

Consumer Interest Drives

Body Shaping

Technologies

By Alison Sahoo, Contributing Editor

Currently, many different technologies and devices are being used for the purpose of reducing cellulite, toning and firming skin as well as emulsifying fat. Europe, in particular, has seen the introduction of dozens of new devices incorporating many different technologies, although more established techniques such as endermologie continue to be used. While consumer demand and product availability have expanded, a weak global economy has constrained consumer spending.



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Submental area before Tx



Submental area one month after Smartlipo MPX Tx
Photos courtesy of Barry DiBernardo, M.D., F.A.C.S.



Arm before Tx



Arm three and a half months after Smartlipo MPX Tx
Photos courtesy of Christine Petti, M.D.



Before Tx



After Body-Jet Tx
Photos courtesy of Todd K. Malan, M.D., F.A.C.O.G.

In 2008, more than 8 million body shaping procedures were performed worldwide, earning physicians over \$2.8 billion in fees. By 2013, this will rise to more than 13 million treatments earning \$5.6 billion. Additionally, 670,000 skin tightening procedures were performed worldwide, earning physicians almost \$970 million in fees. By 2013, this will expand to almost 2 million treatments earning them \$2.3 billion.

Over the past 24 months, a variety of both established and emerging device manufacturers have introduced systems that offer energy-based liposuction. Using radiofrequency (RF), laser and water-jet energy, these minimally invasive devices liquefy adipocytes for easier removal.

Cynosure's (Westford, Mass.) dual wavelength Smartlipo MPX (MultiPlex) delivers a 1320 nm wavelength for high efficiency lipolysis, as well as a 1064 nm wavelength for skin tightening. MultiPlex technology enables the two wavelengths to be blended, or fired sequentially, for optimal fat liquefaction and skin tightening results through tissue coagulation. Furthermore, according to Dave Canavan, Cynosure's senior product manager, two new intelligent delivery systems allow physicians to set temperature thresholds, thus providing a very safe and homogenous way of heating target tissue to avoid under or over heating.

"In clinical studies of Smartlipo MPX, 94% of patients were satisfied with results at one month post treatment and researchers observed 15% tightening of overall treatment areas."

Performed under local anesthesia, Smartlipo's laser energy is delivered through a fiber inside a small cannula. Adipose tissue is liquefied and then expressed or suctioned out. The laser energy carves a path for the cannula to facilitate a much less traumatic procedure.

In clinical studies of Smartlipo MPX, 94% of patients were satisfied with results at one month post treatment and researchers observed 15% tightening of overall treatment areas. What's more, out of nine patients who received treatment with Smartlipo MPX on one side of their body and liposuction on the other, 89% achieved an average of 54% greater shrinkage at three months post treatment on the Smartlipo MPX side. This study also showed a significant difference in skin tightening. At three months, the average improvement in skin tightening was 62% with Smartlipo MPX compared to 5% with liposuction.

Eclipsemed, Ltd. (Dallas, Texas) offers Body-Jet, a water-jet assisted liposuction device that uses a gentle, pulsating spray of fluid to separate clusters of adipocytes without the brute force of traditional liposuction. This results in less pain during the procedure as well as less post-procedure swelling and bruising. Since Body-Jet requires much less fluid and waiting time than conventional liposuction, the procedure is 50% to 75% faster. Additionally, since the fluid used is actually a tumescent solution that includes both lidocaine and epinephrine, Body-Jet can be performed under local anesthesia instead of intravenous sedation or general anesthesia.

"Physicians are realizing the benefits that water-jet assisted liposuction can provide over traditional techniques, including reduced risk, improved accuracy, less bruising and discomfort, reduced swelling, faster turnaround and improved patient satisfaction," said Tom O'Brien, Eclipse's CEO. "Many physicians are

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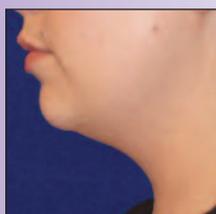


Before Tx



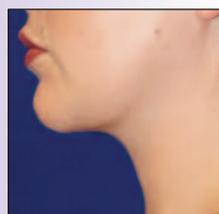
One day after Body-Jet Tx

Photos courtesy of Barry DiBernardo, M.D., F.A.C.S.



Neck before Tx

Photos courtesy of Gregory Keller, M.D.



