

VersaClear™ Skin Therapy System (STS)

FAQs

General

Question: What is the VersaClear Skin Therapy System (STS)

Answer: The VersaClear STS is a platform upon which are mounted interchangeable light modules for the treatment of various skin conditions. Currently available light modules consist of VersaClear STS 420 (blue), STS 615 (red), and STS 368 (UVA1). Additional light modules under development include green, yellow, and other pure light spectra. These new light modules will be commercialized as indications for use for each different wavelength are defined. Thus, should you wish at a future date to upgrade your System, this can be done easily and cost-effectively.

Question: What makes the VersaClear STS different from other light systems?

Answer: The VersaClear STS utilizes patented Osram® Sylvania® Icetron® magnetic induction lighting technology to produce high-intensity light at specific therapeutic wavelengths. TheraLight has the single worldwide license from Osram Sylvania to Icetron lamp technology for the treatment of skin disorders.

The unique feature of the Icetron lamp design is that output power is 4 times that of traditional fluorescent lamps, double the blue spectrum output of products utilizing metal halide lamps, and equivalent output to the most powerful blue LEDs.

Illumination areas are large and a pair of Icetron light modules is well suited for treating both sides of the face, or for broader skin areas (e.g. shoulders, back). Light modules emit mild infrared radiation to speed chemical reactions in the skin. Icetron lamps contain no electrodes to burn out over time, which provides for a long service life (2 year warranty).

The VersaClear platform is highly versatile, in that it allows for easy light module exchange. For example, a pair of Blue light modules can be changed for a pair of Red light modules in less than 30 seconds. In addition, the mobile base and positioning arm design allows for easy light module adjustment to fit whatever profile is most convenient and relaxing for the patient, who may be sitting, reclining, or lying down.

Finally, although Blue (420nm), red (615nm) and UVA1 (368nm) light modules are available today, additional light modules are under development. This makes the VersaClear highly versatile, easily upgradeable and the most cost-effective professional light therapy system in its class.

VersaClear™ Skin Therapy System (STS)

FAQs

Acne

Question: Why use blue light?

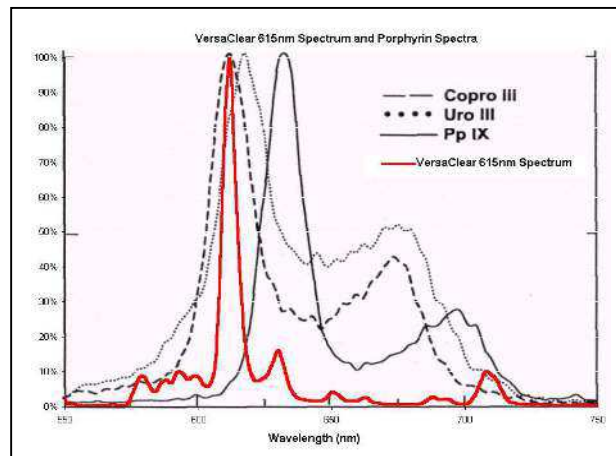
Answer: Inflammatory acne is characterized by colonization of sebaceous glands by *P. acnes* bacterium that produce and accumulate chemical porphyrins, mainly coproporphyrin III (CPIII). CPIII and other porphyrins (e.g. protoporphyrin IX) are endogenous photosensitizers. They are highly absorptive of visible light in the blue spectrum referred to as the “Soret Band”.

Photo-excitation of porphyrins with blue light results in the production of reactive oxygen species (ROS), the main constituents of which are singlet oxygen (1O_2), hydrogen peroxide (H_2O_2) and superoxide anion (O_2^-). ROS in localized high concentrations is bactericidal, and in low concentrations (zones not populated with *P. acnes*) is mitotic and proliferative. Photoactivation of CPIII also imparts anti-erythral effects to the skin.

Question: Why use red light?

Answer: Red light penetrates deeper into the skin than does blue light. It is 10 times less effective than blue light at photo-activating porphyrins, but its greater depth of penetration allows for the treatment of deeper tissues. In addition, red light also has anti-inflammatory properties by influencing cytokine release from macrophages and other cells. The net effect is fibroblast proliferation and the production of growth factors that influence the inflammatory process, healing, and wound repair. Red light also may increase microvascular circulation, thereby promoting the body’s natural healing processes.

