?	Want to know if hirsutism is normal or not.	Counseling regarding effectiveness of treatment.
Do you have polycystic ovary syndrome?	Patient may need more treatments.	Counseling regarding effectiveness of treatment.
Do you have any history of metabolic disorders?	Can increase hair growth.	Counseling regarding effectiveness of treatment.

Pre-Treatment Questions (cont.)

Question	Purpose Of Question	How Information Is Used
Do you have adrenal hyperplasia?	Can increase hair growth.	Counseling regarding effectiveness of treatment.
Have you ever had any thyroid therapy?	Overactive thyroid can change hair growth.	Counseling regarding effectiveness of treatment.
Have you ever had any kidney disease/failure?	Healing properties.	Counseling regarding effectiveness of treatment.
What medications are you currently taking (including over the counter medicine)?	Photosensitivity issues; psychological issues.	Counseling regarding effectiveness of treatment.
Are you allergic to any medication?	Medical history.	If medication is needed for treatment, need to know possible allergic reactions.
Do you have any dental work such as fillings, bridges and crowns?	Extra considerations if treating around mouth and jaw.	A dental guard or gauze may be needed during procedure, and patient should be warned that they may feel the laser's energy in their mouth.
Have you had any significant medical procedures (e.g. pacemaker, etc.)?	Medical history.	Clearance for treatment may be needed from patient's cardiologist.
Do you have breast implants?	Medical history.	Counseling regarding effectiveness of treatment.

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Pre-Treatment Consultation Form

This form may be used to elicit patient history relevant to laser hair removal. Alternately, a user may choose to use a standard history form. In that case, it is important to remember to ask about history of keloid formation, any history of endocrine disorders, presence of recurrent skin infections (e.g., herpes simplex), use of Accutane (isotretinoin), use of glycolics or Retin-A, and skin type.

Name _____Date _____ Date of Birth _____

Desired Treatment _____

How do you tan? ❑ Always burn, never tan ❑ Always burn, sometimes tan

❑ Sometimes burn, sometimes tan ❑ Never burn, always tan

What is your race? _____ What is your eye color? _____

What is your hair color? _____

What is your skin color (non-exposed areas)?

❑ reddish ❑ very pale beige tint ❑ light brown ❑ dark brown

When did you last expose yourself to the sun or sunlamp/bed? _____ days/weeks/months

How often do you expose yourself to the sun or sunlamp/bed (for how long and what body parts)? _____

What is your current form of hair removal? _____

Have you previously had any of the following treatments? When was your last treatment? _____

❑ laser procedure ❑ electrolysis ❑ chemical peels ❑ botox/collagen injections

Do you use any skin care products that contain Retin-A, alpha/beta hydroxy acids or glycolic acid? _____ If so, what was the last date of their use? _____

Have you ever taken Accutane? _____ If so, when? _____

Dosage and date discontinued _____

Do you have any history of abnormal or keloid scarring? _____

Have you ever had any skin pigmentation during or following pregnancy or medications used? _____

Do you have recurrent folliculitis? _____ Do you have herpes or cold sores? _____

Have you every had any gold therapy? _____ What about shingles? _____

Do you have any cosmetic or professional tattoos? _____ If so, where? _____

Are you pregnant? _____ Are you post- or peri-menopausal? _____

Date of last menstrual period? _____

Have you ever had a blood hormonal workup? _____

Do you have polycystic ovary syndrome? _____

SECTION 9.
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Do you have any history of metabolic disorders? _____ If so, what? _____

Do you have adrenal hyperplasia? _____

Have you ever had thyroid therapy? _____

Have you ever had any kidney disease/failure? _____

What medications are you currently taking (including over the counter medications)?

_____

_____

Are you allergic to any medications? _____ If so, what? _____

Do you have any dental work like fillings, bridges and/or crowns? _____

Do you have any significant medical conditions? _____ If so, what? _____

_____

If you are considering treatment on the breasts, do you have breast implants? _____

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Pre-Treatment Consent Form

This consent form is customized to include a description of the risks specific to laser hair removal.

My signature below constitutes my acknowledgment that:

I, _____, consent to and authorize _____

_____ and members of the staff to perform multiple treatment laser-assisted hair removal and related services on me.

THE AREAS TO BE TREATED ARE:

_____

_____

_____

1) The nature and purpose of the treatment have been explained to me, and questions I have had regarding the treatment have been answered to my satisfaction. A darkening or lightening of the skin may occur, at times up to many months following treatment. Also noted in some patients are superficial erosions, bruising, blistering, redness and swelling. There is a rare possibility that a scar at the treatment site may develop.
2) I understand that the treatment may involve risks of complication or injury from both known and unknown causes, and I freely assume these risks.
3) Alternative means of treatment and their risks and benefits have been explained to me, and I understand that I have the right to refuse treatment.
4) No guarantee, warranty or assurance has been made to me as to the result that may be obtained.
5) I agree that any pictures taken of my treatment site may be used for publication or teaching purposes; however, my name will not be disclosed and complete confidentiality will be maintained.
6) I agree to adhere to all safety precautions and regulations during the laser treatment.
7) I certify that I have read this entire Informed Consent and that I understand and agree to the information provided in this form. I certify that I am a competent adult of at least 18 years of age, or that if I am a minor under the age of 18, I understand that the consent of my parent/legal guardian/person having legal custody will also be required before treatment. This Informed Consent is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.
8) I agree to pay $_____ for the above-mentioned services.

