

SPECIALIZED GYNECOLOGY

Improving Diagnostic and Therapeutic Results



UTAH MEDICAL PRODUCTS

FEMCARE



Permanent Female Sterilization

Most Effective Long Term Solution

Patient Friendly

Quick and Easy to Apply

FILSHIE[®]
TUBAL LIGATION SYSTEM

Excellent and Well Known Long Term Effectiveness

In hundreds of published studies, the Filshie System demonstrates an exemplary "typical use" success rate that is superior to all methods studied in the CREST trials¹. Filshie Clips also have a very low rate of ectopic pregnancy.

Since introduction in 1982, with over 12 million clips applied, knowledgeable gynecologists have relied on the Filshie Clip System for high effectiveness and limited complications, whereas numerous studies and even professional recommendations confirm that the long-term benefits versus complications of prophylactic salpingectomy are not established.²⁻⁴ "The risks of decreased ovarian function and/or premature surgical menopause [due to prophylactic salpingectomy] may outweigh the benefit of decreased ovarian cancer incidence."⁵ "Studies investigating patient-based outcomes [of prophylactic salpingectomy] are lacking."⁶

As with salpingectomy, the occlusive nature of the Filshie Clip has been shown to reduce the incidence of ovarian cancer⁷⁻⁹. However, the Filshie Clip System has significant advantages when compared to salpingectomy: Filshie Clip placement involves no electrocautery, sharp dissection or permanent excision of tissue. A well-known and clinically reported potential side effect of Filshie Clip tubal ligation is clip migration. There are no known serious clinical or life-threatening complications that relate directly or indirectly to the Filshie Clips or their migration.¹⁰

Quick and Easy to Apply

Laparoscopic application of Filshie Clips requires basic laparoscopic skills and takes just a few minutes. Compared to salpingectomy, the surgery is easier. In a recent postpartum study, bilateral salpingectomy was successfully completed in only 68% of cases vs 95% successful completion of tubal ligation. Tubal ligation also had a 15 minutes shorter operative time than bilateral salpingectomy.¹¹ In certain women salpingectomy may technically be very difficult, increase intraoperative complication rate or even impossible such as women with abnormal anatomy and women with severe adhesions due to pelvic inflammatory disease or endometriosis.¹² There is no sharp dissection or excision of tissue that increases surgical risks, and operating room costs are lower.

Patient Satisfaction

Many women prefer the least invasive approach when it involves removal of anatomy.



STERISHOT II
APPLICATOR FOR
MINILAPAROTOMY KIT

FILSHIE SYSTEM STERISHOT II Perfectly Calibrated Every Time

Consistently effective results are obtained with a calibrated Filshie Clip closure mechanism confirmed for each application. Since 2008, the patented¹⁷ Sterishot II single patient use Filshie Clip applicator has been providing precise closure pressure and reliable locking of the clip. Compared to a reusable applicator, Sterishot II applicators

- eliminate potential for patient infection due to cross-contamination,
- eliminate annual calibration requirements,
- eliminate the risk of damage from handling and storage, and
- eliminate resources required for post-surgical cleaning, sterile processing and tracking between procedures.

1 Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996;174(4):1161-1170.
2 Szender J, Lele S, Fallopiian tube ligation or salpingectomy as means for reducing risk of ovarian cancer. *AMA J Ethics*. 2015 Sep 1;17(9):843-8.
3 Salpingectomy for ovarian cancer prevention. Committee Opinion 620, ACOG. *Obstet Gynecol* 2015;125:279-81.
4 Venkatesh KK, Clark LH, Stamilio DM. Cost-effectiveness of opportunistic salpingectomy vs tubal ligation at the time of cesarean delivery. *Am J Obstet Gynecol* 2019;220:106.e1-10.
5 Backes FJ. Salpingectomy, why not? *Am J Obstet Gynecol* 2014;210(5):385-386.
6 Castellano T, Zerden M, March L, et al. Risks and benefits of salpingectomy at the time of sterilization. *Obstet Gynecol Surv* 2017;72(11):663-668.
7 Benefits and risks of sterilization. Practice Bulletin No. 208. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2019;133(3):e194-e207.
8 Rice M, Hankinson S, Tworoger S. Tubal ligation, hysterectomy, unilateral oophorectomy, and risk of ovarian cancer in the Nurses' Health Studies. *Fertil Steril* 2014;102:192-8.
9 Gaitskell K, Gren J, Pirie K, et al. Tubal ligation and ovarian cancer risk in a large cohort: Substantial variation by histological type. *Int J Cancer* 2016;138:1076-84.



AVM-954 KIT

Permanent, Yet Reversible

Because Filshie Clips preserve almost the entire fallopian tube, reversal via reanastomosis has been shown to be highly successful.¹³

Minimal Laparoscopic Ports Required

Only a single central instrument port is required for placement. Multiple lateral instrumentation ports that are necessary for salpingectomy are not needed. Therefore risk of epigastric vessel injury is mitigated¹⁴ and port site infection, irritation and herniation is potentially reduced.

Non-Hormonal, Permanent Device

Filshie Clips maintain high effectiveness without replacement or maintenance. Clips do not leach copper or hormones and do not need replacement. Filshie Clips are less worrisome than IUDs for women who have completed their families.

Effective for Postpartum Application

The Filshie Clip's special silicone profile and clip length allows it to be placed onto edematous postpartum Fallopian tubes. The length is able to encompass a swollen tube, and the silicone maintains pressure on the clipped tube as the tube gradually compresses.

Globally Recognized and Recommended

The proven success of the Filshie Clip is the reason that the UK Royal College of Obstetricians and Gynaecologists, in conjunction with the National Health Service, continues to recommend Filshie Clips as the preferred method for laparoscopic female sterilization.¹⁵ The Filshie System is the most common tubal occlusion method in Australia and New Zealand¹⁶, and is one of the most popular permanent sterilization methods in the United States, Canada, and a significant number of other countries worldwide.

Standard Kits

The Filshie System containing the Filshie Clips and Sterishot II applicator are immediately available and provide reliable results in every procedure.

Both kits are sterile and include:

- One single patient use Sterishot II applicator
- One pair of Filshie Clips

ITEM	ITEM NO.
Sterishot II Standard Laparoscopic Kit	AVM-951
Sterishot II Minilaparotomy Kit	AVM-951M

Elite Kit

Versus the standard Sterishot II laparoscopic kit, the Sterishot II Elite Kit adds one 8mm bladeless port for use as the secondary (instrument) port in dual-incision laparoscopic technique.

ITEM	ITEM NO.
Sterishot II Elite Kit w/ Bladeless Port	AVM-954

10 Gad N, Aziz R, Siwicki K, Filshie clip migration into wall of urinary bladder presenting with acute abdominal pain. Case report and review of English literature: from 1990 to April 2009, *Pelvipereineology* 2010;29:84-7

11 Subramaniam A, Blanchard CT, Erickson BK, et al. Feasibility of complete salpingectomy compared with standard postpartum tubal ligation at cesarean delivery: a randomized controlled trial. *Obstet Gynecol* 2018;132:20-7

12 Braaten K, Dutton C, Laparoscopic female sterilization. *UpToDate*. Dec 2018

13 Jayakrishnan K, Baheti SN. Laparoscopic tubal sterilization reversal and fertility outcomes. *J Hum Reprod Sci* 2011;4:125-9

14 Bhoyrul S, Vierra MA, Nezhath CR, et al. Trocar injuries in laparoscopic surgery. *J Am Coll Surg* 2001;192(6):677-683.

15 Faculty of Sexual & Reproductive Healthcare, Royal College of Obstetricians & Gynaecologists, Male and Female Sterilisation, 2014 Sep.

16 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Female sterilisation by Filshie clip tubal occlusion (C-Gyn 22), 2014 Nov.

17 U.S. Patents 9,451,966, 10,092,296

Permanent Female Sterilization

Most Effective Long Term Solution

Patient Friendly

Quick and Easy to Apply

FILSHIE CLIPS AND ACCESSORIES

Filshie Clips are available as individually packaged clip pairs for use as spares when needed.

