



In the EU: The EXILIS ULTRA 360<sup>™</sup> is intended for obesity treatment by means of controlled reduction of fat cells, induced by radiofrequency field in cooperation with ultrasound. Treatment of sexual dysfunction after vaginal delivery by means of improvement of vaginal laxity. ©2019 BTL Group of Companies. All rights reserved. The products, the methods of manufacture or the use may be subject to one or more U.S. or foreign patents or pending applications.

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### Treat:

**DIFFERENT CONDITIONS** such as wrinkles, skin laxity and excessive fat.

**VARIOUS AREAS** including the face, body and women's intimate parts.

**EVERY BODY** with literally no BMI or skin type limitations.

### TREAT EVERYBODY



- ✓ All skin types
- ✓ BMI without limitation
- ✓ Men & women of all ages\*

### FROM HEAD TO TOE



Face



Wrinkles & Skin Laxity

Body



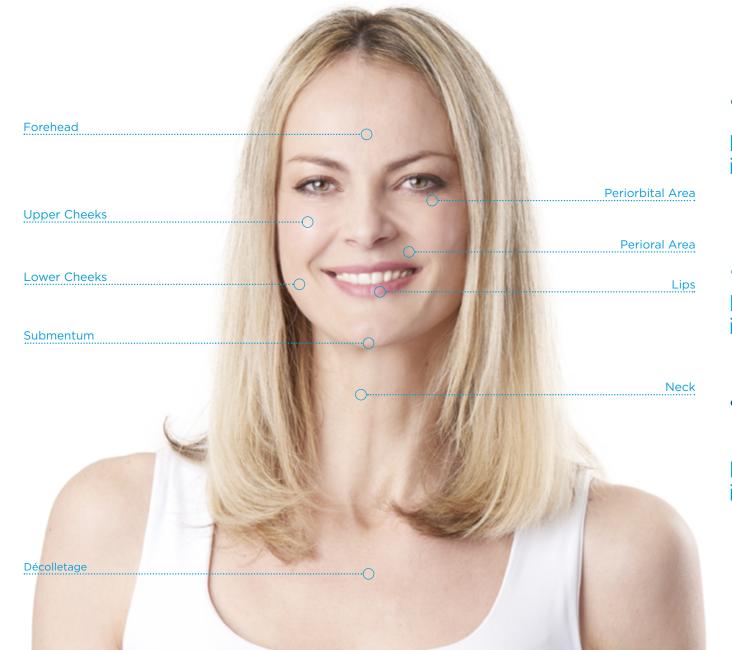
Fat Reduction & Skin Tightening

Intimate Areas



Vaginal Laxity

### FACE: WRINKLE REDUCTION



42%

Reduction in wrinkles<sup>1</sup>

2.9<sub>x</sub>

Increase in collagen<sup>2</sup>

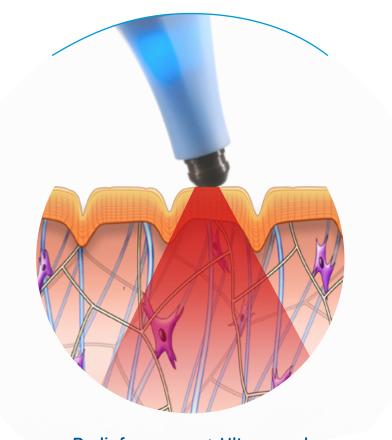
19%
Increase in skin density<sup>1</sup>

### SKIN LAXITY IMPROVEMENT

Skin rejuvenation and wrinkle reduction results are delivered in shorter treatment times due to 360° Volumetric Heating.

Focused thermal energy disrupts collagen fibers.
Collagen triple-helix structure is affected by heat and the unravelling process is initiated. Natural healing process encourages fibroblasts to produce new collagen fibers.