PATIENT NAME _____DATE_____
(please print)

PATIENT SIGNATURE _____

WITNESS SIGNATURE _____DATE_____

Treatment Record

Patient Name ____________________________

Preparation: The risks, benefits/advantages, disadvantages and possible complications were reviewed with the patient in detail. A signed informed consent was obtained for the LightSheer laser procedure. Energy selection and laser parameters were selected by the treatment provider. The patient was placed in the recumbent position. Protective eyewear was provided for the patient and all medical personnel present in the room. The area(s) to be treated were exposed. Pre- and post-treatment instructions were carefully reviewed, and a handout detailing these instructions was provided. The importance of post-treatment care and sun protection was re-emphasized.

AREA TREATED: __________________________________ (one area per report)

Treatment #	Preoperative DX	Energy J/cm^2	Pulse Width (ms)	Estimated # Pulses	Date of Treatment	RN Signature
# ______ tx	❑ Unwanted Hair ❑ Other		❑ Auto ❑ 30 ❑ 100			

Comments:

____
____
____
____
____

Treatment #	Preoperative DX	Energy J/cm^2	Pulse Width (ms)	Estimated # Pulses	Date of Treatment	RN Signature
# ______ tx	❑ Unwanted Hair ❑ Other		❑ Auto ❑ 30 ❑ 100			

Comments:

____
____
____
____
____

Treatment #	Preoperative DX	Energy J/cm^2	Pulse Width (ms)	Estimated # Pulses	Date of Treatment	RN Signature
# ______ tx	❑ Unwanted Hair ❑ Other		❑ Auto ❑ 30 ❑ 100			

Comments:

____
____
____
____
____

Postoperative Instructions Handout

POST-OPERATIVE INSTRUCTIONS AFTER LASER HAIR REMOVAL

You may experience a slight sunburned feeling on the treated area for a couple of hours. Apply cool compresses to the area for 10-15 minutes an hour for 4-5 hours after treatment.

For the next 2-5 days you may develop a fine crust over the treated area. Keep the area clean by washing twice a day with a mild soap followed by a small application of Bacitracin or Polysporin ointment. (These products can be purchased without prescription at any drugstore.) Continue until the crusting disappears. Do not use glycolic cleaners or Retin-A products over the treated area for one week after treatment. If makeup is desired, apply a thin coat of Bacitracin before applying the makeup. Do not use deodorant until the area is healed. Use sun protection with an SPF 15 or greater prior to going outdoors. Avoid excessive sun exposure.

You will notice that the hair will be singed in the treated area. The hair will continue to grow until the hair follicle has grown and fallen out. This process may take up to two weeks. You should not tweeze or wax in between treatments because retreatment is most effective when the hair shafts are present in the hair follicles. Shaving the area, however, is fine.

Please call the office if you have any problems.

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Pre-Treatment & Accessories Checklist

The following checklist is provided as a guide to preparing your patient and LightSheer system for a successful laser procedure. This list is not intended to be a replacement for the clinical experience of the treatment provider.

Pre-Treatment - Check that the patient:

- ✓ Has not had recent sun exposure
- ✓ Has not started any new medications
- ✓ Has not had any tweezing or waxing for previous 6 weeks
- ✓ Has not had Accutane for 6 months
- ✓ Has discontinued glycolics, Retin-A and astringents 3 days prior
- ✓ Has had baseline photographs and history documented
- ✓ Has the area to be treated shaved and cleaned
- ✓ Is not going to have the inside of the periorbital bone treated
- ✓ Has had the hair-shedding process explained to them
- ✓ Understands that effective treatment requires multiple treatments and has scheduled their next treatment

Accessories – Check that you have:

- ✓ Safety goggles
- ✓ Patient goggles
- ✓ Masks
- ✓ Gloves
- ✓ Disposable razor
- ✓ Ice packs
- ✓ White cosmetic pencil
- ✓ Cleaning materials for ChillTip

SECTION 10.
RETURN ON INVESTMENT

The laser hair removal market is expanding, presenting a significant profit-making opportunity both for cosmetic practices (e.g., plastic surgeons, dermatologists and laser hair removal specialists) as well as an ancillary service for other types of physician practices (e.g., OB/GYNs). Marketed properly, the service can provide a large influx of new patients, many of whom will use other services offered by the practice as well.

Whenever making a significant investment in a new product or service, completing a financial analysis to estimate the return on investment is prudent. This section provides information and forms to help you estimate the return your practice will receive on its investment in the LightSheer Diode Laser System.

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The Market–Patients Who Choose Laser Hair Removal

Unwanted hair is a condition that spans age, gender and income distributions, but some generalizations can be made regarding the potential market for your laser hair removal practice. People who choose laser hair removal are predominantly healthy women in their twenties, thirties and forties who feel comfortable sharing personal concerns with their physicians and who are motivated to remove unwanted hair.

In early 2000, an independent consulting firm conducted a survey of 1,189 patients from twelve OB/GYN practices from across the US. The survey quantified patient awareness about laser hair removal and patient interest in receiving laser treatments from their OB/GYNs. Although the survey specifically targeted OB/GYN practices, the results should be relevant to the broader population of women in the target market as well.

