INSTRUCTIONS FOR USE



THE AIO SOLUTION[®] 3.0 INDEXED PRONE HEAD SUPPORT FOR BELLY- & PELVICBOARD AND PRONE BREASTBOARD

Article No. : 38226

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device used for patient positioning and immobilisation in radiation therapy. The product can be used during both the simulation and treatment stage, including MRI simulation.

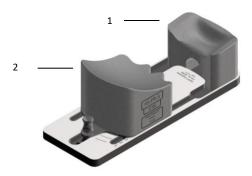
To attain an optimal result, it is recommended to use this product in combination with Orfit immobilisation products.

B. PRODUCT DESCRIPTION

This indexed Prone Head Support is suitable for use in combination with the AIO Solution 3.0 Belly- & Pelvicboard and The AIO Solution 3.0 Prone Breastboard. Together with these parts, it forms a reproducible patient positioning and immobilisation system. Information on these other parts can be found in the respective 'instructions for use' and on www.orfit.com.

The Indexed Prone Head Support can be used to position the head of the patient in a stable and reproducible way while positioned in prone position on the AIO Solution 3.0 Prone Belly- & Pelvicboard or on the AIO Solution 3.0 Prone Breastboard.

The sides of the head support are open and there is a tunnel in the chin cushion to have enough breathing space for the patient to feel comfortable and to allow for the easy use of anaesthetic tubes. The AIO 3.0 indexed prone head support consists of a support plate with 2 cushions. The cushion for the chin (1) is fixed. The cushion for the forehead and nose (2) can be put in 7 different positions to accommodate the differences in patient's anatomy. The support plate contains 2 round knobs on the bottom that fit into the round cut-outs provided in the cranial end of the AIO 3.0 Belly- & Pelvic board base cushion 38107 or the AIO 3.0 Prone Breast Board cranial cushion 38110. There are 3 different positions to index the AIO 3.0 prone head support on the AIO 3.0 Belly- & Pelvic Board base cushion 38107, marked by numbers 1-3. The AIO 3.0 Prone Breast Board cranial cushion 38110 has 2 different indexing positions for the indexed prone head support, marked by numbers 1-2.



This indexed prone head support (ref. 38226) cannot be used on any AIO 3.0 base plate or other High Precision base plate for brain, head & neck treatment in prone position. The support plate of the indexed prone head support is covering the cranial mask fixation slot and doesn't allow the use of any brain, head

The head supports used on the treatment machines are often used more frequently than those on the simulators and during the imaging stages. Therefore we recommend rotating the head supports between the different machines on a regular basis to avoid differences in wear and tear of the cushions. Do not expose the indexed prone head support to a hot air blower and make sure that no sharp objects can come into contact with the cushions. Do not use tape on the cushions. Applying marks on the cushions with ink or other substances are at your own risk.

C. HOW TO USE

& neck mask.

- 1. Fit the head support to the patient before positioning it on the AIO Solution 3.0 cushion.
- 2. Fit the patient's chin in the gutter of cushion no. 1. Move cushion no. 2 forward against the nose by lifting the knob and pushing the cushion in the direction of the chin.
- 3. Position the head support on the AIO Solution 3.0 cushion. Always verify that the devices are positioned correctly on the AIO solution 3.0 cushion.
- 4. Position the patient on the head support and adjust the position of cushion no 2 if required.

D. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of an ethanol or 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.

E. 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 cushions and prevent hard objects from falling onto them to prevent permanent deformations. Avoid pressure points on the cushions during storage as these can cause imprints in the cushions.

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

F. PROPERTIES

Physical properties:

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

L 10.63" x W 4.33" x H 3.94"

Weight: 0.52 kg / 1.15 lbs



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

Mechanical properties:

The AIO 3.0 cushions are made of low density foam that is covered with a coating. This combination results in a stable cushion that keeps its dimensions overtime and under conditions of frequent use.

Dosimetric properties:

The attenuation and skin build-up at 6 MV and 15 MV per cm of material:

Attenuation (± 0.15%)		Skin Build-up (± 0.1 mm)
6 MV	15 MV	
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. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of an ethanol or 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 cushions.** Further cleaning instructions can be found in the <u>Orfit Cleaning Guidelines</u>. The AIO 3.0 cushions are made of a closed-cell foam and will

not absorb any cleaning agent. Periodic checks of these products 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.

These products can be disposed of with household waste

H. ADDITIONAL INFORMATION

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

Note:

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