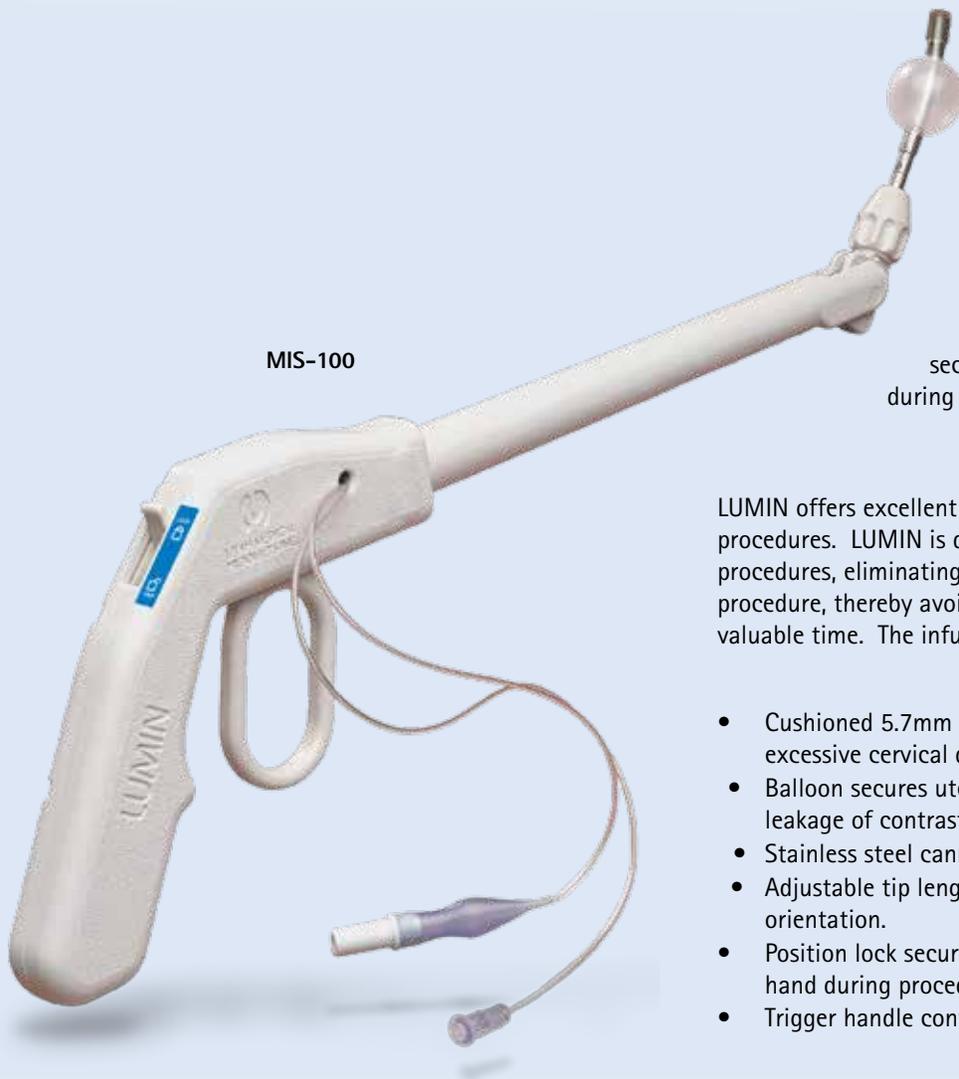
The ideal port size for the Filshie applicator instrument port is 8mm. This port size requires less port site dilation than the commonly available 10mm ports, so is gentler to tissue, may reduce incidence of port site herniation or delayed site healing, and may simplify port site closure.

ITEM	QUANTITY	ITEM NO.
Filshie Clips	10 pair / box	AVM-851J
8mm Bladeless Port	5 / box	FN-100-210



Uterine Manipulation

Cost-Effective High-End Functionality



MIS-100

LUMIN® Disposable Uterine Manipulator

LUMIN™ (Laparoscopic Uterine Manipulator INjector) is a disposable, single-use, sterile device that has set a new standard for controlled uterine manipulation. The ergonomic and unique design of the trigger handle offers control through a wide range of manipulation angles. A positioning lock and intrauterine balloon allow the manipulator to secure uterine position, freeing the surgeon's hands during the procedure.

LUMIN offers excellent versatility for application in a variety of procedures. LUMIN is designed for both diagnostic and surgical procedures, eliminating the need to change manipulators during a procedure, thereby avoiding contamination of surgical fields and saving valuable time. The infusion line provides evaluation of tubal patency.

- Cushioned 5.7mm tip reduces risk of uterine perforation without excessive cervical dilatation.
- Balloon secures uterine position without a tenaculum and prevents leakage of contrast media and fluids.
- Stainless steel cannula provides strength for confident control.
- Adjustable tip length accommodates correct uterine depth and orientation.
- Position lock securely maintains uterine position, freeing surgeon's hand during procedure.
- Trigger handle control offers easy, precise positioning.

ITEM	QUANTITY	ITEM NO.
Lumin Uterine Manipulator	10 / box	MIS-100

Cleaner LETZ[®] Margins

Closely Control Excision to Provide Accurate Samples

Avoid Over-Excision of Tissue

Reduce Thermal Damage to Specimens

Minimize Number of Samples

UTAHLOOP[®] ELECTRODES

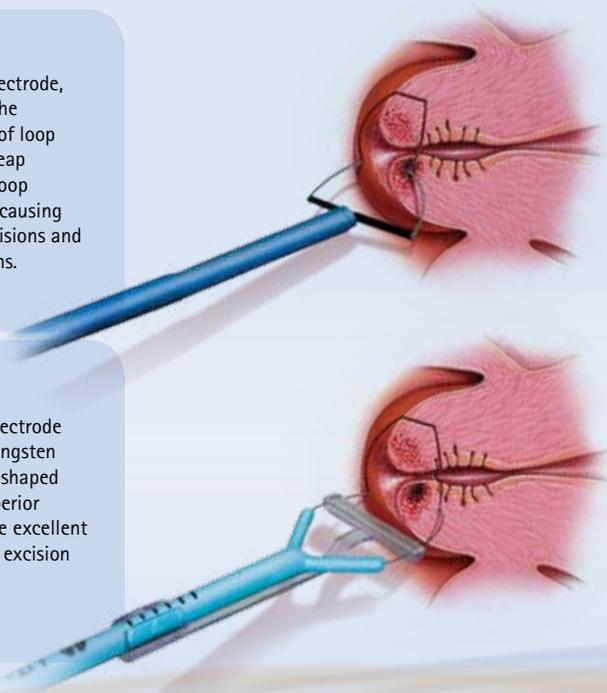
Outstanding Electrodes for HPV Management

Developed and manufactured by UTMD, UtahLoop specialty electrodes deliver highly predictable excisional performance. Why? Because UtahLoops are constructed with UTMD's proprietary ExactFit™ assembly process and have the unique Safe-T-Gauge[®]. The Safe-T-Gauge adjustable depth control device provides several important advantages that ensure the best outcomes possible for LETZ:

- The maximum excision depth can be preset to provide the physician with an accurate reference to avoid removing excess cervical tissue that might compromise patient fertility.
- The high-grade, durable tungsten excision wire is supported, providing extra stability to fix electrode position, avoiding superficial lesion excision and inadequate histopathology.
- A single loop width emulates several loop sizes which would be required without the Safe-T-Gauge, eliminating the risk of not having the right size for a particular excision and reducing the need to stock many loop sizes.

In a standard loop electrode, the combination of the T-shaped shaft, lack of loop wire support, and cheap wire material allow loop wire flex at the hub, causing superficial lesion excisions and fragmented specimens.

UtahLoop's unique electrode wire support, pure tungsten loop material, and Y-shaped shaft, along with superior workmanship, provide excellent rigidity and accurate excision depth control.



