HIGH PRECISION iBEAM® EVO HEAD (& NECK) EXTENSION BASIC MODULE

Article No. : **32132 & 32133**

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices used for patient positioning and immobilisation in radiation therapy. These products may only be used in combination with immobilisation masks produced by Orfit. Orfit prohibits the use of unauthorised third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

32132 – High Precision iBEAM® evo Head Extension

The High Precision iBEAM® evo Head Extension in Carbon Fibre Laminate (CFL) is suitable for use in combination with the range of Efficast® and Nanor® thermoplastic head & neck masks, Raycast® High Precision Head Supports, Blocks and Wedges to form a reproducible patient positioning and immobilisation device in the field of radiotherapy. 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.

Note: The High Precision iBEAM® evo Head Extension can only be used for cranial fields and is only compatible with 3-points immobilisation masks. The base plate doesn't allow the use of 5-points immobilisation masks.

32133 – High Precision iBEAM® evo Head & Neck Extension

The High Precision iBEAM® evo Head & Neck Extension in Carbon Fibre Laminate (CFL) is suitable for use in combination with the range of Efficast® and Nanor® thermoplastic head & neck masks, head, neck & shoulders masks, Raycast® High Precision Head Supports, Blocks and Wedges to form a reproducible patient positioning and immobilisation device in the field of radiotherapy. 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.

Note: The High Precision iBEAM® evo Head & Neck Extension can only be used for lower head & Neck fields (10cm caudal from the patient's skull).

The High Precision iBEAM® evo Head (& Neck) extensions attach to the end of the iBEAM® evo couchtop, Connexion™, HexaPOD™ evo RT Couchtop and iBEAM® evo CT Overaly as the base end of the boards mate precisely with the end piece of these couches.

C. PRECAUTIONS FOR USE

Always make sure the base plates are firmly attached to the iBEAM® evo couch before positioning a patient.

The maximum allowed load distributed evenly on both extensions is 40k g/ 88.18 lbs.

The CFL base plates are constructed to be light in weight and to have superb dosimetric properties. When handled roughly, they may get damaged and fibres may come off. When this happens, stop using the base plates to prevent fibres from getting into 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.

D. STORAGE

Always store the products in a safe place to prevent them from getting damaged or falling onto other objects. Take care not to damage the edges of the plates when storing them in an upright position. Prevent hard objects from falling onto the plates.

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

E. PROPERTIES

E.1. Physical Properties

32132 – High Precision iBEAM® evo Head Extension

Dimensions:	L 45.0 cm x W 53.0 cm x H 5 cm
	L 17.72" x W 20.87" x H 1.97"
Weight:	1.2 kg / 2.65 lbs

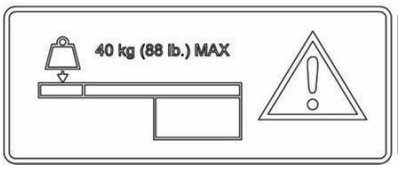
32133 – High Precision iBEAM® evo Head & Neck Extension

Dimensions: L 50.8 cm x W 55.5 cm x H 5.0 cm
L 20.00" x W 21.85" x H 1.97"

Weight: 1.5 kg / 3.31 lbs

E.2. Mechanical Properties

The maximum permissible patient load distributed evenly on the High Precision iBEAM® evo Head (& Neck) Extensions is 40 kg / 88 lb.



E.3. Dosimetric Properties

Following dosimetric properties apply to both extensions:

	6MV	15MV
Attenuation factor (± 0.15 %)	1.50 %	1.30 %

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

The couch top and the extensions contain internal components of solid carbon fibre in the area of the interface. During imaging and treatment this region has to be avoided. If the beam passes through structural materials such as this interface before entering the patient, this can cause unacceptable distortions of the intended dose distribution in the patient. Such distortions are not accounted for in the treatment planning system.

F. UNPACKING AND INSTALLATION

The High Precision iBEAM® evo head (& neck) extensions are designed to be ready for use following removal from their packing container.
When the systems arrive, 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 in case it needs to be returned to Orfit Industries for replacement or repair.

G. MAINTENANCE AND WASTE MANAGEMENT

These products 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 products 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 products 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.

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