



1

EMBRACERF

Embrace can remove the fat and contract the skin utilizing InMode's proprietary Minimally Invasive RFAL and Fractional RF technologies.

Step 1:
Radio-frequency assisted lipolysis (RFAL) technology, which has been clinically proven in peer reviewed studies to provide significant contraction, with or without accompanying fat removal. Minimally invasive handpiece can be used under local anesthesia in the office, with only two days of downtime. Small, non-aspirating cannula allows physicians to work safely in the sub-dermal plane for tissue contraction and contouring.

Step 2:
If the quality of the skin needs to be addressed, then external fractional radio-frequency heat can be used to contour the face. Sub-dermal Adipose Remodeling Device (SARD) that molds the fat in order to morph the aging facial features into a more youthful appearance.

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FACEtite
Minimally Invasive Contouring Solutions

FACEtite
Minimally Invasive Contouring Solutions

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FaceTite

- Complete contouring solution of the face and small areas of the body
- Remarkable results without excisional surgery
- Non-aspirating cannula with a plastic tip that allows physicians to work safely in the sub-dermal plane for RF inspired tissue contraction and contouring

Specifications	
Cannula Diameter	1.3mm
Cannula Length	10cm
Depth of Treatment	Up to 25mm (1")
Internal Temperature	Operator adjustable between 50-70°C
External Temperature	Operator adjustable up to 42°C
Output Frequency	1MHz



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FACETITE

- Deliver surgical results to patients without the scalpel or large visible scars.
- Remarkable results using RFAL accessed through 16 gauge needle entry port.
- Significantly tighten jowls, neck, and other areas with unheralded outcomes.
- Improved surgical outcomes with RFAL for a more complete and natural look than excisional procedures



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FACETITE PROTOCOL

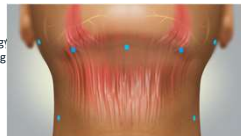
GOAL:

- To safely, effectively and reproducibly apply radiofrequency energy of the lower face, jowls and neck for aesthetic improvement using device.

TREATMENT ZONES:

- Lower third of face and neck
- Mid neck
- Lateral neck
- Jowls (two zones)

(No fly zones: Upper face, commissure lines, forehead, periorbital)



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INDICATIONS

- FDA cleared for electrocoagulation of soft tissue and hemostasis
- This technology is the most advanced and finely controllable tool for minimally invasive fat coagulation and simultaneous tightening of collagenous soft tissue



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UNIQUE TECHNOLOGY WITH UNPRECEDENTED CONTROL

- Thermistors are embedded in the external electrode and in the cannula tip
- Cannula tip has plastic protector to prevent accidental skin perforation



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SAFETY FEATURES



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SAFE & DELIVERS TARGETED RESULTS

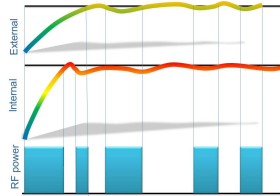
- A contained thermal field ensures a controlled and safe treatment through A.C.E. (Acquire, Control, Extend) technology.
 - ACQUIRE: operators can acquire critical thermal temperatures that are best suited for contraction.
 - CONTROL: the operator programmable internal and external limit allows the treatment to be cut-off when the temperature is achieved.
 - EXTEND: maximize results by exposing the skin and adipose tissue to clinically therapeutic temperatures for long periods without overheating.



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MAIN FEATURES

- Controls External skin temperature
- Controls Internal tissue temperature
- Real time control of RF power according to tissue impedance and temp
- Interface limits treatment time from 15sec to 120sec for safety
- Actual treatment time should not exceed 60sec for safety
- Audible feedback of proper RF delivery
- Temperature Surge Protection - automatically adjusts RF power according to dynamics of measured temperature



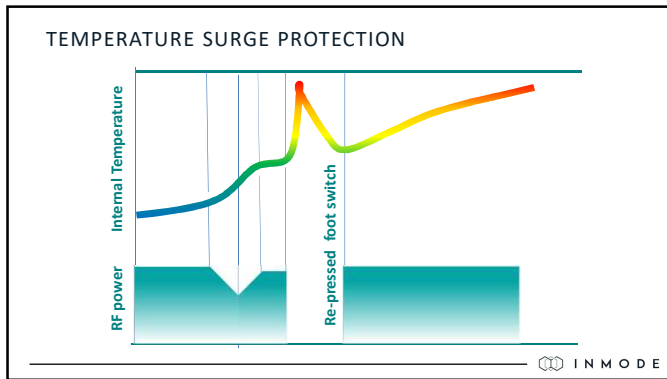
11

TEMPERATURE SURGE PROTECTION – TSP SAFETY FEATURE

- If measured temperature increased speed is 20-35°C/sec then:
 - It indicates that cannula is close to the surface or there is not enough tumescent
 - RF Power is reduced to maintain temperature increase speed below 20°C/sec
- If measured temperature increased speed is above 35°C/sec then:
 - It indicates that cannula touches skin or dry environment around
 - The same spot may be treated too much causing a surge of more than 35°C/sec
 - RF is automatically stopped and footswitch should be re-pressed to continue. Message: "TEMPERATURE SURGE" appears on the screen



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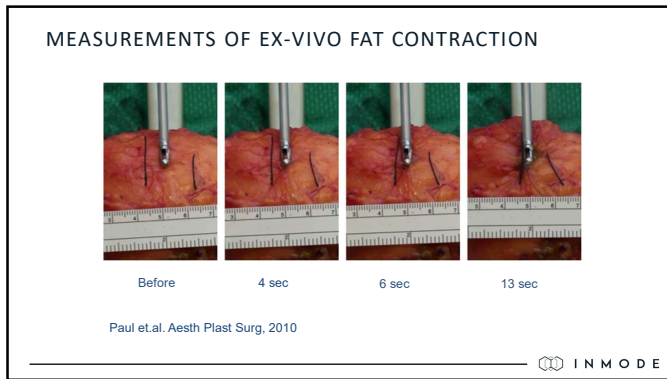
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CLINICAL EFFECTS

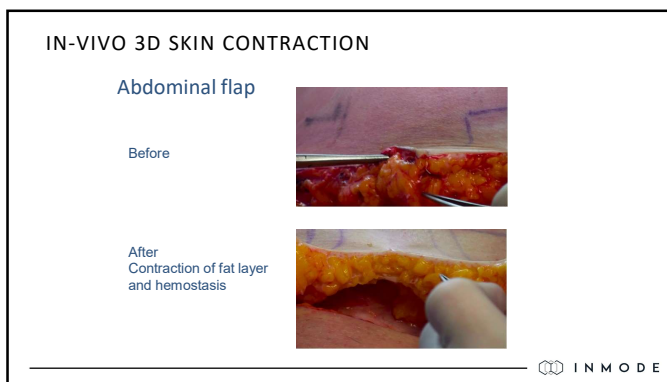
- Fat coagulation - Liquefaction
 - Fibrous tissue coagulation – Skin contraction
 - Blood coagulation – Hemostasis
 - Decreased extraction forces for easy aspiration if needed
 - Less trauma: edema, swelling, pain for short downtime

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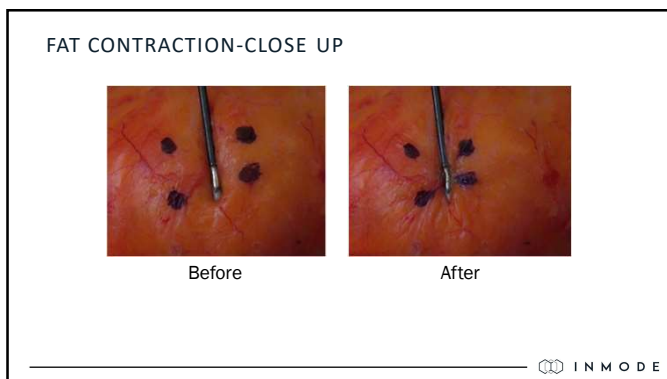
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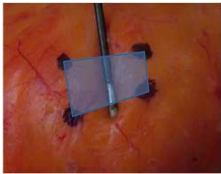
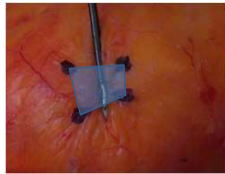


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FAT CONTRACTION-ANALYSIS

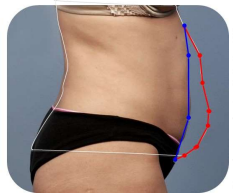
Before: 0.901cm²After: 0.513cm²

42% Area Contraction

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ANALYSIS OF TIGHTENING RESULTS



10% vertical contraction

Photo Courtesy: Stephen Mulholland MD

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EX-VIVO CONTRACTION RESULTS (PAUL ET.AL.)

