OPIC
Office de la propriété intellectuelle du Canada

CIPO
Canadian Intellectual Property Office

(12) (19) (CA) **Demande-Application**

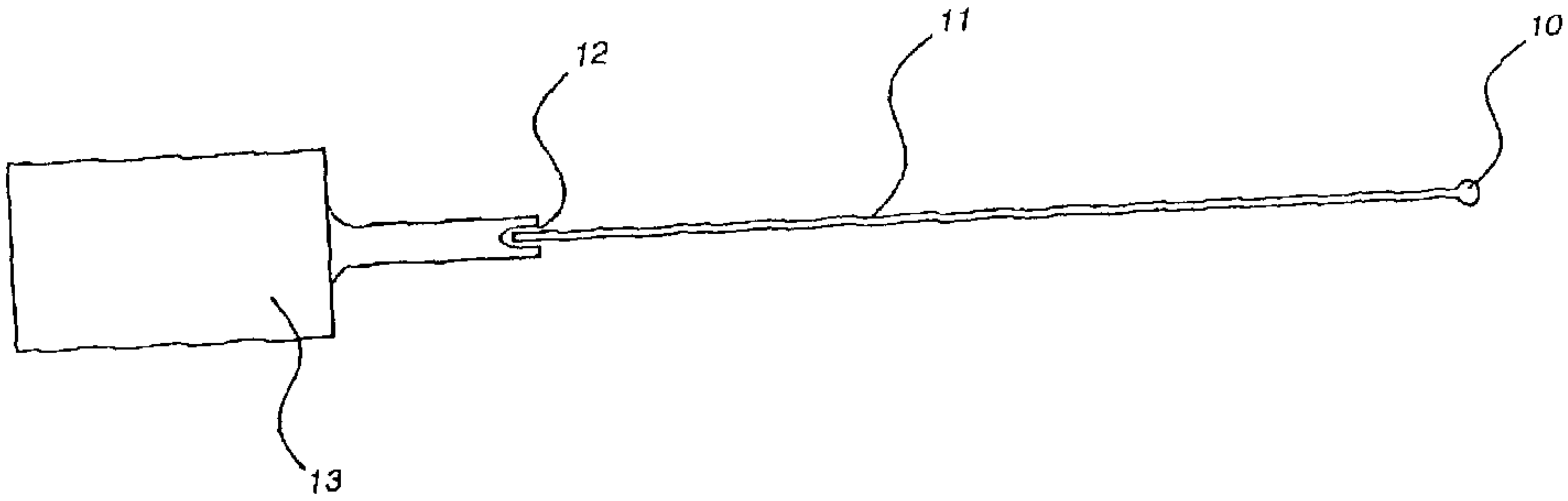
(21) (A1) **2,299,997**
(22) 2000/03/03
(43) 2000/09/05

(72) PETERSON, THOMAS, US
(72) PAL, DHAMENDRA, US
(71) CYBERSONICS, INC., US

(51) Int.Cl.^{7} G10K 9/00, B08B 3/12, B22D 29/08
(30) 1999/03/05 (60/123,041) US

(54) **METHODE ET APPAREIL POUR NETTOYER LES INSTRUMENTS MEDICAUX ET DES OBJETS DE MEME NATURE**

(54) **METHOD AND APPARATUS FOR CLEANING MEDICAL INSTRUMENTS AND THE LIKE**



(57) The present invention provides a process and apparatus for the ultrasonic cleaning of the interior channel of medical instruments and the cleaning of material from small apertures. The present invention describes different embodiments of coupling different types of wire resonators to the ultrasonic transducer horn to allow the ultrasonic waves to be distributed to and along specific lengths of instruments. In addition, the present invention describes the use of the ultrasonic generator and resonator in many different applications, including but not limited to, cleaning brain shunts, facilitating the removal of pacemaker leads, and cleaning investment case moldings. Further, the present invention describes the use of the ultrasonic generator and resonator in drilling and coring applications.

Abstract of the Disclosure

The present invention provides a process and apparatus for the ultrasonic cleaning of the interior channel of medical instruments and the cleaning of material from small apertures. The present invention describes different embodiments of coupling different types of wire resonators to the ultrasonic transducer horn to allow the ultrasonic waves to be distributed to and along specific lengths of instruments. In addition, the present invention describes the use of the ultrasonic generator and resonator in many different applications, including but not limited to, cleaning brain shunts, facilitating the removal of pacemaker leads, and cleaning investment case moldings. Further, the present invention describes the use of the ultrasonic generator and resonator in drilling and coring applications.

PATENT
Attorney Docket No. 018.002600

METHOD AND APPARATUS FOR CLEANING MEDICAL INSTRUMENTS AND THE LIKE

Cross Reference to Related Applications

This patent application claims priority to United States Provisional Patent Application, Serial Number 60/123,041 filed on March 5, 1999.

Field of the Invention

This invention relates generally to an improved method and apparatus for cleaning medical instruments and other small apertures. More particularly, the invention relates to a method and apparatus for ultrasonic cleaning of the interior channels of various types of medical devices such as brain shunts and endoscopes. In addition, the invention relates to a method and apparatus for extracting pacemaker leads as well as other types of leads that are inserted and left in a human body. The same invention may be used in other applications such as cleaning investment castings and other applications that require the cleaning of small apertures. Also, the invention may be used in treating atherosclerotic plaque and thromboses. In addition, the invention may be used to provide low axial drilling and coring of bones and bony structure. The use of this invention in low axial drilling and coring will extend to mineral extraction, especially in interplanetary exploration.

Background of the Invention

Medical procedures for the visualization of surgery on internal body tissues and organs are commonly carried out with the aid of an elongate, flexible, tubular instrument which may be introduced into the body through an incision or natural opening. Such instruments include, for example, the endoscope, bronchoscope, cystoscope, gastroscope, laparoscope, and vaginoscope, as well as narrower bore instruments used for brain shunts, urethra catheterization, or cardiac catheterization.

The thorough cleaning of the lumen or working channel(s) of such instruments is difficult and traditional methods of cleaning are often inadequate and/or very time consuming. Among the traditional methods used for cleaning the internal channels of endoscopes and other such elongate tubular instruments, are the application of water jets and/or long brushes to loosen and remove contaminants such as dirt particles and the like prior to sterilization.

Often particulate contaminants are lodged in crevasses and corners within the instrument and are difficult or impossible to remove by such traditional physical methods of cleaning. Various studies have shown that traditional techniques for cleaning do not adequately remove pathogens and other contaminants prior to sterilization.

It is known that ultrasonic cleaning techniques can be used to supplement or replace traditional methods for cleaning medical instruments and the like. The application of ultrasonic energy to the cleansing of medical instruments such as endoscopes and the like is typically carried out by immersing the instruments in a cleansing tank filled with a cleaning fluid while generating ultrasonic vibrations in the cleaning fluid. The ultrasonic vibrations are created within the fluid by an ultrasonic resonator coupled to, and responsive to an ultrasonic generator or transducer. Typically, frequencies of about 5,000 to 40,000 Hz are employed.

In the latter method, wherein the instrument to be cleaned is immersed in a cleaning fluid in an ultrasonic cleaning tank, the ultrasonic energy is applied in the fluid outside of the instrument. This approach may be adequate for instruments that have thin metal walls, but is generally less than adequate for cleaning the interior of large diameter non-metallic instruments, especially those constructed of plastic materials. Many, or most, endoscopes and similar instruments are made of some type of plastic or polymeric materials. Plastic or polymeric materials attenuate the ultrasonic energy and prevent sufficient cavitational energy from reaching the lumen of the instrument and from dislodging contaminants in tight corners and crevasses in the interior channel(s) of elongated tubular instruments, such as endoscopes. Higher ultrasonic energy, sufficient to penetrate the wall of a plastic endoscope, may cause damage to optical systems that may be enclosed in the wall. A more preferred method of ultrasonically cleaning the interior channel of an endoscope would be to direct ultrasonic energy directly into the channel by placing the open end near a source of focused ultrasonic energy. However, with such a method, most of the usable energy will be attenuated beyond a few centimeters into the working channel.

U.S. Patent 3,957,252 discloses an apparatus for cleaning medical instruments in a conventional

The apparatus comprises an ultrasonic oscillator mounted on a support means to permit engagement of the oscillator with the washing water in the sink.

U.S. Patent 5,380,369 to Steinhauser et al. discloses a process for cleaning and/or disinfecting medical instruments wherein an instrument to be cleaned is first washed internally and externally with a suitable cleansing liquid. The liquid is then drained and the instrument is dried with the application compressed air. Then - in the absence of a liquid medium - ultrasonic cleaning is applied.

U.S. Patent 5,425,815 to Parker et al. discloses a method of cleaning medical instruments comprising placing the instrument in an enclosure and applying a cleansing solution, and a disinfecting solution, then rinsing, purging and drying. The instrument may be pre-cleaned with the aid of a catheter delivering jets or water. Optionally, the catheter may be provided with an ultrasonic transducer.

U.S. Patent 5,462,604 discloses a method for cleaning of workpieces immersed in a container of cleaning solution by a particular application of ultrasonic energy to produce cavitation in the cleaning solution, external to the workpieces being processed.

U.S. Patent 4,016,436 to Shoh describes an ultrasonic processing apparatus wherein ultrasonic energy is applied to tubular flexible resonator which, in turn, subjects a liquid within the resonator to intense vibratory energy from the wall of the resonator.

U.S. Patent 4,537,511 to Frei discloses a hollow tubular resonator which may be employed in combination with a second resonator for producing ultrasonic energy in cleaning baths.

U.S. Patent 5,200,666 to Walter et al. discloses a rod-like resonator having ultrasonic generators coupled to each end. Both generators operate at the same frequency to transmit ultrasonic vibration to the resonator to be emitted radially therefrom.

U.S. Patent 5,240,675 (Wilk et al.) teaches a method for cleaning endoscopes with the aid of an elongate cleaning member containing an optical fiber for the transmission of sterilizing radiation; an electrical conductor for the transfer of hear energy into the channel; and a brush element to scrub the channel of the endoscope while a sterilizing fluid is passed through. The patentees additionally suggest vibrating the elongate cleaning member by the transmission of ultrasonic energy.

In addition to other references showing or suggesting various methods and apparatus for the application of ultrasonic energy in the cleaning of medical instruments and other devices or objects, the prior art discloses the use of ultrasonic "probes" and the like, such as, wires coupled to and extending from an ultrasonic transducer for various purposes, such as the application of ultrasonic energy within narrow channels such as human blood vessels, urinary tracts, and the like for removal of blockages.

U.S. Patent 4,572,184 to Stohl et al. discloses an ultrasonic wire wave guide attachment device, for attaching a wave guide or wire to a power source such as an ultrasonic transducer. The attachment device comprises a screw having an axial passage therethrough providing a slip fit with the wire. The wire is passed into the axial passage and fastened by means of a metallurgical bonding material such as braze alloy or solder. The transducer is provided with a threaded opening to receive the attachment screw. The wave guide is preferably a cobalt base alloy.

U.S. Patent 4,474,180 to Angulo discloses an apparatus for disintegrating kidney stones through the use of ultrasonic energy. The patentee teaches various means for attaching an ultrasonic transducer, using set screws and the like.

U.S. Patents 3,830,240 and 3,861,391, both to Antonevich et al., disclose ultrasonic methods and apparatus for disintegration of urinary calculi. The patents teach the use of a wave guide, in the form of a wire, adapted to be inserted through catheter. The patents further teach various methods of attachment of the wave guide to an ultrasonic transducer.

U.S. Patent 4,870,953 to Michael et al. discloses an apparatus and method for treating atherosclerotic plaque and intravascular blood clots by the application of ultrasonic energy. The ultrasonic apparatus employed includes a solid wire probe having a bulbous tip at one end and coupled to an ultrasonic energy source at the other end. The probe is carried within a hollow catheter to a site of stenosis. At this point, the probe is extended from the catheter and caused to vibrate ultrasonically, resulting the destruction of the plaque or blood clot.

U.S. Patent no. 4,920,954 to Alliger et al. discloses an ultrasonic device for generating and applying cavitational force. The device comprises a solid wire wave guide, a transducer, a generator, and a handpiece enclosing the transducer. The solid wire wave guide is titanium. The device is employed in conjunction with a catheter assembly to introduce the titanium wire wave guide into a human artery where the longitudinal vibration of the wire causes an axial movement of the tip portion of the wire to produce a cavitational force for the removal of plaque. The wire material (titanium) and the design of the device are selected to minimize transverse ultrasonic vibration waves.

It is disclosed that the device may be used for other purposes, such as, for the removal of unwanted contaminants from inaccessible areas.

U.S. Patent 5,304,115 to Russell et al. discloses an ultrasonic angioplasty device comprising an elongate ultrasound wire transmission member having a bulbous head which may be inserted in and advanced through a catheter to a point slightly beyond the distal end of the catheter. The wire serves to transmit longitudinal ultrasonic energy to the bulbous head where the energy effects an ablative treatment of an occluding arterial deposit such as plaque.

It will be apparent to those skilled in the art that although the prior art teaches a variety of useful methods and apparatus, including various ultrasonic methods and apparatus, for cleaning objects such as medical devices, more efficient methods for cleaning the interior channels of elongated tubular instruments, such as brain shunts, is desirable. In addition, it will be apparent to those skilled in the art that this invention may be used with many different types of applications and the invention is especially suited to cleaning materials out of small apertures, such as investment castings. Further, it will be apparent to those skilled in the art that one embodiment of this invention is particularly suited to cleaning hardened materials out of small apertures.

The invention described herein can be used in biomedical arenas, especially for cleaning brain shunts. A ventriculoperitoneal brain shunt is a draining apparatus for removing fluid from around the brain. The brain shunts have minutely tiny holes in the shunt to allow the fluid to drain from the patient's brain at a very slow pace. Approximately 40,000 shunt operations are performed each year in North America to treat hydrocephalus. A high percentage of these shunt operations are performed to remove a failed shunt and replace the failed shunt. The typical causes of brain shunt failure include mechanical obstruction, infection, fracture of components, and growth of the patient. Mechanical obstruction is the most common cause of shunt failure. The medical field has attempted to remove the problem of mechanical obstruction through modification of the shunt's geometry, material and position, to no avail. The current method of cleaning a clogged shunt is a surgical replacement of the defective shunt components. The surgery requires a general anesthetic and one or two surgical scars as well as involving a risk of intraventricular hemorrhage. There is no current method of removing the clogged material from the brain shunt in vitro. Therefore, a method of safely and quickly cleaning the shunts while the shunt remains embedded in the brain is necessary.

