

VEIN STRIPPER

CE marking: 2000

Products references: 2004101 & 2004102

Product sterilized by ethylene oxide
Sterile product as long as the packaging hasn't be opened, damaged or broken
Single use product

For use by trained staff

WARNING: Don't sterilize

WARNING: Store in a cool and dry place with ambient temperature. Avoid extreme temperatures and humidity. Conserve in the original packaging.

WARNING: Read carefully instructions before use.

WARNING: Shelf life - Use this catheter before the expiration date indicated on the packaging.

WARNING: The ISO Med vein stripper is not intended to be used in central venous system.

VEIN STRIPPER USE AND DESCRIPTION

The ISO Med vein stripper is intended to remove varicosis veins segments at the level of lower limbs.

The ISO Med vein stripper contains:

- One or two guides of 1,6 mm diameter and 100 cm length,
- One handle,
- Four olives of 6, 9, 12 and 15 mm diameter.

Its guide and olives design permits to execute the exostripping and endostripping. The handle and olives could be connected on the both extremities of the guide.

CONTRA-INDICATIONS:

All usual contra-indications of anaesthesia and surgery: allergy to anaesthetics, haemorrhagic ground, cancer, systemic disease. Infections, Coagulation disorders,

PRECAUTIONARY MEASURES ON APPLICATION

Check the adjustment of the olive with the guide tip. During stripping procedure, it should avoid to push the guide back. It is recommended to put a recovering suture on the olive or the guide tip for the two stripping methods. It could have a stripper hooking risk when passing into the vein. In this event, it is recommended to use another stripper to remove the first.

It is recommended to carry anticoagulation after stripping to avoid the risk of phlebitis, thrombosis or pulmonary embolism, as well as postoperative compression to avoid oedema risks and antibiotic to reduce infection risks.

VEIN STRIPPER APPLICATION

WARNING: The biggest careful has to be brought on the manipulation's ASEPISIS.

WARNING: Check the integrity of the sterility protector primary packaging. Never use a device which primary packaging is damaged.

WARNING: Check that the introduction area doesn't present any infection sign (red blotches, local inflammation or pain at the palpation). It is recommended to perform a Doppler sonography and Duplex scanning to check the saphenous reflux.

CONVENTIONNAL STRIPPING: EXOSTRIPPING

The product is intended for temporary application. It is recommended to put the patient under local anaesthetic.

1. Wear sterile mask and gloves.
2. Make a local disinfection of the use area.
3. Perform an incision on both ends of the vein to be removed.
4. Place the guide inside the vein. Assemble the olive and the handle. Put a recovering suture
5. Pull the handle to remove the vein.

Figure 1: Olive assembly

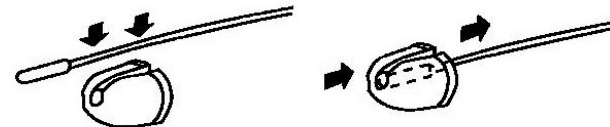
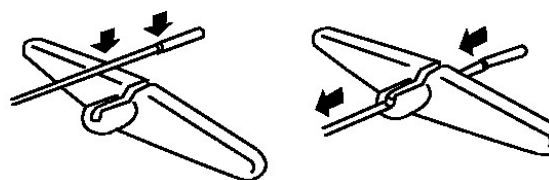


Figure 2: Handle assembly



ENDOSTRIPPING:

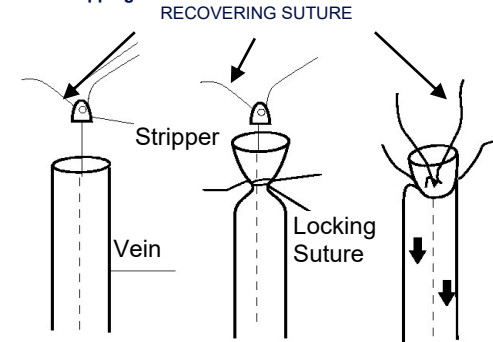
It is recommended to put the patient under local anaesthetic.

1. Wear sterile mask and gloves.
2. Make a local disinfection of the use area.
3. Perform an incision on both ends of the vein to be removed.
4. Place the guide inside the vein.
5. Knot a suture over the vein external perimeter so that the guide is locked (see figure 3). Put also a recovering suture on the hole at the guide tip (olive side). In

case vein breaks during endostripping, guide should be removed by pulling this suture.

6. Assemble the olive (if it's necessary) and the handle. Olive assembly (see figure 1): insert guide into olive's slot and snap in position. Draw guide into olive until it seats.
7. Pull the handle to remove the vein.

Figure 3: Endostripping



POSSIBLE COMPLICATIONS

- Haematoma
 - Infection
 - Difficult cicatrisation
 - Arterial and venous lesions
 - Inflammation
 - Anaesthetic scars
 - Oedema
 - Paraesthesia
- These complications could be avoided or reduced if a complete pre-operative evaluation is performed.

- Nervous lesions
- Lymphatic complications
- Phlebitis
- Pain
- Problems or delayed cicatrisation
- Bleeding or lymph flow on incisions (rare)
- Superficial Venous thrombosis

WARNING: Re-use of the device could increase risk of infection or other improper functioning of the device

WARNING: Dispose of used devices according to local regulations for contaminated waste.

The materials of the catheter are: cable = PA, olives & handle = PP, pouch = PGL + PET / PE

	<p>EN: Do not use if the packaging is damaged FR: Ne pas utiliser si l'emballage est endommagé DE: Nicht verwenden, wenn die Verpackung beschädigt ist ES: No utilizar si el embalaje está deteriorado</p>		<p>EN: Reference number FR: Numéro de référence DE: Bestellnummer ES: Número de referencia</p>		<p>EN: Manufacturing date FR: Date de fabrication DE: Herstellungsdatum ES: Fecha de fabricación</p>
	<p>EN: See instruction for use FR: Lire la notice DE: Anleitung lesen ES: Consulte las intrucciones de uso</p>		<p>EN: Single use FR: Usage unique DE: Zum einmaligen Gebrauch ES: De un solo uso</p>		<p>EN: Use by FR: À utiliser avant la date DE: Verfallsdatum ES: Utilizar antes de</p>
	<p>EN: Sterilized by Ethylene Oxide FR: Stérilisé à l'oxyde d'éthylène DE: Mit Ethylenoxid sterilisiert ES: Esterilizado con óxido de etileno</p>		<p>EN: Manufactured by FR: Fabriqué par DE: Hergestellt von ES: Fabricado por</p>		<p>EN: Batch code FR: Numéro de lot DE: Chargennummer ES: Número de lote</p>