IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SYNERON MEDICAL LTD., CANDELA CORPORATION, AND MASSACHUSETTS GENERAL HOSPITAL	)	CIVIL ACTION NO. _____
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	
JEISYS MEDICAL, INC. AND PERIGEE MEDICAL LLC	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital (collectively, "Plaintiffs") bring this complaint for patent infringement against Defendants Jeisys Medical, Inc. ("Jeisys") and Perigee Medical LLC ("Perigee") (collectively, "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under 35 U.S.C. § 271, *et. seq.*, by Plaintiffs against Defendants for infringement of United States Patent Nos. 9,510,899 ("the '899 patent) and 9,095,357 ("the '357 patent") (collectively, "Patents-in-Suit") by making, using, offering to sell, selling and importing radio frequency micro-needle products, such as Jeisys' INTRAcel and INTRAcel Pro products.

THE PARTIES

2. Plaintiff Syneron Medical Ltd. is an Israeli company with a number of directly and indirectly owned U.S. subsidiaries, including co-plaintiff Candela Corp, acquired by Syneron in 2011. Syneron's principal place of business is Tavor Building, Industrial Zone, Yokneam Illit, 20692, Israel.

3. Syneron is a leading global aesthetic device company with a comprehensive product portfolio and a global distribution footprint. Its technology enables physicians to provide advanced solutions for a broad range of medical-aesthetic applications including body contouring, hair removal, wrinkle reduction, improving the skin's appearance through the treatment of superficial benign vascular and pigmented lesions, and the treatment of acne, leg veins and cellulite.

4. Syneron is the exclusive licensee of the two asserted patents for clinical applications.

5. Following its acquisition of Candela, a separate aesthetic device company, Syneron is sometimes referred to by the brand name "Syneron Candela." Syneron's United States operations are headquartered in Wayland, Massachusetts. Syneron also has operations in other facilities in the United States, including Irvine, California and San Jose, California, and has invested significant resources into domestic research, design, quality control, testing, and technical support for the products that embody the asserted patents.

6. Plaintiff Candela Corporation is a Delaware corporation. Candela's principal place of business is 530 Boston Post Road, Wayland, MA 01778. Candela is a wholly owned subsidiary of Syneron Medical Ltd. through several intervening corporate entities.

7. Plaintiff MGH is a not-for-profit corporation incorporated in the State of Massachusetts. Its principal place of business is located at 55 Fruit Street, Boston, Massachusetts 02114.

8. The inventions of the patents-in-suit were developed at MGH, which received the patent rights from its employee, inventor Dr. Deiter Manstein. MGH subsequently licensed the patented technology first to Candela, and after Candela's acquisition by Syneron, to Syneron. MGH, as the assignee of the two asserted patents, granted Syneron an exclusive license to the asserted patents in the clinical space, and receives ongoing royalties from Syneron for sales of the patented technology.

9. On information and belief, Jeisys is headquartered in Korea at 307 Daeryung Techno Town 8th Gamasan-ro 96, Geumcheon-Gu, Seoul 153-775. On information and belief, Jeisys designs and manufactures aesthetic dermatological devices, including RF micro-needle devices known as INTRAcel and INTRAcel Pro. On information and belief, Perigee Medical ("Perigee") is located at 2227 N Macarthur Dr., Tracy, CA 95376-2830. On information and belief, Perigree Medical distributes the Jeisys INTRAcel and INTRAcel Pro in the U.S. Collectively, Jeisys, Perigee, and their affiliates design, develop, import, and sell after importation the INTRAcel RF micro-needle devices, pictured below:

JURISDICTION AND VENUE

10. Plaintiffs bring this action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271 *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Defendants are subject to this Court's personal jurisdiction pursuant to due process and/or the Massachusetts Long Arm Statute due at least to their substantial presence and business in this State and judicial district, including: (A) at least part of their infringing activities, (B) regularly doing and/or soliciting business in Massachusetts, and (C) engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in Massachusetts. On information and belief, Defendants intentionally offer to sell, sell, and import radio frequency micro-needle products, such as INTRAcel and INTRAcel Pro products in Massachusetts.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

THE ASSERTED PATENTS[1]

The ’899 Patent

13. United States Patent No. 9,510,899, titled “Method and Apparatus for Dermatological Treatment and Tissue Reshaping” issued on December 6, 2016, to inventor Dieter Manstein. The ’899 patent issued from U.S. Application No. 14/458,644, filed on August 13, 2014. The ’899 patent is a continuation of U.S. Patent Application No. 12,914,201, filed on October 28, 2010, now U.S. Patent No. 9,095,357, which is a division of U.S. Patent Application No. 11/098,030, filed on April 1, 2005, now U.S. Patent No. 7,824,394. The ’899 patent claims priority to U.S. Provisional Application No. 60/558,476, filed on April 1, 2004. A true and correct copy of the ’899 patent is attached hereto as Exhibit 1.

14. MGH owns by assignment the entire right, title, and interest in and to the ’899 patent. Syneron is an exclusive licensee of the ’899 patent within a specific field of use.

The ’357 Patent

15. United States Patent No. 9,095,357, titled “Method and Apparatus for Dermatological Treatment and Tissue Reshaping” issued on August 4, 2015, to inventor Dieter Manstein. The ’357 patent issued from U.S. Application No. 12/914,201, filed on October 28, 2010. The ’357 patent is a division of U.S. Patent Application No. 11/098,030, filed on April 1, 2005, now U.S. Patent No. 7,824,394. The ’357 patent claims priority to U.S. Provisional Application No. 60/558,476, filed on April 1, 2004. A true and correct copy of the ’357 patent is attached hereto as Exhibit 2.

16. MGH owns by assignment the entire right, title, and interest in and to the ’357 patent. Syneron is an exclusive licensee of the ’357 patent within a specified field of use.

[1] No part of this complaint, including any sections herein or exhibit hereto, construes, or is intended to construe, the specification, file history, or claims of any of the asserted patents.

FACTUAL BACKGROUND

17. The technology at issue was invented, designed, prototyped, and developed in the United States, through the combined efforts of MGH (in Massachusetts), Candela and Primaeva Medical, Inc. (both in California).

18. The technology was first invented by Dr. Dieter Manstein, an Assistant Professor of Dermatology at MGH and Harvard University. Dr. Manstein, who received an M.D. and a Ph.D. in biomedical physics, is responsible for several ground-breaking developments in dermatology.

19. Dr. Manstein filed the first patent for the technology in 2004, and assigned the patent rights to his employer, MGH. In 2007, MGH originally licensed the exclusive rights to those patents in the clinical setting to Candela, who worked with Primaeva to develop the first working prototype. That same year, the prototype, known as Renasis, was used in clinical trials, demonstrating the effectiveness of the patented technology in treating wrinkles.

20. Starting in 2008, Primaeva worked on implementing the patented technology on a commercial level. The original commercialized product was referred to as Miratone. In 2009, Syneron acquired Primaeva and changed the product name from Miratone to ePrime. In early 2010, Syneron acquired Candela. Upon the latter acquisition, Syneron in 2011 entered into an amendment and restatement of the original MGH-Candela license, to effectively change the licensee from Candela to Syneron.

21. In 2011, ePrime received 510(k) clearance for wrinkle treatment from the U.S. Food and Drug Administration.

22. Ultimately, Syneron changed the name of the commercial patented product from ePrime to Profound, shown below:

23. Syneron's U.S. subsidiary, Candela, in addition to handling marketing and sales for Profound, employs dozens of people in the U.S. to install the patented product, train medical professionals on use of the patented system, service and repair the patented equipment, and perform research and development to improve the existing product.

24. The patented Profound product (and all the accused infringing products) are aesthetic medical devices that deliver radio frequency ("RF") energy through micro-needles to small, localized regions of the dermis, beneath the surface of the skin. This, in turn, causes a pattern of thermal damage in isolated regions within the dermis (fractional wounding). When the dermis is fractionally damaged by the energy emitted from the needles, the subsequent healing process results in the formation of new collagen, a volumizing agent that pushes out wrinkles and smooths the skin.

25. The patented Profound system—and Defendants' accused products—use a handheld applicator with a needle array located on a disposable tip. The handheld applicator is connected to a console containing an RF energy source and a controller, for supplying RF energy to the dermis through the needle tips.

26. The Profound system, the claimed inventions, and Defendants' accused products control application of RF energy through needles to the dermis to cause fractional wounding and

thereby promote improvement in skin aesthetics. Defendants' patent infringement has and will continue to adversely affect the success of the Profound product line, and has and will continue to adversely affect Syneron, Candela, and MGH.

27. Defendants import and sell the INTRAcel products to dermatologists and clinics throughout the U.S. Defendants advertise the use of the INTRAcel products throughout the U.S. on Perigee's website, including a section on customer testimonials describing the use of these products in U.S. practices. On information and belief, at least one dermatologist in Massachusetts advertises about providing a skin rejuvenation treatment using Defendants' INTRAcel products.

COUNT I: PATENT INFRINGEMENT OF U.S. PATENT NO. 9,510,899

28. On information and belief, the accused products that are made, used, sold, offered for sale, or imported within the United States after importation by Defendants infringe one or more claims of the '899 patent, either literally or under the doctrine of equivalents.

29. A claim chart that applies independent claims 1, 15, and 20 of the '899 patent to a representative accused product is attached to this Complaint as Exhibit 3.

30. On information and belief, Defendants directly infringe one or more claims of the '899 patent through their manufacture, use, sale, offer for sale, and importation of one or more accused products, in the United States.

31. On information and belief, Defendants knowingly and intentionally induce users of one or more of the accused products to directly infringe one or more claims of the '899 patent by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to end users who test and operate accused products at the direction of Defendants, to make, use (including testing those devices and methods), sell, offer to sell, or import one or more

of the accused products in the United States, in a manner that infringes the ’899 patent. Defendants have had knowledge and notice of the ’899 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the ’899 patent and with the intent, or willful blindness, that the induced acts directly infringe the ’899 patent.

32. On information and belief, Defendants also contribute to the infringement of one or more claims of the ’899 patent by making, using, selling, offering for sale, and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use. Defendants have had knowledge and notice of the ’899 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the ’899 patent and with the intent, or willful blindness, that they contribute to the direct infringement of the ’899 patent.

COUNT II: PATENT INFRINGEMENT OF U.S. PATENT NO. 9,095,357

33. On information and belief, the accused products that are made, used, sold, offered for sale, or imported within the United States after importation by Defendants infringe one or more claims of the ’357 patent, either literally or under the doctrine of equivalents.

34. A claim chart that applies independent claims 1, 12, and 17 of the ’357 patent to a representative accused product is attached to this Complaint as Exhibit 4.

35. On information and belief, Defendants directly infringe one or more claims of the ’357 patent through their manufacture, use, sale, offer for sale, and importation of one or more accused products, in the United States.

36. On information and belief, Defendants knowingly and intentionally induce users of one or more of the accused products to directly infringe one or more claims of the ’357 patent by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to end users who test and operate accused products at the direction of Defendants, to make, use (including testing those devices and methods), sell, offer to sell, or import one or more of the accused products in the United States, in a manner that infringes the ’357 patent. Defendants have had knowledge and notice of the ’357 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the ’357 patent and with the intent, or willful blindness, that the induced acts directly infringe the ’357 patent.

37. On information and belief, Defendants also contribute to the infringement of one or more claims of the ’357 patent by making, using, selling, offering for sale, and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use. Defendants have had knowledge and notice of the ’357 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the ’357 patent and with the intent, or willful blindness, that they contribute to the direct infringement of the ’357 patent.

JURY DEMAND

38. Pursuant to Federal Rules of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that the Court enter judgment in Plaintiffs' favor against Defendants, and provide Plaintiffs the following relief:

A. a finding that Defendants have infringed one or more claims of the Patents in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) and a final judgment incorporating the same;

B. a finding that Defendants' continued infringement of the Patents-in-Suit has been and is willful and/or an order increasing damages under 35 U.S.C. § 284;

C. equitable relief under 35 U.S.C. § 283, including, but not limited to, an injunction that enjoins Defendants and any of their officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from infringing, contributing to, and/or inducing infringement of the Patents-in-Suit;

D. an award of damages sufficient to compensate Plaintiffs for infringement of the Patents-in-Suit by Defendants through the date of judgment, including Plaintiffs' lost profits, together with prejudgment interest under 35 U.S.C. § 284;

E. entry of an order compelling Defendants to compensate Plaintiffs for any ongoing and/or future infringement of the Patents-in-Suit, in an amount and under terms appropriate under the circumstances, and payment of any supplemental damages as appropriate and post-judgment interest after the date of judgment under 35 U.S.C. § 284;

F. a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorney fees, costs, and expenses;

G. an accounting of Defendants' infringing activities through trial and judgment; and

H. such other relief that the Court deems just and proper.

Dated: April 9, 2018

Respectfully submitted,

/s/ Christopher S. Schultz

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EXHIBIT 1

U 7668839

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 22, 2018

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF:

U.S. PATENT: ***9,510,899***
ISSUE DATE: ***December 06, 2016***

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

SYLVIA HOLLEY
Certifying Officer

US009510899B2

(12) **United States Patent**
Manstein

(10) **Patent No.: US 9,510,899 B2**
(45) **Date of Patent: Dec. 6, 2016**

(54) **METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING**

(71) Applicant: **The General Hospital Corporation**, Boston, MA (US)

(72) Inventor: **Dieter Manstein**, Coral Gables, FL (US)

(73) Assignee: **The General Hospital Corporation**, Boston, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/458,644**

(22) Filed: **Aug. 13, 2014**

(65) **Prior Publication Data**

US 2014/0358069 A1 Dec. 4, 2014

Related U.S. Application Data

(60) Continuation of application No. 12/914,201, filed on Oct. 28, 2010, now Pat. No. 9,095,357, which is a (Continued)

(51) **Int. Cl.**
A61B 18/18 (2006.01)
A61B 18/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/1477*** (2013.01); ***A61B 18/18*** (2013.01); ***A61M 5/158*** (2013.01); *A61B 5/4893* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 18/18; A61B 2018/1495; A61B 2018/1869; A61B 2018/00571; A61B 2018/00577; A61B 2018/00589; A61B 2018/00607; A61B 2018/00636; A61B 2018/00696; A61B 2018/00702; A61B 18/14; A61B 2018/1452; A61B 2018/143; A61B 18/12; A61B 2018/1253; A61B 2018/1263
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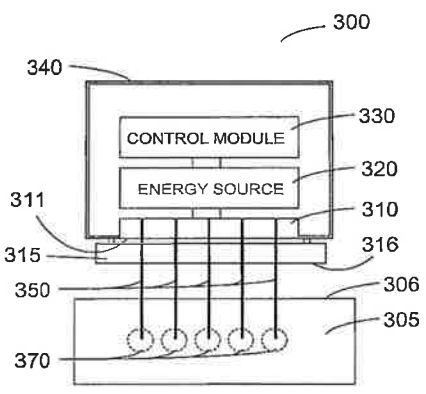
Primary Examiner — Ahmed Farah
(74) *Attorney, Agent, or Firm* — Quarles & Brady LLP

(57) **ABSTRACT**

The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

30 Claims, 4 Drawing Sheets



Related U.S. Application Data

division of application No. 11/098,030, filed on Apr. 1, 2005, now Pat. No. 7,824,394.

(60) Provisional application No. 60/558,476, filed on Apr. 1, 2004.

