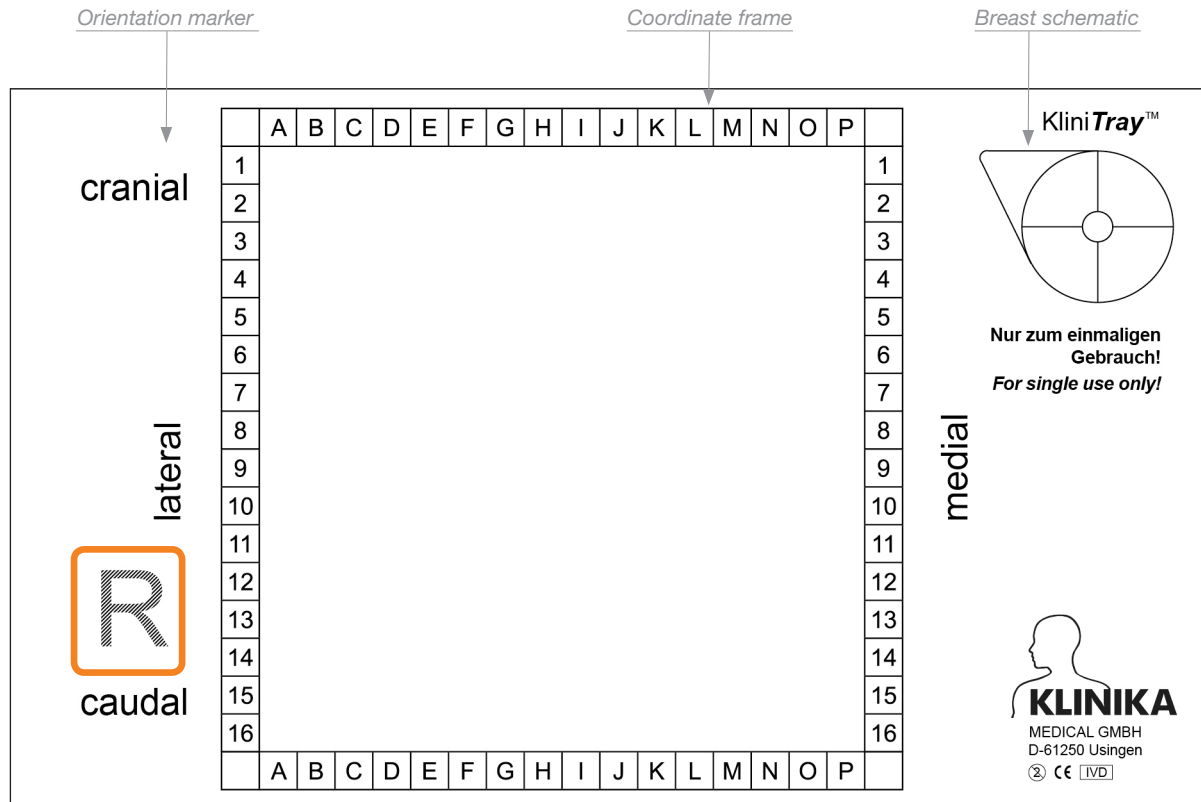
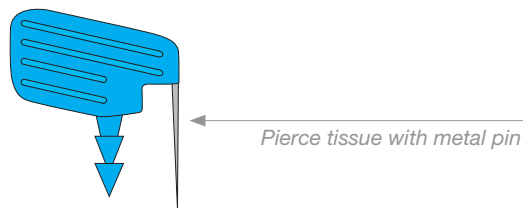


KliniTray™ board



KliniTray™ Pin



REF

2001105, 2001205, 2001155, 2001255 (sterile)
 1000105, 1000205, 1000155, 1000255 (non sterile)
 1000300, 1000350, 1000400



Am Dornbusch 29, D-61250 Usingen
 www.klinika-medical.de

User instruction manual KliniTray™ EN

1. Important note:

Read the user's instructions carefully BEFORE using the **KliniTray™**. Failing to read the instructions completely may result in risks and malfunctions.

2. General information:

The **KliniTray™** system is a system for the transport and examination of tissue removed from the body.

