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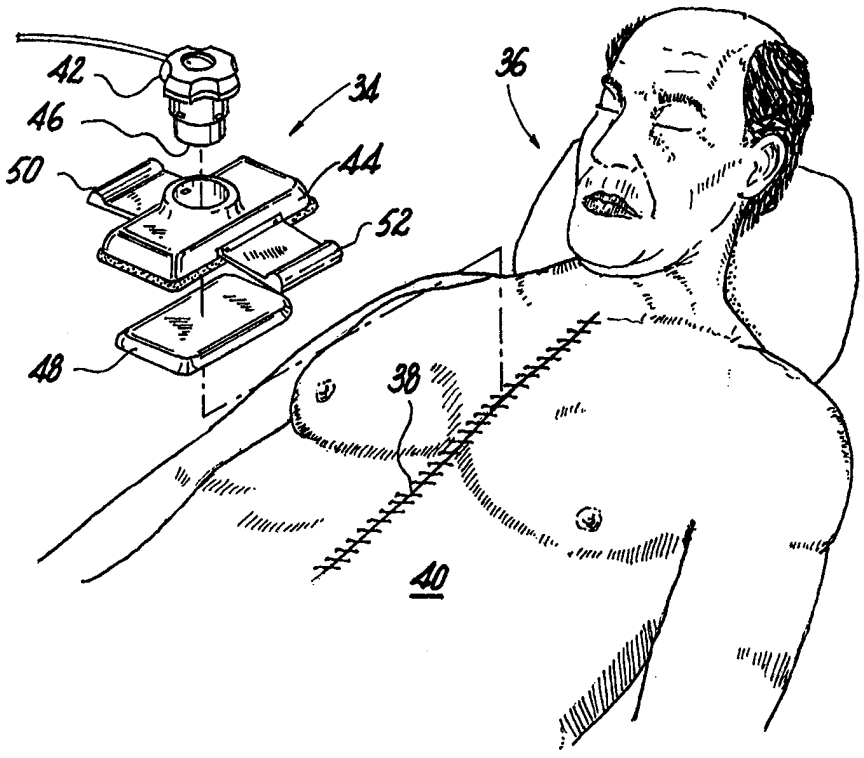
(54) Title: ULTRASOUND APPLICATION DEVICE FOR ACCELERATING STERNUM HEALING

(57) Abstract

Ultrasound application devices and methods of use for sternum healing of a patient includes the steps of positioning an ultrasound application device near a sternum having approximated portions, and applying ultrasound to the approximated portions for promoting healing. The ultrasound application device includes a transducer for generating the ultrasound, and a base for positioning the transducer near to the sternum. A diverging lens may be disposed netween the transducer and the sternum for acoustically diverging the ultrasound to flood the sternum with ultrasound. A plurality of transducers may be included in a plurality of recesses of the base along a longitudinal length of the sternum for applying the ultrasound along the longitudinal length of the sternum. A ring may be included to be positioned and secured about the neck of the patient. The ring may be woven as and/or incorporated in a tie. A metal strip may be used which responds to signals from the transducer for generating the ultrasound applied to the sternum. The metal strip may be implanted within the patient substantially adjacent to the sternum. Also, the ultrasound application device may operate in conjunction with a mesh implanted in the patient subtantially adjacent to the sternum.



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# ULTRASOUND APPLICATION DEVICE FOR ACCELERATING STERNUM HEALING

## BACKGROUND INFORMATION

### 1. Technical Field

This disclosure relates to therapeutic medical applications of ultrasound, and in particular to a method for promoting healing of the sternum using therapeutic ultrasound.

### 2. Description of the Related Art

Referring to FIG. 1, the sternum 10 is a heavily vascularized tissue positioned in the chest 12 between the lateral sets of ribs 14, 16 forming the rib cage. Being composed of both bone and cartilage and heavily vascularized, the sternum 10 has unique characteristics with respect to the skeletal structure of humans.

During conventional open heart surgery, the sternum is typically cut, as shown in FIG. 2, by a saw or by an electrocautery device to separate and spread the rib cage open to expose the heart, as shown in FIG. 3. The cut 18 is

generally positioned longitudinally along the length of the sternum 10 for maintaining the conjunction of the portions 20, 22 of the sternum 10 with the respective sets of ribs 14, 16.

When the sternum is cut in such surgical procedures, the resultant bleeding from the sternum may be significant due to its heavy vascularization. Typically, the bleeding is stopped during the surgery by cautery procedures or by application of bone wax; i.e. wax or wax-like substances for sealing the cut and severed blood vessels.

After completion of the surgical procedure, the chest cavity is closed, which involves positioning and re-approximating the portions of the cut sternum together for subsequent healing, using, for example, stainless steel wires 24-28 and/or bands, as shown in FIG. 4, for affixing the sternum portions 20, 22 together and/or for constricting the patient's chest to force the sternum portions to be adjacent. For example, U.S. Patent Nos. 4,802,477 and

5,330,489 disclose sternum closure devices for retaining split portions of human tissue such as the sternum in adjacent contacting relation to promote healing. Other devices or structure may be used to secure the sternum portions together during healing; for example, U.S. Patent No. 5,163,598 describes a sternum stapling apparatus for stapling the sternum portions together with a bone staple.

U.S. Patent No. 5,139,498 describes a device consisting of a plate having two flat longitudinal parallel anchoring members with through-holes for threading wire to hold the sternum portions together. U.S. Patent No. 4,792,336 describes a surgical repair device composed of absorbable material which is braided and used for securing tissue together. U.S. Patent Nos. 4,792,336 and 5,139,498 are incorporated herein by reference.

Such devices described above may be disposed adjacent to the approximated sternum portions and internally located after the patient's chest is closed and sutured. Such devices may be permanent or may be removed at a later

date after the sternum healing has been sufficiently effected.

Post-operative complications to the union of the sternum portions may be caused due to the cautery or bone wax which, in stopping the bleeding during the surgery, prevent proper healing after the surgery. Other causes of post-operative complications of the cut sternum include ventilation of the chest cavity; i.e. breathing. Due to the position of the sternum between the ribs and over the chest, breathing causes stress and strain on the sternum portions, preventing proper healing.

In addition, as the muscles of the chest are connected to other muscles such as those to the abdomen, upper limbs, and head, muscular movement also may contribute stress and strain on the sternum portions during healing.

Furthermore, known devices such as wires and bands as well as plates and muscle clamps have been used to secure the sternum portions together. The use of these devices have met with some success to promote healing of the

sternum. However, such devices have been found to loosen, such as wire 26, and even migrate, such as wire 28, thus allowing the sternum portions 20, 22 to separate, as illustrated in FIG. 4.

Accordingly, the incidence of dehiscence of the sternum; i.e. the failure of the sternum to heal, which results or causes relatively massive infection to the sternum and surrounding region, is of significant concern. In turn, such infections further reduce the healing of the sternum by reducing the ability of the sternum portions to join and fuse to each other during proper healing.

Further, due to movement of the sternum portions 20, 22 caused by muscular activity and breathing, as well as strain to the spinal joints and intercostal joints 30, 32, shown in FIG. 4, from the separation of the ribs, in addition to nerve exposure due to the surgery, serious pain may occur from even regular activity and movement.

It is generally known that complications from such heart surgery and post-operative effects, such as dehiscence

of the sternum, may occur at a frequency of about .5% to about 7.0% of patients undergoing such heart surgery. Of such patients experiencing complications, mortality occurs in about 14% of such cases.

Post-operative complications associated with the failure of the sternum to heal properly are generally most common among the elderly, diabetics, obese people, smokers, people who have used steroids, patients having chemotherapy or radiation therapy, and patients who have lung disease or lung surgery. In particular, for the elderly who may more often require heart, lung, or other chest surgery, complications in sternum healing generally have an increased likelihood since the sternum is about 1 cm to about 1.5 cm. thick, but such thickness reduces in relation to one's age.

Although known devices are indeed effective for promoting healing of a cut sternum, the frequency of complications and mortality is still considerable. In addition, such devices are limited in effectiveness, as the sternum portions may separate despite such devices, or in

fact because such devices may not operate properly. For example, a bone staple holding the sternum portions together may loosen due to the natural and regular breathing and other muscular movement of the sternum and ribs. Further, such known devices for sternum healing may require replacement or adjustment to compensate for any maladjustment or ineffectiveness.

Accordingly, a need exists for promoting effective sternum healing; for example, a device and/or a method which heals the sternum, individually or in conjunction with such devices known in the art, including wires and bands.

A need also exists for a device and/or a method for promoting sternum healing which is conveniently applied, and which may be applied with less expense. Such a device and/or method may also be non-invasive, to allow recovering patients to avoid additional surgery to replace or adjust known sternum healing devices and methods.

The application of ultrasound to accelerate the healing of tissue and bone has been described, for example,

in commonly assigned U.S. Patent No. 4,530,360 to Duarte and U.S. Patent No. 5,520,612 to Winder et al. For example, as described by the Duarte patent, ultrasound may be applied to bone, with ultrasonic frequencies of about 1.5 MHz with pulse widths which vary between 10 μs and 2,000 μs, and with pulse repetition rates which vary between 100 and 1,000 Hz. Such applications of ultrasound have been shown to accelerate the normal healing process of bone fractures, pseudoarthroses, and the like. Heretofore, ultrasound has not been applied to promote the post-operative healing of the sternum.

SUMMARY

It is recognized herein that the application of therapeutic ultrasound to the sternum accelerates the healing of the sternum, and so minimizes dehiscence and other complications of surgery involving cutting of the sternum.

A method for sternum healing of a patient is disclosed which includes the steps of positioning an

ultrasound application device substantially adjacent to a sternum having approximated portions; and applying ultrasound to the approximated portions of the sternum for promoting healing of the approximated portions together.

The ultrasound application device includes a transducer for generating ultrasound for application to approximated portions of the sternum for promoting healing of the approximated portions together; and a base for positioning the transducer substantially adjacent to the sternum. In one embodiment, an ultrasound diverging lens is included which is disposed between the transducer and the sternum for acoustically diverging the ultrasound to flood the approximated portions of the sternum for healing thereof.

