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(54) Ultrasonic visible surgical needle

Ultraschall sichtbar gemachte chirurgische Nadel

Aiguille chirurgicale visible par ultrasone

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DE-A- 2 314 367 **FR-A- 2 272 633**
US-A- 4 582 061 **US-A- 5 048 530**
US-A- 5 728 124

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Description**Background Of The Invention**

[0001] This invention relates to a medical device that provides enhanced image and response to an ultrasound signal and more particularly to a surgical needle having geometric features that provides an enhanced image and response.

[0002] Ultrasonic imaging has long been used in medical practice to provide images not only of body organs and parts but also of the medical instruments and in particular needles that are used in connection with various medical procedures.

[0003] For example, ultrasonic imaging is used to guide a medical needle into a body part to effect a biopsy, to access fluid collection for sampling or drainage, to obtain vascular access and to access the urinary and biliary tracts. Ultrasonic imaging is also used to place a needle at a tumor or other body structure for subsequent surgical removal.

[0004] A major limitation on the ultrasonic guided intervention or procedures are the inability to image the medical instrument or needle adequately in many circumstances. The visibility of the needle is strongly dependent on the particular geometrical relationship between the transducer that provides the ultrasonic beam and the reflective surface of the instrument. The amount of ultrasonic energy reflected from the instrument toward the transducer (an ultrasonic echo sensor) determines the quality of the image of the instrument on the monitor. If the needle is in the plane of the interrogating ultrasonic beam and horizontal to the face of the sensing transducer, or perpendicular to the direction of the incident beam, the reflected energy is optimized and a useable visible image is obtained. However, as the needle becomes less perpendicular to the direction of the incident beam, lesser amounts of ultrasonic energy are reflected to the sensor and the instrument is imaged poorly or not at all.

[0005] The optimal geometric relationship is difficult to maintain in all but fairly limited applications of ultrasonic guided interventions. It becomes nearly impossible to maintain the optimum geometry in many instances because of intervening organs or structures. This results in poor visualization of the instrument, procedure time is lengthened and complexities are created which would not be present if the needle were easily seen.

[0006] Multiple passes with a needle may have to be made before it can be visualized causing tissue damage within adjacent organs or structures and creating the potential of bleeding and other complications. There are times when the physician is able to visualize the target lesion quite well but not the needle or other instrument. Moving the sensing transducer can result in the needle being imaged but the image of the target lesion is lost. A series of trial and error maneuvers are employed. Breathing motion of the patient further complicates the

process.

[0007] This problem has been addressed by a large number of proposed designs, including those shown in United States Patents No. 4,869,259, No. 4,977,897, No. 5,048,530, No. 5,081,997, No. 5,213,569, No. 5,221,269, No. 5,383,466, No. 5,490,521, No. 5,611,345, No. 5,766,135 and No. 5,769,795.

[0008] The devices shown in the above referenced patents are intended to enhance ultrasonic visibility. Some of these devices are complex and expensive to manufacture. Some of these devices are difficult to manipulate within the patient such as the square rectangular shaped needle suggested in U.S. Patent No. 5611345. Furthermore, many of the devices only marginally enhance ultrasonic visibility.

[0009] FR-A-2272633 discloses a cannula for puncturing internal body organs or the like with a plurality of annular notches extending around its outer surface. Each notch has two surfaces which may extend at 90° to one another.

[0010] Accordingly, it is an object of this invention to provide a design for a surgical needle which will provide enhanced imaging in a wide range of orientations between the axis of the needle and the ultrasonic echo sensor.

[0011] It is a further and related object of this invention to provide this enhanced imaging in a design that is simple and inexpensive to manufacture and relatively simple to operate.

[0012] These two objects are important in order to assure maximum usage of the invention in a large number and a wide variety of applications where an ultrasonically identified needle is important.

[0013] Furthermore, it is another related purpose of this invention to provide the above objectives in a design which provides no additional risk of trauma to tissue.

