

# US Patent & Trademark Office

## Patent Public Search | Text View

---

United States Patent	12390269
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	Weitzner; Barry et al.

---

### Sphincterotomes and methods for using sphincterotomes

---

#### Abstract

Sphincterotomes and methods for making and using sphincterotomes are disclosed. An example sphincterotome may include an elongate shaft having an outer surface and a distal end region. The sphincterotome may also include a sphincterotome wire assembly having a distal end coupled to the distal end region of the elongate shaft and a body portion extending along the outer surface of the elongate shaft. The sphincterotome wire assembly may be designed to shift the distal end region of the elongate shaft between a first configuration and a curved configuration. The body portion of the sphincterotome wire assembly may include a cutting region and a non-conductive region.

---

**Inventors:** Weitzner; Barry (Acton, MA), Smith; Paul (Smithfield, RI), Dayton; Peter L. (Brookline, MA), Wilder; Evan (Boston, MA)

**Applicant:** BOSTON SCIENTIFIC SCIMED, INC. (Maple Grove, MN)

**Family ID:** 1000008762401

**Assignee:** BOSTON SCIENTIFIC SCIMED, INC. (Maple Grove, MN)

**Appl. No.:** 18/074839

**Filed:** December 05, 2022

#### Prior Publication Data

Document Identifier	Publication Date
US 20230097615 A1	Mar. 30, 2023

#### Related U.S. Application Data

continuation parent-doc US 16436598 20190610 US 11517371 child-doc US 18074839  
us-provisional-application US 62768432 20181116  
us-provisional-application US 62683318 20180611

---

## Publication Classification

**Int. Cl.:** **A61B18/14** (20060101); **A61B17/22** (20060101); **A61B17/3205** (20060101); **A61B18/00** (20060101); **A61B18/12** (20060101); **A61B90/00** (20160101)

**U.S. Cl.:**

**CPC** **A61B18/149** (20130101); **A61B17/32056** (20130101); **A61B18/1206** (20130101); **A61B18/1492** (20130101); **A61B90/39** (20160201); A61B2017/22038 (20130101); A61B2018/00553 (20130101); A61B2018/00601 (20130101); A61B2018/126 (20130101); A61B2018/144 (20130101); A61M2205/32 (20130101)

## Field of Classification Search

**CPC:** A61B (2018/1407); A61B (2018/141); A61B (2018/144)

---

## References Cited

### U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
4553545	12/1984	Maass et al.	N/A	N/A
4776337	12/1987	Palmaz	N/A	N/A
5064435	12/1990	Porter	N/A	N/A
5415656	12/1994	Tihon et al.	N/A	N/A
5425765	12/1994	Tiefenbrun et al.	N/A	N/A
5445646	12/1994	Euteneuer et al.	N/A	N/A
5824046	12/1997	Smith et al.	N/A	N/A
6042605	12/1999	Martin et al.	N/A	N/A
6050995	12/1999	Durgin	N/A	N/A
6099559	12/1999	Nolting	N/A	N/A
6099561	12/1999	Alt	N/A	N/A
6120536	12/1999	Ding et al.	N/A	N/A
6139573	12/1999	Sogard et al.	N/A	N/A
6143022	12/1999	Shull et al.	N/A	N/A
6156064	12/1999	Chouinard	N/A	N/A
6159239	12/1999	Greenhalgh	N/A	N/A
6162244	12/1999	Braun et al.	N/A	N/A
6165211	12/1999	Thompson	N/A	N/A
6168619	12/2000	Dinh et al.	N/A	N/A
6254627	12/2000	Freidberg	N/A	N/A
6315794	12/2000	Richter	N/A	N/A
6319278	12/2000	Quinn	N/A	N/A
6334867	12/2001	Anson	N/A	N/A
6352553	12/2001	Van Der Burg et al.	N/A	N/A
6364904	12/2001	Smith	N/A	N/A
6645242	12/2002	Quinn	N/A	N/A
6712817	12/2003	Goto	606/47	A61B 18/1485
6790225	12/2003	Shannon et al.	N/A	N/A

7118592	12/2005	Dang et al.	N/A	N/A
7425219	12/2007	Quadri	N/A	N/A
7645298	12/2009	Hartley et al.	N/A	N/A
7828837	12/2009	Khoury	N/A	N/A
8142431	12/2011	Ducharme	N/A	N/A
8147538	12/2011	Brown et al.	N/A	N/A
8167926	12/2011	Hartley et al.	N/A	N/A
8231665	12/2011	Kim et al.	N/A	N/A
8317854	12/2011	Ryan et al.	N/A	N/A
9056001	12/2014	Armstrong et al.	N/A	N/A
10154917	12/2017	Bogert	N/A	N/A
10405966	12/2018	Johnson	N/A	N/A
11517371	12/2021	Weitzner	N/A	A61B 90/39
2001/0021870	12/2000	Edwin et al.	N/A	N/A
2001/0032009	12/2000	Layne et al.	N/A	N/A
2001/0039446	12/2000	Edwin et al.	N/A	N/A
2002/0002397	12/2001	Martin et al.	N/A	N/A
2003/0199967	12/2002	Hartley et al.	N/A	N/A
2004/0054397	12/2003	Smith et al.	N/A	N/A
2004/0087886	12/2003	Gellman	N/A	N/A
2005/0059923	12/2004	Gamboa	N/A	N/A
2007/0032857	12/2006	Schmid et al.	N/A	N/A
2007/0142904	12/2006	Sorenson et al.	N/A	N/A
2007/0219612	12/2006	Andreas et al.	N/A	N/A
2007/0282358	12/2006	Remiszewski et al.	N/A	N/A
2008/0140176	12/2007	Krause et al.	N/A	N/A
2010/0100170	12/2009	Tan et al.	N/A	N/A
2011/0022154	12/2010	Hamer et al.	N/A	N/A
2012/0130472	12/2011	Shaw	N/A	N/A
2012/0193018	12/2011	Banas et al.	N/A	N/A
2012/0239134	12/2011	Dierking	N/A	N/A
2012/0296406	12/2011	Minion	N/A	N/A
2013/0204343	12/2012	Shalev	N/A	N/A
2013/0261731	12/2012	Zhou et al.	N/A	N/A
2013/0274851	12/2012	Kelly	N/A	N/A
2014/0276808	12/2013	Gittard et al.	N/A	N/A
2015/0223925	12/2014	Rasmussen et al.	N/A	N/A
2016/0058585	12/2015	Seddon et al.	N/A	N/A
2019/0151072	12/2018	Walzman	N/A	N/A

#### FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
203183028	12/2012	CN	N/A
3115014	12/2016	EP	N/A
1996509894	12/1995	JP	N/A
2000237202	12/1999	JP	N/A
2000279532	12/1999	JP	N/A
2010531712	12/2009	JP	N/A
9600103	12/1995	WO	N/A
1998008456	12/1997	WO	N/A

9915105	12/1998	WO	N/A
2001001886	12/2000	WO	N/A
2009145901	12/2008	WO	N/A
2011076408	12/2010	WO	N/A
2013123147	12/2012	WO	N/A
2014107748	12/2013	WO	N/A

## OTHER PUBLICATIONS

International Search Report from PCT/2014/020086 dated Jun. 24, 2014. cited by applicant  
 International Search Report and Written Opinion dated Sep. 19, 2019 for International Application No. PCT/US2019/036390. cited by applicant  
 International Search Report and Written Opinion dated Dec. 3, 2021 for International Application No. PCT/US2021/048178. cited by applicant

---

*Primary Examiner:* Hupczey, Jr.; Ronald

*Attorney, Agent or Firm:* Seager, Tufte & Wickhem, LLP

---

## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent Ser. No. 16/436,598, filed Jun. 10, 2019, now U.S. Pat. No. 11,517,371; which claims the benefit of priority of U.S. Provisional Application Ser. No. 62/768,432, filed Nov. 16, 2018 and U.S. Provisional Application Ser. No. 62/683,318 filed Jun. 11, 2018, the entirety of which are incorporated herein by reference.

### TECHNICAL FIELD

(1) The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to sphincterotomes.

### BACKGROUND

(2) A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

### BRIEF SUMMARY

(3) This disclosure provides design, material, manufacturing method, and use alternatives for medical devices. A sphincterotome is disclosed. The sphincterotome comprises: an elongate shaft having an outer surface and a distal end region; a sphincterotome wire assembly having a distal end coupled to the distal end region of the elongate shaft and a body portion extending along the outer surface of the elongate shaft; wherein the sphincterotome wire assembly is designed to shift the distal end region of the elongate shaft between a first configuration and a curved configuration; and wherein the body portion of the sphincterotome wire assembly includes a cutting region and a non-conductive region.

(4) Alternatively or additionally to any of the embodiments above, the cutting region of the sphincterotome wire assembly is defined by a conductive cutting wire.

(5) Alternatively or additionally to any of the embodiments above, the non-conductive region of the

sphincterotome wire assembly includes a non-conductive wire coupled to the conductive cutting wire.

(6) Alternatively or additionally to any of the embodiments above, the non-conductive wire is coupled to the conductive cutting wire by a housing.

(7) Alternatively or additionally to any of the embodiments above, the elongate shaft includes a distal anchor, wherein the distal end of the sphincterotome wire assembly is coupled to the distal end region of the elongate shaft at the distal anchor, and wherein the sphincterotome wire assembly includes a proximal region that extends through a port formed along the elongate shaft and into a lumen formed in the elongate shaft.

(8) Alternatively or additionally to any of the embodiments above, the elongate shaft includes a proximal anchor, wherein the conductive cutting wire has a proximal end region coupled to the distal end region of the elongate shaft at the proximal anchor, and wherein the proximal anchor is disposed between the distal anchor and the port.

(9) Alternatively or additionally to any of the embodiments above, the elongate shaft includes a distal port, and wherein the conductive cutting wire extends through the distal port and extends proximally within a lumen formed in the elongate shaft.

(10) Alternatively or additionally to any of the embodiments above, the conductive cutting wire includes a conductive coating.

(11) Alternatively or additionally to any of the embodiments above, the conductive cutting wire includes a cutting wire and a ground wire.

(12) Alternatively or additionally to any of the embodiments above, the non-conductive region of the body portion of the sphincterotome wire assembly includes an insulating member coupled thereto.

(13) Alternatively or additionally to any of the embodiments above, the elongate shaft includes an insulating projection and wherein the non-conductive region of the body portion of the sphincterotome wire assembly is coupled to the insulating projection.

(14) Alternatively or additionally to any of the embodiments above, the insulating projection includes one or more of a flap, an opening, and a groove formed therein.

(15) A sphincterotome is disclosed. The sphincterotome comprises: an elongate shaft having an outer surface, a distal end region, and a distal anchor disposed along the distal end region; a cutting wire coupled to the distal anchor and having a cutting region extending along the outer surface of the elongate shaft; a non-conductive cord coupled to the cutting region of the cutting wire and extending proximally therefrom; wherein the cutting wire, the non-conductive cord, or both are designed to shift the distal end region of the elongate shaft between a first configuration and a curved configuration.

(16) Alternatively or additionally to any of the embodiments above, the non-conductive cord extends through a port formed in the elongate shaft and into a lumen formed in the elongate shaft.

(17) Alternatively or additionally to any of the embodiments above, the cutting wire is coupled to the elongate shaft at a medial anchor, the medial anchor being disposed between the distal anchor and the port.

(18) Alternatively or additionally to any of the embodiments above, the non-conductive cord is coupled to the cutting region of the cutting wire at a non-conductive housing.

(19) Alternatively or additionally to any of the embodiments above, further comprising a ground wire coupled to the cutting wire.