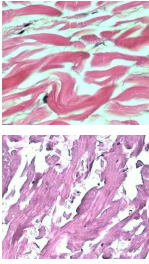
Average values	Dermis	Adipose Septal Tissue	Fascia
Linear contraction mm	2 - 10%	6.5 - 33%	2.75 - 14%
Linear contraction %	10%	33%	14%

Most contraction is in the adipose septae

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HISTOLOGY OF COLLAGEN CONTRACTION (PAUL ET.AL.)



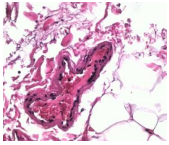
Normal Untreated Collagen

RFAL Treated Collagen
Shows Irreversible Changes

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CLINICAL EFFECTS – HEMOSTASIS



Histology of coagulated vessel



- 20-30% hematocrit
- Liquefied fat aspirate

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TREATMENT PARAMETERS

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PARAMETERS

- External Cut-Off temperature -
 - 35-37°C (Face)
 - 35-37°C (Neck)
 - 36-38°C (Body)
- Internal Cut-Off temperature -
 - 50-55°C (Face)
 - 55-60°C for 5-10mm depth (Neck)
 - 60-65°C for deeper layers (10-50mm Body)
- Treatment time -
 - 15-60sec per linear pass for safety and efficacy

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TREATMENT PARAMETERS

- External Temperature:
 - For safety, set cut-off at 35-38°C
 - Increase of skin temperature above 35°C indicates that all tissue between electrodes is warmed
- Internal temperature
 - Set to 60°C for FSN collagen contraction in superficial layer and can be higher (up to 60°C) for depth >5mm and still higher for depth >10mm (up to 65°C)
- Treatment time
 - Safety feature requiring footswitch reactivation after time is elapsed. Use shorter time until operator is experienced with hand piece manipulation

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COMMON NECK PARAMETERS



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ENERGY PER ZONE (KJ)

- Lower Face: 1.0-1.5kJ per zone (5cm x 5cm)
- Neck: 1.0-2.0kJ per zone (6cm x 6cm)
 - Lower Face/Neck: Typical total energy 9-10kJ, up to 12kJ for thicker fat
- Abdomen: 10-15kJ hand-sized zones (10cm x 15cm)
- Arms: 2.5-5kJ per zone (5cm x 10cm)
-
- *Energies listed are approximate and should be adjusted according to thickness of treated layer

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AMOUNT OF ENERGY [kJ]

- Overtreatment can be dangerous.
 - Prolongs down time exponentially
 - Increases risk of side effects: seromas, fat necrosis, poor healing access ports
 - Provides less aesthetic outcome
 - Overtreatment causes more thermal and mechanical damage of collagen that results in internal scarring and lack of uniformity more than tightening
- Typical treatment is 9-10kJ for lower face and neck.
 - Energy can go up to 12kJ for thick face and neck

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TREATMENT PROCEDURE

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TREATMENT

- Make incision using 11 blade or 14, 16 or 18 gauge needle.
- Apply thin layer of sterile gel to the surface of the treatment zone prior to initiation of RF energy. Maintain thin layer of gel in treatment areas.
- Pre-Tunneling: Insert liposuction or tumescent cannula and create passes in subdermal space without application of energy controlling cannula direction and depth. Do not use small handpiece for pre-tunneling so as not to damage cannula tip.

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TECHNIQUE

- Always start from deeper layer and then move more superficially
- Distance between adjacent layers should be about 10mm
- A few passes can be applied in the zone passing in a fanning pattern, not re-passing repeatedly over same areas
- End point for external temperature is increase 35+°C
- Energy delivery MUST be stopped 1-3cm from access point on face or neck and at least 5cm for body areas. Heating too close to access port may cause prolonged healing or even hypertrophic scarring.
- Treating or sliding out of access point may cause burn of port area

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FACETITE ANIMATION



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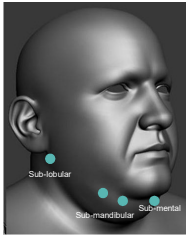
MOVING, HEATING ON WITHDRAWAL FACETITE 10CM APPLICATOR

- The Moving or Heating on Withdrawal (Retrograde) technique is used to contract the collagen uniformly in the sub-dermal space
- If thickness of the fat allows, keep cannula in the depth of 5mm or deeper.
- Insert cannula to the distal position ensuring the tip of the cannula is not too superficial
- Apply RF energy and withdraw hand-piece slowly to hear and achieve periodical internal cut-off. Speed of withdrawal is about 1cm/sec
- If thickness of the fat allows, treat tissue in several depth planes (5mm, 10mm, 15mm ...)



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FACETITE TREATMENT PLANNING – INCISION PORTS

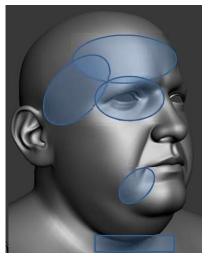


- **Sub-lobular** ear incision access may be used to create improved mandibular angle definition. Use caution to avoid treating near the marginal mandibular nerve branch.
 - Sub-lobular position should be used with care
 - Do not try to extend the tip all the way into the jaw from the sub-lobular incision
- Option to use **sub-mandibular** area to treat jowl area
 - Incision proximity to mandibular nerve is safe
 - Cannula position is more controlled
 - No thermal exposure at the port
 - Mandibular exact incision position may vary depending on anatomy of nerve
- **Sub-mental** incision may be used with caution.



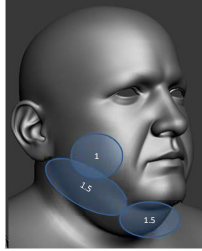
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NEVER TREAT



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TYPICAL ENERGY DEPOSITION - KJ

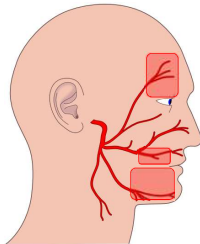


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CONSIDER FACIAL NERVES

- The main nerve trunk emerges anterior to the mid-earlobe and is 20.1 +/- 3.1 mm deep.
- Nerve exits from the parotid edge also deep, averaging 9.1 +/- 2.8 mm for temporal, 9.2 +/- 2.2 mm for zygomatic, 9.6 +/- 2.0 mm for buccal, and 10.6 +/- 2.7 mm for mandibular branches
- Danger areas are where nerve branches become superficial - distal temporal, lower buccal, and upper mandibular branches over the masseter muscle and marginal mandibular as it crosses the facial artery



Rudolph R1. Plast Reconstr Surg. Depth of the facial nerve in face lift dissections.
1990 Apr;85(4):537-44.

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AREAS OF POTENTIAL RISK

- Marginal Mandibular Nerve - Do not heat extensively over risky areas and move cannula faster
- In cases of neuropraxia in the marginal mandibular region, neuromodulators can be used on contralateral side to achieve symmetry during healing period
- Treat areas surrounding high risk sites rather than immediately over areas of nerve branches
- Use caution to avoid platysmal bands when working on submentum

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ENDPOINTS

- Achieving internal and external cut-off temperatures.
- Ease of handpiece movement due to fat coagulation.
- Visible contraction, flattening of the area and asymmetry on treated side indicates tightening.

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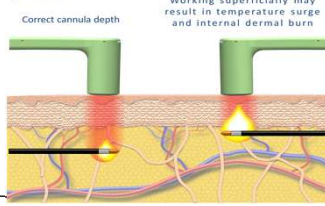
POTENTIAL RISKS

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POTENTIAL COMPLICATIONS

- Superficial cannula placement, close to the skin surface (<5mm), the RF power is applied to smaller volume. Heating is at a rapid rate and temperature sensor is not fast enough to react causing overheating
- Overheating can also occur when movement of cannula is too fast due to temp sensor delay
- 70°C sub-dermally may result in dermal burn causing bumps, nodules and even epidermolysis – Limit internal temp to 60°C



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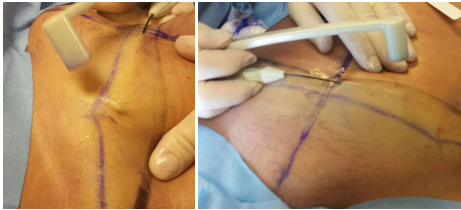
IMPORTANT TIPS

- Do not treat too superficially (<5mm) – may cause red or white nodules, dermal burns in the skin
- Do not tent the internal cannula tip superficially in the skin – may cause an end hit
- FaceTite: Do not heat RF too close to access port (1-3cm) or end in the same spot near the access port – may cause delayed or hypertrophic healing
- Once temperature cutoff is achieved and treatment zone completed, aspirate heated fluid from that area before moving to next treatment zone – avoids risk of seroma, fat necrosis, delayed or uneven healing



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DO NOT TOUCH DERMIS WITH CANNULA TIP WHILE HEATING



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TEMPERATURE RESPONSE VS. CANNULA DEPTH