The invention described below can also be used, within the biomedical arena, for facilitating the removal of pacemaker leads as well as intravascular leads and other leads that are inserted into the human body for extended periods of time. Pacemaker leads are the apparatus that connect the heart and the pacemaker while the human being is using the pacemaker. At various points of the patient's treatment, the pacemaker leads may need to be replaced. This replacement procedure is difficult because arterial tissue and plague tend to grow around the pacemaker lead and surround the lead, thereby obviating the ease of removal of the lead. The current method used to extract the lead is to insert a sheath surrounding the lead into the body. This sheath has a pointed tip.

The surgeon pushes the sheath along the pacemaker lead until an obstruction is reached. The surgeon then manually moves the sheath in a forward and backward motion to attempt to cut or saw through the sheath. When the surgeon breaks through, the sheath is slid along the lead until the next obstruction is encountered. As one can visualize, this type of manual sawing motion can cause serious damage to the artery. In addition, material sometimes gets caught on the sheath and dragged along the lead to another portion of the artery. Thus, a method and apparatus is needed that avoids material being dragged along the sheath and also avoids the sawing motion that the surgeon must use.

The present invention can also be adapted for use in treating atherosclerotic plaque and

To ensure proper health of the heart and body, the arteries must have sufficient elasticity to expand with each heartbeat and to withstand the high pressures resulting from arterial blood flow. When cholesterol, fibrous material, and other substances coat the inner surface of arteries, there can be a severe loss in blood vessel elasticity. This condition is commonly referred to as atherosclerosis. The deposits on the inner surface of the arteries are most frequently associated with the blood vessels supplying the heart. The deposits accumulate at one location and drastically narrow the diameter of the artery, thus restricting and sometimes totally blocking the flow of blood. Present methods for removing atherosclerotic plaque and thromboses include arterial bypass surgery, endarterectomy, balloon angioplasty, applications of laser technology, mechanical and electrical drills as well as other surgical techniques and tools for the removal of the blockages. Each of these methods has its own problems and complications; however, the common problem facing each of the above methods is the risk of perforation of the artery. Thus, there is a need for a device that will dissolve or pulverize atherosclerotic plaque and intravascular obstructions without the above complications.

Summary of the Invention

The present invention provides an apparatus and a process for the ultrasonic cleaning of the interior channel of a flexible, tubular instrument, the removing of materials from small apertures and the facilitation of the extraction of leads, such as pacemaker leads. The present invention also provides an apparatus and a process for low axial drilling and coring.

The apparatus of the present invention comprises a wire ultrasonic resonator having a distal end and a proximal end, adapted to be inserted at its distal end into or around the instrument to be cleaned and inserted at its proximal end to an ultrasonic transducer. An ultrasonic generator, particularly suited for use with the instant invention, is described and claimed in detail in United States Patent No. 5,830,127 that discloses the apparatus and operation of the generator. However, it is apparent to one of ordinary skill in the art that the wire resonator of the subject invention may be adapted to be energized by any transducer and ultrasonic generator.

The invention describes a device for coupling a solid metal wire resonator to an ultrasonic transducer, comprising a crimp screw having a first and second end, the first end being threaded to threadably engage the ultrasonic transducer, the second end having a receptacle portion for receiving the flexible solid metal wire, a flexible solid metal wire with a hole bored into one end; and a metal filler compound for inserting into the bored hole of the wire. The solid metal wire resonator may be flexible or rigid.

The invention also describes a process for coupling a solid metal wire resonator to an ultrasonic transducer, comprising the steps of boring a hole into one end of the solid metal wire, positioning a metal filler compound within the bored hole of the solid metal wire, inserting the filled end of the solid metal wire into a screw having a first and second end, such second end having a receptacle portion for receiving such filled end of the annual wire, physically crushing the screw end to permanently couple the filled end of the solid metal wire to the screw end and threadably engaging the first end of the screw to an ultrasonic transducer. The solid metal wire resonator may be flexible or rigid.

The invention further teaches a device for coupling a solid metal wire resonator to an ultrasonic transducer such that the wire resonator is not fixedly attached to the resonator but can move in a limited transverse fashion. This forward and backward motion allows the solid wire resonator to act much like a jackhammer.

The invention also describes a device for coupling an elongate annular metal wire resonator to an ultrasonic transducer, comprising a crimp screw having a first and second end, the first is threaded to threadably engage the ultrasonic transducer, the second end having a receptacle portion for receiving the elongate annual metal wire; and a metal filler compound for inserting into a bored hole in the elongate annual metal wire. The annular metal wire resonator may be flexible or rigid.

The invention further describes a process for coupling an elongate annual metal wire resonator to an ultrasonic transducer, comprising the steps of positioning a metal filler compound within an end of the elongate annual wire; inserting the filled end of the annual wire into a screw having a first and second end, such second end having a receptacle portion for receiving such filled end of the annual wire, physically crushing the screw end to permanently couple the filled end of the elongate annual wire to the screw end and threadably engaging the first end of the screw to an ultrasonic transducer.

The invention further describes a process for coupling an elongate annual metal wire resonator to an ultrasonic transducer, comprising the steps of positioning a metal filler compound within an end of the elongate annual wire; inserting the filled end of the annual wire into a screw having a first and second end, such second end having a receptacle portion for receiving such filled end of the annual wire, physically crushing the screw end to permanently couple the filled end of the elongate annual wire to the screw end and threadably engaging the first end of the screw to an ultrasonic transducer, removing the metal filler compound from the annular metal wire resonator once the annular resonator is coupled to the crimp screw. The annular metal wire resonator may be flexible or rigid.

The invention further teaches a device for coupling an elongate annular metal wire resonator to an ultrasonic transducer such that the wire resonator is not fixedly attached to the resonator but can move in a limited forward and backward fashion. This forward and backward motion allows the wire resonator to act much like a jackhammer.

The invention describes an ultrasonic probe comprised of various sections coupled together to provide controlled dispersion of ultrasonic energy along its dimensions. The sections may be rigid or flexible, solid or annular, of the same or different materials, round or of some other shape, similar or different geometric dimensions and one or more in quantity. The method of coupling may be fixed or contact. The fixed method may use methods such as coupling, crimping, friction grip, soldering, brazing, welding, or other conventional and non-conventional fixation methods. The contact method may be free or constrained. The method of coupling between various sections may similar or different. The method of coupling between the resonator and the transducer may be similar or different from any of the other sections of the probe.

The process of the invention comprises producing transverse and longitudinal ultrasonic waves within the lumen of the device that is to be cleaned or directing the wire resonator toward the area that is to be cleaned. Ultrasonic waves and cavitation are produced in response to the vibratory motion of a wire resonator positioned within or around the instrument to be cleaned. This invention also discloses and claims the processes by which this invention may be used to clean brain shunts. A solid or annular wire resonator is inserted into the brain shunt such that the distal tip of the wire resonator is near the tip of the brain shunt. The generator is energized and the ultrasonic waves break up the material that is clogging the brain shunt and hampering the operation of the brain shunt for the use for which it is intended.

This invention further discloses the ability of the invention to facilitate removal of pacemaker leads, intervascular wires and other leads that are inserted into a human body. The annular wire resonator of the present invention is sheathed around the pacemaker lead and pushed along the lead until an obstruction is reached. The invention is energized and the obstruction is removed from the lead, using the transverse waves created by the generator to cut through the obstruction. The wire resonator is then pushed farther along the lead until the next obstruction is reached. Once all of the obstructions have been removed the lead may be disengaged and removed.

In addition, this invention discloses a process by which the invention is used to clean investment castings. A solid or annular wire resonator of the subject invention is placed against the obstructed aperture in the investment casting. The invention is energized and the ultrasonic waves break up the material causing the obstruction. The obstruction is thus removed.

Further, this invention discloses a process by which the invention is used as a coring machine to core samples from bones, bony structures, or minerals. An annular wire resonator as described by the present invention is placed adjacent to the material to be cored, abutting the material. The invention is energized and a small sample of the hardened material is drawn into the annular wire resonator. Once the proper amount of a sample is accumulated inside the annular wire resonator, the invention is deenergized and the sample pushed out of the annular resonator.

The subject invention discloses a process by which the invention is used as a drill for drilling through bones, bony structure, or minerals. A solid or annular wire resonator of the subject invention is placed adjacent to the material to be drilled, abutting the material. The invention is energized and the wire resonator drills through the material. Once the desired hole size is achieved, the invention is deenergized.

Lastly, the present invention can also be adapted for use in treating atherosclerotic plaque and thromboses. The wire resonator of the present invention can be sheathed in the manner described in U.S. Patent No. 4,870,953 to DonMichael et al. and used to break up atherosclerotic plaque by insertion into the blocked artery.

It is an object of the present invention to provide an improved method for cleaning the interior channels of elongated tubular medical devices, such as brain shunts and other shunts that are inserted into a human body.

It is a further object of the invention to provide a method and apparatus for the generation of both transverse and longitudinal ultrasonic wave energy within the interior channel(s) of a brain shunt or the like.

It is also an object of the invention to provide a device for connecting different types of wire resonators to an ultrasonic transducer in such ways that prolong the life of the wire and relieves stress along the walls of the wire.

It is a further object of the invention to provide a device that may be sheathed around a pacemaker lead, or other types of similar leads, to facilitate the removal of such a lead from a human's body.

It is an additional object of the invention to provide a device for coupling different types of wire resonators to an ultrasonic transducer in such ways that will allow the wire to move in a limited forward and backward motion.

It is a further object of the present invention to provide a device that may be used to clean the small apertures of investment castings.

It is an additional object of the present invention to provide a device that may be used to drill through bones, bony structures, and/or mineral ores and rocks.

It is a further object of the present invention to provide a device that may be used to core samples of bones, bony structures, and/or mineral ores and rocks.

The apparatus of the present invention is further illustrated by the following detailed description and accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a longitudinal sectional view of an ultrasonic resonator coupled at its proximal end to an ultrasonic generator.

FIG. 2 is a longitudinal view of the ultrasonic resonator and generator with the resonator positioned within the interior channel of a rigid or flexible endoscope to be cleaned and having a "Y" connector assembled over the proximal region of the resonator.

FIG. 3 is a sectional view of the proximal end of the ultrasonic resonator showing an embodiment of the coupling of the solid wire resonator to an ultrasonic transducer.

FIG. 4 is a sectional view of the proximal end of the ultrasonic resonator showing an embodiment of the coupling of the annular wire resonator to an ultrasonic transducer.

FIG. 5 is a plot of driving frequency and transverse wave lengths for various wire diameters.

FIG. 6 depicts an overall view of the crimp screw, which attaches to the ultrasonic transducer, and the solid metal wire resonator with a filled edm hole before the screw is crimped.

FIG. 7 depicts an overall view of the crimp screw, which attaches to the ultrasonic transducer, and the solid metal wire resonator with a filled edm hole after the screw is crimped.

FIG. 8 depicts an overall view of the crimp screw and the solid metal wire resonator with filled edm hole before insertion into the screw.

FIG. 9A is a sectional view of the coupling of an annular wire resonator to the ultrasonic transducer such that the wire resonator may move in a limited fashion.

FIG. 9B is a sectional view of the coupling of a solid resonator to the ultrasonic transducer such that the wire resonator may move in a limited fashion.

FIG. 10 depicts an overall view of the crimp screw, which attaches to the ultrasonic transducer, and the annular resonator and the filler material before the screw is crimped.

FIG. 11 depicts an overall view of the crimp screw, which attaches to the ultrasonic transducer, and the annular resonator and the filler material after the screw is crimped.

FIG. 12 depicts an overall view of the crimp screw and the annular resonator and the filler material before insertion into the screw.

FIG. 13 is a longitudinal detailed view of the ultrasonic transducer that may be utilized with any of the embodiments of the invention described herein.

FIG. 14A, B, and C depict the motion of the ultrasonic resonator that is coupled to the ultrasonic transducer such that the resonator may move in a limited fashion.

Detailed Description of the Preferred Embodiment

STRUCTURE OF THE PRESENT INVENTION

An important characteristic of the apparatus of the present invention is the ability of the wire resonator to generate both transverse and longitudinal ultrasonic vibrations simultaneously. At its proximal end, the resonator is coupled to an ultrasonic transducer and produces substantial transverse vibrations at positions along its entire length, as well as longitudinal vibrations at its distal end. The transducer of the subject invention is comprised of a plurality of ceramic elements that are stacked one on the other with metal separators between the ceramic elements such that one end of the ceramic elements will touch the horn and the other end of the plurality of ceramic elements is attached to a bias bolt. The electrical wires that transport energy from the generator to the transducer are connected to these metal separators to excite the molecules within the ceramic elements. The bias bolt is screwed into the plurality of ceramic elements and compresses the ceramic elements against the horn. In a preferred embodiment, the ceramic elements are PZT 8 or PZT 4 ceramic elements and are arranged such that the polarity of each of the ceramic elements is aligned with the others. In a more preferred embodiment, four PZT 8 ceramic elements comprise the transducer. Within the liquid-filled lumen of the instrument to be cleaned, the combination of ultrasonic transverse and longitudinal wave motion causes a turbulence that results in cavitational cleaning action in the liquid. If the invention is not placed within a liquid-filled lumen, the transverse and longitudinal waves emanate from the distal tip of the wire resonator and act to break up the material abutting the wire resonator.

The transverse vibrations, which occur at antinode positions along the length of the wire resonator, generate cavitational cleaning action in the liquid at each position. As a result, cavitational cleaning action occurs simultaneously at a multiplicity of sites within the interior channel or lumen of the instrument. The cavitational action in the channel of the instrument facilitates and accelerates the detachment of contaminants such as particles embedded or trapped in crevasses and corners.

