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## Multicentre Outpatient Thermal Balloon Endometrial Ablation (Thermablate™) with and without Concomitant Hysteroscopic Fallopian Tube Microinserts (Essure™)

*George A. Vilos, MD 1, Mark H. Emanuel, MD 2, Claude Fortin, MD 3, Nick Leyland, MD 4, Basim Abu-Rafea, MD 5*

**Objective:** To determine feasibility, safety and efficacy of the Thermablate balloon to treat menorrhagia with and without concomitant hysteroscopic fallopian tube microinserts (Essure).

**Design:** Prospective multicentre cohort trial (Canada Task Force Classification II-2).

**Setting:** 5 University affiliated teaching centers.

**Patients:** 80 women with menorrhagia.

**Intervention:** Procedures were performed under general anesthesia (n=30), or conscious sedation with or without paracervical block (n=50). Pre-operative patient assessment included Pap smear, endometrial biopsy and transvaginal sonography with or without intrauterine saline or gel infusion, and/or hysteroscopy. Intra-operative assessment included pelvic examination and uterine sounding to confirm uterine position and cavity length followed by cervical dilatation to 6-7 mm and hysteroscopy prior to Thermablate balloon insertion.

The new Thermablate balloon system delivered preheated glycerin (~1700C) at sustained intra-balloon pressures of ~220 mmHg for 30, 30 and 60 sec treatment cycles. Post-treatment hysteroscopy was performed in all patients and microinserts (Essure) were inserted in 13 women. In 8 women the microinserts were placed prior to Thermablate and in 5 after balloon ablation.

**Measurements and Main Results:** There were no intra- nor post-operative adverse events. At 3 to 12 months (median 6), patients reported amenorrhea-30%, spotting/hypomenorrhea-53%, eumenorrhea-7%, menorrhagia-10%, and overall satisfaction rate of 85%. All microinserts were placed successfully and at 3 months one tube (4%) was patent.

**Conclusions:** 1. Following Thermablate balloon endometrial ablation, patient satisfaction was 85% with amenorrhea rate of 30%. 2. Microinserts (Essure) can be inserted before or after Thermablate balloon ablation.

 **Thermablate EAS™**  
Endometrial Ablation System

*Developed for physicians who want the ultimate in simplicity and patient comfort*





### LiNA Sea Star System

- Self retaining retractor made of lightweight plastic resin
- To be used in conjunction with the LiNA Skin Hooks
- Offering the surgeon numerous and unobtrusive retraction options
- Available in single use and reusable versions
- Five different sizes/shapes
- Three different skin hooks - *small sharp/blunt, large blunt*



### Post Menopausal Assessment Products

#### Prima Series® – Vaginal LEEP Specula

The Prima Series® is made from Ultem® resin, making it light, smooth, easy to maintain and highly resistant to temperature change. This unique non-stick material is noticeably more comfortable for your patients and is LEEP compatible.

Unconditionally guaranteed for life against surface failure. No chipping, peeling or cracking.



*Non-conductive Reusable Stain-Resistant Durable Autoclavable*

CO-PSV-1L	Medium Specula	\$242.00	Speculum Tubing (per 50)	
CO-PSV-2L	Large Specula	\$242.00	With connector (clinically clean)	\$173.00
			Without connector (clinically clean)	\$107.00
			With connector (sterile)	\$192.00
			Without connector (sterile)	\$135.00



#### Embryon Endometrial Sampler

*Embryon Endometrial Sampler for the detection of endometrial carcinoma, monitoring of the endometrium in HRT and endometrial dating to assist diagnosis in infertility.*

R57.509	Endometrial Sampler	\$92.00 / box 25
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#### Embryon OS Finder and Dilator Sets

Smooth moulded profiles for ease of entry and gentle, low trauma dilation  
Guaranteed – Ethylene Oxide Free - Every Embryon product is sterilised by gamma irradiation to remove the significant risk of embryo toxicity from residual contamination with EtO

<u>Disposable</u>		
R57.488	Dilator Set (1 x 23mm, 1 x 45mm, 1 x 85mm)	\$31.00 / set
R57.485	Os Finder 23mm	\$10.00 each
MS 260-600	MedSys Dilators 55mm Slow	\$421.00 box/50
MS 260-700	MedSys Dilators 45mm Quick	\$421.00 box/50
<u>Reusable</u>		
MM 260-600	Marina Medical Finder Set	\$277.00 / set



#### Hunt Cannula Trocar

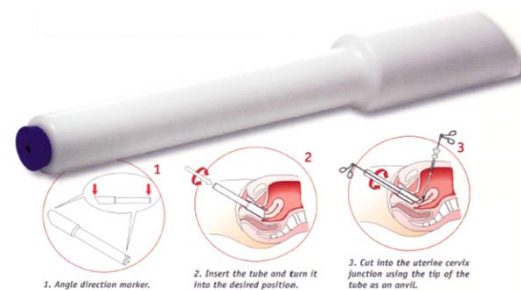


Specially designed, clinically proven fascia anchoring threads hold cannula securely in place, regardless of number of instrument exchanges  
Only device on the market that permits suturing through the cannula.

#### Fischer Cone Biopsy Excisor



Improved control during cervical biopsy procedures, better specimens and more predictable results.  
Positioning is easy and precise; a smooth 360degree motion removes a perfect conical cervical specimen in seconds.



### LiNA Colpotomy Tubes

Lightweight tube with air tight silicone valve for 5mm instruments

Sterile, ready to use, 10 per box

Prevents loss of carbon dioxide from the peritoneum

Easy to use - reduces procedure time

Provides excellent anatomical visualization

### LiNA Loop



Fast and safe sectioning of uterus (3-5 sec)

Clean and effective cut each time

Two loop sizes covering all uteri

Cost effective

Easy removal of myomas  
5mm diameter – for 5mm trocars  
Minimises procedure time

### Staff News

Gytech would like to welcome Daniel Tidey & Dan Hinch to the sales team. Daniel Tidey has joined Gytech as our National Sales Manager and Dan Hinch as our Account Manager servicing Victoria. Welcome to you both.

### Conferences

#### AAGL

Orlando, Florida, USA  
15<sup>th</sup> – 19<sup>th</sup> October