Microline PENTAX™

M/L-10
Multi-Fire Clip Applier

Instructions For Use

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Micro line PENTAX™

ENGLISH

M/L-10 Reusable Multifire Clip Applier

INDICATIONS

The M/L-10 Clip Applier is indicated for occluding and ligating vessels, ducts, tracts and other tubular structures during laparoscopic and general surgical procedures.

CONTRAINDICATIONS

The M/L-10 Clip Applier is not intended for use except as indicated.

INSTRUCTIONS FOR USE

The M/L-10 Multi-Fire Clip Applier consists of:

1. One reusable autoclavable handpiece
2. One removable stainless steel outer tube
3. Optional sterilization tray(s) - CAT. #3705 (sold separately) & 3707 (included w/clip applier & sold separately).
4. One sterile disposable back-loading slide cartridge, containing Titanium medium large clips (*sold separately)*.

WARNING

If during the inspection of the shipping carton, one of the above items shows any sign of damage, do not use the instrument.

LOADING CLIP APPLIER

1. Peel the clip cartridge pouch open and remove it from the pouch.
2. Fully squeeze the handpiece trigger against the handle (Fig. 1).
3. Align the arrow on the back of the clip applier with the arrow of the cartridge as shown in Fig. 3 (arrow of the cartridge should be seen on the “non-clip” side of the cartridge).
4. Insert the cartridge all the way into the back of the handpiece (Fig. 2), making sure it is handled by its sides or proximal end behind “the ladder” in order to avoid any displacement of clips or ladder.
5. Release the trigger. (This will immediately engage a clip into the handpiece jaws).
6. The instrument is ready to be used.

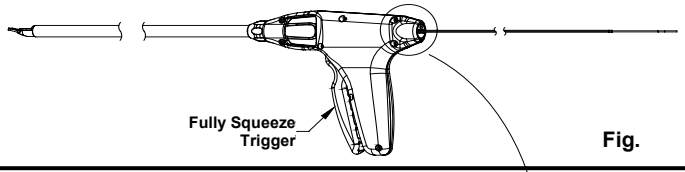

Fig.

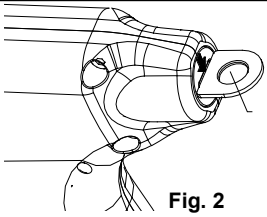

Fig. 2

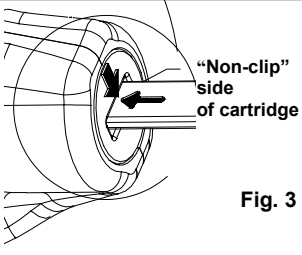

Fig. 3

OPERATION NOTE

Before firing a clip, verify that the ligation site is free of any obstructions.

1. Verify that there is a clip properly loaded in the jaws prior to inserting the clip applier through the cannula.
2. Position the clip carefully around the vessel to be ligated.
3. With full visualization of the ligation site, squeeze the trigger all the way so that the trigger touches the handle to close the clip around the vessel. The trigger will not reopen until the trigger is beyond the 7th click (see 5 below).
4. Releasing the trigger will open the clip applier jaws and will automatically engage the next sequential new clip. Now the clip applier is ready for re-firing.
5. a. For the cholangiogram procedure, whereby a clip is used to temporarily secure the catheter inside the common cystic duct without occluding the catheter, the degree of clip closure can be adjusted. This is accomplished by releasing the trigger anytime after the 7th click at the ratchet mechanism. This earlier release capability allows for the desired amount of clip closure.
   b. For maximum vessel occlusion (clip fully closed) simply depress instrument trigger fully so that the trigger and handle are touching and then fully release so that the subsequent clip can be engaged in the jaws.

CAUTIONS

a) If all the clips are to be used, the last two colored clips will warn the surgeon that cartridge is almost out of clips. The clip applier should be removed from the cavity once the last colored clip has been fired. The cartridge should then be removed and disposed.

b) Engaging the jaws over a previously applied clip should be avoided as it may cause the handpiece to misfire.

WARNING

Make sure cartridge is removed from the handpiece after use, or prior to cleaning and sterilizing process. Microline PENTAX shall not be responsible of any damage occurring as a result of a non-compliance with this warning.

DISASSEMBLING THE CLIP APPLIER HANDPIECE

To disassemble clip applier for reprocessing follow the steps below:

1. Remove and discard the disposable clip cartridge by fully squeezing the trigger against the handle as shown on Fig.4. If all 19 clips have not been fired, squeezing the handle and removing the cartridge will engage and release one clip. In this case, make sure to fire the engaged clip onto something such as a drape so that the contaminated clip does not fall onto the floor, stick to the jaws or fall inside the instrument shaft potentially causing a jam or safety hazard.
   (This step serves as a warning note on the “Cleaning and Sterilization” steps. Microline PENTAX shall not be responsible for any damages occurring as a result of a non-compliance with this warning.
2. Remove the outer tube (Fig. 6) by fully squeezing the trigger and unscrewing the knob clockwise (Fig. 5).

