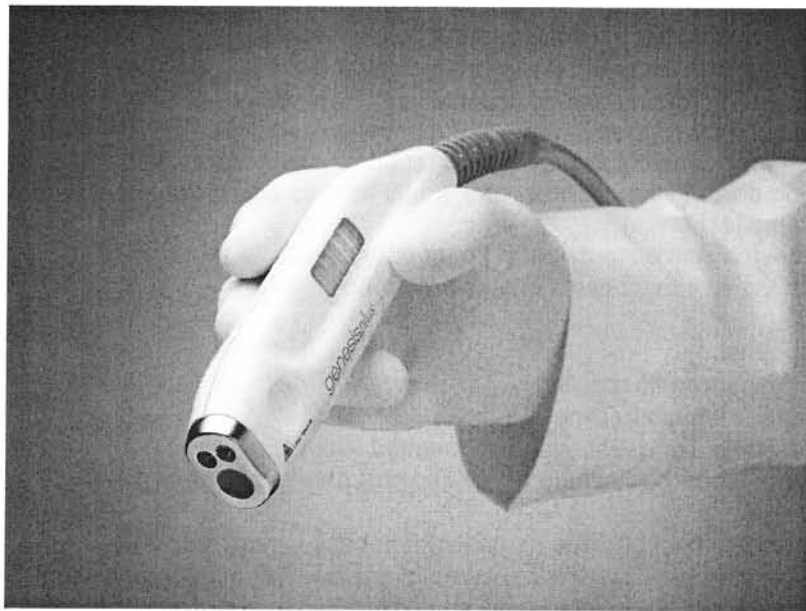


genesis*plus*

Treatment Guidelines

For customers outside the US



CUTERA®

Lasers and Light™

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The Cutera GenesisPlus is an Nd:YAG (1064nm) laser with a patented pulse structure designed for safe and effective treatment on all skin types and tanned skin. It can be safely used on all body parts (excluding the eye and surrounding area). Common indications include:

- Rosacea / Diffuse Redness
- Poikiloderma of Civatte
- Scar reduction: including reduction in hypertrophic and keloid scars
- Wrinkle reduction
- Improvement in texture
- Reduction in pore size
- Warts
- Onychomycosis / Nail Fungus (not FDA approved for treatment in the U.S.)

PREREQUISITE

Review the GenesisPlus Operator Manual (shipped with laser) and Clinical Presentations on Laser Physics, Safety and Maintenance (found on Cutera VIP website) prior to operating the laser.

PATIENT ASSESSMENT

- **Contraindications: Pregnancy and Skin Cancer**
- Obtain a medical history and signed consent.
- Determine ethnicity and skin type by using the attached Fitzpatrick Skin Type scale
 - Re-evaluate patient prior to each treatment
 - Treatment settings may need to be decreased due to sun exposure as sun exposure may increase melanin content of the skin
- Patient Considerations including but not limited to are below.
 - Herpes – pre-treatment with an antiviral may be indicated
 - Current Medications (both routine and occasional use)
 - Accutane – do not treat if taken in the last 6 months
 - Gold Therapy – may cause blue-gray discoloration
 - Photosensitizing drugs (Tetracyclines, etc) – may have to adjust treatment parameters according to clinical response from the test are(s)
 - Anticoagulants – may increase risk of purpura or bruising
 - Vitiligo – heat from the treatment could induce a flare-up
 - Wound infections
 - History of coagulopathies
 - History of keloid or hypertrophic scarring
 - Diabetes – may impede wound healing
 - Do not treat dysplastic nevi or questionable pigmented lesions.
 - Online Melanoma resources include (www.aad.org), (www.cancer.org)
- Avoiding Complications:
 - Topical anesthetics should not be used as patient feedback is required
 - Darker skin types have an increased risk of complications and/or pigmentary issues
 - Always treat outside the orbital rim of the eye aiming the beam away from the orbit
 - Do not treat over or close to tattoos or permanent make-up
 - All traces of make-up must be removed
 - Possible hair loss may occur
 - No self-tanners for at least 2-4 weeks prior to treatment.
 - The Nd:YAG can crack a tooth if teeth are exposed.
 - Moist gauze may be placed between the lips and teeth.
 - Implants
 - Avoid metal implants in thin skinned areas; clavicle, jaw, orbit
 - Ask about surgical implants and threads
 - Do not treat over Pacemaker implant
 - Reaction to fillers unknown
- Ice should NEVER be applied to a suspected burn as it may cause unwanted side effects. Frozen gel packs or cool compresses can be used.

