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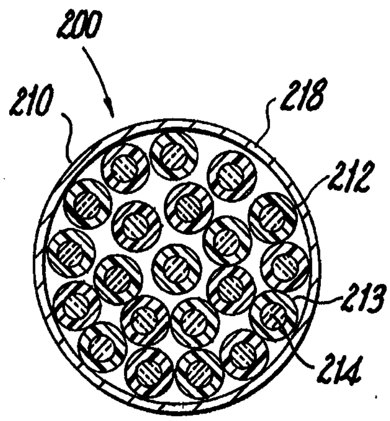
(54) Title: LASER FIBRE OPTIC BUNDLE




**(57) Abstract**

In accordance with the present disclosure, a laser fiber optic bundle (210, 310) is provided that includes a plurality of optical fibers (212, 312) each having an optical core (216, 314). The optical cores (216, 314) are separated from adjacent optical cores (216, 314) to reduce overlapping of laser light being transmitted by the individual fibers (212, 312). The spaced apart configuration of the optical cores (216, 314) can also reduce the occurrence of the tips of the fibers (212, 312) from being damaged due to the magnitude of the laser energy being transmitted. In a first embodiment, the optical cores (216) are coated with glue (214) that can include various types of epoxies. In a second embodiment the optical cores (314) are surrounded by a filler material (318), that can include various grades of powdered glass and/or glue material. The laser fiber bundle (210, 310) is suited for ablating tissue, particularly heart tissue during a TMR procedure.

# LASER FIBER OPTIC BUNDLE

## BACKGROUND

### 1. Technical Field

The present disclosure relates to a laser fiber optic bundle for ablating body matter. The laser fiber optic bundle is particularly suited for performing transmyocardial revascularization (TMR).

### 2. Background of the Related Art

A variety of procedures and apparatus have been developed to treat cardiovascular disease. For example, minimally invasive surgical procedures such as balloon angioplasty and atherectomy have received extensive investigation and are in wide use. In some patients, however, circumstances still require conventional open heart bypass surgery to correct or treat advanced cardiovascular disease. In some circumstances, however, patients may not be suitable candidates for bypass surgery.

An alternative or adjunct procedure to bypass surgery is transmyocardial revascularization (TMR), wherein holes are formed in the heart wall. These holes theoretically provide alternative blood flow channels for ischemic heart tissue and have been attributed to decreased pain (angina) associated with cardiovascular disease. The holes can be created using laser energy. In early laser myocardial revascularization, a $C0_2$ laser was used to produce holes in the heart wall by transmitting laser energy from the laser to the heart wall. Typical $C0_2$ lasers used for transmyocardial revascularization (TMR) are externally located and have an articulated support arm for aiming and directing laser energy through a series of mirrors that reflect the energy onto the heart wall. Thus, some surgical opening of the chest wall is required to access the heart muscle. The entrance wound in the heart can be closed by relatively brief external pressure while the endocardial and myocardial layers remain open to permit blood flow from the ventricle to the heart muscle.

Less traumatic approaches to laser myocardial revascularization have been disclosed. These methods include the use of optical fibers introduced either through a patient's vasculature or, alternatively, directly into the patient's chest cavity. The intravascular method involves the direction of laser energy from inside the heart to form a bore in the heart wall while the other method involves introduction of the lasing apparatus through a relatively small incision in the patient's chest to access the outer wall of the heart.

In these prior art methods, the optical fiber conveying the laser energy and the laser generating source are typically manually advanced and controlled, respectively, to form a bore. This manual advancement and control presents problems in that depth and rate of penetration are difficult to accurately reproduce for the multiple bores at the different areas of the heart which are necessary in myocardial revascularization procedures. For example, if the advancement rate of the laser is too slow and/or the laser generating source is left on for a long period of time, tissue damage from thermal and acoustic shock can result.

As illustrated in the cross-sectional view of FIG. 1, a prior art fiber optic bundle, designated generally at 100, includes a plurality of tightly packed fibers 112 enclosed in casing 110. The individual fibers 112 in the laser fiber bundle 100 include an active area having a core 118 and an inactive area which includes the cladding 120 surrounding the core 118. Typically, the cladding 120 is approximately 5 to 10% of the diameter of the core 118. For the prior art fiber optic bundle of FIG. 1, approximately 80% of the surface area of the fiber bundle is "active" during firing of the laser. When firing the laser fibers 112, there is typically collateral damage from the laser light exiting the fiber 100. For example, a 100 micron fiber can create a 300 micron hole. The 300 micron hole created by the 100 micron fiber relates to a "zone of damage". In other words, when the fibers 112 are tightly packed, such as described above where 80% of the surface area is fibers and 20% is dead space, the laser light exiting the individual fibers 112 overlaps and increases the amount of the laser energy to which the tissue is exposed.