(20) A sphincterotome is disclosed. The sphincterotome comprises: an elongate shaft having a distal anchor, a projection formed in the elongate shaft and disposed proximally of the distal anchor; a cutting wire having a distal end coupled to the distal anchor and a proximal region coupled to the projection; wherein the cutting wire is designed to shift the elongate shaft between a first configuration and a curved configuration; and wherein when the elongate shaft is in the curved configuration, at least a portion of the projection is radially spaced from an outer surface of the

elongate shaft.

(21) Alternatively or additionally to any of the embodiments above, the projection includes an insulating material.

(22) Alternatively or additionally to any of the embodiments above, the projection has a channel formed therein.

(23) The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

---

## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

(1) The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

(2) FIGS. 1-2 are side views of a portion of an example sphincterotome.

(3) FIGS. 3-6 are cross-sectional views of the sphincterotome shown in FIGS. 1-2.

(4) FIG. 7 is a side view of a portion of an example sphincterotome.

(5) FIGS. 8-11 are cross-sectional views of the sphincterotome shown in FIG. 7.

(6) FIG. 12 is a side view of a portion of an example sphincterotome.

(7) FIGS. 13-16 are cross-sectional views of the sphincterotome shown in FIG. 12.

(8) FIG. 17 is a side view of a portion of an example sphincterotome.

(9) FIGS. 18-21 are cross-sectional views of the sphincterotome shown in FIG. 17.

(10) FIG. 22 is a side view of a portion of an example sphincterotome.

(11) FIGS. 23-26 are cross-sectional views of the sphincterotome shown in FIG. 22.

(12) FIG. 27 is an alternative cross-section view of a portion of an example sphincterotome.

(13) FIG. 28 is a side view of a portion of an example sphincterotome.

(14) FIGS. 29-32 are cross-sectional views of the sphincterotome shown in FIG. 28.

(15) FIG. 33 is a side view of a portion of an example sphincterotome.

(16) FIGS. 34-37 are cross-sectional views of the sphincterotome shown in FIG. 33.

(17) FIG. 38 is a side view of a portion of an example sphincterotome.

(18) FIGS. 39-42 are cross-sectional views of the sphincterotome shown in FIG. 38.

(19) FIG. 43 is a side view of a portion of an example sphincterotome.

(20) FIGS. 44-47 are cross-sectional views of the sphincterotome shown in FIG. 43.

(21) FIG. 48 is a side view of a portion of an example sphincterotome.

(22) FIGS. 49-52 are cross-sectional views of the sphincterotome shown in FIG. 48.

(23) FIG. 53 is a side view of a portion of an example sphincterotome.

(24) FIGS. 54-57 are cross-sectional views of the sphincterotome shown in FIG. 53.

(25) While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

### DETAILED DESCRIPTION

(26) For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

(27) All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the terms “about” may include numbers that are rounded to the nearest significant

figure.

(28) The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

(29) As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

(30) It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

(31) The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

(32) Endoscopic retrograde cholangiopancreatography (ERCP) may be utilized to diagnose and treat various disorders of the pancreaticobiliary system. A clinician may use a sphincterotome to cannulate the papillary orifice. The sphincterotome may have a number of features including a cutting wire for performing a sphincterotomy. When performing sphincterotomy, the distal portion of the cutting wire may be used for cutting tissue. The proximal portion of the wire, in general, may not serve a cutting function. Additionally, while performing sphincterotomy, the folds of the duodenal wall may come in contact with the proximal portion of the cutting wire, which could result in an ancillary tissue burn. Disclosed herein are sphincterotomes where the proximal portion of the cutting wire is designed to be non-conductive, insulated, and/or otherwise non-cutting.

(33) FIGS. 1-2 illustrates an example sphincterotome **10**. The sphincterotome **10** may include an elongate shaft **12** having a proximal end region **14** and a distal end region **16**. The sphincterotome **10** may include a sphincterotome wire assembly **18**. The sphincterotome wire assembly **18** may be designed to shift the distal end region **16** of the elongate shaft **12** between a first configuration (e.g., as depicted in FIG. 1) and a curved or bowed configuration (e.g., as depicted in FIG. 2). For example, exerting a proximal force on one or more of the components of the sphincterotome wire assembly **18** may cause the elongate shaft **12** to shift between configurations.

(34) The sphincterotome wire assembly **18** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **18** extending along the outer surface of the elongate shaft **12** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **12** is in the curved configuration (e.g., as depicted in FIG. 2).

(35) The sphincterotome wire assembly **18** may include a first member or portion **20** and a second member or portion **22**. The first member **20** may be coupled to the second member **22** at a joint **17**. In this example, the first member **20** may take the form of a wire having a cutting region **20a** and a proximally-extending region **20b**. A distal end region of the first member **20** may be anchored to the distal end region **16** of the shaft **12** (e.g., using, for example, a metallic anchor). A portion of the cutting region **20a** of the first member **20** may be secured to or otherwise extend through a loop or opening defined at the joint **17** and then the first member **20** may extend generally toward the outer surface of the shaft **12**. In some instances, the first member **20** may extend through a first port **23** formed in the shaft **12** and into a lumen of the shaft **12** (e.g., the second lumen **26** as shown, for example, in FIG. 3). The second member **22** may take the form of a wire or non-conductive cord (e.g., formed from a non-conductive material such as aramid) having a non-conductive region **22a**

and a proximally-extending region **22b**. In some instances, a distal end region of the second member **22** may be secured to the joint **17**. The second member **22** may extend through a second port **25** formed in the shaft **12** and into a lumen of the shaft **12** (e.g., the first lumen **24** as shown, for example, in FIG. **3**). In at least some instances, the first port **23** may be disposed along the shaft **12** at a position between the location where the distal end region of the first member **20** is anchored to the shaft **12** and the second port **25**. In other words, the first port **23** may be disposed between the distal anchor and the second port **25**.

(36) The body portion B of the sphincterotome wire assembly **18** may include the cutting region **20a** of the first member **20** and the non-conductive region **22a** of the second member **22**. In at least some instances, the first member **20** is a conductive wire (e.g., an RF conductive wire) that can be energized. When doing so, the cutting region **20a** may be energized so as to facilitate cutting. In contrast, the second member **22** may be non-conductive. Accordingly, the non-conductive region **22a** may generally be described as being non-energized, non-cutting, and/or otherwise designed so as to not facilitate cutting.