During the ultrasonic cleaning process, liquid is passed through the lumen or channel being

In a typical cleaning procedure, transverse and longitudinal ultrasonic vibrations are produced by the resonator within the lumen or channel to be cleaned, while a liquid, for example, an aqueous solution of a suitable sterilant, disinfectant, and/or cleaning agent is passed through an irrigation port into the proximal end of the lumen and allowed to pass out through the distal end.

In the operation of the transducer, a pulsed mode may be preferred to continuous wave mode. In the pulsed mode (e.g. 50% on; 50% off) the cleaning fluid is degassed very quickly and increases the effects of ultrasonic cavitation.

The resonator can be a solid or annular rod-like or wire member composed of a metallic material capable of producing both transverse and longitudinal ultrasonic waves in response to the action of an ultrasonic transducer. Preferably, the wire resonator may be flexible or rigid. Preferred materials for this purpose include metals or alloys such as nickel or nickel cobalt alloys characterized by a high modulus of elasticity or materials that can be treated, such as by coldworking and/or heat treatment to achieve a high modulus of elasticity, preferably greater than 18 million psi. Such materials are more readily excited into transverse ultrasonic motion at lower stress levels, thus reducing the energy necessary to produce transverse motion in titanium alloys. At lower power levels, less heat is generated, thus reducing heating of the ultrasonic resonator and increasing the resonator life. Especially useful for this purpose are alloys of nickel/cobalt/chrome/molybdenum such as MP-35N alloy or Elgiloy. A most preferred material is Elgiloy (a cobalt alloy containing about 0.15% C, 20.0% Cr, 15.0% Ni, 15.0% Fe, 7.0% Mo and 0.04% Be) wire that has been 48% cold reduced and heat treated at 980 degrees Fahrenheit for approximately five hours. The advantages of the resonator material employed in the apparatus of the present invention over the materials employed in prior art devices is further illustrated by reference to the following table:

Table 1

Alloy	Modulus of Elasticity (EO\) X 10^6 PSI	Endurance Limit X 10^3 PSI	Tensile Strength X 10^3 PSI
Ti (6L-4V)	15-17	60-85	130
Stainless Steel	28	39	85-90
Elgiloy	29.5	NA	230-250

An alternate preferred embodiment of the resonator of the present invention includes the use of a plastic that can approximate the behavior of the above listed metal alloys. The diameter of the rod or wire that constitutes the resonator of this invention is typically about 0.010 - 0.100 inches and preferably about 0.015 - 0.060 inches in diameter. To provide an even higher degree of flexibility, for situations where the resonator must be inserted in, and conform to the shape of, a tightly coiled medical instrument, the wire diameter is preferably in the range of about 0.025 - 0.035 inches.

The length of the metal wire resonator may vary but is preferably greater than the length of the channel to be cleaned and is advantageously a multiple of the wave length of the driving frequency and selected as necessary to terminate the end of the resonator at a longitudinal antinode position.

The operating frequency may vary considerably and will typically be in the range of about 15,000 to 100,000 Hz. In general, the lower the frequency, the stronger the cavitation action and the more thorough the cleaning action. The higher the frequency, the weaker the cavitation action and the less potential for cavitation damage to the instrument being cleaned. At lower frequencies, the space between transverse antinodes is greater. A typical operating frequency is about 20,000 Hz for a solid flexible resonator made of Elgiloy, 15 inches long and 0.035 inches diameter. Other operating frequencies can be used. The lengths are proportioned as necessary to terminate the end of the resonator at a longitudinal motion antinode position. At 20,000 Hz a solid 0.035 inch diameter wire produces concentric transverse motion at intervals of about every 0.5 inches along the length of the resonator. For a 15 inch long resonator, 25 transverse antinode positions are produced. Using the same wire length and driving frequency, but with a wire diameter of 0.020 inches, concentric transverse wave motion is produced at intervals of about 0.325 inches along the entire length of the resonator. Approximately 46 transverse antinode positions are produced.

The transverse half wave lengths of a fixed free bar, such as a wire resonator attached at one end to a transducer, can be determined theoretically by the following equation:

$$\frac{1}{2}\lambda = [(C_n C_c d/2)/2F] * \frac{1}{2}[1/(n-1)]$$

where C_n (boundary condition) = $[(2n-21)/8]\pi$ wherein $n = \frac{1}{2}\lambda$; where $\lambda = C_c/F$; n = bar length; C_c = bar velocity; d= diameter; and F = driving frequency.

The wire resonator, either solid of annular, is attached at its proximal end to a transducer. In one preferred embodiment of the present invention, the attachment is made by means of a crimp screw that is threaded on one end (to be screwed into a threaded hole in the transducer) and provided with a hole in the other end into which the proximal end of the wire resonator may be inserted. In a more preferred embodiment for the solid metal wire resonator, a hole is bored into the proximal end of the solid wire resonator, leaving a ring of metal from the wire resonator encircling the hole. The hole does not extend more than 0.1 inches from the edge of the proximal end. In this embodiment, the hole in the solid wire is formed by an electro-deposition materials (edm) process wherein tiny holes can be bored into tiny areas. The radius of one of the wires described herein is typically approximately 0.0360 to 0.0370 inches. The holes that are bored through the edm process must necessarily be smaller than the radius of the wire. If the annular wire resonator is utilized, no hole need be drilled into the annular resonator since the annular resonator is hollow.

Before insertion into the crimp screw, the hole of the solid wire or the hollow portion of the annular wire is partially filled with a metal filler compound, such as piano wire or the like. The proximal end of the wire resonator is then inserted into the end of the crimp screw. The end of the crimp screw into which the wire is inserted is then crimped around the wire to provide a tight pressure attachment. The combination of the crimping process and the motion of the wire resonator, in a non-filled resonator, places too much pressure on the joint of the wire resonator at the point of coupling to the crimp screw because the wire is deformed at that juncture. The non-filled wire resonator tends to fail or crack at that juncture because of the pressure on the joint. However, with the insertion of the metal filler compound, the pressure on the joint is lessened and the wire resonator then has a longer life span and a slighter risk of failure. This attachment device produces a mismatch boundary condition that reduces the longitudinal motion and promotes transverse wave generation.

In an alternate embodiment, the apparatus may comprise a multiplicity of wire resonators attached to the transducer. In another third alternate embodiment, the wire resonator may comprise an annular metal wire resonator that is coupled to the ultrasonic transducer through the use of a crimp screw as well. In a more preferred form of the alternate third embodiment, the annular wire resonator is partially filled with a metal filler compound such as piano wire or the like, then inserted into the crimp screw. The end of the crimp screw into which the annular wire is inserted is then crimped around the wire to provide a tight pressure attachment. The metal filler material is then removed from the annular wire.

The use of an annular wire, in either embodiment, is only possible if the annular wire is partially filled with a metal filler compound, such as piano wire or the like. Otherwise, the combination of the crimping process and the motion of the wire resonator places too much pressure on the joint of the annular wire resonator at the point of coupling to the crimp screw because the wire is severely deformed at that juncture. The wire resonator will fail or crack at that juncture because of the pressure on the joint. However, with the insertion of the metal filler compound, the pressure on the joint is lessened and the annular wire resonator then has a longer life span.

In a fourth alternate preferred embodiment of the present invention, a capturing member is integral with and surrounds the solid or annular wire resonator that is to be inserted into the ultrasonic transducer horn. More preferably, the capturing member is crimped to the wire resonator. The capturing member is fixedly attached to the wire resonator at a position that allows a portion of the wire resonator to fit within the transducer horn. The wire resonator is inserted into the ultrasonic transducer horn. A barrier member, shaped like a box, possesses a hole in one end for allowing the wire resonator to be sheathed in the hole. The barrier member slides over the wire resonator and the area where the resonator is coupled to the ultrasonic transducer and fixedly attached to the ultrasonic transducer horn. The hole in the barrier member must be smaller in diameter than the combined diameter of the capturing member and wire resonator; yet, larger than the diameter of the wire resonator only. With this arrangement, the capturing member is located between the edge of the ultrasonic transducer horn and the inside edge of the barrier member. When the ultrasonic transducer is activated, the wire resonator moves back and forth in a limited range of motion, i.e., from when the capturing member abuts the edge of the transducer horn to where the capturing member abuts the edge of the barrier member. The wire resonator will move back and forth very quickly. The transverse motion induces the wire resonator to act like a small jackhammer and causes the resonator to become more powerful. In this fourth embodiment, the wire resonator and ultrasonic transducer do not generate the typical amounts of heat that is generated when the wire resonator is fixedly secured to the ultrasonic transducer.

The wire, preferably Elgiloy, may advantageously be provided with a protective coating which may be a hard coating, such as titanium nitride, or a soft coating such as polytetrafluoroethylene (Teflon; fluon; etc.) or the like to protect it from damage due to the cavitational action of the liquid. Hard coatings such as titanium nitride have the advantage of minimizing attenuation of the ultrasonic energy and are preferred.

Referring now to the drawings in detail, for the ease of the reader, like reference numerals designate identical or corresponding parts throughout the views depicted in the drawings. It should be noted that each embodiment is not depicted by a drawing nor are each of the notable applications depicted by a drawing. It should also be noted that wherever a solid resonator appears in one of the drawings, an annular resonator may be substituted.

In Fig. 1, a resonator (11) is shown attached at its proximal end (12) to an ultrasonic transducer (13). The ultrasonic resonator (11) is a solid resonator of a material capable of producing both transverse and longitudinal vibrations in response to ultrasonic transducer (13). The ultrasonic transducer may be of the magnetorestrictive type or, preferably, of the piezoelectric type. One embodiment of the ultrasonic transducer is depicted in Fig. 13. The transducer in Fig. 13 possesses a plurality of piezoelectric ceramic elements (60) stacked one on the other with metal separators (61) between the ceramic elements such that one end of the ceramic elements will touch the horn (64) and the other end of the plurality of ceramic elements is attached to a bias bolt (not shown). The electrical wires (63) that transport energy from the generator to the transducer are connected to these metal separators via metal connectors (62) to excite the molecules within the ceramic elements.

Fig. 2 is a longitudinal sectional view of the ultrasonic resonator (11) attached at its proximal end (12) to the ultrasonic transducer (13), which, in turn, is shown connected to an ultrasonic power generator (16). The resonator (11) is shown positioned in axial alignment with the instrument (18) to be cleaned. The solid resonator (11) may be attached at the proximal end to the tip of the ultrasonic transducer (12) by various means. A preferred form of attachment, as depicted in Fig. 3, is a crimp screw (14) which is provided with threads (31) at one end and a hole (32) at the other end. The hole (32) is adapted to receive the proximal end of resonator (11). When the end of resonator (11) is positioned in hole (32), the end of the crimp screw (14) is crimped to provide a pressure attachment. The other end of the crimp screw (14) is provided with threads (31) which may be conveniently screwed into a compatible threaded opening (not shown) in the end of the transducer horn (13).

Fig. 3 further shows two layers of plastic tubing (33) which may, for example, be of Teflon to provide protection and to attenuate the ultrasonic energy at the attachment site, reducing the possibility of failure at the attachment site.

Fig. 4 is a longitudinal sectional view of the solid resonator (11) which will be attached at the proximal end to the tip of the ultrasonic transducer (13). A preferred from of attachment, as depicted in Fig. 4, is a crimp screw (14) which is provided with threads (31) at one end and a hole (32) at the other end. The hole (32) is adapted to receive the proximal end of resonator (11). When the end of resonator (11) is positioned in hole (32), the end of the crimp screw (14) is crimped to provide a pressure attachment. The other end of the crimp screw (14) is provided with threads (31) which may be conveniently screwed into a compatible threaded opening (not shown) in the end of the transducer horn (13). Fig. 4 also depicts the location of the edm hole (41) and the solid resonator before insertion into the crimp screw.

The relationship between the operating or driving frequency and the transverse wavelength for wires of a given material and various diameters is shown in Fig. 5. In the chart, transverse wavelength (inches) is plotted against driving frequency (Hz) for various diameters of Elgiloy wire. The Elgiloy wire employed was 48% cold reduced and heat treated at 980°F for approximately five hours.

Fig. 6 shows the solid resonator (11) with an edm hole (41) contained within the proximal end (12) and inserted into the crimp screw (14) before crimping occurs. Fig. 6 also depicts the filler material (42) after insertion into the edm hole (41) and the spatial relationship between the crimp screw (14) and the resonator (11). Fig. 7 shows the same elements as Fig. 6 after crimping has occurred. Fig. 8 shows the same elements as Fig. 6 before the resonator is inserted into the crimp screw.

Figs. 9A and 9B depict an embodiment of this invention that allows for limited movement of the resonator with respect to the ultrasonic transducer. The wire resonator (11 or 70) is fitted with a capturing member (50) such that the capturing member is located a small distance from the proximal end of the resonator. The capturing member may be shaped in many different ways, preferably the capturing member is an annular ring that fits over the resonator. A barrier member (51) is placed over the resonator and the ultrasonic transducer such that the capturing member (50) is located in between the inner surface of the barrier member (51) and the tip of the ultrasonic transducer (13). This type of attachment is referred to as a floating attachment.

Fig. 10 shows the annular resonator (70) and inserted into the crimp screw (14) before crimping occurs. Fig. 10 also depicts the filler material (42) after insertion into annular resonator and the spatial relationship between the crimp screw (14) and the resonator (11). Fig. 11 shows the same elements as Fig. 10 after crimping has occurred. Fig. 12 shows the same elements as Fig. 10 before the resonator is inserted into the crimp screw.

Figs. 14A, B, and C depict the motion of the floating attachment through certain stages of the resonator's motion.

