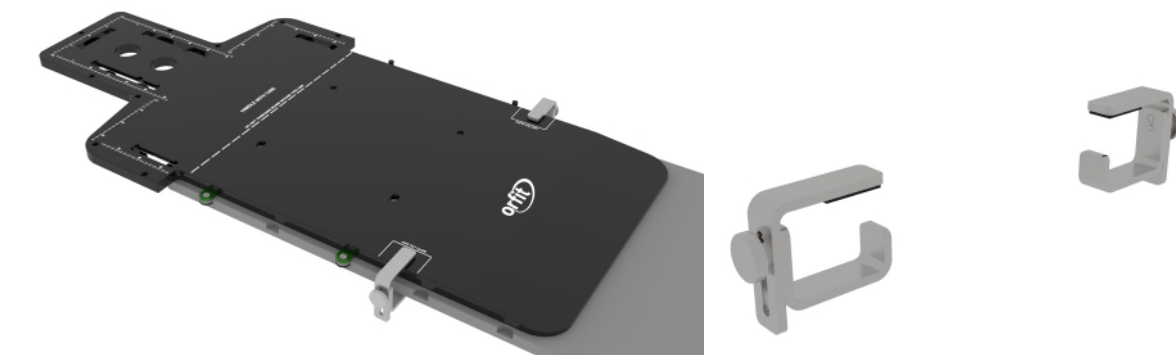


RAYCAST® INTEGRA™ HIGH PRECISION HEAD & NECK BOARD FOR EFFICAST® AND DUON® MASKS



Article Nos. : **INT-3**
INT-3/CL

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices used for patient positioning and immobilization (head & neck) in radiation therapy. This low density base plate can be used during both the simulation and the treatment stage.

This product may only be used in combination with immobilization masks produced by Orfit. Orfit prohibits the use of unauthorized third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

The Orfit Integra Head, Neck and Shoulder Immobilization System provides the immobilization and positioning system necessary to accurately set up and reproduce a patient's head, neck and shoulders position for simulation and treatment. The board is crafted from a core of high strength foam covered with a thin skin of carbon fiber. This makes it light weight, strong and radiographically transparent. It is used in combination with the RAYCAST HIGH PRECISION HEAD SUPPORTS and BLOCKS & WEDGES, and with the HP EFFICAST or DUON MASKS to form a reproducible patient positioning and immobilization device. The board is designed to fit the L-shaped profiles of the 3-points, 4-points and 5-points HP EFFICAST masks into the slots and to fit the DUON head and head, neck and shoulder masks into the pin holes. The L-shaped profiles of the HP EFFICAST masks are

fixed into the slots with the blue EVA handles as illustrated on the first image. The DUON mask is fixed by pushing the pins into the holes as illustrated on the second image.

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.

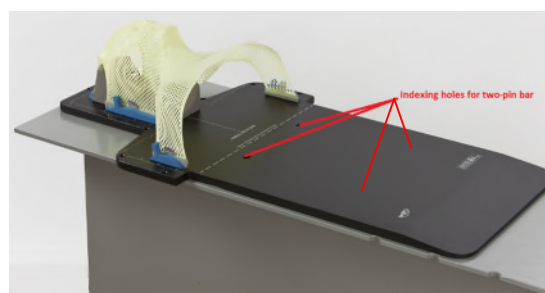


Figure 1

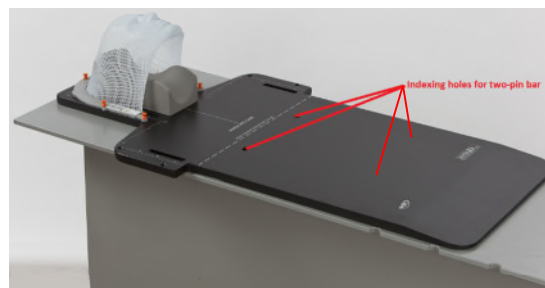


Figure 2

C. PARTS LIST

ART. NO.	DESCRIPTION
1 x INT-3 1 x INT-3/CL	INTEGRA HEAD & NECK BOARD CLAMP SET FOR INTEGRA HEAD & NECK BOARD INT-3
Containing:	
2 x INT-3/CL/1/3	Security clamp short, base
2 x INT-3/CL/1/1	Security clamp top
2 x INT-3/CL/2	Rosette thumb screw
2 x 32110/8	EVA HANDLE SET – SMALL
1 x 32110/9	EVA HANDLE SET – MEDIUM

D. FIXATION OF BASE PLATE TO THE TABLE

The base plate should always be attached to the table by using two fixation devices: two 2-pin indexing bars and the clamps INT-3/CL. The 2-pin indexing bars fit in the holes as shown in figure 1 and 2. The clamps should be used as explained below:

1. Attach the top clamp to the base clamp, by sliding the rod of the base clamp into the groove of the top clamp.

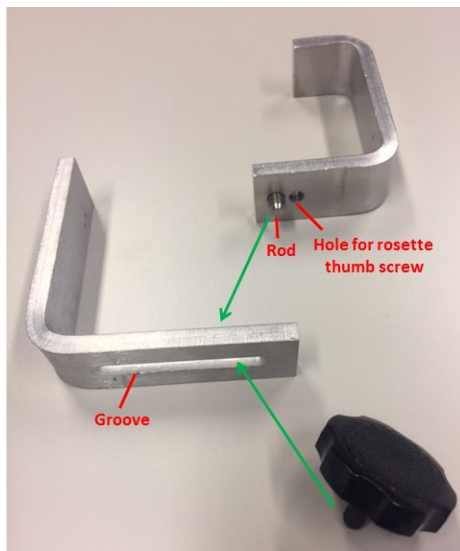


Figure 3

2. Use the rosette thumb screw to fix the top clamp to the base clamp.
3. Position the clamp over the base plate and table. The top clamp is positioned on top of the base plate and the base clamp is positioned underneath the table. Slide both clamps towards each other until they touch the table and base plate. Then close them by turning the rosette thumb screw until the clamps cannot be moved anymore.

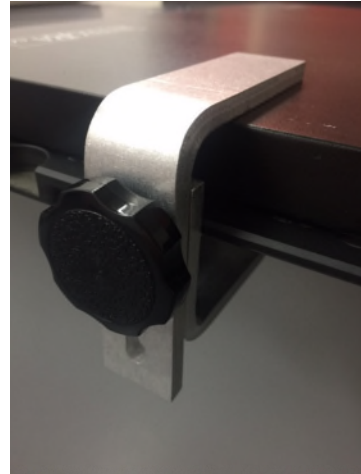


Figure 4

E. PRECAUTIONS FOR USE

This is a fragile product, please handle with care. Always place the base plate on a flat surface. Clear the couch of any debris before positioning the base plate. Fix the base plate securely to the treatment couch before positioning a patient. Use two 2-pin indexing bars and a pair of clamps (INT-3/CL) to attach the base plate to the couch. Section D explains the use of the clamps.

The head and shoulder part of the board can be used in overhang over the couch top up until the line where it is marked 'Do not overhang board behind this line'. **Always use the clamps INT-3/CL when using the board in overhang to prevent it from falling off the couch when the patient moves.**

The CFL base plate is constructed to be light in weight and to have superb dosimetric properties. When handled roughly, it may get damaged and fibers may come off. When this happens, stop using the base plate to prevent fibers from getting in contact with the patient's or user's skin. Periodic checks of the products should be done to insure the parts are not worn and require repair or replacement. **Do not attempt to make repairs yourself**, but contact your distributor if there are any questions or concerns.

A patient set-up form is available on the Orfit website.

F. STORAGE

Always store the product in a safe place to prevent it from getting damaged or falling onto other objects. 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).

G. PROPERTIES OF THE BASE PLATE

G.1. Physical Properties

Dimensions: L 121.9 cm x W 60.5 cm x H 2.16 cm
 L 48.0" x W 23.82" x H 0.85"
 Weight : 4.1 kg
 9.0 lb

G.2. Mechanical Properties

The maximum distributed patient load can be 181 kg/400 lb.

G.3. Dosimetric Properties

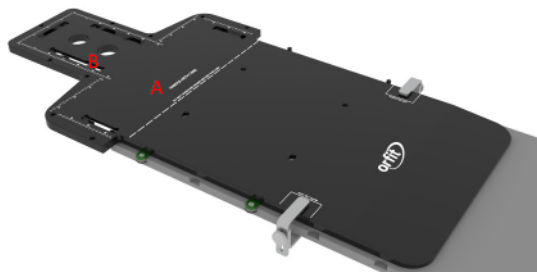


Figure 5

Note:

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Attenuation factor (± 0.15 %)	6MV	18MV
A	2.4 %	1.2 %
B	2.4 %	1.2 %

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

H. UNPACKING AND INSTALLATION

The head & neck base plate is designed to be ready for use following removal from its packing containers.

When the Integra system arrives, inspect all shipping containers for evidence of physical damage. If there are any dents, scratches, or other evidence of physical damage to the boxes, note the damage on the shipper's copy of the bill of lading and file a claim against the shipper.

In the case of shortages or malfunctions, notify your distributor immediately to arrange for replacement or repair. Save all packing containers and materials for the Integra System in case it needs to be returned to Orfit for replacement or repair.

I. 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.

J. 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.



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