(51) **Int. Cl.**

A61M 5/158	(2006.01)
A61B 5/00	(2006.01)
A61B 18/00	(2006.01)
A61B 18/20	(2006.01)
A61B 18/22	(2006.01)

(52) **U.S. Cl.**

CPC *A61B 2018/00005* (2013.01); *A61B 2018/0016* (2013.01); *A61B 2018/0019* (2013.01); *A61B 2018/00452* (2013.01); *A61B 2018/143* (2013.01); *A61B 2018/2005* (2013.01); *A61B 2018/2211* (2013.01); *A61M 2202/048* (2013.01)

(58) **Field of Classification Search**

USPC 606/27, 28, 31, 32, 41–50; 607/6, 607/100–102, 108–112; 604/20, 21; 128/898

See application file for complete search history.

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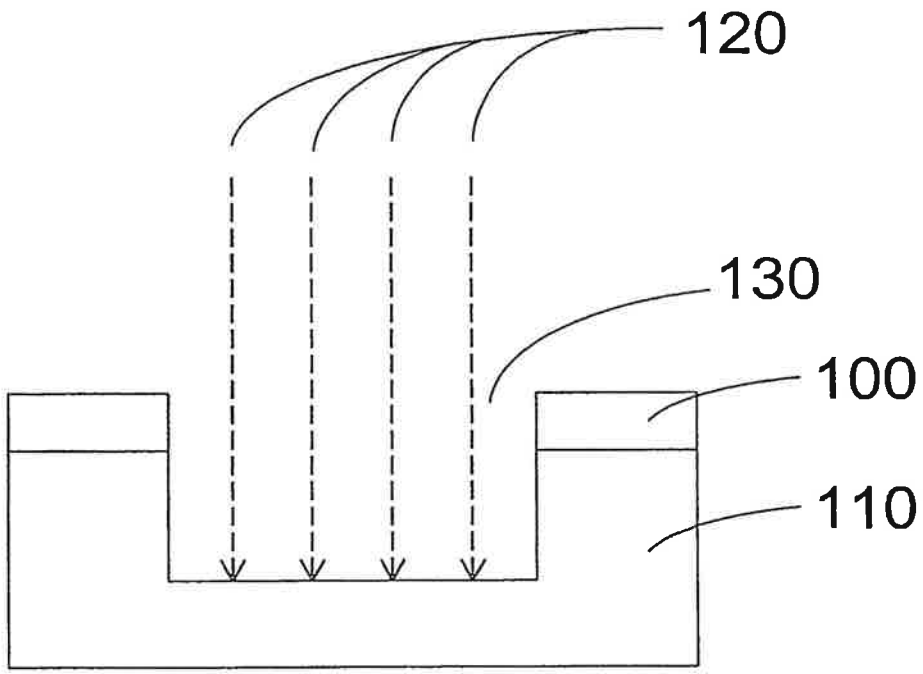

FIG. 1

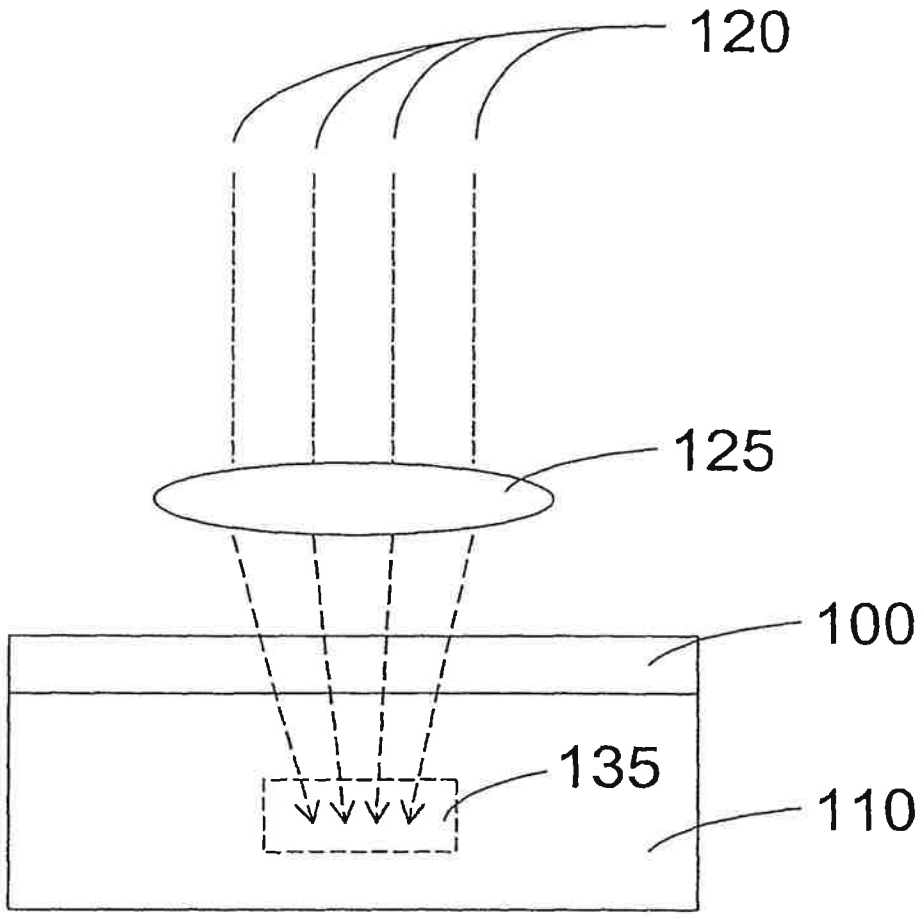

FIG. 2

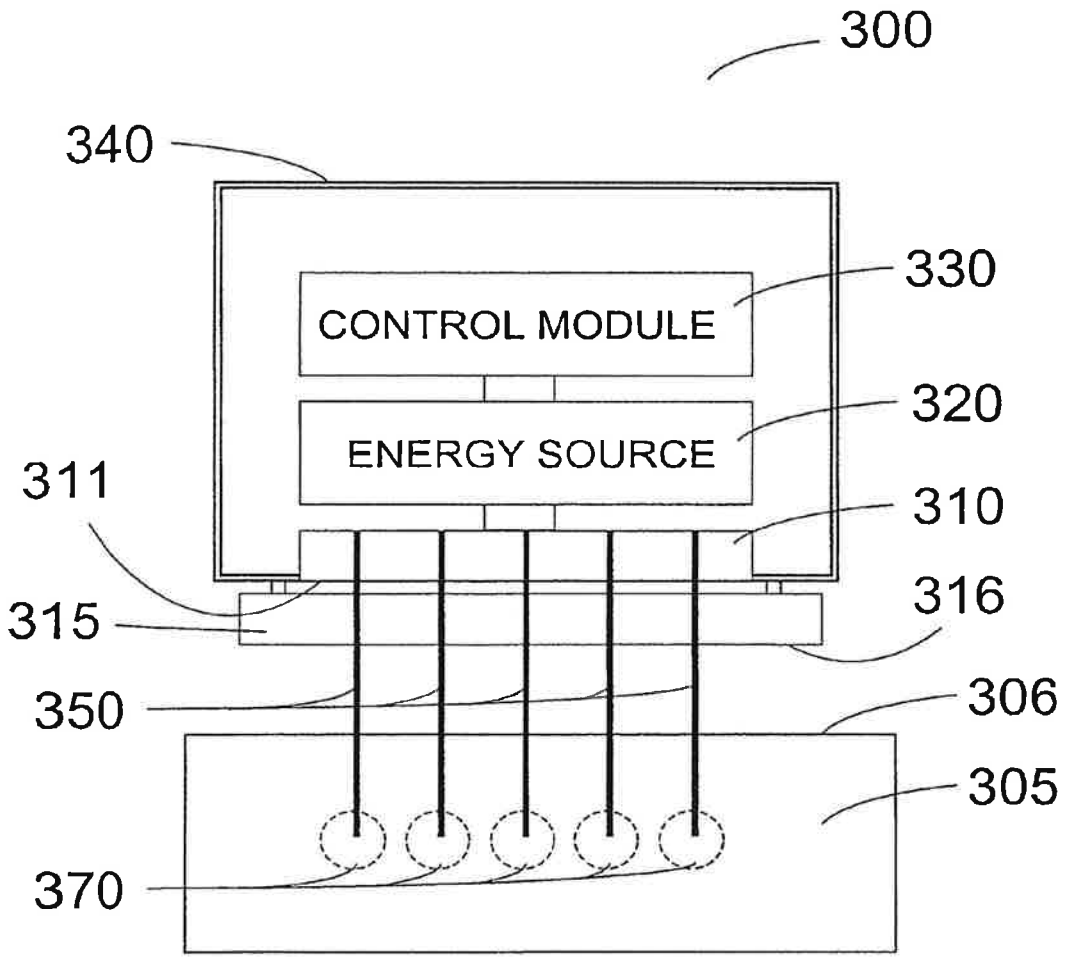

FIG. 3

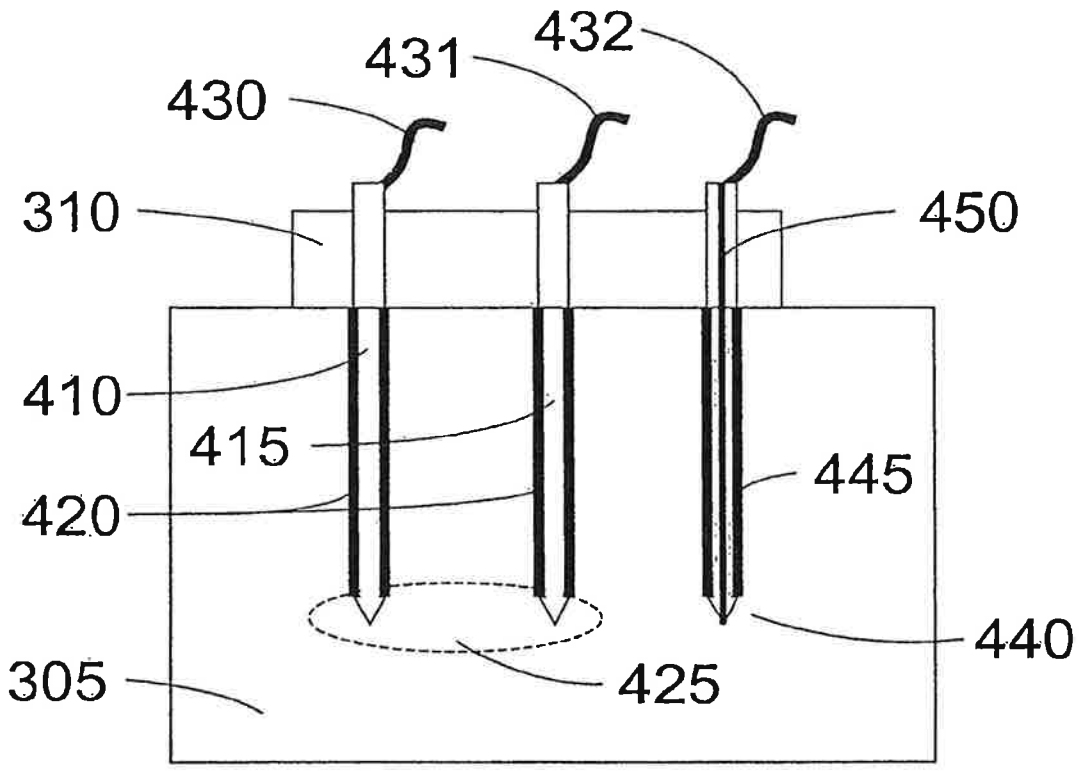

FIG. 4

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

RELATED APPLICATIONS

The present application is a continuation of U.S. application Ser. No. 12/914,201, filed on Oct. 28, 2010, which is a division of U.S. application Ser. No. 11/098,030, filed on Apr. 1, 2005, now issued as U.S. Pat. No. 7,824,394. This application also claims priority to U.S. Provisional Application No. 60/558,476 filed on Apr. 1, 2004. The entire disclosures of such applications are incorporated herein by reference.

INCORPORATION BY REFERENCE

The foregoing applications, and all documents cited therein or during their prosecution ("appln cited documents") and all documents cited or referenced in the appln cited documents, and all documents cited or referenced herein ("herein cited documents"), and all documents cited or referenced in herein cited documents, together with any manufacturer's instructions, descriptions, product specifications, and product sheets for any products mentioned herein or in any document incorporated by reference herein, are hereby incorporated herein by reference, and may be employed in the practice of the invention.

FIELD OF THE INVENTION

The present invention is directed to an improved method for treatment of skin and other tissues. More specifically, it is directed to a method of fractional wounding using arrays of needles to damage selected regions of the skin or subdermal tissue and thereby promote beneficial results including skin tightening and tissue remodeling.

BACKGROUND OF THE INVENTION

Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of approximately 100 μm. The inner layer, or dermis, has depth of approximately 3000 μm from the outer surface of the skin and is primarily composed of a network of fibrous protein known as collagen.

There is an increasing demand for repair of skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There are several well-known surgical approaches to improving the appearance of skin that involve incisions being made in the skin followed by the removal of some tissue and rejoining of the remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and "tummy tucks." Such approaches have many negative side effects including scar formation, long healing times, displacement of skin from its original location relative to the underlying bone structure, and nonuniform skin tightening.

Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in FIG. **1**, a region of the epidermis **100** and a corresponding region of the dermis **110** beneath it are thermally damaged to promote wound healing. Electromagnetic energy **120** is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region **130**. LSR with pulsed CO_2 or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in FIG. **2**, selective portions of dermal tissue **135** within the dermal layer **110** are heated to induce wound healing without damaging the epidermis **100** above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy **120**, which may be a laser beam, onto dermal region **135** using lens **125**. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR proce-

dures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO_2 lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliampere range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the

specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

FIG. **1** is a schematic drawing of a cross section of a tissue treated using the ASR method.

FIG. **2** is a schematic drawing of a cross section of a tissue treated using the NSR method.

FIG. **3** is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

FIG. **4** is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus **300** shown in FIG. **3** may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles **350** attached to a base **310**. The base is attached to housing **340** or formed as a part of the housing. A source of RF 21' current **320** is electrically connected to each of the needles **350**. A control module **330** permits variation of the characteristics of the RF electrical current, which can be supplied individually to one or more of the needles. Optionally, energy source **320** and/or control module **330** may be located outside of the housing.

In one exemplary embodiment, the energy source **320** is a radio frequency (RF) device capable of outputing signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module **330** provides application-specific settings to the energy source **320**. The energy source **320** receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate **315** containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base **310** and the surface of the skin **306**. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base **310** or housing **340** and adjustable with respect to base **310**, supporting the array of needles to control the depth of the needles protruding from the lower surface **316** of spacer substrate **315**, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles **350** pierce the surface **306** of skin tissue **305** and are inserted into the tissue until the bottom surface **316** of spacer substrate **315** (or the bottom surface **311** of base **310** if a spacer substrate **315** is not used) contacts the surface **306** of the skin **305**. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module **330** is then configured to deliver controlled amounts of RF current to one or more needles **350**.

Base **310** and/or spacer substrate **315**, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base **310** and/or a spacer substrate **315**, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

In a preferred embodiment of the present invention, the shafts of conductive needles **350** are electrically insulated except for the portion of the needle near the tip. In the apparatus of FIG. **3**, application of RF current to the needles **350** causes heating in the exposed tip region, inducing thermal damage regions **370** around the tip of each needle. Thermal damage regions **370** result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in FIG. **3**, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles **350** by energy source **320**. In this monopolar configuration, RF current causes heating of the tip regions of the needles **350**, generating thermal damage in tissue regions **370** adjacent to the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module **330** and energy source **320** can be configured to supply electrical current to individual needles, to specific groups of needles within the array, or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing **340** and/or base **310** that supports the array of needles **350**. Vibrations conductively induced in needles **350** by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue.

