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Nita et al.

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(45) **Date of Patent: Feb. 4, 2014**

(54) **CONNECTOR FOR SECURING ULTRASOUND CATHETER TO TRANSDUCER**

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(73) Assignee: **Flowcardia, Inc.**, Sunnyvale, CA (US)

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(21) Appl. No.: **12/831,883**

(22) Filed: **Jul. 7, 2010**

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Related U.S. Application Data

(63) Continuation of application No. 11/192,749, filed on Jul. 29, 2005, now Pat. No. 7,758,510, which is a continuation of application No. 10/666,459, filed on Sep. 19, 2003, now Pat. No. 6,942,620.

(51) **Int. Cl.**
A61B 8/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/466**; 601/2; 600/459

(58) **Field of Classification Search**
USPC 600/300, 437–461; 604/19, 20
See application file for complete search history.

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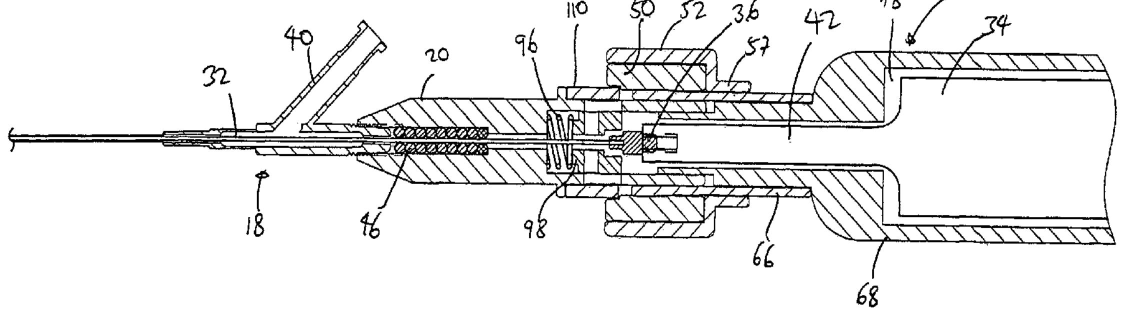
(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

An ultrasound system has an ultrasound transducer having a transducer housing and a horn provided at the distal end of the transducer housing, an ultrasound transmission member, a sonic connector that is connected to the horn and the proximal end of the ultrasound transmission member, and a catheter knob having a proximal end that is coupled to the distal end of the transducer housing. The catheter knob has a proximal bore that houses the sonic connector. The system also includes a nesting piece that is retained inside the proximal bore of the catheter knob. The nesting piece can be moved from a first position where the sonic connector is received inside the nesting piece to a second position where the sonic connector is separated from the nesting piece when ultrasound energy is being propagated through the ultrasound transmission member.

10 Claims, 7 Drawing Sheets



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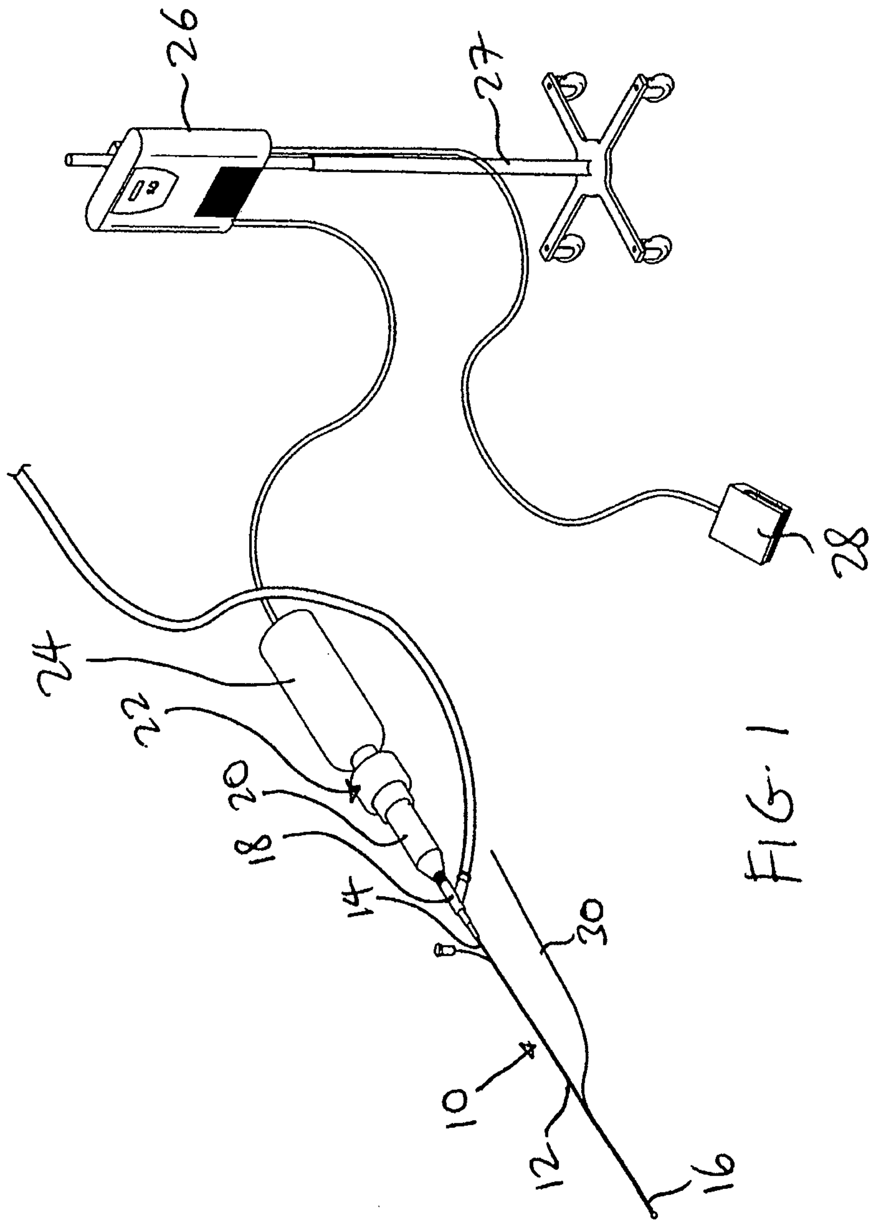