The laser system should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the operator manual.

TEMPERATURE MONITORING

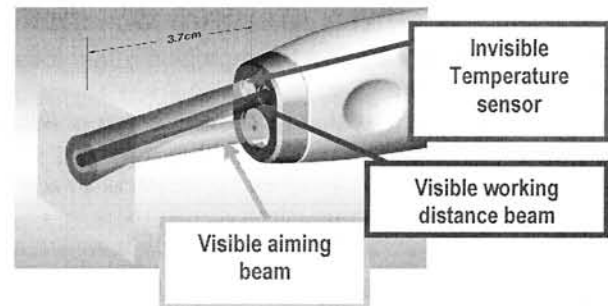
- GenesisPlus features an integrated temperature sensor which monitors temperature when placed approx. 4cm from the target.
- The actual temperature will be displayed on the screen and the LED indicators will light up
 - The 6 LED indicators on the handpiece correspond with temperatures as shown
- Ideal treatment temperature should be between 39-46 ° C (Yellow LED)



LED Color	Temp Range
Green	26-30 ° C
Green	31-34 ° C
Green	° C
Yellow	43-35-38 ° C
Yellow	39-42 46 ° C
Red	47-50 ° C

POSITIONING THE HANDPIECE

- Position the handpiece 3.7 cm above the treatment area maintaining that approximate distance during the entire distance
- Ensure that the smaller working distance beam is centered in the larger aiming beam
- The temperature sensor will not be visible



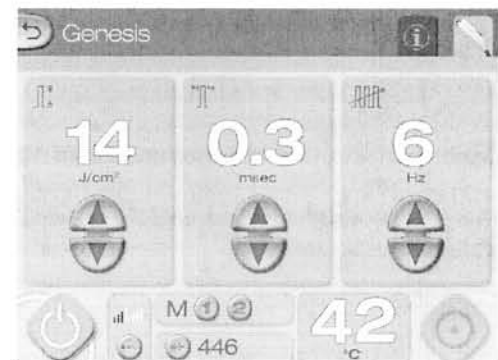
LASER SAFETY AND MAINTENANCE

- It is important to properly maintain your system. Failure to do so may affect the life of your laser. Review the Operator Manual thoroughly for detailed instructions.
- Log on to the Clinical & Training section of the Cutera website's Education tab (www.cutera.com) for important information on Laser Safety and Laser Physics. These presentations review light-tissue interaction and safe laser practices.



Selecting Parameters

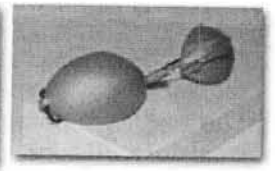
- **Fluence** is the energy measured in J/cm²
 - Lower fluence for darker skin types
- **Pulse Width or Pulse Duration** is the length of each laser pulse measured in milliseconds (ms)
- **Repetition Rate** is the number of pulses per second measured in Hz
 - Lower repetition rate for increased patient comfort



PERFORMING THE PROCEDURE – SKIN REJUVENATION

Prepping the Patient

- Clean skin removing all make-up.
- Pre-treatment photographs should be taken prior to the initial treatment for future reference.
- Shave the treatment area prior to each treatment.
- A white eyeliner pencil can be used to divide the treatment area into smaller grids.
- Treatment of a test area should be performed and observed prior to the treatment.
- Topical anesthetic should not be used as patient feedback is required
- Safety eyewear must be worn by ALL people in the treatment room.
 - Check the wavelength and optical density (≥ 6.1 @ marked on all operator goggles.



