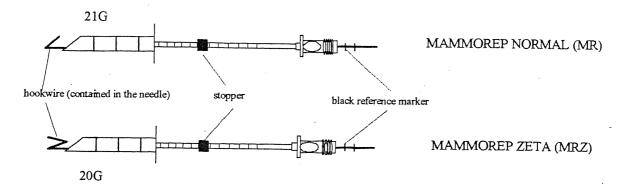


INSTRUCTIONS FOR USE OF THE BREAST LOCALIZATION NEEDLE

MAMMOREP NORMAL® AND

AND MAMMOREP ZETA®



WARNING:

- Store in a dry clean place away from heat sources
- Before use ensure that the packaging is intact: if perforated, damaged or open discard the instrument
- Check the expiry date and that the model corresponds
- Peel open the package
- Pay attention to not compromise the sterility of the instrument before use
- In the event of a product defect or malfunction complete the yellow claim form to be found in the product carton and conserve the defective instrument

N.B.:

The use of this instrument is reserved to qualified medical personnel who are aware of its application.

The instrument is sterile (sterilized by ETO GAS) single use and should be discarded after use (Circ.Min:Sanità 403/9.5/1146-L. 10.81)

Sterylab declines any and all responsability in the event of improper use or reutilisation.

The MAMMOREP needle introduces a fine biocompatible metallic hookwire into the breast parenchyma. The NORMAL version (mod. MR) is supplied with a simple hookwire; the ZETA version (mod. MRZ) is supplied with a double hookwire to prevent migration in both directions.

IMPLANTATION PROCEDURE

- 1) Remove the plastic protective sleeve, and pay attention to not remove also the stopper
- Ensure that the hookwire is contained within the proximal part of the needle: the black reference marker on the wire should be completely visible and aligned with the proximal extremity of the needle cannula (see diagram)
- 3) Insert the MAMMOREP needle into the parenchyma up to the desired location using the depth stopper and the correct type of sterile disposable needle bush guide (upon request) suitable for the stereotactic or echographic technique
- 4) Before freeing the hookwire make a further mammographic / echographic control to verify that the needle tip is in the desired position and make any necessary corrections
- Keeping the proximal extremity of the hookwire firm remove with the other hand the needle; when the black reference marker on the wire completely disappears inside the cannula the hook of the wire has been released form the needle tip
- 6) Before removing completely the needle over the wire slide the stopper from the cannula onto the wire and keeping the wire slightly under traction slide the stopper up against the skin.
- 7) Bend the hookwire over the stopper and secure it to the skin with a plaster.

THE MAMMOREP HOOKWIRES ARE AVAILABLE TOGETHER WITH THE CONTAINER/LOCALIZER FOR BIOPTICALLY EXCISED IMPALPABLE NODULES

X-SCREEN

(request sample)