In another embodiment, a plurality of transducers are included which are positioned in a plurality of recesses of the base along a longitudinal length of the approximated portions of the sternum and substantially adjacent to the skin over the sternum for applying the ultrasound along the

longitudinal length of the approximated portions of the sternum.

A ring may be included which is connected to the base and adapted to be positioned and secured about the neck of the patient. The ring may be woven and/or incorporated in a tie.

In another embodiment, a metal strip is included which is operatively connected to the transducer, and which responds to signals from the transducer for generating the ultrasound and for applying the ultrasound to the sternum. The metal strip may be implanted within the patient substantially adjacent to the sternum.

In another embodiment, the ultrasound application device may operate in conjunction with a mesh implanted in the patient substantially adjacent to the sternum, in which the mesh responds to ultrasound applied thereto to promote healing of the sternum.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the disclosed sternum healing apparatus and method will become more readily apparent and may be better understood by referring to the following detailed description of illustrative embodiments of the present invention, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a diagram of the sternum and chest cavity;

FIG. 2 is a diagram of the sternum having a cut therethrough;

FIG. 3 is a diagram of the cut sternum and associated ribs being separated;

FIG. 4 is a diagram of a cut sternum having portions thereof approximated using wires;

FIGS. 5-6 are diagrams of one embodiment of the application of ultrasound to the cut sternum using a diverging lens;

FIGS. 7-8 are diagrams of an alternative embodiment of the application of ultrasound in FIGS. 5-6 using a plurality of ultrasound transducers;

FIGS. 9-10 are diagrams of another embodiment of an ultrasound application device using a set of transducers which may be secured about the neck of the patient;

FIG. 11 is a diagram of a sterile pad for use with ultrasound application devices to promote sternum healing;

FIG. 12 is a diagram of the use of a mesh in conjunction with an ultrasound application device for applying ultrasound to promote sternum healing;

FIG. 13 is a diagram of a metal plate including an ultrasound transducer for applying ultrasound;

FIGS. 14-15 are diagrams of alternative embodiments of the use of the metal plate of FIG. 13; and

FIG. 16 is a flowchart of a method for healing the sternum.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings, with like reference numerals identifying similar or identical elements, as shown in FIGS. 3-15, the present disclosure describes various apparatus and methods for applying ultrasound to promote healing of a cut sternum. The term "cut sternum" is herein defined to be a sternum which has been apportioned into separable portions by a saw, by an electrocautery device, and/or by other devices and methods known in the art. In this disclosure, for illustrative purposes, the sternum 10 is shown, for example, in FIG. 1, as having been cut into two portions 20, 22 of substantially equal size, and may be referred to as "sternum halves". However, it is to be understood that the relative sizes of the portions 20, 22 of the sternum 10 may be of any proportion.

As shown in an illustrative embodiment in FIGS. 5-6, the disclosed apparatus and method includes an ultrasound application device 34 for use with a patient 36 after surgery in which the patient's sternum 10 has been cut and

then the portions 20, 22 thereof are approximated. The ultrasound application device 34 is positioned substantially adjacent to the skin 38 of the closed chest cavity 40 in which the cut portions 20, 22 of the sternum 10 are approximated as shown, for example, in FIG. 4. The ultrasound application device 34 includes a transducer 42 operatively connected, for example, by a wire to a power source for generating ultrasound. The transducer 42 is disposed in a transducer support housing 44, and has a transmission end 46 which is positioned substantially adjacent to an ultrasonic diverging lens 48, described in detail below, which may be an ultrasound conductive pad, such as a gel pad.

The transducer 42 includes or is operatively connected to ultrasound generation circuitry known in the art, such as the transducer and acoustic system described in U.S. Patent No. 5,520,612 to Winder et al., which is incorporated herein by reference. In an illustrative embodiment, the transducer 42 is connected to an ultrahigh-

frequency generator, a low-frequency signal generator, and a modulator connected to these generators for supplying pulse-modulated ultrahigh-frequency signals to the transducer 42.

In general, an ultrasound carrier frequency between 250 kHz and 10 MHz coupled with a relatively low-frequency modulating signal (e.g. 5 Hz to 10 kHz) and low intensity acoustic signal (e.g. less than 100 milliwatts/$cm^2$) aids, and will be effective for therapeutic treatment.

The transducer support housing 44 may be configured to be stable when positioned on the closed chest cavity 40 of the patient 36, such as a reclining patient, during a session of ultrasonic therapy. In an illustrative embodiment, the transducer support housing 44 includes or is attached to weighted panels 50, 52 for weighing down the ultrasonic application device 34 during the ultrasonic therapy. Alternatively, the transducer support housing 44 may include or be attached to a band or other apparatus for

securing the ultrasonic application device 34 substantially adjacent to the closed chest cavity 40.

As shown in FIG. 6, the ultrasonic application device 34 is positioned substantially adjacent to the skin 38 above the sternum 10 for healing thereof, in which the sternum 10 has portions approximated by wires 24, 25 or, alternatively, other mechanisms for approximating the sternum portions. In the illustrative embodiment, the transducer support housing 44 may include a recess for positioning the ultrasonic diverging lens 48 therein such that ultrasonic waves 54 from the transmission end 46 of the transducer 42 are conveyed through the skin 38 to the sternum 10 to accelerate the healing thereof.

In the illustrative embodiment, the ultrasonic diverging lens 48 may be a pad, bladder, or other structure which is substantially conductive of ultrasound and which is adapted to acoustically diverge such ultrasonic waves 54 from the transmission end 46 of the transducer 42. For example, the ultrasonic diverging lens 48 may be an enclosed

structure for retaining ultrasound conductive gel 56 which transmits ultrasound therethrough with relatively low dissipation. In the illustrative embodiment shown in FIG. 6, a top surface 58 of the ultrasonic diverging lens 48 may include a detent 60, which may be curved or indented at an angle, to form a pocket 62 for air or other substances between the detent 60 and the transmission end 46. The curved or indented shape of the detent 60 and the associated shape of the pocket 62, and optionally the conductive properties of the air or substances therein, acts as an ultrasonic lens which spreads or diverges the ultrasonic waves 54 over a greater range than the range due to typical dissipation of ultrasound through gel pads.

Such diverging ultrasound may thus be applied to a substantial portion of the cut sternum 10 during a single therapy session. In addition, the ultrasonic diverging lens 48 may be positioned over the closed chest cavity 40 and configured to apply the ultrasound substantially directly to

the approximate center of the cut sternum 10 to promote healing thereof.

The application of ultrasound to promote healing of tissue and bone has been described, for example, in commonly assigned U.S. Patent No. 4,530,360 to Duarte and U.S. Patent No. 5,520,612 to Winder et al., with each of these patents being incorporated herein by reference.

The healing in the central region of the cut sternum may be more beneficial in promoting the overall healing of the sternum than healing of the cut sternum at either end thereof; for example, the central region of the sternum may experience the greatest stress and shear forces due to breathing by the patient. Accordingly, the healing of the central region may be more difficult and so of more importance in receiving the therapeutic ultrasound.

Since the sternum 10 lies along the length of the upper chest cavity and is relatively close to the surface of the skin of the patient, flooding the sternum 10 with ultrasonic waves 54 provides sufficient healing of the

sternum 10, and high precision and focussed pinpointing of the ultrasound to a specific location is not required. Accordingly, the intensity of the ultrasound applied is not required to be high, and a shallow penetration of the ultrasound provides effective healing.

In addition, the shallowness of the penetration and the absorption of the ultrasound by the sternum 10 effectively limits the ultrasound from penetrating the underlying heart tissue. In addition, the frequency of the ultrasound may be controlled in a manner known in the art to adjust the shallowness of the penetration of the ultrasound.

The ultrasound may also be applied using the ultrasound application device 34 of FIGS. 5-6 in a manner known in the art; for example, the use of a sweeping carrier frequency of the ultrasound, as described in U.S. Patent No. 5,520,612 may also be used. In addition, phased arrays of transducers and/or sequential irradiation of the sternum 10 may also effectively promote the healing of the sternum 10.

Since the portions of the sternum 10 are approximated by wires 24, 25, the normal healing of the sternum 10 by such approximation occurs. In applying such ultrasound, the ultrasound application device 34 accelerates the healing of the sternum 10, and so complements the use of the wires 24, 25 or other mechanisms for approximating the portions of the sternum 10.

FIGS. 7-8 are diagrams of an alternative embodiment of the application of ultrasound in FIGS. 5-6 for sternum healing. As shown in FIGS. 7-8, the ultrasound application device 64 uses a plurality of ultrasound transducers 66 respectively disposed in corresponding recesses 68 of a transducer support housing 70 such that respective transmission ends 72 of the plurality of transducers may be substantially adjacent to an ultrasonic gel pad 74. The ultrasonic gel pad 74 is positioned substantially adjacent to the skin 38 of the closed chest cavity 40 in which the cut portions 20, 22 of the sternum 10 are approximated by wires 24, 25, as shown, for example, in

FIG. 4, so that ultrasonic waves 76 from the plurality of transducers 66 may be directed to the sternum 10 for accelerating the healing thereof.

As described above with reference to FIGS. 5-6, the transducer support housing 70 of FIGS. 7-8 may include or is attached to weighted panels 78, 80 or other devices as described above for positioning the transducer support housing 70 during ultrasonic therapy.

Referring to FIG. 8, in an illustrative embodiment, the plurality of transducers 66 and corresponding transmission ends 72 are oriented to be substantially parallel for transmitting a substantially uniform set of ultrasonic waves 76 through the skin 38 to the sternum 10 for promoting substantially uniform healing along the longitudinal length of the sternum 10.

In the illustrative embodiments shown in FIGS. 5-8, the ultrasound application devices 34, 64 of FIGS. 5-8, respectively, are used in conjunction with ultrasonic conductive gel pads 48, 74, respectively. In alternative

embodiments, it is understood that the ultrasound application devices 34, 64 may also be used with an ultrasound conductive gel spread over the skin 38 substantially adjacent to the sternum 10 for facilitating transmission of the ultrasonic waves through the skin 38 to the sternum 10 for accelerating the healing thereof.