Additionally, in prior art lasers the increase in magnitude of the laser energy due to the overlap of the laser light exiting the individual fibers 112 can cause the distal ends or tips of the fibers 112 to be damaged or "blown off". As a result, the fiber bundle 100 can be damaged and the fibers or tips need to be replaced.

## SUMMARY

In accordance with the present disclosure, a laser fiber optic bundle is provided which includes a plurality of optical fibers each having an optical core. The optical cores are separated from adjacent optical cores in a manner to reduce overlapping of the laser light being transmitted by the individual fibers. The spaced apart configuration of the optic cores also lessens the likelihood that the tips of the fibers will be damaged. In a first embodiment, the optical cores are separated by fillers, which can include various grades of powdered glass. In a second embodiment, the optical cores are separated by hardened glue, which can include various types of epoxies. The laser fiber optic bundle is suited for ablating tissue, particularly, heart tissue during a TMR procedure or plaque during laser angioplasty.

## BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with references to the drawings:

FIG. 1 is a cross-sectional view of a prior art laser fiber optic bundle;

FIG. 2 is a cross-sectional view of a first embodiment of a laser fiber optic bundle in accordance with the present disclosure;

FIG. 3 is a cross-sectional view of a second embodiment of a laser fiber optic bundle;

FIG. 4 is a perspective view of a laser ablation device in association with the laser fiber optic bundle of FIG. 2;

FIG. 4A is a perspective view of a control module of the laser ablation device of FIG. 4;

FIG. 5 is a side view of the hand piece having a laser fiber optic bundle spaced from epicardium;

FIG. 6 is a side view showing piercing of the epicardium;

FIG. 7 is a side view showing the laser fiber optic bundle being advanced through the myocardium and endocardium; and

FIG. 8 is a side view showing withdrawal of the laser fiber optic bundle from the heart tissue to reveal the channel created therein.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the laser fiber optic bundle will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. While the preferred embodiments are primarily described herein with respect to surgical procedures, the disclosed laser fiber bundle can be used in non-surgical applications.

Two embodiments of the presently disclosed laser fiber optic bundle will now be described with reference to FIGS. 2-3. FIG. 2 illustrates a first embodiment of a laser fiber designated generally at 200 having a laser fiber optic bundle 210. The optic bundle 210 includes a plurality of laser fibers 212. Each laser fiber 212 includes an optical core 216 surrounded by coating material 214. Coating material 214 is preferably a glue, such as epoxy, but can also be any material suitable for encasing the optical cores. The fiber bundle of Fig. 2 can be termed "loosely filled", since the optical cores 216 of laser 200 are spaced from each other due to the presence of coating material 214. The optic bundle 210 is coated with an outside layer/sheath 218 which is preferably plastic. The result of using such a loosely packed laser fiber is more efficient use of energy and less collateral damage from over application of energy to the target material, such as tissue.

In a preferred embodiment, the diameter of each optical fiber 216 is approximately 100 to about 150 $\mu$m (core plus cladding typically 5-10% of core diameter, not shown) and the thickness of coating 214 is approximately 5-20 $\mu$m. Hence, the diameter of fiber unit 212 is approximately 110-170 $\mu$m. Also, preferably, the diameter of the optic bundle 210 typically contains from about 4 to about 100 fiber units 212. Therefore, the diameter of the optic bundle 210 is approximately 400 to about 20,000 $\mu$m. Most preferably optical core 216 is about 140 $\mu$m, coating 214 is about 30 $\mu$m, and bundle 210 has 50 fiber units 212 and a diameter of 1400 $\mu$m. Alternately, a preferred ratio of active to non-active area, in cross section is from about 1:1 (50%) to about 1:4 (20%) and a preferred predetermined distance between adjacent optical core is about 50 to about 100 $\mu$m.

The method of manufacturing laser fiber 200 generally entails fabricating individual fibers from highly purified glass silica or plastic, as is known in the art. Fibers 216 are then dipped or sprayed with coating material

214. A plurality of the individual coated fibers are encased within outside layer 218 to form optic bundle 210. The distal end of optic bundle 210 is then sliced to provide a flush cross-sectional distal end.

