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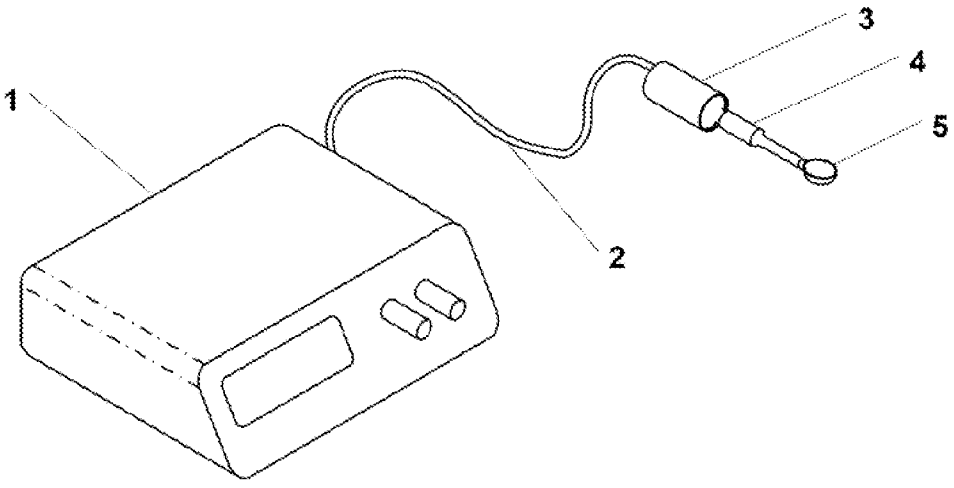
(54) **Title:** APPARATUS AND METHOD FOR THE TREATMENT OF TISSUE WITH ULTRASOUND ENERGY BY DIRECT CONTACT



(57) **Abstract:** Apparatus and method for the treatment of tissue, such as hard and soft tissues, wounds, tumors, muscles, and cartilage, through the direct contact of ultrasound energy is disclosed. Ultrasound energy is delivered to a target area through direct contact with an ultrasound tip. Ultrasound energy is also delivered through direct contact with a coupling medium. The ultrasound tip is specially designed to comprise of a cavity area for controlled fragmentation and the simultaneous sonication of a target area. The specially designed ultrasound tip allows for ultrasound energy to focus on a target area, The ultrasound apparatus may be moved in a variety of different directions during the treatment of tissue.

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Title: Apparatus and Method for the Treatment of Tissue with Ultrasound Energy by Direct Contact

Apparatus and Method for the Treatment of Tissue with Ultrasound Energy by Direct Contract

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to apparatus and method for the treatment of tissue, such as hard and soft tissue, wounds, tumors, muscles, and cartilage, with ultrasound energy by direct contact.

Description of the Related Art:

There are a variety of known methods for the treatment of tissue. These methods include wound dressings, hyperbaric oxygen treatment, growth factor therapy, antibiotics, surgery, physical therapy, vacuum therapy, electrical stimulation, bioengineered tissue, ultraviolet light therapy, and tissue ultrasound. There are also a variety of known methods for the treatment of wounds with ultrasound energy.

U.S. patents that disclose devices and methods for wound treatment using an ultrasound spray include: 6,478,754 to Babaev; 6,761,729 to Babaev; 6,533,803 to Babaev; 6,569,099 to Babaev; 6,663,554 to Babaev; and finally 6,960,173 to Babaev. These devices and methods can only achieve limited results because there is no sufficient delivery of ultrasound energy to the target because there is no direct contact with the target area. U.S. Patent Nos. 7,025,735 to Soring and 6,916,296 also to Soring disclose a method and device for the treatment of septic wounds that uses both a liquid aerosol and direct contact.

U.S. Patent Application 2004/0030254 to Babaev discloses a device and method for ultrasound wound debridement. Babaev discloses a device that causes debridement through mechanical vibration in the ultrasound tip. This device is also limited in that it uses only mechanical vibration for debridement.

Therefore, there is a need for a device and method that can use both mechanical vibration and ultrasound cavitation for fragmentation. There is also a need for a device and method that can simultaneously treat tissue and remove unwanted tissue through fragmentation.

SUMMARY OF THE INVENTION

The present invention is directed towards apparatus and method for the treatment of tissue, such hard and soft tissues, wounds, tumors, muscles, and cartilage, through the direct contact of ultrasound energy. Apparatus and methods in accordance with the present invention may meet the above-mentioned needs and also provide additional advantages and improvements that will be recognized by those skilled in the art upon review of the present disclosure.

The present invention comprises an ultrasound transducer with a specially designed ultrasound tip for the treatment of tissue. The tip is specially designed for controlled fragmentation and the simultaneous sonication of a target area, such as a wound, bone, unwanted tissue layers, an infected area, via direct contact. The tip is also specially designed to focus ultrasound energy on a target area. The tip is comprised of a cavity area – as used herein, the term "cavity area" means a hollowed out area. An example of an ultrasound tip with a cavity area is where the combination of an ultrasound horn and ultrasound tip forms a shape similar to a spoon utensil, where one side of the cavity area is concave and the other side is convex. Other comparable shapes or combination of shapes such as conical or polygonal may be similarly effective. The cavity area may be located on the radial sides at the distal end of the radiation surface. Additionally, the radiation surface at the distal end may form a tilted cavity area. The edges and surfaces of the ultrasound tip may be smooth, rough/jagged, or any combination thereof. The ultrasound tip may also be comprised of an orifice or orifices for the delivery and/or extraction of a coupling medium during treatment. The orifice or orifices may also be used to extract the fragmented unwanted tissue.

The specially designed ultrasound tip may be used for the treatment tissue, including the treatment of wounds and the removal of tumors. Ultrasound energy is generally delivered from the radial side of the specially designed ultrasound tip. The ultrasound energy may be delivered directly by contacting the target area with the ultrasound tip. The ultrasound energy may also be delivered directly by contacting the target area with a coupling medium such as a fluid flow that may emanate out of the orifice or orifices. Coupling medium, as used herein, is any medium through which ultrasound energy is capable of traveling except for a mist, aerosol spray, or atomized liquid. The use of ultrasound energy with a coupling medium may help fragment tissue through both mechanical vibration and cavitation. There are different treatment methods where

the ultrasound apparatus may be moved in various directions such as latitudinal, longitudinal, rotational, vertical or any other similar movement or combination of movements.

The use of ultrasound energy may have multiple beneficial effects that include, but are not limited to, destroying bacteria, disinfecting a wound, stimulating cell growth, increasing blood flow, precise fragmentation of unwanted tissue, painless fragmentation of a wound, exerting less pressure on a wound as compared to mechanical cleansing, and treating fistula and cavities. These effects may aid in the healing process of wounds.

The invention is related to method and device for the treatment of hard and soft tissue, including wound treatment, through the direct contact of ultrasound energy.

One aspect of this invention may be to provide a method and device for more effective treatment of tissue by delivering ultrasound energy by directly contacting the target area.

Another aspect of the invention may be to provide a method and device for more efficient treatment tissue.

Another aspect of the invention may be to provide a method and device for quicker treatment of tissue.

Another aspect of the invention may be to provide a method and device that may exert less pressure on the target area during the treatment of tissue.

Another aspect of the invention may be to provide a method and device that allows for controllable fragmentation.

Another aspect of the invention may be to provide a method and device that destroys bacteria.

Another aspect of the invention may be to provide a method and device for the stimulation of tissue cell growth.

Another aspect of the invention may be to provide a method and device to increase blood flow.

Another aspect of the invention may be to provide a method and device for pain relief.

Another aspect of the invention may be to provide a method and device for cleansing wounds.

Another aspect of the invention may be to provide a method and device for cleansing internal and external post-operation areas.

Another aspect of the invention may be to provide a method and device treating fistula and cavities.

These and other aspects of the invention will become more apparent from the written descriptions and figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

The present Invention will be shown and described with reference to the drawings of preferred embodiments and clearly understood in details.

Fig. 1 is a perspective view an ultrasound apparatus for the treatment of tissue use according to the present invention.

Fig. 2a is a cross-sectional view of an ultrasound apparatus for the treatment of tissue shown in **Fig. 1.**

Fig. 2b is a cross-sectional view of an ultrasound apparatus with a rear entry port.

Fig. 2c is a cross-sectional view of an ultrasound apparatus with a radial entry port.

Fig. 2d is a cross-sectional view of an ultrasound apparatus with a rear entry port and a radial exit port.

Fig. 2e illustrates a cross-sectional view of an ultrasound apparatus with a radial entry port and a radial exit port.

Fig. 2f illustrates a cross-sectional view of an ultrasound apparatuse with a rear entry port and two radial exit ports.

