



(43) International Publication Date
12 June 2014 (12.06.2014)

- (51) International Patent Classification:
H04L 29/08 (2006.01)
- (21) International Application Number:
PCT/US2013/073678
- (22) International Filing Date:
6 December 2013 (06.12.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/734,313 6 December 2012 (06.12.2012) US
61/885,734 2 October 2013 (02.10.2013) US
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: PIXEL ARRAY MEDICAL DEVICES AND METHODS

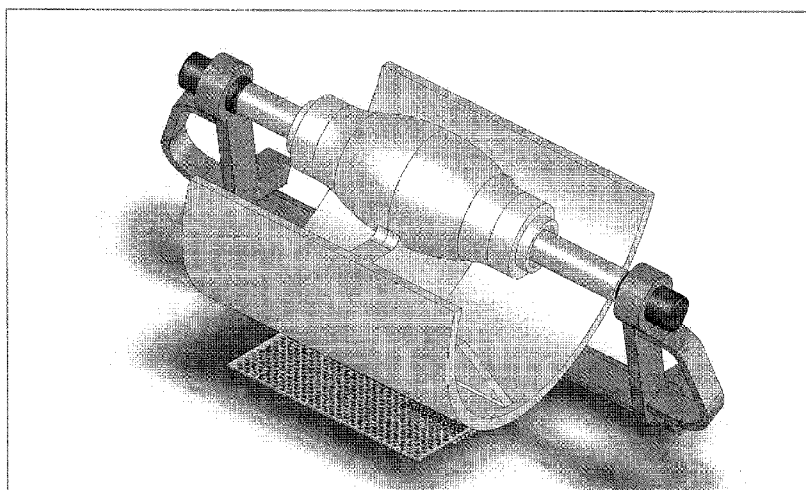


FIGURE 12B

(57) Abstract: Pixel array medical devices, systems and methods are described for skin grafting and skin resection procedures. The procedures involve applying a scalpet array to a target skin site. The scalpet array comprises scalpets positioned on an investing plate. Skin pixels are circumferentially incised at a target skin site by applying a load via the scalpet array onto subjacent skin surface that includes the target skin site. Incised skin pixels are captured on an adherent substrate, where the incised skin pixels are extruded through the scalpet array. Bases of incised skin pixels extruded through the scalpet array are then transected.



PIXEL ARRAY MEDICAL DEVICES AND METHODS

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5 RELATED APPLICATIONS

This application claims the benefit of United States (US) Patent Application Number 61/734,313, filed December 6, 2012.

This application claims the benefit of US Patent Application Number 61/885,734, filed October 2, 2013.

10 This application is a continuation in part of US Patent Application Number 12/972,013, filed December 17, 2010, which claims the benefit of US Patent Application Number 61/288,141, filed December 18, 2009.

TECHNICAL FIELD

15 The embodiments herein relate to medical devices, kits, and methods and, more particularly, to medical instrumentation applied to the surgical management of burns and skin defects.

BACKGROUND

20 The aging process is most visibly depicted by the development of dependent skin laxity. This life long process may become evident as early as the third decade of life and will progressively worsen over subsequent decades. Histological research has shown that dependant stretching or age related laxity of the skin is due in part to progressive dermal atrophy associated with a reduction of skin tensile strength. When combined with the
25 downward force of gravity, age related dermal atrophy will result in the two dimensional expansion of the skin envelope. The clinical manifestation of this physical-histological process is redundant skin laxity. The most affected areas are the head and neck, upper arms, thighs, breasts, lower abdomen and knee regions. The most visible of all areas are the head and neck. In this region, prominent “turkey gobbler” laxity of neck and “jowls”

of the lower face are due to an unaesthetic dependency of skin in these areas. The frequency and negative societal impact of this aesthetic deformity has prompted the development of the “Face Lift” surgical procedure. Other related plastic surgical procedures in different regions are the Abdominoplasty (Abdomen), the Mastopexy (Breasts), and the Brachioplasty (Upper Arms).

Inherent adverse features of these surgical procedures are post-operative pain, scarring and the risk of surgical complications. Even though the aesthetic enhancement of these procedures is an acceptable tradeoff to the significant surgical incisions required, extensive permanent scarring is always an incumbent part of these procedures. For this reason, plastic surgeons design these procedures to hide the extensive scarring around anatomical borders such as the hairline (Facelift), the inframmary fold (Mastopexy), and the inguinal crease (Abdominoplasty). However, many of these incisions are hidden distant to the region of skin laxity, thereby limiting their effectiveness. Other skin laxity regions such as the Suprapatellar (upper-front) knee are not amendable to plastic surgical resections due to the poor tradeoff with a more visible surgical scar. More recently, electromagnetic medical devices that create a reverse thermal gradient (i.e., Thermage) have attempted with variable success to tighten skin without surgery. At this time, these electromagnetic devices are best deployed in patients with a moderate amount of skin laxity. Because of the limitations of electromagnetic devices and potential side effects of surgery, a minimally invasive technology is needed to circumvent surgically related scarring and the clinical variability of electromagnetic heating of the skin.

Even more significant than aesthetic modification of the skin envelope is the surgical management of burns and other trauma related skin defects. Significant burns are classified by the total body surface burned and by the depth of thermal destruction. First-degree and second-degree burns are generally managed in a non-surgical fashion with the application of topical creams and burn dressings. Deeper third-degree burns involve the full thickness thermal destruction of the skin. The surgical management of this serious injury involves the debridement of the burn eschar and the application of split thickness grafts. Due to immunological constraints, permanent split thickness skin

grafting currently requires the harvesting of autologous skin grafts from the same burn patient. Typically, the donor site on the burn patient is chosen in a non-burned area and a partial thickness sheet of skin is harvested from that area. Incumbent upon this procedure is the creation of a partial thickness skin defect at the donor site. Healing by re-

5 epithelialization of the donor site is often painful and may be prolonged for several days. In addition, a visible donor site deformity is created that is permanently thinner and more de-pigmented than the surrounding skin. For patients who have burns over a significant surface area, the extensive harvesting of skin grafts from non-burned areas may also be limited. Thus, there is a need for instruments and procedures that eliminate this donor
10 site deformity and provide the means to repeatedly harvest skin grafts from the same donor site.

INCORPORATION BY REFERENCE

Each patent, patent application, and/or publication mentioned in this specification
15 is herein incorporated by reference in its entirety to the same extent as if each individual patent, patent application, and/or publication was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

20 **Figure 1** shows a Pixel Array Dermatome (PAD) Kit placed at a target skin site, under an embodiment.

Figure 2 is a cross-section of a PAD Kit scalpet, under an embodiment.

Figure 3 is a partial cross-section of a PAD Kit scalpet, under an embodiment.

Figure 4 shows the adhesive membrane with backing of a PAD Kit, under an
25 embodiment.

Figure 5 shows the adhesive membrane with the PAD Kit frame and blade assembly, under an embodiment.

Figure 6 shows the removal of skin pixels with the PAD Kit, under an embodiment.

Figure 7 is a side view of blade transection and removal of skin pixels with the PAD Kit, under an embodiment.

Figure 8 is an isometric view of blade/pixel interaction during a procedure using the PAD Kit, under an embodiment.

5 **Figure 9** is another view during a procedure using the PAD Kit (blade removed for clarity) showing both harvested skin pixels transected and captured and non-transected skin pixels prior to transection, under an embodiment.

Figure 10A is a side view of a portion of the pixel array showing scalpets secured onto an investing plate, under an embodiment.

10 **Figure 10B** is a side view of a portion of the pixel array showing scalpets secured onto an investing plate, under an alternative embodiment.

Figure 10C is a top view of the scalpet plate, under an embodiment.

Figure 10D is a close view of a portion of the scalpet plate, under an embodiment.

15 **Figure 11A** shows an example of rolling pixel drum, under an embodiment.

Figure 11B shows an example of a rolling pixel drum assembled on a handle, under an embodiment.

Figure 11C depicts a drum dermatome for use with the scalpet plate, under an embodiment.

20 **Figure 12A** shows the drum dermatome positioned over the scalpet plate, under an embodiment.

Figure 12B is an alternative view of the drum dermatome positioned over the scalpet plate, under an embodiment.

25 **Figure 13A** is an isometric view of application of the drum dermatome (e.g., Padgett dermatome) over the scalpet plate, where the adhesive membrane is applied to the drum of the dermatome before rolling it over the investing plate, under an embodiment.

Figure 13B is a side view of a portion of the drum dermatome showing a blade position relative to the scalpet plate, under an embodiment.

Figure 13C is a side view of the portion of the drum dermatome showing a different blade position relative to the scalpet plate, under an embodiment.

Figure 13D is a side view of the drum dermatome with another blade position relative to the scalpet plate, under an embodiment.

5 **Figure 13E** is a side view of the drum dermatome with the transection blade clip showing transection of skin pixels by the blade clip, under an embodiment.

Figure 13F is a bottom view of the drum dermatome along with the scalpet plate, under an embodiment.

10 **Figure 13G** is a front view of the drum dermatome along with the scalpet plate, under an embodiment.

Figure 13H is a back view of the drum dermatome along with the scalpet plate, under an embodiment.

Figure 14A shows an assembled view of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment.

15 **Figure 14B** is an exploded view of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment.

Figure 14C shows a portion of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment.

20 **Figure 15A** shows the Slip-On PAD being slid onto a Padgett Drum Dermatome, under an embodiment.

Figure 15B shows an assembled view of the Slip-On PAD installed over the Padgett Drum Dermatome, under an embodiment.

Figure 16A shows the Slip-On PAD installed over a Padgett Drum Dermatome and used with a perforated template or guide plate, under an embodiment.

25 **Figure 16B** shows skin pixel harvesting with a Padgett Drum Dermatome and installed Slip-On PAD, under an embodiment.

Figure 17A shows an example of a Pixel Drum Dermatome being applied to a target site of the skin surface, under an embodiment.

Figure 17B shows an alternative view of a portion of the Pixel Drum Dermatome being applied to a target site of the skin surface, under an embodiment.

Figure 18A shows a top view of an oscillating flat scalpet array and blade device, under an embodiment.

5 **Figure 18B** shows a bottom view of an oscillating flat scalpet array and blade device, under an embodiment.

Figure 18C is a close-up view of the flat array when the array of scalpets, blades, adherent membrane and the adhesive backer are assembled together, under an embodiment.

10 **Figure 18D** is a close-up view of the flat array of scalpets with a feeder component, under an embodiment.

Figure 19 shows a cadaver dermal matrix cylindrically transected similar in size to the harvested skin pixel grafts, under an embodiment.

Figure 20 is a drum array drug delivery device, under an embodiment.

15 **Figure 21A** is a side view of a needle array drug delivery device, under an embodiment.

Figure 21B is an upper isometric view of a needle array drug delivery device, under an embodiment.

20 **Figure 21C** is a lower isometric view of a needle array drug delivery device, under an embodiment.

DETAILED DESCRIPTION

Pixel array medical devices, systems and methods are described for skin grafting and skin resection procedures. In the following description, numerous specific details are
25 introduced to provide a thorough understanding of, and enabling description for, embodiments herein. One skilled in the relevant art, however, will recognize that these embodiments can be practiced without one or more of the specific details, or with other components, systems, etc. In other instances, well-known structures or operations are not

shown, or are not described in detail, to avoid obscuring aspects of the disclosed embodiments.

The following terms are intended to have the following general meaning as they may be used herein. The terms are not however limited to the meanings stated herein as the meanings of any term can include other meanings as understood or applied by one skilled in the art.

“First degree burn” as used herein includes a superficial thermal injury in which there is no disruption of the epidermis from the dermis. A first-degree burn is visualized as erythema (redness) of the skin.

“Second degree burn” as used herein includes a relatively deeper burn in which there is disruption of the epidermis from the dermis and where a variable thickness of the dermis is also denatured. Most second-degree burns are associated with blister formation. Deep second-degree burns may convert to full thickness third degree burns, usually by oxidation or infection.

“Third degree burn” as used herein includes a burn associated with the full thickness thermal destruction of the skin including the epidermis and the dermis. A third degree burn may also be associated with thermal destruction of deeper, underlying tissues (subcutaneous and muscle layers).

“Ablation” as used herein includes the removal of tissue by destruction of the tissue e.g., thermal ablation of a skin lesion by a laser.

“Autograft” as used herein includes a graft taken from the same patient.

“Backed Adherent Membrane” as used herein includes the elastic adherent membrane that captures the transected skin plugs. The Backed Adherent Membrane of an embodiment is backed on the outer surface to retain alignment of the skin plugs during harvest. After harvesting of the skin plugs, the backing is removed from the adherent membrane with harvested skin plugs. The membrane of an embodiment is porous to allow for drainage when placed at the recipient site. The membrane of an embodiment also possesses an elastic recoil property, so that when the backing is removed, it brings

the sides of the skin plugs closer to each other to promote healing at the recipient site as a sheet graft.

“Burn Scar Contraction” as used herein includes the tightening of scar tissue that occurs during the wound healing process. This process is more likely to occur with an untreated third degree burn.

“Burn Scar Contracture” as used herein includes a band of scar tissue that either limits the range of motion of a joint or band of scar tissue that distorts the appearance of the patient i.e., a burn scar contracture of the face.

“Dermatome” as used herein includes an instrument that “cuts skin” or harvests a sheet split thickness skin graft. Examples of drum dermatomes include the Padgett and Reese dermatomes. Electrically powered dermatomes are the Zimmer dermatome and one electric version of the Padgett dermatome.

“Dermis” as used herein includes the deep layer of skin that is the main structural support and primarily comprises non-cellular collagen fibers. Fibroblasts are cells in the dermis that produce the collagen protein fibers.

“Donor Site” as used herein includes the anatomical site from which a skin graft is harvested.

“Epidermis” as used herein includes the outer layer of skin comprising viable epidermal cells and nonviable stratum corneum that acts as a biological barrier.

“Excise” as used herein includes the surgical removal of tissue.

“Excisional Skin Defect” as used herein includes a partial thickness or, more typically, a full thickness defect that results from the surgical removal (excision/resection) of skin (lesion).

“FTSG” as used herein includes a Full Thickness Skin Graft in which the entire thickness of the skin is harvested. With the exception of an instrument as described herein, the donor site is closed as a surgical incision. For this reason, FTSG is limited in the surface area that can be harvested.

“Granulation Tissue” as used herein includes highly vascularized tissue that grows in response to the absence of skin in a full-thickness skin defect. Granulation Tissue is the ideal base for a skin graft recipient site.

“Healing by primary intention” as used herein includes the wound healing process in which normal anatomical structures are realigned with a minimum of scar tissue formation. Morphologically the scar is less likely to be visible.

“Healing by secondary intention” as used herein includes a less organized wound healing process wherein healing occurs with less alignment of normal anatomical structures and with an increased deposition of scar collagen. Morphologically, the scar is more likely to be visible.

“Homograft” as used herein includes a graft taken from a different human and applied as a temporary biological dressing to a recipient site on a patient. Most homografts are harvested as cadaver skin. A temporary “take” of a homograft can be partially achieved with immunosuppression but homografts are eventually replaced by autografts if the patient survives.

“Incise” as used herein includes the making of a surgical incision without removal of tissue.

“Mesh Split Thickness Skin Graft” as used herein includes a split thickness skin graft that is expanded in its surface area by repetitiously incising the harvested skin graft with an instrument called a “mesher”. A meshed split thickness skin graft has a higher percentage of “take” than a sheet graft because it allows drainage through the graft and conforms better to the contour irregularities of the recipient site. However, it does result in an unsightly reticulated appearance of the graft at the recipient site.

“PAD” as used herein includes a Pixel Array Dermatome, the class of instruments for fractional skin resection.

“PAD Kit” as used herein includes the disposable single use procedure kit comprising the perforated guide plate, scalpet stamper, the guide plate frame, the backed adherent membrane and the transection blade.

“Perforated Guide Plate” as used herein includes a perforated plate comprising the entire graft harvest area in which the holes of the guide plate are aligned with the scalpets of the handled stamper or the Slip-on PAD. The plate will also function as a guard to prevent inadvertent laceration of the adjacent skin. The perforations of the Guide Plate
5 can be different geometries such as, but not limited to, round, oval, square, rectangular, and/or triangular.

“Pixelated Full Thickness Skin Graft” as used herein includes a Full Thickness Skin Graft that has been harvested with an instrument as described herein without reduced visibly apparent scarring at the donor site. The graft will also possess an
10 enhanced appearance at the recipient site similar to a sheet FTSG but will conform better to recipient site and will have a higher percentage of ‘take’ due to drainage interstices between skin plugs. Another significant advantage of the pixelated FTSG in comparison to a sheet FTSG is the ability to graft larger surface areas that would otherwise require a STSG. This advantage is due to the capability to harvest from multiple donor sites with
15 reduced visible scarring.

“Pixelated Graft Harvest” as used herein includes the skin graft harvesting from a donor site by an instrument as described in detail herein.

“Pixelated Spilt Thickness Skin Graft” as used herein includes a partial thickness skin graft that has been harvested with an SRG instrument. The skin graft shares the
20 advantages of a meshed skin graft without unsightly donor and recipient sites.

“Recipient Site” as used herein includes the skin defect site where a skin graft is applied.

“Resect” as used herein includes excising.

“Scalpel” as used herein includes the single-edged knife that incises skin and soft
25 tissue.

“Scalpet” as used herein includes the term that describes the small circular (or other geometric shaped) scalpel that incises a plug of skin.

“Scalpet Array” as used herein includes the arrangement or array of multiple scalpets secured to either a base plate or to a handled stamper.

“Scalpet Stamper” as used herein includes a handled scalpet array instrument component of the PAD Kit that incises skin plugs through the perforated guide plate.

“Scar” as used herein includes the histological deposition of disorganized collagen following wounding, and the morphological deformity that is visually apparent.

5 “Sheet Full Thickness Skin Graft” as used herein includes reference to application of the FTSG at the recipient site as continuous sheet. The appearance of an FTSG is superior to the appearance of a STSG and for this reason it is primarily used for skin grafting in visually apparent areas such as the face.

10 “Sheet Split Thickness Skin Graft” as used herein includes a partial thickness skin graft that is a continuous sheet and is associated with the typical donor site deformity.

“Skin Defect” as used herein includes the absence of the full thickness of skin that may also include the subcutaneous fat layer and deeper structures such as muscle. Skin defects can occur from a variety of causes i.e., burns, trauma, surgical excision of malignancies and the correction of congenital deformities.

15 “Skin Pixel” as used herein includes Skin Plug.

“Skin Plug” as used herein includes a circular (or other geometric shaped) piece of skin comprising epidermis and a partial or full thickness of the dermis that is incised by the scalpet, transected by the transection blade and captured by the adherent-backed membrane.

20 “STSG” as used herein includes the Partial Thickness Skin Graft in which the epidermis and a portion of the dermis is harvested with the graft.

“Subcutaneous Fat Layer” as used herein includes the layer that is immediately below the skin and is principally comprised of fat cells referred to as lipocytes. This layer functions as principle insulation layer from the environment.

25 “Transection Blade” as used herein includes a horizontally-aligned single edged blade that can be either slotted to the frame of the perforated plate or attached to the outrigger arm of the drum dermatome as described in detail herein. The transection blade transects the base of the incised skin plugs.

“Wound Healing” as used herein includes the obligate biological process that occurs from any type of wounding whether it be thermal, kinetic or surgical.

“Xenograft” as used herein includes a graft taken from a different species and applied as a temporary biological dressing to a recipient site on a patient.

5 Multiple embodiments of pixel array medical devices and corresponding methods for use are described in detail herein. The devices and methods described herein comprise a minimally invasive surgical approach that contemplates a method and apparatus for skin grafting and for skin resection that tightens lax skin without visible scarring via a device used in various surgical procedures such as plastic surgery
10 procedures. In some embodiments, the device is a single use disposable instrument. This approach circumvents surgically related scarring and the clinical variability of electromagnetic heating of the skin and performs small multiple pixilated resections of skin as a minimally invasive alternative to large plastic surgical resections of skin. This approach can also be employed in areas of the body that are currently off limits to plastic
15 surgery due to the visibility of the surgical scar. In addition, the approach can perform a skin grafting operation by harvesting the transected incisions of skin from a tissue site of a donor onto a skin defect site of a recipient with reduced scarring of the patient's donor site.

For many patients who have age related skin laxity (for non-limiting examples,
20 neck and face, arms, axillas, thighs, knees, buttocks, abdomen, bra line, ptosis of the breast), the minimally invasive surgical approach using the pixel array medical devices performs pixilated transection/resection of excess skin, replacing plastic surgery with its incumbent scarring. Generally, the procedures described herein are performed in an office setting under a local anesthetic with minimal perioperative discomfort, but are not
25 so limited. In comparison to a prolonged healing phase from plastic surgery, only a short recovery period is required, preferably applying a dressing and a support garment worn over the treatment area for a pre-specified period of time (e.g., 5 days, 7 days, etc.). There will be minimal or no pain associated with the procedure.

The relatively small (e.g., 0.5-3.0 mm) skin defects will be closed with the application of an adherent Flexan® sheet. Functioning as a large butterfly bandage, the Flexan® sheet can be pulled in a direction ("vector") that maximizes the aesthetic contouring of the treatment area. A compressive elastic garment will be applied over the dressing to further assist aesthetic contouring. After completion of the initial healing phase, the multiplicity of small linear scars within the treatment area will have reduced visibility in comparison to larger plastic surgical incisions on the same area. Additional subsequently skin tightening is likely to occur over several months due to the delayed wound healing response. Other potential applications of the embodiments described herein include the treatment of Alopecia, Snoring/Sleep apnea, Orthopedics/Physiatry, Vaginal Tightening, Female Urinary incontinence, and tightening of gastrointestinal sphincters.

