

# Instructions for Use

## Reusable Ligation Clip Applier



### ENGLISH



#### IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference for surgical techniques.

#### DESCRIPTION

The GENICON Reusable Clip Appliers are designed to be used on single clips that have to be loaded individually. The overall length of the shaft of the instrument is approximately 12.99 inches (330mm). The clip applier is designed for introduction and use through an appropriately sized GENICON® trocar sleeve or larger sized sleeve.

#### INDICATIONS

The GENICON® reusable clip applier can be applied in endoscopic procedures for occlusion of vessels and other small tissue structures, as well as for radiographic markings.

#### CONTRAINDICATIONS

1. Do not use the GENICON® Clip Applier where metal ligating clips would not normally be used.
2. This device is not intended for contraceptive tubal occlusion, but may be used to achieve hemostasis following transection of the fallopian tube.

#### WARNINGS AND PRECAUTIONS

1. The GENICON® reusable clip applier must be carefully inspected prior to and after each use, because any damage may affect the safe operation of the device. Devices with moving parts should be evaluated for proper function prior to application. If any damage is suspected, contact your local representative for replacement or repair by the manufacturer.
2. The reusable clip applier is provided nonsterile and must be cleaned and sterilized prior to each use.
3. The clip applier and clips should not get in contact with electrosurgical electrodes.
4. The instrument is not intended for use as a grasper or dissector.
5. Appliers should only be used with GENICON clips

#### Contents

P/N	DESCRIPTION	SIZE
350-010-001	Single-Action Jaw Non-Detachable Ligation Clip Applier	10mmx330mm
350-010-002	Dual-Action Jaw Detachable Ligation Clip Applier	10mmx330mm
350-010-003	Single-Action Jaw Detachable Ligation Clip Applier	10mmx330mm
350-010-000	Dual-Action Jaw Non-Detachable Ligation Clip Applier	10mmx330mm
350-005-000	Single-Action Jaw Non-Detachable Clip Applier*	5mmx330mm

#### Contraindications, Warnings, and Precautions

**This product is not intended for use whenever endoscopic techniques are contraindicated.**

**Attention** – Clip applier will arrive in open package. Do not use if package is damaged.

**Attention** – Product must be cleaned and sterilized PRIOR to EACH use. Please see cleaning instructions below.

**Important** – This booklet is designed to provide instructions for the use of an endoscopic clip applier. It is not a reference for surgical endoscopic techniques. This product should only be used by a properly trained surgeon. Before using this product, read the following information thoroughly. Failure to properly follow the instructions may lead to serious surgical injuries.

#### Important:

- This clip is not intended for Fallopian Tube Ligation.
- As a non-magnetic marking clip, it has low magnetic susceptibility and is safe for use in the MRI environment. Positional errors and artifacts may increase dramatically with increasing static magnetic field strength and/or increasing field of view size. Artifact size may vary greatly for different MRI pulse sequences.
- The titanium clip is biologically inert and can remain in body without consequences.

#### Warnings:

To prevent premature closure or release of the clip:

- Never grasp the applier by both shanks when loading the clip.
- Do not squeeze applier handles before jaws are placed around vessel or tissue.
- Ensure appliers are fully closed to handle stop point when applying clip.
- Inspect ligation site to ensure secure application and hemostasis.

To prevent damage to applier jaws:

- Avoid introducing applier tips at an angle into the cartridge rack, this may misalign jaws.
- Inspect applier and jaws before each use.
- Use only GENICON branded clips.
- Open applier for thorough cleaning and sterilization.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

