

# US Patent & Trademark Office

## Patent Public Search | Text View

---

United States Patent	12390209
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	Do; Alexandra et al.

---

### Systems and methods for tissue removal

---

#### Abstract

A guard for providing a cut-resistant pathway through a body orifice or incision to circumferentially protect tissue at the margin is provided. The guard is made of flexible, cut-resistant mesh material having a plurality of interwoven thermosoftening filaments. The guard has a central lumen and at least one flared end. The flared end, which serves to anchor the guard in the body opening, is deformable into a reduced configuration to facilitate its insertion and removal. The layer of mesh stretches laterally to increase the diameter of the central lumen. The flexibility and expandability of the guard allows the guard to conform to body openings of different sizes. The guard may include a drawstring to cinch the flared distal end from the proximal end. The guard is thermoset with the flared distal end that is biased to spring back to its normal, undeformed configuration when released from a deformed configuration.

---

**Inventors:** Do; Alexandra (San Clemente, CA), Pravong; Boun (Rancho Santa Margarita, CA), Wachli; Serene (Rancho Santa Margarita, CA)

**Applicant:** Applied Medical Resources Corporation (Rancho Santa Margarita, CA)

**Family ID:** 1000008766677

**Assignee:** Applied Medical Resources Corporation (Rancho Santa Margarita, CA)

**Appl. No.:** 18/458318

**Filed:** August 30, 2023

#### Prior Publication Data

Document Identifier	Publication Date
US 20230397932 A1	Dec. 14, 2023

#### Related U.S. Application Data

continuation parent-doc US 16773639 20200127 US 11744612 child-doc US 18458318  
continuation parent-doc US 15348089 20161110 US 10568659 20200225 child-doc US 16773639

Publication Classification

**Int. Cl.:** **A61B17/02** (20060101); **A61B17/00** (20060101); **A61B17/34** (20060101); **B29C51/00** (20060101); **B29C67/00** (20170101); A61B17/3211 (20060101); A61B90/00 (20160101); B29C33/48 (20060101); B29C57/02 (20060101)

U.S. Cl.:

CPC **A61B17/0281** (20130101); **A61B17/0293** (20130101); **A61B17/3423** (20130101); **B29C51/004** (20130101); **B29C67/0022** (20130101); A61B2017/00287 (20130101); A61B2017/00526 (20130101); A61B17/0218 (20130101); A61B2017/0225 (20130101); A61B2017/0287 (20130101); A61B17/3211 (20130101); A61B2017/3429 (20130101); A61B17/3431 (20130101); A61B17/3439 (20130101); A61B2090/08021 (20160201); B29C33/485 (20130101); B29C57/02 (20130101)

Field of Classification Search

**CPC:** A61B (17/02); A61B (17/0218); A61B (17/0293); A61B (17/0281); A61B (2017/0225); A61B (2017/0287)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
1550403	12/1924	Turkus	N/A	N/A
2013892	12/1934	Lucas	N/A	N/A
2812758	12/1956	Blumenschein	N/A	N/A
3244169	12/1965	Baxter	N/A	N/A
3762417	12/1972	Textor	N/A	N/A
3807393	12/1973	McDonald	N/A	N/A
4120301	12/1977	Lovick	N/A	N/A
4411655	12/1982	Schreck	N/A	N/A
4553537	12/1984	Rosenberg	N/A	N/A
4573452	12/1985	Greenberg	N/A	N/A
5037379	12/1990	Clayman et al.	N/A	N/A
5143082	12/1991	Kindberg et al.	N/A	N/A
5176659	12/1992	Mancini	N/A	N/A
5213114	12/1992	Bailey, Jr.	N/A	N/A
5215101	12/1992	Jacobs et al.	N/A	N/A
5215521	12/1992	Cochran et al.	N/A	N/A
5224930	12/1992	Spaeth et al.	N/A	N/A
5231974	12/1992	Giglio et al.	N/A	N/A
5308327	12/1993	Heaven et al.	N/A	N/A
5312416	12/1993	Spaeth et al.	N/A	N/A
5320627	12/1993	Sorensen et al.	N/A	N/A
5330483	12/1993	Heaven et al.	N/A	N/A

5337754	12/1993	Heaven et al.	N/A	N/A
5354303	12/1993	Spaeth et al.	N/A	N/A
5368545	12/1993	Schaller et al.	N/A	N/A
5465731	12/1994	Bell et al.	N/A	N/A
5486183	12/1995	Middleman et al.	N/A	N/A
RE35164	12/1995	Kindberg et al.	N/A	N/A
5520610	12/1995	Giglio et al.	N/A	N/A
5611803	12/1996	Heaven et al.	N/A	N/A
5618296	12/1996	Sorensen et al.	N/A	N/A
5636639	12/1996	Turturro et al.	N/A	N/A
5647372	12/1996	Tovey et al.	N/A	N/A
5649550	12/1996	Crook	N/A	N/A
5669927	12/1996	Boebel et al.	N/A	N/A
5769794	12/1997	Conlan et al.	N/A	N/A
5785677	12/1997	Auweiler	N/A	N/A
5788709	12/1997	Riek et al.	N/A	N/A
5810721	12/1997	Mueller et al.	N/A	N/A
5836936	12/1997	Cuschieri	N/A	N/A
5895392	12/1998	Riek et al.	N/A	N/A
5957884	12/1998	Hooven	N/A	N/A
5971995	12/1998	Rousseau	N/A	N/A
6036681	12/1999	Hooven	N/A	N/A
6039748	12/1999	Savage et al.	N/A	N/A
6045566	12/1999	Pagedas	N/A	N/A
6048309	12/1999	Flom et al.	N/A	N/A
6059793	12/1999	Pagedas	N/A	N/A
6142935	12/1999	Flom et al.	N/A	N/A
6162172	12/1999	Cosgrove et al.	N/A	N/A
6206889	12/2000	Bernardo	N/A	N/A
6228095	12/2000	Dennis	N/A	N/A
6254534	12/2000	Butler et al.	N/A	N/A
6258102	12/2000	Pagedas	N/A	N/A
6270505	12/2000	Yoshida et al.	N/A	N/A
6350267	12/2001	Stefanchik	N/A	N/A
6382211	12/2001	Crook	N/A	N/A
6387102	12/2001	Pagedas	N/A	N/A
6406440	12/2001	Stefanchik	N/A	N/A
6569105	12/2002	Kortenbach et al.	N/A	N/A
6685628	12/2003	Vu	N/A	N/A
6814700	12/2003	Mueller et al.	N/A	N/A
6958037	12/2004	Ewers et al.	N/A	N/A
7041055	12/2005	Young et al.	N/A	N/A
7238154	12/2006	Ewers et al.	N/A	N/A
7297106	12/2006	Yamada et al.	N/A	N/A
7377898	12/2007	Ewers et al.	N/A	N/A
7491168	12/2008	Raymond et al.	N/A	N/A
7537564	12/2008	Bonadio et al.	N/A	N/A
7547310	12/2008	Whitfield	N/A	N/A
7670346	12/2009	Whitfield	N/A	N/A
7758500	12/2009	Boyd et al.	N/A	N/A

7758501	12/2009	Frasier et al.	N/A	N/A
7762969	12/2009	Bilsbury	N/A	N/A
7896877	12/2010	Hall et al.	N/A	N/A
7955292	12/2010	Leroy et al.	N/A	N/A
7981130	12/2010	Seeh	N/A	N/A
7998068	12/2010	Bonadio et al.	N/A	N/A
8016771	12/2010	Orban, III	N/A	N/A
8016839	12/2010	Wilk	N/A	N/A
8038611	12/2010	Raymond et al.	N/A	N/A
8075567	12/2010	Taylor et al.	N/A	N/A
8100928	12/2011	Nohilly et al.	N/A	N/A
8114119	12/2011	Spivey et al.	N/A	N/A
8152820	12/2011	Mohamed et al.	N/A	N/A
8157834	12/2011	Conlon	N/A	N/A
8337510	12/2011	Rieber et al.	N/A	N/A
8366754	12/2012	Teague et al.	N/A	N/A
8409112	12/2012	Wynne et al.	N/A	N/A
8409216	12/2012	Parihar et al.	N/A	N/A
8414596	12/2012	Parihar et al.	N/A	N/A
8425533	12/2012	Parihar et al.	N/A	N/A
8517935	12/2012	Marchek et al.	N/A	N/A
8579914	12/2012	Menn et al.	N/A	N/A
8597180	12/2012	Copeland et al.	N/A	N/A
8622897	12/2013	Raymond et al.	N/A	N/A
8721538	12/2013	Bucholz	N/A	N/A
8721658	12/2013	Kahle et al.	N/A	N/A
8734336	12/2013	Bonadio et al.	N/A	N/A
8777849	12/2013	Haig et al.	N/A	N/A
8821377	12/2013	Collins	N/A	N/A
8857440	12/2013	Gundlapalli et al.	N/A	N/A
8864658	12/2013	Wilkins et al.	N/A	N/A
8920431	12/2013	Shibley et al.	N/A	N/A
8956286	12/2014	Shibley et al.	N/A	N/A
8961408	12/2014	Wilkins et al.	N/A	N/A
8961409	12/2014	O'Prey et al.	N/A	N/A
9039610	12/2014	Wilkins et al.	N/A	N/A
9044210	12/2014	Hoyte et al.	N/A	N/A
9168031	12/2014	Copeland et al.	N/A	N/A
2003/0078478	12/2002	Bonadio et al.	N/A	N/A
2004/0097960	12/2003	Terachi et al.	N/A	N/A
2004/0158261	12/2003	Vu	N/A	N/A
2005/0171405	12/2004	Rowland et al.	N/A	N/A
2005/0197537	12/2004	Bonadio et al.	N/A	N/A
2005/0267492	12/2004	Poncet et al.	N/A	N/A
2006/0200169	12/2005	Sniffin	N/A	N/A
2006/0200170	12/2005	Aranyi	N/A	N/A
2006/0247498	12/2005	Bonadio et al.	N/A	N/A
2007/0051375	12/2006	Milliman	N/A	N/A
2007/0135780	12/2006	Pagedas	N/A	N/A
2007/0161866	12/2006	Fowler et al.	N/A	N/A