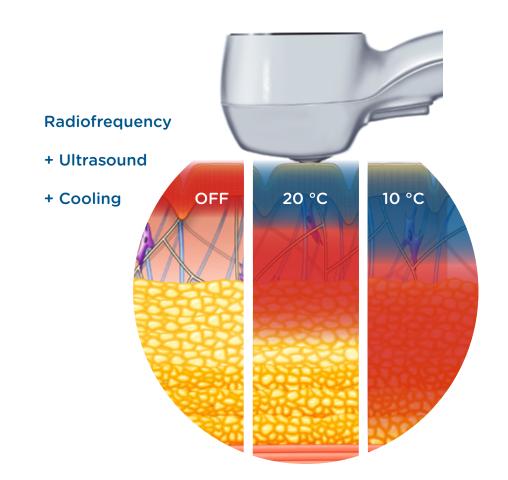
- Treatment of difficult-to-reach areas, such as the periorbital area, has improved with the specially designed 360° applicator tip.
- Larger contact area ensures delivery of even more consistent results.



### **BODY: FAT REDUCTION**

Skin tightening and fat reduction results can be achieved on different body areas without any BMI or skin type limitations.

- Controlled heating and cooling enable energy delivery to the various depths in the tissue.
- Changing the cooling during treatment allows you to treat deep tissue all the way up to the superficial layer.
- Real time temperature monitoring provides additional control for accurate tissue heating.
- Applicator design enables user to check the temperature and adjust treatment parameters.



SKIN TIGHTENING

35% Reduction in skin laxity<sup>1</sup>

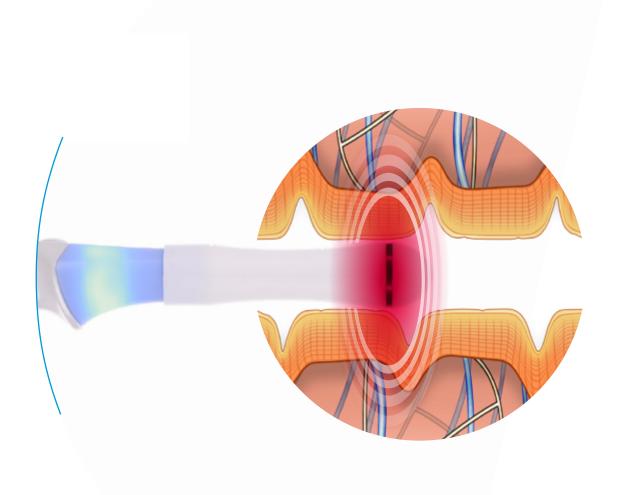
6.4<sub>x</sub>

Increase in apoptotic index<sup>3</sup>

Recognition rate for different body areas<sup>4</sup>



### WOMEN'S INTIMATE AREAS



96%
Vaginal tightness improvement<sup>7</sup>

**93**% Sexual satisfaction improvement<sup>7</sup>

37%
Increase in elastin content<sup>8</sup>

The procedure utilizes a **smooth in-and-out motion** ensuring the maximum level of comfort. **No need to perform** a **side-firing motion**, forcing the provider to twist and turn the applicator inside the vaginal canal.

### LAXITY ENHANCEMENT

Shortest RF treatment on the market due to the 360° applicator tips.

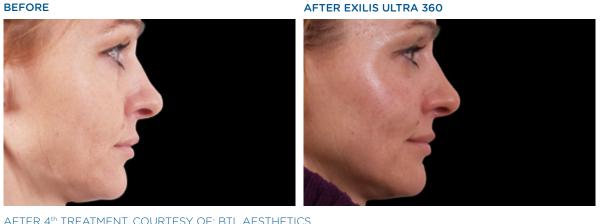
- **360° Volumetric Heating** for faster, safer and more comfortable treatment of female intimate parts.
- Plug & Play tips of various sizes for treatment of internal and external genitalia.
- Groundbreaking **Energy Flow Control (EFC)** system with integrated Impedance Intelligence ensures uniform heating of targeted tissue.



