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(12) **United States Patent**
Kieturakis et al.

(10) **Patent No.: US 6,758,853 B2**
(45) **Date of Patent: *Jul. 6, 2004**

(54) **APPARATUS AND METHODS FOR DEVELOPING AN ANATOMIC SPACE FOR LAPAROSCOPIC HERNIA REPAIR AND PATCH FOR USE THEREWITH**

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(73) Assignee: **General Surgical Innovations, Inc.**, Norwalk, CT (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/076,771**

(22) Filed: **Feb. 13, 2002**

(65) **Prior Publication Data**

US 2002/0107539 A1 Aug. 8, 2002

Related U.S. Application Data

(62) Division of application No. 09/932,156, filed on Aug. 17, 2001, now Pat. No. 6,565,590, which is a continuation of application No. 07/893,988, filed on Jun. 2, 1992, now Pat. No. 6,312,442.

(51) **Int. Cl.**[7] **A61B 17/00**

(52) **U.S. Cl.** **606/190**; 600/207; 128/898; 606/151

(58) **Field of Search** 606/151, 191–200, 606/213; 128/898; 600/201, 204, 207, 210; 604/96.01–109

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,213,005 A	1/1917	Pillsbury
512,456 A	9/1939	Sadilkova
2,854,983 A	10/1958	Baskin
2,936,760 A	5/1960	Gants
3,039,468 A	6/1962	Price

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE	2157727	8/1973
EP	512456	9/1939
EP	0573 273 A3	12/1993
EP	0573 273 B1	12/1993
EP	0573 273 A2	12/1993
RU	594960	2/1992
WO	WO 92/06632 A1	4/1992
WO	WP 92/06638 A1	4/1992

OTHER PUBLICATIONS

Berci, G. "Laparoscopy in General Surgery" in: Berci, G. Endoscopy (New York, Appleton–Century–Crofts, 1976), pp. 382–412.

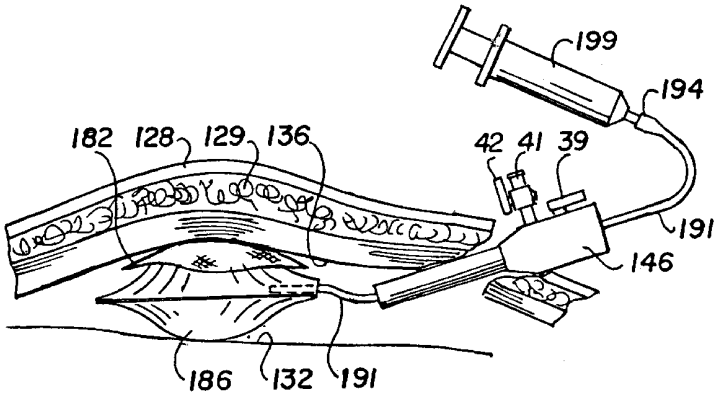
(List continued on next page.)

Primary Examiner—Glenn K. Dawson

(57) **ABSTRACT**

Laparoscopic apparatus and method for insertion into a space or potential space in a body including an introducer device having a tubular member with a bore extending therethrough. A tunneling shaft assembly is provided and is slidably mounted in the bore of the introducer device. The tunneling shaft assembly includes a tunneling shaft having proximal and distal extremities. A tunneling member is mounted on the distal extremity of the tunneling shaft. A balloon assembly is provided which is removably secured to the tunneling shaft. The balloon assembly includes a balloon wrapped about said tunneling shaft. A sheath is provided which encloses the balloon on the tunneling shaft. The sheath has a slit extending longitudinally thereof permitting the sheath to be removed whereby the balloon can be released and inflated. A tubular member is provided which has a balloon inflation lumen thereon and is coupled to the balloon for inflating said balloon.

5 Claims, 12 Drawing Sheets



U.S. PATENT DOCUMENTS

3,253,594	A		5/1966	Matthews et al.
3,417,745	A		12/1968	Sheldon
3,459,175	A		8/1969	Miller
3,545,443	A		12/1970	Ansari
3,774,596	A		11/1973	Cook
3,800,788	A		4/1974	White
3,882,852	A		5/1975	Sinnreich
3,915,171	A		10/1975	Shermeta
RE29,207	E		5/1977	Bolduc et al.
4,077,412	A		3/1978	Moossun
4,083,369	A		4/1978	Sinnreich
4,177,814	A		12/1979	Knepshield et al.
4,198,981	A		4/1980	Sinnreich
4,217,889	A		8/1980	Radovan et al.
4,243,050	A		1/1981	Littleford
4,276,874	A		7/1981	Wolvek et al.
4,312,353	A		1/1982	Shabbabian
4,345,606	A		8/1982	Littleford
4,411,654	A		10/1983	Boarini
4,490,137	A		12/1984	Moukheibir
4,496,345	A		1/1985	Hasson
4,501,266	A		2/1985	McDaniel
4,555,242	A		11/1985	Saudagar
4,574,806	A		3/1986	McCarthy
4,581,025	A		4/1986	Timmermans
4,589,868	A		5/1986	Dretler
4,593,682	A		6/1986	Heckele
4,596,554	A		6/1986	Dastgeer
4,596,559	A		6/1986	Fleischhacker
4,610,662	A		9/1986	Weikl et al.
4,644,936	A		2/1987	Schiff
4,651,717	A		3/1987	Jakubezak
4,654,030	A		3/1987	Moll et al.
4,685,447	A		8/1987	Iversen et al.
4,706,670	A		11/1987	Andersen et al.
4,738,666	A		4/1988	Fuqua
4,754,030	A		6/1988	Kaplan et al.
4,769,038	A		9/1988	Bendavid et al.
4,772,266	A		9/1988	Groshong
4,779,611	A		10/1988	Grooters et al.
4,784,133	A		11/1988	Mackin
4,793,348	A		12/1988	Palmaz
4,798,205	A		1/1989	Bonomo et al.
4,800,901	A		1/1989	Rosenberg
4,802,479	A		2/1989	Haber et al.
4,813,429	A		3/1989	Eshel et al.
4,840,613	A		6/1989	Balbierz
4,854,316	A		8/1989	Davis
4,861,334	A		8/1989	Hawaz
4,865,593	A		9/1989	Ogawa et al.
4,869,717	A		9/1989	Adair
4,875,468	A		10/1989	Krauter et al.
4,888,000	A		12/1989	McQuilkin et al.
4,899,729	A		2/1990	Gill et al.
4,917,668	A		4/1990	Haindl
4,927,412	A		5/1990	Menasche
4,931,042	A		6/1990	Holmes et al.
4,932,956	A		6/1990	Reddy et al.
4,955,895	A		9/1990	Sugiyama et al.
4,966,583	A		10/1990	Debbas
4,994,047	A		2/1991	Walker et al.
5,002,557	A		3/1991	Hasson
5,009,643	A		4/1991	Reich et al.
5,030,206	A		7/1991	Lander
5,030,227	A		7/1991	Rosenbluth et al.
5,042,976	A		8/1991	Ishitsu et al.
5,074,871	A		12/1991	Groshong
5,098,392	A		3/1992	Fleischhacker et al.
5,104,383	A		4/1992	Shichman
5,116,318	A		5/1992	Hillstead
5,116,357	A		5/1992	Eberbach
5,122,122	A		6/1992	Allgood
5,122,155	A		6/1992	Eberbach
5,137,512	A		8/1992	Burns et al.
5,141,494	A		8/1992	Danforth et al.
5,141,515	A		8/1992	Eberbach
5,147,302	A		9/1992	Euteneuer et al.
5,147,316	A		9/1992	Castillenti
5,147,374	A		9/1992	Fernandez
5,152,278	A		10/1992	Clayman
5,158,545	A		10/1992	Trudell et al.
5,159,925	A		11/1992	Neuwirth et al.
5,163,949	A		11/1992	Bonutti
5,176,128	A		1/1993	Andrese
5,176,649	A		1/1993	Wakabayashi
5,176,692	A		1/1993	Wilk et al.
5,183,463	A		2/1993	Debbas
5,183,465	A		2/1993	Xanthakos et al.
5,188,596	A		2/1993	Condon et al.
5,188,630	A		2/1993	Christoudias
5,190,541	A		3/1993	Abele et al.
5,195,506	A		3/1993	Hulfish
5,195,507	A		3/1993	Bilweis
5,197,971	A		3/1993	Bonutti
5,201,742	A		4/1993	Hasson
5,201,752	A		4/1993	Brown et al.
5,201,754	A		4/1993	Crittenden et al.
5,209,725	A		5/1993	Roth
5,215,526	A		6/1993	Deniega et al.
5,220,928	A		6/1993	Oddsen et al.
5,222,970	A		6/1993	Reeves
5,226,429	A		7/1993	Kuzmak
5,226,890	A		7/1993	Ianniruberto et al.
5,232,446	A		8/1993	Arney
5,258,026	A		11/1993	Johnson et al.
5,261,888	A		11/1993	Semm
5,267,965	A		12/1993	Deniega
5,269,753	A		12/1993	Wilk
5,284,474	A		2/1994	Adair
5,290,249	A		3/1994	Foster et al.
5,295,994	A		3/1994	Bonutti
5,308,327	A		5/1994	Heaven et al.
5,309,896	A		5/1994	Moll et al.
5,314,443	A		5/1994	Rudnick
5,318,012	A		6/1994	Wilk
5,330,497	A		7/1994	Freitas et al.
5,331,975	A		7/1994	Bonutti
5,338,305	A		8/1994	Plyley et al.
5,342,307	A		8/1994	Euteneuer et al.
5,346,504	A		9/1994	Ortiz et al.
5,359,995	A		11/1994	Sewell et al.
5,361,752	A		11/1994	Moll et al.
5,370,134	A		12/1994	Chin et al.
5,383,889	A		1/1995	Warner et al.
5,391,178	A		2/1995	Yapor
5,397,311	A		3/1995	Walker et al.
5,402,772	A		4/1995	Moll et al.
5,407,433	A		4/1995	Loomas
5,425,357	A		6/1995	Moll et al.
5,431,173	A		7/1995	Chin et al.
5,450,843	A		9/1995	Moll et al.
5,454,365	A		10/1995	Bonutti
5,496,345	A	*	3/1996	Kieturakis et al. 606/192
5,514,091	A		5/1996	Yoon
5,607,443	A		3/1997	Kieturakis et al.
5,707,382	A	*	1/1998	Sierocuk et al. 606/190
5,755,693	A		5/1998	Walker et al.
5,836,961	A		11/1998	Kieturakis et al.
6,312,442	B1	*	11/2001	Kieturakis et al. 606/190

OTHER PUBLICATIONS

Cinelli, Rafael, M.D., "The Inflatable Silastic Bag: A Practical Devices that Simplifies Augmentation Mammaplasty," from the Division of Plastic Surgery, Department of Surgery, at the Maimonides Medical Center and Medical Arts Center of New York.

Dulucq, J.L. Treatment of Inguinal Hernias by Installation of a Subperitoneal Prosthetic Patch Using Pre–Peritoneoscopy (With a Video Film), Translation of French document from Chirugie, 1992, pp 118.

Ferzli et al, "Extraperitoneal Endoscopic Pelvic LympNode Dissection", J. Laparoendoscopic Surgery (1992), vol. 1, pp 39–44.

Gazayerli, M.M. "The Gazayerli Endoscopic Retractor Model 1" Surgeons Laparoscopy & Endoscopy (1991) vol. 1, pp. 98–100.

Gunning, J.E. "Chapter 2: History of Laparoscopy" in: Phillips, J.M. Laparoscopy (Baltimore, Maryland, Williams & Wilkins Company, 1977), pp. 6–14.

Haykawa, N. et al. "Laparoscopic Cholecystectomy Using Retraction of the Falciform Ligament", Surgical Caparoscopy & Endoscopy, vol. 1, No. 2, 1991, pp 126.

Hodgson, C. "Some Effects of the Peritoneal Insufflation of Carbon Dioxide of Laparoscopy", Anaesthesia, vol. 25, No. 3, Jul., 1970, pp 382–390.

Hoffman, M.D. Henry T. et al., "Nasal Reconstruction with the Rapidly Expanded Forehead Flap", Laryngoscope, 99:1096–1098, Oct. 1989.

Kaplan, L.R., et al. "Retroperitoneoscopy in dogs" Gastrointestinal Endoscopy (1979) vol. 25, No. 1, pp. 13–15.

Manders, M.D., Ernest K., Expert Report executed Dec. 1, 1997.

Marshall, R. L. "Circulatory Effects of Carbon Dioxide Insufflation of the Peritoneal Cavity for Laparoscopy", Brit. J. Anaesth. (1972), 44, pp 681–684.

