INSTRUCTIONS FOR USE



HIGH PRECISION ACCESSORIES PRONE HEAD SUPPORT



Article No.: 32380

A. GENERAL PRODUCT INFORMATION

This product is a medical device used for patient positioning and immobilisation in radiation therapy. This prone head support can be used during both the simulation and the treatment stage, including MRI simulation.

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

B. PRODUCT DESCRIPTION

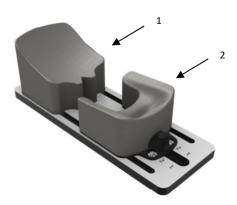
These Prone Head Supports are suitable for use in combination with High Precision Base Plates and Efficast® thermoplastic masks. Together with these parts they form a reproducible patient positioning and immobilisation system in the field of radiotherapy. Information on these other parts and instructions on how to make the masks can be found in the respective 'instructions for use' and on www.orfit.com.

The head supports offer the opportunity to position the patient's head in a stable and reproducible way. The sides of the chin cushion are open and there is a tunnel in this chin cushion to have enough breathing space for the patient to feel comfortable and to allow for the easy use of anaesthetic tubes.

This product consists of a support plate in high pressure laminate with 2 cushions. The cushion for the forehead (1) is fixed. The cushion for the chin (2) can be put in 6 positions to accommodate the patient's size. The cushions are made of coated low density PE foam.

C. HOW TO USE

- Fit the head support to the patient before positioning it on the HP base plate.
- Fit the patient's nose against cushion number 1 so the forehead rests on the cushion. Move cushion no. 2 forward against the chin, by lifting the knob and pushing the cushion in the direction of the chin.



- Position the head support on the base plate. The
 head support can be positioned on the base plates
 by means of the two positioning knobs made of EVA
 foam on the bottom of the head support that fit the
 round recesses in the base plate.
 Always verify that the devices are positioned
 correctly on these base plates.
- Position the patient on the head support and adjust the position of cushion no 2 if required.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged or falling onto other objects. Do not put heavy objects on the device and prevent hard objects from falling onto it because this might cause permanent damage.

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

E. 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. Do not soak the product.** Further cleaning instructions can be found in the <u>Orfit Cleaning Guidelines</u>. 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.

F. PROPERTIES

F.1. Physical Properties

The following physical properties apply to these devices:

Dimensions: L 270 mm x W 110 mm x H 100 mm

Weight: 0.52 kg

Materials: High Pressure Laminate (HPL)

PE foam and PU coating



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

F.2. Mechanical Properties

The cushions of this device are made of low density PE foam that is covered with a PU coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

The cushions used on the treatment machines are often used more frequently than those on the simulators and during the imaging stages. We therefore recommend rotating the sets

between the different machines on a regular base to avoid differences in wear and tear of the cushions.

The maximum deformation measured after 100 uninterrupted pressure cycles with a compression strength of 500N on a surface of 5cm x 5cm is 28.1%. This corresponds to the force of 100 times per day the load of 50 kg applied with the palm of the hand.

E.3 Dosimetric Properties

The head support cushions are made of regular density foam that has the following dosimetric properties **per cm of material** through which the beam passes:

Attenuation (± 0.15 %)		Skin build up (± 0.1 mm)
6 MV	15 MV	mm H₂O equiv.
0.57 %	0.46 %	1.38mm/mm material

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

G. 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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