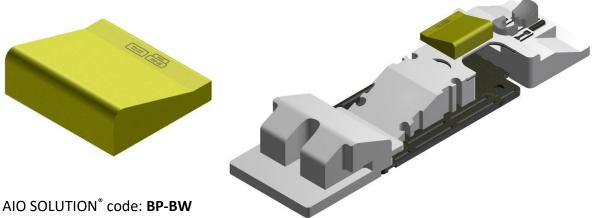


THE AIO SOLUTION[®] PRONE BREASTBOARD SOLUTION **COMFORT WEDGE FOR CONTRALATERAL SIDE**



Article No. : 29006-V2

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device used for patient positioning and immobilisation in radiation therapy.

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

PRODUCT DESCRIPTION

This PRONE BREAST - COMFORT WEDGE FOR CONTRALATERAL SIDE is a part of "THE AIO SOLUTION" PRONE BREAST PACKAGE". It is used in combination with the other PRONE BREAST CUSHIONS, THE AIO SOLUTION® BASE PLATES and the EFFICAST[®] PRE-CUTS to form a reproducible patient positioning and immobilisation system. 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.

C. PRECAUTIONS FOR USE

Always use this cushion in combination with the other AIO SOLUTION® PRONE BREAST CUSHIONS on one of the AIO SOLUTION[®] BASE PLATES.

The cushion has a bulge on the bottom that fits into the positioning hole foreseen in the PRONE BREAST - SUPPORT CUSHION FOR CONTRALATERAL BREAST. Always verify that the cushion is positioned correctly on that support cushion. Do not expose this cushion to a hot air blower and make sure that no sharp objects can come into contact with it.

D. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Do not put heavy objects on the cushion and prevent hard objects from falling onto it, because these will cause permanent deformations.

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

E. PROPERTIES

E.1. Basic Physical Properties

The following physical properties apply to these cushions:

Density:	Foam: 30 kg/m ³	
	Coating: > 1 g/cm ³	
Dimensions:	L 260 mm x W 240 mm x H 95 mm	
Weight:	0,18 kg	

E.2. Mechanical Properties

The AIO Cushions are made of a soft, low density polyester 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 dosimetric build-up of this material (expressed in equivalent mmH₂O) depends largely on the length of the radiation pathway inside the cushion. Each mm of foam passed by the radiation beam will add 0.02 mmH₂O equiv. and each layer of coating that is passed will add another 0.35 mmH₂O equiv. to the total. The total can thus be calculated using the following formula:

mmH₂O = (L x 0.02) + (n x 0.35), where:

L = length of the radiation pathway in the foam (in mm) n = number of coating layers crossed by the radiation beam The attenuation at 6MV and 15MV through the cushion is:

	Attenuation (± 0.15%)		Mm H2O equivalence
	6 MV	15 MV	(± 0.1mm)
Thinnest part of the cushion	0.83 %	0.75 %	1.70mm
Thickest part of the cushion	1.38%	1.00%	3.18mm

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

F. 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 cushion. 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.

G. 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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