### FROM HEAD TO TOE

# **BEFORE AFTER EXILIS ULTRA 360**

AFTER 4th TREATMENT, COURTESY OF: JAYE BIRD AESTHETICS CLINIC



AFTER 4th TREATMENT, COURTESY OF: BTL AESTHETICS





AFTER 5<sup>th</sup> TREATMENT



AFTER 4th TREATMENT, COURTESY OF: BTL AESTHETICS



AFTER 4<sup>th</sup> TREATMENT, COURTESY OF: BTL AESTHETICS

### PROVEN EFFICACY OF ACCELERATED DOUBLE-INJURY PROTOCOL: BIOPSY. ULTRASOUND, CLINICAL OBSERVATIONS

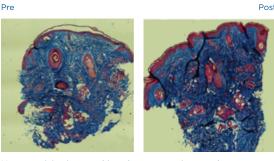
TWO-TREATMENT PROTOCOL FOR SKIN LAXITY USING 90-WATT DYNAMIC MONOPOLAR RADIOFREQUENCY DEVICE WITH REAL-TIME IMPEDANCE MONITORING

David McDaniel M.D., 1 Robert Weiss M.D., 2 Margaret Weiss M.D., 2 Chris Mazur BS.1 and Charrnaine Griffin CCR P1

I. McDaniel Institute of Anti-Aging Research, Virginia Beach, VA; 2. Maryland Laser Skin & Vein Institute, Hunt Valley, MD

#### HIGHLIGHTS

- 24 female subjects enrolled and treated for facial skin laxity.
- 2 treatments with double treatment time instead of 4 standard treatments.
- Results show 35% reduction in skin laxity, 42% reduction in facial wrinkles and 33% reduction in the appearance of global photodamage.
- Histological analysis of biopsy samples proves significant increase in dermal collagen and elastin fibers.
- 19% increase in skin density evidenced by ultrasound measurements.



Masson staining in one subject demonstrates increased Collagen (blue) at 3 months post treatment.

JDD, 2014, 13.9: 1112-1117.

### HISTOLOGICAL STUDY: THE INCREASE OF THE COLLAGEN CONTENT IN THE TISSUE

**EFFICACY OF MONOPOLAR RADIOFREQUENCY** ON SKIN COLLAGEN REMODELING: A VETERINARY STUDY.

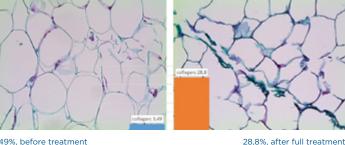
Klaus Fritz<sup>1</sup>, Jan Bernardy<sup>2</sup>, George Sonn Tiplica<sup>3</sup> & Alena Machovcova4

1. Dermatology and Laser Center, Landau, Germany, Universität Osnabrück, Kosmetologie und Gesundheitswissenschaften Department (Leiter Prof. Dr John), Osnabrück, Germany; 2. Veterinary Research Institute, Brno, Czech Republic; 3. Dermatology Department, University Carol Davila, Bucharest, Romania; 4. Dermatology and Venereology, University Hospital Motol, Prague, Czech Republic

### **HIGHLIGHTS**

- Biopsies taken before the treatment and at 3-month follow-up.
- Stereological analysis using the trichome method.
- Increase in collagen content in the treated tissue on average from 9.03 % to 25.89 %.
- The trial proves significant neocollagenesis and collagen remodeling as direct effect of the treatment.