[0014] There are inevitable trade-offs to the design considerations to achieve the above interrelated objectives. Addressing all of these considerations calls for some trade-off between the objectives.

[0015] Accordingly, it is a major object of this invention to provide an enhanced ultrasonically visible needle which achieves the objectives of low cost, simple structure, high visibility, high degree of safety and avoids complicated procedures or new techniques with which medical personnel are not familiar.

[0016] Most particularly, it is an object of this invention to achieve all of these objects with an enhanced trade-off value for the combined objectives.

[0017] According to the present invention, a surgical needle visible to ultrasound of the type comprising a tubular sidewall, which defines a lumen, the tubular sidewall having at least one transverse notch formed therein and the or each notch having a surface, a substantial portion of which extends at an acute angle to the axis of the lumen, is characterised in that the transverse notch extends over less than 180°, preferably less than 120°, of the circumference of the sidewall and that the or each

notch communicates with the lumen via a respective opening in the sidewall.

[0018] The surgical needle will be manufactured of stainless steel or some other material which provides an interface with human tissue that results in ultrasonic echo. One or more transverse notches are cut into the sidewall of the needle. In one embodiment, the or each notch extends over approximately 100° of the circumference of the needle. The notch is wedge-shaped and defines first and second oblique walls in the sidewall of the lumen. If these walls are planar, the plane of each wall intersects the axis of the needle at an acute angle. The acute angle may range from 15° to 75° and in a preferred embodiment each wall extends at 45° to the axis of the lumen. The walls created by the notch provide a large reflective surface area.

[0019] In operation, when the needle is inserted into a patient, the surface of the needle will reflect incident ultrasonic energy in directions that are determined by the needle sidewall and the two notch walls. The result is to reflect ultrasonic energy at a substantial range of angles. When the needle is inserted into a patient, sufficient air is inevitably entrained so as to provide small air bubbles which form on or are trapped in the notches. These air bubbles provide a further sound velocity contrast with tissue so as to enhance wide angle reflection of an incident ultrasonic energy pulse. In this fashion, the ultrasonic echo sensor can have a wide variety of spatial orientations relative to the needle and yet receive a strong enough ultrasonic echo to provide a usable and useful image of the needle.

Brief Description Of The Figures

[0020]

FIG. 1 is a longitudinal sectional view of one embodiment of this invention showing a particular notch arrangement at the distal portion of a needle; the planes of the notch faces 18 and 20 being at 45° to the lumen axis.

FIG. 2 is a plan view of the FIG. 1 needle.

FIG. 3 is a longitudinal view similar to that of FIG. 1 showing a second embodiment in which the plane of the notch faces are at different angles to the axis of the lumen.

FIG. 4 is a plan view of the FIG. 3 needle.

FIG. 5 is a mechanical schematic showing the arrangement of a manually operable spring loaded stylet that can be employed within the needle of this invention to assure the trapping of air bubbles in the notch.

Description Of The Preferred Embodiments

[0021] The FIG. 1 embodiment shows a surgical needle 10. A series of transverse notches 12 near the distal end of the needle extend around substantially less than half the circumference of the needle. Each notch 12 is cut deep enough so that over a small distance, there is an opening 14 which provides communication between the lumen 16 of the needle and the zone defined by the notch.

[0022] The notch 12 is cut with the two notch walls at an angle of 90° to one another. The plane of each of the notch walls 18, 20 are at an angle of 45° to the axis of the lumen 16. These two wall faces 18, 20 provide a relatively significant area to reflect incidence of ultrasonic energy and thus create an ultrasonic echo that can be received over a substantial area. It has an amplitude significant enough to provide the desired image on an appropriate monitor or other imaging device.

[0023] In addition, the opening 14 tends to permit a certain amount of air to be trapped within the notch. Thus air, trapped as small bubbles of air, causes a further significant ultrasonic reflection to the sensor that substantially enhances the image as presented to the physician.