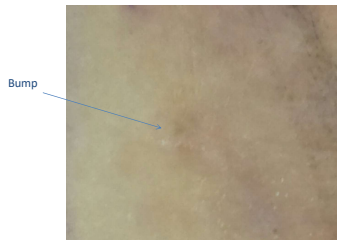
Cannula Depth	Cut-off Temp, °C	Time to Cut-off, Sec	Overheating, °C
20mm	65	3.0	70
10mm	65	2.5	70
5mm	65	2.0	70
1mm (under dermis)	65	<1.0	70

- At superficial depth, temperature may surge too fast and sensor may not react fast enough
- Reaching 50-70 °C at the depth less than 3mm may result in burn due to heat conductivity



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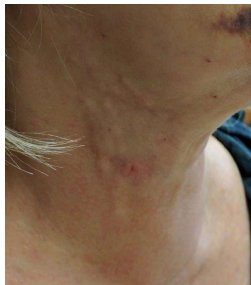
SUPERFICIAL TREATMENT MAY CAUSE NON-UNIFORMITY,
BUMPS, BURNS



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SUPERFICIAL TREATMENT MAY CAUSE NON-UNIFORMITY,
BUMPS, BURNS



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WORKING SUPERFICIALLY ON HAIRD AREA MAY CAUSE
HAIR LOSS



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PRE-TREATMENT



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RF CONTRAINDICATIONS

- DO NOT USE in patients who have electronic implants such as cardiac pacemakers or internal defibrillators without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance, unless deep enough in the periosteal plane.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.



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RF CONTRAINDICATIONS

- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- History of skin disorders, keloids, abnormal wound healing.
- History of bleeding coagulopathies.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Any therapies or medications which may interfere with treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.



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PRIOR TO TREATMENT

- Mark treatment zones in sitting or standing position.
- Plan incisions/access points taking into the account accessibility of treatment zone, tissue curvature and cannula length.
 - Mark a border around planned access port at least 1-5cm around the port, avoiding treatment too close to the incision
- Prep the treatment area in a sterile fashion
- Apply tumescent anesthesia to subcutaneous adipose layer

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ANESTHESIA

- Tumescent anesthesia is mandatory
 - Increases thickness of treated zone
 - Increases turgor of tissue
 - Increases fat electrical conductivity
- Blocking can be used prior to tumescent infiltration
- IV sedation can be used in addition to or as an alternative to oral medications for multiple/large zone treatment or for sensitive patients

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TUMESCENT TECHNIQUE

- ASPS recommended maximum calculated Lidocaine dosage, 35 mg/kg adult body weight
- Single or Double strength Klein solution
- Use a standard infiltrating tumescent cannula or spinal needle
- Infiltrate the subcutaneous and sub-dermal compartments
- End points should be wet or super-wet but "peau d'orange" of the dermis is not required on face and neck, but needed on body areas
- After tumescent infiltration the skin should blanch and be soft to slightly firm to touch
- Allow approximately 15-20 minutes for tumescent for local and epinephrine effect to take full effect
- Tissue massaging can be applied for more uniform distribution of infiltrate

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TUMESCENT SOLUTION

- Single/Double Klein Solution
 - 1000ml LR, NS, IV Solution
 - 50ml, 1-2% Lidocaine plain
 - 1ml, Epinephrine 1:1000
 - 5ml, Bicarbonate (per physician discretion)
- Used for local and for general anesthesia, with large quantity of treatment areas



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POST TREATMENT



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POST TREATMENT

- Immediate cooling prior to application of compression garment – sterile saline-soaked gauze compresses
- Antibiotics: Physician's discretion prescribed for preventative and prophylactic therapy
- Garment
 - 3-4 full days and 1-3 weeks night for neck
 - 3 full weeks and 3 half day (12 hours) weeks for body, including arms
- Anti HSV prophylaxis is given to minimize the risk of HSV, if RFAL is performed around the lips
- Generally, over the counter medications are the only pain relief medication required.



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FACETITE NECK TREATMENT RESULTS



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FACETITE NECK TREATMENT RESULTS

- Research has shown 35% soft tissue contraction over 12 months
- Modest skin tightening can be expected
- Less than a surgical Neck Lift, but the best non excisional option available
- Price is generally ½ the cost of a surgical option
- Longevity = 3-5 years
- Can re-do same FaceTite Neck procedure at 12 months or longer



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NECK – 5 WEEKS POST *FACEtite*




Courtesy: D. Duncan, MD, USA




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BEFORE AND AFTER



FaceTite: Dr. P. Rovatti
Photo Courtesy: P. Rovatti MD



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BEFORE AND AFTER





Photo Courtesy: P. Rovatti MD



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NECK - 5 WEEKS POST **FACEtite**




Jason Champagne, M.D.




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FACETITE: BEFORE AND AFTER




FaceTite without Liposuction

Photo Courtesy: J. Bloom, MD




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FACETITE: BEFORE AND AFTER




FaceTite without Liposuction

Photo Courtesy: J. Bloom, MD



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FACETITE: BEFORE AND AFTER



49 Year Old Female
1 Month After

Photo Courtesy: J. Bloom, MD



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FACETITE: BEFORE AND AFTER




Photo Courtesy: D. Hwang, MD



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FACETITE: BEFORE AND AFTER






Photo Courtesy: J. Altman, MD




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FACETITE: BEFORE AND AFTER

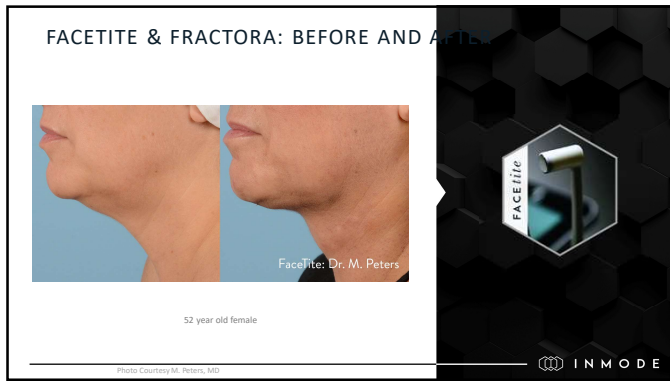


Facelift: Dr. K. Tansavatdi

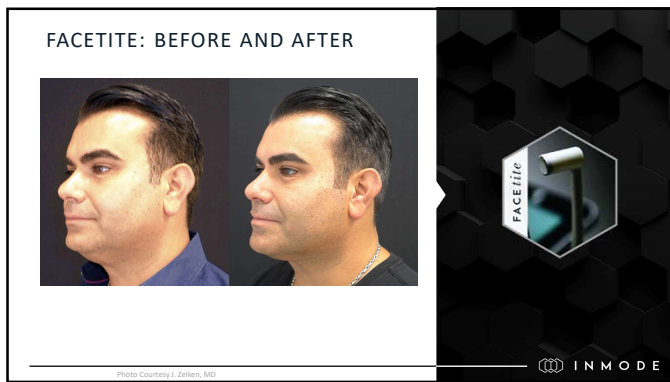
Photo Courtesy: K. Tansavatdi, MD



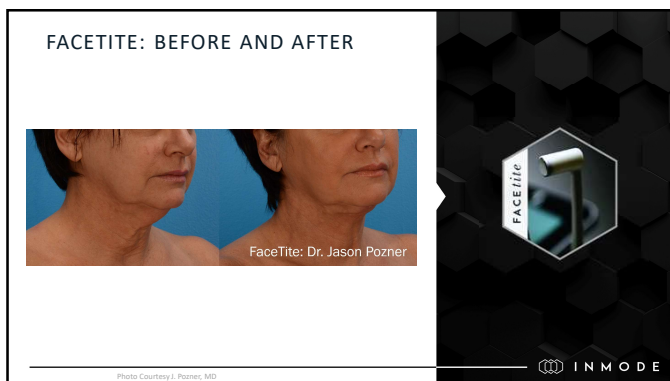
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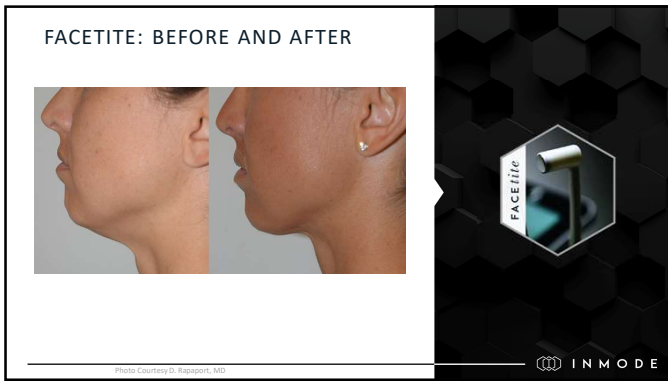
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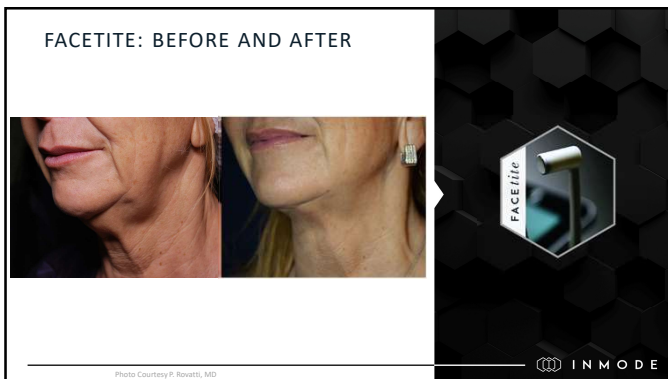
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FACETITE: BEFORE AND AFTER