With reference to FIG. 3, a second embodiment of a laser fiber designated generally at 300 having a laser fiber optic bundle 310. Similarly to optic bundle 210, optic bundle 310 includes a plurality of spaced laser fibers 312. Each laser fiber includes an optical core 314. The optical cores 31 are separated by a filler 318 which can include various types of glue, such as epoxy, and/or glass filler. The diameter of each optical core 314 is approximately 100 to about 160 $\mu$m. The optic bundle 310 can also include an outside layer 318, preferably a plastic sheath.

Laser fiber 300 can be manufactured by suspending fibers 312 in a desired spaced apart configuration and then by introducing a liquified epoxy and/or glass filler between the fibers. The epoxy and/or glass filler is left to solidify or otherwise take a set. Heat and/or pressure can be used to facilitate this process. The optic bundle can then be coated with plastic layer 318. The distal end of optic bundle 310 can then sliced to provide a flush cross-sectional distal end.

In both embodiments, the individual optical cores are separated from adjacent optical cores in order to reduce the amount of overlapping energy transmitted through each optical core. As a result, the zone of damage which is evident by the use of prior art lasers can be eliminated or substantially decreased. Preferably, the fibers in both embodiments are arranged in a manner such that approximately 40% of the surface area of the distal end of the laser is active during transmission of laser energy.

FIGS. 4 and 4A illustrate a laser ablation device shown generally at 10 in association with the laser fiber optic bundle of FIG. 2. Device 10 preferably includes handle portion 12, an optical fiber advancing mechanism 14, a laser generator 16, a foot operated actuator 18, and a control module 20. Control module 20 is shown with a receptacle 19 adapted to engage a terminal of a programmable computer to interface control module 20 with the computer. A toggle switch 24 may be provided on the control module 20 to switch from an operation mode to a test mode. An external selector 26 is provided so that the operator can select the desired maximum extension of the distal end of the optical fiber 200 from the handpiece 12. The optical fiber advancing mechanism 12 is the type capable of precisely transmitting longitudinal motion to the optical fiber bundle 210. The controlled longitudinal motion can be provided by one or more motors and preferably by one or more stepper motors. The laser generator 16 may be either a continuous wave laser or a pulsed, high energy laser, such as, for example, an excimer, $CO_2$, Yag, or an alexandrite laser.

Referring now to FIGS. 5-8, a method for producing a TMR channel utilizing the laser ablation device 10 in conjunction with the laser fiber optic bundle 210 is illustrated. As shown in FIG. 5, handpiece 12 is brought in proximity to the epicardium 52 of a heart patient. Prior to entry into the epicardium 52, the tip of optic fiber 200 protrudes slightly from optional locator ring 28 by distance $D_i$, where $D_i$ is measured from the distal surface 200a of fiber 200 to the front surface 30 of locator ring 28. Alternatively surface 200a can be flush with front surface 30. In any case, the fiber tip surface 200a is disposed substantially adjacent epicardium 52. If initially protruding a distance $D_i$, the fiber tip initially advances through at least a portion of the epicardium 52 and myocardium 50 with less laser energy being applied to tissue as compared to the laser energy applied further into the heart. This is due to the "tented" tissue initially moving towards the handpiece upon commencement of laser firing. This less ablated tissue, 54, will substantially return to its natural position following channel formation and act as a cap to reduce bleeding from the channel.

As depicted in FIG. 7, the TMR channel is formed by transmitting laser energy from the tip of fiber 200 to ablate heart tissue while correspondingly advancing optical fiber 200. The fiber tip is advanced through the myocardium 50 and endocardium 56 until it reaches its maximum extended position corresponding to the distance D2 between fiber tip surface 200a and the surface 30 of locator ring 28.

In methods disclosed herein, while forming the channel below the channel cap, fiber 200 is preferably advanced at a rate that is coordinated with the power level and the frequency of pulsing of the laser generator. For example, optical fiber 200 can be advanced at a rate of between about 0.125mm/sec (0.005 in/sec) to about 12.7mm/sec (0.5 in/sec) with a laser power level of about 10 $mJ/mm^2$ to about 60 $mJ/mm^2$ and a pulsing frequency of about 5 Hz to about 400 Hz. Preferably, the optical fiber 200 is advanced at a rate of about 0.75mm/sec to about 2.0mm/sec with a laser power level of between about 30 $mJ/mm^2$ to about 40 $mJ/mm^2$ and a pulse frequency of about 20 to about 50 Hz. In a most preferred embodiment, the rate of advancement of the optical fiber 200 is no greater than the rate of ablation of tissue in order to minimize mechanical tearing by the fiber 200. Alternatively, if some degree of mechanical tearing is desired in addition to laser ablation, the advancing mechanism can be set to advance the fiber 200 at a rate greater than the ablation rate. Studies have shown that a xenon chloride excimer laser operating at a power level of about 35$mJ/mm^2$ can ablate about 30-35 microns of animal heart tissue per pulse.

