655984

SPRUSON & FERGUSON

AUSTRALIA

PATENTS ACT 1990

PATENT REQUEST: STANDARD PATENT

I/We, the Applicant(s)/Nominated Person(s) specified below, request I/We be granted a patent for the invention disclosed in the accompanying standard complete specification.

[70,71] Applicant(s)/Nominated Person(s):

Vance Products Incorporated, of 1100 West Morgan Street, Spencer, Indiana, 47460, UNITED STATES OF AMERICA

[54] Invention Title:

Surgical Instrument and Method of Use

[72] Inventor(s):

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Details of Basic Application(s):

[31] Appl'n No(s):	[33] Country:	[32] Application Date:
695,222	US	3 May 1991

DATED this TWENTY NINTH day of APRIL 1992

Vance Products Incorporated

By: J. Spruson

Registered Patent Attorney

IRN: 208998

INSTR CODE: 54781

5845/7

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NOTICE OF ENTITLEMENT

I, John Gordon Hinde, of Spruson & Ferguson, St Martins Tower, 31 Market Street, Sydney, New South Wales 2000, Australia, being the patent attorney for the Applicant/Nominated Person in respect of an application entitled:

Surgical Instrument and Method of Use

state the following:-

The Applicant/Nominated Person has entitlement from the actual inventor(s) as follows:-

The Applicant/Nominated Person is the assignee of the actual inventor(s).

The Applicant/Nominated Person is entitled to rely on the basic application~~(s)~~ listed on the Patent Request as follows:

The Applicant/Nominated Person is the assignee of the basic applicant(s).

The basic application~~(s)~~ listed on the Patent Request is/~~are~~ the application~~(s)~~ first made in a Convention country in respect of the invention.

DATED this SIXTEENTH day of JULY 1992

.....

John Gordon Hinde

IRN: INSTR CODE:

1

KRS/665P

AU9215927

(12) PATENT ABRIDGMENT (11) Document No. AU-B-15927/92
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 655984

(54) Title
SURGICAL INSTRUMENT AND METHOD OF USE

International Patent Classification(s)
(51)[5] **A61B 017/00** **A61B 017/42**

(21) Application No. : **15927/92** (22) Application Date : **30.04.92**

(30) Priority Data

(31) Number	(32) Date	(33) Country
695222	**03.05.91**	**US UNITED STATES OF AMERICA**

(43) Publication Date : **05.11.92**

(44) Publication Date of Accepted Application : **19.01.95**

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(56) Prior Art Documents
US 4807626
US 4691705
EP 160870

(57) Claim

1. A surgical instrument for insertion through a longitudinal passageway in an access sheath into a body cavity during minimally invasive surgery, said instrument comprising an elongated member having proximal and distal ends, with a basket formed adjacent to the distal end from a plurality of strips of low durometer material which enables soft tissue to be held by the basket, the basket being collapsible for its insertion through the access sheath, wherein the strips have been pretreated to form them into the shape of the basket so that the strips automatically expand and resume the expanded or preformed condition when the basket exits the access sheath, and so that the strips are in an unstressed relaxed condition when the basket is expanded.

655984 S & F Ref: 208998

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title: Surgical Instrument and Method of Use

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

SURGICAL INSTRUMENT AND METHOD OF USE

This invention relates to surgical instruments.

A number of percutaneous surgical instruments are presently available for removing calculi from, for example, the urinary system. These surgical instruments typically include a wire basket extending from the distal end thereof for capturing and retaining calculi therein. However, these wire baskets are susceptible to causing trauma to surrounding tissue particularly when utilized in other percutaneous procedures such as in percutaneous gynaecological procedures. These gynaecological procedures typically involve grasping and manipulating soft tissue. The use of wire baskets for manipulating ovaries and other soft organs can easily result in undesired trauma. These resilient wire baskets are commonly collapsed and inserted into an introducer sheath and extended therefrom to assume their preformed shape when positioned at the treatment site. Alternatively, longitudinal slits are made about the distal end of a plastic tube and a control wire is inserted in the lumen thereof and attached to the distal end for opening and closing the longitudinal strips in the tubing formed as a result of the slits. Although well-suited for capturing urinary system calculi, the control wire of these plastic baskets prevents easy entry of soft tissue such as ovaries into the basket. Furthermore, the control wire can easily cause trauma to the soft tissue. The longitudinal plastic strips of the basket are usually of a high durometer for maintaining capture of a calculus and, as a result, can also easily cause trauma to the soft tissue.

