Secret, RF TREATMENT GUIDELINES





SECRET RF TREATMENTS AND PATIENT SELECTION

PREREQUISITE

The Secret RF should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the Secret RF User Manual (shipped with system) prior to operating the system.

PATIENT ASSESSMENT

Secret RF is a medical device. It is important to obtain a complete medical history and signed informed consent. Consult the User Manual for additional information, including expected transient events and possible adverse events and set appropriate patient expectations.

CONTRAINDICATIONS

See the User Manual for a complete list of contraindications

- Pregnancy
- Patients with cardiac pacemaker
- Patients with active implantable metal device in treatment area
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash

PRECAUTIONS

See the User Manual for a complete list of precautions

- Face lift or eyelid surgery in treatment area within year prior to treatment
- Treatment with other RF or light device within one month in treatment area
- Dermabrasion, resurfacing, or deep chemical peeling in the treatment area within the last 3 months
- Do not treat over tattoos or permanent makeup
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin
- Tanned skin from sun, tanning beds or tanning creams within the last two weeks
- Use caution in patients with known sensitivities or allergies to the metals (including gold, chromium and nickel)

PATIENT SELECTION

Secret RF is an innovative fractional radio frequency (RF) microneedling system for tissue coagulation and hemostasis designed to stimulate and remodel collagen from the inside out. Secret RF delivers precise, controlled energy at various depths to target patients' most common skin concerns on the face and body with little to no downtime.1

¹Via hemostasis and coagulation





POSSIBLE ADVERSE EVENTS

Medical treatment of any adverse events are at the discretion and medical judgment of the treating clinician. See Secret RF User Manual for a complete list expected possible Adverse Effects.

Patient consent template provided on www.MyCutera.com.

- **DISCOMFORT/PAIN** Some discomfort and/ or pain may be experienced during treatment. A topical anesthetic can be applied to patient's skin before treatment. Other forms of anesthesia, or pain management, may also be used.
- **SWELLING** Swelling (edema) of the treated area is common and may occur. This usually resolves in a few days.
- **REDNESS** Redness (erythema) of the treated area is common and may occur. The erythema typically resolves in about two weeks.
- **SKIN COLOR CHANGES** During the healing process, there is a possibility that the treated area may become either lighter (hypopigmentation) or darker (hyperpigmentation) in color compared to the surrounding skin. This is usually temporary, but, on a rare occasion, it may be permanent. Patient should avoid sun exposure after the treatment and use sunblock.
- **MILIA/ACNE** Ointments that occlude hair follicles, sweat ducts, or sebaceous ducts may lead to milia/acne formation. This is more common in patients with a history of cystic acne or oily skin.
- **WOUNDS** Treatment can result in burning, blistering, or bleeding of the treated areas. It is important that you not pick or scratch the sites as this may lead to permanent scars or promote an infection. If any of these occur, instruct patient to contact treating clinician.
- **INFECTION** Infection is a possibility whenever the skin surface is disrupted which can lead to scarring. Proper wound care and keeping the treated area clean are important. If signs of infection develop, such as pain, heat, blisters, or surrounding redness, instruct patient to contact treating clinician.
- **CONTACT/ALLERGIC DERMATITIS OR SKIN SENSITIVITY –** Potential increased sensitivity, irritation/itching or allergic reaction of the skin due to skin surface disruption.
- **SCARRING** Scarring is a rare occurrence, but it is a possibility if the skin surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that patient follows all post-treatment instructions provided by treating clinician.
- **TREATMENT PATTERN** A persistent spot size pattern may be apparent on the treated skin and usually resolves with time. In rare cases, it may be permanent.
- **PETECHIAE** May appear for several weeks after healing and clear without treatment.
- **DIALATED PORES** Collagen contraction that occurs as part of the resurfacing process may also contract the skin between the pores, which widens the existing pores. This occurrence, though rare, is permanent.
- SUN EXPOSURE / TANNING BEDS / ARTIFICIAL TANNING May increase risk of side effects and adverse
 events.
- ALLERGY There is a risk of an allergic reaction to the topical anesthetic or the metal needles.