The vibrating means can have an amplitude of vibration in the range of about 50-500 μm or, more preferably, between about 100-200 μm. The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in FIG. **4**. Conductive needles **410** and **415** are shown attached to base **310**. Insulation **420** covers the shaft of needles **410** and **415** protruding from base **310** except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue **305**. Electrical conductors **430** and **431**, which may be wires or the like, extend from an upper portion of needles **410** and **415** respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation **420** include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be chosen as an insulator to facilitate penetration and insertion of needles **410** and **415** into tissue **305**.

Needles **410** and **415** are shown operating in bipolar mode in another embodiment of the present invention. Needle **410** is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor **430**. Needle **415** functions as a grounding electrode that is connected to the ground of the energy source via conductor **431**. In this configuration the applied current will travel through the tissue between the tips of needles **410** and **415**, generating an elongated region of thermal damage **425** around and between the tips of the two needles.

An elongated region of damaged tissue **425** can be created between any two adjacent or nearby needles in the array through proper configuration of control module **330** and energy source **320**. In an embodiment of the present invention, elongated damage regions **425** are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue **305**. The regions of thermal damage **325** created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source **320** and control module **330** to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue **305** that may be macroscopically elongated in preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damagng the tissue. A typical depth for targeting collagen in the dermis is about 1500-2000 μm, although shallower or deeper distances may be preferred for different treatments and regions of the body being treated. Needles within a single array may protrude by different lengths from the base **310** or spacer substrate **315**. This will cause the tips of the needles to be positioned at different depths within the tissue being treated, and allow creation of damaged tissue at more than one depth. This variation in needle depth can achieve formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1 mm apart, and may be as large as about 2 cm. The spacing between needles in an array need not be uniform, and can be closer in areas where a greater amount of damage or more precise control of damage in the target area of tissue is desired. In one embodiment, the array of needles may comprise pairs of needles separated from adjacent pairs by larger distances. This geometry may be well-suited for inducing damage in bipolar mode between pairs of needles. Needles may also be arranged in a regular or near-regular square or triangular array. In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

The amount of energy directed to a given needle will vary depending on the tissue being treated and the desired extent of thermal damage to induce. For typical needle spacings noted above, the energy source should be configured to deliver about 1-100 mJ per needle or pair of needles in the array. It may be preferable to initially use lower amouns of energy and perform two or more treatments over the same target area to better control the damage pattens and extent of reshaping.

In yet another embodiment of the present invention, one or more of the needles in the array may be hollow, such as needle **440** in FIG. **4**. Center channel **450** may be used to deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located within or above base **310** into the tissue **305** to reduce or eliminate pain caused by the thermal damage process.

In yet another embodiment of the present invention, hollow needle **440** is bifunctional, capable of conducting RF current or other energy via conductor **432** and also capable of delivering a local analgesic or the like through center channel **450**. Similar to needles **410** and **415**, bifunctional needle **440** has insulation **445** covering the shaft extending from base **310** except for the region near the lower tip. Analgesic may be supplied to the tissue either before or during application of RF or other current to the needle **450**.

In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle **440**. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve

near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliampere range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module **330** can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmey et al. in Regional Anesthesia and Pain Medicine 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He—Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C. can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

The invention is further described by the following numbered paragraphs:

1. A tissue reshaping apparatus comprising:
   - a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
   - an energy source in communication with one or more of the needles; and
   - optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

2. The apparatus of paragraph 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.

3. The apparatus of paragraph 2 wherein the energy source and/or control module is located outside of the housing.

4. The appratus of any one of paragraphs 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputing signals having frequencies in a desired range.

5. The apparatus of any one of paragraphs 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.

6. The apparatus of any one of paragraphs 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.

7. The apparatus of any one of paragraphs 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.

8. The apparatus of any one of paragraphs 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.

9. The apparatus of any one of paragraphs 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.

10. The apparatus of paragraph 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

11. The apparatus of any one of paragraphs 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of paragraphs 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface.

13. The apparatus of paragraph 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of paragraphs 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus paragraph 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus paragraph 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm.

19. The apparatus of any one of paragraphs 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode.

20. The apparatus of any one of paragraphs 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm.

21. The apparatus of any one of paragraphs 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of paragraphs 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

23. The apparatus of any of paragraphs 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of paragraph 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of paragraphs 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of paragraph 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He—Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:

providing a plurality of needles attached to a base;

providing an energy source in communication with one or more of the needles;

inserting the needles into the skin to a predetermined depth; and

supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of paragraph 27 further comprising:

providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of paragraph 28 further comprising:

providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of paragraph 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of paragraph 30 further comprising:

providing a detection device in communication with one or more of the needles;

supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and

preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of paragraph 27 further comprising:

providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

33. The method of paragraph 29 further comprising:

providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

What is claimed is:

1. A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

2. The device of claim **1**, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.

3. The device of claim **1**, wherein at least one of the plurality of needles is a mono-polar needle.

4. The device of claim **1**, wherein the control module is further configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

5. The device of claim **1**, wherein at least two of the plurality of needles have differing lengths.

6. The device of claim **1**, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

7. The device of claim 1, wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

8. The device of claim 1, further comprising a detector for detecting a presence of a nerve near a tip of at least one of the plurality of needles.

9. The device of claim 1, further comprising a spacer having holes through which the needles are configured to move.

10. The device of claim 1, wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.

11. The device of claim 1, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.

12. The device of claim 1, further comprising a vibrator for vibrating at least one of the plurality of needles.

13. The device of claim 12, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

14. The device of claim 12, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm.

15. A skin treatment device, comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

16. The device of claim 1, wherein the control module is configured to cause necrosis in the dermal layer.

17. The device of claim 15, further comprising a vibrator for vibrating at least one of the plurality of needles.

18. The device of claim 17, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

19. The device of claim 17, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm.

20. A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and undamaged regions between bipolar pairs of needles in the group.

21. The device of claim 20, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.

22. The device of claim 20, wherein the control module is configured to cause necrosis.

23. The device of claim 20, further comprising a vibrator for vibrating at least one of the plurality of needles.

24. The device of claim 23, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

25. The device of claim 23, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm.

26. A skin treatment device comprising:

a housing configured to support a plurality of monopolar needles arranged for insertion into a dermal layer of skin, the plurality of monopolar needles being attached to a base and configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions in a vicinity of each tip of each of the plurality of monopolar needles, and undamaged regions between the damaged regions.

27. The device of claim 26, wherein the control module is configured to cause necrosis.

28. The device of claim 26, further comprising a vibrator for vibrating at least one of the plurality of needles.

29. The device of claim 28, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

30. The device of claim 28, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,510,899 B2
APPLICATION NO. : 14/458644
DATED : December 6, 2016
INVENTOR(S) : Dieter Manstein

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 5, Line 46 change "RF 21' current" to --RF current--

Signed and Sealed this
Sixteenth Day of May, 2017

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office

U.S. DEPARTMENT OF COMMERCE
U.S. PATENT & TRADEMARK OFFICE

EXHIBIT 2

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February 22, 2018

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF:

U.S. PATENT: ***9,095,357***
ISSUE DATE: ***August 04, 2015***

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(12) **United States Patent**
Manstein

(10) **Patent No.: US 9,095,357 B2**
(45) **Date of Patent: Aug. 4, 2015**

(54) **METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING**

(75) Inventor: **Dieter Manstein**, Miami, FL (US)

(73) Assignee: **The General Hospital Corporation**, Boston, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1294 days.

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(58) **Field of Classification Search**
CPC A61B 18/00; A61B 18/04; A61B 18/14; A61B 18/1477; A61B 2018/00315; A61B 2018/00452; A61B 2018/1425; A61B 2018/143; A61B 2018/00005; A61B 2018/0019
USPC 606/27, 28, 31, 32, 41–50; 607/96, 607/100–102, 108–112; 128/898
See application file for complete search history.

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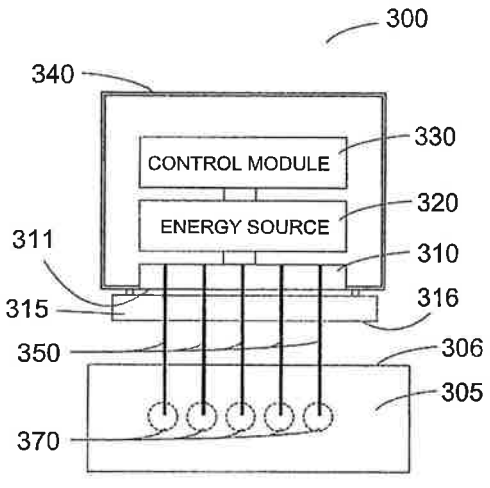
Primary Examiner — Ahmed Farah
(74) *Attorney, Agent, or Firm* — Quarles & Brady, LLP

(57) **ABSTRACT**

The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

21 Claims, 4 Drawing Sheets



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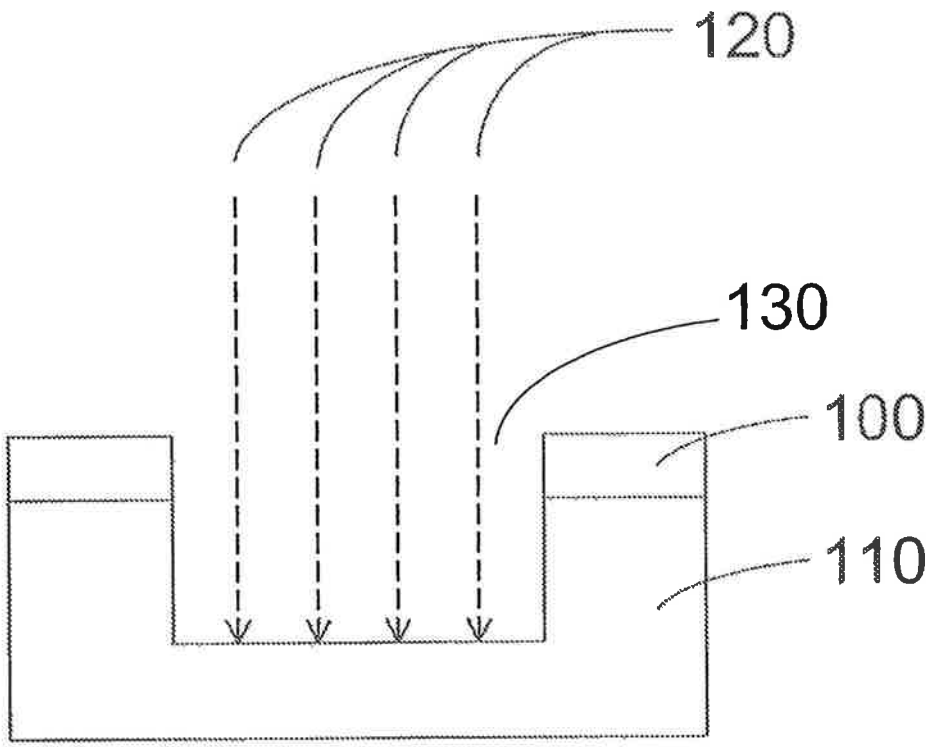