Fig. 3 is a detailed cross-sectional schematic representation of the delivery of ultrasound energy

Figs. 4a-4c are an example tissue treatment method using an ultrasound apparatus.

Figs. 5a-5c are front cross-sectional views of the tissue treatment method with the ultrasound apparatus from **Figs. 4a-4c**.

Figs. 6a-6c are alternative methods and embodiments of an ultrasound tissue treatment apparatus that comprises at least one orifice on the back surface of an ultrasound tip.

Figs. 7a-7c are different embodiments of an ultrasound tip with a cavity area .

Figs. 8a-8f are front cross-sectional views of variety of configurations on the number of orifices on an ultrasound tip.

Figs. 9a-9e are perspective views of a variety of configurations of the edges and back surface of an ultrasound tip

Fig. 10 is a cross-sectional view an ultrasound tip with a polygonal cavity area.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a method and device for the treatment of tissue through the direct contact of ultrasound energy. Preferred embodiments of the present invention in the context of an apparatus and methods are illustrated in the figures and described in detail below.

Figure 1 is a perspective view an ultrasound apparatus for use according to the present invention that comprises an ultrasound generator **1**, a transducer **2,** an ultrasound transducer **3,** an ultrasound horn **4**, and a specially designed ultrasound tip **5**. The ultrasound generator **1** may be battery powered or powered through an electrical outlet.

Fig. 2a illustrates a cross-sectional view of an ultrasound apparatus for the treatment of tissue as shown in **Fig. 1.** The ultrasound apparatus comprises an ultrasound transducer **3** that is mechanically connected to the ultrasound horn **4** by threading or other means **6**. The ultrasound horn **4** is mechanically connected to the ultrasound tip **5** by threading or other means **7**. The preferred embodiment comprises an ultrasound transducer **3** that is connected to the ultrasound horn **4** by a mechanical interface; alternative embodiments could have the ultrasound transducer **3** directly connected to the ultrasound horn **4** to comprise a single piece without a mechanical interface. The preferred embodiment also comprises an ultrasound horn **4** that is connected to the ultrasound tip **5** by a mechanical interface; alternative embodiments could have the ultrasound horn **4** directly connected to the ultrasound tip **5** to comprise a single piece without a mechanical interface.

Fig. 2b is a cross-sectional view of an ultrasound apparatus for the treatment of tissue that comprises a rear entry port **8**. The rear entry port **8** is located at the proximal end of the transducer **3**. The apparatus also comprises an entry lumen **9** that connects the rear entry port **8** to an exit orifice **10** that is located on the ultrasound tip **5**. A coupling medium may be inserted into the rear entry port **8**. The preferred coupling medium to use is a fluid. Fluid is inserted in the rear entry port **8** and moves through the entry lumen **9,** and then is delivered from the entry orifice **10**. A tube or other material can replace a lumen **9.** Fluid may be delivered from the entry orifice **10** to a target treatment area. The preferred method of treatment is to deliver a liquid flow to a target area from the entry orifice **10**.

Fig. 2c is a cross-sectional view of an ultrasound apparatus for the treatment of tissue that comprises a radial entry port **11**. The radial entry port **11** is located on a radial side of the

ultrasound horn **4.** The radial entry port **11** may be perpendicular to or any other angle to the axis of the ultrasound horn **4.** The preferred alignment for the radial entry port **11** is perpendicular to the ultrasound horn **4.** The apparatus also comprises an entry lumen **12** that connects the radial entry port **11** to an entry orifice **10** that is located on the ultrasound tip **5.** Fluid is inserted into the radial entry port **11,** moves through the entry lumen **12,** and then is delivered from the entry orifice **10.** Fluid may be delivered from the entry orifice **10** to the target treatment area.

Fig. 2d is a cross-sectional view of an ultrasound apparatus for the treatment of tissue that comprises rear entry port **8** and a radial exit port **15.** The rear entry port **8** is located at the proximal end of the transducer **3,** and the radial exit port **15** is located on a radial side of the ultrasound horn **4.** The apparatus also comprises an entry lumen **9** that connects the rear entry port **8** to an entry orifice **10** that is located on the ultrasound tip **5.** Fluid is inserted in the rear entry port **8,** moves through the entry lumen **9,** and then is delivered from the entry orifice **10.** Fluid may be delivered from the entry orifice **10** to a target treatment area. Fluid may also be extracted from the treatment area through exit orifice **13** that is also located on the ultrasound tip **5.** Exit orifice **13** is connected to radial exit port **15** by exit lumen **14.** Fluid enters the exit orifice **13,** travels through the exit lumen **14,** and exits out of the radial exit port **15.** Fluid may be extracted from the treatment area in order to continually supply the treatment area with fresh fluid. Fragmented tissue may also be extracted along with the fluid. The preferred embodiment of an ultrasound apparatus for the treatment of tissue comprises a rear entry port and a radial exit port. Alternative embodiments, as described below, may comprise multiple entry and/or exit ports that may be located at different locations with different alignments along the ultrasound apparatus. The preferred embodiment also comprises an entry orifice and an exit orifice. Alternative embodiments may comprise no orifices, one orifice, or multiple orifices.

Fig. 2e illustrates a cross-sectional view of an ultrasound apparatus for the treatment of tissue that comprises radial entry port **11** and a radial exit port **15.** The radial entry port **11** is located on a radial side of the ultrasound horn **4,** and the radial exit port **15** is located on a radial side of the ultrasound horn **4.** The preferred embodiment comprises a radial exit port **15** located on the direct opposite side of the ultrasound horn **4** than the radial entry port **11** with both the exit port **15** and entry port **11** aligned at ninety-degrees to the axis of the horn **4.** Alternate embodiments could have an entry port **11** and exit port **15** positioned at any other location on

the ultrasound horn **4** or aligned at any other angle to the axis of the horn **4**. The apparatus also comprises an entry lumen **12** that connects the radial entry port **11** to an entry orifice **10** that is located on the ultrasound tip **5**. Fluid is inserted in the radial entry port **11,** moves through the entry lumen **12**, and then is delivered from the entry orifice **10.** Fluid may be delivered from the entry orifice **10** to the target treatment area. Fluid may also be extracted from the treatment area through an exit orifice **13** that is also located on the ultrasound tip **5**. Exit orifice **13** is connected to the radial exit port **15** by exit lumen **14.** Fluid enters the exit orifice **13**, travels through the exit lumen **14**, and exits out of the radial exit port **15**. Fluid may be extracted from the treatment area in order to continually supply the treatment area with fresh fluid. Fragmented tissue may also be extracted along with fluid.

Fig. 2f illustrates a cross-sectional view of an ultrasound apparatus for the treatment of tissue that comprises a rear entry port **8** and two radial exit ports **16** and **17**. The rear entry port **8** is located at the proximal end of the transducer **3,** one radial exit port **16** is located on a radial side of the ultrasound horn **4,** and another radial exit port **17** is also located on a radial side of the ultrasound horn **4**. The preferred embodiment comprises of a radial exit port **16** located on the direct opposite side of the ultrasound horn **4** than the radial exit port **17** with both exit port **16** and exit port **17** aligned at ninety-degrees to the axis of the horn **4.** Alternative embodiments could have exit port **16** and exit port **17** positioned at any other location on the ultrasound horn **4** or aligned at any other angle to the axis of the horn **4**. This embodiment also comprises an entry lumen **9** that connects the rear entry port **8** to an entry orifice **10** that is located on the ultrasound tip **5**. Fluid is inserted in the rear entry port **8,** moves through the entry lumen **9**, and then is delivered from the entry orifice **10.** Fluid may delivered from the entry orifice **10** to a target treatment area. Fluid may also be extracted from the treatment area through exit orifice **20** and exit orifice **21** that are also located on the ultrasound tip **5**. Exit orifice **20** and exit orifice **21** are connected to radial exit port **16** and radial exit port **17** by exit lumen **18** and exit lumen **19**, respectively. Fluid enters exit orifice **20** and exit orifice **21**, travels through exit lumen **18** and exit lumen **19**, and exits out of radial exit port **16** and radial exit port **17**. Fluid may be extracted from the treatment area in order to continually supply the treatment area with fresh fluid. Fragmented tissue may also be extracted along with fluid.

Fig. 3 is a detailed cross-sectional schematic representation of the delivery of ultrasound energy a fluid from an ultrasound tip **5** that comprises an entry port and exit port (not shown).

