

CSM-2930

CS Carbon Spine Extension - Merivaara

(Contains CSM-2742 CS Carbon Spine Extension Adaptor- Merivaara, CSM-2730 CS Carbon Spine Extension Frame & CSM-2737 CS Carbon Spine Extension Leg)

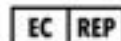
BUILD MANUAL

Rev.02, 04/2024



UK: Care Surgical Ltd
Unit 6 Ringtail Road
Burscough, L40 8JY
United Kingdom
Tel: +44 1704 336671



US: Care Surgical LLC
Marlborough
MA 01752
United States
Tel: +1-866-243-4107



Care Surgical Supplies Ltd, Office 2, 12a Lower Main Street, Lucan Co. Dublin, K78 X5P8 Ireland



Before using this or other medical devices on a patient, you should read the instructions for use and familiarise yourself with the product.

- Before using the product on a patient, read and understand all warnings in these instructions for use and on the product itself.
- This  symbol draws the user's attention to important procedures or safety instructions in connection with the use of this product.
- The  symbol on the labels is designed to highlight when the instructions for use should be consulted.
- The techniques described in this manual are only suggestions from the manufacturer. The final responsibility for patient care in connection with this device lies with the attending physician.
- The functionality of the product should be checked before each use.
This product may only be operated by trained personnel.
- All repairs, modifications or upgrades must be carried out by an authorised specialist.
- Any severe incident related to the product should be reported to the manufacturer and the competent national authority of the user's location.



NEVER EXCEED THE SAFE WORKING LOAD AND LOAD DISTRIBUTION OF THE OPERATING TABLE OR THE PRODUCT



CONTENTS

1. Instructions for Use CSM-2930

- 1.1 Indication for Use
- 1.2 Intended Use
- 1.3 Authorized User and Patients
- 1.4 Remaining Risk

2. Safety Considerations

- 2.1 Safety hazard symbols
- 2.2 Misuse of the Equipment
- 2.3 Non-hazardous Disposal

3. The CS Carbon Spine Extension-Merivaara

- 3.1 Components
- 3.2 Product Specification
- 3.3 Setup and Use
- 3.4 Maintenance of the product
- 3.5 Cleaning and Disinfection

- 3.6 Recommended Accessories Prone Procedures - Instructions & Fitting*

- 3.7 Recommended Accessories Supine/Lateral Procedures - Instructions & Fitting*



1 Instructions for use

1.1 Indication for Use

The CS Carbon Spine Extension - Merivaara is used in a variety of surgical procedures, but is particularly suitable for spine surgery in prone position. The safe working load capacity of 250kg (when attached to the head end of the table) allows it to be used for a large range of patients, subject to prior assessment by specialised personnel. Recommended to be attached to the head end of the operating table, if attached to the foot end of the table the safe working load will be reduced to 180kg and the use of the support leg is required. Only to be used with the table in the neutral position.

1.2 Intended Use

The CS Carbon Spine Extension is intended for positioning and supporting the patient's head, arms, chest, hips, and thighs during a wide range of procedures including, but not restricted to, orthopaedics, trauma surgery, neurosurgery, but is mostly indicated in the field of spinal surgery. It is intended for use by healthcare professionals in the operating theatre.

1.3 Authorized User and Patients

Authorized User: Surgeons, nurses, doctors, medical practitioners and/or healthcare professionals involved in the planned procedure in which the product is used. Not intended for non-professionals.

Patients: These products are designed for use with patients who do not exceed the weight specified in the product specification in section 3.2 within the safe working load range.

1.4 Remaining Risk

This product meets the relevant performance and safety standards. Nevertheless, damage to the product due to misuse, defects to the product function or mechanical hazards cannot be completely ruled out. The user is responsible for ensuring that the appliance is securely fastened and operates safely.

2 Safety Considerations

2.1 Safety hazard symbols



DO NOT USE IF THERE IS VISABLE DAMAGE ON THE PRODUCT.



2.2 Misuse of the Equipment

Do not use the device if the original package is defective or has been mistakenly opened before use.

Any repairs, changes or upgrades must be made by an authorised specialist.

2.3 Non-hazardous Disposal

Customers should adhere to all federal, state and/or local laws and requirements regarding the non-hazardous disposal of medical equipment and accessories.

If in any doubt, the user of the product should first contact Care Surgical Ltd/LLC Technical Support for instructions on non-hazardous disposal.

Icons Used	Description	Reference
	Indicates a medical device	MDR 2017/745
	Indicates the manufacturer of the medical device	EN ISO 15223-1
	Indicates the serial number of the manufacturer	EN ISO 15223-1
	Indicates the Global Trade Item Number of the medical device	21 CFR 830 MDR 2017/745
	Indicates the lot number of the medical device	EN ISO 15223-1
	Indicates the date of manufacturer of the medical device	EN ISO 15223-1
	Indicates the manufacturers product code	EN ISO 15223-1
	Indicates the need for the user to consult the user manual for important cautionary information such as warnings and precautions	EN ISO 15223-1
	Indicates the device do not contain natural rubber latex	EN ISO 15223-1
	Indicates the manufacturers authorised EU representative	EN ISO 15223-1
	Indicates the Medical Device complies to REGULATION UK MDR 2002	UK MDR 2002
	Indicates the Medical Device complies to REGULATION (EU) 2017/745	MDR 2017/745
	Indicates a Warning	IEC 60601-1
	Indicates the need for the user to consult the user manual	EN ISO 15223-1



