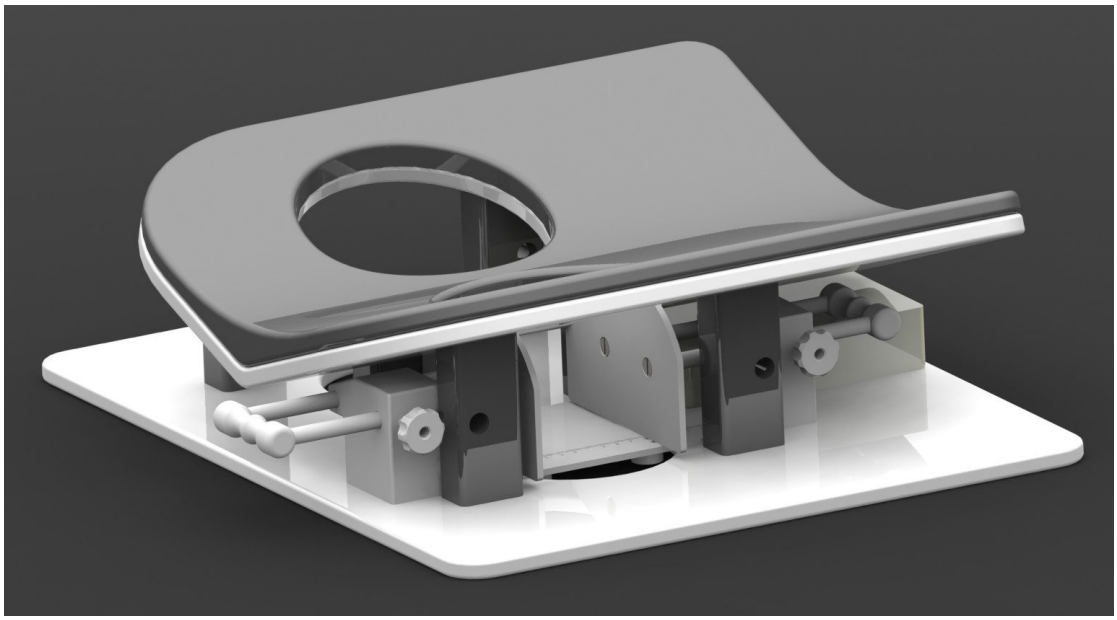
Cranio-caudal Fixation Unit CC-OBC-O

Cranio-caudal Fixation Unit

CC-OBC-O

115011

for Immobilization with the Invivo OBC-O Breast Coil and for vertical field MR systems



Operator‘s Manual
Revision 03

CE

NORAS MRI products

Date Issued: June 2015

Contents

Contents

1 General Information

To ensure safe and trouble free operation of this high quality medical device, please carefully read and follow the instructions in this Operator‘s Manual and pay particular attention to the following information:

The **Cranio-caudal Fixation Unit CC-OBC-O** can only be used with the Invivo OBC-O Breast Coil and for the vertical field MRI systems 0.2T up to 1T.

	**Patient injuries**
	Place a sterile tissue on the base plate. Not covering the base plate with a sterile tissue may lead to infection of the patient.

If you would like to receive up-to-date information about the further development or new accessories for your **Cranio-caudal Fixation Unit CC-OBC-O**, please send an e-mail with the serial number of your coil to mri@noras.de.

The application conditions have a major impact on product life. Since these conditions can vary greatly from user to user, an estimation of life time from our point of view is not possible. The most important factors in influencing product life are the frequency of application and processing method (cleaning, disinfection and sterilization).

As long as the user takes the intended use into consideration and pays attention to the warnings and measures specified in the user manual regarding the visual inspection of all components before each application, there is no significant risk.

 G06	**Prescription use only**
	Country specific laws restrict this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the country in which he practices to use or order the use of the device. This device may only be distributed to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase it.

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2 Intended Use

Intended Use / Indication for Use

The **Cranio-caudal Fixation Unit CC-OBC-O** is a medical product and it is indicated for the cranio-caudal fixation of the female breast. The application must only be performed by trained medical personnel.

Contraindication

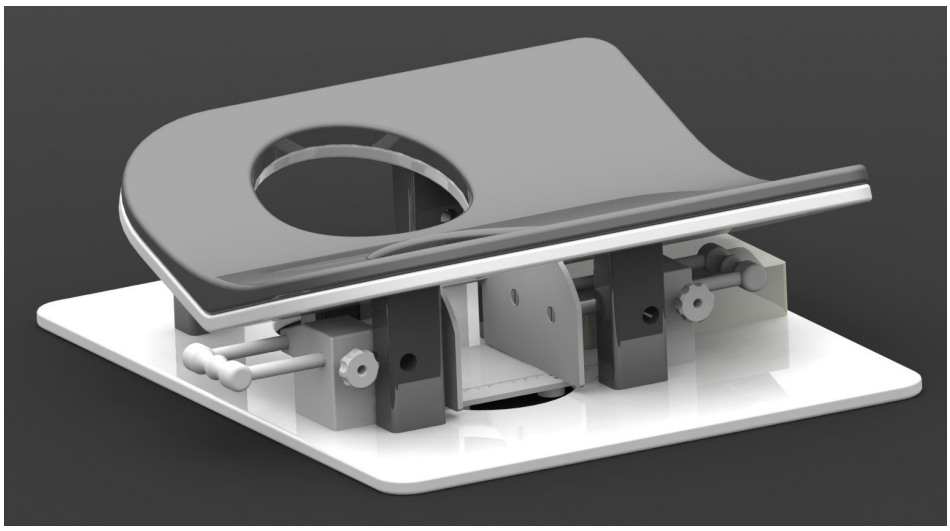
All patient examinations are contraindicated with this system which is also contraindicated in the proximity of the MRI device according to the Information provided by the manufacturer (e.g. breast implants, heart pacemakers, surgical metallic implants or similar objects).

Furthermore, the responsibility lies with the examining physician in case of unclear or critical clinical picture.

	**Notice**
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

3 Operating Principle

The immobilization of the breast in the OBC-O Breast Coil occurs in cranio-caudal access.



After a diagnostic examination with the Cranio-Caudal Fixation Unit CC-OBC-O, the MR-guided breast biopsy, wire localization of lesion and the minimal invasive intervention could take place with the help of Invivo OBC-O Breast Coil for vertical field MRI systems.