Photo Courtesy P. Rovatti, MD



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FACETITE: BEFORE AND AFTER




FaceTite: Dr. P. Rovatti

Photo Courtesy P. Rovatti, MD




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FACETITE: BEFORE AND AFTER



FaceTite: Dr. P. Rovatti

Photo Courtesy P. Rovatti, MD



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FACETITE: BEFORE AND AFTER





Photo Courtesy: P. Rowlett, MD



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FACETITE: BEFORE AND AFTER





Photo Courtesy: P. Rowlett, MD



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FACETITE: BEFORE AND AFTER



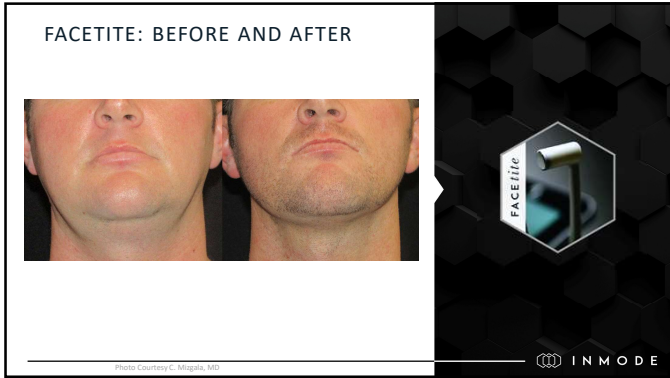


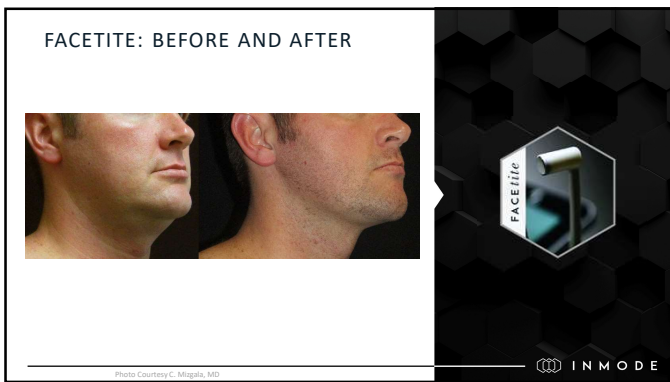
Photo Courtesy: P. Rowlett, MD



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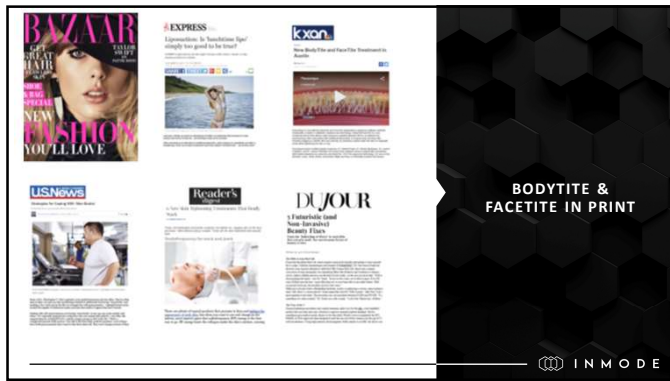
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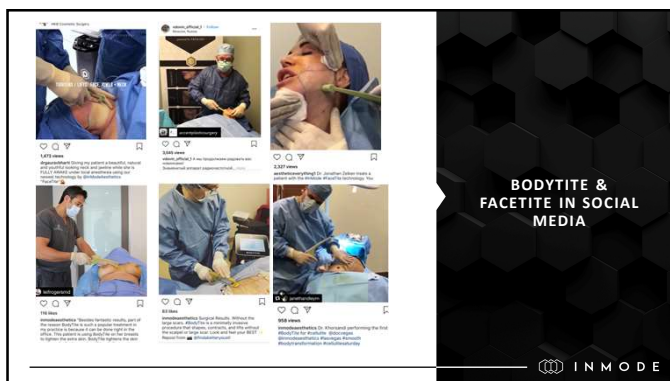
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ACCUTITE INDICATIONS


- FDA cleared for electrocoagulation of soft tissue and hemostasis
- Smallest RFAL Technology
 - Size of a filler cannula, one of the most common tools in aesthetic medicine
- Invisible needle size entry port
- Applications
 - Face
 - Body areas that need precise heating
- Supplements RFAL and SARD (subdermal adipose remodeling device - Morpheus8) technology



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RFAL FAMILY OF PRODUCTS






BODYtite


BodyTite
17 cm cannula length
2.2 mm diameter






FACEtite

FaceTite
10 cm cannula length
1.3 mm diameter



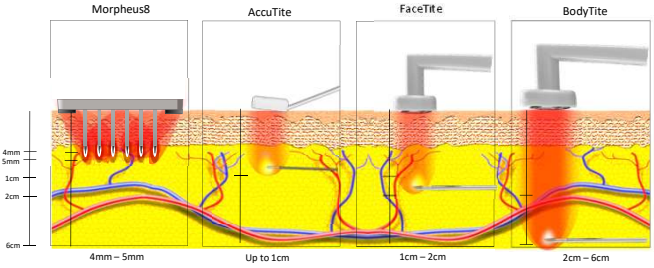


ACCUtite

AccuTite
6 cm cannula length
0.9 mm diameter

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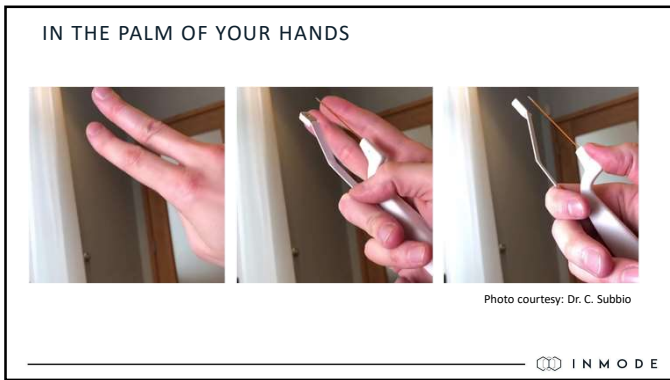
DEPTH OF RF ENERGY



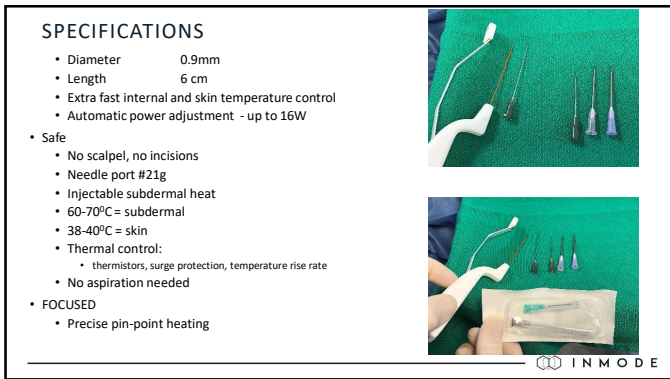
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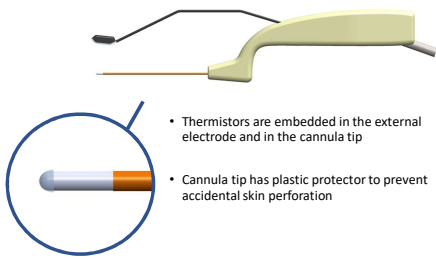
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ACCUTITE SAFETY FEATURES

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HANDPIECE SPECIFICATIONS

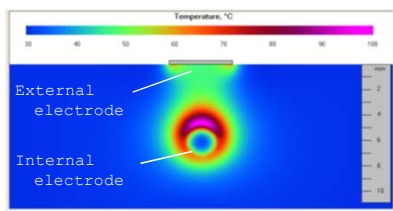


- Thermistors are embedded in the external electrode and in the cannula tip
- Cannula tip has plastic protector to prevent accidental skin perforation