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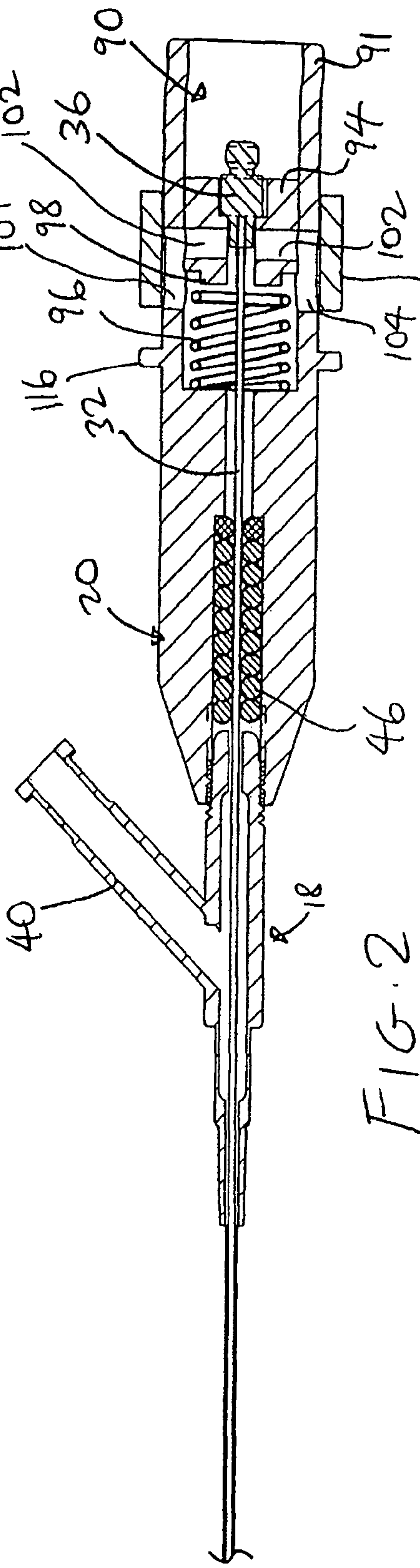

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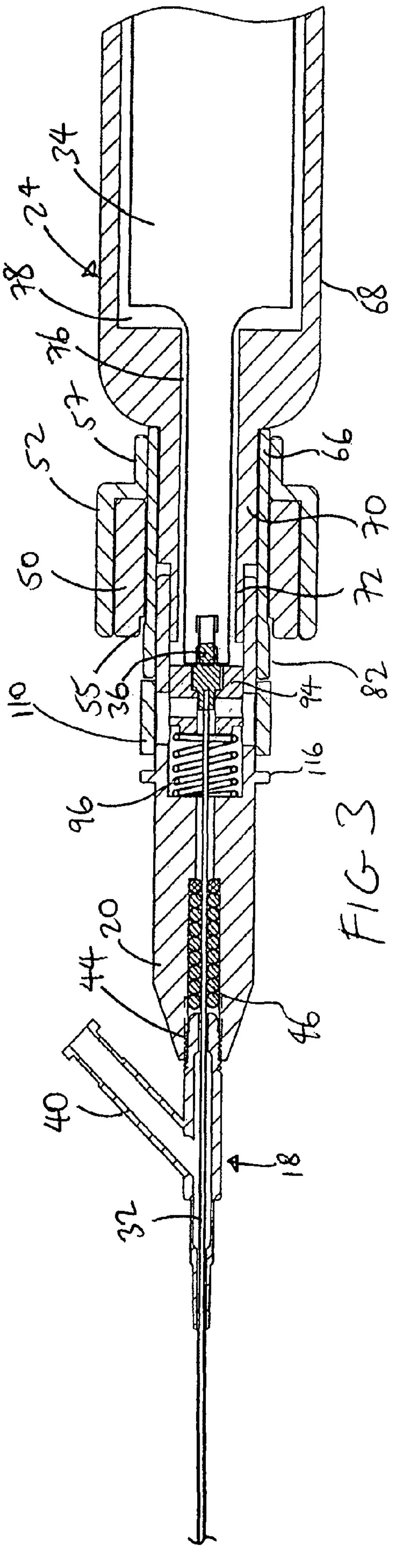

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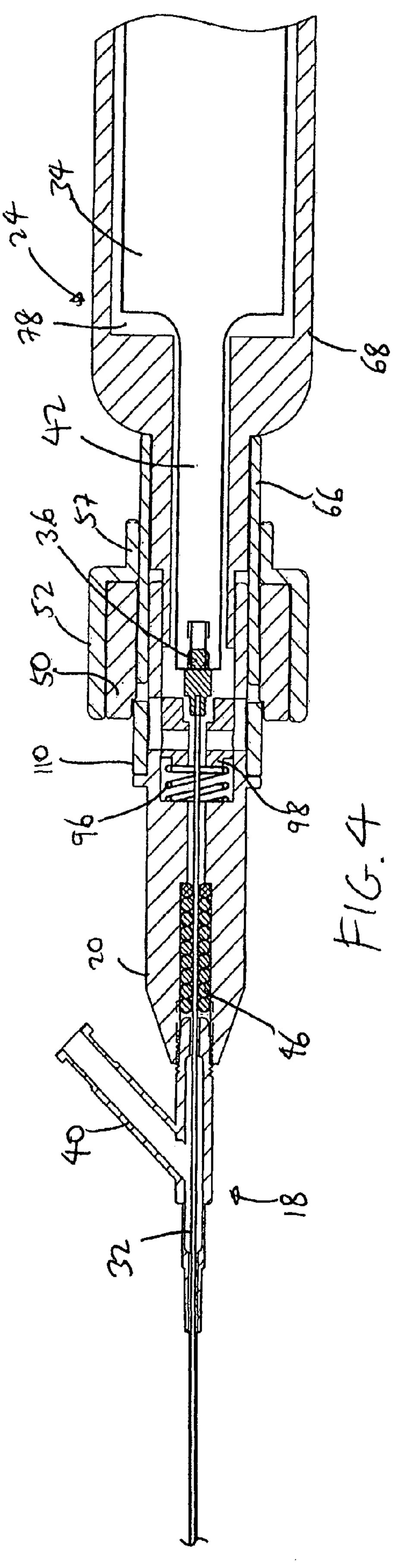

