CLEARPOINT® IMRIS STABILIZER RAMP

INSTRUCTIONS FOR USE

CLEARPOINT
NEURO

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1. **Intended Use**

The ClearPoint® IMRIS Stabilizer Ramp is intended to provide stability to the IMRIS designed adjustable head fixation system and the surgical table while they are inside the scanner bore. The ramp works with all IMRIS surgical tables with the IMRIS HFD100 or HFD200 Head Fixation Devices installed.
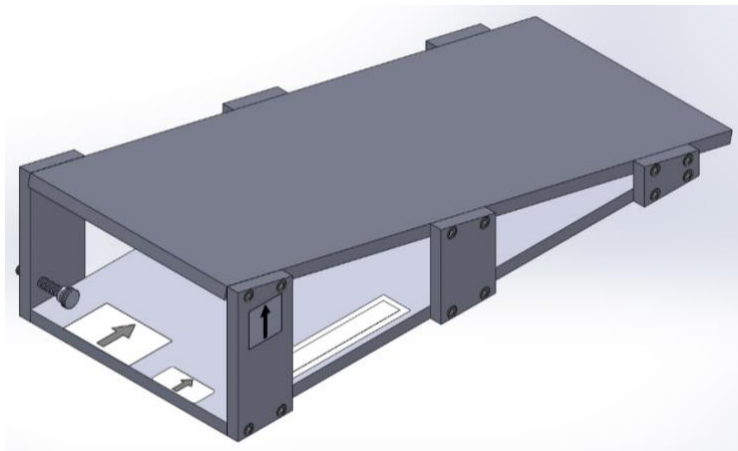
2. **Device Description**

Package Contents:

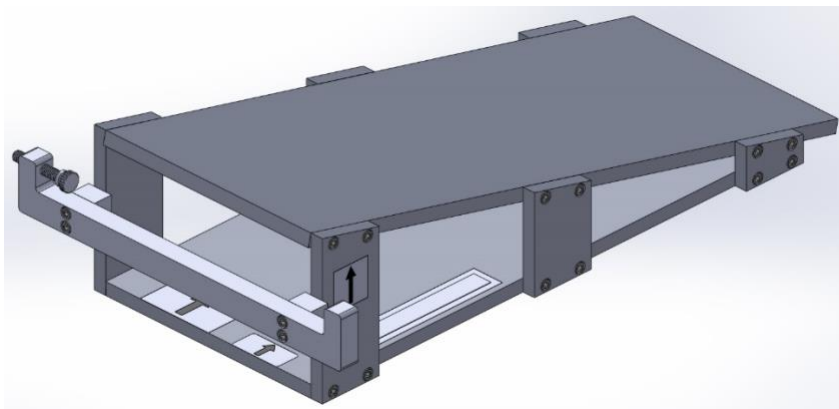CP-STB-211-01:   ClearPoint IMRIS Stabilizer Ramp (1)

Associated Devices:

IMRIS HFD 100 and HFD 200:   IMRIS Head Fixation Devices

Stabilizer Ramp for: Verio 1.5T and Trio 3T

Stabilizer Ramp for: Aera 1.5T and Skyra 3T

3. **General Warnings and Precautions**

Warning: Do not autoclave.

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 will provide the most accurate scans for the procedure.

Caution: The ramp will not return the patient to the same location in MR space (X-Y-Z) after the scanner has been moved away from the surgical table and brought back. Additional scans are required to determine the location of the surgical identifiers after replacing the patient in the scanner.

Caution: The ramp will not prevent the table from moving laterally if it is bumped, leaned on or otherwise moved sideways which may affect the location of the head in MR space (X-Y-Z). Additional scans are required to determine the location of the surgical identifiers after any such movement has occurred.

