INSTRUCTIONS FOR USE



AERIAL® HP PRO® ADULT
CT OVERLAY
AERIAL® HP PRO®
PEDIATRIC CT OVERLAY 07 years





Article No.: **25000/43** Article No.: **25000/63**

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device, used for patient positioning and immobilisation in radiation therapy. This low density overlay base plate is suitable for proton therapy simulation.

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

B. PRODUCT DESCRIPTION

This carbon fibre AERIAL® HP PRO® ADULT CT OVERLAY is used to simulate patients that are being treated on the ORFIT® ADULT HP PRO EXTENSIONS FOR AERIAL® COUCH TOP (25000/34 & 25000/40). The AERIAL® HP PRO® PEDIATRIC CT OVERLAY is used to simulate pediatric patients that are being treated on the ORFIT® PEDIATRIC HP PRO EXTENSIONS 0-7 YEARS FOR AERIAL® COUCH TOP (25000/62). The CT overlay is 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.

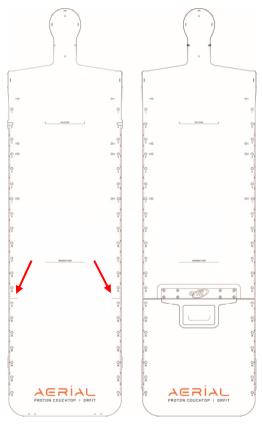
C. PRECAUTIONS FOR USE

- This is a fragile product, please handle with
- Use this base plate as an overlay only.
- Always fix the overlay base plate securely to the couch before positioning a patient or additional equipment. More information on how to fix this overlay to the couch can be found in this document.
- Do not lean or sit on the outer end, beyond the no sitting line. Have the patient sit below the 'NO SITTING' line first and then slide cranially to lay down. Make sure the patient is never mounting on the base plate by sitting

on his or her knees. This might damage the base plate.



- Take into account the maximum weight loads.
- Below images compare the Aerial® HP PRO® Adult CT overlay and the HP PRO® adult extension for Aerial couch top 25000/34 on the Aerial® base part. The lines indicated by the red arrows on the overlay base plate correspond to the transition between the extension and the high density Aerial® base part. The Aerial® HP PRO® Adult CT overlay 25000/43 doesn't contain high density zones (excl. supporting blocks).



- The carbon fibre 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, local product specialist or sales representative.
- Do not use the overlay base plate after it 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 plate. They are mentioned on the bottom side of the plate in between 2 indexing holes at the edge (caudal side).
- In case there are any uncertainties about the safe use of this overlay base plate, 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

AERIAL® HP PRO® ADULT CT OVERLAY (25000/43)

Dimensions : L 1925 x W 540 x H 86.1 mm

: L 75.79" x W 21.26" x H 3.39"

Weight : 8,1 kg / 17,86 lbs

AERIAL® HP PRO® PEDIATRIC CT OVERLAY (25000/63)

Dimensions : L 1850 x W 540 x H 81 mm

: L 72.83" x W 21.26" x H 3.19"

Weight : 7,65 kg / 16,87 lbs

E.2 Material Properties

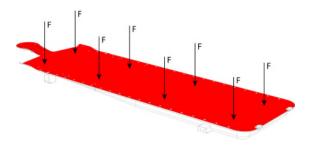
The thin head shell is made from carbon fibre with epoxy. Starting from the neck, the thickness of the foam core gradually increases. Edges are made of a very thin layer of phenolic resin. Other inserts are made from phenolic.

This overlay base plate is labelled 'MR Unsafe' due to the used carbon fibre materials. This is visualized by the following label:



E.3 Mechanical Properties

Max. allowed distributed load on full CT overlay: 235 kg / 518 lbs



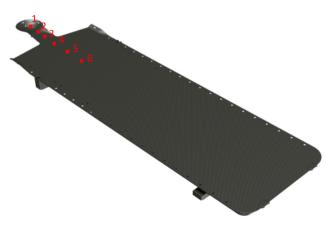
CAUTION

- Prevent point loads at all times!
- The specific load capacity of the CT couch may be less. Please respect the specific safety requirements of the CT couch.
- Make sure to take into account the weight of every item placed on top of the overlay base plate and add it to the patient weight to check that the total weight does not exceed the maximum load limit.

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



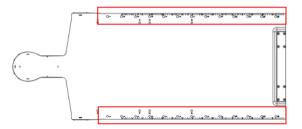
Note: Use these numbers as a guidance only. Perform the measurements again in your department to verify these results.

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

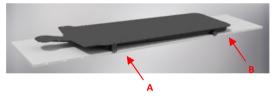
The Base Plate has areas where higher density (± 1.4 g/mm³) materials have been used. The following image shows these areas inside the red lines



F. ATTACHEMENT TO CT COUCH

The Aerial® HP PRO® Adult CT overlay 25000/43 and Aerial® HP PRO® Pediatric CT overlay 25000/63 are indexed to the CT couch using 2 fixation elements; one at the cranial end (A) and one at the caudal end (B) of the overlay. Always use 2 fixation elements for safe use of the overlay.

A loxon™ fixation element can be used at the cranial end while on the caudal end both a loxon™ fixation element or 2-pin indexing bar can be used.



G. ACCESSORIES FOR THE BASE PLATE

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

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

Accessories for the AERIAL HP PRO® PEDIATRIC CT OVERLAY 0-7 YEARS include:

- 25000/39: Head Support Indexing Plate Pediatric
- 25071: Pediatric Flexible Shim
- 25000/6: Cranial Back Stop
- 25000/17/A and 25000/17/B: Hand Holds

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:

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 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 <u>Orfit Cleaning Guidelines</u>. 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 delamination of carbon top and bottom layers.

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 CT overlay if a defect is found. **Do not attempt to make repairs yourself**.

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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