4 Device Description

4.1 Definitions and Symbols

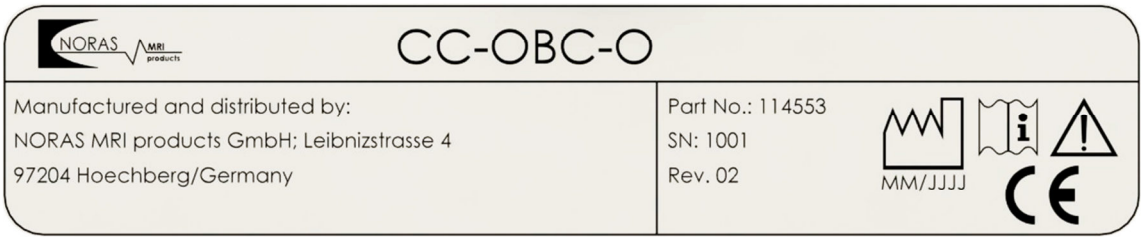
The following symbols are used on the **Cranio-caudal Fixation Unit CC-OBC-O** and in this manual:

	ISO 7000-2493	Item Number
	ISO 7000-2498	Serial Number
	ISO 7000-3082	Manufacturer
	ISO 7000-2497	Date of Manufacture
	EN ISO 7000-1641	Operator's Manual
	ISO 7000-0434B	Caution, read the accompanying documents
	Directive 2002/96/EC	Waste products should not be disposed of with household waste e. g. at a local authority collection point.

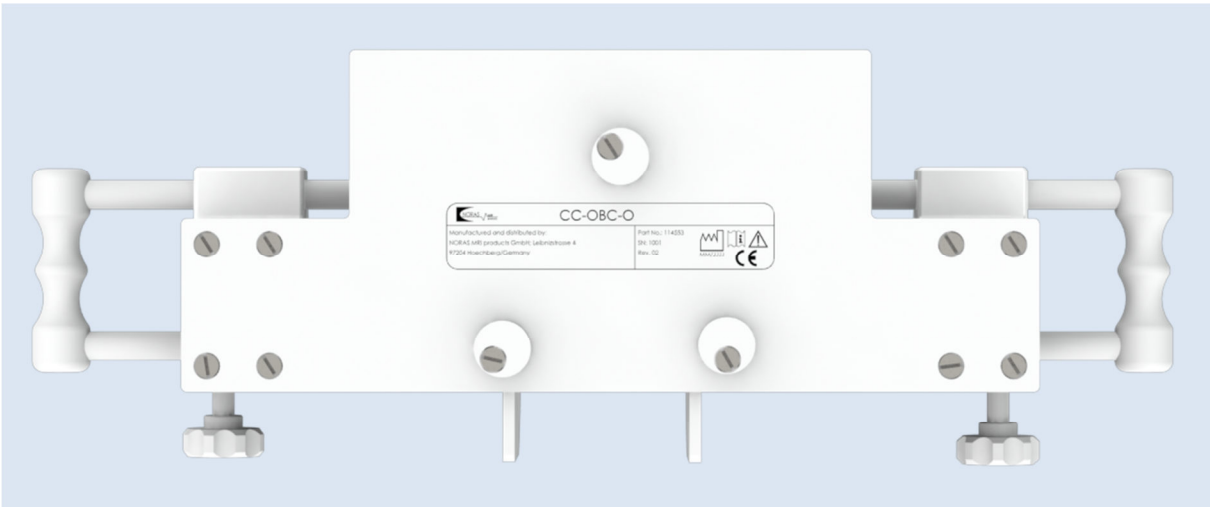
	ISO 780 DIN 55402	This way up
	ISO 7000-0621	Fragile, handle with care
	ISO 7000-0626	Store in a dry place
	ISO 7000-0632	Temperature Limit
		Conforms with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
		Warning regarding risks that may result in minor physical injury or material damage.
		Warning regarding risks that may result in death or serious physical injury.
		Information regarding the optimal use of the product

4.1.1 Rating Plates

On the following page, we describe where you can find our various rating plates on your product. In addition to the above-described symbols, you will also find the model, product and serial number on the plates.