USER INTERFACE







Select Auto or Manual Mode

- Manual Mode (Recommended)

 User selects specific settings with each treatment
- Auto Mode Specific parameters can be programmed into system for later use

Auto Mode

- Enables limits to be placed onto settings available to users
- Set parameter limits in the Information Screen available via Icon on top of user interface





 3 different Auto Preset Modes are available per treatment area.

Manual Mode

- User selects specific settings for treatment
- Select setting and then the Up/Down arrows to adjust
- Specific settings can also be saved in the Storage Mode screen
- Input desired setting, click "Save" and user will be promoted create setting name
- Click "Call" button to have saved setting displayed on Manual Mode screen



PARAMETER SELECTION



TIP TYPE: Type of tip attached to the handpiece.



The user interface will not specify if the 25-Pin tip is Non-Insulated or Semi-Insulated. Operator should review labeling carefully on tip packaging before attaching tip to Secret RF handpiece.

INTENSITY: Percentage of RF energy delivered with each pulse (0 – 100%).

Higher percentage (↑%) = more aggressive treatment

RF: Amount of time the RF energy delivered, measured in milliseconds (ms).

Longer RF time (↑ms) = more aggressive treatment

DEPTH: Needle penetration depth (0.5 – 3.5 mm) measured in millimeters (mm).

• Typically, deeper treatments have longer downtime and are more aggressive

MODE: The number of pulses with foot pedal depressed

- Single = 1 pulse every time foot pedal is depressed
- 0.5 s = 2 pulses every second when foot pedal is depressed
- 1.0 s = 1 pulse every second when foot pedal is depressed
- 2.0 s = 1 pulse every 2 seconds when foot pedal is depressed

DELAY TIME: The total time that the needle is in the skin. Measured in milliseconds (ms).

- Lengthening Delay Time doesn't lengthen the amount of RF time.
- Extending Delay Time to >100 ms than RF Time may reduce downtime



SHOT COUNT: Number of pulses used on the tip. Maximum 1,500 pulses per tip.

• **WARNING!** Each Secret RF tip is single use only and should be disposed of after each treatment

SECRET RF TIPS

SECRET RF TIP USE & CLEANING



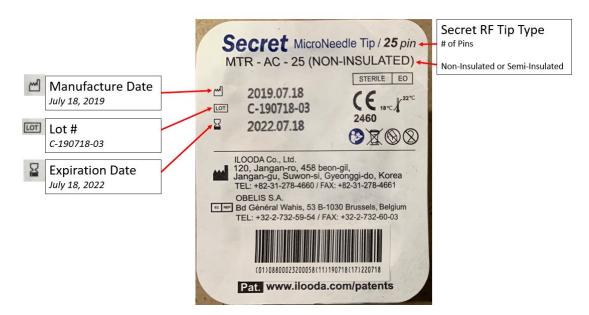
- **WARNING!** Each Secret RF tip is single use only and should be disposed of after each treatment
- There is a maximum limit of 1,500 pulses per Secret RF tip
- Secret RF tips may need to be cleaned during treatment when needles start to "stick" during deeper tissue treatments or if there is debris buildup
- Select "Cleaning/Inspect" Icon at top of screen
 - Never attempt to clean the actual needles
 - Hold handpiece with tip facing upward and away for safety
 - Select "cleaning or inspection" this will allow you to view the cartridge moving smoothly up and down.
 - Select "Cleaning" and needles will protrude from tip
 - Select "Cleaning" again and the needles will retract back into tip
 - Excess blood and secretions can be wiped off the plastic tip with an alcohol swab <u>ONLY</u> when needles are fully retracted into the plastic tip
 - Repeat process as necessary
 - Select "OK" to return to user interface and continue treatment
 - When working with needles, always use universal precautions