The epicardium/myocardial tissue 54 that was pushed aside with less ablation during penetration of fiber 200 returns to its original location coinciding with channel 60 upon the fiber's withdrawal. This tissue 54 forms a flap that acts as the cap for the channel 60 to reduce bleeding from the channel 60 at the epicardium 52. The interface 62 between the flap of tissue 54 and the adjacent tissue is generally an annular ring less than 360_ in extent. As shown, the flap 54 can consist of both epicardial and myocardial tissue, but could alternatively be just epicardial tissue.

Once channel 60 is completed, fiber 200 can be moved to another location on the epicardium 52 to begin forming another channel, without the necessity of applying extended pressure to the portion of the epicardium coinciding with just-formed channel 60. The overall procedure wherein dozens of channels 60 are typically formed can thus be performed much faster as compared to other methods.

It will be understood that various modifications can be made to the embodiments disclosed herein. For example, alternate devices can be used to actuate the laser advancing device and the laser energy source, such as a trigger mechanism associated with the handle portion. In addition, the laser fiber optic bundle 210 and fiber advancing mechanism 14 can also be used to perform other medical procedures, besides TMR, such as laser angioplasty and laser keratotomy. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended thereto.

WHAT IS CLAIMED IS:

1. A laser fiber optic bundle comprising:

a plurality of elongated optical fibers housed within a sheath configured to engage a laser energy generator for transmitting laser energy through said optical fibers, each of said plurality of optical fibers having a coating that surrounds an optical core for providing approximately a 1:1 - 1:4 ratio of active area to non-active area across a cross-section of said laser fiber optic bundle during transmission of laser energy and for maintaining said optical cores a pre-determined distance from adjacent optical cores.

2. The laser fiber according to Claim 1, wherein the coating comprises an epoxy glue.

3. The laser fiber according to Claim 1, wherein the coating comprises powdered glass.

4. The laser fiber according to Claim 1, wherein said pre-determined distance is approximately 50-100 um.

5. A laser fiber optic bundle comprising:

a plurality of elongated optical fibers housed within a sheath configured to engage a laser energy generator for transmitting laser energy through said optical fibers, each of said plurality of optical fibers being arranged in a filler material to provide approximately a 1:1 - 1:4 ratio of active area to non-active area across a cross-section of said laser fiber optic bundle during transmission of laser energy and for maintaining said optical cores a pre-determined distance from adjacent optical cores.

6. A device according to Claim 5, wherein the filler comprises an epoxy glue.

7. A device according to Claim 5, wherein the filler comprises powdered glass.

8. The laser fiber according to Claim 5, wherein said pre-determined distance is approximately 50-100 um.

9. A laser ablation device comprising:

a handle portion having proximal and distal openings;

a laser energy transmission mechanism having first and second ends, the first end being extendible through the handle portion, said laser energy transmission mechanism consisting of a laser fiber optic bundle having a cross-section which is approximately between 50 and 20% active during transmission of laser energy;

a laser energy generator optically connected to the laser energy transmission mechanism second end; and

an advancing mechanism operably connected to the laser energy transmission mechanism, the advancing mechanism being operable to advance the laser energy transmission mechanism through the distal opening of the handle portion at a rate coordinated with the laser generator output to ablate body tissue.

10. A device according to Claim 9, wherein the laser fiber optic bundle includes a plurality of optical fibers, each optical fiber having a coating that surrounds an optical core for maintaining said optical core a pre-determined distance from adjacent optical cores.

11. A device according to Claim 9, wherein the laser fiber optic bundle includes a plurality of optical fibers, each optical fiber having an optical core being suspended in a filler for maintaining said optical core a pre-determined distance from adjacent optical cores.

