

ADJUSTABLE ARM SUPPORTS AND HAND GRIPS PACKAGE

Article No. : **33177**

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy.

Orfit Prohibits the use of unauthorized third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

The Adjustable Arm Supports and Hand Grips Package can be used in combination with the MammoRx® Breast Board and the SBRT solution. It allows positioning of the arms and hands of the patient extended above the head. It is used in combination with the other MammoRx® Breast Board and SBRT Solution products to form a reproducible patient positioning and immobilisation system.

The adjustable arm support cup supports the upper arm between the shoulder and the elbow and holds it out of the radiation beam. For maximal patient comfort the arm support can be adjusted in height. The cup also swivels to obtain a comfortable position for each patient. The Hand Grips provide a tool for the patient to grasp.

Figure 1 illustrates how the Adjustable Arm Supports and Hand Grips are mounted on the arm rest support plate (Art. No. 32317/15) that is attached to the SHORT SBRT base plate (Art. No. 32317/14).

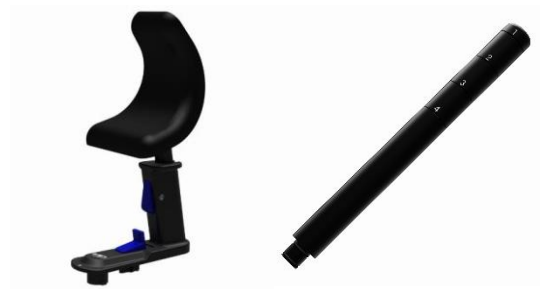


Figure 1: Adjustable Arm Supports and Hand Grips on Short SBRT Base Plate

The Adjustable Arm Supports and Hand Grips can also be indexed on the MammoRx® Breast Board (Figure 2).



Figure 2: Adjustable Arm Supports and Hand Grips on MammoRx® Breast Board

Information on the other parts can be found in the respective 'instructions for use'.

The Adjustable Arm Supports and Hand Grips package consists of the following elements:

	33170	Adjustable Arm Support
	33176	Hand Grips

C. INSTALLATION

C.1. Adjustable Arm Supports: 33170

To mount the Adjustable Arm Support on the SBRT Base Plate or MammoRx Breast Board, pull the bottom blue trigger (see Figure 3) and insert the post with its two tabs into the desired hole. The arrow on the base plate should be pointing towards the line on the support. Then rotate it downwards to the desired position. The Adjustable Arm Supports can be rotated to one of four indexed positions that are marked R1-R4, L1-L4, RA-RD, LA-LD. To remove the support, pull the blue trigger and rotate the Adjustable Arm Support past the R4, RD, L4 or LD position until it stops at the arrow and lift it out of the mounting hole.



Figure 3: Bottom trigger of Adjustable Arm Support

To adjust the height of the arm support, push the superior blue trigger (see figure 4) and move the cup to the desired height. The Adjustable Arm Support can be positioned in 5 different heights that are indexed by numbers at the back of the support (Figure 5). When you have reached the desired position, release the trigger to lock the

support in place. Make sure to write down the indexing position of the Adjustable Arm Support prior to removing it.

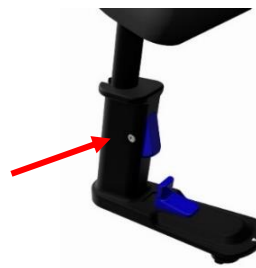


Figure 4: Superior trigger of Adjustable Arm Support



Figure 5: Indexing positions on Adjustable Arm Support

The cup of the arm support can be swivelled 360° in order to find the most comfortable position of the patient.

C.2. Hand Grips: 33176

The Hand Grips are designed to insert into one of the 10 wrist support index holes at the top of the MammoRx® Breast Board or one of the 16 wrist support index holes in the arm rest support plate (32317/15) of the SBRT Solution.

Make sure to write down the indexing position of the Hand Grips prior to removing it.

The Hand Grips also have indexing numbers from 1 to 4 to allow a reproducible patient positioning.

D. PRECAUTIONS FOR USE

Please handle with care. When the products are handled roughly, they may get damaged. When this happens, stop using the product.

Do not apply excessive force on the products. Make sure the patient does not use the Adjustable Arm Support as a support when repositioning herself on the breast board or when getting off the breast board. The maximum allowed load per Adjustable Arm Support is 20 kg.

E. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Prevent hard objects from falling onto the devices.

Store the products between +10°C (50°F) and 40°C (122°F).

F. PROPERTIES

E.1. Physical Properties

ADJUSTABLE ARM SUPPORT:

Dimensions : 293 mm x 135 mm x 165 mm

Weight : 0.44 kg

HAND GRIP:

Dimensions : 309 mm x 19 mm x 19 mm

Weight : 0.209 kg

E.2. Mechanical Properties

The Adjustable Arm Supports and Hand Grips are made of durable materials that keep their dimensions overtime and under conditions of frequent use.

Max. allowed load per Adjustable Arm Support: 20 kg.

E.3. Material Properties

Art. No. 33176

This product is not magnetically attracted, does not create artefacts, does not create significant noise in the MR scan and it does not warm up during the scan. Therefore this product is labelled as 'MR safe'.



Art. No. 33170

This product is made entirely of electrically non-conductive, and non-magnetic materials. It contains one metallic spring and for this reason the product is MRI conditional. The condition for use is that the arm support can only be used in a 1.5 and 3 Tesla MRI environment.



G. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of soapy water or an isopropanol based disinfectant, applied with a soft cloth. If unsure about the cleaning fluid, do not use. **Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.**

Take off the cushion to have access to the entire arm pad, and to be able to clean the cushion on the inside.



Figure 6: Removable cushion of Adjustable Arm Support

Periodic checks of the product should be done to insure the parts are not worn and require repair or replacement. **Do not attempt to make repairs yourself.** Contact your distributor if there are any questions or concerns.

H. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

Note:

The instructions were written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from Orfit Industries. MAMMORX® is a registered trademark of Orfit Industries.



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