Neck after SmoothLipo Tx



Arms before Tx



Arms after BodyTite Tx

Photos courtesy of Diane Duncan, M.D.



Abdomen before Tx



Abdomen after BodyTite Tx

Photos courtesy of Spero Theodorou, M.D.

also exploring the unique capability that Body-Jet offers with the AquaShape LipoCollector for efficient fat harvesting."

Elemé Medical's (Merrimack, N.H.) SmoothLipo laser lipolysis system uses a 980 nm diode laser to achieve a highly efficacious emulsion of fat. During treatment, continuous wave (CW) laser energy uniformly raises the temperature of the targeted area to reach between 45° and 55° C, which leads to apoptosis of the adipocytes. This offers an efficient and effective approach that continues after aspiration has been completed. According to Elemé, it also allows for higher energies to be used safely and results in a smooth and uniform outcome.

Invasix Ltd. (Richmond Hill, Ontario, Canada) offers BodyTite, a device utilizing radiofrequency-assisted lipolysis (RFAL) technology. RFAL simultaneously heats the subcutaneous tissue and aspirates the coagulated fat for body contouring. With a depth of penetration reaching 50 mm BodyTite can effectively reduce flaccidity and loose skin.



Richard D'Amico, M.D.
Past President
American Society of Plastic Surgeons

Thermal heating permits more precise control of dermal temperature than what is currently possible with lasers. Clinical studies with RFAL have found that heating of the soft and subdermal tissue provides as much as 40% re-contouring and body tightening. Furthermore, BodyTite overcomes existing liposuction limitations for heavier patients with excellent outcomes reported on patients up to 250 lbs. "BodyTite provides significant skin tightening following liposuction, less bruising and faster recovery," said Richard D'Amico, M.D., past president of the *American Society of Plastic Surgeons* (ASPS). "We're also seeing less discomfort in our early cases. Some women with lax skin in the abdomen experience enough skin tightening that they eliminate the need for an abdominoplasty. RFAL offers the opportunity to tighten not just the skin, but the entire collagen/fat matrix in the fat layer." BodyTite is currently available in Canada, Europe, Asia, South America and Australia, with U.S. studies ongoing.

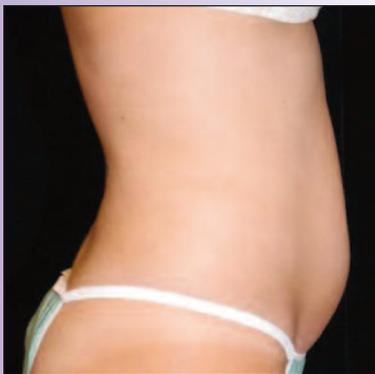
"RFAL offers the opportunity to tighten not just the skin, but the entire collagen/fat matrix in the fat layer."

Lutronic's (Princeton Junction, N.J.) AccuSculpt incorporates a 1444 nm wavelength that offers effective body shaping with the digital precision required for detailed sculpting. This allows contouring of delicate areas not only on the body but also on the face. The AccuLift procedure, using the AccuSculpt system, allows physicians to sculpt the mid and lower face in a safe, effective 30 minute procedure that requires only local anesthesia and results in very little downtime. "With AccuLift, I can deliver facial contouring improvements not previously possible with any other method," said J. David Holcomb, M.D. "AccuLift also improves face-lift results and enables more precise and effective augmentation with injectable dermal fillers."

LipoControl from Osyris Medical (Carrollton, Texas) is an advanced laser-assisted lipolysis device designed for gradual, natural removal of adipose tissue rather than large volume fat removal. By offering an electronic mapping device, this system provides safer treatments and optimizes outcomes. LipoControl uses a 980 nm diode laser and features a tracking device that constantly monitors the position of the handpiece and the amount of energy being delivered to the treatment area. This enables the surgeon to see the area he is treating in real time. When the physician stops moving the cannula, the heated tip shuts off automatically. This reduces risk

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“ProLipo *PLUS* with TempASSURE allows physicians for the first time to have a quantitative clinical endpoint for melting fat and firming tissue.”



Abdomen before Tx



Abdomen after ProLipo *PLUS* Tx
Photos courtesy of Brian V. Heil, M.D.

and enhances procedure safety, offering less bruising and swelling along with more precise results, particularly on more delicate areas of the face and body. As of October 2009, FDA approval was pending.

