LigaV® Ligating Clips
Instructions for use

Ref. no.: 0301-01S, 0301-01M, 0301-01ML, 0301-01L, 0301-01ML04

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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:
LigaV® Ligating Clips are intended for marking and/or 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.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical staff.

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:
LigaV® ligating clips are sterile and disposable. They are made of medical grade titanium. The clips are placed around the tissue and closed with the grip of a clip applier.

MRI safety information for ligating clips:

MR Conditional
The implantable clips made of titanium are MR Conditional. A patient with the implanted clips can be scanned safely immediately after placement of the clips, under the following conditions:
- Static magnetic field of 3,0 Tesla or less
- Highest spatial magnetic gradient field of 6.5 Tesla/m
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.7 W/kg for 20 minutes of scanning (per pulse sequence).

MRI Related Heating
A clip can produce a temperature rise of less than 0.6°C using the following conditions:
- At 3-Tesla, a maximum MR system reported whole body averaged SAR of 1.7 W/kg
- 20 minutes of continuous MR scanning (per pulse sequence) using transmit/receive RF body coil.

Artifact Information
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the clips. Therefore, optimization of MR imaging parameters to compensate for the presence of the clips may be necessary.
The worst case signal void size for a clip can be:

Pulse Sequence	SE	SE	GRE	GRE
Plane orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal void size (mm^2)	199	336	378	348

Instructions for use:
1. Choose the appropriate size of the clip and the compatible applier.
2. Check the compatibility of all devices prior to using.
3. Following aseptic rules remove clips cartridge from the single packing. To prevent any damage of the device place it on a sterile surface.
4. Grip the applier around the bolt (alike pencil is griped). For endo appliers grip applier around the shaft. Holding the applier by the handle while loading the clip is a mistake that can cause the jaws to close to some extent, causing the clip to fall out of the applier.
5. Align applier jaws vertically and laterally over a clip in the cartridge and advance instrument jaws into the slot of the clip cartridge making sure they are perpendicular to the surface of the cartridge. Advance the jaws till they are stopped. The applier should move inside and outside of the slot easily. Incorrect position of the jaws during loading may lead to incorrect seating of the clip in the jaws, which may result in the inability to securely close the clip, scissoring or falling out of the applier.
6. Remove the applier from the cartridge. The clip is affixed in the jaws. It is not required to take any actions to keep the clip in place.
7. Verify that the clip is fully inserted into the applier jaws and the clip legs do not protrude beyond the end of the jaws. Incorrect seating of the clip in the jaws, may result in the inability to securely close the clip, scissoring or falling out of the applier.
8. Handle the applier carefully. The jaws should not close prematurely. Even a slight closing of the jaws prematurely will cause the clip to fall out of the applier
9. Place the clip around the structure intended for ligation or marking. Use appropriate force to close the clip completely making sure it is placed properly. Closure should be made with a smooth, firm continuous motion until clip is fully closed. Releasing the pressure on the handles will cause the applier jaws to spring open. Releasing the pressure on the applier handle before the clip is fully closed will cause the clip to remain partially open, which may result in bleeding or slipping the clip off from the vessel.
10. Remove the applier from the surgical site.

Compatibility:

LigaV® clip size	Compatible LigaV® clip appliers	Ligated structure size in [mm]
S	0301-02S15, 0301-02S185, 0301-02S19, 0301-02S20, 0301-02S28, 0301-02SE	0,3 to 1,5
M	0301-02M15, 0301-02M185, 0301-02M19, 0301-02M20, 0301-02M28, 0301-02ME, 0301-02MEB, 0301-02MEOMN, 0301-02MEOMNB	1,0 to 2,5
ML	0301-02ML20, 0301-02ML28, 0301-02ML275A45, 0301-02MLE, 0301-02MLEB, 0301-02MLEA25, 0301-02MLEOMN, 0301-02MLEOMNB	2,5 to 4,0
L	0301-02L20, 0301-02L28, 0301-02LE, 0301-02LEB, 0301-02LEOMN, 0301-02LEOMNB	3,5 to 7,5

All above appliers are also available as angled version on request which is fully compatible with relevant clips. Angled version is indicated by adding letter A and two digits reflecting jaws angle at the end of any of above reference numbers.
Compatible with Grena LigaV® clips are also all the following rectangular crossection type grip appliers with transverse serrations or rough internal jaw surface:

clip size small – grip width 0,59 to 0,75 mm
clip size medium – grip width 0,84 to 1,00 mm
clip size medium/large – grip width 1,16 to 1,32 mm
clip size large – grip width 1,26 to 1,42 mm

For best results it is highly recommended to use Grena appliers designed for LigaV® clips.

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. LigaV® clips are compatible with LigaV® clip appliers only and are not compatible with Vclip® or Clicka'V® clip appliers. Always ensure that correct Grena applier type was chosen prior to initiation of the procedure. Failure to do this can result in inability to perform surgery.
4. 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.
5. Make sure clip's size is appropriate for the structure to be ligated.
6. 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.
7. 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. Neglecting this check may overlook clips that have been unintentionally mechanically displaced, which may lead to their slipping and subsequent bleeding.
8. Do not squeeze the applier over other surgical instruments, staples, clips, gallstones or other hard structures as it may lead to bleeding.
9. Do not use damaged appliers. Using of damaged applier may result in dislocation of a clip. Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur.due to clip scissoring what can cut the vessel.
10. 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.
11. 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.
12. If endoscopic procedure is performed always confirm that the clip remains in the applier after insertion of the applier and clip through a cannula.
13. Always inspect the site for hemostasis before procedure is finished. Bleeding can be controlled by additional clips placement, electrocautery or surgical sutures.
14. Grena does not promote or recommend any specific surgical practices. Surgical technique, types and sizes of tissues and vessels appropriate for ligation with LigaV® ligating clips are the responsibility of the surgeon.
15. Dispose of all opened clip cartridges no matter if all clips were used or not as sterility and full functionality of the device can be guaranteed if clips are used short after opening the package.
16. Implanted material is a pure titanium. The material used does not require quantitative restrictions on the clips applied to the patient.
17. Use immediately after opening.
18. 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.
19. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
20. 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, in which the user and/or patient is established.


Keep dry

Consult electronic instructions for use


Manufacturer


Do not re-use


Caution

Do not resterilize


Do not use if package is damaged and consult instructions for use


Use-by date

EC REP — Authorized representative in the European Community	REF — Catalogue number	LOT — Batch code	Quantity in package
STERILE EO — Sterilized using ethylene oxide	MD — Medical device	Date of manufacture	Single sterile barrier system
MR — MR conditional			

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.