3 The CS Carbon Spine Extension - Merivaara (CSM-2930)

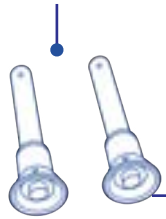
3.1 Components

CSM-2730 CS Carbon Spine Extension Frame

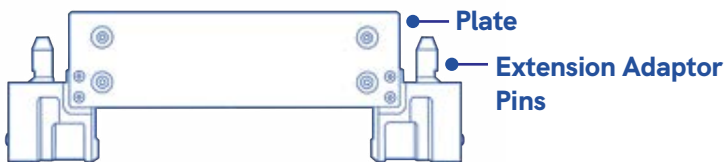
Pin holes



Fixture Pins



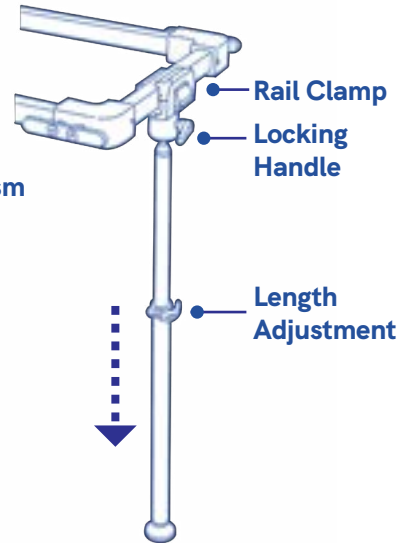
Release mechanism



Plate

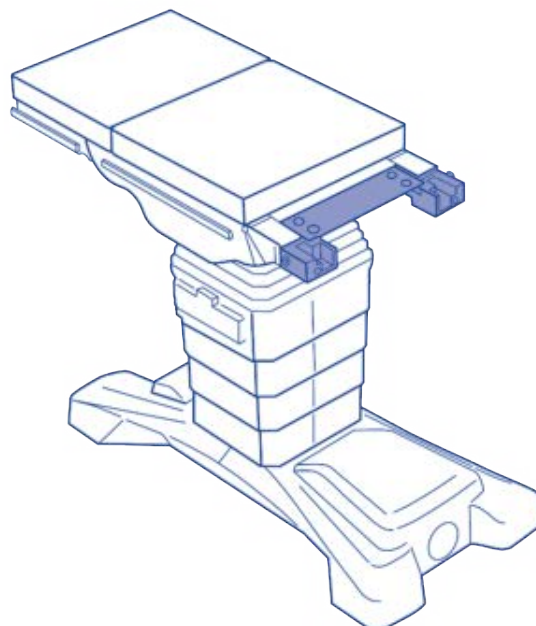
Extension Adaptor Pins

CSM-2737 CS Carbon Spine Extension Leg



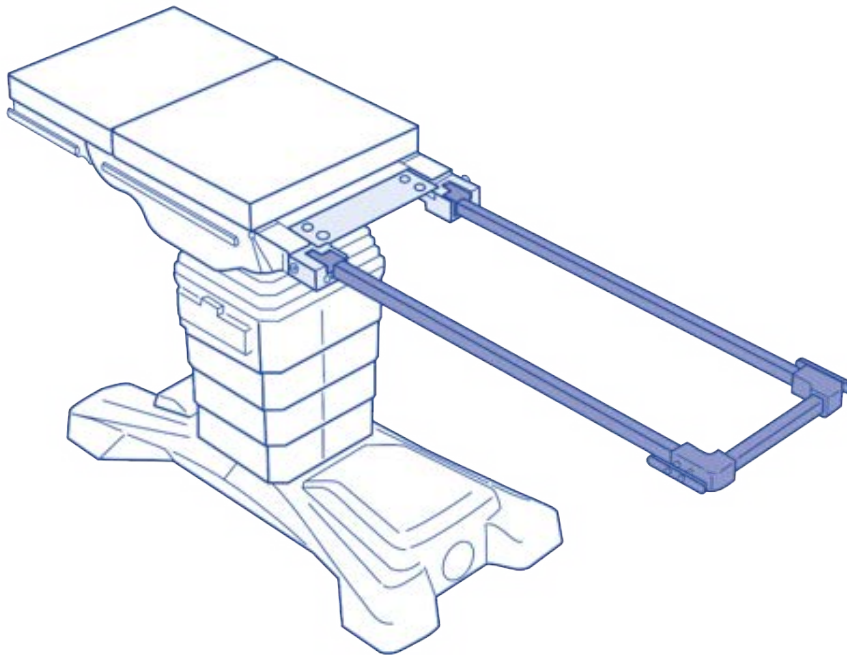
CSM-2742 CS Carbon Spine Extension Adaptor - Merivaara

1. CS Carbon Spine Extension Adaptor - Merivaara CSM-2742

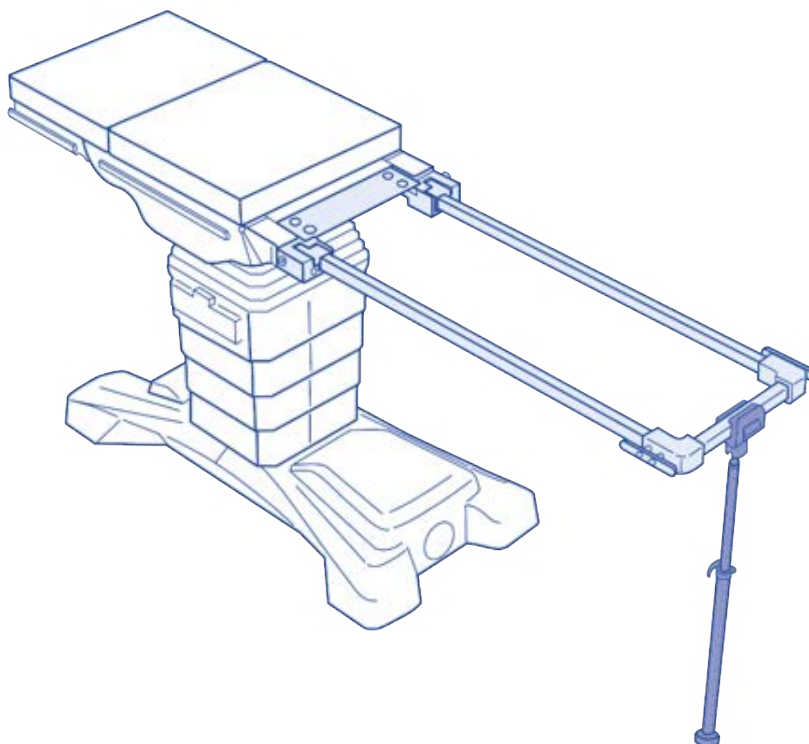




2. CS Carbon Spine Extension Frame - CSM-2730



3. CS Carbon Spine Extension Leg CSM-2737





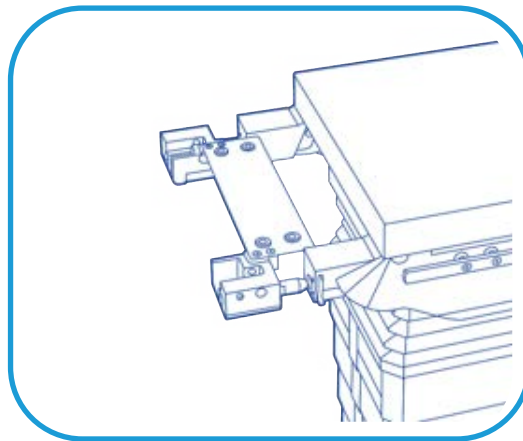
3.2 Product Specification

Mechanical Specifications	Description
Product Dimensions	<p>CS Carbon Spine Frame CSM-2730 (LxWxH) 1220x510x55mm</p> <p>CS Carbon Spine Extension Adaptor CSM-2742 (LxWxH) 180x540x75mm</p> <p>CS Carbon Spine Extension Leg CSM-2737 (LxWxH) 75x105x700mm (lowest position)</p>
Material	Aluminium alloy, Stainless Steel, Carbon Fibre
Safe Working Load on the Device	250kg subject to table in neutral position and Adaptor (CSM-2742) is attached to the head end of the Merivaara Promerix. If the Adaptor is attached to the foot end of the table, table in a neutral position and used with the support leg (mandatory), the SWL is 180kg.
Overall Weight of Device	<p>CS Carbon Spine Frame CSM-2730 6.8kg</p> <p>CS Carbon Spine Extension Adaptor CSM-2742 3.2kg</p> <p>CS Carbon Spine Extension Leg CSM-2737 2.2 kg</p>
Storage Specifications	Description
Storage and Operating Temperature	-30°C - 40°C and -22°F - 104°F
Storage and Operating Relative Humidity Range	40%-80%
Compatibility Specifications	Description
Compatible with:	Compatible with accessories designed for use with standard dual-rail operating table accessories 1.25" (3.2cm) wide and 1.5c" (3.8cm) tall (with 14.5"/36.8cm space between).
To use with:	<p>Recommended for use with:</p> <ul style="list-style-type: none"> CS Head Tray Lowered CSM-2751 CS Chest Support CSM-2709 CS Hip Supports CSM-2717 CS Popper Thigh Supports CSM-2744 CS Popper Hip Supports CSM-2743 CS Universal Arm Support - Moulded CSM-2647 CS Supine Top - Base only - CSM-2722-7 CS Supine Top - 2" - CSM-2722-2 CS Small Supine Top - Base only - CSM-2966
Operating Table Compatibility	Adaptor CSM-2742 is designed to fit on the Merivaara Promerix Operating Table only (Head or food end)

