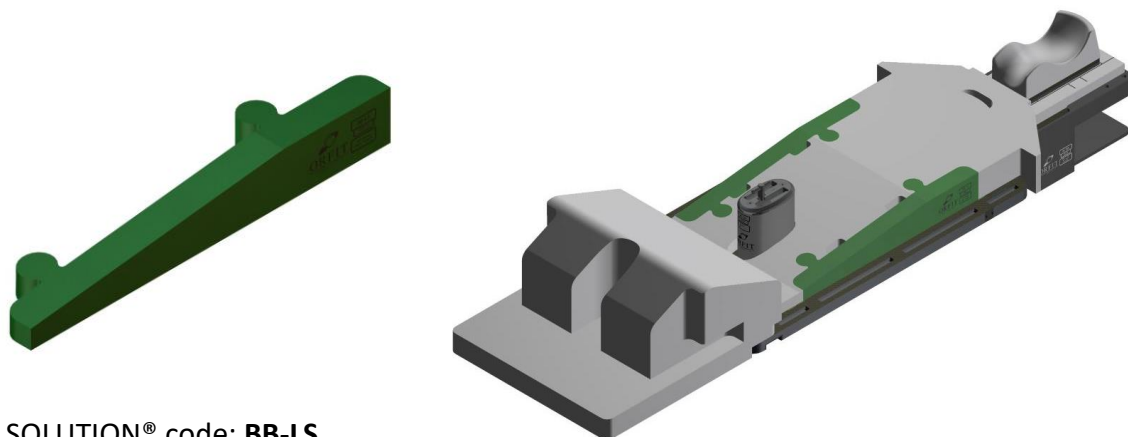


THE AIO SOLUTION® BELLYBOARD & PELVIC SOLUTION BELLY & PELVIC LATERAL SUPPORTS



AIO SOLUTION® code: **BB-LS**
 Article No. : **29021-V2 (L) & 29022-V2 (R)**

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices used for patient positioning and immobilisation in radiation therapy.

These products may only be used in combination with Orfit immobilisation products. Orfit prohibits the use of unauthorised third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

These BELLY & PELVIC LATERAL SUPPORTS (left and right) are a part of the "AIO SOLUTION® BELLYBOARD PACKAGE". They are used in combination with the other BELLYBOARD 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 these cushions in combination with the other AIO SOLUTION® BELLYBOARD CUSHIONS on one of the base plates. The cushions have indexing knobs that fit into the positioning holes foreseen in the BELLY & PELVIC CUSHION. Always verify that the cushions are positioned correctly on the basic cushion. Do not expose these cushions to a hot air blower and make sure that no sharp objects can come into contact with these cushions.

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: 29 kg/m ³ Coating: > 1 g/cm ³
Dimensions:	L 600 mm x W 75 mm x H 80 mm
Weight:	0,11 kg

E.2. Mechanical Properties

The AIO Cushions 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 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:

$$\text{mmH}_2\text{O} = (\text{L} \times 0.02) + (\text{n} \times 0.35), \text{ where:}$$

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 per cm of material through which the beam passes is:

Attenuation ($\pm 0.15\%$)	
6 MV	15 MV
0.12 %	0.09 %

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

F. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of soapy water or 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.**

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 products 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 www.orfit.com.

Note:

The instructions were written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from Orfit Industries. THE AIO SOLUTION® and EFFICAST® are registered trademarks of ORFIT INDUSTRIES N.V.



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