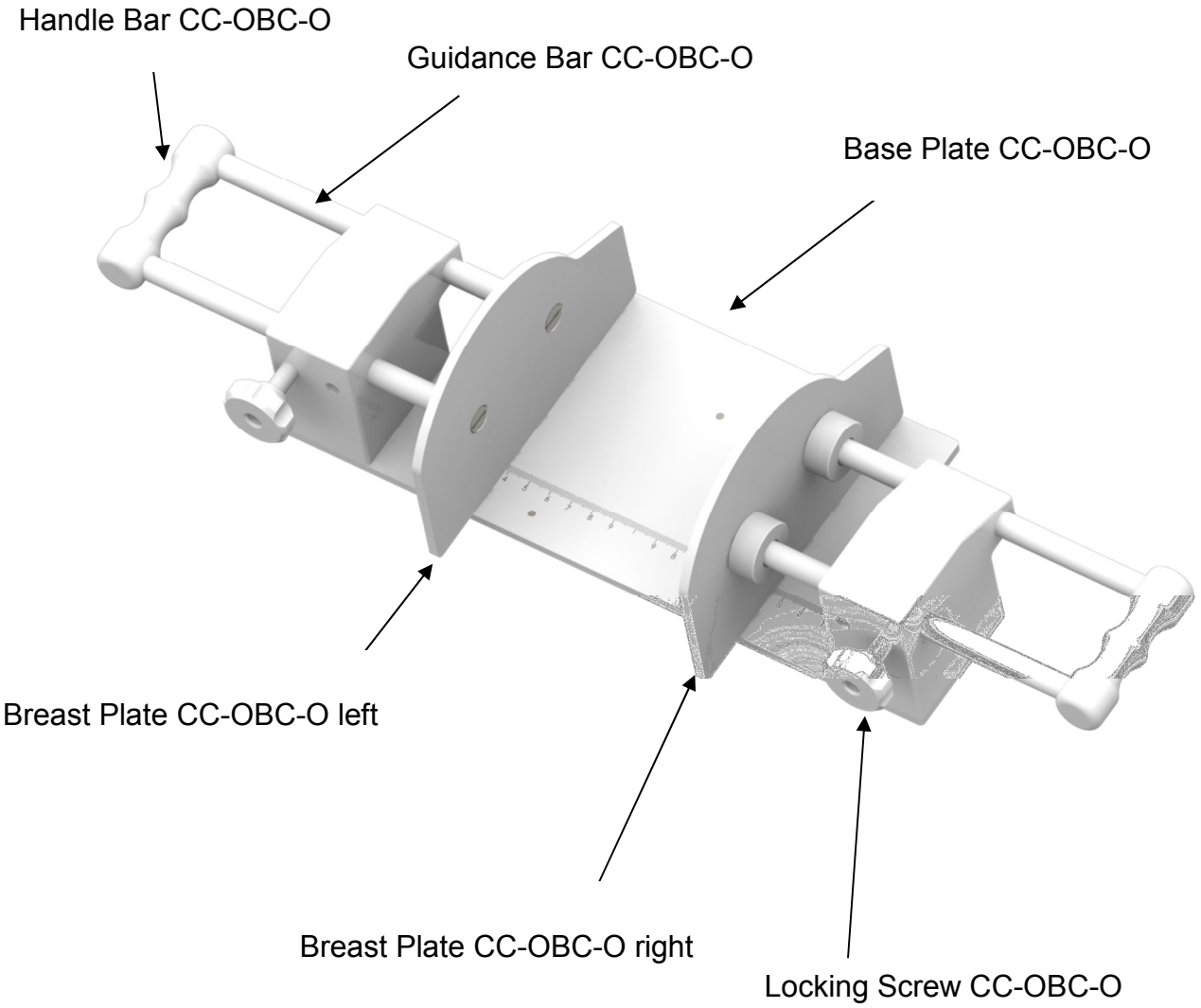


The rating plates are located on the bottom side of both plates.



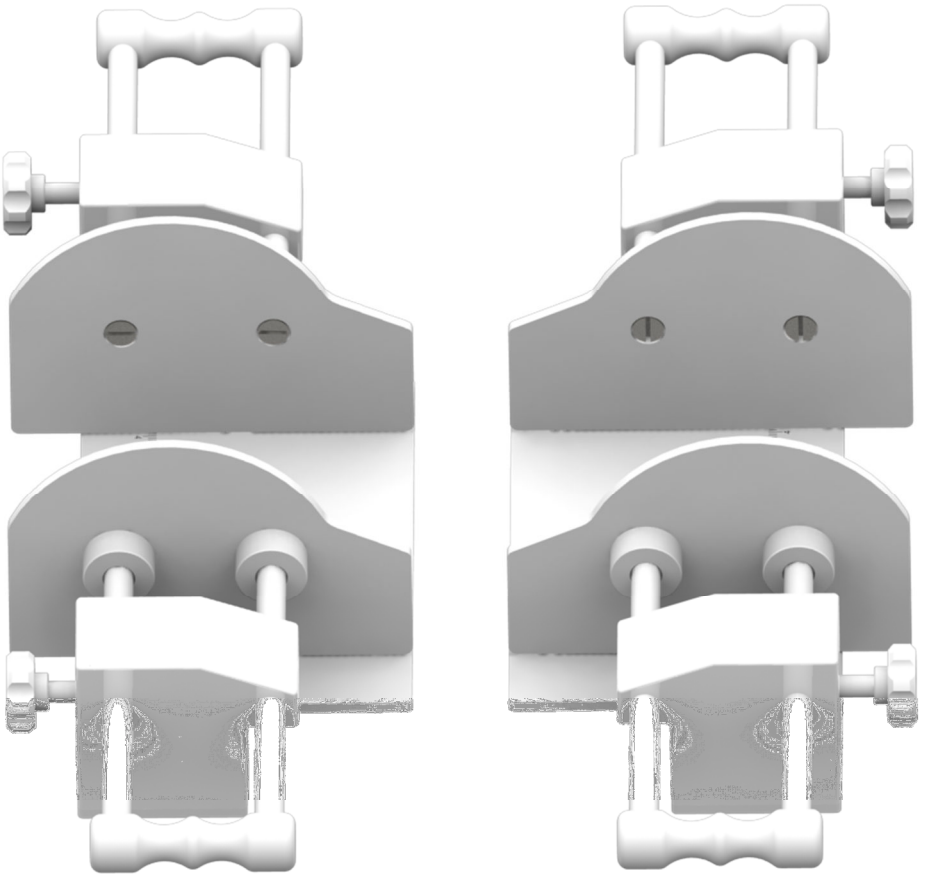
4.2 System Components

The **Cranio-caudal Fixation Unit CC-OBC-O** consists of the following components:



	The scaling on the base plate is not calibrated and should be seen as indicative.

Always two units will be provided.



5 Start-Up

 G12	**Device Damage** The users must be trained before using the device. Handling error can cause permanent damages of the device.

	**Staff Instruction** The users must be trained before using the device (detailed training of the personnel for existing components).

 G11	**Device Damage** Only trained personnel may be assigned to handle the **Cranio-caudal Fixation Unit CC-OBC-O**. Handling error can cause permanent damages of the device.

 G17	**Bodily injuries** Only trained personnel may be assigned to handle the **Cranio-caudal Fixation Unit CC-OBC-O**. Operating errors may cause bodily injuries (e.g. contusions) to the user and/or the patient.

 G03	**Danger of infection**
	Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 7 “Cleaning and Disinfection”. Noncompliance with the above instructions may lead to infection of the patient.

 G15	**Bodily Harm**
	Also MR-compatible accessories can cause injuries to the patient and/or the user. Please follow the instructions of the accessory manufacturer. Non-compliance with these instructions may lead to injuries of the user and/or patient.

 G20	**Use of wrong components**
	The use of components not listed and described in this Operator’s Manual, provided by NORAS, is expressly prohibited.

	**Note**
	Please be sure to pay attention to and comply with the safety information and instructions of the MRI manufacturer for operators, patients and the third party.

The Operator‘s Manual must be read by each operator prior to using this device. In order to become skilled in the proper handling of this system, you should, in addition to participation in training, use a phantom.

 G10	**Bodily harm of the patient**
	Prior to each patient examination, you should make a careful visual inspection of the system components. Damaged parts can be sharp-edged and cause injuries to the patient and/or to the user. In the case of unusual findings and/or damage found, the system must not be used.

 G18	**Danger of destruction**
	Pay attention to and comply with the cleaning and disinfection instructions contained in this Operator‘s Manual (Chapter 7). Noncompliance with the instructions of the coil‘s manufacturer regarding the “Cleaning, Disinfecting, and Sterilizing“ may destroy the coils.