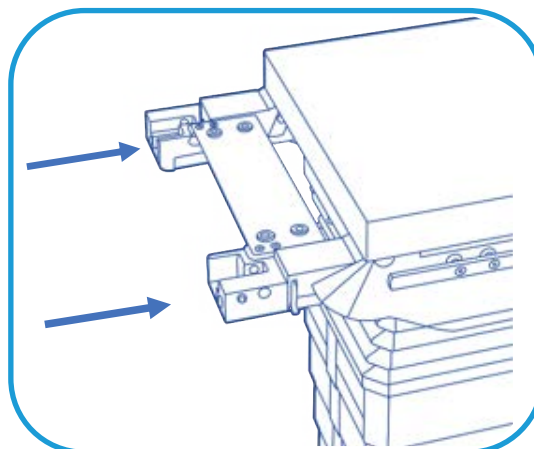


3.3 Setup and Use

1. The patient should be examined and checked for any pre-existing conditions that may prevent safe use of the positioning equipment before the frame is attached to the table.
2. To attach the CS Carbon Spine Extension Frame (CSM-2730) to the table the CS Carbon Spine Extension Adaptor - Merivaara (CSM-2742) needs to be used. Remove all non-fixed table sections from the head or foot end of the operating table (depending on which end the adaptor is to be attached to).
3. Line up the pins of the Adaptor with the Merivaara operating table ensuring it is being fixed to the head or foot end of the table.

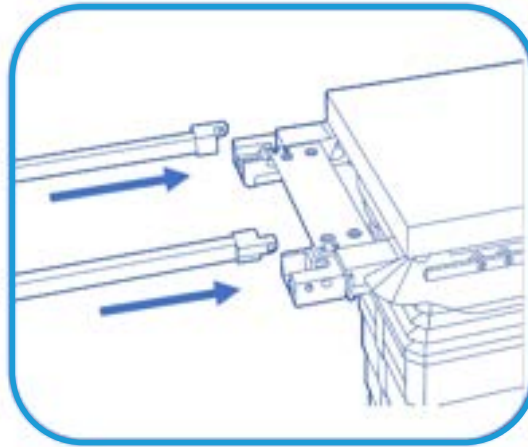


4. Insert the extension adaptor into the operating table until the adaptor locks into place. Ensure the extension adaptor is flush against the operating table.

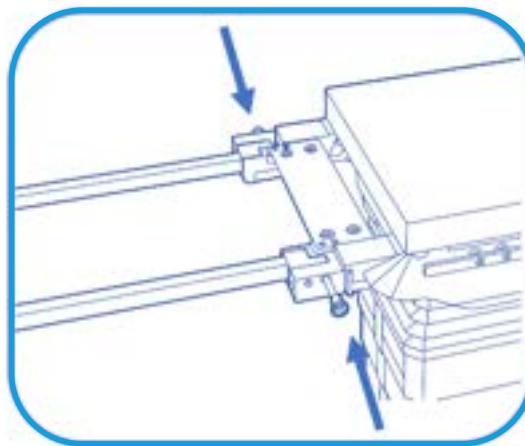




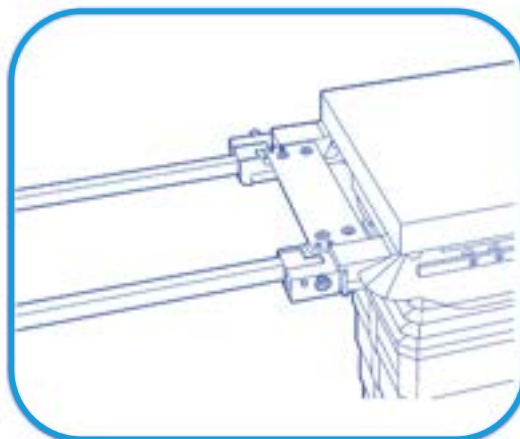
5. Holding the full weight of the extension frame at a 45 degree angle, line the pin holes of the extension frame rails up with the holes of the extension adapter



6. Insert the fixture pin - ensuring to press in the release mechanism in the centre of the pin - through the extension adapter and extension frame rail to secure it. (Ensure pins are locked into place)

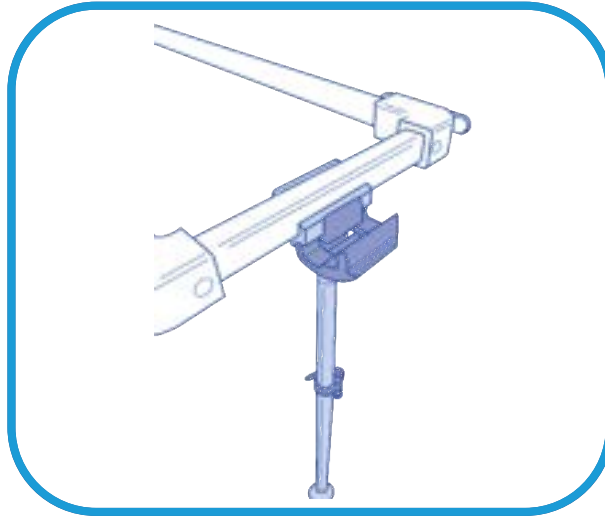


7. Repeat on the opposite side and ensure both sides are secured

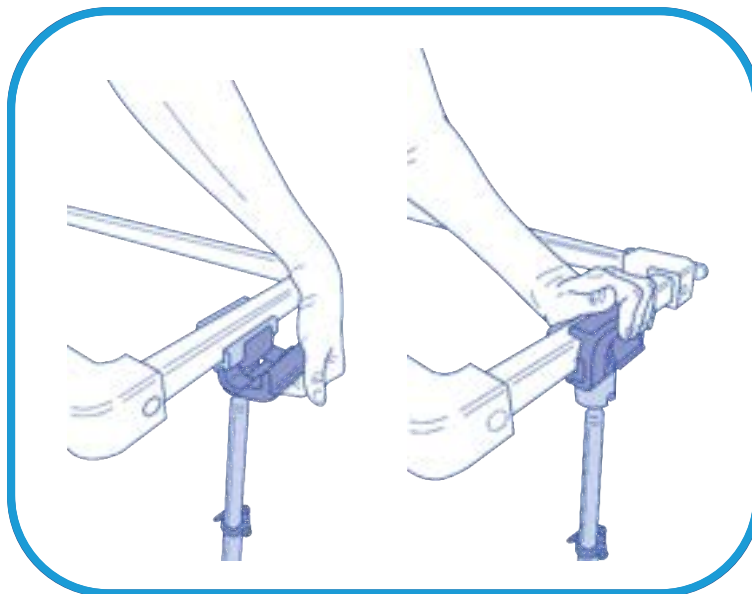




8. Place the support leg in the centre of the head end of the extension frame.



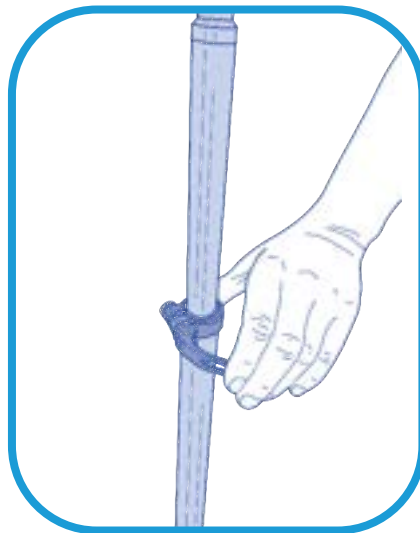
9. Ensure that the clip is closed and the leg is firmly attached to the frame.