The ultrasound tip **5** is specially designed to deliver focused ultrasound energy. The ultrasound tip **5** in this embodiment comprises a cavity area located on the radial sides at the distal end of the radiation surface. The cavity area is shaped similar to the tip of a spoon utensil, where the open side of the cavity area is concave and the back side of the cavity area is convex. The shape of the ultrasound tip **5** in this embodiment allows for the ultrasound energy **23** emanating from the tip **5** to focus **24** on the target area **25**. The ultrasound energy **23** travels through the fluid **22** to the target area **25**. The fluid **22** is delivered to the target area **25** from the entry orifice **10**. The fluid **22** travels in a vortex motion **26:** fluid **22** is delivered from the entry orifice **10,** strikes the side of the open cavity, and then circles back around. The fluid **22** may then be extracted out of the exit orifice **13**. It may be beneficial to extract the used fluid **22** from the treatment area **25** while delivering a fresh fluid **22** to the treatment area **25.** The shape of the ultrasound tip in **Fig. 3** is the preferred embodiment. Alternative embodiments of a cavity area may comprise comparable shapes or combination of shapes such as conical or polygonal that may also be effective at focusing ultrasound energy. The cavity area may be located on the radial sides at the distal end of the radiation surface. Additionally, the radiation surface at the distal end may form a titled cavity area. The preferred location of the cavity area is on the radial sides at the distal end of the radiation surface.

Figs. 4a-4c are an example tissue treatment method using an ultrasound apparatus according to the present invention. **Fig. 4a** depicts the first motion whereby the edges **27** of the ultrasound tip **5** are dragged across the treatment area **25** while delivering ultrasound energy **23** from the open cavity area, where the ultrasound energy **23** focuses **24** on the treatment area **25.** While the tip **5** is moved longitudinally, the fluid **22** may be delivered from the entry orifice **10,** where the fluid **22** would travel in a vortex motion **26** across the treatment area **25.** Unwanted tissue **28** is fragmented from the treatment area **25** due to the mechanical vibration in the ultrasound tip **5** and the cavitation that occurs by delivering ultrasound energy **23** through the fluid **22**. The used fluid and fragmented tissue may be extracted through the exit orifice **13**. **Fig. 4b** depicts that as the ultrasound tip **5** is moved longitudinally across the treatment area **25**, the ultrasound tip **5** is rotated along the axis of the ultrasound horn **4**. Ultrasound energy **29** may be delivered from the external side of the open cavity in the ultrasound tip **5** to the treatment area **25**. **Fig. 4c** shows the ultrasound tip **5** after it been rotated 180 degrees. Ultrasound energy **30** may be delivered from the back surface **31** of the ultrasound tip **5**; the back surface **31** is the side

of the ultrasound tip **5** that is opposite the cavity area. The ultrasound energy that is delivered during this movement is generally radial waves because the ultrasound energy that reaches that target area **25** is mostly from the radial side of the ultrasound tip **5**; however, some shear and longitudinal waves may reach the target area **25**. The ultrasound tip **5** may also be moved latitudinally across the treatment area before, during, or after the longitudinal and rotational movement.

Figs. 5a-5c are front cross-sectional views of ultrasound tips **5** from the corresponding **Figs. 4a-4c**, respectively. **Fig. 5a** shows the corresponding front cross-sectional view of **Fig. 4a** where the edges **27** of the ultrasound tip **5** are dragged longitudinally across the treatment area **25** while ultrasound energy **23** is delivered from the open cavity area to the treatment area **25**. Fluid **22** may be delivered from the entry orifice **10**. Unwanted tissue **28** is fragmented from the treatment area **25** due to the mechanical vibration in the ultrasound tip **5** and the cavitation that occurs by delivering ultrasound energy **23** through the fluid **22**. **Fig. 5b** shows the corresponding front cross-sectional view of **Fig. 4b** where the ultrasound tip **5** is rotated along the axis of the horn. Ultrasound energy **29** may be delivered from the external side of the open cavity on the ultrasound tip **5**. Unwanted tissue **28** may be fragment from the delivery of the ultrasound energy **29** and the mechanical vibration in the ultrasound tip **5**. **Fig. 5c** shows the corresponding front cross-sectional view of **Fig. 4c** where the ultrasound energy **30** may be delivered from the back surface **31** of the ultrasound tip **5** to the treatment area **25**.

Figs. 6a-6c are alternative methods and embodiments of an ultrasound tissue treatment apparatus that comprises at least one orifice on the back surface of an ultrasound tip. **Fig. 6a** shows an alternative embodiment of an ultrasound apparatus that is comprised of a back orifice **32** on the back surface **33** of an ultrasound tip **5**. The back orifice **32** can be used to extract fragmented tissue **28** from the target area **25** through the exit orifice **13**. The entry orifice **10** may still be used to deliver a fluid **22** to the target area **25**. The fluid **22** may also be delivered to the target area **25** through the back orifice **32**; in that instance, a back orifice or orifices may be used to deliver to and extract from the target area **25** a fluid **22**. The fluid **22** may still travel in a vortex motion **26** as it is delivered from the entry orifice **10**. The fluid **22** may also be delivered directly to the target area **25** if the open cavity area on the ultrasound tip **5** is facing the target area **25**. One possible method with this embodiment is depicted in **Fig. 6a** where the back surface **33** of the ultrasound tip **5** is moved longitudinally across the target area **25** during

delivery of ultrasound energy **30** from the back surface **33** while either simultaneously or sequentially lifting and lowering the proximal end of the ultrasound apparatus so that different parts of the back surface **33**, such as the proximal end, the middle, and the distal end, may contact the target area **25**.

Fig. 6b is an alternative method that may be used with an ultrasound tip that has at least one back orifice. The movement in this method is similar to the movement in the method depicted in **Figs. 4a-4c** and **Figs. 5a-5c**. The ultrasound tip **5** is moved in a latitudinal direction across the treatment area **25** while either simultaneously or sequentially rotating the ultrasound tip **5** so that different sections of the back surface **33** may contact the target area **25**. In this method, the ultrasound tip **5** may also be lifted and/or moved in a longitudinal direction across the treatment area during delivery of ultrasound energy **30**. **Fig. 6c** is an alternative embodiment of the ultrasound apparatus depicted in **Fig. 6a.** This embodiment comprises multiple back orifices **34** on back surface **35.**

Figs. 7a-7c are different embodiments of an ultrasound tip **5** with a cavity area. **Fig. 7a** is an ultrasound tip **5** where the radial sides at the distal end of the radiation surface forms a cavity area that is in a shape similar to the tip of a spoon. The cavity area, in this embodiment, is parallel to the axis of the ultrasound horn **4**. This is the preferred embodiment. Alternative embodiments of the ultrasound tip **5** are shown in **figs. 7b** and **7c** where the radiation surface at the distal end forms a titled cavity area, whereby the cavity area is also in a shape similar to that of the tip of a spoon. The cavity areas, in these embodiments, are at angle titled to the axis of the ultrasound horn **4**. The preferred embodiment is shown in **Fig. 7a** where the radial sides at the distal end of the radiation surface forms a cavity area that is in a shape similar to the tip of a spoon. Other comparable shapes or combination of shapes for alternative embodiments, in addition to those in **figs. 7a** and 7c, of an ultrasound tip that comprises a cavity area may be similarly effective.

Figs. 8a-8f are front cross-sectional views of various embodiments of an ultrasound tip **5**. The ultrasound tip **5** may contain no orifices, one orifice, or multiple orifices. The orifices may also be the same or different sizes. The preferred embodiment is to have the exit orifice for extraction larger than the entry orifice for delivery.

Figs. 9a-9e are different embodiments of the edges **27** and back surface **33** of an ultrasound tip according to the present invention. The edges **27** of the ultrasound tip **5** may be smooth, non-smooth, or any combination thereof. The preferred embodiment comprises rough/jagged edges **27**. The back surface **33** may be smooth, non-smooth, or any combination thereof. The preferred embodiment comprises a rough/jagged back surface **33.**

Fig. 10 is an alternative embodiment of an ultrasound tip with a cavity area. This embodiment is comprised of a polygonal-shaped cavity area **36**. The preferred embodiment is the concave-convex spoon shaped open cavity that is described and depicted above. Alternative embodiments of an open cavity may be similarly effective in delivering ultrasound energy.

The ultrasound apparatus shown in **Fig. 1** delivers ultrasound energy to a target area for the treatment of tissue, including the treatment of the wounds and the removal of tumors. The tip is specially designed for controlled fragmentation and the simultaneous sonication of a target area via direct contact. The tip is also specially designed to focus ultrasound energy on a target area. The use of ultrasound energy may have multiple beneficial effects that include, but are not limited to, destroying bacteria, disinfecting a wound, stimulating cell growth, increasing blood flow, exerting less pressure on a wound, treating fistula and cavities, and removing unwanted tissue. These effects may aid in the healing process of wounds.