FIGS. 9-10 are diagrams of another embodiment of an ultrasound application device 82 using a set of transducers 84 disposed on a base 86 which is attached to a ring 88 or other structure for securing the ultrasound application device 82 about the neck of the patient 36. In one embodiment, the ring 88 may be an open ring with ends 90, 92 capable of being attached and secured using a clasp or other securing structures, such as hook and link devices using "VELCRO". In other embodiments, the ultrasonic application device 82 may be incorporated into a necktie or other woven material for positioning the ultrasonic application device 82 substantially adjacent to the skin 38

for promoting healing of the sternum 10 during therapy sessions or during regular activities by the patient 36.

The ultrasound application device 82 may also include a weight 94 for minimizing movement of the base 86 due to movement or shifting of the patient 36 during the application of the ultrasound from the set of transducers 84. In the illustrative embodiment shown in FIGS. 9-10, the ultrasound application device 82 may be used in conjunction with an ultrasound conductive gel 96 spread over the skin 38 substantially adjacent to the sternum 10 for facilitating transmission of the ultrasonic waves 98 through the skin 38 to the sternum 10 for healing thereof. It is understood that, in other embodiments, the ultrasound application device 82 may include or may be used in conjunction with ultrasound conductive gel pads, as described above for FIGS. 5-8.

As shown in FIG. 11, the aforesaid ultrasound application devices of FIGS. 5-10 may be used with a sterile sheet 100 or pad in conjunction with ultrasound conductive

gel pads 102, in which the sterile sheet 100 is positioned substantially adjacent to the skin 38. Sterile sheets 100, such as sheets commercially available from ECHO, are placed onto the healing cut in the skin 38 to prevent infection thereof. The sterile sheets 100 may also reduce friction of the skin 38 or discomfort to the patient 36 as the gel pads 102 and ultrasound application devices (not shown in FIG. 11) are positioned on the sterile sheet 100 substantially adjacent to the skin 38 during the ultrasound therapy sessions.

FIG. 12 is a diagram of the use of a mesh 104 in conjunction with an ultrasound application device 106 for applying ultrasound to promote sternum healing. As shown in FIG. 12, the ultrasound application device 106 may be used in conjunction with an ultrasound conductive gel pad (not shown in FIG. 12) for applying ultrasonic waves 108 through the skin 38 and muscle 110 substantially adjacent to the sternum for accelerating the healing thereof. The ultrasound application device 106 and gel pad used therewith

may be any of the embodiments described above for FIGS. 5-10.

The mesh 104 is composed of a woven material which is conductive of ultrasound. During surgery, the mesh 104 is placed in the body of the patient 36 substantially adjacent to the sternum 10 such that, as the ultrasonic waves 108 is transmitted through the skin 38 and the muscle 110, the mesh 104 promotes the application of the ultrasonic waves 108 to the sternum 10 for healing thereof. The mesh 104 may be absorbable with an absorption rate such that, after the sternum 10 has substantially been healed, the mesh 104 is left in the body of the patient 36 to be absorbed. Alternatively, the mesh 104 may be removed from the patient 36 after sufficient healing of the sternum 10.

In another embodiment, the sternum 10 may be healed by ultrasound using a metal strip or plate. As shown in FIG. 13, the metal strip 112 including a transducer 114 for vibrating the metal strip 112 to generate ultrasound. In one embodiment, shown in FIG. 14, the metal strip 112 may

be positioned substantially adjacent to the skin 38 outside of the body of the patient 36 such that the vibrations 116 of the metal strip 112 generate ultrasonic waves 118 which is transmitted through the skin 38 and muscle 110 to heal the sternum 10. An ultrasound conductive gel pad 120 and/or a sterile sheet may also be used in conjunction with the metal strip 112.

By exciting the metal strip 112 at one end using the transducer 114, harmonic changes are induced in the metal strip 112 such that loops and nodes of ultrasound move along the longitudinal length of the metal strip 112. The depth of the penetration of the ultrasonic waves 118 may be controlled in a matter known in the art, such as by using frequency tracking and gain control using pulse echo techniques as well as feedback control techniques.

Since the metal strip 112 is disposed outside the body of the patient 36, the metal strip 112 may be disposable, such as after a single use, or re-usable. In addition, the metal strip 112 may be removably attached to

the transducer 114 such that the metal strip 112 is disposable, while the transducer 114 may be re-used.

In an alternative embodiment, the metal strip 112 may be implanted during surgery to be substantially adjacent to and running along the longitudinal length of the sternum 10 under the skin 38 and muscle 110. In another embodiment, the metal strip 112 may be secured to the sternum 10 by the wires 24, 25. As the metal strip 112 is implanted, the implanted metal strip 112 does not require the use of conductive gel pads. Such an implanted metal strip 112 may be used to provide substantially continuous amounts of ultrasonic waves 118 to the sternum 10 for accelerated healing thereof. Accordingly, therapy sessions in which the patient is reclining and relatively immobile during the application of the ultrasound may be reduced or even eliminated.

It is to be understood that the vibrations 116 shown in FIGS. 14-15 are exaggerated for illustrative purposes.

As described above, the sternum 10 may be healed by the method as shown in FIG. 16, including the steps of providing an ultrasound application device in step 122 for use with a patient with a sternum having approximated portions after surgery, positioning the ultrasound application device substantially adjacent to the sternum 10 in step 124, and applying ultrasound to the approximated portions of the sternum in step 126 for promoting healing of the approximated portions together to heal the sternum.

While the disclosed ultrasound application apparatus and method for sternum healing have been particularly shown and described with reference to the preferred embodiments, it is understood by those skilled in the art that various modifications in form and detail may be made therein without departing from the scope and spirit of the invention. Accordingly, modifications such as those suggested above, but not limited thereto, are to be considered within the scope of the invention.

WHAT IS CLAIMED IS:

1. A method for accelerating sternum healing comprising the steps of:

positioning an ultrasound application device substantially adjacent to approximated sternum portions; and

applying ultrasound to the approximated portions of the sternum for promoting healing of the approximated portions together.

2. The method of claim 1 further comprising the step of:

positioning an ultrasound conductive material substantially adjacent to the sternum and between the sternum and the ultrasound application device; and

wherein the step of applying the ultrasound includes the step of transmitting the ultrasound through the ultrasound conductive material.

3. The method of claim 2 wherein the ultrasound application device includes a transducer and the ultrasound conductive material includes an ultrasound diverging lens;

wherein the step of positioning the ultrasound application device includes the steps of positioning the transducer substantially adjacent to the diverging lens; and

wherein the step of applying the ultrasound includes the steps of:

generating ultrasound using the transducer; and

acoustically diverging the ultrasound using the diverging lens to flood the approximated portions of the sternum.

4. The method of claim 2 wherein the ultrasound conductive material includes an ultrasound gel pad.

5. The method of claim 2 wherein the ultrasound conductive material includes a coating of ultrasound conductive gel.

6. The method of claim 1 wherein the step of positioning the ultrasound application device includes the step of positioning a plurality of transducers of the ultrasound application device along a longitudinal length of the approximated portions of the sternum and substantially adjacent to the skin over the sternum; and

wherein the step of applying the ultrasound includes the steps of:

generating ultrasound using the plurality of transducers; and

applying the ultrasound along the longitudinal length of the approximated portions of the sternum.

7. The method of claim 6 wherein the step of positioning the ultrasound application device includes the step of positioning the plurality of transducers disposed in a base having a ring adapted to be positioned and secured about the neck of a patient.

8. The method of claim 1 further comprising the step of positioning a sterile sheet between the transducer and the sternum.

9. The method of claim 1 wherein the step of applying the ultrasound includes the step of:

applying the ultrasound to a mesh implanted in a patient substantially adjacent to the sternum, wherein the mesh having ultrasound applied thereto promotes healing of the sternum.

10. The method of claim 1 wherein the ultrasound application device includes a metal strip having a

transducer for generating the ultrasound using the metal strip; and

wherein the step of applying the ultrasound includes the step of transmitting the ultrasound to the sternum.

11. The method of claim 10 wherein the metal strip is implanted within a patient substantially adjacent to the sternum.

12. An ultrasound application device for accelerating sternum healing comprising:

a transducer for generating ultrasound for application to approximated portions of the sternum for promoting healing of the approximated portions together; and

a base configured to be positionable adjacent a sternum portion of the body for positioning the transducer substantially adjacent to the sternum.

13. The ultrasound application device of claim 12 further comprising:

an ultrasound diverging lens disposed between the transducer and the sternum for acoustically diverging the ultrasound to flood the approximated portions of the sternum for healing thereof.

14. The ultrasound application device of claim 12 further comprising:

a plurality of transducers; and

the base includes a plurality of recesses for positioning the plurality of transducers along a longitudinal length of the approximated portions of the sternum and substantially adjacent to the skin over the sternum for applying the ultrasound along the longitudinal length of the approximated portions of the sternum.

15. The ultrasound application device of claim 14 further comprising:

a ring connected to the base and adapted to be positioned and secured about the neck of a patient.

16. The ultrasound application device of claim 12 wherein the base includes:

a metal strip operatively connected to the transducer, the metal strip being responsive to signals from the transducer for generating the ultrasound and for applying the ultrasound to the sternum.

17. The ultrasound application device of claim 16 wherein the metal strip is implanted within a patient substantially adjacent to the sternum.

18. An ultrasound application system for accelerating sternum healing, comprising:

a transducer for generating ultrasound for application to approximated portions of the sternum for promoting healing of the approximated portions together;

a base for positioning the transducer substantially adjacent to the sternum; and

a mesh for being implanted in a patient substantially adjacent to the sternum, wherein the mesh is responsive to the ultrasound applied thereto to promote healing of the sternum.