10. If the operating table needs to be raised, raise using the table hand control and then loosen the black lever on the rod to set the new height before tightening the lever again.

If the table needs to be lowered, first raise the table to remove pressure on the leg. Then make sure that the black lever is released before lowering the table. Once in final position, tighten the lever again.



WARNING: Ensure the table is always in the neutral position and attached to the head or foot end of the operating table (See Figures 1) when using the CS Carbon Spine Extension Frame.



Head End

Fig. 1

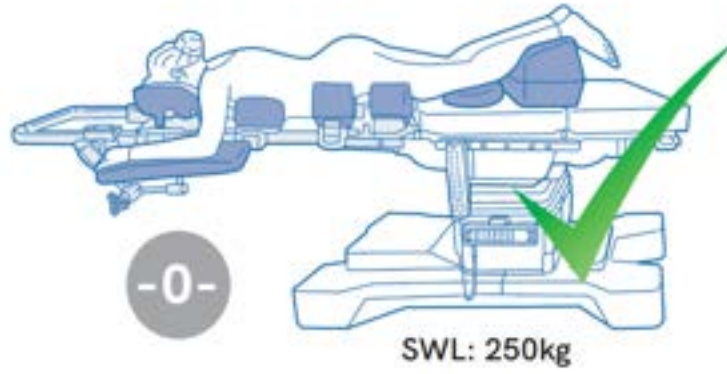
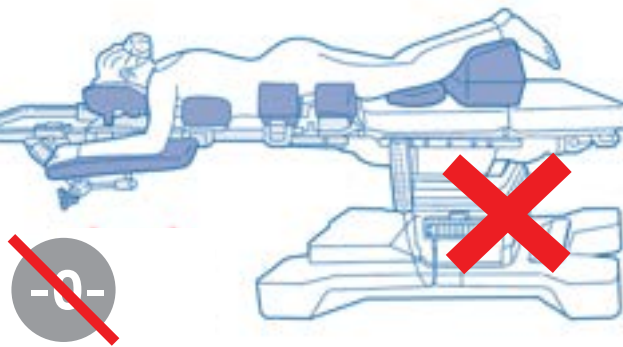


Fig. 2



Foot End

Fig. 1

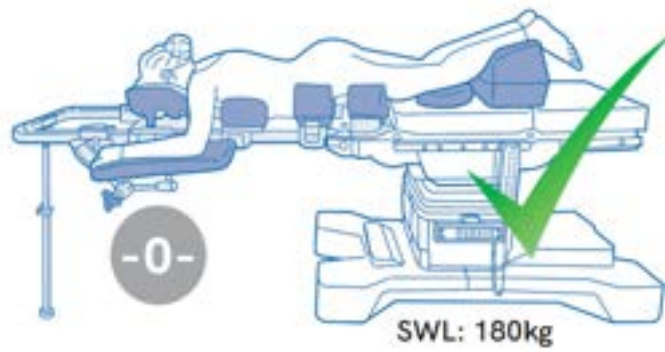
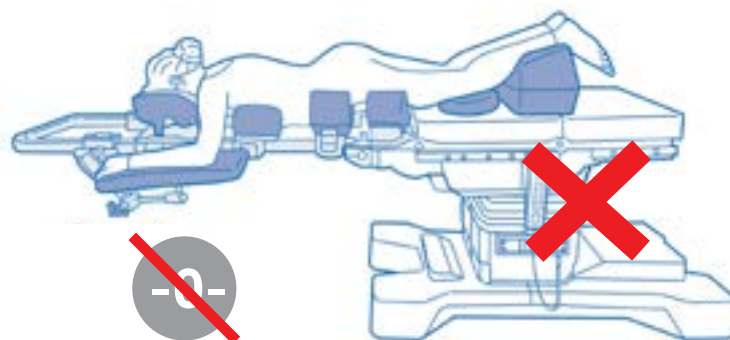


Fig. 2





3.4 Maintenance of the product

Ensure that all labels are attached and legible. If labels need to be replaced, take a photo of the current label and send it to us before removing it by using a plastic scraper and alcohol wipe to remove any adhesive residue.

If you need labels to be replaced, a repair or replacement, contact us (Care Surgical Ltd / LLC) by using the information from the contact details section.

3.5 Cleaning and Disinfection



ATTENTION:

- Clean the product after each use as specified in these instructions for use.
- Do not immerse the device in liquids. This may damage the device.
- Take care in areas where liquid can get into the mechanism.
- Do not use bleach or products containing bleach to clean the product. You could injure yourself or damage the device.
- After cleaning - Wipe the product with a clean, dry cloth.
- Ensure that the product is completely dry before storing it or using it again.

CAUTION: The product may be damaged if it is cleaned with corrosive chemicals or harsh abrasives.

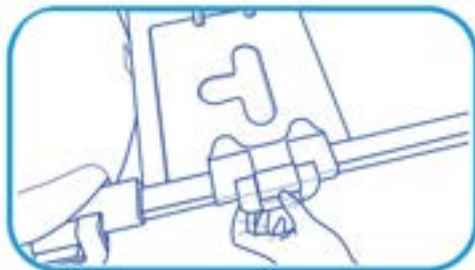
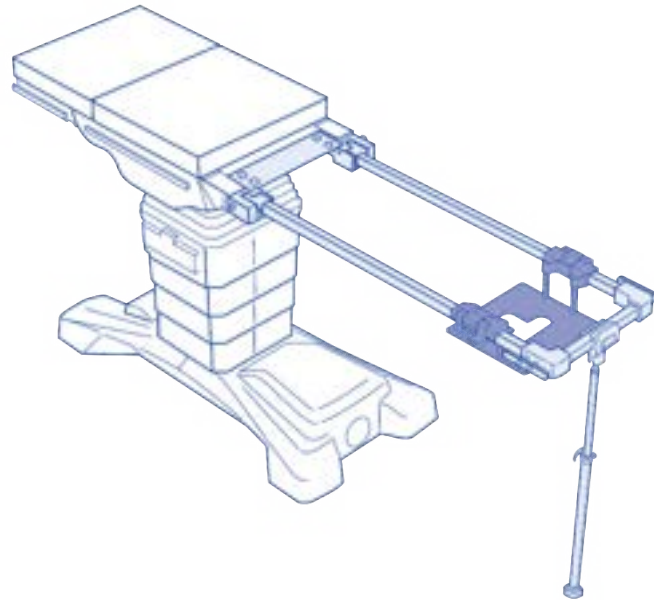
ATTENTION: If any Care Surgical product is damaged, defective or broken, discontinue use and contact Care Surgical Customer Service at 01704 336 671.