INMODE

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THERMAL PROFILE COMPUTER SIMULATION

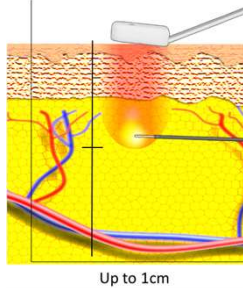


Surface = 38-42°C; Sub-dermal skin = 50-55°C; Deep fat >70°C

INMODE

99

ACCUTITE TECHNOLOGY - DIRECTIONAL THERMAL PROFILE



Up to 1cm

INMODE

100

SAFE & DELIVERS TARGETED RESULTS

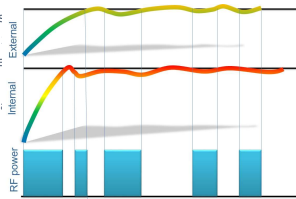
- A contained thermal field ensures a controlled and safe treatment through A.C.E. (Acquire, Control, Extend) technology.
 - **ACQUIRE:** operators can acquire critical thermal temperatures that are best suited for contraction.
 - **CONTROL:** the operator programmable internal and external limit allows the treatment to be cut-off when the temperature is achieved.
 - **EXTEND:** maximize results by exposing the skin and adipose tissue to clinically therapeutic temperatures for long periods without overheating.

INMODE

101

MAIN FEATURES

- Controls *External* skin temperature
- Controls *Internal* tissue temperature
- Real time control of RF power according to tissue
- Interface limits treatment time from 15sec to 60sec
- Actual treatment time should not exceed 60sec
- Audible feedback of proper RF delivery
- Temperature Surge Protection - automatically: measured temperature

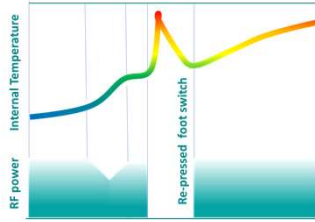


INMODE

102

TEMPERATURE SURGE PROTECTION – TSP SAFETY FEATURE

- If measured temperature increased speed is **20-35°C/sec** then:
 - It indicates that cannula is close to the surface or there is not enough tumescent
 - **RF Power is reduced to maintain temperature**
Increase speed below 20°C/sec
- If measured temperature increased speed is **above 35°C/sec** then:
 - It indicates that cannula touches skin or dry environment around
 - The same spot may be treated too much causing a surge of **more than 35°C/sec**
 - **RF is automatically stopped and footswitch should be re-pressed to continue. Message: "TEMPERATURE SURGE" appears on the screen**



INMODE

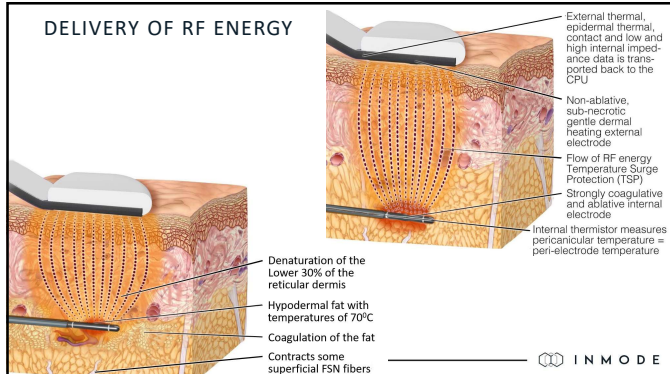
103

ACCUTITE MECHANISM OF ACTION

INMODE

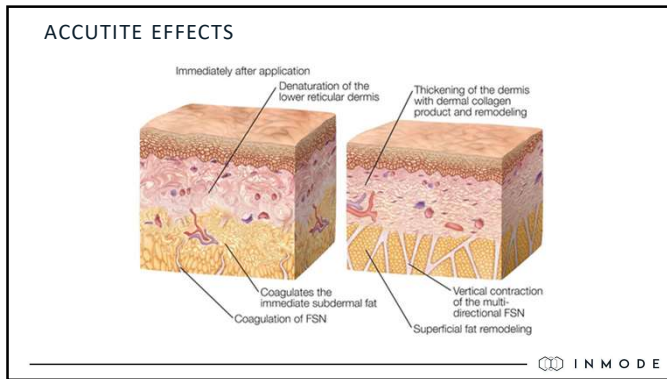
104

DELIVERY OF RF ENERGY



INMODE

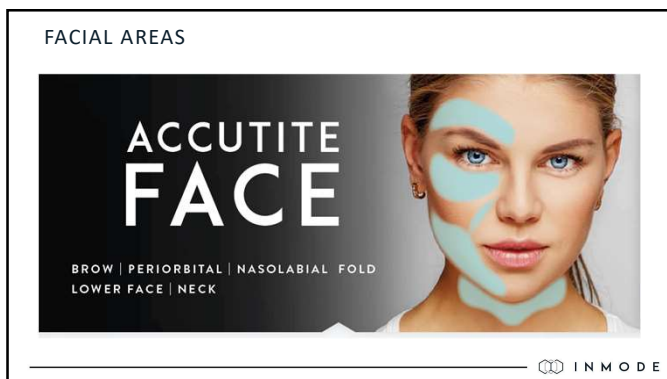
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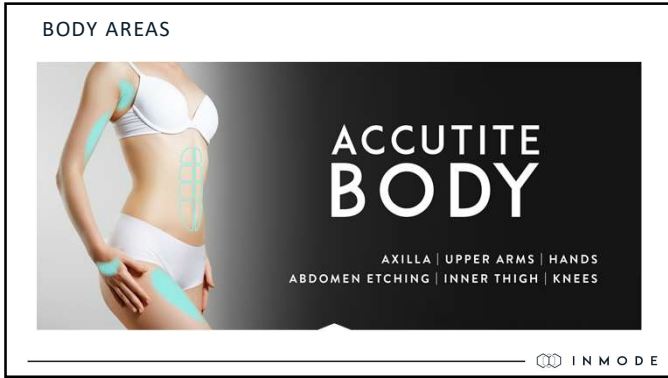
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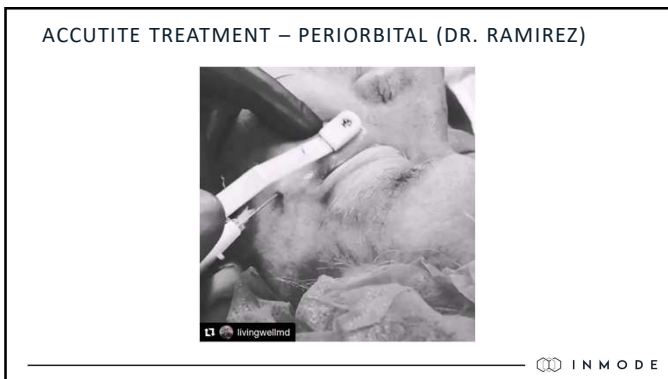
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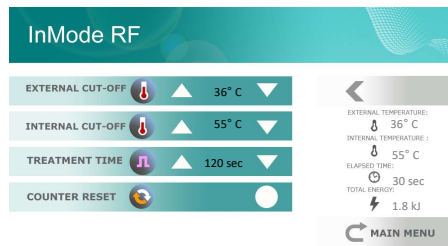


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111

COMMON PARAMETERS



INMODE

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TECHNIQUE

- Always start from deeper layer and then move more superficially
- A few passes can be applied in the zone passing in a fanning pattern, not re-passing repeatedly over same areas
- End point for external temperature is increase 35+ °C
- Energy delivery MUST be stopped 1.5-2cm from access point. Heating too close to access port may cause prolonged healing or even hypertrophic scarring.
- Treating or sliding out of access point may cause burn of port area
- Energy per zone: 1.0-1.5kJ per zone (4cm x 4cm)

*Energies listed are approximate and should be adjusted according to thickness of treated layer

INMODE

113

MOVING, HEATING ON WITHDRAWAL

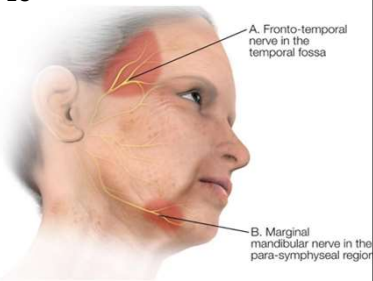
- The Moving or Heating on Withdrawal (Retrograde) technique is used to contract the collagen uniformly in the sub-dermal space
- At each depth, treat the zone in a sequential fanning motion avoiding continuous heating of the same line and avoid applying RF too close to the access port.
- Avoid treating more than 2 minutes continuously through the same access port. Alternate access ports or allow the access port to cool down for about 1-2min using sterile cold compresses.
- Aspiration of fat should be done if more than 50cc of tissue per area is coagulated.