SECRET RF TIPS AND LABEL



- WARNING! Each Secret RF tip is single use only and should be disposed of after each treatment
- There are 3 types of Secret RF tips available
- 25 Pin Non-Insulated tip
- 25 Pin Semi-Insulated tip
- 64 Pin Semi-Insulated tip



25-pin Non-Insulated





25-pin Semi-Insulated





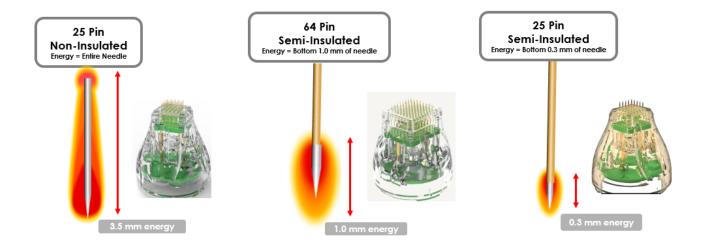
64-pin Semi-Insulated





Secret... RF

SECRET RF NON-INSULATED VS. SEMI-INSULATED TIPS



Non-Insulated Tips

Energy is distributed via the entire needle

Semi-Insulated Tips

- Energy is distributed only through the deeper part of the needle
 - 25 Pin Semi-Insulated
 - Energy distributed via bottom 0.3 mm of the tip
 - 64 Pin Semi-Insulated
 - Energy distributed via bottom 1.0 mm of the tip
 - If treating at depths of 1.0 mm or less, pin will act as a non-insulated tip
 - Skin Types IV-VI: Treat with depths >1.5 mm to prevent RF energy from affecting the epidermis and to help reduce risks of adverse effects such as post inflammatory hyperpigmentation.

Lower intensity is recommended when using 64 Pin Semi-Insulated tip

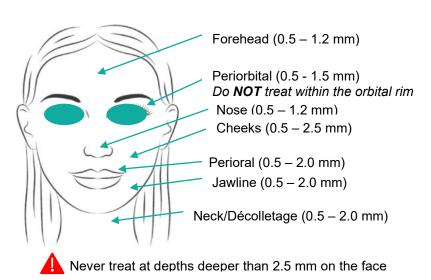


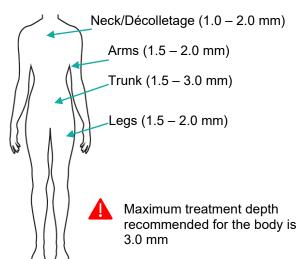


TREATMENT PARAMETERS

The following parameters are provided as a guide only and are based on practitioner feedback. Start with conservative settings and observe tissue interaction and clinical endpoints to determine appropriate settings. Adjust settings based on tissue response.

RECOMMENDED TREATMENT DEPTHS





DEPTH TO RF TIME

Depth to RF Time		
Depth (mm)	RF Time (ms)	
3.0 mm	300 ms	
2.5 mm	250 ms	
2.0 mm	200 ms	
1.5 mm	150 ms	
1.2 mm	120 ms	
1.0 mm	100 ms	
0.7 mm	70 ms	
0.5 mm	50 ms	

REVITALIZATION, BRIGHTNESS, PHOTOAGING¹

Skin Type	Microneedle Tip Type
I – III	25 Pin Non-Insulated
	or 64 Pin
IV – VI	Semi Insulated 25 Pin Semi- Insulated

IMPORTANT Information for Selecting Tips

- Use only the 25-pin semi-insulated tip for skin types IV-VI due to the 1mm of RF energy emitted from the 64-pin tip.
- o 64-Pin Semi-Insulated tip treatments at depths ≤1mm will create a non-insulated treatment due to the 1mm of RF energy emitted from the 64-pin tip.
 - 64-Pin Semi-Insulated tip only recommended for Skin Types I-III due to risks of adverse events on darker skin types.



Higher intensity, deeper depths, longer RF time and/or more passes are more aggressive treatments and can lead to longer downtime.

