



Cartridges for Automatic Clip Appliers

Instructions for use

Ref. no.: 0301-0907MLC10, 0301-0907MLC19

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Important:

This instruction cannot be used as a manual for surgical techniques used during the work with Ligating Clips. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of surgeon experienced in techniques of microinvasive surgery. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, contamination, infection, cross-infection inability of ligation or death.

Indications:

Cartridges for Automatic Clip Appliers are intended to be used with Microline™ Reusable Automatic Clip Applier M/L-10 Ref 1002 for ligating of any linear tissue structures or vessels during an operation for haemostasis or marking purposes where use of non-absorbable clips is required. Conformity of the size of the occluded tissue and the clips is required.

Contraindications:

DO NOT use for tubal ligation as contraceptive method.
DO NOT use on structures where use of metal clips is not appropriate.
DO NOT use in case of just suspicion of allergy to titanium.

Description of the device:

Cartridges for automatic clip appliers are sterile and disposable. Body of back-loading slide cartridge is made of stainless steel. Clips are made of medical grade titanium and are being placed around the tissue and closed with the grip of a clip applier. Cartridges contain 10 or 19 medium-large clips.

Instructions for use:

1. Peel the clip cartridge pouch open and remove it from the pouch.
2. Prepare Microline™ M/L-10 Multi-Fire Reusable Automatic Clip Applier Ref 1002 according to the Instructions for Use from the manufacturer.
3. Fully squeeze the handpiece trigger of the applier against the handle.
4. Align the arrow on the back of the clip applier with the arrow on the cartridge (arrow of the cartridge is seen on the non-clip side of the cartridge).
5. Insert the cartridge all the way in to the back of the handpiece, making sure it is handled by proximal end behind "the ladder" in order to avoid any displacement of clips or "ladder".
6. Release the trigger. This will immediately engage a clip into the handpiece jaws.
7. Applier with the cartridge is ready to use.
8. Verify that ligation site is free of any obstructions.
9. Position the clip around the structure intended for ligation.
10. Squeeze the trigger all the way until it touches the handle. It will close the clip completely.
NOTE: If partial closure is required (for example for the cholangiogram procedure, whereby a clip temporarily secures the catheter inside the common bile duct without occluding the catheter, the degree of clip closure can be adjusted. This is accomplished by releasing the trigger any time after the 7th click which are heard while trigger is being squeezed.
11. Release the trigger to open clip applier jaws and immediately load the next sequential new clip which will be ready for re-firing.
Warning: 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 of.
12. To remove cartridge after use fully squeeze the trigger against the handle and withdraw the cartridge pulling it backwards by the proximal end.
13. If all the clips in the cartridge have NOT been fired squeezing the handle to remove the cartridge will load a clip into the jaws. After handles will be released clip would drop. Make sure that it drops in a controlled way to avoid falling contaminated clip on the floor or into applier's shaft potentially causing a jam or safety hazard.

Warnings and precautions measures:

1. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with those techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
2. Surgical instruments may vary from manufacturer to manufacturer. When surgical instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. Failure to do this can result in inability to perform surgery.
3. Read carefully Instructions for Use of the Microline™ M/L-10 Multi-Fire Reusable Automatic Clip Applier Ref 1002 before initiation of the procedure and follow manufacturer's recommendations for assembling, disassembling, cleaning, sterilization, inspection and environmental protection.
4. After each clip is placed it is required to close the applier fully. A not full squeeze may result in dislocation of the clip and therefore improper ligation.
5. Make sure every clip was placed and closed well on ligated structure. This should be repeated after the use of other surgical devices in the immediate area of the application.
6. Do not squeeze the applier over other surgical instruments.
7. Do not use damaged appliers. Using of damaged applier may result in dislocation of a clip.
8. The following factors have serious influence on the closure of a clip: condition of an applier, force used by surgeon to close the clip, size of ligated structure and features of the clip itself.
9. As for all other ligation technique it is required to check the place of ligation after applying a clip making sure it was located appropriately.
10. Cartridges are compatible with M/L-10 Multi-Fire Reusable Automatic Clip Appliers Ref 1002 manufactured by Microline™ Surgical and cannot be used with other types of appliers. Failure to do this can result in inability to perform surgery.
11. Surgeon is fully responsible to choose proper size of the clip and must determine how many clips is necessary to achieve satisfactory hemostasis.
12. Make sure clip's size is appropriate for the structure to be ligated.
13. Always inspect the site for hemostasis before procedure is finished. Bleeding can be controlled by additional clips placement, electrocautery or surgical sutures.
14. Dispose of all opened clip cartridges no matter if all clips were used or not.
15. Use immediately after opening.
16. The product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
17. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
18. Product is intended to be used exclusively by qualified medical staff.



Keep dry

Caution, consult accompanying documents



Consult instructions for use



Do not resterilize



Manufacturer



Do not use if package is damaged

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