(37) FIGS. **3-6** are cross-sectional views taken at various locations along the shaft **12**. Here it can be seen that the shaft **12** may include a number of different lumens. For example, the shaft **12** may include a first lumen **24**, a second lumen **26**, a third lumen **28**, and a fourth lumen **30**. In this example, the proximally-extending region **22b** of the second member **22** may extend through the first lumen **24**. The proximally-extending region **20b** of the first member **20** may extend through the second lumen **26**. The third lumen **28** may be used for infusing a fluid such as a contrast media. The fourth lumen **30** may be a guidewire lumen.

(38) FIG. **7** illustrates another example sphincterotome **110** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **110** includes a shaft **112** having a distal end region **116**. The sphincterotome **110** may include a sphincterotome wire assembly **118**. The sphincterotome wire assembly **118** may be designed to shift the distal end region **116** of the elongate shaft **112** between a first configuration and a curved or bowed configuration.

(39) The sphincterotome wire assembly **118** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **118** extending along the outer surface of the elongate shaft **112** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **112** is in the curved configuration. The sphincterotome wire assembly **118** may include a first member or portion **120** and a second member or portion **122**. The first member **120** may be coupled to the second member **122** at a joint **117**. In this example, the joint **117** may take the form of a non-conductive housing designed to be secured to both the first member **120** and the second member **122**. This may include a mechanical or other type of connection. The first member **120** may take the form of a wire having a cutting region **120a** and a proximally-extending region **120b**. A distal end region of the first member **120** may extend through a first port **123** formed in the shaft **112** and into a lumen of the shaft **112** (e.g., the second lumen **126** as shown, for example, in FIG. **8**). The second member **122** may take the form of a wire or non-conductive cord having a non-conductive region **122a** and a proximally-extending region **122b**. The second member **122** may extend through a second port **125** formed in the shaft **112** and into a lumen of the shaft **112** (e.g., the first lumen **124** as shown, for example, in FIG. **8**).

(40) The body portion B of the sphincterotome wire assembly **118** may include the cutting region **120a** of the first member **120** and the non-conductive region **122a** of the second member **122**. In at least some instances, the first member **120** is a conductive wire (e.g., an RF conductive wire) that can be energized. When doing so, the cutting region **120a** may be energized so as to facilitate cutting. In contrast, the second member **122** may be non-conductive. Accordingly, the non-conductive region **122a** may generally be described as being non-energized, non-cutting, and/or otherwise designed so as to not facilitate cutting.

(41) FIGS. **8-11** are cross-sectional views taken at various locations along the shaft **112**. Here it can



be seen that the shaft **112** may include a number of different lumens. For example, the shaft **112** may include a first lumen **124**, a second lumen **126**, a third lumen **128**, and a fourth lumen **130**. In this example, the proximally-extending region **122b** of the second member **122** may extend through the first lumen **124**. The proximally-extending region **120b** of the first member **120** may extend through the second lumen **126**. The third lumen **128** may be used for infusing a fluid such as a contrast media. The fourth lumen **130** may be a guidewire lumen.

(42) FIG. **12** illustrates another example sphincterotome **210** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **210** includes a shaft **212** having a distal end region **216**. The sphincterotome **210** may include a sphincterotome wire assembly **218**. The sphincterotome wire assembly **218** may be designed to shift the distal end region **216** of the elongate shaft **212** between a first configuration and a curved or bowed configuration.

(43) The sphincterotome wire assembly **218** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **218** extending along the outer surface of the elongate shaft **212** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **212** is in the curved configuration. The sphincterotome wire assembly **218** may include a first member or portion **220** and a second member or portion **222**. The first member **220** may be coupled to the second member **222** at a joint **217**. The first member **220** may take the form of a wire having a cutting region **220a** and a proximally-extending region **220b**. A distal end region of the first member **220** may extend through a first port **223** formed in the shaft **212** and into a lumen of the shaft **212** (e.g., the second lumen **226** as shown, for example, in FIG. **13**). The second member **222** may take the form of a wire or non-conductive cord having a non-conductive region **222a** and a proximally-extending region **222b**. The second member **222** may extend through a second port **225** formed in the shaft **212** and into a lumen of the shaft **212** (e.g., the first lumen **224** as shown, for example, in FIG. **13**).

(44) The body portion B of the sphincterotome wire assembly **218** may include the cutting region **220a** of the first member **220** and the non-conductive region **222a** of the second member **222**. In at least some instances, the first member **220** is a wire having a conductive member **220c** that can be energized. In some instances, the conductive member **220c** takes the form of a conductive coating, a conductive paint, a conductive coil (e.g., surrounding the cutting region **220a**), and/or the like. The cutting region **220a** may be energized so as to facilitate cutting. In contrast, the second member **222** may be non-conductive. Accordingly, the non-conductive region **222a** may generally be described as being non-energized, non-cutting, and/or otherwise designed so as to not facilitate cutting.

(45) FIGS. **13-16** are cross-sectional views taken at various locations along the shaft **212**. Here it can be seen that the shaft **212** may include a number of different lumens. For example, the shaft **212** may include a first lumen **224**, a second lumen **226**, a third lumen **228**, and a fourth lumen **230**. In this example, the proximally-extending region **222b** of the second member **222** may extend through the first lumen **224**. The proximally-extending region **220b** of the first member **220** may extend through the second lumen **226**. The third lumen **228** may be used for infusing a fluid such as a contrast media. The fourth lumen **230** may be a guidewire lumen.

(46) FIG. **17** illustrates another example sphincterotome **310** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **310** includes a shaft **312** having a distal end region **316**. The sphincterotome **310** may include a sphincterotome wire assembly **318**. The sphincterotome wire assembly **318** may be designed to shift the distal end region **316** of the elongate shaft **312** between a first configuration and a curved or bowed configuration.

(47) The sphincterotome wire assembly **318** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **318** extending along the outer surface of the elongate shaft **312** and that may be described as extending diagonally akin to the string of a bow when the

elongate shaft **312** is in the curved configuration. The sphincterotome wire assembly **318** may include a first member or portion **320** and a second member or portion **322**. The first member **320** may take the form of a wire having a cutting region **320a** and a proximally-extending region **320b**. A distal end region of the first member **320** may be anchored to the distal end region **316** of the shaft **312**. The second member **322** may take the form of a protective mesh or sheath designed to cover and/or insulate a portion of the first member **320**.

(48) The body portion B of the sphincterotome wire assembly **318** may include the cutting region **320a** of the first member **320** and at least a portion of the second member **322**. The cutting region **320a** may be energized so as to facilitate cutting. The second member **322** may be non-conductive and insulate a portion of the first member **320** in a manner so as to not facilitate cutting.

(49) FIGS. **18-21** are cross-sectional views taken at various locations along the shaft **312**. Here it can be seen that the shaft **312** may include a number of different lumens. For example, the shaft **312** may include a first lumen **324**, a second lumen **328**, and a third lumen **330**. In this example, the proximally-extending region **320b** of the first member **320** may extend through the first lumen **324**. The second lumen **328** may be used for infusing a fluid such as a contrast media. The third lumen **330** may be a guidewire lumen.

(50) FIG. **22** illustrates another example sphincterotome **410** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **410** includes a shaft **412** having a distal end region **416**. The sphincterotome **410** may include a sphincterotome wire assembly **418**. The sphincterotome wire assembly **418** may be designed to shift the distal end region **416** of the elongate shaft **412** between a first configuration and a curved or bowed configuration.

(51) The sphincterotome wire assembly **418** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **418** extending along the outer surface of the elongate shaft **412** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **412** is in the curved configuration. The sphincterotome wire assembly **418** may include a first member or portion **420** and a second member or portion **422**. The first member **420** may take the form of a wire having a cutting region **420a** and a proximally-extending region **420b**. A distal end region of the first member **420** may be anchored to the distal end region **416** of the shaft **412**. The second member **422** may take the form of a projection extending from the shaft **412**. In general, the projection **422** is designed to cover and/or insulate a portion of the first member **420**.

(52) The body portion B of the sphincterotome wire assembly **418** may include the cutting region **420a** of the first member **420** and at least a portion of the second member **422**. The cutting region **420a** may be energized so as to facilitate cutting. The second member **422** may be non-conductive and may cover and/or insulate a portion of the first member **420** in a manner so as to not facilitate cutting.

(53) FIGS. **23-26** are cross-sectional views taken at various locations along the shaft **412**. Here it can be seen that the shaft **412** may include a number of different lumens. For example, the shaft **412** may include a first lumen **424**, a second lumen **428**, and a third lumen **430**. In this example, the proximally-extending region **420b** of the first member **420** may extend through the first lumen **424**. The second lumen **428** may be used for infusing a fluid such as a contrast media. The third lumen **430** may be a guidewire lumen.

(54) FIG. **27** is an alternative cross-sectional view of a portion of the shaft **412**. In this example, the projection **422'** is formed as a cutout from the shaft **412**. Thus, the shaft **412** includes a cutout region **427**. In some instances, the projection **422'** may have a shape that mirrors or resembles the shape of the cutout region **427**. In other instances, the projection **422'** may be formed as a cutout and then processed to have a generally smaller shape and/or thickness.

(55) FIG. **28** illustrates another example sphincterotome **510** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **510** includes a shaft **512**

having a distal end region **516**. The sphincterotome **510** may include a sphincterotome wire assembly **518**. The sphincterotome wire assembly **518** may be designed to shift the distal end region **516** of the elongate shaft **512** between a first configuration and a curved or bowed configuration.

(56) The sphincterotome wire assembly **518** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **518** extending along the outer surface of the elongate shaft **512** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **512** is in the curved configuration. The sphincterotome wire assembly **518** may include a first member or portion **520** and a second member or portion **522**. The first member **520** may take the form of a wire having a cutting region **520a** and a proximally-extending region **520b**. A distal end region of the first member **520** may be anchored to the distal end region **516** of the shaft **512**. The second member **522** may take the form of a projection extending from the shaft **512**. The projection **522** may include an opening **522a** through which the first member **520** may extend. In general, the projection **522** is designed to cover and/or insulate a portion of the first member **520**. In some instances, the projection **522** may include a slot or groove (not shown) through which the first member **520** may extend.

(57) The body portion B of the sphincterotome wire assembly **518** may include the cutting region **520a** of the first member **520** and at least a portion of the second member **522**. The cutting region **520a** may be energized so as to facilitate cutting. The second member **522** may be non-conductive and may cover and/or insulate a portion of the first member **520** in a manner so as to not facilitate cutting.

(58) FIGS. **29-32** are cross-sectional views taken at various locations along the shaft **512**. Here it can be seen that the shaft **512** may include a number of different lumens. For example, the shaft **512** may include a first lumen **524**, a second lumen **528**, and a third lumen **530**. In this example, the proximally-extending region **520b** of the first member **520** may extend through the first lumen **524**. The second lumen **528** may be used for infusing a fluid such as a contrast media. The third lumen **530** may be a guidewire lumen.

(59) FIG. **33** illustrates another example sphincterotome **610** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **610** includes a shaft **612** having a distal end region **616**. The sphincterotome **610** may include a sphincterotome wire assembly **618**. The sphincterotome wire assembly **618** may be designed to shift the distal end region **616** of the elongate shaft **612** between a first configuration and a curved or bowed configuration.

(60) The sphincterotome wire assembly **618** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **618** extending along the outer surface of the elongate shaft **612** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **612** is in the curved configuration. The sphincterotome wire assembly **618** may include a first member or portion **620** and a second member or portion **622**. The first member **620** may take the form of a wire having a cutting region **620a** and a proximally-extending region **620b**. A distal end region of the first member **620** may be anchored to the distal end region **616** of the shaft **612**. The second member **622** may take the form of a projection formed by a cutout in the shaft **612**. The projection **622** may include a groove **632** through which the first member **620** may extend. The shaft **612** may include a notch **623** corresponding to where the projection **622** is cut out from the shaft **612**. In general, the projection **622** is designed to insulate a portion of the first member **620**.

