VelaShape III Mastering Body Treatments

Clinical Education









Overview

- Physiology of Cellulite and Adipocyte Metabolism
- The Vela Technology
- VelaShape III
- Clinical Treatment Information





Page 3-77

Physiology of Cellulite and Adipocyte Metabolism







Subcutaneous Tissue Where Does Vela Technology Work?

- Dermis and Hypodermis
 - Collagen
- Superficial layer
 - Organized, compact compartments
 - Fibrous septae
- Deep layer
 - Areolar fat/loose
 - Partitions are haphazard



Improving Cellulite and Reducing Circumference By Improving Adipocyte Metabolism and Tissue Quality



Page 5-77

Process of Cellulite Formation

- Fat cells enlarged creating increased volume in compartments with limited space
- Fibrous septae are firm and skin dimples from the tension
- Blood vessels and lymphatics are compressed
- Accumulation of intercellular fluids and physiological waste







Page 6-77









Page7-77

DHF13441 Rev 00

Classification of Cellulite

Class 1:

- No spontaneous dimpling
- Pinch test positive for dimpling

Class 2:

 Spontaneous dimpling while standing

Class 3:

 Spontaneous dimpling while standing and lying (morbid obesity or menopausal)







Cellulite Treatment

Factors Inducing Cellulite:

- Poor circulation
- Hormonal Influences
- Heredity
- Smoking
- Diet
- Lack of exercise



Solutions for Treatment:

- Improve circulation
- Improve lymphatic drainage
- Improve adipocyte metabolism via improved blood circulation and oxygenation
- Improve dermal structure

Page 8-77



The Vela Technology







History of the Vela Technology

- Syneron was the first company to pioneer the use of radio frequency technologies for body shaping with our VelaShape technology
- VelaShape was **the first** to receive the FDA clearance for non-invasive circumferential reduction
- Many other companies have tried to copy VelaShape technology for non-invasive body shaping (Venus, Alma, Viora, Invasix etc.)

VelaShape Facts:

- Over 8,000 units sold
- 10,000 procedures performed every day
- Over 40 published clinical studies
- 5 million patients treated worldwide

Syneron's vast experience and research in producing effective body contouring devices has contributed to the outstanding success of the VelaShape III.





What Did We Learn from Our Experience with VelaShape Technology?

- Improvements in cellulite and circumference reduction requires heating of connective tissue for the growth of new and healthier collagen and elastin
- Thermal connective tissue injury is based on reaching a "thermal dose" threshold. This is a combination of elevated temperature and exposure time
- Reaching temp end point and maintaining it over time, is a key element in achieving consistent clinical results!
- There is a large variety of tissue impedance between patients

For a better and faster thermal dose effect there's a need for a **more powerful system**, which also measures skin impedance and provides real time feedback on the tissue temperature!





What Did We Learn from Our Experience with VelaShape Technology?

- Adequate heat delivery to the tissue determines treatment success
- Controlled thermal injury is the mechanism of action for collagen
 formation
- Controlled thermal injury is the mechanism of action for metabolic changes to the adipocyte

Temperature + Time => Results





Evolution of Vela Over 8 Years

	VelaSmooth		VelaShape		VelaShape II		VelaShape III	
Launch Year	2005		2007		2009		2013	
FDA Clearance	cellulite reduction*		cellulite reduction*, circumference reduction of thighs		cellulite reduction* circumference reduction of thighs		cellulite reduction*, circumference reduction of abdomen	
	Large App	Small App	Vsmooth	Vcontour	Vsmooth II	Vcontour II	Vsmooth III	Vcontour IN
RF Power	Up to 20W	Up to 20W	Up to 50W	Up to 20W	Up to 60W	Up to 23W	Up to 150W	Up to 150W
IR Power (Optical)	Up to 20W	Up to 20W	Up to 35W	Up to 20W	Up to 35W	Up to 20W	LED Power Up to 3.3W	LED Power Up to 1.7W
Light Spectrum	700-2000nm	700-2000nm	700-2000nm	700-2000nm	700-2000nm	700-2000nm	850nm	850nm
Vacuum	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Tx area	40mmx40mm	25mmx25mm	40mmx40mm	30mmx30mm	25mmx47m m	30mmx30mm	25mmx50mm (with rollers)	10mmx13mm 25mmx30mm 25mmx50
Weight	60lbs		60lbs		83lbs		44lbs	
Dims (WxDxH)	14.2 x 21.6 x 31.5 inches		14.2 x 21.6 x 31.5 inches		14.2 x 21.6 x 31.5 inches		15x19x52 inches	
# of Treatments	12-16 spaced 2 wks apart		4-6 spaced 2 wks apart		4-6 spaced 2 wks apart		1-3 spaced 2 wks apart	