Overall, the survey found that virtually all women have unwanted hair and the vast majority are interested in laser hair removal. In terms of specific findings:

- 88% of patients surveyed have unwanted hair.
- 87% of patients with unwanted hair remove it using methods such as shaving and waxing.
- 71% of patients surveyed are interested in having laser hair removal performed.

By current estimates, only 3% of patients currently obtain laser hair removal services, so the level of interest seen in this survey demonstrates the tremendous income potential in establishing laser hair removal either as an independent service or as an ancillary service to an established medical practice.

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Average Pricing

A key step in estimating your return on investment with the LightSheer system is determining your prices. Prices vary significantly from practice to practice, taking into account factors such as geographical area of the country, population of the town or city where the procedure is performed, and the number of local competitors offering the service. In addition, pricing for laser hair removal reflects the surface area treated and the anatomical location.

Despite all these variables, several generalizations can be made about laser hair removal pricing as it is currently practiced around the country:

- The larger the treatment area, the more expensive the treatment. For example, treating the legs or back is generally more expensive than treating the upper lip.
- Most practices charge more for the first treatment than for subsequent treatments, reflecting the additional work required to set up the patient's chart, perform the initial consultation, etc.
- Many practices offer discounts for treating multiple areas at once or performing multiple treatments. Some offer package deals in which a patient pays up front to cover all treatments over a period of time such as a year.

Overall, the average price of a laser hair removal treatment around the country ranged from $100 to $500 in 2001, with the average patient receiving 3 treatments per body area. Specific pricing from four actual practices is shown in the following table.

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Fee Schedules for Laser Hair Removal in Four Practices (in US$)

Practice	1	2	3	4
Treatment Area				
Initial Treatment				
Upper Lip	250	250	300	195
Chin	250	250	300	225
Entire Face	750	500		595
Underarms	400	400	500	295
Bikini Line	500	300	400	395
Full Legs	1,200	1,200	1,400	995
Back			700	995
Follow-up Treatments				
Upper Lip	100	125	150	195
Chin	100	125	150	225
Entire Face	300	250		595
Underarms	200	200	250	295
Bikini Line	250	150	200	395
Full Legs	600	500	800	995
Back			400	995

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Revenue and Expense Calculation

To estimate the impact of laser hair removal on a practice, several different types of economic proformas have been developed to compare revenue sources and costs to come up with an estimated net figure. Here we present two.

The first is the simpler of the two. To complete the proforma, the customer estimates the number of new patients likely to be seen each month for each type of laser hair removal procedure. The number is multiplied by the cost for the procedure to get a revenue figure, and these figures are added together to get an estimate of the total monthly revenue for laser hair removal.

On the cost side of the proforma, the monthly lease cost is subtracted from the total revenue to get an estimate of the gross monthly profit. This figure is multiplied by 12 to reach the estimated gross annual profit due to laser hair removal.

A blank copy of the proforma is printed on the next page, followed by a completed proforma based on a practice in the Washington DC metro area. The key information to see on the completed proforma is that performing even a relatively small number of procedures per month can have a significant impact on a practice's bottom line.

SECTION 10.
RETURN ON INVESTMENT

Lumenis LightSheer Diode Laser System
Sample Revenue Projections Form

Procedure	# Per Month	Cost per Procedure	Revenue
Lip			
Lip and Chin			
Face			
Neck			
Back			
Bikini Area			
Axilla			
Legs			
Total Revenue			
Laser Lease Payment (monthly)			
Total Monthly Gross Profit			
Total Annual Gross Profit			

SECTION 10.
RETURN ON INVESTMENT

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Lumenis LightSheer Diode Laser System
Sample Revenue Projections

Procedure	# Per Month	Cost per Procedure*	Revenue
Lip	5	$300.00	$1,500.00
Lip and Chin	3	$400.00	$1,200.00
Face	1	$800.00	$800.00
Neck	1	$400.00	$400.00
Back	2	$1,000.00	$2,000.00
Bikini Area	4	$300.00	$1,200.00
Axilla	3	$300.00	$900.00
Legs	2	$1,000.00	$2,000.00
Total Revenue			$10,000.00
Laser Lease Payment (monthly)**			$1,800.00
Total Monthly Gross Profit			$8,200.00
Total Annual Gross Profit			$98,400.00

* Based on current fees in the Virginia/Washington DC area.
** Typical lease payment. Actual lease payment may be lower or higher depending on the terms of the lease.

Disclaimer: Figures used here are for discussion purposes only and do not represent a guarantee of the revenue performance of a LightSheer system.

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SECTION 10.
RETURN ON INVESTMENT

The second proforma is slightly more sophisticated in that it takes into account indirect costs of operating the laser in its income projections. To use the proforma, the customer should multiply the total estimated number of procedures expected to be performed each week by 50 weeks in a year, to get an estimated annual number of laser hair removal patients for the first year. The next step is to multiply the number of patients by the average cost of the procedures (in most practices $100-$500) to get the annual gross receipts attributable to laser hair removal.

Using a similar approach on the expense side, the next step is to calculate the total direct costs (equipment lease and service contract) of treating patients with the laser. The final step is to estimate the indirect costs (operator salary, administration, marketing, etc.) associated with the treatment. The expenses are subtracted from the revenue to get a net figure.