2007/0161867	12/2006	Fowler et al.	N/A	N/A
2007/0219549	12/2006	Marshall et al.	N/A	N/A
2008/0097163	12/2007	Butler et al.	N/A	N/A
2008/0262318	12/2007	Gorek et al.	N/A	N/A
2009/0138024	12/2008	Ichihara et al.	N/A	N/A
2009/0264710	12/2008	Chana et al.	N/A	N/A
2009/0326330	12/2008	Bonadio et al.	N/A	N/A
2010/0219091	12/2009	Turner	N/A	N/A
2011/0054260	12/2010	Albrecht et al.	N/A	N/A
2011/0184311	12/2010	Parihar et al.	N/A	N/A
2011/0184435	12/2010	Parihar et al.	N/A	N/A
2011/0190779	12/2010	Gell et al.	N/A	N/A
2011/0319719	12/2010	O'Prey et al.	N/A	N/A
2012/0078264	12/2011	Taylor et al.	N/A	N/A
2012/0083795	12/2011	Fleming et al.	N/A	N/A
2012/0109144	12/2011	Chin et al.	N/A	N/A
2012/0157777	12/2011	Okoniewski	N/A	N/A
2012/0238823	12/2011	Hagerty et al.	N/A	N/A
2012/0245429	12/2011	Smith	N/A	N/A
2012/0253134	12/2011	Smith	N/A	N/A
2012/0316572	12/2011	Rosenblatt et al.	N/A	N/A
2013/0072759	12/2012	Li et al.	N/A	N/A
2013/0103042	12/2012	Davis	N/A	N/A
2013/0103043	12/2012	Cabrera	N/A	N/A
2013/0131457	12/2012	Seckin	N/A	N/A
2013/0138115	12/2012	Seckin	N/A	N/A
2013/0172684	12/2012	Smith	N/A	N/A
2013/0184536	12/2012	Shibley et al.	N/A	N/A
2013/0190574	12/2012	Smith	N/A	N/A
2013/0253267	12/2012	Collins	N/A	N/A
2013/0284186	12/2012	Touati	N/A	N/A
2014/0052018	12/2013	Hawkins	N/A	N/A
2014/0058210	12/2013	Raymond et al.	N/A	N/A
2014/0058403	12/2013	Menn et al.	N/A	N/A
2014/0135788	12/2013	Collins	N/A	N/A
2014/0235952	12/2013	Haig et al.	N/A	N/A
2014/0236110	12/2013	Taylor et al.	N/A	N/A
2014/0296649	12/2013	Fehling et al.	N/A	N/A
2014/0316210	12/2013	Koehler et al.	N/A	N/A
2014/0330285	12/2013	Rosenblatt et al.	N/A	N/A
2015/0005584	12/2014	Wilkins et al.	N/A	N/A
2015/0018625	12/2014	Miraki et al.	N/A	N/A
2015/0094541	12/2014	Wilkins et al.	N/A	N/A
2015/0119647	12/2014	Vaillancourt et al.	N/A	N/A
2015/0164552	12/2014	Chen et al.	N/A	N/A

#### FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
4405831	12/1994	DE	N/A
102009014525	12/2009	DE	N/A

202013102186	12/2012	DE	N/A
102013217513	12/2014	DE	N/A
1 312 318	12/2002	EP	N/A
1 935 356	12/2003	EP	N/A
2 138 113	12/2008	EP	N/A
2 228 014	12/2009	EP	N/A
2 359 758	12/2010	EP	N/A
2 668 907	12/2012	EP	N/A
WO 00/32116	12/1999	WO	N/A
WO 00/47117	12/1999	WO	N/A
WO 03/061480	12/2002	WO	N/A
WO 03/071926	12/2002	WO	N/A
WO 2004/075730	12/2003	WO	N/A
WO 2008/083222	12/2007	WO	N/A
WO 2011/143410	12/2010	WO	N/A
WO 2013/093030	12/2012	WO	N/A
WO 2013/150391	12/2012	WO	N/A
WO 2015/164591	12/2014	WO	N/A

## OTHER PUBLICATIONS

European Patent Office, Extended European Search Report for European Patent Application No. EP 24177467.8, titled “Systems and Methods for Tissue Removal,” dated Sep. 9, 2024, 7 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 24202663.1, titled “Systems and Methods for Tissue Removal,” dated Oct. 28, 2024, 8 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 24206756.9, titled “Systems and Methods for Tissue Removal,” dated Dec. 6, 2024, 8 pgs. cited by applicant

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2015/045705, entitled “Systems and Methods for Tissue Containment and Retrieval,” mailed Apr. 18, 2016, 18 pgs. cited by applicant

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2015/056978, entitled “Systems and Methods for Tissue Removal,” mailed Jan. 15, 2016. cited by applicant

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2015/027274, entitled “Suture Clinch with Traction Enhanced,” mailed Jul. 10, 2015. cited by applicant

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2016/029154, entitled “Systems and Methods for Tissue Removal,” mailed Aug. 19, 2016, 17 pgs. cited by applicant

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2015/027274, entitled “Systems and Methods for Tissue Removal,” dated Nov. 3, 2016, 9 pgs. cited by applicant

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2015/045705, entitled “Systems and Methods for Tissue Containment and Retrieval,” dated Mar. 2, 2017, 10 pgs. cited by applicant

European Patent Office, Invitation to Pay Additional Fees for International Application No. PCT/US2017/014402, titled “Systems and Methods for Tissue Removal”, mailed Apr. 6, 2017, 10 pgs. cited by applicant

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2015/056978, entitled “Systems and Methods for Tissue Removal,” dated May 26, 2017, 10 pgs. cited by applicant

European Patent Office, The International Search Report and Written Opinion for International Application No. PCT/US2017/014402, entitled “Systems and Methods for Tissue Removal,” mailed Jun. 6, 2017, 20 pgs. cited by applicant

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2016/029154, entitled “Systems and Methods for Tissue Removal,” dated Nov. 2, 2017, 11pgs. cited by applicant

The International Bureau of WIPO, International Preliminary Report on Patentability for International Application No. PCT/US2017/014402, entitled “Systems and Methods for Tissue Removal,” dated Aug. 2, 2018, 11pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 2 0165706.1, titled “Systems and Methods for Tissue Removal,” dated Jul. 9, 2020, 8 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 21163226.0, titled “Systems and Methods for Tissue Removal,” dated Jul. 8, 2021, 9 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 21178022.6, titled “Systems and Methods for Tissue Removal,” dated Sep. 16, 2021, 8 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 22193556.2, titled “Systems and Methods for Tissue Removal,” dated Dec. 12, 2022, 7 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 22195819.2, titled “Systems and Methods for Tissue Containment and Retrieval,” dated Dec. 5, 2022, 8 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 23170203.6, titled “Systems and Methods for Tissue Removal,” dated Jun. 28, 2023, 8 pgs. cited by applicant

European Patent Office, Extended European Search Report for European Patent Application No. EP 23191457.3, titled “Systems and Methods for Tissue Removal,” dated Nov. 3, 2023, 8 pgs. cited by applicant

---

*Primary Examiner:* Hammond; Ellen C

---

## **Background/Summary**

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent application Ser. No. 16/773,639 filed on Jan. 27, 2020 entitled “Systems and methods for tissue removal” which is a continuation of U.S. patent application Ser. No. 15/348,089 filed on Nov. 10, 2016, now U.S. Pat. No. 10,568,659, entitled “Systems and methods for tissue removal” which is a continuation of International Patent Application No. PCT/US2016/29154 filed on Apr. 25, 2016 entitled “Systems and methods for tissue removal” which claims priority to and benefit of U.S. Provisional Patent Application No. 62/151,736 entitled “Systems and methods for tissue removal” filed on Apr. 23, 2015 all of which are incorporated herein by reference in their entirety.

## FIELD OF THE INVENTION

(1) This invention relates to medical devices, and in particular, to systems and methods for the removal of tissue through a body opening.

## BACKGROUND OF THE INVENTION

(2) Systems and methods for the surgical removal of tissue through body openings such as small incision sites and/or body orifices are described. Where needed, a small incision is made in a patient to access surgically targeted tissue located inside a body cavity. Surgically targeted tissue may also be approached through a body orifice without an initial incision. Sometimes the targeted tissue is approached directly through the incision or body orifice. Other times, an access device system is placed and/or positioned into, across, at, and/or within the incision and/or body orifice to retract tissue, enlarge, reshape, and/or isolate the incision or body orifice. The access device system serves as a portal for accessing targeted tissue that is located in or adjacent to the body cavity or body orifice. The targeted tissue is detached from adjacent and surrounding tissue employing known surgical techniques and procedures. Once freed, the targeted tissue is ready for removal through the small incision or body orifice. If the targeted tissue is too large to be removed in whole, then it is reduced in size and removed in parts through the small incision. Ideally, the surgeon will “core” or “peel” the targeted tissue to keep it in one piece as much as possible. However, more likely than not, the targeted tissue will be reduced into multiple pieces.

(3) Reducing the size of the targeted tissue is called morcellation. A morcellation procedure includes cutting the targeted tissue into smaller pieces manually with a scalpel or knife, for example, or employing a power morcellator to cut the targeted tissue so that it is removable through the small incision. Pieces of the targeted tissue are removed from the patient through the small incision. As the targeted tissue is being reduced in size in order to fit through the small incision, small pieces of tissue may be cut off and left behind in the patient. As such, morcellation is contraindicated in cases of malignancy or endometriosis. If cancer is morcellated, it can spread malignant tissue and upstage cancer and increase patient mortality.

(4) A hysterectomy is an example of a surgical procedure that may involve morcellation. More than 500,000 hysterectomies are performed annually on women in the United States. Common reasons that a woman may have a hysterectomy are the presence of fibroids, cancer, endometriosis or prolapse. Of these hysterectomies, about 200,000 are performed laparoscopically. When the uterus is too large (>300 g) to be removed through the vagina or if the cervix is still in place, the specimen must be reduced in size to be removed through an abdominal incision or through the vagina. During myomectomy (fibroid removal), large fibroids may also need to be extracted using a morcellation procedure. During morcellation, the targeted tissue (usually a uterus and sometimes adnexal structures) is brought to the abdominal wall surface such as with a tissue grasper and is reduced in size using a blade and removed through the incision from the pelvic cavity. In another variation, the targeted tissue is removed through a body orifice such as through the vagina. Fibroids, or uterine leiomyoma, account for about 30-40% of hysterectomies. These are benign tumors of the uterus that can lead to heavy and painful bleeding. In the past there has been a mild concern that these tumors could be undetected cancer, or Leiomyosarcoma, and it was believed to affect about 1 in 10,000 women. More recent data has come out to support a much higher risk of undetected malignancy in these tumors, putting the range at 1:1000 to 1:400. Because of this elevated risk, many surgeons have begun changing their technique to try to enclose the specimen to do a closed morcellation process by morcellating in a bag to contain errant pieces and prevent dispersion and seeding of tumor cells, rather than morcellating without a bag in a process called open morcellation. Many GYN societies, including AAGL, ACOG, and SGO, have released statements warning of the potential danger of open morcellation. On Apr. 17, 2014, the FDA issued a statement discouraging the use of open power morcellation for hysterectomies and myomectomies for women undergoing these procedures for fibroids. The FDA also increased their



estimated of malignant likelihood to 1 in 350. For these reasons, systems and methods are needed to safely and effectively reduce tissue specimens. The present invention sets forth such safe systems and methods for both manual morcellation and power morcellation performed in closed system.