DLP-E11
25mm W
22mm D

DLP-B11
25mm W
8mm D

DLP-L11
20mm W
15mm D

DLP-W11
20mm W
12mm D

DLP-M11
15mm W
12mm D

DLP-S11
10mm W
10mm D

DLP-SQ1
10mm W
10mm D

DLP-SQ2
10mm W
4mm D

DLP-T11
5mm W
5mm D

C-LETZ® CONIZATION ELECTRODES Management of Deep Endocervical Disease

Current excisional devices for managing deep endocervical CIN lesions lack the shape needed to preserve healthy cervical tissue. Cone biopsy morbidity seems to be related to the total amount of tissue excised,¹ demonstrating that tissue-sparing excision techniques are important to improving clinical outcomes. Traditional "straight wire" conization electrodes excise an excess of healthy tissue, which may compromise adequate cervical function.

Research has also shown that CIN involvement in most endocervical glands extends no more than 3.8mm from the cervical surface.² The C-LETZ Conization Electrode is designed from this research. Its contoured electrode shape removes a constant thickness specimen to ensure adequate removal of diseased tissue without risking excessive excision of healthy cervical tissue.

- Contoured wire shape provides consistently clear excision margins, providing a 98% rate of certain histopathology diagnosis³
- Provides a single tissue specimen compared to 'top hat' excisions, eliminating thermal injury of the transverse excision component
- Potentially reduces the possibility of cervical stenosis by preserving healthy tissue
- Potentially reduces recurrence and/or progression rates
- Hexagonal shaft feature locks electrode into pen
- Provides simultaneous hemostasis compared to cold knife conization

DCE-125
9mm Rad
13mm D

DCE-120
12mm Rad
10mm D

DCE-115
11mm Rad
18mm D

DCE-110
15mm Rad
23mm D

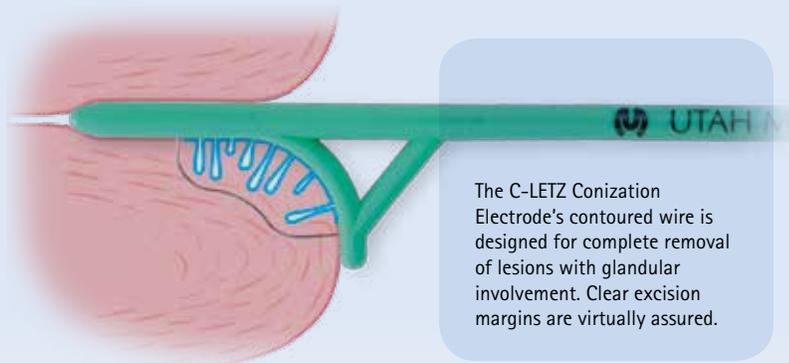
All electrodes are shown actual size, and are packaged 10 per box

DLP-N11
15mm L
Macro Needle

DLP-U11
15mm L
Micro Needle

DBL-511
5mm diameter

DBL-311
3mm diameter



1 Prendiville W, Large loop excision of the transformation zone, Clin Obstet Gynecol, 1995;38(3):622-39
 2 Anderson MC, et al, Cervical crypt involvement by intraepithelial neoplasia, Obstet Gynecol, 1980;55(5):546-50
 3 Mints M, Gaberi V, Andersson S, Miniconization procedure with C-LETZ conization electrode for treatment of cervical intraepithelial neoplasia: A Swedish study, Acta Obstet Gynecol Scand, 2006;85(2):218-23

Improving Cervical Access

Manage Physical Limitations

Improve Cervical Visualization

Focus on the Procedure, Not on Obstacles

DXTENDER® ELECTRODE EXTENDERS FOR LETZ

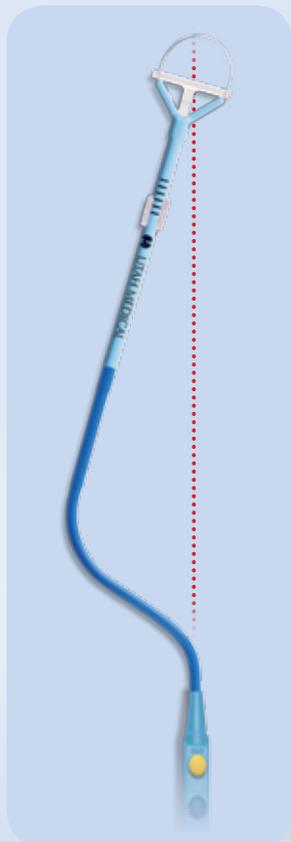
Enabling Cervical Access with Tactility

DXTender Electrode Extenders¹ provide a unique and effective solution for LETZ procedures.

Cervical depth varies among patients. LETZ electrode lengths that are appropriate for one patient will be insufficient to reach another patient's cervix. A traditional straight extender can provide adequate reach, but the additional length may cause hand pencil interference with the colposcope body.

UTMD's DXTender Electrode Extenders are specially configured to:

- Reposition hand and pencil away from colposcope and view axis.
- Place loop electrode on the pencil's long axis, which maintains tactility and control.
- Create additional reach for patients with a deeper cervix.



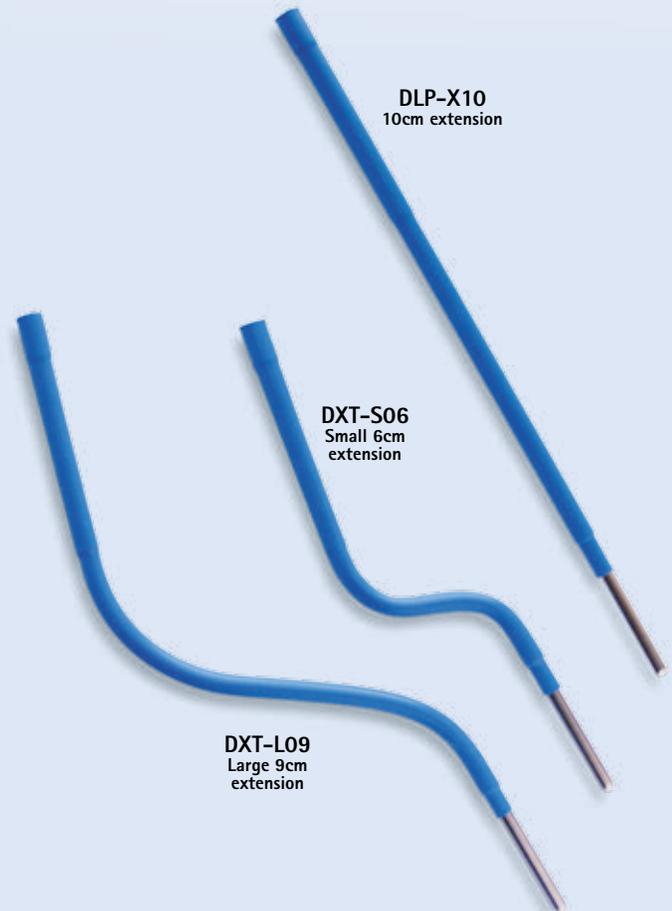
The DXTender Advantage

Tactility is critical during LETZ excisions. DXTender maintains the tactility of a straight electrode by aligning the loop electrode with the pencil's central axis. This eliminates lateral force on the electrode which would cause torque and result in slippage of the extender in the pencil.

Two LETZ Techniques, Two DXTender Electrode Extenders

Two DXTenders are available:

- Large: For use during colposcopically visualized LETZ procedures. Provides adequate clearance of the pencil from the body of the colposcope.
- Small: For use during directly visualized LETZ procedures. Keeps the user's hand away from the visual axis.



OPTISPEC® GYNECOLOGY LIGHT

Hands-Free Cervical Visualization



LITE-WS

Utah Medical Products' patented² OptiSpec Light is a new concept in non-colposcopic illumination of the cervix. An ultra-bright LED selected to provide a pure white light spectrum has been mounted in a small, clip-on disposable package. The result is excellent illumination of the cervix with a device that otherwise seems like it's not even there!