Caution: The Stabilizer Ramp must be separated from the surgical table 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.
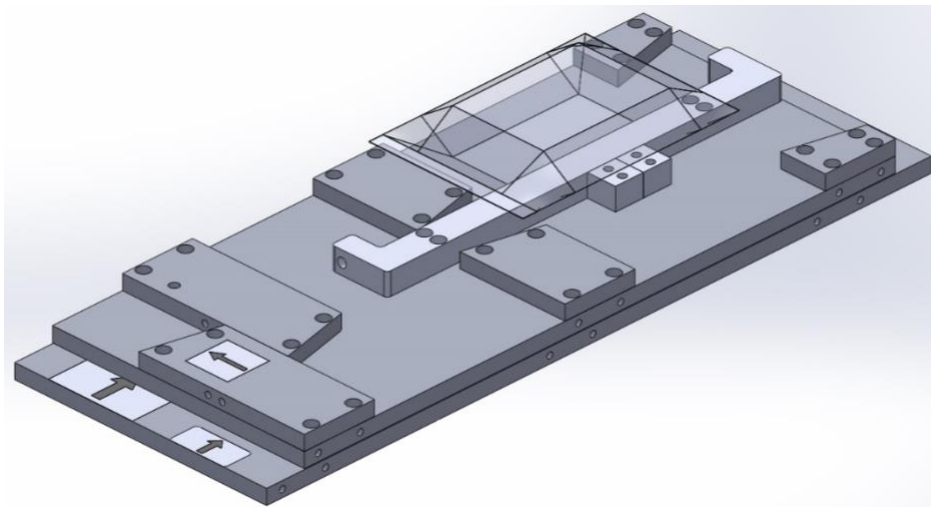
Note: Safe disposal of the device: The Stabilizer Ramp shall be disposed of per hospital policy

1.5T & 3T Environment Compatibility:

Non-clinical 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. **Initial Assembly**

Note: The Stabilizer Ramp is delivered disassembled to protect from damage during shipment.

Note: The Stabilizer Ramp can be used for four different types of IMRIS MRI Scanners based on the following Siemens scanners:
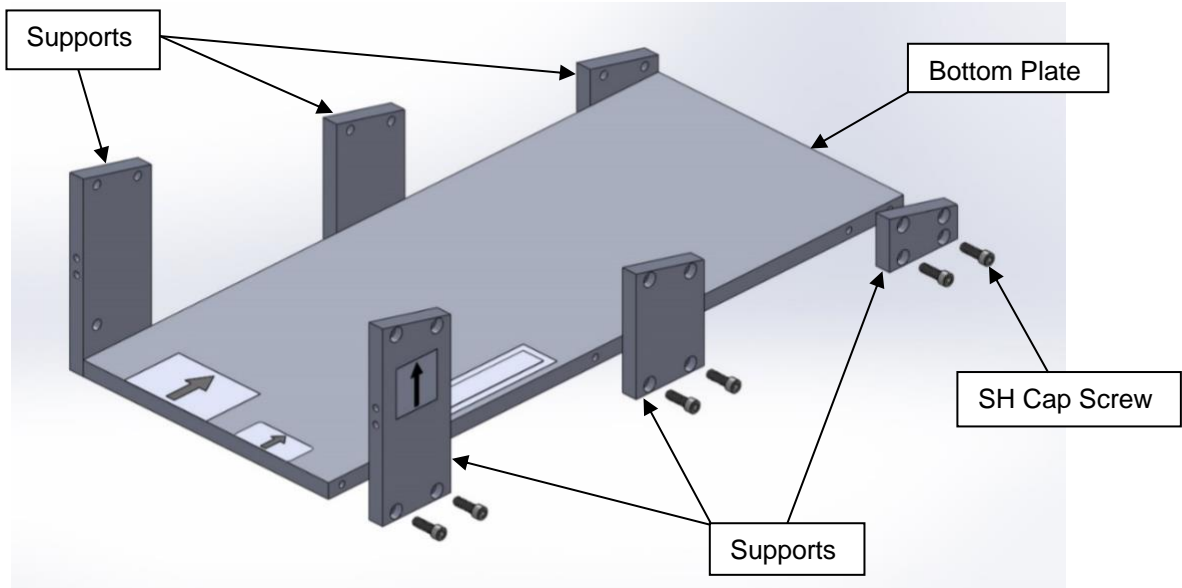
1. **Verio 1.5T and Trio 3T**
2. **Aera 1.5T and Skyra 3T**