SlimLipo from Palomar (Burlington, Mass.) blends 924 nm and 975 nm wavelengths for preferential absorption by fat and dermal tissue. Prior devices simply adapted existing technology for lipolysis and relied on liposuction for the actual removal of fat. However, Palomar found that 924 nm light specifically targeted adipose tissue instead of water; therefore, SlimLipo represents the first use of an adipocyte specific wavelength. The 924 nm wavelength is absorbed by hemoglobin as well as adipose tissue, causing small-vessel coagulation and a reduction in bruising compared to traditional tumescent liposuction. In clinical studies, SlimLipo was shown to have over 20 times the thermal effect of other laser-assisted lipolysis systems, resulting in a 0.15 cm² effect compared with a 0.007 cm² effect for a 1064 nm laser. The device's heating of dermal tissue has also been shown to have skin tightening effects.

Sciton's (Palo Alto, Calif.) next-generation system, ProLipo *PLUS*, combines 1064 nm and 1319 nm wavelengths with TempASSURE, a temperature monitoring device that measures tissue temperature precisely and in real time. "These two devices allow physicians for the first time to have a quantitative clinical endpoint for melting fat and firming tissue," said Robert Ruck, Sciton's vice president of worldwide marketing.

The VASER System from Sound Surgical Technologies (Louisville, Colo.) is an all-inclusive, minimally invasive platform for infiltration, emulsification and aspiration. VASER uses ultrasound energy to break apart and emulsify fatty deposits, which are then removed from the body using proprietary, atraumatic aspiration cannulas. During the procedure, sometimes referred to as LipoSelection, energy is transmitted through small probes, between 2.2 mm and 3.7 mm wide, with special grooves that diffuse the ultrasound waves and liquefy the fat for easy removal. VASER enables the removal of small volumes of fat for precision contouring or larger volumes for rapid debulking. Clinical studies of the procedure have demonstrated excellent results. In one study involving 77 participants, satisfactory outcomes were reported in 100% of VASER treatments with no complications or retreatments.

"The VASER Lipo System is unlike any other device in that it emulsifies the fat and removes it in small clumps of cells," explained Robert Schwartz, M.D. "This emulsion re-injects more smoothly and easily than fat harvested via traditional liposuction." VASER also helps tighten the skin, with preliminary findings from a multi-center clinical study measuring post-operative skin retraction of 40% to 60%.

Syneron's (Irvine, Calif.) LipoLite is a laser-assisted lipolysis device that incorporates OptiPulse technology, which optimizes the mechanical breakdown of target tissue and the thermal destruction of fat cell membranes. OptiPulse utilizes two unique pulsed energy levels and repetition rates to provide physicians with precise control. Some physicians are combining LipoLite laser lipolysis with Syneron's VelaShape, a device that incorporates bi-polar RF energy with manual massage and infrared light energy. Syneron says that compared to a normal recovery period for liposuction alone, which could last up to six months, the recovery time of LipoLite combined with VelaShape is significantly shorter.

New devices are also being introduced for non-invasive fat removal. These devices use laser, light, radiofrequency and ultrasound energy, as well as massage, to address cellulite and subcutaneous fat in a completely non-invasive procedure.

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Before Tx



After SmoothShapes Tx

Photos courtesy of Kenneth Beer, M.D.

"In just a single session with Med Contour, the circumference of the treated area is visibly reduced and the skin is immediately given a smoother, more toned appearance."



Abdomen before Tx



Abdomen after Ultracontour Tx

Photos courtesy of Michael R. Schmidt-Kulbe, M.D.

Elemé Medical's SmoothShapes addresses cellulite and subcutaneous fat by combining light and laser energy with vacuum massage to stimulate natural cell processes and modify cellular activity. Shorter wavelength 650 nm light increases permeability of the fat cell membrane to allow lipids to be released from the cell; then longer wavelength 915 nm light penetrates the fat cells to be absorbed in lipids and liquefy the fat. Mechanical rollers exert suction and pressure to help expel liquefied lipids from the cells, improve circulation and skin elasticity. In addition, dual-band wavelengths stimulate collagen production in the dermis to improve skin firmness.

In one clinical study, 81% of participants experienced "significant volumetric reduction in subcutaneous fat," and 80% said they would definitely continue with a maintenance program. According to Marcel Besse, vice president of sales at Elemé, the device is particularly useful after other body shaping treatments. "SmoothShapes helps every body shaping device work better. It's one of the few systems that can address unevenness, such as cellulite, and repair defects from other body shaping treatments."

