See over the page for a glossary of symbols used in product labelling

ColpoWave™ Colpotomizer (CWD)
CerviGrip™ Uterine Manipulator (CGD)

Federal (USA) Law restricts this device to sale by or on the order of a physician

Last revised 2 November 2017

INSTRUCTIONS FOR USE

PACKAGING

- CWD and CGD are packaged separately.
- Each CWD box contains 6 sterile disposable blister packs.
- Each CGD box contains 6 sterile disposable blister packs.

STERILE unless blister pack has been opened or damaged. Discard if blister pack has been opened or damaged.

Ethylene Oxide Gas Sterilised.

STERILE EO

Single-use

CE
0197

EC REP
Shanghai International Holding Corp. GmbH,
Eiffestrasse 80, 20537 Hamburg, Germany

ARTG 261451
ARTG 261452

US Patents 6,420,375; 9,101,390; 9,451,985;
Australian Patent 773391.
Further Patents Pending.
Patents: www.surgitools.com/patents.html

SurgiTools™
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PRODUCT DESCRIPTION

ColpoWave Colpotomizer and CerviGrip Uterine Manipulator are single use. No parts are made with natural rubber latex. All parts are supplied sterile to be disposed of after use.

INDICATIONS FOR USE

ColpoWave and CerviGrip are indicated for use by a surgeon in laparoscopic procedures where uterine manipulation and visualization of the position of the vaginal fornices for colpotomy incisions is required, and for maintaining pneumoperitoneum during vaginal vault closure.

CONTRAINDICATIONS

ColpoWave and CerviGrip should not be used if the patient is pregnant or is suspected of being pregnant, planning an IVF procedure, fitted with an IUD, or otherwise unsuitable for the use of the device in the opinion of the surgeon.

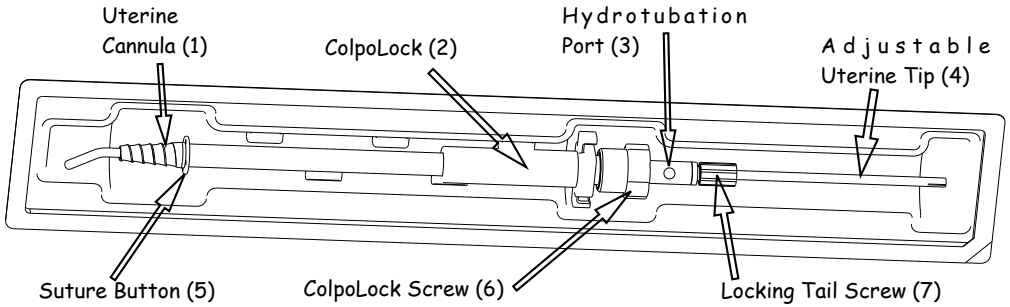
WARNINGS

- Read these Instructions for Use (three pages) before using these devices.
- These devices are for single use only and should be disposed of after use. Manufacturer is not responsible for any possible risks, including patient injury, resulting from or associated with re-use or re-processing of these devices.
- Store in a cool, dry area away from direct sunlight.
- These devices should only be used by physicians having adequate training and familiarity with laparoscopic gynecological procedures.
- Confirm the Uterine Cannula rotates freely on the Adjustable Uterine Tip.
- Only advance the Adjustable Uterine Tip up to the uterine fundus under laparoscopic vision.
- Insert the Colpotomizer with the protruding lips posterior to minimize the possibility of vaginal lacerations.
- Harmonic shears and cutting diathermy (≥60W) can damage the colpotomizer material. For best results, perform incisions inside the colpotomizer lip without touching the lip directly.
- To avoid uterine perforation, never hold or push on Adjustable Uterine Tip.
- Note that the Colpotomizer's second lip is 20mm from the distal lip.

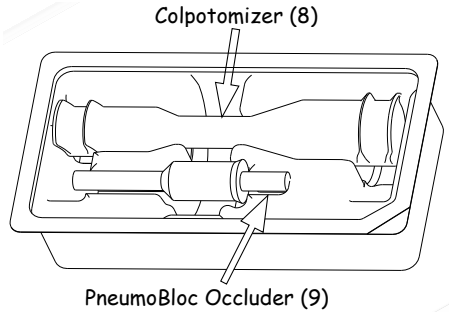
DIRECTIONS FOR USE

Step 1
For best anteversion of the uterus, ensure patient's pubic symphysis is placed at, or over, the edge of the operating table.

