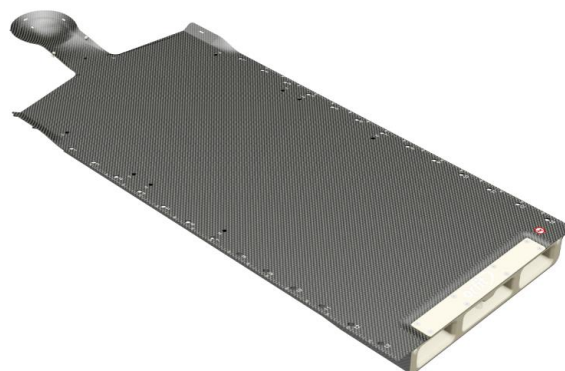


HP PRO® EXTENSION AERIAL® COUCH



Article No. : 25000/34, 25000/40, 25000/62,
25000/64 & 25000/67

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy. These low density base plates are suitable for proton therapy treatments.

To attain an optimal result, it is recommended to use this product in combination with Orfit immobilisation products.

B. PRODUCT DESCRIPTION

These carbon fibre HP PRO® EXTENSION BASE PLATES are compatible with the ORFIT® AERIAL COUCH TOP. They are used in combination with special 3 and 5 points HP PRO masks, a cranial stop and a personalised head rest to form a reproducible patient positioning and immobilisation device. Information on these other parts can be found in the respective 'instructions for use' and on www.orfit.com.

C. PRECAUTIONS FOR USE

- These are a fragile products, please handle with care.
- Use these base plates as an extension only.
- Always fix the extensions securely to the couch before positioning a patient or additional equipment. More information on how to fix these extensions to the couch top can be found in this document.
- Do not lean or sit on the outer end, beyond the 'NO SITTING' line. Have the patient sit on the pedestal area first (or below the 'NO SITTING' line) and then slide cranially to lay down. Make sure the patient is never mounting on the base plates by sitting on his or her knees. This might damage the base plates.



NO SITTING



- Take into account the maximum weight loads.
- The carbon fibre base plates are constructed to be light in weight. When handled roughly, they may get damaged and fibres may come off. When this happens, stop using the base plates to prevent fibres from getting in contact with the patient's or user's skin. Contact your distributor, local product specialist or sales representative.
- Always be careful where to hold the extensions when lifting, moving or (un)locking them. Since the boards are bottom-heavy – and very light at the patient side – they are unbalanced. Therefore; always place your hands around the location of the 'hands here' pictogram labels which are placed around the centre of gravity.



- Do not use the extensions after they had a severe collision with the ground, wall/door or other device in the room. A collision might compromise the strength of the internal structure and could result in failure.
- The article number and lot number can be found on the back of the base plates. They are mentioned on the bottom side of the plates in between 2 indexing holes at the edge (caudal side).
- In case there are any uncertainties about the safe use of these extensions, contact your distributor, local product specialist or sales representative.

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. Do not place any items on top of the extension while in storage.

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

E. PROPERTIES

E.1 Physical Properties

HP PRO Aerial extension 25000/34 without base

Outer dimensions : L 1365 x W 530 x H 65 mm
: L 53.74" x W 20.86" x H 2.56"

Weight : 7,3 kg / 16.09 lbs

HP PRO Aerial extension 25000/34 with base

Outer dimensions : L 1920 x W 530 x H 90 mm
: L 75.59" x W 20.86" x H 3.54"

HP PRO Aerial extension 25000/40 without base

Outer dimensions: L 1645 x W 530 x H 65 mm
: L 64.76" x W 20.86" x H 2.56"

Weight : 9,5 kg / 20.94 lbs

HP PRO Aerial extension 25000/40 with base

Outer dimensions: L 2200 x W 530 x H 90 mm
L 86,61" x W 20.86" x H 3.54"

HP PRO Aerial extension (pediatric 0-7) 25000/62 without base

Outer dimensions: L 1295 x W 530 x H 65 mm
L 50,98" x W 20.86" x H 2.56"

Weight : 7,0 kg / 15.43 lbs

HP PRO Aerial extension (pediatric 0-7) 25000/62 with base

Outer dimensions: L 1850 x W 530 x H 90 mm
L 72,83" x W 20.86" x H 3.54"

