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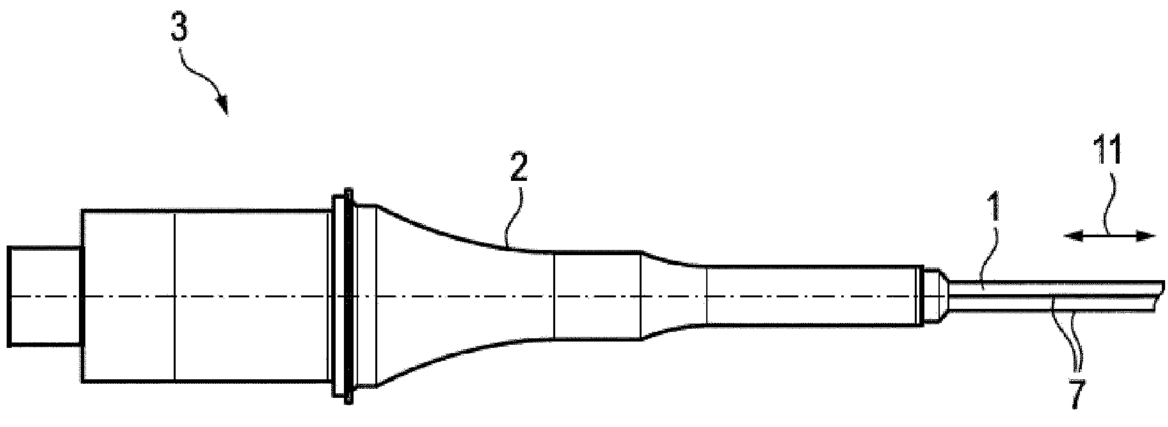

Fig. 3

(57) Abrégé/Abstract:
The invention resides in the field of medical technology. It relates in particular to a sonotrode suitable for use with an ultrasonic surgical instrument. The invention refers further to an ultrasonic surgical instrument for cutting or punching bones, comprising such a sonotrode as well as a method for manufacturing the sonotrode of the invention.

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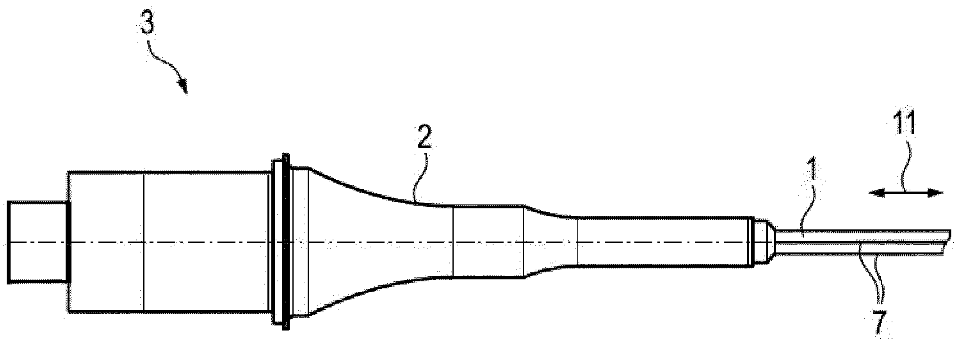

Fig. 3

(57) Abstract: The invention resides in the field of medical technology. It relates in particular to a sonotrode suitable for use with an ultrasonic surgical instrument. The invention refers further to an ultrasonic surgical instrument for cutting or punching bones, comprising such a sonotrode as well as a method for manufacturing the sonotrode of the invention.

WO 2020/182836 A1

DEVICE FOR PUNCHING BONE

FIELD OF THE INVENTION

The invention resides in the field of medical technology and concerns a device for punching or stamping out hard tissues such as bone tissue. It relates in particular to a sonotrode suitable to be used with an ultrasonic surgical instrument.

BACKGROUND OF THE INVENTION

Among the cutting devices for cutting bone tissue, ultrasonic instruments are particularly efficient. The present invention relates to a surgical instrument for removing bone with a shaft that extends in a longitudinal direction, which at its distal end carries a sonotrode, having a distal end piece being equipped as a stamp or a blade for penetration of bones using mechanical vibration.

Surgical punches are used, for example, in autologous chondrocyte transplantation (ACT), see DGU Mitteilungen und Nachrichten 45/2002 1, "ACI und Tissue Engineering" under the auspices of the DGU and DGOOC. A laminectomy or laminotomy are surgical procedure using bone punches to remove a portion of the vertebral bone called the lamina, which is the roof of the spinal canal. Punches of this kind, also called KERRISON Bone Punches, are sold by the company Aesculap®, Tuttlingen, Germany. Nevertheless, these are not using oscillation for cutting the bone.

Another area of application for a bone punch could be arthroscopic treatments. Over the past time, arthroscopy has become one of the most popular orthopedic surgery technics, making it possible to conduct even a very complex surgery without opening a joint. Arthroscopic surgeries are widely supported by constantly improved medical devices and instruments. Today's medicine allows for using arthroscopy not only for bigger joints, like a knee or shoulder, but it is also successfully used for small joints like a wrist or ankle. One small incision is made for introduction of a camera and thus viewing the joint and the device. Additional small incisions at different points around the joint allow the surgeon to insert surgical tools to grasp, cut, grind and provide suction as needed for joint repair. Common blades for arthroscopic surgery consist of an outer hollow sheath and an inner hollow rotating cannula with corresponding windows for suction and cutting. A coating that works as a lubricant should prevent and reduces the release of metal debris when using this rotating blades against a hard surface. One complication known is heat injury to the surrounding structures. The risk is higher with a practice of re-use, because blunt blades increases the risk of heat injury and infection. Therefore most modern instruments are for single use only.

WO 2013/057179 discloses a sonotrode for a surgical instrument. The sonotrode head serves as cutting device extending in a longitudinal direction. These sonotrodes have a planar blade body, with a longitudinal cutting edge.

WO 2008/131884 concerns a punching device for preparing a recess in a bone. The punching device has a punching tool that is an elongated member with a thin-walled portion that has a non-rotational symmetric cross section.

EP 1 987 784 B1 refers to implants to be inserted into a bone, being adapted to be used as a punching tool and to a method for preparing a recess in bone. Here the sonotrode is coupled to a punching tool having a thin walled portion and serving as an implant.

Sonotrodes for an ultrasonic surgical instrument being hollow or having a distal cutting edge corresponding to the contour of a tissue area that is to be punched out and being suitable for punching out tissue areas from bone are not known.

Bone punches, on the one hand need to be equipped to cut through very dense and strong cortical bone tissue, and this at different angles (because of different access situations). On the other hand, cutting devices need to be capable of cutting deep into for example cancellous bone tissue.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved sonotrode for an ultrasonic surgical instrument suitable for punching out tissue areas, as well as an ultrasonic surgical instrument therefor, comprising an improved sonotrode and methods for manufacturing these sonotrodes. One goal to be achieved by the improved sonotrodes is a better cutting performance for cortical bone. Cortical bone is dense and compact. Thereby the reduction of heat produced during cutting of bones is envisaged. In addition, it would be favorable to be able to use a sonotrode having a distal cutting edge which corresponds to the contour of a tissue area that is to be punched out. This may be a hollow blade or a sonotrode with a long, curved cutting edge. One problem for such sonotrodes are bending movements such as oscillations out of plane which have to be avoided. At the same time a thicker blade of the sonotrode should be avoided.

A first aspect of the invention relates to a sonotrode for an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration. The cutting edge of the punch can be located in a plane perpendicular to the longitudinal axis of the tool carrier. Alternatively, the distal end portion of the stamp may be cut slantwise. Thus the cutting edge of the punch is located in a plane that forms an angle with the longitudinal axis of the tool, wherein the angle has to be chosen in a way that the difference between the maximum and the minimum length of the blade is less than 10% of the length of the resonator (the effective length of the vibrating part). Said difference between the maximum and the minimum length of the blade should be so small that no relevant difference in amplitude results.

In many embodiments, therefore, the sonotrode has towards its distal end the shape of a tube (of round or non-round cross section; forming a hollow sonotrode), with the distal edge of the tube forming a cutting edge for stamping out tissue. The distal cutting edge may especially form a closed contour.

The cut may also have a parabolic shape.

An oblique cut at the distal end portion of the sonotrode is a favorite embodiment for sonotrodes used to penetrate the cortex of a bone. The oblique cut is further suitable for methods comprising punching out bone using only a part of a cutting edge of a hollow sonotrode. This method can be used to achieve predetermined geometries within the bone. Thus, the sonotrodes are suitable as shaver blade and as full radius resectors.

The term “proximal” as used herein refers to the nearest to the point of attachment to the housing of an ultrasonic surgical instrument or respectively to the user of that instrument. The term “distal” as used herein refers to being situated away from the point of attachment to the housing of an ultrasonic surgical instrument or respectively to the user of that instrument. The distal edge is used to punch or cut the bone. Thus, the distal end and the proximal end are opposite ends. An alternative formulation of the above embodiment is the following: a sonotrode for an ultrasonic surgical instrument, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch or blade with a distal edge being suitable for punching bone. The distal end piece of the sonotrode according to the first aspect is able to be forced through a bone or into a bone to create a hole. Thus means using the sonotrode according to the invention one can cut or stamp a closed curve/closed contour into a bone. For cutting this curve only one cut or cutting step is necessary.

One embodiment of the first aspect of the invention refers to a sonotrode, wherein the distal end piece comprises a blade whose distal cutting edge corresponds (entirely) to the contour of a tissue area that is to be punched out.

According to the invention, the sonotrode comprises a head, and a distal end piece having a longitudinal axis, wherein the distal end piece is a puncturing device for penetrating into a bone. The distal end piece or the puncturing tool is arranged at said head of the sonotrode, said puncturing tool being a punch or a hollow knife. The head and the distal end piece should be oriented in a way having a common longitudinal central axis.

Another embodiment of the first aspect of the invention refers to a sonotrode, wherein the distal end piece or the blade is designed as a hollow body being open at its distal end. Thereby, in embodiments, the hollow body is not rotationally symmetric. The hollow body may have the form a hollow cylinder, wherein the cross section of the cylinder is a closed curve. The cross section may be round, oval, elliptic, polygonal. A preferred embodiment refers to a sonotrode, wherein the hollow body is a hollow elliptic cylinder, in particular a hollow elliptic cylinder being open at its distal end.

The term “oval shape" or “oval” as used herein refers to a two-dimensional shape being similar to an egg or an ellipse. It also refers to a figure that resembles two semicircles joined by a rectangle. Differentiable, not self-intersecting, convex, closed, plane curves are oval.

For cutting deeply into bone the sonotrode should be longer. But the longer the sonotrode, the higher is the risk of torsion movement. The inventors found that a sonotrode having at least two ribs such as reinforcing ribs, avoids torsional bending and buckling. The ribs may be located on either of the different sides (i.e., they may be inward facing and/or outward facing) and may be symmetrically arranged, in fact axisymmetric to the central axis.

The present invention refers further to a sonotrode, wherein the distal end piece or the blade is designed as body having at least a distal part being hollow wherein the distal end (front end) is open and builds a cutting edge. In accordance with a further embodiment, the sonotrode body can be configured as a hollow body (preferably a hollow cylinder) over approximately 80% of its longitudinal extent and preferably over at least the distal half of its longitudinal extent. An alternative embodiment refers to a sonotrode being solid but having a distal end piece being hollow. In this case the distal end piece may represent only up to 10 percent or even up to 5 percent of the length of the sonotrode.

A sonotrode according to the first aspect may have a stop. The stop can be provided at the distal end piece or at the proximal head of the sonotrode or at both parts. By the provision of a stop that limits the longitudinal movement to a maximum, it is possible, to avoid cutting into underlying tissue not to be punched out.