Significant burns are classified by the total body surface burned and by the depth of thermal destruction, and the methods used to manage these burns depend largely on the classification. First-degree and second-degree burns are usually managed in a non-surgical fashion with the application of topical creams and burn dressings. Deeper third-degree burns involve the full thickness thermal destruction of the skin, creating a full thickness skin defect. The surgical management of this serious injury usually involves the debridement of the burn eschar and the application of split thickness grafts.

Any full thickness skin defect, most frequently created from burning, trauma, or the resection of a skin malignancy, can be closed with either skin flap transfers or skin grafts using current commercial instrumentation. Both surgical approaches require harvesting from a donor site. The use of a skin flap is further limited by the need of to include a pedicle blood supply and in most cases by the need to directly close the donor site.

The split thickness skin graft procedure, due to immunological constraints, requires the harvesting of autologous skin grafts from the same patient. Typically, the donor site on the burn patient is chosen in a non-burned area and a partial thickness sheet of skin is harvested from that area. Incumbent upon this procedure is the creation of a

partial thickness skin defect at the donor site. This donor site defect itself is similar to a deep second-degree burn. Healing by re-epithelialization of this site is often painful and may be prolonged for several days. In addition, a visible donor site deformity is typically created that is permanently thinner and more de-pigmented than the surrounding skin.

- 5 For patients who have burns over a significant surface area, the extensive harvesting of skin grafts may also be limited by the availability of non-burned areas.

Both current surgical approaches to close skin defects (flap transfer and skin grafting) are not only associated with significant scarring of the skin defect recipient site but also with the donor site from which the graft is harvested. In contrast to the
10 conventional procedures, embodiments described herein comprise Pixel Skin Grafting Procedures that eliminate this donor site deformity and provide the means to re-harvest skin grafts from any pre-existing donor site including either sheet or pixelated donor sites. This ability to re-harvest skin grafts from pre-existing donor sites will reduce the surface area requirement for donor site skin and provide additional skin grafting
15 capability in severely burned patients who have limited surface area of unburned donor skin.

The Pixel Skin Grafting Procedure of an embodiment is used as a full thickness skin graft. Many clinical applications such as facial skin grafting, hand surgery, and the repair of congenital deformities are best performed with full thickness skin grafts. The
20 texture, pigmentation and overall morphology of a full thickness skin graft more closely resembles the skin adjacent to a defect than a split thickness skin graft. For this reason, full thickness skin grafting in visibly apparent areas is superior in appearance than split thickness skin grafts. The main drawback to full thickness skin grafts is the extensive linear scarring created from the surgical closure of the full thickness donor site defect.
25 Because of this scarring, the size and utility of full thickness skin grafting has been limited. In comparison, the full thickness skin grafting of the Pixel Skin Grafting Procedure described herein is less limited by size and utility as the linear donor site scar is eliminated. Thus, many skin defects routinely covered with split thickness skin grafts will instead be treated using pixelated full thickness skin grafts.

A full thickness skin defect is most frequently created from burning, trauma or the resection of a skin malignancy. The closure of skin defects can be performed with either skin flaps or skin grafts. Both surgical approaches require harvesting from a donor site. The use of a skin flap is further limited by the need of to include a pedicle blood supply and in most cases by the need to directly close the donor site. Both surgical approaches (Flap transfer and Skin grafting) involve significant scarring of their donor sites. The Pixel Skin Grafting Procedure provides the capability to repeatedly harvest split thickness and full thickness skin grafts with minimal visible scarring of the donor site. During the procedure, a dermatome of an embodiment is used to harvest the skin graft from a chosen donor site. During the harvesting part of the procedure, the pixilated skin graft is deposited onto a semi-porous adherent membrane. The harvested skin graft/membrane composite is then applied directly to the recipient skin defect site. The fractionally resected donor site is closed with the application of an adherent Flexan® sheet in the same manner as the Pixel Skin Resection Procedure described herein. Healing of the donor site occurs rapidly with minimal discomfort and scarring.

The Pixel Skin Grafting Procedure provides the capability to harvest split thickness and full thickness skin grafts with minimal visible scarring of the donor site. During the procedure, a Pixel Array Dermatome (PAD) device is used to harvest the skin graft from a chosen donor site. During the harvesting procedure, the pixilated skin graft is deposited onto a flexible, semi-porous, adherent membrane. The harvested skin graft/membrane composite is then applied directly to the recipient skin defect site. The fractionally resected donor site is closed with the application of an adherent Flexan® sheeting that functions for one week as a large butterfly bandage. The relatively small (e.g., 1.5 mm) intradermal circular skin defects are closed to promote a primary healing process in which the normal epidermal-dermal architecture is realigned in an anatomical fashion to minimize scarring. Also occurring approximately one week postoperatively, the adherent membrane is desquamated (shed) with the stratum corneum of the graft; the membrane can then be removed without disruption of the graft from the recipient bed.

Because the skin graft at the recipient defect site using the Pixel Skin Grafting Procedure is pixelated it provides interstices for drainage between skin pixel components, which enhances the percentage of “takes,” compared to sheet skin grafts. During the first post-operative week, the skin graft will “take” at the recipient site by a process of

5 neovascularization in which new vessels from the recipient bed of the skin defect grow into the new skin graft. The semi-porous membrane will conduct the transudate (fluid) into the dressing. Furthermore, the flexible membrane is designed with an elastic recoil property that promotes apposition of component skin pixels within the graft/membrane composite and promotes primary adjacent healing of the skin graft pixels, converting the
10 pixelated appearance of the skin graft into a more uniform sheet morphology.

Additionally, the membrane aligns the micro-architectural components skin pixels, so epidermis aligns with epidermis and dermis aligns with dermis, promoting a primary healing process that reduces scarring. Moreover, pixelated skin grafts more easily conform to an irregular recipient site.

15 Embodiments described herein also include a Pixel Skin Resection Procedure, also referred to herein as the Pixel Procedure. For many patients who have age related skin laxity (neck and face, arms, axillas, thighs, knees, buttocks, abdomen, bra line, ptosis of the breast, etc.), fractional resection of excess skin could replace a significant segment of plastic surgery with its incumbent scarring. Generally, the Pixel Procedure will be
20 performed in an office setting under a local anesthetic. The post procedure recovery period includes wearing of a support garment over the treatment area for a pre-specified number (e.g, five, seven, etc.) of days. There will be little or no pain associated with the procedure. The small (e.g., 1.5mm) circular skin defects will be closed with the application of an adherent Flexan® sheet. Functioning as a large butterfly bandage, the
25 Flexan® sheet is pulled in a direction (“vector”) that maximizes the aesthetic contouring of the treatment area. A compressive elastic garment is then applied over the dressing to further assist aesthetic contouring. After completion of the initial healing phase, the multiplicity of small linear scars within the treatment area will not be visibly apparent. It is also predicted that additional skin tightening will subsequently occur over several

months due to the delayed wound healing response. Consequently, the Pixel Procedure is a minimally invasive alternative to the extensive scarring of Plastic Surgery.

The pixel array medical devices of an embodiment include a PAD Kit. **Figure 1** shows the PAD Kit placed at a target skin site, under an embodiment. The PAD Kit
5 comprises a flat perforated guide plate, a scalpet punch, (**Figures 1-3**), a backed adhesive membrane, (**Figure 4**), and a skin pixel transection blade (**Figure 5**).

Figure 2 is a cross-section of a PAD Kit scalpet, under an embodiment. **Figure 3** is a partial cross-section of a PAD Kit scalpet, under an embodiment. The partial cross-section shows the total length of the scalpets is determined by the thickness of the
10 perforated guide plate and the incisional depth into the skin, but the embodiment is not so limited.

Figure 4 shows the adhesive membrane with backing of a PAD Kit, under an embodiment. The undersurface of the adhesive membrane is applied to the incised skin at the target site.

15 **Figure 5** shows the adhesive membrane with the PAD Kit frame and blade assembly, under an embodiment. The top surface of the adhesive membrane with backing is oriented with the adhesive side down inside the frame and then pressed over the perforated plate to capture the extruded skin pixels, also referred to herein as plugs or skin plugs.

20 With reference to Figure 1, during a procedure using the PAD Kit, the perforated guide plate is first applied to the skin resection/donor site. The scalpet punch is applied through the perforated guide plate to incise the skin pixels. Following one or more serial applications by the scalpet punch, the incised skin pixels or plugs are captured onto a backed adherent membrane. The top surface of the adhesive membrane with backing is
25 oriented adhesive side down inside the frame and then pressed over the perforated plate to capture the extruded skin pixels or plugs.

As the membrane is pulled up, the captured skin pixels are transected at their base by the transection blade. **Figure 6** shows the removal of skin pixels with the PAD Kit, under an embodiment. The adhesive membrane pulls up the skin pixels or plugs, which

are cut by the transection blade. **Figure 7** is a side view of blade transection and removal of skin pixels with the PAD Kit, under an embodiment. Pixel harvesting is completed by the transection of the base of the skin pixels or plugs. **Figure 8** is an isometric view of blade/pixel interaction during a procedure using the PAD Kit, under an embodiment.

- 5 **Figure 9** is another view during a procedure using the PAD Kit (blade removed for clarity) showing both harvested skin pixels or plugs transected and captured and non-transected skin pixels or plugs prior to transection, under an embodiment.

The skin pixels or plugs deposited onto the adherent membrane can then be applied as a pixelated skin graft at a recipient skin defect site. The membrane has an
10 elastic recoil property to provide closer alignment of the skin pixels or plugs within the skin graft. At the donor site, the pixelated skin resection sites are closed with the application of Flexan® sheeting.

The pixel array medical devices of an embodiment include a Pixel Array Dermatome (PAD). The PAD comprises a flat array of relatively small circular scalpets
15 that are secured onto an investing plate, and the scalpets in combination with the investing plate are referred to herein as a scalpet plate. **Figure 10A** is a side view of a portion of the pixel array showing scalpets secured onto an investing plate, under an embodiment. **Figure 10B** is a side view of a portion of the pixel array showing scalpets secured onto an investing plate, under an alternative embodiment. **Figure 10C** is a top
20 view of the scalpet plate, under an embodiment. **Figure 10D** is a close view of a portion of the scalpet plate, under an embodiment. The scalpet plate is applied directly to the skin surface.

To leverage established surgical instrumentation, the array of an embodiment is used in conjunction with or as a modification to a drum dermatome, for example a Padget
25 dermatome or a Reese dermatome, but is not so limited. The Padget drum dermatome referenced herein was originally developed by Dr. Earl Padget in the 1930s, and continues to be widely utilized for skin grafting by Plastic Surgeons throughout the world. The Reese modification of the Padget dermatome was subsequently developed to

better calibrate the thickness of the harvested skin graft. The drum dermatome of an embodiment is a single use (per procedure) disposable, but is not so limited.

Generally, **Figure 11A** shows an example of rolling pixel drum 100, under an embodiment. **Figure 11B** shows an example of a rolling pixel drum 100 assembled on a handle, under an embodiment. More specifically, **Figure 11C** depicts a drum dermatome for use with the scalpet plate, under an embodiment.

Generally, as with all pixel devices described herein, the geometry of the pixel drum 100 can be a variety of shapes without limitation i.e., circular, semicircular, elliptical, square, flat, or rectangular. In some embodiments, the pixel drum 100 is supported by an axel/handle assembly 102 and rotated around a drum rotational component 104 powered by, e.g., an electric motor. In some embodiments, the pixel drum 100 can be placed on stand (not shown) when not in use, wherein the stand can also function as a battery recharger for the powered rotational component of the drum or the powered component of the syringe plunger. In some embodiments, a vacuum (not shown) can be applied to the skin surface of the pixel drum 100 and outriggers (not shown) can be deployed for tracking and stability of the pixel drum 100.

In some embodiments, the pixel drum 100 incorporates an array of scalpets 106 on the surface of the drum 100 to create small multiple (e.g., 0.5-1.5 mm) circular incisions referred to herein as skin plugs. In some embodiments, the border geometry of the scalpets can be designed to reduce pin cushioning ("trap door") while creating the skin plugs. The perimeter of each skin plug can also be lengthened by the scalpets to, for a non-limiting example, a, semicircular, elliptical, or square-shaped skin plug instead of a circular-shaped skin plug. In some embodiments, the length of the scalpets 106 may vary depending upon the thickness of the skin area selected by the surgeon for skin grafting purposes, i.e., partial thickness or full thickness.

When the drum 100 is applied to a skin surface, a blade 108 placed internal of the drum 100 transects the base of each skin plug created by the array of scalpets, wherein the internal blade 108 is connected to the central drum axel/handle assembly 102 and/or connected to outriggers attached to the central axel assembly 102. In some alternative

embodiments, the internal blade 108 is not connected to the drum axel assembly 102 where the base of the incisions of skin is transected. In some embodiments, the internal blade 108 of the pixel drum 100 may oscillate either manually or be powered by an electric motor. Depending upon the density of the circular scalpets on the drum, a
5 variable percentage of skin (e.g., 20%, 30%, 40%, etc.) can be transected within an area of excessive skin laxity.

In some embodiments, an added pixel drum harvester 112 is placed inside the drum 100 to perform a skin grafting operation by harvesting and aligning the transected/pixilated skin incisions/plugs (pixel graft) from tissue of a pixel donor onto an
10 adherent membrane 110 lined in the interior of the pixel drum 100. A narrow space is created between the array of scalpets 106 and the adherent membrane 110 for the internal blade 108.

In some embodiments, the blade 108 is placed external to the drum 100 and the scalpet array 106 where the base of the incised circular skin plugs is transected. In some
15 embodiments, the external blade 108 is connected to the drum axel assembly 102 when the base of the incisions of skin is transected. In some alternative embodiments, the external blade 108 is not connected to the drum axel assembly 102 when the base of the incisions of skin is transected. The adherent membrane 110 that extracts and aligns the transected skin segments onto the membrane 110, which is later placed over a skin defect
20 site of a patient. In some embodiments, blade 108 (either internal or external) can be a fenestrated layer of blade aligned to the scalpet array 106.

In some embodiments, the conformable adherent membrane 110 can be semi-porous to allow for drainage at a recipient skin defect when the membrane with the aligned transected skin segments is extracted from the drum and applied as a skin graft.
25 In some embodiments, the adherent semi-porous drum membrane 110 can also have an elastic recoil property to bring the transected/pixilated skin plugs together for grafting onto the skin defect site of the recipient, i.e., the margins of each skin plug can be brought closer together as a more uniform sheet after the adherent membrane with pixilated grafts extracted from the drum 100. In some embodiments, the adherent semi-

porous drum membrane 110 can also be expandable to cover a large surface area of the skin defect site of the recipient. In some embodiments, a sheet of adhesive backer 111 can be applied between the adherent membrane 110 and the drum harvester 112. The drum array of scalpets 106, blade 108, and adherent membrane 110 can be assembled
5 together as a sleeve onto a preexisting drum 100, as described in detail herein.

In some embodiments, the internal drum harvester 112 of the pixel drum 110 is disposable and replaceable. Limit and/or control the use of the disposable components can be accomplished by means that includes but is not limited to electronic, EPROM, mechanical, durability. The electronic and/or mechanical records and/or limits of number
10 of drum rotations for the disposable drum as well as the time of use for the disposable drum can be recorded, controlled and/or limited either electronically or mechanically.

During the harvesting portion of the procedure with a drum dermatome, the PAD scalpet array is applied directly to the skin surface. To circumferentially incise the skin pixels, the drum dermatome is positioned over the scalpet array to apply a load onto the
15 subjacent skin surface. With a continuing load, the incised skin pixels are extruded through the holes of the scalpet array and captured onto an adherent membrane on the drum dermatome. The cutting outrigger blade of the dermatome (positioned over the scalpet array) transects the base of extruded skin pixels. The membrane and the pixelated skin composite are then removed from the dermatome drum, to be directly applied to the
20 recipient skin defect as a skin graft.

With reference to Figure 11C, an embodiment includes a drum dermatome for use with the scalpet plate, as described herein. More particularly, **Figure 12A** shows the drum dermatome positioned over the scalpet plate, under an embodiment. **Figure 12B** is an alternative view of the drum dermatome positioned over the scalpet plate, under an
25 embodiment. The cutting outrigger blade of the drum dermatome is positioned on top of the scalpet array where the extruded skin plugs will be transected at their base.

Figure 13A is an isometric view of application of the drum dermatome (e.g., Padgett dermatome) over the scalpet plate, where the adhesive membrane is applied to the drum of the dermatome before rolling it over the investing plate, under an

embodiment. **Figure 13B** is a side view of a portion of the drum dermatome showing a blade position relative to the scalpet plate, under an embodiment. **Figure 13C** is a side view of the portion of the drum dermatome showing a different blade position relative to the scalpet plate, under an embodiment. **Figure 13D** is a side view of the drum dermatome with another blade position relative to the scalpet plate, under an embodiment. **Figure 13E** is a side view of the drum dermatome with the transection blade clip showing transection of skin pixels by the blade clip, under an embodiment. **Figure 13F** is a bottom view of the drum dermatome along with the scalpet plate, under an embodiment. **Figure 13G** is a front view of the drum dermatome along with the scalpet plate, under an embodiment. **Figure 13H** is a back view of the drum dermatome along with the scalpet plate, under an embodiment.

Depending upon the clinical application, the disposable adherent membrane of the drum dermatome will be used to deposit/dispose of resected lax skin or harvest/align a pixilated skin graft.

Embodiments described herein also include a Pixel Onlay Sleeve (POS) for use with the dermatomes, for example the Padget dermatomes and Reese dermatomes. **Figure 14A** shows an assembled view of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment. The POS comprises the dermatome and blade incorporated with an adhesive backer, adhesive, and a scalpet array. The adhesive backer, adhesive, and scalpet array are integral to the device, but are not so limited. **Figure 14B** is an exploded view of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment. **Figure 14C** shows a portion of the dermatome with the Pixel Onlay Sleeve (POS), under an embodiment.

The POS, also referred to herein as the “Sleeve,” provides a disposable drum dermatome onlay for the fractional resection of redundant lax skin and the fractional skin grafting of skin defects. The onlay sleeve is used in conjunction with either the Padget and Reese dermatomes as a single use disposable component. As the primary embodiment, the POS is a three-sided slip-on disposable sleeve that slips onto a drum dermatome. The device comprises an adherent membrane and a scalpet drum array with

an internal transection blade. The transection blade of an embodiment includes a single-sided cutting surface that sweeps across the internal surface of the scalpet drum array.

In an alternative blade embodiment, a fenestrated cutting layer covers the internal surface of the scalpet array. Each fenestration with its cutting surface is aligned with each individual scalpet. Instead of sweeping motion to transect the base of the skin plugs, the fenestrated cutting layer oscillates over the scalpet drum array. A narrow space between the adherent membrane and the scalpet array is created for excursion of the blade. For multiple harvesting during a skin grafting procedure, an insertion slot for additional adherent membranes is provided. The protective layer over the adherent membrane is peeled away insitu with an elongated extraction tab that is pulled from an extraction slot on the opposite side of the sleeve assembly. As with other pixel device embodiments, the adherent membrane is semiporous for drainage at the recipient skin defect site. To morph the pixilated skin graft into a more continuous sheet, the membrane may also have an elastic recoil property to provide closer alignment of the skin plugs within the skin graft.

Embodiments described herein include a Slip-On PAD that is configured as a single-use disposable device with either the Padgett or Reese dermatomes. **Figure 15A** shows the Slip-On PAD being slid onto a Padgett Drum Dermatome, under an embodiment. **Figure 15B** shows an assembled view of the Slip-On PAD installed over the Padgett Drum Dermatome, under an embodiment.

The Slip-on PAD of an embodiment is used (optionally) in combination with a perforated guide plate. **Figure 16A** shows the Slip-On PAD installed over a Padgett Drum Dermatome and used with a perforated template or guide plate, under an embodiment. The perforated guide plate is placed over the target skin site and held in place with adhesive on the bottom surface of the apron to maintain orientation. The Padgett Dermatome with Slip-On PAD is rolled over the perforated guide plate on the skin.

Figure 16B shows skin pixel harvesting with a Padgett Drum Dermatome and installed Slip-On PAD, under an embodiment. For skin pixel harvesting, the Slip-On

PAD is removed, adhesive tape is applied over the drum of the Padgett dermatome, and the clip-on blade is installed on the outrigger arm of the dermatome, which then is used to transect the base of the skin pixels. The Slip-on PAD of an embodiment is also used (optionally) with standard surgical instrumentation such as a ribbon retractor to protect the adjacent skin of the donor site.

Embodiments of the pixel instruments described herein include a Pixel Drum Dermatome (PD2) that is a single use disposable instrument or device. The PD2 comprises a cylinder or rolling/rotating drum coupled to a handle, and the cylinder includes a Scalpet Drum Array. An internal blade is interlocked to the drum axle/handle assembly and/or interlocked to outriggers attached to the central axle. As with the PAD and the POS described herein, small multiple pixilated resections of skin are performed directly in the region of skin laxity, thereby enhancing skin tightening with minimal visible scarring.

Figure 17A shows an example of a Pixel Drum Dermatome being applied to a target site of the skin surface, under an embodiment. **Figure 17B** shows an alternative view of a portion of the Pixel Drum Dermatome being applied to a target site of the skin surface, under an embodiment.

