INSTRUCTIONS FOR USE

AIO SOLUTION®
ACCESSORIES
VACUUM BAG CUSHIONS

A. GENERAL PRODUCT INFORMATION

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

B. PRODUCT DESCRIPTION

These Vacuum Bags have been designed specifically to be used on Orfit base plates (AIO Solution and Raycast types) as a patient positioning aid. The combination of a high quality fabric filled with polystyrene spheres ensures a highly conformal, patient-specific mould. After evacuating the air from these bags they form a stable and patient-specific support mattress. Together with the thermoplastic masks from Orfit Industries they form a highly stable and reproducible patient positioning and immobilization system.

C. PRECAUTIONS FOR USE

C.1. General handling

The Vacuum Bags are completely airtight bags with a valve and a vacuum tube attached to it. Air can be evacuated from the bag (or blown into it) by use of a vacuum pump attached to this vacuum tube. This can be done with an appropriate vacuum hose connector (normally supplied with the pump). With a standard, small vacuum pump it will take around 1.5 minutes to evacuate the air from the small individual head support. This ensures that the vacuum is sufficient to give the vacuum bag a stable shape during at least six weeks.

The larger bags (#18056 and #18057) need to be put under vacuum for minimum 3 minutes to keep the desired shape during six weeks.

Once the air has been evacuated from the bag, the bag is closed with the clamp attached to the vacuum tube and the black sealing pin is inserted in the vacuum tube (see next page).
Never leave the bag unattended when evacuating the air from it. Do not step on the vacuum bag or do not throw it as this may damage the vacuum bag. Never use the vacuum tube to lift or reposition the vacuum bag.

Test the air tightness of the bag before the first use. Evacuate all the air out of the bag and leave it to harden overnight. If the bag is still hard the next morning, you can start using it.

C.2. Individual Head Support (#18055)
The Individual Head Support is designed for use in combination with one of the standard HP head supports. It should be positioned on the head support as shown below.

This ensures that the vacuum bag follows the contours of the head support, which results in a highly reproducible position for each fraction. It also ensures that the patient’s neck region is well supported. The final result is a highly accurate and patient dependant head and neck support.

C.3. AIO Vacuum Bags (#18056 & #18057)
The larger size vacuum bags are used as body support cushions on the AIO Solution or on other Raycast base plates. Indexing a vacuum bag to a base plate is done by means of an indexing bar (#18059) that is inserted into the base plates. Please refer to the “Instructions for Use” of this indexing bar.

D. STORAGE
Always store products in a safe place to prevent them from damage. Store products in such a way that they cannot fall or bump against anything. Especially, contact with sharp edges or objects must be avoided as they may destroy the fabric of the vacuum bags.

Once evacuated, the vacuum bags should be stored on a flat surface with their bottom side down. Do not stack the evacuated vacuum bags on top of each other.

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

E. PROPERTIES

E.1 Material Properties
The vacuum bags are made of Nylon and Polystyrene beads.

E.2 Dosimetric Properties
The attenuation at 6 MV and 15V is measured when the vacuum bag is deflated for the following thicknesses:

<table>
<thead>
<tr>
<th>Thickness</th>
<th>6 MV (± 0.15 %)</th>
<th>15 MV (± 0.15 %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mm</td>
<td>0.20 %</td>
<td>0.30 %</td>
</tr>
<tr>
<td>100 mm</td>
<td>2.90 %</td>
<td>2.10 %</td>
</tr>
</tbody>
</table>

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 soapy water or an isopropanol based disinfectant (alcohol content should not overpass 70%), applied with a soft cloth. If unsure about the cleaning fluid, do not use. Never use aerosol sprays, corrosive cleaning agents, bleach, 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 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.

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.

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