CLEARPOINT® IMRIS TABLE STABILIZER

INSTRUCTIONS FOR USE

Table of Contents

1. Intended Use

The ClearPoint® IMRIS Stabilizer is intended to provide stability to the IMRIS surgical table while it is inside the scanner bore.

2. Device Description

Package Contents:

CP-STB-210-01   *ClearPoint IMRIS Table Stabilizer*

Associated Devices:

CP-ITE-01   *ClearPoint IMRIS ORT 200 Table Extension*
CP-ITE-02   *ClearPoint IMRIS ORT 400 Table Extension*
CP-MPHFF-232-01   *ClearPoint Multi-Positional HFF for IMRIS – Universal*
CP-INHFF-232-01   *ClearPoint Inflexion IMRIS Universal HFF*

3. General Warnings and Precautions

Warning: Do not autoclave the Stabilizer.

Warning: Do not approach the IMRIS surgical table or the scanner while the scanner is in motion. Serious injury could occur.

Warning: Do not reach into the scanner bore to make adjustments while the scanner is moving.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Caution: Prior to the procedure, it is necessary to confirm that the horizontal ISO center of the scanner is in line with the horizontal ISO center of the Head Fixation Frame. This is necessary because the surgical table can be adjusted vertically so its location at any given time is not necessarily known. ISO centering the equipment provides the most accurate scans for the procedure.

Caution: The Stabilizer must be separated from the surgical table / Head Fixation Frame prior to moving the scanner away from the table to prevent damage to the scanner, surgical table, head coil, etc.

Note: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and appropriate Competent Authority of the Member State in which the incident occurred.

1.5T & 3T MRI Compatibility:

Testing has demonstrated the ClearPoint® IMRIS Table Stabilizer is **MR Safe**. It can be scanned safely under a static magnetic field of 1.5 or 3 Tesla.

4. Use Instructions

4.1. Installation of Stabilizer Prior to Procedure

Note: The following shall be performed in the scanner / magnet prior to draping. The Head Fixation Frame shall be installed per the respective HFF instructions for use prior to installation of the Stabilizer.

Caution: Only non-magnetic materials may be used near the scanner.

Caution: Prior to the procedure, it is necessary to confirm that the horizontal ISO center of the scanner is in line with the horizontal ISO center of the Head Fixation Frame.

The Stabilizer is intended for multiple uses and is provided non-sterile. It should be cleaned and disinfected (e.g., using disinfectant wipes) before initial use and after each use. Dry the Stabilizer with a lint free towel or equivalent. Examine the parts when cleaning to look for wear. Also, check that there is no unexpected movement in the system.

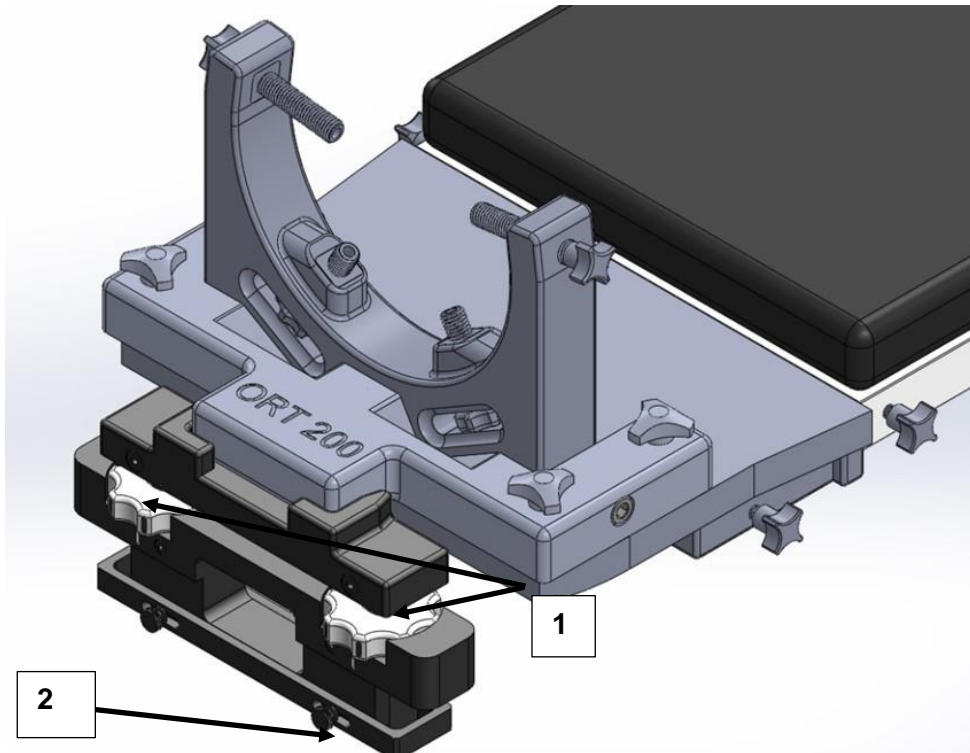4.1.1. Alternately, the assembly can be placed into a sterile bag.

