ONEFIT™ Indexing Device

INSTRUCTIONS FOR USE (IFU)

CQ MEDICAL™

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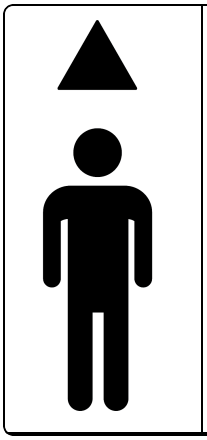


Patient Orientation Indicator

PARTS LIST	
2001717	Elekta Style Indexing Feature
2009508	Prodigy™ 2 Style Indexing Feature
2009509	Prodigy™ Style Indexing Feature
2009510	Varian Style Indexing Feature
3001199	Varian and Prodigy™ Style Screws
3002243	Elekta Style Screws

INTENDED USE

The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

⚠ WARNING

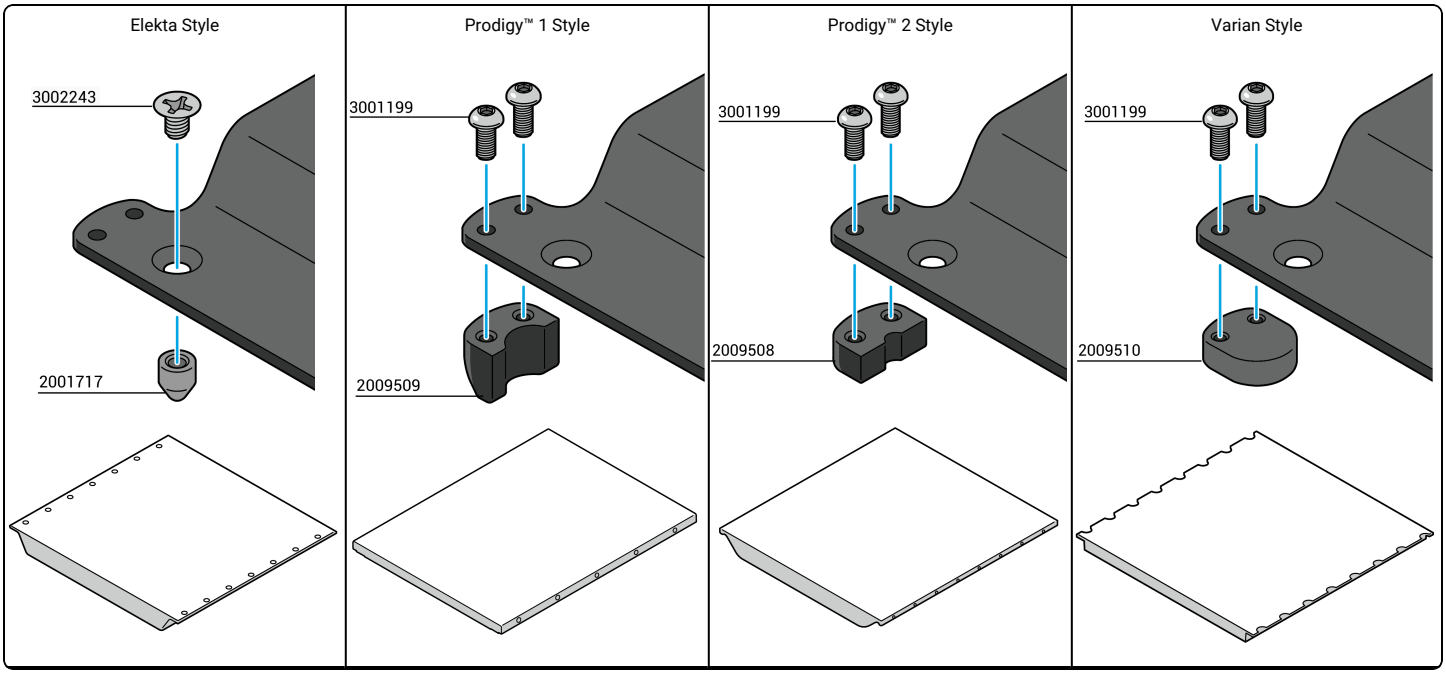
- *No modification of this equipment is allowed. If any part of this device experiences a catastrophic load, appears damaged or functions improperly, discontinue use immediately and contact CQ Medical at info@CQmedical.com.*
- *Only use CQ Medical compatible accessories.*
- *Do not allow patient to reposition themselves using accessories.*
- *Do not exceed safe working load of supporting couchtop, or 500 lbs (227 kg), whichever is less.*
- *Ensure device is fully supported.*
- *Simulation and treatment must be conducted on similar device.*
- *When positioning patient for first time, use setup sheet to record all adjustments. Setup sheet is available at www.CQmedical.com.*
- *Verify patient position with completed setup sheet prior to treatment.*
- *Verify all angles of treatment, attenuation characteristics and WET values prior to treating patients. Refer to Technical Data Sheet at www.CQmedical.com for WET values.*
- *Ensure hands, feet and other extremities are kept away from moving parts.*
- *Ensure device is secure prior to use.*
- *Ensure device orientation is correct prior to use.*
- *Do not transport device with accessories attached.*

NOTE: If any serious incident occurs in relation to device, incident should be reported to manufacturer. If incident occurred within the European Union, also report to the competent authority of the Member State in which you are established.