The PD2 device applies a full rolling/rotating drum to the skin surface where multiple small (e.g., 1.5 mm) circular incisions are created at the target site with a “Scalpet Drum Array”. The base of each skin plug is then transected with an internal blade that is interlocked to the central drum axle/handle assembly and/or interlocked to outriggers attached to the central axle. Depending upon the density of the circular scalpets on the drum, a variable percentage of skin can be resected. The PD2 enables portions (e.g., 20%, 30%, 40%, etc.) of the skin’s surface area to be resected without visible scarring in an area of excessive skin laxity, but the embodiment is not so limited.

Another alternative embodiment of the pixel instruments presented herein is the Pixel Drum Harvester (PDH). Similar to the Pixel Drum Dermatome, an added internal drum harvests and aligns the pixilated resections of skin onto an adherent membrane that is then placed over a recipient skin defect site of the patient. The conformable adherent

membrane is semi-porous to allow for drainage at a recipient skin defect when the membrane with the aligned resected skin segments is extracted from the drum and applied as a skin graft. An elastic recoil property of the membrane allows closer approximation of the pixilated skin segments, partially converting the pixilated skin graft to a sheet graft at the recipient site.

The pixel array medical devices described herein evoke cellular and/or extracellular responses that are obligatory to the clinical outcomes achieved. For the pixel dermatomes, a physical reduction of the skin surface area occurs due to the pixilated resection of skin, i.e., creation of the skin plugs. In addition, a subsequent tightening of the skin results due to the delayed wound healing response. Each pixilated resection initiates an obligate wound healing sequence in multiple phases as described in detail herein.

The first phase of this sequence is the inflammatory phase in which degranulation of mast cells release histamine into the "wound". Histamine release may evoke dilatation of the capillary bed and increase vessel permeability into the extracellular space. This initial wound healing response occurs within the first day and will be evident as erythema on the skin's surface.

The second phase (of Fibroplasia) commences within three to four days of "wounding". During this phase, there is migration and mitotic multiplication of fibroblasts. Fibroplasia of the wound includes the deposition of neocollagen and the myofibroblastic contraction of the wound.

Histologically, the deposition of neocollagen can be identified microscopically as compaction and thickening of the dermis. Although this is a static process, the tensile strength of the wound significantly increases. The other feature of Fibroplasia is a dynamic physical process that results in a multi-dimensional contraction of the wound. This component feature of Fibroplasia is due to the active cellular contraction of myofibroblasts. Morphologically, myoblastic contraction of the wound will be visualized as a two dimensional tightening of the skin surface. Overall, the effect of Fibroplasia is dermal contraction along with the deposition of a static supporting scaffolding of

neocollagen with a tightened framework. The clinical effect is seen as a delayed tightening of skin with smoothing of skin texture over several months. The clinical endpoint is generally a more youthful appearing skin envelope of the treatment area.

A third and final phase of the delayed wound healing response is maturation.

5 During this phase there is a strengthening and remodeling of the treatment area due to an increased cross-linkage of the collagen fibril matrix (of the dermis). This final stage commences within six to twelve months after "wounding" and may extend for at least one to two years. Small pixilated resections of skin should preserve the normal dermal architecture during this delayed wound healing process without the creation of an evident
10 scar that typically occurs with a larger surgical resection of skin. Lastly, there is a related stimulation and rejuvenation of the epidermis from the release of epidermal growth hormone. The delayed wound healing response can be evoked, with scar collagen deposition, within tissues (such as muscle or fat) with minimal pre-existing collagen matrix.

15 Other than tightening skin for aesthetic purposes, the pixel drum 100 described above may have additional medically related applications. In some embodiments, the pixel drum 100 can transect a variable portion of any soft tissue structure without resorting to a standard surgical resection. More specifically, the reduction of an actinic damaged area of skin via the pixel drum 100 should reduce the incidence of skin cancer.
20 For the treatment of sleep apnea and snoring, a pixilated mucosal reduction (soft palate, base of the tongue and lateral pharyngeal walls) via the pixel drum 100 would reduce the significant morbidity associated with more standard surgical procedures. For birth injuries of the vaginal vault, pixilated skin and vaginal mucosal resection via the pixel drum 100 would reestablish normal pre-partum geometry and function without resorting
25 to an A&P resection. Related female stress incontinence could also be corrected in a similar fashion.

Another embodiment of pixel array medical devices described herein includes a device comprising an oscillating flat array of scalpets and blade either powered electrically or deployed manually (unpowered) and used for skin tightening as an

alternative to the drum/cylinder described herein. **Figure 18A** shows a top view of an oscillating flat scalpet array and blade device, under an embodiment. **Figure 18B** shows a bottom view of an oscillating flat scalpet array and blade device, under an embodiment. Blade 108 can be a fenestrated layer of blade aligned to the scalpet array 106. The instrument handle 102 is separated from the blade handle 103 and the adherent membrane 110 can be peeled away from the adhesive backer 111. **Figure 18C** is a close-up view of the flat array when the array of scalpets 106, blades 108, adherent membrane 110 and the adhesive backer 111 are assembled together, under an embodiment. As assembled, the flat array of scalpets can be metered to provide a uniform harvest or a uniform resection. In some embodiments, the flat array of scalpets may further include a feeder component 115 for the adherent harvesting membrane 110 and adhesive backer 111. **Figure 18D** is a close-up view of the flat array of scalpets with a feeder component 115, under an embodiment.

In another skin grafting embodiment, the pixel graft is placed onto an irradiated cadaver dermal matrix (not shown). When cultured onto the dermal matrix, a graft of full thickness skin is created for the patient that is immunologically identical to the pixel donor. In some embodiments, the cadaver dermal matrix can also be cylindrical transected similar in size to the harvested skin pixel grafts to provide histological alignment of the pixilated graft into the cadaver dermal framework. **Figure 19** shows a cadaver dermal matrix cylindrically transected similar in size to the harvested skin pixel grafts, under an embodiment. In some embodiments, the percentage of harvest of the donor site can be determined in part by the induction of a normal dermal histology at the skin defect site of the recipient (**Figure 19**), i.e., a normal (smoother) surface topology of the skin graft is facilitated. With either the adherent membrane or the dermal matrix embodiment, the pixel drum harvester includes the ability to harvest a large surface area for grafting with visible scarring of the patient's donor site significantly reduced or eliminated.

In addition to the pixel array medical devices described herein, embodiments include drug delivery devices. For the most part, the parenteral delivery of drugs is still

accomplished from an injection with a syringe and needle. To circumvent the negative features of the needle and syringe system, the topical absorption of medication transcutaneously through an occlusive patch was developed. However, both of these drug delivery systems have significant drawbacks. The human aversion to a needle
5 injection has not abated during the nearly two centuries of its use. The variable systemic absorption of either a subcutaneous or intramuscular drug injection reduces drug efficacy and may increase the incidence of adverse patient responses. Depending upon the lipid or aqueous carrier fluid of the drug, the topically applied occlusive patch is plagued with variable absorption across an epidermal barrier. For patients who require local anesthesia
10 over a large surface area of skin, neither the syringe/needle injections nor topical anesthetics are ideal. The syringe/needle "field" injections are often painful and may instill excessive amounts of the local anesthetic that may cause systemic toxicity. Topical anesthetics rarely provide the level of anesthesia required for skin related procedures.

15 **Figure 20** is a drum array drug delivery device 200, under an embodiment. The drug delivery device 200 successfully addresses the limitations and drawbacks of other drug delivery systems. The device comprises a drum/cylinder 202 supported by an axel/handle assembly 204 and rotated around a drum rotation component 206. The handle assembly 204 of an embodiment further includes a reservoir 208 of drugs to be
20 delivered and a syringe plunger 210. The surface of the drum 202 is covered by an array of needles 212 of uniform length, which provide a uniform intradermal (or subdermal) injection depth with a more controlled volume of the drug injected into the skin of the patient. During operation, the syringe plunger 210 pushes the drug out of the reservoir 208 to be injected into a sealed injection chamber 214 inside the drum 202 via connecting
25 tube 216. The drug is eventually delivered into the patient's skin at a uniform depth when the array of needles 212 is pushed into a patient's skin until the surface of the drum 202 hits the skin. Non-anesthetized skip area is avoided and a more uniform pattern of cutaneous anesthesia is created. The rolling drum application of the drug delivery device 200 also instills the local anesthetic faster with less discomfort to the patient.

Figure 21A is a side view of a needle array drug delivery device 300, under an embodiment. **Figure 21B** is an upper isometric view of a needle array drug delivery device 300, under an embodiment. **Figure 21C** is a lower isometric view of a needle array drug delivery device 300, under an embodiment. The drug delivery device 300 comprises a flat array of fine needles 312 of uniform length positioned on manifold 310 can be utilized for drug delivery. In this example embodiment, syringe 302 in which drug for injection is contained can be plugged into a disposable adaptor 306 with handles, and a seal 308 can be utilized to ensure that the syringe 302 and the disposable adaptor 306 are securely coupled to each other. When the syringe plunger 304 is pushed, drug contained in syringe 302 is delivered from syringe 302 into the disposable adaptor 306. The drug is further delivered into the patient's skin through the flat array of fine needles 312 at a uniform depth when the array of needles 312 is pushed into a patient's skin until manifold 310 hits the skin.

The use of the drug delivery device 200 may have as many clinical applications as the number of pharmacological agents that require transcutaneous injection or absorption. For non-limiting examples, a few of the potential applications are the injection of local anesthetics, the injection of neuromodulators such as Botulinum toxin (Botox), the injection of insulin and the injection of replacement estrogens and corticosteroids.

In some embodiments, the syringe plunger 210 of the drug delivery device 200 can be powered by, for a non-limiting example, an electric motor. In some embodiments, a fluid pump (not shown) attached to an IV bag and tubing can be connected to the injection chamber 214 and/or the reservoir 208 for continuous injection. In some embodiments, the volume of the syringe plunger 210 in the drug delivery device 200 is calibrated and programmable.

Embodiments described herein include a method comprising applying a scalpet array to a target skin site. The scalpet array comprises a plurality of scalpets positioned on an investing plate. The investing plate is a perforated plate. The method comprises circumferentially incising skin pixels at the target skin site by applying a load via the scalpet array onto subjacent skin surface that includes the target skin site. The method

comprises capturing a plurality of incised skin pixels on an adherent substrate. The incised skin pixels are extruded through the scalpet array. The method comprises transecting bases of incised skin pixels extruded through the scalpet array.

Embodiments described herein include a method comprising: applying a scalpet
5 array to a target skin site, wherein the scalpet array comprises a plurality of scalpets positioned on an investing plate, wherein the investing plate is a perforated plate; circumferentially incising skin pixels at the target skin site by applying a load via the scalpet array onto subjacent skin surface that includes the target skin site; capturing a plurality of incised skin pixels on an adherent substrate, wherein the incised skin pixels
10 are extruded through the scalpet array; and transecting bases of incised skin pixels extruded through the scalpet array.

The applying the load of an embodiment comprises applying the load with a dermatome.

The method of an embodiment comprises configuring at least one dimension of
15 the scalpet array to be consistent with at least one dimension of the dermatome.

The method of an embodiment comprises providing the scalpet array as a separate component from the dermatome.

The method of an embodiment comprises applying the scalpet array directly to the target skin site.

20 The method of an embodiment comprises removeably coupling the scalpet array to the dermatome.

The method of an embodiment comprises coupling the adherent substrate to the dermatome.

The method of an embodiment comprises coupling the adherent substrate to the
25 dermatome prior to the applying of the load.

The method of an embodiment comprises coupling the adherent substrate to the dermatome following the applying of the load.

The method of an embodiment comprises coupling the scalpet array to the dermatome prior to the applying of the load. The method of an embodiment comprises replacing the scalpet array with the adherent substrate following the applying of the load.

5 The transecting of an embodiment comprises transecting with a cutting member that is a component of the dermatome.

The method of an embodiment comprises configuring each scalpet of the plurality of scalpets with a beveled surface.

The applying the load of an embodiment comprises applying the load with a drum dermatome.

10 The method of an embodiment comprises configuring at least one dimension of the scalpet array to be consistent with at least one dimension of a drum of the drum dermatome.

The method of an embodiment comprises coupling the adherent substrate to the drum prior to the applying of the load.

15 The method of an embodiment comprises coupling the adherent substrate to the drum following the applying of the load.

The method of an embodiment comprises providing the scalpet array as a separate component from the drum dermatome.

20 The method of an embodiment comprises placing the scalpet array directly on the target skin site prior to the applying of the load.

The method of an embodiment comprises coupling the adherent substrate to the drum prior to the applying of the load.

25 The method of an embodiment comprises removeably coupling the scalpet array to the drum dermatome prior to the applying of the load, and applying the drum dermatome with the scalpet array to the target skin site.

The method of an embodiment comprises replacing the scalpet array with the adherent substrate following the applying of the load.

The method of an embodiment comprises applying a template plate directly to a skin surface.

The template plate of an embodiment is a perforated plate comprising a first pattern of perforations.

The plurality of scalpets of an embodiment comprises a second pattern.

The second pattern of an embodiment matches the first pattern.

5 The scalpet array of an embodiment is configured to be applied over the template plate in a manner resulting in mating of the plurality of scalpets with perforations in the template plate.

The method of an embodiment comprises forming the scalpet array as an integral component of the drum dermatome.

10 The transecting of an embodiment comprises transecting with a cutting member.

The method of an embodiment comprises coupling the cutting member to the drum dermatome.

Embodiments described herein include a system comprising a scalpet array comprising a plurality of scalpets secured on an investing plate. The scalpet array is configured for application to a skin surface. The system includes a loading member. The loading member is configured to apply via the scalpet array a load onto the skin surface subjacent the scalpet array. The system includes an adherent substrate configured to capture incised skin plugs extruded through the scalpet array as a result of application of the load. The system includes a cutting member. The cutting member transects bases of the incised skin plugs extruded through the scalpet array.

Embodiments described herein include a system comprising: a scalpet array comprising a plurality of scalpets secured on an investing plate, wherein the scalpet array is configured for application to a skin surface; a loading member, wherein the loading member is configured to apply via the scalpet array a load onto the skin surface subjacent the scalpet array; an adherent substrate configured to capture incised skin plugs extruded through the scalpet array as a result of application of the load; and a cutting member, wherein the cutting member transects bases of the incised skin plugs extruded through the scalpet array.

The loading member of an embodiment comprises a dermatome.

At least one dimension of the scalpet array of an embodiment fits at least one dimension of the dermatome.

The adherent membrane of an embodiment is coupled to the loading member.

5 The loading member of an embodiment comprises a dermatome, wherein the adherent substrate is carried on a component of the dermatome.

The cutting member of an embodiment is coupled to the loading member.

The loading member of an embodiment comprises a dermatome, wherein the cutting member is a component of the dermatome.

10 Each scalpet of the plurality of scalpets of an embodiment comprises a beveled surface.

The loading member of an embodiment comprises a drum dermatome.

At least one dimension of the scalpet array of an embodiment fits at least one dimension of a drum of the drum dermatome.

The scalpet array of an embodiment is separate from the drum dermatome.

15 The cutting member of an embodiment is coupled to the drum dermatome.

The cutting member of an embodiment is internal to the drum.

The cutting member of an embodiment is external to the drum.

The adherent substrate of an embodiment is coupled to the drum.

The drum of an embodiment is an array drum comprising the scalpet array.

20 The array drum of an embodiment is detachable.

The array drum of an embodiment is disposable.

The adherent substrate of an embodiment is coupled to an interior of the array drum.

25 Embodiments described herein include a system comprising a scalpet array comprising a plurality of scalpets secured on an investing plate. The scalpet array is configured for application to a skin surface. The system includes an adherent substrate configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load onto the skin surface subjacent the scalpet array. The scalpet array is independent of the adherent substrate.

Embodiments described herein include a system comprising: a scalpet array comprising a plurality of scalpets secured on an investing plate, wherein the scalpet array is configured for application to a skin surface; and an adherent substrate configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load onto the skin surface subjacent the scalpet array, wherein the scalpet array is independent of the adherent substrate.

The adherent substrate of an embodiment is coupled to a dermatome, wherein the dermatome is configured to apply the load via the scalpet array.

The dermatome of an embodiment includes a cutting member, wherein the cutting member transects bases of the incised skin plugs extruded through the scalpet array.

The dermatome of an embodiment is a drum dermatome comprising a drum.

The adherent substrate of an embodiment is carried on the drum.

At least one dimension of the scalpet array of an embodiment is in proportion with at least one dimension of the drum.

The drum of an embodiment is an array drum comprising the scalpet array.

The array drum of an embodiment is detachable.

The array drum of an embodiment is disposable.

The adherent substrate of an embodiment is coupled to an interior of the array drum.

Embodiments described herein include a system comprising a scalpet array comprising a plurality of scalpets fixed on a sleeve. The sleeve is configured to be removeably coupled to and carried on a component of a dermatome. The system includes an adherent substrate configured to be positioned on the component adjacent the sleeve, wherein the adherent substrate is configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load to the scalpet array.

Embodiments described herein include a system comprising: a scalpet array comprising a plurality of scalpets fixed on a sleeve, wherein the sleeve is configured to be removeably coupled to and carried on a component of a dermatome; and an adherent substrate configured to be positioned on the component adjacent the sleeve, wherein the

adherent substrate is configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load to the scalpet array.

The adherent substrate of an embodiment is configured to be positioned on the component between the sleeve and the component.

5 The dermatome of an embodiment is a drum dermatome, and the component is a drum.

The adherent substrate of an embodiment is positioned between an outer surface of the drum and the sleeve, wherein the drum dermatome is configured to apply the load via the scalpet array.

10 The dermatome of an embodiment includes a cutting member, wherein the cutting member transects the incised skin plugs extruded through the scalpet array.

The cutting member of an embodiment is internal to the drum.

The cutting member of an embodiment is external to the drum.

The drum dermatome of an embodiment is a Padgett dermatome.

15 The drum of an embodiment is an array drum comprising the scalpet array.

The array drum of an embodiment is detachable.

The array drum of an embodiment is disposable.

The adherent substrate of an embodiment is coupled to an interior of the array drum.

20 The sleeve of an embodiment is disposable.

Embodiments described herein include a system comprising a scalpet array comprising a plurality of scalpets fixed on a sleeve. The sleeve is configured to be removeably coupled to and carried on a component of a dermatome. The system includes an adherent substrate, wherein the adherent substrate is configured to be removeably
25 coupled to and carried on the component, wherein the adherent substrate is configured to capture skin pixels generated by application of the scalpet array to a skin surface.

Embodiments described herein include a system comprising: a scalpet array comprising a plurality of scalpets fixed on a sleeve, wherein the sleeve is configured to be removeably coupled to and carried on a component of a dermatome; and an adherent

substrate, wherein the adherent substrate is configured to be removeably coupled to and carried on the component, wherein the adherent substrate is configured to capture skin pixels generated by application of the scalpet array to a skin surface.

5 The dermatome of an embodiment is a drum dermatome, and the component is a drum.

The drum dermatome of an embodiment is configured to apply via the scalpet array a load onto the skin surface subjacent the scalpet array.

The adherent substrate of an embodiment is used in lieu of the scalpet array and is configured to capture incised skin plugs resulting from application of the load.

10 The adherent substrate of an embodiment is positioned on an outer surface of the drum.

The drum dermatome of an embodiment includes a cutting member, wherein the cutting member transects the incised skin plugs.

The cutting member of an embodiment is internal to the drum.

15 The cutting member of an embodiment is external to the drum.

The drum dermatome of an embodiment is a Padgett dermatome.

The drum of an embodiment is an array drum comprising the scalpet array.

The array drum of an embodiment is detachable.

The array drum of an embodiment is disposable.

20 The adherent substrate of an embodiment is coupled to an interior of the array drum.

The system of an embodiment comprises a template plate configured for application to a skin surface.

25 The template plate of an embodiment is a perforated plate comprising a first pattern of perforations.

The plurality of scalpets of an embodiment comprises a second pattern on the sleeve.

The second pattern of an embodiment matches the first pattern.

The sleeve of an embodiment is configured to be applied over the template plate in a manner resulting in mating of the plurality of scalpets with perforations in the template plate.

The sleeve of an embodiment is disposable.

5 Unless the context clearly requires otherwise, throughout the description, the words “comprise,” “comprising,” and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in a sense of “including, but not limited to.” Words using the singular or plural number also include the plural or singular number respectively. Additionally, the words “herein,” “hereunder,” “above,”
10 “below,” and words of similar import, when used in this application, refer to this application as a whole and not to any particular portions of this application. When the word “or” is used in reference to a list of two or more items, that word covers all of the following interpretations of the word: any of the items in the list, all of the items in the list and any combination of the items in the list.

15 The above description of embodiments is not intended to be exhaustive or to limit the systems and methods to the precise forms disclosed. While specific embodiments of, and examples for, the medical devices and methods are described herein for illustrative purposes, various equivalent modifications are possible within the scope of the systems and methods, as those skilled in the relevant art will recognize. The teachings of the
20 medical devices and methods provided herein can be applied to other systems and methods, not only for the systems and methods described above.

The elements and acts of the various embodiments described above can be combined to provide further embodiments. These and other changes can be made to the medical devices and methods in light of the above detailed description.

25 In general, in the following claims, the terms used should not be construed to limit the medical devices and methods and corresponding systems and methods to the specific embodiments disclosed in the specification and the claims, but should be construed to include all systems that operate under the claims. Accordingly, the medical devices and

methods and corresponding systems and methods are not limited by the disclosure, but instead the scope is to be determined entirely by the claims.

