V-SERIES - Safety and Performance Information

The indications of use of the V-SERIES platforms are according to treating handpiece:

1. V-ST

In Europe for skin tightening.

In the United States for the temporary relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation

2. V-FORM and V-FC

In Europe for temporarily reduction of cellulite and Body contouring via temporary circumferences reduction

In the United States for relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and temporary reduction in the appearance of cellulite

3. V-FR

In Europe for ablation and resurfacing of the skin

In the United States for dermatological procedures requiring ablation and resurfacing of the skin

4. V-VR

In Europe for electrocoagulation of soft tissues for the treatment of vulvovaginal laxity. The vulva area is referred to the labia majora

In the United States for temporary relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation

5. V-IPL

In Europe for hair reduction, skin rejuvenation treatment of superficial small vascular and pigmented lesions and treatment of mild to moderate inflammatory acne

In the United States for Moderate inflammatory acne vulgaris. Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles). Cutaneous lesions including warts, scars and striae. Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and venous malformations. Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

6. V-Nd:YAG

In Europe for hair reduction, treatment of vascular lesions and treatment of onychomycosis

In the United States for Benign vascular lesions such as but not limited to treatment of port wine stains, hemangiomas, Warts, superficial and deep telangiectasias (venulectasias), reticular veins (0.1-4.0 mm dia.) of the leg, rosacea, venus lake, leg veins, spider veins, poikiloderma of civatte and angiomas. Benign cutaneous lesions, such as, but not limited to warts, scars, striae and psoriasis. Benign pigmented lesions such as, but not limited to: lentigos (age spots), solar lentigos (sunspots), cafe-aulait macules, seborrheic keratosis, nevi and nevus of Ota, chloasma, verrucae, skin tags and keratosis. Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The non-ablative treatment of facial wrinkles, such as, but not limited to periocular wrinkles and perioral wrinkles. Laser skin resurfacing procedures for the treatment of acne scars and wrinkles. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen and treatment of pseudofolliculitis barbae (PFB).

CONTRAINDICATIONS

Contraindications for RF-based treatments (V-ST, V-FORM, V-FC, V-FR, V-VR):

- Pregnancy and breast feeding.
- History or current tattoo or permanent makeup.
- Any Permanent implant in the designated treatment area (including but not limited to silicon or injected chemical material, metal plates or other metal material).
- Any implanted electronic device anywhere in the body (such as cardiac pacemaker, defibrillator and cochlear implant).
- History of hip replacement, hip or femur surgery, or other metallic implants (such as gold threads).
- Severe concurrent conditions (such as cardiac disorders).
- Blood coagulopathy or excessive bleeding or bruising or use of blood thinning medications (anticoagulants), whether prescribed or over the counter.
- Active skin disease in the treatment area (such as psoriasis, sores, eczema and any type of rash).
- Tendency to skin disorders (such as keloids and impaired wound healing process) and extremely dry and fragile skin.
- Skin cancer (active or in the past), pre-malignant moles, malignancy (active or recent) or history of any kind of cancer.
- Immunosuppressive diseases (such as HIV Positive) or the use of immunosuppressive medications.
- Endocrine disorders (such as diabetes and thyroid disease).
- History of disease which may be stimulated by heat, such as recurrent Herpes in the treatment area.
- History of deep vein thrombosis - Thrombosis is the formation of a blood clot ("thrombus") in a deep vein.
- Surgical procedure in the treatment area within the past 6 months (or during the healing process) and plastic surgery such as face lift or eyelid surgery within the past 12 months.
- Use of Accutane within the past 6 months.

- Facial controlled abrasion (such as dermabrasion, facial resurfacing, or medium / deep chemical peeling) within the past 3 months.
- Chemical peel or natural fillers (such as hyaluronic acid) in the past 2-4 weeks
- Botulinum toxin injections in the past 5-7 days

Additional Contraindications for **V-FR handpiece**

- Augmentation techniques with injected biomaterials (such as injections of Botulinum toxin, collagen protein or fat) within the past 6 months.
- Natural filler (such as hyaluronic acid) in the treatment area within the past 6 months.
- Extremely tanned skin (including tanning beds or tanning creams) within the past 2 weeks.
- Any use of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs, such as Nurofen, Advil, and Motrin) 7 days before and 7 days after every treatment.

Additional Contraindications for V-VR handpiece

- Active Sexually Transmitted Diseases
- Any prior aesthetic or medical surgery affecting the treating area (vulvovaginal area), 3 months prior to the treatment or before complete healing.
- Current urinary tract infection
- Greater than a stage 2 pelvic organ prolapse
- Patients in the middle of menstrual cycle (on the day of the treatment)
- Absence of normal physical examination and pap smear

Contraindicated for Light-based treatments (V-IPL, V-Nd:YAG):

- Prolonged exposure to sun or artificial tanning during the past 4 weeks prior to treatment.
- Use of photosensitive medication or herbs (such as St. John's Wort) within 3 months prior to treatment.
- Severe concurrent conditions (such as cardiac disorders).
- Blood coagulopathy or excessive bleeding or bruising or use of blood thinning medications (anticoagulants), whether prescribed or over the counter.