To compress the breast with the **Cranio-caudal Fixation Unit CC-OBC-O** you can plug the base plate in the OBC-O Breast Coil without the breast plate (Fig. 1). Following slid the fixing screws through the openings provided at the coil (Fig. 2). The breast plates are pushed through the coil opening and attached to the fixing plate (Fig. 3 and 4)

Fig. 1: Plug the base plate in the coil

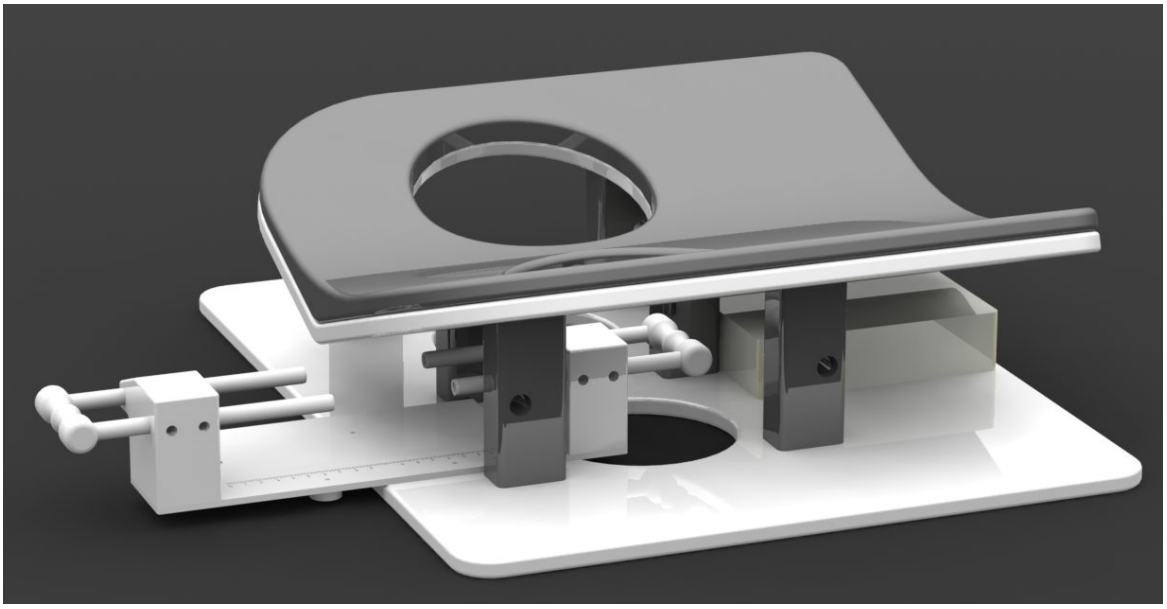


Fig. 2: Slid the fixing screws through the openings