## SUMMARY OF THE INVENTION

(5) According to one aspect of the invention, a guard for providing a cut-resistant pathway through a body opening to protect a tissue margin is provided. The guard includes a sidewall having a tubular shape defining a central lumen. The central lumen extends along a longitudinal axis between a proximal opening at a proximal end and a distal opening at a distal end. The sidewall is made of at least one layer of flexible, cut-resistant mesh material having a plurality of interwoven filaments defining interstices. The sidewall has a generally hourglass shape when in a normal, undeformed configuration with a progressively increasing central lumen toward the proximal end defining a proximal flange in the sidewall and a progressively increasing central lumen toward the distal end defining a distal flange in the sidewall. The proximal flange is configured to anchor the guard with respect to a proximal end of the tissue margin and the distal flange is configured to anchor the guard with respect to a distal end of the tissue margin. The sidewall circumferentially protects the tissue margin along the body opening. The sidewall has a neck portion located between the proximal flange and the distal flange. The sidewall is deformable from the normal, undeformed configuration and biased to return to the normal, undeformed configuration when released.

(6) According to another aspect of the invention, a guard for providing a cut-resistant pathway through a body opening defining a tissue margin is provided. The guard includes a sidewall having a tubular shape defining a central lumen extending along a longitudinal axis between a first end and a second end. The sidewall is made of cut-resistant mesh material having a plurality of interwoven filaments defining interstices in a tubular first layer of mesh material. The sidewall is folded to create a fold at a distal end of the guard with the first end and the second end of the sidewall being adjacent to each other at a proximal end of the guard. The folded sidewall forming a tubular second layer of mesh material substantially coaxial with the tubular first layer of mesh material.

(7) According to another aspect of the invention, a guard for protecting a tissue margin along a body opening is provided. The guard includes a tube of cut-resistant mesh material having a plurality of woven polymer filaments. The tube has a first end and a second end and defining a central lumen along a longitudinal axis. The tube has a normal, undeformed shape having at least one flange formed at one of the first end and the second end. The at least one flange extending circumferentially outwardly from the longitudinal axis defining a progressively increasing diameter. The tube includes a neck portion located between the proximal end and the distal end. The neck portion has a diameter that is smaller than the diameter of the at least one flange. The at least one flange is configured to fold distally to a reduced configuration in which the flange has smaller lateral dimension relative to the normal, undeformed shape.

(8) According to another aspect of the invention, a guard for providing a cut-resistant pathway through a body opening to protect a tissue margin is provided. The guard includes a sidewall having a tubular shape defining a central lumen. The central lumen extends along a longitudinal axis between a proximal opening at a proximal end and a distal opening at a distal end. The sidewall is made of at least one layer of flexible, cut-resistant mesh material having a plurality of interwoven filaments defining interstices. The sidewall has a distal portion with a progressively increasing diameter toward the distal end defining a flared distal flange in the sidewall. The distal flange is configured to anchor the guard with respect to a distal end of the tissue margin. The sidewall circumferentially protects the tissue margin along the body opening. The sidewall has a neck portion located proximally to the distal flange. The guard includes a pull-wire located circumferentially around the distal flange and configured to reduce a lateral dimension of the distal flange when pulled into a reduced configuration to facilitate insertion and removal of the guard when in the reduced configuration.

(9) According to another aspect of the invention, a method for manufacturing a tissue guard is provided. The method includes the step of providing a tube of flexible mesh material having a plurality of interwoven filaments defining interstices. The tube is substantially cylindrical in shape having a central lumen extending along the longitudinal axis between a proximal opening at a proximal end and a distal opening at a distal end. A mandrel is provided having at least one outwardly flared flange. The mesh tube is mounted onto the mandrel such that the mandrel is located inside the central lumen and the tube encompasses the mandrel. The mesh tube is heated while the mesh tube is located on the mandrel. The filaments are plastically deformed when heated so that the mesh tube substantially conforms to the shape of the mandrel when the mesh tube is removed from the mandrel. The mesh tube is removed from the mandrel.

---

## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

- (1) FIG. 1 is a top perspective view of a surgical scalpel and a mesh guard according to the present invention.
- (2) FIG. 2 is a top perspective view of a mesh guard according to the present invention.
- (3) FIG. 3 is a top perspective view of a mesh guard according to the present invention.
- (4) FIG. 4 is a bottom perspective view of a mesh guard according to the present invention.
- (5) FIG. 5 is a side view of a mesh guard according to the present invention.
- (6) FIG. 6 is a side view of a mesh guard with the distal end compressed by a hand according to the present invention.
- (7) FIG. 7 is a partial sectional view of one layer of a mesh braid of a sidewall of a mesh guard according to the present invention.
- (8) FIG. 8 is a partial sectional view of two layers of a mesh braid of a sidewall of a mesh guard according to the present invention.
- (9) FIG. 9 is a top perspective view of a mold for a mesh guard according to the present invention.
- (10) FIG. 10 is a top perspective view of a two-part mold for a mesh guard according to the present invention.
- (11) FIG. 11 is a top perspective view of a mold for a mesh guard according to the present invention.
- (12) FIG. 12 is a top perspective view of a two-part mold for a mesh guard according to the present invention.
- (13) FIG. 13 is a top view of two mesh guards with different lumen diameters at the narrowest section along the longitudinal axis according to the present invention.
- (14) FIG. 14 is a top perspective view of a mesh guard according to the present invention.
- (15) FIG. 15 is a side view of a mesh guard with an injection molded proximal ring according to the present invention.
- (16) FIG. 16 is a cross-sectional side view of a mesh guard with an injection molded proximal ring according to the present invention.
- (17) FIG. 17 is a top perspective view of a mesh guard with an injection molded proximal ring according to the present invention.
- (18) FIG. 18 is a side view of a mesh guard with an extruded proximal ring according to the present invention.
- (19) FIG. 19 is a cross-sectional side view of mesh guard with an extruded proximal ring according to the present invention.
- (20) FIG. 20 is a side view of a mesh guard with an over-molded ring according to the present invention.
- (21) FIG. 21 is a cross-sectional side view of a mesh guard with an over-molded ring according to

the present invention.

(22) FIG. 22 is a top perspective of a mesh guard with an over-molded ring according to the present invention.

(23) FIG. 23 is a top view of a mesh guard with an over-molded ring according to the present invention.

(24) FIG. 24 is a top perspective view of a casting dish for forming an over-molded ring according to the present invention.

(25) FIG. 25 is a side view of a mesh guard with a proximal bead ring according to the present invention.

(26) FIG. 26 is a cross-sectional side view of a mesh guard with a bead ring according to the present invention.

(27) FIG. 27 is a side view of a mesh guard with a heat sealed proximal ring according to the present invention.

(28) FIG. 28 is a cross-sectional side view of a mesh guard with a heat sealed proximal ring according to the present invention.

(29) FIG. 29 is a cross-sectional view of a containment bag and guard placed in an opening in a body wall according to the present invention.

(30) FIG. 30 is a side elevational, sectional view of a guard and retractor according to the present invention.

(31) FIG. 31 is a top view of a guard and retractor according to the present invention.

(32) FIG. 32 is a bottom perspective view of a guard with tether according to the present invention.

(33) FIG. 33 is a top perspective view of a guard with tether according to the present invention.

(34) FIG. 34 is a bottom perspective view of a guard with tether according to the present invention.

(35) FIG. 35 is a side elevational view of a guard according to the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

(36) The following description is provided to enable any person skilled in the art to make and use the surgical tools and perform the methods described herein and sets forth the best modes contemplated by the inventors of carrying out their inventions. Various modifications, however, will remain apparent to those skilled in the art. It is contemplated that these modifications are within the scope of the present disclosure. Different embodiments or aspects of such embodiments may be shown in various figures and described throughout the specification. However, it should be noted that although shown or described separately each embodiment and aspects thereof may be combined with one or more of the other embodiments and aspects thereof unless expressly stated otherwise. It is merely for easing readability of the specification that each combination is not expressly set forth.

(37) Turning now to FIGS. 1-4, there is shown a mesh guard **10** according to the present invention. In FIG. 1, a surgical scalpel **11** with a sharp blade **13** is shown against the mesh guard **10** to illustrate the cut-resistant properties of the mesh guard **10**. The mesh guard **10** includes a sidewall **16** that extends between a proximal end **12** and a distal end **14**. The sidewall **16** has an inner surface **18** and an outer surface **20** and a thickness therebetween. The mesh guard **10** includes a central lumen **22** that extends along a longitudinal axis **24** between the proximal end **12** and the distal end **14**. The central lumen **22** defines a proximal opening **26** at the proximal end **12** and a distal opening **28** at the distal end. The lateral dimension of the mesh guard **10** lies in planes perpendicular to the longitudinal axis **24**.

(38) At the proximal end **12**, the mesh guard **10** has a flared, funnel-like, trumpet-like or horn-like shape formed by the sidewall **16** extending laterally outwardly away from the longitudinal axis **24** to form a smooth radial extension or top flange **30**. Similarly, the distal end **14** also has a flared, funnel-like, trumpet-like or horn-like shape formed by the sidewall **16** extending laterally outwardly away from the longitudinal axis **24** to form a radial extension or bottom flange **32**. The top flange **30** serves as an apron of protection when inserted into a body opening. The top flange **30**

further acts as a cutting board surface against which tissue may be cut with a blade in confidence without damage to underlying, adjacent tissue, containment bag or retractor. The top flange **30** overlays the body at the margins of a body opening, orifice or incision site. If not used directly as a cutting surface, the top flange **30** serves as a protective backdrop to cutting taking place above the top flange **30**, thereby, providing protection against a stray blade. In one variation, the top flange **30** includes a top lip **34** that turns downwardly toward the distal direction to form a smooth curved or rounded perimeter.

(39) Furthermore, the top flange **30** and the bottom flange **32** serve as an anchor to help retain the mesh guard **10** in connection with the human body such that the mesh guard **10** stays in position and does not slip into or out of the body opening, orifice, or incision into which it is placed. The top flange **30** serves as an anchor to prevent the mesh guard **10** from moving distally into the body opening and the bottom flange **32** serves as an anchor to prevent the mesh guard from moving proximally out of the body opening. The mesh guard **10** is easily inserted by scrunching down or squeezing the bottom flange **32** by hand or instrument to reduce its lateral dimension, in particular, the lateral dimension of the bottom flange **32** as shown in FIG. **6** relative to the nominal, resting configuration shown in FIG. **5**. The interstices between the mesh filaments provide space for the filaments to move closer together to reduce the lateral dimension of the distal end. Also, the distal end of the guard may be folded parallel to an axial direction because the mesh is highly flexible to further reduce the lateral dimension of the distal end.