- Goal temperature of 45 degrees Celsius is achieved faster
- End point temperature is maintained longer
- Built in temperature sensor allows the operator to monitor and control the end point temperature
- Closed loop RF for consistent energy delivery

eron

• Higher energy density allows for better heating of the tissue below the skin



Indications

FDA

- Temporary reduction in the appearance of cellulite
- Temporary reduction of abdomen and thighs circumferences
- Temporary improvement in the local blood circulation
- Relief of minor muscle aches and spasms

CE

- non-invasive treatment for body contouring via temporary cellulite and circumference reduction
- Additional treatment programs:
 - Post-liposuction treatment via circumferential reduction
 - Post-partum treatment via circumferential reduction







Powered by **elos** technology, VelaShape III combines a synergistic use of different energies:

- Bi-Polar RF (radio-frequency) for deep and sustained heating
- IR (infrared) for superficial heating in cellulite treatment
- Mechanical tissue manipulation with pulsed vacuum for improved depth of RF penetration and improved circulation of blood and lymphatics





Mechanism of Action



The combination of the IR and vacuum coupled RF technologies causes deep heating of the fat cells (adipocytes), their surrounding connective septae and the underlying dermal collagen fibers.

Efficient heating of the adipocytes is achieved by the **higher output of RF**, the optimal design of the electrodes and the concurrent application of vacuum which allows **for deeper heat penetration**.

This promotes an increase in circulation, lymphatic drainage, cellular metabolism and collagen depositing. Furthermore, it stimulates fibroblast activity and remodels the extracellular matrix.

RESULT: A localized reduction in skin laxity, volume and an overall improvement in skin structure and texture.







Mechanism of Action

Bipolar RF Energy

Thermal effects:

- Increased metabolic reactions in the adipocytes
- Fibroblast stimulation
- Collagen shrinkage
- Collagen synthesis
- Deep heat in the blood vessels -> oxygen dissociation





Mechanism of Action Improved Adipocyte Metabolism

Improved adipocyte metabolism via deep heating with RF allows adipocytes to act in a metabolically more active fashion resulting in decreased size













Mechanism of Action

Thermal Effect on Metabolism

- Deep heat is produced by IR/RF in dermal blood vessels
 - \rightarrow Oxygen dissociation from Oxy-Hb $\uparrow\uparrow$
 - \rightarrow Extravasation of nutrients and oxygen $\uparrow\uparrow$
- Fat metabolic reactions in adipocytes ↑↑
 - Extended use of stored energy within the adipocyte results in shrinkage of the cells themselves
 - Fat chambers shrink and there is less tension on the fibrous septae

 - Collagen shrinkage for overall skin surface improvement



papism of Action

Mechanism of Action Vacuum

- Fibroblast proliferation via stimulation of stretch receptors
- Targeted penetration of the RF
- Negative pressure -> vascular dilatation
- Improved circulation







Vela Shape III Features





MORE POWER-FEWER TREATMENTS

Increased RF energy 150W

- Achieve end point temp faster
- Reduced number of treatments sessions for optimal results







SMART RF TM



Industry's first Smart RF-

a closed loop RF that measures each patient's impedance to ensure consistent energy delivery, reducing the number of non responders



INTELLIGENT FEEDBACK

Built In Temperature Sensor

- Better monitoring of tissue in real time
- Enables a more precise treatment
- Increased patient comfort







NEW DESIGN

- Sleek, sophisticated, ergonomically smart, state of the art design
- Lightweight, highly mobile, 60% smaller to easily fit into any size clinic
- Ability to operate with a foot pedal to reduce operator strain and can treat while sitting or standing





NEW USER INTERFACE

- Based on the 10" multi- touch Android interface with full HD display
- Easy to use, intuitive GUI enables quick and easy set-up of treatments parameters before and during each treatment
- Future upgrades for guided protocol treatments







NEW ELECTRODE DESIGN

New RF electrode design to improve contact with the skin and better energy delivery to the fat layer.

