

Instructions for Use – Hemorrhoidal Ligator

Page 1 of 2

Indications for Use

The Hemorrhoidal Ligator is indicated for use to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

Contraindications

Hemorrhoid ligation is contraindicated if:

- Patient is using anticoagulants.
- Septic conditions in the anorectal region are present.
- Any large grade IV hemorrhoids are evident.
- In cases of hypertrophied anal papilla and/or chronic anal fissure.

Warning

DO NOT flash sterilize the Hemorrhoid Ligators. These instruments have not been validated for flash sterilization. Discard the instrument after suspected Creutzfeldt-Jakob Disease (CJD) exposure, as the instrument has not been validated to withstand the chemical and thermal exposures recommended to eradicate prions. Damage to the product may occur if inappropriate cleaning or disinfecting agents are used, or if exposed to excessive temperatures.

Instructions for Use

Ligation procedures are a frequently used treatment option for hemorrhoids due to their simple and effective application which does not require anesthesia.

1. Load the ligator with a latex-free O-ring by using the loading cone. Place the loading cone onto the ligator barrel and roll the O-ring down the tip of the loading cone until it is seated evenly around the end of the ligator barrel in the maximum expanded diameter. Remove the loading cone.
2. A proctoscope/anoscope should be inserted into the anal opening to provide site visualization. The largest hemorrhoid should be treated first.
3. Grasp the hemorrhoid with forceps approximately 1 centimeter proximal of the dentate line and pull the hemorrhoid into the drum of the ligator. If the patient indicates there is pain, a more proximal position for the band ligation should be selected.
4. With the hemorrhoid pulled taut through the drum of the ligator and the ligator pressed up against the base of the hemorrhoid, the trigger should be squeezed to apply the ligation O-ring to the base of the hemorrhoid.
5. Remove the ligator from the hemorrhoid and repeat as necessary to treat any additional hemorrhoids present.
6. Remove the proctoscope/anoscope from the anal opening. Provide the patient with instructions for follow-up visits and possible complications of band ligation procedures.

Pre-cleaning, Cleaning, and Sterilization Procedures

Before using the instruments, pre-clean, clean (manual or automated), dry, visually examine, and sterilize following the procedures below.

Pre-cleaning

Pre-cleaning should occur as soon as possible after the instrumentation is used.

1. Remove gross debris from surgical instruments with a sponge and sterile water after use, to prevent the drying of blood and bodily fluids on the instruments.
2. Place the instruments in an instrument tray/container and saturate all surfaces for five (5) minutes with a pre-cleaning enzymatic product.

3. Vigorously flush the lumens with 50ml of deionized water using a syringe or similar apparatus.
4. Prepare enzymatic solution per the manufacturer's recommendations/instructions for correct dilution and temperature.
5. Immerse fully opened instruments in the prepared enzymatic solution for ten (10) minutes.
6. Rinse the instruments and flush the lumens with deionized water for two (2) minutes.
7. Proceed to either Manual or Automated Cleaning below.

Manual Cleaning

1. Prepare enzymatic solution per the manufacturer's recommendations/instructions for correct dilution and temperature.
2. Using a small, clean, hand-held brush, remove soil from all surfaces of the instrument while fully immersed in the solution.
3. Use a soft bristled brush to clean the lumens. Never use steel wool, wire brushes, scalpel blades, or highly abrasive detergent or cleaners to remove soil as these will damage the instrument's protective surface and lead to corrosion.
4. Vigorously flush the channels with deionized water. Rinse thoroughly and aggressively for two (2) minutes with deionized water.
5. Using an ultrasonic cleaner, sonicate the instruments for ten (10) minutes.
6. Remove the instruments from the sonicator and rinse for two (2) minutes with deionized water.
7. Visually inspect the instruments for cleanliness and ensure all parts are in proper working order.
8. Force air through the inner lumen until excess water can no longer be seen visually evacuating the device before allowing the instruments to dry on a lint-free cloth for at least twenty (20) minutes at a temperature of no more than 110°C (230°F).
9. Visually inspect the instruments to ensure they are dry.