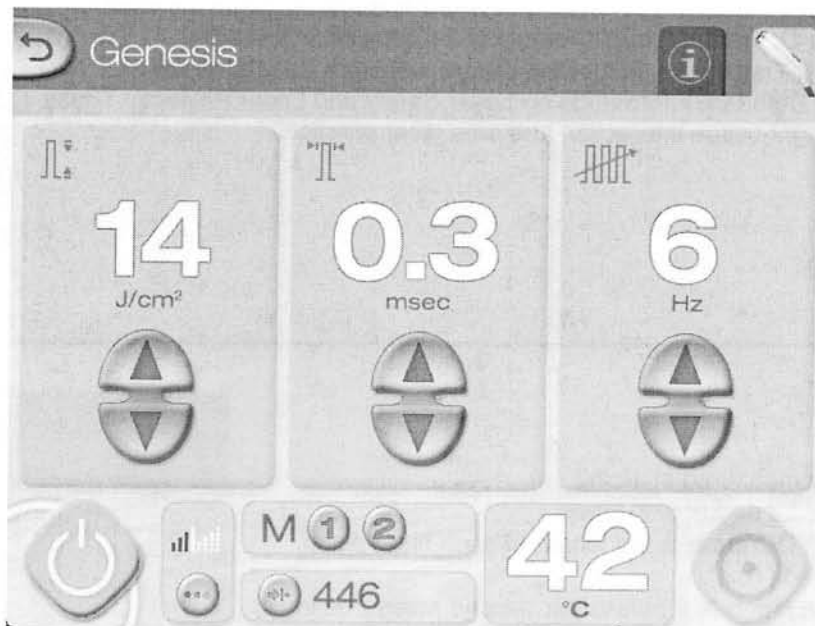
Operator Goggles

Patient Goggles

Selecting Treatment Parameters

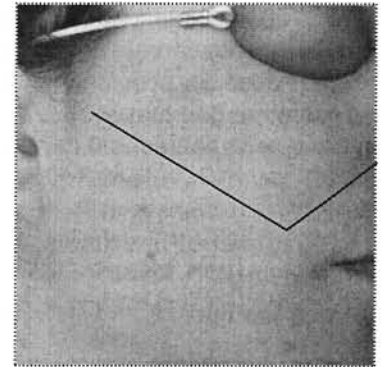
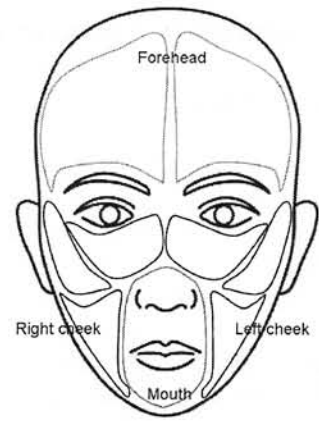
- Start with low fluence and slow repetition rate to observe laser-tissue interaction. Adjust to patient tolerance and epidermal response
- Sensitive areas, darker skin types, and areas of dense hair or recent sun exposure may require lower fluences or lower repetition rates

Size	Skin Type	Fluence	Pulse Width	Repetition Rate	# Tx	# of Pulses
Large Area (face, neck, or chest)	I-IV	12-18 J/cm ²	0.3 ms	7 – 10 Hz	4-6	8,000 – 12,000
	V-VI	8-14 J/cm ²	0.3 ms	5 – 8 Hz	4-6	
Small Area (scars)	I-IV	12-18 J/cm ²	0.3 ms	2 – 7 Hz	1-4	700 - 800



