The NORAS Reference Marker is a component of NORAS Breast Biopsy Unit in which this unit forms a part of the NORAS Immobilization and Biopsy System MR-BI320-PA. The Whole System bears CE Marking, FDA 510(k) clearance K08118 / K082373 and Medical Device Licensing 81638 / 81639 from Health Canada.
**Indication for Use**

The Reference Marker permits MR guided breast biopsy and wire localization of lesion which is performed by a trained physician. The Reference Marker allows an automatic calculation of the location and depth of a targeted region by fully integrated interventional planning software. It will be identified by Breast MRI CAD and helps for automatically detection as well as selection of the target lesion.

**Filling Instructions**

NORAS MRI products GmbH only offers unfilled marker.

The number of required marker depends upon the individual type of system used. For software-supported localization such as Breast MRI CAD system one marker will be only needed. Please pay attention to the following refilling:

1. Open the marker by screwing the cap off by hand.
2. The marker must be filled with diluted MRI contrast agent to make it visible in MRI. To do so, fill a syringe with contrast agent (diluted 1:200 by sodium chloride solution) and then slowly fill the marker with the syringe up to the edge of the marker thread starting at the bottom of the marker. Rotate the syringe during filling to prevent the formation of bubbles.
3. Screw the cap back on and tighten by hand.
4. Test marker imaging by installing the biopsy system and taking a test measurement.
5. The markers must be homogeneously imaged as a straight line. They must not exhibit any “holes” or “kinks”, which are the result of air bubbles.

If the marker cannot be imaged as a straight line, then change the phase code direction during imaging and verify the changed settings.
Cleaning Instructions

1. Marker must be emptied prior to sterilization! To empty them, open the marker as described above and empty them.

2. Use a syringe (filled with distilled water) to rinse out the marker starting at the bottom of the marker to remove any residual marker liquid.

3. Dry them or open and place them in upright position within the steam autoclave.

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Health Hazard for Operator</th>
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<tbody>
<tr>
<td></td>
<td>Marker liquid can be hazardous to health. See instructions of marker liquid manufacturers.</td>
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<tr>
<td><strong>Point of use:</strong></td>
<td>Remove excess soil with disposable cloth/paper wipe.</td>
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<td><strong>Containment and transportation:</strong></td>
<td>No particular requirements. It is recommended that products are processed as soon as is reasonably practical following use.</td>
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<td><strong>Preparation for cleaning:</strong></td>
<td>No particular requirements. If necessary, the assembly must be de-assembled into its individual components.</td>
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| **Cleaning: Automated** | **Equipment:** Washer/disinfector  
**Detergent:** example: alkaline detergent such as Neodisher ® MediClean 0.2 to 1.0 vol% (2-10 ml / l) (Dr. Weigert) at 50 °C. For this purpose, all agents, which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on their labels. |
| **Cleaning: Manual** | **Equipment:**  
**Detergent:** example alkaline cleaning agent such as Neodisher ® MediClean 0.2 to 1.0 vol% (2-10 ml / l) (Dr. Weigert) at 50-60 °C. For this purpose, all agents, which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on the label.  
The cleaning of the parts could be done manually in immersion or ultrasonic bath for 5-10 minutes, preferably at temperatures of up to 50 °C. |
| **Disinfection: Automated** | **Disinfectant:** example Sekusept PLUS ® (Ecolab) 4.0 vol% 3.0 vol% Korsolex ® Plus with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the Robert Koch Institute (RKI), can be used in accordance with the instructions on the label. |
| **Disinfection: Manual** | **Disinfectant:** example Sekusept PLUS ® (Ecolab) 4.0 vol% 3.0 vol% Korsolex ® Plus with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the Robert Koch Institute (RKI), can be used in accordance with the instructions on the label. |
| **Drying:** | When drying is achieved as part of washer disinfector cycle do not exceed 50°C. |
| **Sterilization:** | **Steam Sterilization:**  
134°C; 3.04 bar; 5 min  
The effectiveness of steam sterilization according to the procedure mentioned above has been validated by Dr. Schwarzkopf. |
| **Storage:** | No special requirements |
Important Addresses

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For questions regarding sales outside Europe, the U.S., and Canada refer to: