

### Available languages

DE, EN, FR, IT, SK, GR, BG, RO, DK, SL, CZ, PL, HU, SP

### Scope

These Operating Instructions apply to the following products:

Item: **KliniTray™**

Item numbers: 2001105; 2001205; 2001155; 2001255; 1000105; 1000205; 1000155; 1000255; 2000600; 1000600

### Important note

Improper handling and improper use can pose a danger and cause damage. We therefore ask you to read these Operating Instructions and to follow them carefully. Always keep them within easy reach. To avoid personal injury and property damage, please follow the safety instructions. If you have any questions about the content of these Operating Instructions or how to use the product, please contact the KLINIKA team.

### Product description

The KliniTray™ medical device is a system for precise monitoring, recording, and alignment visualization during surgical procedures. It ensures the exact orientation and positioning of tissue to be removed within the patient's body, enabling improved surgical precision and patient safety. KliniTray™ allows the surgeon to track the exact location and orientation of the target tissue in real time during surgery. With the use of KliniTray™, the removed tissue can be visualized using both ultrasound and X-ray images, with the position information being transmitted directly to the surgeon. This allows the surgeon to optimally orient themselves in the patient's body in order to carry out the procedure more efficiently and successfully. KliniTray™ is designed to improve surgical practice by providing healthcare professionals with a reliable tool to precisely locate tissue during surgery. It helps increase the accuracy, effectiveness, and safety of surgical procedures.

KliniTray™ is available in different versions (sterile and clean packed):

- KliniTray™ Mamma, small and large, each in a right and left version
- KliniTray™ Mini
- KliniTray™ Extra Small
- KliniTray™ Vulva
- KliniTray™ Universal
- KliniTray™ Werthheim
- Accessory: Transport boxes

### Mode of action

With the KliniTray™, X-ray and ultrasound examinations of the tissue can be performed in a given three-dimensional spatial orientation, and it can also be

### Feedback

If serious incidents occur in connection with this medical device, please report them to us and the local authority.

### Feedback about the Operating Instructions

We value your opinion. Please feel free to let us know your wishes and criticisms regarding these Operating Instructions. We will analyze your feedback and take it into account when drafting the next version of the Operating Instructions.

transported safely. The material necessary for the histological examination can be cut directly on the plate using the X-ray and/or ultrasound images.

KliniTray™ is equipped with the orientation markers “cranial”, “caudal”, “lateral”, and “medial” for use in breast cancer surgery. The removal side is indicated using the additional markers “L”, which stands for the “left” page, or “R”, which stands for the “right” page. The location of the finding can be marked on the chest diagram with the radiopaque coordinate frame of the plate.

### Material information

The KliniTray™ is made of PUR rigid foam and plastic-coated cellulose, and the fixing needles are made of polyamide and steel.

### Purpose

The KliniTray™ medical device allows for the precise monitoring, recording, and visualization of alignment information during surgical procedures. It provides the exact positioning of the tissue to be removed in the patient's body, resulting in increased surgical precision and patient safety.

KliniTray™ allows surgeons to track the location and orientation of target tissue in real time. It visualizes removed tissue in ultrasound and X-ray images, whereby the location information is immediately transmitted to the surgeon. This allows the surgeon to maintain optimal orientation in the patient's body and improves the efficiency and success rate of procedures.

KliniTray™ optimizes surgical practice by enabling precise tissue orientation, thereby increasing the accuracy, effectiveness, and safety of procedures.

### Indications

KliniTray™ was specifically designed for surgical procedures in which precise tissue removal from the human body with precise localization is of particular importance. This system enables real-time monitoring and visualization of accurate tissue information, enabling surgeons to precisely position the tissue that is to be removed. This helps increase surgical precision and leads to improved results.

### Contraindications and exclusions

KliniTray™ is intended exclusively for the above-mentioned application areas.

### Intended patient group

Adults

### Intended users

Specialist healthcare professionals

### Intended user environment

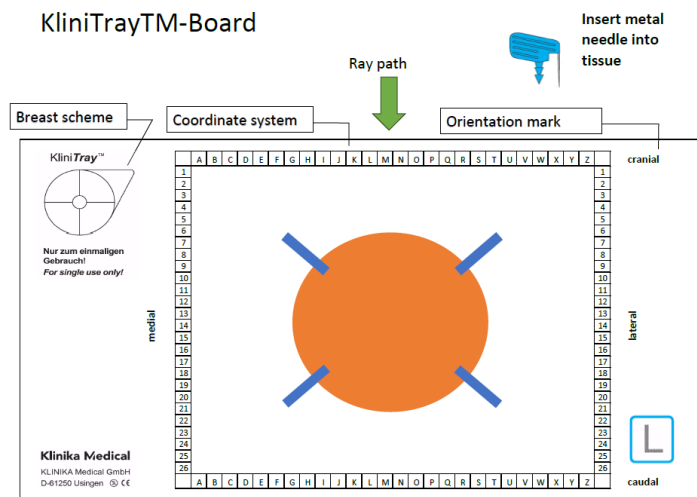
Medical treatment room, operating room

### Operation

- Select the correct plate.
- Before opening the packaging, make sure that it is not damaged or already opened. Check the sterilization expiration date (for the sterile version).
- Open the packaging and remove the plate.
- Label the plate or attach a patient sticker.
- Outside the operating area, mark the location of the tumor on the breast diagram using the orange marking pen and break it off.
- Place the plate on a flat surface.
- Locate the tissue centrally in the coordinate frame of the plate.

- Attach the tissue to the plate with the fixation needle. Pierce the tissue with the metal needle. The thicker plastic pin is used to secure the needle in the plate and not to secure the tissue. Remember to fix the tissue only at the edge with the needle and to place the fixation needle to the side of the tissue so that they do not obstruct further examinations (see illustration).
- Poke the fixation needle through the tissue, securing it to the plate. The plastic end of the pins prevents the plate from being punctured.
- Fill out the patient sticker on the side of the transport container.
- For an X-ray or ultrasound examination, the plate is placed in the can without formalin. Tightly close the can with the provided lid.
- For quick fixation and to allow further histological examinations, fill the transport box halfway with formalin. Place the plate upside down in the box so that it floats on the formalin. This ensures optimal fixation of the tissue.
- Press down on the lid firmly all around.
- Finally, check that the lid is correctly seated on the can.

## KliniTray™-Board



In the radiology department:

- Open the can and remove the plate with the tissue in accordance with the prescribed safety provisions.
- You can place the tissue with the plate directly on the X-ray machine for examinations. Please do not loosen the metal pins.
- You can also leave the tissue on the plate for ultrasound examinations.

In the pathology department:

- Open the can and remove the plate with the tissue in accordance with the prescribed safety provisions.
- Mark the resection margins with a different tissue color
- Carefully remove the fastening pins. The cutting can be done directly on the plate. This minimizes the risk of tissue transfer.

## Disposal

Dispose of the KliniTray™ in accordance with applicable regulations and local clinical practices. Please note: as soon as the KliniTray™ comes into contact with human tissue, it is biohazardous!

## Warning

- The KliniTray™ should only be used by medical professionals with the corresponding level of knowledge and training.
- For single use only.
- Do not reuse or resterilize.
- Note for the sterile version: KliniTray™ is only remains sterile up to the expiry date and if the packaging is unopened and undamaged. DO NOT USE if the expiry date has been exceeded or the packaging is opened or damaged!

## Side effects

Non Known

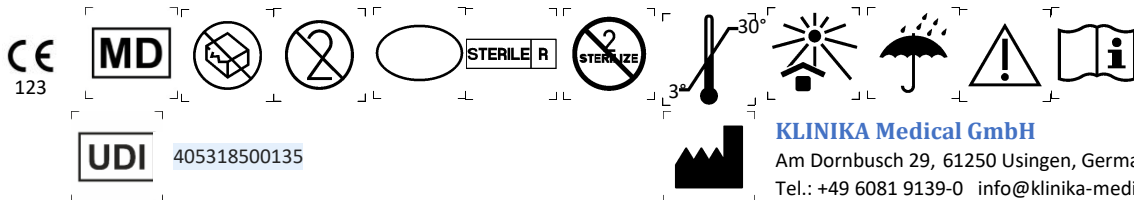
## Product information

Storage	3° –30°C
Sterilization	Gamma, X-Ray
Stability	May be kept for up to 3 years in a clean, cool, and dark environment
Cleaning	Not applicable, as it is a single-use product.
Service, maintenance	N/A
Accessory	Transport boxes

## Symbols

	manufacturer		store in dry place
	catalogue number		temperature limits
	batch number		do not reuse
	radiation sterilized		caution!
	do not re-sterilize		Unique product identification
	do not use if packaging is damaged		follow instruction for use
	simple sterile barrier system		medical device
	protec from sunlight		

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