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(54) **METHOD AND APPARATUS FOR PERISTALTIC PUMP AND SURGICAL HANDPIECE WITH PRESSURE REGULATED FLUID SENSING FOR MAXILLARY SINUS ELEVATION**

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(62) Division of application No. 12/102,085, filed on Apr. 14, 2008, now Pat. No. 7,632,280, which is a division of application No. 11/227,687, filed on Sep. 15, 2005, now Pat. No. 7,510,397.

(60) Provisional application No. 61/211,996, filed on Apr. 6, 2009, provisional application No. 60/619,542, filed on Oct. 15, 2004.

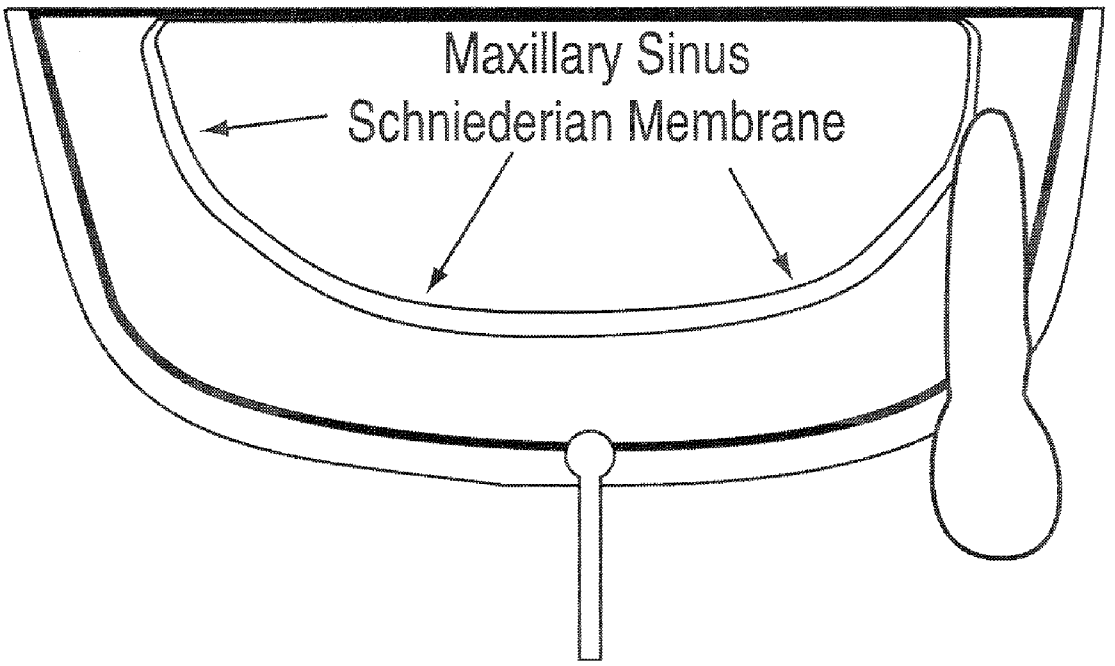
Publication Classification

(51) **Int. Cl.**
A61C 8/00 (2006.01)

(52) **U.S. Cl.** **433/173**

(57) **ABSTRACT**

An apparatus for performing a maxillary sinus membrane elevation is described having a peristaltic or other electronic pump providing a fluid to a sleeve extending to the maxillary sinus through a handle. A pressure sensor monitors the fluid pressure and if the pressure reaches an excessive pressure level, the fluid flow is cut off to protect the membrane. Pressure variations in the fluid pressure due to the operation of the pump are reduced or eliminated using one or more baffles.



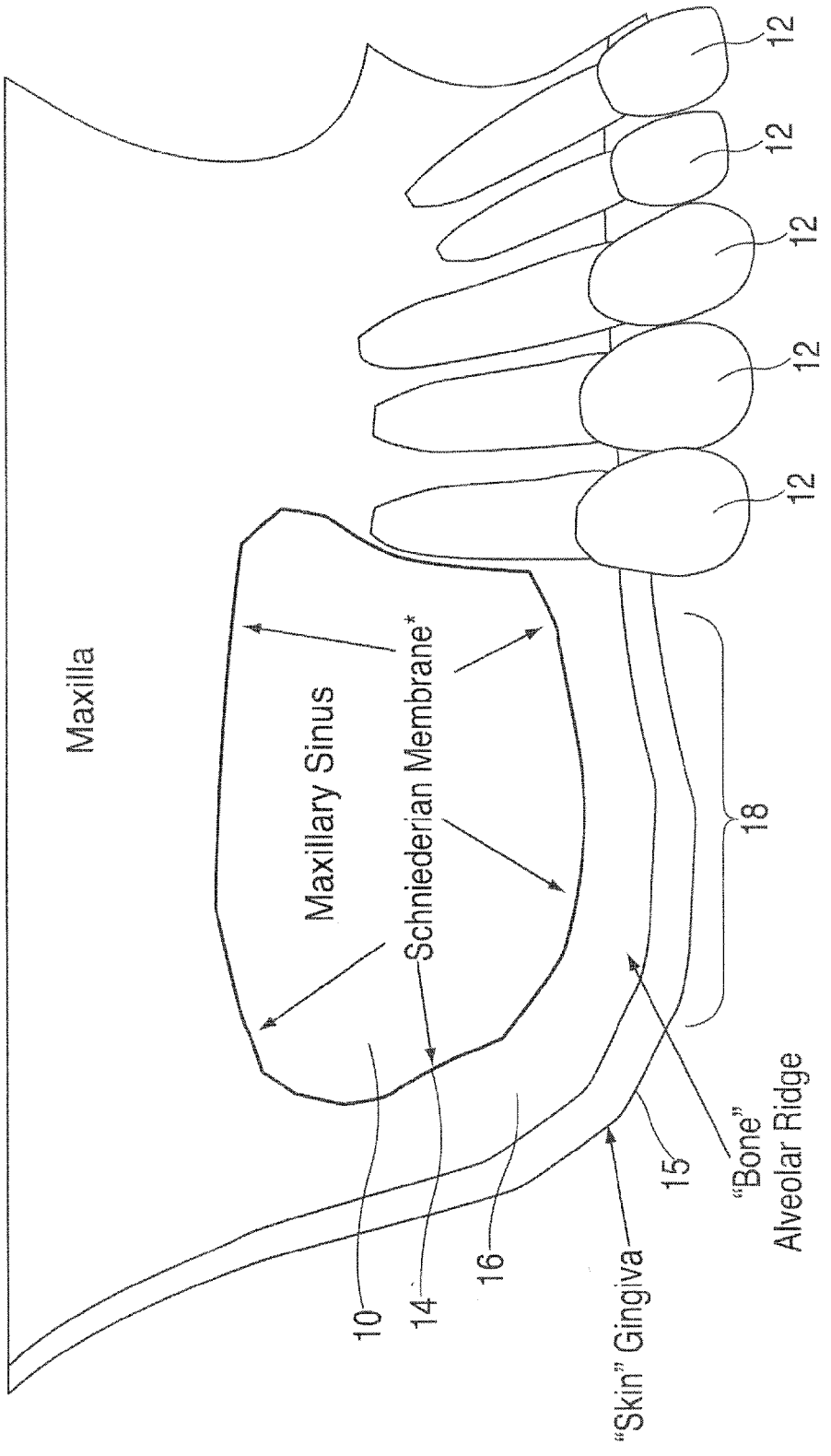


FIG. 1
(PRIOR ART)