HP PRO Aerial extension (pediatric 8-16) 25000/64 without base

Outer dimensions: L 1294 x W 530 x H 65 mm

: L 50.94" x W 20.86" x H 2.56"

Weight : 7 kg / 15.43 lbs

HP PRO Aerial extension (pediatric 8-16) 25000/64 with base

Outer dimensions: L 1849 x W 530 x H 90 mm
: L 72.80" x W 20.86" x H 3.54"

HP PRO Aerial extension (short) 25000/67 without base

Outer dimensions: L 1295 x W 530 x H 65 mm
: L 50.98" x W 20.86" x H 2.56"

Weight : 7 kg / 15.43 lbs

HP PRO Aerial extension (short) 25000/67 with base

Outer dimensions: L 1850 x W 530 x H 90 mm
: L 72.83" x W 20.86" x H 3.54"

E.2 Material Properties

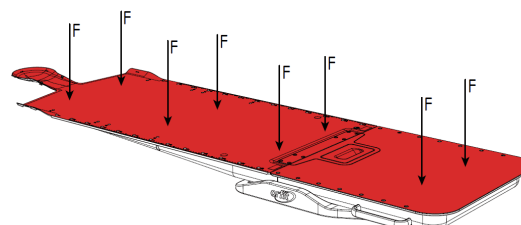
The thin head shell is made from carbon fibre with epoxy. Starting from the neck, the thickness of the foam core gradually increases towards 64 mm at the caudal end of the board. Edges are made of a very thin layer of phenolic resin. The interface is made from aluminium with aluminium reinforcement plates and bolts. Other inserts are made from phenolic.

These base plates are labelled 'MR Unsafe' due to the used metallic and carbon fibre materials. This is visualized by the following label:



E.3 Mechanical Properties

Max. allowed distributed load on full couch (incl. Aerial Couch base part): 235 kg / 518 lbs



CAUTION

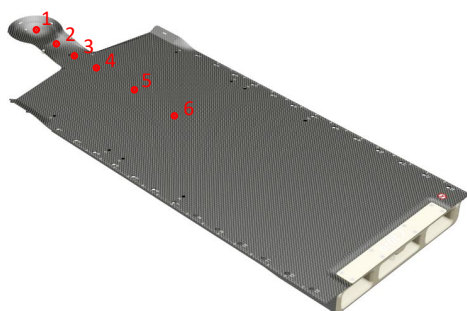
- Prevent point loads at all times!
- The specific load capacity of the robotic system may be less. Please respect the specific safety requirements of the robotic positioning system.

- Make sure to take into account the weight of every item placed on top of the extensions and add it to the patient weight to check that the total weight does not exceed the maximum load limit of the couch top.

E.3. Dosimetric Properties

The WET values depend on the location on the extension. The values given below are for proton therapy.

Location	WET (cm) at 170 MeV
1	0.28
2	0.39
3	0.52
4	0.65
5	0.69
6	0.71



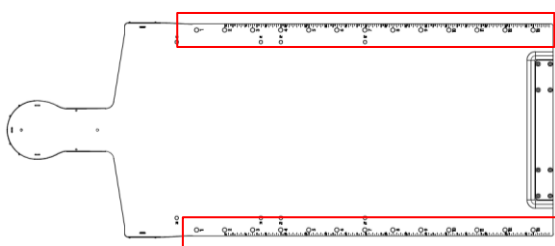
Note: Use these numbers as a guidance only. Perform the measurements again in your department to verify these results.

The attenuation factor for high energy proton beams will be negligible. It is so small that it cannot be measured.

The location where the homogeneous and low density 'treatment zone' starts is marked with the label below:

TREATMENT ZONE

The Base Plate has areas where higher density ($\pm 1.4 \text{ g/mm}^3$) materials have been used. The following image shows these areas inside the red lines.



F. ATTACHEMENT TO COUCH

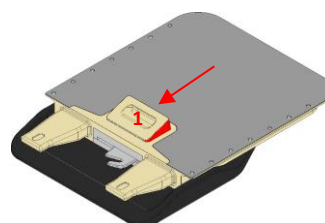
The extensions 25000/34 & 25000/40 are designed to fit the Aerial Couch for Proton Therapy. Consult the respective user manual of the couch to safely operate the system.