Maxwell, "Immediate Intraoperative Expansion in Augmentation Mammoplasty", D18214, videotape.

Meretyk, S. et al. "Retroperitoneoscopy: Foreign Body Retrieval", The Journal of Urology, vol. 147, Jun., 1992, pp 1608–1611.

Rigg, M.D., Bruce M., "Inflatable Device for Intraoperative Use During Augmentation Mamaplasty", Reconstructive Surgery, May 1982.

Sanchez de Badajoz Chammorro et al., "Endoscopic Cervical Anchorage, New Treatment for Stress Incontinence", Archivos Espafioles de Urologia: vol. 41, Issue 2, (1988), pp 127–130.

Sanchez de Badajoz Chammorro et al., "Stress Incontinence: A New Endoscopic Approach", Urology, vol. 36, No. 5, Nov., 1990, pp 403–405.

Sasaki, M.D., Gordon H., "Intraoperative Sustained Limited Expansion (ISLE) as an Immediate Reconstructive Technique", Clinics in Plastic Surgery, vol. 14, No. 3, Jul., 1987.

Sasaki, M.D., Gordon H., "Intraoperative Expansion™ as an Immediate Reconstructive Technique", Facial Plastic Surgery, 5:4, Jul., 1988.

Shafik, "Extraperitoneal Laparoscopic Lymphadenectomy in Prostatic Cancer: Preliminary Report of a New Approach", Journal of Endourology, vol. 6, No. 2, 1992, pp 113–116.

Voeller, M.D. Guy R., Expert Report executed Dec. 1, 1997.

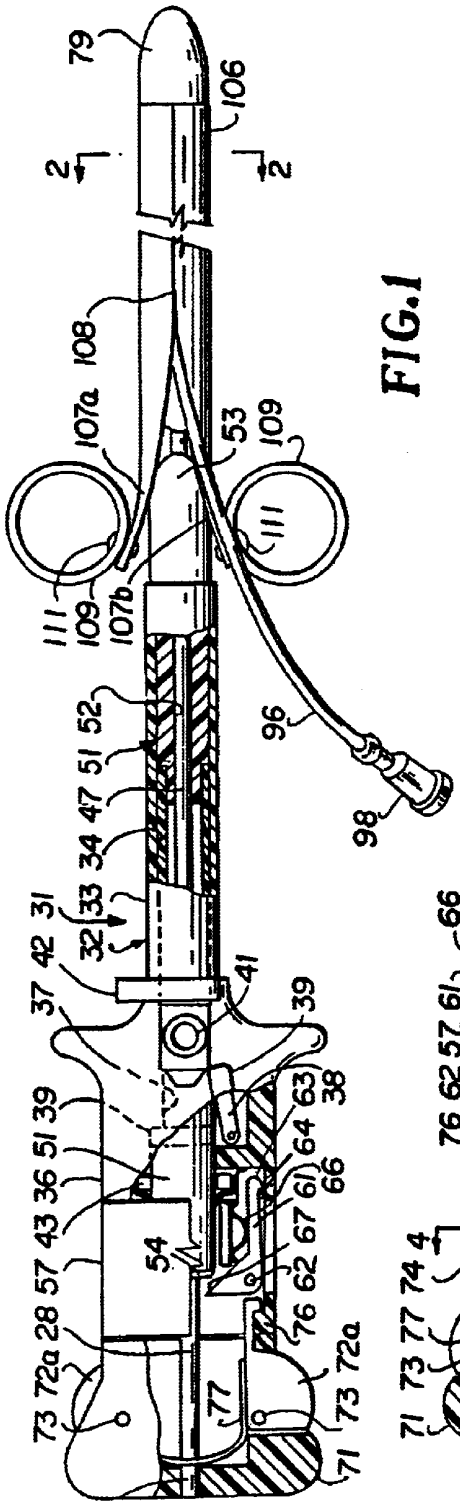
Wickham, J.E.A. and Miller, R.A. Percutaneous Renal Surgery (New York, Churchill Livingstone, 1983), pp. 17–44.

Wittmoser, R. "Retroperitoneoscopy: A Preliminary Report" in: Berci, G. Endoscopy (New York, Appleton–Century–Crofts, 1976), pp. 760–761.

Zhila, V. "Surgical Interventions on the Kidneys and Ureters Using a Retroperitoneoscope", Translation of Russian Document from Urology Department of the Kiev State Institute for Physician Advancement of the USSR Ministry of Public Health.

Zucker, K.A., et al. Surgical Laparoscopy (St. Louis, Missouri, Quality Medical Publishing, Inc., 1991), pp. 25–26, pp. 313–317.

* cited by examiner



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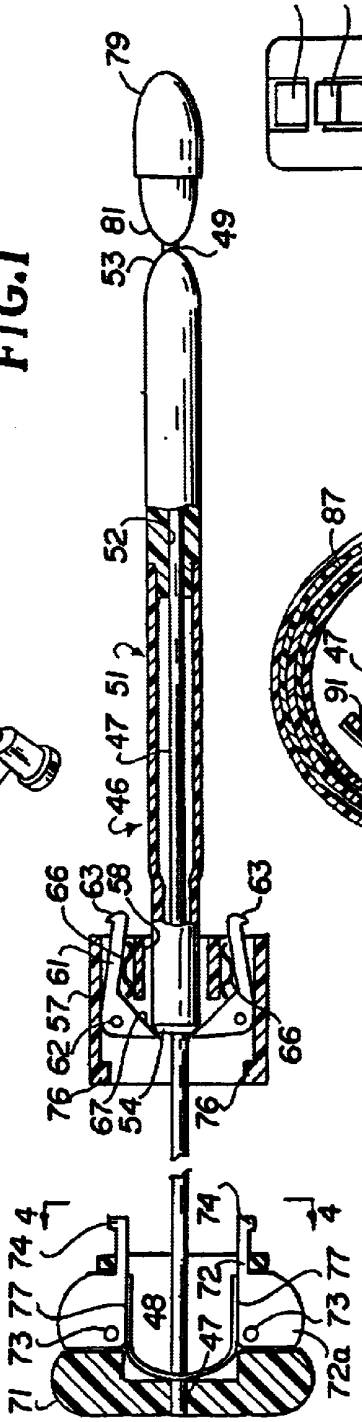
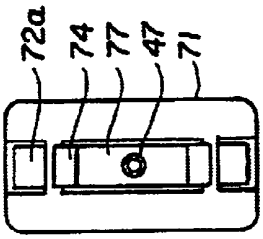


FIG.3



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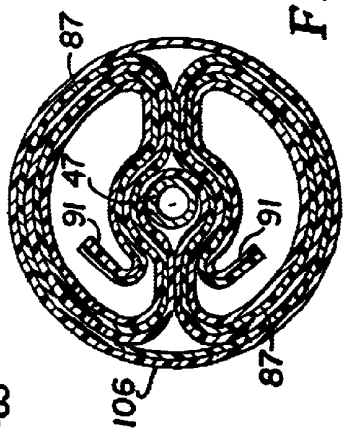
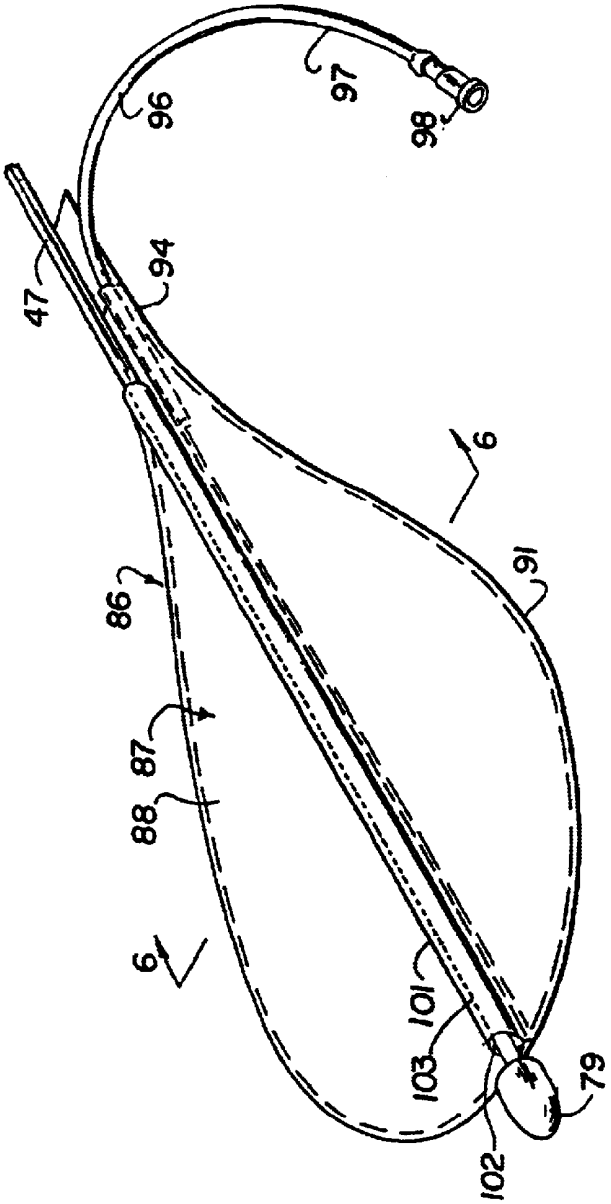


FIG.2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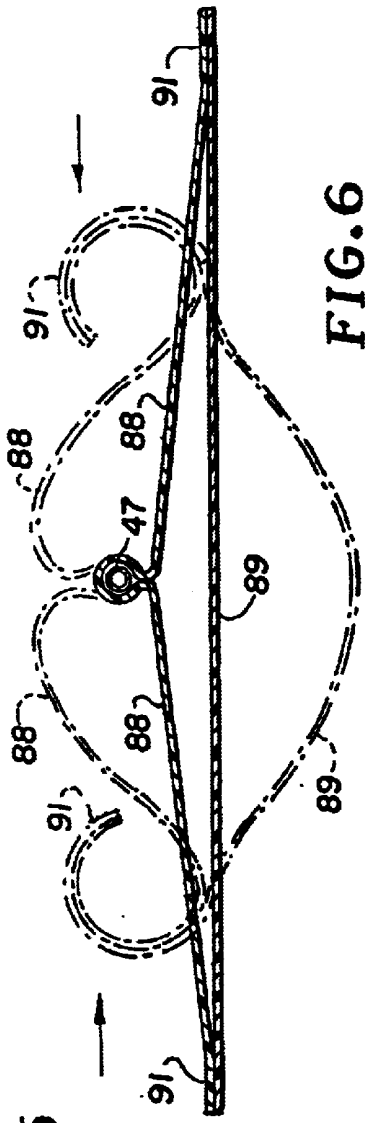
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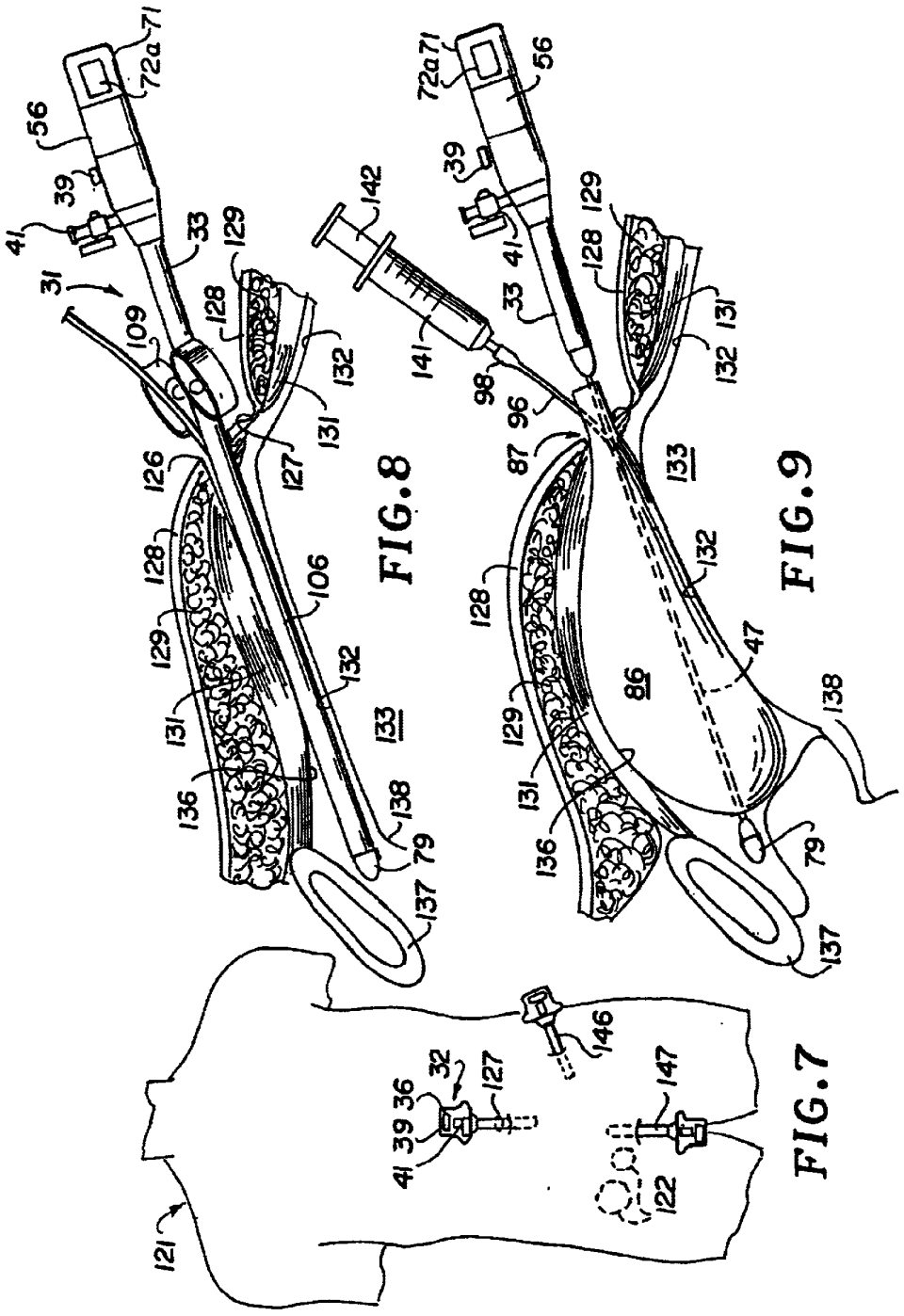