(61) The body portion B of the sphincterotome wire assembly **618** may include the cutting region **620a** of the first member **620** and at least a portion of the second member **622**. The cutting region **620a** may be energized so as to facilitate cutting. The second member **622** may be non-conductive and may cover and/or insulate a portion of the first member **620** in a manner so as to not facilitate cutting.

(62) FIGS. **34-37** are cross-sectional views taken at various locations along the shaft **612**. Here it can be seen that the shaft **612** may include a number of different lumens. For example, the shaft **612** may include a first lumen **624**, a second lumen **628**, and a third lumen **630**. In this example, the proximally-extending region **620b** of the first member **620** may extend through the first lumen **624**. The second lumen **628** may be used for infusing a fluid such as a contrast media. The third lumen **630** may be a guidewire lumen.

(63) FIG. **38** illustrates another example sphincterotome **710** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **710** includes a shaft **712** having a distal end region **716**. The sphincterotome **710** may include a sphincterotome wire assembly **718**. The sphincterotome wire assembly **718** may be designed to shift the distal end region **716** of the elongate shaft **712** between a first configuration and a curved or bowed configuration.

(64) The sphincterotome wire assembly **718** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **718** extending along the outer surface of the elongate shaft **712** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **712** is in the curved configuration. The sphincterotome wire assembly **718** may include a first member or portion **720** and a second member or portion **722**. The first member **720** and the second member **722** may be coupled to one another at a joint **717**. In this example, the joint **717** may take the form of an insulated housing or spacer. The first member **720** may take the form of a bipolar wire assembly having a cutting region **720a** and a proximally-extending region that includes a first wire region **720b** (e.g., a conductive wire) and a second wire region **720c** (e.g., a ground wire). In insulating medium **720d** may be disposed between the first wire region **720b** and the second wire region **720c**. The first wire region **720b** and the second wire region **720c** may extend through ports formed in the shaft **712** into lumens of the shaft **712** (e.g., a second lumen **726a** and a third lumen **726b** as shown in FIG. **39**). The second member **722** may take the form of a wire or non-conductive cord having a non-conductive region **722a** and a proximally-extending region **722b**. The second member **722** may extend through a second port **725** formed in the shaft **712** and into a lumen of the shaft **712** (e.g., the first lumen **724** as shown, for example, in FIG. **39**).

(65) The body portion B of the sphincterotome wire assembly **718** may include the cutting region **720a** of the first member **720** and at least a portion of the second member **722**. The cutting region **720a** may be energized so as to facilitate cutting. The second member **722** may be non-conductive and insulate a portion of the first member **720** in a manner so as to not facilitate cutting.

(66) FIGS. **39-42** are cross-sectional views taken at various locations along the shaft **712**. Here it can be seen that the shaft **712** may include a number of different lumens. For example, the shaft **712** may include a first lumen **724**, a second lumen **726a**, a third lumen **726b**, a fourth lumen **728**, and a fifth lumen **730**. In this example, the proximally-extending region **722b** of the second member **722** may extend through the first lumen **724**. The first wire region **720b** and the second wire region **720c** of the first member **720** may extend through the second lumen **726a** and the third lumen **726b**, respectively. The fourth lumen **728** may be used for infusing a fluid such as a contrast media. The fifth lumen **730** may be a guidewire lumen.

(67) FIG. **43** illustrates another example sphincterotome **810** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **810** includes a shaft **812** having a distal end region **816**. The sphincterotome **810** may include a sphincterotome wire assembly **818**. The sphincterotome wire assembly **818** may be designed to shift the distal end region **816** of the elongate shaft **812** between a first configuration and a curved or bowed configuration.

(68) The sphincterotome wire assembly **818** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **818** extending along the outer surface of the elongate shaft **812** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **812** is in the curved configuration. The sphincterotome wire assembly **818** may

include a first member or portion **820** and a second member or portion **822**. The first member **820** and the second member **822** may be coupled to one another at a joint **817**. In this example, the joint **817** may take the form of an insulated housing. The first member **820** may take the form of a wire for delivering bipolar energy having a cutting region **820a** and a proximally-extending region **820b**. The first member **820** may extend through a first port **823** formed in the shaft **812** into a lumen of the shaft **812** (e.g., a second lumen **826** as shown in FIG. 43). The second member **822** may take the form of a wire or non-conductive cord having a non-conductive region **822a** and a proximally-extending region **822b**. The second member **822** may extend through a second port **825** formed in the shaft **812** and into a lumen of the shaft **812** (e.g., the first lumen **824** as shown, for example, in FIG. 43).

(69) The body portion B of the sphincterotome wire assembly **818** may include the cutting region **820a** of the first member **820** and at least a portion of the second member **822**. The cutting region **820a** may be energized so as to facilitate cutting. In contrast, the second member **822** may be non-conductive. Accordingly, the non-conductive region **822a** may generally be described as being non-energized, non-cutting, and/or otherwise designed so as to not facilitate cutting. A ground pad **834**, which may serve as the return for the cutting wire portion **820a**, may be disposed along the distal end region **816** of the shaft **812**. A ground wire **836** may be coupled to the ground pad **834**.

(70) FIGS. 44-47 are cross-sectional views taken at various locations along the shaft **812**. Here it can be seen that the shaft **812** may include a number of different lumens. For example, the shaft **812** may include a first lumen **824**, a second lumen **826**, a third lumen **828**, a fourth lumen **830**, and a fifth lumen **838**. In this example, the proximally-extending region **820b** of the first member **820** may extend through the second lumen **826**. The proximally-extending region **822b** of the second member may extend through the first lumen **824**. The third lumen **828** may be used for infusing a fluid such as a contrast media. The fourth lumen **830** may be a guidewire lumen. The ground wire **836** may extend through the fifth lumen **838**.