A unique attribute of VersaClear red light (615nm peak) is that its wavelength coincides with the maximum absorption peak of CPIII, a porphyrin that is produced in abundance by *P. acnes* bacterium as shown in the graph below.



VersaClear™ Skin Therapy System (STS)

FAQs

Acne (cont'd)

Question: Why use alternating blue and red light?

Answer: The combination of blue and red light therapy combines the anti-bacterial effects of blue light with the deeper and anti-inflammatory effects from red light. In addition, the mild warmth imparted into the skin by VersaClear Icetron Light Modules speeds chemical reactions (Arrhenius equation). The mild heat also dilates blood vessels to maximize oxygen perfusion. These combined effects work synergistically to optimize the benefits of VersaClear light treatments. Blue and red light modules are easily and quickly interchanged, and maximize instrument versatility.

Question: What treatment protocols are recommended for acne?

Answer:

2 Weeks Prior to Light Therapy – Consider the use of Tazorac 2 weeks prior to initiating light therapy. If this is not possible, then microdermabrasion or a mild peel for removal of the upper stratum corneum is recommended prior to initiating light sessions. In addition, for patients with high-grade inflammation, the physician should consider the use of a topical retinoid such as Tretinoin or Retin-A.

Immediately Before Light Therapy – Cleanse skin thoroughly to remove all makeup, pollutants, sunscreen and dead skin. Microdermabrasion, a mild peel, or a vigorous alcohol or medical-grade acetone scrub are common skin preparation techniques.

Light Therapy

- o Blue Alone (420 nm) light alone; VersaClear STS 420 Light Modules – 20-minute sessions twice per week, spaced at least 48 hours apart, for 4 week to 6 weeks.
- o Alternating Blue and Red; VersaClear STS 420 (blue) and STS 615 (red) Light Modules – Alternate 20-minute Blue (420nm) and Red (615nm) sessions twice per week, spaced at least 48 hours apart, for 4 weeks to 6 weeks.

In Between Sessions – The use of an anticomedonal preparation (e.g. Differin, Retin-A, topical isotretinoin) and/or salicylic wash in between light sessions is essential.

VersaClear™ Skin Therapy System (STS)

FAQs

Acne (cont'd)

Question: What results can I hope to achieve?

Answer: You can expect the average improvement in acne lesions to be from 60% to 80% and to last for 4-6 months. Improvements may be seen during the 2nd week of treatment and will continue through weeks 6-8 weeks, even after light treatments are completed. Alternating blue and red light sessions may provide superior results to blue light alone, with the blue light providing anti-bacterial action and the red light providing anti-inflammatory effects. However, so that patient expectations are in keeping with anticipated results, remember that 20-25% of patients will not respond to light therapy.

Question: What other tips are useful?

Answer: Microdermabrasion or a chemical peel to exfoliate the skin allows for greater light penetration and enhanced results. Physicians report staging these procedures prior to the first light therapy session, and midway through the course of treatments.

Question: What makes the VersaClear STS different from other light systems.

Answer: The VersaClear STS utilizes patented Osram® Sylvania® Icetron® magnetic induction light technology to produce high-intensity light at specific therapeutic wavelengths. Illumination areas are large and a pair of Icetron light modules is well suited for treatment both sides of the face, or broader skin areas (e.g. shoulders, back) during a single treatment session.

The VersaClear platform is versatile, in that it allows for light module interchangeability. Blue (420nm) and red (615nm) Light Modules are currently available. Under development are additional wavelength Light Modules for other indications that will expand product utility. The VersaClear is a platform that is cost-effective to acquire and maintain, and is easily upgradeable.

The red (615nm) Light Module peak wavelength also coincides with the absorption peak for CP III. Thus, porphyrin activation likely will be more efficient per watt delivered to the skin as compared with light sources that emit light with a peak of 630nm.

Question: Why not use one of the LED systems that are on the market today?

