Catalog Numbers
Endoplus 5mm & 10mm diameter laparoscopic devices with lumen length up to 450mm long

Indications For Use
Hand held Laparoscopic instruments are intended for grasping, cutting, dissecting, retracting, clamping, cauterizing, and/or suction/irrigation in conjunction with Laparoscope during laparoscopic surgery. The instruments are designed to be used through a portal, the opening maintained by an introducer or cannula which allows for insertion and removal of the instrument without damage to the surrounding soft tissue. Instruments should be used only by personnel completely familiar with their operation. Using an instrument improperly for a task which it was not intended may result in a damaged or broken instrument.

How Supplied
Endoplus devices are packaged non-sterile. Cleaning and sterilization must occur prior to use.

Limitations on Reprocessing
Repeated reprocessing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

Warnings
Endoplus devices are to be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of the device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.

Do not use Endoplus electrodes in the presence of combustible/explosive gases

To reduce capacitive coupling, the electrosurgical device should only be activated when in position to deliver energy to the target tissue

Activating the electrosurgical unit simultaneously with suction/irrigation may alter the path of energy

Start with the lowest possible power setting on the Electrosurgical Unit and gradually increase the poser to achieve proper cutting and coagulation.

Cautions
If there are any variations between these instructions and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.

Use of instrument for a task other than that for which it is intended will usually result in a damaged or broken device.

Examples:

1. Use of a delicate dissector as a grasper.
2. Use of a dissector to remove clips.
3. Use of a 5mm grasper or dissector instead of a 10mm claw extractor forceps to remove excised tissue through cannula.

Prior to use, inspect device to ensure proper function, insulation, and condition. Do not use devices if they do not satisfactorily perform their intended function or have physical damage.

Inspect insulation prior to use. Any interruptions in the coating may compromise the safety of the device. To prevent the possibility of electrical shock or burns, do not use devices with breaks in the insulation.

Avoid mechanical shock or overstressing devices. Close distal ends prior to insertion or removal through cannulas. Removable inserts must be assembled firmly to the tube assembly for the device to function properly. Excessive tightening of removable inserts to the tube assembly may result in damage to the jaw and linkage mechanism. Inspect the jaw and linkage for cracked, bent, or damaged components.

The flush port cap should cover the flush port during use.

Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.

Proper care and maintenance of hand held laparoscopic instruments is essential for safe and effective operation. Prior to each use, instruments should be thoroughly examined for end of life indicators such as broken or worn parts which may inhibit the function. Specifically, instruments used for electrosurgery must be checked for nicks, cracks, or exposed metal on the shaft and handle insulation. Careful inspection upon receipt and frequent inspection during use for functional integrity is recommended as a safeguard against possible injury to patient or operator. Instruments should be used with extreme care when inserting or

removing from the cannula. Lateral pressure on the device during removal can damage the working tip, shaft of the device and/or insulation. Be sure the tips are closed and the device is pulled straight out until completely clear of cannula to avoid catching the valve assemblies or dislodging the cannula.

Use Only neutral pH (6-8) detergent solutions.

Directions for Removing Insert: does not require mechanical tooling. (i.e. screwdriver, pliers, allen wrench, etc.)

Step 1: Open the handle so the jaws are open. See Figure 1

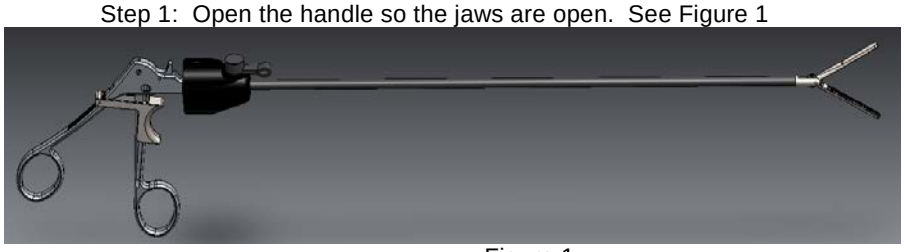

Figure 1

Step 2: Disengage the movable handle from the insert and secure the movable handle in the open position. See Figures 2 & 3

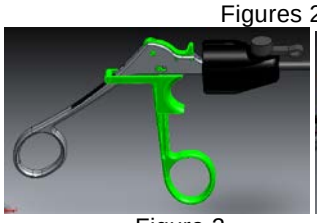

Figure 2

Figure 3

Step 3**:** Unscrew the insert from the tube assembly and remove.

Directions for Installing Insert: does not require mechanical tooling. (i.e. screwdriver, pliers, allen wrench, etc.)

