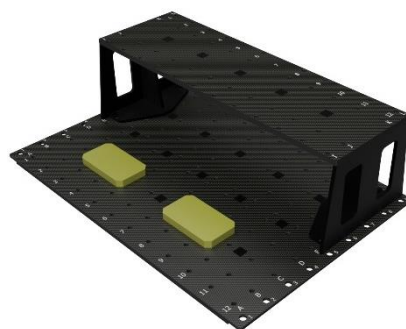


ORFIT® EXTREMITIES SOLUTION



Article No. : **32103**

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices used for patient positioning and immobilization (extremities) in radiation therapy. This product can be used during both the simulation and the treatment stage.

B. PRODUCT DESCRIPTION

The Orfit® Extremities Solution consists of a low density, carbon fibre base plate and leg support, which is designed for the immobilisation of the extremities, such as arms and legs.

The leg support can be attached to the base plate and is designed to lift up one leg of the patient. Thermoplastic Efficast® masks with push-pins are available to immobilise the foot, knee, elbow or hand of the patient. The push-pin masks can be attached on various places on the base plate as a result of the numerous holes in the base plate.

Two comfort cushions are attached to the base plate with Velcro to support the pressure points such as the heel or the palm of the hand of the patient.

The different set-ups for both the arms and legs are clarified in paragraph D.

Holes are provided on the cranial and caudal end of the base plate to position it on two 2-pin indexing bars and attach it to the couch. There is also a possibility to position the base plate out of centre, when using the exterior holes in the base plate. (Figure 1)

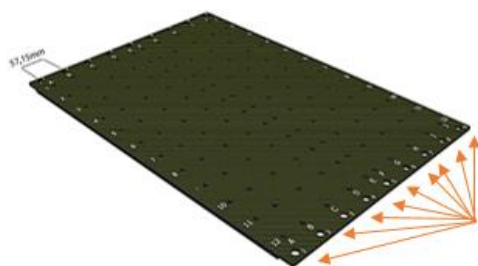


Figure 1

The leg support is positioned on the base plate with the white pins. If necessary the support can be attached to the base plate with push pins. (Figure 2)

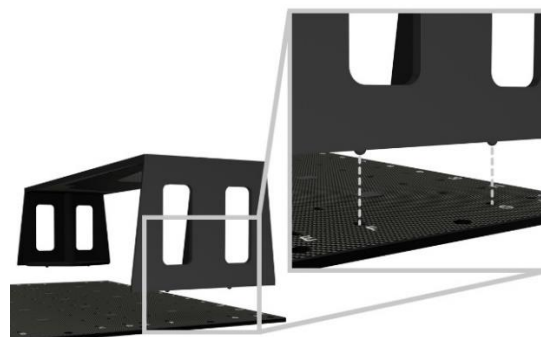


Figure 2

C. PARTS LIST

| ART. NO. | DESCRIPTION |
|--------------|-------------------------------------|
| 32103 | ORFIT® EXTREMITIES SOLUTION, |
| | consisting of: |
| 1 x 32103/1 | CFL Base Plate |
| 1 x 32103/3 | Leg Support |
| 2 x 32103/2 | Comfort cushion |

D. SET-UPS

D.1 Leg: Two legs flat on the table

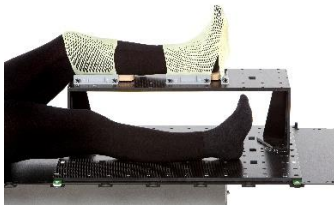
Both legs are positioned flat on the base plate and the leg to be treated is immobilised with thermoplastic masks, one over the knee and one over the foot.



Knee mask: #35793
Foot mask: # 35792

D.2 Leg: One leg lifted

One leg is positioned on the table and one leg is lifted up on the leg support. The raised leg can be the one that is being treated or the one that is not being treated. The goal is to position the contralateral leg outside of the treatment field. A thermoplastic mask is moulded over the knee and the foot of the limb that is being treated.



Knee mask: #35793
Foot mask: # 35792

D.3 Leg: One leg lifted and immobilisation of the pelvis

The patient is positioned on the AIO base plate and the legs are positioned on the Extremities Solution. A mask is moulded over the foot and over the pelvis to prevent rotation of the pelvis.



Foot mask: # 35792
Pelvis mask: #35787

D.4 Arm: Prone with the arm lifted above the head

The patient is positioned prone with the arm to be treated lifted above the head. A mask is moulded over the elbow and the hand. This is for treatment of the lower arm.



Elbow mask: # 35795
Hand mask: # 35794

D.5 Arm: Supine with the arm alongside the body

The patient is lying supine with the arm alongside the body. The base plate can be placed out of centre to have access to the holes to attach the thermoplastic mask over the elbow and hand. Both the upper arm, lower arm and shoulder can be treated.



Elbow mask: # 35795
Hand mask: # 35794

D.6 Arm: Seated with one arm on the table

The patient is sitting next to the table and the arm is positioned bended on the base plate. The elbow and hand are immobilised with a thermoplastic mask. The whole arm can be treated.



Elbow mask: # 35795
Hand mask: # 35794

D.7 Shoulder: Supine with the arm alongside the body

The patient is lying supine with the arm alongside the body. The base plate can be placed out of centre to have access to the holes to attach the thermoplastic mask over the shoulder. A left and right sided version of the 5 points shoulder mask are available.



Shoulder mask Right: # 35799/2MI/R
Shoulder mask Left: #35799/2MI/L

E. PRECAUTIONS FOR USE

This is a fragile product, please handle with care. Always place the base plate on a flat surface. Always fix the base plate securely to the treatment couch before positioning a patient. More information on how to fix this base plate to a couch top can be found on our website <http://www.orfit.com/en/fixation-devices/>. The CFL base plate and leg support are constructed to be light in weight. When handled roughly, it may get damaged and fibres may come off. When this happens, stop using the base plate to prevent fibres from getting in contact with the patient's or user's skin. Contact your distributor.

F. PROPERTIES

F.1. Physical Properties

Base plate

Dimensions: L 730 mm x W 500 mm
Thickness : 12 mm
Weight : 1,22 kg

Leg support

Dimensions: L 686 mm x W 220 mm x
H 200 mm
Thickness : 12 mm
Weight : 1,73 kg

F.2. Dosimetric Properties

The general attenuation factor ($\pm 0,15$ %) for the Base Plate and the Leg Support is as follows:

| | |
|---------------|--------------------------------|
| 6 Mv | 0.5 % |
| 15 Mv | 0.4 % |
| Skin build-up | 2.1 mm H ₂ O equiv. |

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

G. STORAGE

Always store the product in a safe place to prevent it from getting damaged. Take care not to damage the edges of the plate when storing it in an upright position. Prevent hard objects from falling onto the plate.

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

H. 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.

I. 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



ORFIT INDUSTRIES
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com

www.orfit.com



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