Hayden Medical, Inc.
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Instructions for Use – Hemorrhoidal Ligator v2.25

280-145 MCGIVNEY HEMORRHOIDAL LIGATOR (8" (20cm)	Reusable
280-147 MCGIVNEY HEMORRHOIDAL LIGATOR (10" (25cm)	Reusable
280-149 MCGIVNEY HEMORRHOIDAL LIGATOR (16" (40.6cm)	Reusable
280-150 LOADING CONE FOR MCGIVNEY LIGATOR	Reusable
280-155 NON-LATEX O BANDS FOR 280-148, 280-147, 280-149	Single Use

Contents

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1 General Infomation

A Hemorrhoid Ligator is a device consisting of a straight sheath with a built-in ligator head and pistol grip handle for actualization. The ligature is applied by compressing the handle. The Hemorrhoid Ligators are made of stainless steel, reusable and are supplied non-sterile.

2 Intended Use

A Hemorrhoid 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.

3 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
- Cases of hypertrophied anal papilla and/or chronic anal fissure

4 Warning

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

5 Usage

Ligation procedures are a frequently used treatment option for hemorrhoids due to its 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 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 (fig. 1).

Figure 1

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 patient with instructions for follow-up visits and possible complications of band ligation procedures.

6 Reassembly of McGivney Hemorrhoidal Ligator

1. With the device completely unassembled, it is recommended to begin reassembly with the handle portion of the device first (Figure 2).

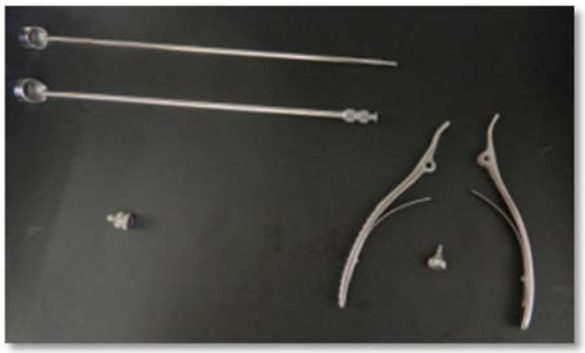

Figure 2

2. Grasp the two portions of the handle assembly as shown (Figure 3a). Ensure the notched assembly is fully seated and compress the handles completely. This will allow the holes in the joint to align for insertion of the screw set. Twist in the screw set until finger tightness has been achieved (Figure 3b).

Figure 3a

Figure 3b

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3. Pick up the inner and outer shafts of the ligator, and insert the solid inner shaft into the hollow outer shaft (Figure 4). Place the palm of your hand on the working end to keep the inner and outer shafts in place for the balance of the assembly process (Figure 5).

Figure 4

Figure 5

4. With the working end held securely against the palm of your hand, partiall screw on the end cap to the shaft. It is important to not completely tighten the cap at this time as you need a gap to facilitate the final assembly of the handle to the shaft (Figure 6).

Figure 6

5. The handle should be held with the screw set facing the assembler. The notches at the top of the handle flare slightly backward from the shaft. With the handle squeezed into the closed position, position the notches on the top of the handle onto the shaft (Figure 7a).
The front notch will align in front of the ring on the end of the outer shaft, and the back notch should align onto the inner shaft before the threads start (Figure 7b).

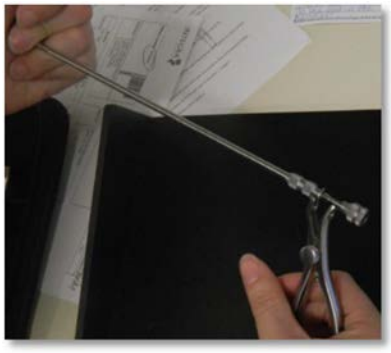

Figure 7a

Figure 7b

6. Once the alignment at the indicated point is achieved, release the compression of the handle confirming proper attachment has been achieved (Figure 8). Finish tightening the cap onto the end of the shaft to the desired level of tension (Figure 9).
   Note: Fully tightening the end cap will prevent shaft rotation, if desired.