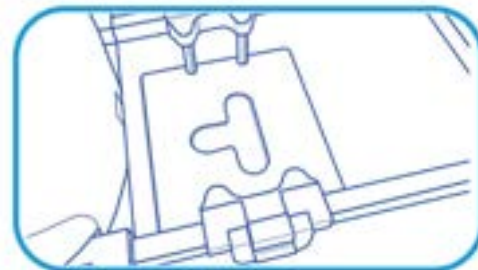
3.6 Recommended Accessories Prone Procedures - Instructions & Fitting*

If using for lateral or supine surgery go to 3.7

3.6.1 CSM-2751 CS Head Tray Attachment - Lowered



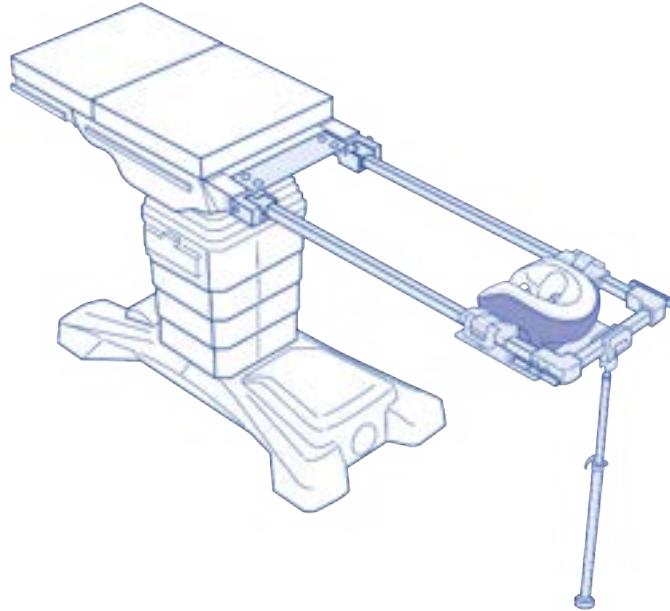
1 Place the attachment on the frame so that the brackets are over the bars.



2 Snap the locking clip shut to secure the attachment in position.



3.6.2 CSM-2565 CS Prone Plus Head Support System /CSM2560 CS Prone Head Support System

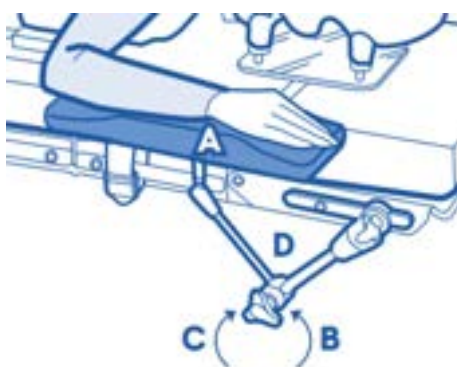
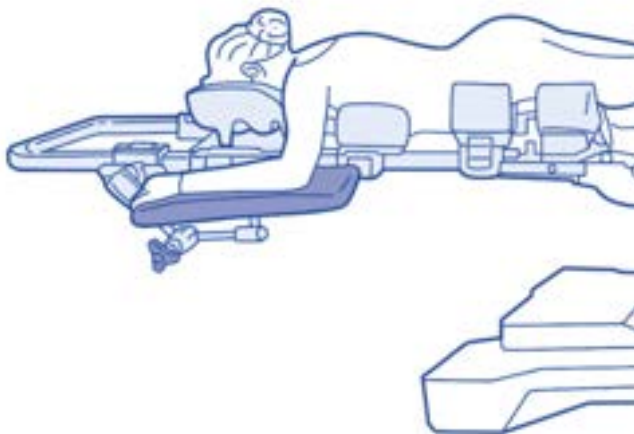
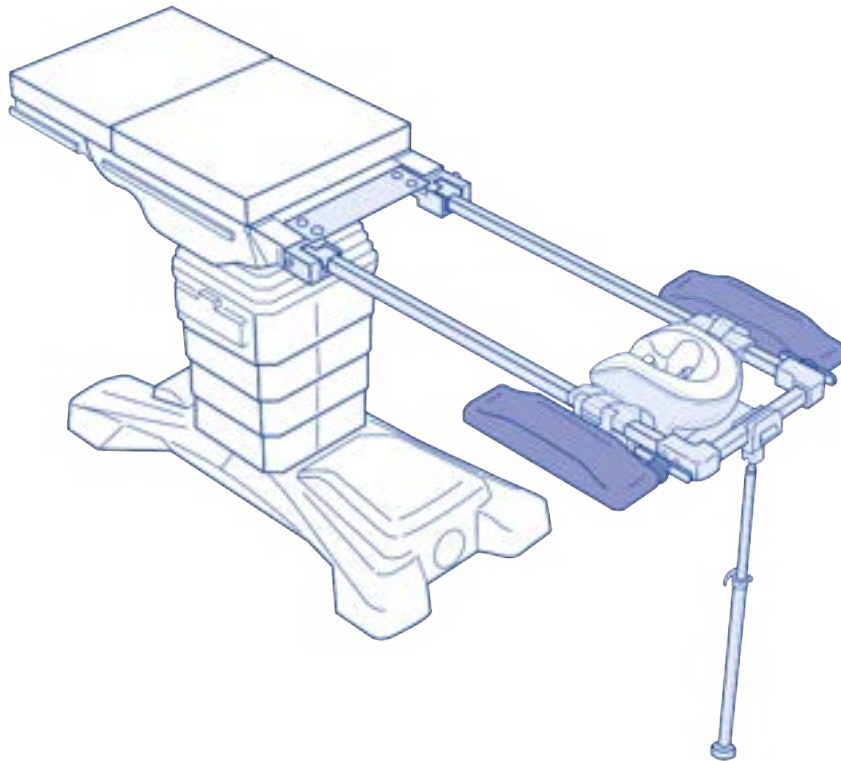


The CS Prone Plus Head Support System used with The CS Prone Plus Face Cushion offers support to your patient's forehead and cheeks whilst ensuring a neutral neckline and assisting with patient monitoring. Ensure the eyebrows are visible to avoid direct pressure to the eyes.

-  1 With patient supine, disconnect ET tubing
-  2 Place cushion onto patient's face*
-  3 Place helmet over cushion
-  4 Turn patient to prone position
-  5 Re-connect ET Tubing
-  6 Lift helmet & locate onto mirror's cogs
-  7 Check face correctly positioned in cushion*
-  8 Adjust cogs to obtain neutral neck line



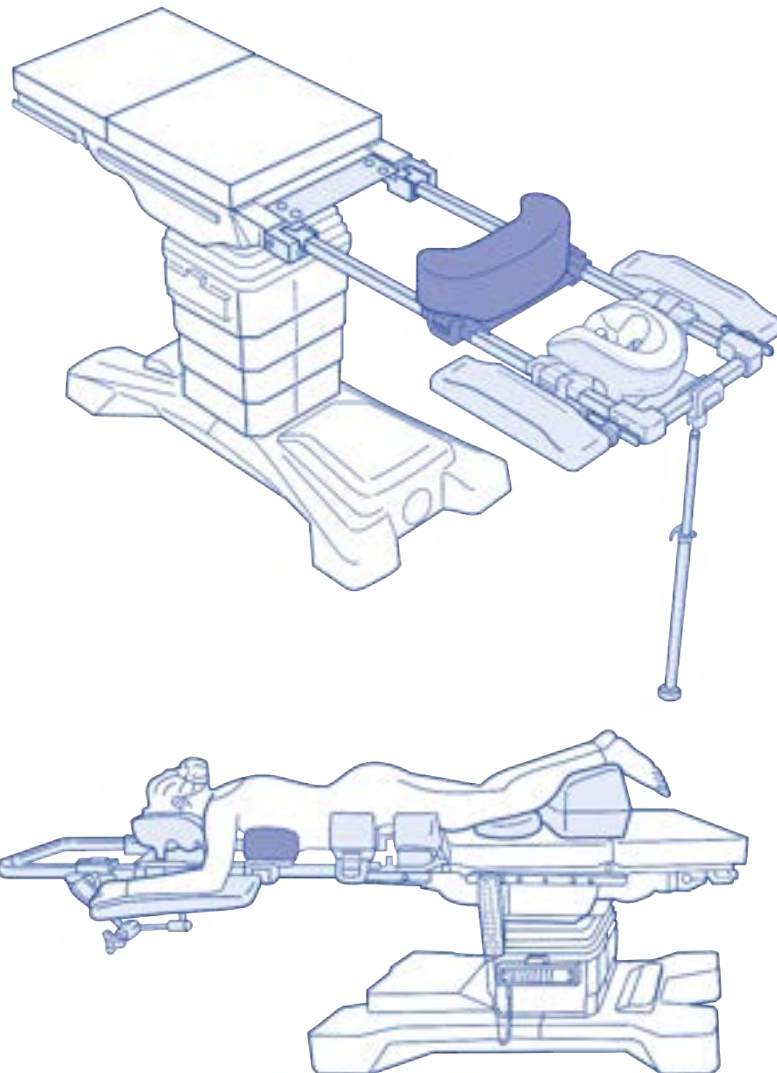
3.6.3 CSM-2647 CS Universal Arm Support - Moulded