(71) FIG. 48 illustrates another example sphincterotome **910** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **910** includes a shaft **912** having a distal end region **916**. The sphincterotome **910** may include a sphincterotome wire assembly **918**. The sphincterotome wire assembly **918** may be designed to shift the distal end region **916** of the elongate shaft **912** between a first configuration and a curved or bowed configuration.

(72) The sphincterotome wire assembly **918** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **918** extending along the outer surface of the elongate shaft **912** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **912** is in the curved configuration. The sphincterotome wire assembly **918** may include a first member or portion **920** and a second member or portion **922**. The first member **920** may take the form of a wire having a cutting region **920a** and a proximally-extending region **920b**. A distal end region of the first member **920** may be anchored to the distal end region **916** of the shaft **912**.

(73) The second member **922** may take the form of an external flap coupled to the shaft **912** (e.g., coupled via an adhesive bond, thermal bond, and/or the like). The second member **922** may be formed of a suitable material such as a polymer (e.g., polyetheretherketone and/or any suitable disclosed herein). The flap **622** may include a body region **929** disposed along the outer surface of the shaft **912**, a projection region **931** extending from the body region **929**, and an end region **933**. The projection region **931** may have a suitable length such as about 1-20 mm, or about 2-18 mm, or about 5-15 mm. In some instances, the projection region **931** may include a groove **932** (not shown in FIG. 48, can be seen in FIG. 50) through which the first member **920** may extend. In some of these and in other instances, the end region **933** may include or otherwise take the form of a loop or opening through which the first member **920** may extend.

(74) The body portion B of the sphincterotome wire assembly **918** may include the cutting region

**920a** of the first member **920** and at least a portion of the second member **922** (e.g., the projection region **931**). The cutting region **920a** may be energized so as to facilitate cutting. The second member **922** may be non-conductive and may cover and/or insulate a portion of the first member **920** in a manner so as to not facilitate cutting. More particularly, the projection region **931** (and/or the second member **922**) may be designed to insulate a portion of the first member **920**.

(75) It can be appreciated that the length of the first member **920** that is exposed or otherwise not covered/insulated by the projection region **931** can vary depending on the extent to which the shaft **912** is curved. For example, a clinician may be able to curve the shaft **912** to a relative small extent. When doing so, only a relatively small proportion of the length of the first member **920** may be covered/insulated by the projection region **931**. Further curving the shaft **912** may shorten the overall length of the first member **920** along the body region B and increase the proportion of the length of the first member **920** that is covered/insulated by the projection region **931**. This allows a clinician to vary the length of the first member **920** available for cutting, which may be desirable in order to tailor the sphincterotome **910** for a number of different interventions.

(76) FIGS. **49-52** are cross-sectional views taken at various locations along the shaft **912**. Here it can be seen that the shaft **912** may include a number of different lumens. For example, the shaft **912** may include a first lumen **924**, a second lumen **928**, and a third lumen **930**. In this example, the proximally-extending region **920b** of the first member **920** may extend through the first lumen **924**. The second lumen **928** may be used for infusing a fluid such as a contrast media. The third lumen **930** may be a guidewire lumen.

(77) FIG. **53** illustrates another example sphincterotome **1010** that may be similar in form and function to other sphincterotomes disclosed herein. The sphincterotome **1010** includes a shaft **1012** having a distal end region **1016**. The sphincterotome **1010** may include a sphincterotome wire assembly **1018**. The sphincterotome wire assembly **918** may be designed to shift the distal end region **1016** of the elongate shaft **1012** between a first configuration and a curved or bowed configuration.

(78) The sphincterotome wire assembly **1018** may include a body portion B generally defined as the portion of the sphincterotome wire assembly **1018** extending along the outer surface of the elongate shaft **1012** and that may be described as extending diagonally akin to the string of a bow when the elongate shaft **1012** is in the curved configuration. The sphincterotome wire assembly **1018** may include a first member or wire **1020** having a cutting region **1020a** and a proximally-extending region **1020b**. A distal end region of the wire **1020** may be anchored to the distal end region **1016** of the shaft **1012**. A plurality of different coatings may be disposed along the wire **1020**. For example, a first coating **1035a** may be disposed along a first portion (e.g., a more distal portion) of the wire **1020** and a second or coating **1035b** may be disposed along a second portion (e.g., a more proximal portion) of the wire **1020**. The first coating **1035a**, the second coating **1035b**, or both may be disposed along the wire **1020** using a suitable process. Some example processes that may be suitable include electroplating, sputter coating, dip coating, spray coating, other coating processes, and/or the like.

(79) In some instances, the first coating **1035a** may be a conductive coating. For example, the first coating **1035a** may have a relatively high conductivity (e.g., on the order of about  $1 \times 10^6$  Siemens/m or greater) and a relatively low resistivity (e.g., on the order of about  $7 \times 10^{-7}$  Ohms/m or less). In some instances, the first coating **1035a** may include a metallic coating such as a gold coating. Other coatings are contemplated.

(80) In some instances, the second coating **1035b** may be a non-conductive or insulating coating that, in general, is designed to insulate a second portion of the wire **1020**. For example, the second coating **1035b** may have a relatively low conductivity (e.g., on the order of about  $1 \times 10^6$  Siemens/m or less) and a relatively high resistivity (e.g., on the order of about  $7 \times 10^{-7}$  Ohms/m or greater). For example, the second coating **1035b** may include a ceramic coating, a polymeric coating, metal oxide (e.g., such as aluminum oxide), a metal nitride, and/or the like.