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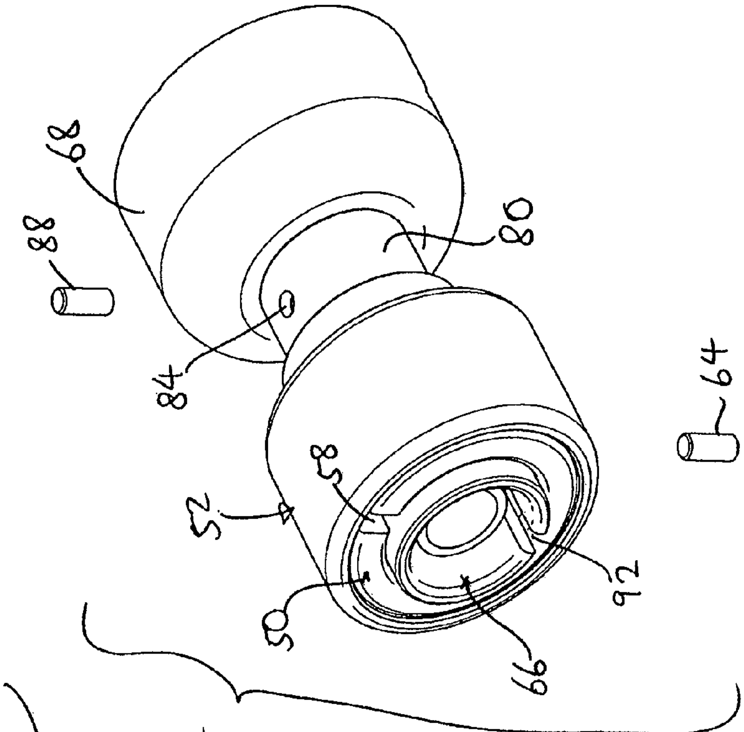
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FIG 6

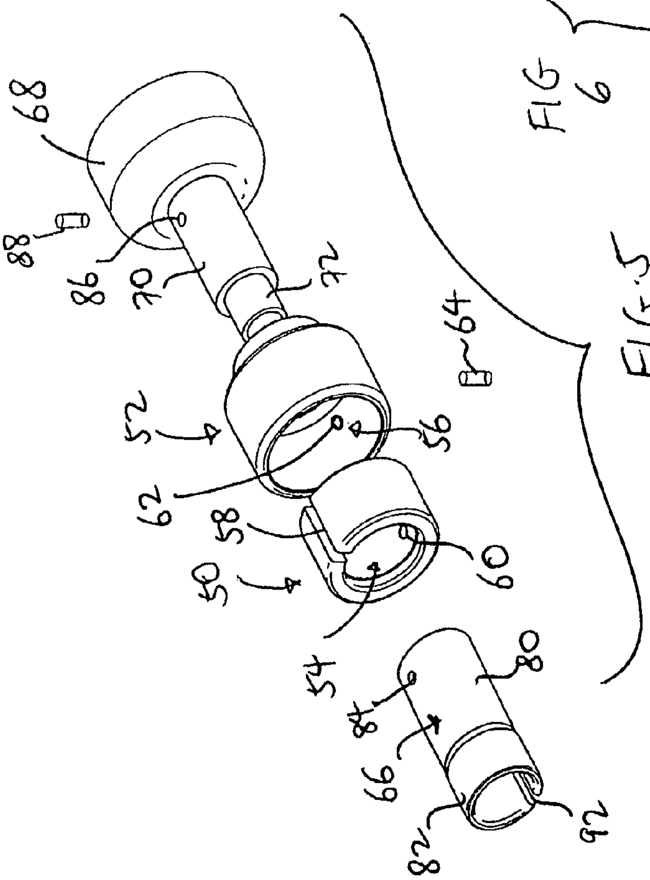
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FIG 5

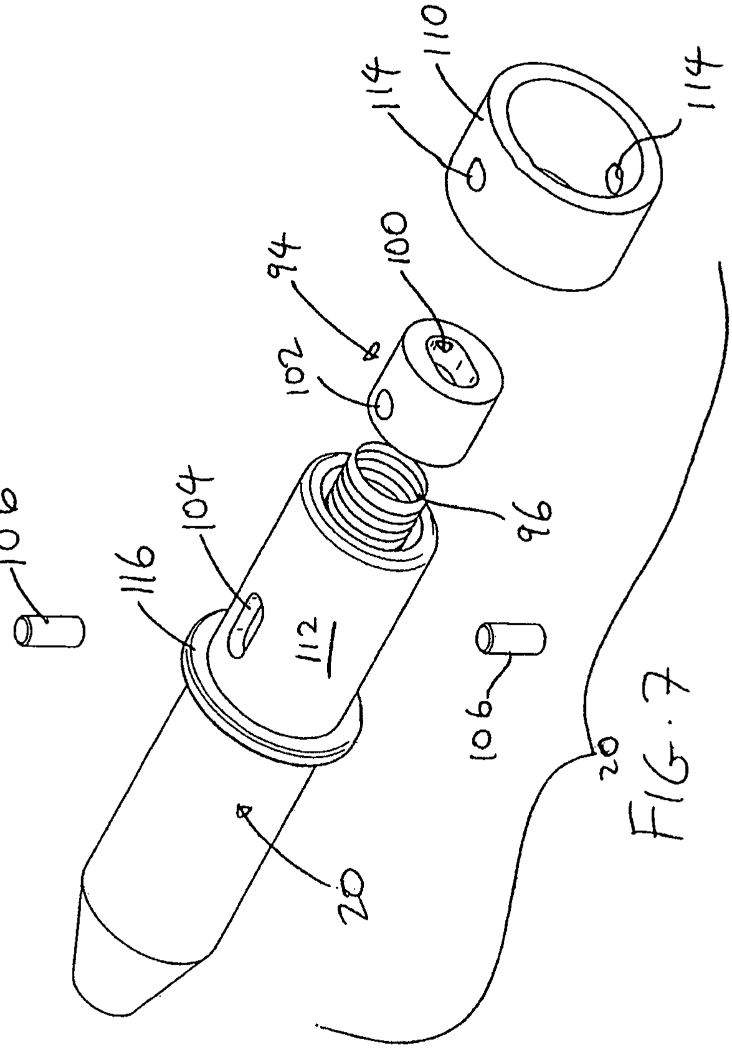
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FIG. 7

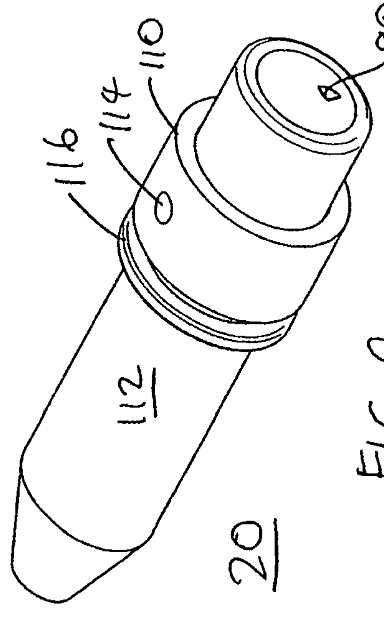
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FIG. 8