1. Hold the Universal Arm Support with one hand via the anterior segment (A) and manipulate the central clamping handle (D) with the other hand.
2. To release turn the central handle (D) counter clockwise (B) as far as necessary.
3. Move the Universal Arm Support into the desired position.
4. Turn the handle (D) clockwise (C) to secure into desired position.
5. Check that the Universal Arm Support is fixed firmly and is functioning correctly.



3.6.4 CSM-2709 CS Chest Support



1 Place the supports on the frame so that the brackets are over the bars



2 Snap the locking clip shut to secure the support in position



3 To adjust the position of the supports, release the clip(s), raise the patient's chest or hips, slide the supports to the correct position, lock the clip(s)

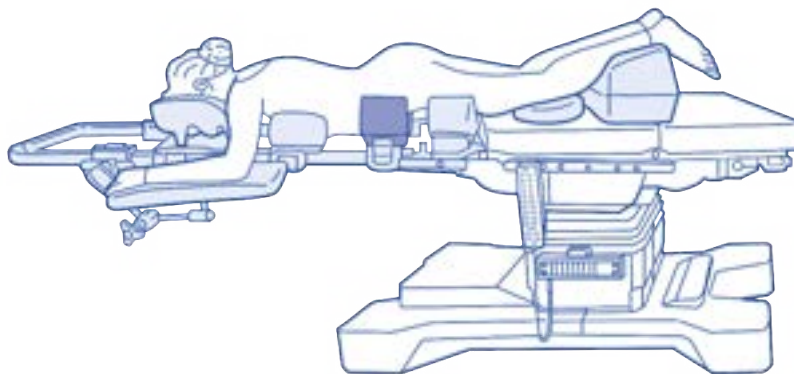
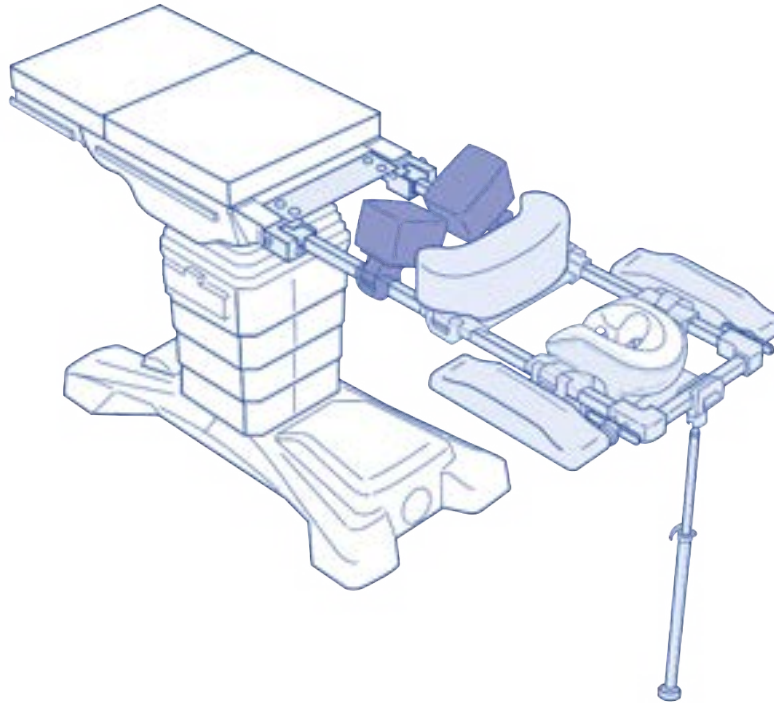
For male patients, the chest support should be positioned directly under the nipples.

For female patients, move the chest support towards the head to allow easier positioning of the breast.

These products will support a patient weight of up to 250kg. Do not exceed the weight capacity of the operating table.



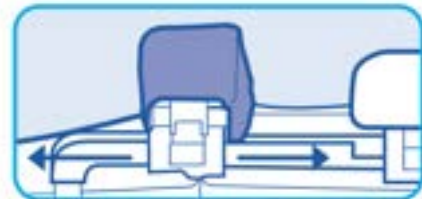
3.6.5 CSM-2717/2719/2723 CS Hip Supports /Large/Small



1 Place the supports on the frame so that the brackets are over the bars



2 Snap the locking clip shut to secure the support in position



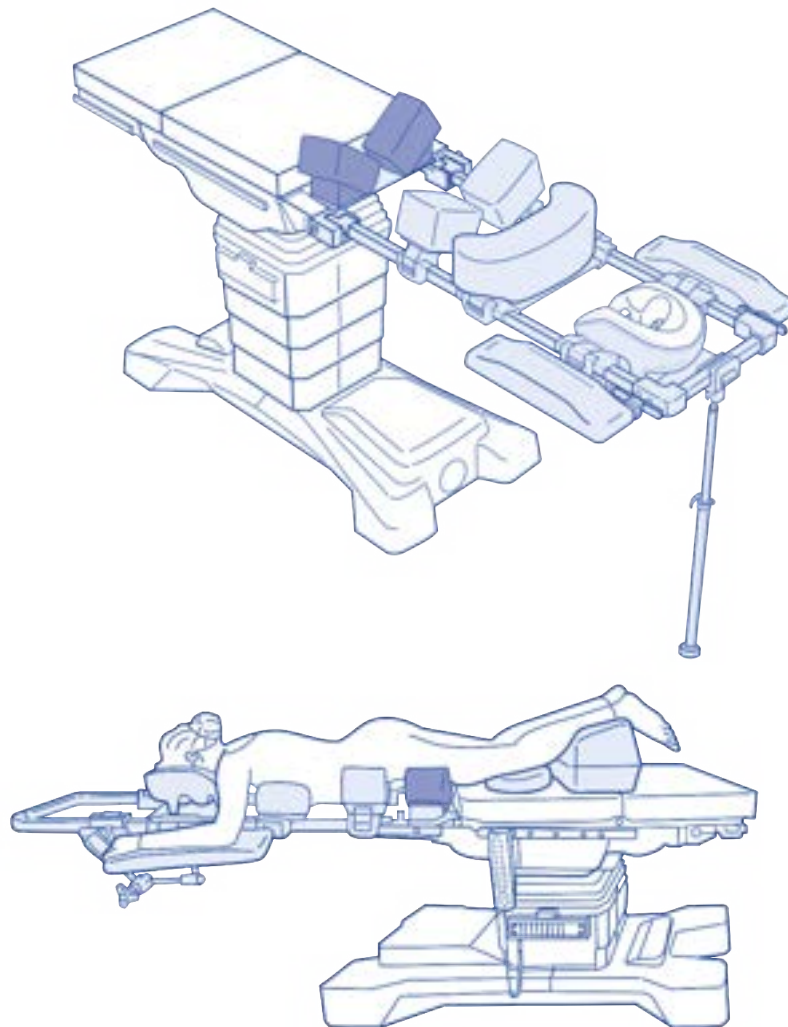
3 To adjust the position of the supports, release the clip(s), raise the patient's chest or hips, slide the supports to the correct position, lock the clip(s)

Ensure the iliac crest is in the centre of the hip pads.