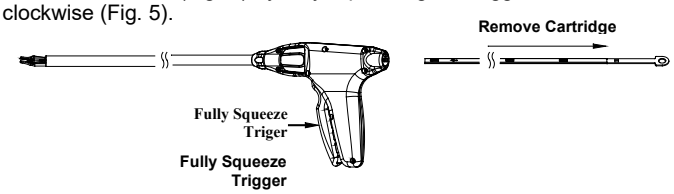

Fig. 4

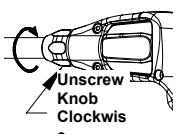

Fig. 5

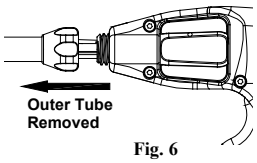

Fig. 6

Notes: Use only Microline PENTAX's sterile disposable back-loading slide cartridge. Microline PENTAX will not be responsible for any damage caused by other clips.

RECOMMENDED CLEANING & STERILIZATION STEPS

Warning

Prior to cleaning the clip applier instrument, make sure that the disposable cartridge is removed and discarded. Microline PENTAX shall not be responsible for any damages occurring as a result of a non-compliance with this warning.

Note

The M/L-10 clip applier should be stored and reprocessed in a protective sterilization tray or tube.

CLEANING

1) Immediately after surgical use, remove the shaft's outer tube. The instrument and its outer tube should be soaked in an enzymatic solution containing 60mL of ENZOL® Enzymatic Detergent per 4 L of water @ 22-40°C.
2) After the soaking cycle, the clip applier and its outer tube should be removed from the enzyme solution and rinsed with regular tap water.
3) The handle, shaft and rotation knob should be cleaned with a soft cloth or sponge soaked in concentrated ENZOL® Enzymatic Detergent until no further bioburden is observed on brush or towel. The distal end of the instrument must be cleaned with a "soft bristle" brush to avoid any damage.
4) The clip applier handpiece and its outer tube should be rinsed in normal tap water, and then rinsed 3 times with deionized water for a final rinse. Wipe instrument with a clean soft cloth.
5) After the hospital cleaning procedure is completed, an inspection of the instrument should be done to ensure it is thoroughly cleaned.
6) It is important, prior to sterilization, that a water-soluble lubricant is used to preserve the articulation and action of all movable parts of the instrument.
7) Re-assemble the outer tube on the instrument. To perform this, squeeze the handpiece trigger, mount the outer tube over the clip applier shaft, and then secure it by screwing the tube knob counterclockwise until it is fully threaded.

Notes

The hospital's reprocessing protocol may require that the applier and the outer tube be reassembled after the sterilization process.

Prior to wrapping the instrument for storage, it must be completely dry. Any residual moisture could result in oxidation and corrosion that could affect its performance, function and useful life.

STERILIZATION

Warning

Prior to sterilizing the clip applier instrument, make sure that the cartridge is removed. Microline PENTAX shall not be responsible for any damages occurring as a result of a non-compliance with this warning.

1. Prior to sterilization, the instrument must be thoroughly cleaned.
2. Wrap the instrument, use sterilization tray (Cat #3705/3707), or tube.

Microline PENTAX recommends the following validated sterilization cycles as guidelines:

Gravity Cycle:	4 minutes @ 270°F (132°C)
Gravity Cycle:	30 minutes @ 250°F (121°C)
Pre-Vacuum Cycle:	4 minutes @ 270°F (132°C)

STERILIZATION PARAMETERS FOR EUROPEAN COUNTRIES

Microline PENTAX recommends the following parameters as minimum sterilization cycle parameters for Europe, except for France and Switzerland:

Pre-Vacuum Cycle: 3-5 minutes at 134°C

For France and Switzerland, the following minimum sterilization cycle parameters are recommended:

Pre-Vacuum Cycle: 18 minutes at 134°C, $2x10^2$ kPa.

INSPECTION

NOTE

M/L-10 Inventory Inspection Procedure (to be performed once a month). An abbreviated inspection should be performed in the OR each time before handing the M/L-10 to the surgeon for use:

1. Check jaws for misalignment, damage and caked on bio- burden.
2. Check shaft for straightness. Remove outer tube and check inner shaft for damage and caked on bio-burden.
3. Squeeze and release handle 20 plus times to check for sticking. Check handle for damage. Never pry handle and trigger open.
4. Fire a minimum of 2 clips to check clip closure, engagement into jaws and clip/jaw alignment.
5. In addition to proper and thorough cleaning (see instructions) make sure the M/L-10 is properly lubricated between cases:
    a. Fully immerse the instrument in an approved instrument lubricant.
    b. If unable to fully immerse the instrument make sure to thoroughly lubricate both jaw and rotation knob area.
    c. After lubrication process perform step 3 and 4 of the inspection if the applier handle was sticking or locking.

WARRANTY

Microline PENTAX warrants that this instrument is free from defects in both material and workmanship. Microline PENTAX shall not be held liable for incidental or consequential damage of any kind. This warranty is valid only to the original purchaser of the instrument and for a period of one (1) year. Work performed on this instrument by anyone other than a Microline PENTAX Authorized Service Center will void this warranty.

SERVICE AND REPAIR

Prior to returning this instrument for repair, call your Microline PENTAX distributor to obtain authorization. The instrument will be returned un-repaired to the sender if the following conditions are not met:

- The instrument must be given a “Return Goods Authorization” (RGA) number.
- The instrument must be cleaned and sterilized prior to returning for repair.
- The RGA number must be clearly visible on the outside of the box it is shipped in.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

CONTACT INFORMATION

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