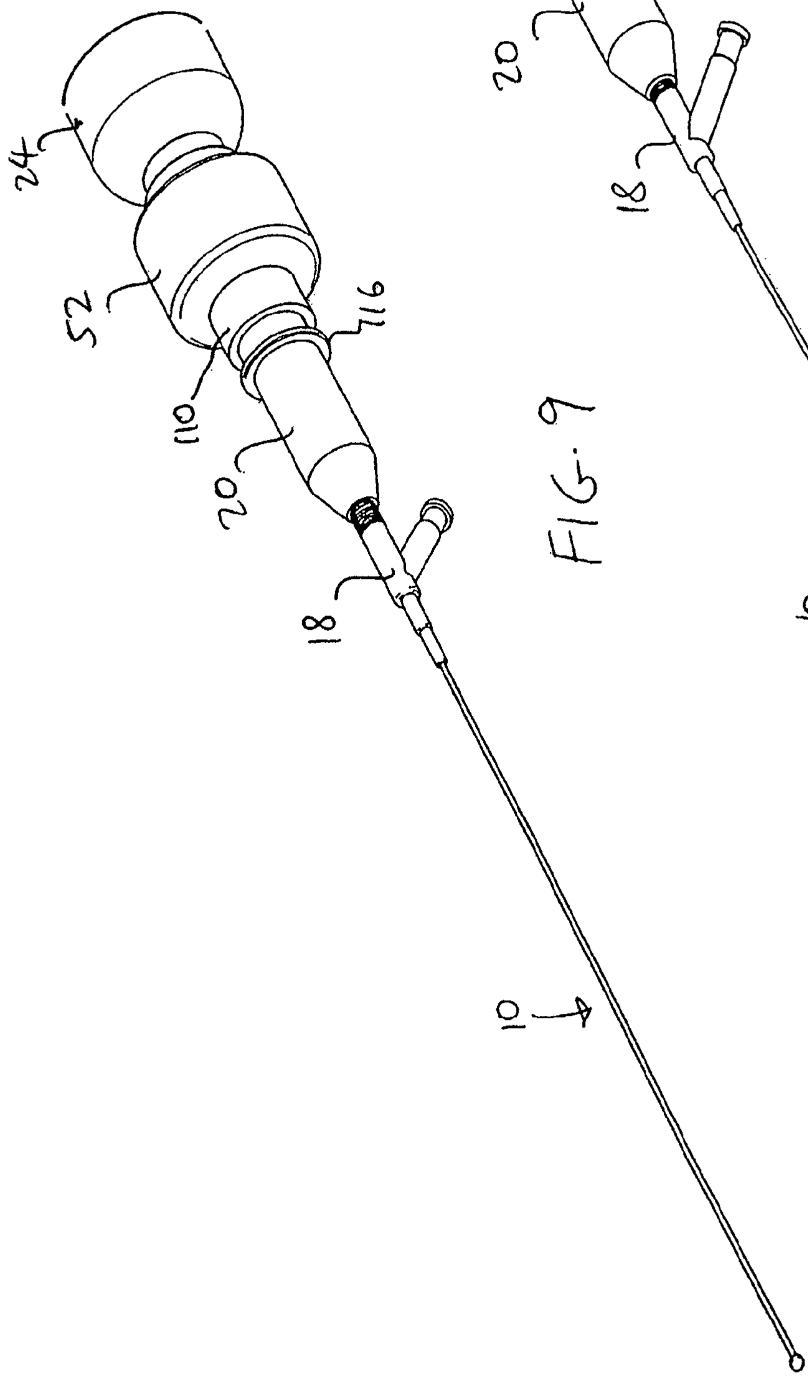

FIG. 9

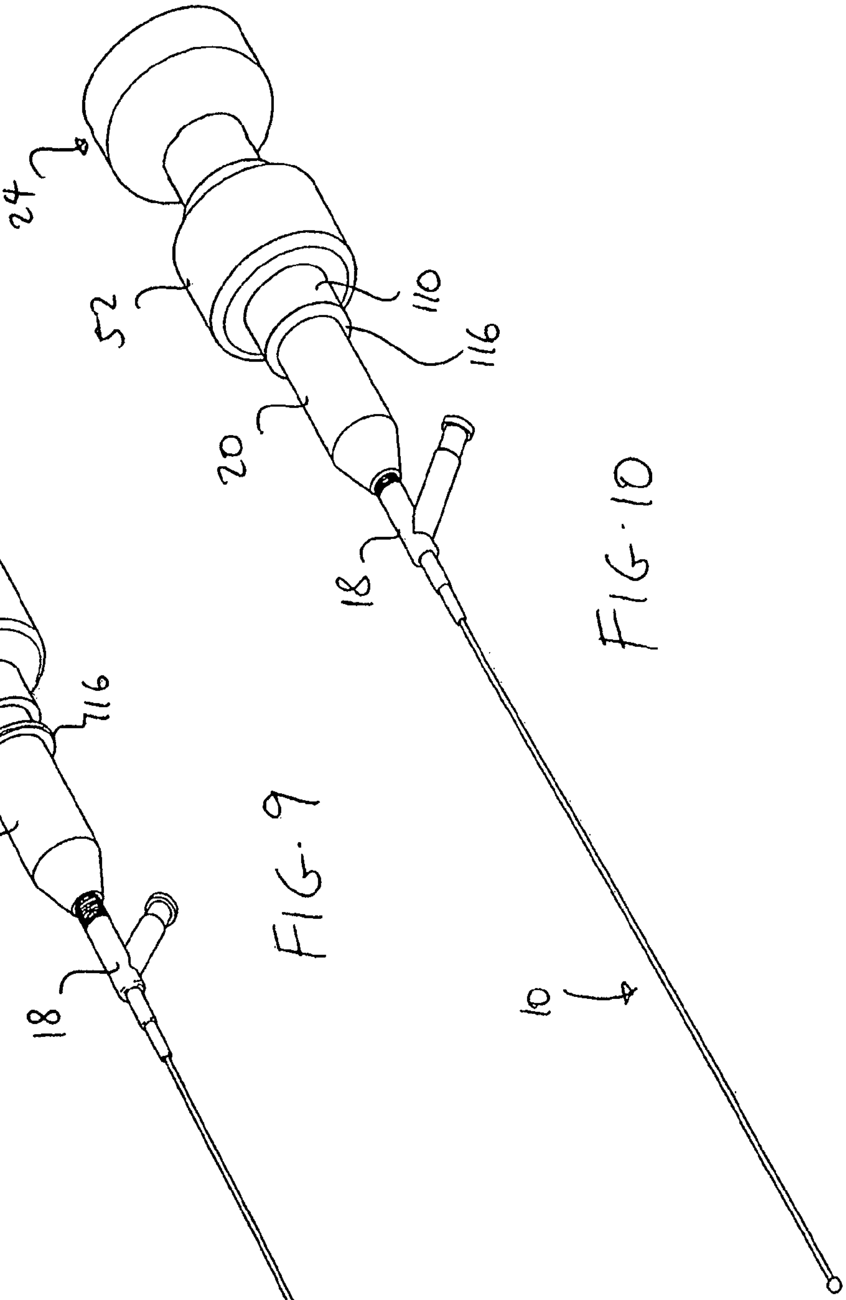

FIG. 10

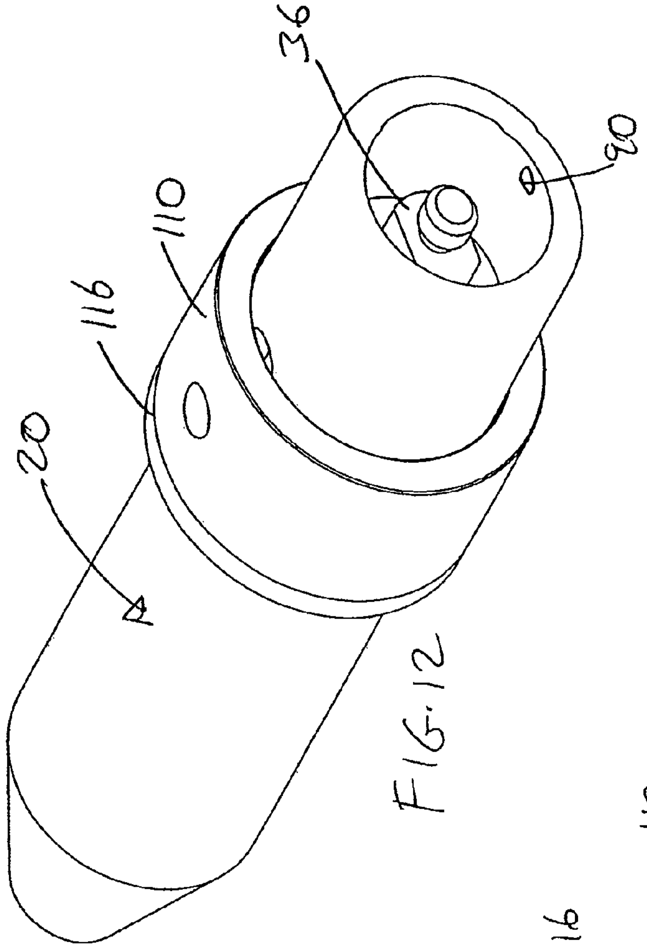

FIG. 12

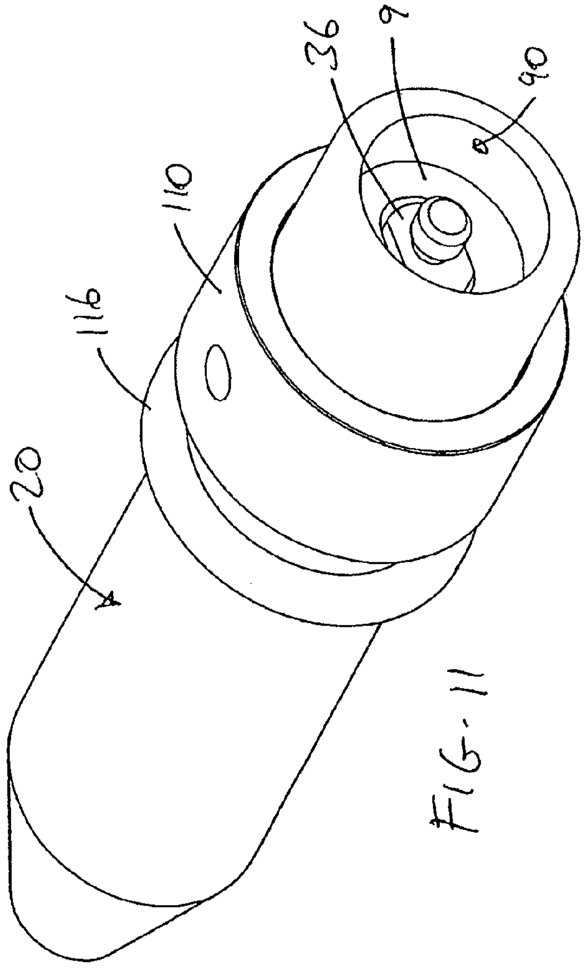

FIG. 11

CONNECTOR FOR SECURING ULTRASOUND CATHETER TO TRANSDUCER

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of Ser. No. 11/192,749, filed Jul. 29, 2005, entitled "Connector for Securing Ultrasound Catheter to Transducer", which is a continuation of Ser. No. 10/666,459, filed Sep. 19, 2003, entitled "Connector for Securing Ultrasound Catheter to Transducer", now U.S. Pat. No. 6,942,620, each of which is incorporated by this reference as though set forth fully herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to medical equipment, and more particularly, to a device and method for attaching an ultrasound catheter to an ultrasound transducer which prevents frequency shifts and minimizes the mechanical impact of the handling connection area during a medical procedure.

2. Description of the Related Art

A number of ultrasound systems and devices have heretofore been proposed for use in ablating or removing obstructive material from blood vessels. Ultrasound catheters have been utilized to ablate various types of obstructions from blood vessels of humans and animals. Successful applications of ultrasound energy to smaller blood vessels, such as the coronary arteries, require the use of relatively small diameter ultrasound catheters which are sufficiently small and flexible to undergo transluminal advancement through the tortuous vasculature of the aortic arch and coronary tree. These ultrasound catheters incorporate a very small diameter ultrasound transmission member which extends through such catheters. The proximal end of the ultrasound transmission member is typically connected to an ultrasound transducer via a sonic connector.

The attachment of the ultrasound transmission member to an ultrasound transducer plays a very important role in ultrasound energy propagation. The attachment region needs to be accurately aligned and free of mechanical stress and other interfaces. For example, undesirable stress at the attachment region can be caused by pressing upon, pushing, pulling, torquing, bending or bumping the attachment region during use of the ultrasound catheter. In addition, it is preferable for the sonic connector to be free from any interface (i.e., contact) with any other component during energy transmission. Otherwise, such stresses and interfaces can negatively impact the propagation of ultrasound energy through the ultrasound transmission member. Contact of the sonic connector with any other part of the catheter housing during the delivery of ultrasound energy might also cause a shift in frequency and impact performance.