Area	Intensity %	Depth mm	RF Time ms	Delay Time ms	Passes
Forehead / Nose	30 – 50 %	0.5 – 1.2 mm	50 – 120 ms	100 - 220 ms	1 – 2 Passes 50 % Overlap
Periorbital	30 – 50 %	0.5 – 1.5 mm	50 – 150 ms	100 – 250 ms	1 – 2 Passes 50 % Overlap
Cheeks	30 – 50 %	0.5 – 2.5 mm	50 – 250 ms	100 – 350 ms	1 – 2 Passes 50 % Overlap
Perioral / Jawline	30 – 50 %	0.5 – 2.0 mm	50 – 200 ms	100 – 300 ms	1 – 2 Passes 50 % Overlap
Neck / Décolletage	30 – 50 %	0.5 – 2.0 mm	50 – 200 ms	100 – 300 ms	1 – 2 Passes 50 % Overlap
NOTES	30 % intensity recommended for first treatment.	Never treat at depths deeper than 2.5 mm on the face	Refer to Depth to RF Time chart to match the RF Time to Depth (i.e. 0.5mm = 50 ms)	Extending Delay Time to >100 ms than RF Time may reduce downtime	Keep Settings same for each pass

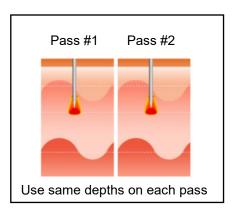


¹Via hemostasis and coagulation

Secret_{RF}

Treatment Parameter Notes for Revitalization, Brightness, Photoaging¹

- Use same depths for each pass
- Skin Types IV VI
 - o Only the 25-Pin Semi-Insulated tip is recommended
 - Darker skin types are at higher risks for longer downtime, pigmentary changes and persistent grid pattern
- Use only the 25-pin semi-insulated tip for skin types IV-VI due to the 1mm of RF energy emitted from the 64-pin tip.
- 64-Pin Semi-Insulated tip treatments at depths <1mm will create a non-insulated treatment due to the 1mm of RF energy emitted from the 64-pin tip.
 - o 64-Pin Semi-Insulated tip only recommended for Skin Types I-III at shallow treatment depths due to risks of adverse events on darker skin types.
- Persistent Grid Pattern may occur with some treatments
 - o May occur with:
 - Higher intensity treatments
 - 25-Pin non-insulated treatments
 - 64-Pin semi-insulated treatments at depths of <1.0 mm
 - If the handpiece is lifted before the needles are completely retracted back into the handpiece
 - o 24 hours after treatment, patient may apply the following until grid pattern resolves
 - Healing ointment
 - Moisturizer (optional: combine with hydrocortisone cream)
 - Aquaphor (optional: combine with hydrocortisone cream)
 - Can cause any milia/acne to worsen
 - Typically resolves within a week for treatments on the face



TEXTURE, SCARS, STRETCH MARKS¹

Skin Type	Microneedle Tip Type
I - VI	25 Pin Semi-Insulated Or 64 Pin Semi-Insulated

IMPORTANT Information for Selecting Tips

- $_{\odot}$ 25-Pin semi-insulated tip recommended for face treatments since will be treated at shallower depths
- Larger 64-Pin semi-insulated tip recommended for large/deeper treatment areas on the body
- Treating Skin Types IV-VI
- 25 Pin Semi-Insulated Tip: treat at any depth
- 64 Pin Semi-Insulated Tip: treat at 1.5mm or deeper to help prevent epidermal injury



Higher intensity, deeper depths, longer RF time and/or more passes are more aggressive treatments and can lead to longer downtime.