Another embodiment of the first aspect of the invention refers to a sonotrode, wherein the sonotrode has at least one longitudinal rib. In this context, a longitudinal rib is a rib that extends along a blade-like portion of the sonotrode, for example along a tube portion if the towards the distal end is tube-like. In this, the longitudinal rib extends along a generally longitudinal direction meaning that is not perpendicular to the longitudinal axis but is for example parallel thereto or at a preferably small angle (of less than 45°, less than 30° or less than 20°) thereto so that it stiffens the sonotrode or at least its blade-like portion with respect to bending forces away from the axis or to torsional forces. In case the blade-like portion is bent (i.e. it is different from plane, which is the case in many embodiments, especially, of course, if the blade-like portion is tube-kike), such reinforcing rib may be arranged on an interior side and/or on an exterior side. Because such rib protrudes away from a (local) blade plane, it is also called "lateral rib" in the present text.

Such rib may extend along a substantial length of the sonotrode, for example along at least 50% of its blade-like portion (i.e. along at least 50% of the axial length of the portion where the sonotrode is flat and thin, for example in the manner of a tube). It may extend to its distal end or may taper off towards the distal end.

Especially if the blade-like portion of the sonotrode (for example hollow, i.e. tube-like sonotrode) is comparably long, it may be advantageous if the center-of-mass line coincides with the longitudinal axis (i.e. in a cut perpendicular to the longitudinal axis, the center of mass/center of gravity is on the longitudinal axis). To this end, the blade-like portion may have a plurality of the ribs, which are arranged symmetrical with respect to the longitudinal axis.

In embodiments that have a more complicated sonotrode geometry, for example by having a cross section as illustrated in Fig. 7 described hereinafter, with a plurality of center-of-gravity-lines, these may be symmetrical with respect to a central longitudinal axis. The arrangement of ribs will be chosen correspondingly, for example by being mirror symmetric. More in general, the sonotrode may be designed to have, in section perpendicular to the longitudinal axis, a mirror symmetry or an n-fold symmetry.

In view of this, especially, in embodiments the sonotrode has at least two lateral ribs running along a longitudinal axis of the sonotrode. These ribs may also be called reinforcing or stiffening ribs. One embodiment of the first aspect of the present invention refers to a sonotrode, wherein the sonotrode has at least one lateral rib inside of the hollow distal end piece or the blade and a second lateral rib outside of the hollow distal end piece or the blade. Another embodiment of said aspect refers to a sonotrode, wherein the sonotrode or respectively the distal end piece of the sonotrode has at least two lateral ribs on each side. Alternatively, the sonotrode may have two lateral ribs being located outside of the hollow distal end piece or blade or two lateral ribs being located inside of the hollow distal end piece or blade. The sonotrode may also have four lateral ribs being located outside of the hollow distal end piece or blade and/or four lateral ribs being located inside of the hollow distal end piece or blade. Each rib or fin may be radially upstanding to a constant height above the blade or distal end piece. It is further preferred that two ribs are located in a way that they protrude from the same point of the circumference, one stands up inside and one outside of the hollow distal end piece or blade. It is generally preferred that the ribs are arranged symmetrically. The ribs may be located at the points where the minor axis and the major axis of an elliptic or oval cross section cuts the circumference of the hollow distal end piece.

The ribs are present along the sonotrode and/or respectively the distal end piece having a longitudinal, hollow form, for example by being attached to a body thereof. It is preferred that the at least two ribs run along the central axis of the sonotrode. It has been found to be advantageously that the at least two ribs run along the head and the distal end piece. Nevertheless, the at least two ribs may run only along the distal end piece of the sonotrode. The ribs are preferably solid. The ribs may have a semicircular or angular cross section. The ribs may be continuous. They may have a high and/or a width of 0.05 mm to 0.5 mm. In other words the high and/or a width of the ribs is between 20 – 100% or even better between 25 – 80 % of the width of the blade. By adjusting the high of the ribs, the resonance frequency can be adjusted. The resonance can be change in a way to differ from the working frequency. Thus, the operating frequency with load can vary in a bigger range (while maintaining the axial vibration).

It is preferred that the ribs have no sharp edges and that the transition of the ribs to the distal end piece or the blade is smooth. Therefore it is preferred that the transition between the ribs and the blade/distal end piece surface is continuously or in form of a curvature.

Another embodiment refers to a sonotrode, wherein the at least two ribs have a flattened distal end. Also the proximal end may be flattened. In this case the flattening out at the proximal end may be steeper than at the distal end. The ribs on the sonotrode do not have to have the same length than the sonotrode or the distal end piece of the sonotrode. One embodiment of the invention refers to a sonotrode, wherein the ribs run only along the distal end piece of the sonotrode. Another preferred embodiment of the present invention refers to a sonotrode, wherein the distal end of the at least two ribs lies in the middle third of the length of the distal end piece or blade.

The extent of the distal end piece in the longitudinal direction can lie between 10 mm and 80 mm, preferably between 15 mm and 30 mm. The largest diameter of the distal end piece can for example lie between 3 mm and 20 mm, preferably between 5 mm and 10 mm. The sonotrode including the blade may have a length of 20 to 300 mm, preferably of 150 to 250 mm.

A sonotrode according to the first aspect of the invention is particular suitable for working axial. It allows to cut or abrade in corners or foramina of bones. One preferred use is cutting osteophytes to get decompression of the spine.

The extent of the blade of a sonotrode according to the first aspect in the longitudinal direction can for example lie between 15 mm and 50 mm, preferably between 18 mm and 30 mm. The maximal extent of the blade in the transverse direction can for example lie between 3 mm and 35 mm. The extent in the transverse direction is regularly less than the extent in the longitudinal direction. The depth perpendicular to the longitudinal direction and the transverse direction can likewise lie between 1 mm and 30 mm. The sonotrode may have a length of 20 to 300 mm, preferably of 50 to 250 mm, and more preferably of 100 to 200 mm.

The sonotrode of the invention may be connected to an ultrasound transducer of a surgical instrument. The instrument can be provided with a feed line through which a liquid can be supplied to the sonotrode. Additionally, or as an alternative thereto, the feed line can be embodied such that a liquid is routed along the sonotrode on the outside and/or the inside.

The sonotrode of the invention may further comprise a sleeve with a window which allows that only a part of the distal end of the sonotrode protrudes out of the sleeve.

The sleeve may be located around the sonotrode and may be connected to the housing or handle of the ultrasonic instrument. It is preferred that the sonotrode is symmetrically attached within the sleeve. The sleeve may have a window at the distal end so that only a part of the sonotrode protrudes out of the sleeve and preferably only a part of the cross section of the distal part protrudes out. This part can be used to punch out bone. The sleeve may further be arranged in a way that it can be rotated around the sonotrode. In embodiments, the angular position of the sleeve relative to the sonotrode body can be adjusted using a scale or can be determined using a scale. The scale may be attached to the housing. By rotation it is possible to used different parts of the distal cutting edge of the sonotrode, wherein the other parts are protected. This allows to cut bone using different parts of the sonotrode and at the same time shielding other parts not be used, so that no damage is caused within surrounding tissue by parts of the sonotrode not used. The window of the sleeve may formed to shield at least the half of the sonotrode cross section at the distal end of the sonotrode. The cross section of the sleeve may be round or may be adapted to the cross section of the sonotrode. This means the cross section may have the same form as the cross section of the sonotrode but may be a (little bit) larger.

When perforating or punching bone, there are several possibilities to dispose the removed bone fragments. One possibility is to impact the cut dense bone core into the underlying trabecular bone which is compacted so that the bleeding can be impaired. The fragments may further be aspirated or removed by special devices. Using the devices according to the present invention the bone may alternatively be removed as one bone core or fragment and not as debris. This bone core may remain within the distal end of the sonotrode. In the following the bone core may either be removed to the outside and flush away from the operation side together with the blood etc. or it may be sucked further into a space of the sonotrode and stored until the device of the invention will be removed from the operation side. In this case the sonotrode may be a disposable article which is removed from the device and through away after each surgery together with the extracted bone. This makes a laborious cleaning of the device redundant. There is no bone debris which may obstruct a liquid supply or a suction device and has to be pushed away.

In all embodiments that comprise removing bone tissue, the bone tissue may optionally be used for diagnostic purposes or, depending on where it has been removed from and from its condition, also for therapeutic purposes.

In special embodiments, the sonotrode further comprises an at least one interior blade arranged in an interior of a hollow body of the sonotrode. By this at least one blade, the bone piece may be broken up (sliced) into fragments so as to be easier to be removed. In a sub-group of these special embodiments, a plurality of interior blades may be arranged in a staggered arrangement. Thereby, the required energy input may be spread over time when a particularly hard bone piece (for example cortical bone tissue) hast to be cut into smaller fragments.

One objective of the invention is to provide a device suitable to reduce the blockage by bone debris within the instrument. The invention refers therefore to a device, wherein the sonotrode or the housing comprises a void space suitable for storage of removed bone fragments. Another embodiment of the invention refers to a device, wherein the sonotrode and/or the housing comprises a pipeline suitable for liquid supply to the distal cutting edge or applying vacuum to the sonotrode. Using the liquid supply it is possible to remove the bone core from the sonotrode and the vacuum is suitable to support retaining the bone core within the opening.

There may be specific elements located interior of the sonotrode that facilitate the breakage of the bone core after cutting into the dense bone. Such elements may be interior ribs, for example of the above-discussed kind serving for stiffening. For example, if such ribs follow a helical path, the sonotrode will exert a torque on the bone tissue within the interior of the sonotrode, and this may ease separation from underlying bone tissue portions. Similarly, if such interior rib is longitudinal (runs in axial direction), a twist on the sonotrode exerted by the operator (surgeon) may have a similar effect. Consequently, another aspect of the invention refers to a device, wherein the sonotrode comprises protruding elements, such as ribs, on the inner surface suitable to exert torsion force to the cut bone.

One field of application for sonotrodes according to the present invention is spinal surgery. The synovial joints between the superior and inferior articular processes on adjacent vertebral bodies are termed the facet joints. Each vertebra contains two facet joints. These joints allow for spine mobility, such as bending forward, standing straight, and rotating left and right. Facetectomy is a surgical procedure which may be a part of an array of procedures, such as decompression when the cervical nerve roots within the intervertebral foramina are decompressed or instrumented posterior lumbar interbody fusion (iPLIF) and transforaminal lumbar interbody fusion, a common spinal fusion surgical technique. Facetectomy is also performed to more clearly define the bony anatomy for placement of pedicle hooks and thoracic pedicle screws.

So far the facetectomy has been conducted using a semilunar-shaped osteotome (or quarter-inch osteotome), identify and outline the inferior articular facet. Once the edges are outlined, bone and cartilage are removed with a curette and a rongeur. Then a small curette is used to scrape off the remaining articular cartilage of the facet joint so that bleeding bony surfaces arise. Using a sonotrode according to the invention having a trapezoid cross section adjusted to the form of the bone fragment to be removed and having a rough surface, only one instrument is sufficient and only one or two cuts are necessary for facetectomy. Therefore one embodiment refers to a sonotrode for an ultrasonic surgical instrument being suitable for facetectomy (partial or complete) or laminectomy, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones, respectively the facet joint, using mechanical vibration, wherein the distal end piece or the blade is designed as a hollow body being open at its distal end. It is preferred that the distal end piece comprises a blade whose distal cutting edge is trapezoid and corresponds to the contour of a bone (and cartilage) to be punched out during facetectomy.

Another aspect of the invention refers to a method performing facetectomy comprising the following steps:
- Exposing of an affected facet joint,
- Removing the affected facet joint, and optionally
- performing one further action such as a microdiscectomy or discectomy, a laminotomy or laminectomy, a foraminotomy or a foraminectomy, or a spinal fusion, wherein an ultrasonic surgical instrument with a sonotrode of the invention is used, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of the facet joint, using mechanical vibration, wherein the distal end piece or the blade is designed as a hollow body being open at its distal end which has a trapezoid distal cutting edge is trapezoid corresponding to the contour of bone (and cartilage) to be punched out during facetectomy. It is preferred that only one or two cuts of the instrument are sufficient for removing the facet joint and that no other instrument is required for the step “removing the affected facet joint”.