SECTION 10.
RETURN ON INVESTMENT

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LightSheer Income Statement Sample (Blank)

REVENUE	
Number of Customers Per Week:	
x 50 Weeks Per Year=Total Number Per Year:	
Avg. Revenue Per Customer Visit:	$
TOTAL REVENUE Per Year	$

COSTS	
Equipment Lease	$
Service	$
Facility Costs*	$
Operator Salary and Benefits*	$
Marketing Costs*	$
Administrative Costs*	$
Other	$
TOTAL COSTS Per Year	$

NET ANNUAL INCOME	$

Key Points to Remember

- Many practitioners have reported significant increases in new patients for photoepilation procedures.
- These procedures are private pay and don't involve third party payers, which can be important to a practice's financial success, particularly over the long term.
- The average charge per patient visit for one or more body area treatments is $100-$500.

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SECTION 10.
RETURN ON INVESTMENT

LightSheer Income Statement Sample

REVENUE	
Number of Customers Per Week:	6
x 50 Weeks Per Year=Total Number Per Year:	300
Avg. Revenue Per Customer Visit:	$500.00
TOTAL REVENUE Per Year	$150,000.00

COSTS	
Equipment Lease	$21,600.00
Service	$4,800.00
Facility Costs*	$5,000.00
Operator Salary and Benefits*	$25,000.00
Marketing Costs*	$10,000.00
Administrative Costs*	$5,000.00
Other	$
TOTAL COSTS Per Year	$71,400.00

NET ANNUAL INCOME	$78,600.00

Key Points to Remember

- Many practitioners have reported significant increases in new patients for photoepilation procedures.
- These procedures are private pay and don't involve third party payers, which can be important to a practice's financial success, particularly over the long term.
- The average charge per patient visit for one or more body area treatments is $100-$500

* Directly attributable to LightSheer practice

Disclaimer: Figures used here are for discussion purposes only and do not represent a guarantee of the revenue performance of a LightSheer system.

SECTION 10.
RETURN ON INVESTMENT

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Return on Investment

Revenue and income calculations can also be used to determine your return on investment. The calculation is performed by dividing your Gross Profit by your Expenses. In the example used above, assuming 300 treatments per year at an average of $500 per visit with an annual lease cost of $21,600, the return on investment is 110%.

The proforma below can be used to calculate your return on investment based on projected number of treatments each month.

The **Cost Per Treatment** is determined by dividing the monthly lease payment for the laser system by the total number of treatments per month. The **Gross Profit Per Treatment** is calculated by subtracting the **Cost Per Treatment** from the revenue generated by each treatment.

The **Gross Profit Per Month** is determined by multiplying the **Gross Profit Per Treatment** by the number of treatments performed each month.

Finally, the **Return on Investment** is calculated by dividing the **Gross Profit Per Month** by the **Total Monthly Payment**.

In the completed sample form, the total monthly lease payment for the laser is $2,428.53, and the estimated revenue per treatment is $250. Using these conservative assumptions, the Return on Investment is 55% with only 15 treatments a month performed. And as the volume increases, of course, the return on investment increases dramatically.

SECTION 10.
RETURN ON INVESTMENT

Lumenis LightSheer Diode Laser System Return on Investment Sample Form

Treatments Per Month	15	30	45	60	75
Total Monthly Payment					
Cost Per Treatment					
Revenue Per Treatment					
Gross Profit Per Treatment					
Gross Profit Per Month					
Return on Investment					

Lumenis LightSheer Diode Laser System Return on Investment Sample

Treatments Per Month	15	30	45	60	75
Total Monthly Payment	$2,418	$2,418	$2,418	$2,418	$2,418
Cost Per Treatment	$161	$80	$54	$40	$32
Revenue Per Treatment	$250	$250	$250	$250	$250
Gross Profit Per Treatment	$89	$169	$196	$209	$218
Gross Profit Per Month	$1,331	$5,081	$8,831	$12,581	$16,331
Return on Investment	55%	210%	365%	520%	675%

Please contact your local Lumenis Area Sales Manager for more information on LightSheer's return on investment possibilities.

Disclaimer: Figures used here are for discussion purposes only and do not represent a guarantee of the revenue performance of a LightSheer system.

SECTION 11.
PRACTICE BUILDING

Laser hair removal, treatment of superficial leg veins, benign pigmented lesions and pseudofolliculitis barbae represent significant new revenue streams for your practice. Because the interest in these treatments is so high, many purchasers of the LightSheer have found that they can realize an attractive return on their investment, often within a few months of setting up the service. Your success is not guaranteed, however, simply by purchasing the system. The most successful practices reach their goals through a combination of planning and consistent follow-through in their marketing. This section provides practical, effective tactics to show you how.

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SECTION 11.
PRACTICE BUILDING

Developing a Marketing Plan

There's an old business adage that goes, "If you fail to plan, you plan to fail."

A marketing plan is nothing more than a roadmap that helps you build a successful practice by focusing on the needs and wants of your patients and then developing strategies and tactics to help you meet those needs.