Automated Cleaning

1. Place the instruments in a wire basket that is suitable for cleaning.
2. Place the wire baskets in an automatic washer-sterilizer or washer-disinfector. When carrying out the reprocessing cycle, the following minimum requirements are recommended:
 - Use an appropriate cleaning/disinfecting agent.
 - Observe the maximum washing temperature of 55°C (131°F).
 - Wash the product for at least ten (10) minutes.
 - Neutralize, if necessary.
 - Carry out an intermediate rinse for at least two (2) minutes.
 - Carry out an intensive final rinse with deionized, demineralized water.
 - For thermal disinfection, rinse for ten (10) minutes at 93°C (199.4°F) with deionized, demineralized water.
 - Complete the program with a drying phase of at least twenty (20) minutes at a temperature of no more than 110°C (230°F).
3. Remove the instruments from the automatic washer.
4. Visually inspect the instruments for cleanliness and ensure all parts are in proper working order.
5. Visually inspect the instruments to ensure they are dry.

Cleaning

Cleaning should occur as soon as possible after the instrumentation is pre-cleaned and followed by either manual or automated cleaning.

1. Rinse the instruments with deionized water for two (2) minutes.
2. Use a clean, soft bristled brush to clean and remove visible soil from the lumens and other surfaces of the instruments.

For Instruments Inside a Tray:

1. Place the clean, dry instruments in a tray and double-wrap the tray with Convertors Bio-Shield Sterilization Wraps.
2. Place tray in a pre-vacuum sterilization chamber using the parameters to achieve SAL of 10⁻⁶ (see table below).

Note: Make certain that all surfaces of the product will be exposed to the sterilizing agent. When sterilizing several products at the same time in one steam sterilizer, make sure that the maximum allowable load capacity of the steam sterilizer is not exceeded.

Allow the product to cool down to room temperature.

Storage Conditions

Store suitably packaged and sterilized instruments in a dry, clean, and dust-free environment.

Maintenance Procedures

Improper, ineffective, and insufficient maintenance can reduce the life of an instrument.

Protect instruments: The use of deionized water, careful preliminary cleaning, use of neutralized pH solutions, adherence to manufacturer's instructions, and visual inspection will help to keep instruments performing accurately and free of stains.

Certain compounds are highly corrosive to stainless steel and will cause serious damage. Instruments should never be exposed to aqua regia, iodine, ferric chloride, sulfuric acid, or hydrochloric acid.

The following substances should be avoided whenever possible. Rinse with copious amounts of water immediately if instruments are inadvertently exposed to any of the following substances: Aluminum chloride, mercury chloride, barium chloride, potassium permanganate, bichloride of mercury, potassium thiocyanate, Dakin's solution, calcium chloride, saline, carbolic acid, sodium hypochlorite, chlorinated lime, or stannous chloride.

Any kind of corrosion will lead to rust on steel, and rust particles can be transferred from one instrument to another. Corroding instruments should therefore be removed from service to prevent formation of rust on other instruments.

Protect sharp cutting edges and fine working ends of inserts during all maintenance procedures. Avoid loading heavy items on top of delicate and hollow instruments.

It is common for instruments to become stained or spotted. Adhering to proper technique during the cleaning and sterilizing procedures will prevent most staining occurrences.

- Brown stains: Detergents containing polyphosphates may dissolve copper elements in the sterilizer resulting in brown stains. A dull blue or brown stain is the result of oxidation on the surface.

- Black stain: May be the result of contact with ammonia.

- Light or dark spots: Spots are often the result of mineral content in the water used for rinsing, or use of a non-neutral instrument or an unclean sterilizer chamber.

- Rust deposits: It is very unlikely for surgical grade steel to rust. Rust colored spots usually appear in localities where water has high iron content.

Sterilization

For double wrapped instruments:

1. Double wrap the clean, dry instruments individually in medical self-seal pouches and seal the pouches. Make sure the instrument is opened inside the pouch.
2. Place pouches in a pre-vacuum sterilization chamber using the following parameters to achieve Sterility Assurance Level (SAL) of 10⁻⁶.

Recommended steam sterilization parameter to achieve SAL of 10⁻⁶:

Sterilizer Type	Configuration	Temperature	Exposure Time
Pre-Vacuum	Wrapped	134°C (273.2°F)	5 minutes

For latex-free O-rings:

Sterilize or dispose of the O-rings in accordance with the manufacturer's recommendations/instructions.