12. A device according to Claim 10, wherein said pre-determined distance is approximately 50 um.

13. A device according to Claim 11, wherein said pre-determined distance is approximately 200 um.

14. A method of making a laser fiber optic bundle comprising the steps of:

coating a plurality of optical core fibers with epoxy material; and

arranging said coated fibers within a sheath to form a laser fiber optic bundle capable of transmitting laser energy from a distal end thereof, said distal end having a cross-sectional area wherein less than 50% of said area is active during transmission of laser energy.

15. A method of making a laser fiber optic bundle comprising the steps of:

providing a plurality of longitudinally disposed optical fibers; and

surrounding the fibers with a filler material, said filler material being selected from the group consisting of epoxy and powdered glass;

wherein a complete cross-section of the longitudinally disposed fibers and filler yields a cross-sectional area that has less than 50% active transmission of laser energy during use.

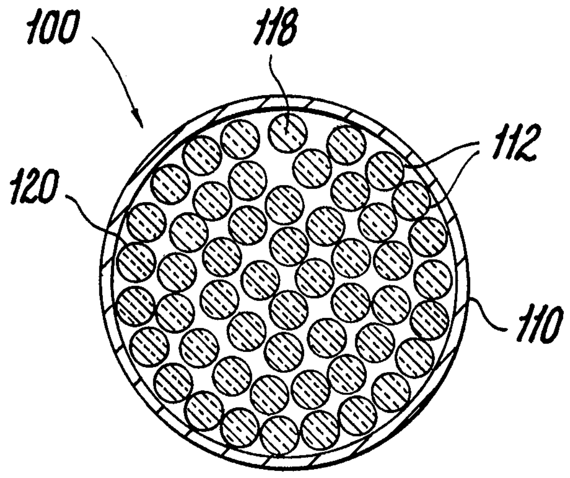



**Fig. 1**

(PRIOR ART)