- VelaShape III electrodes are in the same plane with the plastic, easier to achieve vacuum and good contact with the tissue.
- VelaShape III side walls are curved and notstraight. This makes the vacuum more pleasant and more comfortable for the patient



→Vsmooth applicator





NEW APPLICATORS

New V Contour Applicator with Various

Cover Sizes

- Expended treatment range with multiple cover sizes (L, M, S)
- New RF electrode design improves contact with the skin and delivers precise energy to the tissue





Each cover is sufficient for 4 hours of use



→Vsmooth (+rollers) applicator and new upgrades to be released soon



DHF13441 Rev 00

New User Interface- Energy Set-Up





DHF13441 Rev 00

yneron

New User Interface-Temperature Set-Up





New User Interface- Treatment in Progress









Clinically Relevant Improvements Vela Shape III

- High Power and ability to deliver optimal energy across all impedance ranges
- Impedance Measurements in real time every 1ms
- Optimized protocol to reach temperature and maintain temperature
- Temperature measurements in real time
- Improved electrode configuration for patient comfort and safety
- Operator Comfort and ease
- Interface Design



Treatment Protocol Circumferential Reduction Medium Cover







New System-New Clinical Protocol

New Stacking Mode Clinical Protocol

- The stacking mode clinical protocol has been developed for the optimized treatment of local fat deposits.
- This new protocol provides a reduction of at least 2 cm in as few as 3 treatments, 2 weeks apart, or 1 longer treatment session. The protocol is design for sustained heating of the tissue resulting in optimal, reproducible results.
- Results can also be seen after a one treatment protocol with a longer treatment duration.







3 Sessions vs 1 Session

	VelaShape III – Single Treatment: Longer treatment time for a reduced number of treatments	VelaShape III – 3 Treatments: Much less treatment time for multiple treatments
Treatment Protocol	1 Treatment Performing the treatment twice on each area	3 Treatments, Spaced 2 Weeks Apart
Results	Results seen as early as Week 2 with best results seen at Week 8-10	Results seen as early as Week 2 with best results seen at Week 8-10
Practice and Patient Benefits	 Ideal for practices who can commit to one hour treatment sessions Ideal for practices that would offer VelaShape as a follow up treatment, such as Post Lipo Ideal for busy practices and patients seeking a one time treatment solution 	 Ideal for practices that promote price per treatment Ideal for practices seeking return patients for upselling of other procedures or products Ideal for patients seeking a short 'lunch-time' treatment Ideal for practices who wish to have a close follow up on their patient during the program







Circumferential Reduction and Body Contouring Medium Cover

Stacking Protocol for deep and sustained heating






Parameters: RF + Vacuum

- Radiofrequency Heating
 - Metabolic reactions in the fat cells increased
 - Fibroblast metabolism
 - Collagen shrinkage
 - Collagen synthesis
 - Deep heat in the blood vessels -> oxygen dissociation

Vacuum

- Fibroblast proliferation via stimulation of stretch receptors
- Targeted penetration of the RF
- Negative pressure -> vascular dilatation
- Improved circulation





- 1. Reach the right temperature
- 2. Reach it quickly and deeply with stacking
- 3. Maintain it over time





Clinical Procedure Patient Selection

- Safe for all skin types I-VI
- Make sure there are no medical contraindications to IR/RF/Vacuum treatment (see User Manual for complete list)
- Not recommended to treat:
 - Varicosities
 - BMI under 30
- Marginal results with:
 - Obese patients



- Patients with edema due to lymphatic drainage problem
- Avoid thyroid area, especially if there are thyroid pathologies



Contraindications to Treatment

- Pacemaker or internal defibrillator.
- Superficial metal or other implants in the treatment area.
- Current or history of cancer or pre-malignant moles
- Past history of any kind of cancer. *
- Severe concurrent conditions, such as cardiac disorders.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications. *
- Diseases which may be stimulated by light at the wavelengths used. *
- 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.
- Any active condition in the treatment area, such as open wounds, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies, or use of anticoagulants.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Treating over tattoo or permanent makeup.
- Excessively tanned skin from sun, sun-beds or tanning creams within last 2 weeks.
- As per the practitioner discretion, refrain from treating any condition which might make it unsafe for the patient.

Marked conditions may be treated at the discretion and under the full responsibility of the medical director / physician, although not recommended. In such a case, a small area should be treated and assessed a few days later to determine if the patient will tolerate the treatment without developing adverse effects.