Examples of surgical instruments are disclosed in U.S. Patent No.4,611,594, U.S. Patent No.2,556,783, and U.S. Patent No.4,807,626, which latter patent discloses a basket which is expandable by tensioning a control line. Unfortunately, the control line limits the effective volume within the chamber. As a result, retaining an object in the chamber interferes with the tensioning and releasing of the control line. Another problem with this device is that force must be applied to both open the basket and maintain closure of the basket when calculi are contained therein and being extracted.

It is the object of the present invention to overcome or substantially ameliorate the above disadvantages.

There is disclosed herein a surgical instrument for insertion through a longitudinal passageway in an access sheath into a body cavity during minimally invasive surgery, said instrument comprising an elongated member having proximal and distal ends, with a basket formed adjacent to the distal end from a plurality of strips of low durometer material which enables soft tissue to be held by the basket, the basket being collapsible for its insertion through the access sheath, wherein the strips have been pretreated to form them into the shape of the basket so that the strips automatically expand and resume the expanded or preformed condition when the basket exits the access sheath, and so that the strips are in an unstressed relaxed condition when the basket is expanded.

In an embodiment of the invention, the surgical instrument has a pliable plastic material basket having a collapsible, bulbous-shape formed about the distal end thereof for atraumatically capturing the manipulating soft tissue or an organ such as an ovary in delicate gynaecological endoscopic surgical procedures. Generally, the surgical instrument is insertable through a minimally invasive surgical access sheath for manipulating the soft tissue. The instrument typically comprises an elongated member which preferably has a longitudinal passageway extending therein. The basket may be positioned about the distal end of the elongated member and includes a plurality of strips of pliable plastic material positioned about the distal end of the elongated member. The basket can be part of the elongated member when in tubular form. The strips of the basket may be preformed into a bulbous shape and may be collapsible for positioning in an introducer sheath.

The pliable plastic surgical instrument may further include an introducer sheath having a longitudinal passageway extending therethrough for positioning the basket therein in a collapsed state therein and introducing the basket into a cavity through the access sheath. When introduced into the cavity, the plastic basket automatically expands to resume its bulbous shape without any outside assistance such as a control line. Soft tissue such as an ovary is introduced into the basket between the strips and captured therein for subsequent manipulation. The basket may be advantageously further opened by applying a force to a small portion of the elongated member extending from about the distal end of the basket and elongated member. The preformed bulbous shape and soft material of the basket advantageously minimise trauma to the captured and manipulated tissue as well as surrounding tissue. When the soft tissue is captured in the basket, the proximal end of the basket may be partially retracted into the introducer sheath to securely position the tissue within the basket.

The instrument may further include a collar about the proximal end of the introducer sheath and a longitudinally adjustably positionable clamp positioned around the

proximal end of the elongated member for engaging the collar and maintaining the soft tissue within the partially retracted basket.

The basket is typically comprised of a plurality of longitudinal strips positioned about or at the distal end of the elongated member and comprises, for example, a soft polyurethane plastic material for minimising trauma to soft tissue. The introducer sheath may be formed of a polytetrafluoroethylene material for easily sliding the sheath and collapsed basket through the access sheath. The number of longitudinal strips is preferably four for securely grasping and manipulating the organ. However, three strips may be easily provided for engaging extremely large soft tissue organs. The basket may also be easily opened by pushing the distal end thereof with another instrument or other soft tissue for further opening and spreading apart the longitudinal strips.

Brief Description of the Drawings

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

FIG. 1 depicts an illustrative surgical instrument of the present invention having a pliable plastic material basket in a preformed open position;

FIG. 2 depicts the instrument of FIG. 1 with the basket in a collapsed state positioned in the introducer sheath;

FIG. 3 depicts the instrument of FIG. 1 with the basket of the instrument being extended from the introducer sheath after being introduced in a body cavity through an access sheath;

FIG. 4 depicts the extended basket of FIG. 3 being further opened for capturing a soft tissue organ; and

FIG. 5 depicts the extended basket of FIG. 4 partially retracted into the distal end of the introducer sheath for manipulating the soft tissue organ.