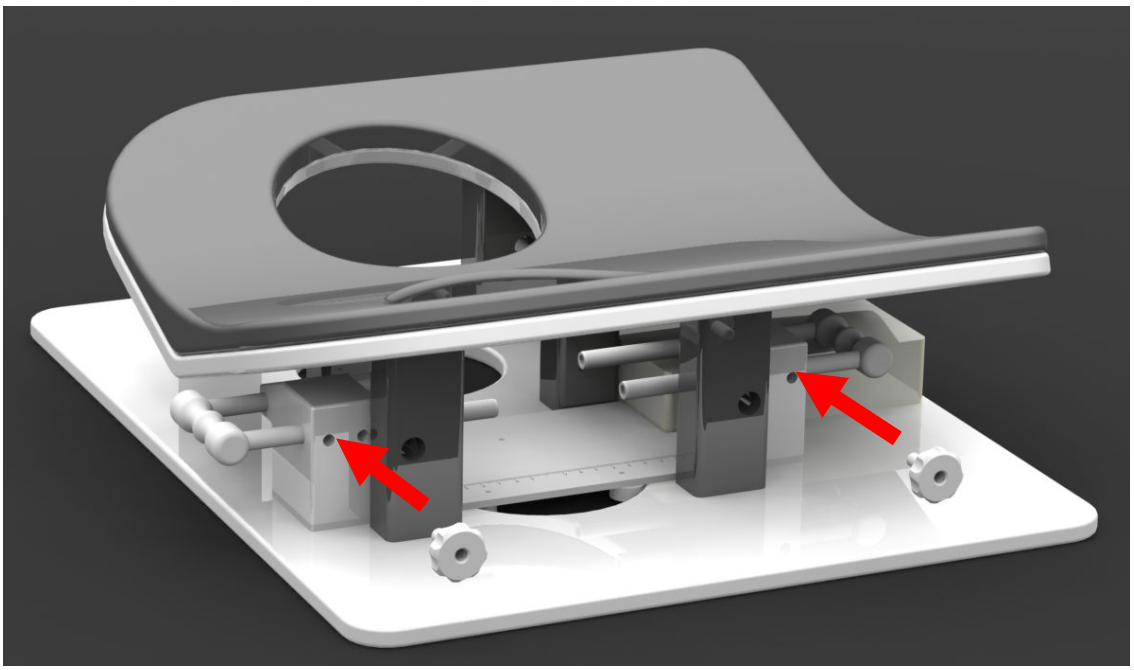


Fig. 3: Insert both breast plates sidewise

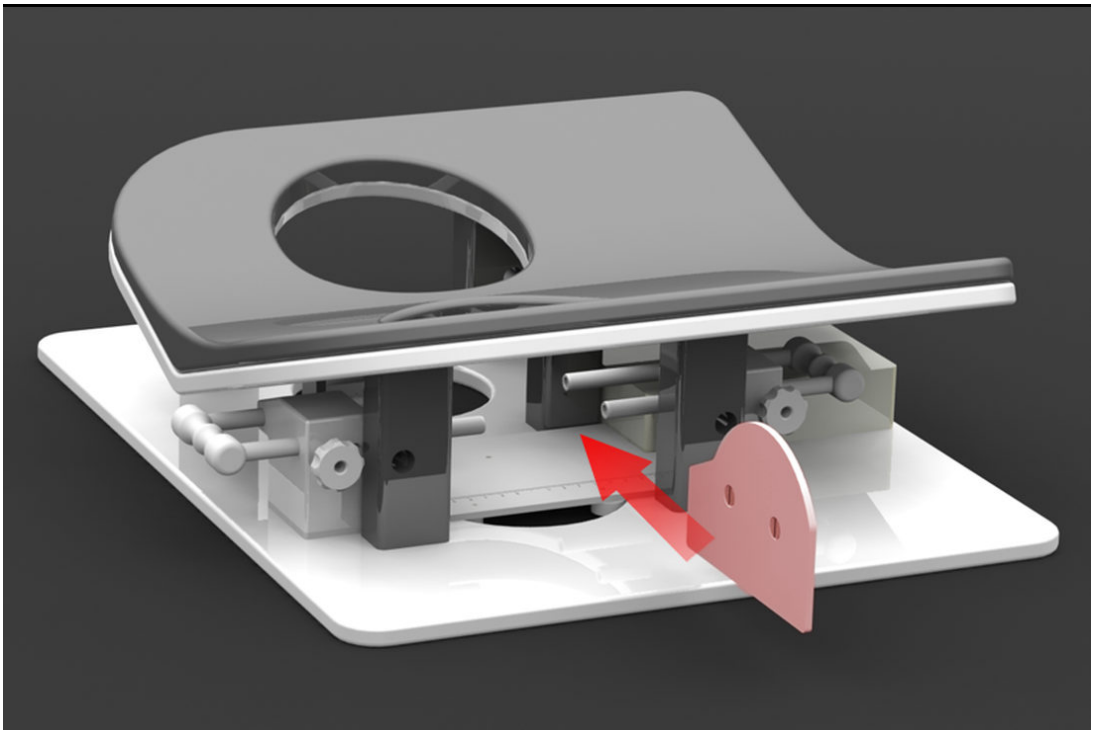
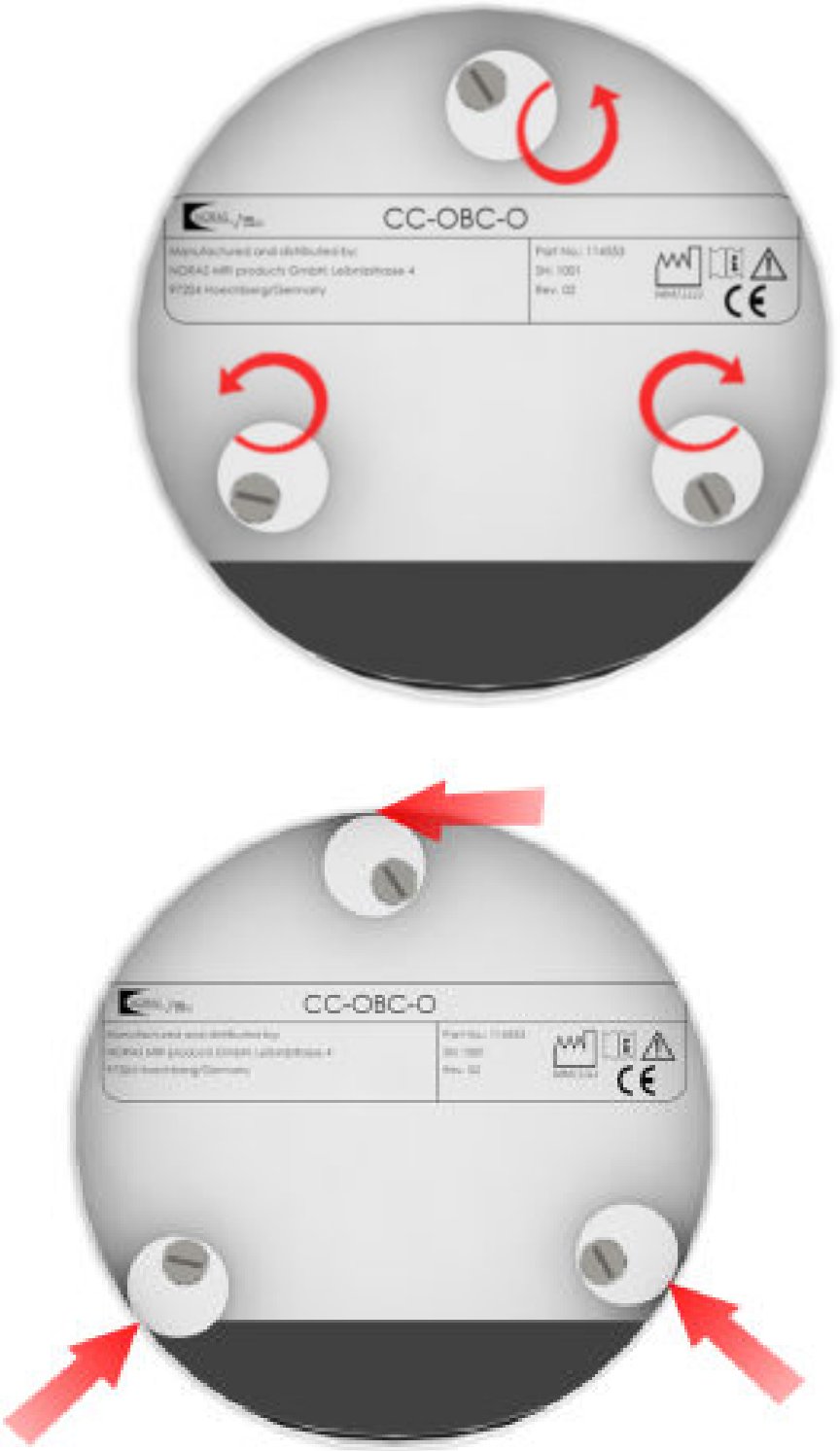


Fig. 4: Turn the eccentric screw on the bottom side in order to position the device into the Insertion Plate Coil



You must move the plate with the push rod for fixation of the breast (Fig. 5). To determine the fixation of the breast, you should tighten the screws by hand (Fig. 6).