Cervical visualization through a colposcope with a bright white light provides critical visual information with minimal clinician fatigue. However, the use of the colposcope for other every-day exams is impractical. Other methods of cervical illumination emit a dull yellow, low intensity light, and usually require one hand to actively hold the lighting device.

- Compact light clips on to most common vaginal specula
- Unobtrusive configuration remains out of visual and working field
- Provides a simple, hands-free light that improves visualization during:
 - gyn exams
 - pap smears
 - LETZ® procedures
 - diagnosis of abnormal obstetric bleeding
 - ER exams for vaginal trauma
 - any other directly visualized vaginal procedures
- Efficient light-emitting diode (LED) provides truer color visualization with a light that is whiter than halogen bulbs
- OptiSpec is provided sterile, for immediate single patient use, eliminating any cleaning requirements



ITEM	QUANTITY	ITEM NO.
DXTender Electrode Extender, Small	10 / box	DXT-S06
DXTender Electrode Extender, Large	10 / box	DXT-L09
Straight Electrode Extender, 10cm	10 / box	DLP-X10
OptiSpec Gynecology Light, White	25 / box	LITE-WS

1 U.S. Patent 9,173,703
2 U.S. Patent 7,631,981

Cold Scalpel Healing with Electrosurgical Modality

- Precise Dissection Yields Excellent Cosmetic Results
- Low Power Settings Reduce Smoke Plume
- Provide Hemostasis with Favorable Healing Process

EPITOME® SCALPEL

Epitome, UTMD's unique blade electrode, significantly reduces thermal tissue injury compared to standard blade tips. In fact, histological analysis of porcine skin incisions shows healing results that closely resemble cold sharp scalpel incisions¹. This means that Epitome provides:

- Cutting precision exceeding that of a cold scalpel.
- Cosmetic results comparable to a cold scalpel.
- Hemostasis of the electrosurgical modality.
- Improved wound healing.

EXTERNAL LESION ELECTRODES

UTMD's short shaft electrodes are ideal for controlled removal of external lesions, allowing better utilization of office-based ESUs. Excision of lesions provides a specimen for dermatopathology, which is not possible with ablative modalities such as cryotherapy.

External lesion electrodes are packaged 10 per box.



CBE-150
Epitome .4, extended 4" shaft



CBE-250
Epitome .2, extended 4" shaft



CBE-100
Epitome .4, standard 2" shaft



CBE-200
Epitome .2, standard 2" shaft



CBE-210
Bendable Epitome .2, standard 2" shaft



CBE-220
Bendable Epitome .2, standard 2" shaft with ZapGuard



CBE-260
Bendable Epitome .2, extended 4" shaft with ZapGuard



CBE-270
Bendable Epitome .2, extended 6" shaft with ZapGuard

ZapGuard™

The ZapGuard is available on select Epitome Scalpels to reduce potential for electrical shocks and burns



DLP-B05
25mm W
8mm D

DLP-M05
15mm W
12mm D

DLP-S05
10mm W
10mm D

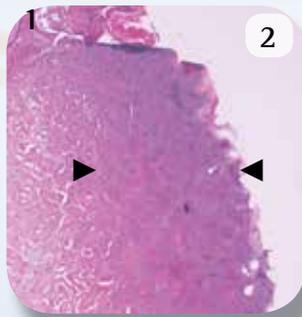
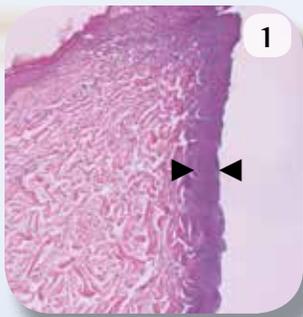
DLP-T05
5mm W
5mm D

DLP-SQ3
10mm W
4mm D

DLP-U05
5mm L
Micro Needle

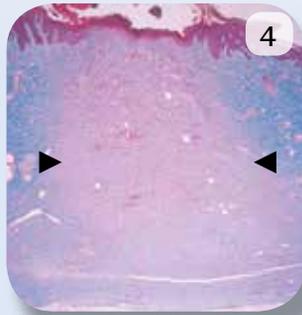
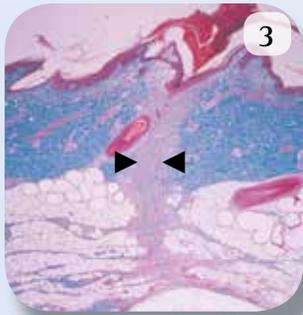
DLP-N05
5mm L
Macro Needle

DBL-505
5mm Ball



Reduced Thermal Injury

Histology reveals significantly reduced thermal injury with Epitome incisions (1) as compared to a standard electro-surgical tip incision (2).



Improved Wound Healing

Mason's Trichrome stain reveals markedly reduced fibroplasia, as shown by the degree of collagen deposition, and minimized inflammatory response in porcine skin incisions made with Epitome (3) as compared to a standard tip incision (4).



OPTIMICRO™ NEEDLE

UTMD's OptiMicro Needle ultra-fine tip electro-surgical electrodes are designed to provide precise dissection with virtually no thermal effects, yielding excellent cosmetic results for small-scale procedures. These micro-needles have the finest geometry available. Because of their extremely small surface area, high current densities are achieved with very low power settings.

UTMD designed and manufactures the OptiMicro Needle to the same exacting standards as the UtahLoop electrodes, and provides the discerning surgeon with critical clinical benefits:

- Thermal tissue injury is virtually eliminated, providing excellent healing results and reduced post-surgical pain.
- Output power settings are very low, which minimizes nerve and muscle stimulation and stray electro-surgical currents.
- Tungsten electrode withstands high current densities, and maintains sharpness throughout procedure.
- Substantially reduces smoke plume and odor compared to standard blade geometry tips.
- Provided sterile for immediate use, 10 needles per box



DN-0800
8cm Long Straight Tip



DN-0810
8cm Long with 10mm Exposed Straight Tip



DN-0400
4cm Long Straight Tip



DN-0300
3cm Long Straight Tip



DN-0200
2cm Long Straight Tip



DN-0345
3cm Long with 3mm Long 45° Tip



DN-0445
3cm Long with 10mm Long 45° Tip



DN-0245
2cm Long with 3mm Long 45° Tip

¹ Vore SJ, Wooden WA, et al, Comparative healing of surgical incisions created by a standard "bovie", the Utah Medical Epitome electrode, and a Bard Parker cold scalpel blade in a porcine model: a pilot study. Ann Plast Surg 2002; 49:635-45

Optimal Excisions

- Produce Specimens for Conclusive Histopathology
- Easily Manage Infectious Potential of Smoke Plume
- Provide Vital Patient and User Safety
- Focus on the Procedure, Not on Equipment

FINESSE[®]+ SYSTEMS

The FINESSE+ and FINESSE II+ Electrosurgical Generator and Smoke Evacuation Systems have been re-designed to meet the highest performance and safety standards currently required for electrosurgery.

Controlled Output Circuitry+

Utah Medical Products, Inc's (UTMD's) electrosurgical experience and research into tissue effects during loop electrosurgery have resulted in an upgrade to system design. FINESSE+ and FINESSE II+ incorporate Controlled Output Circuitry+ to produce a tissue specimen for conclusive histopathology. Controlled Output Circuitry+ is UTMD's advancement of "intelligent cut" circuitry that maintains the output within a prescribed cutting range by continuously monitoring and adjusting the output to produce a specimen with minimal thermal damage at the margins. This also eliminates any need to adjust the output setting when changing loop sizes.

Controlled Output Circuitry+ is a three-tier output delivery and monitoring approach:

- Tier 1:** A microprocessor and specialized electronics continuously monitor the output, adjusting for smooth, char-free cutting.
- Tier 2:** The microprocessor compares the output to mathematically-defined reference curves¹, and further adjusts the output as necessary to ensure that safe output levels are maintained.
- Tier 3:** In the event that output cannot be adjusted to satisfy the reference curves, output is disabled and an error is displayed.