There are multiple methods that may be used to deliver ultrasound energy to a target area. Ultrasound energy may be delivered directly by contacting the target area with the ultrasound tip from areas such as the edges or back surface area of the tip. Ultrasound energy may also be delivered directly by contacting the target area with a coupling medium. The ultrasound energy is generally delivered from the radial side of the ultrasound tip, but it may also be delivered from the distal end of the ultrasound tip. Therefore, the ultrasound energy that is mainly delivered is radial waves. The use of radial waves, as compared to longitudinal waves from the distal end, may allow for a horizontal vibration in the ultrasound tip on the target area rather than a vertical vibration.

The preferred coupling medium to use is a fluid, and the preferred fluid to use is saline. Other fluids such as drugs, antibiotics, antiseptics, etc may also be used. Both micro and macro cavitation may occur from the delivery of ultrasound energy through the coupling medium. Macro cavitation occurs in the coupling medium and results in sterilizing the target surface,

fragmenting tissue, and mechanical cleansing because of the cavitation effect. Micro cavitation creates microstreaming inside tissue, which is beneficial for tissue granulation. Fragmentation of unwanted tissue may result from both the cavitation that occurs and the mechanical vibration of the ultrasound tip on the target area.

The ultrasound tip may comprise an orifice or orifices that may deliver a coupling medium such as a liquid flow to the target area. The orifice or orifices may also be used to extract a coupling medium that is delivered to the target area. The orifice or orifice may be located anywhere on the ultrasound tip; the preferred embodiment comprises an orifice or orifice that is located on the proximal end of cavity area.

The ultrasound tip may be held flat against the target area during treatment or it may be held at an angle. During the treatment, the ultrasound tip, or any portion thereof, may be moved latitudinally, moved longitudinally, rotated, lifted, or any combination thereof. If the ultrasound tip is rotated during treatment, then ultrasound energy may be delivered from the cavity area, the external sides of the cavity area, and the back surface of the cavity area.. If the ultrasound tip is lifted during treatment, then ultrasound energy may be delivered from both the radial side of the ultrasound tip and the distal end of the ultrasound tip.

One preferred method of treatment is to hold the distal end of the ultrasound tip against the target with the cavity area facing the target, while holding the proximal end of the horn above the target, and move the tip longitudinally while delivering and extracting liquid from orifices in the ultrasound tip.

Another preferred method of treatment is to hold one edge of the peripheral boundary of the cavity area against the target with the other edge of the peripheral boundary of the cavity area just above the target, and then move the ultrasound tip latitudinally. Liquid saline is delivered and extracted from an orifice or orifices in this preferred embodiment. Furthermore, while the ultrasound tip is being moved, the ultrasound apparatus/tip may be rotated during delivery so that the cavity area of the tip is no longer facing the target; ultrasound energy is then being delivered from the sides and then the back surface of the cavity area.

The intensity of the ultrasound energy can be controlled through a variation in the ultrasound parameters such as the frequency, the amplitude, and the treatment time. The frequency range for the ultrasound energy is 15 kHz to 20 MHz. The preferred low-frequency

ultrasound range is 20 kHz – 100 kHz, the more preferred low-frequency ultrasound range is 25 kHz – 50 kHz, and the recommend low-frequency ultrasound value is 30 kHz. The preferred high-frequency ultrasound range is 0.7 MHz – 3 MHz, the more preferred high-frequency ultrasound range is 0.7 MHz – 3 MHz, and the recommend high-frequency ultrasound value is 0.7 MHz. The amplitude of the low-frequency ultrasound energy can be 5 microns and above, with the preferred low-frequency amplitude to be in range of 30 microns to 100 microns, and the recommended low-frequency amplitude value is 100 microns. The amplitude of the high-frequency ultrasound energy can be 1 micron and above, with the preferred high-frequency amplitude to be at least 5 microns, and the recommended high-frequency amplitude value is 10 microns. The preferred method of treatment uses low-frequency ultrasound.

There are a variety of factors that may influence the treatment time. These factors may include the type of tissue being treated, the condition of a wound, the size of a wound, and the location of a wound.

Although specific embodiments and methods of use have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that any arrangement that is calculated to achieve the same purpose may be substituted for the specific embodiments and methods shown. It is to be understood that the above description is intended to be illustrative and not restrictive. Combinations of the above embodiments and other embodiments as well as combinations of the above methods of use and other methods of use will be apparent to those having skill in the art upon review of the present disclosure. The scope of the present invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

CLAIMS

I claim:

1) An apparatus for the treatment of tissue with ultrasound energy by direct contact, comprising:
   a) a generator and a transducer for generating ultrasound energy;
   b) an ultrasound horn and ultrasound tip for delivering ultrasound energy;
   c) wherein the radial sides at the distal end of the radiation surface forms a cavity area or wherein the radiation surface at the distal end forms a tilted cavity area;
   d) wherein the ultrasound tip delivers ultrasound energy to a target area; and
   e) wherein the ultrasound energy has an intensity capable of treating tissue.
2) The apparatus according to claim 1, wherein the generator and transducer generate the ultrasound energy with particular ultrasound parameters indicative of an intensity capable of treating tissue.
3) The apparatus according to claim 1, wherein the ultrasound frequency is in the approximate range of 15 kHz – 20 MHz.
4) The apparatus according to claim 1, wherein the preferred low-frequency ultrasound is in the approximate range of 20 kHz – 100 kHz.
5) The apparatus according to claim 1, wherein the more preferred low-frequency ultrasound is in the approximate range of 25 kHz – 50 kHz.
6) The apparatus according to claim 1, wherein the recommended low-frequency ultrasound value is approximately 30 kHz.
7) The apparatus according to claim 1, wherein the preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 3 MHz.
8) The apparatus according to claim 1, wherein the more preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 1 MHz.
9) The apparatus according to claim 1, wherein the recommended high-frequency ultrasound value is approximately 0.7 MHz.

10) The apparatus according to claim 1, wherein the low-frequency ultrasound amplitude is at least 1 micron.

11) The apparatus according to claim 1, wherein the preferred low-frequency ultrasound amplitude range is approximately 30 – 250 microns.

12) The apparatus according to claim 1, wherein the recommended low-frequency ultrasound amplitude value is approximately 100 microns.

13) The apparatus according to claim 1, wherein the high-frequency ultrasound amplitude is at least 1 micron.

14) The apparatus according to claim 1, wherein the preferred high-frequency ultrasound amplitude is at least 5 microns.

15) The apparatus according to claim 1 wherein the recommended high-frequency ultrasound amplitude value is approximately 10 microns.

16) The apparatus according to claim 1, wherein the combination of an ultrasound horn and ultrasound tip form a shape similar to a spoon.

17) The apparatus according to claim 1, further comprised of an orifice or orifices.

18) The apparatus according to claim 17, wherein the orifice or orifices are located on the proximal end of the cavity area, on the distal end of the cavity area, on the middle of the cavity, or any combination thereof.

19) The apparatus according to claim 17, wherein the orifice or orifices are capable of delivering and/or extracting a coupling medium.

20) The apparatus according to claim 17, wherein the orifice or orifices are capable of extracting fragmented tissue.

21) The apparatus according to claim 1, wherein the transducer contains a radiation surface intended to achieve delivery of the ultrasound energy with an intensity capable of treating tissue.

22) The apparatus according to claim 1, wherein the transducer includes a radiation surface having a surface area dimensioned/constructed for achieving delivery of the ultrasound energy with an intensity capable of treating tissue.

23) The apparatus according to claim 1, wherein shape of the peripheral boundary of the cavity area is circular, oval, elliptical, or any other comparable shape or combination of shapes.

24) The apparatus according to claim 23, wherein the shape of the peripheral boundary of the cavity area of the radiation surface is intended to achieve delivery of the ultrasound energy with an intensity capable of treating tissue.

25) The apparatus according to claim 1, wherein the shape of the peripheral boundary of the distal end of the radiation surface is circular, oval, elliptical, polygonal, a straight-line, a non-straight line, or another comparable shape or combination of shapes.

26) The apparatus according to claim 25, wherein the shape of the peripheral boundary of distal end of the radiation surface is intended to achieve delivery of the ultrasound energy with an intensity capable of treating tissue.

27) The apparatus according to claim 1, wherein the edges of the radiation surface are smooth, non-smooth, or any combination thereof.

28) The apparatus according to claim 1, wherein the back surface area of the radiation surface is smooth, non-smooth, or any combination thereof.

29) The apparatus according to claim 1, wherein the transducer is driven by a continuous or pulsed frequency.

30) The apparatus according to claim 1, wherein the transducer is driven by a fixed or modulated frequency.

