



# Nerve Vessel Loops



## Product Information and Instructions for Use

**MEDASIL SURGICAL LIMITED**  
 Medasil House, Hunslet Road  
 Leeds, LS10 1AU (UK)  
 Tel: +44 (0)113 243 3491  
 E-Mail: [orders@medasil.com](mailto:orders@medasil.com)  
 Website: [www.medasil.com](http://www.medasil.com)

European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishop's Town Road, Cork, Ireland T12 9Y1C  
 Tel: +353 (86) 228 0846  
 www.europeandevicelimitations.eu



SYMBOLS			
<b>REF</b>	Catalogue Number		Manufactured By
<b>LOT</b>	Lot Number		Authorized Representative in the European Community
	Use by date (YYMM)		Do Not Use if Packaging is Open or Damaged
	Laser free		Keep Dry
	Phthalate free		Keep away from Sunlight
			Sterile (as per Gamma Irradiation)
			Do Not Re-use
			Instructions For Use

### ENGLISH - INSTRUCTIONS FOR USE

**Intended Use:**  
 Medasil Nerve and Vessel Loops (NVLs) are intended to be used for slinging, 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 (BaSO<sub>4</sub>) which may aid visibility under X-ray and is intended for single use only.

**Indications for Use:**  
 include, but are not limited to:  
 - "slinging" 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 System<sup>1</sup> or Central Circulatory System<sup>2</sup>.

**Contraindications:**  
 include, but are not limited to:  
 - Typing of 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 sterilized 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.  
<sup>1</sup>Central Circulatory System:  
 Pulmonary artery, Ascending aorta, Aortic arch, Descending aorta to the aortic bifurcation, Coronary artery, Common carotid artery, External carotid artery, Central arteries, Shuntocapnic artery, Coronary vein, Pulmonary vein, Superior vena cava, Inferior Vena cava  
<sup>2</sup>Central Nervous System:  
 Brain, Meninges, Spinal cord

Table 1. Product REF Specifications:

Site (mm)	Old REF	Colour	REF		
			1 per Pouch	2 per Pouch	5 per Pouch
1.5	125A	Blue	420-1101-1521	420-1102-1532	N/A
		White	420-1101-1531	420-1102-1532	
		Yellow	420-1101-1541	420-1102-1542	
		Red	420-1101-1551	420-1102-1552	
2.0	125B	Mixed*	420-1101-2091	420-1102-2092	N/A
		Blue	420-1101-2021	420-1102-2032	
		White	420-1101-2041	420-1102-2042	
		Yellow	420-1101-2041	420-1102-2042	
2.5	125C	Mixed*	420-1101-2591	420-1102-2592	N/A
		Blue	420-1101-2521	420-1102-2532	
		White	420-1101-2531	420-1102-2532	
		Yellow	420-1101-2541	420-1102-2542	
3.0	125D	Mixed*	420-1101-2551	420-1102-2552	N/A
		Blue	420-1101-2591	420-1102-2592	
		White	420-1101-2591	420-1102-2592	
		Yellow	420-1101-2591	420-1102-2592	
3.5	125E	Mixed*	N/A	420-1102-3592	420-1105-3595
		Mixed*	N/A	420-1102-3592	

\*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.