Clinical Procedure Aligning Expectations

- Improvement not elimination
- Temporary results maintenance is essential
- Skin tightening by RF may occur
 - Not for excessively loose skin
- Stretch marks may improve not always
- Diet and exercise may improve results not essential
- Weight gain may worsen results



Clinical Procedure Pre Treatment

- Proper patient selection
 - Aligning expectations
- Pre-treatment :
 - Gently exfoliate the skin (recommended)
 - Avoid anticoagulants if medical condition permits (advisable)
 - Shave hair (if necessary)
- Weigh patient, photograph and measure circumference
- Define treatment areas, and set treatment parameters





Beginning the treatment

- Select areas
 - Mark areas as needed to maintain awareness of bony structures and where you will treat once patient is lying on
- Measure areas to plan treatment



Measuring and marking the areas of the body to be treated











Area Templates: Choose a template depending on the size of the area you wish to treat







LARGE 25 x 20 cm

MEDIUM 15 x 20 cm

SMALL 10 x 20 cm

Each small square is approx. 5x5 cm

Choose based on the anatomy of the patient and how well temperature is maintained in a given area







DHF13441 Rev 00

Page 41-77



Set Parameters

- Set parameters on touch screen or on the applicator screen
- In stacking IR is always OFF
- When treating a patient for the first time start with a few pulses on RF of 1 or 2 and Vacuum of 1 so patient can get the sensation for the treatment.
- Tell the patient that s/he is to communicate when the sensation becomes hot so that you will be able to adjust your parameters or pulses accordingly
- Start the treatment with RF 3 and Vacuum 1 (IR is OFF)







Apply a lightly visible layer of Vela Spray

Example of Large Template to treat anterior abdomen



Spray should be reapplied as needed for patient comfort and ease of treatment. Be sure to wipe inside of cover every few passes to ensure accuracy of device thermometer.



Set Temperature and Go







Protocol Step by Step

Cycle Number	Mode		Routine	Direction
Cycle 1	Stacking 5 -> 2 plus maintenance		Pass 1: 5 stacked pulses per sub-area Pass 2: 4 stacked pulses per sub-area Pass 3: 3 stacked pulses per sub-area Pass 4: 2 stacked pulses per sub-area Additional Passes: 2 stacked pulses per sub-area until temperature is reached	Horizontal Snake
Cycle 2	Stacking - 2 stacked pulses		2 stacked pulses per sub-area until temperature is reached and maintained	Vertical Snake
Cycle 3	Same as Cycle 2		Same as Cycle 2	Horizontal Snake
Cycle 4 (optional)		If the total time duration of Cycles 1, 2 and 3 is less than 15 minutes, continue with the Vertical Snake treatment technique and apply one pulse per sub-area until the 15-minute treatment duration for all four cycles is reached.		

Cycle 1 is very important. Use stacks as tolerated and follow protocol until goal temperature is reached.

Cycles 2-4 can be viewed as maintenance. Continue to move the applicator over the selected area in order to maintain goal temperature over time. Total time for the area

- should be a minimum of 15 minutes.



Page 46-77



Horizontal Snake and Vertical Snake Movement Patterns



- Above are the horizontal and vertical snake movement patterns.
- Movement of the applicator will also be based on the anatomy of the patient.
- Keep in mind, it is important to maintain contact over curved areas --adjust movement pattern accordingly.





Pulse Stacking on the Abdomen – 5 pulses







Cycle 1 Horizontal Snake in Summary

- 5 Stacked Pulses in the first pass
- 4 Stacked Pulses in the second pass
- 3 Stacked Pulses in the third pass
- 2 Stacked Pulses until the goal temperature is reached.

 Once goal temperature is reached, move to Cycle 2 (continue with 2 stacked pulses moving in a vertical snake fashion)





Cycle 2 - Vertical Snake









Cycles 3 and 4

- For Cycle 3, continue in the horizontal snake pattern with 2 pulses as tolerated until the treatment endpoint temperature is reached in the area.
- For Cycle 4, maintain the temperature in the area until a treatment time of 15 minutes is reached
- Note: When spray is reapplied, increased stacked pulse by 1. For example, if you were stacking 2 pulses, then do one pass of 3 pulses before returning to 2 pulses.
- Wipe the IR lens frequently with a tissue or soft cloth (ideally between passes initially and then approximately every minute in the latter part of the treatment) The goal is to keep the lens clean and free of spray to maintain accuracy of real time temperature measurements.