[0024] In the FIG. 3 embodiment, notches 26 are cut to provide a first notch wall 28 having an angle of 15° with the lumen axis and a second notch wall 30 having an angle of 75° with the lumen axis. The notch wall 30 faces proximally so that energy reflected from the wall 30 will be directed toward an echo sensor transducer placed near the hub of the needle.

[0025] The relative angles of the two notch wall faces may be established as a function of the particular application of the invention and, most significantly, as a function of the location of the sensor that receives the ultrasonic echo.

[0026] It is believed that the larger the face of the notch wall that looks back to the sensor, the more effective the invention will be in providing a useful image to the physician. It could well be that a curved notch wall would be effective providing that the surface of the curvature defined by the notch wall intersects the axis of the lumen at an acute angle; where the acute angle is sufficiently small to assure a substantial reflecting wall surface that faces toward the sensor being employed.

[0027] The position of the transducer and the direction of the sonar pulses will not usually be uniquely determined with respect to the axis of the needle. Accordingly, it is presently preferred to have the walls of each of the two notches 18 and 20 to be at an angle of 45° to the axis of the needle; in particular, one is at an angle of plus 45° and the other is at an angle of minus 45°. This should provide the needle with the greatest range of reflection.

[0028] However, in order to increase the angles covered by the reflected beams, it is contemplated that multiple notches might be employed in which the angle of

the sidewalls of the notches will differ from notch to notch so that one sidewall may be at 15° to the axis, another at 30° and another at 45°.

[0029] As shown in FIG. 5, a spring 34 placed between the hub 36 of the needle and the hub 38 of a stylet 40 permits the stylet to be pumped with finger pressure. The pumping motion will cause turbulence in the fluid surrounding the needle which is immediately adjacent to the notches thereby enhancing the image provided to the physician.

[0030] The opening 14 has the advantage of providing air bubbles. This advantage may be further enhanced by removing and reinserting the stylet 40 to thereby push trapped air into the notches.

[0031] The nature of the opening 14 is sufficiently small and can be made sufficiently small so that liquid administered through the needle or aspirated from the needle will not come through the opening 14.

[0032] This opening 14 provides the appreciable advantage of permitting the trapping of air in the notch to enhance visibility without creating any risk of compromising the performance of the needle.

[0033] It is generally desired to keep the circumferential arc of the notches 12, 26 to as little as possible to be consistent with providing the small opening 14. In this fashion, the sidewall strength of the needle is minimally compromised.

[0034] The circumferential arc over which the notch is cut is essentially a function of the outer radius R of the needle and the wall thickness T of the needle. A notch cut to communicate to the lumen is a function of the ratio: (R-T)/R. Specifically, the circumferential arc that provides a notch which just meets the lumen, is an angle that is twice the angle having the cosine (R-T)/R. The bigger the wall thickness T, the smaller the ratio and the bigger the angle having that cosine. In formula terms, the circumferential arc angle "A" which must be exceeded to communicate with the lumen is:

$$A=2[\cos^{-1}(R-T)/R]$$

[0035] For example, a 22 gauge needle will have an O.D. of 0.71 mm (28 mils or 0.028 inches) and thus an R of 0.355 mm (14 mils). It may have a wall thickness T of 0.1 mm (4 mils). This provides a ratio of (14-4)/14, which equals 0.7143. The angle having a cosine of 0.7143 is about 44.5°. Thus the notch for such a needle will encompass an arc of needle circumference greater than 89°. Generally, the embodiments of this invention will have notches that encompass less than 120° of needle circumference in order to ensure communication with the lumen.

[0036] It may even be desirable to cut the notch with a laser beam so as to provide a somewhat curved obliquely positioned notch in the sidewall with an optimum trade-off of as much reflective surface area as possible with as little needle strength compromised as possible.

[0037] Experimental needles having notches in accordance with the teachings of this invention have been tested in a laboratory situation and found to have sufficient rigidity so that the structural integrities are not compromised by the notches. It is believed that any notch which would extend close to 180° around the circumference of the sidewall would tend to reduce structural integrity.