FIG. 1

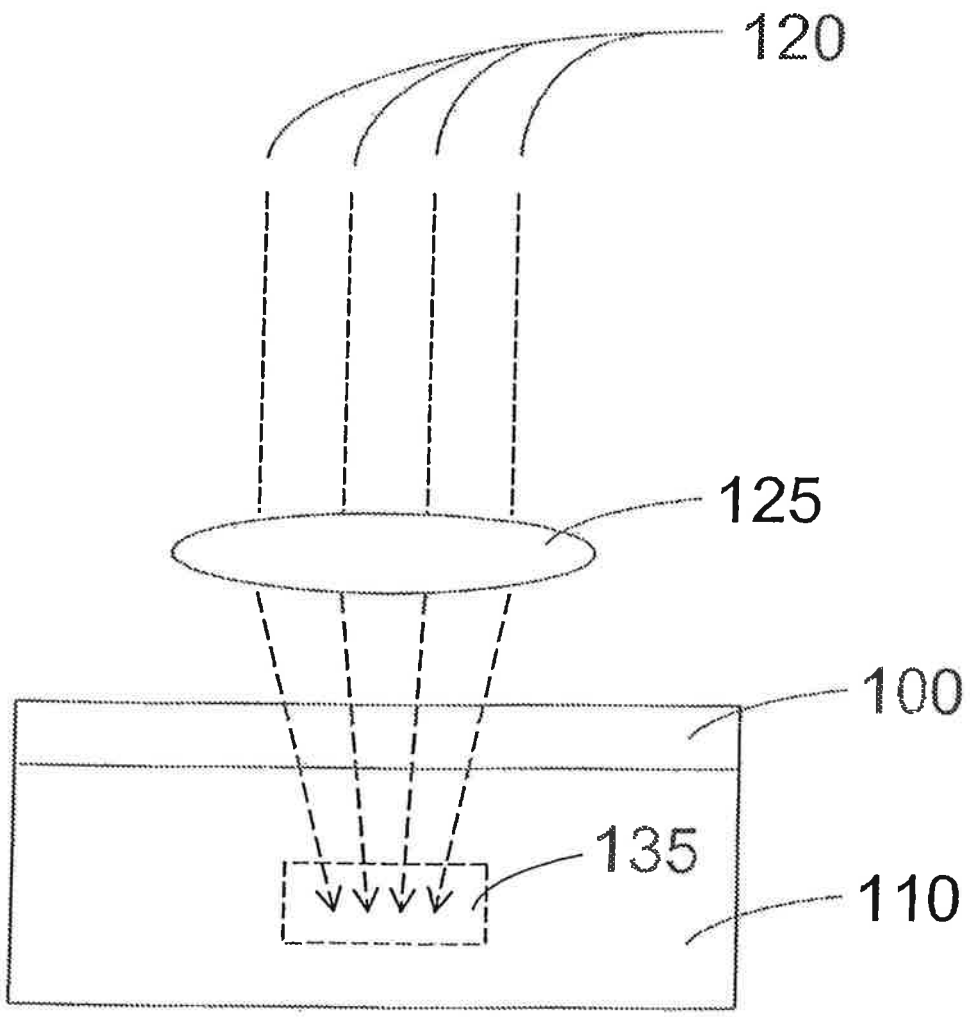


FIG. 2

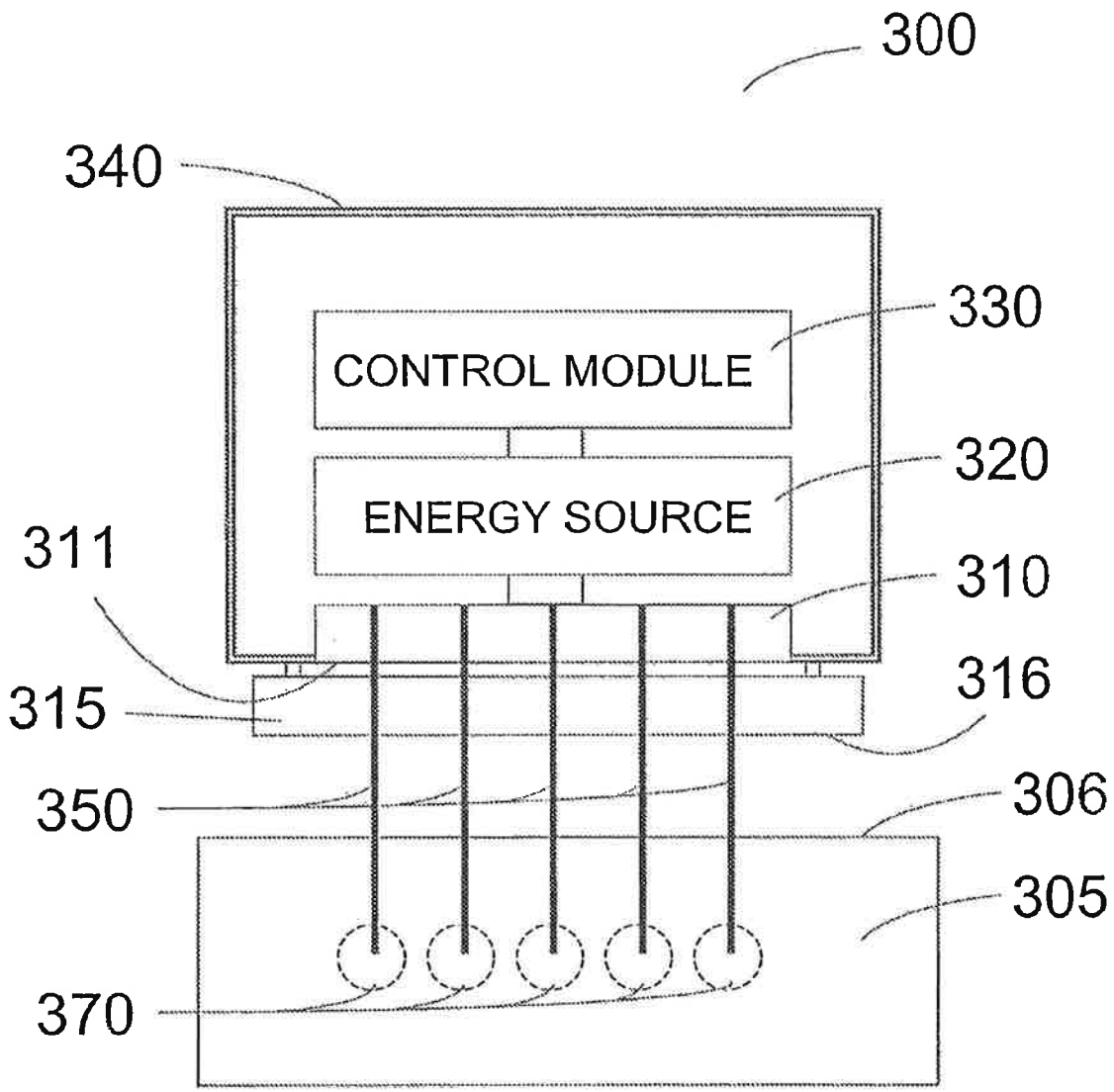


FIG. 3

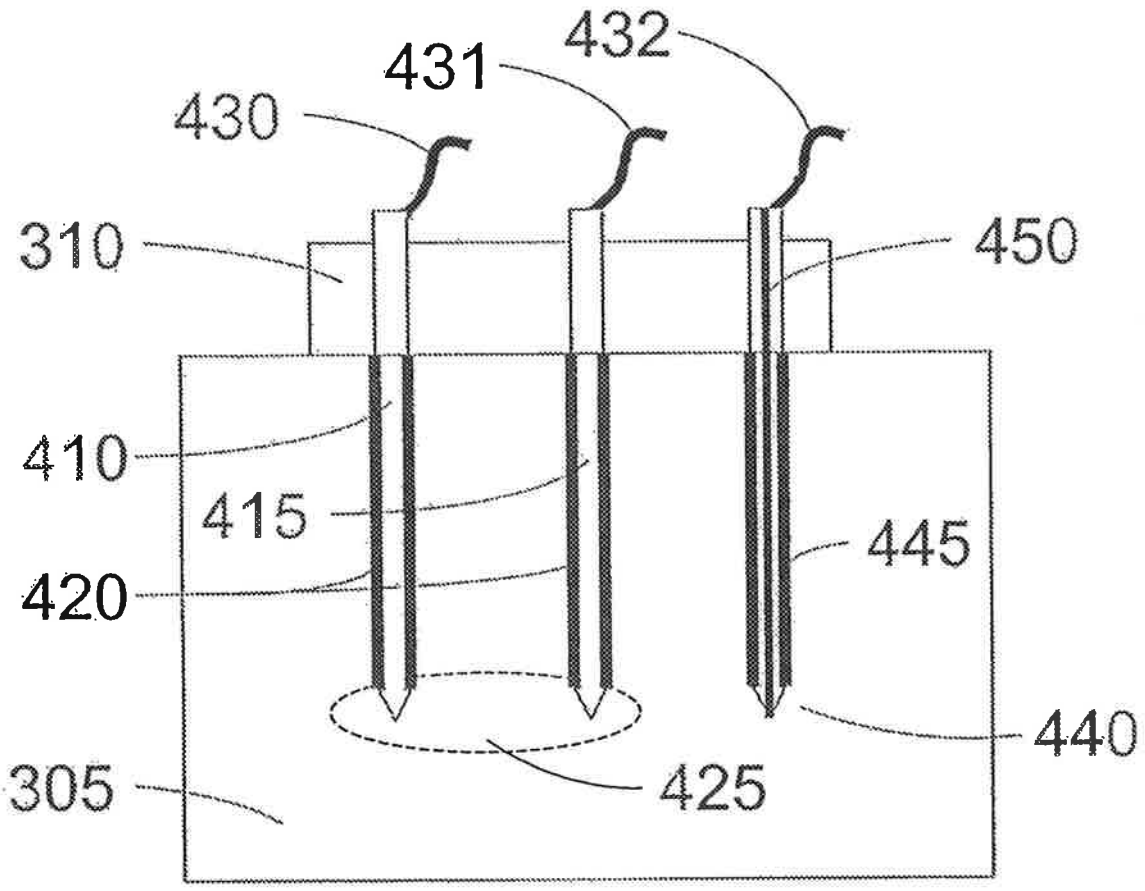


FIG. 4

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

RELATED APPLICATIONS

The present application is a divisional of U.S. patent application Ser. No. 11/098,030 filed on Apr. 1, 2005. This application also claims priority to U.S. provisional Application Ser. No. 60/558,476 filed on Apr. 1, 2004.

INCORPORATION BY REFERENCE

The foregoing applications, and all documents cited therein or during their prosecution ("appln cited documents") and all documents cited or referenced in the appln cited documents, and all documents cited or referenced herein ("herein cited documents"), and all documents cited or referenced in herein cited documents, together with any manufacturer's instructions, descriptions, product specifications, and product sheets for any products mentioned herein or in any document incorporated by reference herein, are hereby incorporated herein by reference, and may be employed in the practice of the invention.

FIELD OF THE INVENTION

The present invention is directed to an improved method for treatment of skin and other tissues. More specifically, it is directed to a method of fractional wounding using arrays of needles to damage selected regions of the skin or subdermal tissue and thereby promote beneficial results including skin tightening and tissue remodeling.

BACKGROUND OF THE INVENTION

Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of approximately 100 μm. The inner layer, or dermis, has depth of approximately 3000 μm from the outer surface of the skin and is primarily composed of a network of fibrous protein known as collagen.

There is an increasing demand for repair of skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There are several well-known surgical approaches to improving the appearance of skin that involve incisions being made in the skin followed by the removal of some tissue and rejoining of the remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and "tummy tucks." Such approaches have many negative side effects including scar formation, long healing times, displacement of skin from its original location relative to the underlying bone structure, and nonuniform skin tightening.

Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in FIG. **1**, a region of the epidermis **100** and a corresponding region of the dermis **110** beneath it are thermally damaged to promote wound healing. Electromagnetic energy **120** is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region **130**. LSR with pulsed CO_2 or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in FIG. **2**, selective portions of dermal tissue **135** within the dermal layer **110** are heated to induce wound healing without damaging the epidermis **100** above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy **120**, which may be a laser beam, onto dermal region **135** using lens **125**. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR procedures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the nonablative laser to have a deeper penetration depth than the very

superficially-absorbed ablative Er:YAG and CO_2 lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliampere range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

FIG. **1** is a schematic drawing of a cross section of a tissue treated using the ASR method.

FIG. **2** is a schematic drawing of a cross section of a tissue treated using the NSR method.

FIG. **3** is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

FIG. **4** is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus **300** shown in FIG. **3** may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles **350** attached to a base **310**. The base is attached to housing **340** or formed as a part of the housing. A source of RF current **320** is electrically connected to each of the needles **350**. A control module **330** permits variation of the characteristics of the RF electrical current, which can be supplied individually to one or more of the needles. Optionally, energy source **320** and/or control module **330** may be located outside of the housing.

In one exemplary embodiment, the energy source **320** is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module **330** provides application-specific settings to the energy source **320**. The energy source **320** receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate **315** containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base **310** and the surface of the skin **306**. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base **310** or housing **340** and adjustable with respect to base **310**, supporting the array of needles to control the depth of the needles protruding from the lower surface **316** of spacer substrate **315**, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles **350** pierce the surface **306** of skin tissue **305** and are inserted into the tissue until the bottom surface **316** of spacer substrate **315** (or the bottom surface **311** of base **310** if a spacer substrate **315** is not used) contacts the surface **306** of the skin **305**. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module **330** is then configured to deliver controlled amounts of RF current to one or more needles **350**.

Base **310** and/or spacer substrate **315**, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base **310** and/or a spacer substrate **315**, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

In a preferred embodiment of the present invention, the shafts of conductive needles **350** are electrically insulated except for the portion of the needle near the tip. In the apparatus of FIG. **3**, application of RF current to the needles **350** causes heating in the exposed tip region, inducing thermal damage regions **370** around the tip of each needle. Thermal damage regions **370** result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in FIG. **3**, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles **350** by energy source **320**. In this monopolar configuration, RF current causes heating of the tip regions of the needles **350**, generating thermal damage in tissue regions **370** adjacent to the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module **330** and energy source **320** can be configured to supply electrical current to individual needles, to specific groups of needles within the array, or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing **340** and/or base **310** that supports the array of needles **350**. Vibrations conductively induced in needles **350** by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue. The vibrating means can have an amplitude of vibration in the range of about 50-500 μm or, more preferably, between about 100-200 μm. The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in FIG. **4**. Conductive needles **410** and **415** are

shown attached to base **310**. Insulation **420** covers the shaft of needles **410** and **415** protruding from base **310** except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue **305**. Electrical conductors **430** and **431**, which may be wires or the like, extend from an upper portion of needles **410** and **415** respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation **420** include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be chosen as an insulator to facilitate penetration and insertion of needles **410** and **415** into tissue **305**.

Needles **410** and **415** are shown operating in bipolar mode in another embodiment of the present invention. Needle **410** is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor **430**. Needle **415** functions as a grounding electrode that is connected to the ground of the energy source via conductor **431**. In this configuration the applied current will travel through the tissue between the tips of needles **410** and **415**, generating an elongated region of thermal damage **425** around and between the tips of the two needles.

An elongated region of damaged tissue **425** can be created between any two adjacent or nearby needles in the array through proper configuration of control module **330** and energy source **320**. In an embodiment of the present invention, elongated damage regions **425** are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue **305**. The regions of thermal damage **325** created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source **320** and control module **330** to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue **305** that may be macroscopically elongated in preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm. Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damaging the tissue. A typical depth for targeting collagen in the dermis is about 1500-2000 μm, although shallower or deeper distances may be preferred for different treatments and regions of the body being treated. Needles within a single array may protrude by different lengths from the base **310** or spacer substrate **315**. This will cause the tips of the needles to be positioned at different depths within the tissue being treated, and allow creation of damaged tissue at more than one depth. This variation in needle depth can achieve formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1 mm apart, and may be as large as about 2 cm. The spacing between needles in an array need not be uniform, and can be closer in areas where a greater amount of damage or more precise control of damage in the target area of tissue is desired. In one embodiment, the array of needles may comprise pairs of needles separated from adjacent pairs by larger distances. This geometry may be well-suited for inducing damage in bipolar mode between pairs of needles. Needles may also be arranged in a regular or near-regular square or triangular array. In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

The amount of energy directed to a given needle will vary depending on the tissue being treated and the desired extent of thermal damage to induce. For typical needle spacings noted above, the energy source should be configured to deliver about 1-100 mJ per needle or pair of needles in the array. It may be preferable to initially use lower amounts of energy and perform two or more treatments over the same target area to better control the damage patterns and extent of reshaping.

In yet another embodiment of the present invention, one or more of the needles in the array may be hollow, such as needle **440** in FIG. **4**. Center channel **450** may be used to deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located within or above base **310** into the tissue **305** to reduce or eliminate pain caused by the thermal damage process.

In yet another embodiment of the present invention, hollow needle **440** is bifunctional, capable of conducting RF current or other energy via conductor **432** and also capable of delivering a local analgesic or the like through center channel **450**. Similar to needles **410** and **415**, bifunctional needle **440** has insulation **445** covering the shaft extending from base **310** except for the region near the lower tip. Analgesic may be supplied to the tissue either before or during application of RF or other current to the needle **450**.

In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle **440**. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliampere range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module **330** can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmey et al. in Regional Anesthesia and Pain Medicine 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber

or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He—Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C. can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

The invention is further described by the following numbered paragraphs:

1. A tissue reshaping apparatus comprising:
   a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
   an energy source in communication with one or more of the needles; and
   optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

2. The apparatus of paragraph 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.

3. The apparatus of paragraph 2 wherein the energy source and/or control module is located outside of the housing.

4. The apparatus of any one of paragraphs 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range.

5. The apparatus of any one of paragraphs 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.

6. The apparatus of any one of paragraphs 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.

7. The apparatus of any one of paragraphs 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.

8. The apparatus of any one of paragraphs 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.

9. The apparatus of any one of paragraphs 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.

10. The apparatus of paragraph 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

11. The apparatus of any one of paragraphs 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of paragraphs 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminates pain when the plurality of needles penetrates the skin surface.

13. The apparatus of paragraph 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of paragraphs 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus paragraph 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus paragraph 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm.

19. The apparatus of any one of paragraphs 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode.

20. The apparatus of any one of paragraphs 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm.

21. The apparatus of any one of paragraphs 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of paragraphs 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

23. The apparatus of any of paragraphs 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of paragraph 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of paragraphs 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of paragraph 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He—Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:

providing a plurality of needles attached to a base;

providing an energy source in communication with one or more of the needles;

inserting the needles into the skin to a predetermined depth; and

supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of paragraph 27 further comprising:

providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of paragraph 28 further comprising:

providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of paragraph 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of paragraph 30 further comprising:

providing a detection device in communication with one or more of the needles;

supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and

preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of paragraph 27 further comprising:

providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

33. The method of paragraph 29 further comprising:

providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

What is claimed is:

1. A skin treatment method comprising:

inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the regulation of the delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

2. The method of claim **1**, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein regulating the delivery of the RF energy includes controlling the RF energy being delivered to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.

3. The method of claim **1**, wherein at least one of the plurality of needles is a mono-polar needle.

4. The method of claim **1**, further comprising selecting an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

5. The method of claim **1**, wherein at least two of the plurality of needles have differing lengths.

6. The method of claim **1**, further comprising cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

7. The method of claim **1**, wherein at least one of the plurality of needles is a hollow needle, and further comprising delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

8. The method of claim **1**, further comprising detecting a presence of a nerve near a tip of at least one of the plurality of needles.

9. The method of claim **1**, wherein inserting the plurality of needles into the dermal layer of skin comprises passing the plurality of needles through a plurality of holes formed in a spacer disposed between the base and a surface of the dermal layer of skin, wherein the plurality of needles are movable relative to the spacer.

10. The method of claim **1**, wherein regulating delivery of RF energy further includes inducing damaged regions surrounding each tip of each of the plurality of needles, with substantially undamaged regions between the damaged regions.

11. The method of claim **1**, wherein each of the needles has a tip, wherein the pattern of fractional damage includes at least two adjacent regions of thermal damage, and wherein

each adjacent region of thermal damage includes a small localized area of thermal damage surrounding each tip.