Figure 8

Figure 9

7 Pre-Use, Handling and Inspection of Instruments

- Read the Instructions for Use and keep them in a safe place.
- Use the product only in accordance with its intended use, see **Intended use**.
- Use of an instrument for a task other than that for which it is intended could result in a damaged or broken instrument, or one which provides an unsatisfactory performance.
- Products should be handled and operated by personnel completely familiar with their use, assembly and disassembly.
- Products must be rendered safe for handling, inspection and assembly by wearing appropriate personal protection equipment (PPE) as promulgated by OSHA and AORN.
- Inappropriate use of products will lead to damage that is usually not repairable.
- Producs must be thoroughly inspected upon receipt and prior to use to assure proper functioning. Failure to make a complete inspection to assure proper operation and function of instrument may result in unsatisfactory performance.
- Store products in a dry, clean and safe place.
- General Working Conditions:
  Temperature: +7°C to +30°C
  Humidity: 40% to 60% relative humidity

7.1 Hemorrhoidal Ligator

Hemorrhoid Ligators are supplied non-sterile and must be pre-cleaned, cleaned, visually examined and sterilized prior to use. Please see pre-cleaning, cleaning, visual examination, and sterilization procedures below.

- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts.

7.2 Ligature rubber ring

!	Risk of infection for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product! ► Do not treat the product with cleaning or disinfection procedures. ► Sterilize the product a maximum of one time.

The product is delivered in an unsterile condition.
The product must not be reused.

- Sterilize the product before use.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Do not use the product after its use-by date.

8 Precleaning, Cleaning and Sterilization Procedures

Before using the instruments pre-clean, clean (manual or automated), dry, visually examine, and sterilize following the procedures below.
Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79:2006, A1:2008, A2:2009 -Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

8.1 Precleaning

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

1. Remove gross debris from surgical instruments with a brush (for medical instruments) and water after use to prevent drying of blood and body fluids on the instruments.

2. Place instruments in an instrument tray/container and saturate all surfaces for five (5) minutes with a pre-cleaning enzymatic product (pH-neutral).

8.2 Cleaning

Cleaning should occur as soon as possible after instrumentation is pre-cleaned.

After performing steps 1-6 below, perform either **“Manual Cleaning”** or **“Automated Cleaning”**.

1. Rinse instrument 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.

3. Vigorously flush lumens with 50ml of deionized water using a syringe or similar apparatus.

4. Prepare enzymatic solution (recommendation: pH-value within 9-10. MediClean forte from Dr.Weigert) per 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 instrument and flush lumens with deionized water for two (2) minutes.

7. Proceed either to **“Manual Cleaning**” or **“Automated Cleaning”** procedures below:

Manual Cleaning:

1. Prepare enzymatic solution (recommendation: pH-value within 9-10. MediClean forte from Dr.Weigert) per manufacturer's recommendations/instructions for correct dilution and temperature.

2. Using a small, clean hand-held brush, remove soil from all surfaces of instrument while fully immersed in solution.

3. Use a soft bristled brush to clean the lumens.

   Note: Never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil as these will damage the instruments protective surface and lead to corrosion.

4. Vigorously flush channels with deionized water. Rinse thoroughly and aggressively for two (2) minutes with deionized water.

5. Using an ultrasonic cleaner sonicate instruments for ten (10) minutes
   - Prepare enzymatic solution per manufacturer's recommendations/instructions for correct dilution and temperature and place in the ultrasonic cleaner.
   - Condition (de-gas) ultrasonic cleaner for 5 minutes.
   - Place instruments in the ultrasonic cleaner manufacturer's instrument tray.
   - Ensure instruments are in the open position.
   - Keep different metal types separated (i.e., separate stainless steel from non-anodized aluminum, brass, copper and chrome-plating to avoid possible transfer of one metal plating to another).
   - Place tray with the instruments into the ultrasonic cleaner.
   - Sonicate instruments for ten (10) minutes.

