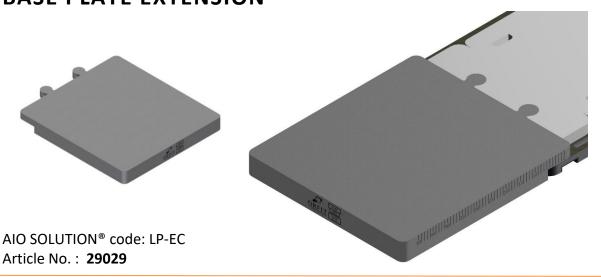


THE AIO SOLUTION® KNEE & LEG POSITIONING BASE PLATE EXTENSION



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.

B. PRODUCT DESCRIPTION

This KNEE & LEG POSITIONING CUSHION – BASE PLATE EXTENSION is a part of the "AIO SOLUTION" KNEE & LEG POSITIONING CUSHIONS". It is used in combination with the other KNEE & LEG POSITIONING 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 AlO SOLUTION* KNEE & LEG POSITIONING CUSHIONS on one of the base plates.

The cushion has positioning knobs on the cranial side that fit into the holes on the basic cushions of the different treatment packages (PRONE BREAST - CAUDAL CUSHION, THORAX ABDOMEN 0° WEDGE, BELLY & PELVIC - BASIC CUSHION and KNEE & LEG POSITIONING - ADAPTOR CUSHION). Always verify that the cushions are positioned correctly. The KNEE & LEG POSITIONING CUSHION – BASE PLATE EXTENSION has a centimetre scale on one side. The KNEE & LEG POSITIONING CUSHIONS – LOW, WEDGE and ELEVATION have an A printed on one side and a B on the other side. There is also a vertical line printed underneath the letters A and B. This line is a reference point for the scale on the extension. The exact position of the KNEE & LEG POSITIONING CUSHIONS - LOW, WEDGE and ELEVATION consists of the letter A or B combined with the number of the position of the vertical line above the centimetre scale.

Do not expose this cushion to a hot air blower and make sure that no sharp objects can come into contact with this cushion.

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 $+10^{\circ}$ 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/m³

Coating: > 1 g/cm³

Dimensions: L 636 mm x W 540 mm x H 60 mm

Weight: 0,62 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 mmH_2O) 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 mmH $_2$ O equiv. and each layer of coating that is passed will add another 0.35 mmH $_2$ O equiv. to the total. The total can thus be calculated using the following formula:

$mmH_2O = (L \times 0.02) + (n \times 0.35)$, 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 6MVand 15MV per cm of material through which the beam passes is:

Attenuation (± 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

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 Orfit Cleaning Guidelines. 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 www.orfit.com.

Note:

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