Answer: LEDs (light emitting diodes) were a significant innovation over previously available light sources that emit a very broad spectrum, and emit high enough heat as to be capable of burning the skin (e.g. metal halide, halogen, high intensity discharge lamps), and/or have relatively low output power (e.g. traditional fluorescent tubes). The patented Icetron technology

VersaClear™ Skin Therapy System (STS)

FAQs

not only has equivalent or comparable output power to that of LED systems, but also applies gentle heat to the skin. Mild temperature elevation imparts the beneficial effects of increased blood flow (oxygenation) and speeding chemical reactions. In addition, VersaClear Ictron based technology is reliable (no electrodes to wear out) and can be acquired and maintained at a significant cost-savings over current professional LED illumination systems.

Question: How do I know VersaClear acne treatments will work?

Answer: Professional blue light therapy systems on the market today emit blue light in the spectrum from 405nm to 420nm, with light intensities from 10 mW/cm² to 40 mW/cm². The VersaClear blue light modules emit a spectrum that is identical to that of the Blu-U[®] (trademark of DUSA Pharmaceuticals) at more than 4 times the output power. The VersaClear output power is equivalent to that of the most powerful blue LEDs, or about 40 mW/cm². The dose reported in the literature for effective acne treatment varies from approximately 10 – 48 J/cm² during a 15-20 minute treatment session. The VersaClear is designed to deliver 48 J/cm² in a 20-minute treatment session.

However, it should be known that 20-25% of patients will not respond to light-alone treatments. It is for these patients that ALA+VersaClear STS 420 blue light treatments should be considered.

Question: Can the VersaClear STS be used for PDT therapy for acne?

Answer: The VersaClear STS is not cleared in the United States for use in photodynamic therapy. However, these restrictions do not apply outside the U.S. where it is common to use blue, red, or other visible spectra for photoactivation of aminolevulinic acid (ALA).

Question: What ALA acne treatment protocol is recommended?

Answer: The benefit of combining ALA with blue light therapy for acne is that fewer treatment sessions may be required, and treatments may be more effective for cystic acne as compared with the use of light alone. However, photosensitizing agents, including ALA, should be used only by physicians who are familiar with their use and potential side effects.

Photosensitizers are potent compounds that provide variable outcomes in relation to skin erythema, pain, swelling, peeling, and desquamation. Moreover, the use of ALA for acne is an evolving technique and treatment protocols vary widely.

Given the variability of treatment protocols reportedly being used, it is recommended that physicians consult contemporary peer-reviewed literature prior to attempting the use of ALA and VersaClear blue or red light therapy for the acne. Upon request, the company will provide a summary of treatment protocols being used by dermatologists for the treatment of acne.

VersaClear™ Skin Therapy System (STS)

FAQs

Skin Rejuvenation

Question: What are VersaClear STS 615 red light treatments?

Answer: VersaClear STS 615 red light treatments involve 20-30 minute sessions of skin exposure to a painless, totally natural method of light-only skin rejuvenation.

Question: How does it work?

Answer: VersaClear Red (615nm) photo-rejuvenation treatments stimulate new collagen production and reactivate the skin's natural ability to prevent further breakdown of existing, healthy collagen. The process may be referred to as "photo-selective cell signaling".

The literature documents three modes of action that likely contribute to favorable outcomes:

- 1) Glutathione depletion increases collagen production – Although high dose oxidative stress causes cell death, low dose oxidative stress is a signal for cell proliferation. Red light activates naturally occurring porphyrins within dermal fibroblasts to produce low dose Reactive Oxygen Species (ROS), mainly singlet oxygen (1O_2), hydrogen peroxide (H_2O_2) and superoxide anion (O_2^-). The key is that ROS production depletes intracellular glutathione. Glutathione reduction is a strong chemical signal for fibroblasts to produce collagen, and for keratinocytes to replicate to form new skin cells.
- 2) ATP production promotes cellular proliferation – Red light has been shown to increase intracellular production of adenosine triphosphate (ATP), which is the major energy source for all cell activities. Thus, increased levels of ATP provide the energy to allow fibroblasts to proliferate and produce new collagen. ATP production in keratinocytes promotes the proliferation of new skin cells.
- 3) Restoration of superoxide dismutase (SOD) prevents collagen degradation – SOD is a naturally occurring skin anti-oxidant that helps prevent the breakdown of collagen. Over time, SOD is deactivated by the ultraviolet rays in sunlight. Red light reactivates "inactive protonated" SOD, thereby making it available to help prevent further breakdown of collagen in the skin.

