

# EASY LOOP™ Ostomy Device

Catalog No. EZL-02-NS

## INSTRUCTIONS FOR USE

These instructions apply to the single use, non-sterile Easy Loop™ Ostomy Device, supplied by Tools for Surgery, LLC. The device is supplied clean, not sterile, and must be sterilized prior to use. The Easy Loop™ is designed for single use due to aspects of the design that would be compromised if used more than once. Single use devices ARE NOT to be re-sterilized or reused.

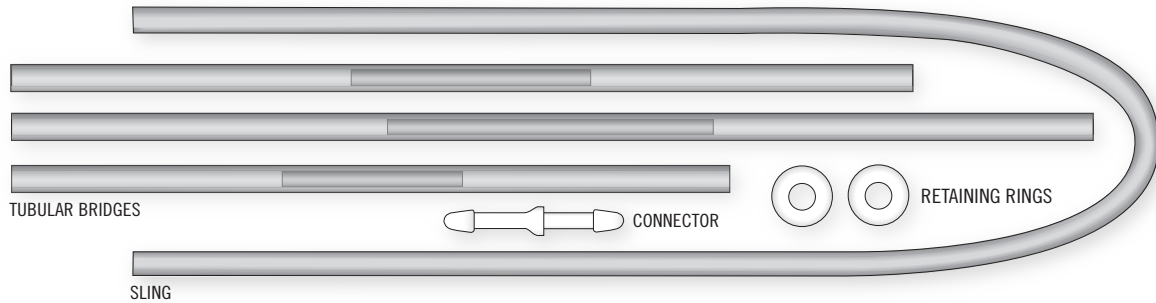


Figure 1

### DESCRIPTION:

A loop ostomy support system comprising a SLING, three alternative TUBULAR BRIDGES, a CONNECTOR, and a pair of RETAINING RINGS. The short, medium, and long TUBULAR BRIDGES each comprise a soft flexible silicone tube and a rigid plastic CENTRAL ROD. The SLING is used to temporarily retract the bowel during the surgical procedure. The RETAINING RINGS maintain the position of the CENTRAL ROD of the chosen TUBULAR BRIDGE under the bowel. The CENTRAL ROD elevates the bowel. The CONNECTOR joins the ends of the TUBULAR BRIDGE to form a closed loop.

### INDICATIONS:

The EASY LOOP™ is used to support the exteriorized loop of bowel of a loop colostomy or ileostomy.

### CONTRAINDICATIONS:

None known.

### INSTRUCTIONS FOR USE:

#### Inspection

The Easy Loop™ Ostomy Device should be inspected prior to sterilization for cleanliness and damage. Unclean or damaged devices should not be used. Make sure all components of the system are present (Figure 1).

#### Packaging

The Easy Loop™ Ostomy Device is to be packaged using FDA cleared pouches, designed for steam sterilization. Refer to the current revision of the ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" for more information on packaging in a sterilization pouch.

#### Sterilization

Use a validated, properly maintained and calibrated steam sterilizer.

Effective steam sterilization can be achieved using one of the following cycles:

Cycle Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre-Vacuum	270 °F (132 °C)	4 minutes	20 minutes
Gravity Displacement	270 °F (132 °C)	15-30 minutes depending on the load configuration	20 minutes

It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials, and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

(Continued)

### Application Instructions

Make sure all components of the system are present (Figure 1). Pass the SLING through the mesentery and use it to retain the ostomy bowel loop externally until ready to apply the EASY LOOP™. The CONNECTOR adapts to the ends of the SLING.

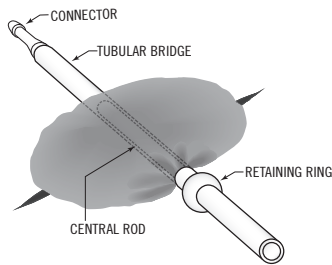


Figure 2

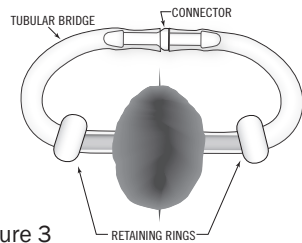


Figure 3

#### Applying the EASY LOOP™

1. Select a TUBULAR BRIDGE appropriate for the size of the bowel.
2. Insert the CONNECTOR into one end of the TUBULAR BRIDGE.
3. Pass the CONNECTOR and TUBULAR BRIDGE through a RETAINING RING until the RETAINING RING is adjacent the end of the CENTRAL ROD opposite the CONNECTOR. Wetting the components will ease passage.
4. Insert the CONNECTOR into one end of the SLING and draw the TUBULAR BRIDGE into position. Remove the SLING. (See Figure 2.)
5. Apply the second RETAINING RING to maintain the CENTRAL ROD beneath the bowel.
6. Mature the ostomy.
7. Use the CONNECTOR to join the ends of the TUBULAR BRIDGE to form a closed loop around the bowel. (See Figure 3.)
8. Arrange the EASY LOOP™ within an ostomy appliance.

#### Removing the EASY LOOP™

1. Separate the CONNECTOR from one end of the TUBULAR BRIDGE.
2. Remove the RETAINING RING from the side opposite the CONNECTOR.
3. Withdraw the device from underneath the bowel.

### STORAGE INSTRUCTIONS:

After sterilization protect packaged devices from dust, moisture, insects, vermin, and extremes of temperature and humidity.

### DISPOSAL INSTRUCTIONS:

After use, dispose of the device components according to local regulations for medical waste to ensure proper environmental safety and compliance with health care facility protocols.

### MANUFACTURER'S CONTACT INFORMATION:

Tools for Surgery, LLC - (631) 444-4448 - [customerservice@toolsforsurgery.com](mailto:customerservice@toolsforsurgery.com)

**Rx only**

**Not made with natural rubber latex**



**We make it simple, by design.**

Tools for Surgery, LLC  
8 Technology Drive, #100 ▪ East Setauket, New York 11733  
PH (631) 444-4448 ▪ FX (631) 689-2943

[www.toolsforsurgery.com](http://www.toolsforsurgery.com)