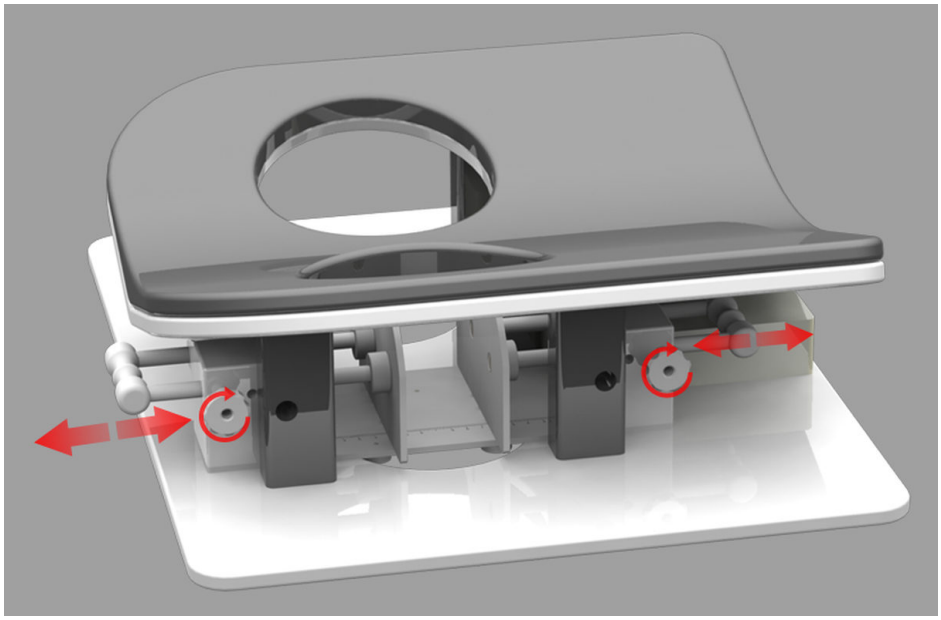


Fig. 5

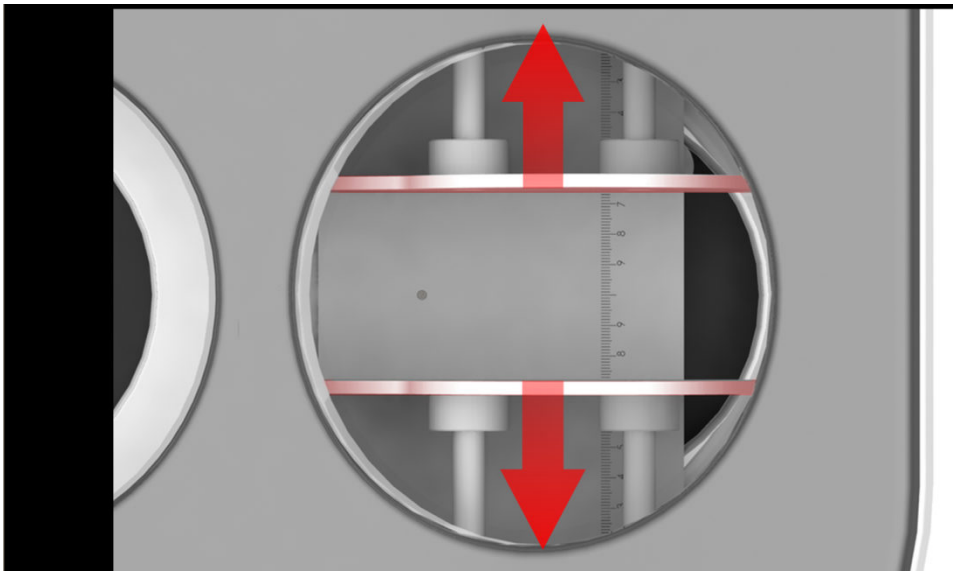


Fig. 6

Follow the instructions of the breast coil‘s manufacturer.

Position the coil with the immobilization unit on the MRT-table in compliance with the instructions of the MRT manufacturer.

	**Prolongation or termination of the treatment**
	While plugging in the coil, ensure and check that proper contact has been made. Check the display of the MRI. If the coil pair is not properly plugged in, no images can be produced.

 G14	**Correct Breast Immobilization**
	The breast must be correctly immobilized. Please check this. If the breast is not immobilized properly, it might slip and the data delivered by the MRI will be incorrect.

6 Application

6.1 MR-Mammography

	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

Following the imaging process in cranio-caudal direction of two immobilization units for simultaneous diagnosis on the left and right mamma is shown.

- The Cranio-caudal Fixation Unit must be assembled and inserted in the coil such as described in the chapter 5 “Start-up“.

- Position the patient on the OBC-O Breast Coil and immobilize the mamma to be examined by pressing the breast plates against the mamma on the variable position bars (loosening or fixation of breast plates is done using the locking screws). Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure.

- It is important to ensure that as much breast tissue as possible is engaged by the breast plates.

- Use the toolbox in your MRI for determination of ROI, FOV and type of sequence imaging.

- Perform the MR-mammographic procedure.

	**Danger of bruising**
	Be absolutely sure to loosen the breast plates before withdrawing the mamma. That way bruises or injuries to the patient can be avoided.

	**Danger of injury**
	Before loosening and withdrawing the mamma, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

6.2 Safety Information

While using the **Cranio-caudal Fixation Unit CC-OBC-O** please follow the below safety information:

 G14	**Correct Breast Immobilization**
	The breast must be correctly immobilized. Please check this. If the breast is not immobilized properly, it might slip and the data delivered by the MRI will be incorrect.

	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

7 Cleaning and Desinfection

	**Danger of destruction**
	Regardless to the cleaning and disinfection instructions in this manual, the cleaning instructions of the coil manufacturer are followed strictly. Noncompliance with the cleaning instructions of the coil‘s manufacturer may cause the destruction of the coils!

WARNINGS:	The instructions must be followed as described. In case of inadequate cleaning or disinfection, you have to carry the risk of infection. Non-respect of the disinfection instructions may cause the destruction of the coils. Non-compliance with the cleaning instructions may destroy the system. No warranty service will be provided for damages due to improper disinfecting. Please always wear protective gloves and carefully comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).
Limitations on reprocessing:	Frequent processing can have an impact on these products (color changes), but do not affect the function of the product. Spare parts can be purchased from NORAS MRI products GmbH.

	**Danger of infection**
	Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 'Cleaning and Disinfection'. Non-compliance with the above instructions may lead to infection of the patient.

	**Note**
	Please always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).

INSTRUCTIONS	
Point of Use:	Remove excess soil with disposable cloth / paper wipe.
Containment and Transportation:	No particular requirements. It is recommended to reprocess the product as soon as possible after its use. The products should be transported in a closed container.
Preparation for Cleaning:	No particular requirements.

7.1 Cleaning

Immobilization and Fixing Unit	Water bath possibly using a soft brush

After each patient examination the **Cranio-caudal Fixation Unit CC-OBC-O** must be cleaned as described above.

The products used should be cleaned within 30 minutes after use to minimize the danger of the drying of contaminants prior to cleaning.

We recommend that the components are cleaned immediately after the examination.

Disassemble the immobilization and fixing unit into its individual parts so that they can be thoroughly cleaned.

Do not use any scouring cleaning agents or, due to possible material incompatibility, any organic solvent or solvent containing cleaning agents (e.g. cleaner‘s solvent, alcohol, stain remover)!

	**Notice**
	Follow the cleaning instructions of the OBC-O Breast Coil.

7.2 Desinfection

All components of the **Cranio-caudal Fixation Unit CC-OBC-O** must be disinfected after each use. Patient examinations may only be performed with disinfected components.

As during the cleaning process, leave the fixation unit in its individual parts so that optimum disinfection can be ensured.