6. Remove instruments from sonicator and rinse for two (2) minutes with deionized water.

7. Visually inspect instruments for cleanliness and ensure all parts are in proper working order.

8. Force air though inner lumen until excess water can no longer be visually seen evacuating the device before allowing instruments to dry on lint-free cloth for at least twenty (20) minutes at a temperature of not more than 110°C (230°F).

9. Inspect instruments for visual dryness.

Automated Cleaning:

1. Place instruments in a wire basket that is suitable for cleaning.
   - Ensure instruments are in the open position and that water can flow out of the openings.
   - Components with lumens and channels should be placed directly on the injector carriage attachment (Figure 10).
   - Keep different metal types separated (i.e., separate stainless steel from non-anodized aluminum, brass, copper and chrome-plating to avoid possible transfer of one metal plating to another).

Figure 10

2. Place wire baskets in an automatic washer-sterilizer or washer-disinfector. Follow the parameters and detergent recommendations provided by the washer-disinfector manufacturer.

When carrying out the reprocessing cycle, the minimum requirements are recommended:

- Use an appropriate cleaning/disinfecting agent according to its manufacturer´s instructions.
- Observe the maximum washing temperature of 55°C (131°F).
- Wash the product for at least ten (10) minutes.
- Neutralize, if necessary.
- Carry out intermediate rinse for at least two (2) minutes.
- Carry out 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 not more than 110°C (230°F).

3. Remove instruments from automatic washer.

4. Visually inspect instruments for cleanliness and ensure all parts are in proper working order.

5. Visually inspect instruments to ensure they are dry.

8.3 Sterilization

After cleaning the reusable instruments, sterilize them using the following procedure.

For Double-Wrapped Instruments

1. Individually, double-wrap the clean, dry instruments 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 Sterility Assurance Level (SAL) of 10-6:

Sterilizer Type	Configuration	Temperature	Exposure Time
Pre-Vacuum	Wrapped	132°C (134°C)	4 minutes

For Instruments inside a Tray

1. Place the clean, dry instruments in tray and double-wrap the tray with Sterilization Wraps.

2. Place tray 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 Sterility Assurance Level (SAL) of 10-6:

Sterilizer Type	Configuration	Temperature	Exposure Time
Pre-Vacuum	Wrapped	132°C (134°C)	4 minutes

Drying & Cooling

The recommended drying time for single wrapped instruments is 20 minutes unless otherwise noted in device specific instructions

Allow the product to cool down to room temperature.

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, as specified by the manufacturer, is not exceeded.

8.4 Lifetime

The steam sterilization procedure for hemorrhoid ligators was validated by laboratory tests. The ligators were sterile validated at a pre-vacuum of at least 4min duration and a temperature of 132/134°C for a lifetime of 50 cycles.
You can continue to use the instruments at your own responsibility over this cycle value if you keep the following in mind:

- the function has been ensured before use
- the instruments must be tested for loose, bent or worn components
- the instrument must not be damage
- there must be no corrosion.

9 Storage conditions

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

10 Maintenance Procedures

Improper, ineffective and insufficient maintenance can reduce the life of an instrument and will invalidate the instrument's warranty.

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
- Sulfuric acid
- Iodine
- Hydrochloric acid
- Ferric chloride

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
- Stannous chloride

Any kind of corrosion will lead to rust on steel. Rust particles can be transferred from one instrument to another, therefore, remove corroding instruments 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.

Diagnosing Spots and Stains: It is common for instruments to become stained or spotted. Adhering to proper technique during cleaning and sterilizing procedures will prevent most staining occurrences. The following identifies some of the various instrument-related problems hospitals may encounter.

- 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 Stains: Black stains may be the result of contact with ammonia.
- Light or Dark Spots: Spots are often the result of the mineral content in the water used for rinsing, use of 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.