

Advincula Delineator™ Uterine Manipulator With Koh-Efficient® Technology

Single Use Device for Total Laparoscopic Hysterectomy,
Laparoscopic Assisted Vaginal Hysterectomy
and/or Supra-Cervical Hysterectomy

STERILE SINGLE-USE

Instructions for Use

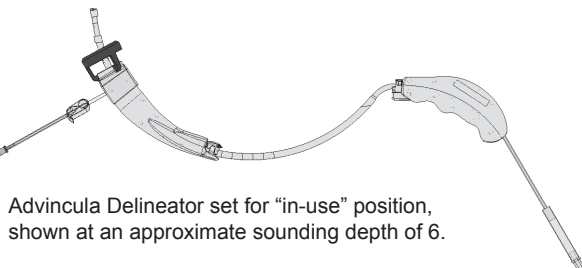
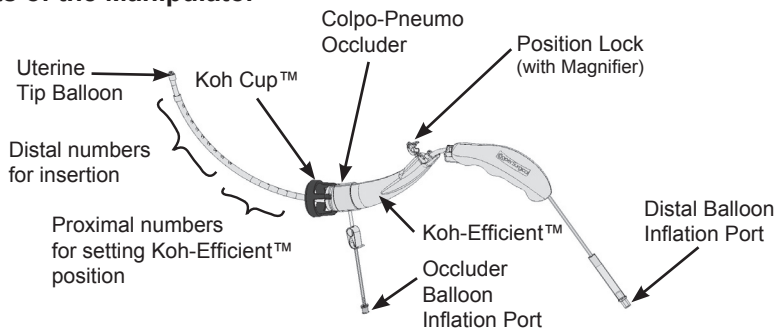
Device Description/Intended Use

The Advincula Delineator™ Uterine Manipulator is a single-use disposable device designed specifically for Total Laparoscopic Hysterectomy, Laparoscopic Assisted Vaginal Hysterectomy and/or Supra-Cervical Hysterectomy. The Advincula Delineator consists of a tip balloon built into the shaft along with an integrated colpotomy solution known as the Koh-Efficient®. This device comes in four (4) different sizes based on the diameter of the colpotomy cups. There are also versions available with steel cups for use with harmonic scalpel, or laser.

ELECTROCAUTERY VERSION

Part Number	Description
AD750SC-KE25	Advincula Delineator™ Uterine Manipulator with 2.5 cm Soft Koh-Efficient®
AD750SC-KE30	Advincula Delineator™ Uterine Manipulator with 3.0 cm Soft Koh-Efficient®
AD750SC-KE35	Advincula Delineator™ Uterine Manipulator with 3.5 cm Soft Koh-Efficient®
AD750SC-KE40	Advincula Delineator™ Uterine Manipulator with 4.0 cm Soft Koh-Efficient®

Parts of the Manipulator



Indications for Use

The CooperSurgical Advincula Delineator™ Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy, Laparoscopic Assisted Vaginal Hysterectomy and/or Laparoscopic Supra-Cervical Hysterectomy.

Contraindications

- The Advincula Delineator is to be used only when complete removal of the uterus is intended.
- This disposable manipulator should not be used when an IUD is in place, when the patient is pregnant, or intends to become pregnant.

Warnings

- The Koh colpotomy cups come in plastic versions for use with electrosurgical devices and stainless steel versions for use with Harmonic Scalpel and Laser. These cups are not interchangeable and should not be used with different, untested energy sources.
- Using an incorrect size Koh Cup could result in patient injury.
- Contents supplied sterile.
- Do not use if sterile barrier is damaged.
- Do not use if the device has been opened or damaged.
- Do not over inflate the Uterine Tip Balloon with more than 10 cc of air.
- Always confirm that the Koh-Efficient is locked in place prior to starting the colpotomy.
- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

Caution

U.S. Federal law restricts this device to sale by or on the order of a physician.

Directions for Use

Sounding

1. Using a Uterine Sounding instrument graduated in centimeters (not included), sound the uterus to determine its depth (external OS to Fundus).

Sizing

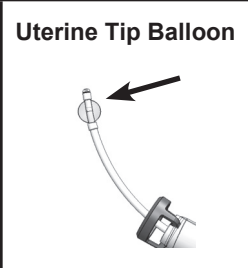
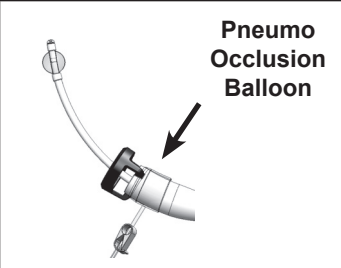
1. Using a Cervical Sizing instrument, graduated in centimeters (not included), measure the cervical diameter to determine the appropriate size Koh Cup (2.5 cm, 3.0 cm, 3.5 cm or 4.0 cm diameter cup) to use.

Dilation

1. Use a tenaculum (not included) to grasp the lip of the cervix.
2. Using a cervical dilator (not included), dilate the cervix to Hegar/Hank 8 (French 24) to ease manipulator insertion
3. Once complete, open the appropriate Advincula Delineator pouch.

Balloon Test Inflation

1. Test Inflate both balloons (refer to the chart below for air volume amounts).

 <p>Uterine Tip Balloon</p>	 <p>Pneumo Occlusion Balloon</p>
<p>Air Volume: 10 cc</p>	<p>Air Volume: 40-60 cc</p>

2. Visually inspect both balloons while they are inflated.
3. Then deflate both balloons completely.

Insertion

1. Use a tenaculum (not included).
2. Slowly insert the tip of the manipulator, to the pre-determined sounding depth using the distal sounding depth numbers on the device.



Distal numbers for insertion

3. Inflate the Uterine Tip Balloon slowly with up to 10 cc of air or until you feel resistance. Remove tenaculum.
4. Using the proximal set of numbers, slide the Koh-Efficient forward to the sounded number and push down on the position lock to secure it in place. Once completely engaged, the clear lens of the position lock should magnify the sounding depth number for enhanced readability.



Proximal numbers for setting Koh-Efficient

5. Once fully inserted confirm visually or by palpation, that the cervix is completely seated into the colpotomy cup.
6. Gently pull on the device to test for proper engagement of the tip in the uterus.
7. Just prior to colpotomy, inflate the Pneumo Occlusion Balloon with 60 cc of air. Should loss of pneumoperitoneum occur, up to an additional 60 cc can be added.












Tip Disengagement/Completion

Prior to removing the Advincula Delineator from the uterus, remove air from both the Uterine Tip Balloon and the Pneumo Occlusion Balloon. Discard the device in accordance with your hospital's guidelines.

Storage

Store at room temperature, avoid extreme temperatures.

Explanation of Symbols

	Reorder number		Not made with natural rubber latex
	Lot number		Do not re-use
	Use-by date		Do not resterilize
	Sterilized using ethylene oxide		Do not use if package is damaged
	Consult instructions for use		Manufacturer
	Caution		
R_x Only	U.S. Federal law restricts this device to sale by or on the order of a physician.		

Advincula Delineator™ is a trademark of CooperSurgical, Inc.
Koh-Efficient® is a registered trademark of CooperSurgical, Inc.
Koh Cup™ is a trademark of CooperSurgical, Inc.
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CooperSurgical



95 Corporate Drive
Trumbull, CT 06611 USA

Phone: (800) 243-2974 • Fax: (800) 262-0105

International

Phone: +1(203) 601-9818 • Fax: +1(203) 601-4747

www.coopersurgical.com

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