




VACUUM BAG CUSHIONS

<p>Article No. : 18208</p> <p>Vacuum Bag Individual Head Support (200 x 450 mm / 0.9 litres)</p>	
<p>Article No. : 18209</p> <p>AIO Vacuum Bag Half Body – Adult (480 x 900 mm / 16 litres)</p>	
<p>Article No. : 18210</p> <p>AIO Vacuum Bag Full Body – Paediatric (340 x 1240 mm / 16 litres)</p>	
<p>Article No. : 18200</p>	<p>Vacuum Bag (700 x 1825 mm / 50 litres)</p>
<p>Article No. : 18200/INDEX</p>	<p>Vacuum Bag (700 x 1825 mm / 50 litres) - Indexed</p>
<p>Article No. : 18201</p>	<p>Vacuum Bag (1130 x 1375 mm / 51 litres / T-shape)</p>
<p>Article No. : 18201/INDEX</p>	<p>Vacuum Bag (1130 x 1375 mm / 51 litres / T-shape) - Indexed</p>
<p>Article No. : 18202</p>	<p>Vacuum Bag (850 x 1825 mm / 75 litres)</p>
<p>Article No. : 18202/INDEX</p>	<p>Vacuum Bag (850 x 1825 mm / 75 litres) - Indexed</p>
<p>Article No. : 18203</p>	<p>Vacuum Bag (900 x 2325 mm / 117 litres)</p>
<p>Article No. : 18203/INDEX</p>	<p>Vacuum Bag (900 x 2325 mm / 117 litres) - Indexed</p>
<p>Article No. : 18204</p>	<p>Vacuum Bag (700 x 1625 mm / 45 litres)</p>
<p>Article No. : 18204/INDEX</p>	<p>Vacuum Bag (700 x 1625 mm / 45 litres) - Indexed</p>
<p>Article No. : 18205</p>	<p>Vacuum Bag (750 x 1025 mm / 35 litres)</p>
<p>Article No. : 18205/INDEX</p>	<p>Vacuum Bag (750 x 1025 mm / 35 litres) - Indexed</p>
<p>Article No. : 18206</p>	<p>Vacuum Bag (700 x 1625 mm / 58 litres)</p>
<p>Article No. : 18206/INDEX</p>	<p>Vacuum Bag (700 x 1625 mm / 58 litres) - Indexed</p>
<p>Article No. : 18207</p>	<p>Vacuum Bag (850 x 1540 mm / 53 litres)</p>
<p>Article No. : 18207/INDEX</p>	<p>Vacuum Bag (850 x 1540 mm / 53 litres) - Indexed</p>
<p>Article No. : 18211</p>	<p>Vacuum Bag (595 x 600 mm / 7 litres / T-shape HNS)</p>
<p>Article No. : 18212</p>	<p>Vacuum Bag (700 x 1000 mm / 30 litres)</p>

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, 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

The vacuum bag cushions have been designed to comfortably position and immobilise patients in a customized way. The combination of high quality fabrics filled with polystyrene spheres ensures a highly conformal, patient-specific mould. After evacuating the air from the bags, they form a stable and patient-specific support mattress.

Vacuum bags cushions 18208, 18209 and 18210 have been designed specifically to be used on Orfit base plates (AIO Solution and Raycast types) as a patient positioning aid. Together with the thermoplastic masks from Orfit they form a highly stable and reproducible patient positioning and immobilisation system. More information on these parts can be found in the respective 'Instructions for Use' or on www.orfit.com.

Other sizes are available with or without indexing laths. These indexing laths allow indexing the vacuum bags directly on the couch with the help of a 2-pin indexing bar.

C. PRECAUTIONS FOR USE

C.1. General handling

The vacuum bag consist out of 2 fabrics. The orange fabric should be facing downwards resting on the table. It is an anti-slip fabric that will help limit movement of the vacuum bag on the table.

The vacuum bags are completely airtight bags with a valve and a vacuum tube attached to it. The valve can easily be opened with one hand due to its small size and is permeable to X-rays and MRI.

Air can be evacuated from the bag (or blown into it) by use of a vacuum pump attached to the vacuum tube. This can be done with an appropriate vacuum hose connector (supplied with the pump).

With a standard, small vacuum pump it will take 1.5 minutes to evacuate the air from the small individual head support vacuum bags (Art. No. 18208). This ensures that the vacuum is sufficient to give the vacuum bag a stable shape during at least six weeks. All other vacuum bags need to be put under vacuum for minimum 3 minutes to keep the desired shape during six weeks. With longer storage times, the status of the vacuum cushion should be checked regularly. The use of a normal vacuum pump (Art. No. 18058) is sufficient for the smaller size vacuum bags (Art. Nos. 18208, 18209 and 18210). All other sizes require the use of a high capacity vacuum pump (Art. No. 18076).

Once the air has been evacuated from the bag, the bag is closed by closing the valve attached to the vacuum tube. The valve consists of an anterior and posterior part that are connected with a safety latch (figure 1). The valve is closed by pushing the grey button so the anterior and posterior part are partly disconnected (figure 2). To open the valve, push the anterior part backwards so both parts are connected again (figure 3).

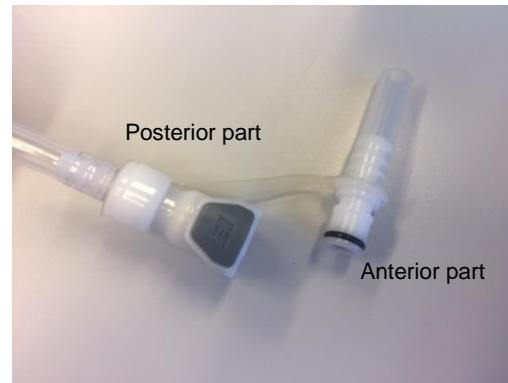


Figure 1



Figure 2 – Valve closed



Figure 3 – Valve open

Do not use any cloth or similar between the couch and the vacuum bag cushion. 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. Avoid all contact with sharp objects. 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 Vacuum Bag (Art. No. 18208)

The Individual Head Support Vacuum Bag 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 nicely 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 personalised head and neck support.



The AIO Vacuum Bags can also be indexed directly on the couch top by means of an indexing bar (Art. No. 18059) and a 2-pin indexing bar. Always use 2 indexing bars per vacuum bag.



C.3. AIO Vacuum Bags (Art. Nos. 18209 & 18210)

The AIO 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 (Art. No. 18059) that is inserted into the base plates. More information can be found in the respective 'Instructions for Use' or on www.orfit.com.



C.3. Larger Size Vacuum Bags (Art. Nos. 18200(/INDEX) – 18207(/INDEX))

The Larger Size Vacuum Bags are used as body support cushions. The vacuum bags are available with (/INDEX) or without indexing laths. The indexing laths allow to index the vacuum bags on the couch by means of 2-pin indexing bars. The vacuum bags without indexing laths can be indexed on the couch top by means of an indexing bar (Art. No. 18059) and a 2-pin indexing bar. Always use 2 indexing bars per vacuum bag. Only for Art. Nos. 18203 and 18203/INDEX 3 indexing bars or 3 2-pin bars respectively are required.



The AIO Vacuum Bags are more narrow than the larger size vacuum bags or other conventional vacuum bags. This ensures a much more intimate contouring to the patient's anatomy and allows the use of extracranial masks when the vacuum bag is used on the AIO solution base plate or on other Raycast base plates.

D. PROPERTIES

D.1. Material Properties

The orange fabric is made of TPU ether film 300 µm and the grey fabric is made of TPU ether laminated nylon. The bags are filled with polystyrene spheres of low flammability.

The bags are completely radio-translucent and don't create artefacts on the images. The bags are also made entirely of electrically non-conductive, non-metallic and non-magnetic materials and are MRI safe.



D.2. Dosimetric Properties

The attenuation and water equivalence at 6MV and 15MV was measured when the vacuum bag was deflated. Measurements were performed for thicknesses of 10 mm and 100 mm.

	Attenuation Factor ($\pm 0.15\%$)	
10 mm thickness	6 MV	0.2%
	15 MV	0.2 %
100 mm thickness	6 MV	3.2 %
	15 MV	2.0 %

	H ₂ O Equivalence (mm)	
10 mm thickness	6 MV	0.62 mm
	15 MV	0.58 mm
100 mm thickness	6 MV	9.44 mm
	15 MV	8.73 mm

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

E. STORAGE

Always store the products in a safe place to prevent them from getting damaged. Store the 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. The vacuum bags can be stored using

the hole to hang them on a hook. When not used, the vacuum bags should be evacuated and stored on a flat surface with their bottom side (orange fabric) down. Do not stack the evacuated vacuum bags on top of each other.

When not used, store the vacuum deflated or under a mild vacuum. This will increase the lifespan of the vacuum bags. Store the devices between +10°C (50°F) and 40°C (122°F).

F. MAINTENANCE AND WASTE MANAGEMENT

These products 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 (acetone or similar), solvents or abrasive detergents since these may damage the surface irreparably. Do not soak the products.** 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. Repair kits for both the orange and grey fabric are available. 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. ORFIT is a registered trademark of ORFIT Industries



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