Treatment Technique

- Gel is not used
- Topical anesthetics should not be used as patient feedback is required
- To ensure bulk heating, divide the face into multiple regions (example shown).
 - Forehead –divide in half
 - Periocular – Do **NOT** treat upper lids
 - Cheeks divide into 2-3 sections
 - Perioral areas
 - The vermillion border may be treated
 - The Nd:YAG can crack a tooth if teeth are exposed
 - Moist gauze may be placed between lips and teeth
- Hold the handpiece approximately 3-4 cm from the skin's surface
 - Ensure the distance beam is centered in the aiming beam.
 - The handpiece should be continuously moved in a zig-zag motion with even distribution of pulses
 - Movement should be controlled and speed adjusted according to the patient's tolerance
 - Treat each region to point of discomfort and erythema (example shown), then move to adjacent regions using multiple passes
- Depending on the user setting, the laser emits a distinct water drop sound every 100, 1000 and 5000 pulses or every 25, 100 and 500 pulses. These sounds can help keep track of treatment progress without looking at the screen.
- Dark skin, scars or hot spots may need cooling or a short break during treatment
- Scars
 - Check with surgeon before starting treatment on fresh scars
 - Always include the tissue surrounding the scar observing for erythema of the scar as endpoint
 - Scar will absorb more energy than surrounding skin
 - Do not rely on heat in surrounding skin as an endpoint
 - Decreased sensation of scar increases risk of burn
 - Several treatments may be necessary
- Extreme caution should be used when treating near the eye.
 - Patient eye protection is required to avoid ocular damage.
 - The laser beam should ALWAYS be pointed away from the eye and only applied to the skin outside of the orbital rim.
 - Distance from the orbit can often be increased by pulling the skin away from the eye for treatment.



Post Operative Care

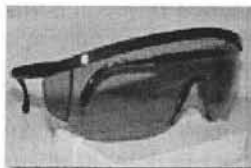
- No special post operative care is typically required
- Erythema is normal and expected and resolves with time
- Edema is a normal reaction
- The average time interval between treatments is 2 - 4 weeks
- If a blister or crusting develops, treat as a wound
 - Do not ice a suspected burn – use a cold compress
 - Apply lubricating ointment until re-epitheliation occurs

PERFORMING THE PROCEDURE – ONYCHOMYCOSIS / NAIL FUNGUS

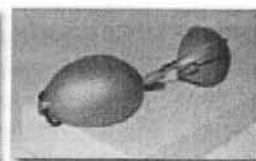
Not FDA approved for treatment in the U.S.

Prepping the Patient

- Remove nail polish
- Remove jewelry
- Clean all nails thoroughly with alcohol
- Topical anesthetic should not be used as patient feedback is required
- If nail is thicker than 2mm, the nail should be debrided
- Nail may be notched with a file to assess improvement
- Pre-treatment photographs should be taken prior to the initial treatment for future reference
- Safety eyewear must be worn by ALL people in the treatment room.
 - Check the wavelength and optical density ($\geq 6.1 @ 1064\text{nm}$) marked on all operator goggles.
 - Patients can opt to wear Operator Goggles
- The laser operator should wear gloves at all times
- It is recommended that everyone in the treatment room wear laser surgery masks filtered to 0.1 microns