General Project (Montespertoli, Florence, Italy) offers three non-invasive body contouring devices: Slim Project, Med Sculpt and Med Contour. Slim Project is a massage device with an external ultrasonic option. During treatment, micro-processor-controlled action is performed on the skin through a membrane of elastomeric material made of synthetic rubber. The patient's skin is lifted, folded, pressed and stretched according to a computerized sequence, which can be adjusted depending on the pathology of the body area to be treated.

Med Sculpt is similar to Slim Project, allowing concomitant massage and ultrasound. The ultrasound and massaging actions produce both a thermic and cavitation effect. The final result is a more toned body, smoother, compact and younger skin, as well as circumference reduction. Med Contour is an ultrasonic device that delivers low frequency ultrasound energy to the area being treated. It incorporates two low frequency ultrasound waves for a more concentrated effect. Using vacuum-based technology, the device's handpiece lifts the adipose tissue and spreads it out at an angle to focus its action onto the tissue. "In just a single session, the circumference of the treated area is visibly reduced and the skin is immediately given a smoother, more toned appearance," stated Francesca Soggi, General Project's marketing manager.

In 2008, Medicis Technologies Corp. (Bothell, Wash.), introduced its first commercial device, LipoSonix, in Europe. This non-invasive body shaping system delivers high intensity, focused ultrasound energy (HIFU) across the skin's surface at a relatively low intensity and then focuses this energy in the subcutaneous fat. At the surface, the intensity of the ultrasound energy is low enough so that no damage occurs. However, this focused ultrasound beam provides high intensity beneath the skin to break down targeted adipose tissue. In clinical studies, average circumference reduction after treatment of the abdomen and waist was 5 cm and 6 cm, respectively, with treatment of the full abdomen performed in just 30 to 60 minutes. As of late 2009, Medicis was continuing to pursue FDA approval.

Ultracontour from MedixSysteme (Nimes, France) is a dual ultrasound device utilizing both HIFU and ultrasound-mediated vasodilation (UMD) for body shaping. The unit non-invasively applies energy below the surface of the skin in the subcutaneous tissue, targeting fat cells. Laetitia Poulencq, export director for the company notes that Ultracontour contains 18 transducers for multi-sequential lymphatic drainage. In one clinical study, patients experienced an average 5 cm reduction in body circumference following treatment. Another clinical study involving 56 patients reported up to a 10 cm reduction and 98% patient satisfaction. For best results, the company recommends three sessions within a period of 21 days. Ultracontour is currently sold in Europe, South America and Asia.

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Before Tx



After Accent^{XL} Tx

Photos courtesy of Ramon H. Rosado, M.D.



Before Tx



After Accent^{XL} Tx

Photos courtesy of Raald Varon, M.D.



Before Tx

Photos courtesy of Peter Hajduk, M.D.



After four Exilis treatments



Before Tx

Photos courtesy of Peter Hajduk, M.D.



After four Exilis treatments

In May 2009 Syneron introduced VelaShape II the next-generation version of their VelaShape. Compared to the original, the VelaShape II features increased power so more RF current reaches the fat, thus creating more heat. This results in shorter treatment times and a reduced number of sessions. An advanced diagnostic digital user interface improves both consistency in treatment results and patient comfort. With FDA clearance for temporary reduction of cellulite and thigh circumference, the system provides superior results due to its high power level, body specific vacuum optimization and electrode design.

Another, more established segment of body shaping is skin tightening. With a longer history of use, skin tightening treatments may be used to address laxity on the face or body.

Alma Lasers (Buffalo Grove, Ill.) offers the freestanding Accent^{XL}, featuring radiofrequency technology distributed through UniPolarTM, bi-polar, periorbital and UniLarge energy sources. In bi-polar mode, RF energy penetrates the skin superficially, facilitating the treatment of thinner, more delicate skin, such as areas of the face where the skin rests directly over the bone. Alma's proprietary UniPolar mode delivers RF energy deep into the dermal and subdermal layers to efficiently treat large volumes of tissue. Alma also obtained clearance for UniLarge, a high powered unipolar handpiece with a larger tip for faster body treatments. Unlike other RF based technologies, the Accent system does not require consumables, has dual modes, high power and requires no anesthesia.