While certain aspects of the medical devices and methods and corresponding systems and methods are presented below in certain claim forms, the inventors

5 contemplate the various aspects of the medical devices and methods and corresponding systems and methods in any number of claim forms. Accordingly, the inventors reserve the right to add additional claims after filing the application to pursue such additional claim forms for other aspects of the medical devices and methods and corresponding systems and methods.

10

CLAIMS

What is claimed is:

1. A method comprising:

5 applying a scalpet array to a target skin site, wherein the scalpet array comprises a plurality of scalpets positioned on an investing plate, wherein the investing plate is a perforated plate;

circumferentially incising skin pixels at the target skin site by applying a load via the scalpet array onto subjacent skin surface that includes the target skin site;

10 capturing a plurality of incised skin pixels on an adherent substrate, wherein the incised skin pixels are extruded through the scalpet array; and

transecting bases of incised skin pixels extruded through the scalpet array.

15 2. The method of claim 1, wherein the applying the load comprises applying the load with a dermatome.

3. The method of claim 2, comprising configuring at least one dimension of the scalpet array to be consistent with at least one dimension of the dermatome.

20 4. The method of claim 3, comprising providing the scalpet array as a separate component from the dermatome.

5. The method of claim 4, comprising applying the scalpet array directly to the target skin site.

25

6. The method of claim 4, comprising removeably coupling the scalpet array to the dermatome.

7. The method of claim 2, comprising coupling the adherent substrate to the dermatome.

8. The method of claim 7, comprising coupling the adherent substrate to the dermatome prior to the applying of the load.

9. The method of claim 7, comprising coupling the adherent substrate to the dermatome following the applying of the load.

10. The method of claim 2, comprising:
coupling the scalpet array to the dermatome prior to the applying of the load;
replacing the scalpet array with the adherent substrate following the applying of the load.

11. The method of claim 2, wherein the transecting comprises transecting with a cutting member that is a component of the dermatome.

12. The method of claim 2, comprising configuring each scalpet of the plurality of scalpets with a beveled surface.

13. The method of claim 1, wherein the applying the load comprises applying the load with a drum dermatome.

14. The method of claim 13, comprising configuring at least one dimension of the scalpet array to be consistent with at least one dimension of a drum of the drum dermatome.

15. The method of claim 14, comprising coupling the adherent substrate to the drum prior to the applying of the load.

16. The method of claim 14, comprising coupling the adherent substrate to the drum following the applying of the load.

5 17. The method of claim 14, comprising providing the scalpet array as a separate component from the drum dermatome.

18. The method of claim 17, comprising placing the scalpet array directly on the target skin site prior to the applying of the load.

10

19. The method of claim 18, comprising coupling the adherent substrate to the drum prior to the applying of the load.

15 20. The method of claim 14, comprising removeably coupling the scalpet array to the drum dermatome prior to the applying of the load, and applying the drum dermatome with the scalpet array to the target skin site.

21. The method of claim 20, comprising replacing the scalpet array with the adherent substrate following the applying of the load.

20

22. The method of claim 20, comprising applying a template plate directly to a skin surface.

25 23. The method of claim 22, wherein the template plate is a perforated plate comprising a first pattern of perforations.

24. The method of claim 23, wherein the plurality of scalpets comprise a second pattern.

25. The method of claim 24, wherein the second pattern matches the first pattern.

26. The method of claim 25, wherein the scalpet array is configured to be applied over the template plate in a manner resulting in mating of the plurality of scalpets with perforations in the template plate.

27. The method of claim 14, comprising forming the scalpet array as an integral component of the drum dermatome.

28. The method of claim 14, wherein the transecting comprises transecting with a cutting member.

29. The method of claim 28, comprising coupling the cutting member to the drum dermatome.

30. A system comprising:

a scalpet array comprising a plurality of scalpets secured on an investing plate, wherein the scalpet array is configured for application to a skin surface;

a loading member, wherein the loading member is configured to apply via the scalpet array a load onto the skin surface subjacent the scalpet array;

an adherent substrate configured to capture incised skin plugs extruded through the scalpet array as a result of application of the load; and

a cutting member, wherein the cutting member transects bases of the incised skin plugs extruded through the scalpet array.

31. The system of claim 30, wherein the loading member comprises a dermatome.

32. The system of claim 31, wherein at least one dimension of the scalpet array fits at least one dimension of the dermatome.

33. The system of claim 30, wherein the adherent membrane is coupled to the loading member.

5 34. The system of claim 33, wherein the loading member comprises a dermatome, wherein the adherent substrate is carried on a component of the dermatome.

35. The system of claim 30, wherein the cutting member is coupled to the loading member.

10

36. The system of claim 35, wherein the loading member comprises a dermatome, wherein the cutting member is a component of the dermatome.

15 37. The system of claim 30, wherein each scalpet of the plurality of scalpets comprises a beveled surface.

38. The system of claim 30, wherein the loading member comprises a drum dermatome.

20 39. The system of claim 38, wherein at least one dimension of the scalpet array fits at least one dimension of a drum of the drum dermatome.

40. The system of claim 39, wherein the scalpet array is separate from the drum dermatome.

25

41. The system of claim 39, wherein the cutting member is coupled to the drum dermatome.

42. The system of claim 41, wherein the cutting member is internal to the drum.

43. The system of claim 41, wherein the cutting member is external to the drum.

44. The system of claim 41, wherein the adherent substrate is coupled to the drum.

45. The system of claim 39, wherein the drum is an array drum comprising the scalpet array.

46. The system of claim 45, wherein the array drum is detachable.

47. The system of claim 45, wherein the array drum is disposable.

48. The system of claim 45, wherein the adherent substrate is coupled to an interior of the array drum.

49. A system comprising:

a scalpet array comprising a plurality of scalpets secured on an investing plate, wherein the scalpet array is configured for application to a skin surface; and

an adherent substrate configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load onto the skin surface subjacent the scalpet array, wherein the scalpet array is independent of the adherent substrate.

50. The system of claim 49, wherein the adherent substrate is coupled to a dermatome, wherein the dermatome is configured to apply the load via the scalpet array.

51. The system of claim 50, wherein the dermatome includes a cutting member, wherein the cutting member transects bases of the incised skin plugs extruded through the scalpet array.

52. The system of claim 51, wherein the dermatome is a drum dermatome comprising a drum.

53. The system of claim 52, wherein the adherent substrate is carried on the drum.

54. The system of claim 52, wherein at least one dimension of the scalpet array is in proportion with at least one dimension of the drum.

55. The system of claim 48, wherein the drum is an array drum comprising the scalpet array.

56. The system of claim 55, wherein the array drum is detachable.

57. The system of claim 55, wherein the array drum is disposable.

58. The system of claim 55, wherein the adherent substrate is coupled to an interior of the array drum.

59. A system comprising:

a scalpet array comprising a plurality of scalpets fixed on a sleeve, wherein the sleeve is configured to be removeably coupled to and carried on a component of a dermatome; and

an adherent substrate configured to be positioned on the component adjacent the sleeve, wherein the adherent substrate is configured to capture incised skin pixels extruded through the scalpet array as a result of application of a load to the scalpet array.

60. The system of claim 59, wherein the adherent substrate is configured to be positioned on the component between the sleeve and the component.

61. The system of claim 60, wherein the dermatome is a drum dermatome, and the component is a drum.

62. The system of claim 61, wherein the adherent substrate is positioned between an outer surface of the drum and the sleeve, wherein the drum dermatome is configured to apply the load via the scalpet array.

63. The system of claim 62, wherein the dermatome includes a cutting member, wherein the cutting member transects the incised skin plugs extruded through the scalpet array.

64. The system of claim 63, wherein the cutting member is internal to the drum.

65. The system of claim 63, wherein the cutting member is external to the drum.

66. The system of claim 61, wherein the drum dermatome is a Padgett dermatome.

67. The system of claim 61, wherein the drum is an array drum comprising the scalpet array.

68. The system of claim 67, wherein the array drum is detachable.

69. The system of claim 67, wherein the array drum is disposable.

70. The system of claim 67, wherein the adherent substrate is coupled to an interior of the array drum.

71. The system of claim 59, wherein the sleeve is disposable.

72. A system comprising:

a scalpet array comprising a plurality of scalpets fixed on a sleeve, wherein the sleeve is configured to be removeably coupled to and carried on a component of a dermatome; and

an adherent substrate, wherein the adherent substrate is configured to be removeably coupled to and carried on the component, wherein the adherent substrate is configured to capture skin pixels generated by application of the scalpet array to a skin surface.

73. The system of claim 72, wherein the dermatome is a drum dermatome, and the component is a drum.

74. The system of claim 73, wherein the drum dermatome is configured to apply via the scalpet array a load onto the skin surface subjacent the scalpet array.

75. The system of claim 74, wherein the adherent substrate is used in lieu of the scalpet array and is configured to capture incised skin plugs resulting from application of the load.

76. The system of claim 75, wherein the adherent substrate is positioned on an outer surface of the drum.

77. The system of claim 75, wherein the drum dermatome includes a cutting member, wherein the cutting member transects the incised skin plugs.

78. The system of claim 77, wherein the cutting member is internal to the drum.

79. The system of claim 77, wherein the cutting member is external to the drum.

80. The system of claim 73, wherein the drum dermatome is a Padgett dermatome.

81. The system of claim 73, wherein the drum is an array drum comprising the scalpet
5 array.

82. The system of claim 81, wherein the array drum is detachable.

83. The system of claim 81, wherein the array drum is disposable.

84. The system of claim 81, wherein the adherent substrate is coupled to an interior of
10 the array drum.

85. The system of claim 72, comprising a template plate configured for application to
15 a skin surface.

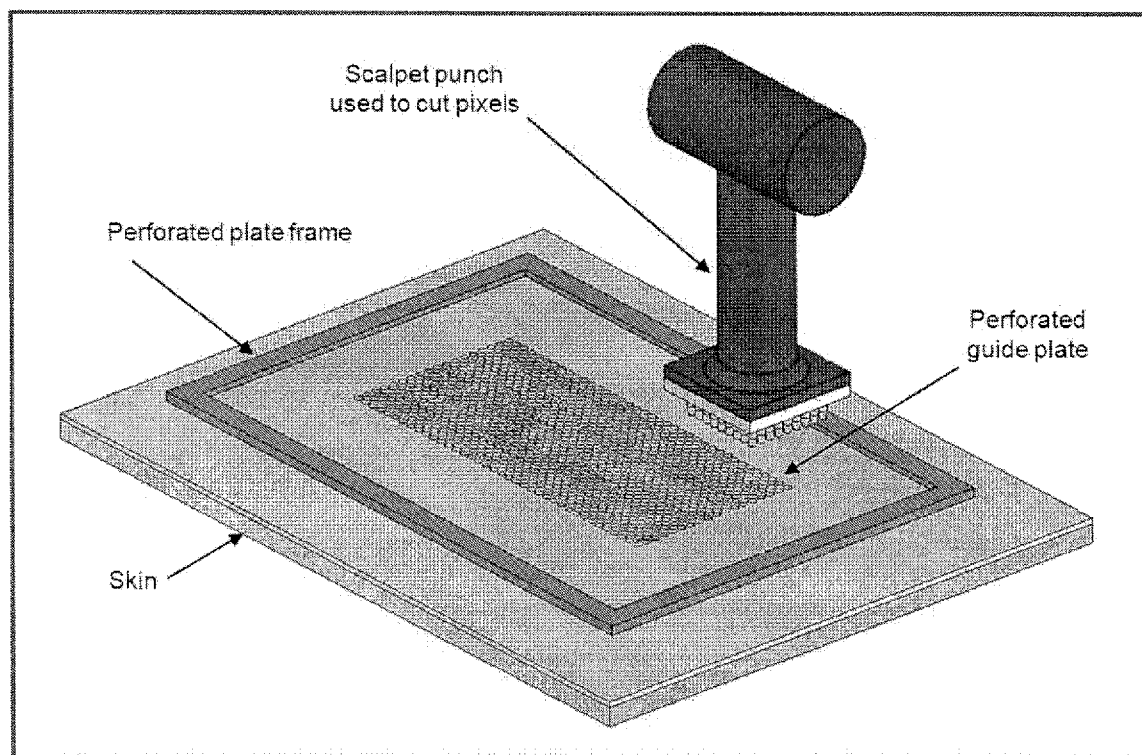
86. The system of claim 85, wherein the template plate is a perforated plate
comprising a first pattern of perforations.

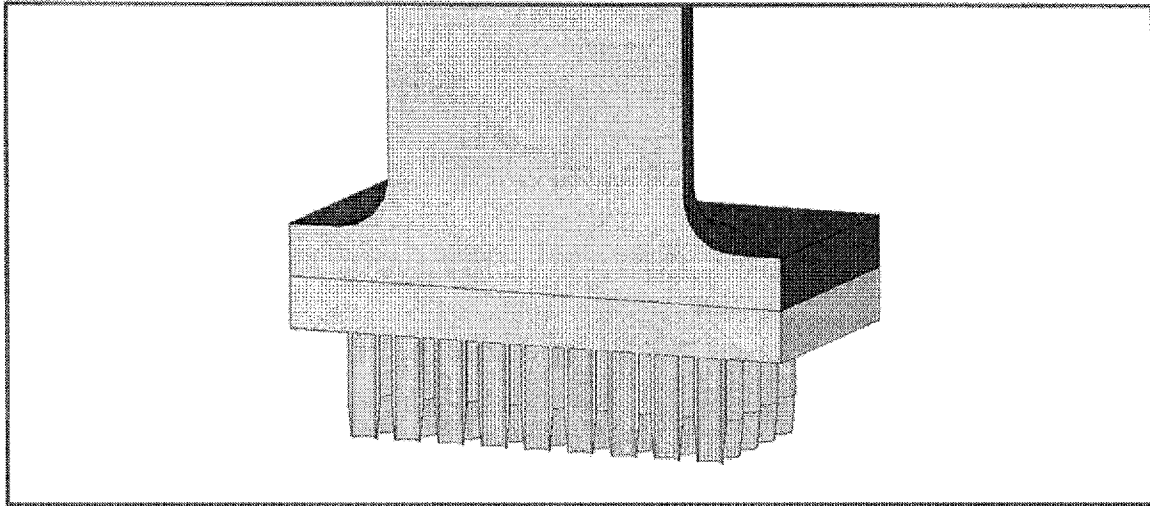
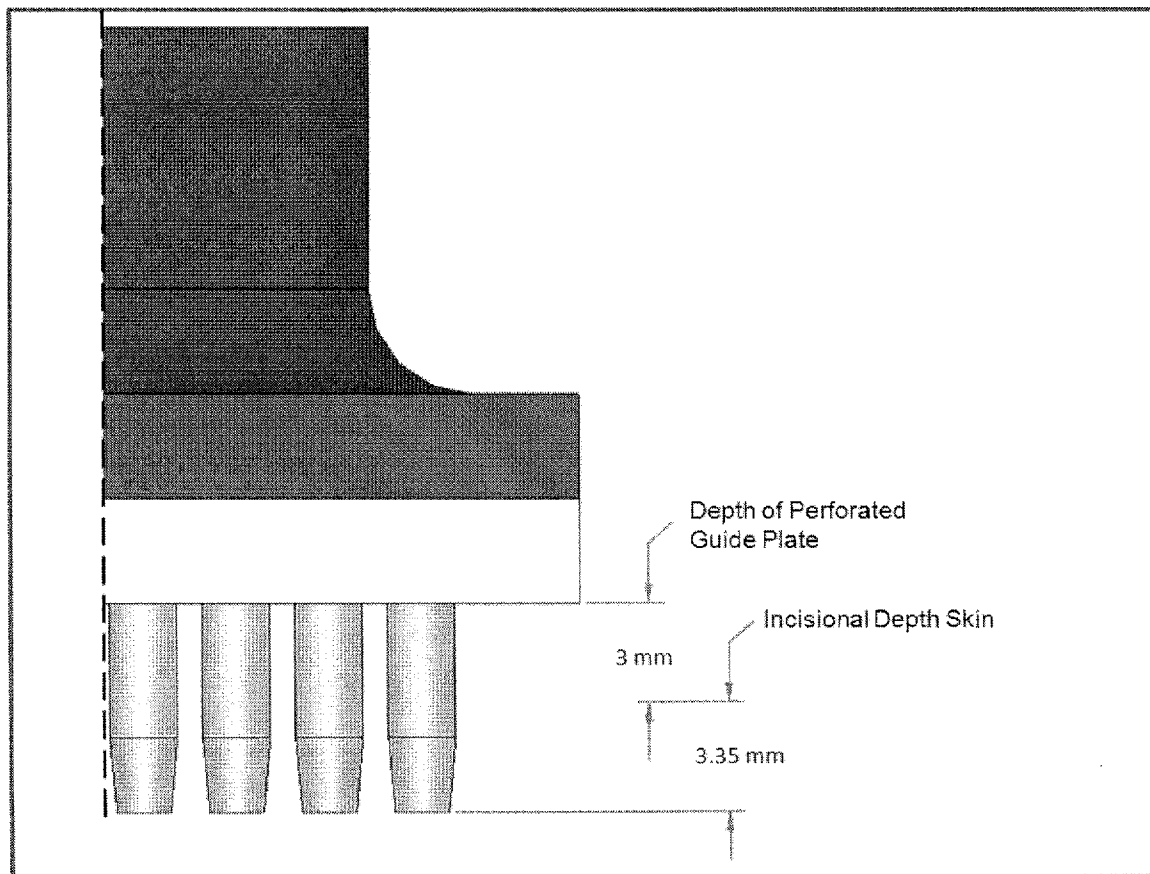
87. The system of claim 86, wherein the plurality of scalpets comprise a second
20 pattern on the sleeve.

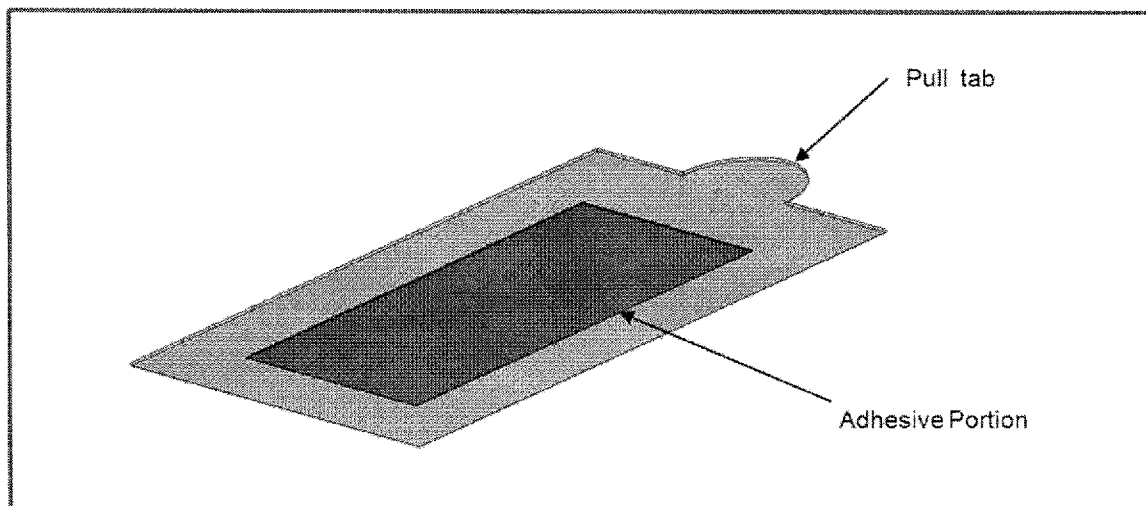
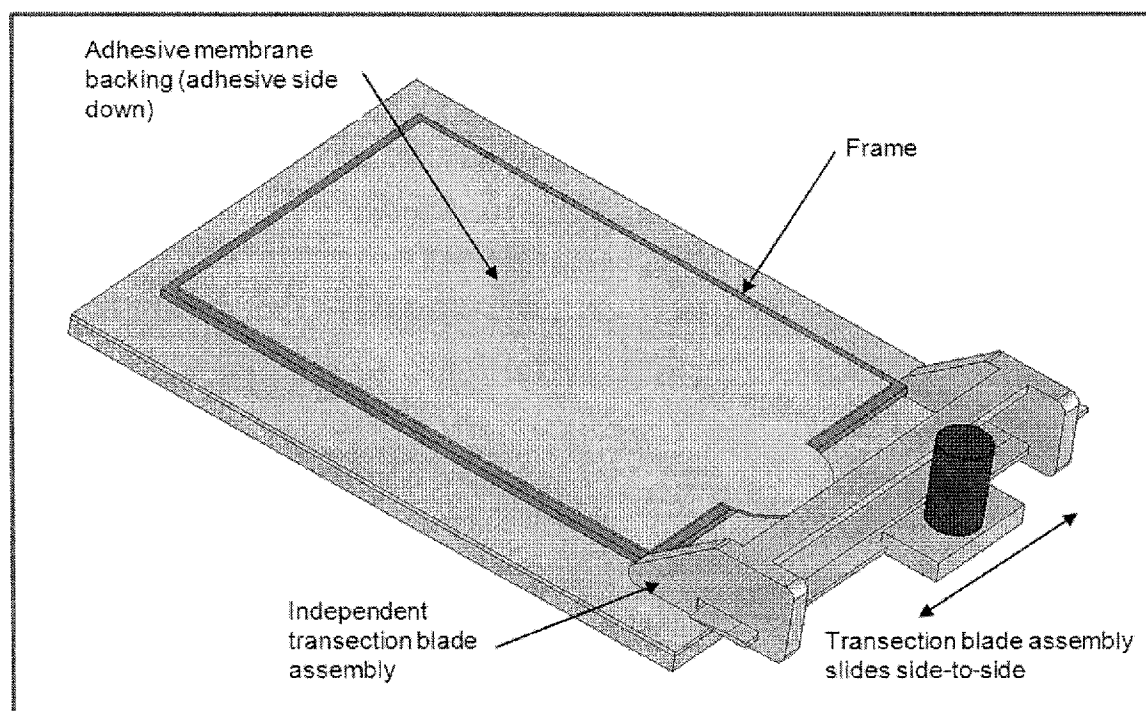
88. The system of claim 87, wherein the second pattern matches the first pattern.

