



# Click'aV® Ligating Clips

## Instructions for use

Ref. no.: 0301-03M, 0301-03ML, 0301-03L, 0301-03XL, 0301-03M04, 0301-03ML04, 0301-03L04, 0301-03XL04, 0301-03ML02, 0301-03L02, 0301-03XL02

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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:

Click'aV® ligating clips are intended for ligating of any linear tissue structures or vessels during an operation for haemostasis 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 for renal artery ligation during laparoscopic live donor nephrectomy.

DO NOT use as a tissue marker.

### Description of the device:

Click'aV® ligating clips are sterile and disposable. They are made of non-absorbable polymer suitable for implantation. Clip is equipped with latch for reliable closure and lateral clip legs stability. The clips are placed around the tissue and closed with the grip of a clip applicator.

### MR Safe:

Click'aV® Ligating Clips are made of a non-absorbable polymer material and are considered MR Safe. It means they poses no known hazards in all MR imaging environments as they are nonconducting, nonmetallic and nonmagnetic items.

### Instructions for use:

- Choose the appropriate size of the clip and the compatible applicator.
- Check the compatibility of all devices prior to use.
- Following aseptic rules remove clips cartridge from the single packing. To prevent any damage of the device place it on a sterile surface.
- Grip the applicator around the bolt (like pencil is gripped). For endo applicators grip applicator around the shaft.
- Align applicator jaws vertically and laterally over a clip in the cartridge and advance product jaws into the slot of the clip cartridge making sure they are perpendicular to the surface of the cartridge. Advance the jaws till there is an audible click. Do not use force to push the applicator. The applicator should move inside and outside of the slot easily.
- Remove the applicator from the cartridge. It may be necessary to hold the cartridge to allow the clip to be removed. Make sure the clip is affixed in the jaws securely. The clip bosses should seat in the notches of the applicator jaws.
- Sufficiently skeletonize the structure to be ligated to allow locking mechanism of the clip to be clear of tissue.
- If endoscopic applicator is used compress the applicator handles (but take care not to lock the clip shut) and insert the applicator jaws and shaft down the cannula. Maintain compression on the applicator handles until the jaws clear the cannula. This procedure is necessary because cannula inner diameter is in most of the cases smaller than external dimension of opened applicator jaws. Compression on the applicator handles may be also necessary during applicator withdrawal from the cannula.
- During application, rotate endoapplicator shaft this way that the single tooth of the clip will go down and can be seen from the top and side at a time. This allows the user to visually confirm encapsulation of the structure being ligated. For open surgery it is also recommended that single tooth will be in down position.
- Position the clip around the structure intended for ligation in a manner that provides clear visualization of the locking mechanism. Use appropriate force to close the clip completely until it locks shut, making sure it is placed properly. Releasing the pressure on the handles will cause the applicator jaws to spring open.
- Remove the applicator from the surgical site.
















### Compatibility:

Click'aV® clip size	Compatible Click'aV® clip applicators	Ligated structure size in [mm]
M	0301-04M20, 0301-04M27, 0301-04M27A70, 0301-04ME, 0301-04MEA20, 0301-04MEA45, 0301-04MEA20B, 0301-04MEB, 0301-04MMLEHS, 0301-04MMLEHSB, 0301-04MEI, 0301-04MEA20I, 0301-04MEA45I, 0301-04MEIB, 0301-04MEA20IB, 0301-04MEA45IB, 0301-04MEHS, 0301-04MEOMN, 0301-04MEOMNB, 0301-04MEOMNBX, 0301-04MEOMNX, 0301-04MEN, 0301-04MEA20N, 0301-04MEA45N, 0301-04MEBN, 0301-04MEA20BN, 0301-04MEA45BN	2 to 7
ML	0301-04ML20, 0301-04ML27, 0301-04ML27A70, 0301-04MLE, 0301-04MLEA20, 0301-04MLEA45, 0301-04MLEB, 0301-04MMLEHS, 0301-04MMLEHSB, 0301-04MLEI, 0301-04MLEA20I, 0301-04MLEA45I, 0301-04MLEIB, 0301-04MLEA20IB, 0301-04MLEA45IB, 0301-04MLEHS, 0301-04MLEOMN, 0301-04MLEOMNB, 0301-04MLEOMNBX, 0301-04MLEOMNX, 0301-04MLEN, 0301-04MLEA20N, 0301-04MLEA45N, 0301-04MLEBN, 0301-04MLEA20BN, 0301-04MLEA45BN	3 to 10
L	0301-04L20, 0301-04L27, 0301-04L27A70, 0301-04LE, 0301-04LEA20, 0301-04LEA45, 0301-04LEB, 0301-04LEA20B, 0301-04LXLEHS, 0301-04LXLEHSB, 0301-04LEI, 0301-04LEA20I, 0301-04LEA45I, 0301-04LEIB, 0301-04LEA20IB, 0301-04LEA45IB, 0301-04LEOMN, 0301-04LEOMNB, 0301-04LEOMNBX, 0301-04LEOMNX	5 to 13
XL	0301-04XL20, 0301-04XL27, 0301-04XL27A70, 0301-04XLE, 0301-04XLEA20, 0301-04XLEA45, 0301-04XLEB, 0301-04XLEA20B, 0301-04XLEHS, 0301-04XLEHSB, 0301-04XLEI, 0301-04XLEA20I, 0301-04XLEA45I, 0301-04XLEIB, 0301-04XLEA20IB, 0301-04XLEA45IB, 0301-04XLEHS, 0301-04XLEOMN, 0301-04XLEOMNB, 0301-04XLEOMNBX, 0301-04XLEOMNX	7 to 16