Step 2
Open sterile packages and place the contents ready for use:



(A) CerviGrip™ Uterine Manipulator



(B) ColpoWave™ Colpotomizer

Step 3
Slide ColpoLock (2) and ColpoLock Screw (6) off Uterine Cannula (1).

Step 4
Measure the length of the uterine cavity using a uterine sound. If there is stenosis, dilate the cervix to Hegar 5-7. If there is not stenosis, do not dilate.

Step 5
Push out Adjustable Uterine Tip (4) so that the distance between the end of the tip and Suture Button (5) is half the measured uterine length.

***WARNING**:*
- *Confirm* Uterine Cannula (1) *rotates freely on* Adjustable Uterine Tip (4).
- *Only advance* Adjustable Uterine Tip (4) *up to the uterine fundus under laparoscopic vision.*

Step 6
Insert Adjustable Uterine Tip (4) into the uterine cavity and rotate Uterine Cannula (1) clockwise until Suture Button (5) is flush against the external cervix. An optional stay suture can be placed around Uterine Cannula (1) or through one of Suture Button (5)'s holes.

Step 7
Choose appropriate colpotomizer end based on size of vagina. Insert Colpotomizer (8) over the tail end of the Uterine Cannula (1), with lips posterior, and advance it up to the vaginal vault.

***WARNING**: Insert* Colpotomizer (8) *with the protruding lips posterior to minimize the possibility of vaginal lacerations.*

Step 8
Place ColpoLock (2) behind Colpotomizer (8) to prevent Colpotomizer (8) from sliding down, and turn ColpoLock Screw (6) clockwise.

Step 9
Under laparoscopic vision, advance Adjustable Uterine Tip (4) slowly to the uterine fundus. Secure it in place by turning Locking Tail Screw (7) clockwise.

***WARNING**: Never advance* Adjustable Uterine Tip (4) *beyond the uterine fundus.*

Step 10
Rotate Colpotomizer (8) to provide a visual landmark. Perform coagulation and colpotomy incisions inside the distal lip.

***WARNING**:*
- *Harmonic shears and cutting diathermy (≥60W) can damage colpotomizer material. For best results, perform incisions inside colpotomizer lip without touching lip directly.*
- *To avoid uterine perforation, never hold or push on* Adjustable Uterine Tip (4).
- *Note that* Colpotomizer (8)*'s second lip is 20mm from the distal lip.*

Step 11
When colpotomy is complete, remove the uterus and disassemble the device.

Step 12
Use Colpotomizer (8) as a vaginal vault closure probe by screwing PneumoBloc Occluder (9) clockwise into its tail end. PneumoBloc Occluder (9) contains an airtight port for inserting a 5-10mm instrument or retrieval bag.

ALTERNATIVE USES:
(i) **General Uterine Manipulator:** use only Pack A and Steps 1-2, 4-5 & 9.
Use Hydrotubation Port (3) for injection and ColpoLock (2) as tenaculum holder.
It is only necessary to screw Uterine Cannula (1) in enough to get an adequate grip (e.g. 2-3 turns).
(ii) **Standalone vaginal delineator:** use only Pack B and Steps 7 & 10-12, with Colpotomizer (8) and PneumoBloc Occluder (9) assembled as in Step 12.

Glossary of Symbols Used in Product Labelling

REF	Product code/catalog number
QTY	Quantity supplied in package
	Expiration date (YYYY-MM-DD)
LOT	Batch code
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	Do not re-use
	Read Instructions for Use before using this device
	Do not use if packaging has been opened or damaged
STERILE EO	Sterilised using Ethylene Oxide
FDA	US Food and Drug Administration Device Listing Number
ARTG	Australian Register of Therapeutic Goods Listing Number
CE 0197	CE-Mark and identification number of Notified Body. Certified in accordance with MDD (93/42/EEC)
EC REP	Authorised Representative in the European Community