



PRODUCT GUIDE & USER MANUAL

RT-4600-03 SRS Adapter
RT-4600-03-MRI SRS MR Adapter
for Portrait™ and S-Type Devices



EC REP

Advena Limited
Tower Business Centre, 2nd Flr
Tower Street, Swatara, BKR 4013
Malta

Made in the USA by

Qfix
440 Church Rd,
Avondale, Pennsylvania, USA
+1 484-720-6053 www.Qfix.com

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! 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 QFIX AT +1 484-720-6053 OR TECH SUPPORT@QFIX.COM.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

TREATMENT BEAM ATTENUATION

Treatment through any device will lead to an increase in skin dose. Thermoplastic masks will attenuate a radiotherapy beam and increase skin dose. Attenuation and increased skin dose should be taken into account during planning and treatment

MRI SAFETY INFORMATION

MR SRS MR Adapter (RT-4600-03-MRI) is MR Safe.

- SRS MR Adapter device must be used with an MR Safe S-frame compatible device clearly labeled with the following symbol prior to MR scanning:



MR The Encompass™ Fibreplast® Masks are MR Safe.

MR The IntegraBite™ is MR Safe.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.



MR SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

! NOTE ! FOR RT-4600-03-MRI ONLY.

INTENDED USE

The SRS Adapter for Portrait and S-Type Devices provides noninvasive stereotactic head and neck immobilization by using a patient specific thermoplastic mask that conforms to the patient's features to provide accurate, reproducible positioning, repositioning, and immobilization. The SRS Adapter for Portrait and S-Type Devices allows the patient to undergo diagnostic imaging in the same position as that of the treatment position enabling more accurate radiation therapy.

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

Patient Target Groups

Patient's undergoing radiation therapy or diagnostic imaging procedures.

Intended Users

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

OPERATING INSTRUCTIONS

SET UP FOR PIN ATTACHMENTS

1. Place the SRS Adapter onto an S-frame compatible device as shown in Fig. 1 aligning the holes in the SRS Adapter to the holes in the S-frame compatible device (Fig. 1).
2. Refer to Fig. 1 for fixation locations—2 locations at the base and 1 location at the top of the head.
3. Press the pin downward until it snaps into place. Repeat with the 2 remaining pins.
4. Attach the S-frame compatible device to the Couch Top.

! NOTE ! Refer to the Instructions for Use for the S-frame compatible device for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the device.

5. Place the SRS Headrest into the SRS Adapter. The SRS Headrest may be adjusted by sliding backwards and forwards until desired position is reached (Fig. 3).
6. The device is ready for use.

! NOTE ! Refer to the Product Guide and User Manual for the Encompass SRS Immobilization System and the Encompass Fibreplast Variable Perf™ Open View Mask System (P/N 2005445) for mask creation, operating instructions, patient setup sheet, product features, specifications, warnings, cautions, and other general precautions related to the use of the Encompass and Encompass masks.

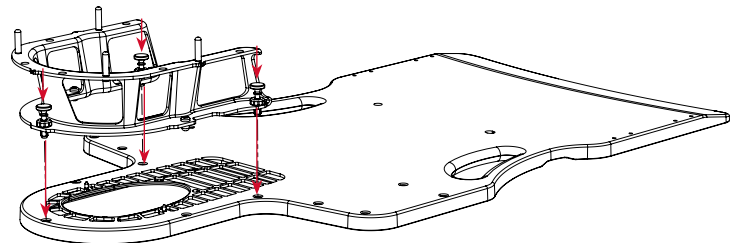


Fig. 1

Thermoplastic Mask Removal

Refer to the Product Guide and User Manual for the Encompass SRS Immobilization System and the Encompass Fibreplast Variable Perf Open View Mask System (P/N 2005445) for instructions for removing the thermoplastic mask.

Removal of the SRS Adapter with Pin Attachments

1. Remove the SRS Headrest from the SRS Adapter.
2. Remove the S-frame compatible device from the couch top.
3. Pull up on the pin until the pin releases from the S-frame compatible device. Repeat for each pin.
4. Remove the SRS Adapter from the S-frame compatible device.

SET UP FOR SCREW AND KNOB ATTACHMENTS

1. Place the SRS Adapter onto an S-frame compatible device as shown in Fig. 2 aligning the holes in the SRS Adapter to the holes in the S-frame compatible device (Fig. 2).
2. Refer to Fig. 2 for fixation locations—2 locations at the base and 1 location at the top of the head.
3. Place the knob above the hole on the SRS Adapter and hold firmly. Position the screw at the aligning hole on the underside of the S-frame compatible device. Using the Allen key (provided) twist the screw until tight (Fig. 2). Repeat with the 2 remaining screws and knobs.
4. Attach the S-frame compatible device to the Couch Top.

! NOTE ! Refer to the Instructions for Use for the S-frame compatible device for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the device.

5. Place the SRS Headrest into the SRS Adapter. The SRS Headrest may be adjusted by sliding backwards and forwards until desired position is reached (Fig. 3).
6. The device is ready for use.

! NOTE ! Refer to the Product Guide and User Manual for the Encompass SRS Immobilization System and the Encompass Fibreplast Variable Perf Open View Mask System (P/N 2005445) for mask creation, operating instructions, patient setup sheet, product features, specifications, warnings, cautions, and other general precautions related to the use of the Encompass and Encompass masks.