31) The apparatus according to claim 1, wherein the driving wave form of the transducer is selected from the group consisting of sinusoidal, rectangular, trapezoidal and triangular wave form.

32) A method for the treatment of tissue with ultrasound energy by direct contact, comprising the steps of:

a) providing a means for delivering ultrasound energy by direct contact to a target area with the radial side of the distal end of a radiation surface that forms a cavity area or the radiation surface at the distal end that forms a tilted cavity area;

b) directly contacting the target area;

c) delivering ultrasound energy through the direct contact with the target area;

d) wherein the ultrasound energy has an intensity capable of treating tissue.

33) The method according to claim 32, further comprising the step of generating the ultrasound energy with particular ultrasound parameters indicative of an intensity capable of treating tissue.

34) The method according to claim 32, wherein the ultrasound frequency is in the approximate range of 15 kHz – 20 MHz.

35) The method according to claim 32, wherein the preferred low-frequency ultrasound is in the approximate range of 20 kHz – 100 kHz.

36) The method according to claim 32, wherein the more preferred low-frequency ultrasound is in the approximate range of 25 kHz – 50 kHz.

37) The method according to claim 32, wherein the recommended low-frequency ultrasound value is approximately 30 kHz.

38) The method according to claim 32, wherein the preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 3 MHz.

39) The method according to claim 32, wherein the more preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 1 MHz.

40) The method according to claim 32, wherein the recommended high-frequency ultrasound value is approximately 0.7 MHz.

41) The method according to claim 32, wherein the low-frequency ultrasound amplitude is at least 1 micron.

42) The method according to claim 32, wherein the preferred low-frequency ultrasound amplitude range is approximately 30 – 250 microns.

43) The method according to claim 32, wherein the recommended low-frequency ultrasound amplitude value is approximately 100 microns.

44) The method according to claim 32, wherein the high-frequency ultrasound amplitude is at least 1 micron.

45) The method according to claim 32, wherein the preferred high-frequency ultrasound amplitude is at least 5 microns.

46) The method according to claim 32, wherein the recommended high-frequency ultrasound amplitude value is approximately 10 microns.

47) The method according to claim 32, wherein the direct contact with the target area is with the edges and/or back surface area of the ultrasound tip, is with a coupling medium, or any combination thereof.

48) The method according to claim 47, further comprising the step of delivering the coupling medium to the target area.

49) The method according to claim 48, wherein the coupling medium is delivered from an orifice or orifices in the ultrasound tip.

50) The method according to claim 48, further comprising the step of extracting the coupling medium from the target area.

51) The method according to claim 50, wherein the coupling is extracted through an orifice or orifices in the ultrasound tip.

52) The method according to claim 48, wherein the coupling medium is a fluid.

53) The method according to claim 32, wherein the ultrasound apparatus/tip is held stationary, is moved latitudinally, is moved longitudinally, is lifted, or is rotated during the treatment of tissue or any combination thereof.

54) The method according to claim 32, wherein the ultrasound tip is held flat against the target area during the treatment of tissue, is held at an angle to the target area during the treatment of tissue, or any combination thereof.

55) The method according to claim 32, wherein the proximal end of the ultrasound tip is positioned above the target area during the treatment of tissue.

56) The method according to claim 32, wherein the distal end of the ultrasound tip is positioned above the target area during the treatment of tissue.

57) The method according to claim 32, further comprising the step of fragmenting the target area.

58) The method according to claim 57, wherein the fragmentation occurs through mechanical scraping/vibrating the target area, through ultrasound cavitation, or any combination thereof.

59) The method according to claim 57, further comprising the step of removing the fragmented tissue from the target area.

60) The method according to claim 59, wherein the fragmented tissue is removed through an orifice or orifices in the ultrasound tip.

61) A method for the treatment of tissue with ultrasound energy by direct contact, comprising the steps of:

a) providing a means for delivering ultrasound energy by direct contact to a target area with the radial side at the distal end of a radiation surface that forms a cavity area that of a spoon or with the radiation surface at the distal end that forms titled cavity area;

b) contacting the target area with the radiation surface that forms a cavity area;

c) delivering a coupling medium to the target area;

d) delivering ultrasound energy through the direct contact of the radiation surface with the target area;

e) delivering ultrasound energy through the direct contact of the coupling medium; and

f) wherein the ultrasound energy has an intensity capable of treating tissue.

62) The method according to claim 61, further comprising the step of generating the ultrasonic energy with particular ultrasound parameters capable of treating tissue.

63) The method according to claim 61, wherein the ultrasound frequency is in the approximate range of 15 kHz – 20 MHz.

64) The method according to claim 61, wherein the preferred low-frequency ultrasound is in the approximate range of 20 kHz – 100 kHz.

65) The method according to claim 61, wherein the more preferred low-frequency ultrasound is in the approximate range of 25 kHz – 50 kHz.

66) The method according to claim 61, wherein the recommended low-frequency ultrasound value is approximately 30 kHz.

67) The method according to claim 61, wherein the preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 3 MHz.

68) The method according to claim 61, wherein the more preferred high-frequency ultrasound is in the approximate range of 0.7 MHz – 1 MHz.

69) The method according to claim 61, wherein the recommended high-frequency ultrasound value is approximately 0.7 MHz.

70) The method according to claim 61, wherein the low-frequency ultrasound amplitude is at least 1 micron.

71) The method according to claim 61, wherein the preferred low-frequency ultrasound amplitude range is approximately 30 – 250 microns.

72) The method according to claim 61, wherein the recommended low-frequency ultrasound amplitude value is approximately 100 microns.

73) The method according to claim 61, wherein the high-frequency ultrasound amplitude is at least 1 micron.

74) The method according to claim 61, wherein the preferred high-frequency ultrasound amplitude is at least 5 microns.

75) The method according to claim 61, wherein the recommended high-frequency ultrasound amplitude value is approximately 10 microns.

76) The method according to claim 61, wherein the coupling medium is delivered from an orifice or orifices in the ultrasound tip.

77) The method according to claim 62, further comprising the step of extracting the coupling medium from the target area.

78) The method according to claim 77, wherein the coupling medium is extracted through an orifice or orifices in the ultrasound tip .

79) The method according to claim 61, wherein the coupling medium is a fluid.

80) The method according to claim 61, wherein the ultrasound apparatus/tip is held stationary, is moved latitudinally, is moved longitudinally, is lifted, or is rotated during the treatment of tissue or any combination thereof..

81) The method according to claim 61, wherein the ultrasound tip is held flat against the target area during the treatment of tissue, is held at an angle to the target area during the treatment of tissue, or any combination thereof.

82) The method according to claim 61, wherein the proximal end of the ultrasound tip is positioned above the target area during the treatment of tissue.

83) The method according to claim 61, wherein the distal end of the ultrasound tip is positioned above the target area during the treatment of tissue.

84) The method according to claim 61, further comprising the step of fragmenting the target area.

85) The method according to claim 84, wherein the fragmentation occurs through mechanical scraping/vibrating the target area, through ultrasound cavitation, or any combination thereof.

86) The method according to claim 84, further comprising the step of extracting the fragmented tissue from the target area.

87) The method according to claim 86, wherein the fragmented tissue is extracted through an orifice or orifices in the ultrasound tip.