[0038] As indicated above, by incorporating multiple air bubbles in the notches, there would be a substantially expansion on the angles covered by the reflective surfaces.

[0039] Although tests have been made showing the effectiveness of a needle having the design shown herein, it is believed that it is the combination of the angle or oblique sidewalls together with the air bubbles in the notch that provide the highest enhancement of imagery.

[0040] As may be appreciated, for the reasons indicated above, the structure of this invention provides an optimized trade-off of providing enhanced echo image while minimizing degradation to either the structural strength of the needle or the functional performance of the needle.

[0041] Although this invention has been described in connection with particular embodiments, it should be understood that there would be variations on the embodiment shown which would provide the advantage of the invention that are included in the teachings herein.

[0042] For example, reference is made throughout the specification in claims to a needle. However, it is conceivable that there may be certain situations in which some cannula other than a needle would advantageously employ the arrangement of this invention. It should be understood herein that a needle is defined to include such cannulas.

[0043] Although the two notch walls are shown at an angle of 90° to one another, they need not be at 90° to each other in order to provide the effect of this invention. Nor, need the notch wall angles equal one another. The angle of each of the two notch walls to the lumen axis is selected to optimise reflecting ultrasonic energy.

[0044] The needle according to the present invention shows communication of the notches 12 and lumen 16 through the opening 14. However, although not part of the present invention, it will be appreciated that the notch itself, even if it were not cut through to the lumen, would provide enhanced ultrasonic visibility because of the surface area of the notches and the oblique angling of those surfaces.

[0045] The introduction of air into the notches 12 might be accomplished by placing a diaphragm with a small hole in it over the entry to the lumen at the hub. The physician could place a thumb on the hole and pump air within the lumen into the notches.

Claims

1. A surgical needle visible to ultrasound comprising a tubular sidewall, which defines a lumen, the tubular sidewall having at least one transverse notch (12) formed therein and the or each notch (12) having a surface (18, 20), a substantial portion of which extends at an acute angle to the axis of the lumen, **characterised in that** the transverse notch (12) extends over less than 180°, preferably less than 120°, of the circumference of the sidewall, and that the or each notch communicates with the lumen via a respective opening (14) in the sidewall.

2. A surgical needle as claimed in Claim 1 wherein there is a plurality of notches (12) formed in the tubular sidewall.

3. A surgical needle as claimed in Claim 1 or 2 wherein the or each notch has two surfaces (18, 20), a substantial portion of each of which extends at an acute angle to the axis of the lumen .

4. A surgical needle as claimed in any one of the preceding claims wherein the or each said surface (18, 20) of the or each notch (12) is substantially flat and extends at an angle of between 15° and 75° to the axis of the lumen.

5. A surgical needle as claimed in any one of the preceding claims further comprising a finger actuated spring loaded stylet (4) within the lumen.

6. A surgical needle as claimed in Claim 5 wherein the stylet (4) has a hub (38), the needle has a hub (36) and the spring is positioned between the two hubs (38, 36).

Patentansprüche

1. Eine im Ultraschall sichtbare chirurgische Nadel, umfassend eine röhrenförmige Seitenwand, die ein Lumen definiert, wobei die röhrenförmige Seitenwand zumindest eine darin ausgebildete quer laufende Kerbe (12) aufweist und die oder jede Kerbe (12) eine Oberfläche (18, 20) aufweist, von der sich ein wesentlicher Teil unter einer spitzen Winkel zur Achse des Lumens erstreckt, **dadurch gekennzeichnet, dass** sich die quer laufende Kerbe (12) über weniger als 180°, vorzugsweise weniger als 120°, des Umfangs der Seitenwand erstreckt, and das die oder jede Kerbe mit dem Lumen über eine entsprechende Öffnung (14) in der Seitenwand in Verbindung steht.

2. Chirurgische Nadel gemäß Anspruch 1, mit einer Mehrzahl von in der röhrenförmigen Seitenwand

ausgebildeten Kerben (12).