(81) The body portion B of the sphincterotome wire assembly **1018** may include the cutting region **1020a** of the wire **1020**. The cutting region **1020a** may be energized so as to facilitate cutting. When doing so, the first coating **1035a** can conduct energy to facilitate cutting. The second coating **1035b** may be non-conductive and may cover and/or insulate the wire **1020** in a manner so as to not facilitate cutting. It can be appreciated that variations in the difference in conductivity between the first coating **1035a** and the second coating **1035b** may alter the cutting characteristics of the sphincterotome wire assembly **1018**. For example, relatively large differences in conductivity between the first coating **1035a** and the second coating **1035b** may generate more aggressive tissue burns at positions more adjacent to the first coating **1035a** and less aggressive tissue burns (e.g., or no tissue burns) at positions more adjacent to the second coating **1035b**. Relatively small differences in conductivity between the first coating **1035a** and the second coating **1035b** may result in more evenly distributed burns along the sphincterotome wire assembly **1018**. In some instances, the first coating **1035a**, the second coating **1035b**, or both may terminate adjacent to the outer surface of the shaft **1012**.

(82) FIGS. **54-57** are cross-sectional views taken at various locations along the shaft **1012**. Here it can be seen that the shaft **1012** may include a number of different lumens. For example, the shaft **1012** may include a first lumen **1024**, a second lumen **1028**, and a third lumen **1030**. In this example, the proximally-extending region **1020b** of the first member **1020** may extend through the first lumen **1024**. The second lumen **1028** may be used for infusing a fluid such as a contrast media. The third lumen **1030** may be a guidewire lumen. In other instances, the first coating **1035a**, the second coating **1035b**, or both may extend through the outer surface of the shaft **1012** and into a lumen of the shaft **1012**. For example, the second coating **1035b** may extend into the first lumen **1024**.

(83) The materials that can be used for the various components of sphincterotomes disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to the shaft **12**. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other devices and/or components of devices disclosed herein.

(84) The shaft **12** may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), perfluoroalkoxy alkane (PFA), polyether block ester, polyurethane (for example, Polyurethane **85A**), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly (alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), high-density polyethylene, low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro (propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-b-isobutylene-b-styrene) (for example, SIBS and/or SIBS **50A**), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some

embodiments the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

(85) Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-NR and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

(86) In at least some embodiments, portions or all of the sphincterotome **10** may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of the sphincterotome **10** in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of the sphincterotome **10** to achieve the same result.

(87) In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the sphincterotome **10**. For example, the sphincterotome **10**, or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (e.g., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The sphincterotome **10**, or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

(88) It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

## Claims

1. A sphincterotome, comprising: an elongate shaft having an outer surface and a distal end region; a sphincterotome wire assembly coupled to the elongate shaft, the sphincterotome wire assembly including a first member and a second member; wherein the first member includes a cutting region disposed along the outer surface of the elongate shaft and a first proximally-extending region; wherein the second member includes a non-conductive region disposed along the outer surface of the elongate shaft and a second proximally-extending region; a joint member disposed between and coupling the cutting region of the first member with the non-conductive region of the second member; and wherein the sphincterotome wire assembly is designed to shift the distal end region of the elongate shaft between a first configuration and a curved configuration.

2. The sphincterotome of claim 1, wherein the non-conductive region of the second member is non-



energized when the cutting region of the first member is cutting tissue.

3. The sphincterotome of claim 1, wherein the joint member includes a housing.

4. The sphincterotome of claim 1, wherein the first member is a conductive wire.

5. The sphincterotome of claim 1, wherein the first proximally-extending region of the first member extends through a first lumen formed in the elongate shaft.

6. The sphincterotome of claim 1, wherein a distal end of the first member is anchored to the distal end region of the elongate shaft.

7. The sphincterotome of claim 1, wherein a proximal end region of the cutting region of the first member extends through an opening in the joint member.

8. The sphincterotome of claim 1, wherein a proximal end region of the cutting region of the first member is attached to the joint member.

9. The sphincterotome of claim 1, wherein the second member is a non-conductive wire.

10. The sphincterotome of claim 5, wherein the second proximally-extending region of the second member extends through a second lumen formed in the elongate shaft.

11. The sphincterotome of claim 1, wherein a distal end region of the non-conductive region of the second member is attached to the joint member.

12. The sphincterotome of claim 1, wherein the first member extends through a first port formed in the elongate shaft.

13. The sphincterotome of claim 12, wherein the second member extends through a second port formed in the elongate shaft.

14. The sphincterotome of claim 13, wherein the second port is disposed proximally of the first port.

15. A sphincterotome, comprising: an elongate shaft having an outer surface and a distal end region; a sphincterotome wire assembly coupled to the elongate shaft, the sphincterotome wire assembly including a first member and a second member; wherein the first member includes a cutting region disposed along the outer surface of the elongate shaft and a first proximally-extending region; wherein a transition between the cutting region and the first proximally-extending region is defined adjacent to a distal port formed in the elongate shaft; wherein the second member includes a non-conductive region disposed along the outer surface of the elongate shaft and a second proximally-extending region; a housing member disposed between and coupling the cutting region of the first member with the non-conductive region of the second member; and wherein the sphincterotome wire assembly is designed to shift the distal end region of the elongate shaft between a first configuration and a curved configuration.

16. The sphincterotome of claim 15, wherein the distal port is disposed distally of the housing member.

17. The sphincterotome of claim 15, wherein the second member extends through a second port formed in the elongate shaft.

18. A sphincterotome, comprising: an elongate catheter shaft having an outer surface and a distal end region; a sphincterotome wire assembly coupled to the elongate catheter shaft, the sphincterotome wire assembly including a first wire and a second wire; wherein the first wire is a conductive wire having a cutting region disposed along the outer surface of the elongate catheter shaft and a first proximally-extending region; wherein the second wire is a non-conductive wire having a non-conductive region disposed along the outer surface of the elongate catheter shaft and a second proximally-extending region; a housing member disposed between and coupling the cutting region of the first wire with the non-conductive region of the second wire; and wherein the sphincterotome wire assembly is designed to shift the distal end region of the elongate catheter shaft between a first configuration and a curved configuration.

19. The sphincterotome of claim 18, wherein a transition between the cutting region and the first proximally-extending region is defined adjacent to a distal port formed in the elongate catheter shaft.

20. The sphincterotome of claim 19, wherein the distal port is disposed distally of the housing member.

---