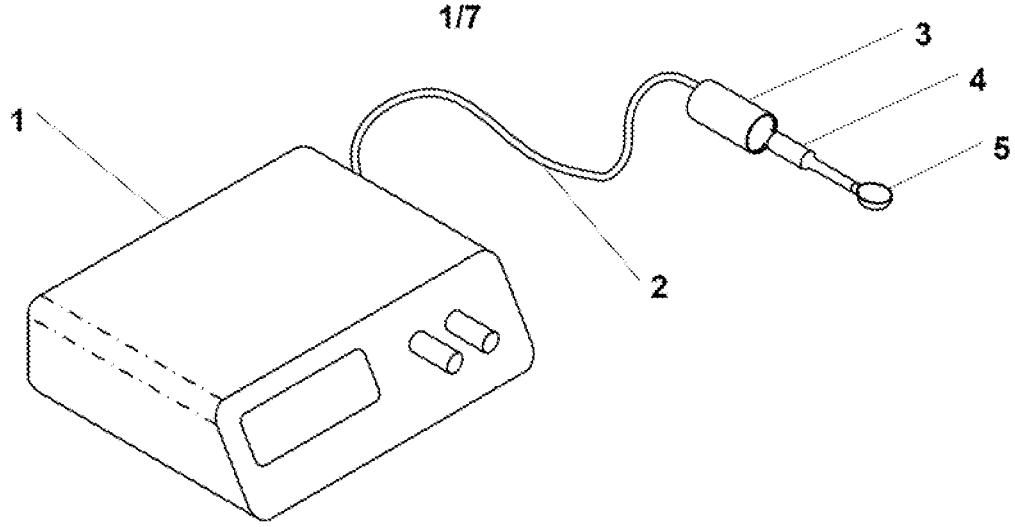

Fig. 1

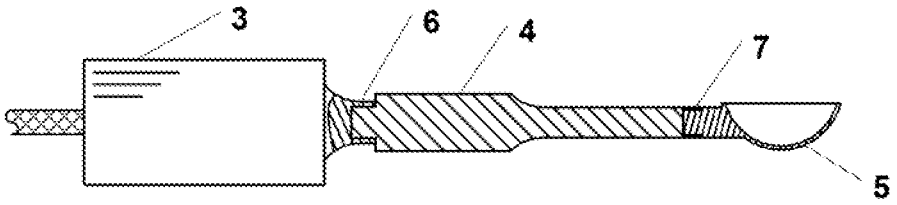

Fig. 2A

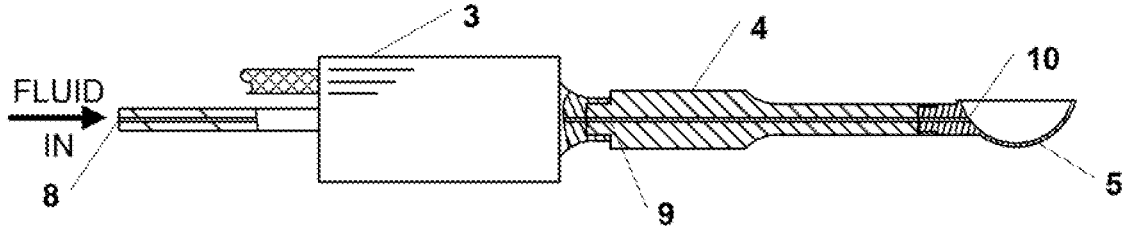

Fig. 2B

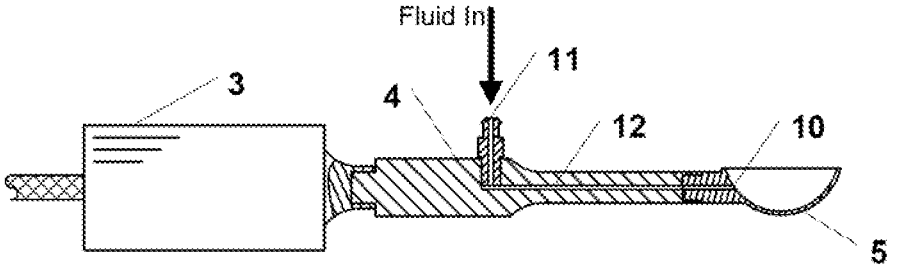

Fig. 2C

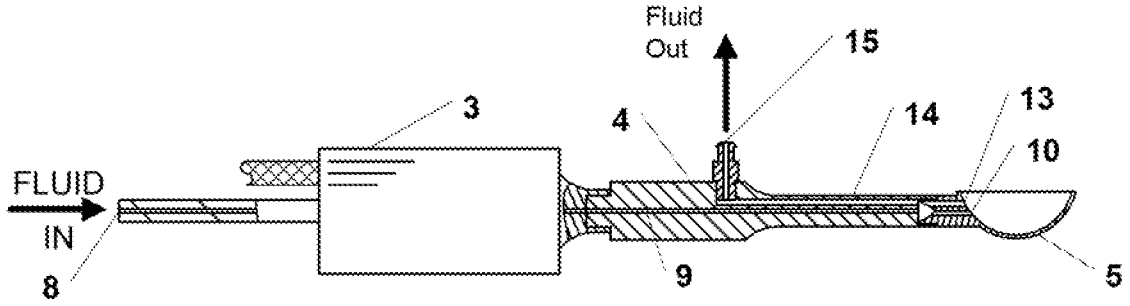

Fig. 2D

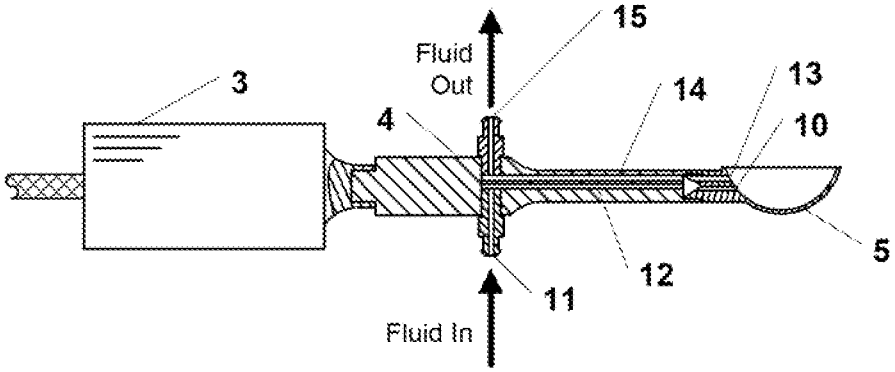

Fig. 2E

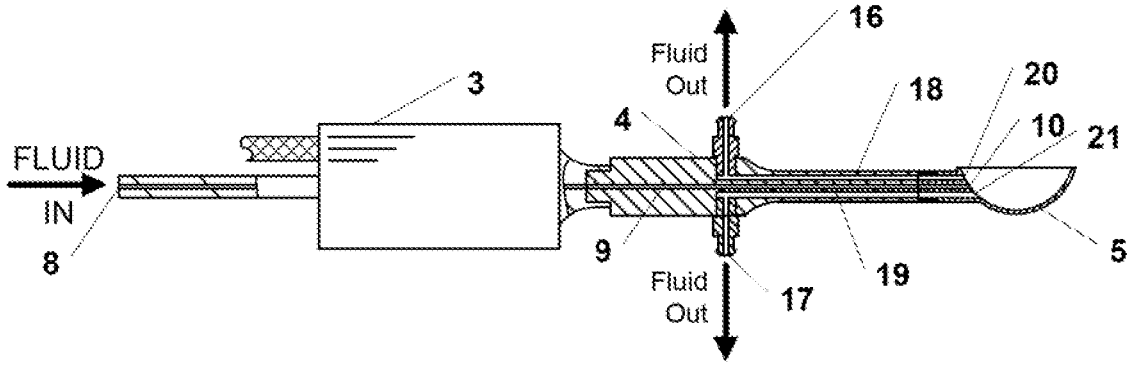

Fig. 2F

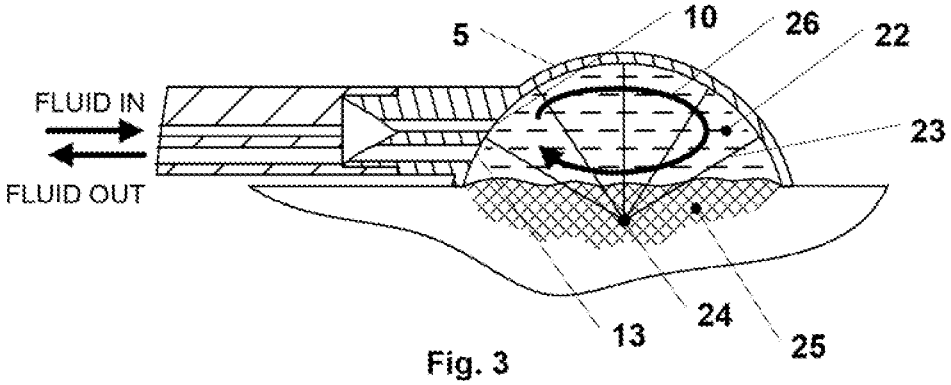

Fig. 3

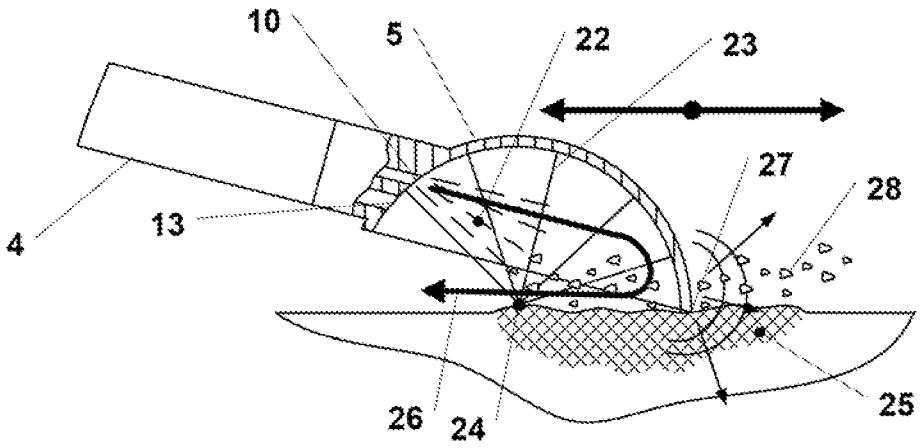

Fig. 4A

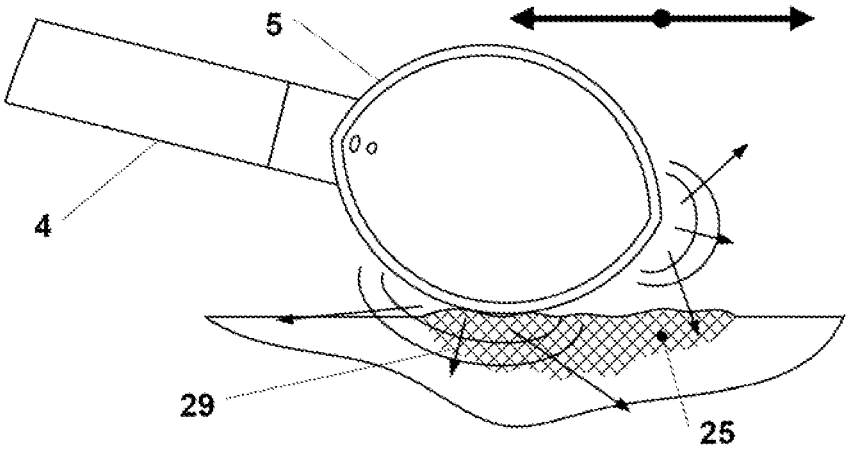

Fig. 4B

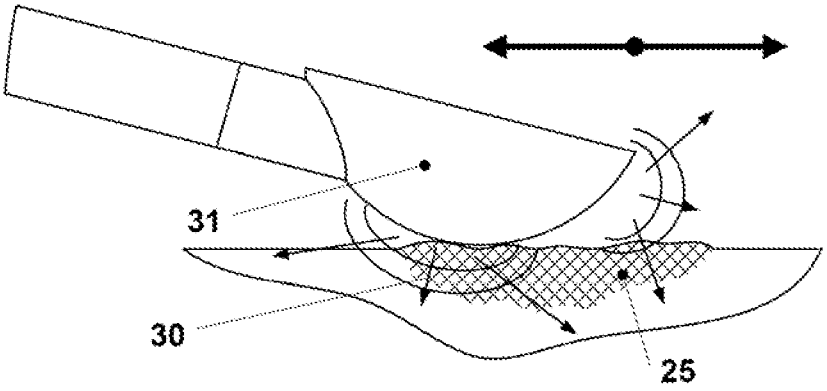