- Recent or history of cancer, particularly skin cancer.
- Immunosuppressive diseases (such as HIV Positive) or the use of immunosuppressive medications.
- History of disease which may be stimulated by heat, such as recurrent Herpes in the treatment area.
- Diseases which may be stimulated by light.
- Endocrine disorders (such as diabetes and thyroid disease).
- Hepatitis or liver disease.
- Pregnancy, expectation of pregnancy, postpartum or nursing.
- Use of oral isotretinoin (Accutane) within the last 6 months.
- Epilepsy.
- Fragile and dry skin.
- Hormonal disorders (such as diabetes), unless under control.
- Use of anticoagulants.
- History of Keloid scarring.
- Active skin disease and Koebnerization of skin, such as Vitilgo (Hypopigmentation) and psoriasis.
- History of hip replacement, hip or femur surgery, or other metallic implants (such as gold threads).
- History of deep vein thrombosis - Thrombosis is the formation of a blood clot ("thrombus") in a deep vein.

Treatment area exclusion criteria:

- Undiagnosed lesions.
- Inflammation at the treatment area
- History or current tattoos or permanent makeup
- Moles, nevi
- Silicone implants in the treatment area.

- Any inflammatory skin condition, active infection or herpes simplex in the treatment area.
- Any metallic implants (such as gold threads) in the treatment area.
- Use of Tretinoin (Retin A) within the last 2 weeks.
- Surgical procedure in the treatment area within the past 6 months (or during the healing process) and plastic surgery such as face lift or eyelid surgery within the past 12 months.
- Facial controlled abrasion (such as dermabrasion, facial resurfacing, or medium/deep chemical peeling) within the past 3 months.
- Botulinum toxin injections in the past 5-7 days
- Chemical peel or natural fillers (such as hyaluronic acid) in the past 2-4 weeks

NOTE: A qualified practitioner is solely responsible for assessing each patient's suitability for V-SERIES treatment and for providing comprehensive information about potential risks, pre- and post-treatment care, and any other relevant information.

WARNINGS AND CAUTIONS

WARNING: Before using the system, check local regulations. If any local legislation is violated, use cannot be authorized.

WARNING: In the United States, federal law restricts prescription medical devices to sale by or on the order of a physician, or properly licensed practitioner. Sinclair makes no representations regarding federal, state, or local laws or regulations that might apply to the use and operation of this system.

WARNING: Any intense radiofrequency (RF) device can cause injury if used improperly.

WARNING: Any light-based device can cause injury if used improperly.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

WARNING: No modification of this equipment is allowed.

WARNING: It is important that the operators of this system familiarize themselves with all safety requirements and operating procedures prior to operating the system.

WARNING: Objects such as superficial metal or conductive implants, rods, plates or pins in the treatment areas are contraindicated to the treatment.

WARNING: In case of improper coupling using an RF handpiece, an alert is indicated on screen and by audio signal the trigger should be released immediately, and the handpiece should be re-oriented on the skin. In rare cases, superficial burns may occur from the heat generated by the RF electrodes.

WARNING: Improper treatment may cause local burns.

WARNING: Untrained operators should not operate the system.

WARNING: During treatment, do not allow anyone who is not essential to the treatment into the treatment room.

WARNING: Reflective objects such as jewelry, watches and surgical instruments or mirrors should be kept away from the flash lamp to avoid any light reflections.

WARNING: IR emitted from the device may cause eye injury. Avoid eye exposure.

WARNING: Always wear protective eyewear when applying light-based technology.

WARNING: The V-VR treatment tips should only be used for a single treatment application on a single patient to avoid cross contamination.

WARNING: V-FR Tips are sterile. Individual tips should be discarded if they come in contact with an unsterile surface after being removed from package (floor, hands, etc.). Treatment tips should only be used for a single treatment application on a single patient to avoid cross contamination.

WARNING: The maximum ocular hazard distance (OHD) for the V-IPL handpiece is 10 meters.

WARNING: The maximum nominal ocular hazard distance (NOHD) for the V-Nd:YAG handpiece is 836 meters.

CAUTION: UV is emitted from this device. Eye or skin irritation may result.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION: Though the treatment is not advised for any of the above conditions (the contraindication list of IFU), patients may be treated in some cases after consulting with their primary physician and providing a written consent for the treatment at their physician’s discretion.

CAUTION: In the event side effects persist or are more severe than the above (possible side effects as indicated in IFU), the patient should consult a physician and notify Sincalir immediately.

CAUTION: Do not use any anesthesia or numbing cream before procedure (except for V-FR) to ensure proper patient feedback during the treatment.

SIDE EFFECTS

All side effects are considered mild, of a short duration, self-resolving which did not require medical attention. This includes discomfort and local pain, erythema, edema, changes in skin texture, urticaria, bruising, allergic contact dermatitis to the contact oil or gel, itching and sensitivity to touch, hyper- and hypopigmentation. For the V-FR handpieces it also may include mild or strong pain, in-grown hair and skin infection. For the V-VR handpieces it also may include transient sensitivity during intercourse, bleeding due to atrophy and vaginal laceration in case of stenotic vagina. For the light-based hair removal with V-IPL and V-Nd:YAG handpiece, it may also include paradoxical unwanted hair growth.