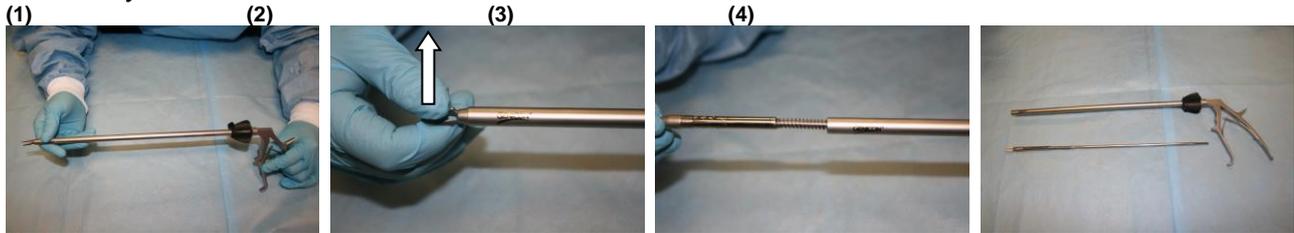
#### Instructions

1. Inspect the integrity of the individual protection (packaging) before initial use. The package is not reusable discard of it appropriately after shipment.
2. Open the packaging. \*product DOES NOT come sterilized. All appliers MUST be CLEANED AND STERILIZED PRIOR to EACH use\*
3. Place clip cartridge firmly on a stable surface and hold clip cartridge in place while removing clips.
4. Select applier according to clip size.
5. Hold applier at the box lock or grasp one shank of the applier in the palm with forefinger at the box lock.
6. Introduce the jaws of the applier vertically into the cartridge clip rack.
7. Push the applier all the way into the cartridge rack and withdraw to remove the clip.
8. Place the loaded clip and jaws of the applier around the vessel or tissue to be occluded.
9. Firmly squeeze the handles together closing the clip. The clip closes tip to tip preventing vessel slippage before fully closing.
10. Release the handle and remove applier. If handle is not fully decompressed clip may remain on applier resulting in improper ligation, injury or other serious surgical complications.

#### Cleaning instructions

**\*Detachable clip applier must be disassembled and thoroughly cleaned and sterilized prior to EACH use. This includes first use. Non-Detachable clip appliers are not disassembled for sterilization.**

**Disassembly:**



The clip applier disassembles into two pieces. Firmly grasp the handle in your left hand while placing the thumb and forefinger of your right hand around the prongs (1). Turn your right hand counter-clockwise (towards body) to release insert (2). After loosening the insert, pull slightly to remove insert from applier. If when you pull, the insert does not move; continue turning the prongs counter-clockwise (3). When complete, there will be two parts; the applier and the insert (4).

**Cleaning:**

The user must ensure that cleaning and sterilization are conducted in accordance with the appropriate guidelines, standards or national Health Authorities' requirements.

Applier jaws are delicate and can easily become damaged. Mishandling of appliers may result in improper load and/or closure of the ligating clips. Appropriate care, cleaning and maintenance are important to ensure proper function. All GENICON's reusable clip appliers are supplied non-sterile. The instrument should be cleaned and sterilized prior to each use. Clean the instrument before sterilization and in the same manner as any reusable instrument and in accordance with hospital practice. Endoscopic clip appliers do not need to be disassembled for cleaning and sterilization but inner shaft mechanism should be thoroughly cleaned through flushing channel.

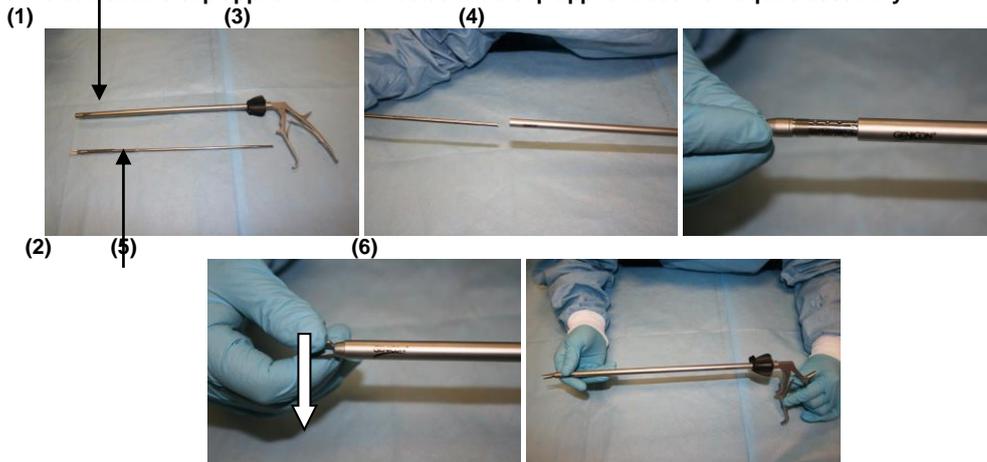
Minimum validated steam sterilization parameters required to achieve a 10<sup>-6</sup> sterility assurance level (SAL) are as follows:

- cycle type – gravity - temperature - 121°C (250°F) - exposure time – 30 minutes - pressure - 1,3 bar (18,2 psi) - drying time – 30 minutes
- cycle type – gravity - temperature - 134°C (273°F) - exposure time – 15 minutes - pressure - 2,3 bar (33,2 psi) - drying time – 30 minutes
- cycle type – prevacuum - temperature - 132°C (270°F) - exposure time – 4 minutes - pressure – 2,1 bar (30,7 psi) - drying time – 30 minutes
- cycle type – prevacuum - temperature - 134°C (273°F) - exposure time – 3 minutes - pressure – 2,3 bar (33,2 psi) - drying time – 30 minutes

NOTE: The Sterilizer Manufacturer's Instructions for operations and load configuration should be followed explicitly.

**Assembly:**

**\*This applies to the detachable clip applier. The non-detachable clip applier does not require assembly.**



The detachable clip applier is composed of two pieces, the applier (1) and the insert (2). Firmly grasp the applier handle in your left hand and the insert in your right hand. Line the insert up with the opening of the applier (3). Gently push the insert into the applier until you feel resistance (4). At that point, begin twisting the insert in a clockwise manner – away from your body (5). Continue twisting the insert until it is snug (it is locked when it can no longer twist) (6).

**Storage**

Store the clip applier in a cool dry area, with good ventilation away from areas of extreme temperature and humidity. The clip applier should be stored assembled to avoid misplacing the insert.

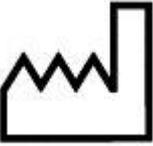
**Shelf Life**

Do not use if package is damaged.  
The manufacturer declines responsibility for problems resulting from improper use.  
Prices, specifications, and model availability are subject to change without notice.

This product may be covered by one or more U.S. patents and their foreign counter parts. Other Patents may be pending.  
GENICON and the GENICON logo design are U.S. registered trademarks of GENICON Rights Reserved.

Disclaimer of Warranties on Re-Processing or Re-Sterilizing of Vendor's Disposable (Single-Patient) Products: Any reprocessing or re-sterilizing of disposable single patient devices voids Vendor's warranty. Vendor assumes no liability for reprocessed or re-sterilized products. Vendor warrants that reasonable care has been used in the manufacture of these disposable single patient devices and that they are free from defects in workmanship or materials at the time of shipment from Vendor. Vendor's sole obligation shall therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of these devices are beyond Vendor's control, Vendor cannot warrant for a good effect or against a bad effect in the application and use of these disposable single patient devices. The Purchaser therefore assumes all liability resulting from re-sterilization or re-processing of these disposable single patient products. Vendor therefore gives no warranty of merchantability or fitness for a particular purpose. Vendor will not be liable for any direct, indirect, incidental or consequential damages resulting from or related to a disposable product that has been re-sterilized or re-processed. Vendor shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of these said products. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual or entity has the authority to vary the terms of this warranty.

**REMAINDER OF PAGE  
INTENTIONALLY LEFT BLANK**

	EN	Manufacturer		EN	See Instructions for Use
	EN	Latex Free		EN	Do not Use if Package is Damaged
	EN	Caution		EN	Authorized Representative in EU
	EN	Manufacture Date		EN	Authorized For Sale or Use by Physician Only
	EN	Serial Number	<b>INTENTIONALLY LEFT BLANK</b>		

	<p>6869 Stapoint Court Suite #114  Winter Park, Florida 32792 USA  TEL: 1-407-657-4851  FAX: 1-407-677-9773  www.geniconendo.com  info@geniconendo.com</p>		<p>European Authorized Representative  Genicon Europe  44 Airedale Avenue  Chiswick, London  United Kingdom W4 2NW  TEL: 44-203-286-3414</p>
---	--	--	--