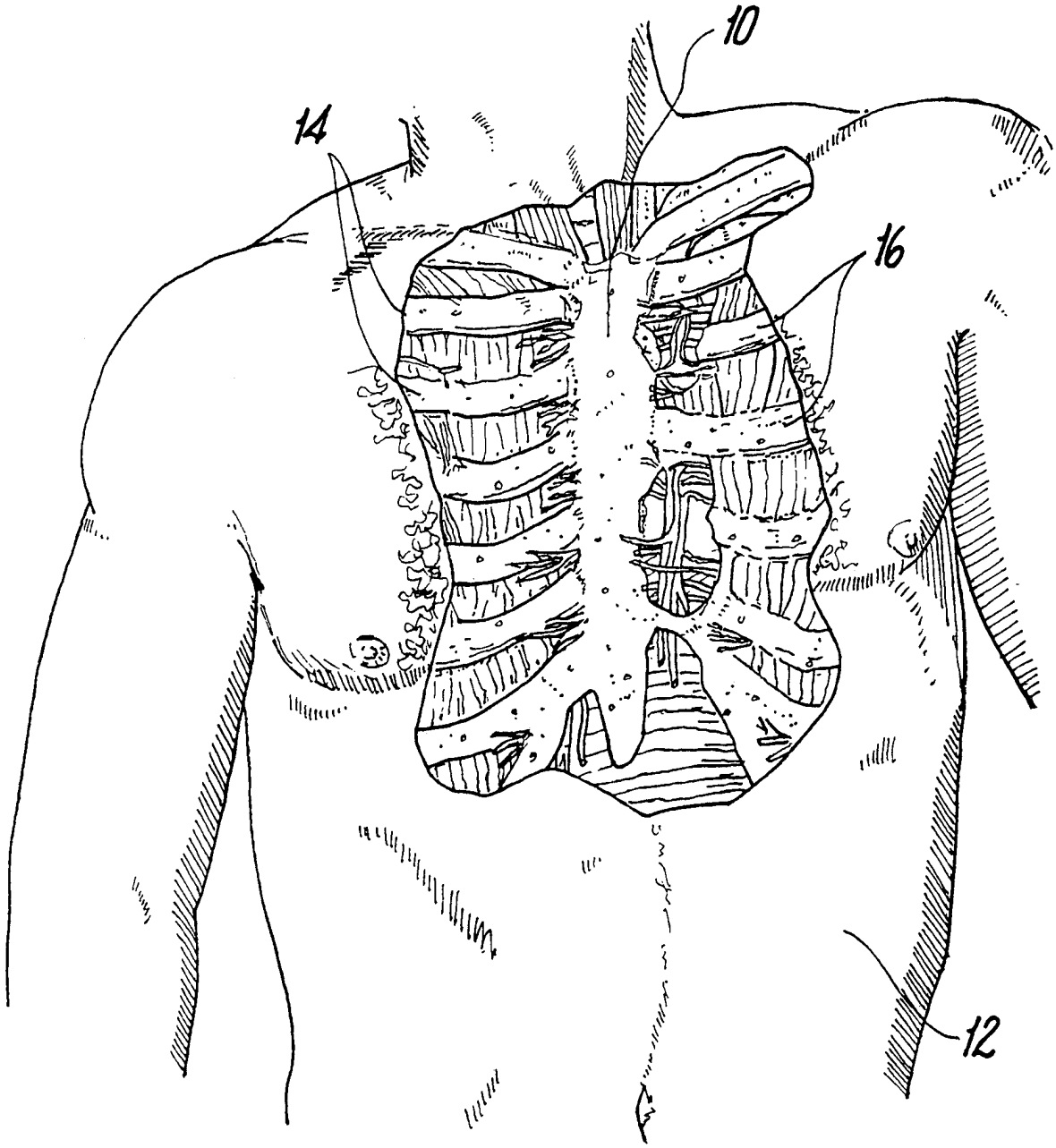



Fig. 1

**Fig. 2**
**(Prior Art)**

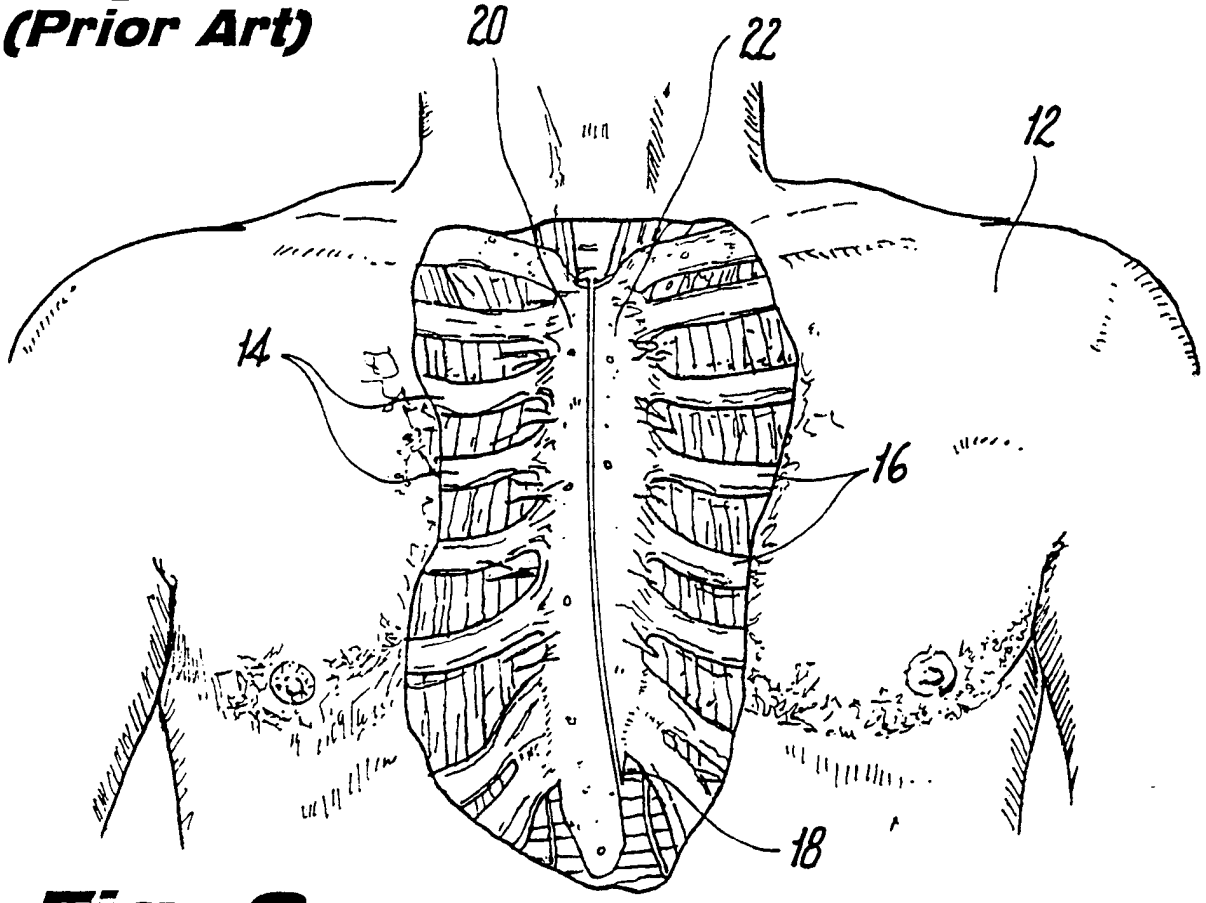
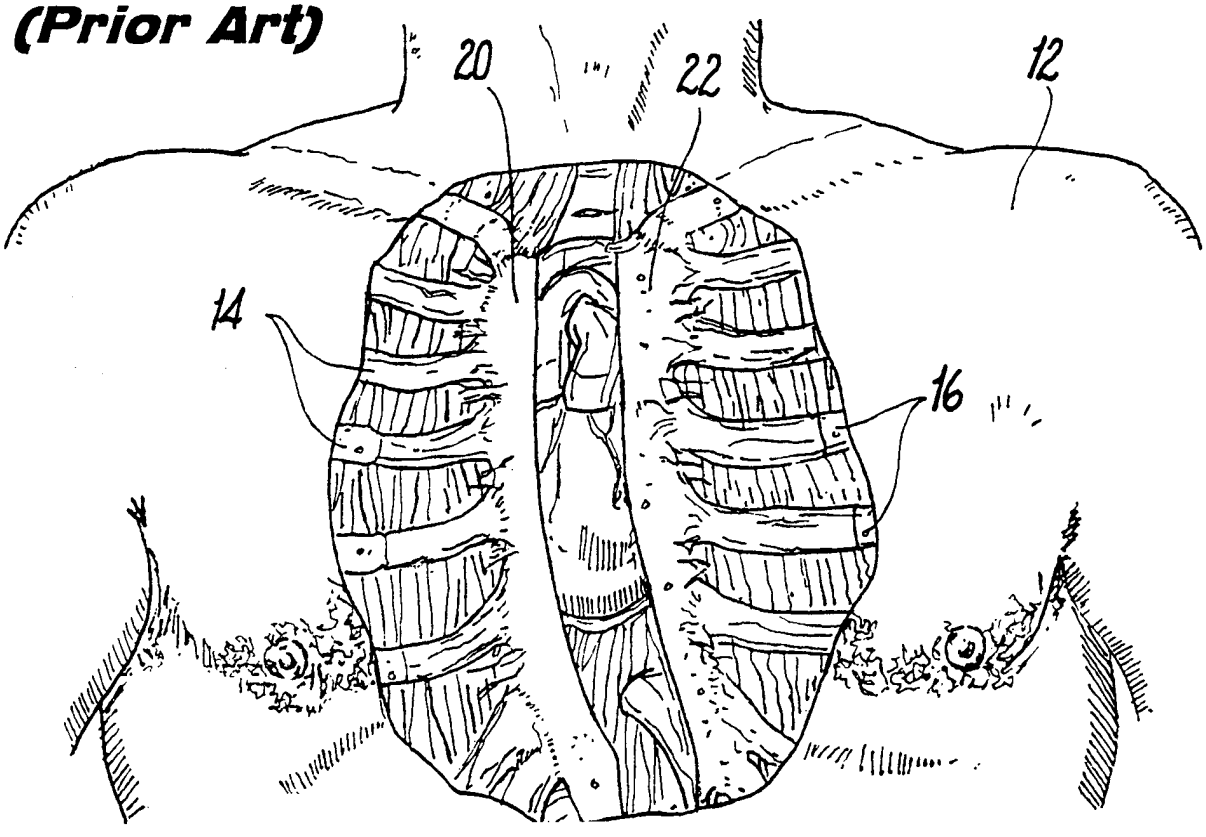