Fig. 4C

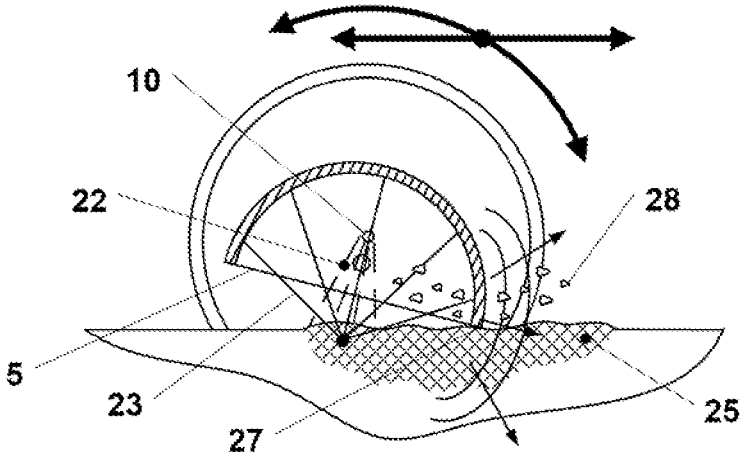

Fig. 5A

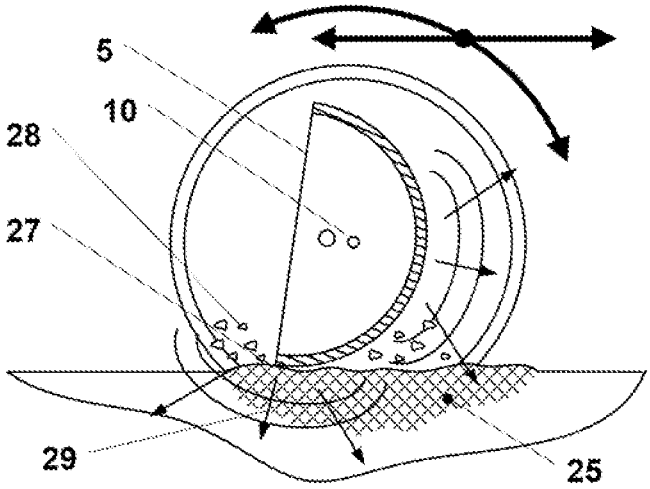

Fig. 5B

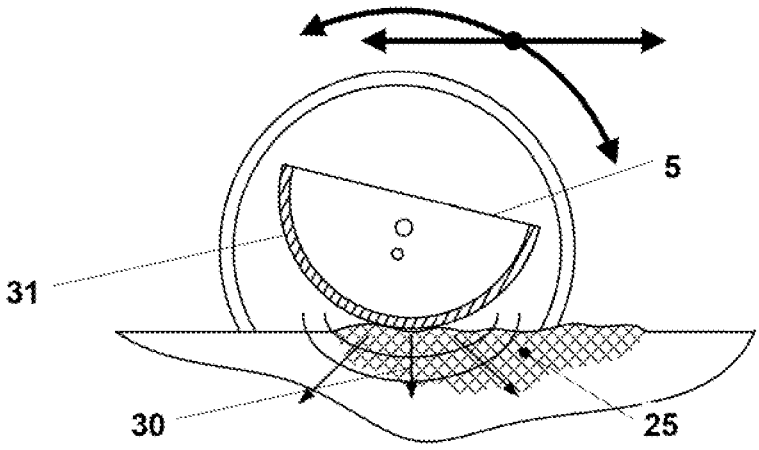

Fig. 5C

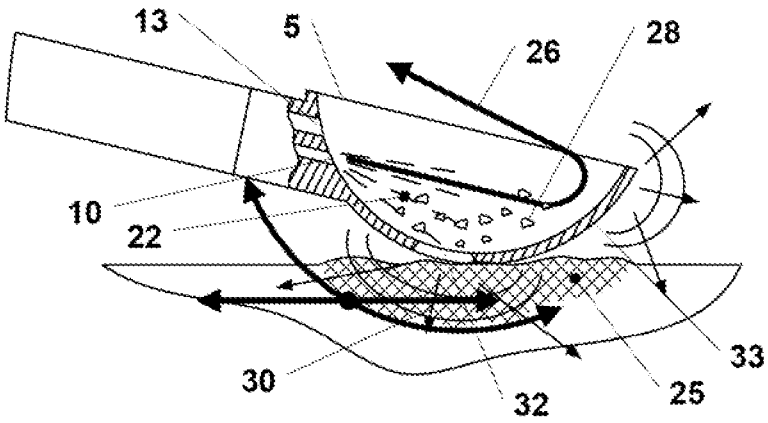

Fig. 6A

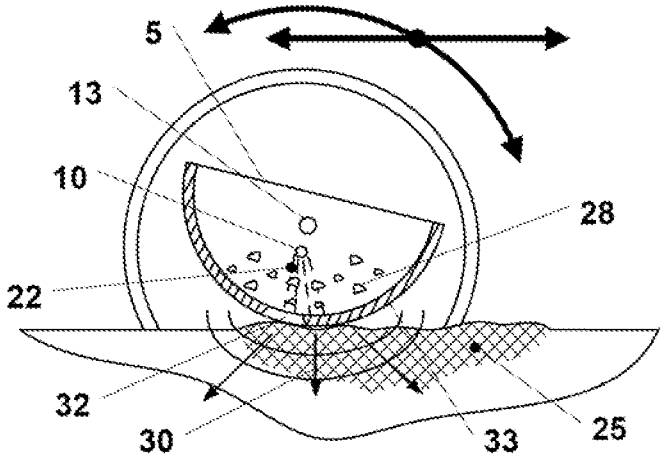

Fig. 6B

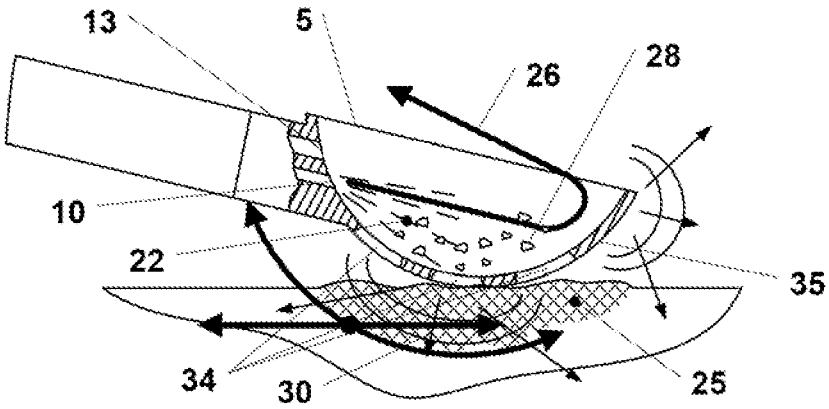

Fig. 6C

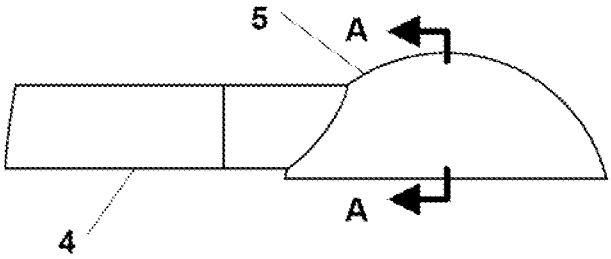

Fig. 7A

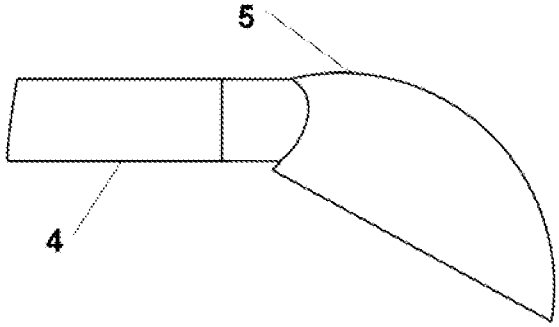

Fig. 7B

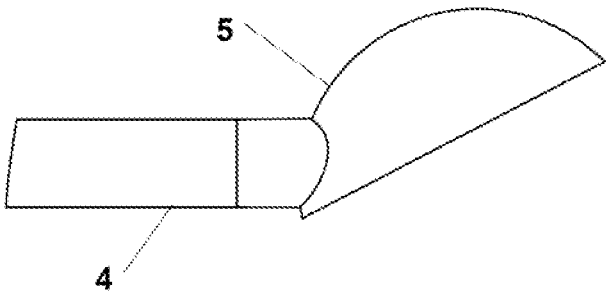

Fig. 7C

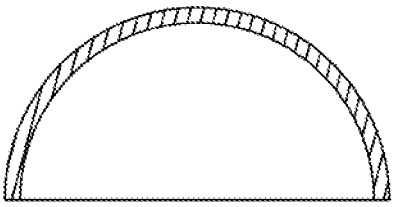

Fig. 8A