VersaClear STS red light modules also emit mild infrared energy that gently heats the skin. This mild temperature increase speeds chemical reactions and opens pores. Drainage of sebaceous unit pollutants and debris is enhanced. Blood flow is increased, increasing oxygen saturation and natural repair processes that promote a healthier skin appearance, improvement of tone, and smoothing of fine lines and wrinkles.

VersaClear™ Skin Therapy System (STS)

FAQs

Question: Is this a “miracle” treatment?

Answer: No. The VersaClear stimulates natural chemical and physical processes that combat the effects of skin aging. These processes effect beneficial changes in the skin that are seen gradually over the course of treatments, and improvements may continue for months after light sessions are completed. Adopting a responsible program of skin maintenance will further enhance treatment benefits, including glycolic peels and the use of skin care formulations that cleanse and hydrate the skin.

Question: How do I get the best results?

Answer: In general, 12 treatment sessions, performed twice per week for 6 weeks, will provide maximum improvement in the appearance of fine lines and wrinkles, as well as improvement in skin tone and texture.

However, the favorable effects of VersaClear red (615nm) photo-rejuvenation treatments will be enhanced by other commonly available skin treatments. For example, microdermabrasion performed prior to the first VersaClear treatment will improve light penetration. In addition, the regular application of high quality topical anti-oxidants, moisturizers, and sunscreens will be beneficial.

It is therefore recommended that a variety of treatment strategies be made available to the patient. For example, the following protocols are commonly used. Treatment regimes commonly are preceded by a mild chemical peel or microdermabrasion.

- 1 Treatment – as a facial “pick-me-up”. Patients frequently report a sensation of skin tightening, with mild improvement in skin tone and texture after a single treatment session.
- 3 Treatments, twice per week – Patients frequently report a reduction in pore size, resulting in smoother application of make-up, after 3 treatment sessions.
- 6 Treatments, twice per week – Patients frequently report pore size reduction and noticeable changes to overall skin tone, texture, and radiance.
- 12 Treatments, twice per week – This advanced treatment regime will result in maximum photorejuvenation effects, including a reduction in the appearance of fine lines and wrinkles, as well as overall improvements in skin tone and texture.
- Maintenance treatments – monthly 30 minute treatment sessions to prolong the improvements achieved.

VersaClear™ Skin Therapy System (STS)

FAQs

Skin Rejuvenation (cont'd)

Question: When will improvements be observed?

Answer: Patients frequently report the following:

- 1 Treatment session – within 24 hours after treatment, a sensation of skin tightening, with mild improvement in skin tone and texture.
- 3 Treatments, twice per week – a reduction in pore size, resulting in smoother application of make-up.
- 6 Treatments, twice per week – pore size reduction and noticeable changes to overall skin tone, texture, and radiance.
- 12 Treatments, twice per week – This advanced treatment regime will result in maximum photorejuvenation effects, including a reduction in the appearance of fine lines and wrinkles, as well as overall improvements in skin tone and texture.

Question: How long to treatments take?

Answer: The first session should take 45 minutes, including the initial consultation. Thereafter, sessions will involve 30-40 minute appointments, during which light treatments take 20-25 minutes.

Question: What is the recovery time?

Answer: There is no recovery time. Makeup can be applied immediately after treatment.

Question: How long will the results last?

Answer: Results will vary in accordance with the patient's overall skin condition and lifestyle. A commitment to a responsible after-treatment skin care regimen using glycolic and/or anti-oxidant formulations will enhance results. One maintenance light treatment every 4-6 weeks also will prolong results.

VersaClear™ Skin Therapy System (STS)

FAQs

Question: Can VersaClear treatments be combined with chemical peels?

Answer: This is an ideal combination. Chemical peels remove the top layer of dead skin, and induce a healing response that produces new, supple, and healthy looking skin. VersaClear red (615nm) light treatments enhance and compliment these effects by inducing collagen production and cell proliferation using completely different biological pathways. In addition, red light is known to accelerate the wound healing response and reduce inflammation. As a result, these two different treatment methods act synergistically to maximize the benefits of each.