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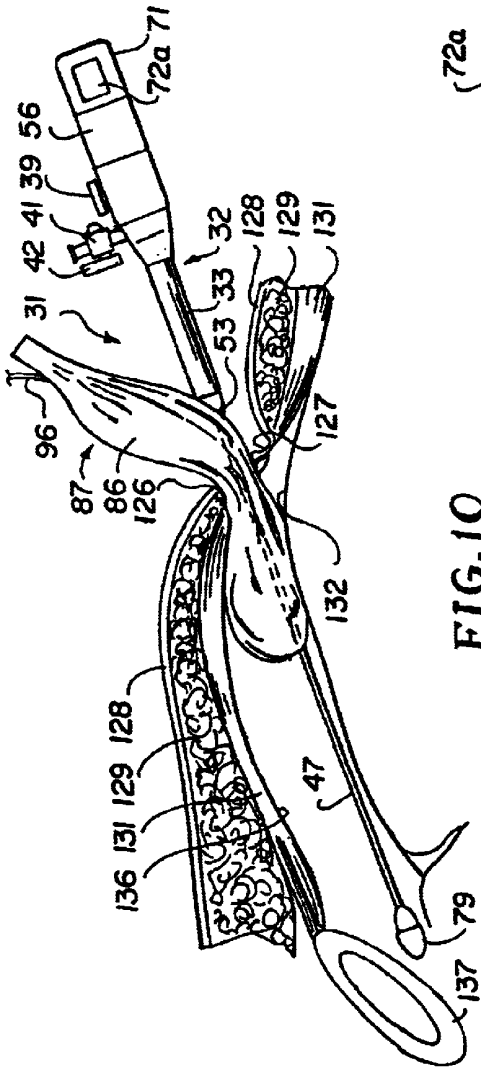
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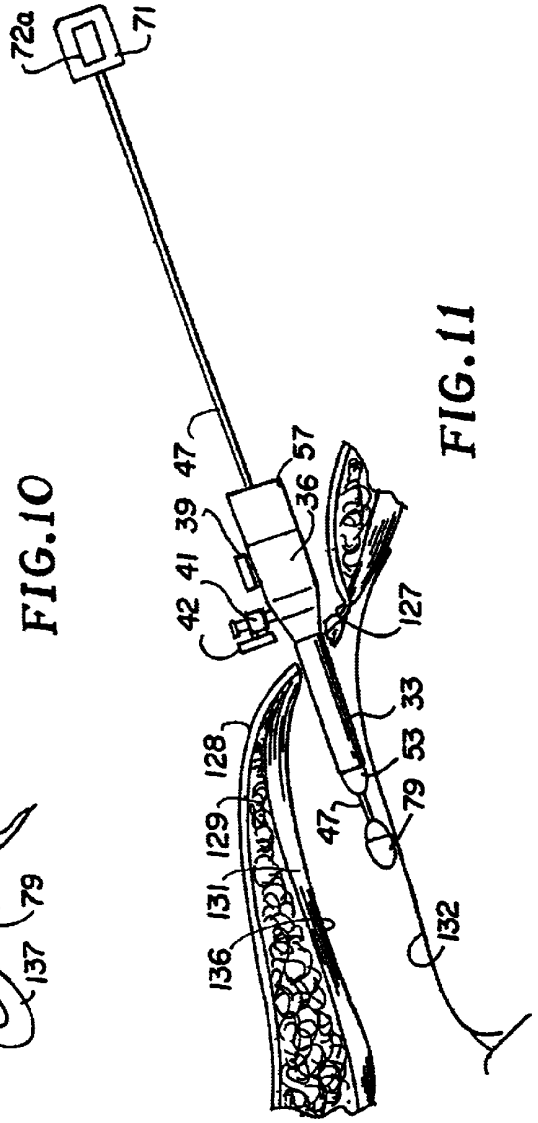
FIG. 10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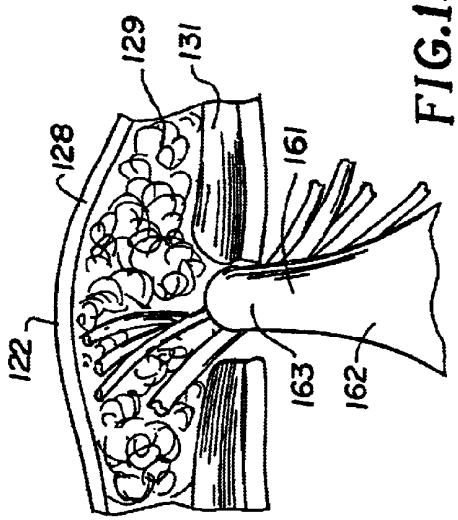

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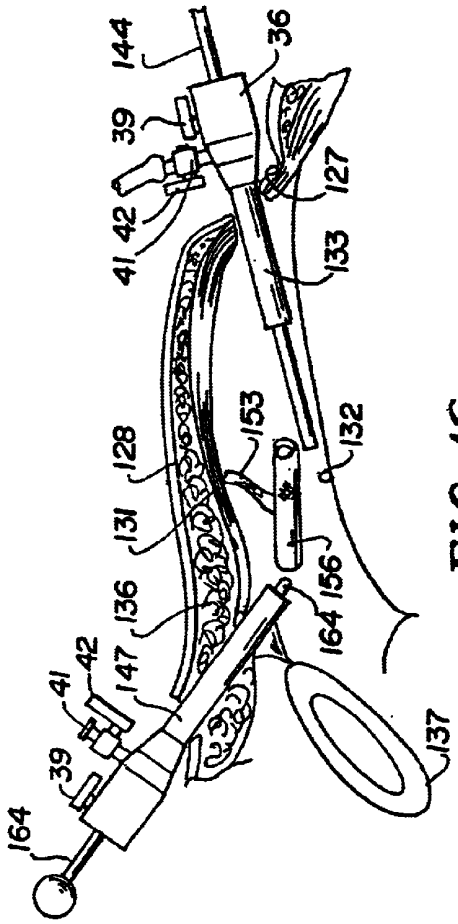

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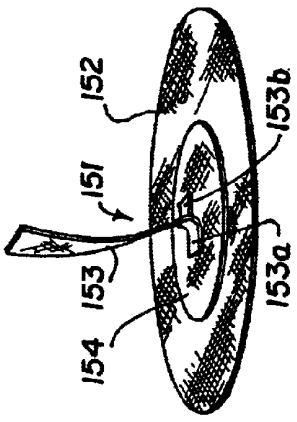


FIG.12

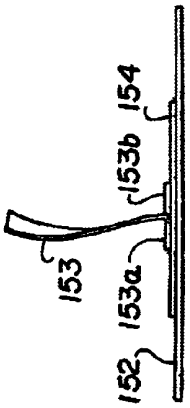


FIG. 13

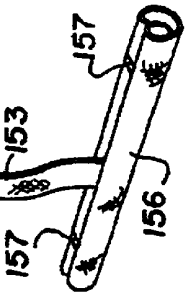


FIG.14

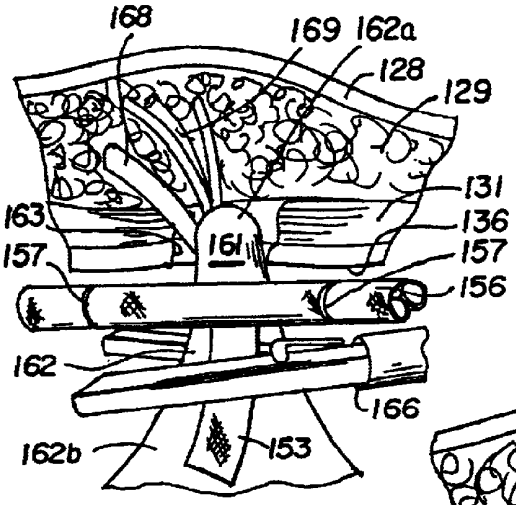


FIG.17

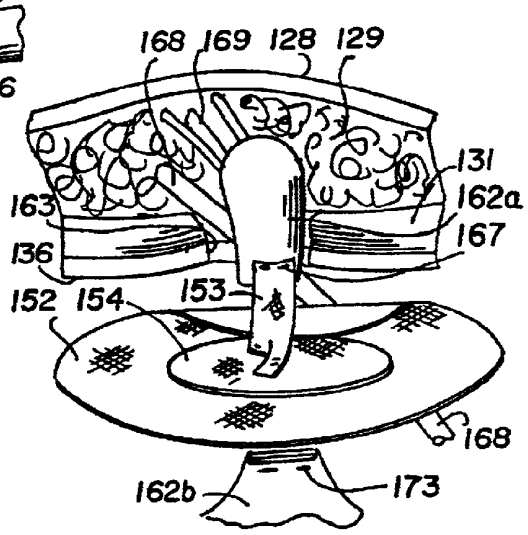
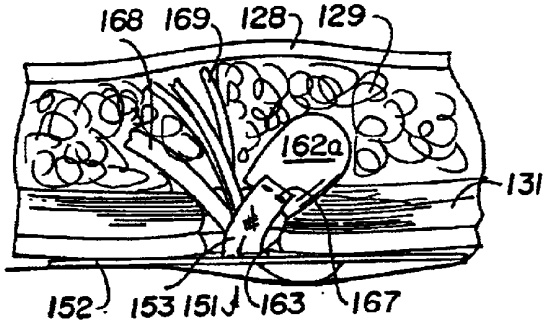


FIG.18



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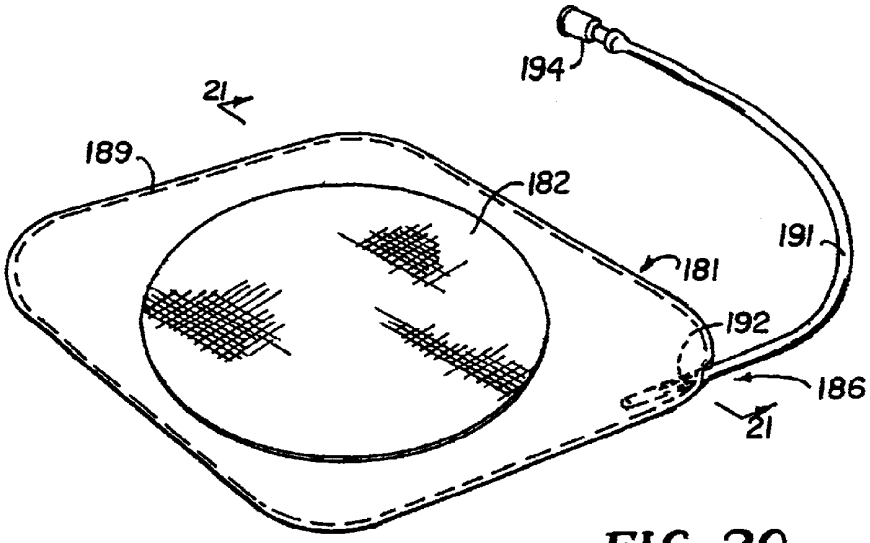