Caution: Do not autoclave the Stabilizer.

4.1.2. Move the scanner over the surgical table until the table is fully inside the scanner.

4.1.3. Sufficiently loosen the 4 screws that hold the adjustment slider on the bottom of the Stabilizer so that the slider moves freely.

4.1.4. Slide the Stabilizer into the MRI bore until the Head Fixation Frame is fully engaged with the Stabilizer. This may require moving the Stabilizer to the left or right to correct for misalignment between the scanner and the surgical table.

4.1.5. Tighten the adjustment slider to the Stabilizer by hand using the 2 screws on the front of the adjustment slider. The Stabilizer may be removed to tighten the two screws on the back of the Stabilizer.

4.1.6. The scanner can be draped at this time.

Figure 1: Stabilizer Attached to HFF (Fixed HFF shown)

1	Turn white knobs to left (clockwise) to raise and support surgical table
2	Adjustment slider.

4.2. During Procedure - Placing the Stabilizer in the Scanner

Caution: The following shall be performed after the first part of the surgical procedure has been performed and the patient has returned into the scanner for re-scanning and confirmation of target location(s).

Caution: Do not damage the sterile barrier by damaging the integrity of the bore drape and/or patient drapes while performing the following steps.

4.2.1. Turn the two white knobs to the right (counterclockwise) to lower the top mating support and provide clearance from the table and sterile drapes.

4.2.2. Place the Stabilizer between the surgical table and the scanner bore. Insert the Stabilizer until the top of the Stabilizer has fully engaged with the Head Fixation Frame on the Table Extension / Head Fixation Frame.

4.2.3. Slowly rotate the large white knobs to the left (clockwise) until resistance is felt on both sides. Additional upward adjustment is possible but is not required and may move the table and Head Fixation Frame out of ISO center.

Caution: In the event that the patient must be removed from the scanner prior to the completion of the procedure, lift the end of the Head Fixation Frame and remove the Stabilizer. Reverse the process after the patient is brought back into the scanner.
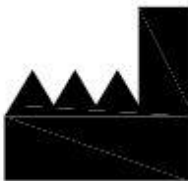
Warning: Upon returning the patient to the scanner, it is necessary to re-acquire and confirm the target(s). Re-location of the Stabilizer between the drapes may cause changes in the Head Fixation Frame location and may impact the accuracy of the procedure.

4.3. **Post Procedure - Removing the Stabilizer from the Scanner and Storage**
Warning: The Stabilizer MUST be lowered or the end of the surgical table manually lifted (using the Head Fixation Frame), and the Stabilizer must be moved prior to any movement between the scanner and the surgical table. Attempting to move the scanner with the Stabilizer in place could result in damage to the scanner, damage to the surgical table, damage to the surgical draping, and/or damage to the Stabilizer.

4.3.1. Rotate the white knobs to the right (counter-clockwise) so that there is sufficient room to move the Stabilizer without damage to the sterile drapes, scanner, or surgical table.

4.3.2. Carefully remove the Stabilizer.

4.3.3. Notify the technician / physician that the Stabilizer has been removed and that the scanner can be retracted.

4.3.4. Disinfect the Stabilizer prior to storage. The Stabilizer is intended for multiple uses and is provided non-sterile. It should be cleaned and disinfected (e.g., using disinfectant wipes) before initial use and after each use. Dry the Stabilizer with a lint free towel or equivalent. Examine the parts when cleaning to look for wear. Also check that there is no unexpected movement in the system..

4.3.5. Re-assembly of the Stabilizer prior to storage is recommended to prevent loss of components.

4.3.6. If it is necessary to dispose of the Stabilizer, safely dispose of the Stabilizer per hospital policy.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
MR	MR Safe	**REF**	Catalogue number
LOT	Batch code	(umbrella with raindrops)	Keep dry
(factory with line graph)	Date of Manufacture	(sun over house)	Keep away from sunlight
(factory)	Manufacturer	(open book with i)	Consult instructions for use
NON STERILE	Non-sterile	**Rx Only** or **℞ Only**	Prescription Device
(do not use if package damaged)	Do not use if the product sterilization barrier or its packaging is compromised		

Manufactured by:

ClearPoint Neuro, Inc.
6349 Paseo Del Lago
Carlsbad, CA 92011
USA
949-900-6833