NOTABLE APPLICATIONS OF THE SUBJECT INVENTION

It is obvious to one skilled in the art that this invention, in any of the embodiments described above, can be used in many applications. As examples, six applications that are different from the application of cleaning endoscopes are described herein. The first application of note is the use of this invention in cleaning ceramic investment castings. These castings are made to order to mold one type of ceramic product and are very expensive. These castings tend to possess tiny holes that, invariably, get clogged with ceramic material. The ceramic material hardens within the tiny holes. Because the openings in the molding are so small, it is impossible to remove the hardened ceramic material by any mechanical methods without destroying the investment casting. The investment castings are very expensive to produce, especially if made as a one-time use apparatus. Any of the embodiments of the invention described herein, including the floating attachment, is well suited, without physical changes to the apparatus, to removing the hardened ceramic material from the openings. The investment casting is, preferably, immersed in a liquid and the wire resonator placed near the openings that are clogged. It should be apparent to one skilled in the art that the step of immersing the investment casting into water is not a required step; however, it is a preferred step. The ultrasonic generator is switched on to generate the longitudinal and transverse ultrasonic waves and the ultrasonic waves emanating from the tip of the wire resonator break up the ceramic material, thereby removing the ceramic material, without harming the investment casting. The fourth alternate embodiment described above is especially suited to the removal of the hardened ceramic from the apertures of the castings. The resonator is placed against the hardened ceramic material, the ultrasonic generator is energized and the resonator abuts against the hardened material until it is broken into pieces and removed from the aperture.

The second application of note is the use of this invention in cleaning brain shunts. Any of the embodiments of the subject invention, as basically described herein including the floating attachment, are especially well suited to clean this type of delicate apparatus. The invention must, of course, be modified to meet acceptable governmental standards for materials that are to be inserted into a human being, and, into a human being's brain. Contemplated changes include modifying the type of material used for the resonator, such as pure alloys of Nickel-Cobalt or Titanium. An alternate embodiment includes the resonator being constructed of plastic. In addition, various modifications must be made to the length and diameter of the resonator. In a preferred embodiment, the diameter of the resonator is approximately 0.0355 inches and the length of the resonator is approximately 12 inches. The resonator may be flexible or rigid. However, it should be apparent to one skilled in the art that many different lengths and diameters may be used, dependent on the length and diameter of the shunt. In a preferred embodiment of the process of using this invention for this application, the resonator is inserted into the shunt up to the tip of the shunt and the ultrasonic generator is energized, generating longitudinal and transverse waves. Those ultrasonic waves break up the material clogging the brain shunt by pushing the brain material out of the holes in the brain shunt, thereby cleaning the shunt without removal or harm to the patient. In an alternative preferred embodiment of the process, the choroid plexus (brain material) in the shunt is initially cauterized by transmitting a high voltage through the wire resonator to the shunt. This crystallizes the material and releases its ties to the brain thereby reducing the risk of hemorrhage. Hardened material is typically easier to break up than the softer materials. However, this step is not necessary for the invention to accomplish the goal of cleaning the shunt; but is a preventive step to prevent hemorrhaging in the person's brain.

The third application of note is the use of this invention in assisting in the extraction of pacemaker leads or other leads that have been inserted into a human or animal. For the purposes of simplicity, this discussion is limited to the specific application of removing pacemaker leads. However, it should be apparent to one skilled in the art that this process may be adapted to the removal of many other types of leads. The invention, in the embodiments as basically described herein including the floating attachment, is well suited to facilitate the removal of the pacemaker leads. Again, the invention must be modified to meet acceptable government standards for insertion into human beings. One contemplated change is the material of the resonator from the current embodiment to a pure alloy of stainless steel, Eligloy or Titanium. An alternate embodiment includes the resonator being constructed of plastic. In addition, various modifications must be made to the length and diameter of the resonator. In a preferred embodiment, the diameter of the resonator is 0.148 inches and the length is approximately 12 inches. However, it should be apparent to one skilled in the art that many different lengths and diameters may be used, dependent on the length and diameter of the pacemaker lead. An annular wire resonator must be used for this application. The annular resonator is then inserted into the body such that the resonator sheathes the lead. The annular wire resonator, either flexible or rigid, is glided along the lead until an obstruction is reached. Then, the ultrasonic generator is switched on, longitudinal and transverse waves are generated dependent on the type of connection to the horn and transducer, and the ultrasonic waves break up the material surrounding the lead. The mechanical excursion of the tip also provides a cutting mechanism. This process is continued until the entirety of the material surrounding the lead is broken up and the lead can be extracted without any physical damage to the arteries or surrounding tissue. The lead can then be extracted without causing severe trauma to the patient.

The fourth application of note is the use of the subject invention in coring arenas, especially planetary exploration coring. The most overwhelming problem with coring on other planets in the solar system or in space is the lack of gravity. A low gravity atmosphere requires the use of low axial coring, an aspect not easily attained through typical coring mediums. The invention, in the embodiments as basically described herein including the floating attachment, is well suited to provide low axial load coring for use in interplanetary applications. The annular wire resonator, either flexible or rigid, may be used to core into a rock or other hardened material by abutting the annular wire resonator against the material to be cored. The ultrasonic generator is energized and the annular wire resonator cores into the hardened material. The core becomes lodged in the tip of the wire resonator and can be dislodged to provide a sample for geological testing and analysis. The wire resonator, coupled to the ultrasonic generator, can withstand large temperature ranges such as those found in interplanetary conditions. In addition, the ultrasonic generator and wire resonator can be made of suitable material to withstand the rigors of travelling to and from the interplanetary worksite. It should be apparent to one of skill in the art that this invention could be adapted to take samples from bones or other hardened materials.

The fifth application of note is the use of the subject invention in drilling arenas, especially planetary exploration drilling. The most overwhelming problem with drilling on other planets in the solar system or in space is the lack of gravity. This low gravity atmosphere requires the use of low axial drilling, an aspect not easily attained through typical drilling mediums. The invention, in the embodiments as basically described herein including the floating attachment, is well suited to provide low axial load drilling for use in interplanetary applications. The solid or annular wire resonator, either flexible or rigid, may be used to drill into a rock by abutting the wire resonator against the material to be drilled. The generator is then energized and a hole is drilled into the material. If the annular wire resonator is used, the invention provides both drilling and coring in one use of the generator. The wire resonator, coupled to the ultrasonic generator, can withstand large temperature ranges such as those found in interplanetary conditions. In addition, the ultrasonic generator and wire resonator can be made of suitable material to withstand the rigors of travelling to and from the interplanetary worksite. It should be readily apparent to one skilled in the art that this invention could be used in drilling through bones or other hardened materials as well.

The sixth application of note is the use of the present invention in treating atherosclerotic plaque and thromboses. The wire resonator of the present invention can be sheathed in the manner described in U.S. Patent No. 4,870,953 to DonMichael et al. and used to break up atherosclerotic plaque by insertion into the blocked artery. The invention, in the embodiments as basically described herein including the floating attachment, is well suited to assist in the treatment of atherosclerotic plaque and thromboses. The wire resonator will be placed against the plaque or the material blocking the artery. The ultrasonic generator is energized and the ultrasonic waves will break up the material blocking the artery. If the coupling mechanism that allows limited transverse motion of the wire resonator is used for this application, the tip of the wire resonator does not heat up and can thus be used continuously until the arterial plaque or material blocking the artery is removed.

Although, for convenience, the method and apparatus of the present invention have been described hereinabove primarily with respect to the cleaning of instruments as well as a few other applications, it will be apparent to those skilled in the art that the invention applies also to the many similar instruments characterized by an elongate tubular configuration as well as to other situations and devices wherein contaminants may difficult to dislodge or remove by traditional cleaning methods. In addition, it will be apparent to those skilled in the art that the invention applies also to the many removal applications characterized by materials clogging small apertures that must be removed from the apertures. Further, it is apparent to those skilled in the art that the invention applies to many small drilling and coring applications where low axial and drilling and coring are necessary.

What I Claim Is:

1. An ultrasonic resonator comprising:

an elongate solid wire capable of generating both transverse and longitudinal ultrasonic vibrations to produce cavitational action in a liquid-filled medium at a multiplicity of transverse antinode sites along the length of the elongate solid wire in response to energization by an ultrasonic transducer and generator.

2. A resonator according to claim 1 wherein said resonator is constructed of metal.

3. A resonator according to claim 1 wherein said resonator is constructed of plastic.

4. A resonator according to claim 1 wherein said resonator is used to clean investment castings.

5. A resonator according to claim 1 wherein said resonator is used to clean brain shunts.

6. A resonator according to claim 1 wherein said resonator is used as a drill.

7. A resonator according to claim 1 wherein said resonator is used to collect core samples.

8. A resonator according to claim 1 wherein said resonator is used to remove plaque and hardened materials from an inside of a blood vessel in a human or an animal.

9. A device for coupling a solid resonator to an ultrasonic transducer, comprising:

a crimp screw having a first and second end, the first end being threaded to threadably engage the ultrasonic transducer, the second end having a receptacle portion for receiving the solid resonator;

a solid resonator with a hole bored into one end; and a filler compound for inserting into the bored hole of the solid resonator.

10. A device according to claim 9 wherein the filler compound is constructed of metal.

11. A device according to claim 9 wherein the solid resonator is constructed of metal.

12. A device according to claim 9 wherein the solid resonator is constructed of plastic.

13. A process for coupling a solid resonator to an ultrasonic transducer, comprising:

boring a hole into one end of the solid resonator;

positioning a filler compound within the bored hole of the solid resonator;

inserting the filled end of the solid resonator into a screw having a first and second end, such second end having a receptacle portion for receiving such filled end of the solid resonator;

physically crushing the screw end to permanently couple the filled end of the solid resonator to the screw end; and

threadably engaging the first end of the screw to an ultrasonic transducer.

14. An ultrasonic resonator comprising:

an annular wire capable of generating longitudinal ultrasonic vibrations to produce cavitational action in a liquid-filled medium at a multiplicity of transverse antinode sites along the length of the elongate annual wire in response to an ultrasonic transducer.

15. A resonator according to claim 13 wherein said resonator is constructed of metal.

16. A resonator according to claim 13 wherein said resonator is constructed of plastic.

17. A resonator according to claim 13 wherein said resonator is used to clean brain shunts.

18. A resonator according to claim 13 wherein said resonator is used to clean investment castings.

19. A resonator according to claim 13 wherein said resonator is used to facilitate the extraction of pacemaker leads by removing tissue surrounding the lead.

20. A resonator according to claim 13 wherein said resonator is used as a drill.

21. A resonator according to claim 13 wherein said resonator is used to collect core samples.

22. A resonator according to claim 13 wherein said resonator is used to remove plaque and other hardened materials from an inside of a blood vessel of a human or an animal.

23. A device for coupling an annular resonator to an ultrasonic transducer, comprising:

a crimp screw having a first and second end, the first is threaded to threadably engage the ultrasonic transducer, the second end having a receptacle portion for receiving the annual resonator; and

a filler compound for inserting into a bored hole in the annular resonator.

24. A device according to Claim 23 wherein the filler compound is constructed of metal.

25. A device according to Claim 23 wherein the annular resonator is constructed of plastic.

26. A device according to Claim 23 wherein the annular resonator is constructed of metal.

27. A process for coupling an annular resonator to an ultrasonic transducer, comprising:

positioning a filler compound within an end of the annular resonator;

inserting the filled end of the annular resonator into a screw having a first and second end, such second end having a receptacle portion for receiving such filled end of the annular resonator;

physically crushing the screw end to permanently couple the filled end of the annular resonator to the screw end; and

threadably engaging the first end of the screw to an ultrasonic transducer.

28. A process according to claim 23 comprising the additional step of removing the filler compound from the annular resonator.

29. A device for coupling a resonator to an ultrasonic transducer, comprising:

a resonator having a proximal end to be inserted into an ultrasonic transducer;

a capturing member integral with and surrounding the resonator near the proximal end;

a barrier member having a hole in one end and an opposite open end;

said open end fitting over and fixedly secured to the ultrasonic transducer;

said hole fitting over and encircling the resonator such that the capturing member is positioned between the ultrasonic transducer and the barrier member.

30. A device according to Claim 29 wherein the capturing member is physically crushed to the resonator to permanently couple the resonator to the capturing member.

31. A device according to Claim 29 wherein the resonator is an annular resonator.

32. A device according to Claim 29 wherein the resonator is a solid resonator.

33. A device according to Claim 29 wherein the resonator is constructed of metal.

34. A device according to Claim 29 wherein the resonator is constructed of plastic.

35. A process for cleaning investment castings comprising:

placing the tip of a resonator against the clogged portion of the investment case molding; the resonator being coupled to and responsive to an ultrasonic transducer and generator; and,

generating both longitudinal and transverse ultrasonic waves, wherein the longitudinal and transverse ultrasonic waves are generated by a flexible solid metal wire resonator, wherein cavitational cleaning action is generated in the liquid medium by ultrasonic energy produced simultaneously at a multiplicity of transverse antinode sites along the length of the flexible solid wire resonator.

36. A process for facilitating the removal of leads by cleaning tissue away from the lead comprising:

sheathing the lead with an annular resonator, the annular resonator being coupled to and responsive to an ultrasonic transducer and generator;

gliding the resonator along the lead until an obstruction of tissue is encountered;

generating both longitudinal and transverse ultrasonic waves, wherein the ultrasonic waves break up the tissue obstruction; and,

repeating the process until the lead can be disengaged and removed without obstructions.

37. A process for low axial drilling of materials comprising:

placing a tip of a resonator against the material, the resonator being coupled to and responsive to an ultrasonic transducer and generator; and,

generating ultrasonic waves wherein the waves drill through the material.

38. A process for low axial coring of samples comprising:

placing a tip of an annular resonator against the material, the resonator being coupled to and responsive to an ultrasonic transducer and generator, the resonator having a hollow interior;

generating ultrasonic waves wherein the waves drill through the material;

capturing a portion of the material being drilled in the hollow interior of the annular resonator; and,

removing the captured portion of the material from the hollow interior of the annular resonator.

39. A process for removing plaque and other obstructions from an interior of a blood vessel comprising:

inserting a resonator into the blood vessel until the resonator abuts the plaque or other obstruction;

generating ultrasonic waves wherein the waves break up the plaque or other obstruction in the blood vessel.

40. A process for cleaning brain shunts that are obstructed with fluid or brain material

comprising:

inserting a resonator into a brain shunt, the resonator being coupled to and responsive to an ultrasonic transducer and generator;

generating both longitudinal and transverse ultrasonic waves wherein the ultrasonic waves break up the obstructions in the brain shunt, pushing the obstructions out of holes located in the shunt; thereby, cleaning the shunt.