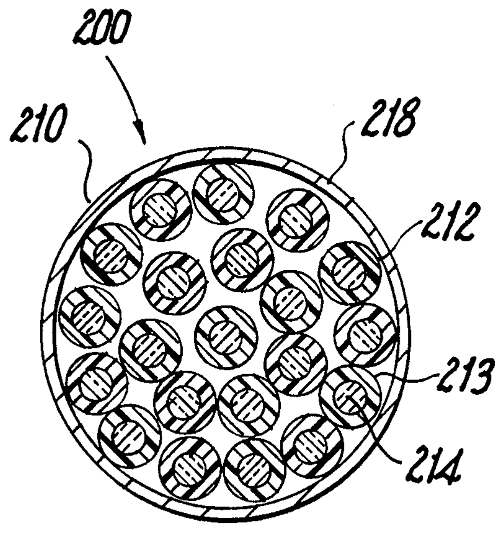



**Fig. 2**

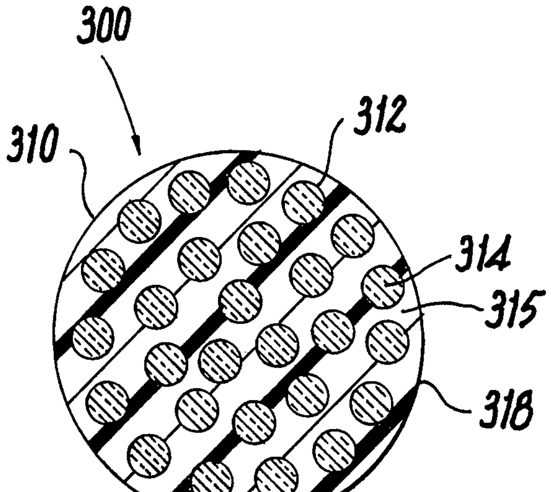
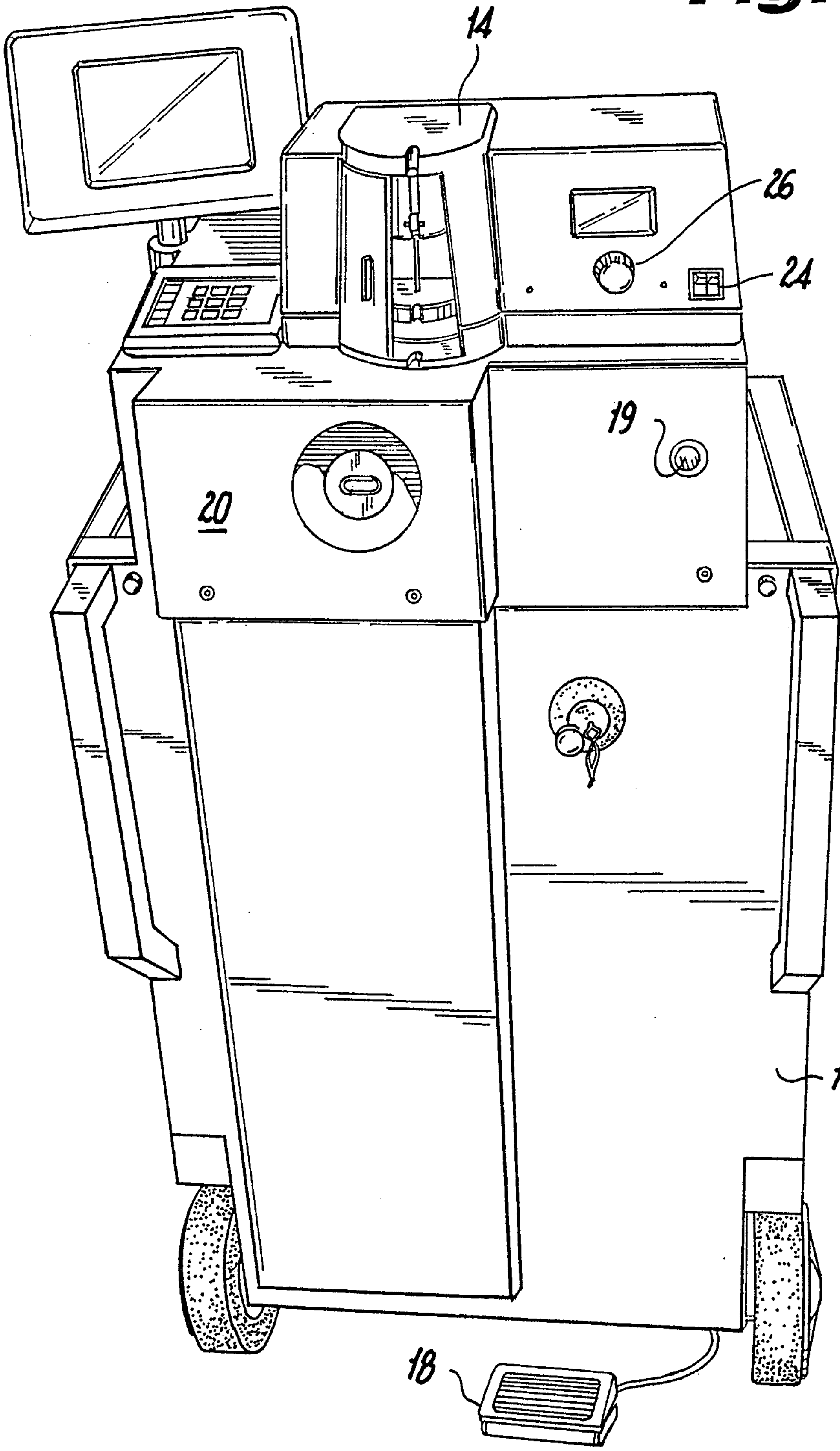