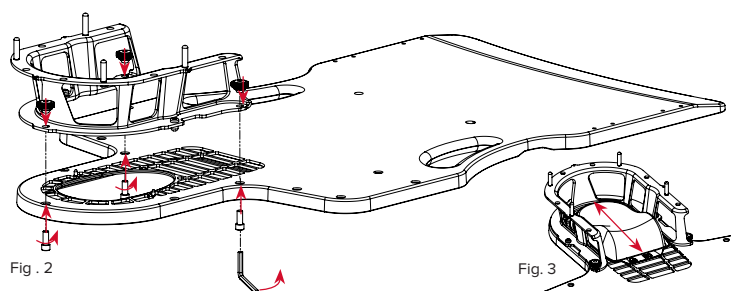


Fig. 2

Fig. 3

Thermoplastic Mask Removal

Refer to the Product Guide and User Manual for the Encompass SRS Immobilization System and the Encompass Fibreplast Variable Perf Open View Mask System (P/N 2005445) for instructions for removing the thermoplastic mask.

Removal of the SRS Adapter with Screw and Knob Attachments

1. Remove the SRS Headrest from the SRS Adapter.
 2. Remove the S-frame compatible device from the couch top.
- ! NOTE !** Refer to the Instructions for Use for the S-frame compatible device for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the device.
3. Using the Allen key, twist the screw clockwise until screw separates from the knob. Repeat for each screw and knob.
 4. Remove the SRS Adapter from the S-frame compatible device.
 5. Gather the knobs, screws, and Allen wrench and store securely with the SRS Adapter.

MAINTENANCE

CLEANING THE SYSTEM

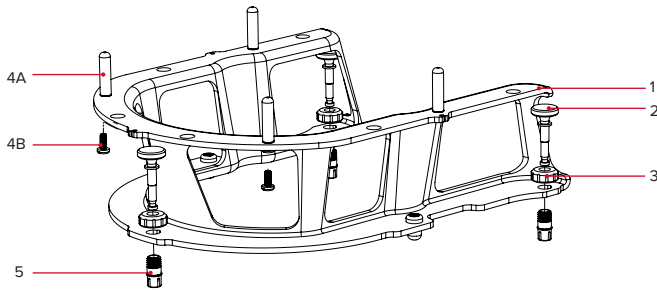
The SRS Adapter can be cleaned with a mild, non-abrasive cleaning solution. If necessary, disassemble the device by removing all parts shown in the parts list. No particular order is necessary. To clean, apply solution to clean cloth and wipe the surface. Visually inspect the device, if it is not clean, repeat the previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe the device to remove any cleaning agent residue. To dry, wipe the device with a clean, dry cloth.

DISINFECTING THE SYSTEM

To disinfect the SRS Adapter, use an alcohol or Super Sani-Cloth® wipe by PDI Healthcare. Wipe the surface of the headframe with the cloth and allow the device to dry before use. If the device was disassembled, reassemble the device ensuring all parts in the list are put back in place.

PARTS LIST

PIN AND FINGER ATTACHMENT ASSEMBLY



Parts List

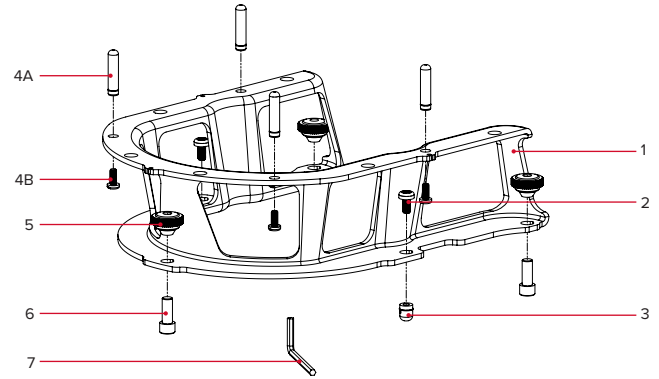
1. RT-4600-03: SRS Adapter or RT-4600-03-MRI: SRS MR Adapter
2. 2008106: Pin
3. 2008107: Screw
4. 8002499: Locating Pins
 - 4A. 2005148: Locating Pin, SRS
 - 4B. 3001479: Screw (M5 x 0.8 x 12 mm)
5. 2008123: Finger

Tools Required but Not Provided

- Flathead screwdriver

To disassemble device, remove all parts as shown above in no particular order.

SCREW AND KNOB ATTACHMENT ASSEMBLY



Parts List

1. RT-4600-03: SRS Adapter or RT-4600-03-MRI: SRS MR Adapter
2. 3002121: Screw (M6 x 1 x 12 mm)
3. 2008093: Locating Pin
4. 8002499: Locating Pins
 - 4A. 2005148: Locating Pin, SRS
 - 4B. 3001479: Screw (M5 x 0.8 x 12 mm)
5. 2008094: Knob
6. 2008095: Screw M8
7. 3002176: 6 mm Allen key

Tools Required but Not Provided

- Flathead screwdriver

To disassemble device, remove all parts as shown above in no particular order.

ACCESSORIES

- RT-4600-10 E0 SRS Headrest
- RT-4600-12 E2 SRS Headrest
- RT-4600-14 E4 SRS Headrest

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Fibreplast is a registered trademark of Qfix.
Super Sani-Cloth is a registered trademark of PDI Healthcare.