Why You Need a Marketing Plan

The value of a marketing plan is three-fold:

- **Process**. When you develop the plan, you will critically evaluate where you are in your practice, where you want to take your practice, and how to get there. In other words, the process makes you focus on these critical issues.
- **Action**. A well developed marketing plan will include a plan of action, with concrete steps and a timeline for their implementation. In other words, once the plan is developed it will tell you what you should be doing, and when.
- **Tracking Results**. Every plan of action needs to be periodically re-evaluated. By allowing you to check your progress against the goals you've set, your marketing plan will help you track your results over time and to modify your marketing to adapt to changing circumstances.

Steps in Developing and Implementing a Marketing Plan

Although developing a marketing plan can be a complicated process, it needn't be. The steps are straightforward and relatively simple, as follows:

1. **Setting goals**. Exactly what do you want to achieve with your new LightSheer service? What are your revenue goals? How many new patients do you want to see? The answers to questions like these will greatly affect your plan of action.
2. **Assessing your practice**. What are the strengths and weaknesses of your practice? What are the strengths and weaknesses of your staff? Is your staff willing to be part of your marketing team? What training will they require to be effective team members? What is the state of your office? Is it pleasant and inviting?
3. **Assessing your patient base**. Who are your patients? What needs and wants do they have? What percentage of them are candidates for LightSheer treatments. How many are interested in the new services you plan to offer? What feedback can they provide to help you provide better service to them?
4. **Building an action plan for internal marketing (to your staff) and external marketing (to your existing and new patients).**
5. **Creating a timeline and budget for implementation of your plan.**
6. **Putting the plan in motion.**
7. **Periodically evaluating (tracking) your progress.**

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SECTION 11. PRACTICE BUILDING

Internal Marketing

Building Your LightSheer Team

In terms of marketing, the most successful practices work as a team.

Every member of the staff that comes in contact with patients has a role and a stake in the success of your practice.

Every patient you see in your practice represents a marketing opportunity. Every contact your staff makes with patients is marketing. Even though it may feel odd, LightSheer patients and prospective patients should be considered clients with the potential to cultivate a personal, long-time commitment to your practice. Every time you and your staff have the opportunity to assist your patients, it is an advertisement for your ability, concern and commitment to their satisfaction.

In many practices, this is a foreign concept. Staff members feel their primary role is to assist patients, not to "sell" to them. The extent of your success in offering cosmetic procedures will, in large part, be determined by how well you can counter this perception, by how well you can communicate and how well you can instill in your staff the message that good marketing is simply recognizing and meeting the needs of your patients.

The following tactics should be useful in this training process.

- **Communicate to your staff the importance of their role in building the practice**. If your staff is typical, they know their importance in terms of the smooth operation of your office, but many do not realize that their attitude and actions have an important influence on patient satisfaction and patient retention. Especially when patients are paying out-of-pocket for expensive elective procedures, they rightly expect a high level of service. They expect your staff to be professional, courteous, attentive and responsive. It is important for your staff to know that these are your expectations as well.
- **Show your staff the importance of being proactive**. Patients signal in many ways their possible interest in treatment with the LightSheer. They may pick up a brochure in the front office; they may show signs of using other hair removal techniques; they may have visible superficial leg veins or benign pigmented lesions. By training your staff to look for these opportunities and encouraging them to ask patients for the opportunity to help, you are showing them how they help you provide better patient care by paying attention to the patient's needs and wants.

- **Train your staff in the LightSheer procedure so that they can answer questions**. The role of your staff should not be to describe an entire procedure or to discuss treatment options, but it is critical that they can accurately answer general questions and steer patients toward consults when approached by patient inquiries. Many practitioners provide free LightSheer treatments to their staff members so that they can speak from experience and share their excitement with potential customers.
- **Set up regular, structured communication between the front office and back office staff**. Regular communication will give you the opportunity to evaluate how your marketing efforts are working, to head off potential problems, to reinforce your marketing messages, to elicit ideas and suggestions from front-line personnel and to adapt to changing circumstances.

Getting the Word Out to Existing Patients

It's a truism that patients can't take advantage of your services if they don't know about them. Especially if you are offering LightSheer treatment as an ancillary service in an existing practice, it is important to let your existing patient base know about the new service. Fortunately, several tools are available to you or can be inexpensively produced to get the word out to your existing patient base. Realize that a picture is worth a thousand words, so anything you can show prospective patients about the procedure will have a more profound impact.

Examples include the following (samples are inserted at the end of this section or can be found in your Building Blocks Kit upon purchase of a LightSheer system):

- **LightSheer Patient Brochures**–to provide patients with a brief overview of how the procedure works. These should be printed and placed in highly visible locations in the waiting room and treatment rooms.
- **LightSheer Information Video**–to play in your waiting room and encourage prospective patients to inquire about the service.
- **LightSheer Poster**–to be placed in a high visibility location in the waiting room or treatment room to encourage questions.
- **Postcards**–to be sent to existing patients to announce new services.
- **Newsletters**–to be distributed to patients who express an interest.

- **Slide Presentations**–to be set up in a consultation room so that patients can see the procedure and results others have achieved. It can also be used for external workshops to discuss this service to prospective patients.
- **Before & After Photographs**–to allow your patients to see results of the procedure from pre-treatment to extended post-treatment.

Encouraging Patient Referrals

Without doubt, satisfied patients and positive word-of-mouth are the best marketing tool for any type of practice. Patients who are excited about the results of their treatment and who are satisfied with the level of service they received from you and your staff can generate significant interest in your services with new patients.