41. A process for cleaning brain shunts as described in claim 40, further comprising: flowing a sterile solution through the brain shunt to cauterize the material obstructing the brain shunt.

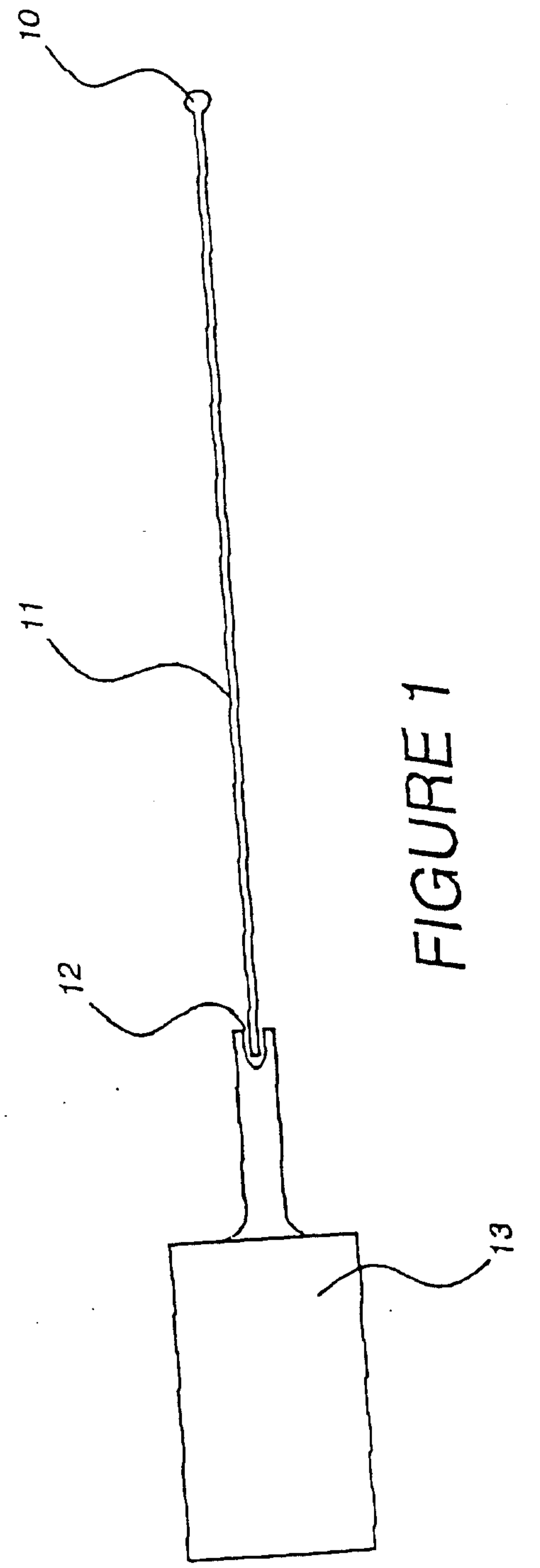


FIGURE 1

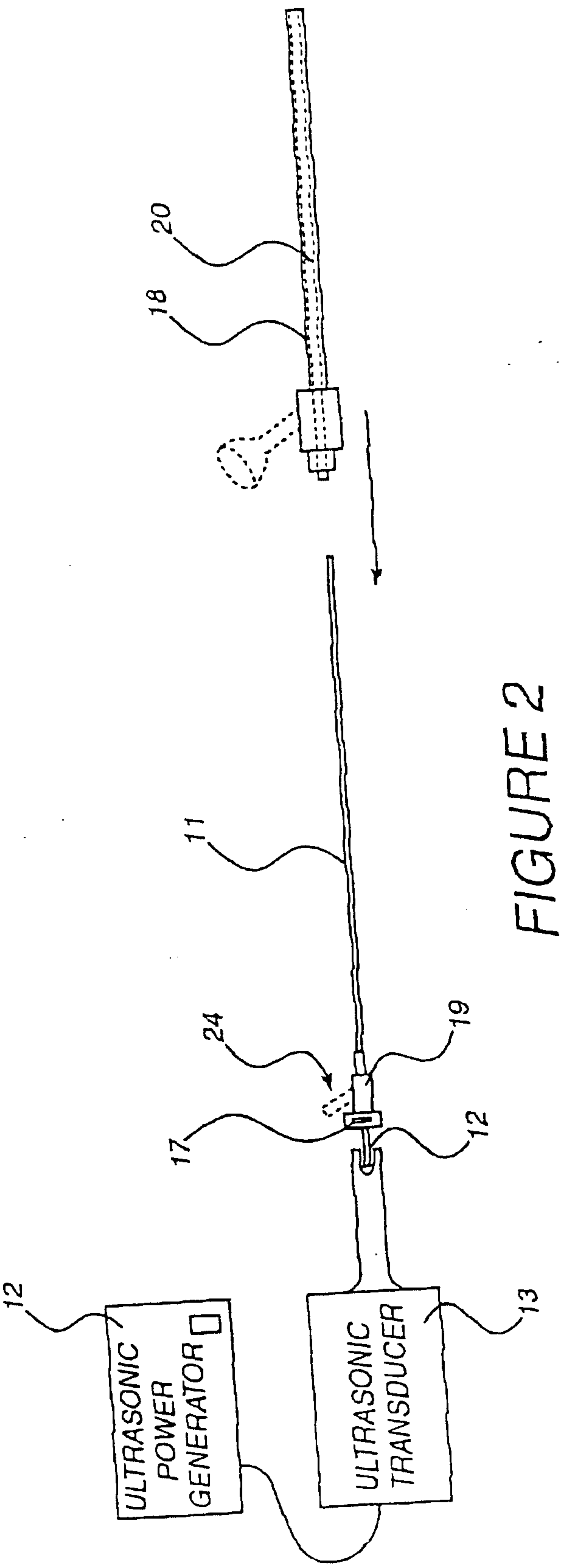


FIGURE 2

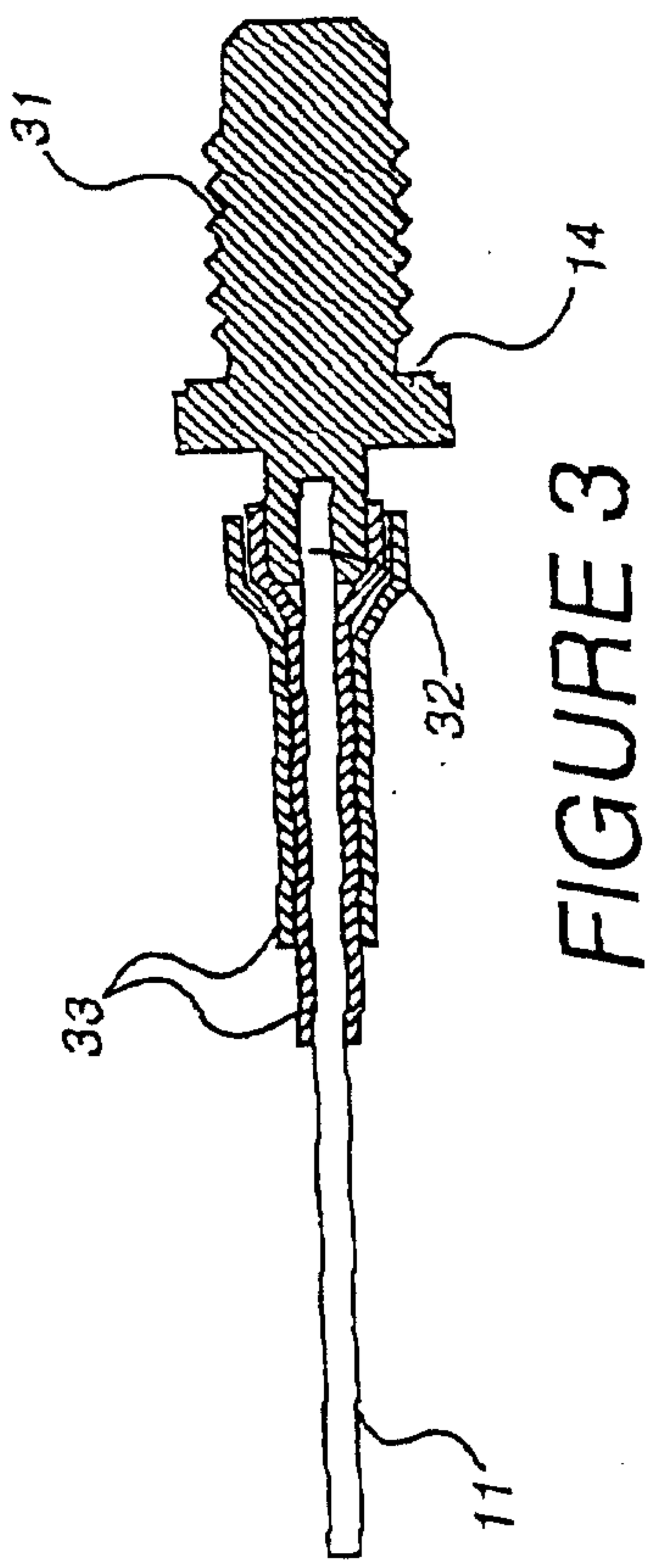


FIGURE 3

Gowling, Strathy & Henderson

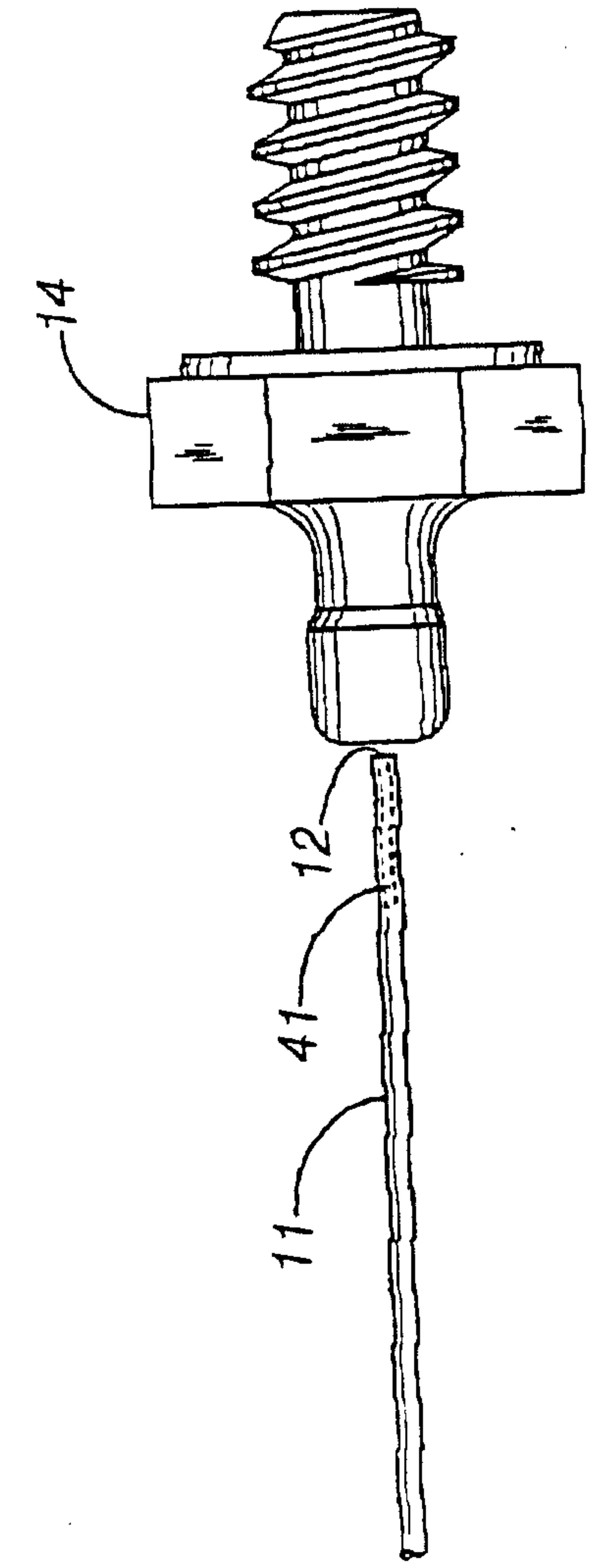


FIGURE 4

Gowling, Strathy & Henderson

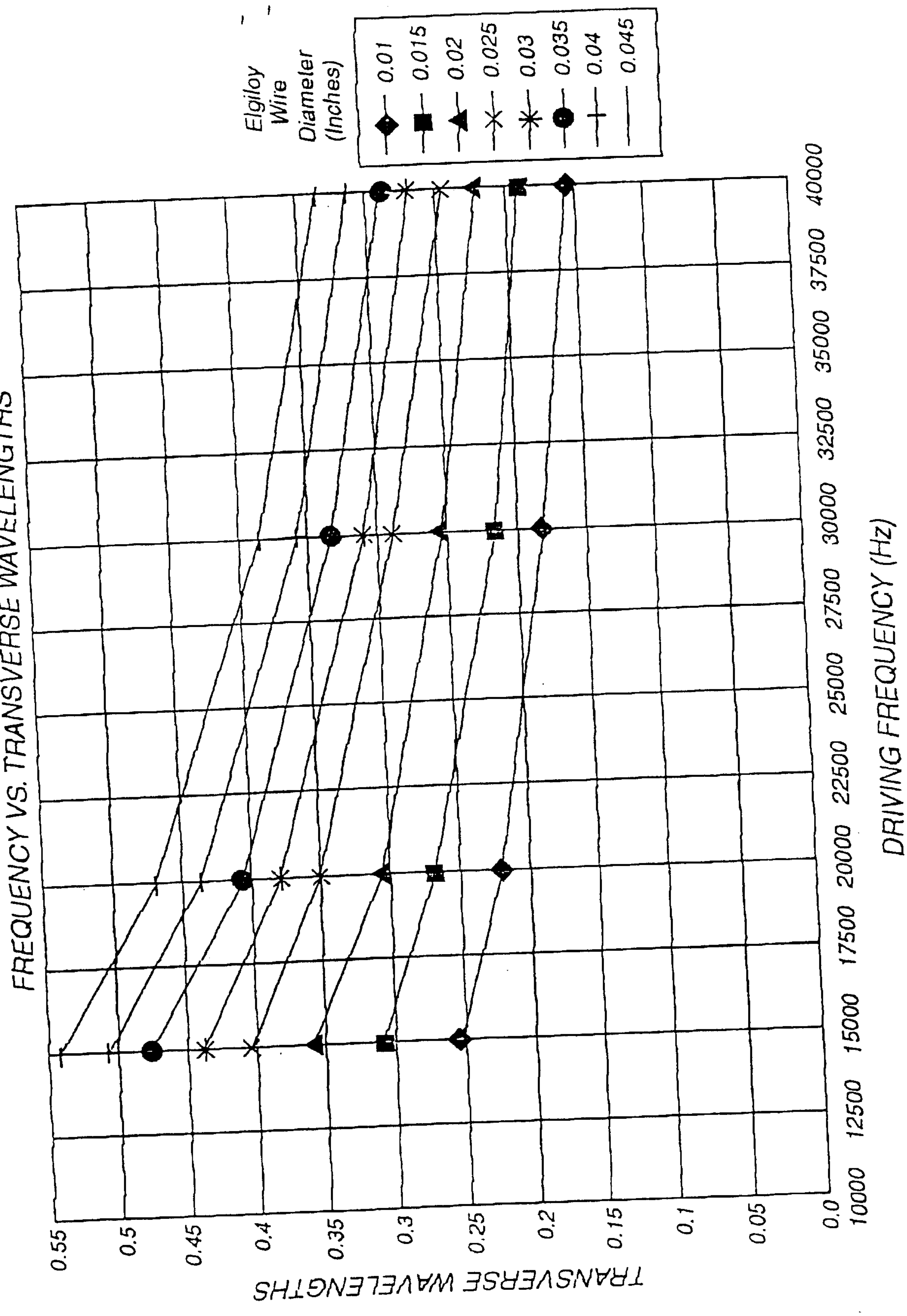

FREQUENCY VS. TRANSVERSE WAVELENGTHS
Elgiloy Wire Diameter (Inches)
0.01
0.015
0.02
0.025
0.03
0.035
0.04
0.045
TRANSVERSE WAVELENGTHS
0.55
0.5
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0.0
DRIVING FREQUENCY (Hz)
10000
12500
15000
17500
20000
22500
25000
27500
30000
32500
35000
37500
40000