Under a “Light and Peel” treatment regime, a 20-minute VersaClear red (615nm) light treatment is performed immediately after the chemical peel is completed. Thereafter, a series of 6-9 VersaClear treatments are performed twice per week. If a series of mild to moderate peels are planned, VersaClear treatments may be stages at convenient intervals between each peel appointment.

Additional benefits may be achieved through the use of retin-A compounds and antioxidants.

Directions and cautions related to chemical peels should be followed at all times. For example, after each peel, sun exposure should typically be avoided for 72 hours.

Question: How do VersaClear treatments compare with IPL (Intense Pulsed Light) and Laser treatments?

Answer: IPL and Laser treatments are based upon the principle of “selective photo-thermolysis”. These treatments cause cellular damage and invoke a wound healing response, including the production of collagen to repair the wound. In contrast, VersaClear treatments are based upon the principle of “photo-selective cell signaling”. VersaClear treatments activate selected chemicals in the skin (porphyrins) that result in the production of reactive oxygen species (ROS). ROS in turn are chemical signals that invoke cell proliferation and collagen production.

The following table summarizes important differences:

VersaClear	IPL and Laser
Collagen production via photo-selective cell signaling	Collagen production via selective photo-thermolysis
Broad illumination and effects	Localized, focused effects
No downtime	Several days to a week of downtime due to pain, swelling, and redness
Cost-effective	Expensive

VersaClear™ Skin Therapy System (STS)

FAQs

Question: Can VersaClear and IPL / Laser procedures work together?

Answer: Yes! Red light is known to complement and accelerate the wound healing process. As a result, VersaClear treatments performed after IPL / Laser treatment(s) can further enhance clinical results.

Question: Can VersaClear treatments reduce the appearance of fine lines, wrinkles, pigmented lesions, and superficial vascular lesions?

Answer: VersaClear treatments enhance collagen production, which will reduce the appearance of fine lines and wrinkles. Although the VersaClear is approved for the treatment of “superficial, benign vascular, and pigmented lesions”, work continues to identify optimal treatment protocols for these indications. In general, after 6-12 VersaClear red (615nm) treatments, patients have reported an “evening of pigmentation”. Whether these effects result from photobleaching of certain skin chromophores, or the result of new cell production, or both, is not yet known.

Question: Can the VersaClear be used for photodynamic photorejuvenation (ALA + VersaClear STS 615)?

Answer: The VersaClear STS 615 is not cleared in the United States for use in photodynamic therapy. However, these restrictions do not apply outside of the U.S.

Treatment protocols vary widely and a consensus as to the optimal treatment variables has yet to be defined.

However, protocols typically involve skin exfoliation or microdermabrasion prior to application of the ALA in order to enhance penetration. ALA concentrations, skin contact times, and dosages (J/cm^2) of red light delivered to the skin vary widely.

It should be recognized that the use of ALA + VersaClear STS 615 or any red light source may be associated with pain, as well as the production of erythema and skin peeling. Aggressive treatment may result in several days of downtime. Yet photodynamic photorejuvenation is an exciting innovation on the basis of the results that physicians have achieved to date.

Upon request, the company will provide a summary of select treatment protocols reportedly being used by leading Dermatologists for photodynamic photorejuvenation.

VersaClear™ Skin Therapy System (STS)

FAQs

Other PDT

Question: Can the VersaClear STS be used for PDT of AKs and BCC?

Answer: The VersaClear STS is not cleared in the United States for use in photodynamic therapy. However, these restrictions do not apply outside of the U.S. where it is common to use blue, red, or other visible spectra for protoporphyrin IX photoactivation.

Question: What skin conditions have been reported as being treatable using ALA (aminolevulinic acid) and VersaClear STS 420 (blue) or STS 615 (red) light therapy?

Answer: Treatment of the following conditions has been reported:

- Removing pre-cancerous actinic keratoses (AKs)
- Improving skin texture
- Preventing skin cancer
- Improving pigmentation
- Improving wrinkles
- Treating moderate to severe cystic acne
- Reducing pore size
- Treating sebaceous hyperplasia