INMODE

114

CONSIDER FACIAL NERVES

- The main nerve trunk emerges anterior to the mid-earlobe and is 20.1 +/- 3.1 mm deep.
- Nerve exits from the parotid edge also deep, averaging 9.1 +/- 2.8 mm for temporal, 9.2 +/- 2.2 mm for zygomatic, 9.6 +/- 2.0 mm for buccal, and 10.6 +/- 2.7 mm for mandibular branches
- Danger areas are where nerve branches become superficial - distal temporal, lower buccal, and upper mandibular branches over the masseter muscle and marginal mandibular as it crosses the facial artery



Rudolph R1. Plast Reconstr Surg. Depth of the facial nerve in face lift dissections. 1990 Apr;85(4):537-44.

INMODE

115

AREAS OF POTENTIAL RISK

- Marginal Mandibular Nerve - Do not heat extensively over risky areas and move cannula faster
- In cases of neuropraxia in the marginal mandibular region, neuromodulators can be used on contralateral side to achieve symmetry during healing period
- Treat areas surrounding high risk sites rather than immediately over areas of nerve branches
- Use caution to avoid platysmal bands when working on submentum

INMODE

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PRE-TREATMENT

INMODE

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RF CONTRAINDICATIONS

- DO NOT USE in patients who have electronic implants such as cardiac pacemakers or internal defibrillators without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance, unless deep enough in the periosteal plane.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.



118

RF CONTRAINDICATIONS

- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- History of skin disorders, keloids, abnormal wound healing.
- History of bleeding coagulopathies.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Any therapies or medications which may interfere with treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.



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PRIOR TO TREATMENT

- Mark treatment zones in sitting or standing position.
- Plan incisions/access points taking into the account accessibility of treatment zone, tissue curvature and cannula length.
 - Mark a border around planned access port at least 1.5cm around the port, avoiding treatment too close to the incision
- Prep the treatment area in a sterile fashion
- Apply tumescent anesthesia to subcutaneous adipose layer



120

ANESTHESIA

- Tumescence anesthesia is mandatory
 - Increases thickness of treated zone
 - Increases turgor of tissue
 - Increases fat electrical conductivity
- Blocking can be used prior to tumescence infiltration
- IV sedation can be used in addition to or as an alternative to oral medications for multiple/large zone treatment or for sensitive patients



121

POST TREATMENT



122

POST TREATMENT

- Immediate cooling prior to application of compression garment - sterile saline-soaked gauze compresses
- Antibiotics: Physician's discretion prescribed for preventative and prophylactic therapy
- Garment
 - 3-4 full days and 1-3 weeks night for neck
 - 3 full weeks and 3 half day (12 hours) weeks for body, including arms
- Anti HSV prophylaxis is given to minimize the risk of HSV, if RFAL is performed around the lips
- Generally, over the counter medications are the only pain relief medication required.



123



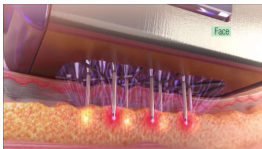
1

INDICATIONS FOR USE

Morpheus8 is programmable fractional technology delivering RF energy to the subdermal space according to treatment area

Deepest FDA approved fractional technology: **Applicator is intended for use in Dermatological and General Surgical procedures for Electrocoagulation and Homeostasis**

Health Canada approved fractional technology: **The Morpheus8 applicators is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.**

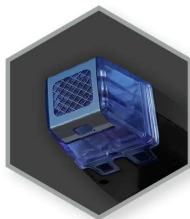


INMODE

2

NEW TECHNOLOGY FOR SUBDERMAL – MORPHEUS8

- New technology for subdermal adipose remodeling, dermal treatment and epidermal resurfacing:
 - Mold the fat subdermally in order to morph aging facial and body features into a more youthful appearance.
 - Safe treatment of ethnic skin with little to no risk of PIH
 - Perfect for face and body



INMODE

3

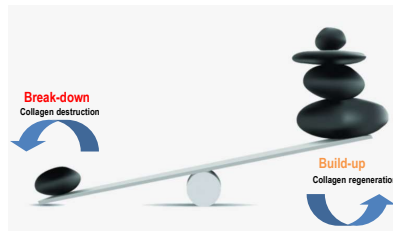
MECHANISM OF ACTION



4

AGING

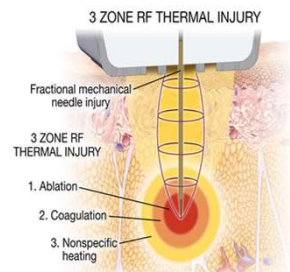
- Aging skin
- Loss of skin elasticity
- The appearance of visible lines and wrinkles
- An overall deterioration in skin texture



5

THE MECHANISM OF ACTION

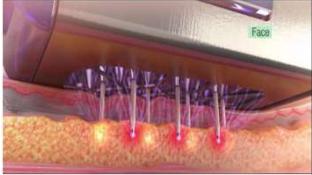
- Fractional RF takes advantage of the healing power of healthy tissue around the treated zones
- Thermal injury induces Neocollagenesis
- Improves Laxity & Wrinkles common with intrinsic aging




6

MORPHEUS8

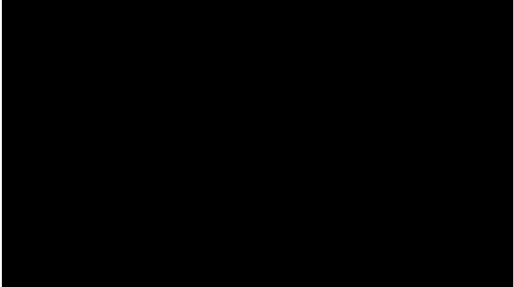
- Deep fractional technology
- Penetration into the adipose – 4mm (4000 microns)
 - Plus additional 1mm Heat Profile
- Uniform effect
- Little to no thermal damage to epidermis
- Disposable tips
- Versatile tips: 24 pin, 12 pin, Resurfacing tip
- Supplements RFAL technology






7


MORPHEUS8 ANIMATION VIDEO






8

HOW DOES IT WORK?



Footage courtesy: Dr. C. Sabbatini


9

THERMAL BIOLOGICAL EFFECTS

- What happens at specific temperatures:
 - Heating (Stimulation) 40 – 50°C
 - Coagulation (Necrosis) with Collagen Contraction 50 - 80°C
 - Collagen Denaturation >80°C
 - Ablation (Evaporation) >100°C
- Wound Healing Response
 - Increased metalloproteinase & collagenase activity
 - The enzymes initiate dermal remodeling process, helping to remove photo aged dermal tissue, thus allowing for deposition of new dermal tissue

INMODE

10

COAGULATION ZONE CALCULATION

- RF energy distribution around the needle were computerized
- Coagulation zone was calculated as volume where temperature is above 50° C in the end of the RF pulse
- Needle diameter is 250um
- Uncoated tip length is 0.5mm



INMODE

11

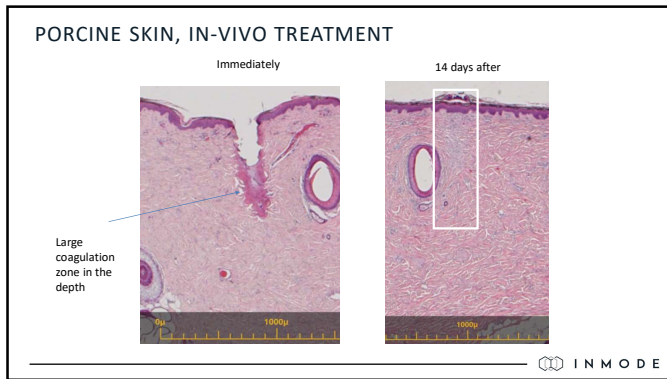
COAGULATION ZONE AROUND THE NEEDLES

Energy level – 5	Energy level – 20	Energy level – 40	Energy level – 60
Coagulation – 750um	Coagulation – 1060um	Coagulation – 1260um	Coagulation – 1400um
Area coverage – 4.7%	Area coverage – 9.5%	Area coverage – 13.4%	Area coverage – 16.4%