Fig 5

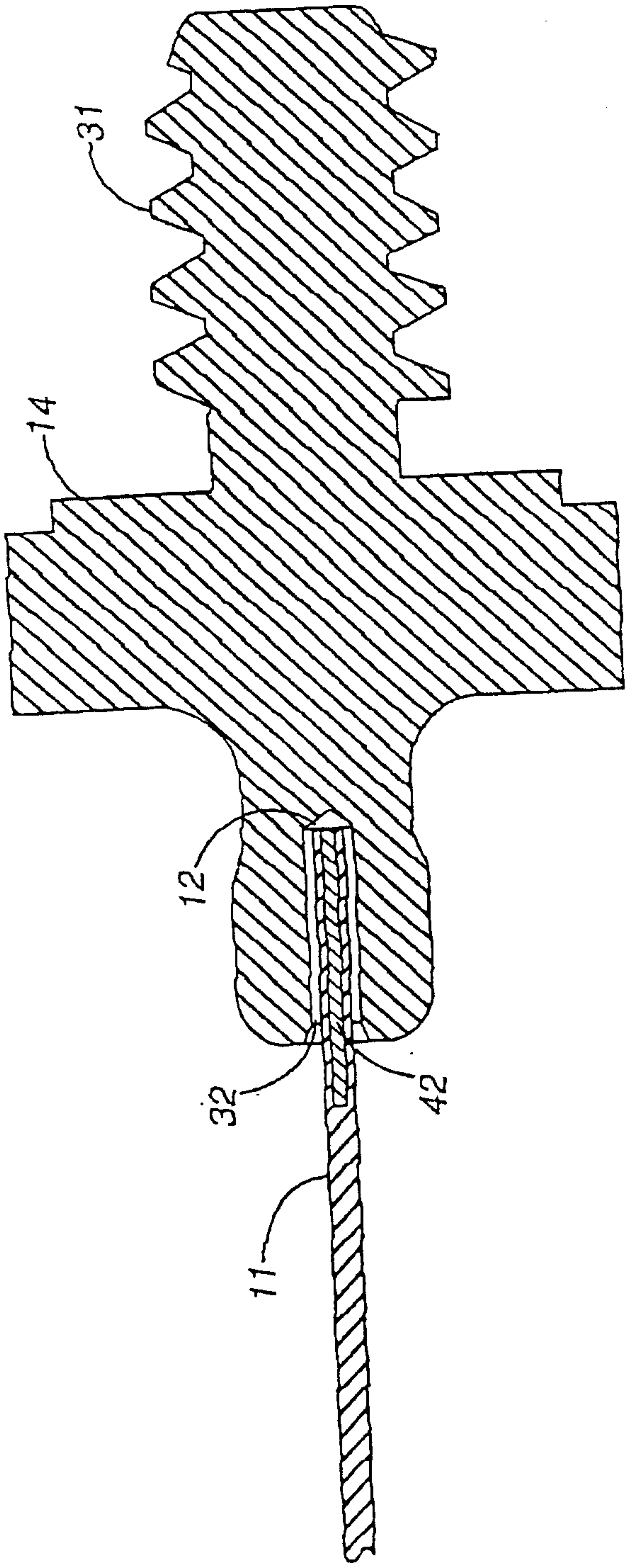


FIGURE 6

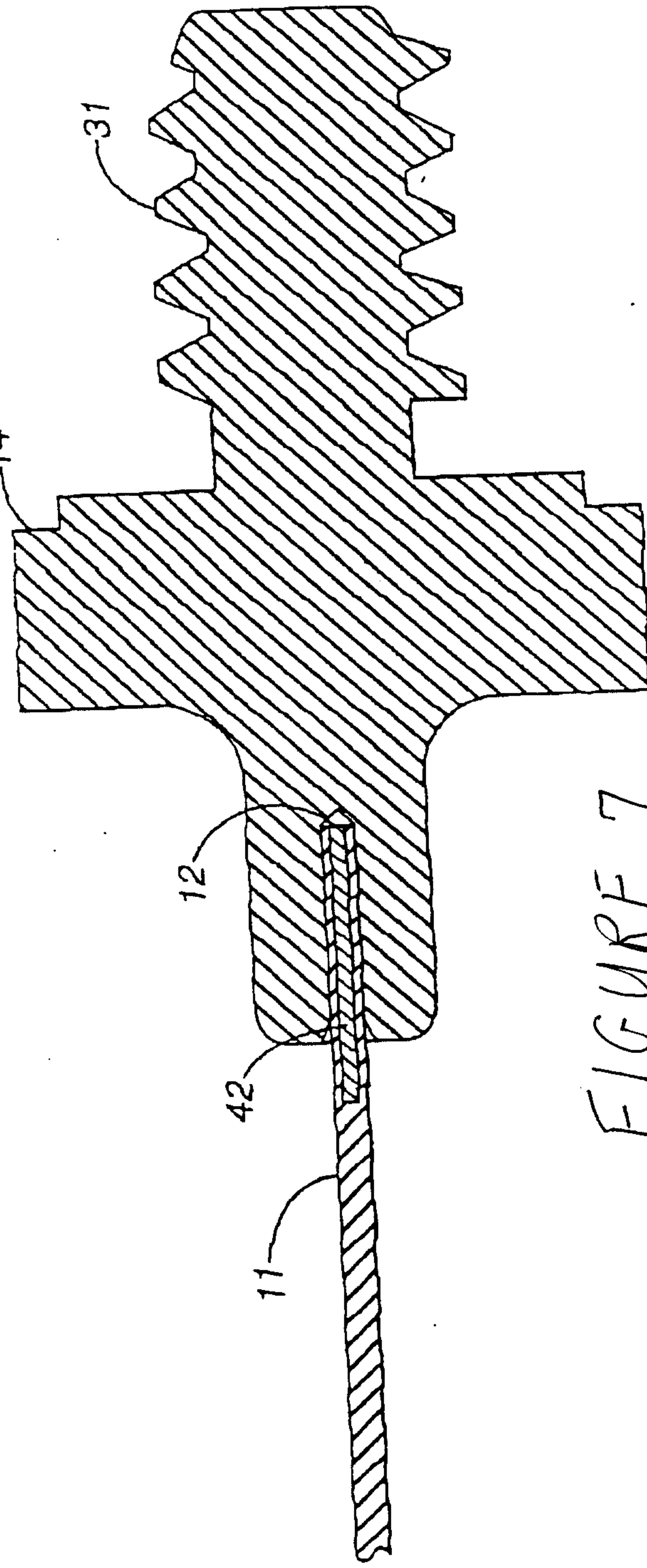


FIGURE 7

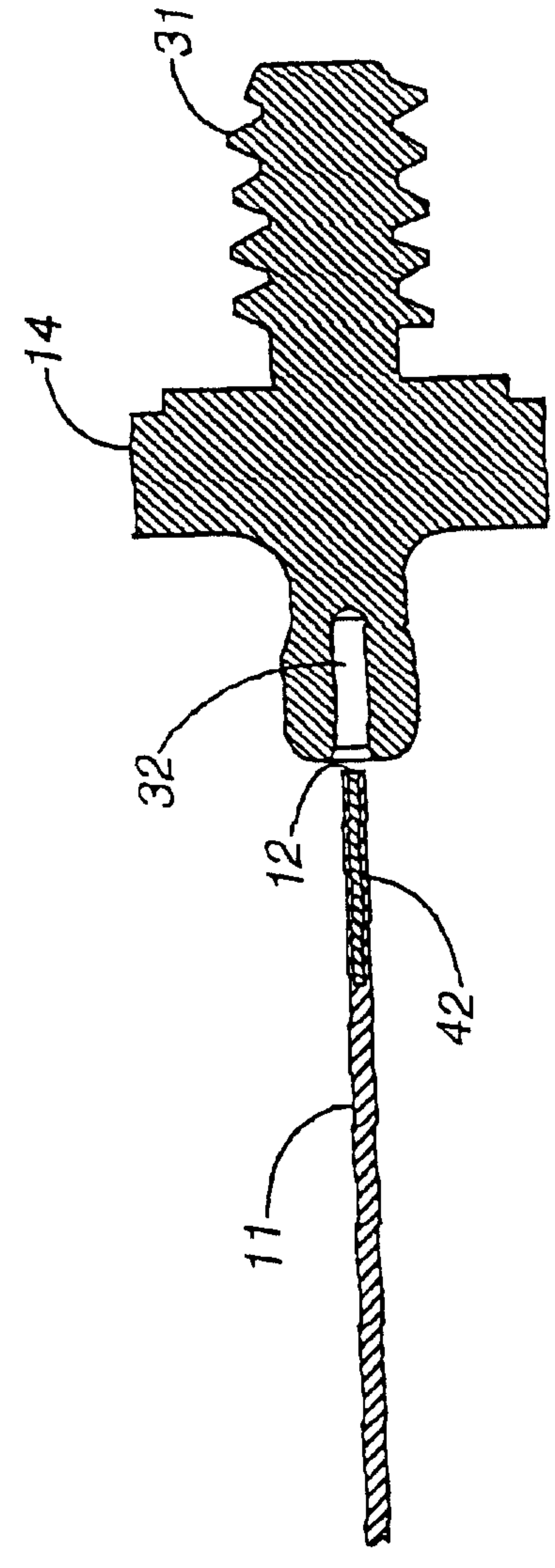


FIGURE 8