Another spinal surgery the sonotrodes according the invention are useful is artificial disc replacement which is a procedure that replaces the damaged or degenerated cervical discs in the spine. Instead of fusing the vertebra together to prevent back pain, the damaged cervical disc is removed and replaced with an artificial one. It is preferred that the sonotrode used is a sonotrode for an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration, wherein the distal end piece comprises a blade whose distal cutting edge has a rectangular cross section being designed as a hollow body being open at its distal end. It is preferred that the distal end has further structures attached at its contour which corresponds to inclined teeth which may be part of the disc replacement implants.

Another aspect of the invention refers to a method for disc replacement comprising the following steps:
- Removing a disc
- Cleaning the vertebra
- Optionally relieving pressure from root nerve and
- Inserting an implant, in particular a disc replacement device, wherein an ultrasonic surgical instrument with a sonotrode of the invention is used, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration, wherein the distal end piece comprises a blade whose distal cutting edge has a rectangular cross section being designed as a hollow body being open at its distal end. It is preferred that the distal end has further structures attached at its contour which corresponds to inclined teeth that may be part of the disc replacement implants.

A second aspect of the invention relates to a sonotrode for an ultrasonic surgical instrument having a head and a distal end piece, the distal end piece being equipped as a blade for cutting bones using mechanical vibration, wherein the blade is arched. The arched or crescent shape of the blade may be symmetrical to the longitudinal axis defined by the middle axis of the sonotrode head. In addition, the tangent that touches the curve of the blade in the point where the curve cuts the longitudinal middle axis of the sonotrode head built an acute angle of at least 5° with the tangent that touches the curve in the outermost point.

The second aspect of the present invention refers preferably to a sonotrode, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch for penetration of bones or a blade for cutting and the distal end piece has a maximal diameter being at least one and a half times the size of the diameter of the head. It is preferred that the distal end piece has a maximal diameter being at least two times and even more preferred at least three times the size of the diameter of the head.

The blade may be mainly rectangular. Nevertheless, the blade or the distal end of the blade may be curved or bent. One embodiment of the present invention refers to a sonotrode, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch for penetration of bones or a blade for cutting and the distal end piece or the cutting edge of distal end piece or respectively of the blade has a form being different from the form of the first sonotrode and having a larger diameter. It is preferred that the sonotrode according the invention has a curved blade or punch. A particular embodiment of the invention refers to a sonotrode, wherein the distal end piece comprises a blade having a distal cutting edge with a form corresponding to the contour of a tissue area that is to be punched out. The cutting edge may even entirely correspond to the contour of a tissue area that is to be punched out.

The head of the sonotrode according to second aspect of the present invention is preferably formed as a (solid) circular cylinder but the blade is a rather thin part. One possibility to adapt the distal end of the head to the proximal end of the distal end piece is to include a flattening area at the distal end of the sonotrode head. Therefore, one embodiment of the invention refers to a sonotrode wherein the head has a flattened distal end. Another possibility to adapt the distal end of the head to the proximal end of the distal end piece is to include an intermediate element. One embodiment of aspect three refers to a sonotrode, wherein the distal end piece comprises an intermediate element (between sonotrode head and blade).The intermediate element may also widen the diameter from the head to the diameter of the blade. The intermediate element and the blade may be made separately or may be one piece.

One embodiment of the invention, therefore, refers to a sonotrode, wherein the intermediate element comprises through holes. These holes may have the form of slits or elongated recesses running parallel to the longitudinal direction of the sonotrode or perpendicular to the cutting edge. The recesses may be trough-holes.

The intermediate element is preferably an oscillating body which can oscillate with adapted impedance at the frequency of the sonotrode and can in this manner relieve the mount of oscillations or can keep it almost fully free thereof. The recesses of the oscillating body can in this respect serve to adapt the resonant frequency of the oscillating body to the frequency of the sonotrode.

The distal (cutting) end of the blade may be flattened or sharpened. Thus, one embodiment of the invention relates to a sonotrode for an ultrasonic surgical instrument having a head and a distal end piece, the distal end piece being equipped as a blade for cutting bones using mechanical vibration, wherein the blade has a sharpened distal edge as cutting edge. In another embodiment of the sonotrode according to the third aspect the corners of the distal edge are not rounded but sharp and serves as cutting edge.

A sonotrode for an ultrasonic surgical instrument having a head and a distal end piece, may be equipped with a blade having a lateral depression.

Especially, the sonotrode may comprise a distal rim being a distal outward protrusion extending along the cutting edge, for example circumferentially along the cutting edge.

Thereby, an outer cross section of the sonotrode proximally of the rim is smaller than an outer cross section of the rim. In embodiments, therefore, a sonotrode for an ultrasonic surgical instrument having a head and a distal end piece is suggested, the distal end piece being equipped as a blade for cutting bones using mechanical vibration, wherein the blade has an area of reduced thickness proximally of the distal end. The depression or central area of reduced thickness may optionally by rectangular in cross section. The depression or central area of reduced thickness may encompass 50 – 90 % of the surface of the blade. Thus, the sonotrode may comprise a blade having a rim surrounding the depression or central area of reduced thickness. The width of said rim may be 0.3 to 1.5 mm. One embodiment of the first aspect of the invention refers to a sonotrode wherein the lateral depressions have the same depth and are symmetrically arranged within the blade. The blade or the rim around the depression may have a constant or unvaried thickness. It is possible that the blade of the sonotrode as well as the sonotrode is symmetrically build.

Another embodiment of the first aspect of the invention refers to a sonotrode, wherein the lateral depressions have each a depth of 0.2 to 5 mm and preferably of around 0.1 mm. This means the blade has an area (which may be central with respect to the axial dimension, which means that the thickness is larger proximally as well as distally of this area) where the thickness is reduced. It is preferably reduced about 0.5 to 10 mm and more preferred the thickness is reduced about 0.2 mm. Another embodiment of the first aspect of the invention refers to a sonotrode, wherein the blade of the sonotrode has rim surrounding the depression or the central area of reduced thickness and further has a groove running parallel to that rim. In other words the depression or the central area of reduced thickness of the sonotrode blade is bound by a rim and a groove inside that rim. The groove defines a level being lower than the level of the rim and the depression. It is preferred that the depression has no sharp edges and that the transition of the rim to the depression or the groove is smooth. Therefore it is preferred that the transition between the rim and the surface of the groove or respectively the depression is continuously or in form of a curvature. In case that the transition is curved, it is possible to create a defined but stable cutting edge.

Furthermore, the area of reduced thickness of a sonotrode according to the first aspect may have an elevated structure. This structure can comprise ribs running parallel to each other and preferably parallel to the longitudinal axis of the sonotrode blade. The ribs may also be arranged to form a grid or regular mesh. It is preferred that the cross section of the elevated structure and in particular of the at least one rib is selected in a way that the structure (or rib) does not protrude above the rim of the blade surrounding the depression. The ribs increase the stiffness of the blade and respectively the sonotrode. Nevertheless the friction is lowered and the cooling capacity is still improved. Alternatively to ribs the elevated structure may also be formed by cubes, cuboids, frustums of pyramid, cylinders (right circular cylinder, oblique circular cylinder) or of n-gonal prisms where n is between 3 and 16.

In order to reduce the torsion of the sonotrode the elevated structure in form of ribs may be oblique to the longitudinal axis of the blade. It may be preferred that the ribs form an angle with the longitudinal axis of the sonotrode or the blade of 10° to 60° or of 30 to 60 °. These ribs being oblique may be crossed and thus form a grid. The distance between the ribs may be between 0.2 and 0.7 mm. The distance between the elevated structures may also be formed by cubes, cuboids, frustums of pyramid, cylinders (right circular cylinder, oblique circular cylinder) or of n-gonal prisms where n is between 3 and 16 may be between 0.2 and 1.0 mm. The height of the elevated structures is preferably between 0.1 and 0.5 mm.

Another embodiment of the first aspect of the invention refers to a sonotrode, wherein the blade of the sonotrode has channels running from the area of the depression to the edge of the blade. In other words there are channels or grooves running from the area of reduced thickness to the edge of the blade. The channels or grooves may have the same deep than the depression. It is preferred that the channels or grooves are present on each lateral side of the blade. The channels may be at corresponding position on each side or are staggered. It is preferred that the channels or grooves are open towards the surface of the blade. Therefore, they can have a semicircular or edged shape. The channels or grooves may be arranged towards the cutting edge only. They may also run towards the distal end. There may also be embodiments wherein the channels and grooves are arranges symmetrically around the depression or area of reduced thickness. There may be between 5 to 10 channels or grooves per lateral side of the blade.

The extent of the blade in the longitudinal direction can lie between 15 mm and 40 mm, preferably between 18 mm and 30 mm. The maximal extent of the blade in the transverse direction can for example lie between 20 mm and 75 mm. The extent in the longitudinal direction is regularly less than the extent in the transverse direction. The depth perpendicular to the longitudinal direction and the transverse direction can likewise lie between 1 mm and 30 mm. One embodiment of the invention relates to a sonotrode, wherein the blade of the sonotrode has a length of 15 to 40 mm. The sonotrode (including the intermediate element and the blade) can have a length of 20 to 300 mm, preferably of 150 to 250 mm. The distal end of the sonotrode may be rounded. This means that the corners of the rectangular blade are rounded. Thereby it is preferred that the radius of circular arcs forming the edges is < 0.5 mm.

The following issues refers to all sonotrodes according to the invention (not to one aspect only):

The sonotrode may belong to a surgical punching device that further has a tube encompassing the sonotrode. In a space between the sonotrode and the tube, a liquid for cooling and/or rinsing may be transported to the distal cutting edge or possibly also away from it.

The ultrasonic system may be any conventional system and will typically comprise a press and a vibrating acoustic element consisting of an emitter, an amplifier and a sonotrode supplied by a high-frequency generator. Longitudinal vibrations in frequencies between 20 kHz and 40 kHz with tool amplitudes between 5 µm and 50 µm are introduced into the bone under the action of force. Ultrasonic vibrations may be focused by means of special design of the components or tools.

A sonotrode according to the invention may comprise a shaft being part of the sonotrode head. A connection to the ultrasound transducer can be established via the proximal end of the shaft. The shaft is preferably aligned in the longitudinal direction of the distal end piece. The shaft forms the proximal end of the sonotrode head; the distal end is situated opposite thereto. For connection of the sonotrode according to the invention the shaft may comprise or be built by a thread. Therefore, one embodiment of the invention refers to a sonotrode wherein the head has a thread at its proximal end. In addition the head of the sonotrode and the distal end piece respectively the blade are formed together as one piece or are rigidly attached to each other. Therefore the distal end of the sonotrode head may have the same cross section as the proximal end of the distal end piece or respectively the blade or a cross section adapted to the proximal end of the distal end piece. The inventors found that sonotrodes made by additive manufacturing methods, in particular using sintering (such as selective laser sintering) have some surprising advantages. The ultrasonic surgical instrument according to the invention is regularly equipped with a line by means of which a rinsing liquid (e.g. water) can be supplied to the operating field. The surface structure generated using the afore-mentioned method of manufacturing increases the cooling efficiency by that liquid. One explanation could be that the surface structure provide for and maintain a proper liquid film on the surface of the sonotrode blade. It seems that on possible effect is that pockets created by the sintering process, which are not open to the side provide for a hydrostatic cushion.