(40) Once placed inside a body opening, the mesh guard **10** serves as a protective portal into the body and/or across a body wall between inside a patient and outside the patient. The funnel-like shape of the bottom flange **32** at the distal end **14** also helps to lead or guide tissue into the central lumen **22** of the mesh guard **10** when tissue is being pulled through the central lumen **22** from inside the patient through the mesh guard **10** and out the proximal opening **26** outside the patient. Of course, the tissue may first be placed inside a containment bag inside the patient and the mesh guard **10** placed inside the containment bag across the body opening to serve as a portal from inside the containment bag to outside the containment bag. Tissue too large to be extracted through the body opening (e.g. orifice, incision) is reduced by cutting with a blade **11** with the mesh guard **10** in position so that the surrounding tissue, bag and retractor, if either one or more are used in conjunction with the guard **10**, are protected. The smaller portions of tissue that were reduced in size by a blade **11** are then removed from the patient. The funnel-like shape of the top flange **30** at the proximal end **12** helps to safely guide needed instruments such as surgical graspers or blades into the central lumen **22** into the proximal opening **26** to perform the tissue reduction/morcellation without damaging any surrounding tissue, containment bag and/or retractor at the margin of the body opening. Of course, the body opening is used to describe any opening into the body of a patient and may include and is not limited to an opening created by an incision, and a natural orifice such as the vagina or anus. The mesh guard **10** need not be limited to use as a portal to inside the patient from outside the patient, but may also find application for use wholly inside the patient such as in portions of a bowel, colon, stomach and other organs, for example. In essence, the mesh guard **10** can be used wherever protection of tissue, and/or easily puncturable containment systems including bags and retractors, at the margins is desired.

(41) With reference to FIG. **5**, the mesh guard **10** can be divided into approximately three interconnected sections including a proximal section **38** that includes the top flange **30**, a midsection **40** that includes the smallest resting diameter or throat of the central lumen **22**, and a distal section **42** that includes the bottom flange **32**. The midsection **40** is located between the proximal section **38** and the distal section **42** along the longitudinal axis **24**. The midsection **40** is located distally of the proximal section **38** and the distal section **42** is located distally of the midsection **40**. All three sections **38**, **40**, **42** are integrally formed and the sidewall **16** transitions smoothly across all three sections **38**, **40**, **42**. The central lumen **22** serves as a protected working channel for the passage of instruments and tissue specimens.

(42) The mesh guard **10** has an hourglass-like shape wherein the outer surface **20** is curved and concave relative to the longitudinal axis **24**. The outer surface, excluding any top lip **34** and bottom lip **36** is defined by any curve **44**, such as including but not limited to a parabola, hyperbola, circular section, or elliptical section, having a single point of inflection transcribed by rotation about the longitudinal axis at a radial distance from the longitudinal axis to form the central lumen **22**. In one variation, the point of inflection of the transcribed curved is located midway between the proximal end **12** and the distal end **14** making the mesh guard **30** vertically symmetrical. In other variations, the mesh guard **10** is not vertically symmetrical and the point of inflection may be located more proximally or more distally from the midpoint between the proximal end **12** and the distal end **14**. For example, in FIG. 5, the point of inflection is located slightly distally from the midpoint near the distal end **14**. The inner surface **18** conforms closely to the outer surface **20** and is curved and convex relative to the longitudinal axis **24**. In one variation of the mesh guard **10**, the sidewall **16** at the midsection **40** includes a substantially straight portion and is not curved or is slightly curved and the inner surface **18** and the outer surface **20** are substantially parallel to the longitudinal axis **24**. In the variation shown in FIGS. 1-6, the sidewall **16** has a more aggressive curvature near the distal end, that is, the rate of change of the curve **44** near the distal end is greater than the rate of change of the curve near the proximal end **12**. The aggressive curve **44** at the distal end **14** provides for stronger anchoring properties needed at the distal end **14**. Also, the aggressive curve **44** at the distal end **14** helps keep the walls of a containment bag out of the way. When the mesh guard **10** is placed in a containment bag, the bottom flange **32** will expand outwardly and deflect with it any portion of the containment bag that is near or in contact with the guard.

(43) It can be said that the geometry of the mesh guard **30** closely resembles a cooling tower. The shape can be generalized to a hyperboloid, a surface of revolution about a given axis with a defined height. Three main radii can be used to describe the shape: the radius at the proximal end **12** (RP), the radius at the distal end **14** (RD) and the radius at the throat (RT) where the height of RT lies between the height of RD and the height of RP along the vertical axis. The throat can be further defined as the region of the midsection having the smallest resting diameter or where the curves of different hyperboloids meet. To account for the thickness of the sidewall **16**, the inner and outer radius is defined for any number of layers of mesh therebetween. Furthermore, the surface of revolution may be defined by one or more curves joined together to form a smooth transition. For example, the proximal section **38** may be defined by a first curve of revolution, the midsection **40** defined by a second curve or line of revolution to form a cylindrical section, and the distal section **42** defined by a third curve or revolution that may be the same as or different from the first curve. Hence, there may be three points of inflection, one for each curve, for the length of the sidewall **16**.

(44) When the mesh guard **10** is in an unstressed and resting position, the central lumen **22** is substantially circular in a plane perpendicular to the longitudinal axis **24**. The mesh guard **10** may also be molded to have an elongated, elliptical, oval central lumen **22**. The central lumen **22** has the smallest diameter at the midsection **40**. From the smallest resting diameter at the midsection **40**, successively proximal cross-sections of the mesh guard **10** taken perpendicular to the longitudinal axis **24** define circles having progressively increasing diameters towards the proximal end **12**. While in a resting configuration, successively distal cross-sections of the mesh guard **10** taken perpendicular to the longitudinal axis **24** define circles having progressively increasing diameters from the smallest resting diameter at the midsection **40** towards the distal end **14**. Hence, the mesh guard **10** is narrow in the middle and wide at its proximal and distal ends **12**, **14**. The mesh guard **10** is substantially symmetric about the longitudinal axis **24** when in its resting configuration.

(45) The mesh guard **10** is made of mesh. In one variation, the entire sidewall **16** of the mesh guard **10** from the proximal end **12** to the distal end **14** is made of a mesh material. In one variation, the sidewall **16** is made of a single first layer **46** of mesh material as shown in FIG. 7. In another variation, the sidewall **16** is made of a first layer **46** of mesh material that overlaps a second layer **48** of mesh material as shown in FIG. 8. FIG. 7 is an exemplary layer **46** of mesh material. The

mesh is an interwoven or intertwined braid or network of grouped or ungrouped interlocking filaments **52** creating an open texture structure with small substantially uniform windows/interstices **50**. The circumferential surface of the sidewall **16** is made up of a number of mutually offset filamentary elements which are braided together to form a braid with a multiplicity of polygonal cells. The braid can be constructed such that two intersecting systems of filamentary elements are interlaced so that each filamentary element of one system is alternately guided over and under each filamentary element of the other system. Such a pattern of the braid is referred to as a plain weave.

(46) With reference still to FIGS. **6-7**, four mono-filaments **52a**, **52b**, **52c**, **52d** are grouped into a single strand or band **54**. Each band **54** is woven under and over one or more other bands **54** at an angle. For example, in FIG. **7**, a plurality of parallel bands **54a** that are angled in a first direction are interwoven with a plurality of parallel bands **54b** that are angled relative to the first direction. Each band **54a**, **54b** contains four filaments **52a**, **52b**, **52c**, **52d**. The mesh layer **46** is woven such that each band **54a** passes underneath or intersects two consecutively adjacent bands **54b** before passing above or intersecting the following two consecutive bands **54b**. Each band may pass underneath one or more adjacent bands before passing over the following one or more band. The weave forms a plurality of quadrilateral substantially rhomboid windows **50** therebetween with band intersections **55** at the apexes. The number of intersections **55** within a unit length of measure defines the density of the weave. More intersections **55** make the weave tighter and the size of the windows **50** becomes smaller. The second layer **48** of mesh material at least overlaps and partially closes some or all of the windows **50** to provide greater protection as shown in FIG. **8**. Also, the entire length of the sidewall comprises a double wall. In other variations, only a part of the sidewall is double-walled mesh and the other part is single-walled mesh to provide greater flexibility. Because of the weave arrangement and density, the mesh material can stretch along the lateral axis **56** as the bands **54** can slide over and relative to each other making the windows **50** larger in size. Widening of the mesh when stretched laterally reduces the length **62** of the mesh layer **46**. The mesh material can also stretch along the longitudinal axis **58** of the mesh. Lengthening of the mesh when stretched longitudinally reduces the width **60** of the mesh layer **46**. The amount of stretch for the first layer **46** in the lateral direction **48** is greater than the amount of stretch that the first layer **46** is capable of in the longitudinal direction **50**. Each window **50** has a width measured along the lateral axis **56** and a window length **66** measured along the longitudinal axis **58**. Stretching of the mesh in the lateral direction **56** is in part limited by the sum of the widths **64** of the windows **50** along the lateral direction **56** and stretching of the mesh in the longitudinal direction **58** is limited by the sum of the lengths **66** of the windows **50**. Because the length **66** of the window **50** is longer than the width **64** of the window **50**, the mesh will stretch more in the lateral direction **56**. Hence, for the mesh pictured, the dominant direction of stretch is along the lateral axis **56** of the mesh. The second layer **48** of mesh material is of the same density as the first layer **46** and is oriented in the same direction when overlaid. The second layer **48** is the same as the first layer **46**. The weave density is dense enough to prevent a blade such as a scalpel from penetrating and loose enough so that the mesh is still flexible and capable of stretching. Stretching of the mesh guard in the lateral direction is often accompanied by a reduction in the length of the guard along the longitudinal axis as the longitudinal dimension of the windows is reduced by the stretching action.