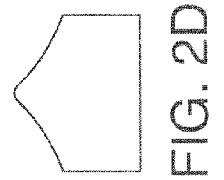


FIG. 2D

FIG. 2C

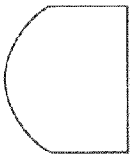


FIG. 2B

FIG. 2A

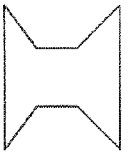


FIG. 2G

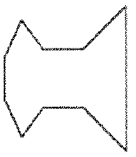


FIG. 2F

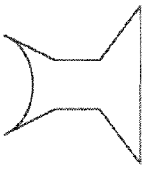


FIG. 2E

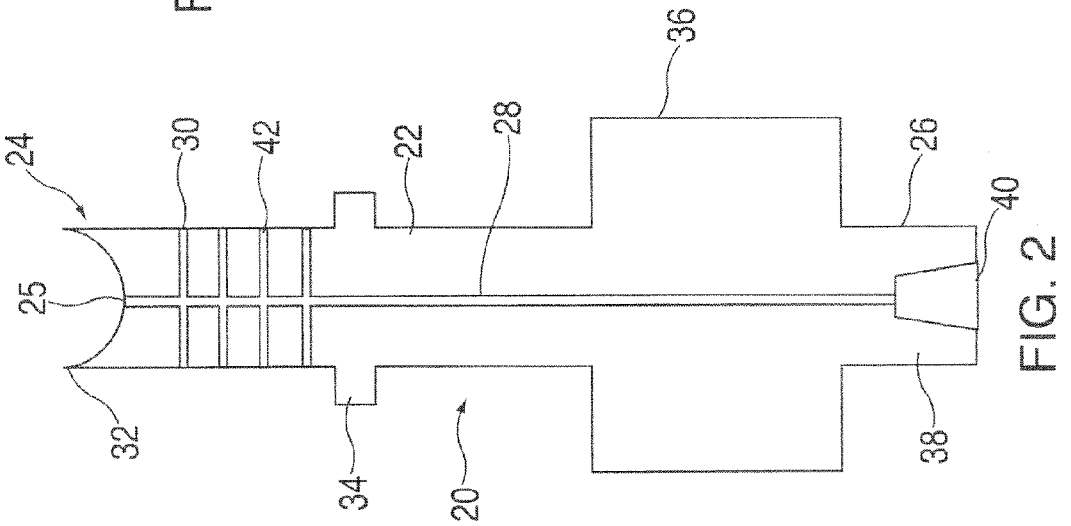


FIG. 2

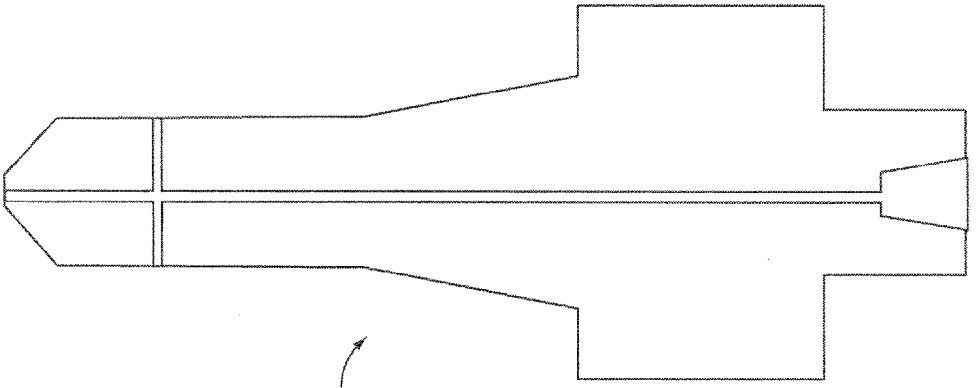


FIG. 2I

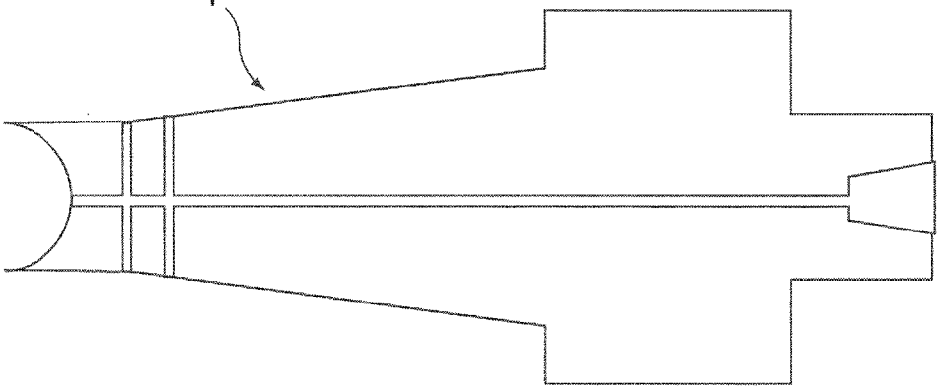


FIG. 2H

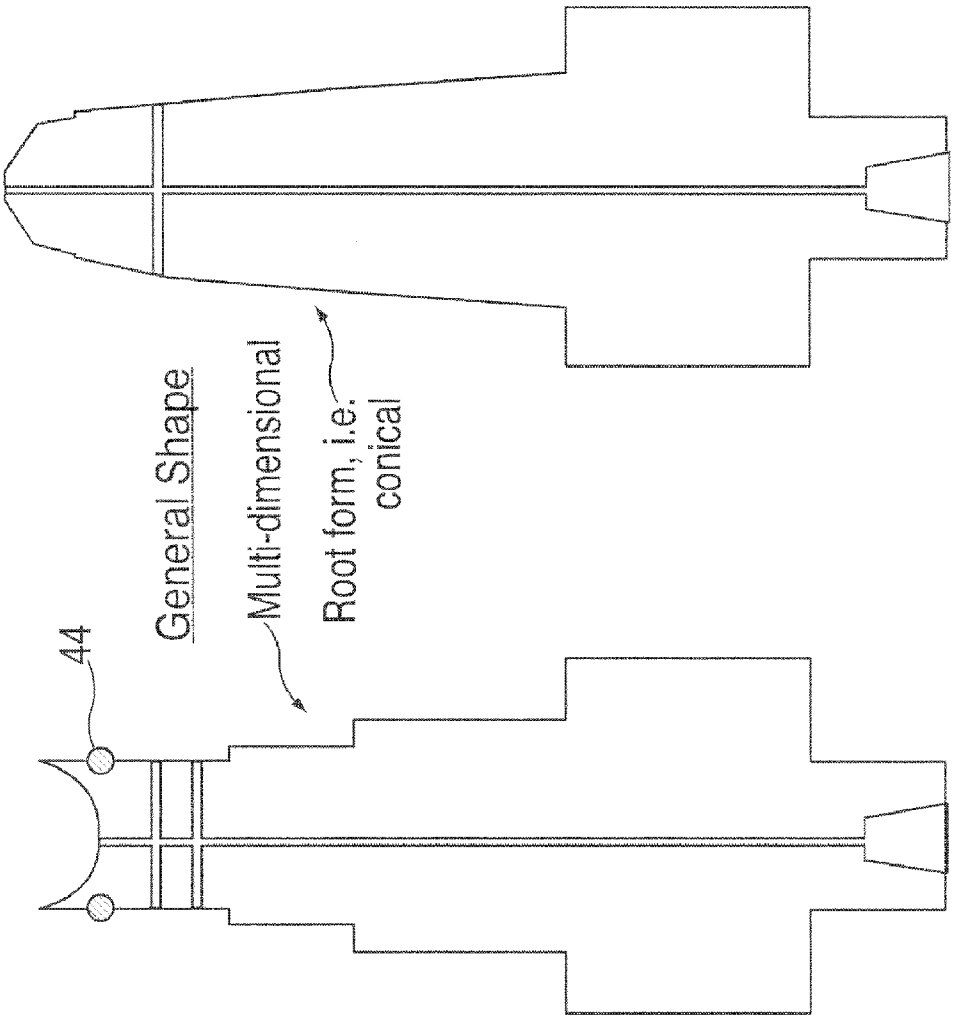


FIG. 2J

FIG. 2K

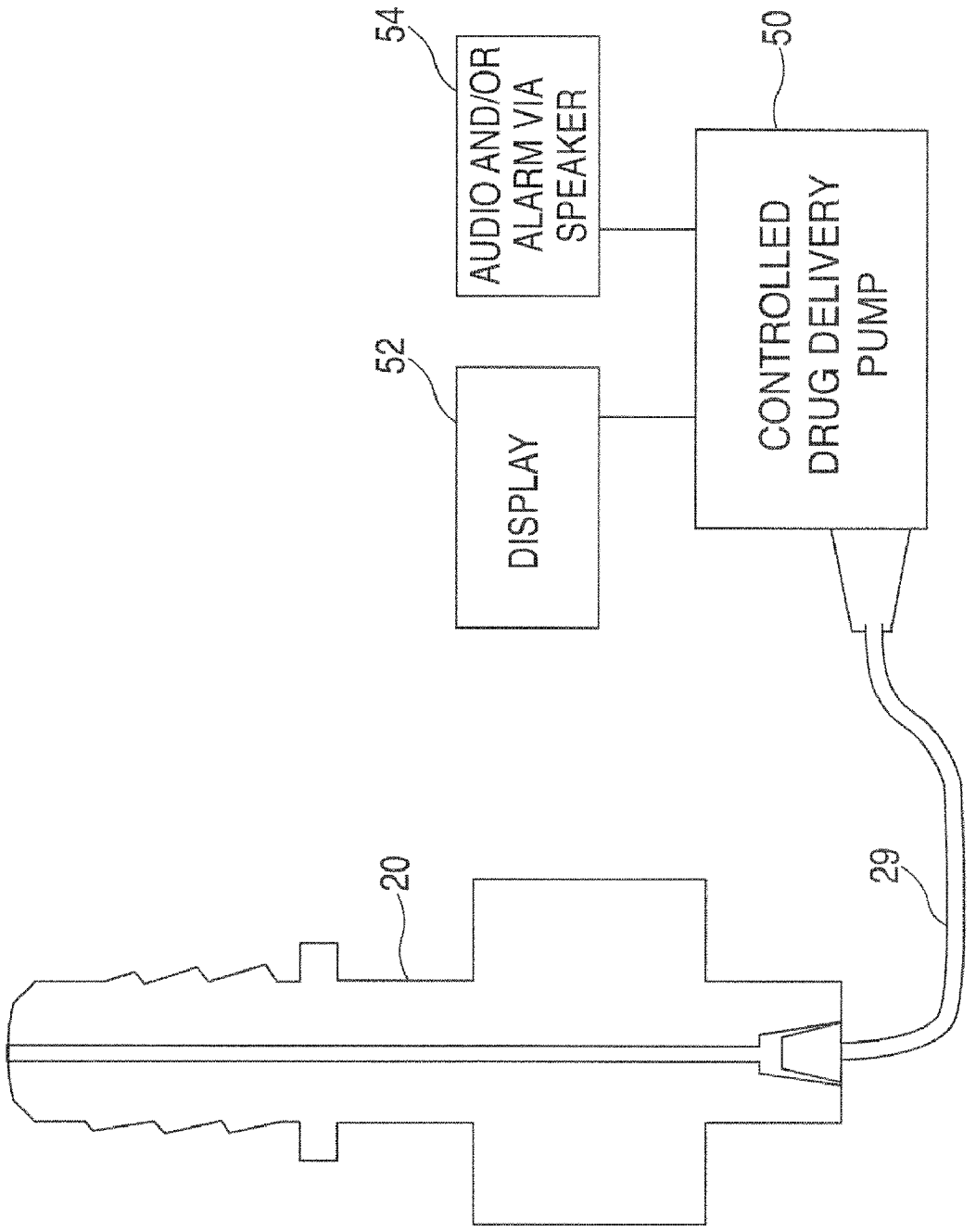

54
AUDIO AND/OR ALARM VIA SPEAKER
50
CONTROLLED DRUG DELIVERY PUMP
52
DISPLAY
20
29

FIG. 3

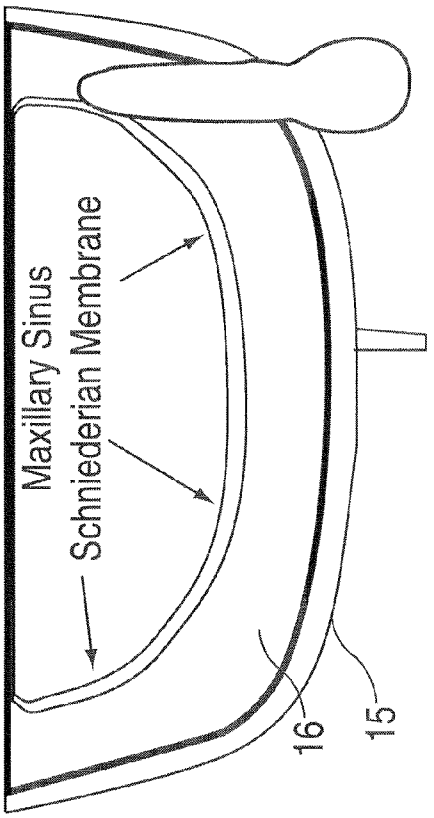

Maxillary Sinus
Schniederian Membrane
16
15

FIG. 4A

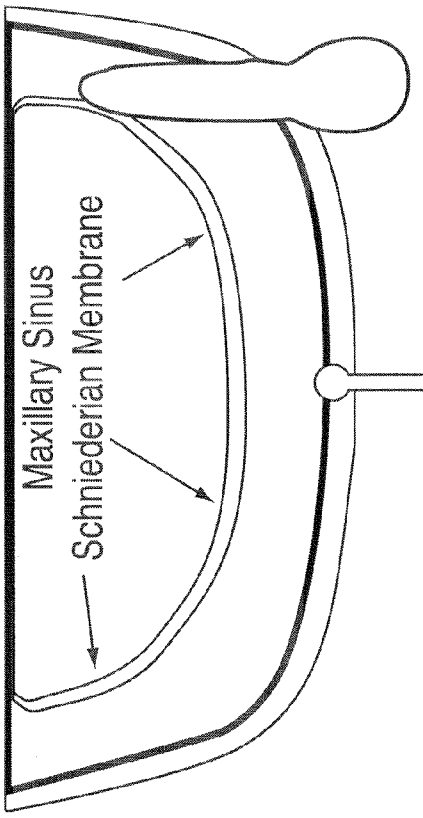

Maxillary Sinus
Schniederian Membrane

FIG. 4B

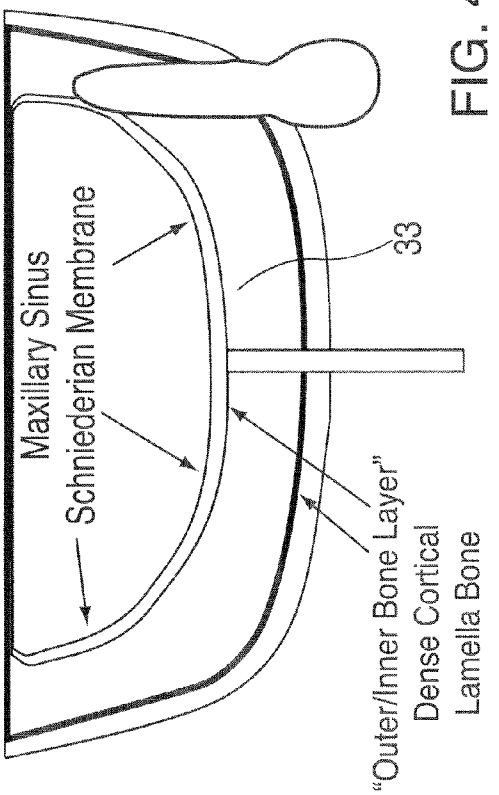

Maxillary Sinus
Schniederian Membrane
33
"Outer/Inner Bone Layer"
Dense Cortical
Lamella Bone

FIG. 4C

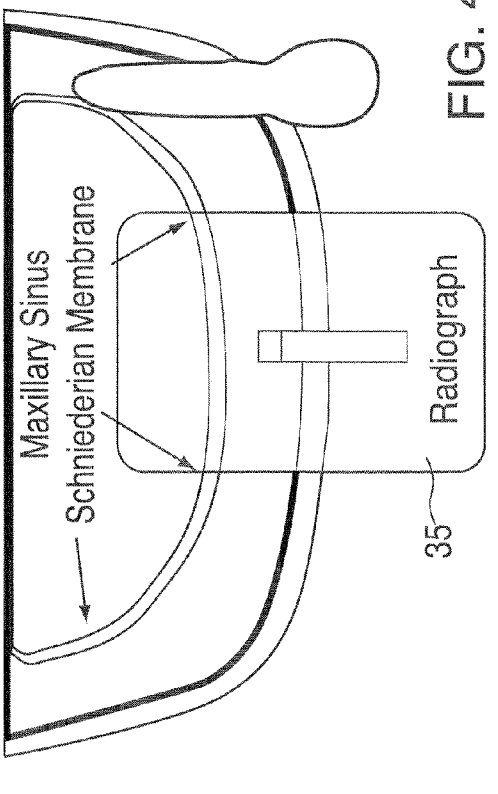

Maxillary Sinus
Schniederian Membrane
Radiograph
35

FIG. 4D

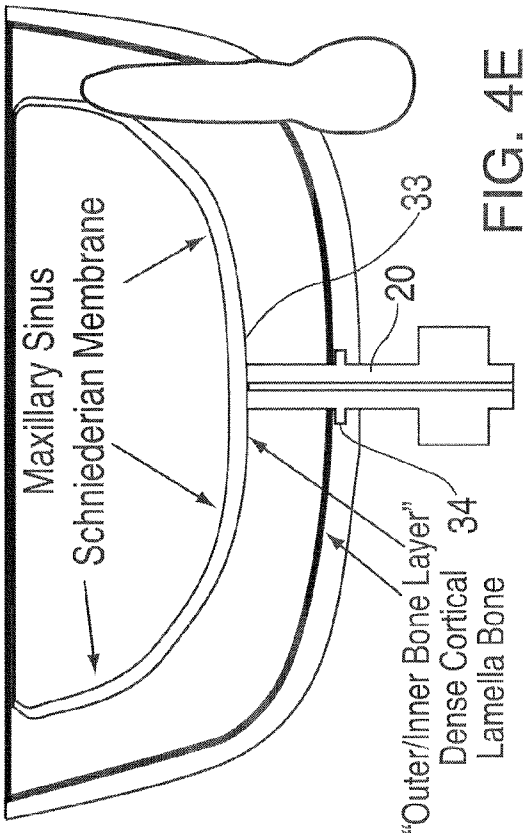

Maxillary Sinus
Schniederian Membrane
33
20
"Outer/Inner Bone Layer"
Dense Cortical
Lamella Bone
34

FIG. 4E

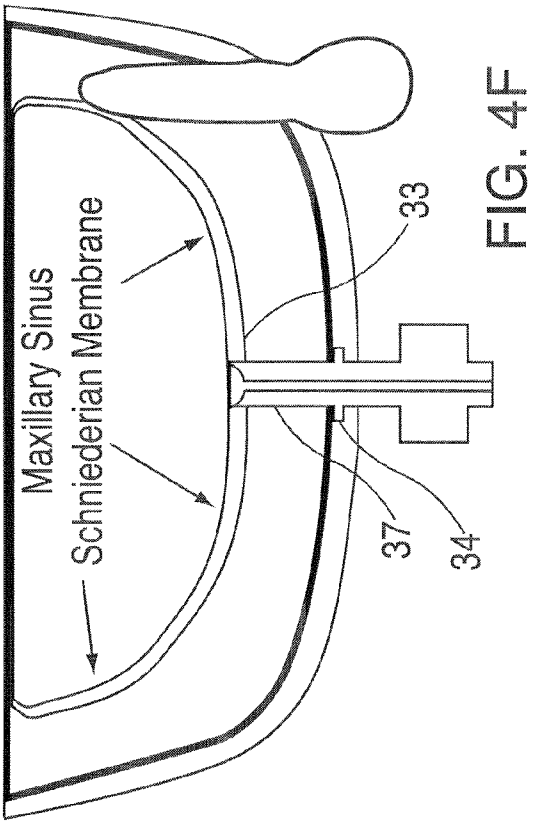

Maxillary Sinus
Schniederian Membrane
33
37
34

FIG. 4F

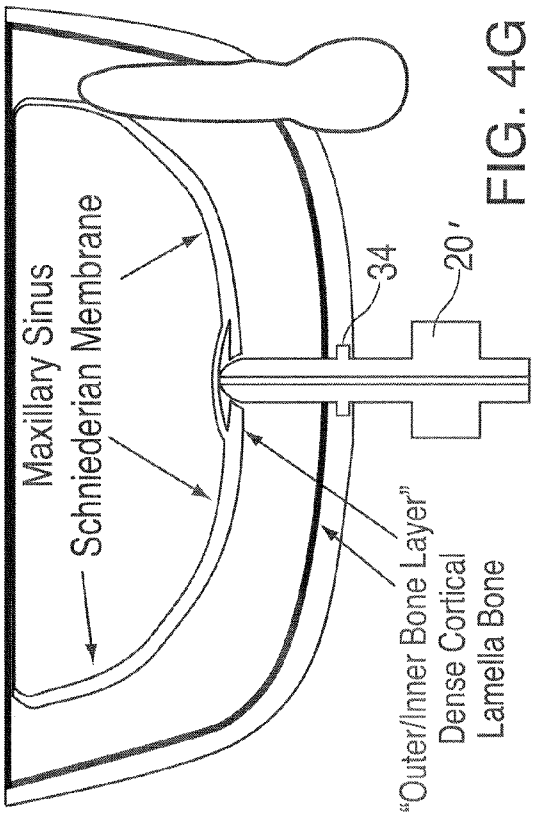

Maxillary Sinus
Schniederian Membrane
34
20'
"Outer/Inner Bone Layer"
Dense Cortical
Lamella Bone