FIG. 20

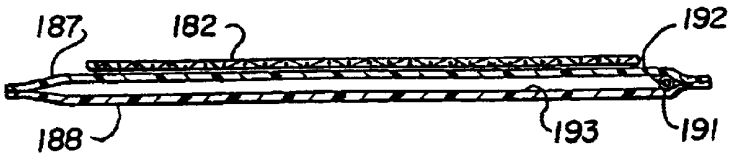

FIG. 21

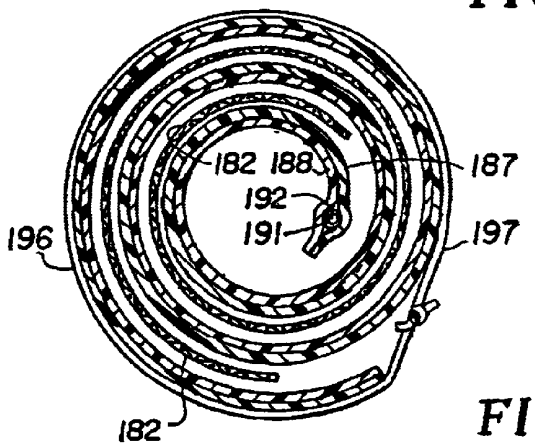

FIG. 22

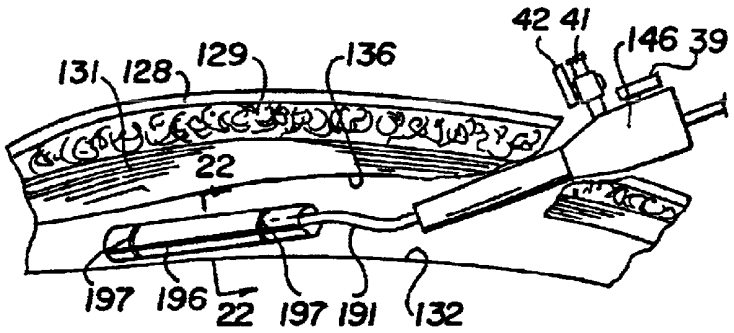
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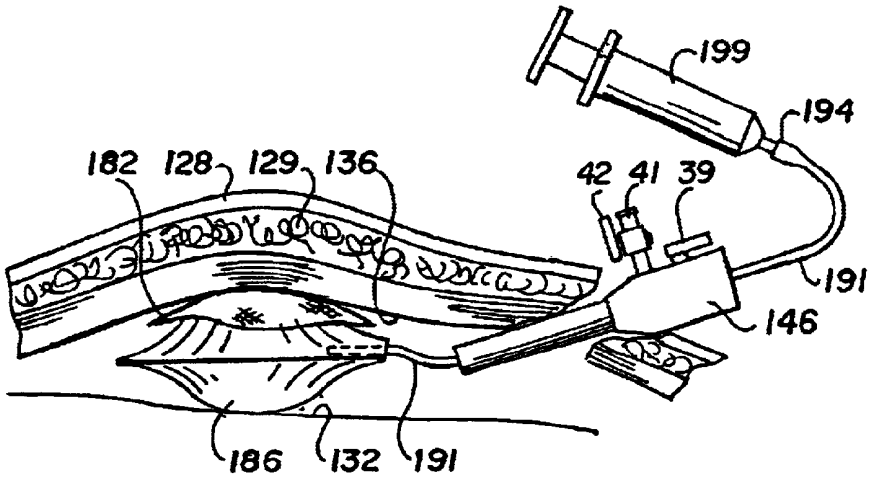
FIG. 23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191
146
186
132
191