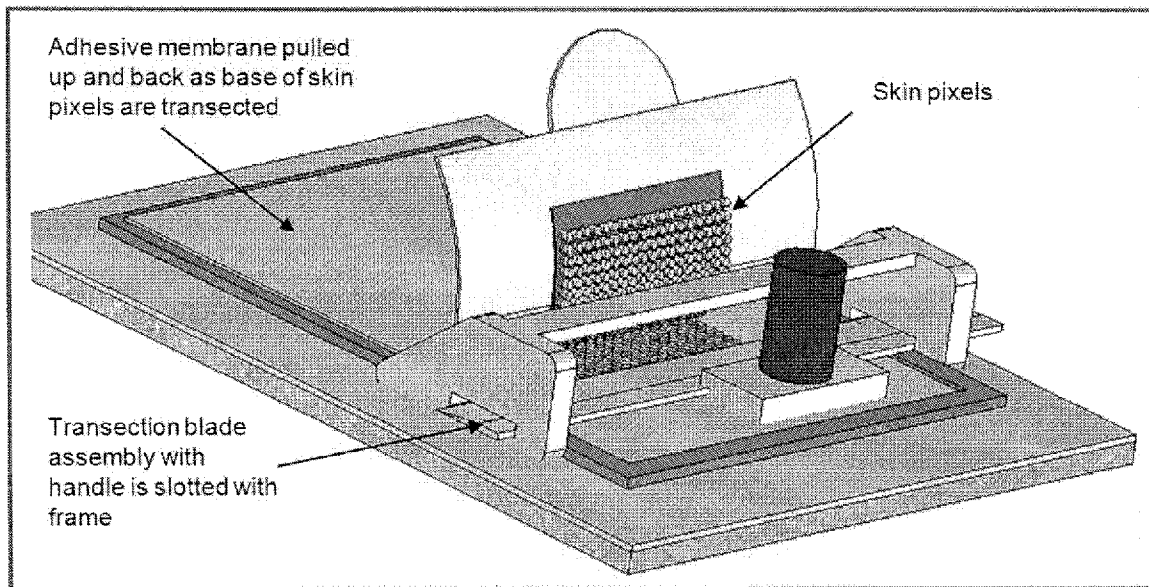
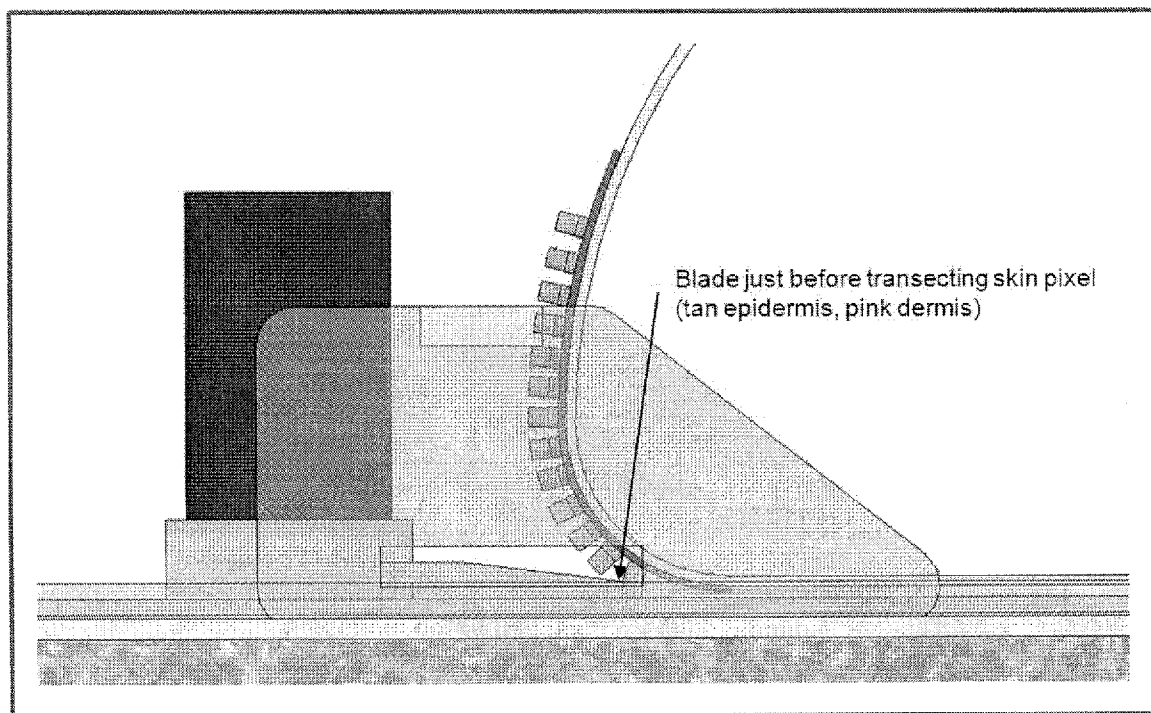
89. The system of claim 88, wherein the sleeve is configured to be applied over the
25 template plate in a manner resulting in mating of the plurality of scalpets with
perforations in the template plate.

90. The system of claim 72, wherein the sleeve is disposable.

**FIGURE 1**

**FIGURE 2****FIGURE 3**

**FIGURE 4****FIGURE 5**

**FIGURE 6****FIGURE 7**

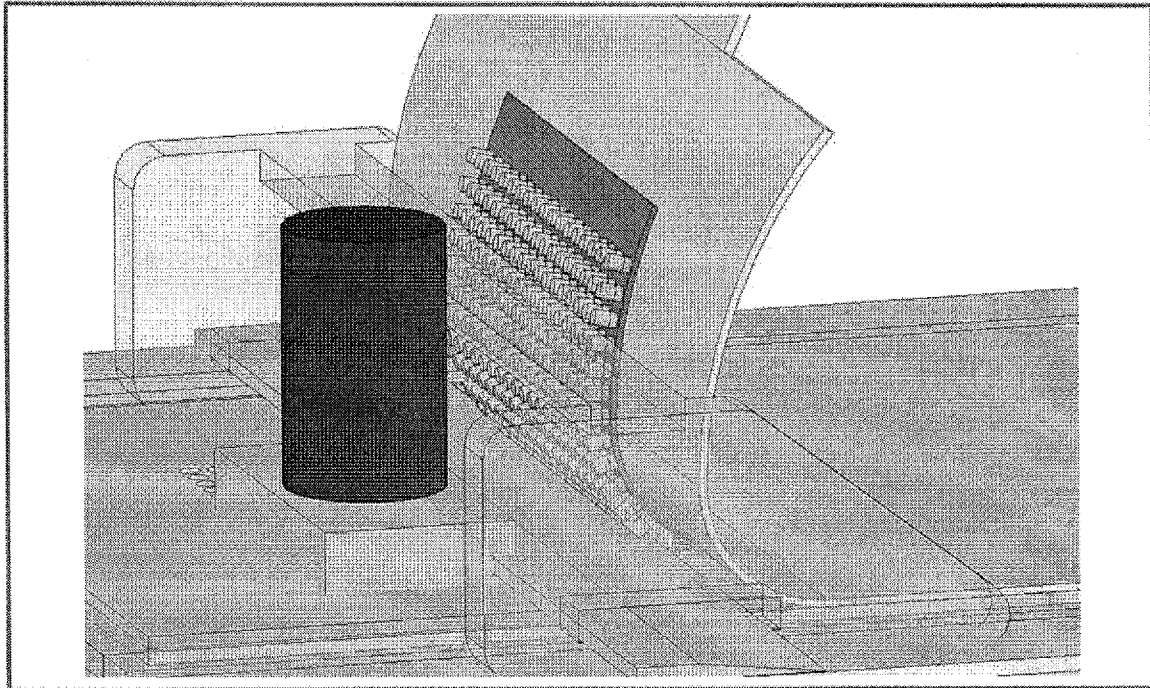


FIGURE 8

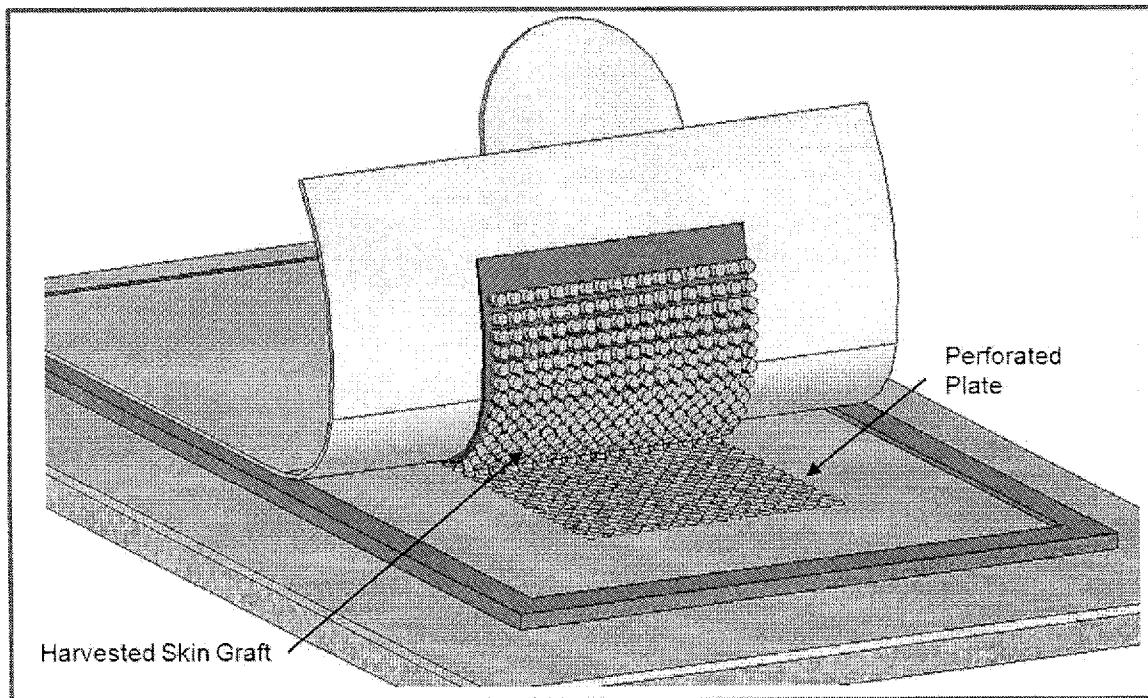
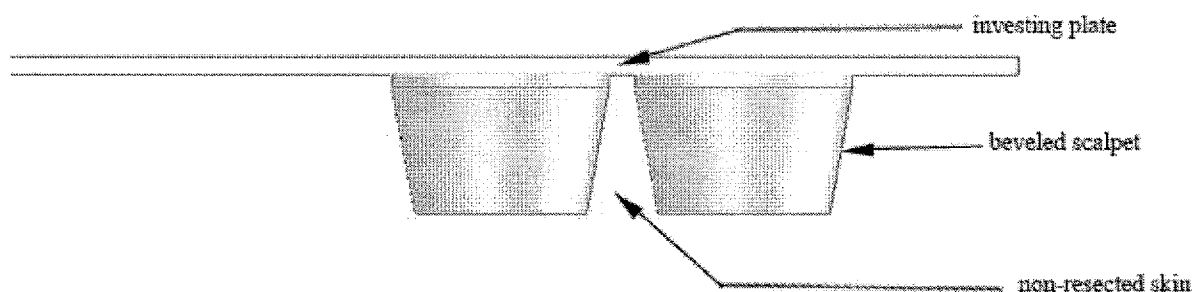
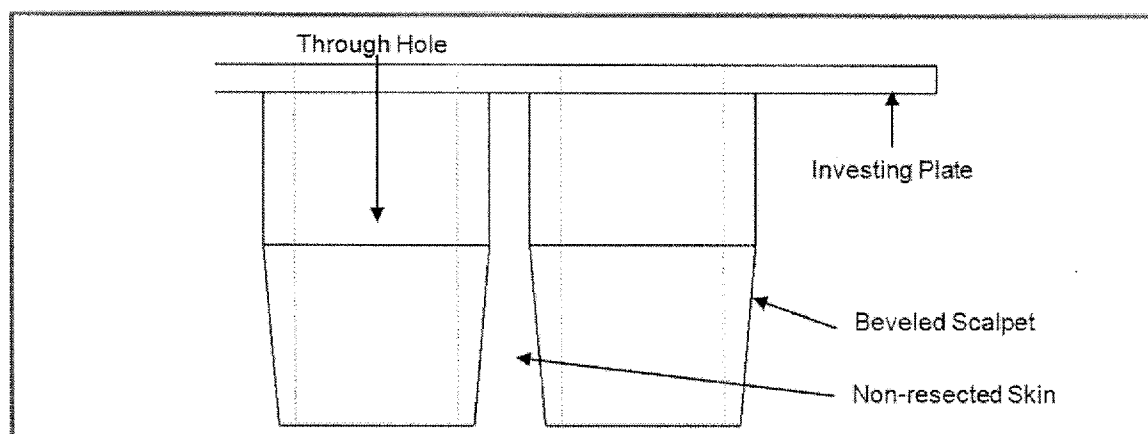


FIGURE 9

**FIGURE 10A**

**FIGURE 10B**

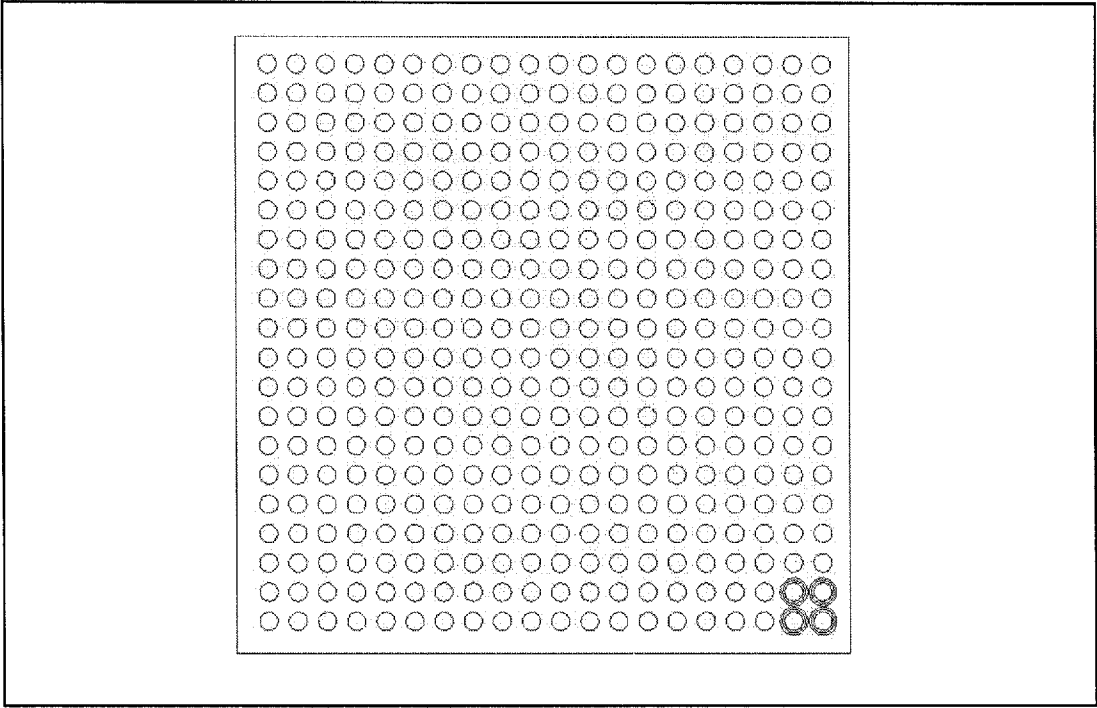
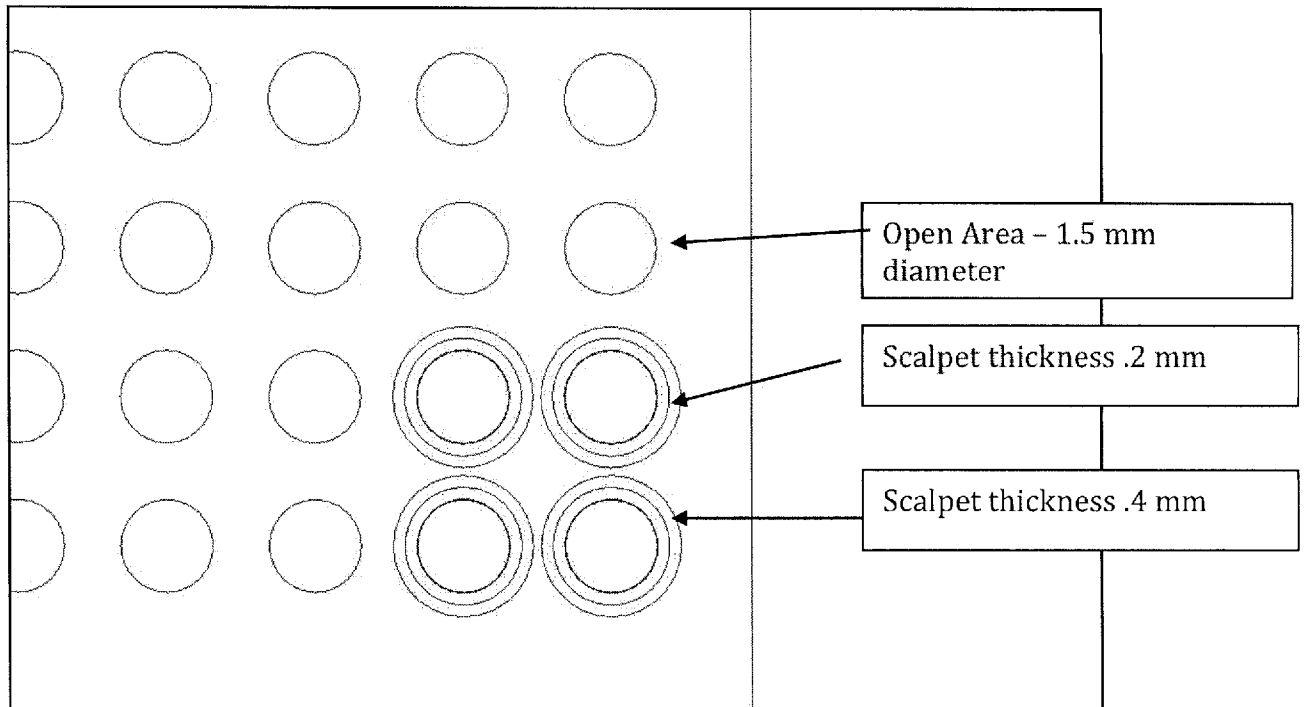