FIG. 4G

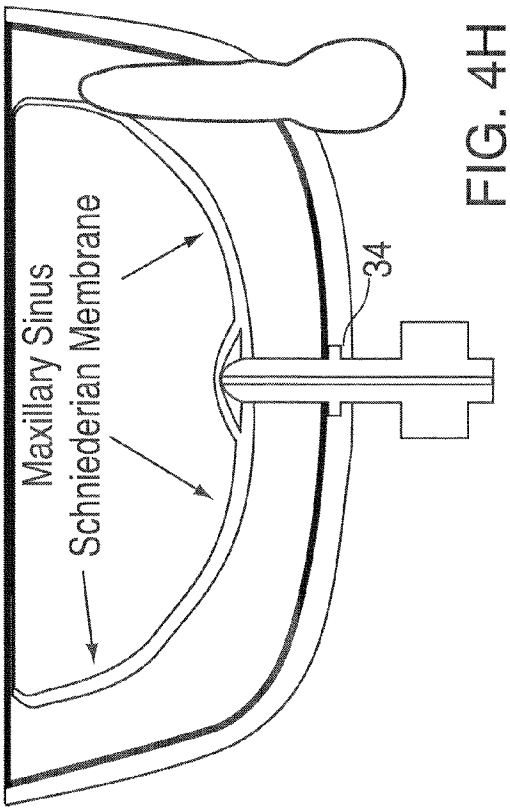

Maxillary Sinus
Schniederian Membrane
34

FIG. 4H

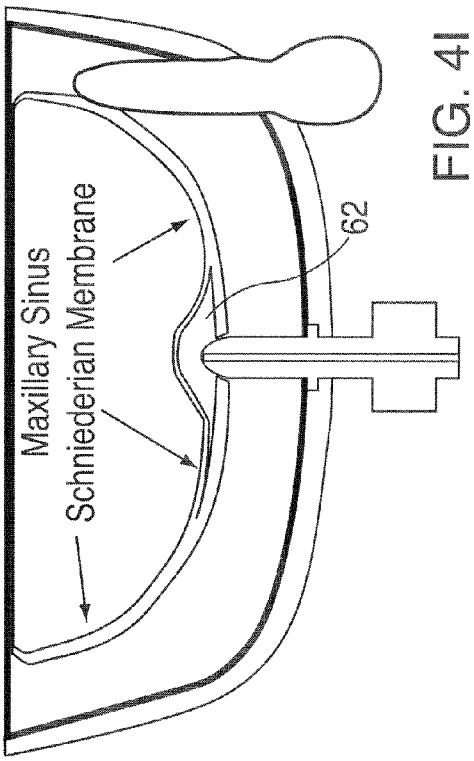

Maxillary Sinus
Schniederian Membrane
62

FIG. 4I

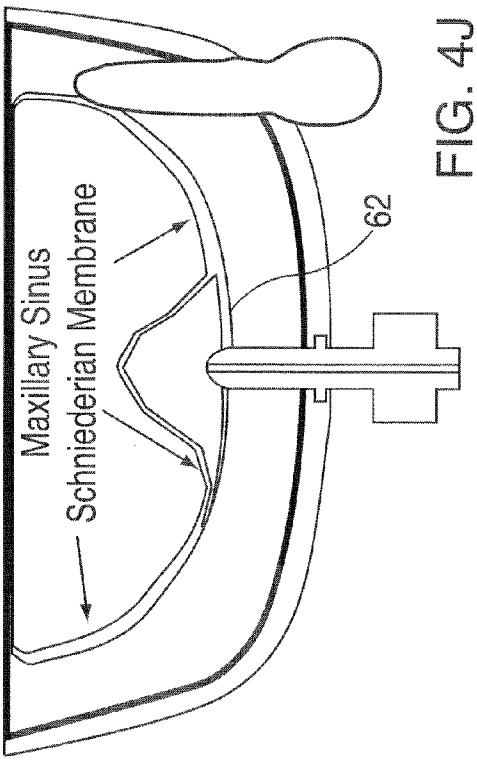

Maxillary Sinus
Schniederian Membrane
62

FIG. 4J

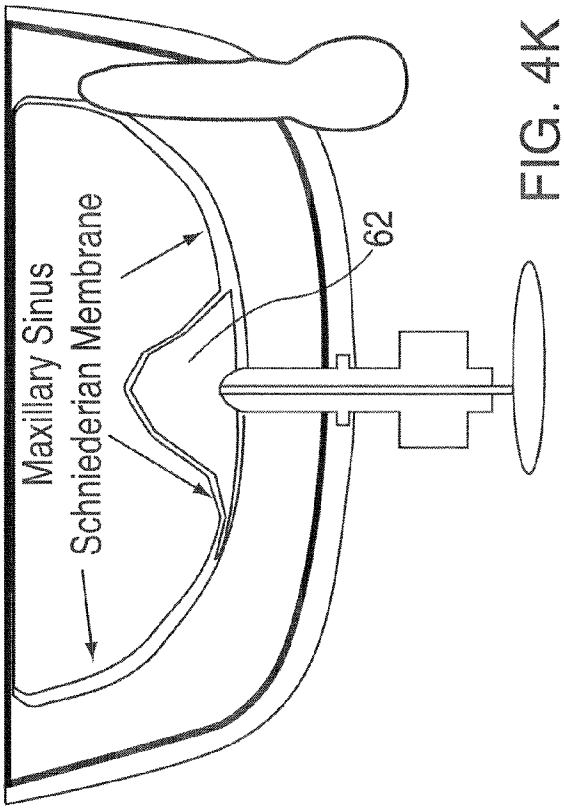


FIG. 4K

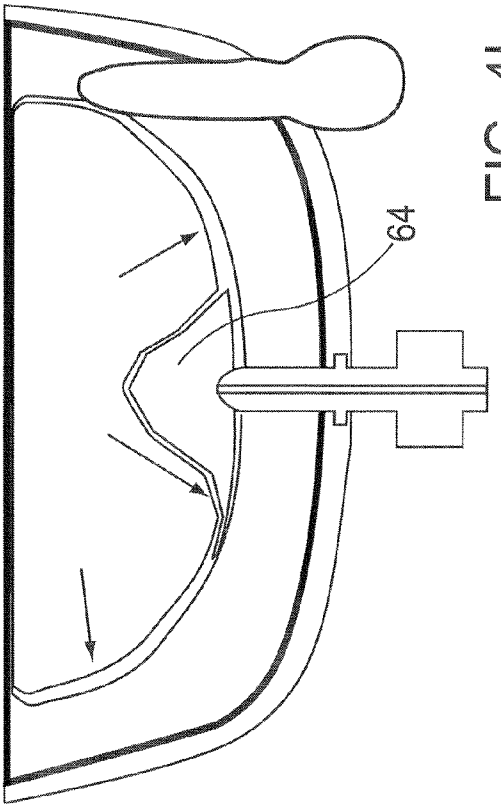


FIG. 4L

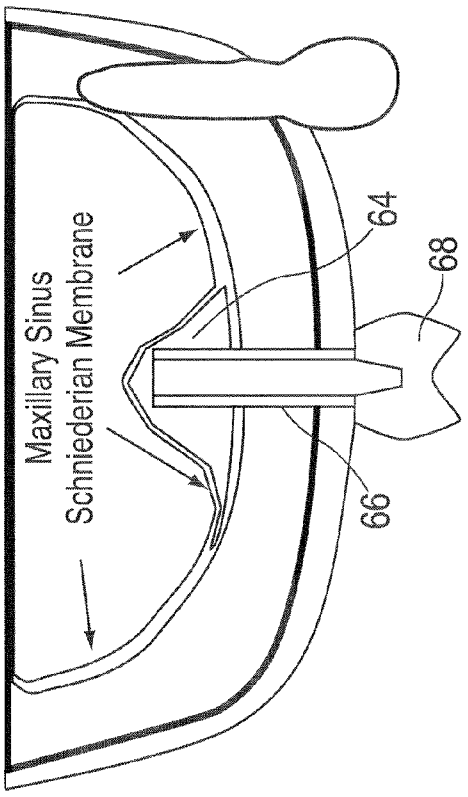

Maxillary Sinus
Schniederian Membrane
64
68
66

FIG. 4M

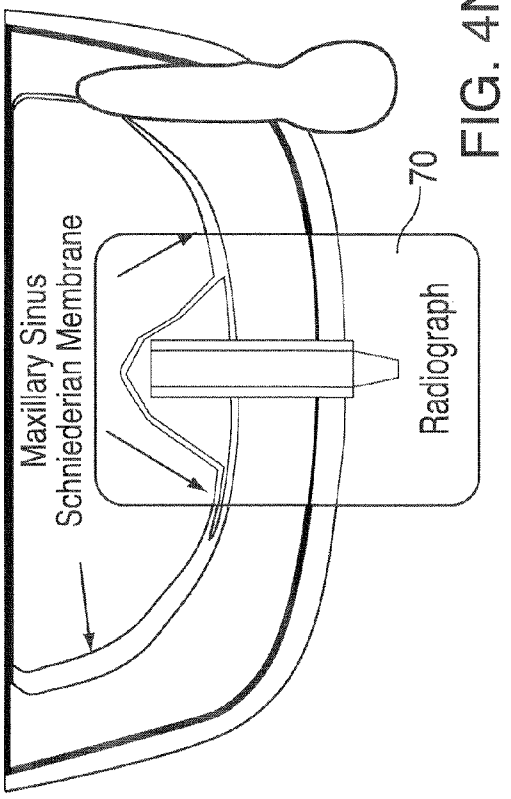

Maxillary Sinus
Schniederian Membrane
70
Radiograph

FIG. 4N

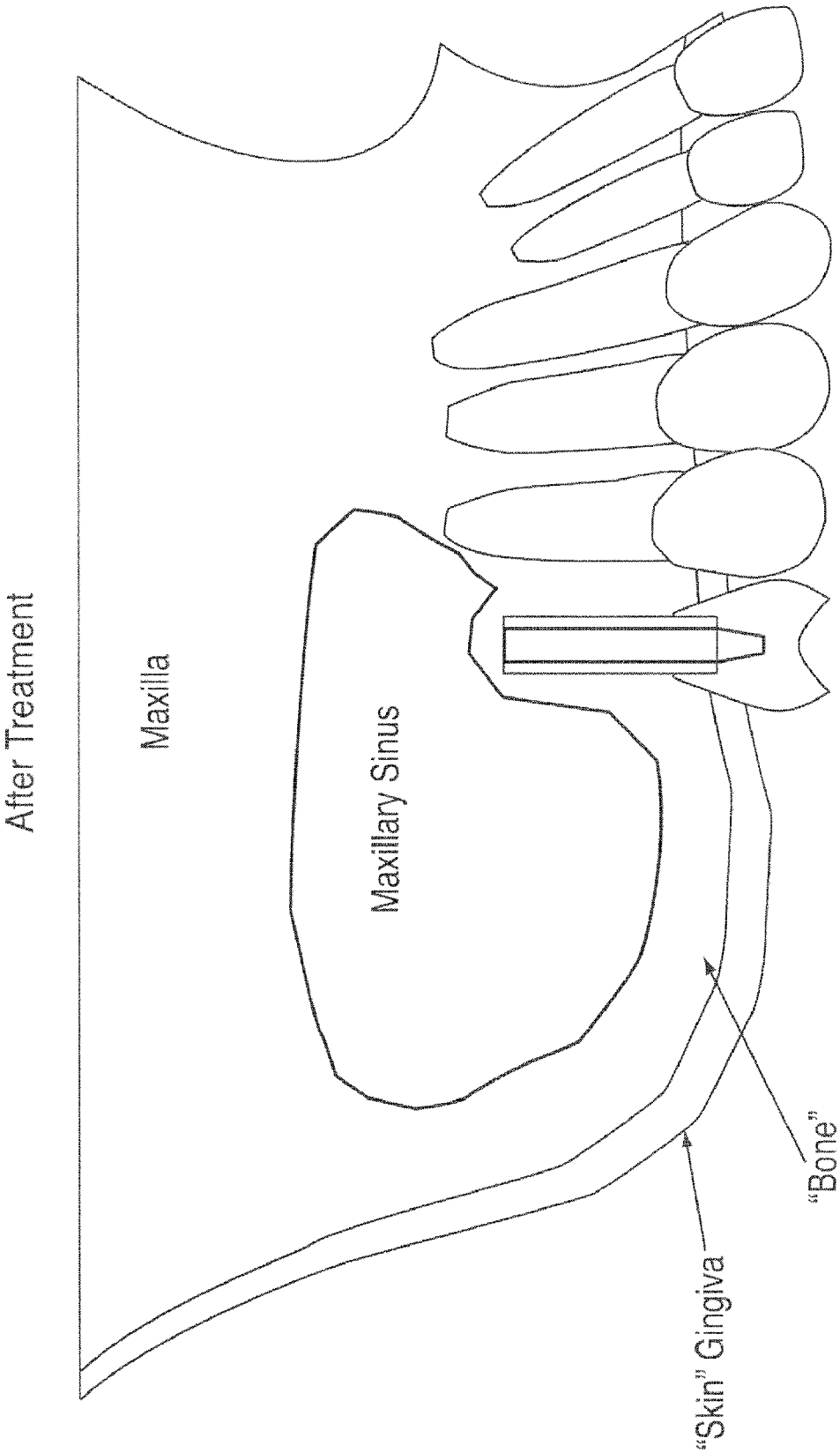

After Treatment
Maxilla
Maxillary Sinus
"Skin" Gingiva
"Bone"
Alveolar Ridge

FIG. 4O

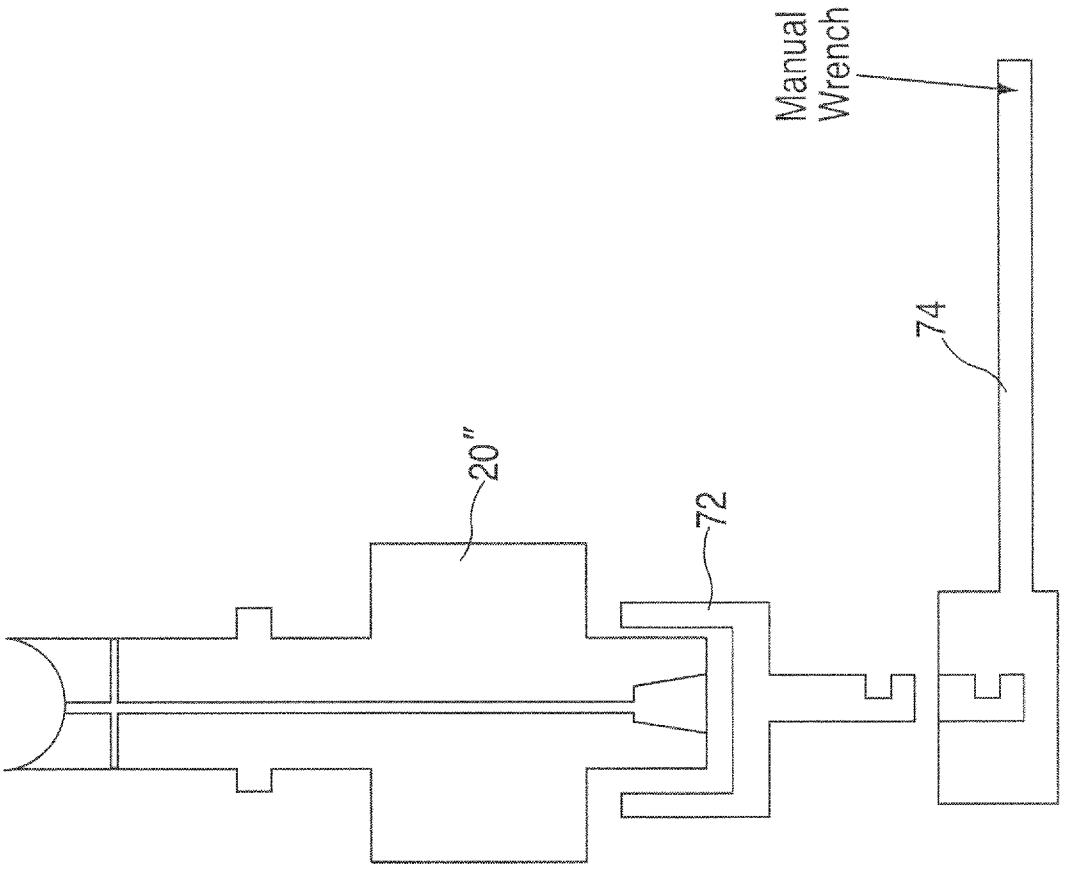


FIG. 5A

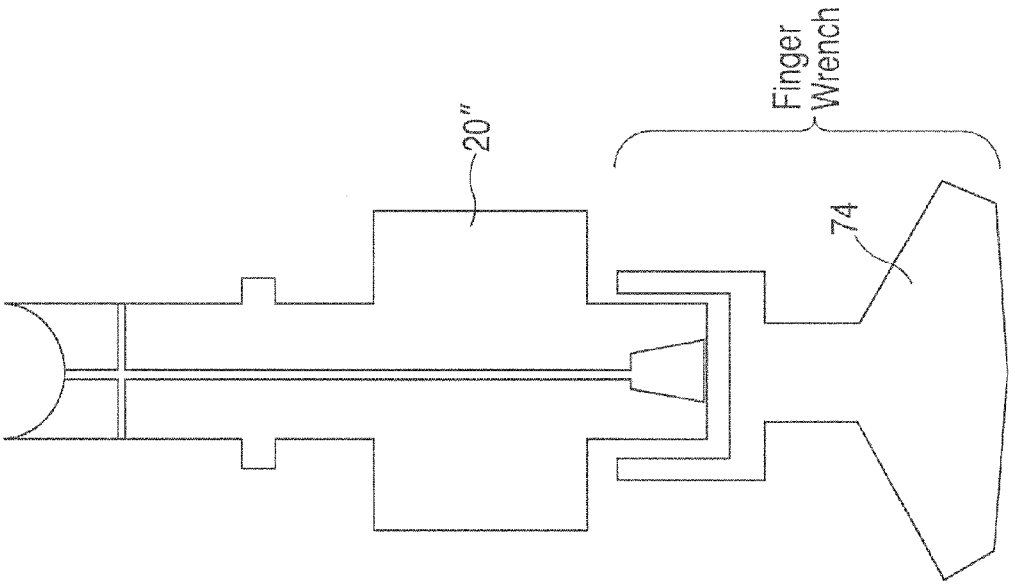


FIG. 5B

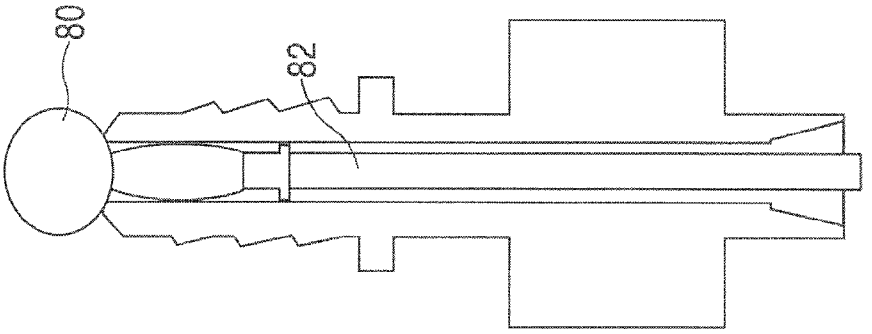


FIG. 6C

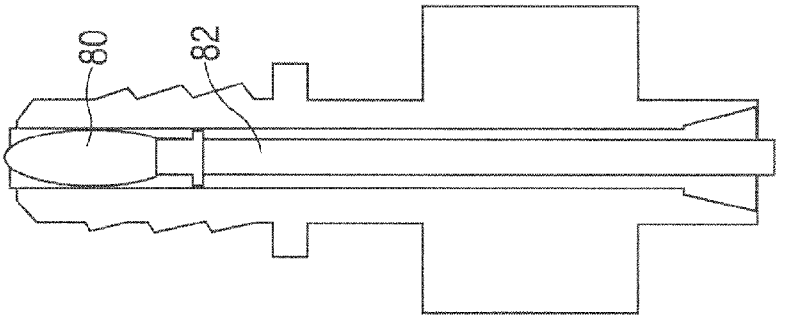


FIG. 6B

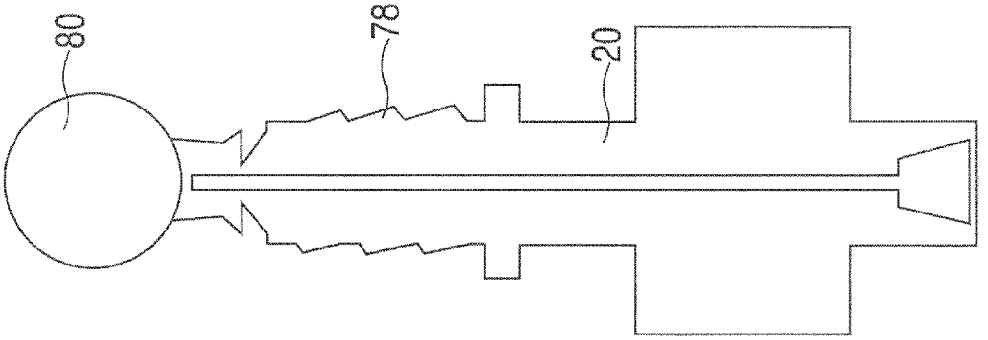


FIG. 6A

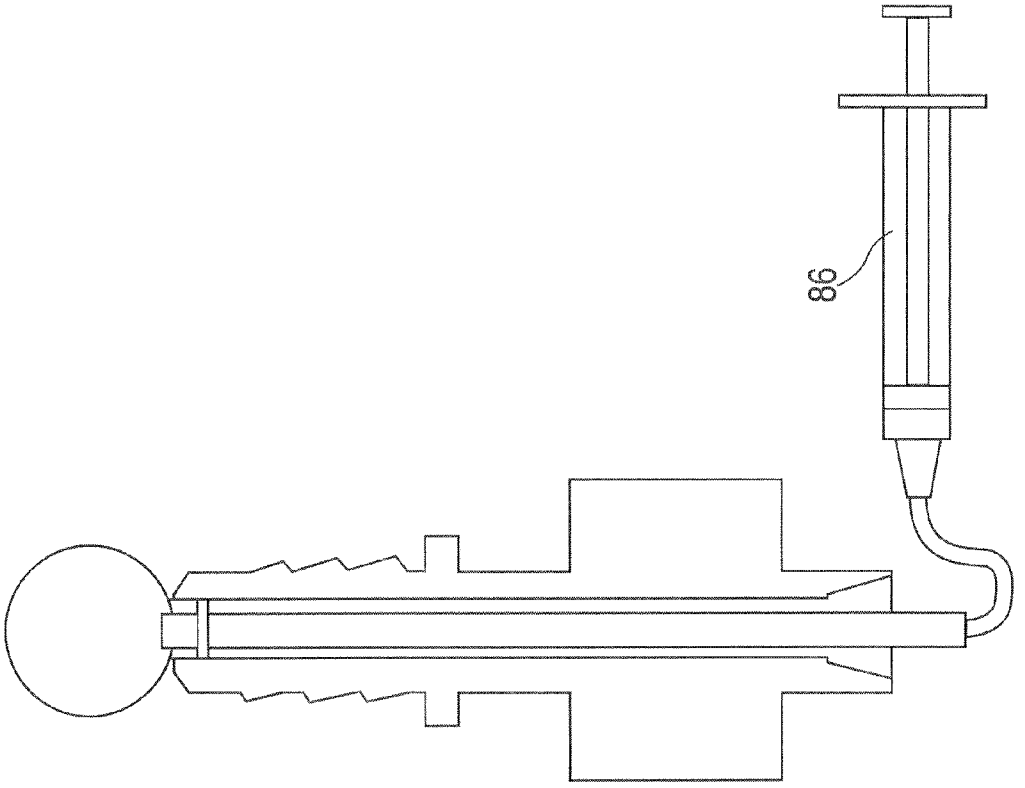


FIG. 6D

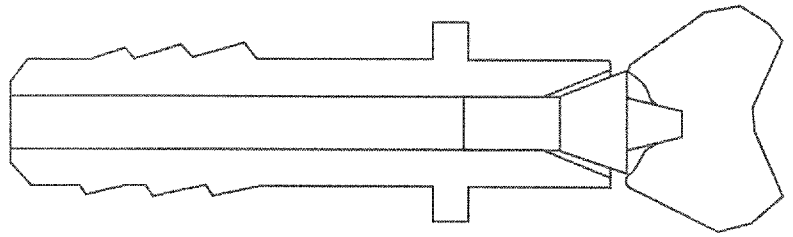


FIG. 7C

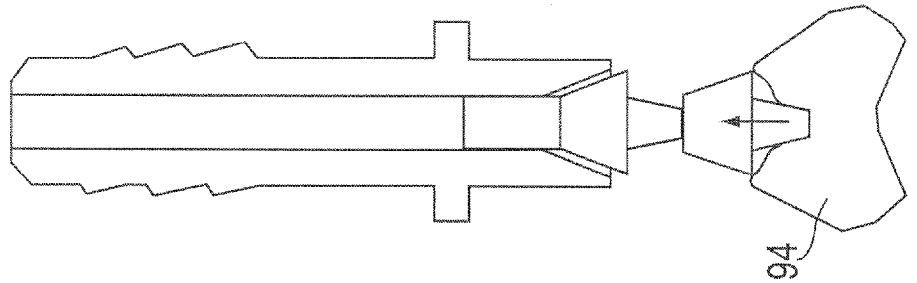


FIG. 7B

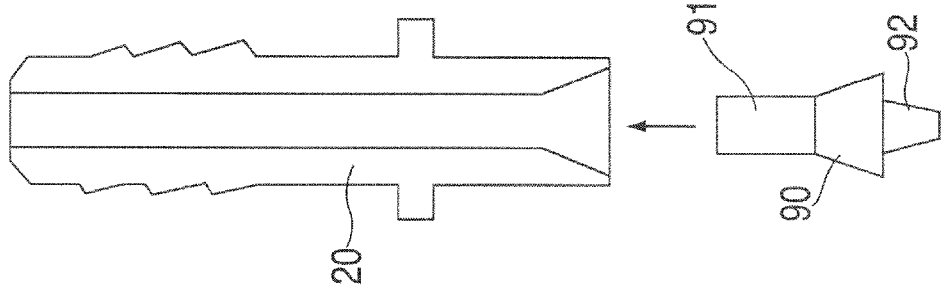


FIG. 7A

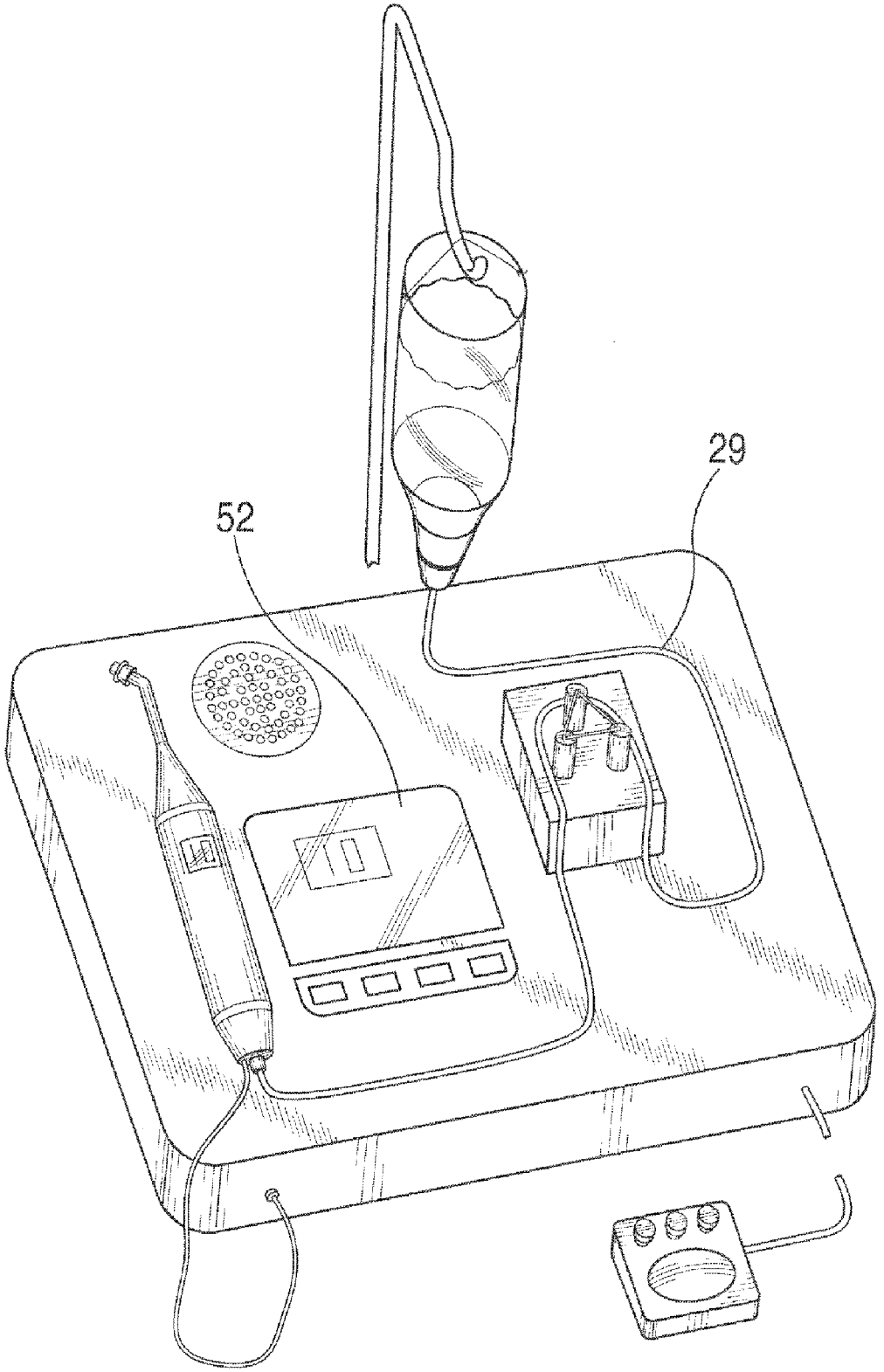


FIG. 8A

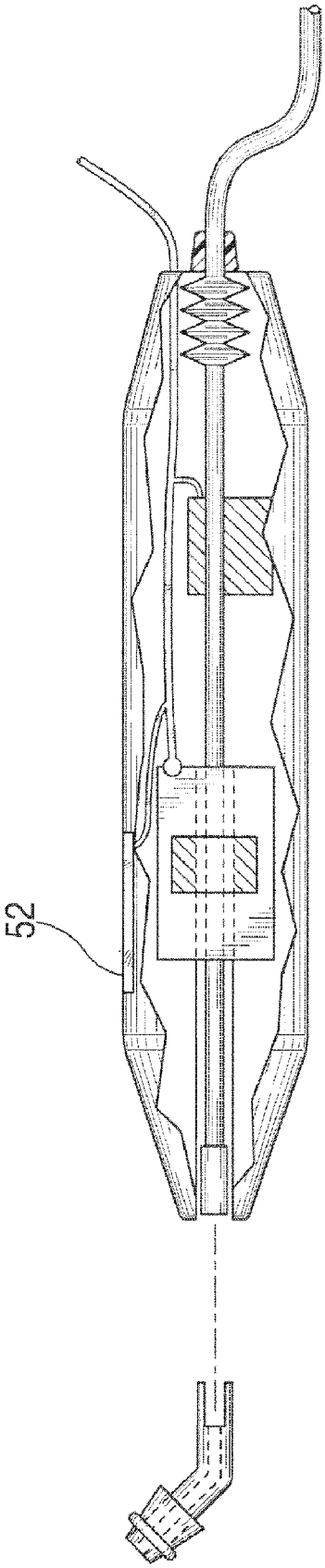


FIG. 9A

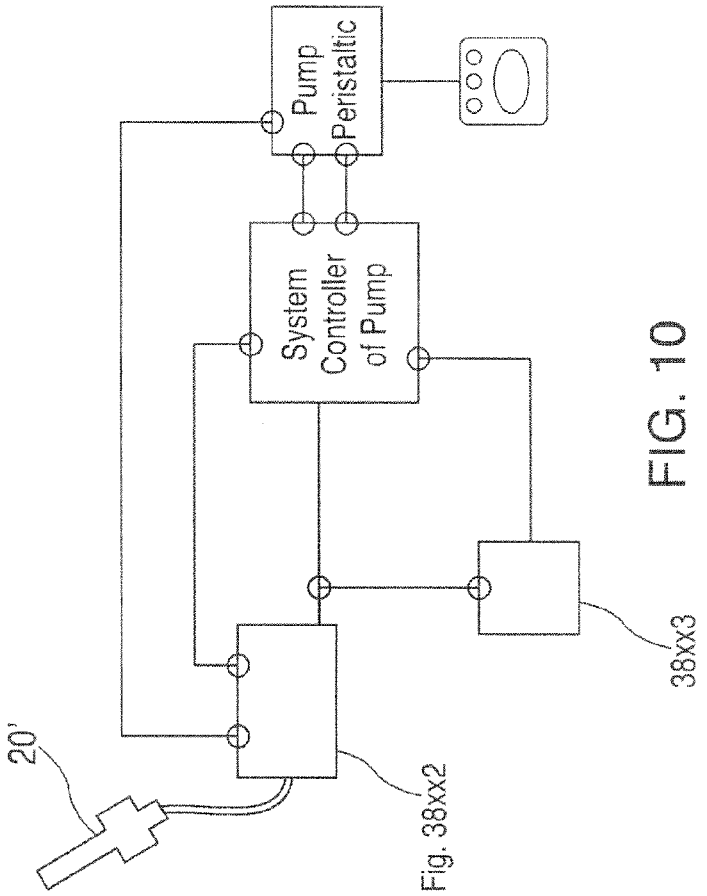


FIG. 10

FIG. 10A

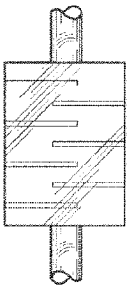


FIG. 10B

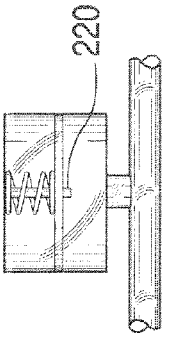


FIG. 10B

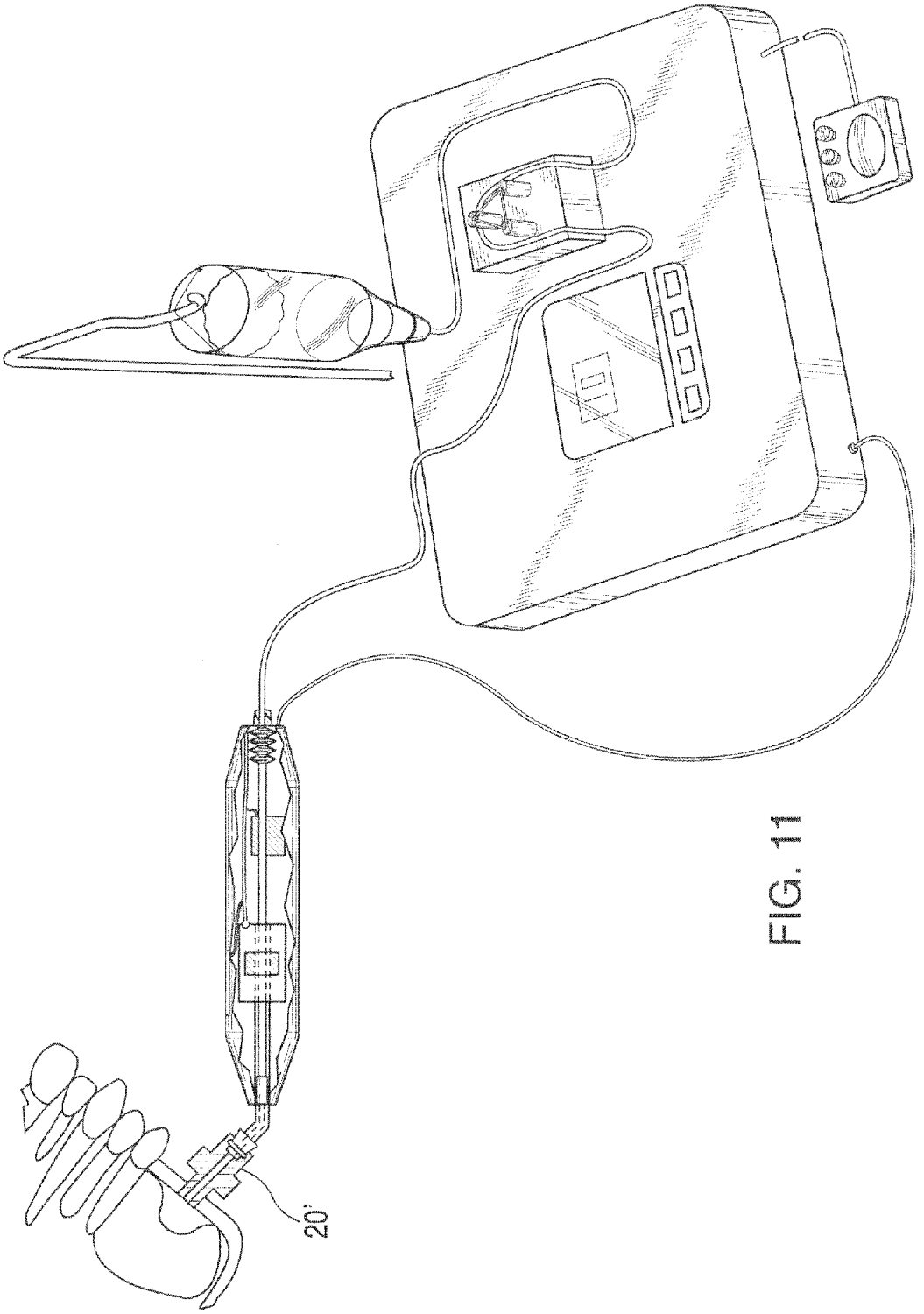


FIG. 11

METHOD AND APPARATUS FOR PERISTALTIC PUMP AND SURGICAL HANDPIECE WITH PRESSURE REGULATED FLUID SENSING FOR MAXILLARY SINUS ELEVATION

RELATED APPLICATIONS