Thus, there still exists a need for an improved connection of the proximal end of the ultrasound transmission member to an ultrasound transducer.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved connection between the ultrasound catheter and the ultrasound transducer.

It is yet another object of the present invention to improve the propagation of ultrasound energy by limiting and minimizing the impact of undesirable external forces.

In order to accomplish the objects of the present invention, there is provided an ultrasound system and method of using the ultrasound system during a medical procedure. The ultrasound system has an ultrasound transducer having a transducer housing and a horn provided at the distal end of the transducer housing, an ultrasound transmission member, a sonic connector that is connected to the horn and the proximal end of the ultrasound transmission member, and a catheter knob having a proximal end that is coupled to the distal end of the transducer housing. The catheter knob has a proximal bore that houses the sonic connector. The system also includes a nesting piece that is retained inside the proximal bore of the catheter knob. The nesting piece can be moved from a first position where the sonic connector is received inside the nesting piece to a second position where the sonic connector is separated from the nesting piece when ultrasound energy is being propagated through the ultrasound transmission member.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an ultrasound system according to one embodiment of the present invention.

FIG. **2** is a cross-sectional view of the Y-connector and catheter knob of the system of FIG. **1**.

FIG. **3** is a cross-sectional view of the Y-connector, the catheter knob, the slide collar assembly and the transducer housing of the system of FIG. **1** with the slide collar assembly in the non-supporting position.

FIG. **4** is a cross-sectional view of the Y-connector, the catheter knob, the slide collar assembly and the transducer housing of the system of FIG. **1** with the slide collar assembly in the supporting position.

FIG. **5** is an exploded perspective view of some of the elements of the slide collar assembly of the system of FIG. **1**.

FIG. **6** is an assembled perspective view of the elements of FIG. **5**.

FIG. **7** is an exploded perspective view of the catheter knob of the system of FIG. **1**.

FIG. **8** is an assembled perspective view of the catheter knob of FIG. **7**.

FIG. **9** is a perspective view of the system of FIG. **1** with the slide collar assembly in the non-supporting position.

FIG. **10** is a perspective view of the system of FIG. **1** with the slide collar assembly in the supporting position.

FIG. **11** is a perspective view of the catheter knob of the system of FIG. **1** with the slide collar assembly in the non-supporting position.

FIG. **12** is a perspective view of the catheter knob of the system of FIG. **1** with the slide collar assembly in the supporting position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following detailed description is of the best presently contemplated modes of carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating general principles of embodiments of the invention. The scope of the invention is best defined by the appended claims. In certain instances, detailed descriptions of well-known devices, compositions, components, mechanisms and methods are omitted so as to not obscure the description of the present invention with unnecessary detail.

FIG. **1** illustrates an ultrasound system according to the present invention for use in ablating and removing occlusive material inside the vessel of an animal or human being. The ultrasound system includes an ultrasonic catheter device **10** which has an elongate catheter body **12** having a proximal end **14**, a distal end **16**, and defining at least one lumen extending longitudinally therethrough. The ultrasound catheter device **10** is operatively coupled at its proximal end **14**, by way of a Y-connector **18**, a catheter knob **20**, and a slide collar assembly **22**, to an ultrasound transducer housing **24** As shown in FIGS. **3-4**, an ultrasound transducer **34** is housed inside the transducer housing **24**. The ultrasound transducer **34** is connected to a signal generator **26**, which can be provided with a foot actuated on-off switch **28**. The signal generator **26** can be supported by an IV pole **27**. When the on-off switch **28** is depressed, the signal generator **26** sends an electrical signal to the ultrasound transducer **34**, which converts the electrical signal to ultrasound energy. Such ultrasound energy subsequently passes through the catheter device **10** and is delivered to the distal end **16**.

Referring also to FIGS. **2-4**, an ultrasound transmission member **32** extends through the lumen of the catheter **10** from the distal end **16** to the proximal end **14**. The ultrasound transducer **34** is coupled via a sonic connector **36** (described in greater detail below) to the ultrasound transmission member **32**, so that the ultrasound energy can be passed through the sonic connector **36** and the ultrasound transmission member **32** to be delivered to the distal end **16** of the catheter **10**. A guidewire **30**, which can be any conventional monorail or over-the-wire guidewire, may be utilized in conjunction with the catheter **10** in a manner that is well-known in the catheter art.

The frontal portion of the Y-connector **18** is connected to the proximal end **12** of the catheter **10** using techniques that are well-known in the catheter art. An injection pump (not shown) or IV bag (not shown) can be connected, by way of an infusion tube (not shown), to an infusion port or sidearm **40** of the Y-connector **18**. The injection pump can be used to infuse coolant fluid (e.g., 0.9% NaCl solution) into and/or through the lumen of the catheter **10**. Such flow of coolant fluid may be utilized to prevent overheating of the ultrasound transmission member **32** extending longitudinally through the lumen of the catheter **10**. Such flow of the coolant fluid through the lumen of the catheter **10** serves to bathe the outer surface of the ultrasound transmission member **32**, thereby providing for an equilibration of temperature between the coolant fluid and the ultrasound transmission member **32**. Thus, the temperature and/or flow rate of coolant fluid may be adjusted to provide adequate cooling and/or other temperature control of the ultrasound transmission member **32**. In addition to the foregoing, the injection pump may be utilized to infuse a radiographic contrast medium into the catheter **10** for purposes of imaging.

Examples of iodinated radiographic contrast media which may be selectively infused into the catheter **10** via the injection pump are commercially available as Angiovist 370 from Berlex Labs, Wayne, N.J. and Hexabrix from Malinkrodt, St. Louis, Mo.

The proximal end of the ultrasound transmission member **32** is attached to the sonic connector **36** which is configured to effect operative and removable attachment of the proximal end of the ultrasound transmission member **32** to the distal horn **42** of the ultrasound transducer **34**. The sonic connector **36** is preferably configured and constructed to permit passage of ultrasound energy through the ultrasound transmission member **32** with minimal lateral side-to-side movement of the ultrasound transmission member **32** while, at the same time, permitting unrestricted longitudinal forward/backward vibration or movement of the ultrasound transmission member **32**.

The ultrasound transmission member **32** may be formed of any material capable of effectively transmitting the ultrasonic energy from the ultrasound transducer **34** to the distal end **16** of the catheter **10**, including but not necessarily limited to metal, plastic, hard rubber, ceramic, fiber optics, crystal, polymers, and/or composites thereof In accordance with one aspect of the invention, all or a portion of the ultrasound transmission member **32** may be formed of one or more materials which exhibit super-elasticity. Such materials should preferably exhibit super-elasticity consistently within the range of temperatures normally encountered by the ultrasound transmission member **32** during operation of the catheter **10**. Specifically, all or part of the ultrasound transmission member **32** may be formed of one or more metal alloys known as "shape memory alloys". Such super-elastic metal alloys are well-known in the art and will not be described in any further detail herein.