(47) The mesh guard **10** is constructed such that the mesh sidewall has a dominant direction of stretch that is perpendicular to the longitudinal axis **24** of the mesh guard **10**. In this arrangement, the central lumen **22** of the mesh guard **10** is free to stretch open and enlarge uniformly, conformingly, or irregularly around the circumference. Also, the central lumen **22** can be reduced in size in the lateral direction to a smaller diameter when the incision or body opening is smaller. Expansion in the lateral direction advantageously permits larger specimens to pass through the central lumen **22** while still providing protection to the surrounding tissue. After the stretch forces are released, the sidewall **16** is biased toward its resting configuration and will spring back. When

any latitudinal extensions forces act on the guard **10**, it relaxes elastically into its original width on account of its cell-like weave structures. Hence, the central lumen **22** is self-adjusting. For example, when in the vaginal canal, the mesh guard **10** accommodates for different female anatomy. The central lumen is able to adjust to how narrow or wide the patient's vagina is. The central lumen is also able to stretch and increase in diameter as described above to accommodate varying size uteri intended to be extracted in a hysterectomy. When placed inside an abdominal incision, for example, the mesh guard **10** conforms to and can accommodate for varying incision sizes. Hence, the mesh sidewall **16** can readily expand and stretch in the radial direction perpendicular to the longitudinal axis **24** as well as be compressed to close the throat diameter either by reducing the throat diameter or by creating a longitudinal fold or vertical wrinkle. This ability permits the sidewall to conform to anatomy as well as to be selectively deformed by the user such as for insertion purposes and/or for purposes of accommodating various body opening lengths. For example, FIG. **6** illustrates the mesh guard being deformed by the user at the distal end **14** for insertion through a body opening. Also, the configuration shown in FIG. **6** is also illustrative of an exemplary inserted configuration of the guard that has been inserted into a vagina and in which it has conformed to longer body opening such as a longer vagina with the bottom flange **32** still providing anchoring characteristics relative to the length and width of the guard shown in FIG. **5**. In the hypothetical inserted configuration shown in FIG. **6**, the mesh guard **10** is longer than its resting undeformed configuration shown in FIG. **5**. Hence, the guard **10** advantageously can be increased in length and width as well as be reduced in length and width to less than its resting configuration. When released, the mesh guard **10** pops back to its resting undeformed configuration of FIG. **5**.

(48) Each filament **52** has a cross-sectional shape that is circular; however, other shapes, including to but not limited to oval, elongate, and rectangular, are within the scope of the present invention. Each filament **52** is cylindrical in shape and has a diameter of approximately 0.01-0.02 inches. The mesh is made of any biocompatible polymer such as resin, polyester and nylon. The mesh can also be made of any biocompatible metal such as nitinol. In one variation, the filament **52** is made of polyethylene terephthalate.

(49) The mesh guard **10** is manufactured by providing a sleeve or tube of mesh material. For example, FLEXO® Original braided sleeve by Techflex in Sparta, New Jersey is employed. The tubular sleeve has an open proximal end and an open distal end. The sleeve is braided from 10 mil polyethylene terephthalate (PET) monofilament yarns. The material has a wide operating temperature range, is resistant to chemical degradation, UV radiation and abrasion. The material is capable of being heat set, heat formed, is flexible, has low or zero moisture absorbance, is biocompatible, and has a high abrasion resistance. The sleeve has a nominal resting diameter size anywhere in the range of approximately 1.75-2.75 inches. However, dependent upon the application of use of the guard, a larger or smaller nominal diameter sleeve can be selected. Also, the manufacturing process of forming the guard by heating may result in the guard having a nominal resting diameter that varies along its length and may be larger or smaller than the selected nominal diameter of the sleeve from which it is made. If a two-inch nominal diameter sleeve is selected, it has an expansion range between a minimum expansion of approximately 1.5 inches and a maximum expansion of approximately 3.5 inches in the lateral direction **56**. The resting nominal expansion is approximately 2.0 inches. A tighter weave for a two-inch nominal size diameter may be selected. For the tighter or higher density weave, the expansion range is between a minimum expansion of approximately 1.75 inches and a maximum expansion of 3.125 inches. The resting nominal expansion is approximately 2.0 inches. Each window or cell a resting inner dimension of approximately equal to or less than 2 millimeters, along the longitudinal axis, lateral axis or perpendicular thereto. In another variation, the resting inner dimension of a window/cell is approximately equal to or less than 1 millimeter measured along the longitudinal axis, lateral axis or perpendicular thereto. Depending upon the desired flexibility and expansion characteristics, the

desired density weave may be selected.

(50) After the desired mesh sleeve is selected, the desired length of the guard is ascertained and the mesh sleeve is cut such as with scissors, a hot knife, soldering iron, or hot wire. The length of the sleeve is approximately a little longer than two times the desired length of the final mesh guard. One end of the mesh sleeve is turned or tucked into the lumen of sleeve and rolled down such that the mesh sleeve overlaps onto itself forming a double wall structure. Alternatively, one end of the mesh sleeve is turned outwardly instead of inwardly into the lumen of the sleeve. Either way, if the sleeve is tucked inwardly or outwardly, the sleeve is rolled down. The result is a double-layered tube with a fold **68** formed at one end of the guard which can be seen in FIGS. **2**, **3** and **5**. The other end will have the two free ends of the sleeve approximately side-by-side. The free ends of the sleeve will begin to fray as the braid unravels and filaments splay apart. Adhesive such as LOCTITE sealant may be applied to the ends of the mesh sleeve to prevent fraying of the filaments **52**. Also, a hot knife may be used to reduce fraying. Further encasement and sealing of the filament ends at the proximal end of the guard will be described in detail below. The fold **68** is provided at the distal end **14** of the guard **10** as it forms a nice rolled lip without any exposed filaments **52** that may abrade tissue during use.

(51) Turning now to FIGS. **9-12**, a mandrel **70** for forming the guard **10** is shown. The mandrel **70** includes a first part **72** and a second part **74** that are removably interconnected. The first part **72** includes a first flared flange **76** and the second part **74** includes a second flared flange **78**. The mandrel **70** includes a neck portion interconnecting the first flange **76** and the second flange **78**. The first part **72** of the mandrel **70** is disconnected by unscrewing it from the second part **74** of the mandrel **70** as shown in FIGS. **10** and **12** to facilitate mounting the mesh sleeve onto the mandrel **72**. The two parts **72**, **74** are reconnected after the mesh sleeve is in position on the mandrel **70**. The mandrel **70** and the mesh sleeve are placed into an oven at a temperature of approximately 160 Celsius for about one hour. Less time is required in the oven if a higher temperature is used and a longer time is needed in the oven if a lower temperature is used. A thermoplastic or thermosoftening polymer is generally employed and it is heated to a glass transition temperature of the polymer. The heat will plastically deform the filaments **52** such that the mesh sleeve conforms around mandrel **70** assuming the shape of the mandrel **70** and heat set thereto. The filaments will retain the new shape corresponding to the mandrel shape when the mesh returns to room temperature. This heat settability or memory retention of the mesh material allows it to form the hourglass shape which when deformed springs back to its retained shape when released. One or more heat guns/lamps may be directed at the mesh sleeve on the mandrel **70** instead of or in addition to placing the mandrel and mesh sleeve in the oven. Once cooled, the mesh sleeve is removed from the mandrel **70** by disassembling the mandrel parts **72**, **74**. FIGS. **9-10** illustrate a mandrel **70** having a narrower neck portion **80** relative to the wider neck portion of the mandrel **70** shown in FIGS. **11-12**. The resulting differences in the size of the central lumen **22** is shown in FIG. **13** wherein the mesh guard **10a** on the lefts side is made with a mandrel **70** having a narrower neck portion **80** such as shown in FIGS. **9-10** and the mesh guard **10b** on the right side is made with a mandrel **70** having a wider neck portion **80** such as shown in FIGS. **11-12**. A smaller mandrel can be used to make a smaller mesh guard **10** such as the one shown in FIG. **14**. The mesh guard **10** of FIG. **14** is suitable for placement across an abdominal incision, for example. For an abdominal guard, the guard **10** is sized and configured to accommodate incision sites that are approximately 1.5-7.0 centimeters wide. For a vaginal guard, the guard **10** is sized and configured to accommodate diameters of approximately 0.75-3.5 inches. The guard is approximately 2.5-3.0 inches long in its resting configuration.

(52) After the mesh guard **10** has cooled and been removed from the mandrel **70**, it is prepared for an optional dispersion coating. The mesh guard **10** is cleaned with isopropyl alcohol to insure that a dispersion coating will adhere to the mesh. The proximal end **12** and top flange **30** are dipped into a dispersion material of silicone and/or urethane. Alternatively, the proximal end **12** and top flange



**30** are placed into a casting dish and dispersion material is poured into the casting dish. The dispersion coating enters, fills, covers and coats the filaments **52** and windows **50** of the dipped portion of the guard. The guard may be dipped more than once to create a desired coating. The guard **10** is allowed to completely dry. The mesh guard **10** may further or alternatively coated with an antimicrobial coating. The dispersion coating makes the dipped portion of the guard more rigid, stronger and more resistant to cutting. Dipping of the proximal end of the guard **10** is desirable to provide a reinforced flange for cut-resistant purposes. Also, the proximal end of the guard does not have to be squeezed or reduced in size for inserting into a body opening in application in which the proximal end of the guard resides outside of the body opening, making it more suitable for dispersion material.

(53) Turning now to FIGS. **15-17**, there is shown a mesh guard **10** with an injection molded ring **82**. The ring **82** is attached to the top flange **30** at the proximal end **12**. The ring **82** is sized and configured to circumferentially encompass the proximal end to cover and contain the free ends of the filaments **52** and to prevent any fraying of the loose filament ends, covering any exposed filaments to prevent abrasion of the surroundings. The ring **82** is made of polymeric material and may be rigid or flexible. The ring **82** has a smooth outer surface and a channel **84** formed by the inner surface of the ring **82**. The ring **82** is formed by injection molding. Adhesive or sealant is placed inside the channel **84** of the ring **82**. The proximal end **12** of the mesh guard **10** including any free filament ends, frayed or loose filaments **52** are tucked into the channel **84** of the ring **82**. The adhesive is allowed to cure and the ring **82** remains attached to the mesh guard **10**. The ring **82** not only captures and contains the filaments **52** at their free end, but also, the ring **82** provides added rigidity and protection at the proximal end because of the guard otherwise being made entirely of flexible mesh.

(54) Turning now to FIGS. **18-19**, there is shown another variation of a ring **82** connected to the proximal end of the mesh guard **10**. In this variation, the ring **82** is an extruded ring **82**. The ring **82** is attached to the top flange **30** at the proximal end **12**. The ring **82** is sized and configured to circumferentially encompass the proximal end **12** to cover and contain the free ends of the filaments **52** of the mesh sleeve and to prevent fraying of the loose filament ends. The ring **82** is made of polymeric material and may be rigid or flexible. The ring **82** has a smooth outer surface and a channel **84** formed by the inner surface of the ring **82**. The ring **82** is formed by extrusion. Adhesive or sealant is placed inside the channel **84** of the ring **82**. The proximal end **12** of the mesh guard **10** including any free filament ends, frayed or loose filaments **52** are tucked into the channel **84** of the ring **82**. The adhesive is allowed to cure and the ring **82** remains attached to the mesh guard **10**. The ring **82** not only captures and contains the filaments **52** at their free end, but also, the ring **82** provides added rigidity and protection at the proximal end **12**.