Treating Thigh Circumference



Pulse stacking on the thigh









Area Size	One Tx Protocol (Each area treated twice in one session)	3 Tx Protocol (every 2 weeks)
Large: 25 cm X 20 cm	30 minutes	15 minutes
Medium: 15 cm X 20 cm	18 minutes	9 minutes
Small: 10 cm X 20 cm	12 minutes	6 minutes

- Abdomen and flanks are treated in ~45 minutes
- Thigh is treated in ~30 minutes

Times listed are for an average body habitus







What is needed to achieve consistent and predictable results with VelaShapeIII

- Reaching end point temperature of 43°-45°C
- Maintaining end point temperature of 43°-45°C over time
- Controlling end point temperature
- Creating more heat below the skin surface and sustaining this heat in the tissue longer





VelaShape Treatment Evolution 2004-2013







Clinical Results

2.6 cm of average circumference reduction following single session protocol









Clinical Results Vela III success rate following a single session protocol (45 – 1hr)







Significant Increase In Collagen Deposition



A. Non treated site on upper arm

ron



B. Histology results at 1 month follow up after 5 treatments in same subject.



CANDELA



Local Inflammatory Response In Fat Tissue



10 days





24 days







Clinical Results- Summary

- Vela III heats up target tissue faster
- Vela III maintains target temperature longer
- Vela III reduces the overall treatment duration over time
- Vela III offers fewer and shorter treatment sessions
- Vela III treatment protocols are optimized for treatment of small, medium and large areas of the body and all are based on a similar, simple and easy to learn mode of treatment
- Real time Impedance Measurements Adjustable high power to deliver optimal energy across all impedance ranges
- Measuring temp in real time



Clinical Results- Summary

Proven Clinical Results

- The safety and effectiveness of the VelaShape treatment has been demonstrated in multi-center clinical trials and in more than 5 million independent treatments performed on patients globally.
- VelaShape III demonstrated over 2 cm reduction in the abdomen and over 1.5 cm reduction in the thighs
- Most patients reported no discomfort during or following treatment







2 weeks post 1session of whole abdomen treatment (360°) -1.5 cm waist, -1.7 cm abdomen -2.0 cm hip (weight change: +0.3kg)





2 weeks post 1session of whole abdomen treatment (360°) -1.5 cm waist, -2.0 cm abdomen -1.0 cm hip (weight change: +0.5kg)





CANDE

2 weeks post 1 session of whole abdomen treatment (360°) -3.0 cm abdomen -2.0 cm hip (weight change: -1.4kg)







2 weeks post 1session of whole abdomen treatment (360°) -0.5 cm waist, -2.0 cm abdomen -1.0 cm hip (weight change: +1.8kg)







2 weeks post 1session of whole abdomen treatment (360°) -4.0 cm waist, -2.5 cm abdomen (change weight: -1.4Kg)









4 weeks post 1session of whole abdomen treatment (360°) -3.5 cm waist, -4.0 cm abdomen (weight change: +0.8Kg)






Maintenance







Please read carefully **











Figure 1: VelaShape III System



Page 61-77

Rubber stops for Applicator Arm

 Be sure the arms of the device are equipped with the rubber stop to keep applicators securely in place when hung



















Note: foot peddle plug needs to be securely attached. Make certain the cuff is turned and securely connected. Be certain the foot peddle cord is not kinked or stepped on during treatment.



DHF13441 Rev 00

yneron



Clean Filter and Filter Cup







Troubleshooting

Symptom	Corrective Action
No vacuum suction	 Turn the system off. Check that air filter is clean and the
	cover's sealing O-ring should be properly installed).
	 Check the applicator connection to the umbilical cable, and the umbilical cable's connection to the system.
	4. Verify that the cover is correctly attached to the applicator.
	Replace applicator filters or cover.
No IR output	1. Turn the system off.
	2. Call your Syneron representative for further instructions.
Electrodes are not rotating (Large Applicator).	1. Turn the system off.
	Check that the applicator chamber is clean and that nothing is obstructing the electrodes.
	3. Connect a new applicator cover.





Filter Maintenance

- Replace filter every 30 minutes
- Filters can be washed with warm water, dried thoroughly and reused for a total use time of 90 minutes
- If suction seems diminished check/replace filter
- Once filter is removed, be sure to clean recess under filter area with tissue or Q-tip





Wiping the lens

(during treatment it is done with cover still on the hand piece)







Tips and Pearls







Remember...

- Temperature
- Time
- ...and patient Tolerance

Adjust parameters (RF) and number of stacked pulses when necessary for comfort and for continued maintenance of temperature over time





Be comfortable...

- Hold applicator comfortably
- Use the foot peddle
- Trigger on Hand piece can be used and is generally meant for small cover use







Patient Positioning: Making a flat work surface





Patient lying on back with rolled towel under flank to bring Forward tissue from the side and flatten the work area. Here you can divide the abdomen in two parts and treat One-half with medium template from umbilicus to side



Page 73-77





Patient Positioning: Lying on abdomen with rolled towel to expose optimal flank and side area











Smaller area templates can be used based on anatomy of the patient.





Keep the IR lens clean for accurate temperature measurements







Thank You!