FIGURE 10C

**FIGURE 10D**

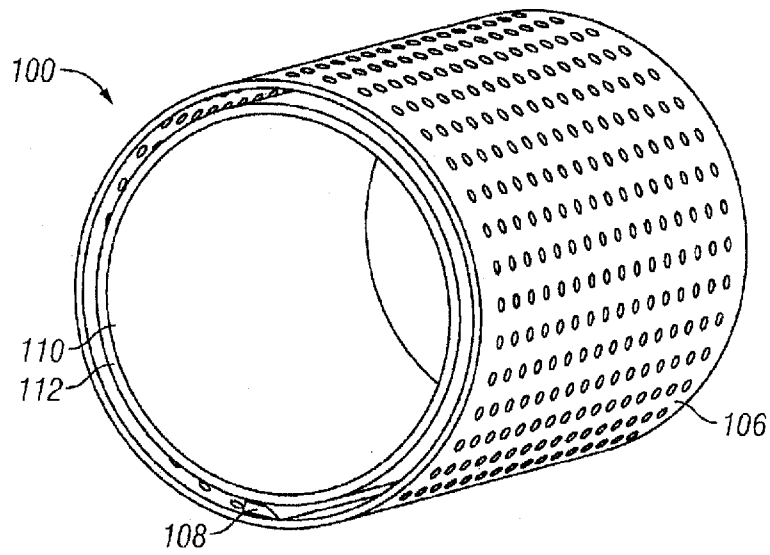


FIG. 11A

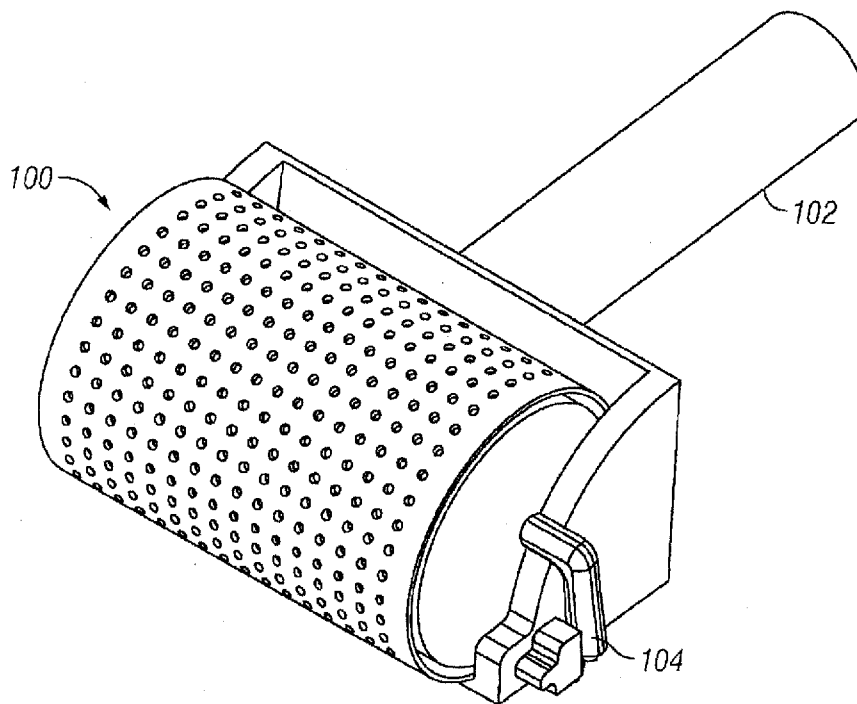


FIG. 11B

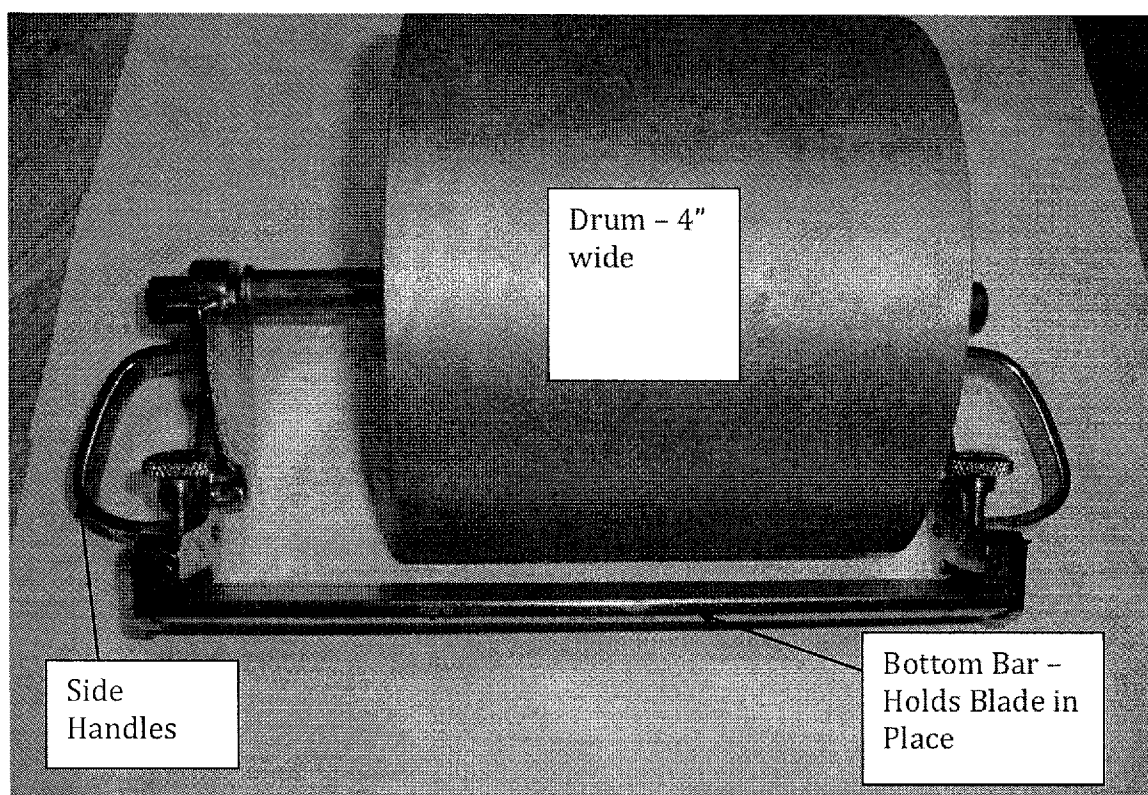


FIGURE 11C

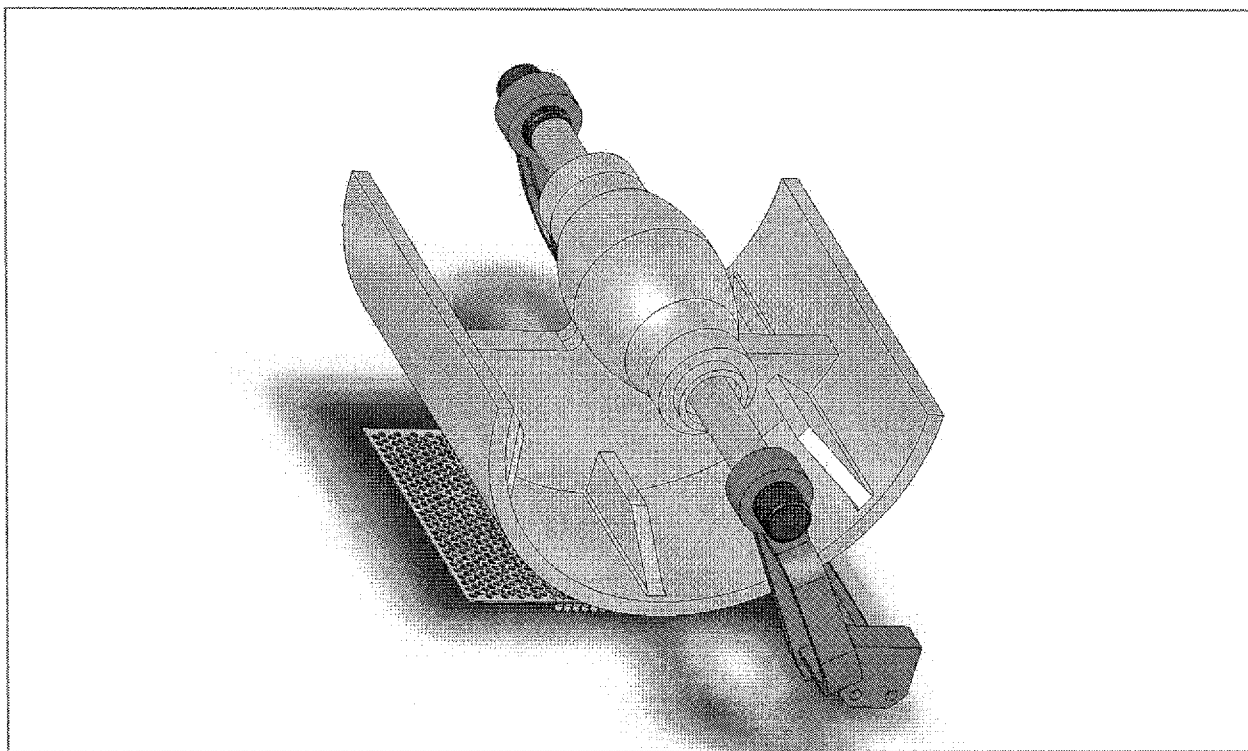


FIGURE 12A

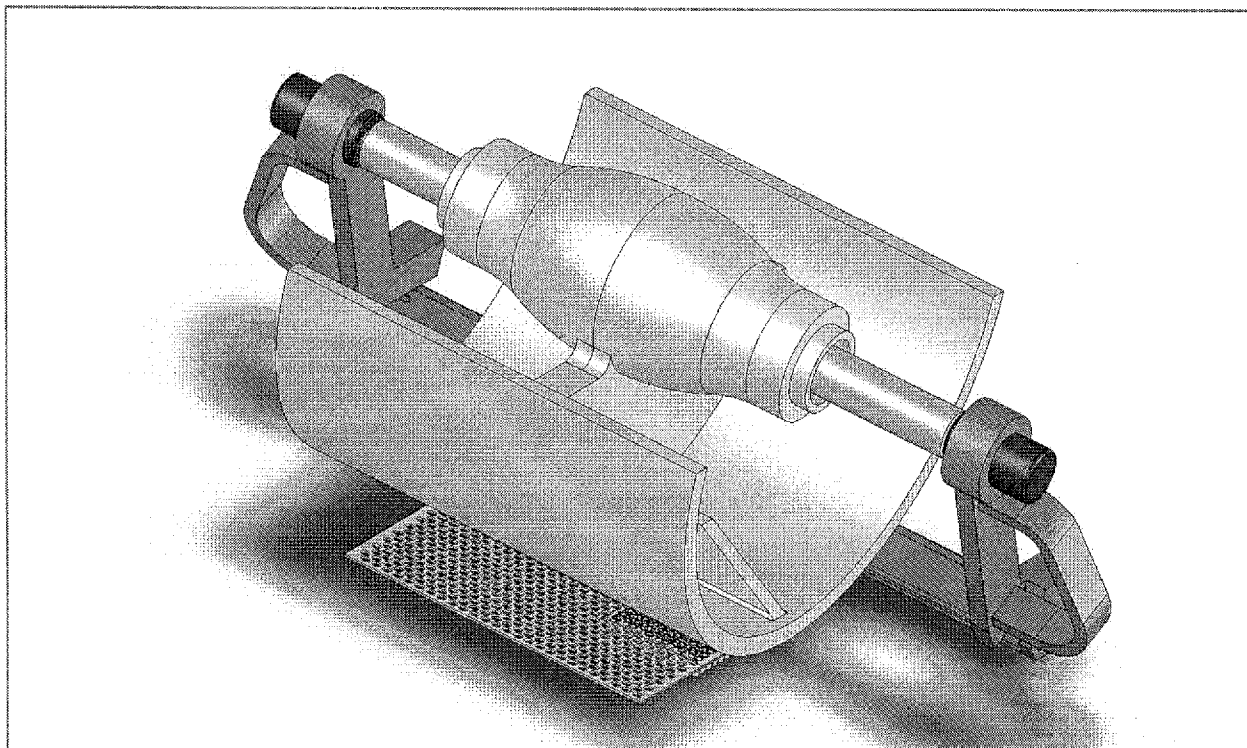
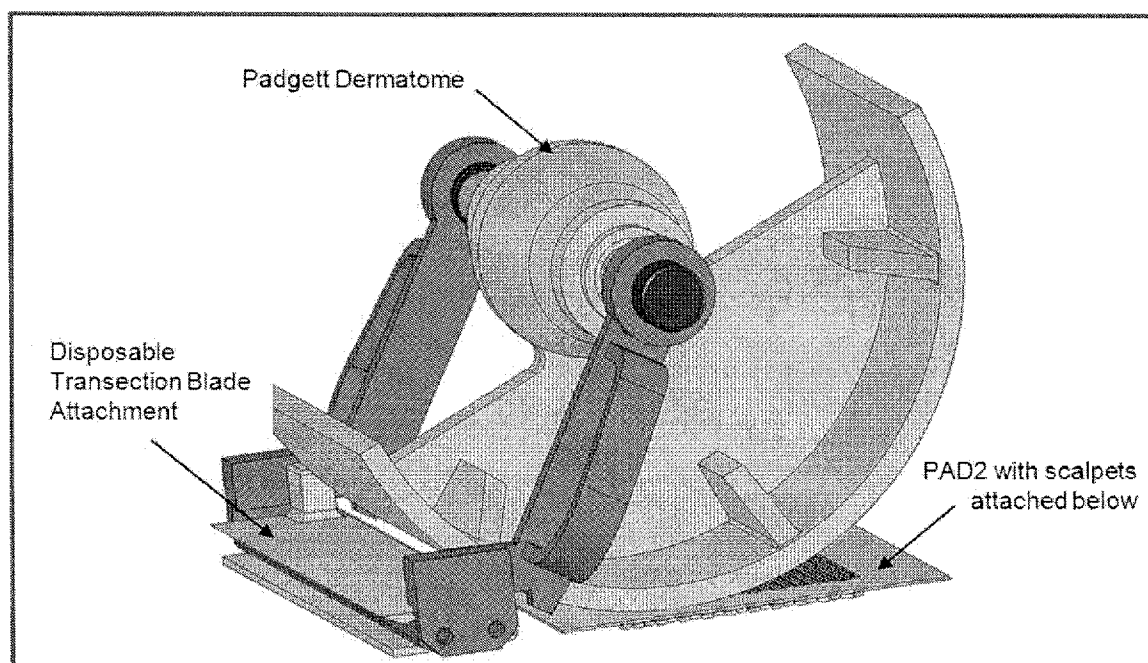


FIGURE 12B

**FIGURE 13A**

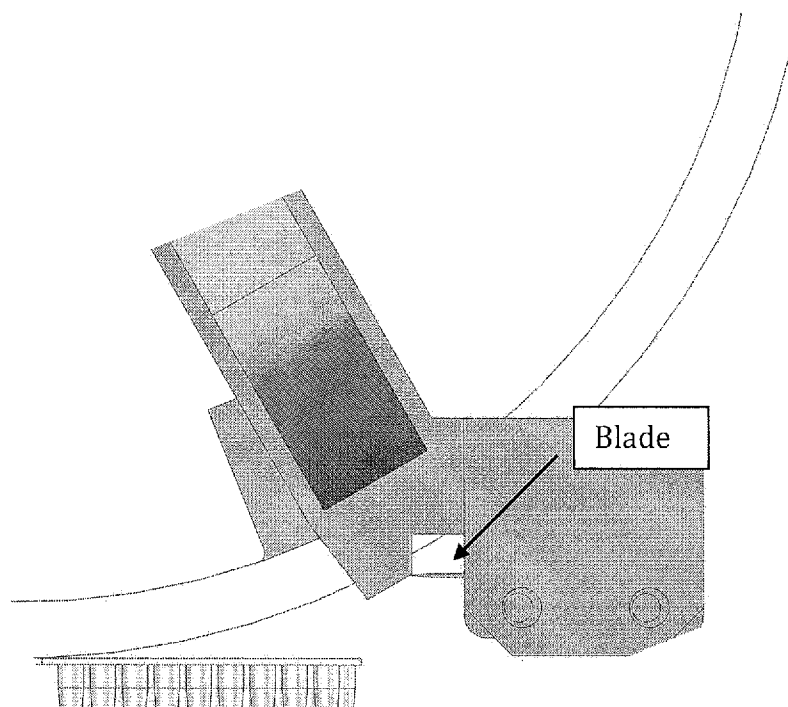
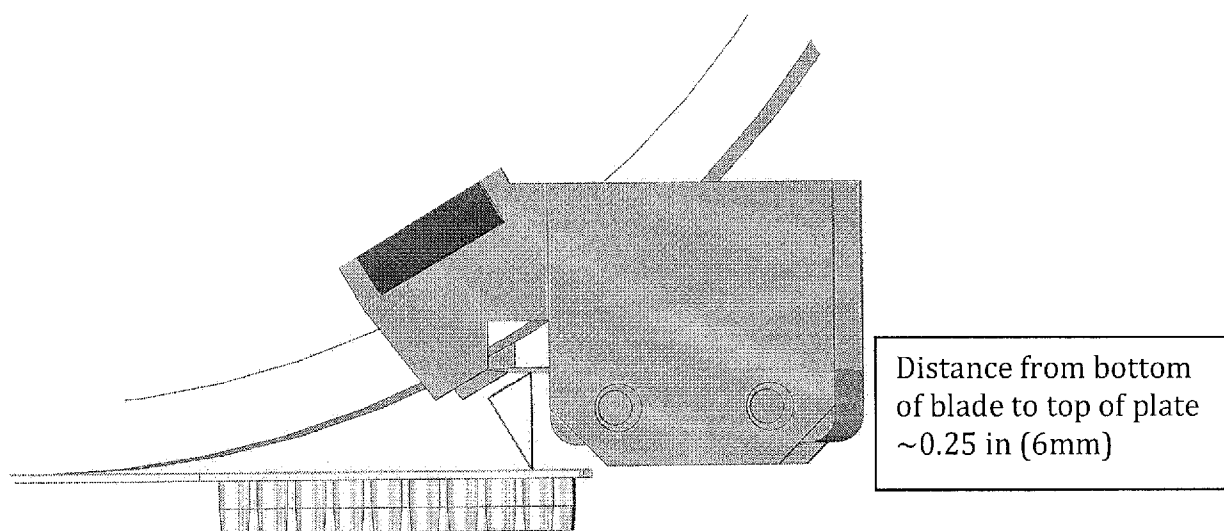
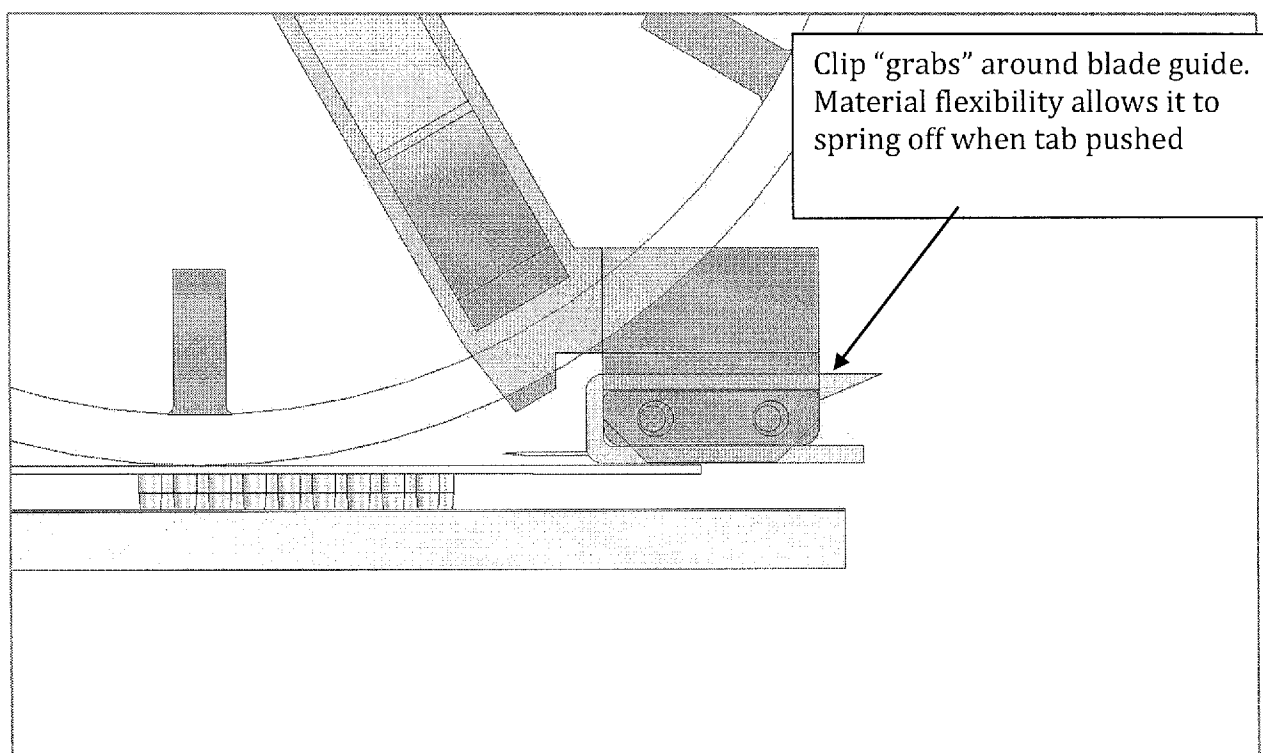
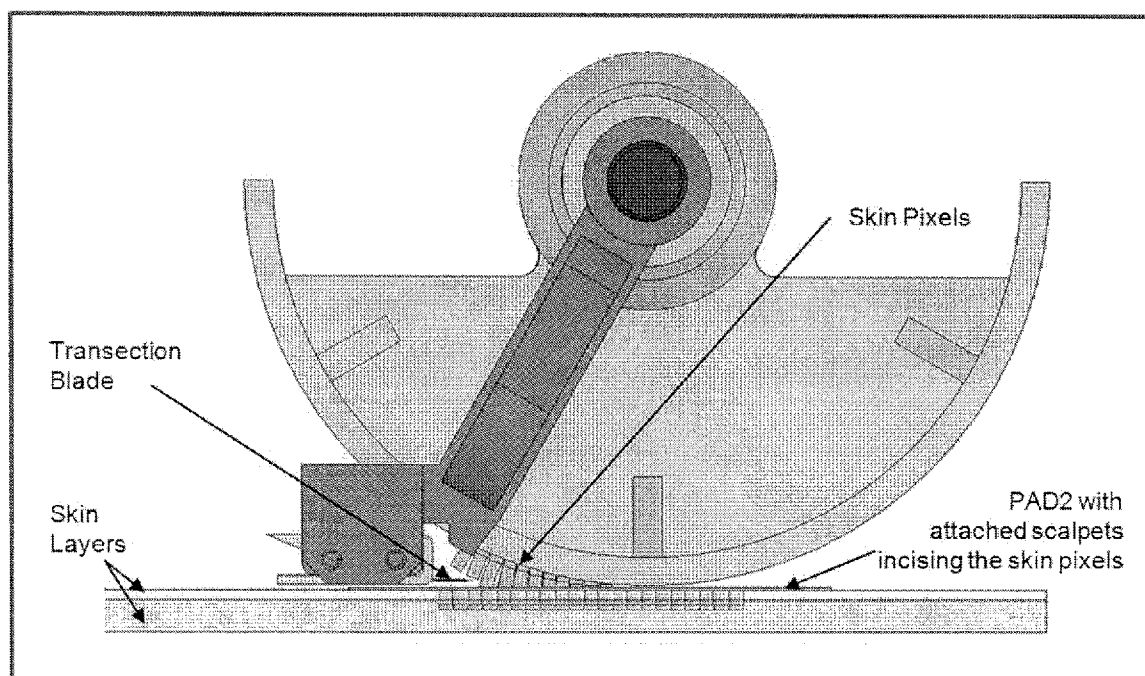


