



Nerve Vessel Loops



Product Information and Instructions for Use

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SYMBOLS					
REF	Catalogue Number		Manufactured by	STERILE R	Sterilisation by Gamma Irradiation
LOT	Lot Number	EC REP	Authorized Representative in the European Community		Do Not Reuse
	Use by date (YY-MM)		Do Not Use if Packaging is Open or Damaged		Do Not Resterilise
	Latex Free		Keep Dry		Instructions For Use
	Phthalate Free		Keep away from Sunlight		

ENGLISH - INSTRUCTIONS FOR USE

Intended Use:
 Medasil Nerve and Vessel Loops (NVLs) are intended to be used for silinging, retraction and identification of blood vessels, nerves and tendons during a surgical procedure, suitable for short term use (up to 29 days).

Device Description:
 Silicone NVLs are manufactured from silicone elastomer which is biocompatible and latex free and Phthalate free. The loops are semi-elastic, flexible, and oval in structure dissipating pressure more effectively between the loop and tissues. Available in five widths to accommodate a wide range of anatomical requirements, and four distinct colours to aid identification. The device contains Barium Sulphate (BaSO₄) which may aid visibility under X-ray and is intended for single use only.

Indications for Use:
 Include, but are not limited to:
 - "silinging" and "retraction" of vessels and nerves during surgical procedures.
 - Assisting in the identification of nerves and vessels during surgery.

Medasil NVLs must not be used in contact with the Central Nervous System¹ or Central Circulatory System².

Contraindications:

- Include, but are not limited to:
- Tying 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.
 - The closure of fasciotomy wounds.

Possible Adverse Effects:

- Include, but are not limited to:
- Intra-operative haemorrhage/damage due to excessive constriction.
 - Post-operative pain.

Warnings and Precautions:

- Prior to use, the HCP should consider the following:
- Must not be used in contact with Central Nervous System or Central Circulatory system.
 - Must not be used if the patient has known allergic reaction towards silicone.
 - For devices supplied sterile, the sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
 - Must not be used beyond expiry date on the label.
 - Must not be used if the packaging has been compromised.
 - Must be stored in the original unopened packaging and away from moisture and direct sunlight.
 - NVLs are single use devices.

Sterility:

NVLs are supplied STERILE and have been terminally sterilised using Gamma Radiation. Do not re-sterilise.

Single Use:

Medasil NVLs have not been validated for re-use. Anyone re-using a single use device, may be held legally liable for the safe performance of the device.

Disposal of Devices:

Devices must be disposed of in accordance with the local and national regulations.

¹Central Circulatory System:
 Pulmonary artery, Ascending aorta, Aortic arch, Descending aorta to the aortic bifurcation, Coronary artery, Common carotid artery, External carotid artery, Cerebral arteries, Brachiocephalic artery, Coronary veins, Pulmonary vein, Superior vena cava, Inferior Vena cava

²Central Nervous system:
 Brain, Meninges, Spinal cord

Table 1. Product REF Specifications:

Size (mm)	Old REF	Colour	REF		
			1 per Pouch	2 per Pouch	5 per Pouch
1.5	125A	Blue	420-1101-1521	420-1102-1522	
		White	420-1101-1531	420-1102-1532	
		Yellow	420-1101-1541	420-1102-1542	N/A
2.0	125B	Red	420-1101-1551	420-1102-1552	
		Mixed*	420-1101-1591	420-1102-1592	420-1105-1595
		Blue	420-1101-2071	420-1102-2072	
2.5	125C	White	420-1101-2031	420-1102-2032	
		Yellow	420-1101-2041	420-1102-2042	
		Red	420-1101-2051	420-1102-2052	N/A
3.0	125D	Mixed*	420-1101-2091	420-1102-2092	420-1105-2095
		Blue	420-1101-2521	420-1102-2522	
		White	420-1101-2531	420-1102-2532	
3.5	125E	Yellow	420-1101-2541	420-1102-2542	N/A
		Red	420-1101-2551	420-1102-2552	
		Mixed*	420-1101-2591	420-1102-2592	420-1105-2595
			N/A	420-1102-3592	420-1105-3595

*Mixed Colours:

1 per Pouch: 1 of any of colour in a pouch – Mixture of colours in a box of 30 units.

2 per Pouch: 2 of the same colours in a pouch – Mixture of colours in a box of 30 units.

5 per Pouch: 1 Blue, 1 White, 1 Yellow, 2 Red - in each pouch, - box of 30 units.