Many successful practices encourage patients to refer their friends and colleagues by providing incentives for each referral. For example, a patient may receive a discounted or free treatment by referring one or more patients who receive treatment. By taking advantage of this approach, you involve not only your staff but also your entire patient base in marketing your services.

External Marketing

Internal marketing to your existing patient base is probably the most cost-effective way to generate business for your LightSheer practice. However, it is also important to bring new patients into practice through external marketing. Several different strategies and tactics can be used inexpensively for external marketing. They include producing seminars/presentations, advertising (e.g., print, radio, cable television), using a public relations approach, doing direct mail advertising, operating a telemarketing campaign and providing information through the internet.

Seminars/Presentations

Seminars and presentations can be an effective way to get your message out to potential customers. The value of holding seminars and presentations is that you can reach many potential patients at one time with a focused marketing and educational message. People who may be reluctant to schedule an appointment for a consultation often are willing to attend a free presentation. By introducing the public to your staff, you're virtually guaranteed to generate interest and build a pipeline of

prospective LightSheer patients. If you have satisfied patients who may be willing to join you for this type of venue, have them sit up front and answer questions from patients at the conclusion of the program.

It is often useful and effective to set up a seminar or presentation in concert with a larger event. Possible venues include:

- **Local groups:** Women's groups, professional organizations, societies, etc.
- **Local health fairs:** Many hospitals and community groups offer health fairs. These large events can be great opportunities to showcase the LightSheer and other practice services.

Advertising

Advertising in print, radio and cable television is a tried and true approach to building patient interest. The disadvantage, of course, is expense. By judicious selection of venues and time slots, however, such advertising can be surprisingly affordable while offering a significant return on your investment. See your Practice Enhancement Kit for camera-ready ad slicks that can be used in advertising campaigns.

Public Relations

Local media outlets are always looking for interesting local content. By associating your practice with a newsworthy event, you can get what is essentially free advertising in your local market. Effective strategies include donating part of your revenue for specific services to a charity or other local cause over a specified period or as part of a local charity event.

Direct Mail

Direct mail can be an effective way to generate patient interest. The key, of course, is to find the mailing list that will provide the highest return. Broadcast mailing to everyone in a specific range of zip codes often provides a very low rate of return. A better strategy is to identify mailing lists of people who may be interested in your services. Examples include the membership lists of local health clubs or spas, customer lists of local hair or tanning salons, etc. The more accurately you can target you direct mail piece, the higher your likely rate of return.

Telemarketing

Although telemarketing has a bad reputation among many people, it is also an effective means of communicating your products and services to your community. If you decide to use this approach, you can run the telemarketing campaign with your own staff, or you can hire outside consultants to provide the entire service.

Internet

The Internet is becoming an increasingly important venue to publicize healthcare and cosmetic services. Having a presence on the internet in terms of a web site and email address will soon (if it is not already) be a basic business necessity. A web site gives you the opportunity to provide more information to your patients and potential patients than is possible in a short consultation or treatment visit. In addition to describing your services, a web site can provide extensive background information about the benefits (and risks) of specific procedures. Samples of before and after photographs can be provided. Your web site can also be an easy place for patients (or members of the media) to download information about you and your practice.

Most Internet service providers (ISPs) offer inexpensive web site hosting. Depending on your interests, you can develop your own web site with the tools provided by most ISPs. Alternatively, you can hire programmers to design a professional interface and site for a reasonable fee.

Additional Resources

Following this section, we've inserted a sample patient brochure that could be used to promote your new LightSheer hair removal service to your patients. These and many other materials are provided in your Building Blocks Kit upon purchase of a LightSheer system.

Section 12.
Lumenis Service and Support

Lumenis is committed to providing the highest level of service and support to our customers with LightSheer Diode Laser Systems. This section briefly describes the basics of our service, training and marketing support programs in the United States. For all other countries, please inquire with your local Lumenis representative about specific service and support programs

SECTION 12.
LUMENIS SERVICE AND SUPPORT

Overnight Replacement Service

It is important to keep your office running on schedule. The next-day LightSheer loaner program minimizes system downtime, patient rescheduling and the potential of lost revenue. All LightSheer service is performed at the factory by experts with ready access to advanced diagnostic equipment, replacement parts and engineering expertise.

Report your service need by 3:00 PM PST, and you will receive a LightSheer service loaner by 11:00 AM the next business day, anywhere in the continental United States with overnight service provided by Federal Express*. To report a service need, United States customers just have to call (866) 206-8977 to reach the LightSheer service department.

Clinical Training

Lumenis offers a range of training solutions for you and your system operators. Included in the price of your LightSheer system is a credit for personalized training with an experienced clinical nurse or physician preceptor. On-going training is provided through local and regional workshops and seminars. These feature didactic training and live patient treatment demonstrations to help treatment providers remain updated about new laser and treatment information.

Practice Marketing Materials

To help you spread the word to your current and potential patients about your new LightSheer hair treatment services, Lumenis provides a comprehensive LightSheer Building Blocks Kit. Informational brochures for your patients, a poster, a patient information video, and a CD containing digitized logos, images, ad slicks and more are included. See the Practice Building section for more information.

*Based on Federal Express service availability.

SECTION 13. COMMONLY ASKED QUESTIONS AND ANSWERS

As with any new medical technology, both healthcare professionals and patients have questions about the use of the LightSheer Diode Laser System. The following are some of the most frequently asked (with short answers).