Integrated Smoke Evacuation

The FINESSE+ and FINESSE II+ Systems utilize a design that integrates the electrosurgical generator and smoke evacuation system into a single compact unit. This allows placement in operating areas with limited space. It also allows simultaneous "single switch" activation of both modules by either the handswitch control pen or footswitch.

FINESSE+ and FINESSE II+ use a three-stage filtration system to evacuate and filter the smoke plume produced during electrosurgery. The filtration system includes an activated charcoal filter which adsorbs odorous gases, and two high-efficiency particulate filters which remove solid particles and aerosols, particularly helpful for smaller offices. The system has a minimum efficiency of 99.999% for 0.1 micron particles.

COMMON SPECIFICATIONS

Dimensions:	14.0" W x 14.7" D x 7.3" H, 24 lbs. (35.6cm x 37.3cm x 18.5cm, 11 kg)
Electrical Options:	115 Volt, 5.65 Amps, 50/60 Hz, or 230 Volt, 3.75 Amps, 50/60 Hz
Dispersive Pads:	Compatible Types Auto-detects and displays pad type: Dual (CQM) or Standard
CQM Circuit	Initial threshold detect, with threshold auto-adjust with improved contact. 10-130 ohms operating range
Activation:	Handswitch, Footswitch

FINESSE+

Electrical Output:

Frequency	450kHz
Cut/Blend Power	6-99 Watts @ 500 Ohm load
Cut Mode	Continuous Sinusoid
Blend 1 Mode	Interrupted Sinusoid 62.5% Duty Cycle
Blend 2 Mode	Interrupted Sinusoid 50% Duty Cycle
Blend 3 Mode	Interrupted Sinusoid 37.5% Duty Cycle
Coag Power	6-75 Watts @ 500 Ohm load
Coag Voltage	2,400 Volts zero-to-peak max (open circuit)

Smoke Evacuation:

Flow Rate	Normal >70 liters/min (2.5 CFM) High >100 liters/min (3.5 CFM)
Efficiency	>99.999% at 0.1 microns



Dispersive Pad Contact Quality Monitoring (FinCQM™)

UTMD's FinCQM circuit design adjusts to skin type variations and was validated to detect partial pad detachment before a pad site burn can occur. Output is automatically disabled and an error is displayed with separation of approximately 30% of the pad surface².

Patient and User Safety

The FINESSE+ and FINESSE II+ Systems meet global standards for patient lead isolation. This provides protection for both patient and clinician by reducing the possibility of creating an alternate current path that could result in a burn.

Enhanced Logic Integration

Output waveforms and a majority of logic functions are hard-coded into a microprocessor-linked complex programmable logic device (CPLD). Reliability of the FINESSE+ and FINESSE II+ systems is enhanced by minimizing component usage.

Error Indicators and Safety Interlocks:

CQM System	Unacceptable pad peel Pad contact out of range
Pad Status	Pad not connected to system Pad type mismatch
Output Monitor	Hazardous output power limit Output current limiting circuit
Cross-Key	Simultaneous Cut/Coag activation
Mode Change	Mode change during activation (FINESSE+)
Power Adjust	Control lockout during activation (FINESSE+)

230 VAC systems are CE Marked

FINESSE II+

Electrical Output:

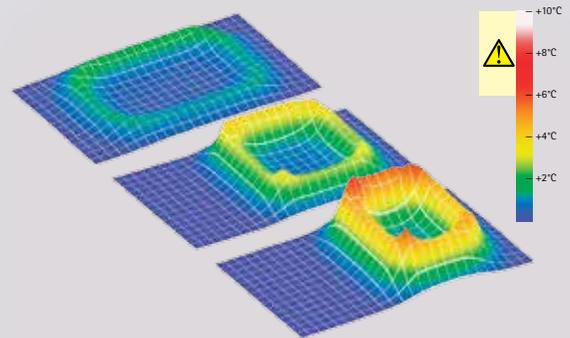
Frequency	450kHz
Cut Power	65 Watts @ 500 Ohm load
Cut Mode	Blended Cut Interrupted Sinusoid 62.5% Duty Cycle
Coag Power	60 Watts @ 500 Ohm load
Coag Voltage	2,180 Volts zero-to-peak max (open circuit)

Smoke Evacuation:

Flow Rate	>80 liters/min (2.8 CFM)
Efficiency	>99.999% at 0.1 microns



PREVENTING PAD SITE BURNS



To help prevent skin burns to patients during electrocautery procedures, the global electrocautery safety standard mandates a 6°C limit on temperature rise beneath a dispersive pad³. Thermography tests certify that the FINESSE+ and FINESSE II+ FinCQM system safely shuts down output well before pad site burns can occur. The top image shows a maximum temperature rise of 2.2°C for a fully attached dispersive pad. As the pad peels laterally away from the patient's skin, the FinCQM system will detect an error condition. In the most extreme condition allowed by FinCQM, the maximum temperature rise detected is 5.0°C (center image). Without FinCQM (bottom), continued pad separation results in significant skin heating, which likely causes a serious patient burn.

ITEM	Voltage Option:	115 VAC	230 VAC
FINESSE+		FIN-110	FIN-220
FINESSE II+		FIN2-110	FIN2-220

1 ANSI/AAMI/IEC 60601-2-2, §201.12.4.4.101

2 when using a pad certified for the Finesse+/Finesse II+

3 ANSI/AAMI/IEC 60601-2-2, §201.15.101.5; skin temperature rise after 700mA is applied for 60 seconds.

Electrosurgical Accessories

A Comprehensive Range for
Your Electrosurgical System

Contact Quality Monitoring (CQM) Dispersive Pads

CQM (split surface) dispersive pads allow pad contact monitoring when used with compatible electrosurgical systems such as FINESSE+ and FINESSE II+. These LATEX-FREE dispersive pads have a hydrogel surface to provide excellent contact to the patient's skin.

- Pads are certified for use with FINESSE+ and FINESSE II+ systems' FinCQM system, meeting IEC 60601-2-2 electrosurgical safety standard for Maximum Safe Temperature Rise.
- Available with a pre-attached cord

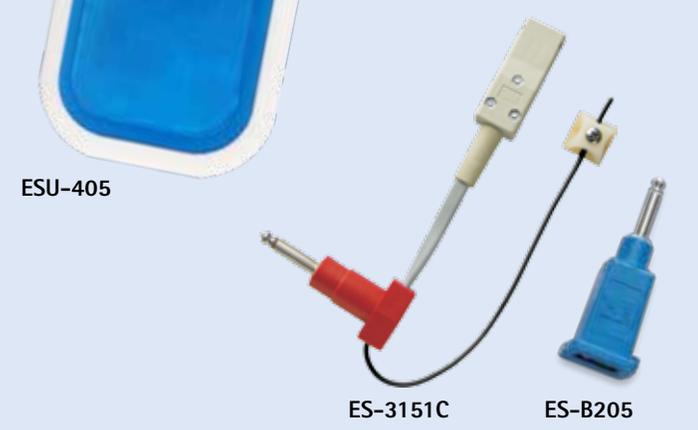
ITEM	QUANTITY	ITEM NO.
Dispersive pad, Split CQM, with pre-attached 10' cable	Box of 10	ESU-420

Standard Dispersive Pad and Adapters

UTMD offers a LATEX-FREE pre-corded dispersive pad for non-CQM electrosurgical systems that incorporates a hydrogel surface to provide excellent contact to the patient's skin.