(55) Turning now to FIGS. **20-24**, there is shown another variation of a ring **82** connected to the proximal end **12** of the mesh guard **10**. In this variation, the ring **82** is molded over the proximal end **12**. The ring **82** is molded to the top flange **30** at the proximal end **12**. The ring **82** encompasses the proximal end **12** to cover and contain the free ends of the filaments **52** of the mesh sleeve and to prevent fraying of the loose filament ends. The ring **82** is made of silicone such as room temperature vulcanization silicone or other polymeric material and may be rigid or flexible. A mold such as a casting dish **84** shown in FIG. **23** is created. The casting dish **84** includes an annular reservoir **88** that is sized and configured to receive the proximal end **12** of the mesh guard **10**. Casting material is poured into the reservoir **88** and the proximal end **12** of the mesh guard **10** is inserted into the reservoir **88**. The casting material is allowed to cure and the mesh guard **10** is carefully removed from the casting dish **86**. The ring **82** not only captures and contains the filaments **52** at their free end, but also, the ring **82** provides added rigidity and protection at the proximal end **12**. The resulting mesh guard **10** with the over molded ring **82** is shown in FIGS. **22-23**.

(56) Turning now to FIGS. **25-26**, there is shown another variation of covering the frayed filaments

**52** at the proximal end **12** of the guard **10** includes laying a bead **90** of sealant or caulking. The bead **90** of sealant is placed along the frayed edges of the mesh and excess sealant is carefully removed. Care is taken to ensure that the frayed edges are completely concealed. The sealant is allowed to cure to form the rigid or flexible bead **90**. The bead **90** not only captures and contains the filaments **52** at their free end, but also, the bead **90** provides added rigidity and protection at the proximal end **12**.

(57) Turning now to FIGS. **27-28**, there is shown another variation of covering the frayed filaments **52** at the proximal end **12** of the guard **10** includes heat sealing. In this variation, no extra materials are needed conceal the frayed edges. The excess distal ends of the filaments **52** are trimmed using a hot tool such as a soldering iron, hot wire or hot knife. The heat melts and seals the ends of the mesh together to prevent further fraying of the filaments. The process results in a small band **92** of hot sealed filaments **52**. The heat sealed band **92** not only seals and contains the filaments **52** at their free end, but also, the band **92** provides added rigidity and protection at the proximal end **12**. Although FIGS. **15-23** describe a ring **82** and FIGS. **25-28** describe a bead **90** at the proximal end **12** of the guard **10**, the invention is not so limited and a ring **82** can be formed at the proximal end **12** and/or the distal end **14** of the guard and a bead **90** can be formed at the proximal end **12** and/or the distal end **14** of the guard **10**.

(58) Turning now to FIGS. **30-31**, there is shown a system comprising a retractor **100** and guard **10**. The retractor **100** includes a first ring **102** and a second ring **104** interconnected by a flexible sidewall **106**. The tubular sidewall **106** defines a central opening **108** extending along the longitudinal axis of the retractor **100**. The second ring **104** is resilient and compressible. The second ring **104** can be compressed and inserted into an incision or body orifice where it expands to create a securement. For example, when inserted through an incision in the abdomen, the second ring **104** is compressed to pass through the incision and allowed to expand against the abdominal wall inside the abdominal cavity. When inserted into a vaginal canal, for example, the second ring **104** is compressed and then allowed to expand to create a securement against the vagina. The first ring **102** resides above the abdominal wall or proximally outside the patient. If inserted into the vaginal canal, the first ring **102** of the retractor **100** resides above the entrance to the vagina outside the patient. The first ring **102** is configured such that it can be rolled down to retract and enlarge the opening in the abdominal wall or other incision or to retract and enlarge the vaginal canal or other orifice while the second ring **104** remains anchored in an expanded state inside the patient. The first and second rings **102**, **104** have approximately the same diameter. In another variation, a larger first ring **102** relative to the second ring **104** allows for more space to work and cut tissue against. The sidewall **106** can be made of a polymer polyurethane laminate or similar flexible material and, in one variation, including woven material to resist cutting through the sidewall **106**. The first ring **102** is configured to be rolled/flipped over itself to wrap the sidewall **106** around the first ring **102**, shortening the length of the sidewall **106** between the rings **102**, **104**. This action pulls the second ring **104** of the retractor **100** closer to the first ring **102** and the sidewall **106** into a taut relation between the rings **102**, **104** so as to retract tissue located between the two rings **102**, **104**. In use, for example, the retractor **100** is inserted prior to insertion of the guard **10** into the cavity or orifice. The second ring **104** of the retractor **100** is compressed for easy insertion into the orifice/incision and then allowed to expand into an open configuration inside the patient. The first ring **102** of the retractor **100** that is resident outside the body is rolled about itself to roll the sidewall **106** of the retractor **100** onto the first ring **102**. This action retracts tissue at the margin to create a wide open working channel for the surgeon to operate. The guard **10** is then inserted into the central lumen of the retractor **100**. The distal end **14** of the guard **10** may be scrunched down and reduced in width into a compact configuration during insertion and then allowed to expand to self-anchor into position. The proximal end **12** of the guard **10** is located within the first ring **102** of the retractor **100** as shown in FIGS. **30-31**. The diameter of the proximal end **12** of the guard **10** is approximately equal to or less than the inner diameter of the first ring **102** of the retractor **100** in

the relaxed state as shown in FIGS. 30-31. The surgical procedure such as morcellation may then be carried out with the working channel protected by the guard **10**. The guard **10** advantageously protects the surrounding tissue as well as the retractor **100** from any sharp blade used in the surgical procedure helping to maintain the integrity and preventing inadvertent contamination of the surgical site while providing the surgeon with a mechanism to perform morcellation safely and quickly.

(59) Turning now to FIGS. 32-34, there is shown another variation of the guard **10** that includes a drawstring tether **111**. The tether **111** is a polyester filament or other string or pull-wire that is weaved around the distal end **14** of the guard **10**. The tether **111** is connected to the distal end **14** such that it is movable with respect to mesh sidewall **16** in drawstring fashion when pulled to cinch and reduce the lateral width of the distal end **14** of the guard **10** into a reduced configuration shown in FIG. 34 relative to the expanded configuration shown in FIGS. 32 and 33. In one variation, the tether **111** is weaved in and out of the windows **50** of the mesh sidewall **16** as is clearly visible in FIG. 32. The tether **111** is connected to a tag **113** at one end. When pulled at the tag **113**, the width of the distal end **14** will be moved to a reduced configuration that facilitates insertion and removal of the guard **10**. When the tag **113** is released, the heat-set distal end **14** will tend to return to its normal width into an expanded or relaxed configuration shown in FIGS. 32 and 33. When being inserted into the patient, care is taken to keep the tether **111** outside of the central lumen **22**. If a system in which a retractor **100** and guard are employed together, the tether **111** is located between the retractor sidewall **106** and the sidewall **16** of the guard **10** and along the longitudinal axis of the guard **10** such that the tag **113** is resident outside the patient. Upon removal of the guard **10**, the spring-back feature of the distal end **14** that is biased to return to its heat set expanded configuration may hamper removal of the device and even splash any bodily fluid when removed from the patient. The tether **111** advantageously alleviates these removal problems. During the surgical procedure, the tag **113** remains outside the body. When it is time to remove the guard **10** from the patient, the tether **111** is first pulled and held while the guard **10** is removed from the patient. Once the guard **10** is extracted the tether **111** can be released carefully to return the distal end **14** to its expanded configuration. The tether **111** advantageously aids the insertion and removal of the guard **10**.

(60) Turning now to FIG. 35, there is shown a side elevational view of a guard **10** according to the present invention. The guard **10** includes a top flange **30** and a bottom flange **32** that extend outwardly away from the longitudinal axis. The longitudinal axis is normal to a plane. The top flange **30** is angled circumferentially with respect to this plane at an angle **117**. Angle **117** is approximately 45 degrees with respect to the plane normal to the longitudinal axis. An angle **117** greater than 45 degrees generally results in the top flange **30** losing its retention abilities and would tend to slide down into the orifice and generally create a longer working channel. An angle **117** less than 45 degrees would result in reduced visualization and space for contained, protected morcellation. The bottom flange **32** is angled circumferentially with respect to a plane normal to the longitudinal axis at an angle **119**. Angle **119** is approximately 0 to 45 degrees with respect to the plane normal to the longitudinal axis. This range for angle **119** allows for maximum bottom flange **32** retention inside the body preventing the guard **10** from easily being pulled proximally out of the body. An angle **119** that is much greater than 45 degrees would reduce surface area contact between the bottom flange **32** and the area inside the body, thereby, reducing retention abilities. A negative angle **119** would result in the bottom flange **32** losing its retention abilities and cause the guard **10** to slip outside the body. In another variation, the guard **10** is provided with inflatable fixation at the distal end **14** such as an inflatable balloon located circumferentially around the distal end **14** of the guard **10** and having an inflation pathway extending toward the proximal end **12**.

(61) The mesh guard **10** is composed of a single piece of mesh formed to fit vaginally or abdominally. The device is intended to aid surgeons during procedures that require tissue morcellation. During procedures that require tissue morcellation, surgeons risk accidentally cutting

marginal tissue and organs other than the targeted tissue as well as damaging containment bags and/or retractors used in conjunction with the morcellation procedure. The guard **10** provides needed protection and advantageously provides 360 degrees of protection around the working channel, central lumen **22** against scalpels and sharp instruments. For vaginal use, such as during a hysterectomy, the uterus is detached. A retractor is inserted vaginally and anchored securely with respect to the body orifice. Clamps are used to grasp the bottom flange **32** of the mesh guard **10**. In grasping the bottom flange **32** the flared distal end **14** is reduced in its lateral dimension such as shown in FIG. **6**. The mesh guard **10** with reduced distal end is inserted into the vagina. The bottom flange **32** is released. Upon release of the distal end **14**, the mesh guard **10** tends to spring back towards its nominal resting configuration. In doing so, the bottom flange **32** expands laterally to anchor the mesh guard **10** with respect to the anatomy with the distal end **14** and bottom flange **32** of the mesh guard **10** residing inside the patient, the midsection **40** of the guard **10** traversing the vagina and the top flange **30** residing outside the patient and resting above the body opening and visible outside vagina. The surgeon may check to see if the guard **10** is anchored properly by adjusting and pulling on the guard **10** or adjusting the bottom flange **32**. The vaginal hysterectomy is continued. The detached uterus is grasped with graspers and pulled through the central lumen **22** of the guard **10** until at least a portion of the tissue is visible from outside the vagina. The surgeon will then use a scalpel to cut into the detached uterus such that a smaller portion of it can be pulled out through the guard **10**. The surgeon will repeat this cutting process until the entire uterus is removed or reduced in size sufficient for extraction. The guard **10** advantageously provides protection for the cutting process, giving the surgeon confidence to perform the surgery quickly and easily. A containment bag may also be employed with the tissue guard **10**. A containment bag is deployed inside the patient and the detached uterus is placed inside the bag. The uterus is too large to be removed and must be morcellated for removal. The mouth of the bag is pulled to the surface through the vaginal canal and through the retractor if one is in position at the orifice. The mesh guard **10** according to the present invention is inserted into the mouth of the bag and anchored with respect to the orifice. Alternatively, the bag may be placed first and followed by a retractor. In such a case, the guard **10** is placed into the working channel of the retractor to protect both the bag and the retractor.