1. **How does the LightSheer Diode Laser System work?**
   The near-infrared laser light emitted by the system is absorbed by the pigment located in the hair follicle. The laser is pulsed, or turned on, for only a fraction of a second. The duration of each pulse is just long enough to damage the follicle, while the system's unique, patented contact-cooling handpiece (the ChillTip) helps protect the skin by conductive cooling during the laser energy delivery.

2. **Who is eligible for hair removal using the LightSheer system?**
   The LightSheer system is designed to be safe and effective for all skin types, including FItzpatrick Skin Types I-VI as well as tanned skin. For darker skin types and people with tans, appropriate fluences are generally lower and appropriate pulse widths are generally longer to prevent damage to the epidermis. Using the appropriate treatment parameters, however, people with all skin types can benefit from laser hair removal with the LightSheer.

3. **Is the hair removal permanent?**
   All patients treated with the LightSheer System experience short-term hair removal, but because of the nature of hair and the many factors that influence the growth of hair, the extent of long-term hair reduction will vary among individuals.

   The permanence of hair reduction is correlated with the fluence used, so in clinical practice, patients with dark hair and fair skin tend to have the best long-term results. Most patients do experience permanent reduction in number, diameter and color of terminal hairs. In clinical trials, patients treated twice with optimized treatment parameters experienced nearly 50% hair reduction even 12 months after treatment.

4. **Is it safe?**
   As with any medical treatment, use of the LightSheer Diode Laser System can have side effects. The most common are transient erythema or swelling. Transient changes in skin pigmentation may occur as well. However, side effects have been minor and manageable in clinical use of the LightSheer. The precise laser parameters used for the LightSheer Diode Laser System were carefully defined by studying the anatomy of the hair follicle and precisely matching the color of laser light and the pulse duration to the size, depth and location of the hair follicle. This research has resulted in a safe technique that effectively eliminates the risk of scarring and substantially reduces most other complications following treatment.

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SECTION 13. COMMONLY ASKED QUESTIONS AND ANSWERS

5. **Is it painful?**
   The LightSheer Diode Laser System's ChillTip cooling lens helps reduce discomfort while protecting the skin surface from thermal injury during delivery of the pulse of the laser light. If large or sensitive areas with unwanted hair are to be treated, a topical anesthetic cream may be applied to the site to further reduce discomfort.

6. **What will the treated area look like after the procedure?**
   Immediately after treatment, the site will be somewhat swollen, appear slightly red in color, and will feel like a mild sunburn. This reaction subsides over a few hours, and then the treated sites usually return to their normal appearance. The amount of discomfort after this procedure is usually minimal and does not limit most normal physical activities. Since light is used to remove the hair, there is no bleeding and no open wound is created. For this reason, there is no need to apply a bandage and wound care is generally not required.

7. **What other complications have been associated with treatment?**
   In addition to transient epidermal injury (pain, erythema, edema blistering), transient hypopigmentation and hyperpigmentation and transient textural changes (crusting or scabbing) have been observed in some patients treated with the LightSheer Diode Laser System. Proper patient selection, pre-treatment and matching treatment parameters with skin type can help minimize these complications.

   Patients who carry the herpes simplex virus and receive treatment on their upper lip, chin or lower cheeks may have a "flare-up" of their condition. The risk of this complication can be reduced if the patient takes an antiviral medication for a few days before and after each treatment.

8. **How long does the procedure take?**
   Each pulse of laser energy from the LightSheer Diode Laser System will treat a square area of skin of approximately three-eighths of an inch (9 mm). For this reason, the amount of time required depends on the size of the area requiring treatment. For example, the upper lip and bikini line may require only 5-15 minutes of treatment, while a longer period of time will be required to treat the back or legs.

SECTION 13. COMMONLY ASKED QUESTIONS AND ANSWERS

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9. **Why should I use the LightSheer Diode Laser System rather than the methods I've been using for years?**
   The LightSheer Diode Laser System's design provides for enhanced comfort during treatment, minimal risk of infection, speed and accuracy. Since the system uses a unique cooling handpiece, it minimizes skin irritation that other methods may create. Since it is non-invasive (no needles to penetrate the skin), the risk of introducing bacteria into the skin is reduced. Because the system is fast, it allows for larger areas to be treated, considerably increasing the efficiency of the hair removal process. Finally, the LightSheer Diode Laser is a precise instrument that can be adjusted to damage only the hair follicle while minimally affecting the surrounding skin.

10. **What advantages does the LightSheer have over other laser hair removal systems?**
    The LightSheer Diode Laser System was designed from the ground up for laser hair removal, so it has the wavelength, fluence, pulse width and active epidermal cooling system (the ChillTip) ideally suited for laser hair removal. The system is small, compact and (in some models) portable, so it fits well into virtually every type of existing practice. The system's solid state construction makes it durable; it's state-of-the-art user interface makes it easy to use. Finally, Lumenis has been in the business of making medical and cosmetic lasers for more than 30 years, so we've been able to develop unparalleled service and support–from our extensive training and practice building resources to our 24-hour replacement service. No other hair removal system offers the same combination of product excellence and customer service and support.