ITEM	QUANTITY	ITEM NO.
Dispersive pad, with pre-attached 10' cable	Box of 10	ESU-405
<i>ESU-405 does not provide CQM</i>		

ELECTROSURGICAL SYSTEM	PAD	ADAPTER
Finesse, Finesse II (ESU and ESU2 models, 1998 to 2012)	ESU-405	none
Finesse, Finesse II (ESU and ESU2 models, pre-1998)	ESU-405	Contact UTMD
Cryomedics, Aspen, Leisegang, Cameron Miller	ESU-405	ES-3151C
Cooper 1000	ESU-405	ES-B205
Cooper 6000	ESU-405	none



ESU-170



FINESSE Footswitch

UTMD's two-pedal footswitch is for use with FINESSE+ and FINESSE II+ Systems. It allows activation of the generator in either the cut or coagulation mode, as well as simultaneous activation of the smoke evacuation system. The footswitch comes with a 10 foot cord.

ITEM	QUANTITY	ITEM NO.
Footswitch Assembly	1 each	ESU-170
<i>Not compatible with early models of Finesse and Finesse II with 3-pin connector</i>		

ESU-501



ESU-502



Smoke Evacuation Filters and Tubing

The Finesse Filter Pack incorporates an activated charcoal filter, a HEPA filter, a 10 foot filter tube, and a speculum tubing and adapter. Each filter pack can be used up to 15 times. The speculum tubing with adapter is a single use item which connects onto the speculum's smoke evacuation port. A complete replacement tubing set is also available.

ITEM	QUANTITY	ITEM NO.
Finesse Filter Pack	Box of 5	ESU-501
Speculum Tubing and Reducer	Box of 15	ESU-502
Universal Disposable Tubing Set	Box of 10	951-712

ESU-700



SSE-500



Electrosurgery Pens

Electrosurgical pens are for use with any standard (3/32" diameter) shaft electrosurgical electrode. Each pen comes with a 10 foot cord. Packed sterile and disposable.

ITEM	QUANTITY	ITEM NO.
Two-Button Electrosurgery Pen, Handswitch Control	Box of 10	ESU-305
Electrosurgery Pen for Footswitch Activation, Direct Fit	Box of 10	ESU-306
Electrosurgery Pen for Footswitch Activation	Box of 20	ESU-301
<i>ESU-301 requires an existing adapter</i>		

FINESSE Internal Filter

To keep the FINESSE and FINESSE II systems' smoke evacuator functioning efficiently, the internal filter should be replaced annually.

ITEM	QUANTITY	ITEM NO.
Finesse+ Internal Filter (for model nos. starting with "FIN")	1 each	SSE-500
Finesse Internal Filter (for model nos. starting with "ESU")	1 each	ESU-700

ESU-700 includes tool to access internal filter

Cost Effective Smoke Plume Management

SMOKE EVACUATION AND FILTRATION

Minimizing the Dangers of Smoke Plume

Organizations such as NIOSH, OSHA, ANSI, and AORN have issued recommendations for the use of smoke evacuation during laser surgery and electrosurgery. These recommendations are based on the outcomes of numerous clinical studies that have shown significant problems with surgical smoke plume:

- The smoke plume produced during electrosurgery is as harmful as the smoke plume from laser surgery.
- The smoke plume contains hazardous chemical compounds, ranging from respiratory irritants to known carcinogens.
- The smoke plume may transmit infectious viruses such as HIV and HPV.

The FILTRESSE™ Smoke Filtration System

Elimination of smoke plume requires an efficient and reliable filtration system. The solution is UTMD's Filtresse Smoke Filtration System.

- Three-stage disposable filter system efficiently removes odors and particulate matter, and reduces operational costs
- Easily attaches to most wands and instruments to yield quick smoke plume evacuation at the source
- Variable motor speed provides flow rate adjustability and yields enhanced noise suppression
- Pneumatic footswitch provides easy, hands-free operation
- Compact, portable and stylish design uses little office space

ITEM	QUANTITY	ITEM
Filtresse Smoke Filtration System, 110 VAC operation	1 each	SSE-100
Filtresse Smoke Filtration System, 220 VAC operation	1 each	SSE-200
Filtresse Internal ULPA Filter Cartridge	1 each	SSE-500
Filtresse External Filter Pack (Nonsterile)	Box of 5	SSE-501
7/8" Tubing Set with 1/4" Instrument Tubing/Reducer (Nonsterile)	Box of 10	SSE-503
7/8" x 10' Large Bore Tubing (Sterile)	Box of 10	SSE-513
1/4" x 12" Speculum Tubing and 7/8" Reducer Fitting (Nonsterile)	Box of 15	ESU-502
1/4" x 36" Flexible Tubing and 7/8" Reducer Fitting (Sterile)	Box of 15	SSE-512
Filtresse External Filter Cartridge for SSE-503 and SSE-513	1 each	SSE-511
Filtresse Pneumatic Footswitch	1 each	SSE-600
Filter Retaining Ring	1 each	SSE-610
Fuse, 10A Slo-Blo (for SSE-100)	1 each	SSE-710
Fuse, 5A Slo-Blo (for SSE-200)	1 each	SSE-720

FILTRESSE®

Dimensions:	9" W x 17" D x 9" H, 18 lbs. 23cm x 43cm x 23cm, 8kg)
Electrical Options:	110 Volt, 10 Amps, 45-65 Hz, or 220 Volt, 5 Amps, 45-65 Hz
Flow Rate:	>3.5 cubic feet per minute (>100 liters per minute) through 1/4" I.D. tubing >9.5 cubic feet per minute (>270 liters per minute) through 22mm I.D. tubing
Minimum Sealed Vacuum:	45" H ₂ O (86 mmHg) at maximum speed
Filtration Efficiency:	>99.999% at 0.1 microns, 3 CFM (86 liters/minute)
Internal Filter Life:	One Year
External Filter Pack Life:	Up to 15 procedures



FILTRESSE



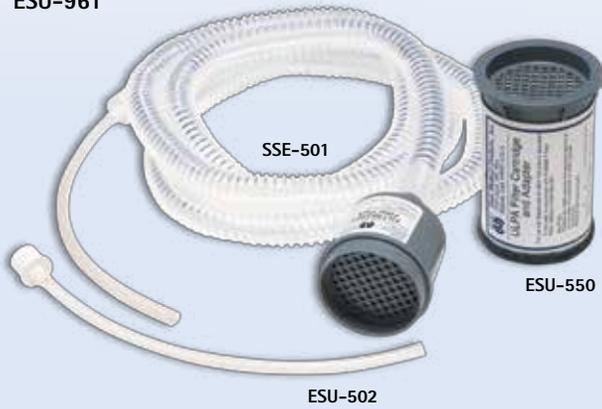
SMOKE EVACUATION CONVERSION KITS

Components for Single-Source Convenience

UTMD has high quality components for use with many other brands of smoke evacuators. They can reduce operational costs, yet provide these benefits:

- Three-stage filtration design consists of activated charcoal plus two high performance filter elements, providing 99.999% or greater particle filtration efficiency.
- Large filter surface area yields high airflow while ensuring long-term particle entrapment. Achieves quick, effective removal of the surgical plume.
- System components fit directly into smoke filtration unit for immediate use – no adaptation required.

ESU-961



ESU-962



FILTRATION KIT ESU-961

Contents:	1	ESU-550	Internal ULPA Filter
	1	SSE-501	External Filter Pack
	15	ESU-502	Speculum Tubing/Reducer

Compatibility: Aspen/ConMed AirSafe AspenVac
BEI Medical LLETZ-Plus
Cabot/Cryomedics MiniVac
Corometrics Model 201
Stackhouse AirSafe MiniVac
Nordex/Walker ProtectAir
Valleylab ValleyVac
ZSI LLETZ-Plus

FILTRATION KIT ESU-962

Contents:	1	ESU-540	ULPA/Charcoal Filter
	5	ESU-541	Prefilter
	5	ESU-542	Reducer Fitting
	5	951-712	Complete Tubing Set

Compatibility: CooperSurgical 6080
Surgimedics Surgifresh Mini
Surgimedics Plume-inator
Valleylab AirForce

ITEM	QUANTITY	ITEM NO.
Universal Disposable Tubing Set	Box of 10	951-712
ULPA/Charcoal Filter for Cooper, Surgimedics, Valleylab	Box of 3	ESU-540
Prefilter for Cooper, Surgimedics, Valleylab	Box of 30	ESU-541
Prefilter Reducer to 7/8" Tubing	Box of 5	ESU-542
ULPA Filter Cartridge for Stackhouse AirSafe MiniVac	1 each	ESU-550

Stackhouse, AirSafe, and MiniVac are trademarks of Stackhouse Inc. Valleylab is a trademark of Medtronic PLC. Surgifresh is a trademark of Surgimedics. CooperSurgical is a trademark of The Cooper Companies.