Cleaning / Disinfection Manual:	**Equipment:** **Detergent:** Example: **Sekusept® PLUS (Ecolab) 4,0 vol %, Korsolex® Plus 3,0 vol % with exposure time of 15 minutes. For this purpose all aldehyde-free surface disinfectants, which have been approved and released by the RKI and the VAH** 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 **10-30 minutes,** preferable at temperatures of up to **50°C.** **Procedure:** 1. Rinse excess soil from components. 2. Using soft brush, apply detergent solution to all surfaces ensuring that hinged components are cleaned in both open and closed positions. 3. The part is held under running water for 5 minutes. In this case, the running water must flow through the cannulas. The blind holes must be repeatedly filled and emptied.

	4. The parts must be cleaned as long as no visible blood or tissue residues more on the products to be seen. For manual disinfection, it is advisable to insert the parts (for expected parts see left column) in the solution immediately after use. Ensure that the parts are completely sub-merged in the solution. Take the parts from the solution after the described time 15 minutes and rinse by water (the quality of water must be at least equal to drinking water, better would be using aqua. Demineralized water). Changing in color due to continuous disinfection cannot be excluded, but can be largely prevented by sufficient rinsing after each use. The solution is distributed on the surfaces by a fluff-free cloth. The disinfectant permeates the dirt particles and because of mechanical forces (pressure, abrasion), this ensures effective cleaning. Additionally, the wiping motion ensures that spores, which are resistant to the disinfectant, will be re-moved. The cloth must be re-placed after the disinfection in order to prevent the spreading of the spores on other areas. Moreover, it is essential that the wiping solution is renewed regularly (daily

	**Notice**
	Follow the disinfection instructions of the OBC-O Breast Coil.

	**Notice**
	Please always wear protective gloves and comply with the application times for Hepatitis B and HIV viruses (See the instructions for use of the respective disinfectant solution).

As during the cleaning process, leave the fixation unit in its individual parts so that optimum disinfection can be ensured.

	**Danger of destruction**
	Improper disinfection may result in malfunction of the device. Noncompliance with the disinfection instructions may destroy the system! No warranty service will be provided for damages due to improper disinfection.

 G04	**Danger of infection**
	The instructions for disinfection must be followed. In case of inadequate disinfection, the operator and/or the patient may be infected.

Maintenance, Inspection and Testing:	Damaged parts should be discarded. All parts: Visually inspect for damage and wear.
Storage:	Safe, dry, dust-free and protected from light. Constant temperature {min.50 F (10°C) / max. 86 F (30°C)} Constant air humidity (min. 10% / max. 95%)
Manufacturer Contact:	See Chapter 10

8 Maintenance, Storage and Waste Disposal

8.1 Maintenance

Prior to each use, all components of the **Cranio-caudal Fixation Unit CC-OBC-O** must be visually inspected. Check the immobilization and fixing unit for breaks or cracks.

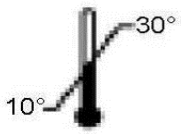
Defective products must not be used.

In such a case, please contact NORAS MRI products GmbH.

Comply with the cleaning and disinfection instructions!

 G20	**Injury of the patient**
	Prior to each patient examination, a visual inspection of all components is mandatory. In case of unusual findings and /or damage, the coil must not be used. Damaged parts can be sharp-edged and can cause injuries to the patient and/or the user. Do not use damaged coils and do not produce images with a defective coil.

8.2 Storage



After use, the device should be stored dry and at room temperature {min. 50 F (10°C), max. 86 F (30°C)} in a dust-free, UV radiation-protected location.

- Relative Humidity: Min.10%, Max. 95%
- Air Pressure: Min. 500 hPa, Max.1060 hPa

8.3 Waste Disposal

All of the materials used in the production of the system components can be conveniently recycled and therefore do not present any particular or unusual hazards during their disposal.

Prior to disposal, the system must be disinfected as described above to eliminate any risk of infection.

Disposal of the **Cranio-caudal Fixation Unit CC-OBC-O** is to be handed back to the manufacturer.

We would be happy to provide you with additional information about disposal upon request.

9 Technical Specification

9.1 Historical Device Data

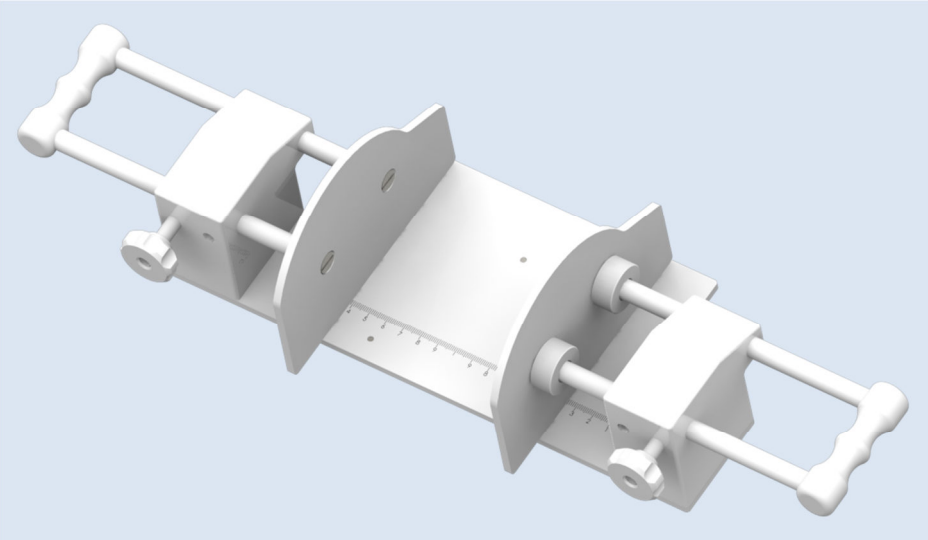
Model / Type Cranio-caudal Fixation Unit CC-OBC-O	**Product Type / Device Type (according to UMDNS / DIMDI)** Biopsy System Mammograpy (17-833)
Manufacturer NORAS MRI products GmbH Leibnizstraße 4 97204 Hoechberg Germany	**Supplier** NORAS MRI products GmbH Leibnizstraße 4 97204 Hoechberg Germany
Operation Type active☐ non-active☒	**Test / Control (Time Limits / Type)**
Product Class / Device Class Class I (MDD Annex IX, Chapter III, Clause 1, Paragraph 1.1/1.4, Rule 1 and 4)	**Intended Purpose according to information provided by the Manufacturer:** Cranio-caudal fixation of the female breast (both breasts) for MRI diagnostic examination
Identification no. of Notified Body **(CE- Marking):**	**Serial Number** 1001 incremental