12. A skin treatment method, comprising:

inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

regulating delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein regulating the delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

13. The method of claim **12**, wherein the thermal damage to the dermal layer includes necrosis.

14. A skin treatment method comprising:

inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source;

regulating delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the needles; and

vibrating at least one of the plurality of needles.

15. The method of claim **14**, wherein vibrating at least one of the plurality of needles includes generating a vibration at a frequency of between about 10 Hz to about 10 kHz.

16. The method of claim **14**, wherein vibrating at least one of the plurality of needles includes generating a vibration at an amplitude of between about 50 μm and about 500 μm.

17. A skin treatment method comprising:

inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and substantially undamaged regions between bipolar pairs of needles in the group.

18. The method of claim **17**, wherein the damaged regions are elongated between the needles of the bipolar pairs.

19. The method of claim **17**, wherein the fractional damage is sufficient to cause necrosis.

20. A skin treatment method comprising:

inserting a plurality of monopolar needles into a dermal layer of skin, the plurality of monopolar needles being attached to a base and configured to receive radio frequency (RF) energy from a RF energy source; and

regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions in a vicinity of each tip of each of the plurality of monopolar needles, and substantially undamaged regions between the damaged regions.

21. The method of claim **20**, wherein the fractional damage is sufficient to cause necrosis.

* * * * *

U.S. DEPARTMENT OF COMMERCE
PATENT & TRADEMARK OFFICE

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
1. [1a] A skin treatment device comprising:	 The Jeisys INTRAcel[1], offered by Perigee Medical, is a skin treatment device. *See, e.g.*, Jeisys INTRAcel Mobile Webpage, http://www.jeisys.com/mobile/intracel/: "Fractional RF Microneedle™ provides excellent efficacies for **skin rejuvenation**, large pores, acnes and acne scars by selective treatment on various skin depth."[2] Jeisys's 510(k) Summary filed with the U.S. FDA explains that the INTRAcel Premium Fractional RF Micro Needle (FRM) system[3] is "indicated for use in **dermatological** and general surgical procedures for electrocoagulation and hemostasis."

[1] The INTRAcel PRO is an upgraded model of the INTRAcel with the same functionality, except that the PRO model includes the capability of performing "SRT Selective RF" treatment. "What is New in INTRAcel Pro?", https://shop.perigee.com/product/intracel-to-intracel-pro-upgrade/. Both the INTRAcel and INTRAcel PRO include the accused Fractional Micro Needle (FRM) functionality. *Id.* The differences are not material to the claims at issue. Therefore, for ease of discussion, this chart collectively refers to all of the INTRAcel fractional needling products as "INTRAcel."

[2] All emphasis in quotes is added, unless otherwise noted.

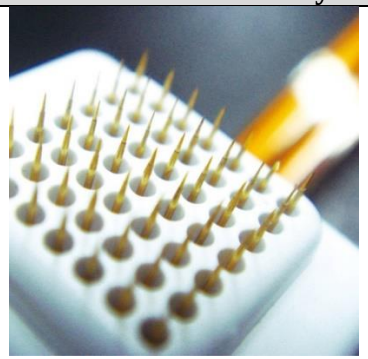
Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
[1b] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	The INTRAcel includes a housing configured to support a plurality of needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/: "Fractional Radiofrequency **Microneedling**" "Less pain with new **16 Pin** Non-Insulated **Micro-Needle Tip**" 

[3] On information and belief, the INTRAcel *Premium* Fractional RF Micro Needle (FRM) system described in Jeisys's 510(k) Summary to the U.S. FDA is substantially identical to the marketed INTRAcel products discussed in this claim chart.

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO



The needles are arranged in an array for insertion into a dermal skin layer. *Id.*:

3 Different Tips to treat different depth and symptoms.

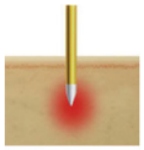
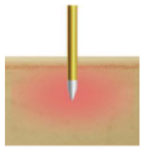
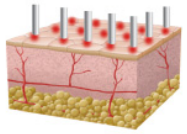
	FRM (Bipolar)	FRM (Monopolar)	SRR (Superficial Rejuvenation)
			
Emission Area	Narrow	Wide, Deep	Narrow, Shallow
Target	Dermis	Mid-dermis	Epidermis
Recommendation Depth	0.8 - 1.5 mm	0.8 mm	-
Treatment Interval	4 - 5 Weeks	3 Weeks	1 Week
Recovery Time	48 Hours	24 Hours	12 Hours
Application	Wrinkles / Pores / Acne / Scar	Fine Wrinkles / Tightening	Periorbital Wrinkles / Rejuvenation

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	See also, e.g., 510(k) Summary for the INTRAcel Premium Fractional RF Micro Needle (FRM) System: "Histologically, both Subject [sic] device and predicate device created conical diamond shaped tissue coagulation inthe [sic] **dermis** and show similar coagulated column." *See also, e.g.,* Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has microneedles and it delivers fractional RF energy to induce the thermal damage in the **target area of the dermis**." The INTRAcel applicator contains a plurality of needles attached to a base. *See, e.g.,* INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=26s at 0:26:

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

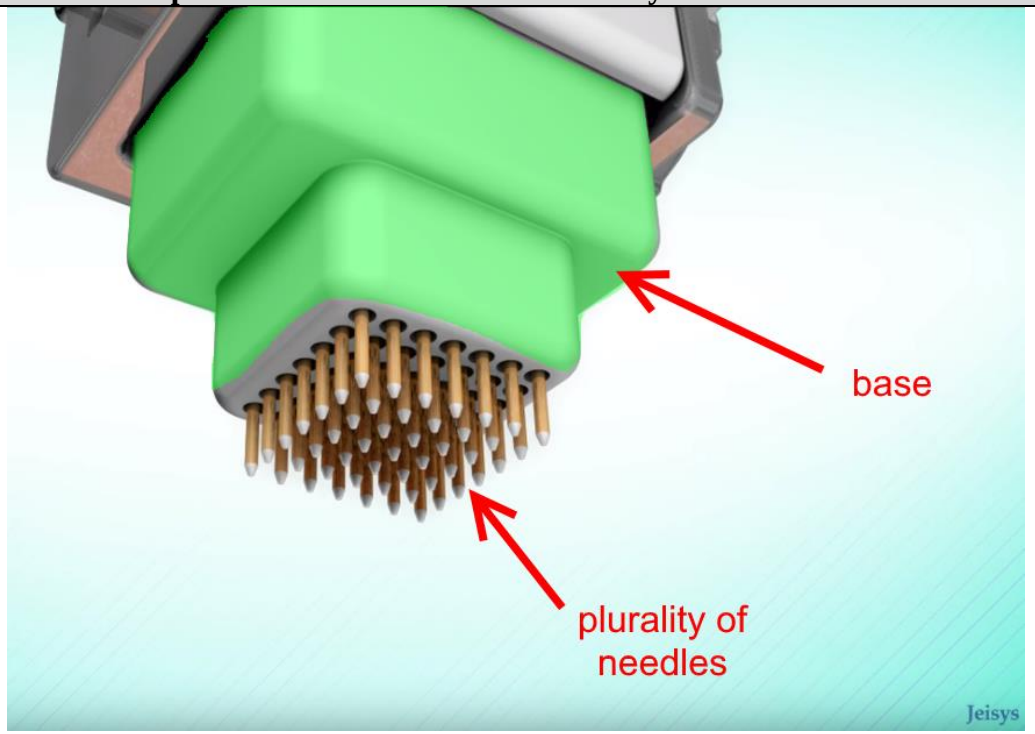
Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	
[1c] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	The INTRAcel applies radio frequency (RF) energy from a RF energy source through a plurality of needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/: "Fractional **Radiofrequency Microneedling"** **"RF** Selective Thermolysis is using different conductivity of each cell area" "Less pain with new 16 Pin Non-Insulated **Micro-Needle Tip**" Jeisys product literature for the INTRAcel describes applying RF energy to the plurality of needles. *See, e.g.*, Jeisys INTRAcel Mobile Webpage,

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	http://www.jeisys.com/mobile/intracel/: "The **RF energy from the end of needle** transfers energy from its point circle to nearby areas that causes coagulation and denaturalization." *See also, e.g.*, 510(k) Summary for the INTRAcel Premium Fractional RF Micro Needle (FRM) System: "Devices use **RF energy delivered through micro needle electrodes** to provide treatment controlled by a user controlled interface." *Id.*:

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO

Manufacturer		Lutronic	Jeisys Medical, Inc.
Trade Name		Predicate Device INFINI	Subject Device INTRAcel Premium
510(k) Number		K121481	K153727
Intended Use		The device is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles.	The INTRAcel Premium is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Design		The device uses Bipolar radiofrequency to apply heat therapy to the skin, resulting skin resurfacing and collagen remodeling for treatment of wrinkles.	The device uses Bipolar radio frequency to apply therapy for use in Dermatologic and General Surgical procedures electrocoagulation and hemostasis.
Materials		Plastic and metal enclosure with hand-piece for application	Plastic and metal enclosure with hand-piece for application
Construction		Constructed of materials that conform to safety standards and requirements	Constructed of materials that conform to safety standards and requirements
Interface		Touch screen user applied interface to program and setthe controls for the patient application; there is a hand-piece utilized to deliver the treatment	Touch screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment
Electrosurgical Unit	Energy Source	Radio Frequency	Radio Frequency
	Mode of Operation	Bipolar	Bipolar
	Power Source	Unknown	120 VAC, 50/60 Hz
	Frequency	1 MHz	1 MHz
	Nominal Operating Power	50W (Up to 20 Level)	12.5W (Level 1 -4), 32W (Level 5) 40.5 W(Level 6) 50 W(Level 7)
	Maximum power delivered to the patient	50W	50W
	Maximum power of per pin delivered to the patient	50W	50W
	Impedance	_	200 ohm
	Treatment temperature range	36 – 43°C	39°C - 42°C
	Treatment levels	20 Level	1 – 7 levels (1 low, 7 high)
	Dimensions	362 mm (W) x 40 mm (L) x 108 mm (H)	350 mm (W) x 400 mm (L) x 108 mm (H)
	Weight	28 kG	63 kG

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
[1d] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles	The INTRAcel contains a control module (*i.e.*, hardware and software accessed through a control panel interface) for controlling delivery of RF energy, and a RF energy source. For example, the graphical user interface of the control module for the INTRAcel shows various controls that can be adjusted, including the power level and duration of the RF pulse. *See, e.g.*, INTRAcel - Dr Natalie. demonstrates YouTube video, https://youtu.be/_QXQjvc-dRE?t=20s at 0:20:  *See also, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/:

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	 Jeisys's 510(k) Summary to the U.S. FDA explains that with the INTRAcel system, the energy level and depth of microneedling can be adjusted.: "The treatment was performed at the energy level, 0.5J, 1.25J and 3.0J and in depth ofmicroneedling0.5mm, [sic] 0.8mm, 1.5mm and 2.0mm." The 510(k) Summary also discloses that the device contains a control unit. *Id.*: "The **devices have a control unit** that can be programmed utilized for the patient parameters. The devices are equipped with an **input device either a stylus or touch screen to program the parameters**. In addition, they are equipped with manual

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	interface, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters.
[1e] to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	The INTRAcel induces a pattern of fractional damage by the RF energy in the dermal layer. For example, the INTRAcel is described as a fractional RF product. *See, e.g.*, Jeisys INTRAcel Mobile Webpage, http://www.jeisys.com/mobile/intracel/: "**Fractional** RF Microneedle™ provides excellent efficacies for skin rejuvenation, large pores, acnes and acne scars by selective treatment on various skin depth." *See also, e.g.*, Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has **microneedles** and it **delivers fractional RF energy** to induce the thermal **damage** in the target area of the **dermis**." Jeisys's product literature for the the INTRAcel depicts a pattern of fractional damage. *See, e.g.*, INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=35s at 0:35, **illustrating a pattern of damage** when the needles are **inserted in the dermal layer**:

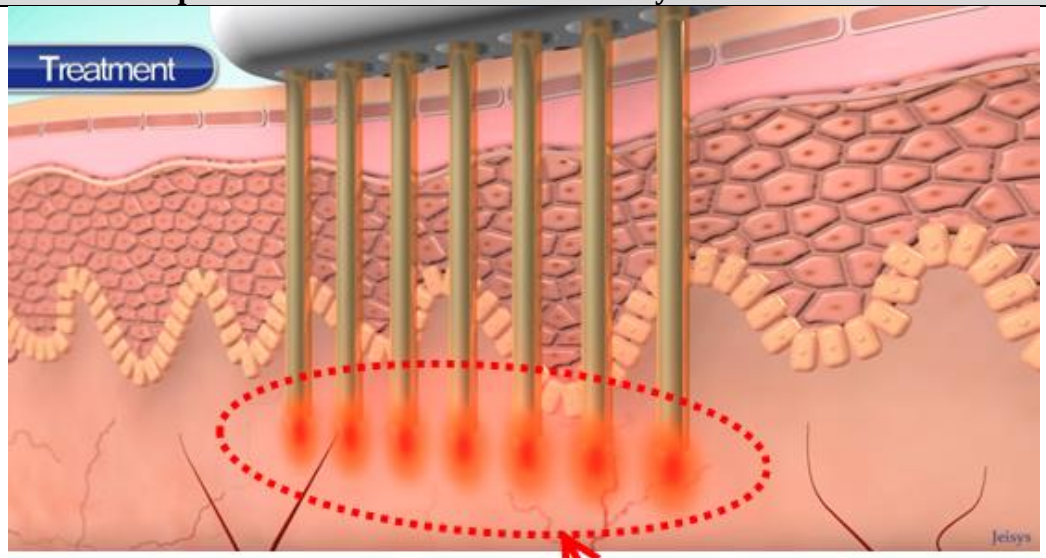
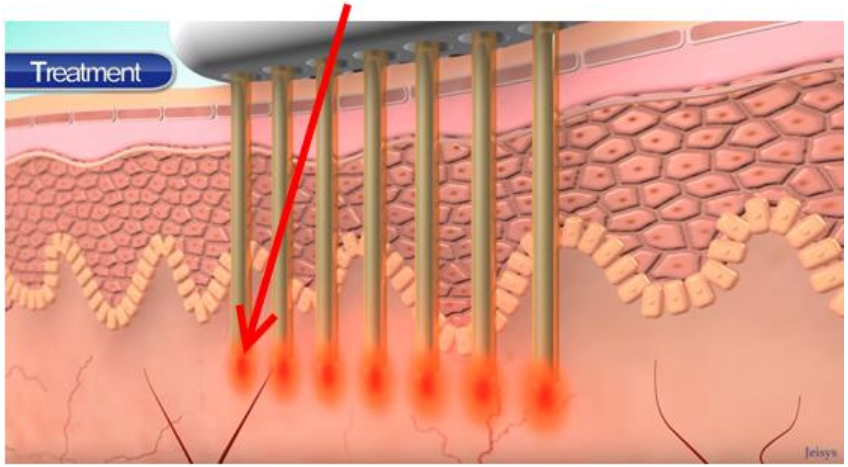
Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	 *See also, e.g.*, Asian Aesthetic Guide, Intracel's FRM Technology Addresses Market Demand: "This ability to create such a wide variety of effective **wound patterns** gives us a lot of control and handles different pathologies in a single treatment session." Jeisys's 510(k) Summary to the U.S. FDA also describes the INTRAcel system as a "**Fractional** RF Micro Needle (FRM) System."
[1f] wherein the controlled delivery of the	The INTRAcel uses controlled delivery of RF energy (see element [1d] above) to stimulate

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 1	**Representative Accused Product: Jeisys INTRAcel PRO**
RF energy is configured to stimulate formation of new collagen in the skin.	formation of new collagen. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/: "**Neocollagenesis** [i.e., formation of new collagen] & Neoelatstogenesis [i.e., formation of new elastin] . . . **Collagen** damage is **repaired** with time" *See also, e.g.*, Jeisys INTRAcel Mobile Webpage, http://www.jeisys.com/mobile/intracel/: "Instantly make the collagen fiber shrinking, and **regenerate new collagen** by the stimulus of fibroblast." Jeisys's 510(k) Summary to the U.S. FDA describes that with the INTRAcel system "the thermally coagulated collagen after treatment was **replaced by new collagen**."