(62) The mesh guard **10** may also be used abdominally. An incision is made through the abdominal wall to access the abdominal cavity, such as during a hysterectomy, in which the uterus is detached. A retractor is inserted into the incision and anchored securely with respect to the incision. Clamps are used to grasp the bottom flange **32** of the mesh guard **10**. In grasping the bottom flange **32** the flared distal end **14** is reduced in its lateral dimension such as shown in FIG. **6**. The mesh guard **10** with reduced distal end is inserted into the abdominal cavity. The bottom flange **32** is released. Upon release of the distal end **14**, the mesh guard **10** tends to spring back towards its nominal resting configuration. In doing so, the bottom flange **32** expands laterally to anchor the mesh guard **10** with respect to the anatomy with the distal end **14** and bottom flange **32** of the mesh guard **10** residing inside the patient, the midsection **40** of the guard **10** traversing the incision site and the top flange **30** residing outside the patient and resting atop the abdominal wall. The surgeon may check to see if the guard **10** is anchored properly by adjusting and pulling on the guard **10** or adjusting the bottom flange **32** as needed. The vaginal hysterectomy is continued. The detached uterus is grasped with graspers and pulled through the central lumen **22** of the guard **10** until at least a portion of the tissue is visible from outside the patient. The surgeon will then use a scalpel to cut into the detached tissue such that a smaller portion of it can be pulled out through the guard **10**. The surgeon will repeat this cutting process until the entire uterus is removed or reduced in size sufficient for extraction. The guard **10** advantageously provides a protection for the cutting process, giving the surgeon confidence to perform the surgery quickly and easily. A containment bag may also be employed with the tissue guard **10**. A containment bag is deployed inside the patient and the detached tissue specimen such as the uterus is placed inside the bag. The uterus is too large to be

removed and must be morcellated for removal. The mouth of the bag is pulled to the surface through the abdominal incision and through the retractor if one is in position across the incision site. The mesh guard **10** according to the present invention is inserted into the mouth of the bag and anchored with respect to the orifice. Alternatively, the bag may be placed first and followed by a retractor being placed inside the mouth of the bag. In such a case, the guard **10** is placed into the working channel of the retractor to protect both the bag and the retractor. Although the guard was described for use in a hysterectomy, it can be used for other medical procedures as well, including but not limited to procedures that involve the extraction of target tissue.

(63) The bottom flange **32** functions as a retention flange that anchors the guard **10** into the body. The bottom flange is also able to adjust to how long or short the patient's vaginal canal is or to how thick the patient's abdominal wall is. The flange shape and material allows the mesh to shift and stretch and advantageously increase in channel length and conform to the anatomy in which it is placed. Also, the dual mesh layers provide a thick surface to prevent sharp instruments from cutting through. The mesh guard may be used at any point during a surgical procedure when a cutting surface or protection against sharp objects is needed. Using the guard with a retractor is optional when performing a procedure. The guard may also be selectively coated with a polymer material, meaning that only part of the guard such as the top flange is coated with a polymer solution and the bottom flange is left uncoated in order to provide more flexibility at the distal end **14** when adjusting to a patient's anatomy. Of course, the guard may be scaled appropriately and proportionally in size to fit in different body openings.

(64) Turning now to FIG. **29**, there is shown an exemplary closed morcellation procedure according to the present invention. A small incision is made in a patient in the location of an abdominal wall **110** and a body cavity **112** is accessed through an opening **114** across the abdominal wall **110**. Opening **114** in FIG. **29** may also be representative of a vaginal canal and the abdominal wall **110** representative of the tissue margin. Laparoscopic techniques and instruments such as trocars, laparoscopes, graspers and scalpels may be employed to create the single site opening, spy the targeted tissue and detach the targeted tissue from surrounding tissue structures. Additional incisions or access sites may be employed to insert instruments and scopes to facilitate the procedure. After the targeted tissue **116** such as at least a part of the uterus in a hysterectomy procedure is completely detached, a specimen retrieval bag **118** is inserted through the opening **114** in the wall **110** and placed inside the body cavity **112**. The bag **118** may be delivered through a trocar or cannula that is placed across the wall **110** or inside the vagina. The bag **118** is unfurled and oriented inside the body cavity **112**. The targeted tissue **116** is placed into the bag **118** through an opening **120** in the bag **118**. Various types of bags **118** may be employed. The bag **118** may be transparent such that the contents may be observable from outside the bag **118** via a scope placed into the body cavity **112** through a secondary incision site across the abdominal wall **110**. The contents of the bag **118** may be illuminated from outside the bag **118**. The location of the targeted tissue **116** may also be observed through a transparent bag **118** to ascertain the progress of morcellation as well as the position and proximity of the targeted tissue **116** relative to the opening **114**. Also, the bag **118** is observed via a secondary site insertion to ascertain the state of the bag **118** making sure that it is not tangled and twisted and that the specimen is moved toward the opening without pulling the bag **118** along with it which may result in the bag being accidentally coming into contact with a blade and being severed. An opaque bag **118** may also be employed. The material of the bag **118** is also important. Generally, made of plastic, the bag is strong enough to withstand pulls and tugs, has sufficient stretch properties and is relatively thin, flexible and resilient to puncture and tears. The bag is folded and reduced in size such that it can be inserted through the small incision/trocar of approximately at least 5 mm in diameter. Also, when opened, the bag is large enough to receive a large piece of tissue, extend through the opening **114** to the surface of the abdominal wall **110** and create a sufficiently large working space inside the bag **118** for instruments, scopes, morcellators **124**, and scalpels **126** as shown in FIG. **29**. The bag **118** includes

a tether or drawing string **122** configured to cinch the opening closed and to open the bag **118**. The bag **118** withstands insufflation pressures and does not leak.

(65) After the targeted tissue **116** is placed inside the bag **118**, the tether **122** is grasped by hand or with a laparoscopic grasper and at least a portion of the bag **118** is pulled through the abdominal wall opening **114**. Pulling the tether **122** closes the bag opening **120**. The initial incision may be increased to approximately 15-40 mm prior to pulling the bag **118** through the opening **114**. If the targeted tissue **116** is too large to fit through the opening **114**, the targeted tissue **116** will sit inside the body cavity **112** below the abdominal wall **10**. The remainder of the bag **118** including the opening **120** of the bag **118** will be pulled through the abdominal wall opening **114** and extend through the opening **114** to outside the patient and along the upper surface of the abdominal wall **110** as shown in FIG. 29. The bag **118** may be rolled down and/or pulled taut across the surface of the abdominal wall **110** to maintain its position and provide some tissue retraction at the opening **114**.

(66) A guard **10**, according to the present invention, is inserted in through the opening **120** of the bag **118**. Once the guard **10** is placed, the surgeon will grasp the specimen **116** and pull it up through the central lumen **22** as far as possible. The surgeon will then begin morcellating the specimen **116** with a scalpel **126**, cutting the specimen **116** to reduce its size. Ideally, the surgeon will “core” or “peel” the specimen **116** to keep it in one piece as much as possible. However, more likely than not, the specimen **116** will be reduced in multiple pieces. While morcellating through the incision, the surgeon may maintain pneumoperitoneum in the abdominal cavity **112** so that the progress of the morcellation can be observed laparoscopically through a lateral port placed at a secondary site into the cavity **112**. Once the specimen **116** is morcellated, crushed, reduced enough to pull the remaining portion through the incision, the guard **10** is removed, and the bag **118** and its contents that may include the pieces created during morcellation, are pulled out of the patient. The bag **118** will prevent the remaining small pieces from being left in the abdominal cavity **112**, thereby, maintaining the closed system; whereas in a traditional morcellation, the surgeon must go back and painstakingly search and collect the pieces scattered amid the pelvic cavity to prevent potentially seeding new tumor sites. The surgeon may choose to take a final look at the patient laparoscopically and then close the wounds. While described for an abdominal removal and morcellation, the above-described procedure can be performed via the vagina orifice as well if the cervix has been removed. Following the same process, the bag **118** will be introduced and the specimen **116** placed into the bag **118** laparoscopically. Rather than pull the tether **122** through the abdominal wall opening **114**, it would be pulled through the vagina. The surgeon may roll the bag **118** down or pull it taut to maintain its position and provide some retraction. The surgeon would place the guard **10** vaginally to protect integrity of bag **118**, protect the tissue margin and to maintain a closed system, grasp the specimen **116** to bring it out, and morcellate to reduce the size of the specimen **116**. Morcellation of the specimen is performed in the location of the guard **10** and/or against the guard **10** surface protecting the surrounding tissue and bag from inadvertent incisions. The surgeon may maintain pneumoperitoneum and watch the progress of the morcellation laparoscopically. Once the specimen **116** is morcellated, crushed, reduced enough to pull the remaining portion through the vagina, the guard **10** is removed, and the bag **118** and its contents, including the pieces created during morcellation, are pulled out of the patient. The bag **118** will prevent the remaining small pieces from being left in the abdominal cavity preventing harmful material such as cancerous cells from being disseminated in the abdominal cavity, maintaining the closed system; whereas in a traditional morcellation, the surgeon must go back and painstakingly search and collect the pieces scattered amid the pelvic cavity search for the pieces amid the pelvic cavity. The surgeon may choose to take a final look at the patient laparoscopically and will close the vaginal cuff and abdominal incisions.