Operator Goggles

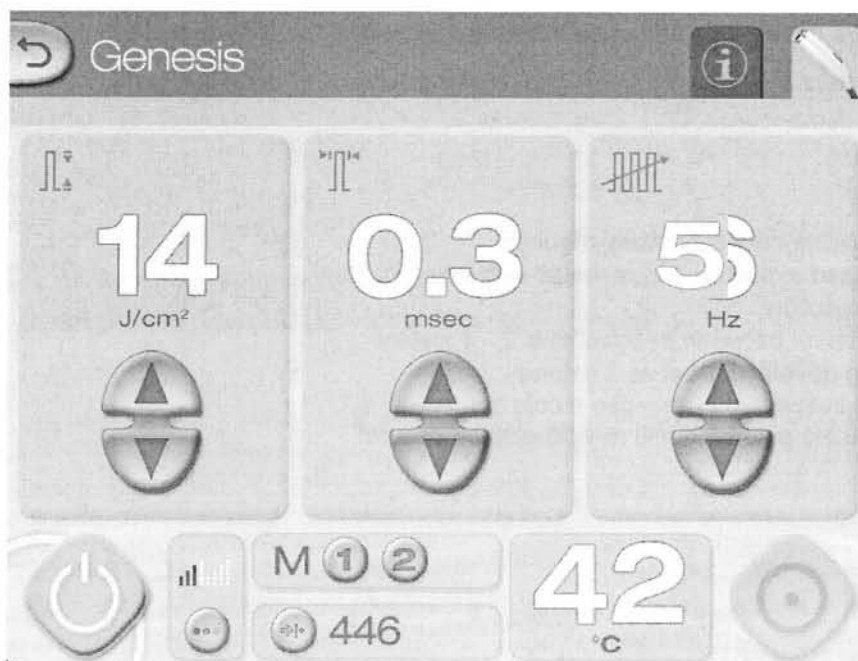


Patient Goggles

Selecting Treatment Parameters

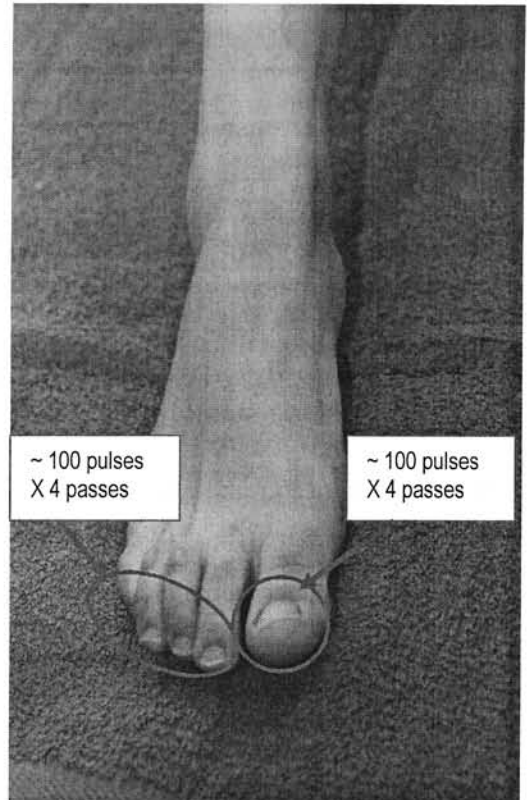
- Start with low fluence and slow repetition rate to observe laser-tissue interaction.
- Adjust to patient tolerance
- Number of treatments will depend on severity of the Onychomycosis / Toenail Fungus

Size	Skin Type	Fluence	Pulse Width	Repetition Rate	# Tx	# of Pulses
Toenails or Fingernails	I-IV	12-18 J/cm ²	0.3 ms	2 – 5 Hz	1-5	700-800 per hand/foot
	V-VI	10-16 J/cm ²	0.3 ms	2 – 5 Hz	1-5	



Performing the Treatment

- Gel is not used
 - Topical anesthetics should not be used as patient feedback is required
 - Hold the handpiece approximately 3-4 cm perpendicular from the nail's surface
 - Ensure the distance beam is centered in the aiming beam
 - The handpiece should be continuously moved in a zig-zag motion with even distribution of pulses
 - Movement should be controlled and speed adjusted according to the patient's tolerance
 - Treat the entire nail bed and matrix, extending approximately 2mm past the nail
 - All 10 toes/fingers should be treated
 - Treat each toe/finger to point of discomfort, then move to the adjacent toe/finger using multiple passes
 - Start treatment on the hallux (big toe) or thumb
 - When patient feels slight discomfort, move to the adjacent smaller toe/finger
 - At least 100 pulses should be delivered to the big toe/thumb before moving onto the smaller toes/fingers
 - Continue treating the smaller toe/finger until the onset of discomfort
 - Repeat the process for the subsequent toes/fingers
 - Four passes of 100 pulses should be delivered to big toe/thumb. Four passes of 100 pulses should be delivered to rest of smaller toes/fingers. The number of passes may change from patient to patient depending on patient tolerance.
 - ~ 400 total pulses recommended per big toe/thumb
 - ~ 400 total pulses recommended for the smaller toes
 - It should be noted that the pain tolerance lowers with each pass
- White flashes can occur during treatment and are due to imperfections in the nail
- It is okay to pause treatment 5-10 seconds for patient comfort



