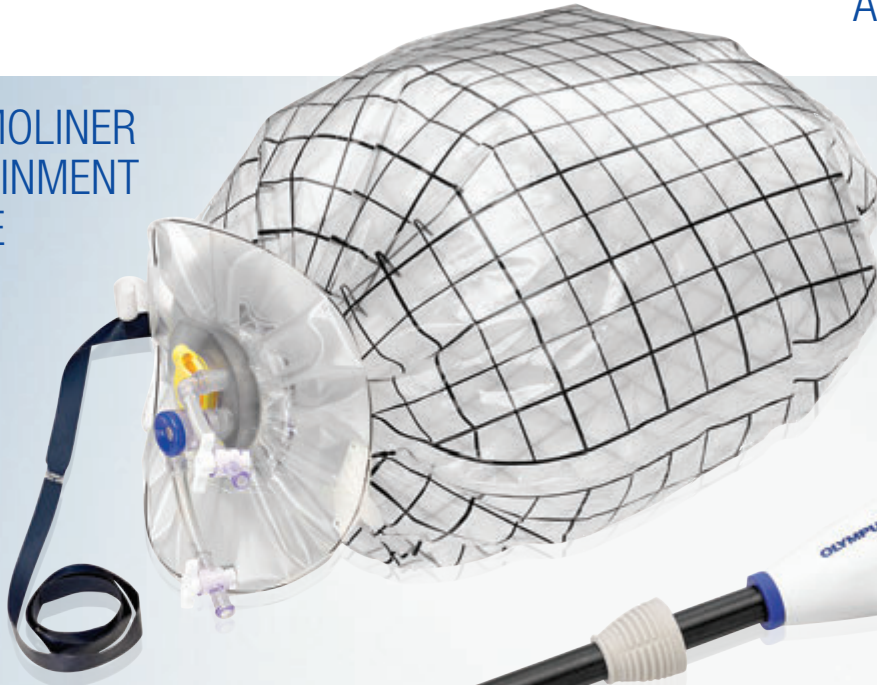


Contained Tissue Extraction System

MADE UP OF THE PNEUMOLINER™
AND PK® MORCELLATOR

PNEUMOLINER CONTAINMENT DEVICE



PK MORCELLATOR



PneumoLiner

WARNING: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.

CONTRAINDICATIONS: Do not use on tissue that is known or suspected to contain malignancy. Do not use for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal; or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision. Do not use in women with undiagnosed uterine bleeding. Do not use this device on patients with known or suspected allergies to polyurethane. Do not use where the abdominal wall thickness is larger than 10 cm. This device should only be used by physicians who have completed the formal validated required training program administered by Olympus and/or Advanced Surgical Concepts.

PK Morcellator

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINDICATIONS: The use of the PK Morcellator is contraindicated for surgical procedures in which the tissue to be morcellated is known or suspected to contain malignancy. The PK Morcellator is contraindicated for removal of uterine tissue containing suspected fibroids in the following patient groups:

- Peri- or post-menopausal patients.
- Candidates for en bloc tissue removal. For example, through the vagina or via a mini-laparotomy incision.

The use of the electrocautery generator ESG-400 is contraindicated when, in the judgment of the physician, bipolar electrocautery procedures with the PK Morcellator would be contrary to the best interests of the patient or user. For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrocautery.

The PK Morcellator should not be used if the patient is not considered suitable for a laparoscopic hysterectomy procedure or a laparoscopic myomectomy procedure.

CONTAINED TISSUE EXTRACTION SYSTEM

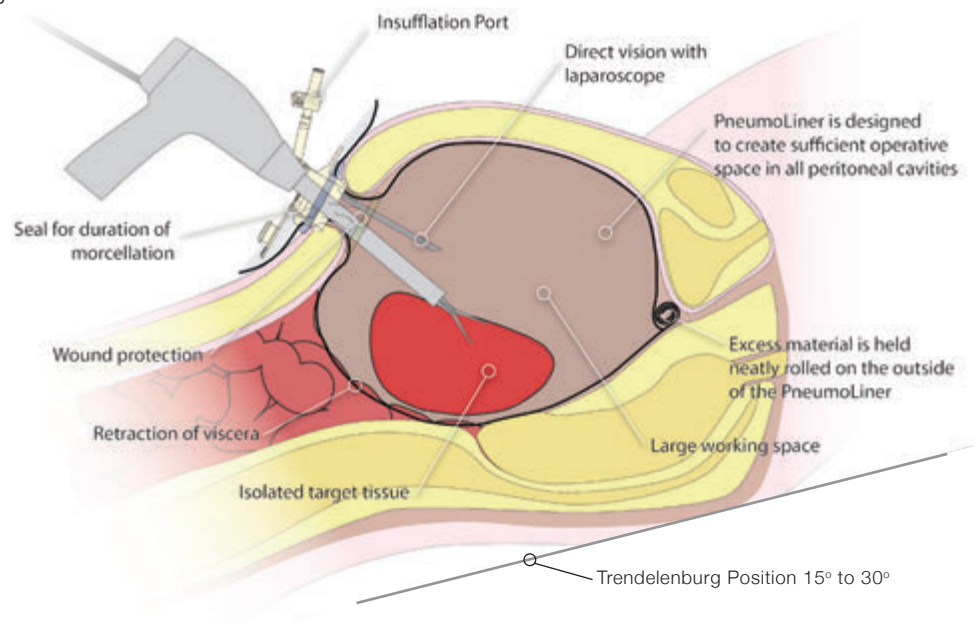
The Olympus Contained Tissue Extraction (CTE) System is made up of the PneumoLiner™, a first-of-its-kind tissue containment device approved under De Novo application, and the next-generation laparoscopic PK® Morcellator cleared via 510(k) application to provide certain patients with a laparoscopic surgery option to avoid open hysterectomy and myomectomy. Surgeons can operate with the confidence that comes with a closed containment device that prevents the escape of cells during power morcellation.