[0001] This application claims priority to U.S. provisional 61/211,996 filed Apr. 6, 2009. The subject matter of this application is also a continuation in part application to U.S. provisional application Ser. No. 60/619,542 filed Oct. 15, 2004 corresponding to U.S. application Ser. No. 11/227,687, now issued U.S. Pat. No. 7,510,397, and its divisional application Ser. No. 12/102,085 filed Apr. 14, 2008, all incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] A. Field of Invention

[0003] This invention relates generally to improvements to the delivery of drugs, particularly for osseous regeneration for the maxillary sinus. The invention provides a method and device to the elevation of the floor of the maxillary sinus using a Peristaltic pump with a Surgical Handpiece with Pressure regulated fluid sensing capabilities to increase the amount of bone available based on hydro-dissection to raise the subantral membrane floor of the sinus (a.k.a. the Schneiderian membrane). More specifically a powered drug delivery device herein described and detailed as a delivery device composed of a Peristaltic Pump fluid source providing fluid drug, surgical handpiece with fluid exit-pressure sensing feedback elements to regulate the exit pressure. The surgical handpiece system contains design features to eliminate irregularities of fluid pressure from the Peristaltic pump mechanism during operation to ensure that exit-pressure sensing measurements are accurate during hydro-dissection and elevation of the subantral membrane floor of sinus. These design features ensure controlled fluid hydro-dissection enabling the continuous, real-time reporting of the status of the sinus membrane and detecting an intact sinus membrane from a torn or perforated sinus membrane when encountered.

[0004] B. Description of the Prior Art

[0005] Dental implants have been used in dentistry for about 20 years. They offer a tremendous benefit to patients by allowing the replacement of missing teeth. Prof. Per-Ingvaar Branemark introduced the use of titanium dental implants that showed that predictable, stabile implant integration occurs when implants have sufficient contact with the surrounding bone. Initially the placement of dental implants were limited to the anterior lower jaw, as this region provided sufficient bone quantity, quality and strength to support and hold a dental implant having an effective length.

[0006] Dental implants have revolutionized the treatment of many patients who previously lost dental function as a result of losing teeth. Today's standards of care now dictate that tooth loss is best treated with dental implants which then could be used for supporting an appropriate dental appliance. The previous alternative of dental bridges is now considered an inferior alternative in comparison to dental implants.

[0007] The success of dental implants is based on a variety of factors including; surgical technique, health of the patient, operator skill and, to a significant part, sufficient bone for the placement and integration of dental implants. To that end, the replacement of the maxillary posterior teeth have presented a considerable challenge because, after the loss of maxillary posterior teeth the quality and quantity of the remaining supporting bone may be insufficient to support implants properly or reliably.