Post Operative Care

- To help prevent re-infection:
 - Apply anti-fungal cream 2X per day for approximately 3 months
 - Apply anti-fungal powder to all shoes at least 1x per week for approximately 1 month
- It is okay to apply nail polish after 24 hours
- The average time interval between treatments is 1-6 weeks
- Due to slow nail growth, results may not be noticeable for 2-3 months

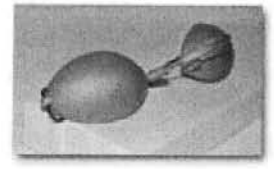
PERFORMING THE PROCEDURE – WARTS

Prepping the Patient

- Clean skin thoroughly with alcohol.
- Pre-treatment photographs should be taken prior to the initial treatment for future reference.
- Shave the treatment area prior to each treatment.
- Topical anesthetic should not be used as patient feedback is required
- It is recommended that everyone in the treatment room wear laser surgery masks filtered to 0.1 microns
- A smoke evacuator is recommended
- Safety eyewear must be worn by ALL people in the treatment room.
 - Check the wavelength and optical density (≥ 6.1 @ 1064nm) marked on all operator goggles.
 - Patients can opt to wear Operator Goggles



Operator Goggles



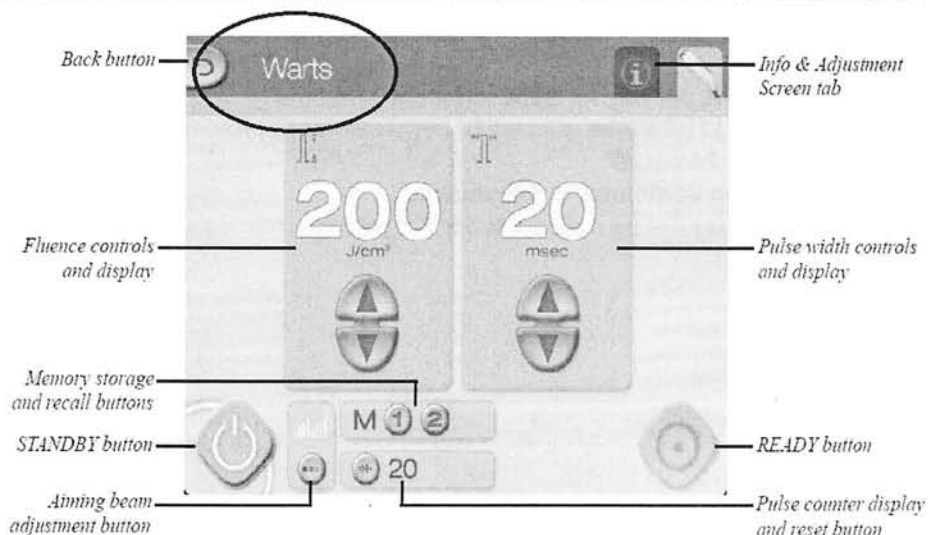
Patient Goggles

Selecting Treatment Parameters

- Start with low fluence
- Adjust to patient tolerance and epidermal response

Size	Skin Type	Fluence	Pulse Width	Repetition Rate	# Tx	# of Pulses
Wart	I-VI	140-200 J/cm ²	6 – 20 ms	N/A	1-2	1+

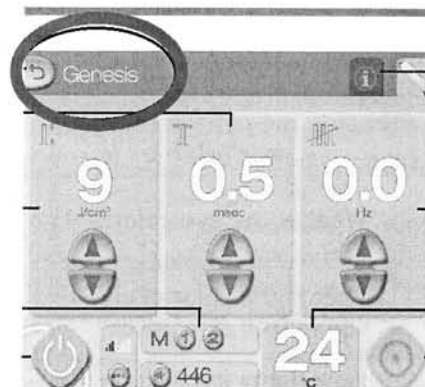
GenesisPlus User Interface Design Features



Performing the Treatment

The treatment of warts should only be attempted by experienced practitioners.