CAUTION

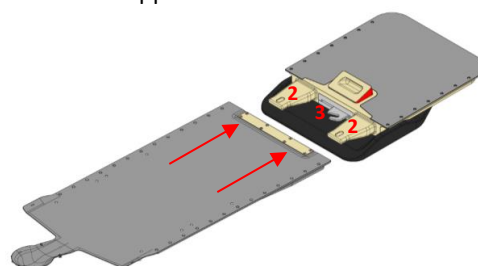
- The couch extensions are not allowed to be used on another couch than specified in this document.
- Take into account any precautions and instructions described in the user manual of the couch base.

MOUNTING OF EXTENSIONS

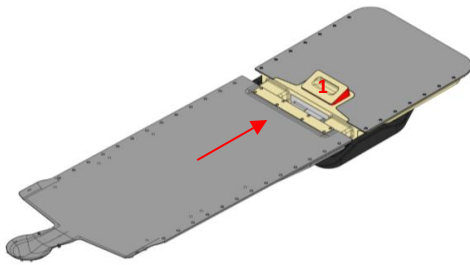
1. Before mounting the extension, make sure the couch is unlocked and no extension is attached. This can be verified by checking if the handle (1) of the Aerial couch base is in upright position (see below).



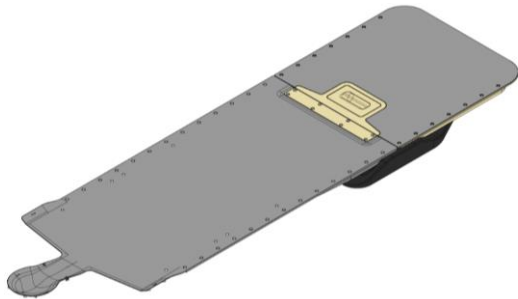
2. Grab the extension at the sides and hold the extension in front of the tabs (2) and make sure the tabs are positioned within the opposite cavities.



3. Slide the extension towards the base. By sliding the extension towards the base, the latch plate (3) will turn into the locked position. The release handle (1) – which is connected with the locking pin – will fall down into the locking position.

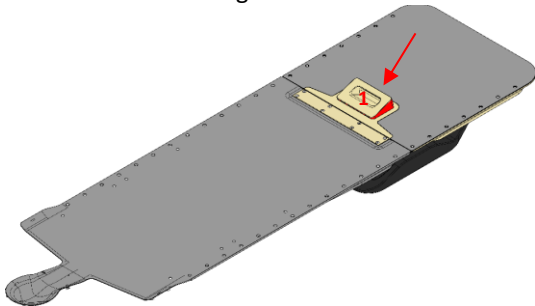


4. When the handle surface is flush with the top surface of the couch (the red unlocked sign is not visible), and when there is a small seam of +/- 1 mm between the couch base and the extension, then the couch extension is correctly secured to the couch base.

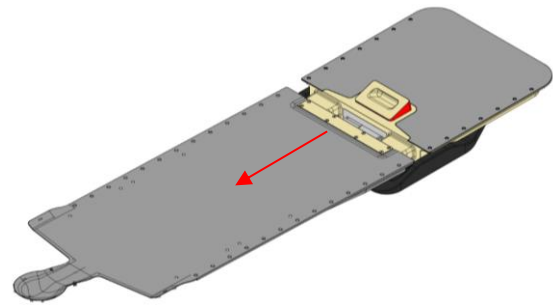


DISMOUNTING OF EXTENSIONS

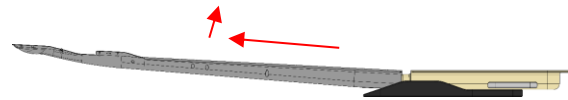
1. Pull the release handle (1). By pulling the release handle (1), the latch plate will be actuated and unlocked. The handle will stay in the upright position, showing an 'unlocked' sign at the sides.



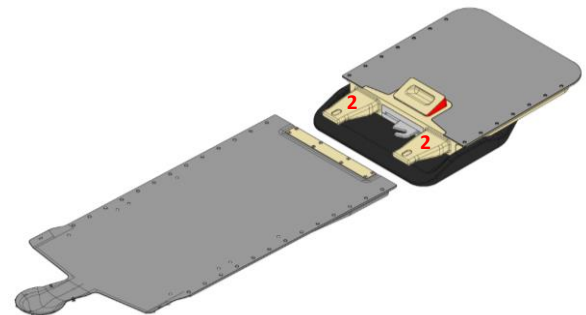
2. Grab the extension and slide it outwards - in longitudinal direction - away from the couch base part.