The proximal end of the Y-connector **18** is attached to the distal end of the catheter knob **20** by threadably engaging the proximal end of the Y-connector **18** inside a threaded distal bore **44** at the distal end of the catheter knob **20**. O-rings **46** are provided in the threaded distal bore **44** to minimize transverse vibrations. The proximal end of the catheter knob **20** receives the extension **70** of the transducer housing **24** and is supported by the slide collar assembly **22**. The slide collar assembly **22** is positioned over the distal end of the transducer housing **24**, and has a non-supporting position where the slide collar assembly **22** is retracted towards the transducer housing **24**; and has a supporting position where the slide collar assembly **22** is extended to cover at least a portion of the catheter knob **20**. Thus, the slide collar assembly **22** functions as a support member that is disposed on the transducer housing **24** to support at least a portion of the catheter knob **20**.

Referring also to FIGS. **5** and **6**, the slide collar assembly **22** has an inner ring **50** (also referred to as collar **50**) and an outer ring **52** (also referred to as collar **52**). The inner ring **50** has a bore **54** and a longitudinal slit **58** that extends through the length of the inner ring **50**. The distal portion of the bore **54** can be stepped as shown at **55** (see FIG. **3**) to function as a pushing surface that pushes a nesting piece **94** (described below) in a distal direction as the inner ring **50** is moved from the non-supporting position to the supporting position. The outer ring **52** also has a bore **56**, and has a narrowed proximal end **57**. The inner ring **50** is retained inside the bore **56** of the outer ring **52** and abuts the narrowed proximal end **57** which acts as a stop to limit the proximal movement of the inner ring **50**. Each of the inner ring **50** and the outer ring **52** has an opening **60** and **62**, respectively, that are aligned with each other and that are adapted to receive a locking pin **64**. A tubular inner sleeve **66** extends through the inside of the bore **54** of the inner ring **50** to ensleeve the first extension **70** of the transducer housing **24**, as explained below. The sleeve **66** has a proximal section **80** and an enlarged distal section **82**. The inner ring **50** is normally fitted around the proximal section **80** when the slide collar assembly **22** is in the non-supporting position, but the inner ring **50** is fitted around the distal section **82** when the slide collar assembly **22** is in the supporting position. Thus, providing the distal section **82** in an enlarged configuration allows for the inner ring **50** to achieve a friction-fit with the distal section **82**, while the inner ring **50** experiences a loose fit over the proximal section **80**.

The transducer housing **24** has a cylindrical wall **68** having a distal extension that comprises two stepped cylindrical extensions **70** and **72** extending from the distal end of the cylindrical wall **68**. The first extension **70** is attached to the distal end of the cylindrical wall **68**, and has a greater outer diameter than the second extension **72** that is attached to the distal end of the first extension **70**. A throughbore **76** extends from the hollow interior **78** of the cylindrical wall **68** and through the extensions **70** and **72**. The throughbore **76** can have the same diameter throughout its length. The second extension **72** is adapted to be received inside the proximal bore **90** of the catheter knob **20**, while the first extension **70** is received inside the sleeve **66**. In addition, an opening **84** is provided in the proximal section **80** of the sleeve **66** and is aligned with a corresponding opening **86** on the first extension **70**, with the openings **84**, **86** adapted to receive a locking pin **88** that secures the sleeve **66** to the first extension **70** at a fixed position.

A longitudinal slot **92** is provided on the sleeve **66**. When the slide collar assembly **22** is in the non-supporting position (i.e., inner ring **50** positioned over the proximal section **80**), the slot **92** is opened. However, when the slide collar assembly **22** is moved to the supporting position, the inner ring **50** is positioned over the distal section **82** and compresses the enlarged distal section **82** to close the slot **92**. With the slot **92** closed, the sleeve **66** provides a frictional grip of the proximal end **91** of the catheter knob **20**.

Referring now to FIGS. **2-4** and **7-8**, the catheter knob **20** has a proximal bore **90** that can be sleeved over the second extension **72** in a manner such that the outer surface of the catheter knob **20** can be substantially flush with the outer surface of the first extension **70** (as best shown in FIGS. **3** and **4**). The proximal bore **90** houses the sonic connector **36** and a nesting piece **94**. An elastic element **96**, such as a spring, is seated in the distal part of the proximal bore **90**, and has one end carried on a projection **98** provided at the distal end of the nesting piece **94**. The nesting piece **94** has a generally cylindrical configuration and has a receptacle **100** which functions to selectively retain the sonic connector **36**, as will be explained in greater detail below. In addition, a control ring **110** is positioned around the outer surface **112** of the catheter knob **20**. The control ring **112** cooperates with the nesting piece **94** to move the nesting piece **94** in a reciprocal manner inside the proximal bore **90** of the catheter knob **20**, as explained below.

The nesting piece **94** has two opposite and aligned openings **102**; only the top opening **102** is shown in FIG. **7**, but the bottom opening is the same and is aligned on a straight line with the top opening **102**. Similarly, the catheter knob **20** has two opposite and aligned channels **104**; only the top channel **104** is shown in FIG. **7**, but the bottom channel is the same and is aligned on a straight line with the top channel **104**. In addition, the control ring **110** has two opposite and aligned openings **114**. The channels **104** and the openings **102**, **114** are aligned, as best shown in FIGS. **3** and **4**. Two opposing pins **106** are provided, with each pin **106** adapted to be fitted inside a corresponding set of channel **104** and openings **102**, **114**, so as to couple the control ring **110** and the nesting piece **94** as a unitary moving piece. The width of the channels **104** define the distal and proximal limits of movement for the control ring **110** and the nesting piece **94**. The catheter knob **20** also has an annular flange **116** provided about its outer surface **112** that also defines the distal limit of the movement of the control ring **110**.

In use, the sonic connector **36** is shown in FIGS. **3-4** as connecting the transducer horn **42** (e.g., with a threaded connection) with the ultrasound transmission member **32**. The sonic connector **36** is always located at a fixed position inside the proximal bore **90** of the catheter knob **20**. When the slide collar assembly **22** is in the non-supporting position shown in FIGS. **3**, **9** and **11**, the elastic element **96** normally biases the nesting piece **94** in the proximal direction so that the sonic connector **36** is received inside the receptacle **100** of the nesting piece **94** to be supported by the nesting piece **94**. The proximal movement of the nesting piece **94** will cause the pins **106** to move in the proximal direction inside the channels **104**, thereby causing the control ring **110** to move proximally away from the flange **116**. The outer ring **52** and the inner ring **50** are positioned completely over the proximal section **80** of the sleeve **66**, with the narrowed proximal end **57** positioned adjacent the cylindrical wall **68** of the transducer housing **24**.