FIG. 24

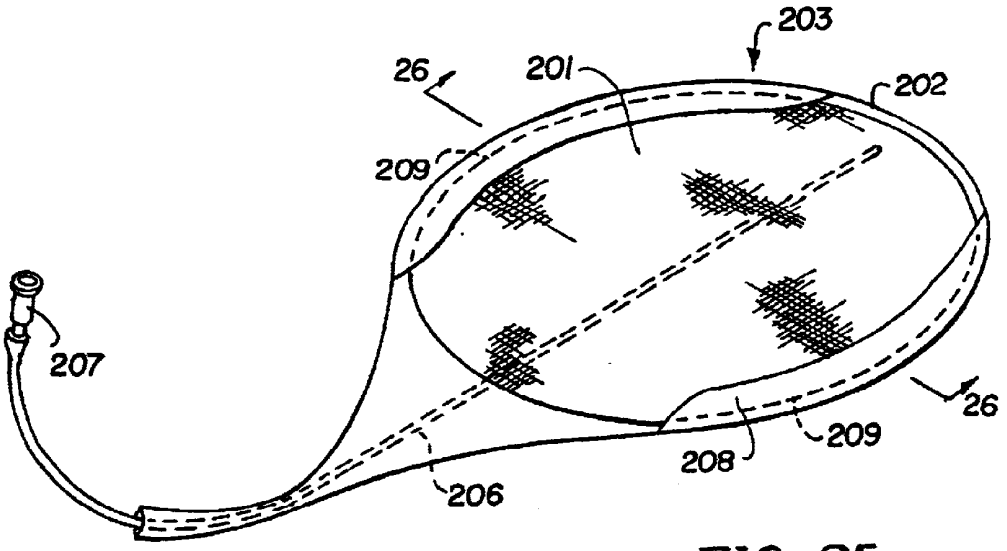

FIG. 25

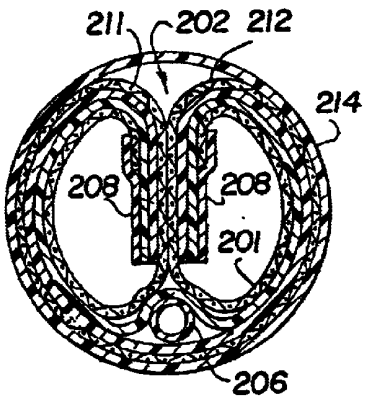

FIG. 26

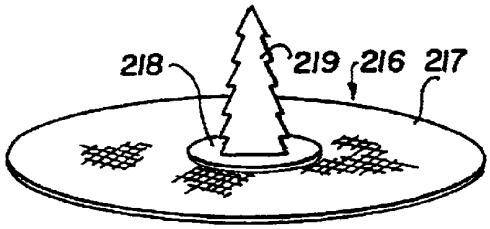

FIG. 27

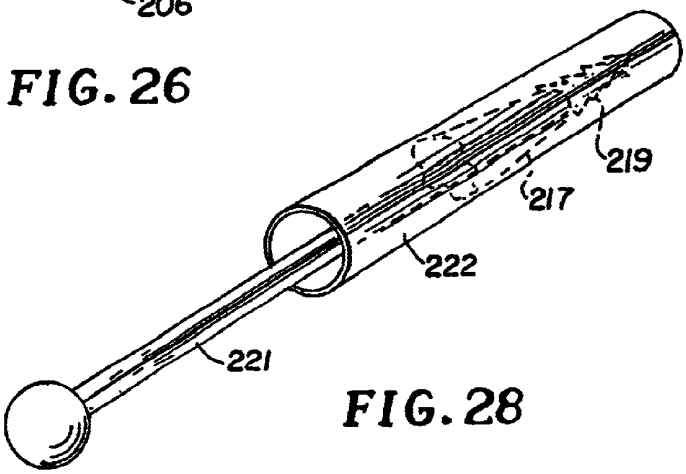

FIG. 28

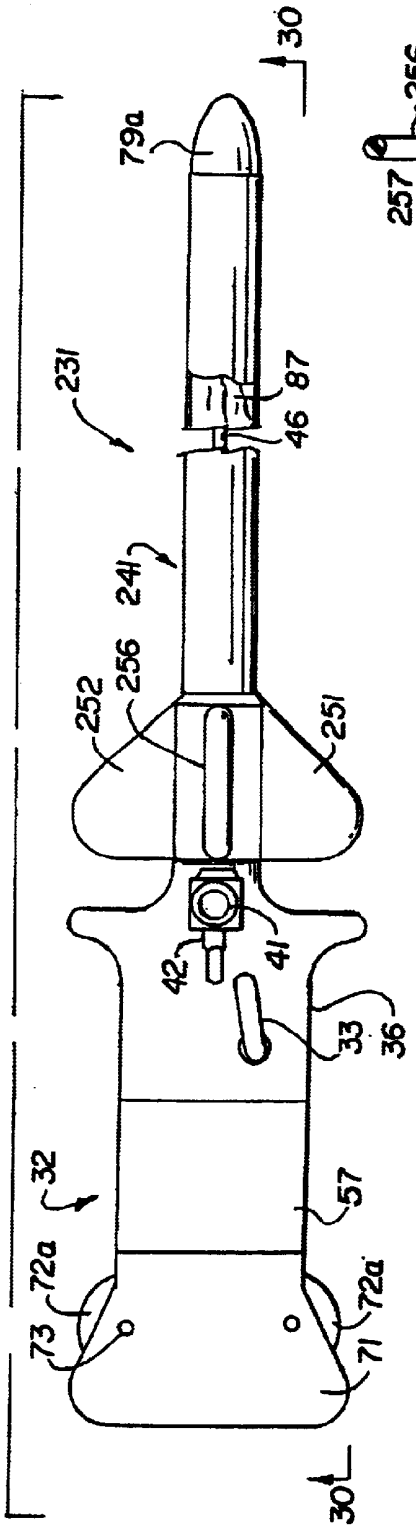

FIG. 29

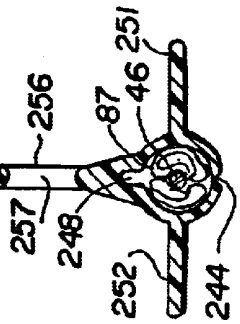

FIG. 31

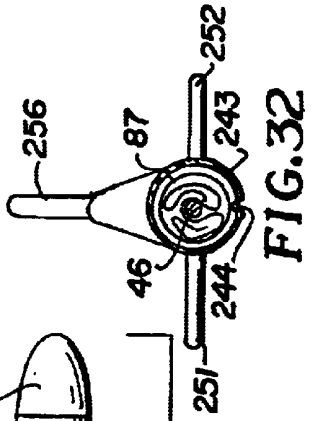

FIG. 32

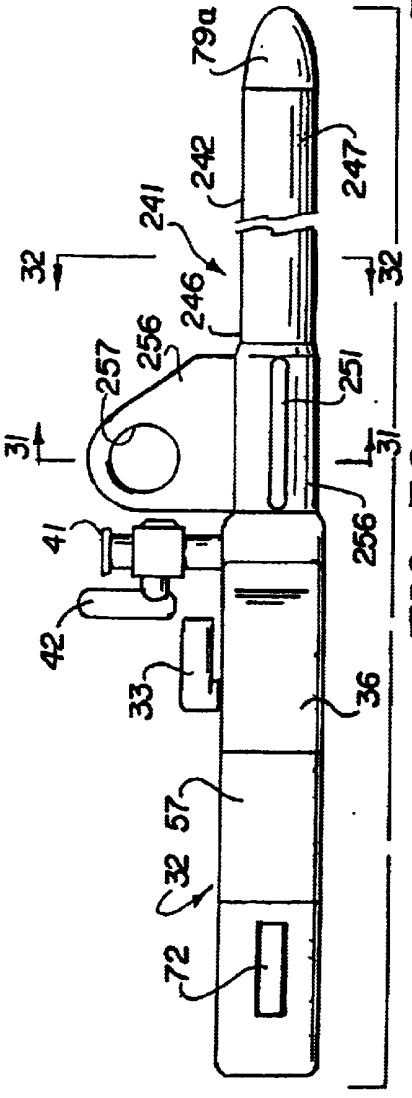

FIG. 30

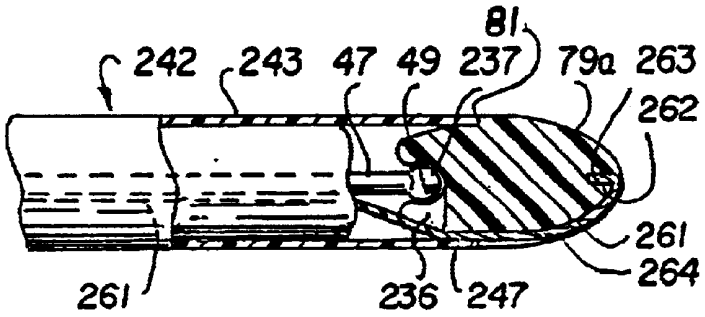

FIG. 33

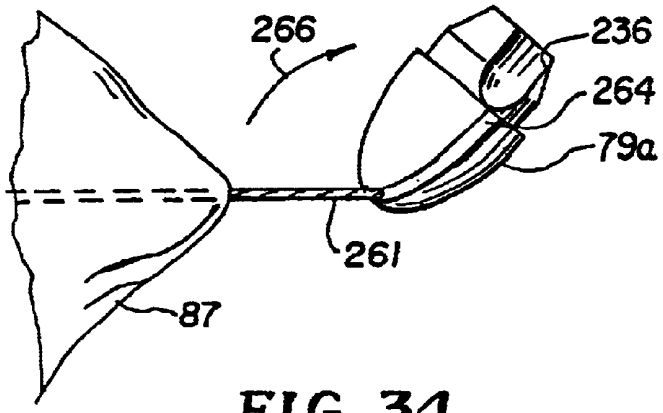

FIG. 34

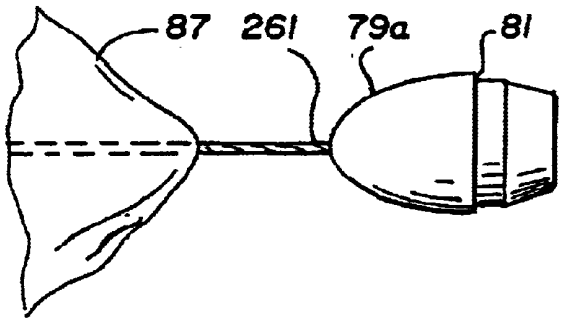

FIG. 35

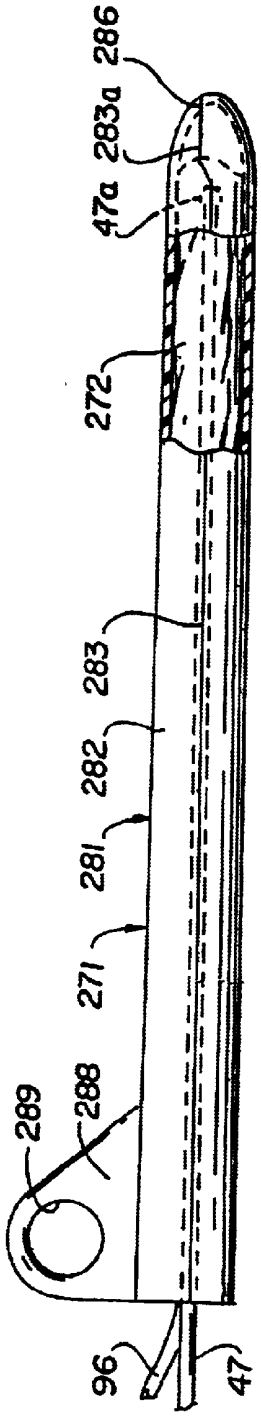

FIG. 36

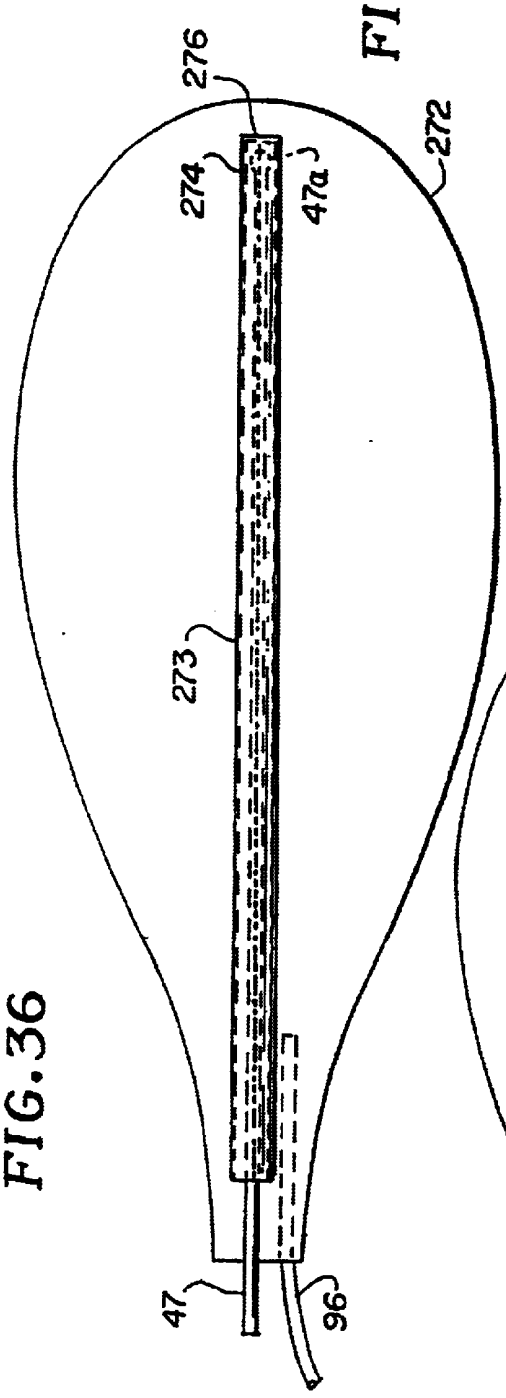

FIG. 37

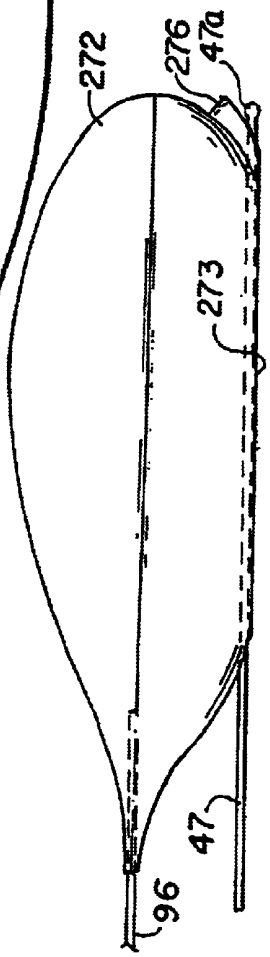

FIG. 38

APPARATUS AND METHODS FOR DEVELOPING AN ANATOMIC SPACE FOR LAPAROSCOPIC HERNIA REPAIR AND PATCH FOR USE THEREWITH

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is divisional of U.S. application Ser. No. 09/932,156, filed Aug. 17, 2001, now U.S. Pat. No. 6,565,590, which is a continuation of U.S. application Ser. No. 07/893,988, flied Jun. 2, 1992, now U.S. Pat. No. 6,312,442, the disclosures of which are hereby incorporated by reference in their entirety.

This invention relates to an apparatus and method for developing an anatomic space for laparoscopic hernia repair and a patch for use therewith.

In the past, in developing spaces and potential spaces within a body, blunt dissectors or soft-tipped dissectors have been utilized to create a dissected space which is parallel to the plane in which the dissectors are introduced into the body tissue. This often may be in an undesired plane, which can lead to bleeding which may obscure the field and make it difficult to identify the body structures. In utilizing such apparatus and methods, attempts have been made to develop anatomic spaces in the anterior, posterior or lateral to the peritoneum. The same is true for plural spaces and other anatomic spaces. Procedures that have been performed in such spaces include varocele dissection, lymph node dissection, sympathectomy and hernia repair. In the past, the inguinal hernia repair has principally been accomplished by the use of an open procedure which involves an incision in the groin to expose the defect in the inguinal floor, remove the hernial sac and subsequently suture the ligaments and fascias together to reinforce the weakness in the abdominal wall. Recently, laparoscopic hernia repairs have been attempted by inserting laparoscopic instruments into the abdominal cavity through the peritoneum and then placing a mesh to cover the hernia defect. Hernia repair using this procedure has a number of disadvantages, principally because the mesh used for hernia repair is in direct contact with the structures in the abdominal cavity, as for example the intestines, so that there is a tendency for adhesions to form in between these structures. Such adhesions are known to be responsible for certain occasionally serious complications. Such a procedure is also undesirable because typically the patch is stapled into the peritoneum, which is a very thin unstable layer covering the inner abdomen. Thus, the stapled patch can tear away from the peritoneum or shift its position. Other laparoscopic approaches involve cutting away the peritoneum and stapling it closed. This is time consuming and involves the risk of inadvertent cutting of important anatomic structures. In addition, such a procedure is undesirable because it requires the use of a general anesthesia. There is therefore a need for a new and improved apparatus and method for developing an anatomic space and particularly for accomplishing hernia repair by laparoscopy.

In general, it is an object of the present invention to provide an apparatus and method for developing an anatomic space.

Another object of the invention is to provide an apparatus and method in which such an anatomic space is developed by applying perpendicular forces to create the anatomic space at the weakest plane to create a more natural, less traumatic and bloodless region in which to work.

Another object of the invention is to provide an apparatus and method to obtain surgical exposure in the preperitoneal space.

Another object of the present invention is to provide an apparatus and method of the above character for developing an anatomic space for laparoscopic hernia repair through the anatomic space.

Another object of the invention is to provide an apparatus and method for decreasing the time and risk associated with creating a preperitoneal working space.

Another object of the present invention is to provide an apparatus and method of the above character for developing an anatomic space for laparoscopic hernia repair through the anatomic space.

Another object of the invention is to provide an apparatus and method of the above character which requires a minimally invasive procedure.

Another object of the invention is to provide an apparatus and method of the above character which can be accomplished without the use of a general anesthesia.

Another object of the invention is to provide an apparatus and method of the above character which can be accomplished with a spinal or epidural anesthesia.

Another object of the invention is to provide an apparatus and method of the above character which provides substantially reduced medical costs and a greatly reduced patient recovery time.

Another object of the invention is to provide an apparatus of the above character which is relatively simple and compact.

Another object of the invention is to provide an apparatus and method of the above character which can be readily utilized by surgeons.

Another object of the invention is to provide a patch for use in the apparatus which is firmly secured during the hernia repair.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevational view partially in cross-section of a laparoscopic apparatus incorporating the present invention.

FIG. **2** is a cross-sectional view taken along the **2**—**2** of FIG. **1**.

FIG. **3** is a side elevational view partially in cross-section of the tunneling shaft forming a part of the apparatus shown in FIG. **1** after it has been removed from the apparatus shown in FIG. **1**.

FIG. **4** is a cross-sectional view taken along the line **4**—**4** of FIG. **3**.

FIG. **5** is an isometric view of the inflatable balloon utilized in the apparatus in FIG. **1** secured to the tunneling rod.

FIG. **6** is a cross-sectional view taken along the line **6**—**6** of FIG. **5**, and showing by dotted lines the manner in which the balloon as it unfolds develops the anatomic space.

FIG. **7** is a partial plan view of a prone human body, showing the lower abdomen showing the manner in which the laparoscopic apparatus of the present invention is utilized for performing a hernia repair through the preperitoneal space.

FIG. **8** is a sagittal view of the lower abdominal cavity of the human being shown in FIG. **7** showing the apparatus of the present invention introduced into the preperitoneal space.

FIG. **9** is a view similar to FIG. **8** but showing the sleeve removed from the apparatus and with the balloon inflated.

FIG. **10** is a sagittal view similar to FIG. **8** showing the balloon deflated and being removed.

FIG. **11** is a sagittal view similar to FIG. **8** showing removal of the tunnelling shaft.

FIG. **12** is an isometric view of a patch incorporating the present invention.

FIG. **13** is a side elevational view of the patch shown in FIG. **12**.

FIG. **14** is an isometric view showing the patch in FIGS. **12** and **13** in a rolled-up, generally cylindrical configuration.

FIG. **15** is a sagittal view showing the hernia sac of hernia that is to be repaired.

FIG. **16** is a sagittal view showing the introducer through which the rolled-up patch in FIG. **17** has been introduced into the preperitoneal space by an introducer rod.

FIG. **17** is a sagittal view similar to FIG. **16** showing the attachment of the patch to the hernia sac.

FIG. **18** is a sagittal view similar td FIG. **17** showing the dissection of the hernia sac and the unrolling of the patch.

FIG. **19** is a sagittal view showing the patch in place to provide the hernia repair.

FIG. **20** is an isometric view of another embodiment of a balloon with a patch disposed thereon for use with the apparatus of the present invention.