[0008] The maxillary complex is a three-dimensional bone structure composed of alveolar bone and basal bone. The teeth, and more specifically, their roots are imbedded in the alveolar bone. The top of the structure forms the floor of the maxillary sinus and is covered by thin diaphanous membrane known as the subantral or Schneiderian membrane. Once a tooth is removed from the complex, the surrounding alveolar bone is frequently resorbed because of the lack of physical stimulation and support of the teeth. This leads to a loss of bone mass and a corresponding reduction in the effective height and thickness of the bone of the maxillary complex. In addition, with the loss of teeth from the upper jaw (and the maxillary complex) the compensatory enlargement of the maxillary sinus occurs that also reduces the vertical height of the remaining bone of the maxillary complex. These effects further compromise the option for dental implants to be used.

[0009] To overcome the deficiency of insufficient vertical bone mass of the maxilla, several surgical techniques have been developed to increase available bone mass for the replacement of dental implants by bone augmentation. The process includes augmenting the region with a filler or regenerative material made of natural and/or artificial (synthetic) materials by placement of these elements on the roof of the maxillary structure, under the subantral membrane so that it does not interfere with the function of the maxillary sinus.

[0010] Collectively, these procedures are known within the dental profession as "sinus elevation procedures" with the goal of increasing the vertical height available for placement of dental implants. What makes these techniques unique from other techniques, such as distraction osteogenesis, is that the bone is increased within a body cavity, i.e., the maxillary sinus cavity. The first of these surgical techniques requires a window into the maxillary sinus from a lateral and superior approach to the floor of the sinus. Great care must be taken during the entry to the sinus as it is critical not to perforate the subantral membrane that lines the sinus cavity. Bone augmentation of the maxillary sinus requires delicate dissection of the subantral membrane from the floor of the sinus. If the membrane is not properly dissected from the bone, bone augmentation may not occur, or may not be sufficient. Unintentional perforation of the subantral membrane may also lead to undesirable short and long-term consequences. If the perforation is large, for example, several millimeters in diameter, the surgeon must either abort the procedure or must use some means of containing the regenerative material placed on the floor of the sinus to encourage new bone growth. A lack of integrity of the membrane can also lead to the migration of regenerative bone materials leading to long-term chronic infections. Therefore, the maintenance of membrane integrity is of utmost importance during the elevation of the membrane to allow placement of regenerative materials with a goal of increasing bone mass in the maxilla.

[0011] Most patients and dental surgeons acknowledge that entrance into the maxillary sinus utilizing a lateral window approach (also known as the Caldwell-Luc procedure) is an invasive procedure. This technique is fraught with many risks and complications because of the limitations of healing potential in the maxillary sinus. In spite of these risks many patients undergo this procedure because of the strong desire to replace missing maxillary teeth with dental implants.

[0012] An alternative approach to the maxillary sinus from the inferior approach of the alveolar ridge utilizing solid cylindrical osteotomes was described by Dr. Summers. It is a more conservative approach and is less invasive. It was developed to eliminate the risks described above. This technique is referred to as the "osteotome sinus elevation technique", and it gains access to the floor of the sinus from an inferior approach directly through the remaining alveolar ridge. The technique vertically "lifts" the floor of the sinus, or more specifically, the subantral membrane via an infracture of the bony floor and placement of bone regenerative material from an inferior approach. The bone regenerative materials are actually used to raise the subantral membrane. The infracture can be performed using solid cylindrical osteotomes with specific diameters that are vertically advanced toward the maxillary sinus producing a mechanical lifting action on the membrane. The technique has a variety of shortcomings as well, including the ability to carefully dissect (or separate) the subantral membrane from the floor of the sinus. While, this technique is safer, an overzealous use of an osteotome during the placement of the regenerative material can result in the perforation of the subantral membrane with disadvantages discussed above.

[0013] More recently several new techniques have been introduced to overcome some of the limitations of the Summers osteotome technique. The new technique also uses an inferior approach to the membrane via the alveolar ridge. One such technique was presented by Dr. Emmanuel Sotirakas using a medical syringe to raise the floor of the sinus by injecting fluid. This technique has many deficiencies owing to the inability to properly adapt a standard medical syringe to an opening created in the bone. A second technique used to elevate the subantral membrane is taught by Dr. Geraldo Nicolau Rodriguez that using a catheter balloon placed under the subantral membrane of floor of the sinus. This procedure requires an infracture of the underlying bone similar to the Summer procedure or a lateral window approach previously described. The catheter balloon is passed through the maxillary complex and the balloon is inflated. During inflation the subantral membrane is separated and forced away from the bony bed. Unfortunately, tearing or ripping of the subantral membrane may still occur and it is difficult, if not impossible, to detect it during the inflation of the balloon. In fact a perforation or tear in the membrane may take place no matter how carefully the balloon is inflated. After the membrane is separated, the balloon is withdrawn and a regenerative material is injected under the membrane, in a manner similar to the Summer technique. If a tear has occurred, the bone regenerative material may be placed unintentionally by the operator into the maxillary sinus necessitating the need for surgical removal of the regenerative material. In addition to the methods described above, an additional technique described by Dr. Leon Chen called the "Hydraulic Sinus Condensing Technique" advocates using a small round bur to gain access to the floor of the sinus exposing the membrane. Using a second larger round bur provides access which results in the exposure of the membrane to condense regenerative material below the membrane. A stream of water from a dental handpiece is used to create hydraulic pressure to elevate the subantral membrane. This technique has multiple deficiencies owing to the inability to control the pressure and forces applied to the subantral membrane owing to the lack of precision of this technique.

[0014] More recently a method and apparatus for sinus elevation has been described in my related U.S. Pat. No. 7,510,397 utilizing a novel approach to elevate the sinus membrane. This system describes the use of bone connection sleeve to which a controlled delivery pump provides a drug to which the pressure within the sleeve or the cavity is monitored to detect and prevent the rupture of the subantral membrane. The patent describes an apparatus comprising an automated injection device or syringe to provide a source of fluid to the system.

[0015] The deficiencies and limitations of current techniques for sinus elevation relate to primarily: (1) the inability of the operator to utilize a peristaltic pumping source of fluid for hydro-dissection, (2) the inability to eliminate the irregularities of fluid pressure caused by the peristaltic pumping mechanical action, and (3) a lack of feedback indication to the peristaltic pumping mechanism providing a means to producing precise and accurate exit-pressure in the bone connection sleeve when using a peristaltic pumping mechanism. Overcoming these previous limitations in the technique of sinus elevation will simplify the technique resulting in a reduced infection, bleeding, swelling, pain, suffering and failure when using dental implants in the maxillary sinus.

[0016] To summarize, the following are the deficiencies of previous methods and devices:

[0017] 1. Traumatic invasive surgical procedures that include extensive mucogingival flap elevation methods to gain access to the surgical site.

[0018] 2. The use of instrumentation that comes into direct physical contact with the subantral membrane with the risk of perforating or tearing the membrane during separation of membrane from the floor of the sinus.

[0019] 3. The need to use a infracture, i.e. "green-stick" fracture of the floor of the sinus or lateral aspect of the sinus that could once again perforate or tear the delicate subantral membrane leading to failure.

[0020] 4. Using previous methods there is a lack of subjective indication or feedback to the operator that the membrane has been torn or perforated during is separation and elevation from the floor of the sinus.

[0021] 5. Inability to precisely control the infracture of the bone that is required to gain access to the floor of the sinus using previous methods.

[0022] 6. Inability to precisely control the force used to raise the subantral membrane.

[0023] 7. Inability to precisely control the delivery of the regenerative material and to determine weather a tear or perforation of the membrane has occurred during the placement of such regenerative material.

[0024] 8. Difficulty in accessing the integrity of the membrane prior to the placement of the regenerative material that will be placed on the floor of the sinus.

[0025] 9. Inability to create a seal between the delivery device, such as a syringe and the prepared bony site during the elevation of the membrane and delivery of regenerative materials beneath the subantral membrane.

[0026] 10. Inability to use a peristaltic pumping fluid source, such as a surgical irrigation system owing to the irregularities in the pressure fluid propagation from the pumping system leading to the potential perforation of the sinus membrane.

[0027] 11. Inability to use a surgical handpiece to connect to a bone connection sleeve to provide a fluid drug delivery conveniently and easily.

[0028] If a peristaltic pump fluid source is utilized during maxillary sinus and a perforation or tearing of the subantral membrane occurs during surgery owing to the sinusoidal fluid pressure propagation that leads to uncontrolled erratic pressures from this type of pumping system, this will result in the membrane perforation. Failure to control pressure from a peristaltic pumping system will lead to the need for additional surgeries to correct such outcome and/or retrieve materials placed within the sinus and may require extensive medical follow-up to corrective this iatrogenic outcome.

SUMMARY OF THE INVENTION

[0029] A method and device is disclosed that provides a new approach to utilizing a peristaltic pump drug fluid source in combination with a surgical handpiece that modulates the pressures generated while using a peristaltic pumping system. The method is used in combination with a drug delivery bone connection sleeve previously described by the inventor (U.S. Pat. No. 7,510,397). The method and device enables sinus elevation to be performed more effectively within bone tissues of the oral cavity.

[0030] Moreover, a method and device is described to improve the quality and quantity of bone during the placement of dental implants. This innovation is particularly well suited to allow an increase of bone mass, including bone quality and quantity in the posterior maxilla when the elevation of the maxillary sinus floor is required. It is also well suited when poor bone quality exists in either jaw of the oral cavity.

[0031] Briefly, a system for increasing bone mass in the posterior maxilla in accordance with this invention includes one or more sleeves having various lengths and diameters. A peristaltic pump provides the fluid for hydro-dissection. A surgical handpiece with integrated pressure sensing and pressure modulating is provided to attenuate the irregular pressures produced by the peristaltic pump source. A real-time pressure feedback system to provide the user with audible and visual information as to the status of the fluid pressure and status of the sinus membrane, a foot control mechanism to control fluid flow from the peristaltic pump mechanism. A connecting element is attached to the surgical handpiece allowing the surgical handpiece to create a fluid seal with the described bone sleeve that is placed within the patient's tissues.

[0032] One or more of these bone connection drug sleeves are used in each procedure that can be connected to the surgical handpiece with pressure sensing capability. Each sleeve is preferably cylindrical and includes a tip used to cut or otherwise form a hole into the maxillary sinus but under the subantral membrane. The bone connection sleeve may also be used after an osteotomy has been initially performed with a rotary instrument or a piezo-ultrasonic surgical tip, such as that available from Satelec Acteon Group, Inc., Mectron Piezosurgery, Inc, and others. The bone connection sleeve is hollow to allow a fluid to be inserted under the membrane to cause it to be gently lifted from the sinus floor and form a cavity by such fluid. In the present invention the fluid is provided by a peristaltic pumping source via the surgical handpiece with pressure sensing. The cavity is then filled with a suitable material such as a material that promotes bone growth. In one embodiment, the sleeve also has cross-channels that allow the same material to be disbursed in the alveolar ridge itself to change the quality of the bone type from a less dense to a more dense bone density type.

[0033] After the material is inserted, the sleeve is removed and an implant is inserted and anchored in the alveolar ridge with portions of the implant extending into the maxillary sinus. A dental appliance or prosthesis is mounted on the implant.

[0034] One disadvantage of peristaltic pumps and other electronic pumps using piezo-electric elements have inherently an intermittent operation which leads to a distinct and significant pressure variation in the fluid output. This variation may be detrimental to the tissues contacting the device and makes it difficult to get an accurate and instantaneous pressures sending in the line leading to the maxillary membrane. In order to solve this problem, one or more baffles are provided to absorb this pressure variation.

[0035] Several alternate embodiments are also provided. The regenerative material and elevation of the sinus membrane can be performed as one procedure. In another such embodiment, the sleeve also acts as the implant. In still another embodiment, a balloon is used at the tip of the sleeve for separating the membrane and forming the cavity.

[0036] The sleeve overcomes the deficiencies of the prior art methods and devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] FIG. **1** shows a cross sectional view of a typical maxillary sinus for a person who has lost several molars;

[0038] FIG. **2** shows a cross sectional view of a sleeve constructed in accordance with this invention;

[0039] FIGS. **2**A-**2**K show cross-sectional views of alternate tips and/or body of the sleeve of FIG. **2**;

[0040] FIG. **3** shows a block diagram of a device constructed in accordance with this invention connected to a controlled drug delivery pump;

[0041] FIGS. **4**A-**4**O show side views of the maxillary sinus during the subject process;

[0042] FIGS. **5**A and **5**B show embodiments of the sleeve modified so that it can be installed using a standard dental wrench;

[0043] FIGS. **6**A-**6**C show an embodiment of the invention wherein a balloon is used to perform hydro-dissection of the subantral membrane; and

[0044] FIGS. **7**A-**7**C show a sleeve constructed in accordance with this invention being converted into an implant and receiving a dental prosthesis.

[0045] FIG. **8** shows an embodiment of the invention with peristaltic pump, drug delivery tubing connected to an embodiment of a surgical handpiece with connecting element to the sleeve.

[0046] FIG. **9**A shows embodiments of surgical handpiece with pressure sensing transducers located at different locations to the handpiece.

[0047] FIG. **10** shows a block diagram of the control system used to eliminate or at least reduce fluid pressure variations;

[0048] FIGS. **10**A, **10**B and **10**C show various devices used as pressure modulating elements;

[0049] FIG. **11** shows another embodiment for fluid pressure modulation with a peristaltic pump.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0050] FIG. **1** shows a typical cross section of the maxillary sinus **10**. Several teeth **12** are seen in the Figure in a normal configuration. The maxillary sinus **10** is separated from the

mouth by the alveolar ridge **16** formed of bone. The bone is covered on top by the subantral membrane **14** and on the bottom by the gingiva **15**. As shown in the Figure, because this person has lost several molars, the floor of the maxillary sinus has been depressed or lowered in the area **18**. As a result, the alveolar ridge **16** in this region has lost considerable bone mass and quality. Frequently, the bone in this area is porous and is not strong enough to support an implant of sufficient length and an associated final dental prosthesis. Typically, in a health person the ridge **16** in this area may be about 8 to 14 mm however, in persons who have lost their molars, the thickness of the ridge **16** may be no more than about 4 mm.