#### Results of stereological analysis.



<sup>3,49%,</sup> before treatment

### THE THERAPEUTIC TEMPERATURE IN THE DEEP TISSUE: ADJUSTABLE COOLING ALLOWS EFFECTIVE HEATING IN THE FAT LAYER

A FOCUSED MONOPOLAR RADIOFREQUENCY CAUSES **APOPTOSIS: A PORCINE MODEL** 

David McDaniel M.D., 1 Klaus Fritz, M.D., 2,3 Alena Machovcova MD PhD MBA,4,5 and Jan Bernardy PhD6

1. McDaniel Institute of Anti-Aging Research, Virginia Beach, VA; 2. Dermatology and Laser Centers Landau, Germany 3. University of Osnabrück - Department of Health Sciences; 4. University Hospital Motol, Department of Dermatology and Venereology, Prague, Czech Republic; 5. Department of Occupational Medicine, 1st Faculty of Medicine at Charles University, Prague, Czech Republic: 6, Veterinary Research Institute, Brno, Czech Republic

#### **HIGHLIGHTS**

- A unique veterinary apoptosis study on Vietnamese pigs proving terminal killing of fat cells.
- Temperature probes evidenced fat tissue temperature increase to 42-46°C during the treatments while maintaining safe skin temperature.
- Histological analysis of biopsies using TUNEL method proved apoptotic index increase from average of 7% (before the first treatment) to an average of **53.4%**, **39.6%**, **40.2%** and **44.7%** respectively after each of the 4 treatments.
- Histopathological examination demonstrated complete safety.



Adipocyte (A) apoptotic nucleus is stained brown (B), other nuclei are blue (C) (400x).

### TREATING MULTIPLE BODY PARTS FOR SKIN LAXITY AND FAT DEPOSITS USING A NOVEL FOCUSED RADIOFREQUENCY DEVICE WITH AN ULTRASOUND COMPONENT: SAFETY AND EFFICACY STUDY

CONFIRMATION OF CLINICAL

EFFICACY ACROSS MULTIPLE

**BODY PARTS** 

Suneel Chilukuri M.D.<sup>1</sup>, Dominique Denjean M.D.<sup>2</sup>, Linda Fouque M.D.<sup>3</sup>

1. Refresh Dermatology, Houston, TX, USA; 2. Cabinet de Dermatologie Esthetique, Paris, France; 3. Dermatologue Esthetique, Nice, France

#### **HIGHLIGHTS**

- Unique multiple body part study demonstrating excellent results from **head to toe**.
- 34 patients treated on face, arms, abdomen and thighs using the novel tips.
- 90% responsive patients for each body part.
- Highly **consistent satisfaction** of all enrolled patients.
- The study concludes superior efficacy due to combination of RF, US and 360° emission.



<sup>3.</sup> DAVID MCDANIEL, M. D.; FRITZ, Klaus. A focused monopolar radiofrequency causes apoptosis: a porcine model. Journal of Drugs in Dermatology, 2014, 13.11: 1336-1340.

4. CHILUKURI, Suneel; DENJEAN, Dominique; FOUQUE, Linda. Treating multiple body parts for skin laxity and fat deposits using a novel focused radiofrequency device with an ultrasound component: Safety and efficacy study. Journal of cosmetic dermatology, 2017, 16.4: 476-479.



<sup>1.</sup> MCDANIEL, David, et al. Two-treatment protocol for skin laxity using 90-Watt dynamic monopolar 2. FRITZ, Klaus, et al. Efficacy of monopolar radiofrequency on skin collagen remodeling: radiofrequency device with real-time impedance intelligence monitoring. Journal of drugs in dermatology: a veterinary study. Dermatologic therapy, 2015, 28.3: 122-125.

# COMPARATIVE SUMMARY OF NON-INVASIVE SKINTIGHTENING DEVICES

### "DEEP HEATING" NONINVASIVE SKIN TIGHTENING DEVICES: REVIEW OF EFFECTIVENESS AND PATIENT SATISFACTION

#### Suneel Chilukuri MD FAAD FASDS<sup>1</sup> and Jason Lupton MD<sup>2</sup>

1. Refresh Dermatology, Houston,TX; 2. San Diego Dermatology & Laser Surgery, San Diego,CA

#### HIGHLIGHTS

Comparison of all existing peer-reviewed evidence on 3 leading skin tightening devices shows that EXILIS ULTRA 360:

- Has higher efficacy
- Has fewer non-responders
- Is less painful
- · Generates higher patient satisfaction

	Clinical Efficacy	Patient Satisfaction
EXILIS ULTRA 360	89-93%	77-95%
ThermaCool	47-95%	53-78%
Ultherapy	58.1-96%	65.6-95%

	Non-responsive Patients	Serious Adverse Events
EXILIS ULTRA 360	3-8%	None
ThermaCool	5-14%	Rare
Ultherapy	14-20%	Rare

	Treatment Time (Full Face)	Anesthetics
EXILIS ULTRA 360	40-45min	NO
ThermaCool	60-120min	YES
Ultherapy	60-85min	YES

5. CHILUKURI, Suneel; LUPTON, Jason. "Deep Heating" Noninvasive Skin Tightening Devices: Review of

Effectiveness and Patient Satisfaction. Journal of drugs in dermatology: JDD, 2017, 16.12: 1262-1266.

# DEMONSTRABLE IMPROVEMENT OF SKIN LAXITY, CIRCUMFERENTIAL REDUCTION OF THE ARMS AND REDUCTION OF SUBMANDIBULAR FAT PADS

DYNAMIC MONOPOLAR RADIOFREQUENCY FOR SUCCESSFUL NON-INVASIVE TREATMENT OF SKIN LAXITY AND BODY CONTOURING

R. A. Weiss, MD, FAAD, M. A. Weiss, MD, FAAD

Whitenane

#### **HIGHLIGHTS**

- **30 patients** (28 female, 2 male) treated for facial skin laxity, neck skin laxity and arm fat reduction.
- 4 treatments **7-10** days apart.
- 93,3% of subjects showed significant decrease in facial skin laxity.
- Average circumferential reduction for arm contour patients was 2.1cm.
- Device proven to have consistent efficacy across various body parts while being completely safe (no adverse events reported) and while maintaining patient comfort.

fore





Reduction of submandibular fat.

### 6. WEISS, Robert A. Noninvasive radio frequency for skin tightening and body contouring. Semin Cutan Med Surg, 2013, 32.1: 9-17

### VAGINAL LAXITY & SEXUAL SATISFACTION

#### RADIO FREQUENCY VOLUMETRIC HEATING FOR VAGINAL LAXITY TREATMENT AND EFFECTS ON SEXUAL SATISFACTION

#### Evans, K.L.

Obstetrics, Gynecology and Wellness, Houston, TX

#### HIGHLIGHTS

- 51 patients enrolled.
- All patients received 3 treatments with **EXILIS ULTRA 360**.
- Both intravaginal and extravaginal application.
- 93% of patients experienced improvement in sexual satisfaction.
- Over **55%** of patients reported complete absence of any dysfunction 90 days post treatment.
- Vaginal Laxity Questionnaire showed vaginal tightness improvement in 96% of patients.
- Significant improvement of sexual life satisfaction.
- At the follow-up, all patients uniformly reported they did not feel any degree of vaginal laxity at all.
- The level of discomfort was reported in 0.03 % of treatments, with the average VAS discomfort score reaching zero.

# HISTOLOGICAL IN VIVO STUDY: QUANTITATIVE IMPROVEMENT IN A VAGINAL TISSUE

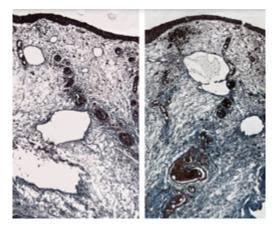
SAFETY AND MECHANISM OF ACTION
OF NON-INVASIVE RADIOFREQUENCY TREATMENT
FOR VAGINAL LAXITY: HISTOLOGICAL STUDY
IN THE SWINE VAGINAL MODEL

David E. Kent MD1, Jan Bernardy MVD2

1. Dermatologic Surgery Specialists, Macon, Georgia; 2. Veterinary Research Institute Brno, Czech Republic

#### **HIGHLIGHTS**

- EXILIS ULTRA 360 once per week for the course of three weeks.
- **Biopsy specimens** and ultrasound video measurements were obtained after each treatment and follow-up session.
- The results showed a measurable increase in elastin (36.8%) and collagen fibers (17.1%).