Area	Intensity	Depth	RF Time	Delay Time	Passes
	%	mm	ms	ms	
Forehead /	30 – 60 % (25 Pin)	0.5 – 1.2 mm	50 – 120 ms	100 - 220 ms	
Nose	30 – 50 % (64 Pin)				
Periorbital	30 – 60 % (25 Pin)	0.5 – 1.5 mm	50 – 150 ms	100 – 250 ms	
	30 – 50 % (64 Pin)				2 – 3 Passes
Cheeks	30 – 60 % (25 Pin)	0.5 – 2.5 mm	50 – 250 ms	100 – 350 ms	
	30 – 50 % (64 Pin)				Start at deepest
Perioral / Jawline	30 – 60 % (25 Pin)	0.5 – 2.0 mm	50 – 200 ms	100 – 300 ms	recommended
	30 – 50 % (64 Pin)				depth, decreasing
Neck / Décolletage	30 – 60 % (25 Pin)	0.5 – 2.0 mm	50 – 200 ms	100 – 300 ms	by 0.5 – 1.0 mm
	30 – 50 % (64 Pin)				with each pass
Arms /	30 – 60 % (25 Pin)	1.5 – 2.0 mm	150 – 200 ms	200 – 300 ms	
Legs	30 – 50 % (64 Pin)				
Trunk	30 – 60 % (25 Pin)	1.5 – 3.0 mm	150 – 300 ms	250 – 400 ms	
	30 – 50 % (64 Pin)				
NOTES	30% Intensity	Skin Types IV-VI:	Refer to Depth	Extending	Do not perform a
	recommended for	Treat at depths of	to RF Time	Delay Time to	3 rd pass on thinned
	first treatment	1.5 mm or greater	chart to match	>100 ms than	skinned areas
		when using 64 Pin	the RF Time	RF Time may	such as Forehead,
		Semi-Insulated	to Depth	reduce	Periorbital, Nose
		tips	(i.e. 0.5mm =	downtime	
			50 ms)		
		Never treat at			
		depths deeper			
		than 2.5 mm on			
		the face			
		Maximum			
		treatment depth			
		recommended for			
		the body is 3.0			
		mm			

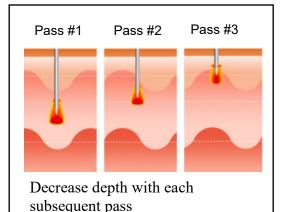
¹Via hemostasis and coagulation



Secret_{**} RF

Treatment Parameter Notes for Texture, Scars, Stretch Marks¹

- Pass 1 treat at deepest recommended depths
 - Decrease each subsequent pass by 0.5 to 1.0 mm
- Larger 64-Pin tip recommended for large treatment areas such as the body
- 30% Intensity recommended for first treatment
 - o Increase intensity on subsequent treatments
 - o Some patients may not be able to tolerate >40% on the 64pin tip
 - Longer downtime has been associated with intensity >40% when using the 64pin tip
- Skin Types IV VI
 - Treat at depths of 1.5 mm or greater when using 64 Pin Semi-Insulated tips
 - 64-Pin Semi-Insulated tip treatments at depths <u>11mm</u> will create a non-insulated treatment due to the 1mm of RF energy emitted from the 64-pin tip.
 - Use lower intensity to help reduce risk of adverse effects
- Thinner Skin Areas (such as Forehead, nose, periorbital, etc.)
 - o 25-Pin tip recommended for skin types IV-VI
 - o Treat at shallower depths & do not perform a 3rd pass
- Persistent Grid Pattern may occur with some treatments
 - May occur with:
 - Higher intensity treatments
 - 64-Pin semi-insulated treatments at depths of <1.0 mm
 - Treatments on the body
 - If the handpiece is lifted before the needles are completely retracted back into the handpiece
 - 24 hours after treatment, patient may apply the following until grid pattern resolves
 - Healing ointment
 - Moisturizer (optional: combine with hydrocortisone cream)
 - Aquaphor (optional: combine with hydrocortisone cream)
 - Can cause any milia/acne to worsen
 - Typically resolves within a week for treatments on the face
 - Typically resolves within a few weeks for treatments on the body