Alma's proprietary UniPolar mode delivers RF energy deep into the dermal and subdermal layers to efficiently treat large volumes of tissue.

BTL (Prague, Czech Republic) offers Exilis, a non-invasive device for subcutaneous adipose tissue reduction and skin tightening. Exilis is based on the simultaneous delivery of monopolar RF and ultrasound energy through a single handpiece to reduce fat cells. The applicator tip is continuously cooled throughout treatment to protect the skin and permit effective heating of the subdermal fat layers. Re-shaping and volume reduction are achieved through targeted energy absorption and subsequent initiation of lipolytic processes and collagen remodeling.

Exilis offers sophisticated features that ensure precise control of energy flow to optimize safety and efficacy. Among its safety features are a Dermal Temperature Control (DTC) system and an Energy Flow Control (EFC) system. The procedure is considered painless and no consumables are required. "In my opinion, there is no other device available on the market today that can offer such a quick, effective and problem free aesthetic treatment. The procedure is easy to perform and patients are highly satisfied with the comfort and speed of the treatment, as well as the visible results," reported Peter Hajduk, M.D., head of the Aura Medical Clinic in Prague, Czech Republic.

First introduced in late 2004, Cutera's (Brisbane, Calif.) Titan is a module configured for the company's Xeo and Solera platforms. At the time of its launch, Titan was the first infrared light source for deep dermal heating. By affecting collagen denaturation, the system is able to reduce the appearance of wrinkles and tighten the skin. Cutera now offers three versions: Titan V, Titan XL and Titan S. The former has a treatment tip that extends beyond the handpiece housing to provide enhanced visibility of the skin's surface and effectively treat delicate areas such as the skin around the eyes and nose. Titan XL also has a treatment tip that extends beyond the housing for improved visibility; in addition, it has a larger spot size to treat larger body areas faster, such as the arms, abdomen and legs.

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Abdomen before Tx



Abdomen one month after one SkinTyte Tx
Photos courtesy of Marie N. DiLauro, M.D.



Abdomen before Tx



Abdomen after Thermage Tx
Photos courtesy of Ruth Hillelson, M.D.



Abdomen before Tx



Abdomen three months after Thermage Tx
Photos courtesy of Robert Weiss, M.D.

Palomar's LuxDeepIR handpiece delivers deep columns of infrared light beginning at 1 mm into the dermis (thus preserving the epidermis and upper dermis), and extending as far as 4 mm into the dermis and fat layer. LuxDeepIR incorporates several unique safety features, including a contact sensor attached to the handpiece tip, which prevents pulsing until the handpiece is in full contact with the skin. Once in contact, the handpiece delivers 3-Stage Contact Cooling before, during and after each pulse, with the handpiece tip cooled to 2° C to prevent skin damage. This device can tighten the skin through collagen stimulation. A multi-center study is underway to evaluate these changes, measuring collagen and elastin levels before and after treatment through histological and electron micrographic studies.

In late 2006, Sciton introduced the SkinTyte (ST) accessory for its BroadBand Light (BBL) system. The ST is used for selective photocoagulation of soft tissue to selectively target and treat dermal collagen, effecting collagen contraction. Used in conjunction with an integral thermo-electric cooler to cool the epidermis prior to, during and after treatment, patient discomfort is reduced and thermal injury to non-target structures is minimized. Since discomfort is minimal, many practitioners find they do not require an anesthetic. At 15 x 45 mm, the large spot size of the BBL enables quick treatment of large areas – up to 1.5 centimeters per second.

For smaller and/or hard to reach areas, the BBL has small, magnetically attached adapters sized at 15 x 15 mm. Patients typically see a 20% to 30% improvement, which occurs over a 30 to 60 day period following a set of three to four treatments. According to Mr. Ruck, "Patients attain excellent results on the abdomen in one treatment and many are treated on the face, neck and chest in combination with BBL phototherapy to enhance the effect."

Solta Medical's (Hayward, Calif.) Thermage system can be used for reduction of wrinkles, skin tightening and tissue contouring. Full-face clearance was first obtained in August 2004, expanding the device's original U.S. clearance obtained in 2002 for treatment of periorbital wrinkles and rhytides. Excellent results are possible due to its ability to treat deeper regions. "You can achieve tightening on the face from traditional ablative laser technologies, but with those modalities, you're only treating the top 300 to 400 microns of the skin," explained Kate Gilbert, managing director of product marketing and communications. "Thermage treats to a depth of several millimeters into the skin, deep into the dermis and subcutaneous tissue, to therapeutically produce a significant contouring effect on the face. It also addresses skin laxity on many areas of the body, which ablative lasers cannot address due to the risk of complications."