An example of comparison of elastin content after 1st treatment (left) and at 1-month follow-up (right). An increase of 36.5% in elastin content (from 14.6% to 51.1%) was observed.

7. EVANS, K. L. 009 Radio Frequency Volumetric Heating for Vaginal Laxity Treatment and Effects on Sexual Satisfaction. The Journal of Sexual Medicine, 2018, 15.6: S102.

8. KENT, David E. Safety and mechanism of action of non-invasive radiofrequency treatment for vaginal laxity: histological study in the swine vaginal model. 2018 ASLMS



# MONOPOLAR RF IS AN EFFECTIVE AND SAFE TREATMENT OF SUI AND VULVO-VAGINAL LAXITY

EVALUATION OF THE SAFETY AND EFFICACY OF A MONOPOLAR NONABLATIVE RADIOFREQUENCY DEVICE FOR THE IMPROVEMENT OF VULVO-VAGINAL LAXITY AND URINARY INCONTINENCE

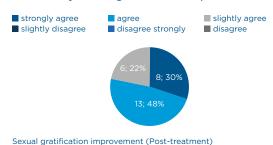
### Shelena Lalji M.D.<sup>1</sup>, Paula Lozanova M.D.<sup>2</sup>

Dr. Shel Wellness & Medical Spa, Houston,TX, USA
 Department of Dermatology and venerology, Medical University, Sofia, Bulgaria

#### HIGHLIGHTS

- 27 women with indications of mild/moderate stress urinary incontinence (SUI) as well as vulvovaginal laxity.
- Three once-a-week sessions.
- Intravaginal treatment followed by treatment of labia majora and the perineum.
- 26 subjects reported a decrease in the frequency of urine leak.
- 15 women becoming completely leak-free at the 1-month follow-up.
- All subjects reported improvement in vaginal laxity.
- High satisfaction rate when evaluating improvement in sexual gratification.

### My sexual gratification improved



# IMPROVEMENT IN THE APPEARANCE OF WOMEN'S INTIMATE PARTS

LABIAL TISSUE REJUVENATION AND SEXUAL FUNCTION IMPROVEMENT USING A NOVEL NON-INVASIVE FOCUSED MONOPOLAR RADIO FREQUENCY DEVICE.

#### Zeljka Clark, M.D.

Rahima Moosa Mother and Child Hospital, O&G, Johannesburg, South Africa

### **HIGHLIGHTS**

- 19 women treated with ULTRA FEMME 360
- Sexual satisfaction measured by FSFI increased from 63 % to 90 % at 1 month and remained at 83 % one year after the treatments
- No non-responding patients
- 18 out of 19 women reported moderate or **excellent improvement** in the appearance of their intimate parts.

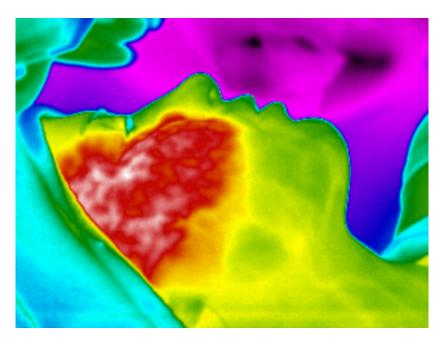
### Changes in sexual function

FSFI Dimension	Pre Tx	1-Month post Tx
Desire	3.15 ± 0.90	4.68 ± 0.93
Arousal	3.43 ± 1.23	5.33 ± 0.43
Lubrication	3.25 ± 1.23	5.47 ± 0.68
Orgasm	3.41 ± 0.95	5.49 ± 0.47
Satisfaction	3.55 ± 0.95	5.52 ± 0.70
Pain	5.80 ± 0.75	5.89 ± 0.23
TOTAL	22.59 ± 4.00	32.38 ± 1.68
Satisfaction Pain	5.80 ± 0.75	5.89 ± 0.23

