

EN KliniMark CLIP
INSTRUCTIONS FOR USE



Table of contents

- Available languages
- Scope
- Important notice
- Product description
- Operating principle
- Information about the material
- Intended use
- Indication
- Contra-indications
- Designated patient group
- Designated users
- Designated environment for use
- Use
- Storage and storage life
- Warning notes
- Side effects
- Residual risks
- SSCP
- Product information

Available languages

DE	EN	FR	SK	GR	EE
ES	IT	BG	RO	LT	
PL	CZ	SL	DK	LV	

Scope

These instructions for use apply to the following products:

Article: KliniMark CLIP
Article number: REF: 105880900N

Important notice

Improper handling and use can result in hazards and damage. We therefore ask you to read through these instructions for use and follow them exactly. Keep them close at hand at all times. To avoid personal injury and damage to property, please also observe the safety instructions. If you have any questions about the contents of these instructions for use or the use of the product, please contact us. Your KLINIKA team

Product description

The KliniMark CLIP is a sterile, disposable product consisting of a puncture cannula (18G, 12 cm long) and a preloaded, non-absorbable Nitinol clip marker. The clip marker has an omega shape with dimensions of 5.9 x 2.1 mm and a diameter of 4.5 mm. The cannula has space markings (1 cm) for measuring the penetration depth and a bevelled tip for insertion into the tissue. The product is intended for long-term use.

Operating principle

The preloaded, non-magnetic Nitinol CLIP is placed in the area to be marked through a cannula (18G). By removing the spacer, the CLIP is pushed into the tissue. Nitinol is clearly visible on ultrasound and x-ray images. Under an imaging procedure, such as mammography or ultrasound, the target area is punctured with the cannula. The marker is placed by removing the spacer on the stylet and pushing the stylet forward. The position of the marker is documented. Then the cannula is removed. It is helpful to mark tumours or other areas in this way so that they can be relocated or observed (e.g. in neoadjuvant therapy). Due to its shape (omega V), the KliniMark Clip is easy to relocate three-dimensionally.

Information about the material

The Clip is made from Nitinol (nickel-titanium alloy), the cannula from steel.

Intended use

The KliniMark CLIP is a medical device used for diagnosis, treatment and monitoring in medical procedures. KliniMark CLIP is used for tissue marking in breast tissue and lymph nodes: Before or after chemotherapy or radiotherapy to mark the location of a biopsy removal or a removed tumour, in the case of unclear findings.

Indication

The markers are used, for example, in lesions before or after chemotherapy or radiotherapy, or at the site of a biopsy removal or a removed tumour. KliniMark CLIP can also be used for preoperative tissue marking.

Contra-indications

- Nitinol is a nickel-titanium alloy and should therefore, in the case of a known, pronounced nickel allergy, only be used after a doctor's recommendation.
- The marker must not be used on the heart, central nervous system or central circulatory system.
- The cannula is not MRI capable and must not be placed under MRI. The Clip is made of Nitinol, Nitinol is MR-compatible, there is no data available for this product.

Designated patient group

Adults. The product must not be used on children, pregnant women or breastfeeding women.

Designated users

Medical staff

Designated environment for use

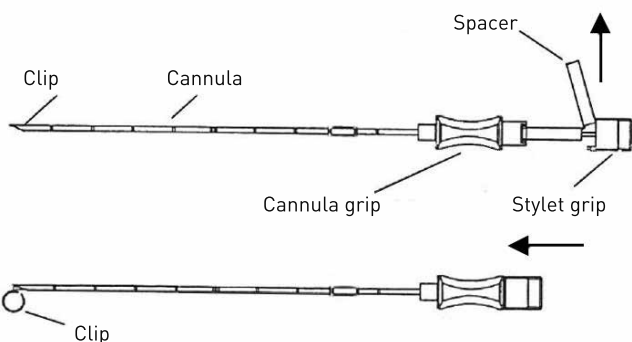
Medical treatment room, surgery

Use:

1. Before use, it must be checked that the packaging is closed and not damaged. Please check the expiry date.
2. Open the packaging at the tear-off flap with the foil side facing up. Remove the foil and take out the product aseptically.
3. Disinfect the area of the procedure and, if necessary, perform local anaesthesia.
4. Remove the protective cap from the needle.
5. Under an imaging procedure, such as mammography or ultrasound, puncture the target area with the cannula.
6. Place the marker by removing the spacer on the stylet and pushing the stylet forward.
7. The CLIP unscrews on the opposite side to the blue mark on the cannula holder.
8. Document the position of the marker. Then remove the cannula.
9. Treat the wound.
10. After treatment, the cannula must be disposed of properly in a suitable cannula container.

Storage and storage life

The product must not be used if the packaging is open, damaged or damp. Store in a dry place, away from direct light and heat. Do not store or use the product at temperatures below +5 °C. Sterility is guaranteed by the complete packaging. The KliniMark CLIP has a storage life of three years in clean, cool, dry and dark conditions.



Warning notes

- The KliniMark CLIP should only be used by qualified physicians who have sufficient experience and expertise in the percutaneous marking of soft tissue.
- This product was manufactured expressly for single use. It must not be resterilised or recycled after a single application. Resterilisation or recycling may result in material defects of the product or the medical device becoming no longer safe for use. Resterilisation may lead to serious infections, cross-contamination and injury to the patient. The preloaded Nitinol marker in the cannula is non-absorbable and intended for single use only. KLINIKA Medical GmbH rejects any responsibility in the case of reesterilisation and reuse of even one of the product components.
- The marker must not be used on the heart, central nervous system or central circulatory system.

- Only the CLIP may remain in the tissue.
- The cannula is not MRI capable and must not be placed under MRI.
- Please only use the KliniMark CLIP before the expiry date and with undamaged, unopened packaging. Otherwise the sterility of the product cannot be guaranteed.

Side effects

None known

Residual risks

- If the surface of the Clip becomes damaged, this may lead to allergic reactions (nickel).
- In rare cases, the Clip may migrate in the tissue and thus fail to mark the desired area.
- Crosslinking of the Clip may occur which can reduce visibility in the ultrasound image.
- The cannula may become hot in MRI and cause burns.
- If the product is not applied properly, this can result in injury, hematomas and pain for the patient.
- Bleeding may occur if a blood vessel is damaged by the cannula or Clip.
- Reuse may lead to infections and cross-contamination.

SSCP

A summary report of the safety and clinical performance pursuant to EU 2017/745, Art. 32 on implantable products (SSCP) will be made available on the website www.klinika-medical.de.

Product information

Design	KliniMark CLIP, sterile steel cannula with Nitinol marker
Diameter (Gauge)	18
Length of cannula (mm)	120
Cannula material	Steel
Size of Clip (mm)	4.9 x 2.1
Diameter of Clip (mm)	4.5
Clip material	Nitinol
PU	2 x 5
Article no.	105880900N

Manufacturer's contact details

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Feedback

In the event of serious incidents occurring in connection with this medical product, please report these to us as well as to the responsible authorities.

Feedback on the instructions for use

Your opinion is important to us. Feel free to share your suggestions and criticism about these instructions with us. We will assess your feedback and consider it for the next version of the instructions.