- The target chromophore for the wart is the vascular component
- Select the back button icon on the upper left side of the screen to access Wart Settings
- Parameters may need to be adjusted according to skin type and/or color of wart
- Handpiece should be 2 cm away from skin instead of the 4cm recommended for Skin Rejuvenation or Onychomycosis treatment
 - Only the larger aiming beam will appear, the smaller working distance beam and the temperature readout will not be displayed
- Warts may need to be debrided prior to treatment
- Gel is not used
- Treat the entire wart
 - Overlap pulses slightly by 10%
 - Do not treat outside the wart border Try to stay within the border of the wart
 - Wart may spark when treated
- The wart may become ashen or dusky immediately after treating
- Immediate post cooling with frozen gel pack, zimmer, etc. will help with patient comfort

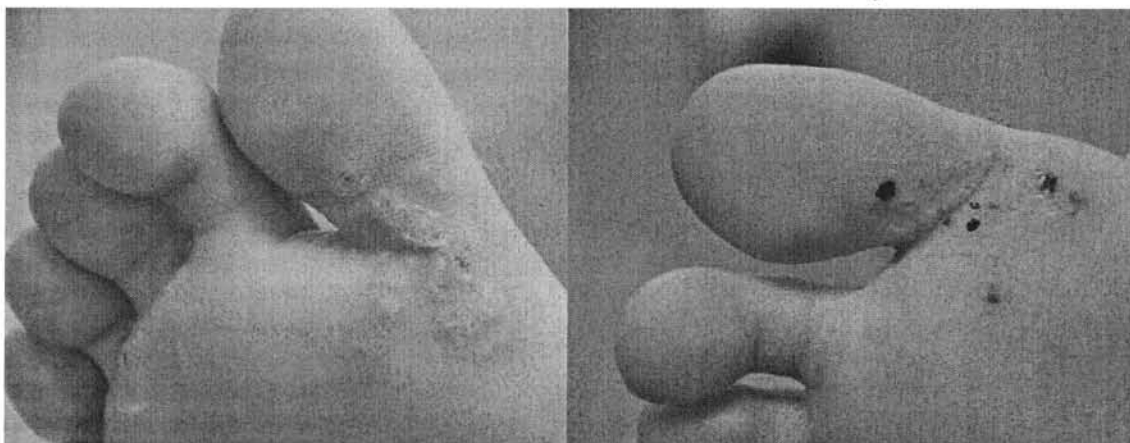


Post Operative Care

- Warts usually have a black or crusty appearance within 24 hours after treatment and usually slough off in 1-2 weeks
- May apply ointment of choice and non-stick dressing for patient comfort
- If a blister develops, treat as a wound
- More than 1 treatment may be necessary (3-4 weeks apart)

200 J/cm² 20 msec

Photos Courtesy of Dr. D Weiss



Before

4 weeks s/p treatment

Fitzpatrick Classification Questionnaire

SCORE		0	1	2	3	4
	What is the natural color of your hair?	Sandy red	Blond	Chestnut, dark blond	Dark brown	Black
	What is the eye color?	Light blue, Gray, Green	Blue, Gray, Green	Blue	Dark Brown	Brownish Black
	What is the color of sun unexposed skin areas?	Reddish	Very pale	Pale with beige tint	Light brown	Dark brown
	How many freckles on unexposed skin areas?	Many	Several	Few	Incidental	None
	What happens when you are in the sun TOO long without sunblock?	Painful redness, blistering, peeling	Blistering followed by peeling	Burns, sometimes followed by peeling	Rarely burns	Never had a problem
	How well do you turn brown?	Hardly or not at all	Light color tan	Reasonable tan	Tan very easily	Turn dark very quickly
	Do you turn brown within one day of sun exposure?	Never	Seldom	Sometimes	Often	Always
	How does your face respond to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem
	When did you last expose yourself to the sun or artificial sun treatments?	More than 3 months ago	2-3 month ago	1-2 months ago	Less than 1 month ago	Less than 2 weeks ago
	Do you expose the area to be treated to the sun?	Never	Hardly ever	Sometimes	Often	Always
	TOTAL					

- 00-07 points = Skin type I
- 08-16 points = Skin type II
- 17-25 points = Skin type III
- 25-30 points = Skin type IV
- 30-40 points = Skin type V & VI