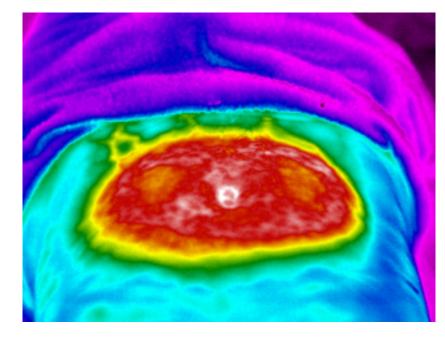
Data are mean ± SD

### SUPPORTED BY EXTENSIVE RESEARCH

Post procedure thermography scan of face and abdomen.



Post procedure thermography scan of periorbital area and cheeks.



Post procedure thermography scan of abdomen.

10. CLARK, Zeljka. Labial tissue rejuvenation and sexual function improvement using a novel noninvasive focused monopolar radio frequency device. Journal of Cosmetic and Laser Therapy, 2018, 20.2: 66-70.

LALJI, Shelena; LOZANOVA, Paula. Evaluation of the safety and efficacy of a monopolar nonablative radiofrequency device for the improvement of vulvo-vaginal laxity and urinary incontinence. Journal of cosmetic dermatology, 2017, 16.2: 230-234.

### WHY PHYSICIANS SAY YES TO

### FROM HEAD TO TOE

Five different tips enable treatment of different indications on more than 20 areas.



### SUITABLE FOR EVERY BODY

No BMI, skin type or sex restrictions.



### **EXCEPTIONAL ROI**

No costly consumables and many years of proven reliability contribute to fast ROI.



## ULTRA 360°

**TECHNOLOGY** 

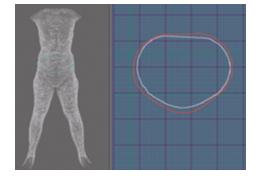
EXILIS ULTRA 360

The only simultaneous combination of monopolar radiofrequency and ultrasound with brand new 360° technology for shorter treatments and even more consistent results.



### FAST & LASTING RESULTS

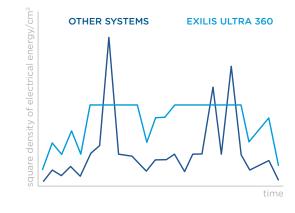
Short treatment times with early visible results for different indications on various body areas are supported by strong clinical evidence.



Prevas laser system – compares and measures dimensions and changes.

### ULTIMATE TREATMENT CONTROL

Due to the integrated EFC technology and Impedance Intelligence, any risk of overheating is minimized.



### LISTEN TO YOUR PEERS



Jason Lupton, M.D.
San Diego Dermatology & Laser Surgery
San Diego, CA

"I would estimate that more than 75% of the patients I see who undergo an Exilis Ultra 360 procedure end up doing at least one other body area because they were pleased with their initial treatment in such a short time."



Suneel Chilukuri, M.D. Refresh Dermatology Houston, TX

"What I found with the Exilis Ultra is there is no limitation. The only limitation is our imagination. So I can treat any part of the body on either sex."



Grace Liu, M.D.

Newport Beach Dermatology

Newport Beach, CA

"Patients become really excited about their next application because they see the results so quickly. There aren't too many devices on the aesthetic market that people will say they love and need to have. This is one of them."



M. Christine Lee, M.D., M.P.H.

The Skin and Laser Treatment Institute
Walnut Creek, CA

"The Ultra Femme is a quick, easy to perform, non-invasive procedure with no downtime that is a safe and effective treatment to help with feminine issues."