TREATMENT STEPS

PATIENT PREPARATION

- Prescription-strength compounded topical anesthetic is recommended
 - CAUTION Toxicity may result from overuse. Consult the product labeling for any anesthetic used
 - o Completely remove topical anesthetic from skin
 - o Use alcohol to thoroughly clean the skin prior to treatment to help minimize the risks of infection
- Excess hair may need to be shaved
 - o Men should be clean shaved
- No sun-tanning or self-tanners 4 weeks prior to treatment
 - o Includes spray tans, tanning lotions, tanning beds, sun exposure, etc.
- Avoid skin irritants (examples below) a few days before and after treatment
 - Products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, vitamin
 C/ascorbic acid, astringents, etc. Avoid treatments that may irritate the skin for 1-2 weeks prior to treatment (waxing, depilatories, etc.)
- Do not treat patients with an allergy to gold or metal
- Be aware of current medications (both routine and occasional use) which could affect treatment
 - Accutane do not treat if taken in the last 6 months.
 - Gold Therapy may cause blue-gray discoloration
 - Anticoagulants may increase risk of purpura or bruising
- Patients with Vitiligo may experience de-pigmentation
- Patients with Herpes may be pre-treated with an antiviral
- Do not treat over open wounds
- Not recommended to treat over melasma
- Patients with history of keloid or hypertrophic scarring have an increased risk creating a new keloid/hypertrophic scar
- Do not treat over or close to tattoos or permanent make-up
- Remove any piercings in the treatment area
- All traces of make-up must be removed prior to treatment
- Outcome of treating over implants and threads is unknown
- Only treat over known benign lesions
 - o Do not treat over dysplastic nevi or questionable pigmented lesions
 - o Online Melanoma resources include (www.aad.org), (www.cancer.org)



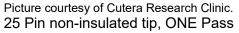
TEST PULSES

- Perform test pulses in the treatment area
 - Test Spots should be performed on each general treatment area (face, body) and prior to each treatment
 - Perform a test spot for each of the recommended intensity settings
 - Wait 3-5 minutes to observe clinical endpoint
 - o Correct endpoint is mild to moderate erythema and with edema around each spot
 - Adjust Intensity depending on clinical endpoint and patient comfort
 - Higher Intensity = More Aggressive; Lower Intensity = Less Aggressive
 - o RF time can also be adjusted if necessary
 - Longer RF time = More Aggressive; Shorter RF time = Less Aggressive
- Subsequent treatment can use more aggressive settings if the previous treatments didn't provide optimal results
- If patient displays an urticaric response to treatment (localized rash with or without redness and/or itching), an antihistamine can be administered and/or hydrocortisone can be applied. Symptoms should resolve within a few days.

ENDPOINT

- Correct endpoint is mild to moderate erythema and with edema around each spot
- Bony areas of treatment may have pinpoint bleeding

Immediate
Pre Treatment Post treatment





Secret_{**}RF

TREATMENT TECHNIQUE

- Ensure treatment area is completely cleansed of any makeup, lotion or topical anesthetic
- Wiping treatment area with alcohol prior to treatment is recommended to help minimize the risks of infection



- **WARNING!** Each Secret RF tip is single use only and should be disposed of after each treatment
- RF tip must keep contact with the skin during the entire pulse
- Place handpiece perpendicular to skin and pulse, ensuring that the needles are <u>completely retracted</u> back into the tip prior to moving tip to next treatment location

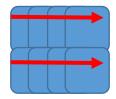


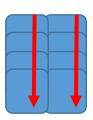
CAUTION

- Failure to wait until the needles are completely retracted into the tip before moving can result in extended downtime and increased risks of side effects
- The audible tone is NOT an indicator of when the pulse is completed
 - The audible tone sounds only when the RF is being emitted and is not on during entire pulse
- If treating over wrinkles, stretch marks or lax skin, hold the skin taut
- Do NOT glide RF tip against skin between pulses
 - Lift handpiece and place in next treatment area in between pulses

PULSE OVERLAP AND NUMBER OF PASSES

- Place passes with approximately 50% overlap of pulses
- Multiple passes should be completed per area before moving to next treatment area