**Fig. 3**

Fig. 4



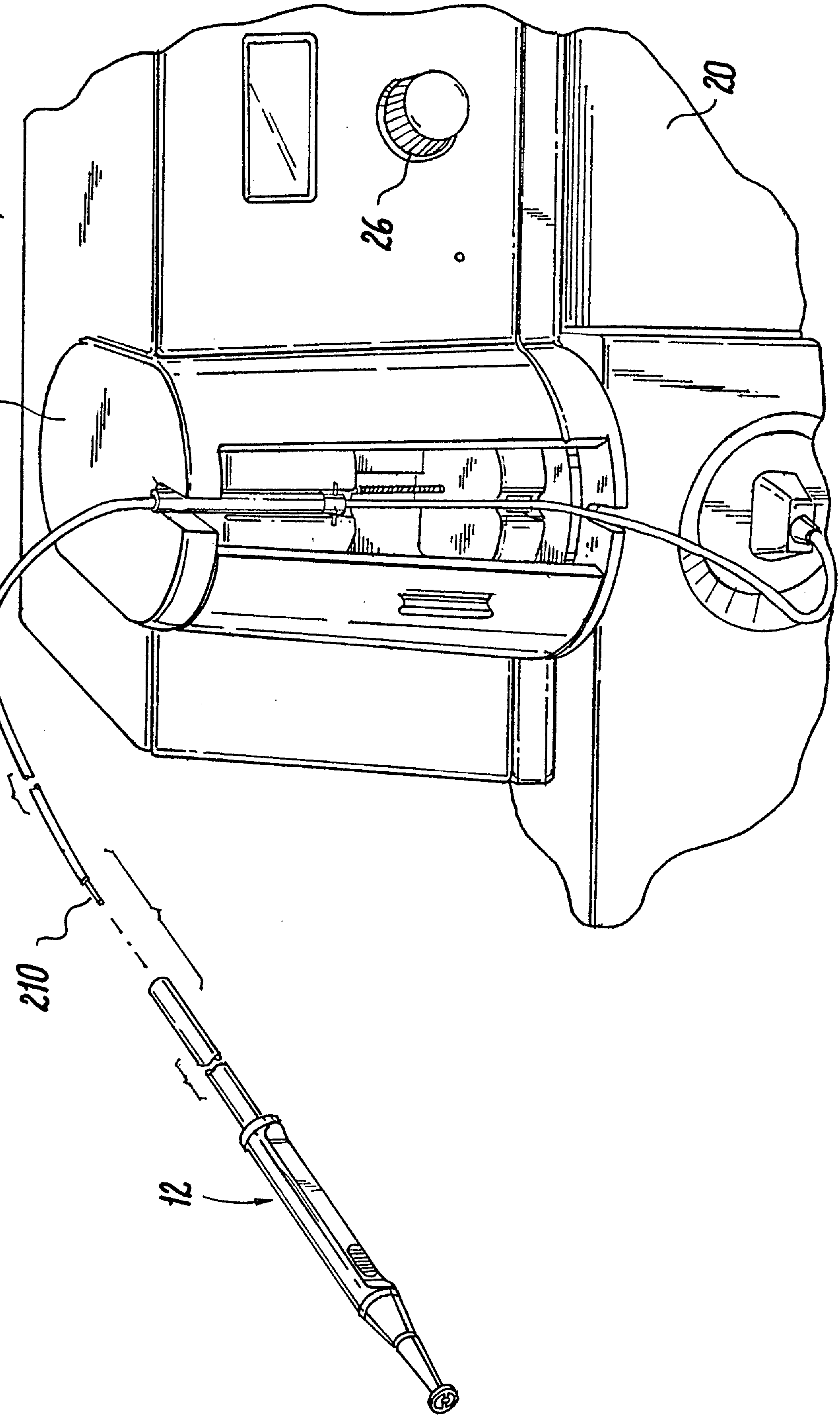



Fig. 4A

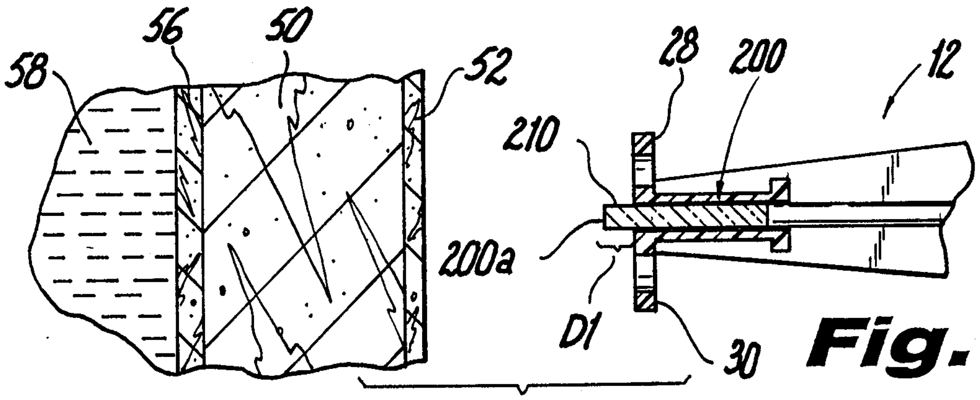



Fig. 5

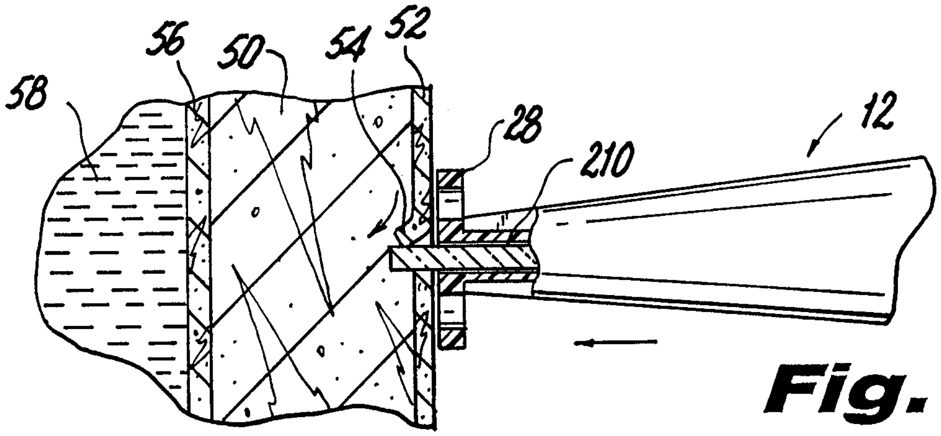



Fig. 6

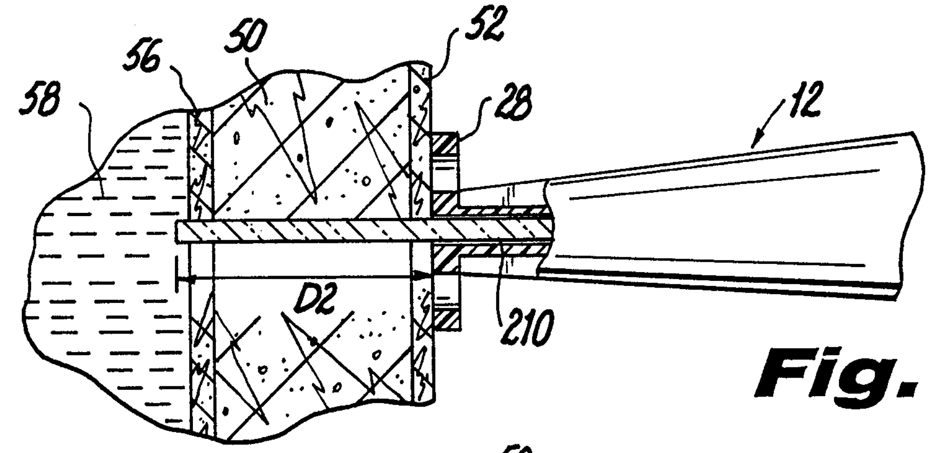



Fig. 7

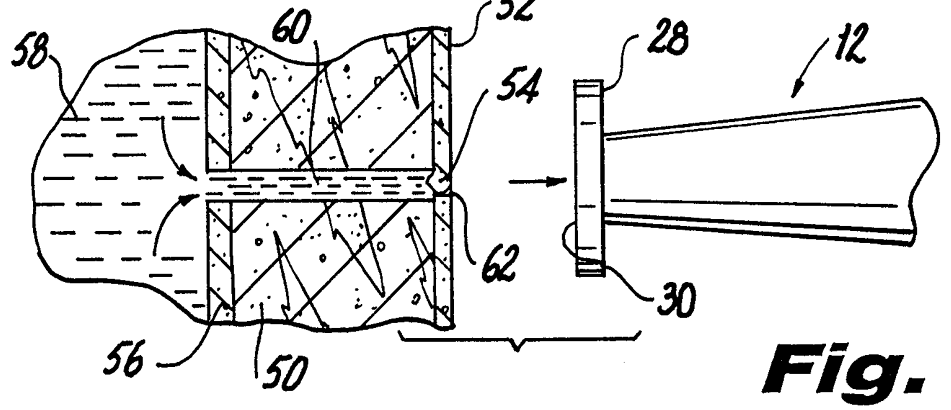



Fig. 8

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/14928

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 17/36
US CL :606/16
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 385/100, 104, 109, 111, 115, 120; 501/37; 606/2, 7, 13-16; 607/88-90, 92, 93

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

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

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 5,297,226 A (FUKUNISHI) 22 March 1994, entire document. | 1-10 , 13-15 |
| Y | US 4,289,375 A (ANDERSEN et al.) 15 September 1981, entire document. | 1-4, 9, 11-14 |
| Y | US 5,148,509 A (KANNABIRAN), 15 September 1992, entire document. | 1-4, 9, 11-14 |
| Y,P | US 5,703,985 A (OWYANG) 30 December 1997, entire document. | 9 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 27 AUGUST 1998 | 13 OCT 1998 |


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