These products will support a patient weight of up to 250kg. Do not exceed the weight capacity of the operating table.



3.6.6 CSM-2744 CS Popper Thigh Supports (For use with CS Hip Supports (Pair), CS Hip Supports - Large (Pair) or CS Hip Supports - Small (Pair))



1 First place one and then the other thigh support on the adaptor.



2 Make sure that the poppers are directly above the holes before pushing them down.

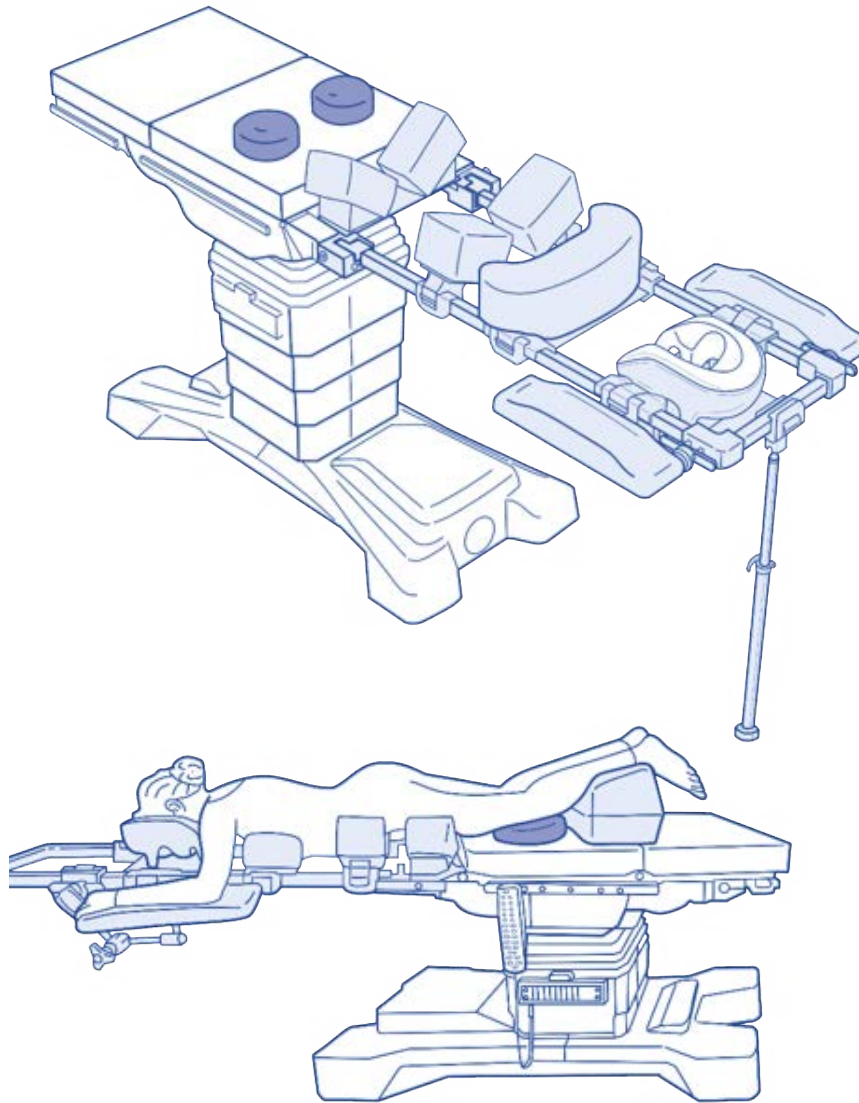


3 Caution: to remove the supports, only pull them straight upwards to avoid damaging the fastening mechanisms.

Make sure that the iliac crest is in the centre of the hip supports. The thigh supports should not be positioned too close to the knee to ensure optimum pressure distribution. These products will support a patient weight of up to 250kg. Do not exceed the weight capacity of the operating table.

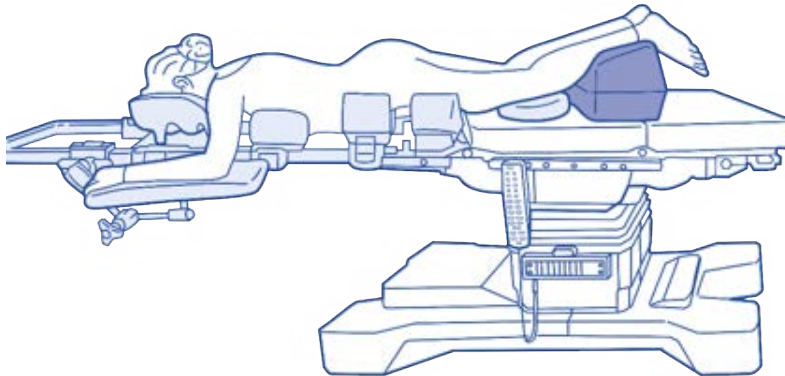
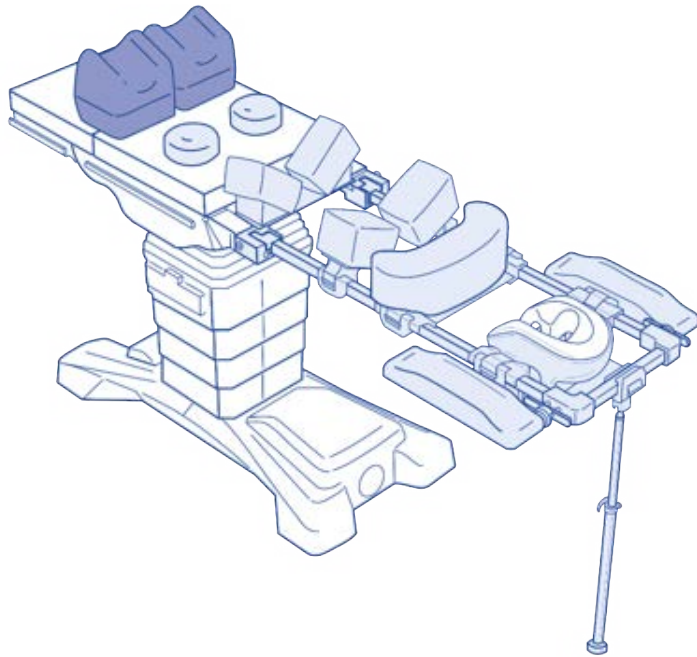