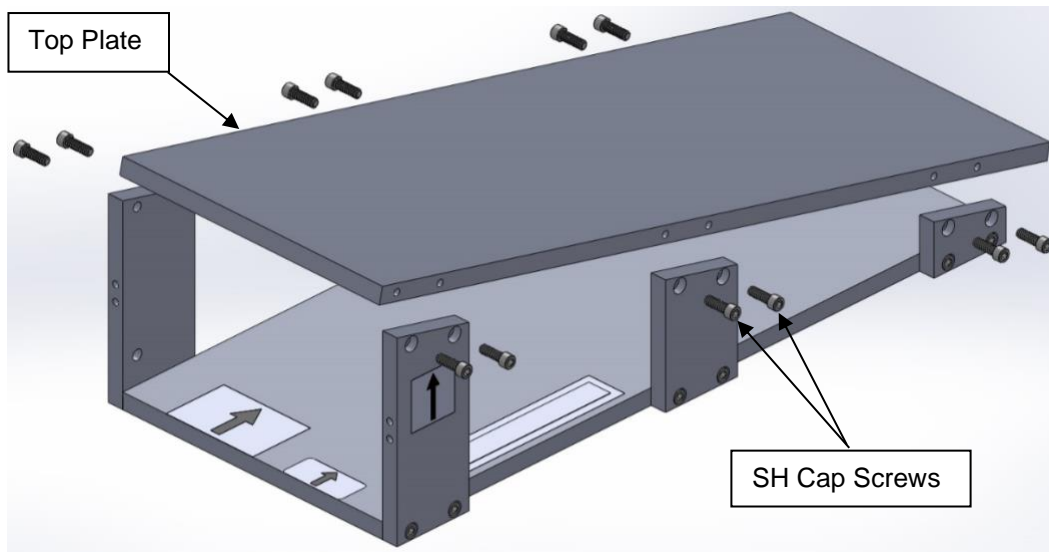**Assembly steps 4.1 thru 4.3 are required for Verio 1.5T and Trio 3T type Scanners.**

Assembly steps 4.1, 4.2, 4.4 and 4.5 are required for the Aera 1.5T and Skyra 3T type Scanners.