Detailed Description

Depicted in FIG. 1 is a preferred embodiment of an illustrative endoscopic surgical instrument 10 having a preformed pliable plastic material basket 11 which is collapsible within introducer sheath 12pp for insertion through a minimally invasive access sheath into a cavity of a patient. When introduced into the cavity of the patient, the

basket is extended from the distal end of the introducer sheath to assume a preformed bulbous shape. The preformed basket is positioned about distal end 13 of elongated member tube 14 of pliable plastic material such as polyurethane. The elongated member includes distal end 13, proximal end 15, and longitudinal passageway (16) extending therethrough. For percutaneous insertion through an access sheath into the patient's body cavity, the elongated member tube is positioned within the longitudinal passageway of introducer sheath 12 and extends from distal end 17 and proximal end 18. When extended from the distal end of the introducer sheath, preformed basket 11 assumes a preformed bulbous shape formed from a plurality of longitudinal strips 19-22 of the pliable plastic material about the distal end of the elongated member. The preformed bulbous shape is formed by placing the longitudinal strips around a form and applying heat such as steam to the polyurethane material. Each of the strips has been pre-treated in such a way that the characteristics of the strips themselves have been altered. When fully expanded in the preformed shape, the basket includes a highly elongated chamber within the strips for surrounding soft tissue or an organ such as an ovary. The pliable plastic material strips atraumatically capture the soft tissue organ for subsequent manipulation when the proximal end of the basket is partially retracted into the introducer sheath. When captured within the basket, the soft tissue organ may be easily and atraumatically manipulated or repositioned for more direct visualization or convenient access with other endoscopic surgical instruments.

Elongated member 14 is formed from a pliable plastic material, preferably tubular, and of approximately 50cms. in length with a 12 French outside diameter (0.156") and an inside diameter of 0.254cms. (0.1"). A 30 cms. long stainless steel stylet rod 23 having a 0.173cms. ((0.068") diameter is inserted into passageway 16 about proximal end 15 of the elongated member tubing to stiffen the pliable material tubing for controlling introduction of the tubing into the proximal end of the introducer sheath. A commercially available proximal end connector 24, is fixedly positioned about the

proximal end of the elongated member tubing through which the stylet rod is inserted and fixedly positioned with proximal end cap 25. The proximal end cap is a pin vise having a connector portion mating with proximal end connector 24 which is commercially available from Sabin Corporation, Bloomington, Indiana, or alternatively is moulded on to the proximal end of the stylet rod. Adhesive is applied to the proximal end cap and connector to fixedly position the two components together.

The surgical instrument further includes a releasable clamp 26 that is longitudinally slideable and adjustable along the length of the elongated member about the proximal end thereof. Releasable clamp 26 is commercially available, for example, from Halkey Medical of St. Petersburg, Florida. The clamp is slideable along the length of the proximal end of the elongated member to fixedly position the proximal end of the basket within the distal end of the introducer sheath. Introducer sheath includes a commercially available stop 27 such as a modified Molnar disk available from Vesta Corporation of Glendale, Wisconsin, positioned about proximal end 18. The stop and releasable clamp engage each other to prevent distal longitudinal withdrawal of the basket with the soft tissue therein from the distal end of the introducer sheath.

Introducer sheath is comprised of a polytetrafluoroethylene material tube approximately 33cms. in length and having an outside diameter of 13 French (0.194") and an inside diameter of 0.442cm. (0.174"). The introducer sheath is made of a rigid material and has a slick outside surface for sliding easily into and through the minimally invasive access sheath.

Preformed basket 11 in an open position is approximately 5.2cms. in length with a 3.4cms. diameter. The basket is formed into a bulbous, ellipsoidal shape for further expansion and entry of soft tissue organs therein. A short portion 28 of approximately 5mms. in length elongated member tubing extends from the distal end of the basket to the distal end of the tube. This short portion of tubing is formed by heating, moulding, and buffing the distal end of the tubing to a rounded surface for engagement against other tissue in the

cavity or another surgical instrument. When the short portion is engaged, the strips of the bulbous-shaped basket are spread further apart to receive large soft tissue organs such as an ovary therein. Alternatively, basket 11 may be formed of a soft plastic material and attached at the distal end of a stiffer material elongated member. As a result, the stiffer elongated member need not have the stylet rod positioned at the proximal end thereof and need not be tubular.

The method of manipulating soft tissue such as an ovary with minimally invasive surgical instrument 10 includes introducing access sheath 30 percutaneously through abdominal wall 31 into cavity 32 as depicted in FIG.2. Basket 11 in a collapsed state is positioned into longitudinal passageway 33 of introducer sheath 12 as shown. The introducer sheath is introduced through the access sheath and into body cavity 32. When basket 11 is positioned in the introducer sheath, the stylet rod, which is proximally positioned in elongated member 14, extends into introducer sheath passageway 33 about proximal end 18. This may be helpful in allowing the physician to extend the basket from distal end 17 of the introducer sheath into the body cavity to assume its preformed bulbous shape.

Depicted in FIG.3 is basket 11 in its preformed bulbous shape extended into body cavity 32 from distal end 17 of introducer sheath 12. The basket is extended from the distal end of the introducer sheath by the physician pushing proximal end 15 of elongated member tube 14 into proximal end 18 of the introducer sheath, thereby extending the basket from the distal end of the introducer sheath.

Depicted in FIG.4 is basket 11 in body cavity 32 with strips 19-22 being further spread apart for capturing ovary 34 therein. Distal portion 28 further spreads the strips of the bulbous, ellipsoidal shaped basket further apart by engaging soft tissue 35 within the cavity or another endoscopic instrument inserted in the cavity. Ovary 34 is positioned within the basket, and the longitudinal strips allowed to collapse around the ovary. As a result, the ovary is easily manipulated to allow the physician to better visualize irregularities such as cyst 29 thereon.

Depicted in FIG.5 is ovary 34 within basket 11 with

longitudinal strips 19-21 (22 not shown) partially retracted into distal end 17 of introducer sheath 12. The partially retracted basket permits the longitudinal strips of the basket to securely and atraumatically engage ovary 34. To fixedly position the relative longitudinal position of the basket with the ovary therein with respect to the introducer sheath, slideable clamp 26 is slid along proximal end 15 of elongated member tube 14 to engage stop 27 about proximal end 18 of the introducer sheath. This allows the physician to manipulate the surgical instrument with the ovary fixedly positioned within the basket thereof.

The particular preformed bulbous shape of the basket may be elongated or shortened or extended into a larger spherical shape to capture and manipulate various size soft tissue organs atraumatically. Furthermore, the basket may be utilized to capture and retrieve other tougher tissue such as fibrous tumours, myomas, muscle, etc., that may be encountered in minimally invasive surgical procedures.

The claims defining the invention are as follows:

1. A surgical instrument for insertion through a longitudinal passageway in an access sheath into a body cavity during minimally invasive surgery, said instrument comprising an elongated member having proximal and distal ends, with a basket formed adjacent to the distal end from a plurality of strips of low durometer material which enables soft tissue to be held by the basket, the basket being collapsible for its insertion through the access sheath, wherein the strips have been pretreated to form them into the shape of the basket so that the strips automatically expand and resume the expanded or preformed condition when the basket exits the access sheath, and so that the strips are in an unstressed relaxed condition when the basket is expanded.

2. The instrument of claim 1, wherein the elongated member has an internal passageway, and wherein a stylet is to be positioned about the proximal end of said elongated member and is to extend into the passageway of said introducer sheath when said basket in said collapsed state is positioned in said introducer sheath.

3. The instrument of claim 2, wherein a collar is fixedly positioned about the proximal end of said introducer sheath.

4. The instrument of claim 3, wherein a clamp is adjustably positionable longitudinally about said proximal end of said elongated member for engaging said collar, and wherein a connector fixedly positions said stylet about said proximal end of said elongated member.

5. The instrument of claim 1, wherein said elongated member includes a portion extending between said distal end and said basket for engaging tissue and enlarging said basket when longitudinal pressure is applied to said portion.

6. The instrument of any one preceding claim, wherein the basket includes three or four longitudinal strips.

7. The instrument of any one preceding claim, wherein the plastic material is soft polyurethane.

8. A surgical instrument substantially as hereinbefore described with reference to the accompanying drawings.

Dated 24 October, 1994
Vance Products Incorporated
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