3. When reaching the stop (second safety mechanism), lift the extension slightly. **Make sure you hold the extension around the 'hand' pictogram stickers with two hands because the extension is heavier towards the bottom!** The weight of the extension is not evenly distributed.



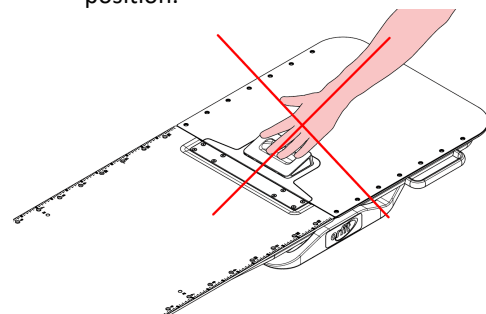
4. Remove the extension from the tabs (2).



5. Store the extension safely in a storage cart or against the wall to make sure it will not get damaged.

CAUTION

1. Never try to force the handle downwards because it might be blocked by the safety mechanism. It should lock by itself when moving the extension towards the end position.



2. Once the release lever is pulled upwards, you have to remove of the extension completely (!) from the tabs before you can lock it again.
3. Always verify that the extension is securely fixed by checking if it is flush with the couch (horizontal), if the handle is flush and if there is a seam between couch and extension of about 1 mm.

G. ACCESSORIES FOR THE BASE PLATE

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

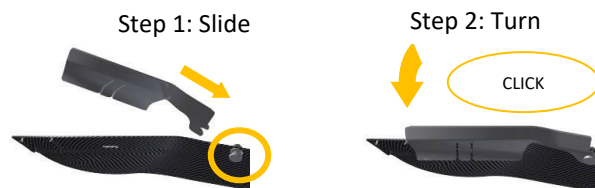
- 25000/6: Cranial Back Stop
- 25000/7: Head Support Indexing Plate
- 25000/38: Pediatric Head Support Indexing Plate
- 25070: HP Pro flexible Shim
- 25000/17/A and 25000/17/B: Hand Holds
- 32191: 2-pin bar for couch.

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

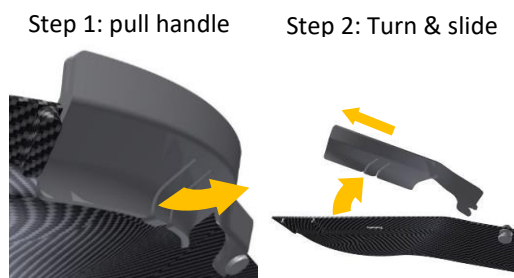
H. HP PRO THERMOPLASTIC MASKS

Various thermoplastic masks are available in a 3-points and 5-points version to immobilise 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:



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

If the patient has medium or 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 both in Efficast and Nanor. The profiles are made from Polycarbonate (PC).

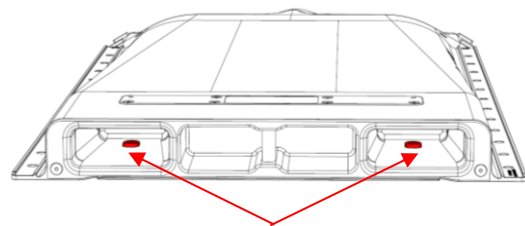
I. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of 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.** Further cleaning instructions can be found in the [Orfit Cleaning Guidelines](#). The product can be disposed of with household waste.

Periodic checks of the product should be done to insure safe use.

Weekly:

- No damages (cracks/dents) of any kind which might indicate a collision occurred.
- No visible defects on the aluminium adapter.
- All bolts still firmly in place.
- No delamination of carbon top and bottom layers.
- Two 'Secondary Locking Pins' still in place inside the aluminium adapter.



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.

Immediately stop using the extensions if a defect is found. **Do not attempt to make repairs yourself.**

Also make sure to respect and perform the maintenance procedures of the Aerial couch base. These can be found in the respective 'Instructions For Use'.
Contact your distributor if there are any questions or concerns.

J. **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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