4.1. Attach the 6 ea Supports to the mounting holes on the side of the Bottom Plate using the provided Allen Wrench and SH Cap Screws.
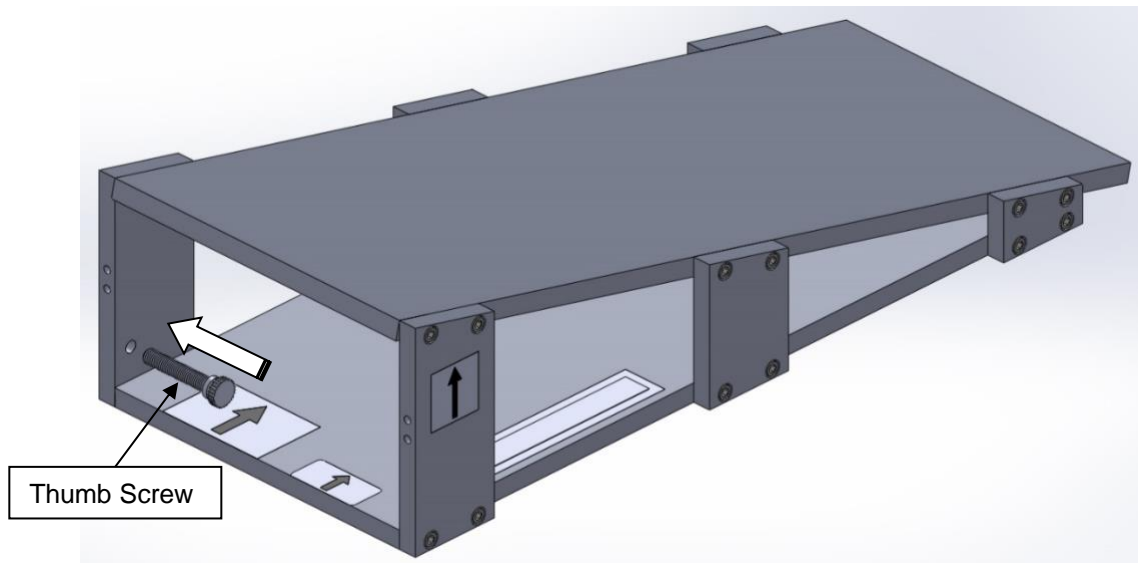
Note: The Supports have been placed next to their corresponding mounting holes.
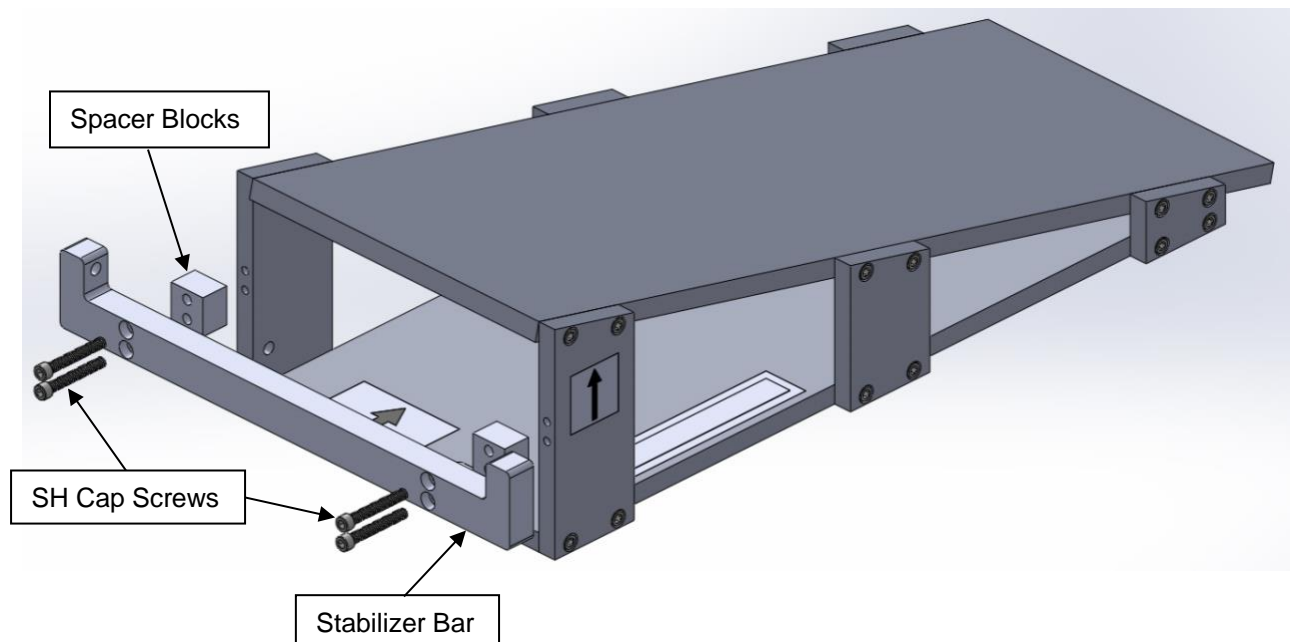

