



Prymax Surg Silicon Vessel Loop

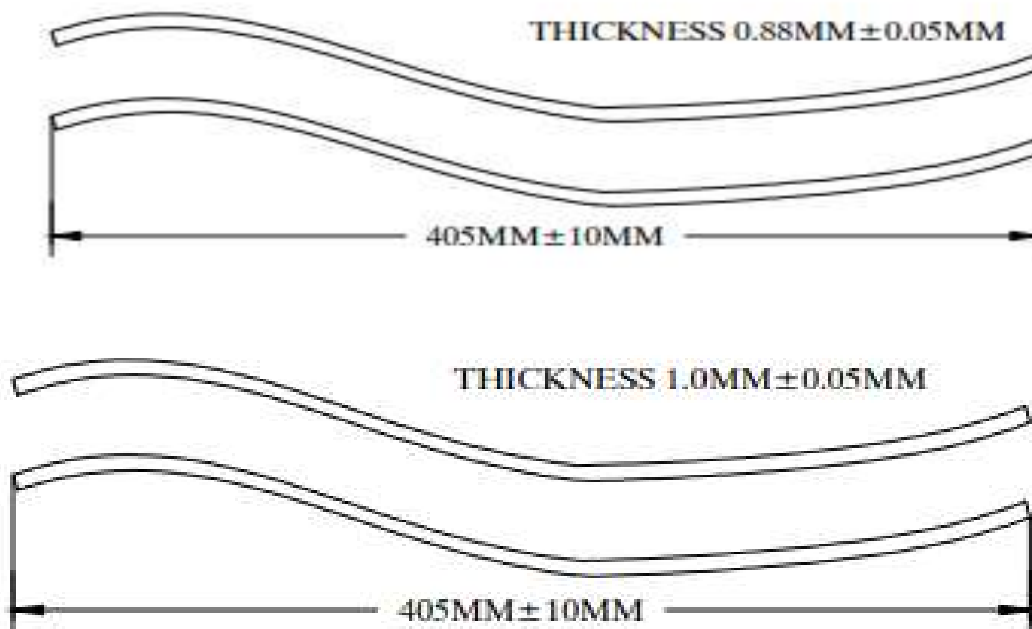
DEVICE DESCRIPTION:

The products of this category are generally used in Operation Theatres of hospitals/ Health Research Centers / Clinics during different Medical/Surgical Procedures. Vessel Loop are designed to aid the surgeon in complicated surgical fields by providing retraction, occlusion and identification of arteries, Veins, Nerves and ureters.

AVAILABLE VARIANTS:

Red, Blue, Yellow and White
Size: Mini and Maxi

Drawing of product:



MATERIAL USED:

Silicon

INTENDED PURPOSE:

INTENDED USE: Vessel loop is intended to be used to occlude, retract, and identify arteries, veins, tendons and nerves in Surgical Procedures.

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INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender

INDICATIONS:

- “Slings” and “Retraction” of vessels and nerves during surgical procedure
- Assisting in the identification of nerves and vessels during surgery

CONTRAINDICATIONS:

- Trying off any vessels to stop the flow of blood where forceps/clamps should be used
- For any long term treatments, such as acting as a drain
- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

CLINICAL BENEFITS:

Vessel loop is very helpful for identification when multiple structures are available and having some common origin as in the infraclavicular dissection in brachial plexus. The branches from cords can be tagged with different coloured loops to avoid confusion.

PERFORMANCE CHARACTERISTICS:

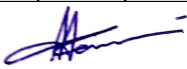
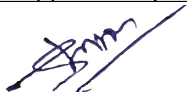
Ability to accurately place stitches

INSTRUCTIONS FOR USE:

- Open the product in sterile environment
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- After removing loops from package, the surgeon may do as follows
- Retract-wrap around vessel. Clamp loop to drape or hang outside wound.
- Occluding-wrap loop around vessel twice. Clamp adjacent to vessel to secure.
- Identify-wrap loop around vessel, nerve and ureter or intestine.
- At the end of procedure, dispose of loop in an appropriate manner.

WARNING & PRECAUTIONS:

- The use of this product is restricted to a qualified medical professional.
- Read all the information mentioned in instruction for use. Failure to do so may result in severe patient injury or death. The product should be used according to the instructions for use.
- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- Do not use if the sterile pack is opened or damaged.

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- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

ADVERSE EFFECTS:

- Wound complications like Pain, Nerve injury, Infection & Breakage

RE-USE HAZARDS:

- Transmission of infection from one patient to another.

PACKAGING:

- The device is packed in paper Pouch, which is further packed in inner carton & master carton.

STERILIZATION:

- Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:

- Temperature Limit: 15°C to 40°C.

DEVICE SHELF LIFE: 3 Year

COUNTRY CODE: 356

DISPOSAL

- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.


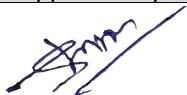
REPORTING OF ADVERSE EVENTS:

- In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.
- Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY

Refer to the company's return good policy.

Please contact the branch office or customer service at info@prymaxhealthcare.com or [call +91 129 4011818](tel:+911294011818).

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SYMBOLS USED ON PRODUCT LABEL

Lot number	Do not re-use	Sterilized by Ethylene Oxide
Manufacturing date	Use-by date	Caution
Non-pyrogenic	Do not re-sterilize	Catalogue number
Manufacturer Européenne	Storage Temperature Range	Conformité
	Do not use if package is damaged and consult Instructions for Use instructions for use	
		Consult
Single Sterile Barrier System	UDI Carrier	Medical Device

Prepared by:	Approved By:

Country of Manufacturer



Manufactured By:

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Haryana, INDIA -121001

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