3. Chirurgische Nadel gemäß Anspruch 1 oder 2, wobei die oder jede Kerbe zwei Oberflächen (18, 20) aufweist, von jeder von denen sich ein wesentlicher Teil unter einer spitzen Winkel zur Achse des Lumens erstreckt.

4. Chirurgische Nadel gemäß einem der vorstehenden Ansprüche, wobei die oder jede Oberfläche (18, 20) der oder jeder Kerbe (12) im wesentlichen flach ist und sich unter einem spitzen Winkel zwischen 15° und 75° zur Achse des Lumens erstreckt.

5. Chirurgische Nadel gemäß einem der vorstehenden Ansprüche, weiterhin umfassend ein fingerbetätigtes, Feder-belastetes Stilett (4) innerhalb des Lumens.

6. Chirurgische Nadel gemäß Anspruch 5, wobei das Stilett (4) eine Nabe (38) aufweist, die Nadel eine Nabe (36) aufweist, und die Feder zwischen den zwei Naben (38, 36) lokalisiert ist.

Revendications

1. Aiguille chirurgicale visible aux ultrasons comprenant une paroi latérale tubulaire qui définit une lumière, la paroi latérale tubulaire comportant au moins une encoche transversale (12) formée sur elle et l'encoche (12) ou chaque encoche (12) ayant une surface (18, 20) dont une partie substantielle s'étend selon un angle aigu par rapport à l'axe de la lumière, **caractérisée en ce que** l'encoche transversale (12) s'étend sur moins de 180°, de préférence moins de 120°, de la circonférence de la paroi transversale, et **en ce que** l'encoche ou chaque encoche communique avec la lumière à travers une ouverture respective (14) dans la paroi latérale.

2. Aiguille chirurgicale selon la revendication 1 dans laquelle se trouvent une pluralité d'encoches (12) formées dans la paroi latérale tubulaire.

3. Aiguille chirurgicale selon la revendication 1 ou 2 dans laquelle l'encoche ou chaque encoche est dotée de deux surfaces (18, 20), dont une partie substantielle s'étend selon un angle aigu par rapport à l'axe de la lumière.

4. Aiguille chirurgicale selon l'une quelconque des revendications précédentes dans laquelle la surface ou chacune desdites surfaces (18, 20) de l'encoche (12) ou de chaque encoche (12) est sensiblement plate et s'étend selon un angle entre 15° et 75° par rapport à l'axe de la lumière.

5. Aiguille chirurgicale selon l'une quelconque des revendications précédentes comprenant en outre un stylet (40) à ressort actionné par le doigt à l'intérieur de la lumière.

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6. Aiguille chirurgicale selon la revendication 5 dans laquelle le stylet (40) comporte une garde (38), l'aiguille comporte une garde (36) et le ressort est positionné entre les deux gardes (38, 36).

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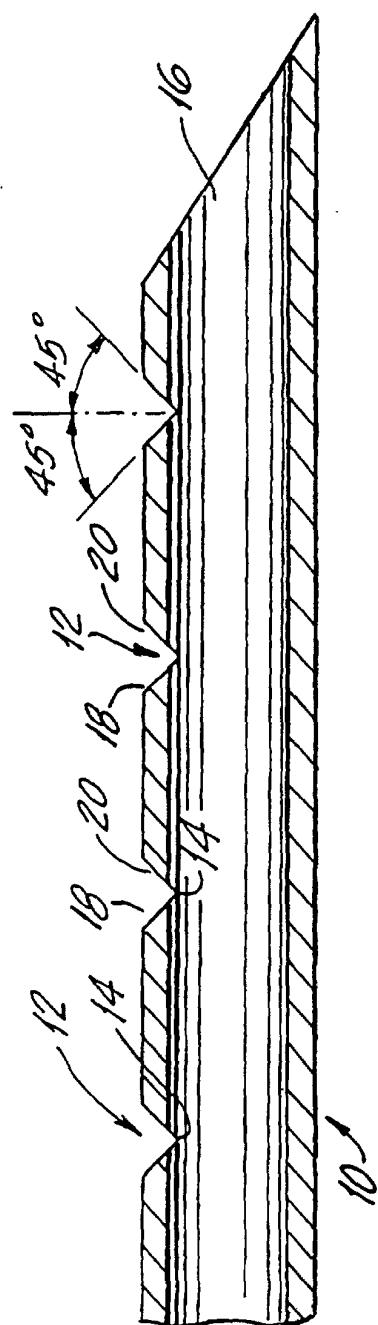