INSTALLING INDEXING FEATURES

NOTE:
- Device comes with Varian indexing features installed.
- Ensure indexing feature orientation matches illustration.

1. To change indexing features, remove installed indexing features. Assemble appropriate new indexing features.



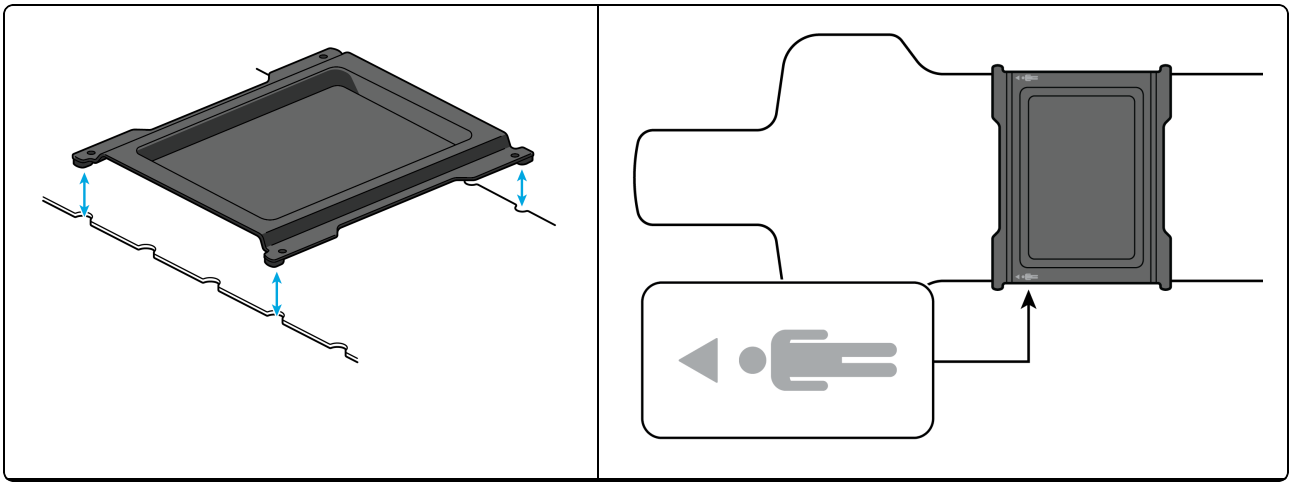
2. Tighten screws until indexing features are securely attached.

⚠ WARNING

- *Do not overtighten.*

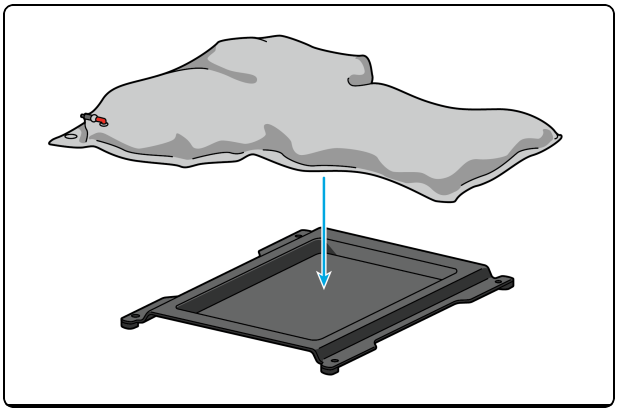
USING ONEFIT™

1. Place ONEFIT™ on couchtop.



NOTE: Ensure patient orientation indicator points towards gantry.

2. Dock desired accessories *(refer to accessory instructions)*.



NOTE: Always use vacuum cushion with device.

REPROCESSING

⚠ WARNING

- *Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.*

1. If necessary, clean surface by removing visual contamination with 70% alcohol or Theracide (Super-Sani-Wipes) wipes. If visual contamination cannot be removed, repeat cleaning steps and if necessary, discard device.

MAINTENANCE

NOTE: Inspect device prior to use for signs of damage and general wear.

EC REP

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