FIG. **21** is a cross-sectional view taken along the line **21**—**21** of FIG. **20**.

FIG. **22** is an enlarged cross-sectional view taken along the line **22**—**22** of FIG. **23**.

FIG. **23** is a sagittal view showing the manner in which the balloon and patch shown in FIG. **20** are disposed in the preperitoneal space.

FIG. **24** is a sagittal view showing the placement of the balloon and the patch of FIG. **20**, and the inflation of the balloon in the preperitoneal space.

FIG. **25** is an isometric view of another embodiment of a balloon and patch for use with the apparatus of the present invention.

FIG. **26** is a rolled-up cross-sectional view of the balloon and patch shown in FIG. **25**.

FIG. **27** is an isometric view of another embodiment of a patch for use with the apparatus of the present invention.

FIG. **28** is an isometric view of the patch shown in FIG. **27** wrapped in an introducer assembly.

FIG. **29** is a top plan view of another embodiment of a laparoscopic apparatus incorporating the present invention.

FIG. **30** is a side elevational view taken along the line **30**—**30** of FIG. **29**.

FIG. **31** is a cross-sectional view taken along the line **31**—**31** of FIG. **30**.

FIG. **32** is a cross-sectional view taken along the line **32**—**32** of FIG. **30**.

FIG. **33** is an enlarged cross-sectional view of the distal extremity of the laparoscopic apparatus shown in FIG. **29**.

FIG. **34** is a partial plan view showing the balloon after it has been removed from the laparoscopic apparatus with the obturator tip shifting its position.

FIG. **35** is a plan view of the balloon shown in FIG. **34** as it is being removed from the body of the patient and bringing along with it the obturator tip.

FIG. **36** is a side elevational view of another embodiment of a laparoscopic apparatus incorporating the present invention.

FIG. **37** is a plan view showing the balloon from the apparatus shown in FIG. **36** in an inflated condition and showing the tunneling rod mounted therein being prevented from being advanced beyond the distal extremity of the balloon.

FIG. **38** is a plan view showing the manner in which the balloon is separated from the tunneling rod as it is retracted.

In general, the apparatus of the present invention is used for insertion into a body to create an anatomic space. The apparatus is comprised of a tubular introducer member having a bore extending therethrough. A tunneling shaft is slidably mounted in the bore and has proximal and distal extremities including a bullet-shaped tip. A rounded tunneling member is mounted on the distal extremity of the tunneling shaft. An inflatable balloon is provided. Means is provided on the balloon for removably securing the balloon to the tunneling shaft. Means is also provided for forming a balloon inflation lumen for inflating the balloon. The balloon is wrapped on the tunneling shaft. A sleeve substantially encloses the balloon and is carried by the tunneling shaft. The sleeve is provided with a weakened region extending longitudinally thereof, permitting the sleeve to be removed whereby the balloon can be unwrapped and inflated so that it lies generally in a plane. The balloon as it is being inflated creates forces generally perpendicular to the plane of the balloon to cause pulling apart of the tissue along a natural plane to provide the anatomic space.

More in particular, as shown in the drawings, the apparatus or device **31** for creating such an anatomic space for use in a laparoscopic procedure (see FIG. **1**) includes an introducer sleeve or device **32** which consists of a tubular member **33** formed of a suitable material such as plastic which is provided with a bore **34** extending throughout the length thereof. A handle section **36** is mounted on one end of the tubular member **33** and is also formed of a suitable material such as plastic. It is provided with a bore **37** which is in communication with the bore **33**. A flapper valve **38** is mounted within the section **36** and is movable between a position in which it closes off the bore **37** and position out of the way of the bore **37**, by means of a finger operated actuator **39** mounted on the exterior of the section **36**. A stopcock **41** is mounted on the section **36** and is in communication with the passage **37**. A lever **42** is provided for opening and closing the stopcock **41**.

A tunneling shaft assembly **46** is slidably mounted in the bores **37** and **34** of the introducer sleeve **32**. The tunneling shaft assembly **46** consists of a tunneling shaft or rod **47** formed of a suitable material such as stainless steel, of a suitable length, as for example 18 inches, and a suitable diameter of approximately ⅛ inch. The tunneling rod **47** is provided with proximal and distal extremities **48** and **49**.

An introducer member **51** is slidably mounted on the tunneling shaft or rod **47** and is formed of a suitable material such as plastic. The introducer member **51** is substantially hollow as shown and is provided with a bore **52** through which the tunneling shaft **47** extends. The introducer member **51** is provided with a substantially hemispherical tip **53** to form a rounded protrusion or first obturator through which the rod **47** extends. The introducer member **51** has a length such that when it is introduced into the bore **34** of the introducer sleeve, it extends out of the distal extremity of the introducer sleeve **32**, as shown particularly in FIG. **1**. This diameter of the introducer member **51** is sized so that it can be slidably mounted in the bore **34**. The other end of the introducer member **51** is provided with a chamfer **54**.

A disk-type seal **43** having a central opening is provided in the section **36** in alignment with the bore **37**, and is

adapted to permit the introduction of the introducer member **51** therethrough.

The section **36** forms one part of a three-piece handle **56** of the laparoscopic apparatus **31** which is sized so that it is adapted to be grasped by the human hand. As can be seen particularly in FIG. **4**, the handle **56** is generally rectangular in cross-section. The handle **56** is provided with an intermediate section **57** which has a bore **58** extending therethrough in registration with the bore **37** and has the same general diameter as the bore **37** so that the introducer member **51** can travel therethrough. The sections of the handle **56** can be characterized as having first, second and third sections, in which section **36** is the first section and intermediate section **57** is the second section. Latching means is provided for interconnecting the intermediate section **57** to the end section **36**, and consists of a pair of oppositely disposed latches **61** pivotally mounted on the pins **62** in the intermediate section **57**. Each of the latches **61** is provided with a latch portion **63** adapted to engage a protrusion **64** provided on the end section **36**, and is yieldably urged into engagement therewith by a spring **66**. Each of the latches is provided with a cam surface **67** which is adapted to be engaged by the chamfer **54** of the introducer member **51** to cam the latch portion **63** out of engagement with the protrusion **64** to release the intermediate section **57** from the end section **36** for a purpose hereinafter described.

The handle **56** also consists of another end section **71**, which can also be characterized as the third section, which is secured to the proximal extremity of the tunneling shaft or rod **47**. A pair of latches **72** are provided in the end section **71** and are pivotally mounted on pins **73**. The latches **72** are provided with latch portions **74** adapted to engage projections **76** provided in the intermediate section **57**. Means is provided for yieldably retaining the latches **72** in engagement with the projections **76** and consists of a U-shaped spring **77** mounted within the end section **71** and engaging the latches **72**. The latches **72** are provided with knurled portions **72***a* which extend outwardly which are adapted to be grasped by the fingers of the hand so that the latch portions **74** can be moved out of engagement with the projections **76** against the force of the spring **77**.

The tunneling shaft assembly **46** also includes a tunneling member or tip **79** which is mounted on the distal extremity of the tunneling shaft or rod **47**. As shown, the tip **79** is substantially olive-shaped and can also be called a second obturator. It is provided with a rounded hemispherical surface on its distal extremity which has a maximum diameter which is slightly less than the diameter of the bores **34** and **37** so that it can pass through the introducer sleeve **32**. The proximal extremity of the tip **79** is of smaller diameter to provide an annular step **81** in the tip. The proximal extremity of the tip **79** is also hemispherical, as shown. The tunneling member or tip **79** can be formed of a suitable material such as plastic and can be secured to the distal extremity of the tunneling shaft or rod **47** by suitable means such as an adhesive. As hereinafter explained, the tunneling shaft or rod **47** is movable so that the tip **79** can be brought into engagement with the hemispherical end **53** of the introducer member **51** for a purpose hereinafter described.

The laparoscopic apparatus **31** also includes a balloon assembly **86** which is shown in FIGS. **2**, **5** and **6**. As shown in FIG. **5**, when the balloon assembly **86** consists of a balloon **87** which in plan, when deflated, has a pear-shaped configuration. The balloon is preferably formed of a non-elastomeric, medical-grade material of a suitable type such as PVC. Thus, the balloon **87** can be formed of two sheets **88** and **89** of such a material which have their outer margins bonded together by suitable means such as by a heat seal **91** extending around the perimeter of the flat balloon **87**. The balloon **87** is provided with a neck **94** into which a flexible tubular member **96** extends, and is secured therein in a suitable airtight fashion such as by an adhesive. The tubular member **96** is provided with a lumen **97** which is in communication with the interior of the balloon and which can be used for inflating the balloon through a Luer-type fitting **98** mounted on the free end of the tubular member **96**.

Means is provided for removably securing the balloon **87** to the tunneling rod or shaft **47**, and consists of a sleeve **101** formed of the same material as the balloon **87**, and which can be formed integral or separate therefrom and adhered thereto by suitable means such as an adhesive. The sleeve **101** extends longitudinally of the balloon **87** and is disposed generally equidistant from the side margins of the same. The sleeve **101** is provided with a passage **102** extending therethrough which is sized to slidably accommodate the tunneling shaft or rod **47**. Means is provided for permitting separation of the balloon **87** from the tunneling rod by movement sidewise from the axis of the passage **102** and takes the form of longitudinally spaced apart perforations **103** in the sleeve **101** extending longitudinally the length of the sleeve **101**. The perforations **103** are spaced close enough together to form a weakened region so that the balloon can be readily separated from the tunneling rod by separating the plastic sleeve **101** by tearing the plastic between the perforations as hereinafter described.

As shown in FIG. **6**, the sleeve **101** is disposed equidistant from the side margins of the balloon, permitting the balloon to be inflated as hereinafter described and as also shown by the dotted lines in FIG. **6**, to be inflated around the rod **47**. When deflated, the side margins of the balloon **87** can be rolled inwardly toward the rod **47** as shown by the broken lines in FIG. **6** to permit the same to be folded into a generally cylindrical configuration as shown in FIG. **2**, and to be enclosed within a removable sleeve **106** carried by the tunneling shaft or rod **47**. The removable sleeve **106** is formed of a relatively thin-walled tubular member **107** of a suitable material such as Teflon which has a weakened region **108** in its wall extending longitudinally the length thereof. This weakened region **108** can take the form of a slit as shown, or can be a series of perforations or slots formed in the wall, or a combination thereof. The proximal extremity of the tubular member **107** is provided with split-apart or separable end portions **107***a* and **107***b* to which are secured finger rings **109** of a suitable material such as plastic and secured thereto by fasteners **111**.

Operation and use of the laparoscopic apparatus in performing the method for laparoscopic hernia repair through preperitoneal space may now be briefly described as follows. Let it be assumed that the laparoscopic apparatus **31** has been assembled as shown in FIG. **1**. As shown in FIG. **7**, let it be assumed that a human patient **121** is in a prone position and has a hernia **122** in the lower abdominal area which he wishes to have repaired. The patient is prepared in an appropriate manner by administering a suitable anesthesia, as for example a spinal anesthesia, and any other necessary preparation. The surgeon first makes an infraumbilical incision **126** in the skin below the navel or umbilicus **127** and separates the fat **129** and then incises the anterior rectus sheath or fascia **131** in the midline. Care should be taken not to penetrate the peritoneum overlying the abdominal cavity **133** (see FIG. **8**).

After the incision **126** has been made in the manner hereinbefore described, the laparoscopic apparatus **31** is then taken by one hand of the surgeon, grasping the handle

56 and utilizing the other hand to facilitate the insertion of the rounded blunt tip **79** into the incision **126**. The blunt tip **79** is caused to enter the slit in the fascia **131** and pass anterior to the peritoneum **132**, in between the rectus muscles (laterally), and enters the potential preperitoneal space **136** to be provided for the laparoscopic procedure. The blunt tip **79** is then utilized as a tunneling device by the surgeon using one hand **56** to advance the blunt end **79** toward the pubic region of the patient while the surgeon places his other hand on the abdomen to feel the apparatus or device **31** as it is being advanced. The advance of the device **31** is continued until the blunt tip **79** is below the symphysis pubis **137** as shown in FIG. **8**, and preferably is disposed between the symphysis pubis **137** and the bladder **138**.

