

KOLLER SURGICAL

2055 Glenwood Drive, Winter Park, FL 32792. 407.645.3555. www.kollersurgical.com or www.endoassist.com

INSTRUCTION FOR USE: ENDO-ASSIST™

MANUFACTURER: KOLLER SURGICAL, LLC

PRODUCT CODES: Endo-Assist™ Model EB10
Trumpet 7mm Model KS-T700
Trumpet 14mm Model KS-T140
Post 1 - Model AP10
Post 2 – Model AP20 (Optional)
Ring Clamp – Model RC00
Case Model KOM-0001

PURPOSE OF PRODUCT: The Endo-Assist™ is a U.S. Patented and U.S. Trademark protected device that manages and protects multiple laparoscopic instruments during laparoscopic surgical procedures aiding in patient safety, instrument organization and preventing instrument damage. Compared to the traditional method of laying instruments on patients or on a Mayo stand where they can fall, become disorganized, damaged or injure the patient, the Endo-Assist™ organizes the instruments and their associated cords providing a coordinated and streamlined approach to laparoscopic surgery. The Endo-Assist™ holds up to seven laparoscopic instruments at any given time and supports instruments and laparoscopes up to 13 mm in diameter. The Endo-Assist™ comes with removable “trumpets” of varying sizes, precision engineered to safely cradle delicate laparoscopic instruments and prevent instrument damage due to inadvertent falls from the operative field. The Endo-Assist™ is supported by an adjustable mast arm that is secured to the side rail of the operating room table using a universal Clark clamp allowing the device to be infinitely adjustable from either the left or right side of the patient and in all three x, y and z axes. The Endo-Assist™ comes ready to sterilize and use in a custom, state-of-the-art, all aluminum fenestrated case, manufactured in the U.S.A.

KEY SPECIFICATIONS: Product materials are compatible with steam. Product is intended for use with surgical wrap or sterilization pouches. All product components listed are intended to be sterilized in the provided case together.

MECHANICAL CLEANING: Machine cleaning is recommended in a washer disinfector cleared by the FDA. Products should be positioned in the washer to allow maximum water penetration and drainage. No overlapping – partially covered components will not be washed properly. Lids should be open. Products can be cleaned with enzymatic neutral pH detergents. For final rinse, DI or RO water is recommended.

The standard program should include: 1. Pre-wash with cold water (<100°F) rinse for a minimum of 2 minutes. 2. Washing cycle with enzymatic neutral pH detergent at temperature recommended by the detergent manufacturer for 5 minutes. 3. Washing cycle with neutral pH detergent at the temperature recommended by the detergent

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manufacturer for 5 minutes. 4. Rinse cycle for 2 minutes (preferably with DI or RO water). 5. Thermal disinfection of up to 195°F in compliance with the washer manufacturer recommendations for time and temperature. 6. Drying cycle at temperature not to exceed 240°F. 7. Caution when unloading machine as products will be hot. 8. Visual inspection is required to ensure complete removal of soil. 9. If product still shows soil repeat program.

STERILIZATION:

Disassemble all parts, including ring clamp, into individual components within case prior to sterilization.

Pre-vacuum Sterilizer: Wrapped case with all other products inside should be exposed to 132° C to 135° C (270° F to 275° F) for at least four minutes. Dry for 20 to 40 minutes.

After the sterilizer door is opened, all trays should be allowed to cool to room temperature before handling. The amount of time required depends on load content and ambient conditions (temperature and humidity). The potential for condensation may increase if the case is not allowed to cool properly. If wet spots on the packaging are observed, the set must be treated as non-sterile and be thoroughly reprocessed.

VALIDATION:

Steam Pre-Vacuum Efficacy Validation and Mechanical Cleaning Validation completed in June 2016 by High Power Validation Testing & Lab Services, Rochester, NY. Reports available upon request.

PRODUCT VIDEO:

Please go to www.kollersurgical.com for a video overview and demonstration of the Endo-Assist™ system assembly and use.