**Fig. 3**
**(Prior Art)**



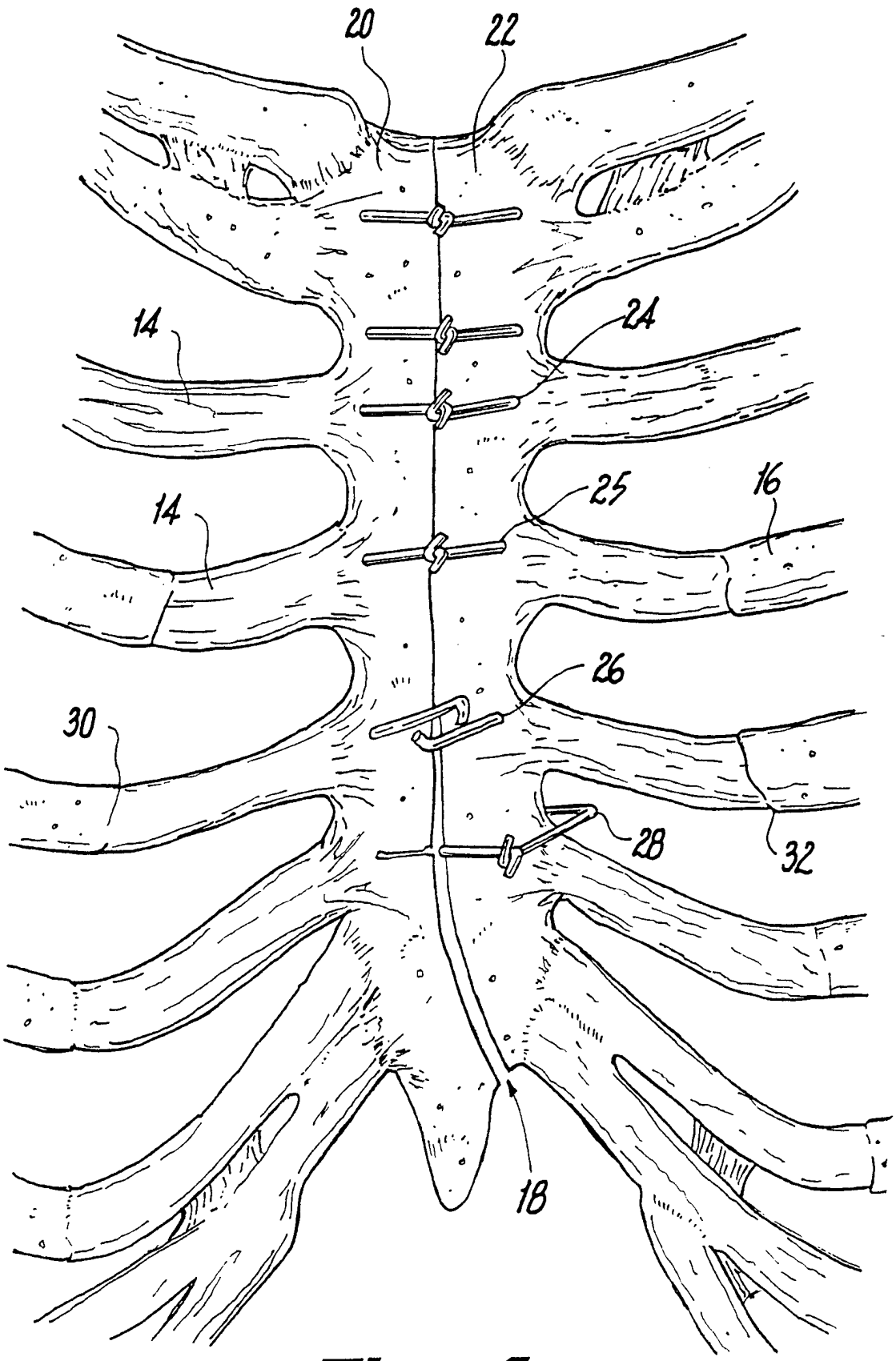



Fig. 4

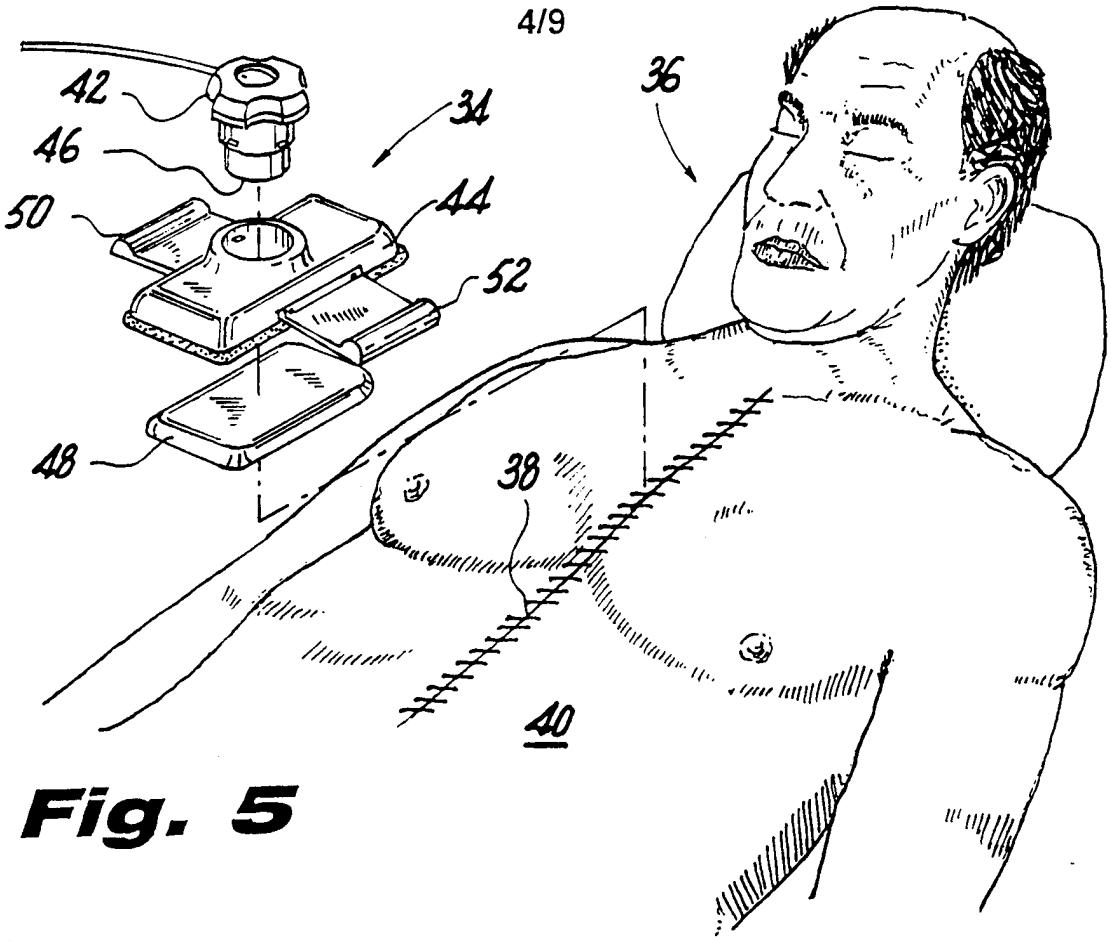



Fig. 5

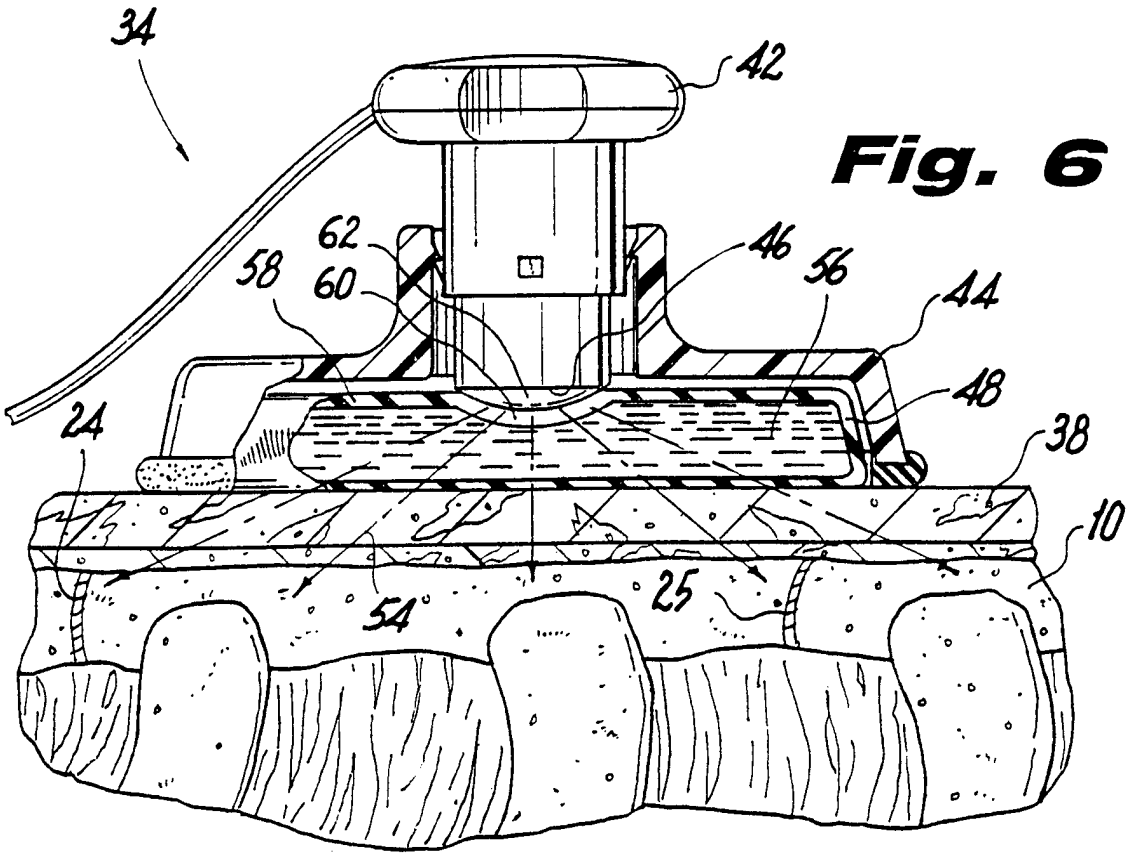



Fig. 6

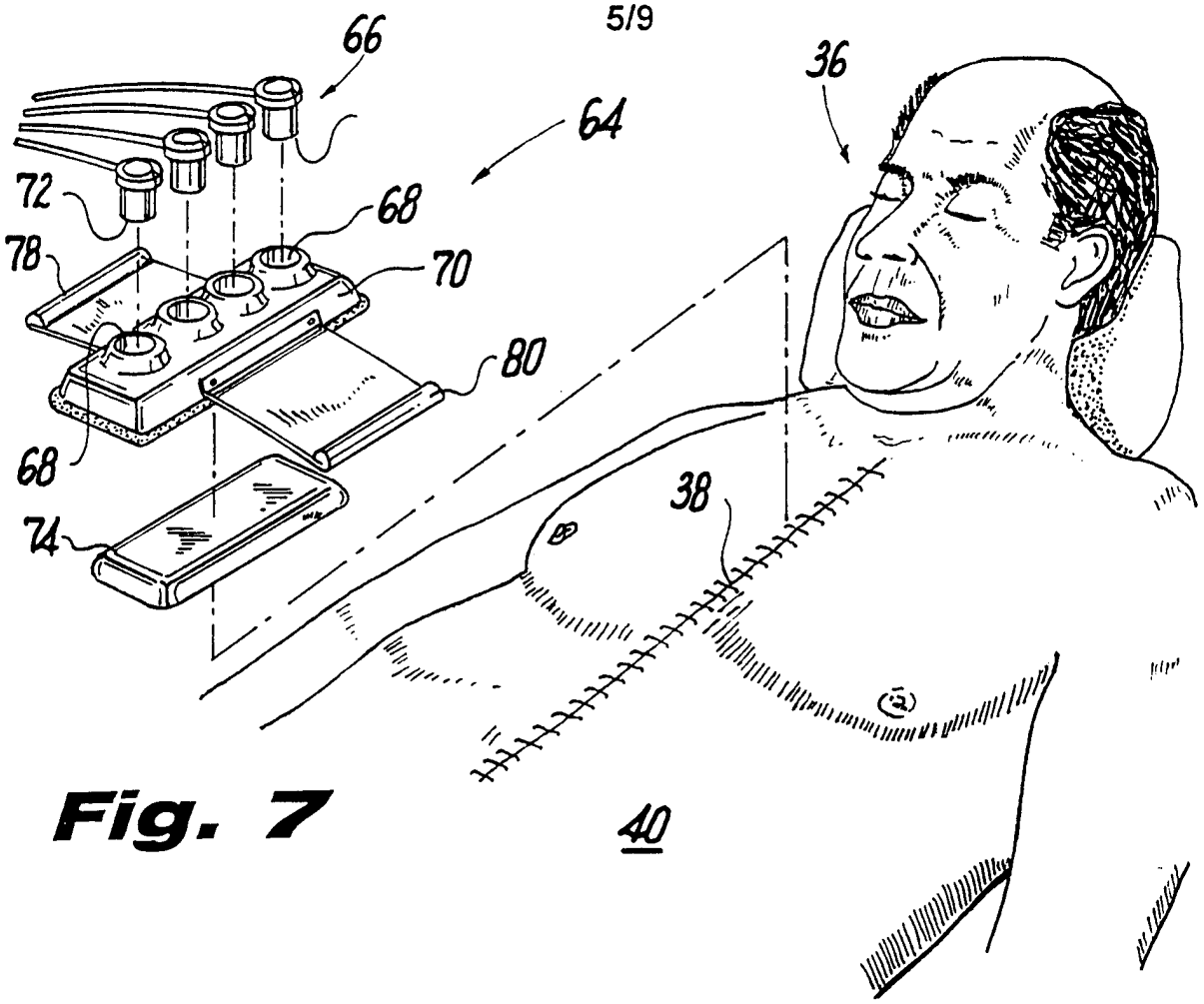



Fig. 7

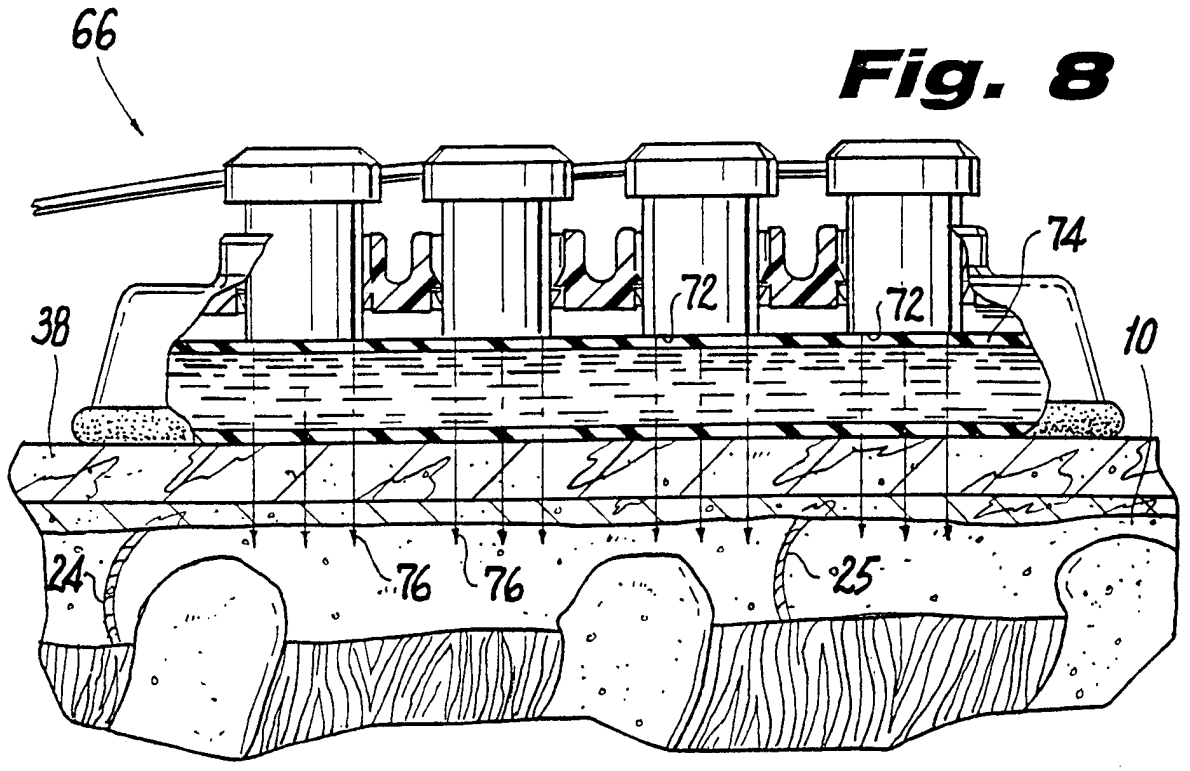



Fig. 8

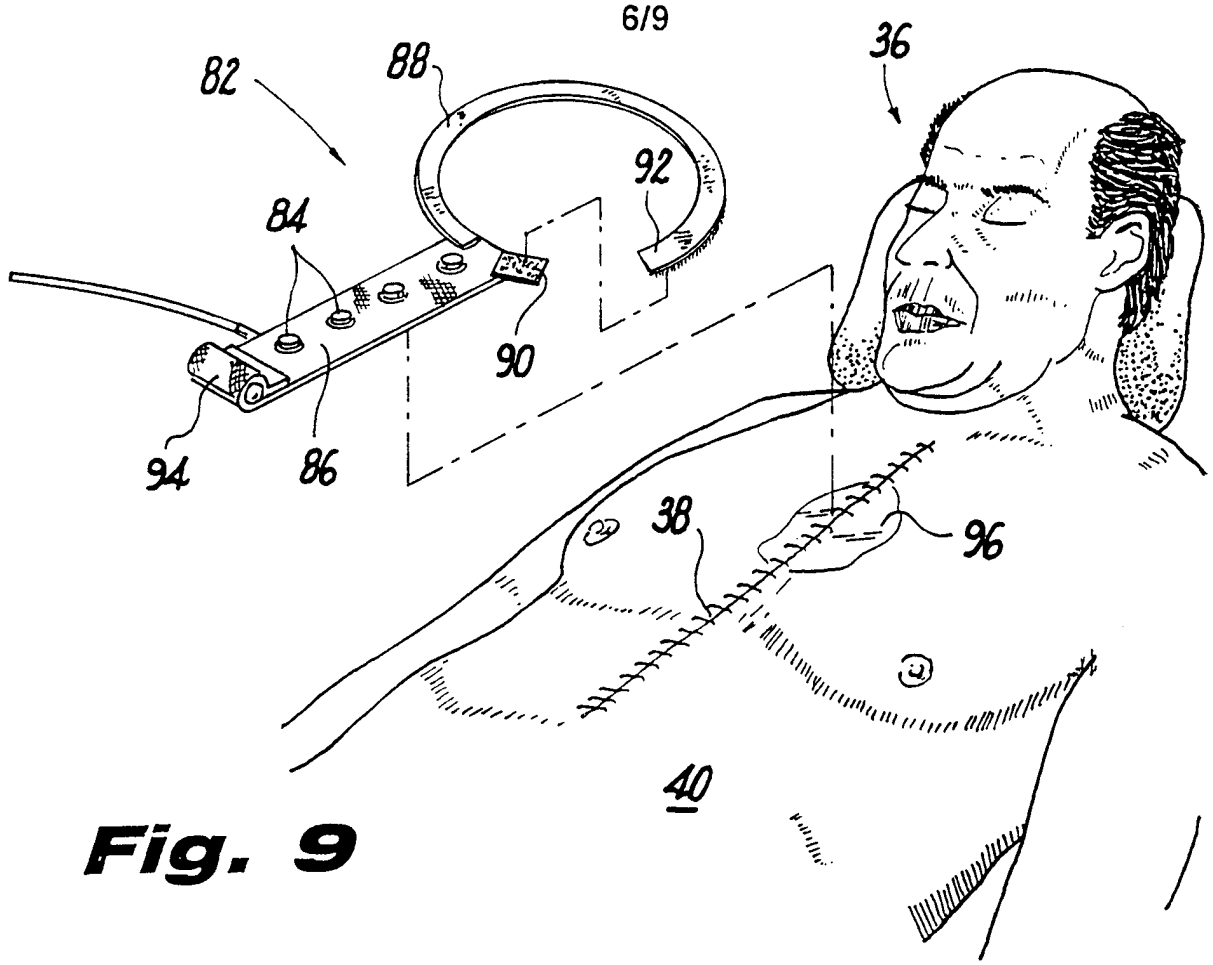



Fig. 9

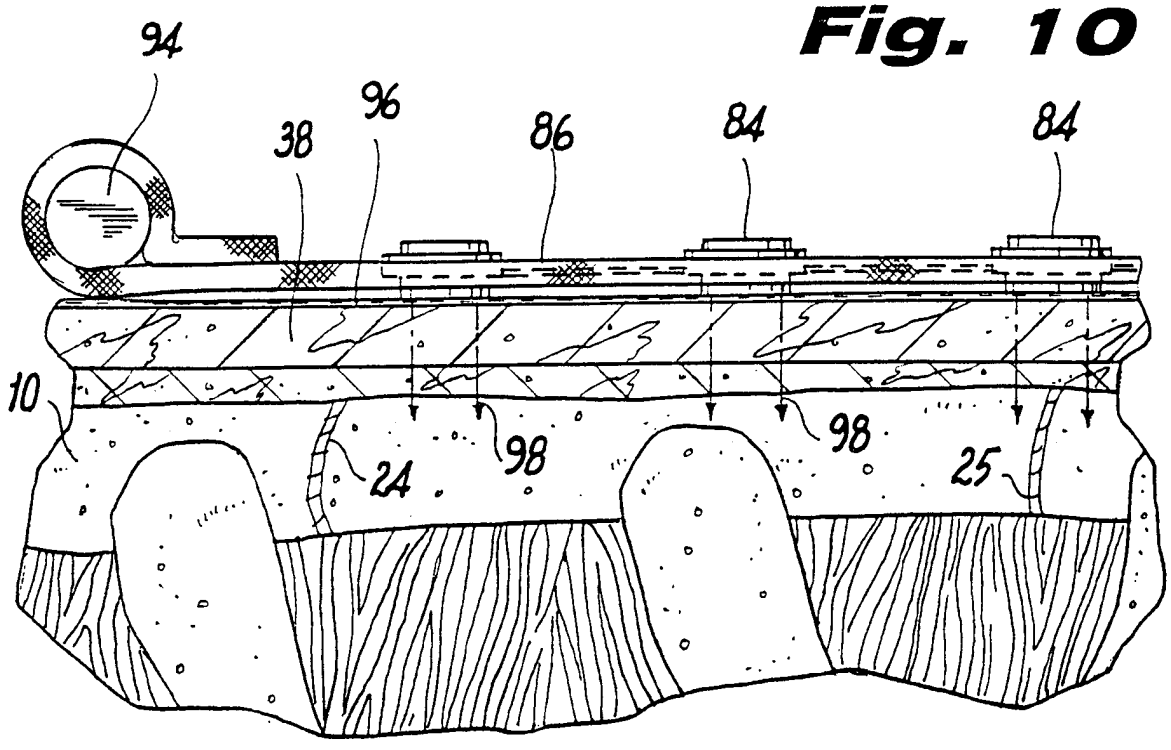



Fig. 10

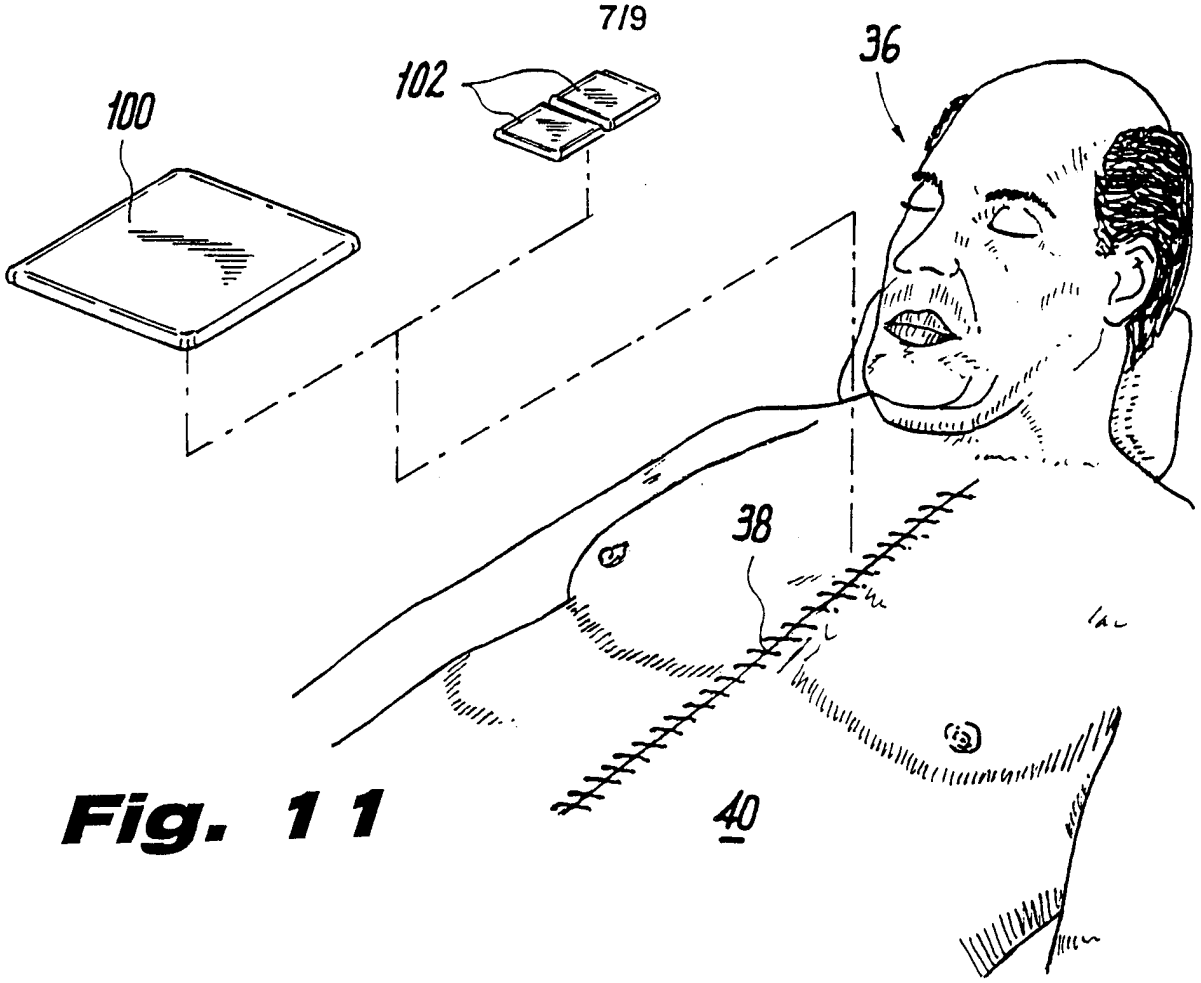



Fig. 11

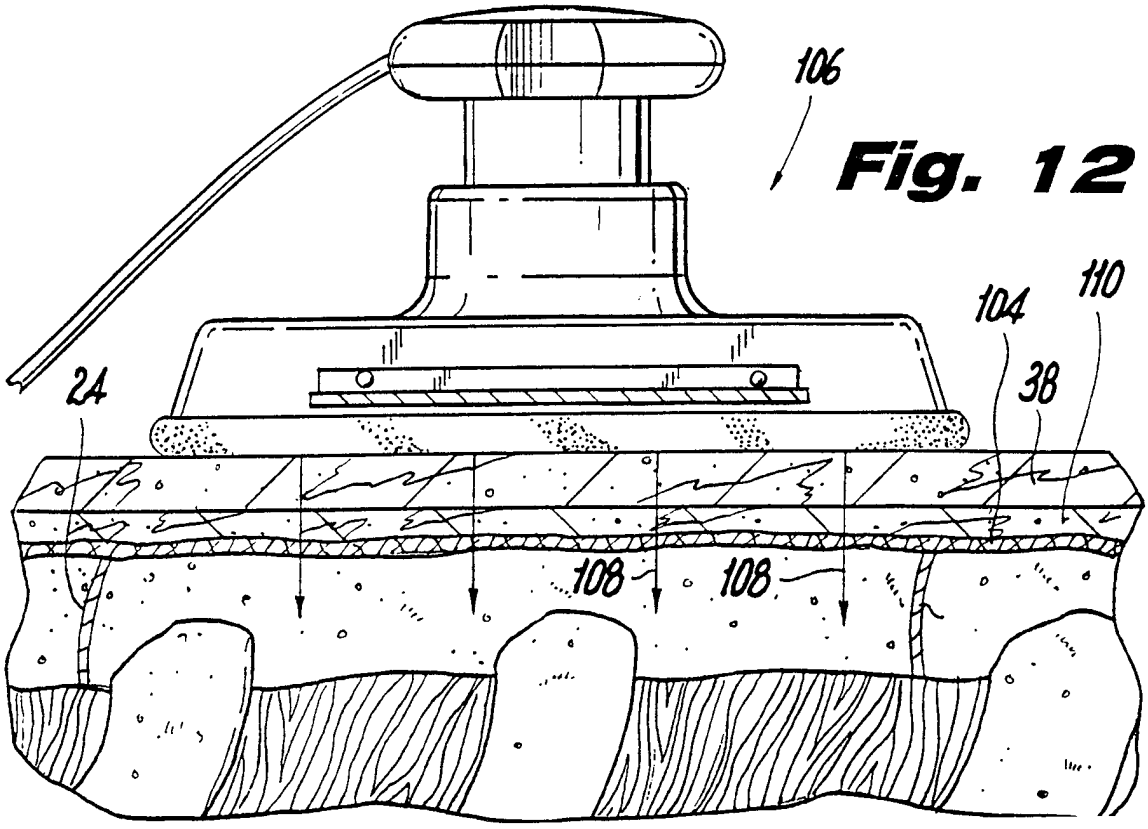



Fig. 12

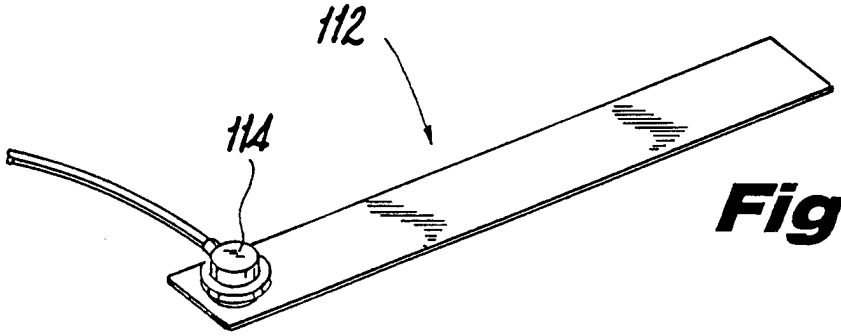



Fig. 13

