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

ColpoWave™ Balloon (CBD)

for ColpoWave Colpotomizer (CWD)

Last revised 2 November 2017

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

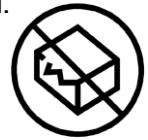
INSTRUCTIONS FOR USE

PACKAGING

Each CBD 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

PRODUCT DESCRIPTION

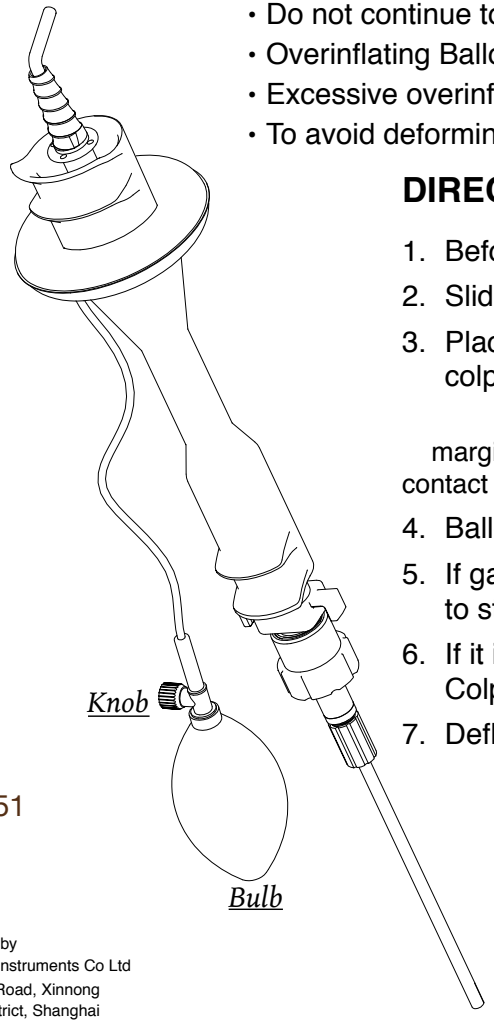
ColpoWave Balloon is a single use vaginal occluder for use with ColpoWave Colpotomizer and CerviGrip Uterine Manipulator. No parts are made with natural rubber latex. This device is supplied sterile to be disposed of after use.

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 (two pages) before using this device.
- This device is 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 this device.
- Store in a cool, dry area away from direct sunlight.
- This device should only be used by physicians having adequate training and familiarity with laparoscopic gynecological procedures.
- Do not continue to inflate Balloon after the gas leak has been stopped.
- Overinflating Balloon can make it difficult to rotate ColpoWave Colpotomizer.
- Excessive overinflation can cause balloon deformity or rupture.
- To avoid deforming Balloon, do not inflate more than 3 squeezes of the bulb.

DIRECTIONS FOR USE

1. Before use, confirm Balloon inflates and deflates correctly.
2. Slide deflated Balloon over Colpotomizer's small end.
3. Place Balloon approximately 2cm below the 20mm margin on the colpotomizer end that you will use. Do not apply lubrication.

(Note: Balloon can be placed between the distal lip and 20mm margin in benign cases, but care must be taken to avoid instrument contact with Balloon during colpotomy which may cause rupture.)

4. Balloon must be deflated when Colpotomizer enters the vagina.
5. If gas escapes during the procedure, inflate Balloon just enough to stop the leak. Never inflate more than necessary.
6. If it is difficult to rotate Colpotomizer, deflate Balloon. Then rotate Colpotomizer to new position and reinflate Balloon if necessary.
7. Deflate Balloon fully before removing Colpotomizer from vagina.

****How to Inflate & Deflate****

a) Inflate by squeezing bulb (do not overinflate).
b) Deflate by unscrewing knob.
c) Tighten knob before reinflating.
d) Do not overtighten knob as this can damage inflation mechanism.

CE 0197

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

ARTG 261451

SurgiTools™ www.surgitools.com

Surgitools Pty Ltd
231 Timberlane Drive,
Woodvale, WA, Australia

Made in China by
Surgitools (Shanghai) Medical Instruments Co Ltd
No 6, Lane 381, Hong An Road, Xinnong
Zhujing Zhen, Jinshan District, Shanghai

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