KliniTray™ is available in a sterile and non-sterile version. To determine the particular version, please refer to the product's reference number.

3. Areas of application:

KliniTray™ is intended for the transportation and examination of the tissue removed from the body to determine free resection margins. It is ideal for providing a three-dimensional image of the sample from the surgeon's view point. It is also suitable for safe transport to radiology, sonography and/or pathology departments for examination.

4. Contraindications:

KliniTray™ must be used for the aforementioned areas of application only.

5. Warning notes:

- The device should only be used by skilled medical personnel with the relevant knowledge and training.
- For single use only. Do not re-use or re-sterilize.
- For sterile version: **KliniTray™** remains sterile only up to the expiration date and in unopened and undamaged packaging. DO NOT USE if the expiration date has been exceeded or if the packaging is open or damaged! **KliniTray™** has a shelf-life of three years.
- Store it in a cool, dry location and protect from direct sunlight and heat.

6. Product description:

KliniTray™ is available as a sterile or a non-sterile single-use system, intended for tissue examination to determine free resection margins. It consists of a non-radiopaque



board with radio-opaque orientation markers, coordination frame and breast schematic. The breast schematic (in conjunction with the orange colored pin) is intended to mark the position of the tumor. Metal pins are used to attach the tissue.

KliniTray™ is available in the sizes:

small left, small right

large left, large right

Additionally available, are small and large transport containers and also stands, that are necessary for x-ray imaging in the cranio-caudal orientation.

For more details, please refer to the description of the reference numbers.

7. Use:

- Choose the required board.
- Before opening the packaging, make sure that it is not damaged or that it has not already been opened. Check the expiration date of the sterilization (for the sterile version).
- Open the packaging and remove the board.
- Annotate the board or attach a patient label to it.
- Outside the operating area, mark the location of the tumour on the breast schematic using the orange marker pen and break it off.
- Place the board onto a flat surface.
- Position the tissue centrally in the coordinate frame on the board.
- Attach the tissue on the board using the metal pins. When doing so, use the metal needle to pierce through the tissue. The thicker plastic pin is intended for attaching the needle to the board. Only the edge of the tissue should be pierced by the metal pin, so that further examination is not obstructed.
- Push the metal pins through the tissue into the board. The pin is so designed, that it cannot penetrate the board completely.
- Insert the patient information on the label on the side of the transport container.
- The board is inserted into the box without formalin (for x-ray or ultrasound tests) and the lid is then firmly closed

- For a rapid preservation of the tissue and for additional histological tests, fill the transport container up to half-way with formalin. Place the board upside down in the container so that it floats in the formalin. This ensures optimum preservation of the tissue.

- Firmly press the lid down all the way around.

- Finally, check the watertight seal.

At the radiology:

- Open the container and remove the board with the tissue according to current safety regulations.
- The board, with attached tissue can be placed directly onto the x-ray device. Please do not remove the metal pins.
- The tissue can also remain on the board for sonographic examination.

In pathology:

- Open the container and remove the board with the tissue according to current safety regulations.
- Mark the resection margins with different tissue dyes
- Carefully remove the (fixation) pins. Sections may be carried out on the board (directly). This reduces the risk of cross contamination of the tissue.

8. Disposal:

Dispose of the **KliniTray™** according to current regulations and the local clinical procedures. Bio-Hazard!

9. Safety: KLINIKA Medical GmbH does not accept any responsibility should the product re-sterilized or re-used.












A safe and correct use cannot be guaranteed in this case and the risk of injury, infection and cross-contamination is increased dramatically.

10. Production and sales:

KliniTray™ is exclusively manufactured by KLINIKA Medical GmbH, at its manufacturing facility in 61250 Usingen, Germany. If you have any questions about **KliniTray™**, please contact KLINIKA Medical GmbH, call: +49 (0) 6081 9139 0.

KliniTray™ is a trademark of KLINIKA Medical GmbH:

11. Description:

	Manufacturer
	Product Code
	Gamma sterilized
	Do not use if packaging is damaged
	Keep away from water
	For single use only
	Refer to instruction for use
	Do not re-sterilize
	Batch code
	Expiry date (yyyy-mm-dd)
	Bio-hazard