Step 1: Ensure that the movable handle is secured in the open position. See Figures 2 & 3

Step 2: Screw the insert assembly into the lumen with the jaws open

Step 3**:** Engage the movable handle with the insert. See Figures 4 & 5

Figure 4

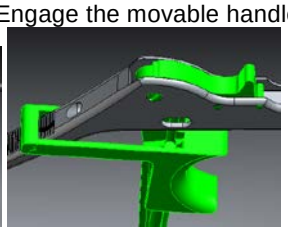

Figure 5

Pre-processing instructions

Initiate cleaning of device within 30 minutes of use.

Transport devices via the institutions established transport procedure.

Remove excess gross soil as soon as possible after use by rinsing or wiping the device.

All devices must be processed in the completely open position (i.e. flush port cap open, jaws open etc.) to allow solution contact of all surfaces.

Manual Cleaning:

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent, utilizing tap water entailing a temperature range of 27°C to 44°C, as per vendor's directions.
3. Place device in the open/relaxed position and completely immerse devices in the pH-neutral/enzymatic detergent solution

and allow device to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.

4. Place the device in the open/relaxed position and completely immerse devices in the pH-neutral/enzymatic detergent solution in an ultrasonic cleaner for a minimum of 10 minutes. Actuate all movable parts during the initiation of the soak time.
5. Using a soft bristled brush, remove all visible soil from the device. Actuate device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. **Note:** It is recommended that enzymatic or neutral pH detergent solution should be changed when it becomes grossly contaminated (bloody and/or turbid).

Manual cleaning of take-apart lumen devices (insert can be removed for cleaning)

a) remove the insert. Note that applicable device disassembly should not require any mechanical tooling. (i.e. screwdriver, pliers, allen wrench, etc.)

b) Using a soft bristled brush, remove all visible soil from the insert. Actuate insert while brushing, paying particular attention to hinges, crevices and other difficult to clean areas.

c) Using a soft bristled brush entailing a brush diameter and length that is equivalent to lumen diameter and length, scrub the lumen (i.e. angulated/nonangulated positions) until no visible soil is detected regarding the lumen rinsing described below.

d) Place the device in the open/relaxed position with the distal tip pointed down and flush the device with a minimum of 50mL of pH-neutral/enzymatic detergent solution by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times) ensuring all fluid exiting the lumen is clear of soil.

e) if visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen

6. Rinse the device by completely immersing in tap water with a temperature range of 27°C to 44°C, for a minimum of 30 seconds to remove any residual detergent or debris-
7. For lumen devices, following the rinsing step above, place the device into the open/relaxed position with the distal tip pointed down and flush the device with a minimum of 5OmL of tap water, entailing a temperature range of 27°C to 44°C, by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
8. Drying: dry the device with a clean, lint-free towel.
9. For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
10. Visually examine each instrument for cleanliness.
11. If visible soil remains, repeat cleaning procedure.

Automated Cleaning Option #1:

1. Device must have been cleaned manually and be in the completely open configuration. Note that applicable device disassembly should not require any mechanical tooling. (i.e. screwdriver, pliers, allen wrench, etc.)
2. Clean the laparoscopic devices via the Automatic cleaning parameters below.

Phase	Recirculation time (minutes)	Water Temperature	Detergent Type and Concentration (If Applicable)
Pre-wash 1	00:15	Cold tap water 1º C – 16º C (33º F – 60º F)	N/A
Enzyme Wash	01:00	Hot tap water 43º C – 82º C (110º F – 179º F)	• Detergent: Enzol™ (pH-neutral/enzymatic detergent) • Concentration: Per the detergent manufacturer's recommendations
Wash 1	02:00	Tap water 43º C – 82º C (110º F – 179º F)	• Detergent: NpH-Klenz® (pH-neutral cleanser) • Concentration: Per the detergent manufacturer's recommendations
Rinse 1	00:15	Tap water 43º C – 82º C (110º F – 179º F)	N/A
Pure Rinse	00:10	Purified water 43º C – 82º C (110º F – 179º F)	N/A
Drying	00:00	N/A	N/A

3. Manipulate the device to allow rinse water to drain from the lumen.
4. If visible moisture is present dry the instrument with a clean, lint-free towel.
5. Visually examine each instrument for cleanliness.
6. If visible soil remains, repeat cleaning procedure

Automated Cleaning Option #2:

1. Device must be in the completely open configuration. Note that applicable device disassembly should not require any mechanical tooling. (i.e. screwdriver, pliers, allen wrench, etc.)
2. Clean the laparoscopic devices via the Automatic cleaning parameters below.
    a. Attach canulated instruments to either lure lock fitting, recessed hole fitting or compression fitting.
    b. Attach other tube end to manifold which is integral to each of the two baskets.
    c. Load both baskets onto carriage frame work by sliding basket manifold over each fluid feed line.
    d. Press start.
    e. Carriage frame supporting two baskets loaded with ported instruments/devices lower into tank chamber.
    f. 120 degree F. facility water fills the tank while including a 1/2% concentration of enzymatic cleaner.
    g. Digital Ultrasonic transducers begin with 2 minute degas phase
    h. Digital Ultrasonic transducers continue for additional 18 minutes
        - While ultrasonic cleaning cycle addresses exterior bioburden, interior lumen bioburden is expelled.
    i. Enzymatic cleaner is seeded into the interior lumen via the ported tubes. (30 seconds).
    j. Flow is cut to allow this enzymatic/water mix to work within the tube and loosen bioburden for (4 minutes)
    k. Two phase air/water flush provides mechanical action to remove bioburden worked clean by interior enzymatic soak (30 seconds)
        - Steps 10, 11 and 12 are repeated two additional times while ultrasonic action continues
    l. Fluid flow to manifold ceases, drains are opened and tank is drained of entire bath.
    m. Drains remain open for remainder of cycle
    n. 120 degree F facility water is directed through integral, in-line supplemental heating element in order to boost fluid temperature to 190 degrees F.
    o. This 190 degree F straight water stream rinses interior of lumens as well as exterior of all devices in order to both remove residual bioburden that may have inadvertently re-contaminated the devices during the ultrasonic bath drain phase. (2 minutes)
    p. Exterior final cold, ozonated water flush to supplement the previous thermal disinfection (2 minutes)
    q. Fluid stream ceases
3. Manipulate the device to allow rinse water to drain from the lumen.
4. If visible moisture is present dry the instrument with a clean, lint-free towel.
5. Visually examine each instrument for cleanliness.
6. If visible soil remains, repeat cleaning procedure

Inspection/Maintenance

Proper care and handling is essential for satisfactory performance of any surgical device. The steps in these instructions for use should be taken to ensure long and trouble-free service from all your surgical devices. Inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, and chipped or worn parts. Specifically, instruments used for electrosurgery must be checked for nicks, cracks, or exposed metal on the shaft and handle insulation. Careful inspection upon receipt and frequent inspection during use for functional integrity is recommended as a safeguard against possible injury to patient or operator. If any of these conditions appear, do not use the device. Return device to authorized repair service center for repair or replacement.

Before sterilizing, lubricate the device with instrument milk or a steam permeable/water soluble lubricant, following the lubricant manufacturer's instructions. Check for smooth action of all moving parts.

Let devices drip dry for (3) minutes before packaging for sterilization

Packaging

Devices can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by your countries regulatory body. Use in accordance with packaging manufacturers sterilization instructions being sure to protect jaws and cutting edges from damage.

Sterilization

All devices must be processed in the completely open position (i.e. flushports, jaws etc.) to allow sterilant contact of all surfaces. The flush port must not be covered during sterilization. Take-Apart lumen devices may be sterilized with the insert installed.

All devices with concave surfaces shall be configured so that water pooling does not occur.

Prevacuum Steam Sterilization Parameters

Minimum Preconditioning Pulses: 3
Minimum Temperature: 132°C (270°F)
Minimum Exposure Time: 4 minutes
Minimum Dry Time: 20-30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Gravity Steam Sterilization Parameters
Minimum Temperature: 132°C (270°F)
Minimum Exposure Time: 15 minutes
Minimum Dry Time: 15-30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Storage
After sterilization, devices must remain in sterilization packaging and be stored in a clean, dry environment.

Instruments must be completely dry and lubricated to prevent damage. Store instruments in areas which provide protection from extremes in temperature and humidity. Instruments are delicate and should always be stored with tip guards to prevent damage to working end of the instrument.

Warranty
Endoplus instruments carry a one year warranty for defects in materials and workmanship. Instruments returned for warranty service which Endoplus determines to be defective in materials or workmanship will either be repaired or replaced by Endoplus without charge. This warranty is void if the instrument has been used for purposes other than intended, damaged by misuse or accident or has been repaired or altered by unauthorized persons.

Repair Service
Regardless of age, if any Endoplus device needs service, return it to Endoplus.

Note: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions for use prior to shipment.

Contact Information

Endoplus
750 Tower Road, Suite A
Mundelein, IL 60060
www.Endoplususa.com

Other Resources:
To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org, or www.iso.org