One embodiment of the present invention refers to a sonotrode, wherein the surface of the sonotrode or the surface of the distal end piece has convex microstructures. Said microstructures are curved or rounded outward like the exterior of a sphere or circle. Another embodiment of the present invention refers to a sonotrode, wherein the surface of the sonotrode or the surface of the distal end piece has a roughness average R_a between 5 – 20 µm. Thereby surface roughness as a component of surface texture is quantified by the deviations in the direction of the normal vector of a real surface from its ideal form. The arithmetic average roughness, R_a is the arithmetic average value of filtered roughness profile determined from deviations about the center line within the evaluation length and the most widely used one-dimensional roughness parameter.

Due to the surface roughness resulting from the sintering process there are point contacts between the distal end piece and the bone. Thus a higher energy density occurs. However, the convex surface portions which arise by the grain size distribution are more stable than for example roughness structures made by sandblasting.

Consequently, one embodiment of the present invention relates to a method for manufacturing a sonotrode as defined herein, wherein the sonotrode is manufactured by using additive manufacturing method. Direct Metal Laser Sintering (DMLS) is such an additive manufacturing process suitable to be used to produce the sonotrodes according to the invention. Thereby the sonotrodes or at least the distal end pieces are built using a laser to selectively sinter (heat and fuse) a powdered metal material into layers.

An alternative method suitable for manufacture of the sonotrodes or distal end pieces thereof is shot blasting or respectively shot peening. Sandblasting is less suitable. The surface structure resulting from the sintering process of metal grains cannot be entirely described by parameter such as roughness and grain size. Nevertheless, this particular surface structure has to be proven to be advantageously. Therefore, the present invention refers to a sonotrode according to the invention, wherein the sonotrode or at least the distal end piece of the sonotrode is manufactured using additive manufacturing method such as direct metal laser sintering. In particular, the present invention refers to a sonotrode for an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration, wherein the sonotrode or at least the blade of the sonotrode are manufactured using an additive manufacturing method such as direct metal laser sintering. The powder to be used may have an average particle diameter of 40 – 80 µm. In addition, the present invention refers to a sonotrode for an ultrasonic surgical instrument, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch for penetration of bones or a blade for cutting and the distal end piece has a maximal diameter being at least one and a half times the size of the diameter of the head, wherein the sonotrode or at least the blade of the sonotrode are manufactured using an additive manufacturing method such as direct metal laser sintering. The method may further comprise one or more steps of heat treatment. It is preferred that the surface as resulted due to the additive manufacturing is not smoothed (evened or polished). It is further preferred that the sonotrode made using additive manufacturing may be undergo heat-treatment but no smoothing procedure (smoothing of the surface).

The invention refers further to an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, comprising a hand-piece containing an ultrasonic transducer and a sonotrode as defined herein being mechanically coupled to said transducer.

The term “ultrasonic surgical instrument” as used herein refers to a surgical instrument with an ultrasound transducer. This ultrasonic surgical instrument of the invention comprises a sonotrode as described herein being connected to the ultrasound transducer. The ultrasound transducer may comprise a piezoelectric element, by means of which a high-frequency AC voltage is converted into a corresponding mechanical vibration. By way of example, the frequency of the vibration can lie between 20 kHz and 40 kHz.

Preferably, the ultrasound transducer or the housing of the ultrasonic surgical instrument of the invention and the head of the sonotrode (via the shaft of the head) are coupled to each other, wherein the shaft of the head is designed to transmit the vibration energy as fully as possible from its proximal end to the distal end piece or the blade of the sonotrode respectively.

Another aspect of the present invention refers to an ultrasonic surgical instrument being suitable for punching out tissue areas from bone during arthroscopy, comprising a hand-piece containing an ultrasonic transducer and a sonotrode as defined herein being mechanically coupled to said transducer. The invention refers also to a system of a sonotrode as described herein together with a common known catheter or arthroscopic tube. Either the sonotrode or the catheter/ arthroscopic tube may be attached to a hand piece. Between the sonotrode and the catheter tube or the arthroscopic tube should be a free space. This space may be 0.2 to 1 mm width. This space may be used for a liquid which can flow along the sonotrode. The liquid may be used to cool the sonotrode, to fill the joint and/or to rinse the operation side. Alternatively the liquid may be introduced through the sonotrode being hollow and the space between sonotrode and tube may be used to suck liquid and debris of the bone out of the operational side. Therefore the catheter or arthroscopic tube may have at least one feed line.

The sonotrode according to the invention, is preferably designed to be adapted to a vibration frequency, e.g. in the range of 20 to 40 kHz and for vibrating substantially longitudinally in a stationary wave with anti-node positions (positions with maximum amplitude) and at least one node position (position of minimum amplitude) between the two sonotrode ends.

A sonotrode according to the invention may comprise, in at least the most distal node position an increased cross section. The portion extending between two node positions of the sonotrode may comprise a constant cross section. Adjoining the sonotrode portion of increased cross section in the most distal node position in distal and in proximal direction are sonotrode portions of lesser cross section (larger radial clearance). Transition between the differing cross sections may comprise a step or may be a gradual transition. The cross section of the sonotrode portion on the distal side of the portion of increased cross section may be smaller than the cross section of the sonotrode on the proximal side of the portion with increased cross section. This means that radial clearance between sonotrode and catheter or arthroscopic tube is reduced in at least one distal node position of the sonotrode.

The invention refers further to a method comprising

providing an ultrasound catheter comprising a hand-piece containing an ultrasonic transducer and a sonotrode as defined herein being mechanically coupled to said transducer

inserting the catheter (or arthroscopic tube) into a joint by use of conventional arthroscopic portals, and cutting, stamping or punching out bone within the joint using mechanical vibration.

Within this method the sonotrode located in a catheter or an arthroscopic tube can be shifted or moved relative to said catheter or tube. This means the sonotrode may be moved longitudinally in respect to the catheter or the arthroscopic tube.

Preferably, the material of the sonotrode according to the invention is a metallic material, such as e.g. stainless steel or titanium. The sonotrode or at least the distal end piece thereof may be coated with titanium nitride (TiN). Thus, the present invention refers to a sonotrode for an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration, wherein the sonotrode or at least the distal end piece of the sonotrode is coated with titanium nitride and is preferably be manufactured using an additive manufacturing method such as direct metal laser sintering. In addition, the present invention refers to a sonotrode for an ultrasonic surgical instrument, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch for penetration of bones or a blade for cutting and the distal end piece has a maximal diameter being at least one and a half times the size of the diameter of the head wherein the sonotrode or at least the distal end piece of the sonotrode is coated with titanium nitride and is preferably be manufactured using an additive manufacturing method such as direct metal laser sintering.

It has been shown that the spherical microstructures on the surface of the sonotrode or respectively the blade may be deformed caused by the forces acting during the cutting or rasping of the bones. Therefore, it is preferred to coat the sonotrodes or blades to harden the surface. TiN has an ideal combination of hardness, toughness, adhesion and inertness, that will not blister, flake or chip during cutting or rasping bones.

Another advantages is an optimized distribution of heat along the length of the surface created by the TiN coating. In this manner, hot spots are avoided, and the heat distribution or dispersion along the length of the surgical cutting instrument prohibits concentration of heat at the cutting edge or tips of the convex microstructures on the surface as would occur with no coating or coating only at the cutting edge.

The TiN coating may be applied by environmentally safe, Physical Vapor Deposition (PVD) vacuum system. Some processes use low temperature arc vapor deposition to deposit the titanium nitride coating, but it could also be applied by high temperature sputtering or other well-known coating processes (electron beam heating or chemical vapor deposition (CVD)). In general, pure titanium is sublimed and reacted with nitrogen in a high-energy, vacuum environment. TiN film may also be produced on Ti workpieces by reactive growth (for example, annealing) in a nitrogen atmosphere.

The TiN coating is preferably applied as a thin coating of less than 5 μm, more preferably of less than 3 μm. The thin titanium nitride coating provides the blade with a hard outer surface with a low coefficient of friction.

Preferably, the connection between the head and the vibration generator is releasable and the sonotrode comprising the head and the distal end piece is disposable.

The ultrasonic surgical instrument according to the invention is e.g. a hand-held device wherein a handle portion thereof houses the vibration generator being supplied with the necessary energy by a battery or through a corresponding cable connecting the hand piece to a control and supply unit. The preferred frequency for the vibration is in the ultrasonic range, preferably in the range 15 and 40 kHz or between 20 and 30 kHz and of an energy sufficient for achieving an amplitude in the micrometer range for the distal end of the perforator, between 20 and 120μm or preferably between 60 and 100μm.

The device according to the invention may further comprise a cannula or a guide shaft around the shaft and sonotrode of the ultrasonic surgical instrument. Thereby transmission of vibrational energy though the instrument shaft is to be as efficient as possible and friction between the shaft and the cannula as low as possible. This can be achieved by providing, in an axial position in which the most distal node position of the shaft is situated, a region in which radial clearance between instrument and cannula is at a minimum. This is realized by the shaft of the instrument comprising, at least in the most distal node position an increased cross section, and by the through opening of the cannula portion extending form the distal end portion to beyond the most distal node position of the sonotrode comprising a constant cross section. The shaft may further comprise portions of a larger cross section at other node positions. In addition also the cannula may have regions of larger cross sections at one or more node positions. It is further preferred that the arrangement comprising shaft and cannula has polymeric sliding surfaces to minimize friction loss. These surfaces may be formed by a polymeric ring around the distal end of the shaft or the perforator, respectively its cutting tube. The polymeric ring may be made of PEEK. Alternatively, there may be a polymeric bushing attached at the inner surface of the cannula, which can also be made of PEEK. Consequently, the region or larger cross section may be formed as polymeric attachment to the cannula or the shaft. The region of larger cross section may also have a polymeric coating.

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary embodiments of device and method according to the invention are described in further detail in connection with the appended Figures.

Figure 1	shows in a schematic drawing a cross section of an exemplary embodiment of a sonotrode.
Figure 2	shows in a schematic drawing a cross section of an exemplary embodiment of a sonotrode.
Figure 3	shows the distal part of an ultrasonic surgical instrument for cutting bones comprising a piezoelectric stack located inside a housing with a sonotrode according to the invention at the tip of the housing.
Figure 4	shows a schematic drawing of an exemplary embodiment of a sonotrode.
Figure 5	shows in a schematic drawing a cross section of an exemplary embodiment of a sonotrode.
Figure 6	shows in a schematic drawing a cross section of an exemplary embodiment of a sonotrode.
Figure 7	shows in a schematic drawing a cross section of an implant which may be cut out using a sonotrode according to Figure 5 or 6.
Figure 8	shows in a schematic drawing an exemplary embodiment of a sonotrode with a slanting cut.
Figure 9	shows in a schematic drawing an exemplary embodiment of a sonotrode with a parabolic cut.

Figure 10	shows in a schematic drawing an exemplary embodiment of a sonotrode with a rim.
Figure 11	shows in a schematic drawing an exemplary embodiment of a sonotrode with a rim.
Figure 12	shows in a schematic drawing an exemplary embodiment of sonotrode within an arthroscopic tube.
Figure 13	illustrates two examples of the sonotrode (B and C) according to the invention.
Figure 14	shows a cross section of a sonotrode according to Figure 13 B located within an arthroscopic tube.
Figure 15	shows the distal part of an ultrasonic surgical instrument.
Figure 16	shows the cross section of an exemplary embodiment of a sonotrode.
Figure 17	shows the distal part of an exemplary embodiment of a sonotrode.
Figure 18	shows a longitudinal section of an exemplary embodiment of a sonotrode.
Figure 19	shows a longitudinal section of an exemplary embodiment of a sonotrode.
Figure 20	shows an exemplary embodiment of a sonotrode.
Figure 21	depicts the distal part of a further with encompassing tube.

Figures 22-24 show, in longitudinal section and bottom view, distal ends of sonotrodes with interior blades.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In all appended Figs., same reference numerals designate same elements or similar elements serving same functions.