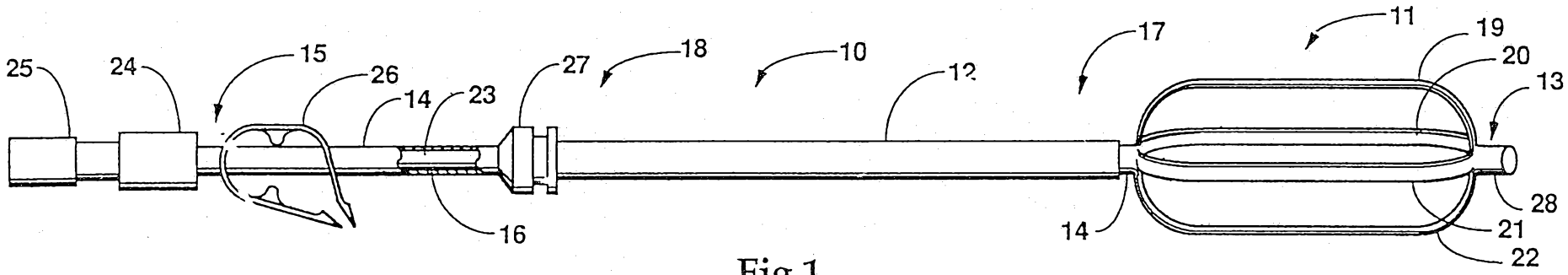

Fig.1

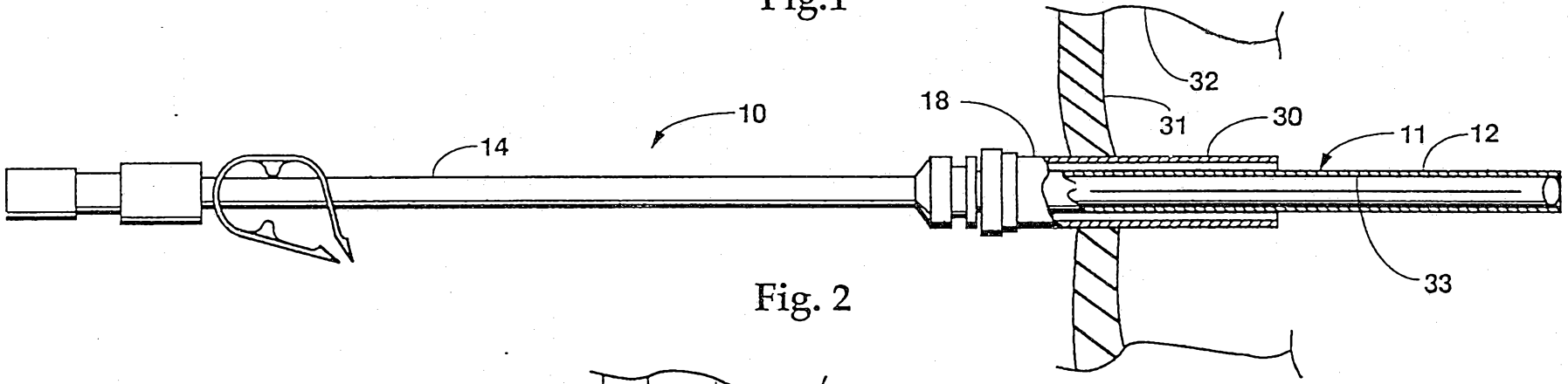

Fig. 2

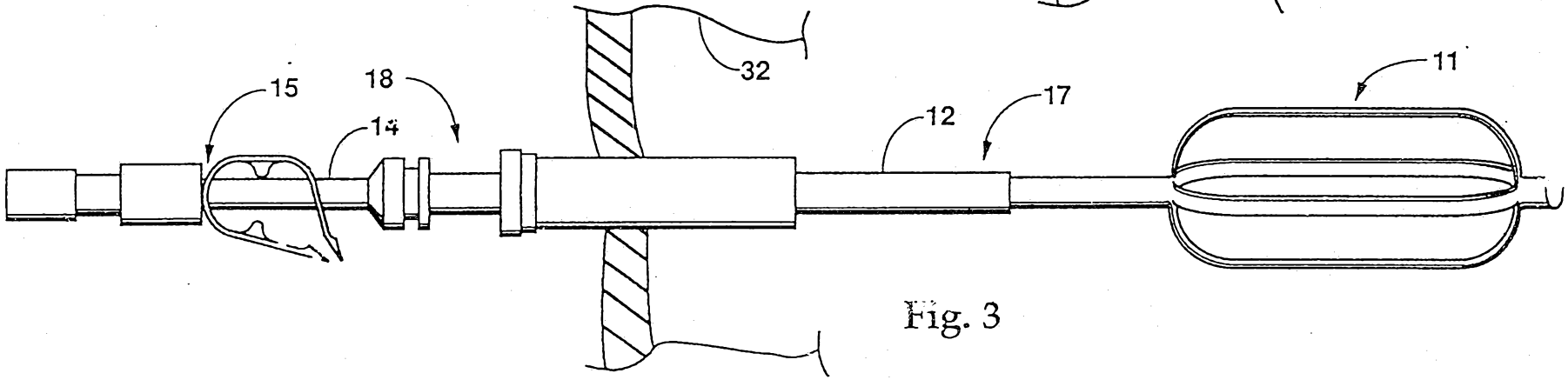

Fig. 3

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