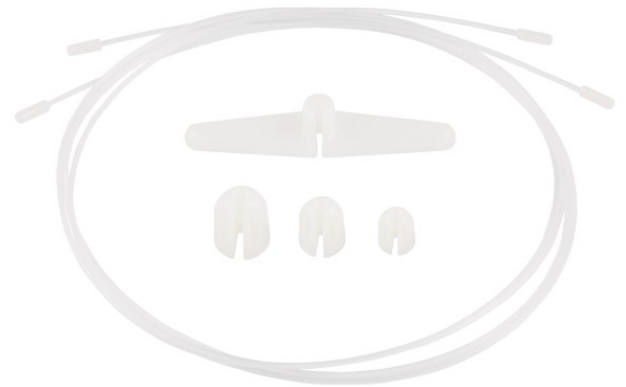


Dormo-Strip

Blayco

> Product description

The vein strippers are a single use medical device sterilized by EtO, intended to use on surgical interventions where stripping a vein is required. The vein stripper could be used on the two most common removal techniques: conventional stripping and invagination stripping.



> Product characteristics

- Ref. VE-022, conventional stripping: No hole.
- Ref. VE-025, invagination stripping: One side hole.

> Technical specifications

> Materials

- Cable, olives, end cap: Polyamide-6
- Packaging directly in contact with product:
- Protective pouch: LDPE
- Sterile pouch:
- PA/PP film
- Cellulose paper, medical grade

> Main dimensional properties

- Cable length: 100 ± 10 cm
- Cable diameter: 1.54 – 1.66mm
- End cap diameter: 3.25 ± 0.10 mm
- Big olive diameter: 15.40 ± 0.10 mm
- Medium olive diameter: 12.85 ± 0.15 mm
- Little olive diameter: 9.5 ± 0.10 mm

> **Funcionality tests**

- Cable – Stopper tensile strength: >25kg
- Cable breaking force: >45kg

> **Biocompatibility**

- No cytotoxic (ISO 10993-5)
- Negative intracutaneous irritation test (ISO 10993-10)
- No sensitizing (ISO 10993-10)

> **Sterilization and expiry date**

- Sterile by Ethylene Oxide
- Shelf life: 3 years after manufacturing date

> **Storage and maintenance**

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Single use product. No maintenance required
- Do not re-sterilize.

> **Packaging**

Ref	Packaging
VE-022	Conventional stripping : Pouch content: 2 cables, 3 olives (big, medium and small size), 1 handle. 12 pouches per service box
VE-025	Invagination stripping: Pouch content: 2 cables with hole in the case, 3 olives (big, medium and small size), 1 handle. 12 pouches per service box.

> Instructions for use

- The olive and the handle must be attached in the opposite ends of the cable, once the cable has been introduced in the vein to be removed.
- Olive assembly: Insert the cable into the slot. A “click” must be heard to ensure it has been well inserted. Press the stopper, located in the cable end, into the olive so that it is locked.
- Handle assembly: Insert the cable into the slot. Press the stopper, located at the end of the cable, into the handle so that it is.

Date: March 2023

Specification N°: ETP/022/15

> Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with Regulation (EU) 2017/745 and that it has been manufactured following the directives of the Quality Assurance System certified as ISO 13485.

This product is classified as:

- Class IIa-Sterile product according to Annex VIII of Regulation (EU) 2017/745, rule 7.
- GMDN code: 32321 Single use vein strippers.
- EMDN code: C0699 (Cardiovascular surgery instruments, single-use-other).