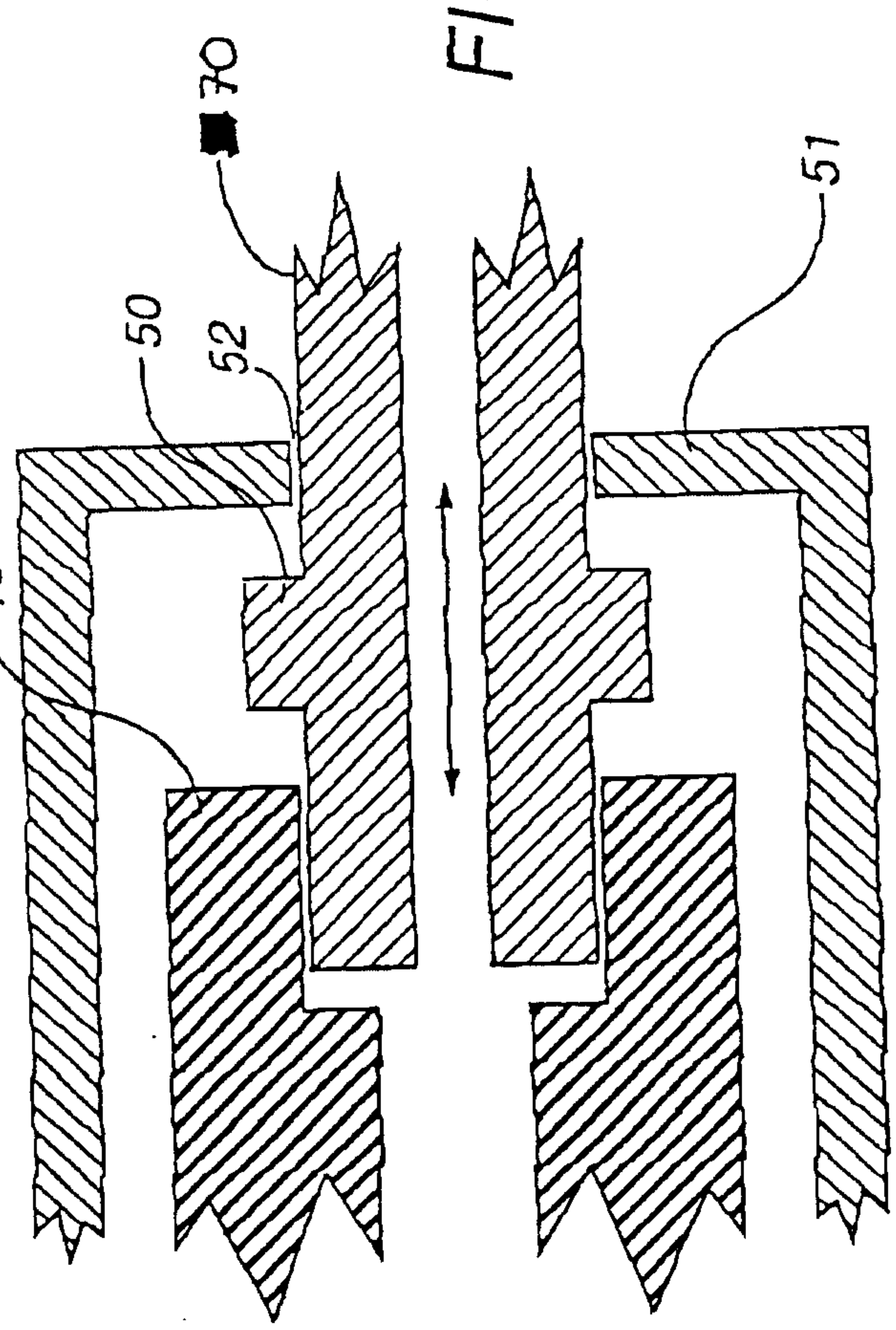


FIGURE 9A

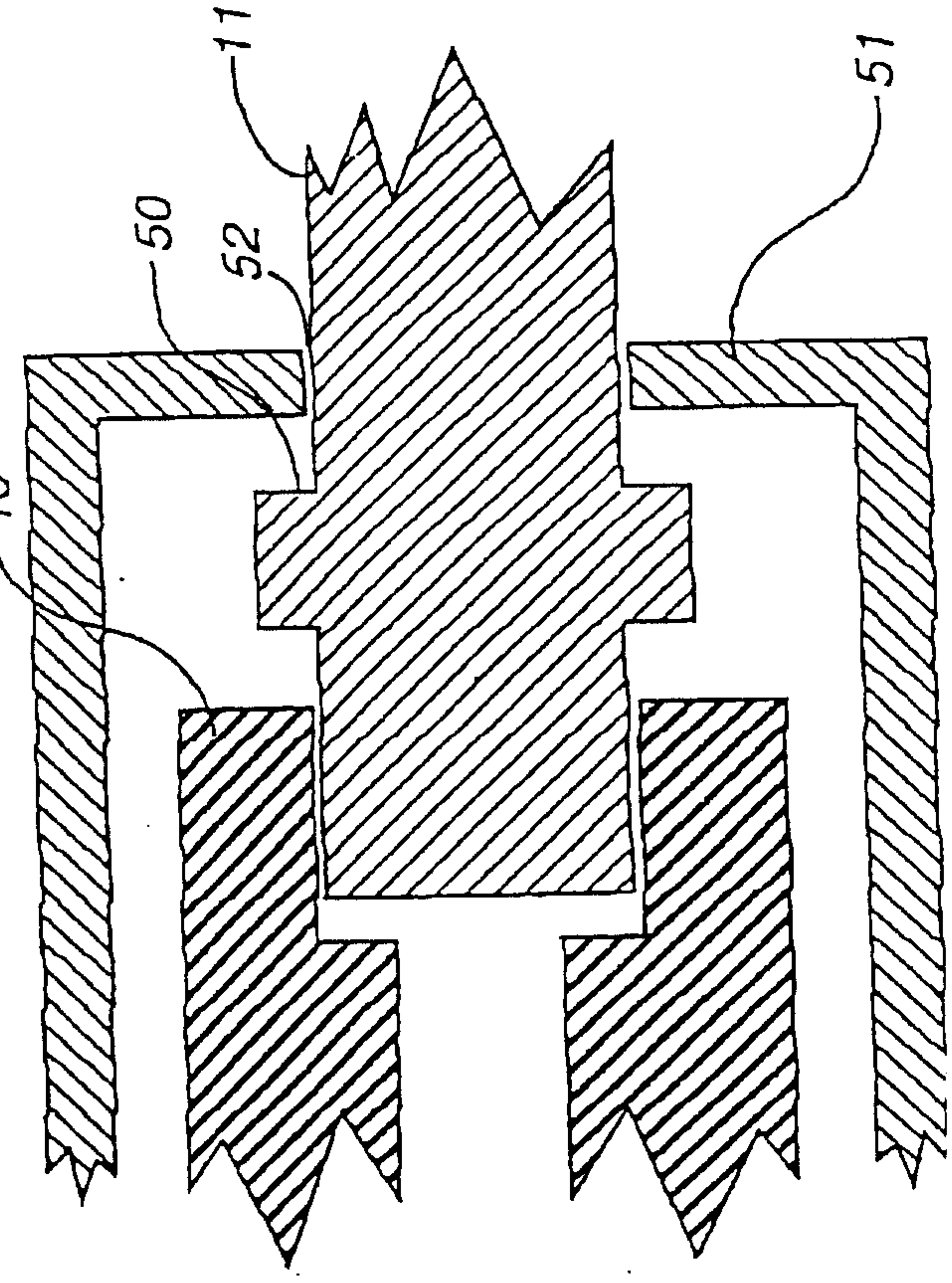


FIGURE 9B

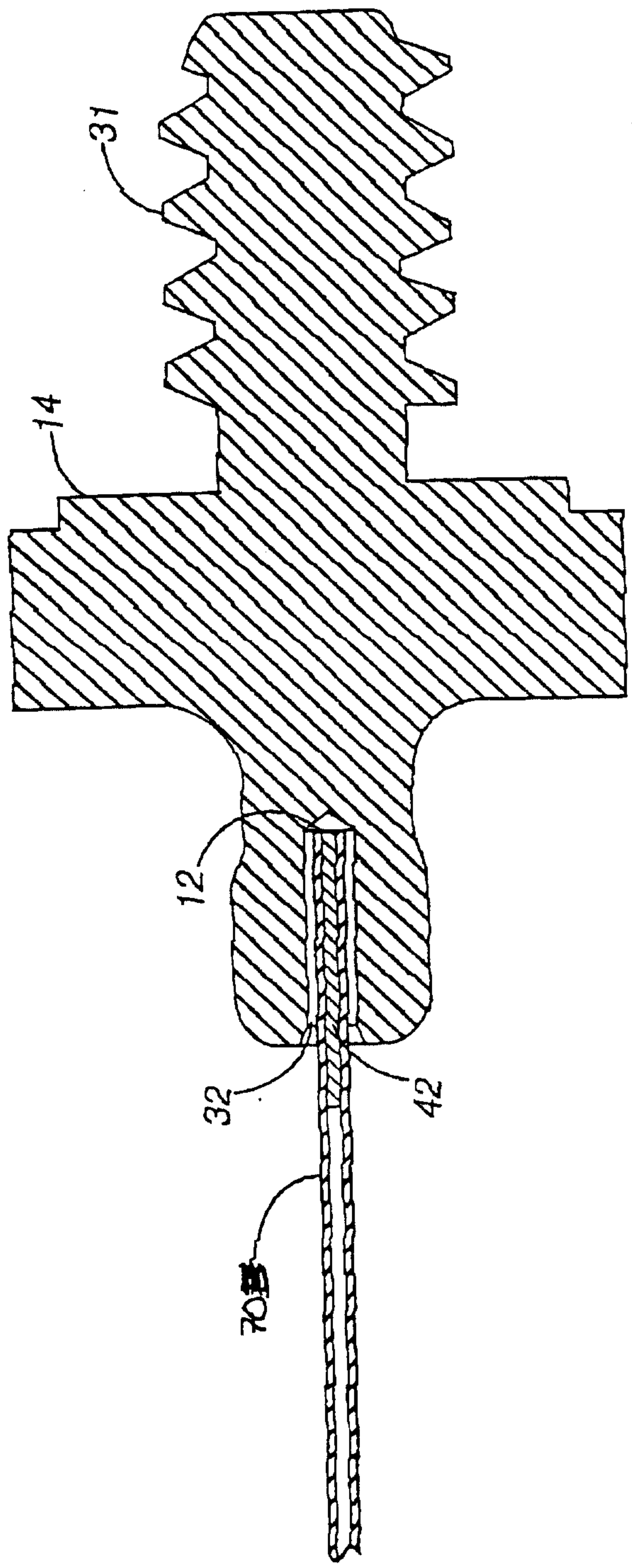
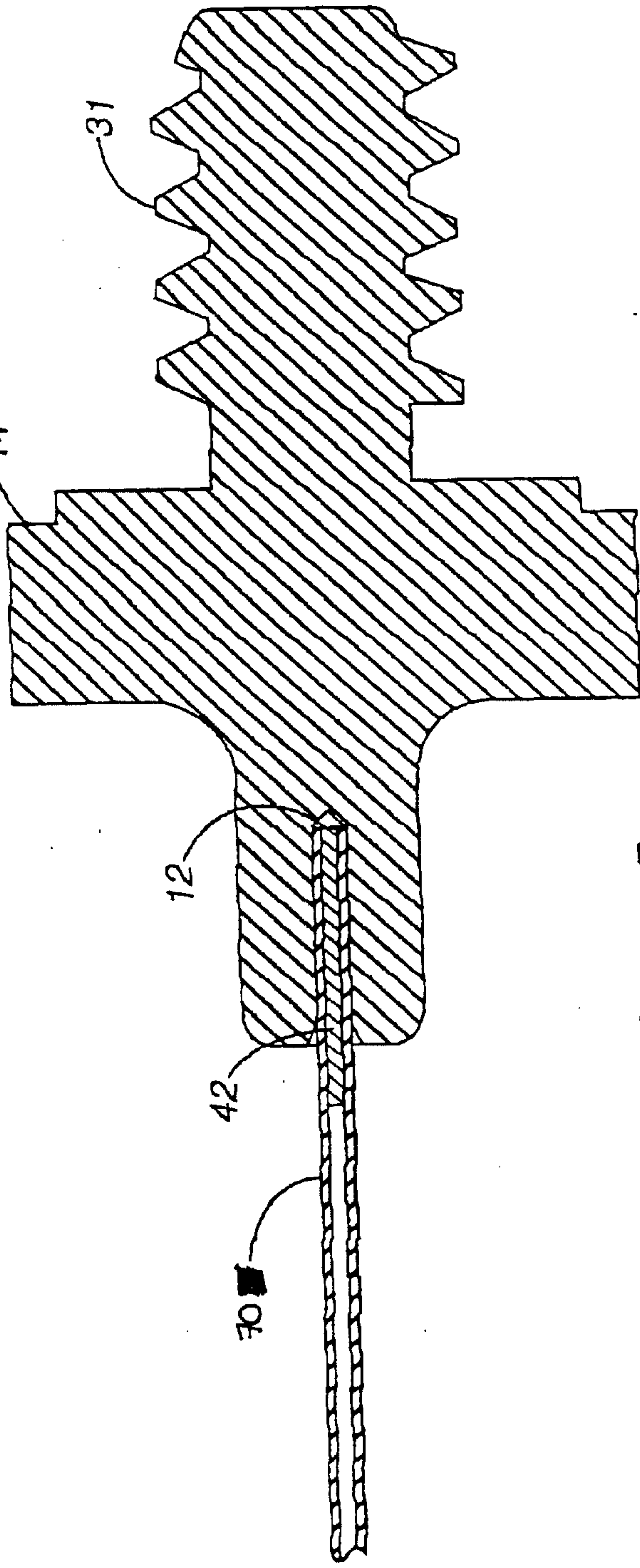


