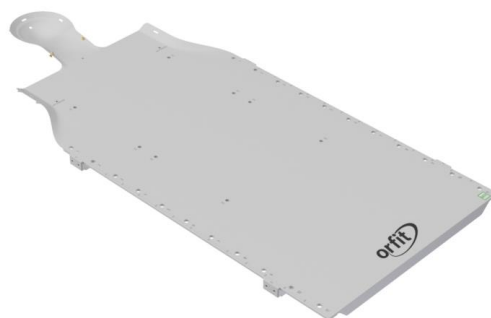


HP PRO® SOLUTION OVERLAY BASE PLATE - PAEDIATRIC 8-16 YEARS - MRI COMPATIBLE



Article No. : 25000/16/MR

A. GENERAL PRODUCT INFORMATION

This product is a medical device used for patient positioning and immobilisation in radiation therapy. This low density base plate can be used during both the simulation and the treatment stage, including MRI simulation, and is suitable for proton as well as photon treatments.

This product may only be used in combination with immobilisation masks produced by Orfit. Orfit prohibits the use of unauthorized third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

This fibreglass BASE PLATE is the basic element of the ORFIT PAEDIATRIC MRI COMPATIBLE HP PRO SOLUTION. It is used in combination with special 3 and 5 point paediatric masks, a cranial stop and a personalised head rest to form a reproducible patient positioning and immobilisation device. More information on these other parts can be found in the respective 'instructions for use' and on www.orfit.com.

The PAEDIATRIC HP PRO BASE PLATE has a narrow shoulder part specifically designed to immobilise children between 8 and 16 years old in a comfortable and reproducible way.

C. PRECAUTIONS BEFORE USE

- This is a fragile product, please handle with care. Always place the base plate on a flat surface. Clear the treatment table of any debris before positioning the base plate.
- Always fix the base plate securely to the treatment couch before positioning a patient. More information on how to fix this base plate to the couch top can be found on our website: www.orfit.com/en/fixation-devices.
- When a robotic arm is used to transfer the table onto a stretcher with the base plate attached to it, the base plate should be fully supported at all times. For safety reasons the base plate cannot hang over the table past the 'maximum overhang line' at the level of the shoulders. Always verify that the base plate is attached safely to the table before performing the transfer.
- The fibreglass base plate is constructed to be light in weight. When handled roughly, it may get damaged and fibres may come off. When this happens, stop using the base plate to prevent fibres from getting in contact with the patient's or user's skin. Contact your distributor.
- The article number and lot number can be found on the back of the base plate. They are mentioned on the bottom side of the plate in between 2 indexing holes at the edge.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Take care not to damage the edges of the plate when storing it in an upright position. Prevent hard objects from falling onto the plate.

Store the base plate between +10°C (50°F) and 40°C (104°F).

E. PROPERTIES

E.1. Physical Properties

Dimensions ($\pm 0,2$ mm / ± 0.079 "):

L 1210 mm x W 540 mm x H 28 mm

L 47.64" x W 21.26" x H 1.10"

Weight ($\pm 0,05$ kg / ± 11.02 lbs):

5 kg

11.02 lbs

The thin head shell is made from fibreglass with epoxy. Starting from the neck, the thickness gradually increases to 30 mm using a foam core covered with fibreglass and epoxy. Edges are epoxy resin. Other inserts are made from hardwood/epoxy.

This product is made entirely of electrically non-conductive, non-metallic and non-magnetic materials and is MR safe.

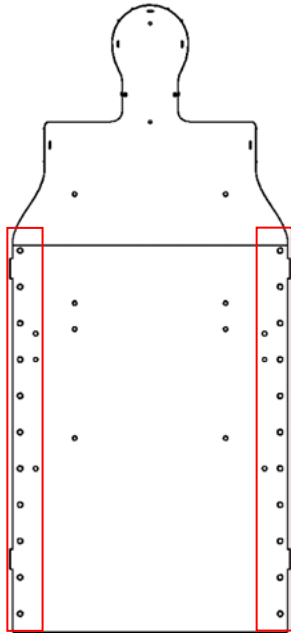


E.2. Mechanical Properties

Always use the base plate on a flat surface. For safety reasons, the base plate cannot hang over the table.

E.3. Dosimetric Properties

The Base Plate has areas where higher density (± 1.4 g/mm³) materials have been used. The following image shows these areas inside the red lines.



F. ACCESSORIES FOR THE BASE PLATE

Various accessories can be used in combination with the HP PRO base plate, such as:

- 25000/6: Cranial Back Stop
- 25000/7: Head Support Indexing Plate
- 25000/17/A and 25000/17/B: Hand Holds

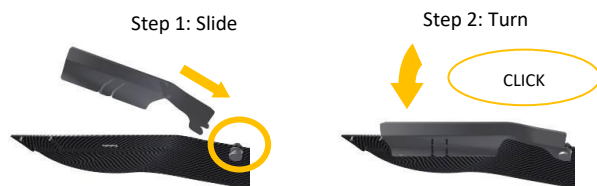
More information about these accessories can be found in the respective 'instructions for use' and on www.orfit.com.

G. HP PRO THERMOPLASTIC MASKS

Various paediatric thermoplastic masks are available in a 3-points and 5-points version to immobilise paediatric head and neck patients.

To attach the lateral head profiles to the base plate you have to work in a few steps. First slide the caudal side of the profile over the indexing pin and secondly swivel the profile inwards until it clicks over the base plate.

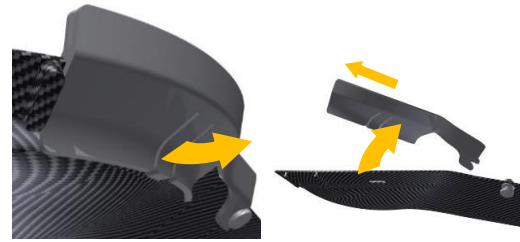
Attaching a lateral profile to the base plate:



Removing a lateral profile from the base plate:

Step 1: pull handle

Step 2: Turn & slide



The cranial head profile and the shoulder profiles simply click onto the base plate.

If the patient has medium to long hair it is helpful to add a hair cover. This will automatically clear the areas where the mask profiles must be attached. It provides more time to mould the mask and prevents hair getting stuck in between the mask profile connection.

Different shapes and sizes are available in Nanor material. The profiles are made from Polycarbonate (PC).

H. MAINTENANCE AND WASTE MANAGEMENT

This product 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.**

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.

The product can be disposed of with household waste.

Periodic checks of the following parts is extremely important in order to safeguard a good fixation of the mask to the base plate:

- The holes where the mask profiles click into.
- The guidance ribs to position the mask profiles.
- The pin to attach the inferior part of the profile to the base plate.
- The profile of the mask.

I. 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:

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