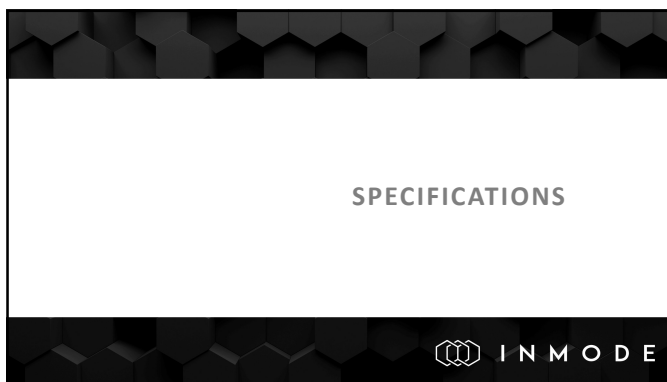


INMODE

12




13



14

SPECIFICATIONS

- Matrix of 24 or 12 thin gold-coated micro pins
- Advance lattice design creates a uniform effect
- Little to no thermal damage to epidermis
- Disposable tips
- Automatic synchronization between penetration of needles and RF energy delivery
- Multiple treatment depths with the same tip 24 or 12 pin:
 - 1mm, 2mm, 3mm, 4mm
- Superficial treatment with additional Resurfacing Tip (fixed pins length)
- Repetition - can be set to single pulse mode or autorepeat mode when pulses are delivered automatically with predetermined pulse repetition rate



INMODE

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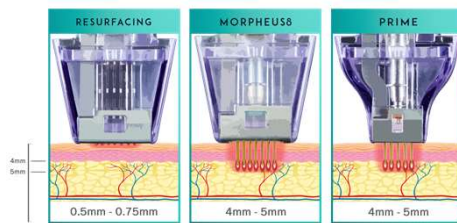
COMPARING MORPHEUS8 TIPS



Morpheus8 24 pin	Morpheus8 resurfacing	Morpheus8 prime 12 pin
Length 1mm - 4 mm	Length 0.5mm	Length 1mm - 4 mm
Additional 1mm heat profile	Additional 0.25mm heat Profile	Additional 1mm heat profile
24 micro pins	24 micro pins	12 micro pins
Computerized Treatment Depth	Fixed Length	Computerized Treatment Depth
Isolated with 0.5mm Conductive Tip	0.5mm Conductive Tip	Isolated with 0.5mm Conductive Tip
1-3 Sessions	3-6 Sessions	1-3 Sessions
Subdermal and dermal remodeling of facial areas such as cheeks, nasolabial folds, neck, and jowls and through fractional coagulation and sub-necrotic bulk heating	Epidermal resurfacing of the superficial layer of the skin	Subdermal and dermal remodeling of small hard-to-reach areas such as the preorbital area, forehead, inner arms, and delicate female region through fractional coagulation and sub-necrotic bulk heating

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COMPARING MORPHEUS8 DEPTH OF PENETRATION



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INTERFACE

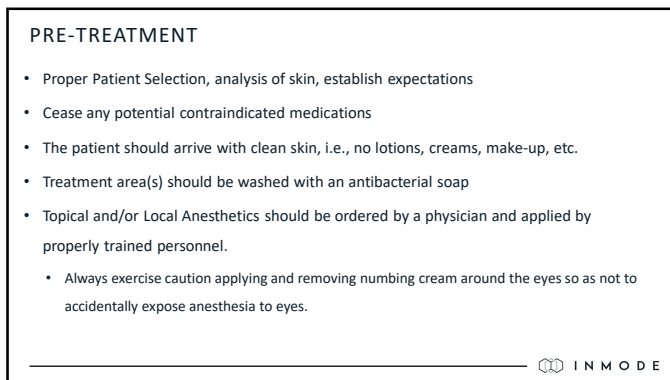
- LED BAR on the applicator indicates penetration depth
- Tip: 24, 12 or Resurfacing
- Operation Modes:
 - **Cycle** – needles penetrate the skin and retract from the skin with every pulse
 - **Fixed** – needles stay protruded and RF pulses are delivered with predetermined repetition rate



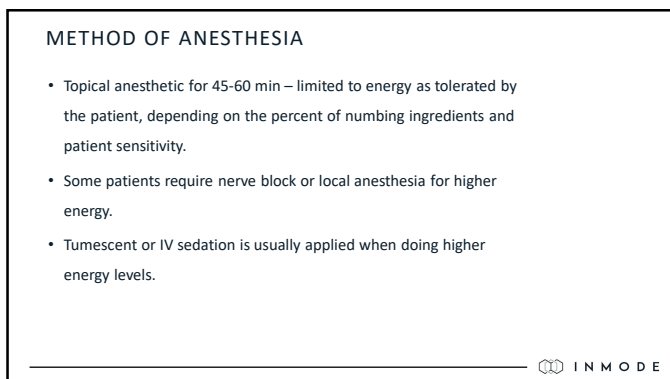
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19



20



21

PRE-TREATMENT

- Inspect the tips for any damage.
- Anti HSV viral prophylaxis is recommended for patients with history of Herpes Simplex
- Remove numbing cream from treatment area – clean and degrease skin with cleanser and 70% rubbing alcohol.
- Apply a few test spots and wait 10-15min for light skin and longer for dark skin. If the spot pattern is uneven, remove the tip and apply a new tip.



22

TIP

- Tip is GAMMA sterilized.
- Inspect all components of the Handpiece for visible damage.

The Morpheus8 tip is single use only!



23

CONTRAINDICATIONS

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body.
- Permanent implant in the treated area such as metal plates, screws and metal piercing or silicon.
- Intra-dermal or superficial sub-dermal areas injected with Botox®/HA/collagen/fat injections or other augmentation methods with bio-material, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days).
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.



24

CONTRAINDICATIONS

- History of bleeding coagulopathies or use of anticoagulants in the last 10 days
- Any treatment area surgery performed within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Treating over tattoo or permanent makeup to be kept, treating over the lips.
- Skin type VI and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.



25

SELECTING TREATMENT PARAMETERS

- Treatment may be applied to all skin types.
- The deeper the treatment the higher RF energy can be applied.
- Reduce ~20% energy when working on thin skin like neck, or on bony area like forehead or jawline.
- Further ~20% reduction on thin skin over bone, like upper chest and back of hands.
- Use **1-2 mm** and **Cycle Mode** settings ONLY on bony areas such as: Forehead, Periorbital, etc.



26

SELECTING TREATMENT PARAMETERS

- When treating dark skin restrict energy, starting at energy level 8 or lower, and avoid treating or treat with over caution over bone and curved areas, preferably following bleaching regimen.
- Safety - Use lower energy for thin skin, darker skin and bony areas. Start with lower settings for patient's first treatment.
- Types of lesions - Higher energy for deeper lesions such as acne scars and deep wrinkles.
- Higher settings may be used if the user is experienced and is determined and ordered by the physician.



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MORPHEUS8 TREATMENT – LOWER FACE & NECK



Treatment by Dr. B. DiBenedetto

INMODE

28

GOOD COUPLING IMPORTANCE

Partial contact of external frame due to partial needles penetration caused by:

- very soft tissue,
- not enough pressure,
- bone or muscle at the depth 5mm or less
- Treated area bounces/moves without firm support (typical for arm or side of the face and even curved areas of the forehead)



INMODE

29

GOOD COUPLING IMPORTANCE

- Apply the hand piece perpendicular to the treated area
- Apply firm pressure.
- Stretch skin on very soft tissue or pinch on bony areas
- Ensure that the patient is steady and still during the procedure. Use towels or pillows if needed.
- Bony areas use with extra caution: reduce the energy levels, use 1-2 mm depth. Exclude zones with extremely thin skin and high curvature such as upper part of the forehead or temple.



30

TREATMENT CONDITIONS

Surgical Conditions

- Tumescence infiltration makes tissue thicker
- Tumescence increases skin turgor in sub-dermal
- Less sensitivity to temporal marks
- Higher settings can be used

Clinic Conditions

- Topical anesthesia, cooling or nothing
- High sensitivity to marks
- Use lower settings



31

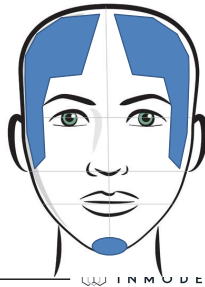
FOR SAFER TREATMENT AND BETTER RESULTS

Clinic Treatment

- Reduce treatment energy to 8-15
- Apply 2-3 passes with 50% overlap
- Exclude or treat with extra caution over bony/curved area
- Blue area – Do not treat or treat with extra Caution

Surgical Treatment with Tumescence Anesthesia

- Treatment energy can be higher
- Apply 1-2 passes with 50% overlap
- Exclude or treat with extra caution over bony/curved area
- Blue area – Do not treat or treat with extra Caution



32

TREATMENT TECHNIQUE



33

TREATMENT PROCEDURE

- Apply the handpiece perpendicular to the treated area, with complete contact and firm pressure.
- Press footswitch to deliver RF energy – one press for each pulse for sensitive and small areas like eyelids, or continuous press for the Fixed Mode.
- When performing treatment, move the handpiece to the adjacent area with overlap of approximately 50%.
- 1-2 additional pulses may be triggered at the same site (Stacking) in Fixed Mode. However, **DO NOT stack pulses on bony areas** such as Forehead, Periorbital, etc.



