



Distributed by :

MCA
MICRO Companies Alliance
Birmingham, Alabama • USA
Phone. +1 (205) 941 01 11
fax. +1 (205) 941 15 22

Manufactured by :

VITALITEC INTERNATIONAL SA
ZA vogue de la Noé • F-35680 Domalain - FRANCE

GEM-CLIP



MICROCLIP SYSTEM

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION CAREFULLY

Failure to properly follow the instructions may lead to serious surgical consequences.

IMPORTANT: This package insert is designed to provide instructions for the use of hemostatic clips. It is not a reference to surgical techniques.

STERILE EO Ethylene Oxide Sterilization

Single Use

Check the packaging integrity before use.
Sterility guaranteed unless package opened or damaged.

YYYY - MM Expiration Date

LOT Lot N°

Do not resterilize

See Instructions for Use

CONTENTS

30 cartridges of 6 Clips micro

Color Code: White

GEM 2431

INDICATIONS

The micro titanium hemostatic clip has been specifically designed to securely grip the vessel or tissue to provide complete occlusion atraumatically. User shall select appropriate clip size according to procedure ensuring that all tissues are completely encompassed by clip.

Note

- This micro 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 vivo without sequelae.

INSTRUCTIONS

- Inspect the integrity of the individual sterility protection (packaging) before using;
- Open the sterile packaging;
- Remove the protective strip from the adhesive base of the clip cartridge and press firmly on a stable surface;
- Select applicator according to clip size (color coding);
- Hold applicator at the box lock, or grasp one shank of the applicator in the palm with forefinger at the box lock;
- Introduce the jaws of the applicator vertically into the clip cartridge;
- Push the applicator all the way into the clip cartridge and withdraw to remove the clip;
- Place the loaded clip and jaws of the applicator around the vessel or tissue to be occluded;
- Firmly squeeze the handles together closing the clip. The clip closes tip to tip preventing vessel slippage before fully closing;
- Release the handle and remove applicator.

WARNINGS

To prevent premature closure or release of the clip:

- Never grasp the applicator by both shanks when loading the clip;
- Do not squeeze applicator handles before jaws are placed around vessel or tissue;
- Ensure applicators are fully closed to handle stop point when applying clip.

Inspect ligation site to ensure secure application and hemostasis.

To prevent damage to applicator jaws:

- Avoid introducing applicator tips at an angle into the cartridge rack, this may misalign tips

Inspect applicator and jaws before each use.

Use recommended applicators.

Open applicator for thorough cleaning and sterilization.

Federal (USA) law restricts this device to sale by or on the order of a physician.

STORAGE

Store the unopened sterile package in a cool dry area, with good ventilation away from areas of extreme temperature and humidity.

SHELF LIFE

Contents sterile if package is unopened, undamaged and within the validity date printed on the package.

THIS CLIP IS INTENDED FOR SINGLE USE AND CANNOT BE RESTERILIZED.

Do not use if package is opened or damaged.

The manufacturer declines responsibility for problems resulting from improper use. Prices, specifications, and model availability are subject to change without notice.