(67) A retractor having a central lumen may also be employed and placed inside the mouth of the bag **118** to retract tissue along with the bag enlarging the opening. Then, the tissue is morcellated

with the bag in place. A mesh guard **10** as previously described is provided and used in conjunction with the bag **118** and the retractor. The guard **10** is placed inside the central lumen of the retractor with the retractor being located between the guard **10** and the bag **1**. Of course, the guard **10** may be used without the retractor. If a retractor is not used, the guard is placed into the mouth **120** of the bag **118** in the location of the incision/vaginal canal. The guard is inserted into the mouth **120** of the containment bag **118** after the bag **118** is placed inside the patient and pulled through the incision/vaginal canal. The guard **10** protects the plastic bag **118** and adjacent tissue at the margin from being inadvertently cut by the blade used by the surgeon to morcellate the target tissue. The guard **10** may also serve as a cutting board against which a surgeon may cut the target tissue if needed.

(68) If a retractor is used inside the bag **118**, the retractor advantageously not only retracts the tissue but also retracts part of the bag, keeping the bag out of the way of a morcellating blade and, thereby, protecting the bag from cuts and punctures. A typical retractor includes a top ring and bottom ring with a flexible sidewall connected therebetween. The bottom ring is inserted through the incision and resides inside the patient whereas the top ring of the retractor resides above the patient. The top ring is rolled/flipped over itself like the bag to pull the lower ring of the retractor closer and the sidewall into a taut relation between the rings. The lower ring of the retractor advantageously retracts the portion of the bag **118** inside the patient and away from potential damage arising from punctures and tears from the blade.

(69) The tissue is morcellated in a fashion desired by the surgeon. Generally, a small part of the target tissue is pulled to the outside of the patient while the larger portion of the target tissue remains inside the patient. The surgeon will take a blade and make a circumferential cut of approximately 180 degrees or 360 degrees around the circumference of the protruding tissue without severing the protruding tissue from the remainder of the target tissue. Keeping the protruding tissue intact with the larger piece inside the patient permits the surgeon to continue to grasp the tissue without losing it inside the bag. The surgeon pulls the grasped tissue little-by-little out of the patient making periodic circumferential cuts of any size so that more of the tissue can be pulled out until the entire piece of target tissue is removed. The result is a single elongated piece of removed target tissue instead of multiple small pieces. If not removed in one piece, the target tissue is removed in fewer pieces and in a more controlled manner. The bag **118** may be further retracted in between morcellations to bring the specimen closer to the surface. Once the tissue remaining in the bag **118** is small enough to easily fit through the incision, the bag **118** is completely removed.

(70) The tissue guard described herein is typically employed with a containment bag. The bag is placed inside the body through a body opening. The body opening refers to any entranceway into the patient and may include and is not limited to incision sites and natural orifices. The target specimen is typically too large to be safely removed through the body opening and requires to be manipulated such as by cutting with a blade in order to extract the target specimen through the body opening. The body opening is generally smaller than the target specimen size. The target specimen is placed inside the bag and the mouth of the bag is pulled to the outside of the patient. The guard is placed inside the mouth of the bag and anchored across the body opening and the target specimen is pulled into the lumen of the guard. While in the lumen of the guard, the target specimen is in a protected morcellation zone wherein the surgeon may reach in with a blade to cut the target specimen for extraction. The guard protects against the stray blade and also provides a direct cutting surface against which tissue may be placed for reduction. The entire length of the guard typically defines the length of the morcellation zone protecting the bag and the tissue at the margins of the body opening. Additionally, a retractor may be employed. The retractor may be integrally formed with the bag or be a separate stand-alone device. A typical retractor described herein is a two-ringed retractor with a flexible sidewall material located between the two rings. The sidewall of the retractor is configured to be capable of being rolled about the first ring to retract the tissue at the margin of the body opening. If a retractor is employed it may be placed between the

marginal tissue and the bag or inside the bag between the bag and the guard. The above description describes different variations of use of the guard, bag and retractor that is employed in manual morcellation. For power morcellation, the guard is inserted inside the bag and morcellation is carried out in a closed system. In another variation for power morcellation, a stability cap is connected to the proximal ring of the bag or to the proximal end of the guard and power morcellation is carried out. The stability cap serves to locate the vertical position of the blade ensuring that the blade does not extend beyond the predetermined morcellation zone inside the guard or at a short distance safely beyond the distal end of the guard. In another variation for power morcellation, a retractor is employed in which case the retractor is located between the marginal tissue and the bag or between the bag and the guard as previously described and power morcellation is carried out. In the previous variation, a stability cap may be employed in such a manner that it connects to the proximal ring of the retractor, the proximal ring of the bag, or to the proximal end of the guard and morcellation is carried out. In addition to the above variations, any one of the following approaches may be employed in conjunction with any of the variations above when performing a procedure such as a hysterectomy. In one variation, the bag is placed in through the vagina, the target specimen (e.g. uterus) is placed inside the bag while the bag is inside the body cavity, and then the mouth of the bag is pulled through an abdominal incision wherein the guard is inserted into the mouth of the bag, and morcellation, extraction and bag removal take place at the abdominal opening. In another variation, the bag is placed in through the vagina, the target specimen (e.g. uterus) is placed inside the bag while the bag is inside the body cavity, and then the mouth of the bag is pulled back through the vaginal canal wherein the guard is inserted into the mouth of the bag, and morcellation, extraction and bag removal take place at the vagina. In yet another variation, the bag is placed in through an abdominal incision, the target specimen (e.g. uterus) is placed inside the bag while the bag is inside the body cavity, and then the mouth of the bag is pulled through the vaginal canal wherein the guard is inserted into the mouth of the bag, and morcellation, extraction and bag removal take place at the vagina. In one other variation, the bag is placed in through an abdominal incision, the target specimen (e.g. uterus) is placed inside the bag while the bag is inside the body cavity, and then the mouth of the bag pulled back through the abdominal incision wherein the guard is inserted into the mouth of the bag, and morcellation, extraction and bag removal take place at the vagina. In another approach to morcellation of the uterus or other target specimen, the bag may be omitted. In such a case, an incision is made in the abdominal wall, the guard is placed across the incision in the abdominal, and the uterus or target specimen is detached and pulled through the central lumen of the guard with morcellation and extraction taking place at the abdominal incision. Alternatively, the target specimen (e.g. uterus) is approached through the vagina, the guard is placed inside the vaginal canal, and the target specimen is detached and pulled through the central lumen of the guard with morcellation and extraction taking place at the vagina. As a further variation of the abdominal approach with or without a bag, the procedure may be observed via a laparoscope inserted through the vagina. As a further variation of the vaginal approach with or without a bag, the procedure may be observed via a laparoscope inserted through an incision in the abdomen.

(71) International PCT Application Ser. No. PCT/US2015/27274 entitled “Systems and methods for tissue removal” filed on Apr. 23, 2015, is hereby incorporated herein by reference in its entirety.

(72) It is understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

## Claims



1. A guard for providing a cut-resistant pathway through a body opening to protect a tissue margin, the guard comprising: a sidewall having a tubular shape defining a central lumen; the central lumen extending along a longitudinal axis between a proximal opening at a proximal end and a distal opening at a distal end; the sidewall being made of at least one layer of flexible, cut-resistant mesh material having a plurality of interwoven filaments defining interstices; the sidewall having a distal portion with a progressively increasing diameter toward the distal end defining a flared distal flange in the sidewall; the flared distal flange being configured to anchor the guard with respect to a distal end of the tissue margin; the sidewall circumferentially protecting the tissue margin along the body opening; the sidewall having a neck portion located proximally to the flared distal flange; and a pull-wire located circumferentially around the flared distal flange and configured to reduce a lateral dimension of the flared distal flange when pulled into a reduced configuration to facilitate insertion and removal of the guard when in the reduced configuration.
2. The guard of claim 1 wherein when the pull-wire is released the flared distal flange is biased to return to a normal, undeformed configuration.
3. The guard of claim 1 wherein the pull-wire is weaved through the interstices circumferentially around the distal end of the guard and configured to reduce a lateral dimension of the distal end when pulled.
4. The guard of claim 1 wherein the mesh material is configured to stretch laterally relative to the longitudinal axis such that the sidewall is expandable to enlarge a lateral dimension of the central lumen at the neck portion relative to the lateral dimension of the central lumen at the neck portion when in a normal, undeformed configuration.
5. The guard of claim 1 wherein the mesh material is configured such that the neck portion is adapted to be laterally expandable to lengthen a lateral dimension of the guard while reducing an axial dimension of the guard along the longitudinal axis.
6. The guard of claim 1 wherein the interstices at the flared distal flange are larger than the interstices at the neck portion in a normal, undeformed configuration.
7. The guard of claim 1 wherein the mesh material is configured to stretch laterally relative to the longitudinal axis such that the sidewall is expandable to enlarge the interstices of the central lumen at the neck portion relative to the interstices of the central lumen at the neck portion when in a normal, undeformed configuration.
8. The guard of claim 1 wherein the guard has a deformed configuration in which the flared distal flange is flexed distally, lengthening the axial dimension of the guard such that the lateral dimension of the distal end and flared distal flange are reduced relative to a normal, undeformed configuration.
9. The guard of claim 1 wherein the guard has a deformed configuration in which the lateral dimension at the distal end is reduced relative to the lateral dimension of the distal end in a normal, undeformed configuration.
10. The guard of claim 1 wherein the flared distal flange extends circumferentially outwardly from the longitudinal axis when in a normal, undeformed configuration.
11. The guard of claim 10 wherein the flared distal flange is flexible in the distal direction to reduce the degree to which the flared distal flange extends circumferentially outwardly from the longitudinal axis relative to the normal, undeformed configuration to facilitate insertion into the body opening.
12. The guard of claim 1 wherein the flared distal flange is adapted to be folded down in a distal direction to reduce the lateral dimension of the distal end of the guard to facilitate insertion and removal of the guard from the body opening.
13. The guard of claim 1 further comprising a circumferential ring or bead at the proximal end of the guard.
14. The guard of claim 1 further comprising a proximal flange formed at the proximal end of the

guard; the proximal flange defined by a progressively increasing central lumen toward the proximal end.

15. The guard of claim 1 wherein the proximal end of the guard comprises a band of heat sealed filaments.

16. The guard of claim 1 further comprising a dispersion coating at the proximal end of the guard and/or an antimicrobial coating.

17. The guard of claim 1 wherein the sidewall is made of thermosoftening polymer filaments.

18. The guard of claim 1 wherein the guard has an hourglass shape.

19. The guard of claim 1 wherein the distal portion of the guard is adapted for lateral reduction.

20. The guard of claim 1 wherein the sidewall includes a fold at the distal end such that the sidewall overlaps itself to form two coaxial layers of mesh material circumferentially enclosing the central lumen.

---