

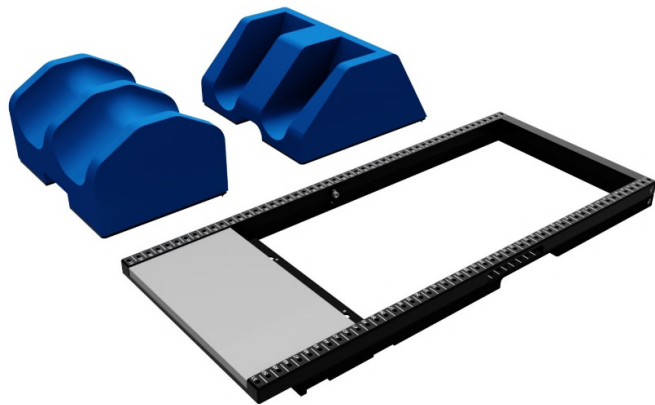


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THE AIO SOLUTION® ACCESSORIES AIO INDEXABLE KNEE & FOOT FRAME

INSTRUCTIONS FOR USE

Article No. :
29054



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

The AIO INDEXABLE KNEE AND FOOT FRAME is used to index a knee and foot cushion (29054/3 and 29054/4). It can be combined with the AIO BASE PLATE (32301), with the BLUE or GREEN AIO CUSHION SET, as a stand-alone product on the couch top or with an SBRT COMPRESSION BELT (32317/9) to create a complete SBRT system. Combined with these products, the indexation frame forms a reproducible patient positioning and immobilization system. Information on these other parts can be found in the respective 'Instructions for use', which can be found on our website.

The system consists of two frames: the Top frame and the Bottom frame. The combination of the two frames is only used together with the AIO cushions. In other product combinations, only the bottom frame is used. The system also contains a knee (29054/3) and foot cushion (29054/4).

C. USE

The bottom frame can be fixed onto the couch with a 2-pin bar. Two positions, A and B, can be used to make sure that the frame is positioned right behind the AIO BASE PLATE (Figure 1).

The top and bottom frame are attached to each other by locking it with a clamp, one on each side of the frames (Figure 2).

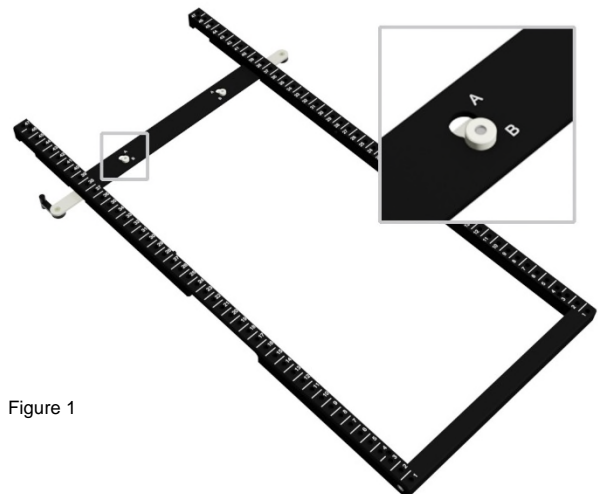


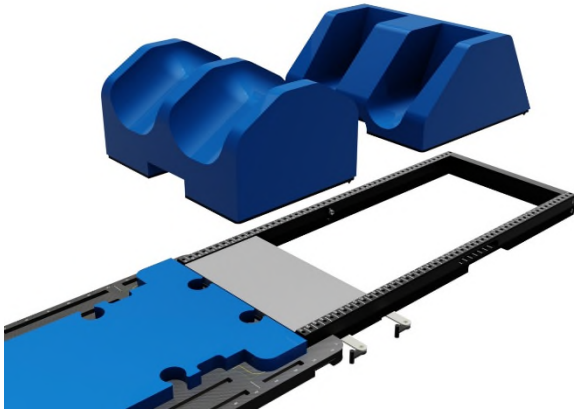
Figure 1



Figure 2

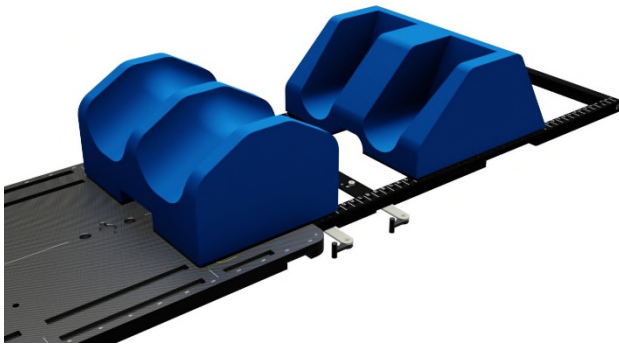
C.1. Set-up with the AIO cushions

If the system is used in combination with AIO BASE PLATE and AIO CUSHIONS, the top frame has to be used to make sure the KNEE & FOOT CUSHIONS are at the correct height. The top frame, that holds the knee & foot cushion, indexes on the bottom frame.



C.2. Set-up without the AIO cushions

If the system is used without AIO BASE PLATE or with an AIO BASE PLATE but without AIO CUSHIONS only the bottom frame is used. In this case the KNEE AND FOOT CUSHIONS index directly to the bottom frame.



Both the knee and foot cushion have 2 pins at the bottom. These 2 pins fit into the holes of the indexation frame and make sure that the cushions are fixed onto the frame.

Always write down in the patient's file what the position of the cushions on the frame is, in order to have a reproducible position for every fraction.

Verify that the cushion is positioned straight on the frame, by looking at the indexing numbers on the left and right side of the frame. These numbers should be the same. If this is not the case, the cushion is twisted on the frame.

D. PARTS LIST

| Art. No. | Description |
|--------------|--|
| 29054 | AIO INDEXABLE KNEE AND FOOT FRAME |
| containing: | |
| 1 x 29054/1 | Bottom Frame |
| 1 x 29054/2 | Top Frame |
| 1 x 29054/3 | Knee Cushion |
| 1 x 29054/4 | Feet Cushion |
| 1 x 29053/4 | Small Knee Cushion |

E. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Store the product in such a way that it cannot fall or bump against anything. Never place the cushion under constant load or pressure.

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

F. PROPERTIES

F.1. Basic Physical Properties

The following physical properties apply to the complete indexation system:

Dimensions:

L 1020 mm x H 278 mm (with cushions) x W 440 mm

Weight: 12.50 kg

F.2. Mechanical Properties

The frames are made of POM, which keeps its dimensions overtime and under conditions of frequent use.

The cushions are made from polyether foam, with a polyurethane coating.

The screws are made of nylon.

G. MAINTENANCE AND WASTE MANAGEMENT

This product 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 product can be disposed of with household waste.

H. 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.

THE AIO SOLUTION® is a registered trademark of ORFIT Industries



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