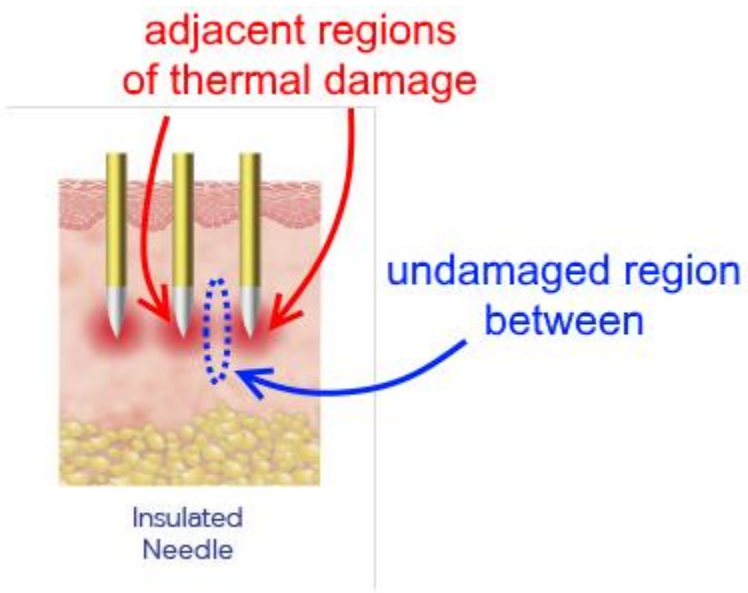
Claim 15	**Representative Accused Product: Jeisys INTRAcel PRO**
15. [15a] A skin treatment device comprising:	See element [1a] above.
[15b] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	See element [1b] above.
[15c] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	See element [1c] above.
[15d] a control module for controlling delivery of the RF energy from the RF	See element [1d] above.

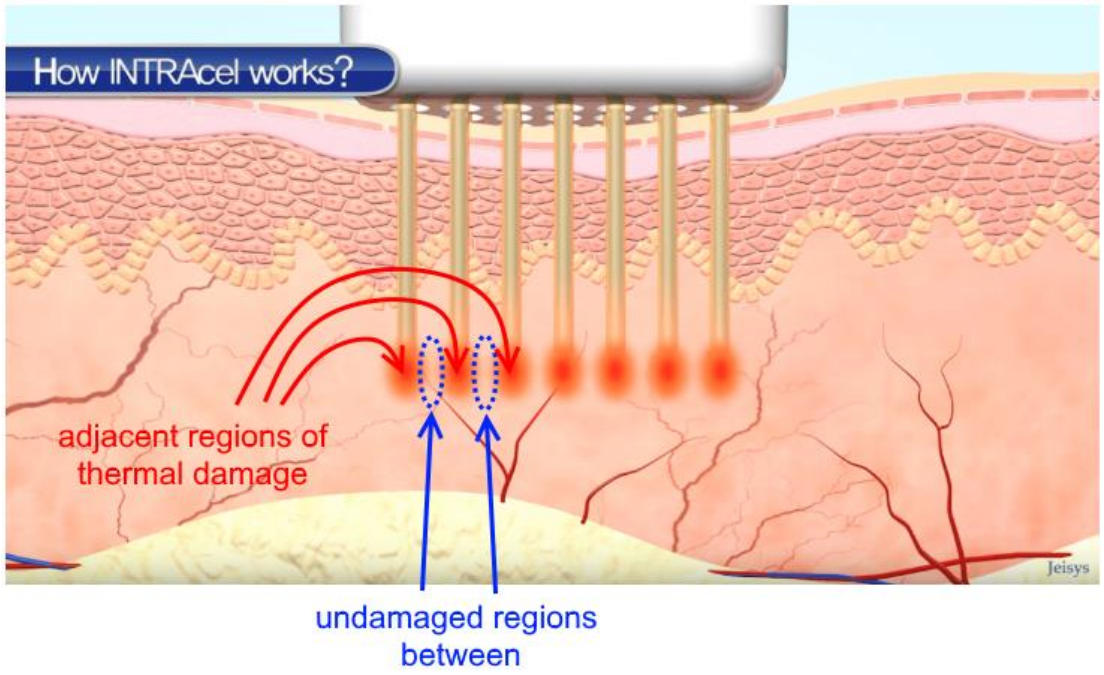
Claim 15	**Representative Accused Product: Jeisys INTRAcel PRO**
energy source to the plurality of needles	
[15e] to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,	See element [1e] above. The pattern of fractional damage caused by the INTRAcel is produced in the dermal layer in a vicinity of the tips of the needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=35s at 0:35:

Claim 15	Representative Accused Product: Jeisys INTRAcel PRO
	  *See also, e.g.*, Jeisys INTRAcel Mobile Webpage, http://www.jeisys.com/mobile/intracel/: "The **RF energy from the end of needle** transfers energy from its point circle to **nearby areas** that causes coagulation and denaturalization."
[15f] wherein delivery of the RF energy is	See elements [1d] and [1e] above.

Claim 15	**Representative Accused Product: Jeisys INTRAcel PRO**
controlled to cause a pattern of regions of thermal damage within the dermal layer, and	The INTRAcel is described as causing a pattern of regions of thermal damage within the dermal layer. *See, e.g.*, Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has microneedles and it delivers fractional **RF energy to induce the thermal damage** in the target area of the **dermis**." *See also, e.g.*, Jeisys INTRAcel Mobile Webpage, http://www.jeisys.com/mobile/intracel/: "Additionally, RF energy from INTRAcel produces enough **thermal energy** to **denaturalize** [*i.e.*, damage] the cell and destroy the causes of acne, acne bacteria, and sebaceous gland." "Direct RF emission on the target tissue by Fractional RF thermolysis (**Thermal damage** by sengmented [sic] RF Emission) Selectively degenerate the collagen fiber from superficial dermis to muscle band." The RF energy delivery is controlled so that the thermal damage occurs in a pattern.: "The **devices have a control unit** that can be programmed utilized for the patient parameters." As an additional example, see the illustration of thermal damage pattern in element [1e] above.
[15g] wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.	Jeisys's product literature describes and illustrates at least two adjacent regions of thermal damage having an undamaged region therebetween. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ at 2 and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18:

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

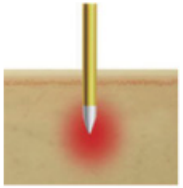
Claim 15	Representative Accused Product: Jeisys INTRAcel PRO
	

Claim 15	Representative Accused Product: Jeisys INTRAcel PRO
	

Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
20. [20a] A skin treatment device comprising:	See element [1a] above.
[20b] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and	See element [1b] above.

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
[20c] arranged in a group of bipolar pairs,	INTRAcel provides needles arranged in a group of bipolar pairs. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/:

	FRM (Bipolar)
	
Emission Area	Narrow
Target	Dermis
Recommendation Depth	0.8 - 1.5 mm
Treatment Interval	4 - 5 Weeks
Recovery Time	48 Hours
Application	Wrinkles / Pores / Acne / Scar

Id.:

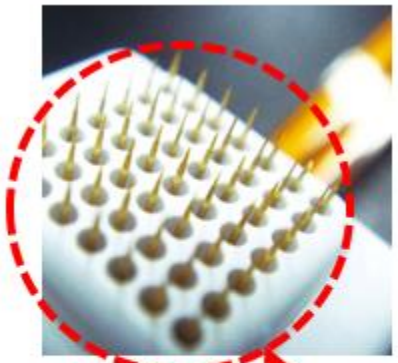
Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
	 Jeisys's 510(k) Summary to the U.S. FDA describes that the INTRAcel has a "**Bipolar**" mode of operation.
[20d] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	See element [1c] above.
[20e] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles	See element [1d] above.
[20f] to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	See element [1e] above.

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

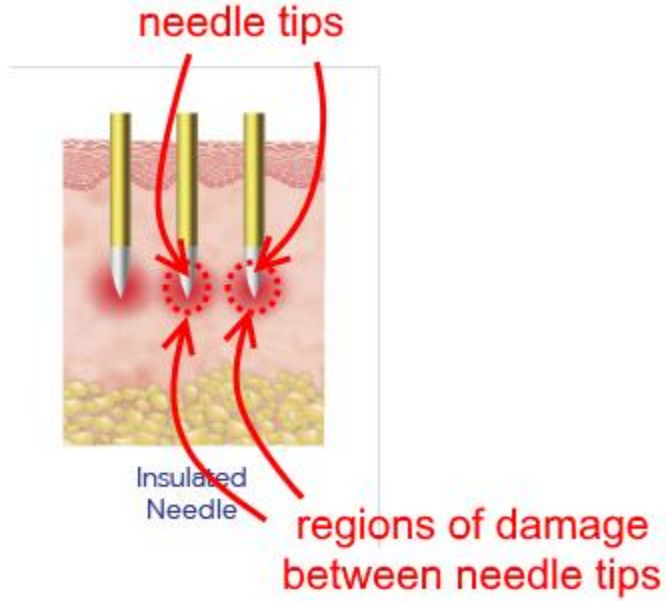
Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
[20g] wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs,	The INTRAcel product literature describes a pattern of fractional damage (see element [1e]), and depicts damaged regions between tips of needles of the bipolar pairs. For example, as Jeisys illustrates, the damaged regions occur on either side of each needle, between the needle tips. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18: 

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

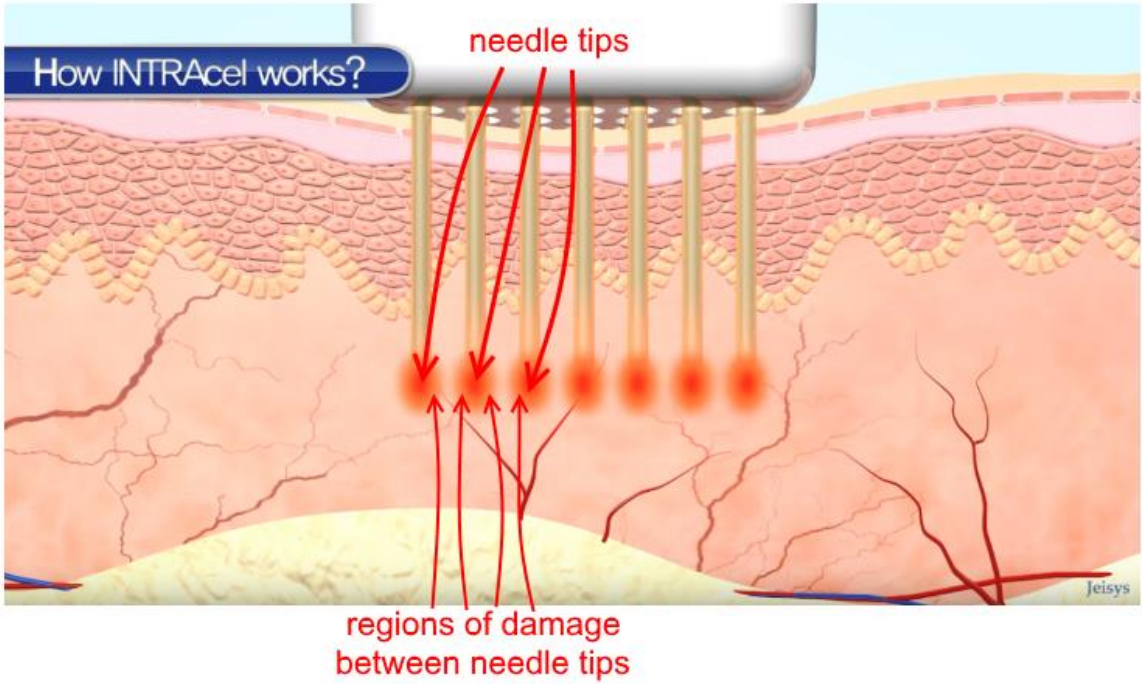
Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
	
[20h] and undamaged regions between bipolar pairs of needles in the group.	The INTRAcel creates undamaged regions between the bipolar pairs of needles in the group. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18:

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

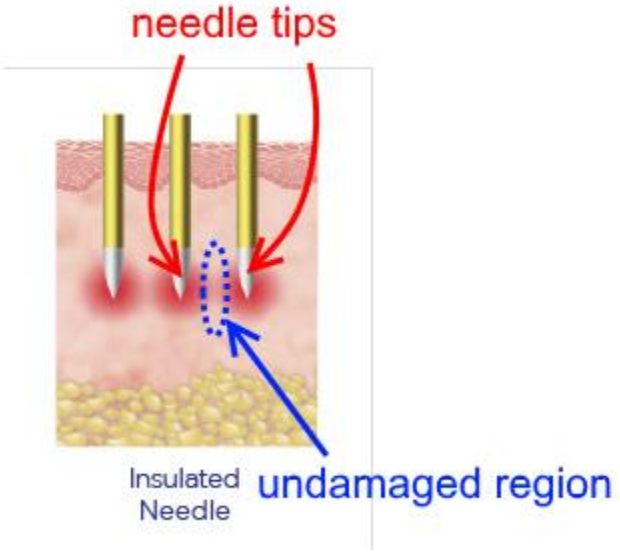
Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
	

Exhibit 3
Exemplary Infringement Claim Chart for U.S. Patent No. 9,510,899 – Jeisys INTRAcel PRO

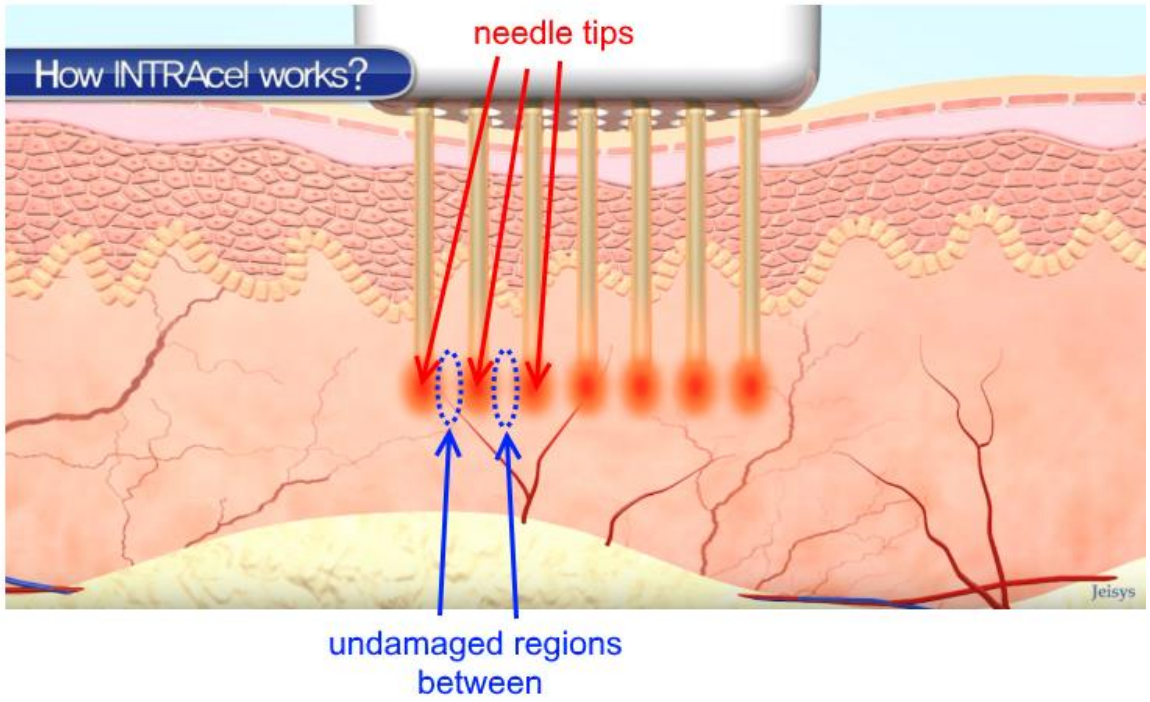
Claim 20	Representative Accused Product: Jeisys INTRAcel PRO
	

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
1. [1a] A skin treatment method comprising:	 The Jeisys INTRAcel[1], offered by Perigee Medical, performs a skin treatment method. *See, e.g.*, Jeisys INTRAcel website, http://www.jeisys.com/mobile/intracel/: "Fractional RF Microneedle™ provides excellent efficacies for **skin rejuvenation**, large pores, acnes and acne scars by selective treatment on various skin depth."[2] Jeisys's 510(k) Summary filed with the U.S. FDA explains that the INTRAcel Premium Fractional RF Micro Needle (FRM) system[3] is "indicated for use in **dermatological** and general surgical procedures for electrocoagulation and hemostasis."

