**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.

**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.

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**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 electrosurgical generator ESG-400 is contraindicated when, in the judgment of the physician, bipolar electrosurgical 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 electrosurgery.

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

PK MORCELLATOR

- **Constant and intermittent smoke evacuation** provides option of continuous surgical smoke removal
- **Smoke evacuation button**
- **Compact, lightweight design** provides optimal surgeon comfort
- **Smoke evacuation intake** for surgical smoke management at distal end
- **Peeling Tip** promotes tissue peeling to avoid tissue coring
- **In-line filter** for additional surgical smoke capture
- **Integrated Smoke Management** offers improved visibility
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

**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

**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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