9.2 Performance Data

Operating Temperature	Corresponding with the airconditioned room temperature of the MRI room
Storage Temperature	See 8.2
Protection Class	I
Dimensions	Width: approx. 460 mm Height: approx. 140 mm Depth: approx. 160 mm

9.3 Part List

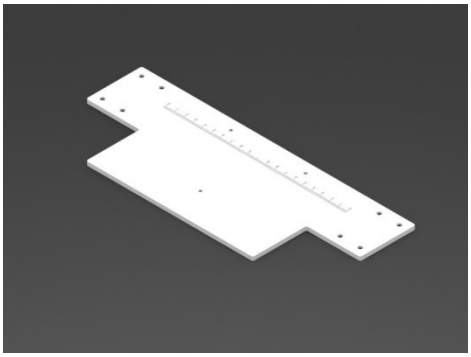
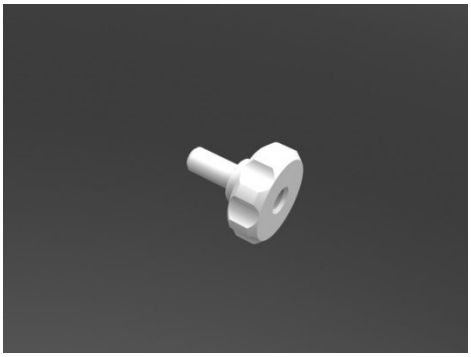
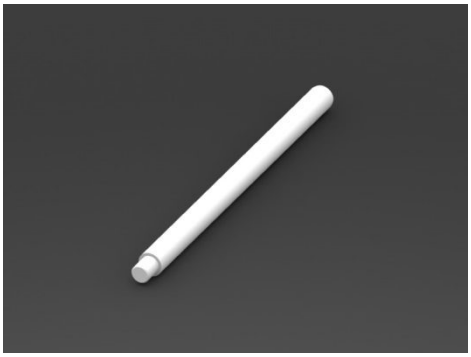
Description	Part Number
Cranio-Caudal Fixation Unit CC-OBC-O (consists of two units)	115011

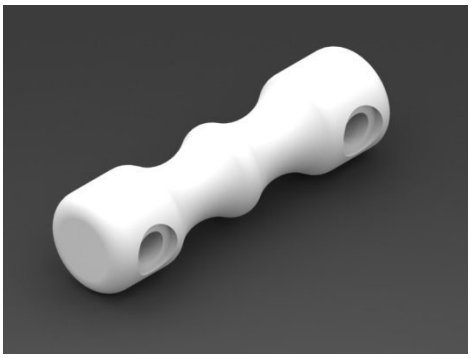
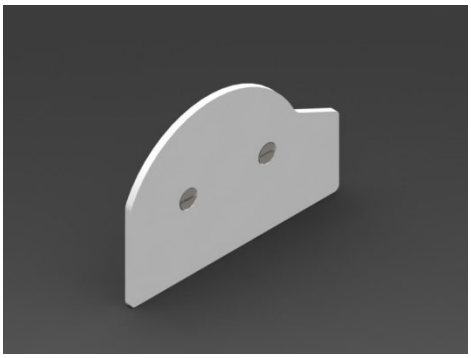
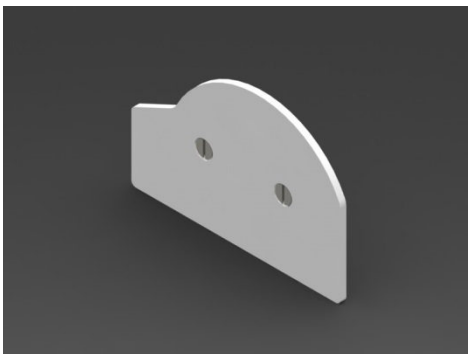


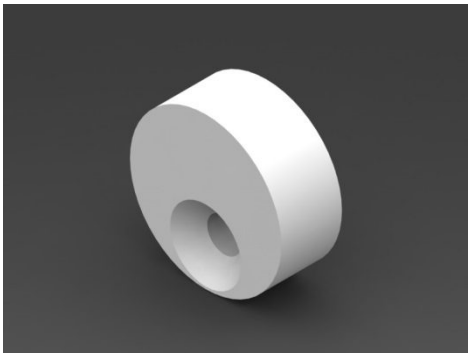
9.4 Combination with other devices

	Note
G19	The **Cranio-caudal Fixation Unit CC-OBC-O** may only be used in combination with those indicated in this Operator‘s Manual and included devices and coils of NORAS MRI products GmbH accessories. Use of other accessories is permitted only with written approval by the NORAS MRI products GmbH.

9.5 Accessories

Description	Part Number	Illustration
Base Plate CC-OBC-O	114552	
Locking Screw CC-OBC-O	112506	
Guidance Bar CC-OBC-O	114928	

Description	Part Number	Illustration
Handle Bar CC-OBC-O	114927	
Breast Plate left	114930	
Breast Plate right	114932	

Description	Part Number	Illustration
Eccentric	114443	
Fixationblock	112266	n/a
Operator's Manual	114901	n/a

10 Important Adresses

Manufacturer (Development and Production)

NORAS MRI products GmbH
Leibnizstraße 4
97204 Hoechberg / Germany
Phone: +49 (0)931/2 99 27-0
Fax: +49 (0)931/2 99 27-20
E-Mail: info@noras.de
www.noras.de

11 Training Outline

I have reviewed the **Cranio-Caudal Fixation Unit CC-OBC-O** Training Outline and understand the topics discussed, and verify that the training outlined is complete.

The training delivered was reflective of the details in the **Cranio-Caudal Fixation Unit CC-OBC-O** user manual. I will read (or have read) this appropriate manual, including the Cleaning and Disinfecting section of the manual.

I understand…

the intended use and the functionality of the **Cranio-caudal Fixation Unit CC-OBC-O**	☐
and am aware of the components of the **Cranio-caudal Fixation Unit CC-OBC-O**	☐
the installation of the **Cranio-caudal Fixation Unit CC-OBC-O**	☐
the complete setup of the **Cranio-caudal Fixation Unit CC-OBC-O**	☐
the application on patients	☐
the cleaning instructions	☐
the disinfection instructions	☐
that it is NOT NORAS' responsibility for timely replacement of worn out parts.	☐

Training Outline

Title	Name	Department
Date & Signature:		
☐ **Contact Person**	**E-Mail Adress:** **Phone No.:**	
Customer:		
Trained By:	**NORAS Application Trainer**	
Date & Signature:		

Notes

Notes