[0051] FIG. **2** shows a first embodiment of a sleeve **20** constructed in accordance with this invention. The sleeve is preferably cylindrical. As discussed in more detail below, the sleeve performs several functions. One of these functions is to raise or elevate the subantral membrane **14**. The subantral membrane may be initially raised and separated from the floor of the maxillary sinus by the end of the sleeve. The sleeve may also placed beneath the membrane after access to the membrane is achieved using a piezo-ultrasonic bone osteotomy technique or other means to expose the membrane. The sleeve may or may not come into contact the membrane and provides indirect elevation to the membrane from the fluid pressure generated beneath the membrane surface. The membrane is raised further to create a cavity. For this purpose, an appropriate flowing material is injected through the sleeve under the membrane. This material may be a gas, e.g. air, a powder, a paste, a gel or a liquid, such as a salient solution.

[0052] A second function of the sleeve is to provide a means of cutting and/or condensing bone at the floor of the sinus prior to and during assessing to the subantral membrane.

[0053] A third function of the sleeve is to provide a means of delivering material into the bone and under the subantral membrane **14**. This function is optional.

[0054] A fourth function is to form a passageway for mounting and supporting an implant.

[0055] Optionally, a fifth function is to inject stimulating substances to be delivered into and around the bone of the ridge **12**. These substances can be materials and medications for bone regeneration that can be conductive, inductive or substitutions thereof including fluids and particulate matter. In this embodiment, the sleeve can be used for the delivery of bone stimulating substances into bone as well as for the elevation of the maxillary sinus membrane. Importantly, this same sleeve also serves to facilitate hydro-dissection of the maxillary membrane from the floor of the maxillary sinus, as discussed below.

[0056] The sleeve **20** includes a cylindrical body **22** with a tip **24** and a bottom **26**. A channel **28** is disposed essentially coaxially within the body **22** to allow fluids to flow to the tip **24**. Optionally, several cross-channels **30** are also provided to allow fluids to be delivered to the bone of the ridge as well. In FIG. **2**, the tip **24** is shown as having a relatively concave or bowl shape forming a circular cutting edge **32**. FIGS. **2**A-**2**G show alternate shapes for the tip, including a square shape (FIG. **2**A), a sharp or blunt convex shape (FIGS. **2**B, **2**C), a pointed tip (FIG. **2**D). A blunter tip may prevent injuring of the subantral membrane. Moreover, as shown in FIGS. **2**E-**2**G, the tip **24** may be formed with a narrow neck **32**. FIGS. **2**H-**2**K show alternate shapes for the whole sleeve. In FIGS. **2**H, **2**I the sleeve has frustoconical shapes. FIG. **2**J shows a sleeve with a decreasing diameter in steps as it approaches the tip while in FIG. **2**K the sleeve has a paraboloidal shape to mimic the shape of a tooth root.

[0057] Below the egresses from the cross-channels **30** (if any), the sleeve **20** is formed with an annular ring or several wings **34** that define a stop for the sleeve to limit advancement into the bone. Under the wings **34** there is provided a thumb hold **36** by which the sleeve can be held and advanced, preferably between the thumb and the index finger.

[0058] Below hold **36** there is a short connector **38** that can be used to attach the sleeve **20** to a surgical handpiece to be discussed. In a preferred embodiment, the connector **38** is sized and shaped to mate with a female or male connector attached to a connecting element that is attached to the surgical handpiece that connects to the peristaltic pump fluid source providing the drug. The bottom **26** is also formed with an entrance hole **40** communicating with the passageway **28**. The outer surface of the sleeve may be provided with markers **42** to indicate the depth of the tip **24** within the ridge **16**. These depth markets could be laser etched, engraved or ridges upon the surface. The markers **42** could be in the form of circular bands about the outside of the implant.

[0059] The sleeve may be designed of a metal such as titanium or an alloy such as stainless steel. Alternatively, the sleeve may be composed of plastic, composite or other suitable materials.

[0060] The cylindrical shape of the sleeve mimics the shape of a typical dental implant. Typically, the sleeve may range from 3.0 mm to 6.0 mm in diameter. The sleeve may have a variety of different length ranging from 2 mm to 14 mm, but not limited to any of these lengths or diameters. In one embodiment, a kit may be provided with a plurality of sleeves of different diameters and/or lengths. The outer surface of the sleeve can be either threaded or smooth. The texture of the surface could be polished or acid-etched, or can have other kinds of surface textures.

[0061] The sleeve could also be optionally designed with an O-ring or a tip gasket **44** (shown in FIG. **2**J) to ensure an intimate fit between the sleeve and the bone ridge **16**. The O-ring or tip gasket **44** could be made of a soft silicone material or any other soft material that allows adaptation and an intimate fit. It could be made of a latex or non-latex deforming material. It could also be made of a hard material such as nylon or some other material to allow intimate contact to the bony surface. The O-ring or gasket could be one or more on the surface of the sleeve. It could be positioned anywhere along the surface, most probably in an encircling pattern on the surface, as shown. The O-ring on the sleeve insures that the materials introduced under membrane **14** do not leak out.

[0062] Referring now to FIGS. **8**A, **9**A, **10** and **11** in one embodiment, a device **200** is provided in which a drug from a drug reservoir **202** through a peristaltic pumping system **204** and provided to a surgical handpiece **206** via tubing **207**. The handpiece includes a handpiece display **208** and receives power through a power cord **210**. Cord **210** may have additional wires for data transmission. Device **200** further includes a foot control **212**, a visual display **52** and, optionally, a speaker **54** providing either alarm signals, or audible information to a health care provider or physician.

[0063] As shown in FIG. **9**A in the present invention, connector **38**XX**1** with a fluid channel **37** allows the surgical handpiece **206** to connect directly with the sleeve **20** via a short connector **38** shown in FIG. **2**. The handpiece connection tip **38**XX**1** can be designed as a re-usable or disposable tip that is connected to the surgical handpiece **206**. The hand-

piece connection tip **38**XX**1** ensures an intimate fit between the sleeve **38** and the surgical handpiece **206**. The handpiece connection tip may be provided with an O-ring, tip gasket **211** or other means of providing intimate contact to the bone connection sleeve. It could be made of a soft silicone material or any other soft material that allows adaptation and an intimate fit. It could be made of a latex or non-latex deforming material. It could also be made of a hard material such as nylon, stainless steel, titanium or some other material to allow intimate contact to the bony surface. The O-ring or gasket **211** could be one or more on the surface of the handpiece connection tip. It could be positioned anywhere along the surface, most probably in an encircling pattern on the surface, as shown. The O-ring **211** on the sleeve insures that the materials introduced into the bone connection sleeve **38** do not leak out.

[0064] The handpiece connection **38**XX**1** is mounted onto the surgical handpiece **206** by threaded mounting or other means of frictional seating of the handpiece connection tip to the surgical handpiece. The handpiece connection tip **38**XX**1** may also be designed to be flexible to allow multiple positions of the surgical handpiece to be established during operation. The handpiece connection tip is has an internal hollow bore channel **37** to allow the flow of fluid and the detection of exit-pressures generated during hydro-dissection.

[0065] The surgical handpiece **206** is connected to tubing **207** that is then attached to peristaltic pump system **204** providing an appropriate material such as fluid, e.g., as a sterile saline, a drug or bone stimulating material. In the preferred embodiment the surgical handpiece **206** contains an integrated fluid pressure transducer **38**XX**2**, such as, or similar to, that used in the Meritrans® MER212 from MERIT-MEICAL, South Jordan Utah, USA, and it is capable of being sterilized and re-usable. It may however be an integrated single-use disposable surgical handpiece. The pressure transducer provides real-time pressure data within the surgical handpiece **206** from the bone connection sleeve **38** via the handpiece connection tip **38**XX**1**. The fluid pressure transducer **38** XX**2** may be piezo-electric, piezo-crystal design, film-based pressure sensing design and any other means of electronic and/or physical sensing of fluid pressure. Alternatively, the pressure sensing element can be placed outside the surgical handpiece distal to the handpiece or in any position between the peristaltic pump fluid source and the surgical handpiece. The pressure sensing element **38**XX**2** provides control to the central drive unit and provides controls to the peristaltic pumping system **204**. The controlled drug delivery device provides audible and visual information related to the pressures detected and the status of the sinus membrane either on display **52**, speaker **54**, a display **208** on the handpiece **206** or all of the above.

[0066] A switch **39** may be provided in the fluid path that is manually operated by a button (not shown) to selectively turn the fluid flow on and off. The switch **39** may be placed elsewhere in the system as well.

[0067] Preferably, a fluid pressure modulating element **38**XX**3** is also provided in the system to eliminate, or at least reduce the pressure variations that are characteristically produced by the peristaltic pumping system. The fluid pressure modulating element **38**XX**3** may be implemented using several different designs. In one embodiment, it is implemented as a physical fluid baffle structure shaped as an accordion folded inner surface that is in-line with the fluid flow path and thus modulates the pressure wave normally produced from a peristaltic pump system. This embodiment is shown in FIG. **10**A.

[0068] In another embodiment, the pressure regulating element is provided as a cartridge **38** XX**4** with an internal path forming a labyrinth similar to automobile muffler, as shown in FIG. **10**B. In yet another embodiment, the pressure modulating element is an over-flow reservoir **38**XX**5** with an internal spring-biased piston **220** as shown in FIG. **100**. In this embodiment, pressure variations in the tubing **209** due to the operation of the peristaltic pump are dynamically damped by the movement of the piston. The pressure modulating element can be located at various locations within the system. In one embodiment it may be within the surgical handpiece **206**. In another embodiment it may be within the tubing set between the surgical handpiece and the peristaltic pump and still in another embodiment it may be integrated within the peristaltic pump system itself.

[0069] In still another embodiment an electronic pressure modulating element **38**XX**5** may be used exclusively or in conjunction with the physical fluid pressure modulating elements previously described. The electronic pressure modulating element detects the electrical pulsating wave produced by the peristaltic pumping motor via an electrical signal. The signal is analyzed with the microprocessor of the control unit and is filters out that signal to produce a uniform pressure reading. The electronic pressure modulating element is an electronic filter for detecting pulsating pressure signals and re-interpreting this signal to create a uniform pressure signal to be provided to the controller of the system. The electronic pressure modulating element can be located at various locations within the system, in one embodiment it may be within the surgical handpiece, in another embodiment it may be within the tubing set between the surgical handpiece and the peristaltic pump and still in another embodiment it may be integrated within the peristaltic pump system itself.

[0070] The bone connection sleeve may also be directly connected to the tubing that connects to peristaltic pump. In this embodiment the pressure modulating element and/or the electronic pressure modulating element may be integrated in either the disposable tubing set or integrated directly into the peristaltic pump system itself. A variety of interlocking mechanisms may be used between the tubing, pressure modulating pressure elements (electronic and physical) and the connector **38**. As shown in FIG. **3**, in one embodiment of the invention, a sleeve **20** is connected by tubing **29** to a peristaltic pumping drug delivery device **50** such as that provided by surgical drilling unit with peristaltic pump or provided by a surgical piezo-ultrasonic bone cutting unit described in U.S. Pat. No. 6,695,847 or US patent application 2004/0102782 or US patent application 2008/0275379, incorporated herein by reference. The device **50** includes, or is associated with a display **52**, auditory sound that corresponds to pressure and/or an audio alarm **54**. The display **50** or the sound or alarm component **54** generate an output indicative of the pressure within chamber **28** as well as the fluid pressure at the tip **24**.

[0071] The method of using the sleeve is now described in conjunction with FIGS. **4**A-**4**B. In the following example, a 10 mm sleeve having a 3.3 mm diameter is inserted into a 4 mm deep ridge. As described above, the purpose of the present invention is to increase the body mass of ridge **16** so that it can support and hold a dental implant permanently of sufficient length (8 mm to 16 mm dental implant length).

After the implant has been installed, a dental appliance (such as a crown or a bridge) is mounted on the implant in the usual manner.

[0072] The first step is to make a preliminary hole through the ridge **16**. As part of this step, first an incision can be made in the gingiva **15** to expose the bone forming the ridge. Alternatively, a hole can be punched in the gingival, or a round drill can be used to remove parts thereof.

[0073] Next, as shown in FIG. **4**B a drill is used to make a 2 mm hole in the bone. The hole can be made using a round drill, a pilot drill, a twist drill, etc.

[0074] In the following step (FIG. **4**C), a 2.8 mm hole is made to the subantral membrane **14**. Typically, the bone **16** includes a harder bone layer **33** (known as the dense cortical lamella bone) that can be easily felt by the surgeon as he approaches the membrane **14**. Preferably, as the surgeon approaches the membrane **14**, one or more radiographs **35** are taken to show the exact position of a measuring device, i.e. depth gage, as shown in FIG. **4**D. As discussed above, it is important to insure that the membrane **14** does not get punctured or otherwise damaged during this procedure. Means for insuring that the membrane is not damaged, and for detecting membrane rupture are discussed below.

[0075] Next, in FIG. **4**E sleeve **20** is inserted. Preferably the insertion is accomplished by rotating the sleeve about its longitudinal axis while simultaneously translating or advancing it. This technique may be performed manually if the surface of the sleeve **20** is smooth. Alternatively, the outer surface of the sleeve **20** is threaded and therefore rotating the sleeve causes it to automatically translate as well. The wings **34** are spaced 4 mm from the tip **24**, again to insure that the membrane **14** is not damaged. The sleeve **20** is slowly inserted into the hole **37** and advanced (FIG. **4**F) and rotated causing it to cut or punch through layer **33**. In another embodiment, the access of layer **33** may be achieved using piezo-ultrasonic bone tip to remove the bone adjacent and beneath the sinus membrane. The sleeve **20** would be positioned inferior to the membrane without direct contact to the exposed sinus membrane.

[0076] Next the surgical handpiece with handpiece connection tip is inserted into the sleeve. The intimate fit of the handpiece connection tip assures that fluid leakage will not occur and that a frictional seal between the two elements has been established.

[0077] The next phase requires that Hydro-dissection is initiated by starting the flow of fluid from the peristaltic pumping system causing a sterile saline solution or other liquid into channel **28**. The liquid causes the membrane to rise some more generating a cavity **62** under the membrane **14**, as shown in FIGS. **4**H, **4**I and **4**J. Preferably, sufficient fluid is pumped under the membrane so that the cavity **62** reaches between 4 mm to 8 mm to provide a total vertical height of 8 mm to 16 mm, a greater bone mass may also be created utilizing this same technique. An alternative embodiment of creating a greater bone mass may also be accomplished by utilizing a specific measured volume of the appropriate flowing material measured from within the drug delivery system selected for use. A volume 15 cc is provided as an example but not be limited to, the range is only limited by the space available within the sinus cavity.