Compatible with Grena's Click'aV® clips are also all applicators for polymer clips of other manufacturers with the same type and size of locking mechanism provided clip size corresponds with applicator size. For best results it is highly recommended to use Grena applicators designed for Click'aV® ligating clips.

### Warnings and precautions measures:

- 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.
- 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.
- Click'aV® ligating clips are compatible with Click'aV® ligating clip applicators only and are not compatible with LigaV® or Vclip® clip applicators. Always ensure that correct Grena's applicator type was chosen prior to initiation of the procedure. Failure to do this can result in inability to perform surgery.
- Grena recommends ligation of the renal artery in procedures other than laparoscopic live donor nephrectomy with more than one clip on the patient side with a minimum distal renal artery cuff of 2-3mm beyond the distal clip.
- Surgeon is fully responsible to choose proper size of the clip and must determine how many clips is necessary to achieve satisfactory hemostasis and closure security.
- Ligated structure sizes for each clip size is given for general information purposes only. Make sure clip's size is appropriate for the structure to be ligated. Clip should completely encompass the vessel or tissue structure.
- Do not use the clip or applicator as a dissecting instrument.
- The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure of the clip. This should be repeated after the use of other surgical devices in the immediate area of the application.
- Leave a distal cuff of tissue approximately 2-3mm from the ligating clip if the tissue is to be divided, i.e. do not use the side of the clip as a cutting guide.
- Do not squeeze the applicator over other surgical instruments.
- Do not attempt to close the jaws on any tissue structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure may result in patient injury.
- Do not use damaged applicators. Using of damaged applicator may result in improper location of a clip. When closed, jaw tips should be directly aligned and not offset. Always check the alignment of the applicator jaws before use. If this is not done, patient injury may occur.
- The following factors have serious influence on the closure of a clip: condition of an applicator, force used by surgeon to close the clip, size of ligated tissue and features of the clip itself.
- 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.
- If endoscopic procedure is performed always confirm that the clip remains in the applicator after insertion of the applicator and clip through a cannula.
- Always inspect the site for hemostasis before procedure is finished. Bleeding can be controlled by additional clips placement, electrocautery or surgical sutures.
- Click'aV® ligating clips can be opened with specially designed clip remover. It is highly recommended that remover be readily available during surgery involving the use of Click'aV® ligating clips. Opened clip must be discarded and should not be reapplied again even if there are no any damages visible.
- Grena does not promote or recommend any specific surgical practices. Surgical technique, types and sizes of tissues and vessels appropriate for ligation with Click'aV® ligating clips are the responsibility of the surgeon.
- Dispose of all opened clip cartridges no matter if all clips were used or not.
- Use immediately after opening.
- Take care to discard the product and packing after use, as well as unused but opened devices in accordance with hospital waste disposal practices and local regulations including, without limitation, those pertaining to human health and safety and the environment.
- This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
- Product is intended to be used exclusively by qualified medical staff.
- If any serious incident has occurred in relation to the device it should be reported to the manufacturer and the competent authority of the Member State.

 <p>Keep dry</p>	 <p>eIFU indicator www.grena.co.uk/IFU</p>	 <p>Manufacturer</p>	 <p>Do not re-use</p>
 <p>Caution, consult accompanying document</p>	 <p>Do not re-sterilize</p>	 <p>Do not use if package is damaged and consult instructions for use</p>	 <p>Use-by date</p>
 <p>Authorized Representative in the European Community</p>	 <p>Catalogue number</p>	 <p>Batch code</p>	 <p>Quantity in package</p>
 <p>Sterilized using ethylene oxide</p>	 <p>MR safe</p>	 <p>Date of manufacture</p>	 <p>Single sterile barrier system</p>
 <p>Medical device</p>			

*The hard copies of instructions for use delivered with Grena products are always in english language.  
If you require a hard copy of IFU in other language, you can contact Grena Ltd.  
at **ifu@grena.co.uk** or + 44 115 9704 800.*

*Please scan the below QR code with the appropriate application.  
It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.*

*You can enter the website directly by typing in **www.grena.co.uk/IFU** in your browser.*

*Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.  
Always use the IFU in the latest revision.*