Figures 1 and 2 illustrate each an embodiment of a sonotrode according to the first aspect of the invention. Shown is a cross section of the distal end piece 5 of the sonotrode. The distal end piece 5 is designed as a hollow elliptic cylinder being open at the very distal end by having a cylindrical body. The distal end piece can serve as a punch or hollow cutting device using mechanical vibration. Therefore the very distal end of the punch or hollow cutting device may be flattened. The sonotrode or respectively the distal end piece may have lateral ribs 7. These ribs run along a longitudinal axis of the distal end piece and face inwardly from the body.

The sonotrode of figure 1 has four ribs 7. Each rib 7 is located inside of the distal end piece. It is preferred that these ribs 7 are evenly distributed, in particular the ribs 7 are located at points where the minor axis and the major axis of the elliptic cross section cut the circumference of the cross section or respectively the surface of the distal end piece. It is also possible that the ribs 7 may each be placed at points of the circumference located half the way between the aforementioned points. Each rib 7 may be radially upstanding (radially protruding, inwardly protruding in the depicted embodiment) to a constant height above the inner surface of the distal end piece. The cross section of the ribs can vary. Here the cross section of the ribs is nearly triangular, but it may also be nearly semicircular or rectangular. Nevertheless, it is generally preferred that no sharp edges at the ribs and at the transition between rib and surface of the sonotrode body exist.

The sonotrode of figure 2 has eight ribs 7. Four ribs 7a are located inside of the distal end piece body and four ribs 7b are located outside of the distal end piece body. In case that a sonotrode has several ribs it has been shown to be advantageous that these ribs are placed symmetrically. It is preferred that the ribs 7 are located at the points the minor axis and the major axis of the elliptic cross section cut the circumference of the cross section or respectively the surface of the distal end piece. Each rib 7a may be radially upstanding (radially inwardly protruding) to a constant height above the inner surface of the distal end piece and in addition each rib 7b may be radially upstanding (radially outwardly protruding) to a constant height above the outer surface of the distal end piece. The sonotrodes according to figure 1 and 2 are suitable to be used to treat spinal stenosis in particular to trim or remove bone spurs or synovial cysts.

Figure 3 shows the distal part of an ultrasonic surgical instrument comprising a transducer, such as a piezoelectric stack 3 located inside a housing 2 with a sonotrode 1 at the tip of the housing. The sonotrode 1 has been attached to the housing 2 via its proximal end of the head. Therefore the head may have a thread or a plug-in connector or bayonet coupling or other suitable coupling structure at its proximal end. The sonotrode 1 connected to the housing may have longitudinal ribs 7. The ribs 7 may be located only on the distal end piece of the sonotrode, as an alternative to extending to the proximal head of the sonotrode as shown here. The sonotrode 1 may be a sonotrode according to figure 1 or 2 having an oval or elliptic cross section. It may alternatively have a different hollow cross section. However it is preferred that the cross section does not vary over the length of the sonotrode 1, i.e. that the sonotrode is cylindrical (in this text, generally “cylindrical” is not restricted to the shape of a rotational cylinder but pertains to any general cylinder the base of which is a closed curve. The direction of oscillation is indicated by arrow 11. The oscillation is thus a longitudinal oscillation.

Figure 4 shows a schematic side view of a sonotrode arrangement comprising a piezoelectric stack 3 (not shown) located inside a housing 2 coupled to a sonotrode according to the second aspect of the invention. The head 9 of the sonotrode may be formed as a solid rod. At the distal end of the sonotrode head 9 follows an intermediate element 8, which may be a separate part or a main body when produced one piece with the blade 5. The sonotrode blade 5 and/or the intermediate element (if present) comprises elongate holes 10 (through slits) in the direction of oscillation 11. In addition the blade 5 may be tapered towards the cutting edge 12. The width of the blade is about 5 times the size of the diameter of the sonotrode head 9. The intermediate element or the main body may have a thickness of 5 - 12 mm at the point of connection to the sonotrode head 9 which thickness tapers down to 2 -6 mm towards the cutting edge 12 of blade 5, of which the width may be between 10 - 60 mm.

The blade 5 may have a straight cutting edge 12. Nevertheless, the cutting edge is preferably formed having the contour of the area to be cut or stamped out. The intermediate element 8 is used to transfer the oscillation towards the blade and the cutting edge. The intermediate element thereby may be a booster. Alternatively, the arrangement does not comprise a separate intermediate element, but the structure thereof may be formed by a main body of the blade 5. In addition to serving as a booster or as an alternative thereto, the intermediate element or corresponding structure forming the blade main body may serve for the expansion of the width (see Fig. 5) and the transition to the form of the cutting edge.

Figures 5 and 6 each show each a schematic bottom views on the cutting edge 12 of a blade of an exemplary sonotrode according to the second aspect of the invention. Both blades are adapted to cut out (for a removal process) an implant as shown in figure 7. **Figure 7** shows a cross section of an implant to be removed with the aid of sonotrodes having blades as illustrated in figures 5 and 6. The implant is a dual-anchor with two pin-shaped anchorage portions 13 and a stabilization portion 14 situated between the two anchorage portions 13, for example as taught in WO2010/045749. It may be used as a fusion device particularly suited for fusion of a human lumbar facet joint. The blade as shown in figure 5 is formed to have the contour of one half of the implant. This means the sonotrode has to be used twice (once on each side of the implant) to stamp out the implant after being implanted and ingrown into the bone. The blade as shown in figure 6 is formed to encompass at one lateral side a slightly more than half of the contour of the implant to be stamped out. Thus, it can be ensured that there is an overlap of the cuttings, when using the sonotrodes twice, once on each side.

Figure 8 shows a sonotrode with a distal end piece being hollow and having a slanted cut. The distal end portion of the sonotrode is cut slantwise. Thus the cutting edge 12 of the punch is located in a plane that forms an angle with the longitudinal axis 40 of the sonotrode. The distance d between the maximum and the minimum length of the distal end portion or the blade is less than 10% of the length of the resonator (the effective length of the vibrating part). **Figure 9** shows a sonotrode with a distal end piece having a parabolic cut 16 at the distal end.

Figures 10 and 11 show each an axial section of alternative distal end pieces of a sonotrode. The sonotrode according to figure 10 has a rim 17, i.e. a radially outwardly protruding feature that is for example flange-like. The rim 17 at the distal end of the sonotrode according to figure 11 bounds a depression. The depression consists of a groove 19, especially circumferential groove, which runs parallel to the rim 17. The area 18 proximal to the rim 17 and the groove 19 is elevated in regard to the groove 19 but low-rise compared to the rim 17, i.e. the outer diameter of the section 18 proximally of the groove is smaller than the outer diameter of the rim but larger than the outer diameter of the sonotrode at the axial position of the groove 19. The area 18 may be between 0.1 and 5 µm lower than the rim 17. The groove 19 may be between 0.2 and 5 µm lower than the area 18. The minimal depth of the area 18 is sufficient to adequately lower the friction compared to a situation in which no rim was present or in which the outer diameter proximally of the groove was the same as the outer diameter of the rim.

The rim 17 may also be formed with a curvature or parabolic. The (axial) width of the rim may be < 1mm and preferably between 0.2-0.5mm. The rim 17 runs preferably perpendicular to the longitudinal axis of the sonotrode.

Figure 12 shows in an axial section a distal part of a sonotrode 1 within an arthroscopic tube 20. The sonotrode can be moved in a distal direction relative to the tube 20. Within tube 20 is a lumen being all in all a lumen similar to a lumen as used for the optical instruments (camera) used within an arthroscopy. The sonotrode is equipped with a portion 21 of a larger cross section in a node position N. This larger cross section is caused by a ring around the sonotrode wall. This ring may be a polymeric ring or a ring made of the same material as the sonotrode.

The arthroscopic tube may comprise a supply 23 for a liquid which may be used to cool the sonotrode, to fill the joint and/or to flush the operating side of the sonotrode. The liquid should be sterile and may be physiological saline solution.

Figures 13 B and C are axial sections and show each a distal portion of a sonotrode, which is adapted to a selected vibration frequency to vibrate with a node position N. **Figure 13 A** illustrates the vibration of the sonotrode by showing the deflection in dependence on the axial position. N1 and N2 denote nodes.

An arthroscopic tube (not shown in Figs. 13B and 13C) reaches distally to cover the distal end of the sonotrode 1. The sonotrode 1 is equipped with a portion 22 of a larger cross section in the node position N. The larger cross section is caused by a bulge of the wall of the sonotrode. The bulge may be an integral part of the sonotrode wall and can be formed as a ring around the sonotrode having a square cross section (Figure 13 B). Alternatively, there may be several rectangles sitting on one cycle around the sonotrode with some space between them. These rectangles can be arranged within a consistent interval on that circle. Instead of rectangles there may also be spherical bulges attached on one circle around the sonotrode. The circle is always located in a node position N.

Figure 14 shows a cross section of the sonotrode according to Figure 13 B in the node position N1. The sonotrode 1 is located within an arthroscopic tube 20. As can be seen, four rectangle bulges causes a larger cross section of the sonotrode in the node position N. Between these bulges is space 61, which may serve as channel for a liquid (cooling/flushing). Alternatively, the liquid may flow through the lumen of the sonotrode 1 and the space 61 may be used to suck liquid and debris.

Figure 15 shows the distal part of an ultrasonic surgical instrument comprising a transducer 3 located inside a housing 2 with a sonotrode 1 at the tip of the housing. The sonotrode 1 has been attached to the housing 2 via its proximal end of the head. The device may further comprise a sleeve 24 around the sonotrode 1, which sleeve may be connected to the housing. The sonotrode 1 may be any sonotrode according to an embodiment of the present invention. In many embodiments, it is preferred that the sonotrode is symmetrical. The sleeve may have a window at the distal end so that only a part of the sonotrode protrudes out of the sleeve. Therefore the window is like a longitudinal cut starting at the distal edge and ending in a curve leveling off. Alternatively the window is a like a cut cutting away a part of the cross section from the sleeve. The window of the sleeve 24 may be formed to shield at least the half of the sonotrode cross section at the distal end of the sonotrode.

Figure 16 shows the cross section of an embodiment of a sonotrode according to the invention. This sonotrode is particularly suitable to be used during total disc replacement surgery. The sonotrode as shown in Fig. 16 may be used for preparation of a vertebral body before implantation of a disc replacement implant or artificial disc. It may also be used for removing the problematic or damaged disc and/or to clean the space between the vertebral bodies. The most commonly used total disc replacement designs have two plates. One attaches to the vertebrae above the disc being replaced and the other to the vertebrae below. The plates have an essentially planar level, side or area to come into contact with the vertebral body. Nevertheless the vertebral body are not planar. Therefore, the surgeon may cut the vertebral body. It is preferred that the cross section of the sonotrode is (essentially) rectangular or has at least one planar side. These plates may have inclined teeth for generating stability. Therefore the sonotrode may have structures 29 attached to the distal end corresponding to the inclined teeth of the plates. Alternatively the distal end piece may have a cross section including structures 29 corresponding to such teeth. The structures 29 may be ribs attached to the sonotrode having a triangular cross section or the cross section of the sonotrode may comprise triangular bulges.

It is possible that the sonotrode may optionally comprise a sleeve 24 as described for the sonotrode shown in Figure 15 and 17.

Figure 17 shows the distal part of a sonotrode 1. Around the sonotrode 1 is attached a sleeve 24. The sonotrode 1 may be any sonotrode according to an embodiment of the present invention. It is preferred that the sonotrode is located symmetrically within the sleeve. The sonotrode may have a symmetrical cross section. The sleeve may have a window at the distal end so that only a part of the sonotrode protrudes out of the sleeve. Alternatively the sleeve may be completely or partly (concerning only a part of the cross section) retractable. The part of the sonotrode protruding out of the sleeve can be used to punch out bone.