FIGURE 13B

**FIGURE 13C**

**FIGURE 13D**

**FIGURE 13E**

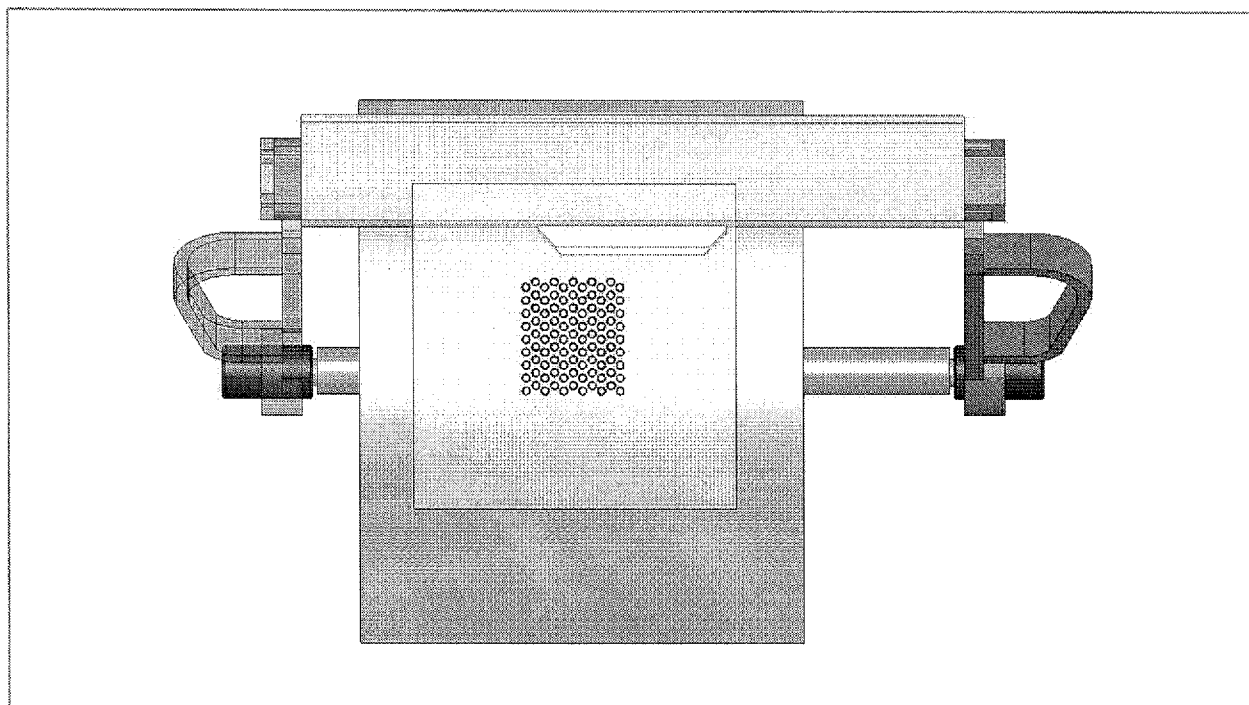


FIGURE 13F

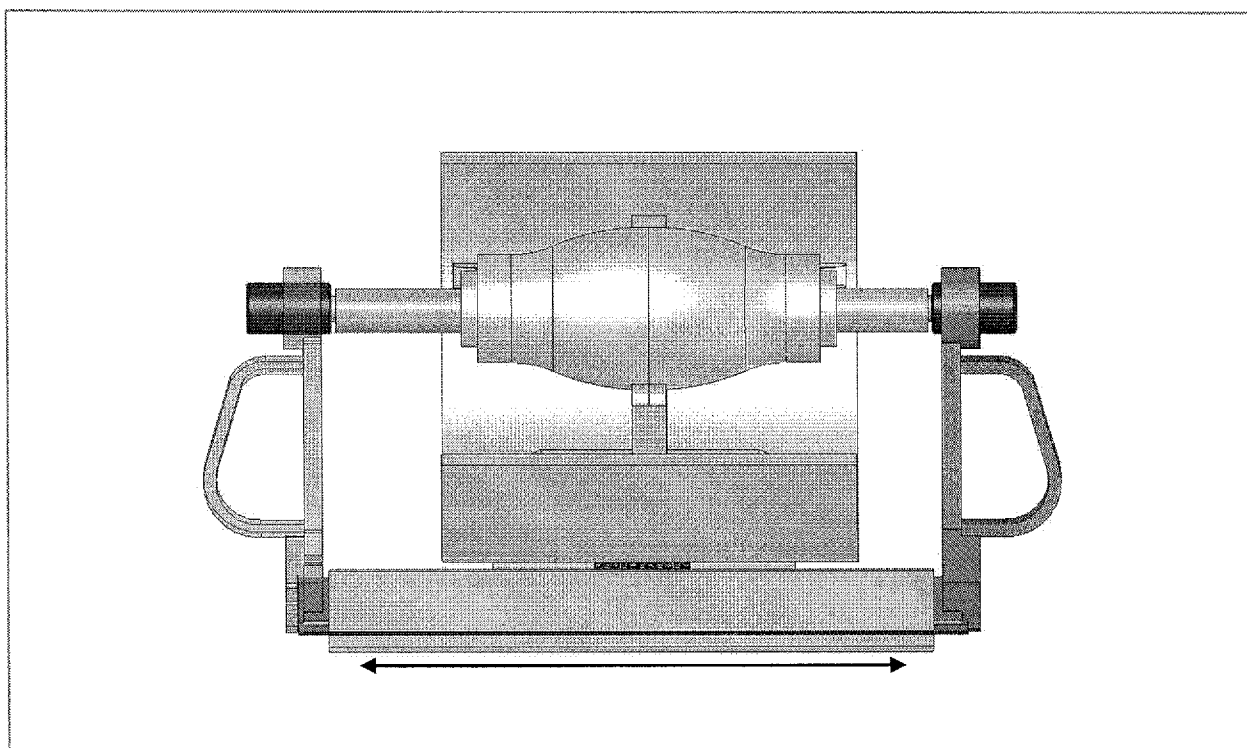


FIGURE 13G

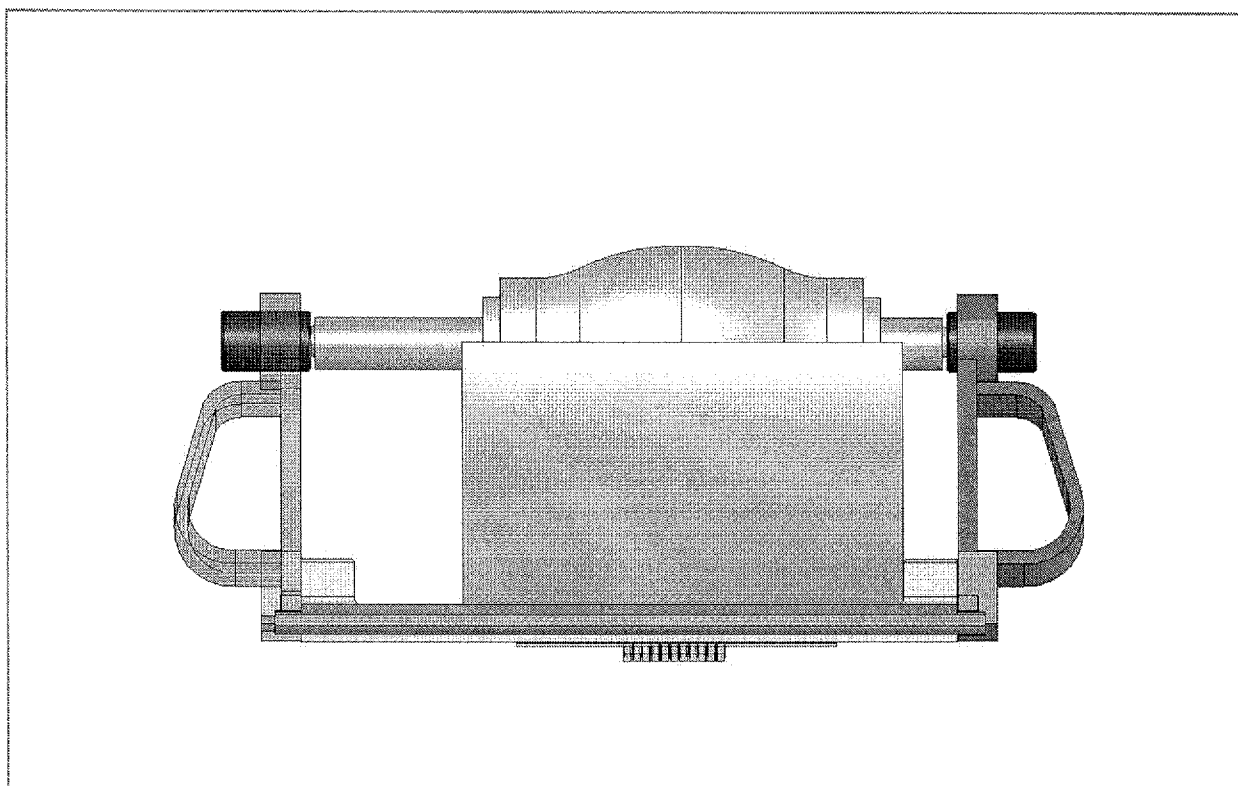
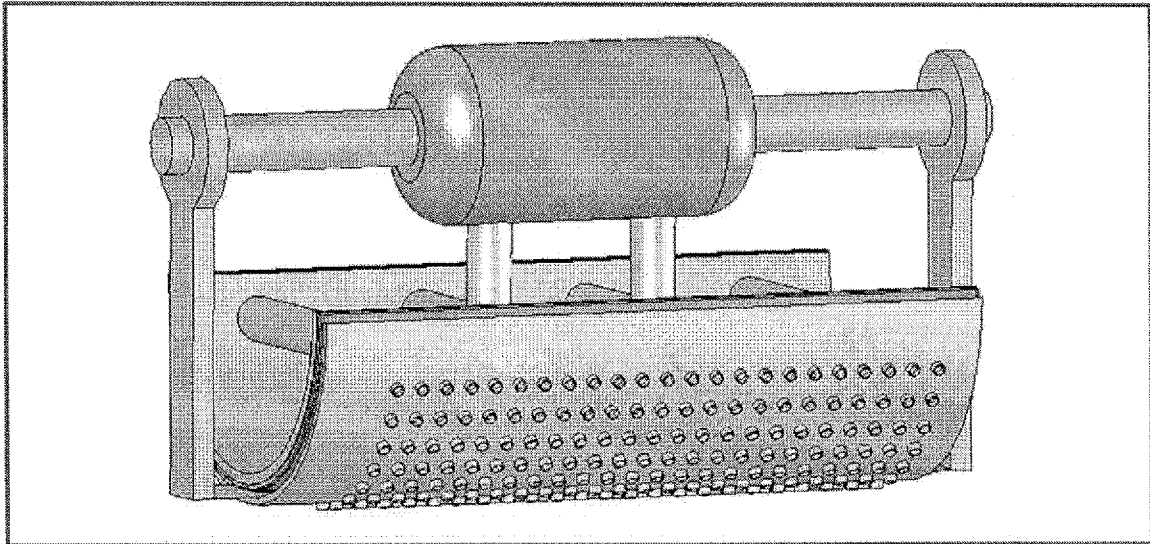
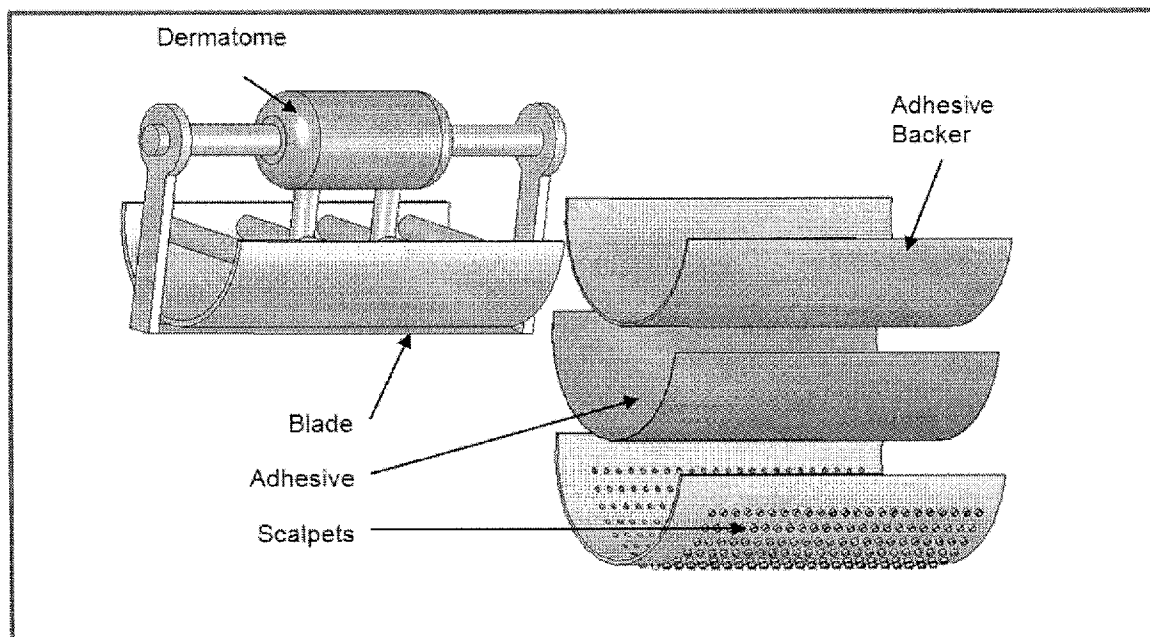


FIGURE 13H

**FIGURE 14A****FIGURE 14B**

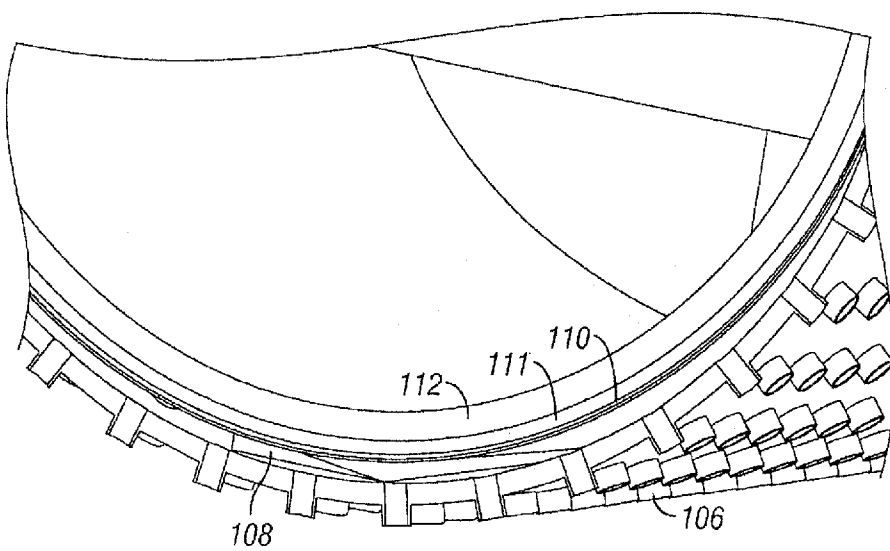
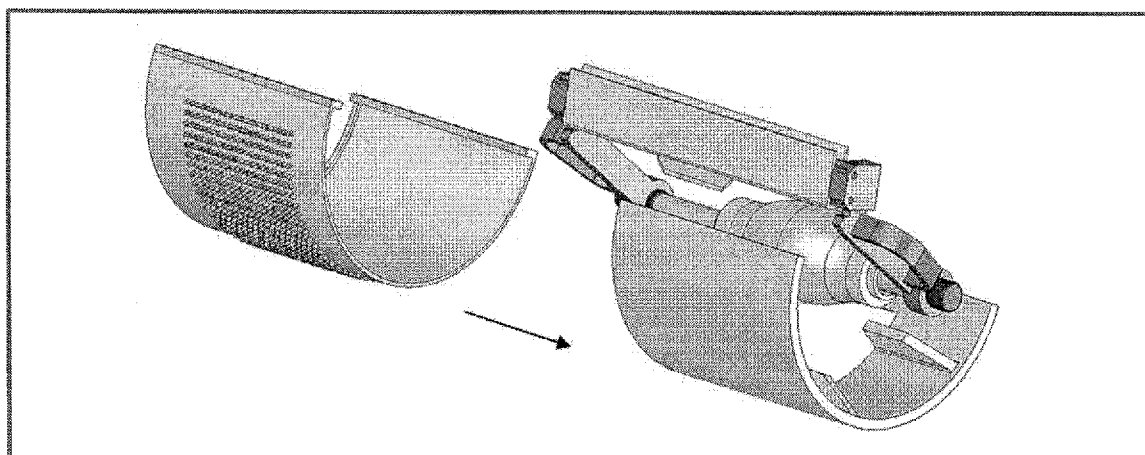
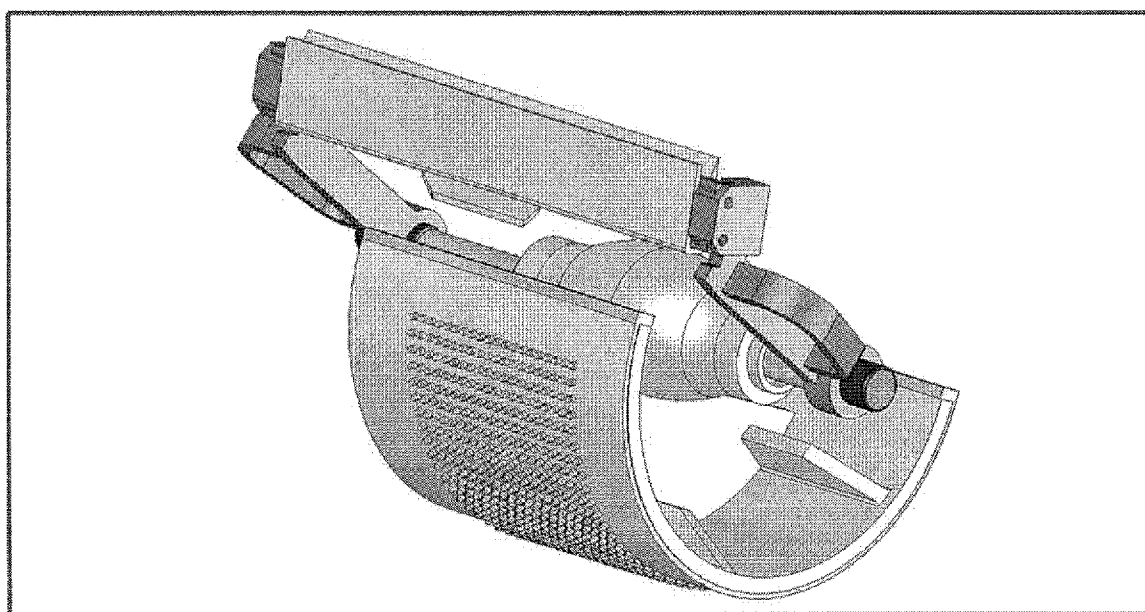
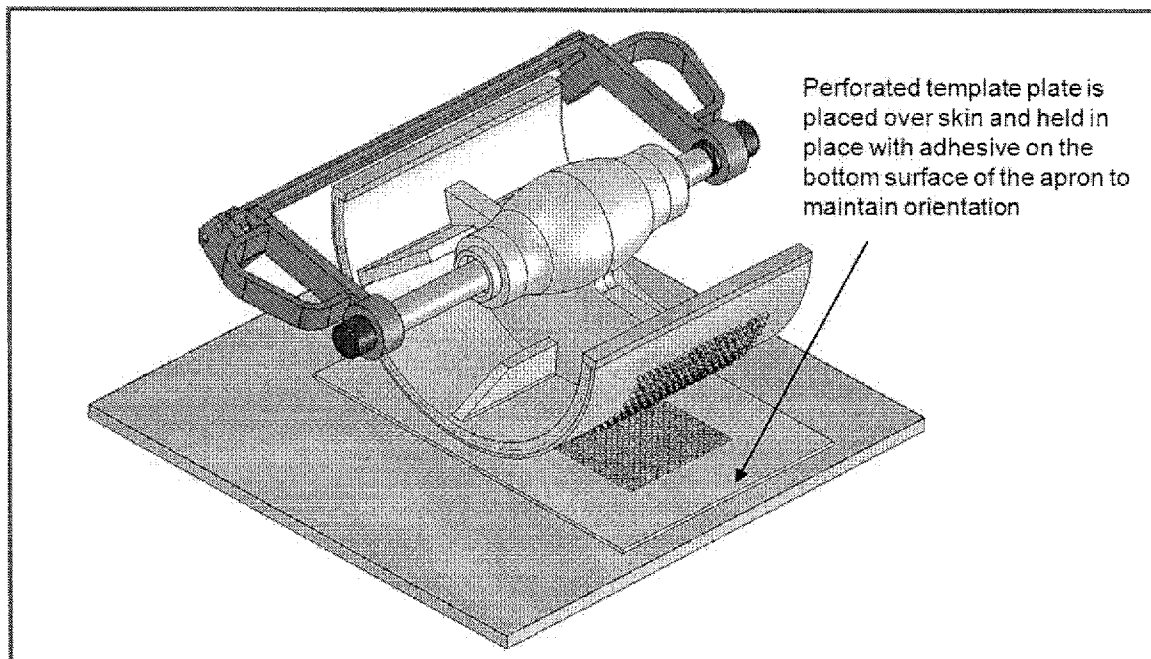
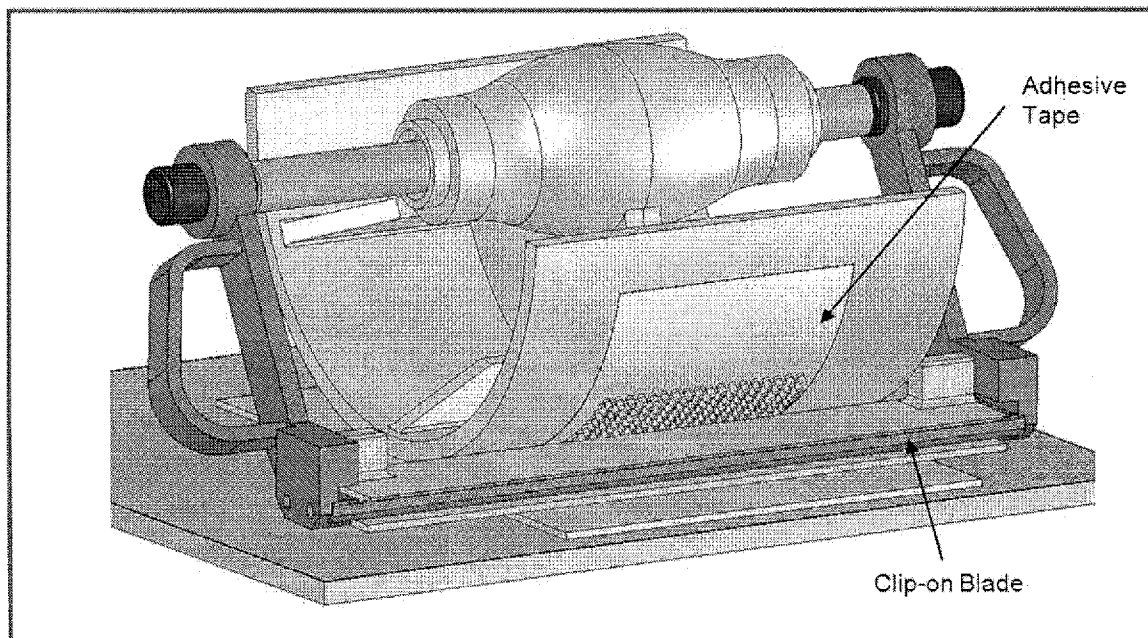


