



Non-Absorbable Polymer Ligating Clips

DEVICE DESCRIPTION

Vas-Q-Clip™ Ligating Clips are single-use, non-absorbable, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. The clips are manufactured from medical grade acetyl homopolymer.

Vas-Q-Clip™ Ligating Clip Appliers are designed for use as delivery devices for Vas-Q-Clip™ Ligating Clips. Ligating clip appliers are reusable instruments that manually load and deliver one clip at a time. The appliers are not designed for compatibility with any other type of ligating clip.

INDICATIONS

Vas-Q-Clip™ Ligating Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

CONTRAINDICATIONS

Vas-Q-Clip™ Ligating Clips are not intended for use as a fallopian contraceptive tubal occlusion device.

Vas-Q-Clip™ Ligating Clips should not be used for ligation of the renal artery during a laparoscopic living-donor nephrectomy because of serious risks to the donor.

WARNING

Vas-Q-Clip™ Ligating Clips

Re-processing of products intended for single use only may result in degraded performance or a loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these products. This product is not designed to be cleaned, disinfected, or re-sterilized.

Vas-Q-Clip™ Ligating Clips are intended for permanent ligation of vessels and tissue structures. Should clip removal be necessary, the Vas-Q-Clip™ may be removed using a polymer ligating clip remover or other appropriate equipment. Should breakage of the clip occur during the removal process, the surgeon should remove the broken clip from the surgical site.

NOTE: Vas-Q-Clip™ Ligating Clips are supplied sterile. DO NOT re-sterilize ligating clip cartridges.

CAUTION

Vas-Q-Clip™ Ligating Clips

Vas-Q-Clip™ Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomy. In procedures other than laparoscopic donor nephrectomy, Nanova Biomaterials, Inc. recommends ligation of the renal artery with more than one clip on the patient side with a minimum distal renal artery cuff of 2-3mm beyond the distal clip. 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. Security of the closure should be confirmed after ligation.

Application of a second clip on all vessels other than the renal artery should be dictated by the surgeon's judgement.

Rx Only: Federal Law restricts this device to sale by or on the order of a physician.

The Vas-Q-Clip™ Ligating Clip is not designed for use as a tissue marker.

Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper size clip. Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and confirm clip security after placement, and after the use of other surgical devices in the immediate area of the application.

CLIP APPLICATION INSTRUCTIONS FOR USE

Vas-Q-Clip™ Ligating Clips are generally suited to vessel and tissue structure sizes indicated in the accompanying chart. Surgeon judgement should dictate clip selection for specific applications.

Loading Clips

1. To load the applier, grasp the applier and carefully insert the jaws of the applier into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible double click. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.

2. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws. The clip bosses should seat in the notches of the applier jaws (**Illustration 1**). It may be necessary to hold the cartridge to allow the clip to be removed.

Clip Positioning and Closure

3. Properly prepare the structure to be ligated to allow the locking mechanism of the clip to be clear of tissue. Do not use the clip or applier as a dissecting instrument.

Clip Size	Cartridge	Vessel Range
ML-Medium Large	Green	3-10 mm
L-Large	Purple	5-13 mm
XL-Extra Large	Gold	7-16 mm



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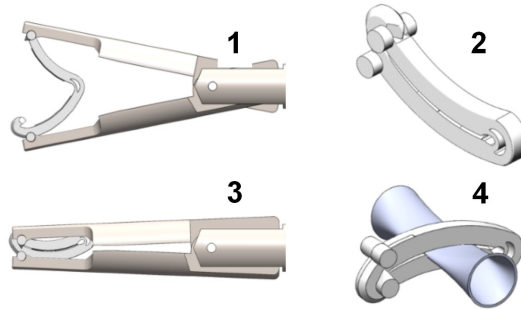
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4. During application, orient the single tooth of the clip as shown in the image (**Illustration 1**). This allows the user to visually confirm encapsulation of the structure being ligated. Position the clip around the tissue to be ligated in a manner that provides clear visualization of the locking mechanism (**Illustration 2**).

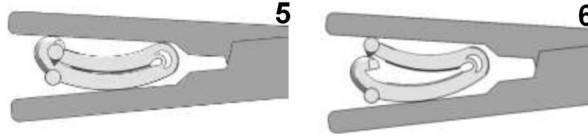


5. Apply sufficient force to the applier handles so the jaws close and the clip locks shut (**Illustration 3**). Avoid excess tissue in the locking mechanism of the clip.

NOTE: Leave a distal cuff of tissue approximately 2-3mm from the ligating clip if the vessel is divided (Illustration 4). DO NOT use the side of the clip as a cutting guide.

Clip Removal Instructions for Use

1. To remove a clip, grasp the remover and carefully place the jaws of the remover over the closed clip so the clip is fully positioned inside the jaws (**Illustration 5**).



2. Once the jaws have been placed, close the handles of the remover until there is an audible click, indicating the clip has unlocked (**Illustration 6**). Ensure the clip has opened sufficiently to allow removal. Use forceps to remove the opened ligating clip from the surgical site.

ENVIRONMENTAL CONDITIONS

Vas-Q-Clip™ Ligating Clips are constructed of acetyl homopolymer material and are considered MR Safe according to the current criteria and labeling terminology (MR safe is an item that poses no known hazards in all MRI environments. Using the terminology, "MR Safe" items are nonconducting, nonmetallic and nonmagnetic items).

PRODUCT INFORMATION DISCLOSURE

Nanova Biomaterials, Inc. excludes all warranties, except Nanova Biomaterials' applicable Standard Warranty whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. NBI shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product except for intended use specified. NBI does not assume nor authorize any person to assume for them any other or additional liability or responsibility in connection with these products.

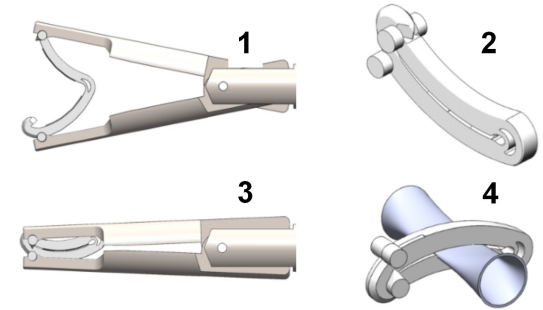
LIGATING SYSTEM COMPATIBILITY

There are a number of Ligating Clips on the market today in addition to Vas-Q-Clip™ Ligating Clips from Nanova Biomaterials, Inc. Vas-Q-Clip™ Ligating Clips have been verified to work with appliers that are marketed for Hem-O-Lok® Ligating Clips. Applier color coding matches the color of the ligating clip cartridge with which it is to be used. Nanova Biomaterials, Inc. does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Nanova Biomaterials, Inc. as an integral part of this specific system.

For additional information, contact your Nanova Biomaterials, Inc. Sales Representative or Nanova Biomaterials, Inc. Customer Service at:

3806 Mojave Court
Columbia, MO 65202
Phone: (573) 875-6682
Customer Service E-mail: support@nanovabio.com

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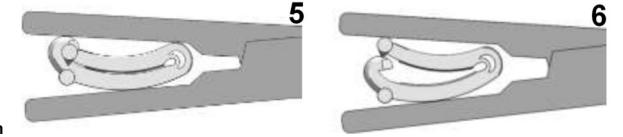


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