Electrosurgical Instruments

Quality Instruments For Your Practice

FOUR-WAY VAGINAL EXPANDERS

UTMD's Four-Way Vaginal Expanders provide a new approach to the visualization of the cervix during examinations, colposcopy, and LETZ procedures. The Expanders feature two laterally opening blades which solidly retain collapsing vaginal walls, ensuring clear access to the cervix for Pap smears and confident protection against vaginal wall burns during LETZ.

Increased Working Area

The use of two separate instruments reduces a physician's critical access and view. Combining two instrument functions into the Four-Way Expanders provides 50% more lateral working space at the introitus than a standard Graves speculum.

Patient Comfort

The Four-Way Expander's optimized configuration is more comfortable to the patient:

- Slender blades insert more comfortably than a Graves instrument for increased patient tolerance
- Unique design eliminates interference between components to avoid pinching of vaginal and perineal tissues.

Traditional Intuitive Design

The Four-Way Expanders insert and operate like a standard bivalve speculum. The physician maintains the functional feel of a traditional instrument when distending the introitus, and the traditional top blade design reliably elevates the cervix.

Multiple Configurations Available

- **High-Temperature Plastic Resin** is an economical choice for a small gynecology practice. This instrument is ideal for diagnostic and therapeutic procedures.
- **Stainless Steel** provides solid vaginal wall retraction for exams and colposcopies in the most problematic patients, such as bariatrics.
- **LETZ-Coated Stainless Steel** incorporates UTMD's high-quality autoclave-tolerant coating to protect the physician and patient from shock and burn during electrosurgical procedures.

ITEM	SIZE	DIMENSIONS	ITEM NO.
Four-Way Expander LETZ-Coated ¹	Medium	4.25" x 0.8"	ES-16122-MLE
Four-Way Expander LETZ-Coated ¹	Large	4.75" x 0.9"	ES-16132-LLE
Four-Way Expander LETZ-Coated ¹	Extra-Large	6.0" x 1.0"	ES-16135-XLE
Four-Way Expander Stainless Steel	Medium	4.25" x 0.8"	ES-16121-MST
Four-Way Expander Stainless Steel	Large	4.75" x 0.9"	ES-16131-LST
Four-Way Expander Stainless Steel	Extra-Large	6.0" x 1.0"	ES-16134-XST
Four-Way Expander Autoclavable Resin ¹	Medium	4.25" x 0.8"	ES-16101-MPL
Four-Way Expander Autoclavable Resin ¹	Large	4.75" x 0.9"	ES-16110-LPL

Instrument Holder for Four-Way Expander	ES-16141-INS
Disposable Smoke Evacuation (DSE) Tubing (Box of 50)	ES-16145-TUB

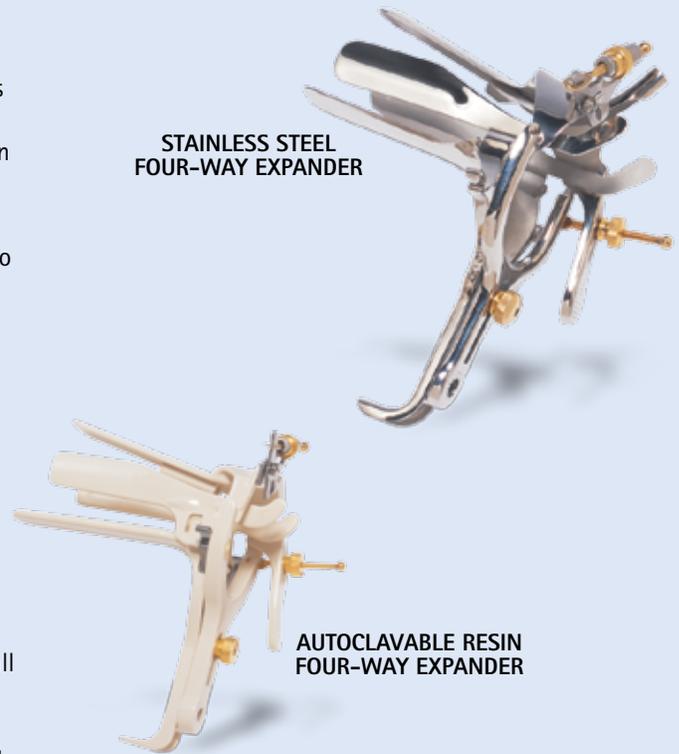
¹ Requires DSE Tubing (ES-16145-TUB)

LETZ-COATED
FOUR-WAY EXPANDER

DSE TUBING



STAINLESS STEEL
FOUR-WAY EXPANDER



An optional instrument holder and line of custom instruments are available for hands-free physician assistance when using the Four-Way Expander. Each instrument has an angled handle to preserve physician view and working area, essentially providing the physician a 'third hand'!



TISSUE FORCEPS



DRESSING FORCEPS



KOGAN ENDOCERVICAL SPECULUM (5mm shown)



RING FORCEPS



ATRAUMATIC TENACULUM



SCHROEDER TENACULUM



UTMD also has a complete line of instruments that are specially configured for use with the Four-Way Expander System.

- Each instrument has an angled handle to preserve physician view and working area
- Each instrument is coated for use during electrosurgical procedures to avoid unintentional shock and burns

ITEM	SIZE	DIMENSIONS	ITEM NO.
Schroeder Tenaculum		10"	ES-16201-SCT
Atraumatic Tenaculum		10"	ES-16207-STT
Emmett Tenaculum		10"	ES-16205-EMT
Iris Hook		10"	ES-16203-IRH
Straight Hook		10"	ES-16209-LEH
Two-Prong Hook		10"	ES-16211-TPH
Three-Prong Hook		10"	ES-16213-TRH
Kogan Endocervical Speculum	Standard	1.00" x 5mm	ESI-140
Kogan Endocervical Speculum	Narrow	1.00" x 3mm	ESI-141
Tissue Forceps		8"	ESI-401
Tissue Forceps		10"	ESI-402
Dressing Forceps		8"	ESI-403
Dressing Forceps		10"	ESI-404
Ring Forceps		9"	ES-16215-LRF
Lateral Wall Retractor		3.25" x .75"	ESI-300

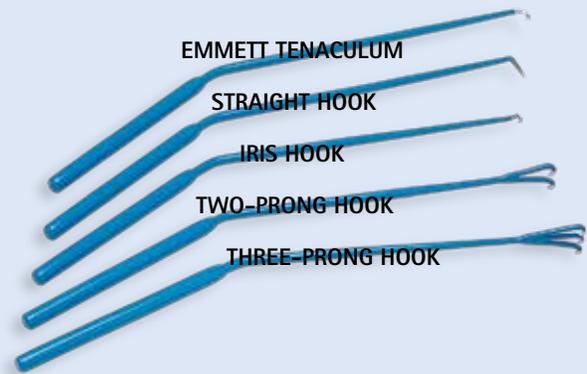
EMMETT TENACULUM

STRAIGHT HOOK

IRIS HOOK

TWO-PRONG HOOK

THREE-PRONG HOOK



LATERAL WALL RETRACTOR



LETZ® Coated Instruments

Quality Instruments For Your Practice

As part of our commitment to providing physicians with a complete line of LETZ® products, UTMD offers a full range of coated instruments.

Non-Conductive Coating

All reusable instruments have a special, extremely durable coating designed to insulate against transmission of electrical current, ensuring the highest level of protection for the patient and physician from possible burns or shocks during electrosurgical procedures.