POST TREATMENT CARE

- Can immediately apply gauze soaked in saline solution to the treatment area for 5-15 minutes
- After saline solution soak, apply a post-procedure product if desired (Aquaphor is not recommended immediately post-treatment)
- If patient displays an urticaric response to treatment (localized rash with or without redness and/or itching), an antihistamine can be administered and/or hydrocortisone can be applied
 - Symptoms should resolve within a few days
- Higher Intensity, deeper depths or multiple passes may produce prolonged erythema, edema and/or grid pattern in the treatment area
- If persistent grid pattern appears, wait at least 24 hours to begin post-healing ointment regimen
 - Some practitioners apply Aquaphor or a moisturizer (with or without hydrocortisone cream) or alternate healing ointment daily until grid pattern resolves
 - Note: Aquaphor can worsen existing acne
 - Some practitioners have reported grid patterns lasting 1+ month post-treatment for treatments on body

Patient Post-Care Instructions (Provide to Patient):

- Wait at least 4 hours before washing face or applying soap, cream or makeup to the treatment area
- Avoid sun exposure and use a broad spectrum (UVA/UVB) sunscreen to prevent further sun damage
- Avoid heat hot tubs, saunas, etc. for 1-2 days
- Avoid skin irritants (examples below) a few days before and after treatment
 - Products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, vitamin C/ascorbic acid, astringents, etc.
- Bruising, redness and swelling may occur and resolve with time
 - More aggressive treatments or use of irritants in the days prior to or after treatment can lead to longer downtime
- o Notify clinic of any concerns (blistering, excessive redness/swelling, grid pattern, etc.)

TREATMENT PROTOCOL

Treatment Interval

• Space treatments 4 – 6 weeks apart

Number of Treatments

- Patients typically receive 3 4 treatments
- Scars/Stretch Marks More than 4 treatments if desired and continued improvement is seen



SYSTEM CARE & MAINTENANCE

- See Operator Manual for detailed instructions on system care and maintenance.
- Refer to the Secret RF Cleaning Addendum and Operator Manual for detailed instructions on cleaning and disinfecting your system and handpieces after each treatment.

CLINICAL SUPPORT

Cutera provides complimentary phone and email clinical support for Cutera customers. Cutera clinical staff cannot dispense medical advice or diagnose, but can provide guidance on appropriate patient selection, parameter choices and treatment technique.

Phone: 888-4-CUTERA or +1-415-657-5500

Email: ClinicalSupport@cutera.com



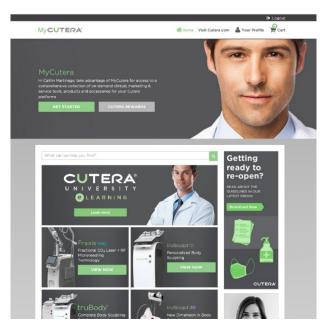
MyCutera.com is a customer portal that provides updated Clinical and Marketing materials.

Check back regularly for updates!

Website: www.MyCutera.com
email: websupport@cutera.com
Customer ID required for Login:

- View
 - Tutorial Videos
 - Practice Support Webinars
- Download
 - Treatment Guidelines
 - o Operator Manuals
 - Patient Forms
 - Informed Consent Template
 - Patient Pre & Post Treatment Instruction
 - Consultation & Health History
 - Treatment Record
 - Marketing/Promotional materials
- Purchase
 - Secret RF Microneedle Tips
 - System& Marketing Accessories
 - Additional Clinical Training







SKIN TYPE CLASSIFICATION QUESTIONNAIRE1

Type	Skin Characteristics	Skin Color
I	Burns easily, never tans	Ivory white
II	Burns easily, tans minimally with difficulty	White
III	Burns moderately, tans moderately and uniformly	White
IV	Burns minimally, tans moderately and easily	Beige-olive, lightly tanned
V	Rarely burns, tans profusely	Moderate brown or tanned
VI	Never burns, tans profusely	Dark brown or black

¹Sachdeva S. Fitzpatrick skin typing: Applications in dermatology. Indian J Dermatol Venereol Leprol 2009;75:93-6. doi:10.4103/0378-6323.45238