Figure 18 shows a longitudinal section of a sonotrode 1 according to the invention. It illustrates that behind a distance used for punching, structures 27 may be attached, which are suitable for rasping or scratching bone. They may further be suitable for cutting into bone by moving the sonotrode along a longitudinal direction. It is preferably possible to remove or ablate bone by back and/or forth movement (bidirectional movement in regard to the surgeon). As shown the structure 27 may comprise circumferential ribs which may have a triangular cross section or a rectangular cross section. Alternatively, these structure may be formed like spikes or may be helical.

Figure 19 shows a longitudinal section of a sonotrode 1 according to the invention having a structure 27 that is stepped, for example by being formed by several ribbons (bands) of rectangular cross section being attached around the circumference.

Figure 20 shows a further embodiment of a sonotrode suitable for the device according to the invention. The sonotrode is particularly suitable for creating a series of bone openings before being removed from the operation site, and for removal of bone tissue (in particular the complete bone fragments punched out) from the openings created using the device. Bone fragments 30 punched out of a bone opening created with the aid of the sonotrode 1 may be stored within the hollow sonotrode or a space within the sonotrode, which may be formed by an extended cross section of the sonotrode. Thus, the sonotrode may comprise a space suitable as depot for bone fragments 30 or bone debris. The sonotrode 1 may be designed as disposable item, suitable to create several bone openings within one operation side and store the resulting (stamped or punched out) bone fragments. After removal from the operation side the bone fragments may be used as sample for tests or as allogenic transplant material. The sonotrode may through away (with or without the bone fragments) or may easily be cleaned. The embodiment may be designed so that the vibration of the sonotrode facilitates transport of the bone fragments 30 and retain them within the open space.

In another embodiment the bone fragments may further be transported using hydraulic pressure. Therefore, there may be a channel within the device suppling a liquid such as water from the handle to the sonotrode. This liquid flow can be stopped or reversed to generate negative pressure. Alternatively, the liquid may be used to transport (or eject) the bone fragment out of the sonotrode. The bone fragment can be ejected into the operation side and flush away using the liquid generally used to clean the operation side (e.g. from blood). When using this alternative the liquid flow into the sonotrode is not stopped, but in the moment the sonotrode cuts into the bone the outflow of the liquid is stopped. Therefore, the pressure within the sonotrode increases and this pressure can be used to remove the bone fragment from the sonotrode. In case that a negative pressure is used to transport and store bone fragments punched out, the bone fragments are suctioned. This supports the process of breaking away the portion of the dense bone punched out. Therefore, it is possible to remove the bone within the cutting edge of the sonotrode in one piece and without less damage to the surrounding tissue.

The liquid fed through the instrument may further be used to cool the sonotrode and/or to rinse the operation side. A space between the sonotrode and a cannula or guide shaft may be used to suck liquid and debris of the bone out of the operational side.

A further embodiment of the sonotrode 1 for removal of bone tissue (in particular the complete bone fragments punched out) from the bone openings created using the sonotrode the sonotrode may be designed so that vacuum facilitates transport of the bone fragments 30 and retains them within the sonotrode 1. Therefore, there may be a suction port 30.1 communicating with an interior 42 of the sonotrode 1 for pulling out air and applying vacuum within the sonotrode. Fig. 20 illustrates two possibilities (in reality, often the sonotrode will only have one suction port). A first suction port 30.1 (first possibility) is laterally attached to the sonotrode head. . A second suction port 30.2 (second possibility) communicates with a proximal end of the sonotrode. Especially, the suction port may be present in an connecting piece 31 that is coupled to the proximal end of the sonotrode 1 in an airtight manner but from which the sonotrode may be removed.

In embodiments, the suction port 30.1, 30.2 is attached to the sonotrode in a node position. A suction port 30.1, 30.2 comprised within the sonotrode head and perhaps the handle or housing has to be cleaned after each operation (each treatment of a patient). A suction port 30.1 integrated in the distal end piece of the sonotrode 1 has the advantage that it has not be cleaned in case the sonotrode is a disposable item or is easier to clean because it is very short and without bend structure. On the other side it is more expensive to include such a suction port in the sonotrode, in particular in case that it is a disposable item.

A vacuum as applied by a suction port may also be used to support or facilitate breaking away the portion of the dense bone punched out. Therefore, it is possible to remove the bone within the cutting edge in one piece and without less damage to the surrounding tissue. In Fig. 20, reference number 25 denotes dense bone tissue (cortical bone), and reference number 26 denotes cancellous bone tissue.

Figure 21 illustrates the possibility of using a tube 20 or a sleeve for supplying a liquid, as explained referring to Fig. 24 hereinbefore, in combination with removing material via the interior 42 of the sonotrode. The liquid is supplied to the tube 20 and flows in the space between the tube and the sonotrode towards distally. It flows, together with any tissue/material flushed away, back through the sonotrode, as illustrated by the arrows. As mentioned referring to Fig. 14 hereinbefore, also the reverse arrangement is possible.

In approaches of this kind, the liquid is not only a cooling/flushing liquid but also serves for promoting the transport of tissue and debris material away from the operation site. To this end, a vacuum may be applied to the interior 42 of the sonotrode, for example by providing a suction port as explained hereinbefore.

In embodiments, it may be advantageous if the to-be removed tissue, especially dense bone tissue, is not only punched out of the live tissue but also broken up into smaller pieces, as a larger bone fragment 30 of the kind illustrated in Fig. 20 may plug up the transport path. Figure 22 illustrates the sonotrode with at least one interior blade 51 that disintegrates bone fragments that are transported towards proximally relative to the sonotrode.

In a most simple design, such an interior blade just extends transversely across the interior of the sonotrode.

The interior blade (this pertains to all embodiments with an interior blade) may have a cutting edge that extends in a plane perpendicular to the axis of the sonotrode, or, often preferably, it may have a cutting edge that is not parallel to such plane but is curved and/or at an angle therewith, as illustrated in Fig. 22, for cutting more smoothly into the tissue.

In special embodiments, a plurality of interior blades is present in a staggered arrangement, with a first interior blade 51 distally and a second interior blade 52 that is at a different angular position (i.e. angularly offset) more proximally (at a distance d). This is schematically illustrated in Fig. 22 as well as, in bottom views, in Figs. 23 and 24 for different interior blade geometries.

In embodiments that comprise braking up the to-be removed tissue into smaller pieces, the device that comprises the sonotrode may be used as morcellator.

Of course, the approaches of Figs. 20/21 and of Figs. 22-24 can be combined. Also, combinations of either or both with the features described referring to the other embodiments, especially a distal outward protrusion and/or inwardly facing ribs, are possible and often advantageous also.

Embodiments that comprise supplying a liquid to the site where the sonotrode acts (operation site) may comprise using the effect of cavitation for targeted tissue treatment. Cavitation (the creation and implosion of small vapor-filled bubbles due to the pressure variations) may lead to a highly aggressive environment around the sonotrode. This may be used in a targeted manner for removal of tumors etc. In view of this, the configuration of Figs. 20-24 involving removal of tissue via the interior of the sonotrode may be advantageous by preventing tissue and debris from being spread around in an uncontrolled manner.

In embodiments, the effect of the stamping out (punching out) and cavitation can be supplemented by supplying an according chemical agent, for example a cytostatic, in the supplied liquid.

The distal end piece of the hollow sonotrode according to the invention may have ribs on its inner side. These ribs may run parallel to the longitudinal axis of the sonotrode and along the complete length or may be arranged only in a distal part. The ribs may alternatively run along paths different from parallel to the longitudinal axis, for example by along a helical or other curve on the inner side of the distal end piece of the sonotrode. The ribs or protruding spikes or alternative protruding elements attached to the inner side of the sonotrode may facilitate breaking away of bone fragments after introduction of the sonotrode into the dense bone. Therefore the sonotrode or the complete device may be rotated, so that torsion is applied to the bone fragment within the sonotrode. Alternatively, slicing elements may be arranged within the tube or sonotrode. These elements are suitable for cutting or breaking the bone core into small fragments respectively bone debris which may be aspirate from the sonotrode. The slicing elements may be formed as thin blades (e.g. two, three, four or five blades) which are arranged in a way to meet one another at the central axis of the tube. The sonotrode may cut into the dense bone with its distal end and when cutting deeper into the bone the slicing elements chop the bone core into smaller fragments. The distal ends of the slicing elements or blades may be sharp and may be slanting.

WHAT IS CLAIMED IS:

1. A sonotrode for an ultrasonic surgical instrument being suitable for punching out tissue areas from bone, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a stamp for penetration of bones using mechanical vibration.

2. The sonotrode according to claim 1, wherein the distal end piece comprises a blade whose distal cutting edge corresponds to the contour of a tissue area that is to be punched out.

3. The sonotrode according to claim 1 or 2, wherein the distal end piece or the blade is designed as a hollow body being open at its distal end.

4. The sonotrode according to claim 3, wherein the hollow body is not rotationally symmetric.

5. The sonotrode according to claim 3 or 4, wherein the hollow body is a hollow elliptic cylinder.

6. The sonotrode according to any one of the previous claims, wherein the sonotrode has a lateral rib running along a longitudinal axis of the sonotrode.

7. The sonotrode according to claim 6, wherein the sonotrode has one lateral rib inside of the distal end piece or the blade and a second lateral rib outside of the distal end piece or the blade.

8. The sonotrode according to claim 6 or 7, wherein the sonotrode has two lateral ribs being located outside of the distal end piece or blade or two lateral ribs being located inside of the distal end piece or blade.

9. The sonotrode according to any one of claims 6-8, wherein the rib or ribs run only along the distal end piece of the sonotrode.

10. The sonotrode according to any one of claims 6-9, wherein the at least one rib has a flattened distal end.

11. A sonotrode for an ultrasonic surgical instrument, wherein the sonotrode has a head and a distal end piece, the distal end piece being equipped as a punch for penetration of bones or a blade for cutting and the distal end piece has a maximal diameter being at least one and a half times the size of the diameter of the head.

12. The sonotrode according to claim 11, wherein the distal end piece has a maximal diameter being at least three times the size of the diameter of the head.

13. The sonotrode according to claim 11 or 12, wherein the distal end piece comprises a blade whose distal cutting edge corresponds to the contour of a tissue area that is to be punched out.

14. The sonotrode according to any one of claims 11-13, comprising an intermediate element between the distal end piece and the head.

15. The sonotrode according to claim 15, wherein the intermediate element comprises through holes.

16. The sonotrode according to any one of claims 11-15, wherein the distal end piece has a sharpened distal edge as cutting edge.

17. The sonotrode according to any one of the previous claims, further comprising a sleeve with a window which allows that only a part of the distal end of the sonotrode protrudes out of the sleeve.

18. The sonotrode according to any one of the previous claims, wherein the surface of the sonotrode or the surface of the blade has a roughness average R_a between 5 – 40 μm.

19. The sonotrode according to any one of the previous claims, wherein the sonotrode or at least the blade of the sonotrode is manufactured using an additive manufacturing method such as direct metal laser sintering.

20. The sonotrode according to any one of the previous claims, comprising a distal rim being a distal outward protrusion extending along the cutting edge, whereby an outer cross section of the sonotrode proximally of the rim is smaller than an outer cross section of the rim.

21. The sonotrode according to any one of the previous claims, further comprising a suction port for applying a vacuum in an interior of the sonotrode.

22. The sonotrode according to any one of the previous claims, comprising at least one interior blade arranged in an interior of a hollow body of the sonotrode, the hollow body being open at its distal end, the blade configured for breaking up punched-out bone fragments.

23. The sonotrode according to claim 22, comprising a plurality of interior blades, at least two of the interior blades being arranged in a staggered manner.

24. The sonotrode according to any one of the previous claims, wherein a distal end forming a cutting edge forms a closed contour.