[1] The INTRAcel PRO is an upgraded model of the INTRAcel with the same functionality, except that the PRO model includes the capability of performing "SRT Selective RF" treatment. "What is New in INTRAcel Pro?", https://shop.perigee.com/product/intracel-to-intracel-pro-upgrade/. Both the INTRAcel and INTRAcel PRO include the accused Fractional Micro Needle (FRM) functionality. *Id.* The differences are not material to the claims at issue. Therefore, for ease of discussion, this chart collectively refers to all of the INTRAcel fractional needling products as "INTRAcel."
[2] All emphasis in quotes is added, unless otherwise noted.

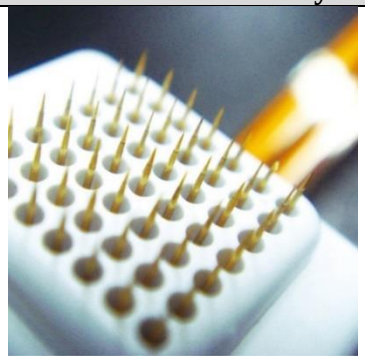
Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	**Representative Accused Product: Jeisys INTRAcel PRO**
[1b] inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base,	The INTRAcel contains a plurality of needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/: "Fractional Radiofrequency **Microneedling**" "Less pain with new **16 Pin** Non-Insulated **Micro-Needle Tip**" 

[3] On information and belief, the INTRAcel *Premium* Fractional RF Micro Needle (FRM) system described in Jeisys's 510(k) Summary to the U.S. FDA is substantially identical to the marketed INTRAcel products discussed in this claim chart.

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO



The plurality of needles are inserted into a dermal layer of skin. *Id.*:

3 Different Tips to treat different depth and symptoms.

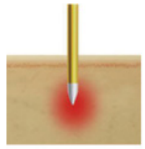
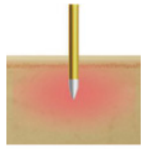
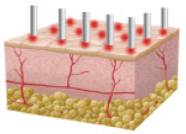
	FRM (Bipolar)	FRM (Monopolar)	SRR (Superficial Rejuvenation)
			
Emission Area	Narrow	Wide, Deep	Narrow, Shallow
Target	Dermis	Mid-dermis	Epidermis
Recommendation Depth	0.8 - 1.5 mm	0.8 mm	-
Treatment Interval	4 - 5 Weeks	3 Weeks	1 Week
Recovery Time	48 Hours	24 Hours	12 Hours
Application	Wrinkles / Pores / Acne / Scar	Fine Wrinkles / Tightening	Periorbital Wrinkles / Rejuvenation

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	See also, e.g., 510(k) Summary for the INTRAcel Premium Fractional RF Micro Needle (FRM) System: "Histologically, both Subject [sic] device and predicate device created conical diamond shaped tissue coagulation inthe [sic] **dermis** and show similar coagulated column." *See also, e.g.,* Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has microneedles and it delivers fractional RF energy to induce the thermal damage in the **target area of the dermis**." The INTRAcel applicator contains a plurality of needles attached to a base. *See, e.g.*, INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=26s at 0:26:

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

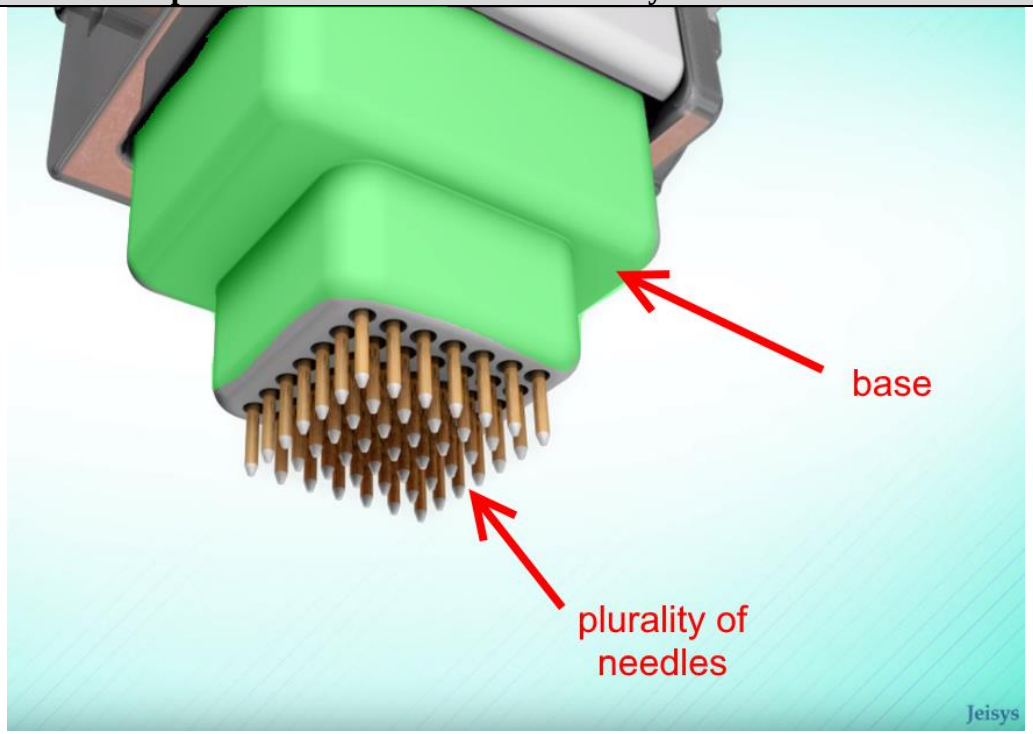
Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	
[1c] the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and	The INTRAcel is configured to apply radio frequency (RF) energy from a RF energy source through the plurality of needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/: "Fractional **Radiofrequency Microneedling"** **"RF** Selective Thermolysis is using different conductivity of each cell area" "Less pain with new 16 Pin Non-Insulated **Micro-Needle Tip**"

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	 Jeisys product literature for the INTRAcel describes applying RF energy to the plurality of needles. *See, e.g.*, Jeisys INTRAcel website, http://www.jeisys.com/mobile/intracel/: "The **RF energy from the end of needle** transfers energy from its point circle to nearby areas that causes coagulation and denaturalization." *See also, e.g.*, 510(k) Summary for the INTRAcel Premium Fractional RF Micro Needle (FRM) System: "Devices use **RF energy delivered through micro needle electrodes** to provide treatment controlled by a user controlled interface." *Id.*:

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO

Manufacturer		Lutronic	Jeisys Medical, Inc.
Trade Name		Predicate Device INFINI	Subject Device INTRAcel Premium
510(k) Number		K121481	K153727
Intended Use		The device is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles.	The INTRAcel Premium is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Design		The device uses Bipolar radiofrequency to apply heat therapy to the skin, resulting skin resurfacing and collagen remodeling for treatment of wrinkles.	The device uses Bipolar radio frequency to apply therapy for use in Dermatologic and General Surgical procedures electrocoagulation and hemostasis.
Materials		Plastic and metal enclosure with hand-piece for application	Plastic and metal enclosure with hand-piece for application
Construction		Constructed of materials that conform to safety standards and requirements	Constructed of materials that conform to safety standards and requirements
Interface		Touch screen user applied interface to program and setthe controls for the patient application; there is a hand-piece utilized to deliver the treatment	Touch screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment
Electrosurgical Unit	Energy Source	Radio Frequency	Radio Frequency
	Mode of Operation	Bipolar	Bipolar
	Power Source	Unknown	120 VAC, 50/60 Hz
	Frequency	1 MHz	1 MHz
	Nominal Operating Power	50W (Up to 20 Level)	12.5W (Level 1 -4), 32W (Level 5) 40.5 W(Level 6) 50 W(Level 7)
	Maximum power delivered to the patient	50W	50W
	Maximum power of per pin delivered to the patient	50W	50W
	Impedance	_	200 ohm
	Treatment temperature range	36 – 43°C	39°C - 42°C
	Treatment levels	20 Level	1 – 7 levels (1 low, 7 high)
	Dimensions	362 mm (W) x 40 mm (L) x 108 mm (H)	350 mm (W) x 400 mm (L) x 108 mm (H)
	Weight	28 kG	63 kG

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
[1d] regulating delivery of the RF energy from the RF energy source to the plurality of needles	The INTRAcel regulates the delivery of RF energy from a RF energy source to the plurality of needles. For example, the graphical user interface for the INTRAcel shows various controls that can be adjusted, including the power level and duration of the RF pulse. *See, e.g.*, INTRAcel - Dr Natalie. demonstrates YouTube video, https://youtu.be/_QXQjvc-dRE?t=20s at 0:20:  *See also, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/:

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	 Jeisys's 510(k) Summary to the U.S. FDA explains that with the INTRAcel system, the energy level and depth of microneedling can be adjusted.: "The treatment was performed at the energy level, 0.5J, 1.25J and 3.0J and in depth ofmicroneedling0.5mm, [sic] 0.8mm, 1.5mm and 2.0mm." The 510(k) Summary also discloses that the device contains a control unit. *Id.*: "The **devices have a control unit** that can be programmed utilized for the patient parameters. The devices are equipped with an **input device either a stylus or touch screen to program the parameters**. In addition, they are equipped with manual interface, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters.
[1e] to induce a pattern of fractional damage by the RF energy in the dermal layer when	The INTRAcel induces a pattern of fractional damage by the RF energy in the dermal layer. For example, the INTRAcel is described as a fractional RF product. *See, e.g.*, Jeisys

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	**Representative Accused Product: Jeisys INTRAcel PRO**
the needles are inserted therein,	INTRAcel website, http://www.jeisys.com/mobile/intracel/: "**Fractional** RF Microneedle™ provides excellent efficacies for skin rejuvenation, large pores, acnes and acne scars by selective treatment on various skin depth." *See also, e.g.*, Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has **microneedles** and it **delivers fractional RF energy** to induce the thermal **damage** in the target area of the **dermis**." Jeisys's product literature for the the INTRAcel depicts a pattern of fractional damage. *See, e.g.*, INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=35s at 0:35, **illustrating a pattern of damage** when the needles are **inserted in the dermal layer**:

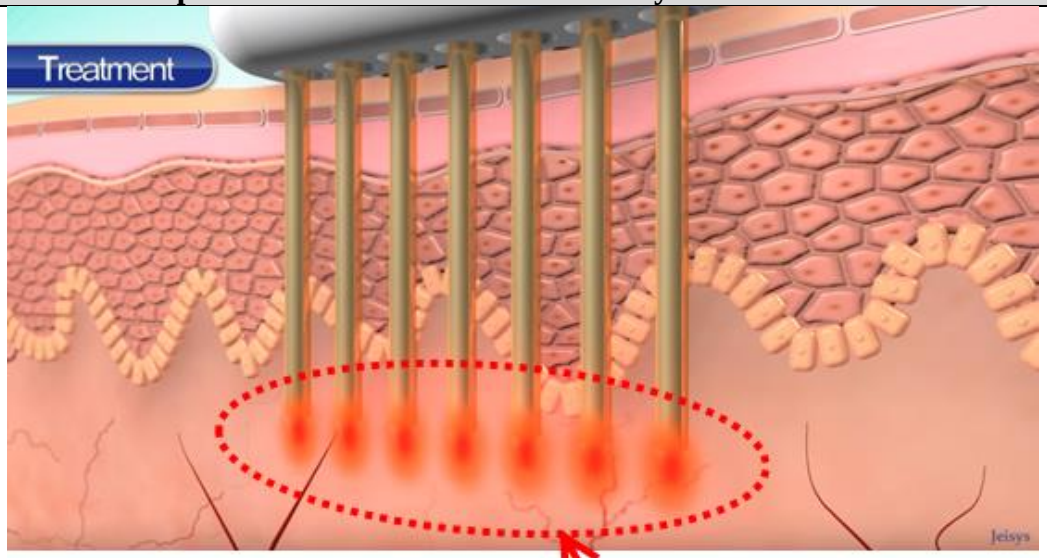
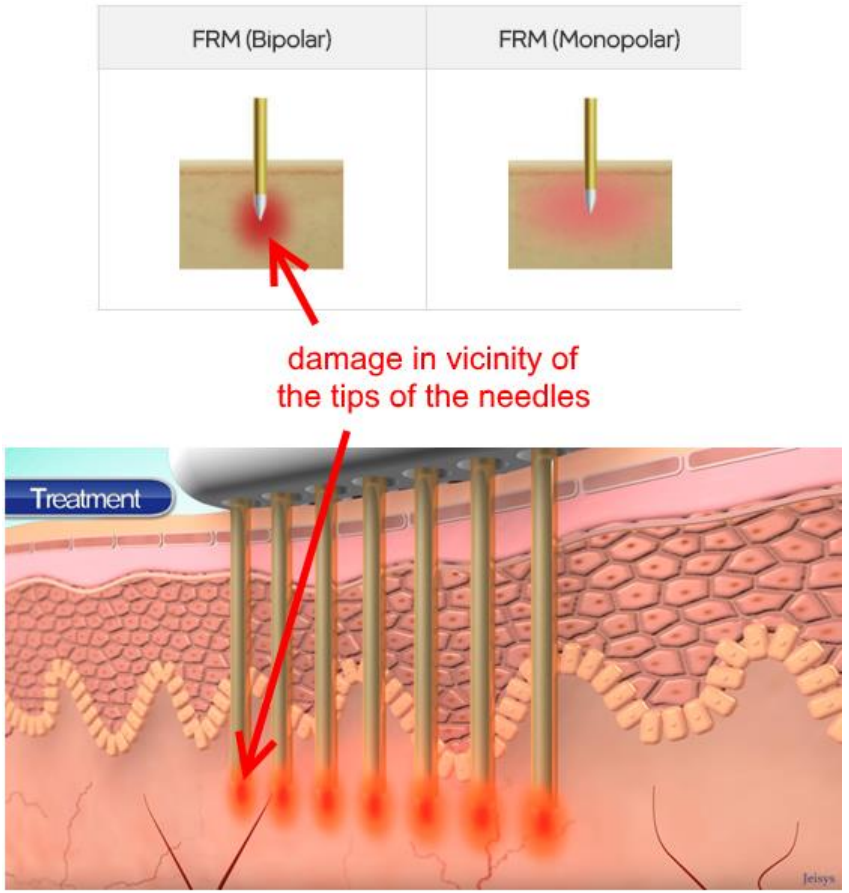
Claim 1	Representative Accused Product: Jeisys INTRAcel PRO
	 *See also, e.g.,* Asian Aesthetic Guide, Intracel's FRM Technology Addresses Market Demand: "This ability to create such a wide variety of effective **wound patterns** gives us a lot of control and handles different pathologies in a single treatment session." Jeisys's 510(k) Summary to the U.S. FDA also describes the INTRAcel system as a "**Fractional** RF Micro Needle (FRM) System."
[1f] wherein the regulation of the delivery of the RF energy is configured to stimulate	The INTRAcel uses regulated delivery of RF energy (see element [1d] above) to stimulate formation of new collagen. *See, e.g.,* Jeisys INTRAcel PRO website,

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 1	**Representative Accused Product: Jeisys INTRAcel PRO**
formation of new collagen in the skin.	http://www.jeisys.com/2016/product/intracel/: "**Neocollagenesis** [i.e., formation of new collagen] & Neoelatstogenesis [i.e., formation of new elastin] . . . **Collagen** damage is **repaired** with time" *See also, e.g.,* Jeisys INTRAcel website, http://www.jeisys.com/mobile/intracel/: "Instantly make the collagen fiber shrinking, and **regenerate new collagen** by the stimulus of fibroblast." Jeisys's 510(k) Summary to the U.S. FDA describes that with the INTRAcel system "the thermally coagulated collagen after treatment was **replaced by new collagen**."