INMODE

34

TREATMENT PROCEDURE

- If gaps are visible after the full area treatment, they may be re-treated immediately.
- Occasionally, an additional 1-2 passes are necessary to optimize results. Wait until the full area is treated before attempting a second pass, allowing for a delayed response. An additional pass may be applied in a different direction to the first pass, to ensure complete area coverage.
- The endpoints are minimal to substantial erythema and edema often accompanied by tingling heat sensation. Minor pin-point bleeding can be observed.
- Use firm pressure to ensure good contact and coupling of the tip.
- Do not slide tip over the treatment area to avoid skin scratching. Make sure to lift and place the tip for complete placement and apply pressure before pulsing.

INMODE

35

TREATMENT PROCEDURE

- Cooling the treated skin is recommended after the treatment to relieve discomfort.
- During treatment, air cooling can be used to increase comfort. If other means of cooling are used, use clean technique and make sure skin remains completely dry to prevent arcing and to facilitate maximum coupling.

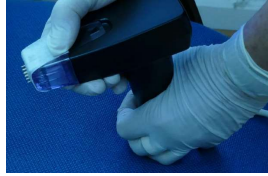


INMODE

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CLEANING TIPS

- Clean the tips every ~200 penetrations into the skin (stacked pulses are not counted)
- Adjust treatment parameters to maximal Depth in Fixed Mode. Any Energy and Repetition rate may be used.
- Hold the Morpheus8 Applicator with one hand and with the other hand firmly stretch a 70% alcohol-soaked pad (ethanol or isopropyl alcohol) over the tip.
- Press the footswitch and allow the pins to fully penetrate through the pad several times.



INMODE

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POST-TREATMENT

- Cooling the skin can reduce discomfort and excessive skin response.
- Apply healing ointment or antibiotic ointment, immediately post treatment for 1-3 days.
- As soon as the needle holes close (1-3 days), apply moisturizer, sun-screen, and make-up.

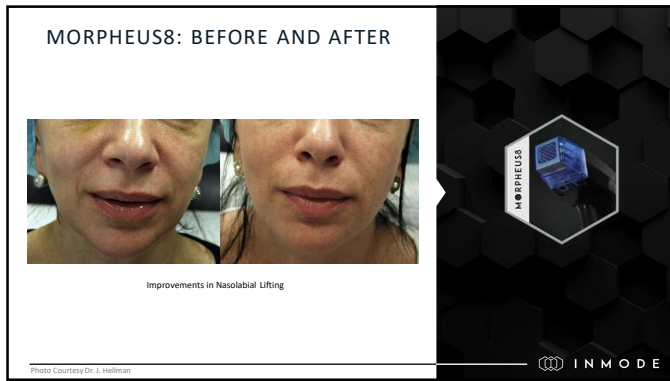
INMODE

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BEFORE AND AFTER

INMODE

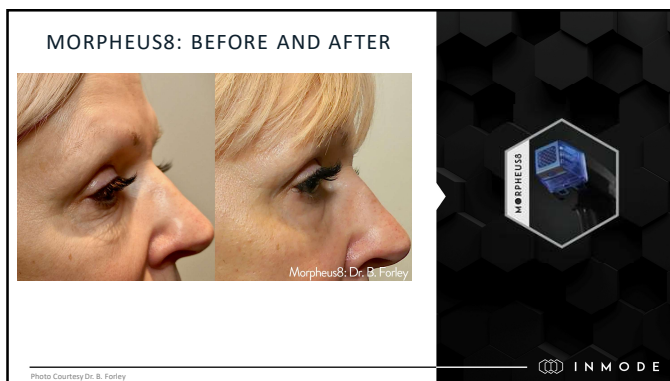
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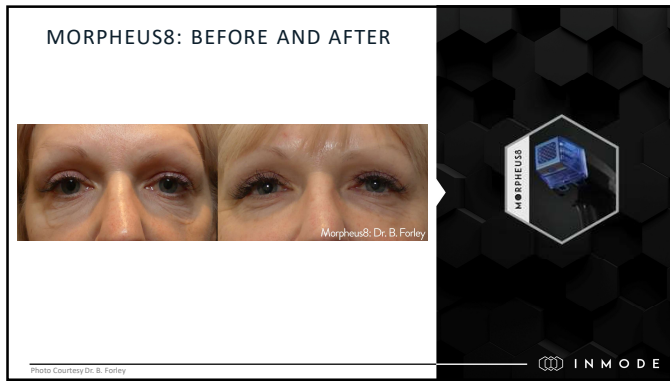
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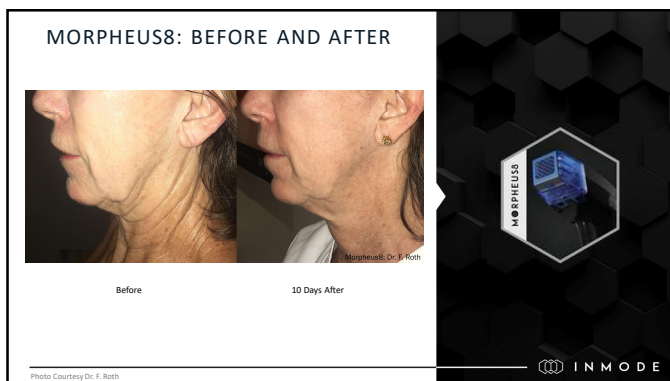
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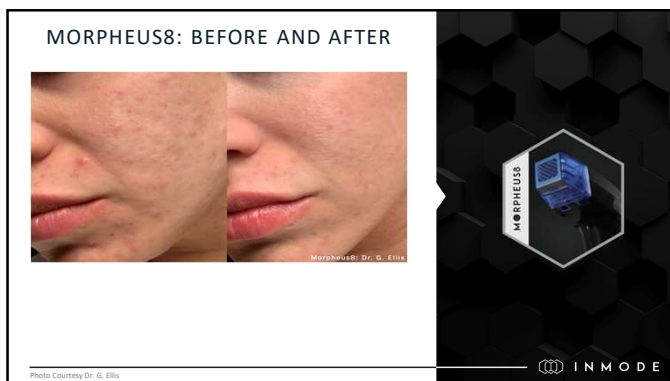
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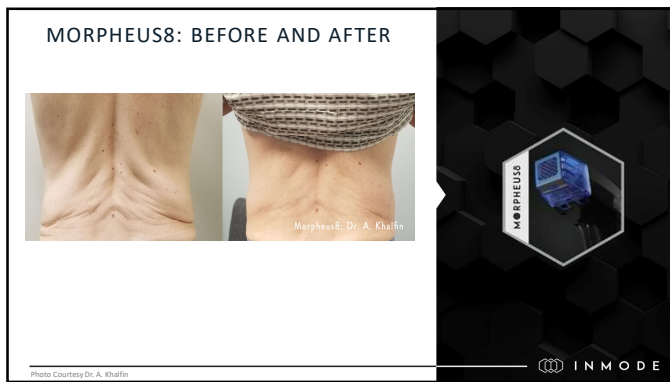
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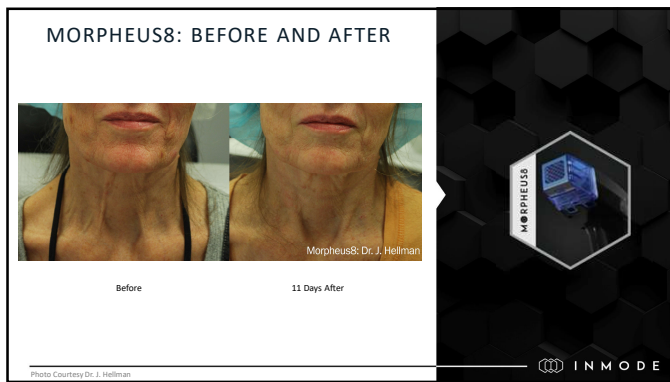
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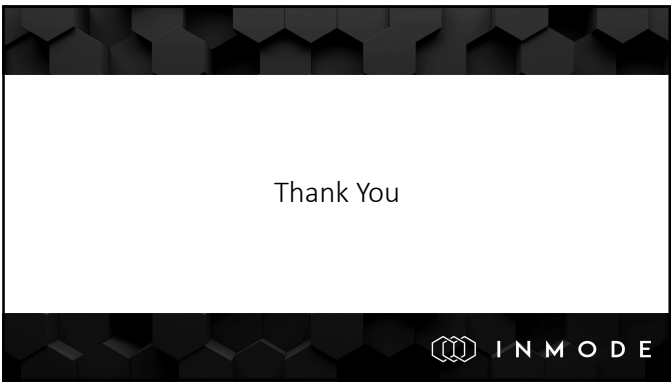
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