25. The sonotrode according to any one of the previous claims, wherein the distal end piece defines an axis around which the distal end piece extends, and wherein a distal end forming a cutting edge follows a curve in 3D space, which curve is different from a curve extending in a plane perpendicular to the axis.

26. The sonotrode according to claim 25, wherein the curve extends in a plane that is at an angle to the axis, which angle is different from 90° and different from 0°

27. A surgical punching device, comprising a sonotrode according to any one of the previous claims, and further comprising a tube encompassing the sonotrode.

28. The device according to claim 27, wherein the tube is equipped to supply a liquid to the distal end of the sonotrode.

29. An ultrasonic surgical instrument for cutting bones, comprising a housing containing an ultrasonic transducer and a sonotrode as defined in any one of claims 1 - 26 mechanically coupled to said transducer.

30. The instrument according to claim 29, further comprising a suction device equipped to apply a vacuum in an interior or the sonotrode or in a vicinity of the sonotrode.

31. The instrument according to claim 29 or 30, further comprising a liquid supply for supplying a liquid to a distal end of the sonotrode.

32. The instrument according to claim 31, wherein the liquid supply comprises a tube encompassing the sonotrode, the instrument being equipped to conduct the liquid through a space between an outer surface of the sonotrode and in inner surface of the tube.

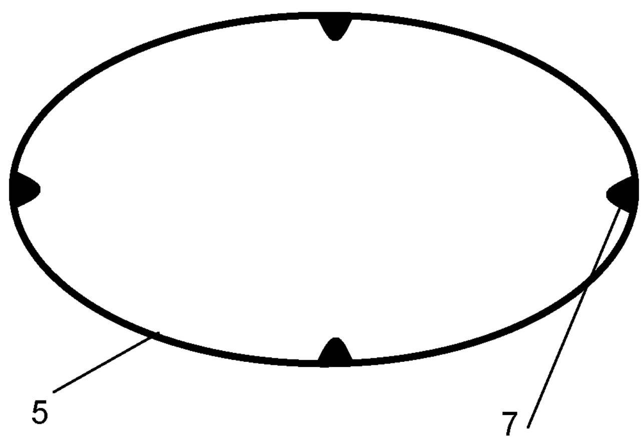

Fig. 1

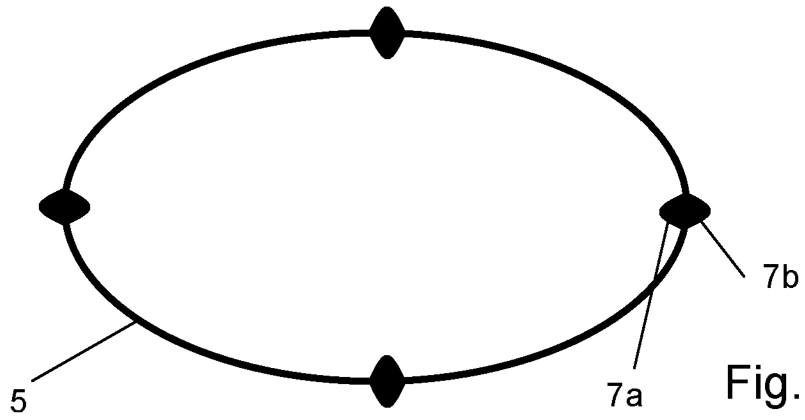

Fig. 2

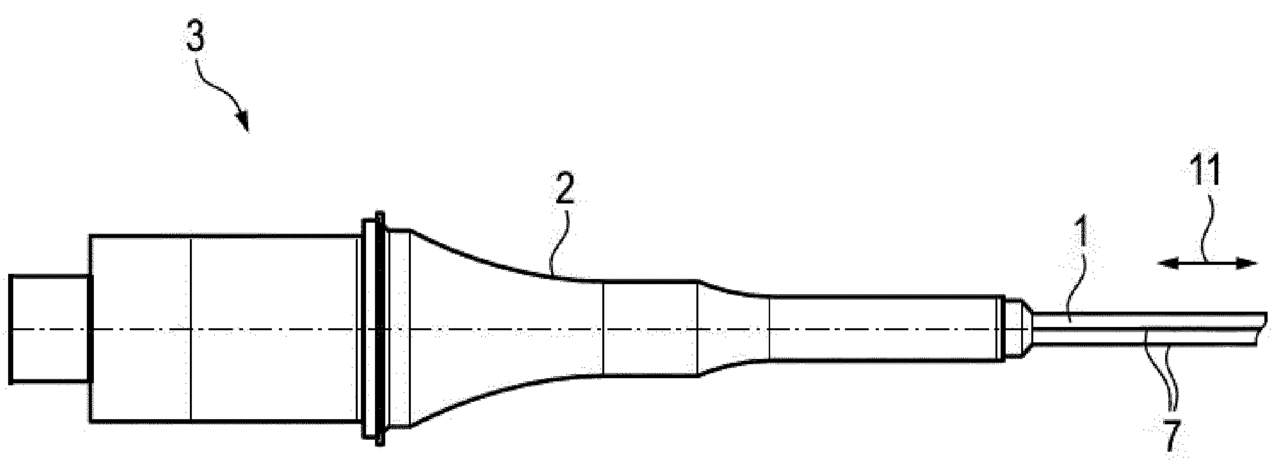

Fig. 3

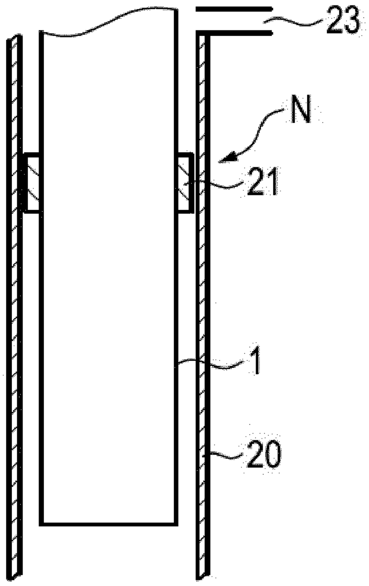

Fig. 12

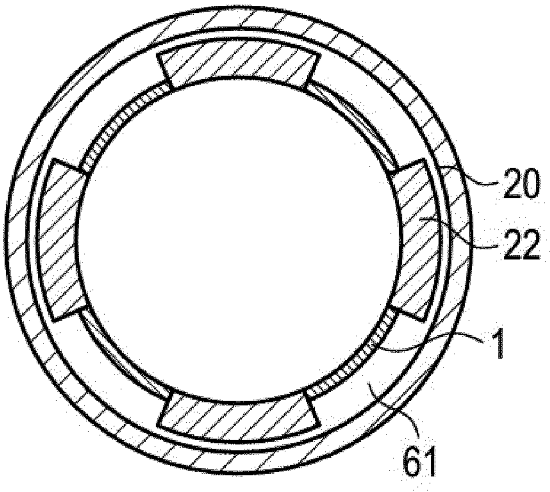

Fig. 14

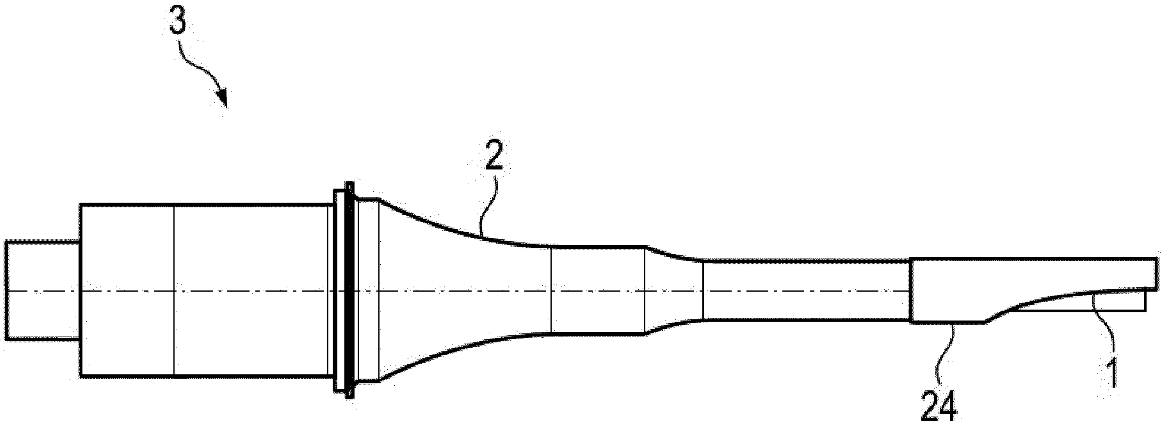

Fig. 15

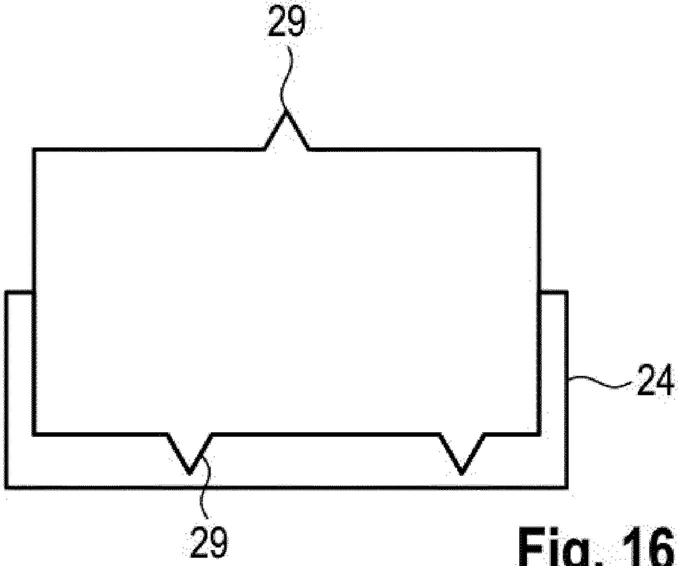

Fig. 16

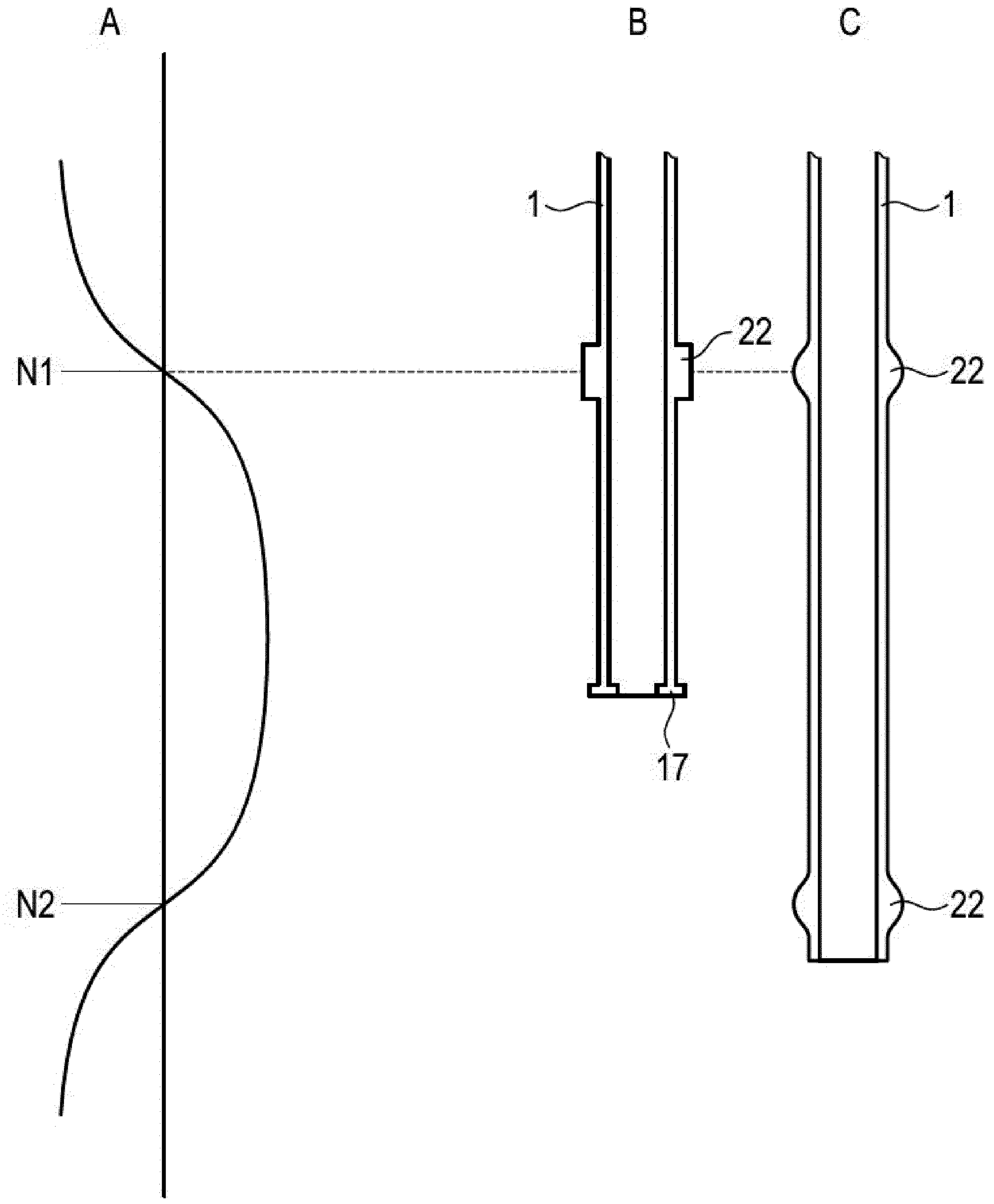

Fig. 13

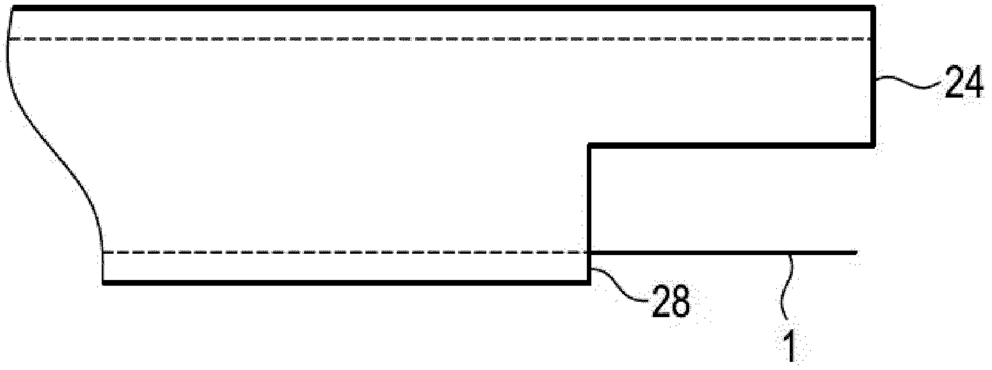

Fig. 17

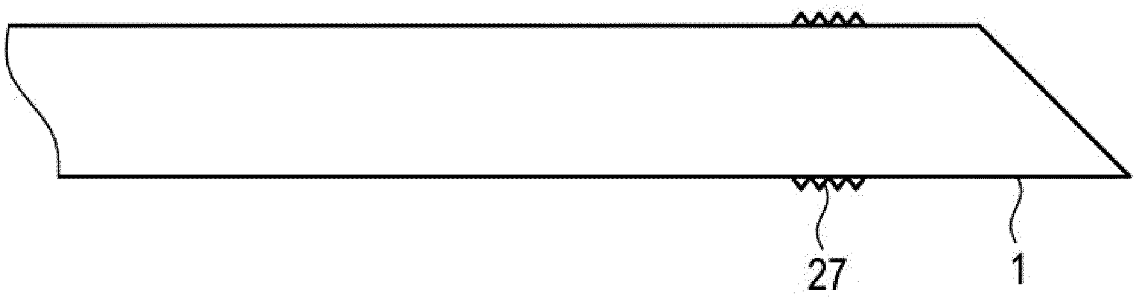

Fig. 18

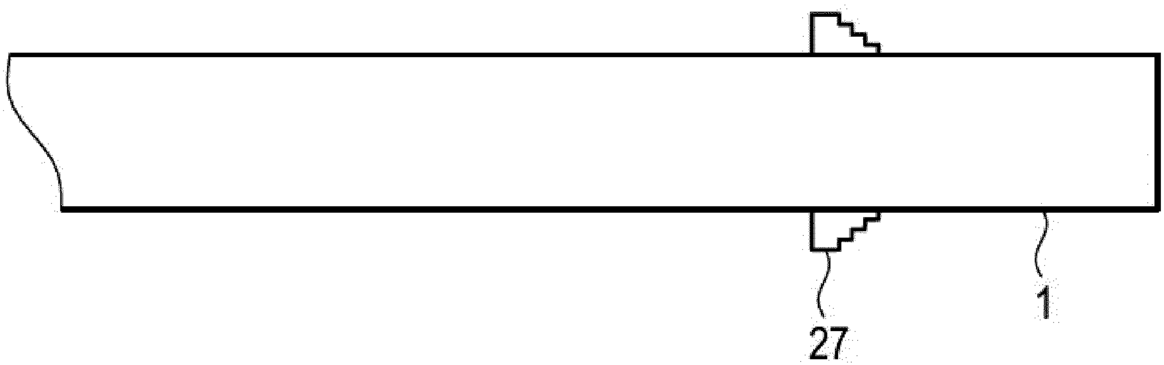

Fig. 19

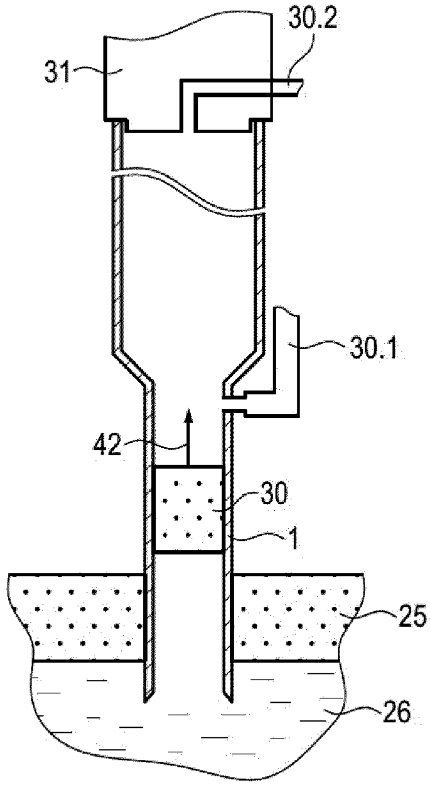

Fig. 20

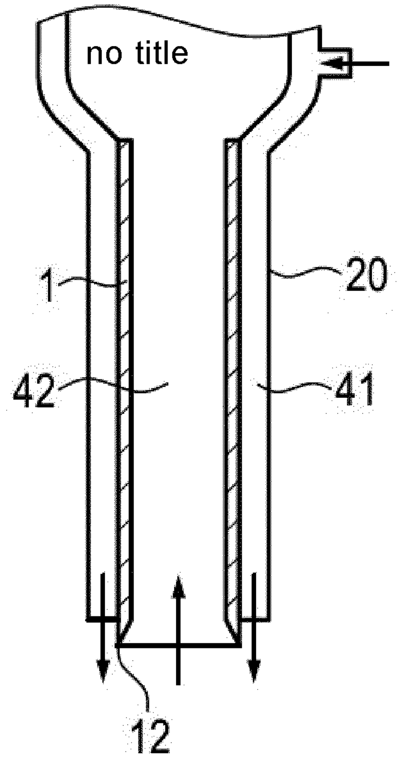

Fig. 21

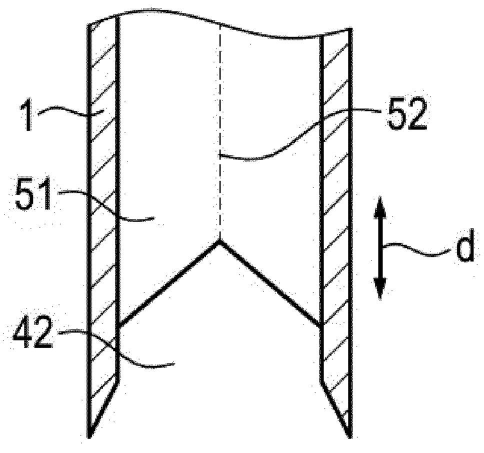

Fig. 22

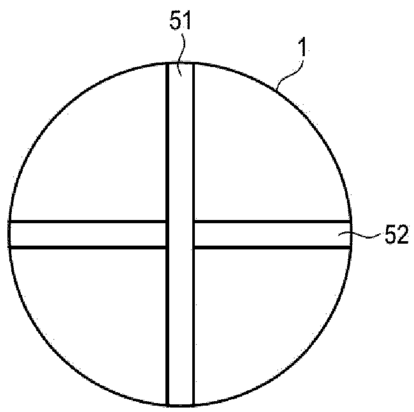

Fig. 23

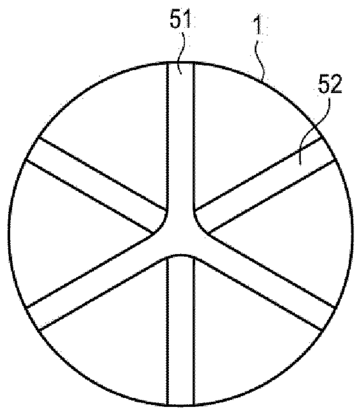

Fig. 24

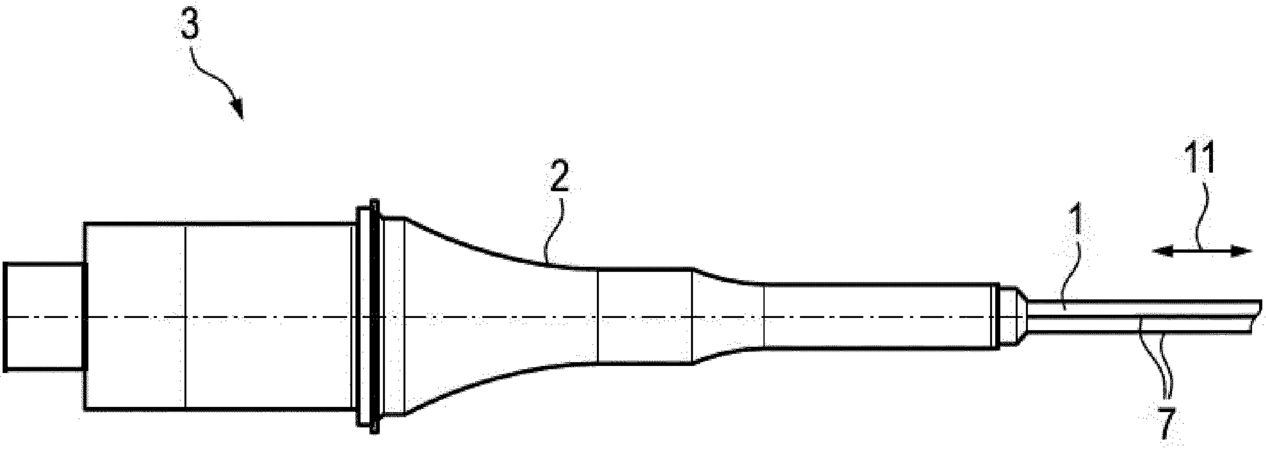

Fig. 3