After the apparatus or device **31** has been properly positioned as shown in FIG. **8**, the removable sleeve or sheath **106** is removed by the surgeon using one hand to engage the finger rings **109** which are exterior of the body of the patient and outside of the incision **126**. At the same time, the other hand of the surgeon is utilized to stabilize the portion of the device **31** which is within the preperitoneal space. The sheath **106** can be readily withdrawn since it is formed of Teflon and is split or weakened along its length, by pulling it proximally and away from the longitudinal axis of the tubular member **33**. As the sheath **106** opens and slips off, it exposes the balloon **87** of the balloon assembly **86**. When the sheath **106** is completely removed, a sterile saline solution serving as a balloon inflation medium is introduced into the balloon **87** through the tubular member **96** by connecting a conventional syringe **141** to the Luer fitting **98**. The balloon **87** typically can be inflated to a suitable size by introducing 500 cc or less of normal saline solution into the balloon by pressing on the plunger **142**. As the balloon **87** is inflated, the balloon progressively unwraps with its side margins rolling outwardly from the center while expanding into a plane to cause progressive separation or dissection of tissue (i.e. **131**, **132**) along its weakest points by application of forces generally perpendicular to the plane of the balloon as indicated by the arrows **143** in FIGS. **6** and **9**, to create the preperitoneal or anatomic space. The balloon **87** expands around the tunneling shaft **47** in the manner shown in broken lines in FIG. **6** to achieve the progressive separation until complete inflation is achieved. The surgeon can sense the filling of the balloon by feeling the abdomen of the patient as the balloon is inflated. The balloon **87** serves to open up the preperitoneal space **136** to provide a bloodless space for the procedures hereinafter to be performed. Since the balloon is formed of a non-elastomeric material, it is a volume-limited balloon to prevent overexpansion. Different sizes of balloons can be utilized for different patient sizes. With a smaller balloon it is possible to deflate the balloon and then shift the balloon and again reinflate it to obtain the desired bloodless preperitoneal space.

After the desired bloodless anatomic space or pocket **136** is formed, the balloon **87** is deflated by withdrawing the normal saline solution by withdrawal of the plunger **142** of the syringe **141** or via a hospital vacuum aspirator. After the balloon **87** has been deflated, the balloon assembly **86** can be removed by grasping the handle **56** of the laparoscopic apparatus or device **31** with one hand and using the other hand to grasp the tubular member **96** and the proximal extremity of the balloon **87** and to remove the same through the incision **126**, as shown in FIG. **10**. As the balloon **87** is being removed, it is progressively separated from the tunneling rod or shaft **47** by causing the sleeve **101** to split apart along the longitudinal perforations **103** provided in the sleeve **101**. This makes it possible to separate the balloon **87** from the tunneling rod **47** without the necessity of removing the tunneling rod **47** or the introducer device **32**.

After the balloon assembly **86** has been removed, the introducer device **32** can be advanced distally over the tunneling shaft or rod **47** so it extends well into the preperitoneal space **36** as shown in FIG. **11**. The end section **71** of the handle **56** is then removed by depressing the latches **72** by having the fingers engage the portions **72***a* to disengage the latch portions **74** from the intermediate section **57** of the handle **56**. The end section **71** is then drawn proximally as shown in FIG. **11** to bring the olive-shaped tip **79** into engagement with the obturator **53** disposed in the distal extremity of the tubular member **33** to cause both the tip **79** and the obturator **53** to be withdrawn or retracted. As the introducer member **51** is being withdrawn, its chamfer **54** will strike the cam surfaces **67** of the latches **61** to cause them to disengage from the end piece **36** to carry it along with the introducer member **51** and shown in FIG. **2**. Thus, it can be seen that the tunneling shaft assembly **46** can be readily removed merely by one motion of the surgeon's hand. Thereafter, a conventional laparoscope **144** (see FIG. **16**) can be introduced through the introducer sleeve **32** to permit the surgeon to view the preperitoneal space **136**.

The dissected preperitoneal space **136** is then insufflated with carbon dioxide through the stopcock **41** to a pressure ranging from 6 to 8 mm of mercury. Thereafter, two additional trocars **146** and **147** are introduced through the abdominal wall into the dissected preperitoneal space **136** in appropriate locations. Thus, as shown in FIG. **7**, trocar **146** is introduced into the left side of the abdomen of the patient below the introducer sleeve **32** and the trocar **147** is introduced into the dissected preperitoneal space immediately above the symphysis pubis and directly below the introducer sleeve **32**. As can be appreciated, the locations of the trocars **146** and **147** is generally dictated by the location of the hernia **122** to be repaired.

A patch **151** of the present invention to be utilized in the hernia repair procedure is shown in detail in FIGS. **12**, **13** and **14**. The patch **151** can be characterized as a hernia patch or graft and is made of a suitable plastic mesh such as a Prolene mesh manufactured by Ethicon, Inc. The patch **151** can be of any desired configuration. For example it can be generally circular as shown, and consists of a disk **152** of a suitable diameter, as for example 2 inches. A tail **153** is secured to the disk substantially in the center thereof, in a suitable manner. For example, as shown, the tail **153** can be provided with split portions **153***a* and **153***b* which are split apart and offset with respect to each other, which are secured to a smaller reinforcing disk **154** formed of the same material as disk **152** and secured to the disk **152** by suitable means such as surgical thread (not shown). The tail **153** is formed of the same material as the disk **152** and **154**, or it can be formed of a different material, such as Goretex. It can have a size such that it has a width of approximately ½ inch and a length of approximately 1½ inches. As shown particularly in FIG. **14**, the side margins of the disk **152** can be rolled inwardly towards the center adjacent the tail **153** to form a cylindrical roll **156** such as shown in FIG. **14** with the tail **153** extending outwardly therefrom. The roll **156** can be maintained in its rolled-up condition by means of sutures **157** disposed adjacent opposite ends of the roll and on opposite sides of the tail **153**.

Conventional laparoscopic instruments are utilized which are introduced through the trocars **146** and **147** while visualizing the same through the laparoscope **144** introduced through the introducer device **32** to dissect the hernia **161** to

permit visualization of its neck **162** as it is entering the internal inguinal ring **163**. The hernia sac **161** is dissected from the surrounding tissue (spermatic duct and vessels) (see FIG. **15**). The process is facilitated by CO_2 pressure impinging on the neck of the hernia sac. As soon as this dissection is completed, the roll **156** is pushed into the trocar **147** and advanced through the same by suitable means such as a deployment rod **164** (see FIG. **16**) to enter the dissected preperitoneal space **13** as shown in FIG. **16**. Alternatively, the roll **156** can be placed in a tubular member (not shown) which can be used to position the roll **156** within the trocar **157**. Thereafter, by the deployment rod **164**, the roll **156** can be pushed out of the tubular member into the dissected preperitoneal space **136**.

The roll **156** after it is in the preperitoneal space is then manipulated so that its tail **153** is disposed alongside the neck **162** of the hernia sac **161** as shown in FIG. **17**. A conventional stapling device **166** is then introduced through the trocar **146** to staple the tail **153** to the neck **162** by placing staples **167** therein. These staples **167** serve to divide the neck of the sac into distal and proximal portions **162***a* and **162***b*. As soon as this stapling operation is completed, the two portions **162***a* and **162***b* are separated from each other because of the pressure of the insufflation gas to cause the tail **153** of the patch **151** to be pulled upwardly into the inguinal ring to pull with it the disk **152**. The sutures **157** are cut apart to permit the disk **152** to unroll and to be placed across the inguinal ring **163** which created the main weakness in the abdominal wall permitting the hernia which is being repaired to occur. The proximal portion **162***b* of the neck **162** is stapled together by staples **173** as shown in FIG. **18**. The proximal portion **162** is then permitted to fold back into the desired anatomical location within the abdomen.

Thereafter, while observing the procedure under the laparoscope, the dissected preperitoneal space **136** can be deflated by permitting the carbon dioxide gas to escape to the atmosphere through the stopcock **41** in the introducer device **32** by operation of the stopcock lever arm **42**. As deflation is taking place, the movement of the patch **151** is observed through the laparoscope **144** so that it does not become misplaced. When the deflation has been completed, the patch **151** is in a position over the inguinal ring **163** and serves to provide enforcement to prevent the occurrence of another hernia in that area. The tail **153** is disposed with the inguinal ring **163** and retains the mesh disk **152** so that it surrounds the inguinal ring **163**.

After deflation has been accomplished, the trocars **146** and **147** as well as the introducer device **32** can be removed. Small sutures can then be utilized to close the various small openings which have been provided in the abdominal wall so that upon healing there will be minimal noticeable scars from the procedure. The scar in the navel or umbilicus typically is almost nearly invisible.

It has been found that the use-of the laparoscopic apparatus **31** in accomplishing the method as hereinbefore set forth provides a procedure in which the pain after the operation is markedly reduced. This is particularly true since the operation does not involve suturing of any ligaments which typically produces the pain. In addition, the recovery time for the patient is greatly accelerated. In the procedure of the present invention, a patient can return to work within a matter of 3 to 5 days rather than in a number of weeks as in a conventional hernia repair procedure. The procedure also has other advantages. For example, there is a lack of necessity for a general anesthesia. Another principal advantage of the procedure is there is no contact of mesh patch **151** with the intestines of the patient or other intra-abdominal structures, thus greatly reducing the possibility of adhesion formation. In addition, the graft which is formed by the patch **151** is more secure and is positioned in an anatomically correct position. This is because the hernia sac is in exact alignment with the hernia and pulls with it the tail **153** of the graft to ensure that the graft formed by the patch **151** is drawn into the correct position and is maintained in that position to prevent migration. In addition, the graft, by having an additional central disk **154**, ensures that additional reinforcement is provided in the proper location in the center where the weakest region in the abdominal wall has occurred. In addition, by such proper centering, the mesh construction of the patch **151** serves to uniformly reinforce the area surrounding the hernia.

Another embodiment of the present invention is shown in FIGS. **20**, **21** and **22** with respect to another embodiment of a balloon assembly **181** and another embodiment of a patch or graft **182**. The balloon assembly **181** consists of a balloon **186** formed of two sheets **187** and **188** which are rectangular in shape, as for example square as shown in FIG. **20**, which are heat-sealed together at their outer margins as indicated by the broken line **189**. A tubular member **191** is provided which has one end sealed into one corner of the balloon **186** as shown in FIG. **20**. The tubular member **191** is provided with a lumen **192** which opens up into the interior space **193** of the balloon. The sheets **187**, **188** are formed of a non-elastomeric material of the type hereinbefore described. A Luer fitting **194** is connected into the free end of the tubular member **191** and is utilized for introducing a saline solution into the balloon **186** for inflating the same.

The graft or patch **182** can have a desired configuration, as for example circular as shown in FIG. **20**. It is formed of a non-absorbable synthetic surgical mesh, as for example from polypropylene manufactured by Ethicon Inc. As shown, the mesh patch **182** overlies the sheet **187**.

The balloon assembly **182** with the patch **182** thereon can be rolled up into a roll **196** as shown in FIG. **22** in which the patch or graft **182** is disposed within the roll. The roll can be maintained in the roll configuration by sutures **197** wrapped about the same. The roll **196** can then be introduced through a side trocar **146** and introduced into the dissected preperitoneal space **136** with the tubular member **191** extending through the trocar **146** and having its Luer fitting **194** disposed outside of the trocar. After the roll **196** has been introduced, the sutures **197** can be removed and the balloon can be inflated by introducing a saline solution through the fitting **194** by use of a syringe **199**. Before the saline solution is introduced to inflate the balloon, the roll **196** is properly positioned so that when it is inflated and begins to unroll it will unroll in the proper direction so that the graft or patch **182** carried thereby is properly positioned as shown in FIG. **23**. After the roll **196** has been completely unrolled, continued inflation of the balloon **186** moves the patch **182** so that it is pressed against the portion of the fascia through which the hernia has occurred as shown in FIG. **24**. As soon as the graft **182** has been properly positioned, the balloon **186** is deflated. The trocar **146** is then removed, and thereafter the balloon can be withdrawn through the opening in which the trocar was present. Thereafter, the gas utilized for insufflation can be permitted to discharge through another trocar so that the fascia **131** comes into engagement with the peritoneum **132** with the large-area patch **182** held in place therebetween. Thereafter, the trocars can be removed in the manner hereinbefore described to complete the procedure.

Another embodiment of a balloon assembly for deploying a large-area patch or graft through a trocar is shown in FIG. **25**. The large-area graft **201** shown in FIG. **25** is formed of

a mesh material of the type hereinbefore described and has a generally oval-shaped configuration conforming to the general shape of the balloon **202** of the balloon assembly **203**. The balloon **202** is constructed of a non-elastomeric material in the manner hereinbefore described. A tubular member **206** is provided for inflating the balloon and has a Luer fitting **207** on the free end thereof. Means is provided for retaining the mesh graft **201** on one side of the balloon and consists of plastic flaps **208** provided on opposite sides of the balloon **202**, and secured thereto by a suitable means such as a heat seal along the broken line **209**. The inner margins of the flaps **208** are free and are adapted to receive the outer margins of the graft **201** as shown particularly in FIG. **25**.