FIG. 14C

**FIGURE 15A****FIGURE 15B**

**FIGURE 16A****FIGURE 16B**

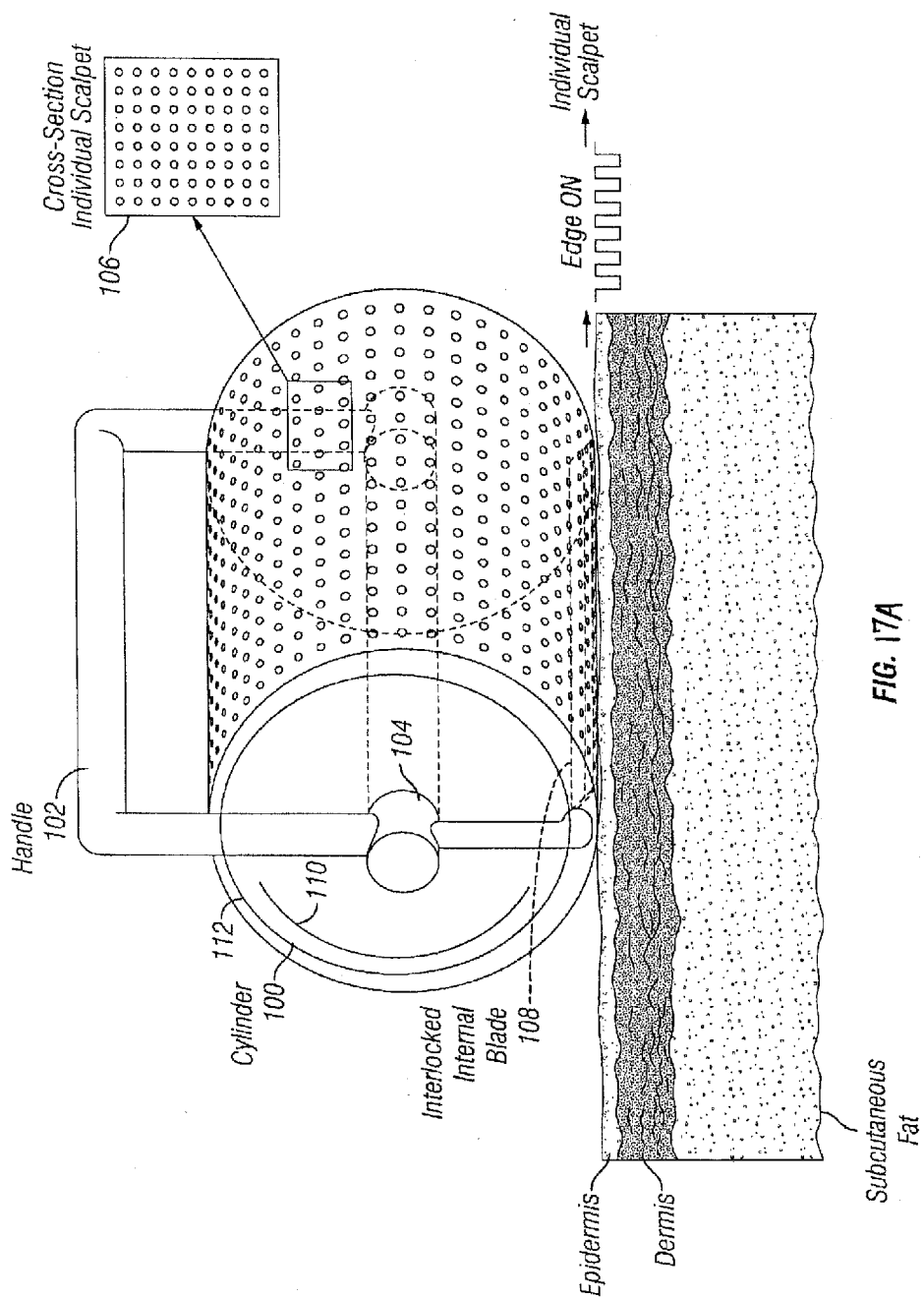
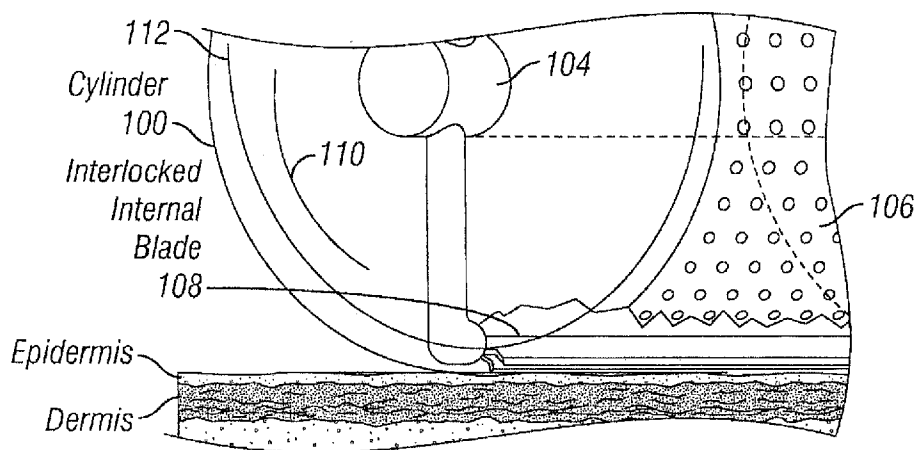
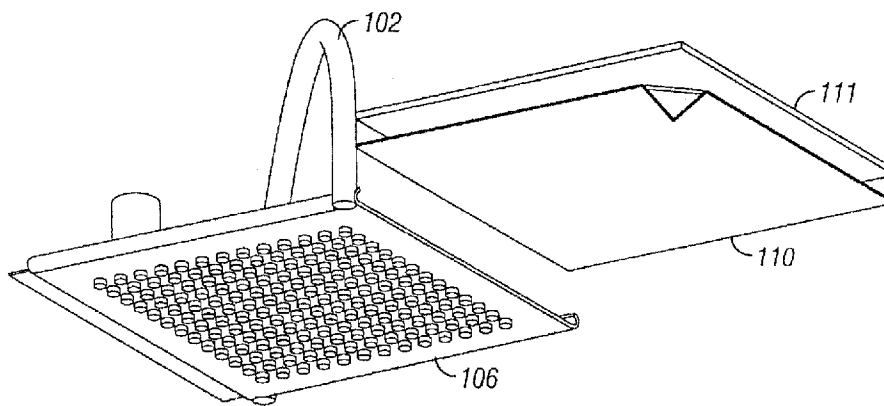
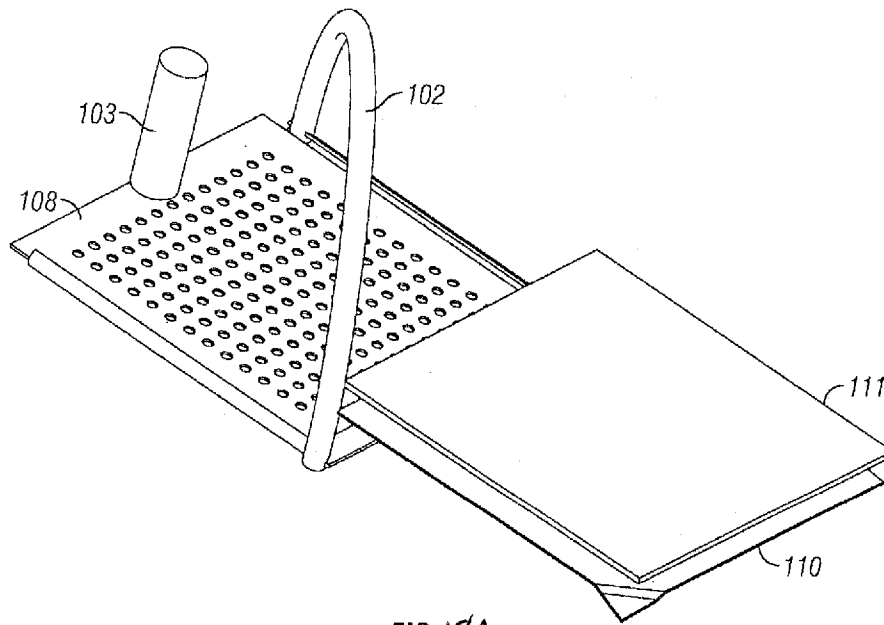


FIG. 17A

**FIG. 17B**



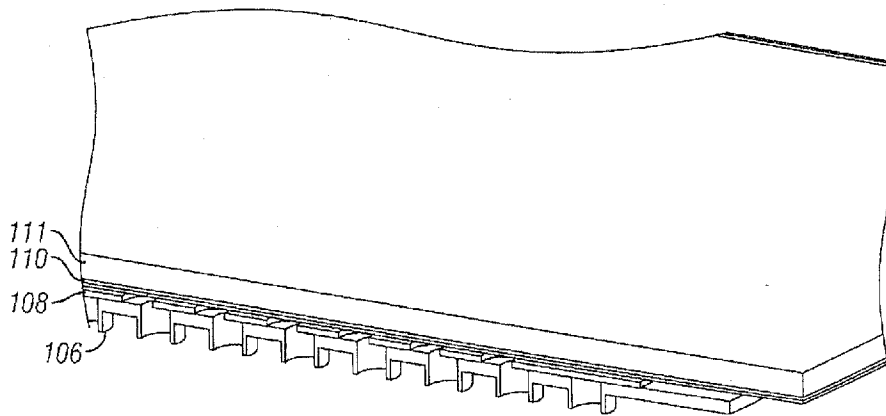


FIG. 18c

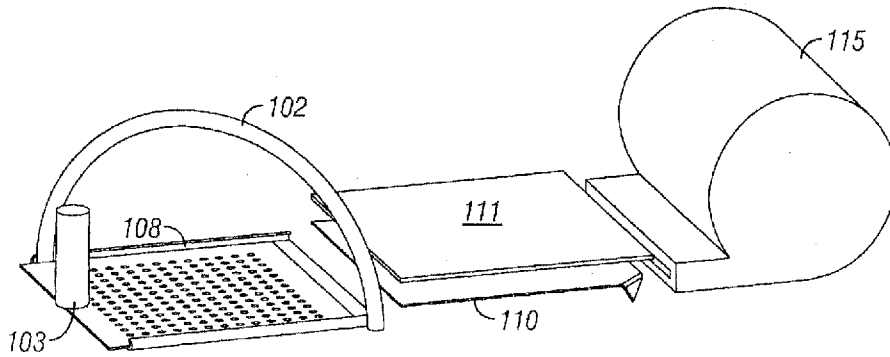
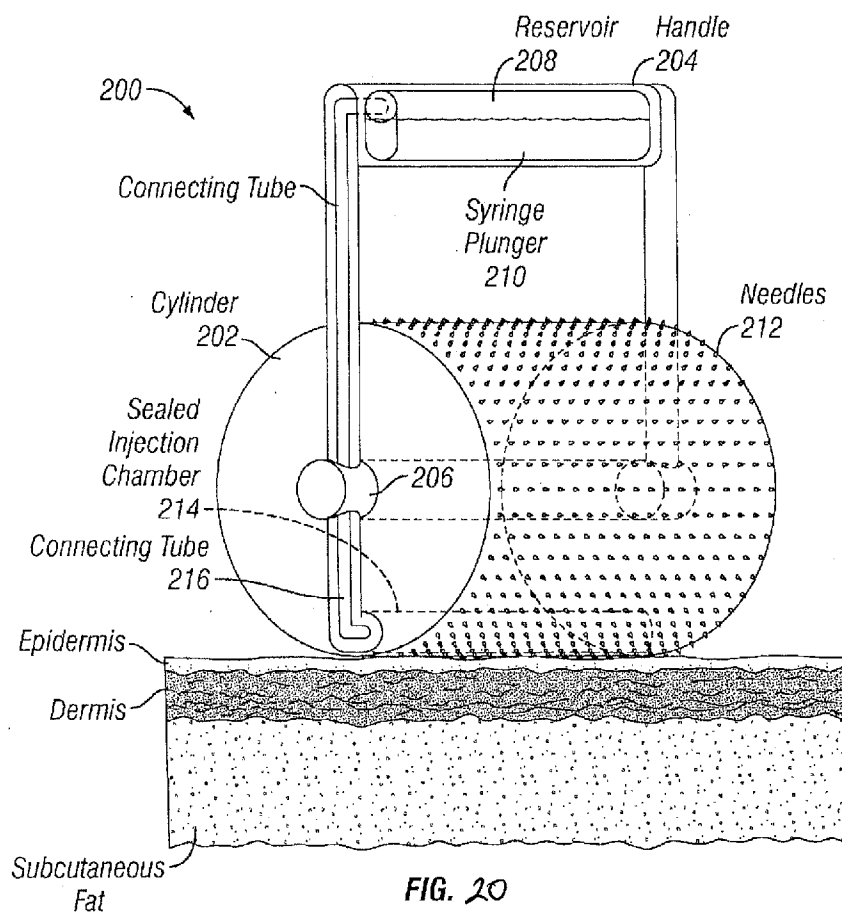
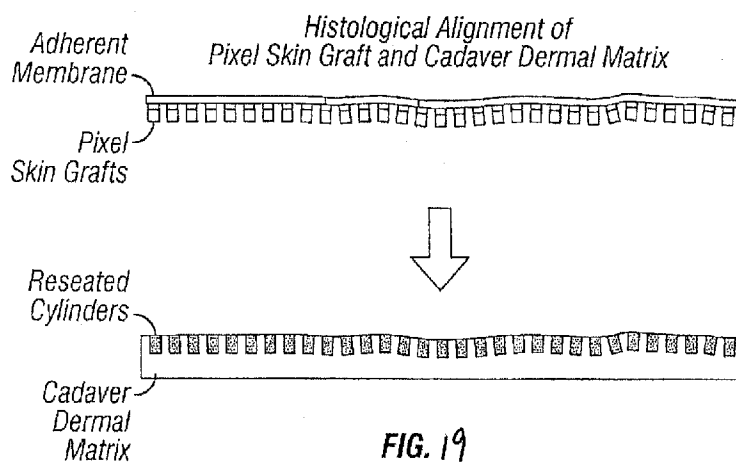


FIG. 18d



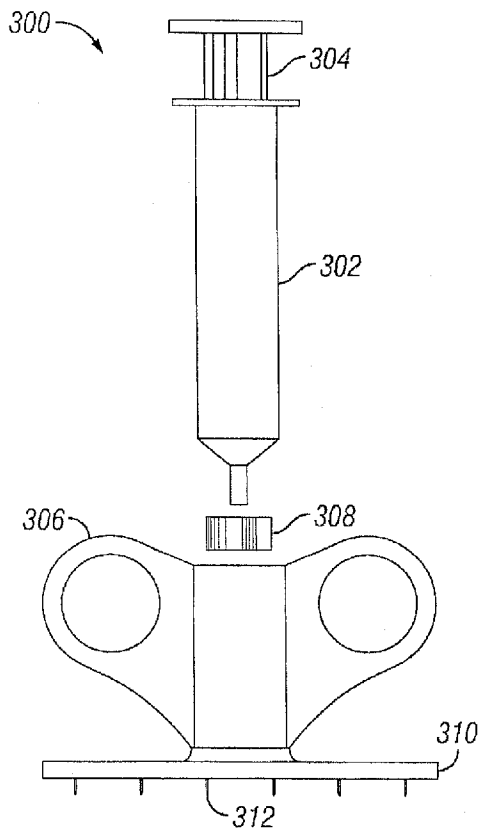


FIG. 2A

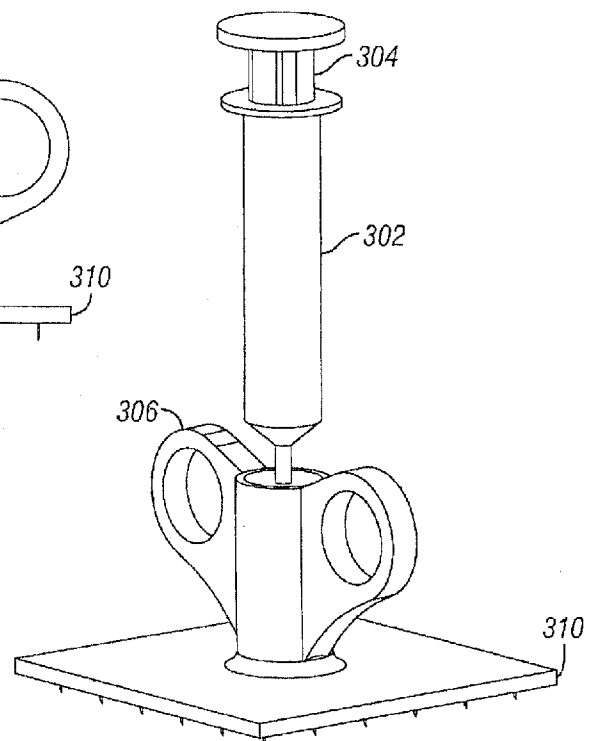
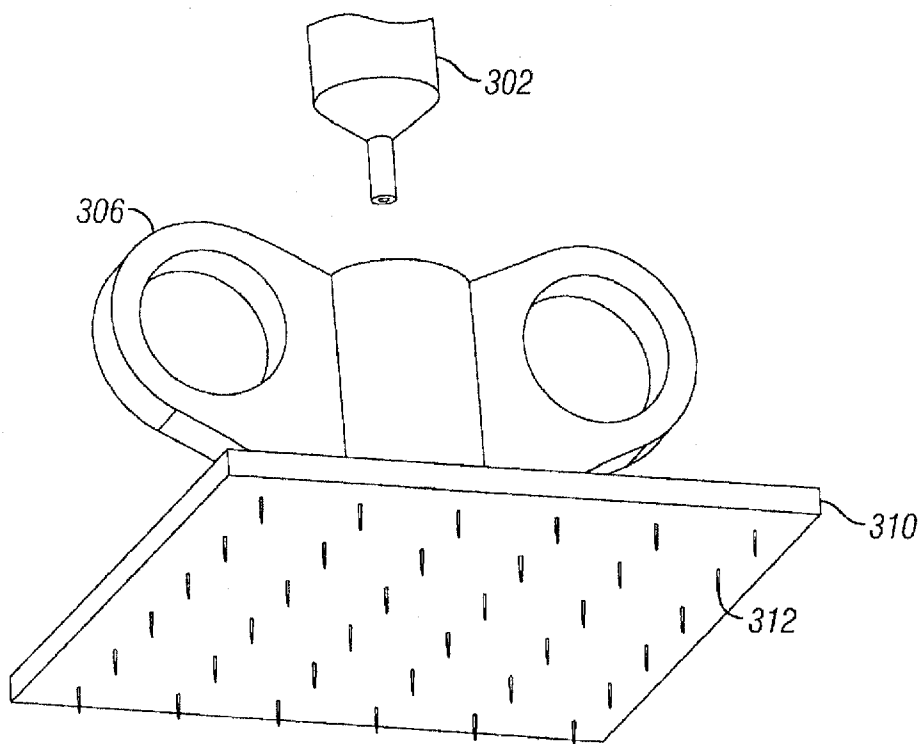


FIG. 2B

**FIG. 21C**