Smoke Evacuation Port

All specula have a built-in smoke evacuation port for complete removal of the smoke plume from the operating field, preserving physician view and minimizing the potential hazards from smoke plume exposure.

Sterilization

All coated instruments can be processed using standard autoclave cycles. In addition, these instruments are certified compatible with the Sterrad process.

ITEM	SML (3 1/2")	MED (4 1/4")	LRG (4 3/4")	EXT LONG (6")
Graves Speculum	ESI-100	ESI-101	ESI-102	ES-15162-XSLT
Graves Wide-View Speculum		ESI-151	ESI-152	
Graves View-Maxi Speculum		ESI-171	ESI-172	
Pederson Speculum	ESI-110	ESI-111	ESI-112	
Pederson View-Maxi Speculum		ESI-117	ESI-118	
Weisman Graves Speculum, Left Open		ESI-131	ESI-132	
Weisman Graves Speculum, Right Open		ESI-133	ESI-134	
Collin Speculum		ESI-121	ESI-122	



GRAVES SPECULUM
standard bivalve speculum



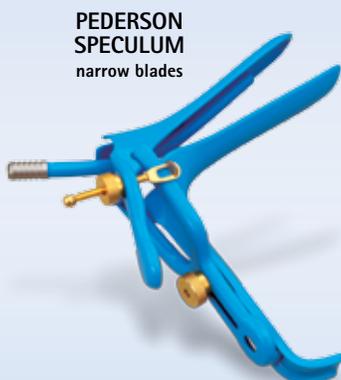
GRAVES WIDE-VIEW
40% wider at introitus than Graves



GRAVES VIEW-MAXI
minimal access restriction



GRAVES EXTRA-LONG SPECULUM



PEDERSON SPECULUM
narrow blades



COLLIN SPECULUM

Incontinence Therapy

Manage Patients, Not Insurance

Encourage High Patient Compliance to Therapy Plan

Maintain Revenue in Your Practice

THE LIBERTY® SYSTEM

A Logical First Choice for Pelvic Floor Therapy

Non-surgical pelvic floor treatments and therapies avoid the significant complications that are associated with many current surgical treatments for urinary incontinence (UI). In cases of mild to moderate cases of UI, doesn't it make sense to provide a therapy that has high patient success without the risk of complication?

Pelvic floor stimulation (PFS) is a non-surgical treatment which activates natural neuromuscular mechanisms. In the case of stress incontinence, PFS automates Kegel exercises via a pudendal nerve reflex. In the case of urge incontinence, PFS inhibits inappropriate bladder contractions.

Unlike other treatments, PFS has no side effects, always exercises the correct muscles, and does not require active patient participation.

The Liberty® System is the easiest to use and most cost-effective PFS system available. It consists of a stimulation device and a choice of three comfortable exercisers.

Liberty's simplified design exercises the correct muscles and is easy to use, therefore helping increase patient compliance to the therapy program you prescribe. Because it uses simple controls, patients of all ages find Liberty's use very intuitive. Liberty is preprogrammed to deliver stimulation waveforms found to be effective for stress and urge incontinence, with a simple toggle of the plainly labeled switch. Stimulation therapy is automatically programmed to cease after 30 minutes.

- Maintain UI patients in your practice, rather than referring them out to a specialist.
- Covered by Medicare and many private insurers.



PFS-042
Extended
Handle
Exerciser

PFS-041
Standard
Exerciser

PFS-043
Rectal
Exerciser

ITEM	QUANTITY	ITEM NO.
Liberty Pelvic Floor Stimulation System	1 each	PFS-200
Liberty Standard Vaginal Exerciser	1 each	PFS-041
Liberty Extended Handle Vaginal Exerciser	1 each	PFS-042
Liberty Rectal Exerciser	1 each	PFS-043

Uterine Assessment

Effective First-Line AUB Diagnostic Tools

Increase Detection Probability

TVUS/HSG-CATH™

for Saline Infusion Sonography and Hysterosalpingography

TVUS/HSG-Cath has been designed to offer clinical advantages when performing effective sonohysterography, or saline infusion sonography (SIS). TVUS/HSG-Cath is a dual-lumen system that integrates a highly durable polyurethane balloon that minimizes saline leakage when placed at the internal os. Its small diameter (8mm) results in minimal visual artifact to allow sufficient time to visualize the uterine image. Also, because its smaller diameter is easily controlled, intracervical balloon placement can be used to provide ideal imaging conditions and better patient tolerance¹.



- Depth markings ensure accurate placement of the catheter, and helps avoid fundal injury
- Enhanced infusion cross section to provide rapid contrast media infusion with less physical effort
- A choice of catheter introducer methods — a pre-loaded stylet is ready for immediate use when stenosis is present, and a peel-away introducer maintains catheter tactility during insertion and can be removed prior to imaging

The 30cm long dual-lumen, radiopaque polyurethane catheter body makes TVUS/HSG-Cath highly suitable during Hysterosalpingography (HSG) for fertility assessment.

MIS-50P



MIS-50ST



ENDOCURETTE® Unique Endometrial Sampler Designed to Minimize False Negatives

In-office endometrial sampling is a cost-efficient method for first-line diagnosis of abnormal uterine bleeding (AUB). However, published studies^{2,3} demonstrate that existing suction curette devices do not provide consistent specimen volume or quality, and insinuate the cause may be due to sampling tissue through a single, small port. Consequently, false negative assessment often occurs in patients with focal pathology.

EndoCurette uses four bowed curetting elements to remove endometrium independent from the orientation of the four elongated sampling ports. This specialized configuration is most effective with a single fundus-to-os draw with a twisting motion. In a recent clinical study⁴, EndoCurette was shown to obtain robust tissue samples with intact glands and stroma, yielding 100% accuracy for detection of hyperplasia, endometrial carcinoma, and proliferative and secretory endometrium. The study also showed 99.3% accuracy for detection of endometritis and 98.6% accuracy for detection of endometrial polyps.

EndoCurette's exclusive four-slot sampling head eliminates the directional dependence that limits the effectiveness of single-hole samplers.

- Multi-port tip configuration is designed to obtain a sample representative of a majority of the endometrial surface to improve detection of focal pathology.
- Deliberate fundus-to-os sampling motion prevents patient discomfort and risk of trauma by eliminating repeated fundal contact of tip.
- Tip profile, vacuum plunger, and cannula rigidity provide stiffness that facilitates insertion and may help provide access through mildly stenotic cervix.
- Two options available – a traditional plunger style for easy sampling, and a syringe-driven model that maintains suction with aspiration.

ITEM	QUANTITY	ITEM NO.
TVUS/HSG-Cath, 5Fr, with Integral Stylet	10 / box	MIS-50ST
TVUS/HSG-Cath, 5Fr, with Peel-Away Introducer	10 / box	MIS-50P
EndoCurette	25 / box	CUR-100
EndoCurette Clear, with 30cc syringe	20 / box	CUR-120

1 Spieldoch RL, et al, Optimal catheter placement during sonohysterography, *Obstet Gynecol* 2008;111(1): 15-21
 2 Rodriguez GC et al, A comparison of the Pipelle device and the Vabra aspirator as measured by endometrial denudation in hysterectomy specimens: The Pipelle device samples significantly less of the endometrial surface than the Vabra aspirator, *Am J Obstet Gynecol* 1993;168:55-9
 3 Guido RS et al, Pipelle endometrial sampling: sensitivity in the detection of endometrial cancer, *J Reprod Med* 1995;40:553-5
 4 Abdelazim IA, et al, Pipelle endometrial sampling versus conventional dilatation & curettage in patients with abnormal uterine bleeding, *J Turkish-German Gynecol Assoc* 2013;14:1-5

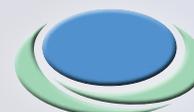
CUR-100

CUR-120



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FEMCARE



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Contact Utah Medical Products/Femcare for product
availability in your area.