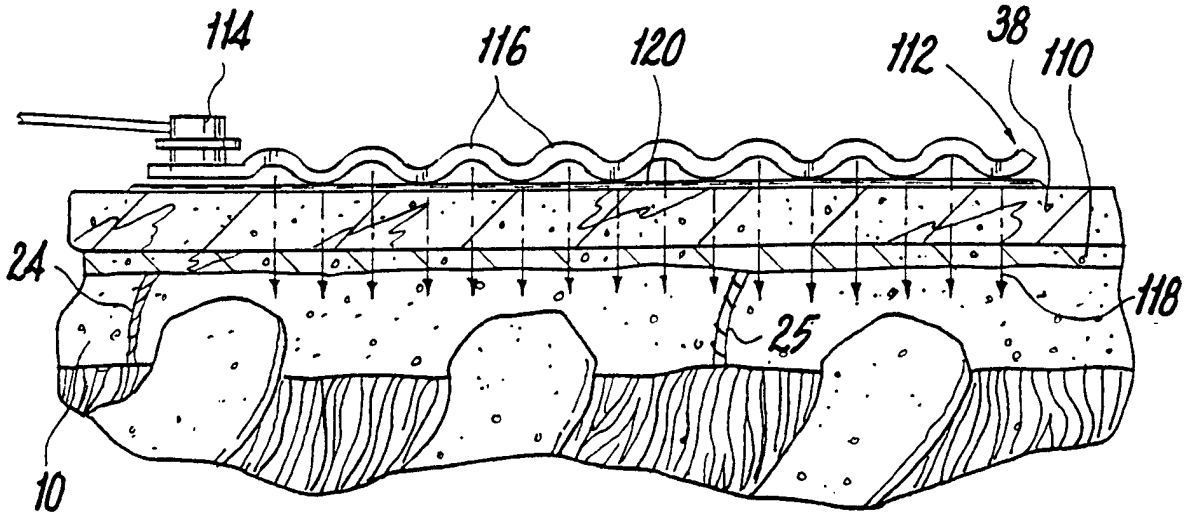



Fig. 14

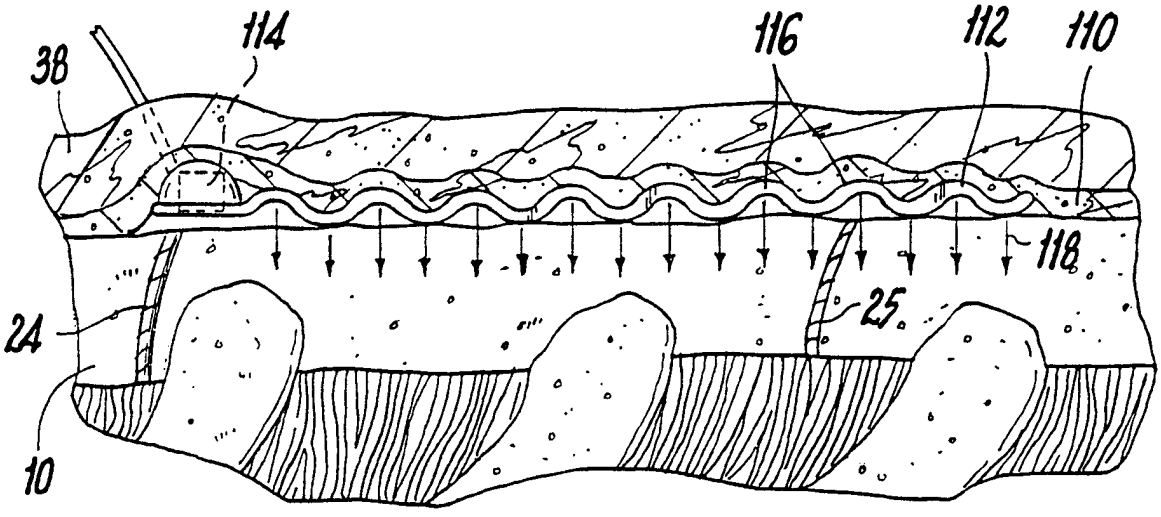



Fig. 15

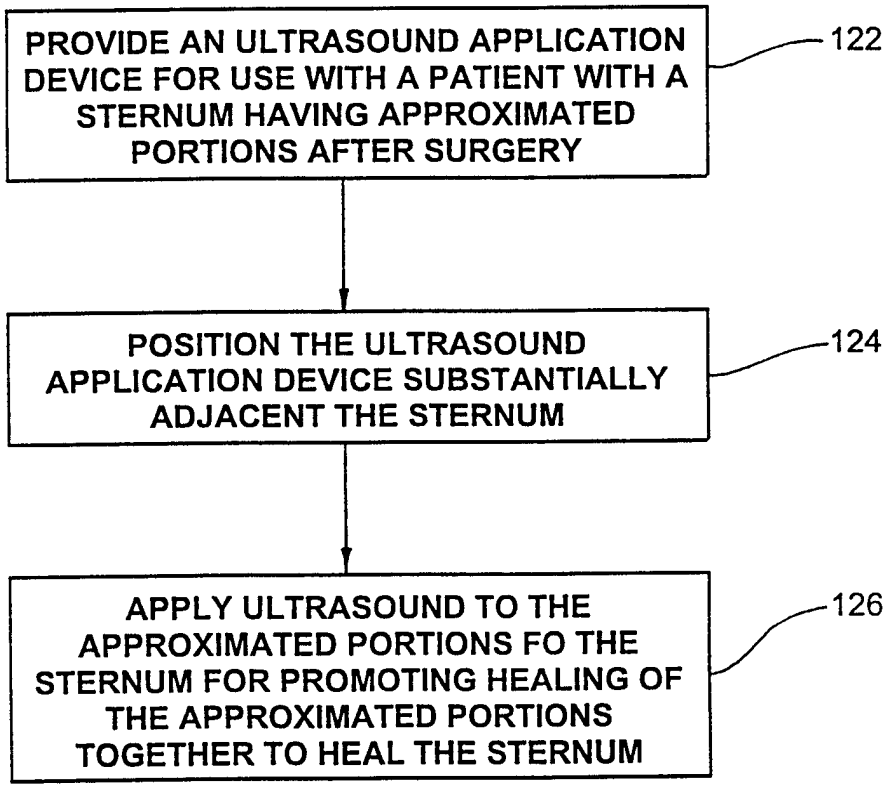

PROVIDE AN ULTRASOUND APPLICATION DEVICE FOR USE WITH A PATIENT WITH A STERNUM HAVING APPROXIMATED PORTIONS AFTER SURGERY
122
POSITION THE ULTRASOUND APPLICATION DEVICE SUBSTANTIALLY ADJACENT THE STERNUM
124
APPLY ULTRASOUND TO THE APPROXIMATED PORTIONS FO THE STERNUM FOR PROMOTING HEALING OF THE APPROXIMATED PORTIONS TOGETHER TO HEAL THE STERNUM
126

Fig. 16

# INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 98/07532

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y<br>A | WO 95 03744 A (SONEX INTERNATIONAL) 9 February 1995<br>see figure 4 | 12,14,15<br>18 |
| Y<br>A | EP 0 695 559 A (LAZZARI) 7 February 1996<br>see abstract; figure 2 | 12,14,15<br>18 |
| A | WO 96 12519 A (ORTHOLOGIC CORP.) 2 May 1996<br>see claim 23 | 12,18 |
| A | US 5 520 612 A (WINDER ET AL) 28 May 1996<br>see the whole document | 12,18 |
| A | EP 0 324 711 A (DORNIER MEDIZINTECHNIK) 19 July 1989<br>see claims 1,3,4 | 12,18 |

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 July 1998 | 24 July 1998 (24.07.98) |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Raybould, B |

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# INTERNATIONAL SEARCH REPORT

Inter...ional Application No
PCT/US 98/07532

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 4 530 360 A (DUARTE) 23 July 1985<br>see the whole document<br>----- | 12,18 |

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/07532

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-11
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 98/07532

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