



Sterile Silicone Nerve Vessel Loops



Product Information and Instructions for Use

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SYMBOLS			
REF	Challenge Number	LOT	Lot Number
	Manufactured by		Manufactured date
	Keep Dry		Sterilization by Gamma irradiation
	Keep away from sunlight		Do not Use if Packaging is Open or Damaged
	Do Not Reuse		Prehabile free
	Sterile Barrier Which inner non sterile Barrier		Medical Device
	Do Not Penetrate		Consult Instructions for Use

INSTRUCTIONS FOR USE

- **INTENDED USE:**
Medasil Silicone Nerve 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).
- **INTENDED PATIENT POPULATION**
Medasil Silicone Nerve Vessel Loops are intended for use on the general patient population applied on adults and children.
- **INTENDED USERS**
Medasil Silicone Nerve Vessel Loops are intended to be used by Healthcare Professionals only (HCP) within a clinical/healthcare setting only.

DEVICE DESCRIPTION:

Medasil Silicone Nerve Vessel Loops are manufactured from Silicone elastomer which is biocompatible latex and Phtalate 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. BaSO₄ is listed as a medicine, classed as a radiopaque contrast agent in the Pharmacopoeia. As used in this device the included BaSO₄ does not function as a medicine and no clinical claims are made.

INDICATIONS FOR USE:

- Include, but are not limited to:
- "slinging" and "retraction" of blood vessels, nerves and tendons during surgical procedures.
- Identification of blood vessels, nerves and tendons during surgery.

Silicone Nerve Vessel Loops must not be used in contact with the Central Circulatory System* or Central Nervous System*.

PERFORMANCE CLAIMS:

- Identification of blood vessels, nerves and tendons during surgical procedures.
- Atrumatic retraction.

SAFETY CLAIMS:

- Biologically safe

CONTRAINDICATIONS:

- Include, but are not limited to:
- Tying of blood vessels to stop the flow of blood where forceps/clamps should be used.
- Long-term treatments, such as acting as a drain.
- 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 if the packaging has been compromised.
- Must not be used beyond expiry date on the label.
- Must be stored in the original unopened packaging.
- Nerve Vessel Loops are single use devices.
- In the event of any serious adverse effects, medical attention must be sought immediately.

- Re-use, reprocessing, restertilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Re-use, reprocessing, restertilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
- **STERILITY:**
The device is supplied STERILE and having been terminally sterilised using Gamma Radiation. **Do not resterilise.**
- **SINGLE USE:**
Device has not been validated for re-use. Anyone reusing a single use device, may be held legally liable for the safe performance of the device.
- **DISPOSAL OF DEVICES:**
Device must be disposed of in accordance with the local and national regulations.

Table 1. Product REF Specifications:

Size (mm)	Colour	1 per Pouch	2 per Pouch	5 per Pouch
1.5	Blue	420-1101-1521	420-1102-1522	
	White	420-1101-1531	420-1102-1532	
	Yellow	420-1101-1541	420-1102-1542	N/A
	Red	420-1101-1551	420-1102-1552	
2.0	Mixed*	420-1101-2021	420-1102-2022	420-1105-1595
	Blue	420-1101-2031	420-1102-2032	
	Yellow	420-1101-2041	420-1102-2042	
	Red	420-1101-2051	420-1102-2052	
2.5	Mixed*	420-1101-2091	420-1102-2092	420-1105-2095
	White	420-1101-2521	420-1102-2522	
	Blue	420-1101-2531	420-1102-2532	
	Yellow	420-1101-2541	420-1102-2542	N/A
3.0	Mixed*	420-1101-2591	420-1102-2592	420-1105-2595
	White	420-1101-3031	420-1102-3032	
	Blue	420-1101-3041	420-1102-3042	
	Red	420-1101-3051	420-1102-3052	
3.5	Mixed*	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 pouches.
 2 per Pouch: 2 of the same colours in a pouch - Mixture of colours in a box of 30 pouches.
 5 per Pouch: 1 Blue, 1 White, 1 Yellow, 2 Red - in each pouch, - box of 30 pouches.

LIABILITY AND WARRANTY:

Medasil declare that reasonable care has been applied in the design and manufacture of this product. In the event of any alleged damage, please contact Medasil or your supplier. The responsibility of Medasil or your supplier under this warranty is limited to the replacement of product if faulty. On no account may Medasil or your supplier be held responsible for damage, whether direct, indirect and/or incidental resulting from the misuse and/or the manipulation of this device.

NOTES:

- This device:
- Is not made with natural rubber/latex.
- Does not contain any animal or human cells, tissues and/or derivatives thereof, rendered non-viable: cells, tissues and/or derivatives of microbial or recombinant origin, and/or irradiating components, ionizing or non-ionizing.
- Are not intended for use by lay persons.

Any serious incident that has occurred in relation to the Nerve Vessel Loops should be reported to Medasil and/or the MHRA.

- Central Circulatory System:
Pulmonary artery, Ascending aorta, Aortic arch, Descending aorta to theortic bifurcation, Coronary artery, Common carotid artery, External carotid artery, Cerebral arteries, Brachiocephalic artery, Axillary vein, Pulmonary vein, Superior vena cava, Inferior Vena cava
- Central Nervous system:
Brain, Meninges, Spinal cord