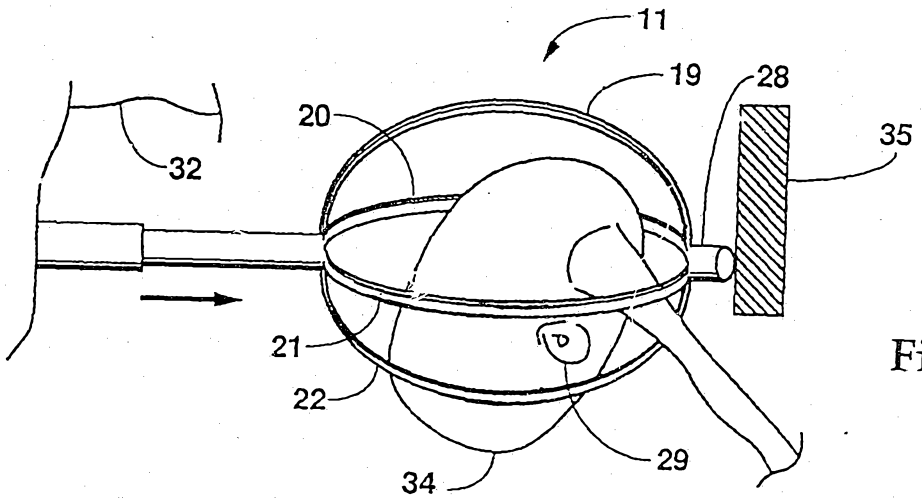

Fig.4

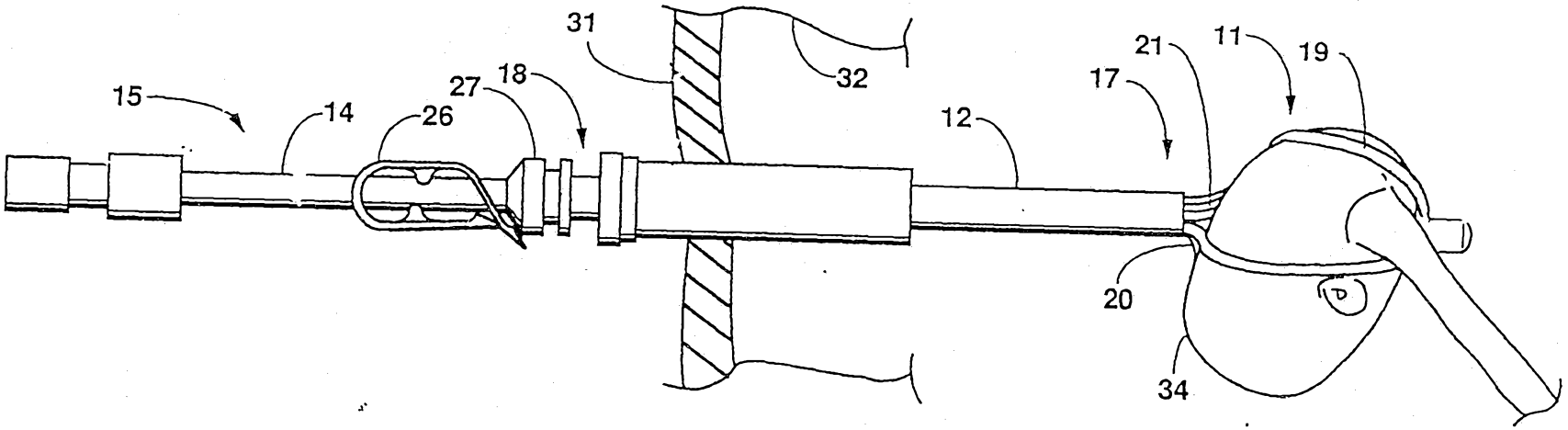

Fig. 5

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