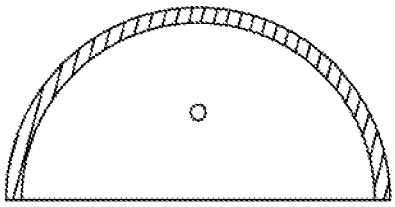

Fig. 8B

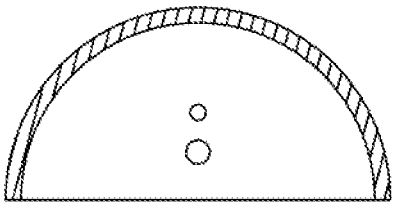

Fig. 8C

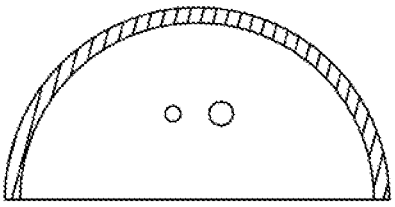

Fig. 8D

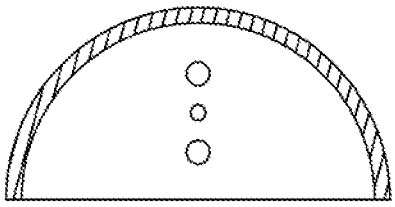

Fig. 8E

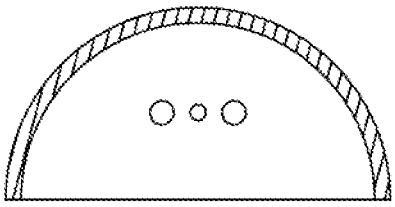

Fig. 8F

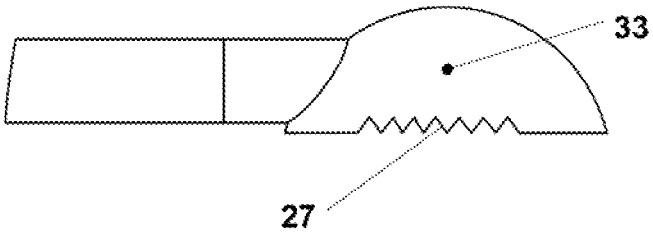

Fig. 9A

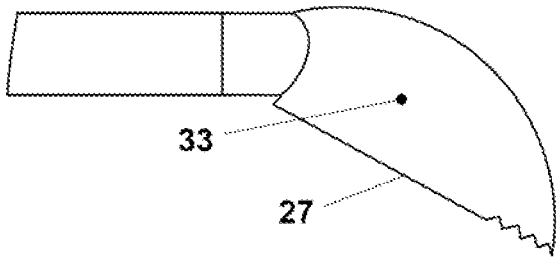

Fig. 9B

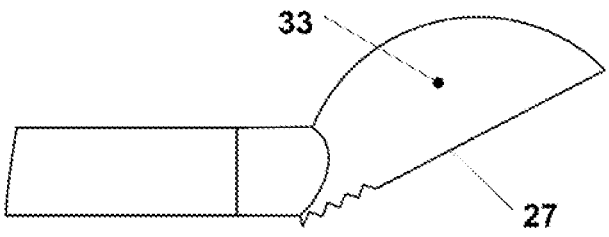

Fig. 9C

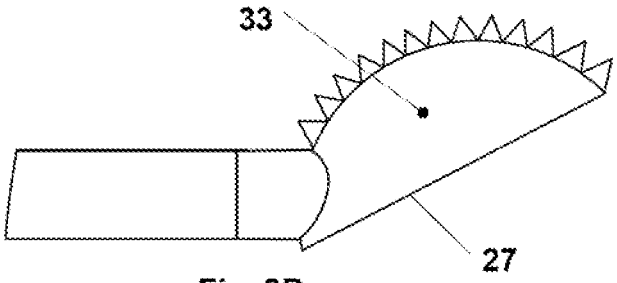

Fig. 9D

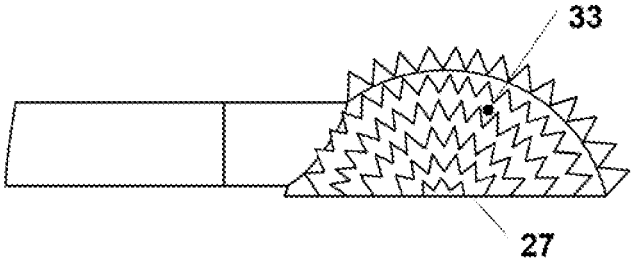

Fig. 9E

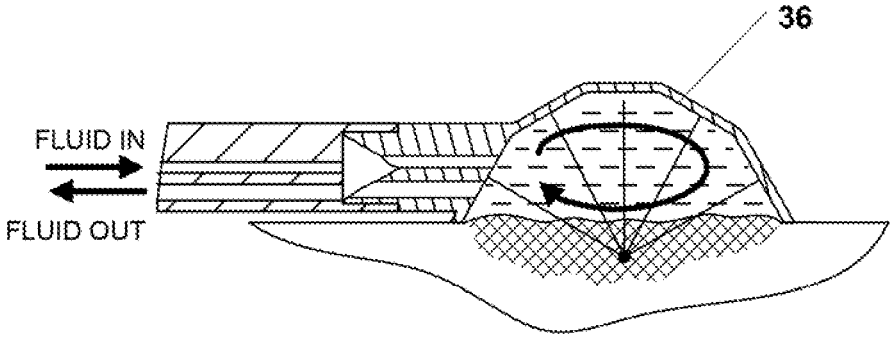

Fig. 10