

STERILE SUPPLY

- Vessel Loops



Product Function

The Vessel Loop is used to retract, occlude, isolate & identify arteries, veins, tendons, nerves & ureters.

Product Description

The disposable Vessel Loop is a single use device, and is supplied sterile.

The Vessel Loop is a soft, pliable, oval shaped silicone loop that is available in 4 colours & 2 sizes. The Loops are radio opaque & provide an even dispersion of pressure significantly reducing possibility of an unintended atheroma (blocking of the vessel).

Dimensions:

- Mini Version Diameter 1.5 mm/Length 470 mm
- Maxi Version..... Diameter 2.5 mm/Length 470 mm

Product Range

PS3001	Vessel Loop – Mini White
PS3002	Vessel Loop – Mini Red
PS3003	Vessel Loop – Mini Blue
PS3004	Vessel Loop – Mini Yellow
PS3201	Vessel Loop – Maxi White
PS3202	Vessel Loop – Maxi Red
PS3203	Vessel Loop – Maxi Blue
PS3204	Vessel Loop – Maxi Yellow

Standardisation

Device Classification (Defined by 93/42/EEC Directive)	Class IIA, Rule 6
CE Marking	C 1639
GMDN	61916
Quality System Certified to	ISO 13485:2016

Sterilisation

Supplied in Sterile Condition	YES
Sterilisation Method	Ethylene Oxide
Product Shelf Life	4 years from date of sterilization

Single Use Warning

These device(s) are designed and sold for single use only as defined in Article 1 (n) of directive 2007/47/EC. As such re-processing and/or re-sterilisation after initial use is not permitted.

The effects of any unauthorized re-processing or re-sterilisation can result in the following complications:

- Cross contamination due to ineffective re-processing/re-sterilisation.

2. Mechanical fatigue, and associated failure, due to the effects of the re-processing/re-sterilisation method.

Compatibility and Connectivity

The Vessel Loop has been designed to retract, occlude, isolate & identify arteries, veins, tendons, nerves & ureters.

The Loops are radio opaque & provide an even dispersion of pressure when tied, which significantly reduces possibility of an unintended atheroma (blocking of the vessel).

Product Materials

Components	Material	Grade	CAS#
Vessel Loop	Silicone	VMQ Polymer	90337-93-2

Materials Data

Latex Free	YES
Phthalate (DEHP, BBP & DBP) Free	YES

Packaging

Unit Packaging	Sterile Unit Packing – Pouch, Packed (MM70 Medical Paper with PET/PE Film)				
Box Packaging	Shelf Box		Shipping Carton		
Product Code	Qty. (Pcs)	Dimensions (mm)	Qty. (Pcs)	Dimensions (mm)	Gross Wt. (Kg)
PS3001	10	135 × 60 × 57	300	210 × 220 × 445	2.50
PS3002	10	135 × 60 × 57	300	210 × 220 × 445	2.50
PS3003	10	135 × 60 × 57	300	210 × 220 × 445	2.50
PS3004	10	135 × 60 × 57	300	210 × 220 × 445	2.50
PS3201	10	135 × 60 × 57	300	210 × 220 × 445	3.00
PS3202	10	135 × 60 × 57	300	210 × 220 × 445	3.00
PS3203	10	135 × 60 × 57	300	210 × 220 × 445	3.00
PS3204	10	135 × 60 × 57	300	210 × 220 × 445	3.00

Disposal

After single patient use, the device is to be immediately disposed of as controlled medical waste.

Availability of Instructions for Use:

YES ☐

NO ☒

Storage and Handling Instructions:

Store and Handle with Care

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Document Revision History

Revision	Change Detail	Date	Approved
1.	First revision for EO sterilised version of product.	2018-10	CW
2.	Label transition from CE 0120 to CE 1639 (UK SGS office to Belgium).	2020-02	M. Cihal