FIGURE 10



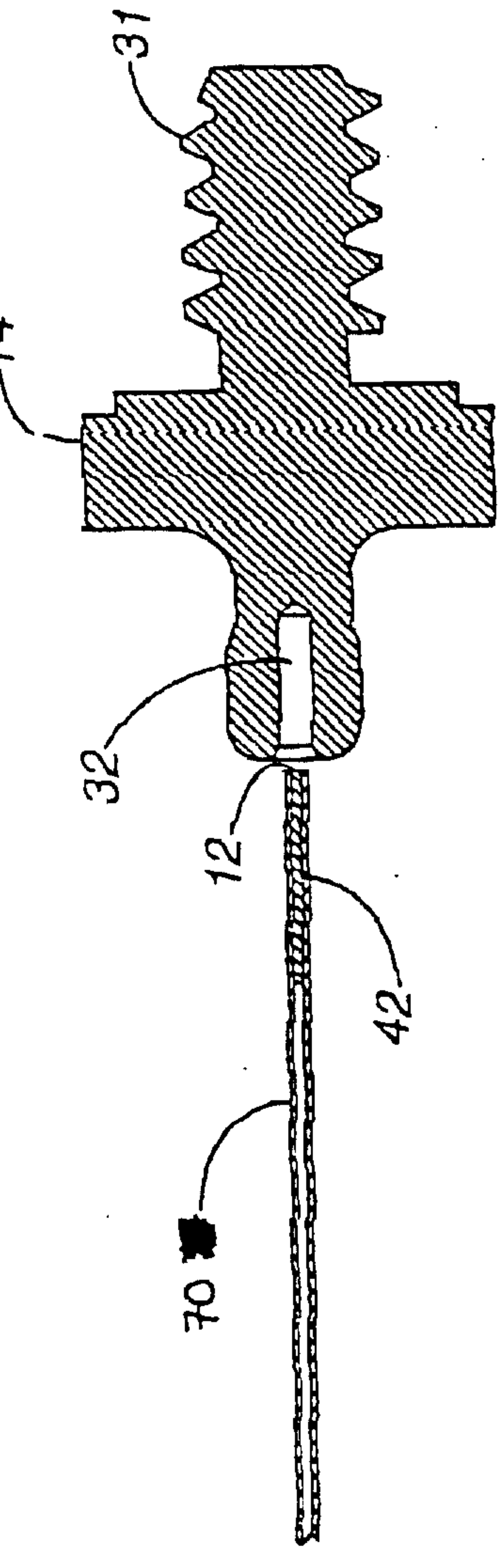


FIGURE 12

Gowling, Strathy & Henderson

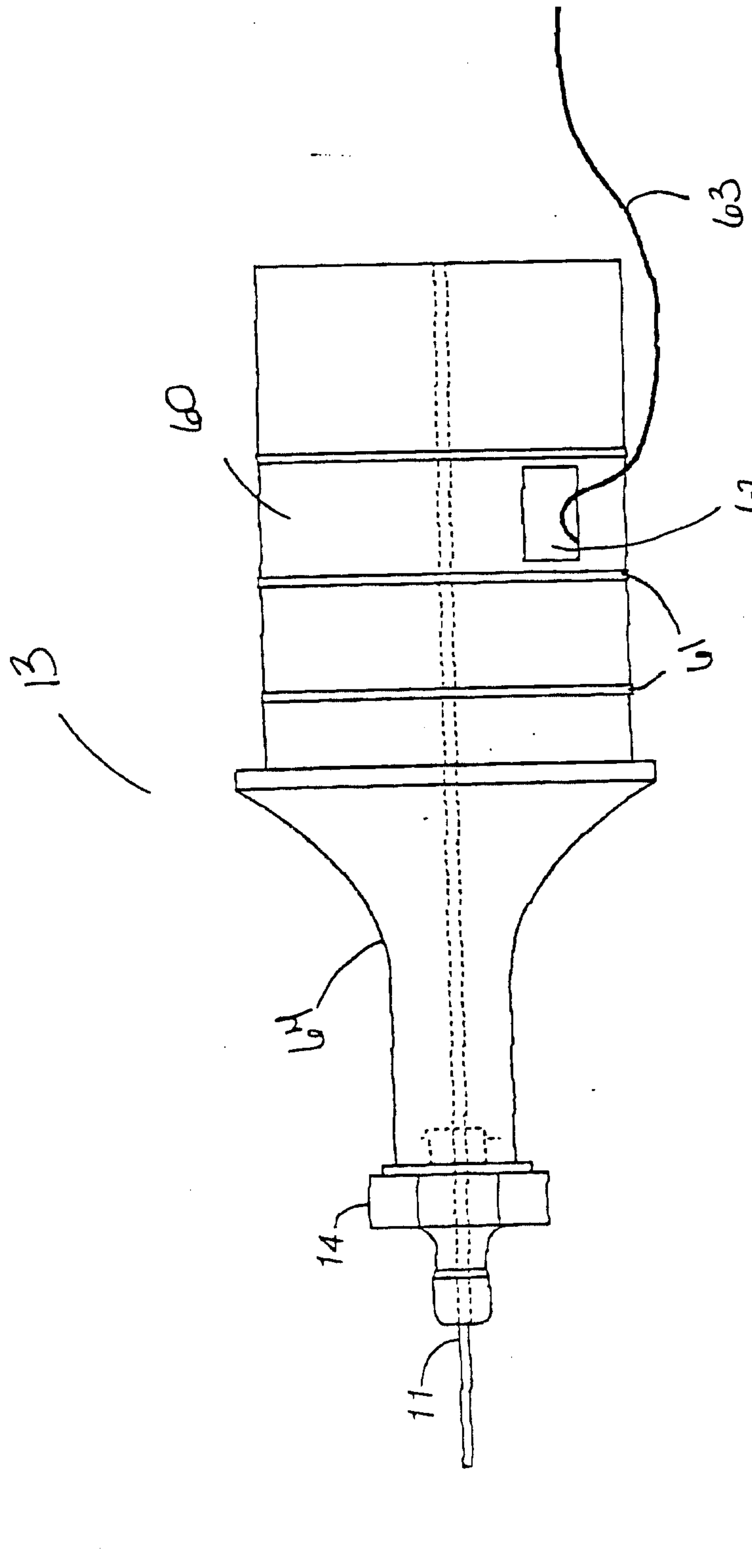


FIGURE 13

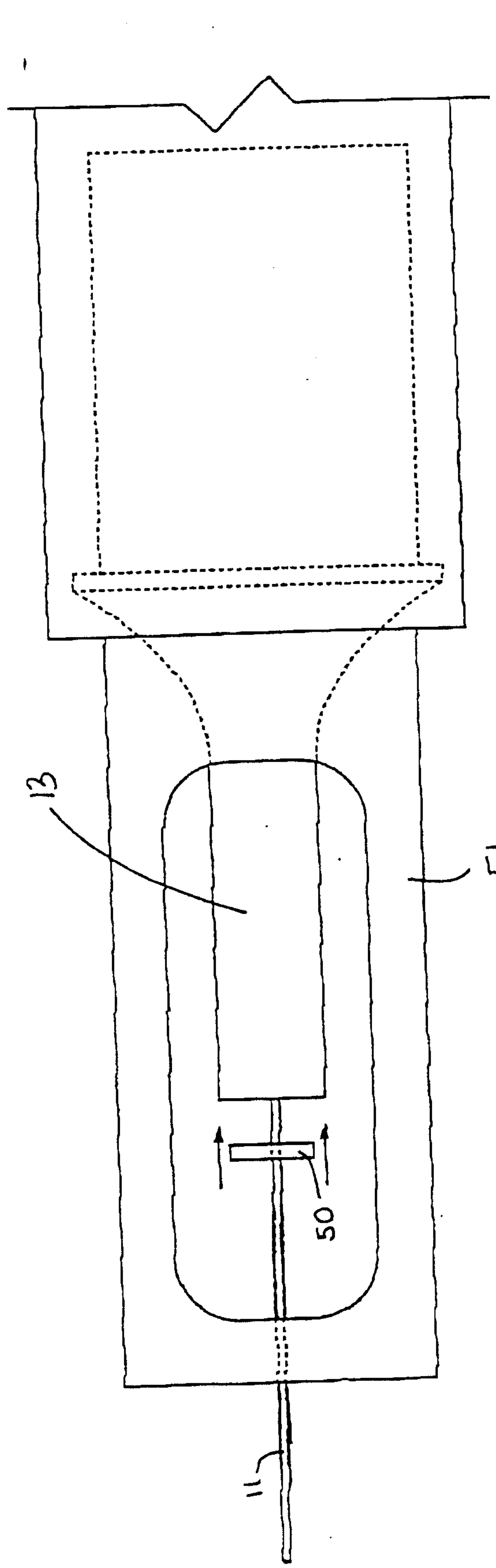


FIGURE 14A

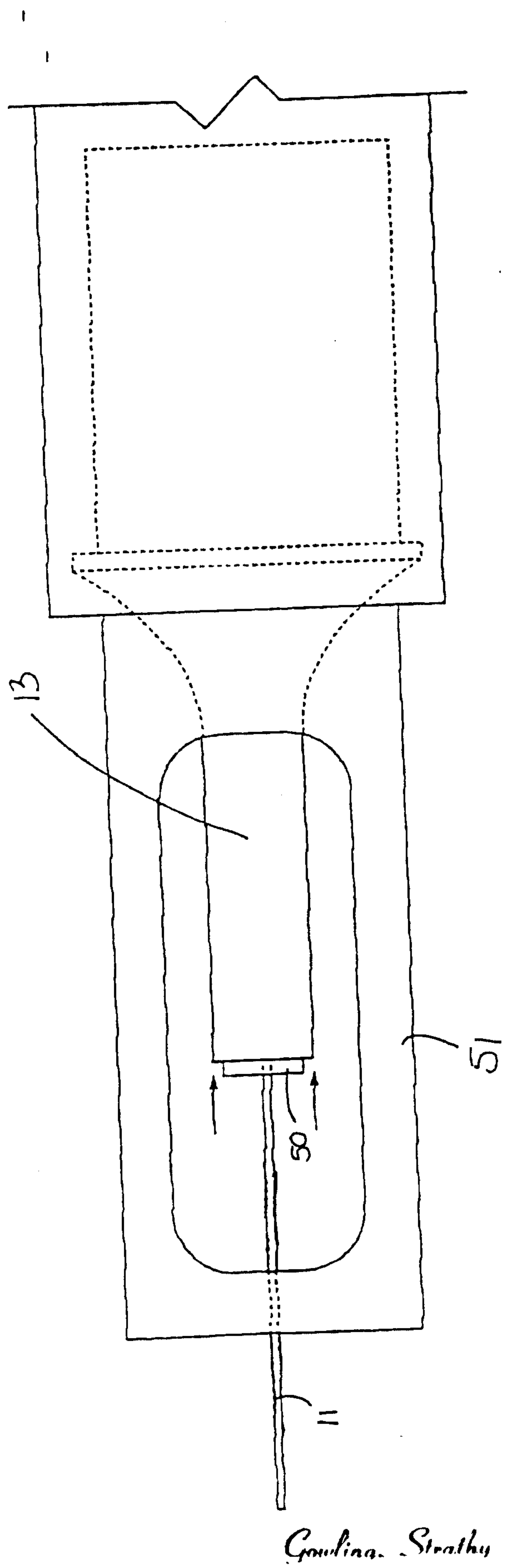


FIGURE 14B

Gowling, Strathy & Henderson

Gowling, Strathy & Henderson

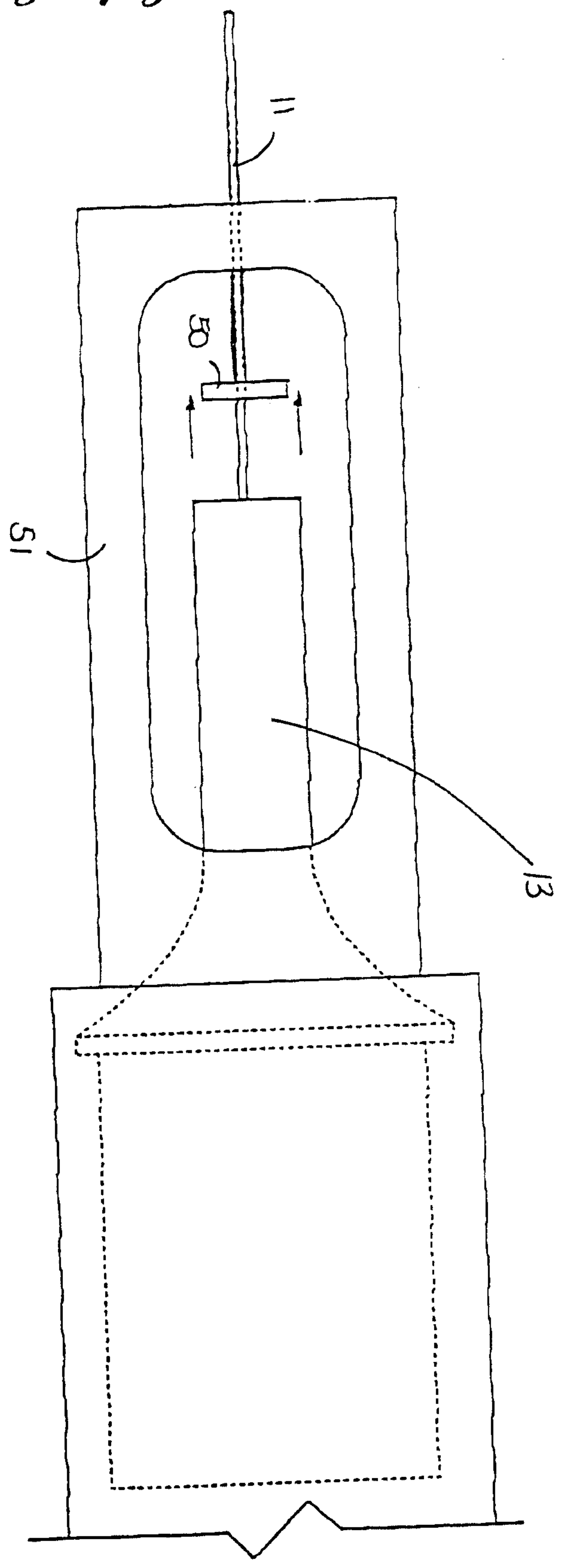
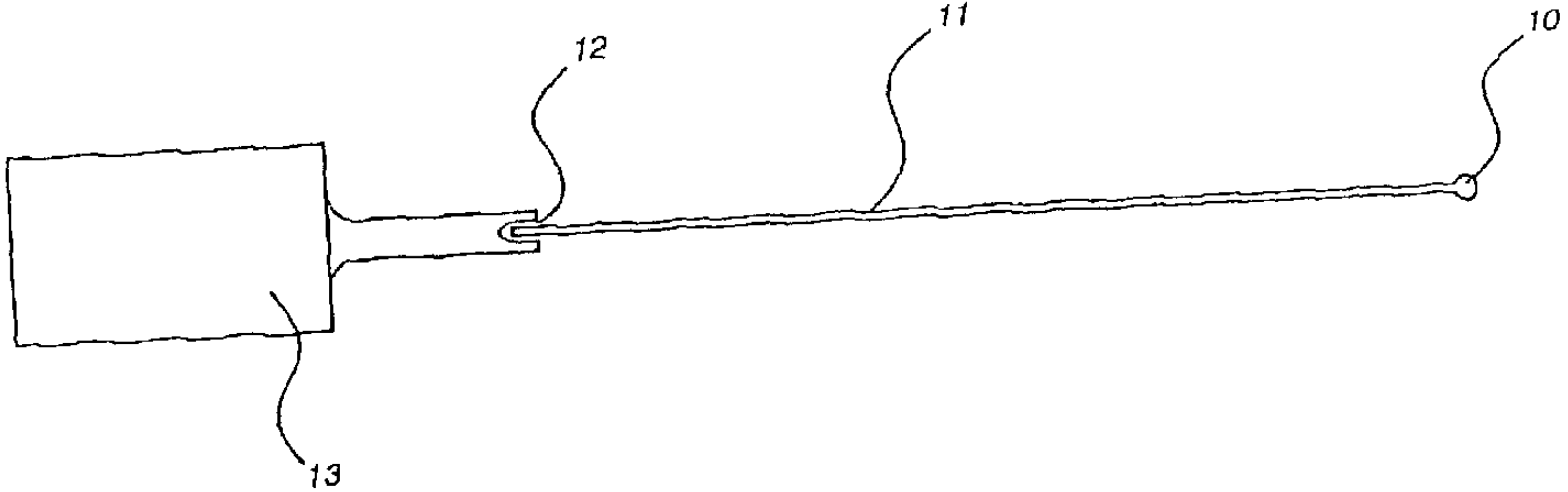


FIGURE 14C



12
11
10
13