Solta has continued to roll out skin tightening applications for various body areas including the hands and abdomen. In October 2007, Thermage introduced the ThermoTip DC and Body Shape procedure to provide deeper heating into the subcutaneous layer for increased collagen tightening to shape the abdomen, love handles, thighs, buttocks and arms. In February 2008, the company launched the ThermoTip CL treatment tip for reduction of cellulite. Solta introduced a new treatment tip in January 2009 that offers five times the surface area coverage of its previous tips allowing practitioners to perform rapid body treatments.

Significant consumer interest in body shaping treatments is driving device manufacturers to invest considerably in the research and development of novel technologies to combat cellulite and fat. These emerging body shaping technologies appear promising.

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In one clinical study, patients lost an average of 3.64 inches from their waist, hips and thighs. Interestingly, clinical trials also found a 10% improvement in cholesterol and triglyceride levels.

Zerona from Erchonia (McKinney, Texas) is a non-invasive treatment utilizing a low intensity laser to emulsify adipose tissue and release it into the interstitial space. Excess fat is then passed through the body and eliminated naturally. The patient demographic for the procedure is broad, including persons of all skin types and weights, with a body mass index (BMI) of up to 35. The company recommends a series of six 40 minute treatments (20 minutes front, 20 minutes back) over a period of two weeks to change the way fat is processed by the body and achieve a lasting improvement.

In one clinical study, patients lost an average of 3.64 inches from their waist, hips and thighs. Interestingly, clinical trials also found a 10% improvement in cholesterol and triglyceride levels. Rather than charging a fixed price for the platform, the company is placing devices in medical offices in return for 30% of the average \$2,400 treatment fee. As of July 2009, Erchonia had signed agreements with 350 physicians and shipped 127 systems.

Zeltiq Aesthetics (Pleasanton, Calif.) is an early stage start-up focused on cryolipolysis. Cryolipolysis is a non-invasive means of cooling fat cells to induce lipolysis without damaging other structures such as nerves, muscles and bones. During the procedure, heat energy is precisely extracted from tissue, protecting the dermis but triggering fat cell death. Natural biological inflammatory processes then remove these dead cells over time. Zeltiq sales have begun outside the U.S. with its recent introduction in Europe. ■

PRODUCT PROFILES



VASER Lipo System

The VASER® Lipo System, from Sound Surgical Technologies, is an advanced ultrasonic technology that allows you to perform a wide-range of body contouring applications – from significant fat reduction to precise sculpting on all areas of the body. By selectively emulsifying fat cells prior to removal, the VASER Lipo System enables optimal control during the procedure and provides your patients with smooth, predictable results and minimal downtime. VASER Lipo continues to be a highly sought after procedure even in today's economy with thousands of patient inquiries each week.

Sound Surgical: 888-471-4777 or visit www.VASER.com



HydraFacial MD

HydraFacial MD® non-invasive, hydrating skin resurfacing treatments provide faster return on investment and excellent results on all skin types. With proven patient satisfaction and retention, this multi-modality system offers a turnkey solution to maximize service menu diversity. It can be offered as a stand-alone treatment or pre- and post intense pulsed light treatment. According to Glenn Weissman, M.D., "We have a case load of patients for the HydraFacial just by word-of-mouth. Our product sales and cross-selling to ancillary services also doubled after we offered the HydraFacial."

Edge Systems: 562-597-0102 or visit www.hydrafacial.com or www.edgesystem.net



QuadraLASE

The QuadraLASE fractional CO₂ laser incorporates QuadraSCAN™, an innovative scanning technology that helps to minimize heat build-up and enhance patient comfort. Practitioners can expect maximum performance and versatility across a wide-range of treatments. Equipped with both QS 300 µ and QD 180 µ handpieces, this system offers true variable depth ablation. QuadraLASE offers cost-effective operation for increased profit margins and outstanding Candela service and support to reduce downtime and increase throughput.

Candela: 800-668-2691 or visit www.quadralase.com