Claim 12	**Representative Accused Product: Jeisys INTRAcel PRO**
12. [12a] A skin treatment method comprising:	See element [1a] above.
[12b] inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base,	See element [1b] above.
[12c] the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and	See element [1c] above.
[12d] regulating delivery of the RF energy from the RF energy source to the plurality of needles	See element [1d] above.
[12e] to cause a pattern of fractional	See element [1e] above.

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 12	Representative Accused Product: Jeisys INTRAcel PRO
damage to be produced in the dermal layer in a vicinity of the tips of the needles,	The pattern of fractional damage caused by the INTRAcel is produced in the dermal layer in a vicinity of the tips of the needles. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ at 2 and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=35s at 0:35: 

Claim 12	Representative Accused Product: Jeisys INTRAcel PRO
	See also, e.g., Jeisys INTRAcel website, http://www.jeisys.com/mobile/intracel/: "The **RF energy from the end of needle** transfers energy from its point circle to **nearby areas** that causes coagulation and denaturalization."
[12f] wherein regulating the delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer,	See elements [1d] and [1e] above. The INTRAcel is described as causing a pattern of regions of thermal damage within the dermal layer. *See, e.g.*, Histologic Evaluation of Deep Dermal Heating by Fractional Radiofrequency According to Energy, Dr. Un-Cheol Yeo, Dr. Doo-Rak Lee, Dr. So-Dug Lim: "This machine has microneedles and it delivers fractional **RF energy to induce the thermal damage** in the target area of the **dermis**." *See also, e.g.,* Jeisys INTRAcel website, http://www.jeisys.com/mobile/intracel/: "Additionally, RF energy from INTRAcel produces enough **thermal energy** to **denaturalize** [*i.e.*, damage] the cell and destroy the causes of acne, acne bacteria, and sebaceous gland." "Direct RF emission on the target tissue by Fractional RF thermolysis (**Thermal damage** by sengmented [sic] RF Emission) Selectively degenerate the collagen fiber from superficial dermis to muscle band." The RF energy delivery is controlled so that the thermal damage occurs in a pattern. *See, e.g.*, 510(k) Summary for the INTRAcel Premium Fractional RF Micro Needle (FRM) System: "The **devices have a control unit** that can be programmed utilized for the patient parameters." As an additional example, see the illustration of thermal damage pattern in element [1e]

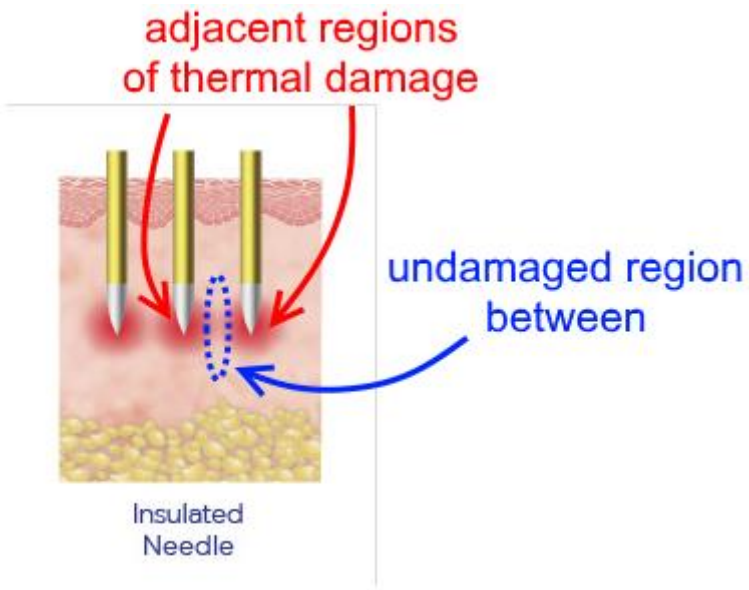
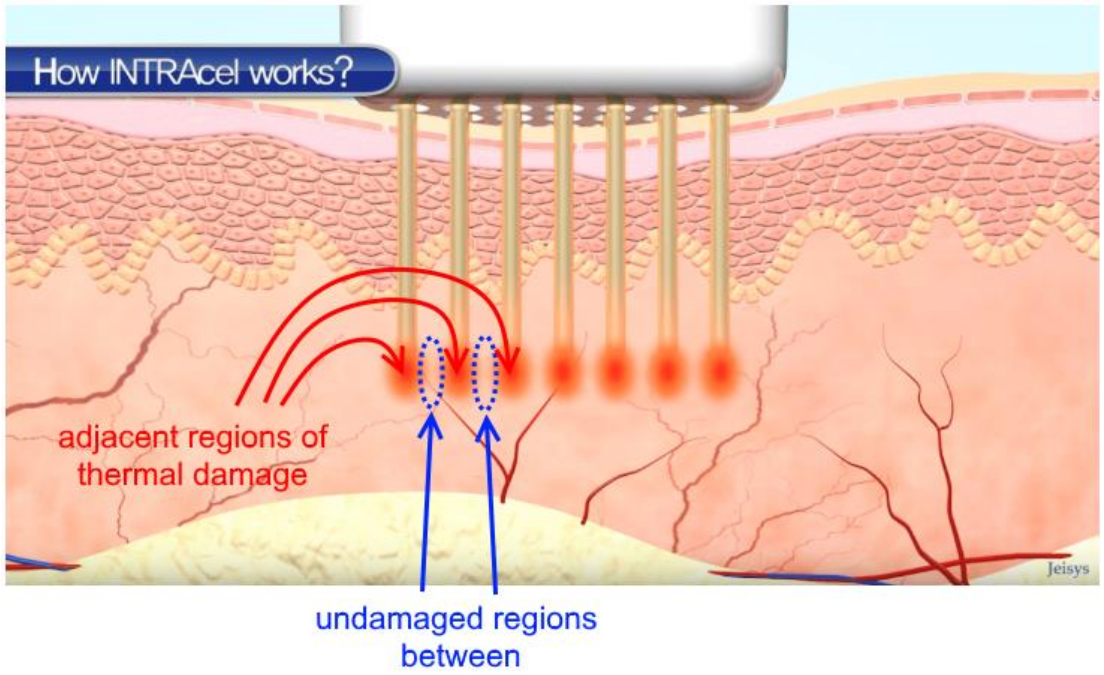
Claim 12	Representative Accused Product: Jeisys INTRAcel PRO
	above.
[12g] and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.	Jeisys's product literature describes and illustrates at least two adjacent regions of thermal damage having an undamaged region therebetween. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18: 

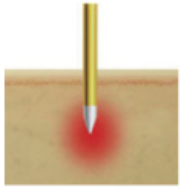
Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 12	Representative Accused Product: Jeisys INTRAcel PRO
	

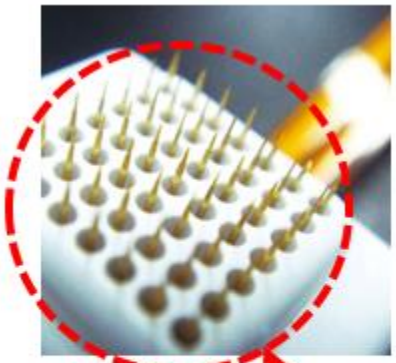
Claim 17	Representative Accused Product: Jeisys INTRAcel PRO
17. [17a] A skin treatment method comprising:	See element [1a] above.
[17b] inserting a plurality of needles into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs,	See element [1b] above. INTRAcel provides needles arranged in a group of bipolar pairs. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/:

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 17	Representative Accused Product: Jeisys INTRAcel PRO

	FRM (Bipolar)
	
Emission Area	Narrow
Target	Dermis
Recommendation Depth	0.8 - 1.5 mm
Treatment Interval	4 - 5 Weeks
Recovery Time	48 Hours
Application	Wrinkles / Pores / Acne / Scar

Id.:

Claim 17	Representative Accused Product: Jeisys INTRAcel PRO
	 Jeisys's 510(k) Summary to the U.S. FDA describes that the INTRAcel has a "**Bipolar**" mode of operation.
[17c] the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and	See element [1c] above.
[17d] regulating delivery of the RF energy from the RF energy source to the plurality of needles	See element [1d] above.
[17e] to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	See element [1e] above.
[17f] wherein the pattern of fractional	The INTRAcel product literature describes a pattern of fractional damage (see element

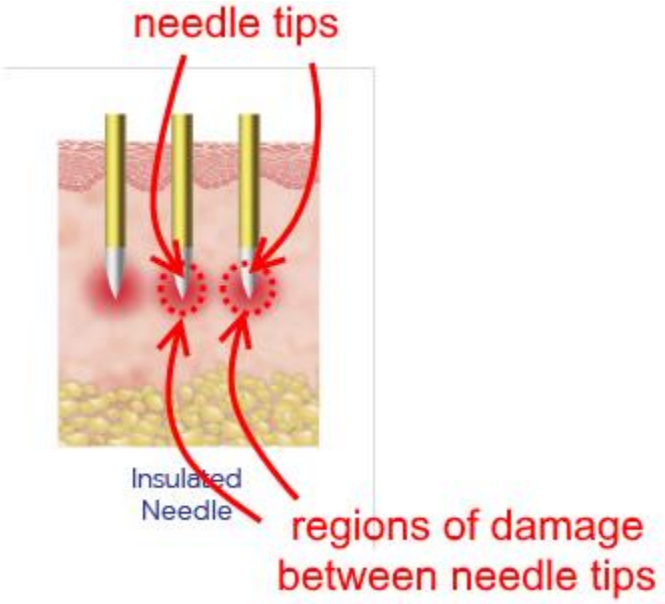
Claim 17	Representative Accused Product: Jeisys INTRAcel PRO
damage includes damaged regions between tips of needles of the bipolar pairs, and	[1e]), and depicts damaged regions between tips of needles of the bipolar pairs. For example, as Jeisys illustrates, the damaged regions occur on either side of each needle, between the needle tips. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18: 

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

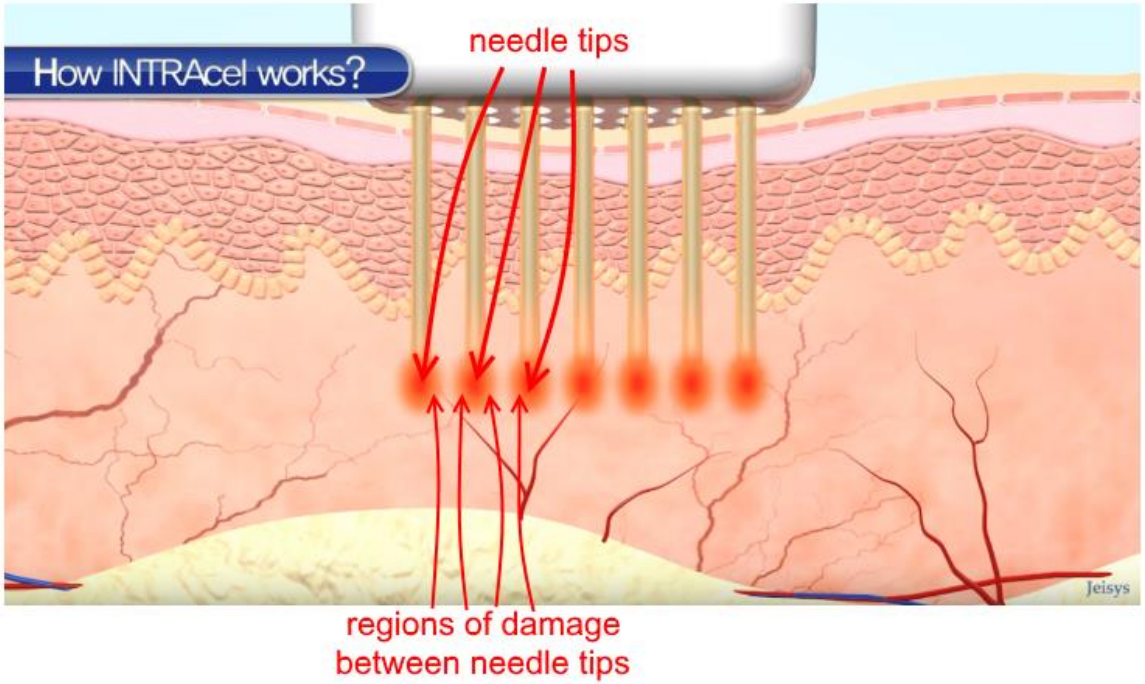
Claim 17	Representative Accused Product: Jeisys INTRAcel PRO
	
[17g] substantially undamaged regions between bipolar pairs of needles in the group.	The INTRAcel creates undamaged regions between the bipolar pairs of needles in the group. *See, e.g.*, Jeisys INTRAcel PRO website, http://www.jeisys.com/2016/product/intracel/ and INTRAcel microneedling with Fractional Radiofrequency YouTube video, https://youtu.be/cUXkZU0Ejhk?t=18s at 0:18:

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

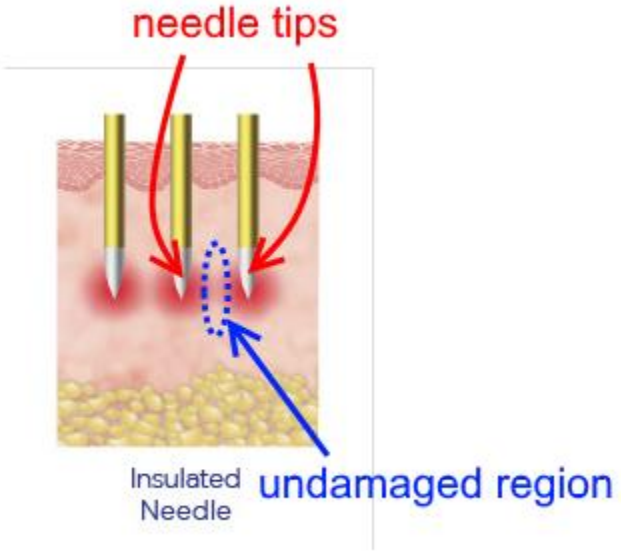
Claim 17	Representative Accused Product: Jeisys INTRAcel PRO
	

Exhibit 4
Exemplary Infringement Claim Chart for U.S. Patent No. 9,095,357 – Jeisys INTRAcel PRO

Claim 17	Representative Accused Product: Jeisys INTRAcel PRO