The balloon **202** with the mesh graft **201** thereon can be rolled up into a substantially cylindrical roll **211** by rolling the outer margins of the balloon inwardly on top of the mesh material to provide two rolls **211** and **212** which are brought in adjacent to each other as shown in FIG. **26** with the mesh graft **201** being wrapped up therewith. The two rolls **211** and **212** can then be inserted into a tubular sheath **214**. The sheath **214** can then be introduced through a trocar in a manner hereinbefore described and then pushed out of the sheath into the abdominal cavity. The balloon can then be inflated with a saline solution to cause the two rolls **211** and **212** to unroll in opposite directions and then for the balloon to inflate to-move the patch **201** carried thereby into engagement with the portion of the fascia having the hernia therein. Thereafter, the balloon can be deflated, the trocar removed, the balloon removed, and the dissected preperitoneal space deflated so that the large mesh graft **201** is disposed between the fascia and the peritoneum and is retained in position therebetween.

Another embodiment of a graft which can be utilized in connection with the present invention is shown in FIG. **27**. The patch or graft **216** is constructed in a manner similar to the graft or patch **151** shown in FIGS. **12** and **13**, with the exception that it is constructed in a manner so that it can be utilized with a direct hernia rather than an indirect inguinal hernia hereinbefore described. The graft **216** is formed of a sheet of circular mesh in the form of a disk **217** with a reinforcing central disk **218** which has a barbed head **219** secured thereto. The barbed head **219** is formed of a biodegradable material such as polyglycolic acid. The mesh graft **216** can be folded over a deployment rod **221** and introduced into a cylindrical sheath **222** (see FIG. **28**) which is sized so that it can be introduced through a conventional trocar, then deployed from the sheath **22** by pushing on the deployment rod **221**. After the graft **216** has been deployed into the dissected preperitoneal space **136**, it can be positioned in an appropriate manner so that the barb **219** is positioned so that it is in alignment with the inguinal ring whereby upon deflation of the preperitoneal space **136**, the barb **219** will extend through the inguinal ring to serve to retain the graft **201** firmly in place.

Another embodiment of a laparoscopic apparatus incorporating the present invention is laparoscopic apparatus **231** as shown in FIGS. **29** through **32**. The laparoscopic apparatus **231** includes introducer sleeve or device **32** identical to that hereinbefore described. It also includes a tunneling shaft assembly **46** which is provided with a tunneling shaft or rod **47** and a proximal extremity **49** (see FIG. **32**). In the previous embodiment of the laparoscopic apparatus, the tunneling shaft assembly is provided with an olive-shaped or bullet-shaped tip **79** which was secured to the distal extremity **49** of the tunneling shaft **47**. In the present embodiment of the apparatus shown in FIGS. **29** through **32**, the obturator tip **79***a* is detachably mounted on the distal extremity **49** of the tunneling rod **47**. The proximal extremity of the tip **79***a* is provided with a slot **236** which extends through one side of the proximal extremity into the central portion of the proximal extremity of the tip **79***a*. The slot **236** is adapted to receive the rounded extremity **237** provided on the distal extremity **49** of the tunneling rod **47** (see FIG. **32**). A removable sleeve **241** is provided as a part of a laparoscopic apparatus **231**, and is similar in many respects to the removable sleeve or sheath **106** hereinbefore described. The removable sleeve **241** is formed of a suitable material such as Teflon as hereinbefore described and is provided with a tubular member **242** which is provided with a relatively thin wall **243** that has a weakened portion extending longitudinally thereof in the form of a slit **244** (see FIG. **31**). The tubular member **242** is provided with a proximal extremity **246** and a distal extremity **247**. The proximal extremity **246** has a thicker cross-section than the distal extremity **247**, as shown in FIGS. **31** and **32**. The proximal extremity **246** is provided with a recess **248** formed in the wall which is diametrically opposite the slit **244** that serves as a relief region to permit the movable sleeve **241** to be split apart when it is removed from the balloon.

The proximal extremity **246** is provided with wing-like members **251** and **252** which extend diametrically therefrom, spaced 90° apart from the slit **244**. These outstretched wings **251** and **252** serve to help the physician orient the laparoscopic apparatus **231** as it is being utilized. The proximal extremity **246** is also provided with a handle **256** which is formed integral therewith and which extends radially from the tubular member **242**. The handle **256** is provided with a finger hole **257** extending therethrough through which a finger can be inserted to facilitate pulling the removable sleeve **241** off of the balloon as described in connection with the previous embodiment.

As shown in FIG. **33**, the tip **79***a* is detachably mounted in the proximal extremity of the removable sleeve **241** so that the tip **79** can serve as a second obturator during introduction of the laparoscopic apparatus **231** as hereinbefore described. Means is provided for securing the detachable tip **79***a* to prevent it from becoming separated from the laparoscopic apparatus **231** and for permitting its withdrawal after the laparoscopic procedure is being completed. As shown in FIGS. **33** and **34**, such means consists of a flexible elongate element **261** in the form of a braided string formed of a suitable fabric such as Nylon, which has one end **262** secured in a slot **263** provided on the distal extremity of the tip **79***a* by suitable means such as an adhesive (not shown). The flexible elongate element **261** extends from the distal extremity of the tip **79***a* in a recess **264** opening through the external surfaces of the tip **79***a*. The proximal extremity of the flexible elongate element **261** can be secured directly to the balloon **87** or, alternatively, it can extend through the perforated sleeve **101** provided in the balloon along the tunneling shaft so that it extends beyond the proximal extremity of the tunneling shaft.

The use of the laparoscopic apparatus **231** in performing a laparoscopic procedure is substantially identical to that hereinbefore described with the exception that when the removable sleeve **241** is removed from the balloon **87**, the removable sleeve can be pushed forwardly to detach the tip **79***a* from the tunneling shaft **47**. The removable sleeve **241** then can be pulled rearwardly to separate it from the balloon along the slit **244**. As soon as this occurs, the tip **79** becomes free of the sleeve and begins to rotate in the direction of the arrow **266** shown in FIG. **34**. When the balloon has been inflated and has performed its functions as hereinbefore

described and it is now desired to remove the balloon **87**, the balloon **87** can be withdrawn in the manner hereinbefore described, and since the tip **79***a* is tethered to the balloon **87** itself or flexible elongate element **261** attached thereto extends out proximally of the balloon **87**, the tip **79***a* is withdrawn or can be withdrawn with the balloon **87**.

This laparoscopic apparatus **231** with its detachable obturator tip **79***a* will be useful in certain applications of the present invention. With the previous laparoscopic apparatus hereinbefore described, there is a possibility that when the obturator tip **79** is withdrawn, critical structures, as for example small arteries, may be inadvertently incised between the tip **79** and the distal extremity of the tubular member **33** of the introducer device **32**. This possibility is eliminated by having the detachable tip **79***a*, which is withdrawn when the balloon is withdrawn.

Still another embodiment of the laparoscopic apparatus incorporating the present invention is shown in FIGS. **36**, **37** and **38**, in which the laparoscopic apparatus **271** consists of a balloon **272** of the type hereinbefore described, which is provided with a perforated sleeve **273** through which the tunneling rod **47** extends. The distal extremity **274** of the sleeve is closed by an end piece **276**. The balloon **272** is wrapped in the manner hereinbefore described around the tunneling shaft **247**. The tunneling shaft or rod **47** is not provided with a tunneling member or second obturator of the type hereinbefore described but its end is rounded as shown by providing a rounded tip **47***a*.

The wrapped balloon **272** is enclosed within a removable sleeve **281** which is similar to those hereinbefore described. It is provided with a tubular member **282** that has a weakened region in the form of a slit **283** extending longitudinally the length thereof. The removable sleeve **281** differs from those hereinbefore described in that rather than being open at the end as in previous embodiments, it is provided with a closed-end, bullet-shaped or olive-shaped tip **286**. The slit **283** is provided with a curved portion **283***a* which extends through the bullet-shaped tip **286** so that the sleeve can be peeled off of the balloon **272** in the manner hereinbefore described by pulling on the handle **288** having a finger hole **289** therein. During the time that the removable sleeve **281** is being peeled off or separated from the balloon **272**, the balloon is held in place by the tunneling rod **47** which engages the end **276** of the perforated sleeve **273**. The balloon **272** after it is inflated can be separated from the tunneling rod **47** by pulling on the balloon and causing its distal extremity to lift up and to break apart at the perforations and peel away from the rounded extremities **47***a* of the tunneling shaft **47** as shown in FIG. **38**. Continued pulling on the balloon **272** will cause it to separate from the tunneling rod **47** so that the balloon **272** can be removed as hereinbefore described. Thus, it can be seen that there has been provided an embodiment of the laparoscopic apparatus of the present invention in which the need for an obturator carried by the distal extremity of the tunneling rod **47** has been eliminated by providing the second obturator as a part of the removable sleeve **281**. In all other respects, the operation and use of the laparoscopic apparatus **271** is similar to that hereinbefore described.

From the foregoing it can be seen that there has been provided an apparatus and method for developing an anatomic space by the use of a wrapped balloon which, as it is inflated, gradually unwraps to tend to form a plane to cause forces to be created perpendicular to the plane for pulling apart tissue along a natural plane to provide an anatomic space, thereby providing a dissection in the weakest plane creating a more natural, less traumatic and bloodless region in which to perform various medical procedures. Such anatomic spaces can be created in various parts of the human body, for example in the preperitoneal area to provide a space anterior to the peritoneum for hernia repair and for varocele dissection. Spaces can also be developed lateral to the peritoneum and spaces posterior to the peritoneum for performing medical procedures such as a sympathectomy and a lymph node dissection.

As hereinbefore explained, the apparatus and method is particularly appropriate for performing laparoscopic hernia repair, permitting the use of grafts and patches which can be used for direct and indirect hernias with minimal pain to the patient and with the patient being able to return to work within a few days.

What is claimed is:

1. In a method for laparoscopic hernia repair through the preperitoneal space of a patient having an abdominal area with overlying tissue and a peritoneum with a preperitoneal area being disposed between the overlying tissue and the peritoneum using laparoscopic apparatus having an introducer device with a tubular member having a bore therein, a tunneling assembly disposed in the bore and a balloon wrapped about a tunneling shaft and a removable sleeve enclosing the balloon, the method comprising the steps of making an incision in the abdominal area, introducing the laparoscopic apparatus into the incision so that the tubular member of the introducer device is disposed in the preperitoneal area, advancing the tunneling shaft with the balloon thereon to separate the overlying tissue from the peritoneum, removing the sleeve to expose the balloon, inflating the balloon with a balloon inflating medium to create a dissected preperitoneal space between the peritoneum and the overlying tissue, deflating the balloon, removing the balloon, insufflating the dissected preperitoneal space with a gas, introducing a graft into the dissected preperitoneal space, positioning the graft in the desired location, and deflating the preperitoneal space to permit the graft to come into contact with tissue overlying the peritoneum, removing the introducer device and closing the incision.

2. A method as in claim **1** together with the step of introducing the graft into the dissected preperitoneal space with an additional balloon as the additional balloon is introduced in the dissected preperitoneal space.

3. A method as in claim **2** together with the step of forming the additional balloon and the graft into at least one roll and wherein the additional balloon and the graft are introduced into the dissected preperitoneal space as a roll.

4. A method as in claim **3** together with the step of causing the additional balloon to unroll in a single direction as it is inflated.

5. A method as in claim **3** wherein the additional balloon is unrolled in first and second directions as the additional balloon is inflated.

* * * * *

专利名称(译)	用于开发用于腹腔镜疝修补的解剖学空间的装置和方法以及与其一起使用的贴片		
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摘要(译)

用于插入身体中的空间或潜在空间的腹腔镜设备和方法，包括具有管状构件的导引器装置，所述管状构件具有穿过其延伸的孔。提供了一种隧道轴组件，该隧道轴组件可滑动地安装在导引装置的孔中。隧道轴组件包括具有近端和远端的隧道轴。隧道构件安装在隧道轴的远端上。提供了一种球囊组件，其可拆卸地固定到隧道轴上。球囊组件包括围绕所述隧道轴缠绕的球囊。提供护套，其将球囊包围在隧道轴上。护套具有纵向延伸的狭缝，允许护套被移除，由此球囊可以被释放和膨胀。提供管状构件，其上具有球囊膨胀腔并且连接到球囊以使所述球囊膨胀。