[0078] Next, as shown in FIG. **4**K, the saline solution is drained from cavity **62** and in the next step shown in FIG. **4**L a regenerative material **64** is used to replace it in the cavity **12**, again, using a syringe, the device of FIG. **3**, or other known means. The regenerative material **64** is a known regenerative material including allographs, autogeneous bone grafts, xenografts. Such materials may include natural materials, artificial materials, or a mixture thereof. Examples include freeze dried allograph bone, Emdogain (Straumann ITI, Inc.), Pepgen 15 (Dentsply, Inc) or any other bone stimulation substance derived from the patient's blood or other biological sources such as Platelet Rich Plasma (PRP), or a variety of growth factors such as: insulin-like growth factor-1 (IGF-1), a transforming growth factor-beta, (TGF-.beta.), a basic fibroblast growth factor (bFGF), a cartilage-inducing factor-A, a cartilage-inducing factor-B, an osteoid-inducing factor, a collagen growth factor and osteogeninbone morphogenic proteins (BMP).

[0079] These materials promote bone grow in and around cavity **62**. In order to strengthen the existing bone structure of the ridge itself, especially around the sleeve, one or more cross-channels are provided in the sleeve to allow the bone stimulating material to dissipate directly into the porous bone of the ridge.

[0080] In one embodiment of the invention, the regenerative material is pumped directly through the sleeve **20** via the peristaltic pump system. In another embodiment of the invention, the sleeve **20** is removed, and the material **64** is pumped into the cavity **62** (and the bone of the ridge **16**) through the hole **37**. In yet another embodiment of the invention, the step of injecting the salient solution to pump up cavity **62** is omitted and the material **64** is pumped in and used to raise the membrane **14** and to generate cavity **62**.

[0081] As discussed above, one major concern during the steps of hydro-dissecting is that the membrane **14** could be damaged or ruptured, because obviously, if this occurs the material **64** should not be pumped into the cavity **62**. However, since the membrane **14** is insubstantial, it is difficult to determine whether it has been damaged or not. Therefore, in the preferred embodiment, during hydro-dissection, the liquid pressure within the channel **28** and the cavity **62** is continuously monitored from within the surgical handpiece previously described or other embodiment thereof. For example, if the device of FIG. **3** is used, then this device automatically determines this pressure from measurements made within the device **50** itself. It is also anticipated that the surgical handpiece itself can display the pressure measurement on the surgical handpiece itself via an electronic display within direct view of the operator. The pressure can be displayed on the screen **52** or to the surgical handpiece or both and is provided to the surgeon as an audible signal as well. This audible signal may be a sound or spoken words. The surgeon either listens to corresponding information that provides fluid pressure during hydro-dissection or can watch this pressure during hydro-dissection and can decrease the fluid flow into the cavity **62** if this pressure approaches a threshold or safety level. This level may be about 2 psi to 10 psi. Moreover, a sudden drop in the pressure during continuous fluid flow is a clear indication of a rupture of the membrane **14**. This event is indicated on the screen **52** and/or the audio alarm **54**. If a rupture occurs, the procedure is halted, and the patient is sent home for several days to allow the membrane to heal. During this time, the sleeve **20** can stay in place thereby allowing the process to be readily resumed at a later time.

[0082] Monitoring of the pressure within the channel **28** or cavity **62** can be performed during the injection of the salient solution, the injection of material **64** or both.

[0083] Alternatively, monitoring of the pressure can also be achieved using a "loss of resistance" method in which a conventional syringe or glass (epidural syringe) is used. If a rupture of the subantral membrane occurs the surgeon will feel a loss of resistance of the plunger of the medical syringe immediately and an appropriate action can be taken. Once the syringe is used to raise the membrane an appropriate material can be placed with or without the syringe.

[0084] Additionally, monitoring of the pressure with a syringe with integrated manometer such as the Viceroy® Inflation Syringe from (Merit Medical, Inc.) that allows pressure monitoring directly from a gauge affixed to the syringe or other syringe devices incorporating a pressure sensing/monitoring like device capability as such as Hadzic, et. al. described in U.S. Pat. No. 6,866,648. Devices presenting alternative means to monitor and sense pressure from a drug delivery vessel or syringe.

[0085] After a sufficient amount of material **64** is injected into the cavity **62**, the sleeve **20** is removed and replaced with a standard implant **66** (See FIG. **4**M). A crown or other appliance **68** is then affixed to the implant **66**. As shown in FIG. **4**N, the position of the implant and the placement of the material **64** is checked either before or after the appliance **68** is installed.

[0086] In an alternate embodiment, either after the material **64** is inserted, after the sleeve **20** is removed, or after the implant **66** is installed the process is halted for a period of time, example several weeks or months to allow the sinus and the ridge **12** to heal itself, for additional bone material to grow at the site thereby increasing the bone mass, and/or to allow material **64** to set.

[0087] After awhile, the bone regrows around the material **64** and the implant thereby effectively increases the thickness of the ridge **12**, as illustrated in FIG. **4**O.

[0088] Several other alternatives may be used to practice the invention as well. In one embodiment, the sleeve **20** may be placed with a delivery tool (not shown) that can attach to the sleeve temporarily to transfer it into the patient's mouth without directly handling it. The tool also allows the sleeve to be inserted or screwed-in providing mechanical advantages of placement.

[0089] As illustrated in FIG. **5**A, a sleeve **20"** may be designed so that its connector **38** is shaped to fit into a latch adapter **72**. During the insertion and/or removal of the sleeve, the adapter **72** is positioned over the bottom of the sleeve **20"** and then a standard manual wrench **74** is used to advance or retract the sleeve from the ridge **12**.

[0090] Alternatively, the latch adapter **72** may also be designed so that it will fit directly into a rotary dental hand piece or manual wrench commonly used in dentistry, as already shown in FIG. **5**A. The sleeve delivery tool may also be designed in a "Ratchet type" form to allow the sleeve to be ratcheted into the bone of a patient.

[0091] As illustrated in FIG. **5**B, a sleeve **20"** may be designed so that its connector **38** is shaped to fit into a manual wrench adapter **74**. During the insertion and/or removal of the sleeve, the adapter **74** is positioned over the bottom of the sleeve **20"** and is used to advance with the thumb and index finger to allow for greater mechanical force and manipulation as the sleeve **20"** is placed into and removed from the ridge **12**.

[0092] In another embodiment of the invention, instead of using a separate standard implant, the sleeve **20** itself is designed to accept on its lower portion a dental appliance. In this embodiment, the steps shown in FIG. **4**M are omitted, and the sleeve **20** is not removed but instead, the device **68** is mounted on the sleeve. Hence, in this embodiment, the sleeve **20** acts as an implant **66** as well.

[0093] As discussed above, the sleeve **20** can be inserted into hole **37** by several means, such as tapping or screwing. If screwing is used, then the outer surface of the sleeve is threaded as it **78** in FIG. **6**A.

[0094] An alternate embodiment, a balloon is used for performing the dissection. In the embodiment shown in FIG. **6**A, the sleeve **20** is provided with the narrow neck and flared tip shown in FIG. **2**E. This shape allows a balloon **80** to be mounted externally onto the sleeve. In this embodiment, the sleeve **20** is first used to make the whole **37** and, optionally, to separate the subantral membrane from the sinus floor. Then the sleeve **20** is removed, the balloon **80** is mounted on the sleeve, and the sleeve is replaced with the balloon mounted thereon as shown in FIG. **6**A. The connector **38** is then coupled to an appropriate source of air or salient solution and the balloon is blown up thereby implementing the membrane separation from the floor of the sinus.

[0095] In another embodiment, the balloon **80** is mounted at the end of a catheter or stylet **82**. The balloon **80** is then inserted through the channel **28** until it reaches the desired site as shown in FIGS. **6**B and **6**C. The catheter **82** is connected to a source, such as a syringe **86** shown in FIG. **6**D and then inflated for separation of the subantral membrane from the bone.

[0096] FIGS. **7**A-**7**C shows how a sleeve **20** constructed in accordance with this invention is modified to act as an implant. As shown in FIG. **7**A, first an abutment **90** is attached to the sleeve. More particularly, the abutment **90**, has a cylindrical end **91** and a conical end **92** interconnected by a portion **93** having a slanged sidewall. The end **91** and portion **93** fit into the central channel **28** of sleeve **20**. The abutment **90** is secured to the sleeve **20** by using an adhesive or cement. Alternatively, the abutment is secured by an interference fit, or by providing a threaded engagement therebetween.

[0097] Once the abutment is firmly attached to the sleeve, prosthesis **94** is then attached to the abutment in the usual manner as shown in FIG. **7**B. FIG. **7** shows the prosthesis **94** mounted on the sleeve **20**.

[0098] To summarize, the subject device provides several improvements and advantages over the prior art to enable the improvement of bone quantity and quality and increase bone mass in the upper jaw for the placement of dental implants. Some of these advantages include:

[0099] A means to allow the use of a peristaltic pumping system to delivery a drug for maxillary sinus elevation;

[0100] A pressure modulating element, either physical or electronic or both is used to eliminate the sinusoidal pressure wave produced by the peristaltic pumping motor system;

[0101] A surgical handpiece that incorporates a pressure monitoring element to detect fluid pressure in real-time to provide a signal to the pumping system and operator;

[0102] The fluid pressure is monitored to determine if a tear or breach in the sinus membrane has occurred and that data is provided to the operator as a visual and/or audible signal to determine a course of action. The pressure monitoring ensures that the integrity of the sinus membrane is intact and results in a safer and simplified means of elevation of sinus membrane;

[0103] A means to allow the use of medications and bone stimulating substances to be placed in and around existing

bone, and more specifically, the alveolar ridge. The bone stimulating substances can be placed prior to, during or after dental implant placement.

[0104] A means to raise/elevate the sinuous floor of the maxillary sinus without damaging the subantral membrane. The membrane is raised off of the bony surface by hydrostatic pressure that can be delivered through a sleeve. During this process, the exit pressure from the sleeve is monitored to insure that it does not increase beyond a threshold level. A drop in the exit pressure is indicative of a ruptured membrane. Medications including bone stimulating substances can be delivered through both the removable sleeve.

[0105] In one embodiment, a balloon catheter is placed through the sleeve to allow additional space to be created around the implant prior to the placement of medications or bone stimulating substances. The ballooning technique will provide additional space for the placement of materials. In the maxilla, additional space may be created by elevation of the sinuous floor. The method and device herein disclosed for the first time presents a method and device that allows a multi-purpose sleeve to be placed in the bone forming the alveolar ridge. The advantage allows an adequate and precise seal between the delivery system and the prepared bony site thus allowing precise and adequate pressure to be used to effectively control the delivery of such biological products within the alveolar ridge and sinus cavity. An advantage of this system is that it minimizes the risks of damage to tissues.

[0106] The seat platform or seating collar design ensures that the drug delivery dental implant sleeve or dental implant will be placed to a specified depth within the bone. The seat will prevent the sleeve or implant from accidentally being advanced into the maxillary sinus requiring a subsequent surgical procedure to be performed to remove the implant from within the maxillary sinus. The seat also ensures that during the initial elevation of the sinus from the bony floor that the dental implant or sleeve will not tear or damage the membrane by premature contact to the membrane. It is noted that in still another embodiments, the sleeve it does not require the feature of a seat platform or seating collar design and a smooth surface design is discussed and shown in the figures.

[0107] Numerous modifications may be made to the invention without departing from its scope as defined in the appended claims.

I claim:

1. An apparatus for performing maxillary membrane elevation comprising:

a fluid source;

a fluid delivery tube;

an electrically operated pump connected to said fluid source and pumping said fluid to said tube;

a baffling element arranged to absorb pressure variations in said tube resulting from the operation of the pump; and

a sleeve sized and shaped to be inserted in a patient to provide maxillary membrane elevation when receiving fluid through said tube.

2. The apparatus of claim **1** wherein said sleeve has a tubular body with a bottom and said tube includes a connector attaching said tube to said bottom.

3. The apparatus of claim **1** wherein said pump is peristaltic pump.

4. The apparatus of claim **1** wherein said baffling element includes a fluid path in form of a continuous labyrinth.

5. The apparatus of claim **1** wherein said baffling element includes a fluid chamber with a variable volume controlled by a spring-biased piston.

6. The apparatus of claim **1** further comprising a pressure sensor sensing the pressure of the fluid applied to the sleeve and an indicator indicating the pressure detected by the pressure sensor.

7. The apparatus of claim **6** further comprising a control line coupling said pressure sensor to said pump to deactivate said pump if the pressure detected by the pressure sensor reaches a predetermined threshold.

8. An apparatus for performing maxillary membrane elevation comprising:

a peristaltic pump generating a fluid output with pressure variations;

a handle having a fluid connector, a fluid input and a fluid path connecting said fluid connector to said fluid input;

a sleeve adapted for positioning to extend into the maxillary cavity for said membrane elevation, said sleeve being selectively coupled to said connector;

a tube connecting said pump to said input to provide said fluid;

a baffle positioned to absorb said pressure variations;

a pressure sensor arranged to sense a fluid pressure at said sleeve;

a controller coupled to said pressure sensor and adapted to automatically turn said pump off if said pressure reaches a limit.

9. The apparatus of claim **8** wherein said pressure sensor is incorporated into said handle.

10. The apparatus of claim **8** further comprising an indicator coupled to said pressure sensor to provide an indication to a user of said pressure.

11. The apparatus of claim **8** wherein said indicator is a visual indicator.

12. The apparatus of claim **10** wherein said indicator is an audible indicator.

13. The apparatus of claim **11** wherein said indicator is disposed in said handle.

14. The apparatus of claim **8** wherein said baffle is positioned in said handle.

15. The apparatus of claim **8** wherein said baffle is a chamber with a labyrinthical path.

16. The apparatus of claim **8** wherein said baffle is an electronic pressure modulator.

17. The apparatus of claim **8** wherein said baffle includes a cylinder through with the fluid flows with a spring loaded piston.

18. The apparatus of claim **8** further comprising a manual switch for selectively controlling the delivery of fluid from said handle to said sleeve.

19. The apparatus of claim **14** wherein said manual switch is incorporated in said handle.

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