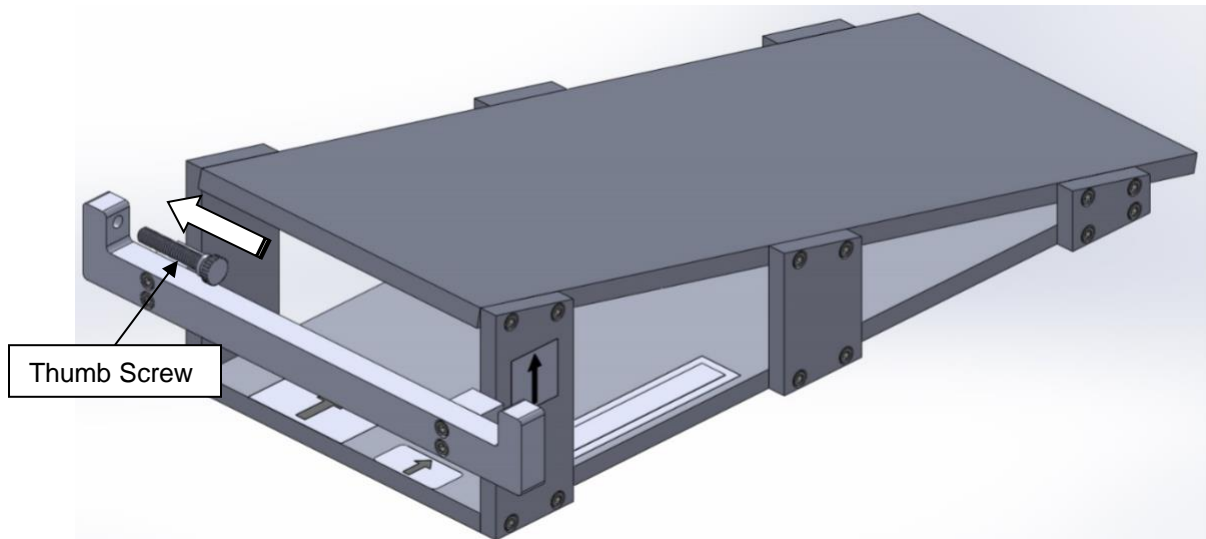4.2. Attach the Top Plate using the provided Allen Wrench and SH Cap Screws.

4.3. Insert the provided Thumb Screw in the direction indicated (Verio or Trio only).

Thumb Screw

4.4.   Attach the Stabilizer Bar and Spacer Blocks using the provided Allen Wrench and SH Cap Screws (Aera or Skyra only).

Spacer Blocks

SH Cap Screws

Stabilizer Bar

4.5.   Insert the provided Thumb Screw in the direction indicated.

Thumb Screw

5.   Use Instructions

Caution: The following to be performed away from the scanner/magnet.

5.1.   Stabilizer Ramp Preparation

5.1.1.   Terminally clean the ramp with suitable wipes**.** The assembly should be disinfected / sterilized using liquid disinfectants per hospital policy.

Caution: Do not autoclave

5.1.2.   Place the ramp inside a sterile bag / pouch and maintain on a sterile surface in preparation for use.

5.2.   Pre-procedure (prior to draping).

Note: The following to be performed in the scanner / magnet

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.

5.3.   Procedure use. Placing the stabilizer in the scanner.

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

Photo of ramp prior to inserting under IMRIS adjustable fixation frame.

5.3.1.   Place the stabilizer ramp between the fixation frame and the scanner bore.

5.3.2.   Insert the stabilizer ramp until the top of the stabilizer has fully engaged the fixation frame and the surgical table is supported.

5.3.3.   Tighten the side screw on the stabilizer ramp to prevent the ramp from moving within the scanner bore.

Caution: In the event that the patient must be removed from the scanner prior to the completion of the procedure follow the removal instructions below. Reverse the process after the patient has been brought back into the scanner.
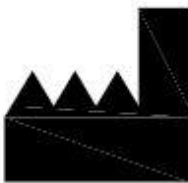
5.4.   **Post Procedure. Removing the stabilizer ramp from the scanner during or at the end of the procedure.**

Warning: The stabilizer ramp MUST be removed 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

- Damage to the Stabilizer Ramp

1.   Rotate the side screw so that there is sufficient room to move the Stabilizer Ramp without damage to the sterile drapes, scanner, or surgical table. Remove the Stabilizer Ramp carefully.

2.   Notify the technician / physician that the stabilizer has been removed and that the scanner can be retracted.

3.   Clean the Stabilizer prior to storage.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
MR	MR Safe	**REF**	Catalogue number
LOT	Batch code	☂	Keep dry
� (date)	Date of Manufacture	☀	Keep away from sunlight
�	Manufacturer	📖	Consult instructions for use
NON STERILE	Non-sterile	**Rx Only** or **℞ Only**	Prescription Device
⊘	Do not use if the product sterilization barrier or its packaging is compromised		

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