PNEUMOLINER CONTAINMENT DEVICE

- **Contained System** — The PneumoLiner System affords a complete and closed system specifically designed for intra-abdominal insufflation maintaining a barrier to the escape of fluids, cells and tissue fragments during power morcellation.
- **Closed System** — When insufflated, the PneumoLiner creates a barrier between the targeted tissue and non-targeted abdominal contents, to minimize the risk of inadvertent damage to adjacent structures.
- **Impermeable System** — The PneumoLiner is designed to be impermeable to the passage of liquid or tissue, measured down to a cellular level. When used as directed, the PneumoLiner will significantly reduce the risk of disseminating cells and tissue into the peritoneal cavity during power morcellation.

PK MORCELLATOR

- **Peeling Tip** — Integrated peeling tip promotes peeling on target tissue and avoids tissue coring throughout the procedure.*
- **Reduced Surgical Smoke** — The smoke management of the PK Morcellator maintains clear visibility of the morcellator, the target tissue and collateral tissue compared to PKS™ PlasmaSORD.™*
- **Faster Morcellation Speed** — PK Morcellator completes morcellation at a faster rate than PKS™ PlasmaSORD.™*



*The respective claim has been generated by bench testing.

PNEUMOLINER CONTAINMENT DEVICE

PneumoLiner neck design allows for easy specimen encapsulation

PneumoLiner should conform to each patient's abdominal size while avoiding intra-abdominal folding of material

Grid pattern allows the operator to visually identify the PneumoLiner location throughout the procedure to minimize risk of inadvertent damage with surgical instrumentation

Boot assembly
Multiple instrument port allows insertion of morcellation device and 5 mm laparoscope

PK MORCELLATOR

Constant and intermittent smoke evacuation provides option of continuous surgical smoke removal

Compact, lightweight design provides optimal surgeon comfort

Smoke evacuation intake for surgical smoke management at distal end

Smoke evacuation button

Peeling Tip promotes tissue peeling to avoid tissue coring

Integrated Smoke Management offers improved visibility

In-line filter for additional surgical smoke capture

ORDERING INFORMATION

CONTAINED TISSUE EXTRACTION SYSTEM

CTE-1	Contained Tissue Extraction System
WA90500US	PneumoLiner Containment Device
WA90200A	PK Morcellator

THUNDERBEAT HANDPIECE FOR OPEN SURGERY

TB-09200E	THUNDERBEAT, 9 mm, 20 cm, Open Extended Jaw
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ADDITIONAL THUNDERBEAT HANDPIECES

TB-0545FC	THUNDERBEAT, 5 mm, 45 cm, front actuated
TB-0535FC	THUNDERBEAT, 5 mm, 35 cm, front actuated
TB-0520FC	THUNDERBEAT, 5 mm, 20 cm, front actuated

PK TECHNOLOGY INSTRUMENTS

PK-CF0533‡	PK Cutting Forceps, 5 mm, 33 cm, 5/pkg.
PK-SP0533‡	PK Spatula, 5 mm, 33 cm, 5/pkg.
PK-NE0533‡	PK Needle, 5 mm, 33 cm, 5/pkg.
PK-JH0533‡	PK J-Hook, 5 mm, 33 cm, 5/pkg.
WA90300A‡	PK Lap Loop, 5 mm, 33 cm, 5/pkg.

EVEREST BIPOLAR INSTRUMENTS

3700‡	Everest LYONS Dissecting Forceps, 5 mm, 33 cm
3740‡	Everest LYONS Dissecting Forceps, 5 mm, 45 cm
3300‡	Everest MOLly Forceps, 3 mm, 33 cm
3330‡	Everest MOLly Forceps, 5 mm, 33 cm
3345‡	Everest MOLly Forceps, 5 mm, 45 cm

‡ Supplied sterile, single-use, disposable.

INSUFFLATION DEVICE

UHI-4	Insufflator with smoke evacuation
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SONICBEAT HANDPIECES

SB-0545FC	SONICBEAT, 5 mm, 45 cm, Front Actuated
SB-0535FC	SONICBEAT, 5 mm, 35 cm, Front Actuated
SB-0520FC	SONICBEAT, 5 mm, 20 cm, Front Actuated

GENERATORS AND ACCESSORIES

EPF-1	Surgical Tissue Management System (includes ESG-400 Generator, USG-400 Generator, communication cable, monopolar single & dual footswitches)
EPF-1C	EPF-1 Surgical Tissue Management System with Energy Cart TC-E400
TC-E400	Energy cart for EPF-1 System
TD-TB400	Transducer for THUNDERBEAT
MAJ-1870	Footswitch for THUNDERBEAT
MAJ-1871	Communication cable — short
MAJ-1872*	Communication cable — long
MAJ-1873*	Adapter for the connection to UHI-2 or UHI-3 insufflator
MAJ-1876	Docking fixture
AO451	Instrument Cleaning Brush
MH-507	Transducer Cleaning Brush
MAJ-619	8 mm Mono Footswitch Adapter with Screw Clamp
MAJ-620	8 mm Mono Footswitch Adapter for 5 mm Banana Plug

*Required for the automatic mist and smoke evacuation function.



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