FIG. 1

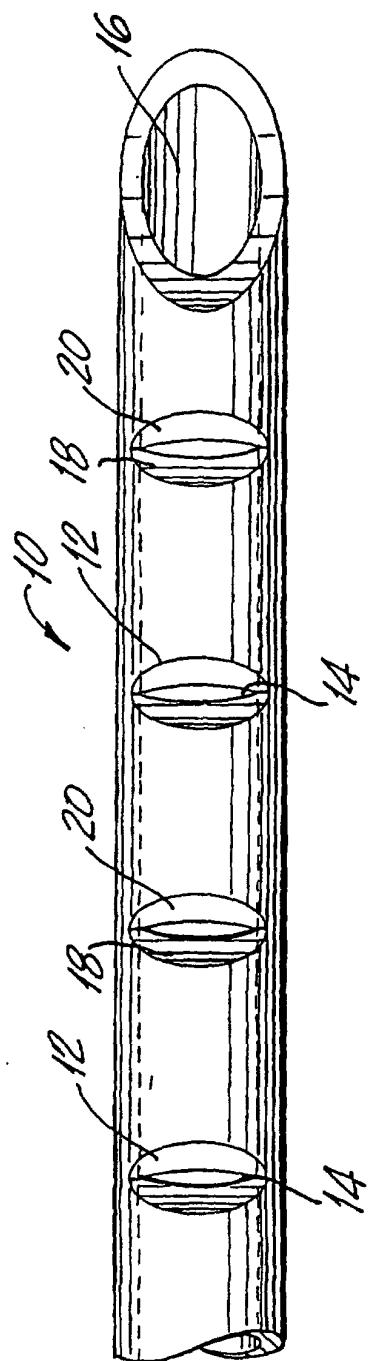


FIG. 2

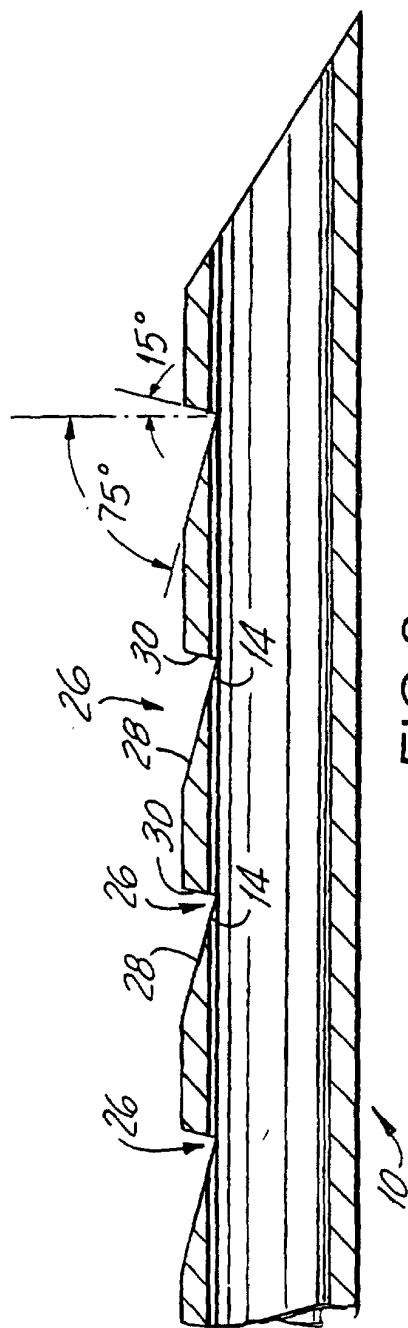


FIG. 3

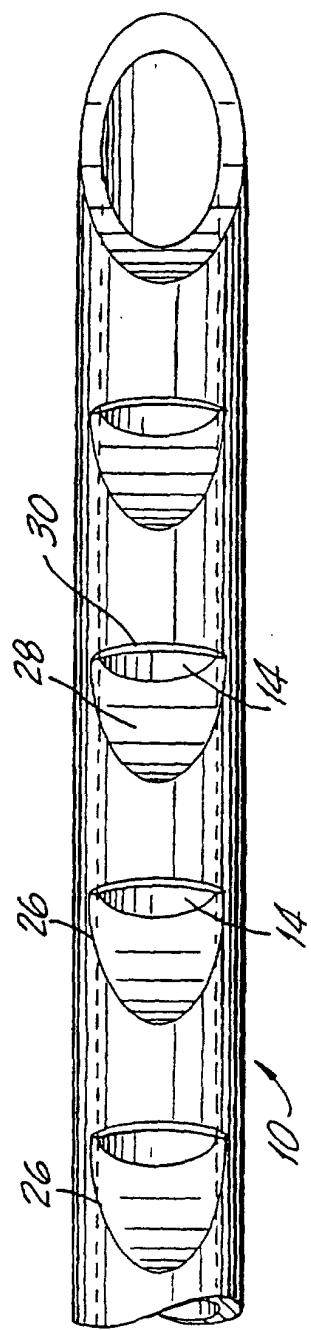


FIG. 4

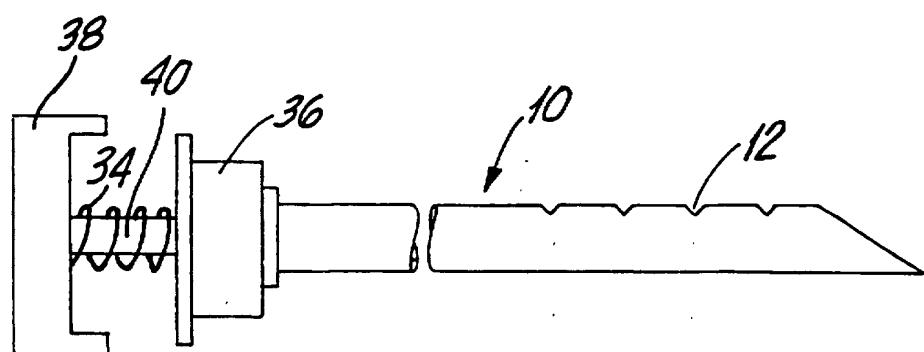


FIG.5

专利名称(译)	超声波可见手术针		
公开(公告)号	EP1132049B1	公开(公告)日	2004-09-08
申请号	EP2000301956	申请日	2000-03-09
申请(专利权)人(译)	ANGIODYNAMICS INC.		
当前申请(专利权)人(译)	ANGIODYNAMICS INC.		
[标]发明人	FULTON III RICHARD EUSTON		
发明人	FULTON III, RICHARD EUSTON		
IPC分类号	A61B8/08 A61B10/00 A61B10/02 A61B17/34 A61B90/00		
CPC分类号	A61B10/0283 A61B8/0833 A61B17/3417 A61B2017/3413 A61B2090/3925		
其他公开文献	EP1132049A1		
外部链接	Espacenet		

摘要(译)

手术针包括限定内腔的管状侧壁。在侧壁中形成多个横向凹口 (12) , 其在侧壁的圆周的小于120°的范围内延伸。凹口的两个表面与针的轴线成锐角延伸 , 并提供增加的区域 , 用于反射超声能量 , 从而增加对超声波的可视性。

$$A = 2 \left[\cos^{-1} \left(\frac{R-T}{R} \right) \right]$$