11. **Who can perform the laser hair removal procedure?**
    Regulations vary from state to state, but they typically fall under three categories: 1) states that require a physician to perform the procedure, 2) states that allow the procedure to be performed by other allied health-care professionals (e.g., nurses, electrologists, etc.) under the supervision of an affiliated physician, or 3) states that have no specific regulations on who can perform the procedure. For more information about the regulations in your state, contact your state's regulatory board or your Lumenis sales representative.

12. **Is laser hair removal covered by insurance plans or managed care organizations?**
    In general, laser hair removal is not covered by insurance plans or other third-party payers. Many purchasers of the LightSheer feel such lack of coverage is actually an advantage. Patients have shown their willingness to pay out of pocket for laser hair removal, so you and your staff can spend less time trying to get reimbursement from payers and more time treating patients.

Section 13.
Commonly Asked Questions and Answers

SECTION 14.
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Glossary

absorb • To take up matter or energy.

absorption • Transformation of radiant energy to a different form of energy by the passage through, or reflection from, matter.

absorption coefficient • A measure of how strongly light is absorbed in a particular material. A large number indicates strong absorption.

active medium • Collection of atoms or molecules capable of undergoing stimulated emission.

amplitude • Magnitude or height of an electromagnetic wave.

attenuation • The decreasing intensity (power) of light as it passes through a medium, caused by the interaction of the photons with the medium.

beam • A collection of electromagnetic rays that may be parallel, convergent or divergent.

chromophore • A colored material in tissue (in hair removal generally melanin; in treatment of leg veins, hemoglobin) that absorbs laser light.

coherent radiation • Electromagnetic energy of the same wavelength and phase.

collimated • Parallel. Laser light is collimated, because all of the rays are parallel to each other.

continuous wave • Constant delivery of laser energy without pulses.

diode • An electronic device that allows current to flow one direction but not the reverse direction.

divergence • Angle of spread on the outer edges of a laser beam.

electromagnetic spectrum • The entire spectrum of energies (wavelengths and frequencies) emitted by atomic systems. The EM spectrum ranges from long wavelength radio waves and microwaves, through visible light, to the short wavelength, high energy ionizing radiation of X-rays and cosmic rays.

electron • Negatively charged part of an atom.

emission • Any radiation of energy by means of particles or electromagnetic waves.

energy • A measurement of the capacity to do work. The energy (in joules) produced by a laser is defined as the amount of power (in watts) multiplied by the duration (in seconds) of the pulse.

excited state • An atom with an electron in a higher energy level than the ground state.

fiber optics • Thin, flexible devices used to carry light or other optical energy.

fluence • Energy density measured in Joules/cm^2.

focal length • The distance between the focusing lens and the point at which the smallest spot size of the light beam is achieved.

focus • The point at which light rays converge to form the smallest possible beam diameter, thus achieving the greatest power density.

frequency • The number of waves that pass a fixed point per unit time. The frequency of a wave is the inverse of its wavelength.

ground state • The lowest energy level of an atom, also known as the resting state.

intensity • The power transmitted by a light wave across a unit area perpendicular to the wave.

laser plume • Smoke, water vapor and airborne particles that are the byproducts of laser vaporization.

melanin • The pigment that gives color to the skin. It is located at the junction between the epidermis and the dermis and in hair follicles.

micron • A measurement of distance representing one one-millionth of a meter or 1,000 nanometers.

monochromatic • Literally, "of one color." Laser light is monochromatic because it consists of electromagnetic radiation having a very small range of wavelengths.

optical cavity • The space between the mirrors in which lasing occurs; also known as the resonator.

optically pumped laser • A laser in which the medium is excited by absorption of light from an external source (often xenon flash-lamps).

oxyhemoglobin • The oxygenated form of hemoglobin in the blood.

phlebectomy • Excision of a vein or part of a vein.

photon • A small discrete packet of light energy.

population inversion • A state in which an active medium has been excited so that more of its atoms or molecules are in excited states compared to the number in the ground or resting state.

power density • The power of a laser beam per unit area. It is measured in watts per square centimeter.

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Q-switching • A method of switching a laser on and off in which energy is stored within the lasing medium and then suddenly released in a short, single burst (approximately 30 nanoseconds) resulting in extremely high peak power output.

radiation • The emission and/or propagation of energy through space or through a medium in the form of either waves or particle emission.

sclerotherapy • the injection of sclerosing (hardening) solutions for the treatment of varicose veins, spider veins or hemorrhoids.

semiconductor • a material that will not conduct electricity below a certain threshold voltage but can become a conductor of electricity at higher voltages.

spontaneous emission • Spontaneous decay of an excited atom to a ground or resting state, causing the emission of one photon.

spot size • Diameter of the laser beam spot.

stimulated emission • Emission of a photon from an excited atom triggered by the proximity of the atom to another photon of similar energy.

telangiectasias • Permanent dilation of pre-existing blood vessels creating small focal lesions, usually in the skin or mucous membranes.

thermal relaxation time • The time it takes heat energy to diffuse out of a tissue. If the thermal relaxation time of a tissue is longer than the duration of a laser pulse, thermal damage will be limited to the tissue treated and will not spread to adjacent tissues.

wave • A progressive disturbance propagated from point to point in space or in a medium.

wavelength • The distance from one wave peak to the next. The wavelength of an electromagnetic wave is the inverse of the wave's frequency.