When the slide collar assembly **22** is now moved from the non-supporting position to the supporting position shown in FIGS. **4**, **10** and **12**, the user pushes the outer ring **52** in the distal direction. The step **55** on the distal end of the inner ring **50** engages the proximal end of the control ring **110** and pushes the control ring **110** in the distal direction. Movement of the control ring **110** in the distal direction will cause the pins **106** to move in the distal direction inside the channels **104**, thereby causing the nesting piece **94** to counter the bias of the elastic element **96** and move in the distal direction. As the nesting piece **94** moves in the distal direction, the sonic connector **36** becomes free from the receptacle **100** of the nesting bore **94**. In addition, the distal movement of the inner ring **50** will cause the inner surface of the inner ring **50** to engage the enlarged distal section **82** of the sleeve **66**, which functions to close the slot **92** so as to frictionally grip the proximal portion **91** of the knob **20** when the slide collar assembly **22** is in the supporting position. The flange **116** and the width of the channels **104** function as stops to limit the distal movement of the control ring **110**.

In the supporting position, the sonic connector **36** is not supported by the nesting piece **94** so that the sonic connector **36** can be free from any component or material interfaces, thereby promoting improved ultrasound energy propagation. The medical procedure can then be carried out while the slide collar assembly **22** is in the supporting position. Upon completion of the medical procedure, the above-described steps are reversed. In particular, the combined inner and outer rings **50**, **52** (slide collar assembly **22**) are retracted in the proximal direction so that they are now positioned over the proximal section **80** of the sleeve **66**. The bias of the elastic element **96** will push the nesting piece **94** in the proximal direction so that the sonic connector **36** is received inside the receptacle **100** of the nesting piece **94**. In addition, the proximal movement of the nesting piece **94** will cause the pins **106** to move in the proximal direction inside the channels **104**, thereby causing the control ring **110** to move proximally away from the flange **116**. Now, the catheter **10** can be disconnected from the transducer **34**.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

What is claimed is:

1. An ultrasound system, comprising:

an ultrasound transducer housing containing

a transducer horn that is connected to a signal generator and has a distal end;

a transducer mechanism comprising a slide collar disposed around an inner ring wherein the transducer mechanism is movable from a first position to a second position wherein the second position is distal from the first position and wherein movement of the transducer mechanism from the first position to the second position engages a control ring on a catheter and moves a catheter mechanism from a first position to a second position;

and

the catheter having:

an elongated flexible body,

a proximal end,

a distal end,

a knob having a proximal end, and a distal end, wherein the elongated flexible body extends from the distal end of the knob,

the control ring disposed around the proximal end of the knob,

a nesting piece disposed within the knob near the proximal end of the knob and operatively coupled to the control ring,

at least one longitudinal lumen,

an ultrasound transmission member, having a proximal end, extending through the lumen,

a sonic connector that is secured to the proximal end of the ultrasound transmission member and disposed within the nesting piece;

and

the catheter mechanism comprising the control ring and the nesting piece that is movable from the first position that engages the nesting piece around the sonic connector restraining the sonic connector and substantially preventing the transmission of ultrasound energy and a second position that disengages the nesting piece from the sonic connector, permitting the transmission of ultrasound energy from the transducer horn to the ultrasound transmission member;

wherein the transducer housing operatively couples to the proximal end of the catheter.

2. The system of claim **1**, wherein the catheter mechanism has a longitudinal interface.

3. The system of claim **1**, wherein the catheter mechanism has a transverse interface.

4. The system of claim **1**, wherein the sonic connector and the transducer horn have a threaded connection.

5. The system of claim **1**, wherein the sonic connector and the transducer horn have a frictional connection.

6. The system of claim **1**, wherein the catheter mechanism freely overlaps the sonic connector.

7. The system of claim **1**, wherein the catheter mechanism comprises removable components.

8. The system of claim **1**, wherein the catheter mechanism comprises fixed and removable components.

9. The system of claim **1**, wherein the catheter mechanism is movable in a direction parallel to the ultrasound transmission member.

10. A method of using an ultrasound system during a medical procedure comprising:

providing an ultrasound system having:

an ultrasound transducer housing containing

a transducer horn that is connected to a signal generator and has a distal end;

a transducer mechanism comprising a slide collar disposed around an inner ring wherein the transducer mechanism is movable from a first position to a second position wherein the second position is distal from the first position and wherein movement of the transducer mechanism from the first position to the second position engages a control ring on a catheter and moves a catheter mechanism from a first position to a second position;

and

the catheter having:

an elongated flexible body,

a proximal end,

a distal end,

a knob having a proximal end, and a distal end, wherein the elongated flexible body extends from the distal end of the knob,

the control ring disposed around the proximal end of the knob,

a nesting piece disposed within the knob near the proximal end of the knob and operatively coupled to the control ring,

at least one longitudinal lumen,

an ultrasound transmission member, having a proximal end, extending through the lumen,

a sonic connector that is secured to the proximal end of the ultrasound transmission member and disposed within the nesting piece;

and

the catheter mechanism comprising the control ring and the nesting piece that is movable from the first position that engages the nesting piece around the sonic connector restraining the sonic connector and substantially preventing the transmission of ultrasound energy and a second position that disengages the nesting piece from the sonic connector, permitting the transmission of ultrasound energy from the transducer horn to the ultrasound transmission member;

and

operatively coupling the transducer housing to the proximal end of the catheter using the transducer and catheter mechanisms.

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专利名称(译)	用于将超声导管固定到换能器的连接		
公开(公告)号	US8641630	公开(公告)日	2014-02-04
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[标]申请(专利权)人(译)	FLOWCARDIA		
申请(专利权)人(译)	FLOWCARDIA INC.		
当前申请(专利权)人(译)	FLOWCARDIA INC.		
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摘要(译)

超声系统具有超声换能器，其具有换能器壳体和设置在换能器壳体的远端处的喇叭，超声传输构件，连接到喇叭和超声传输构件的近端的声波连接器，以及导管旋钮具有近端，该近端连接到换能器壳体的远端。导管旋钮具有容纳声波连接器的近端孔。该系统还包括嵌套件，该嵌套件保持在导管旋钮的近端孔内。嵌套件可以从第一位置移动到第二位置，在第一位置，声波连接器被接收在嵌套件内，在第二位置，当超声能量传播通过超声传输构件时，声波连接器与嵌套件分离。