3.6.7 CS Knee Supports (Pair)





3.6.8 CS Shin Supports (Pair)



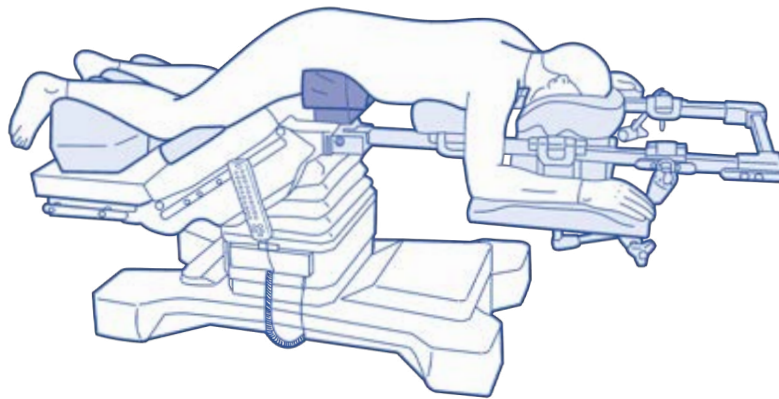
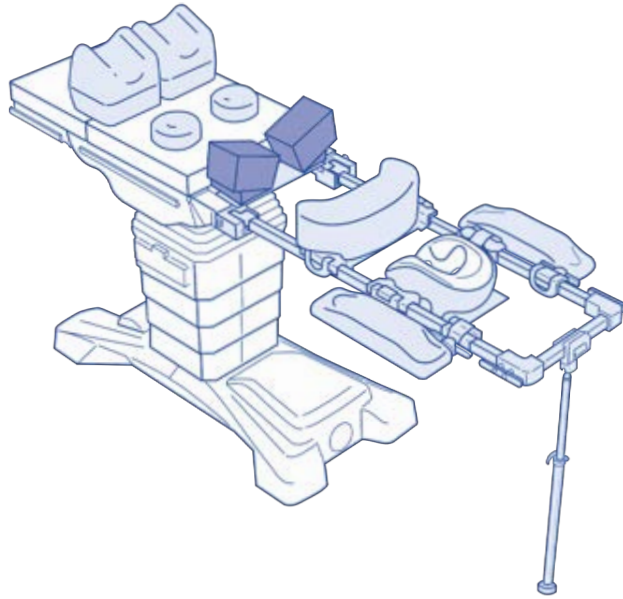
- + Ensure feet do not touch operating table
- + Ankles should extend beyond Shin support





3.6.9 CSM-2743 CS Popper Hip Supports

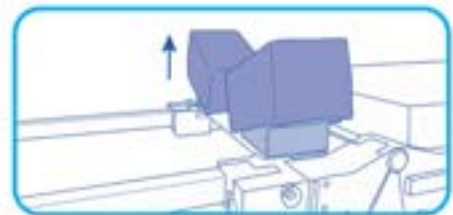
If you want to flex the patient, remove the CS Hip Supports (CSM-2717/2719/2723) and CS Popper Thigh Supports (CSM-2744). Then attach the CS Popper Hip Supports (CSM-2743) to the Carbon Plate of the CS Carbon Spine Extension Adaptor - Merivaara CSM-2742



1 First place one and then the other hip support on the adaptor.



2 Make sure that the poppers are directly above the holes before pushing them down.



3 Caution: to remove the supports, only pull them straight upwards to avoid damaging the fastening mechanism.

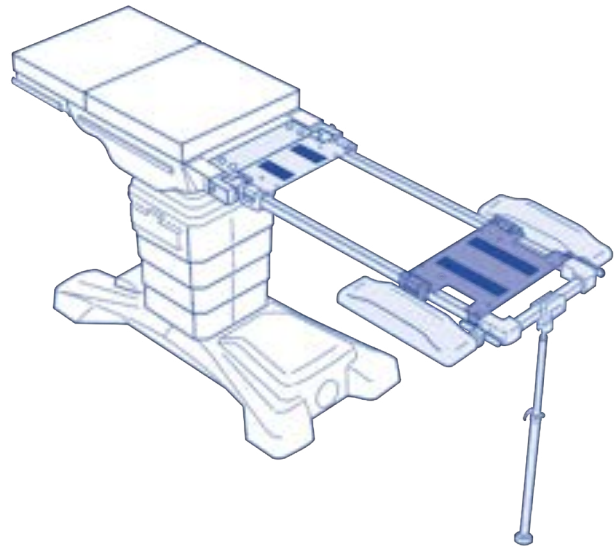
Ensure the iliac crest is in the centre of the hip pads.

These products will support a patient weight of up to 250kg. Do not exceed the weight capacity of the operating table.

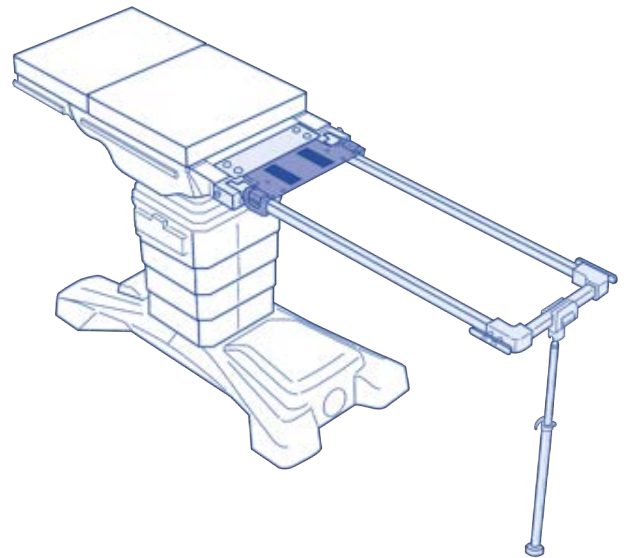


3.7 Recommended Accessories Supine/Lateral Procedures - Instructions & Fitting*

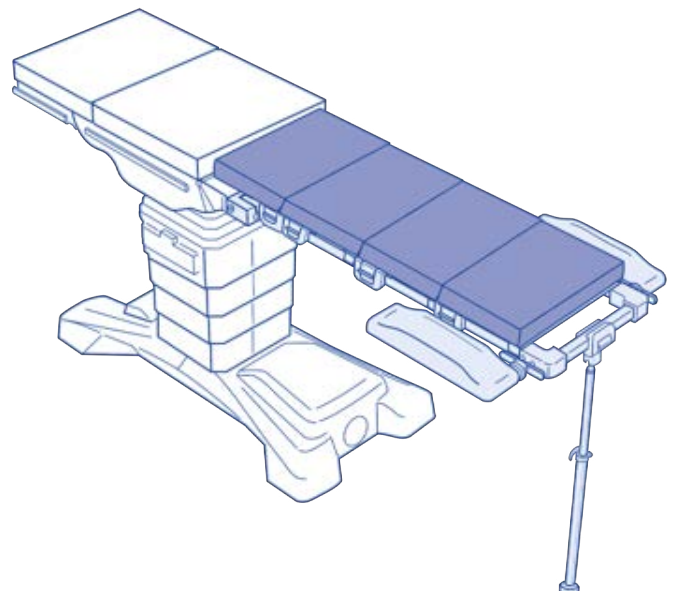
**3.7.1 CS Supine Top - Base Only
CSM-2722-7**



**3.7.2 CS Small Supine Top - Base Only
CSM-2966**

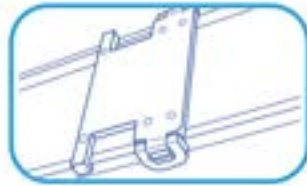


**3.7.3 CS Supine Tops - 2" or 3"
CSM-2722-2 or -3**





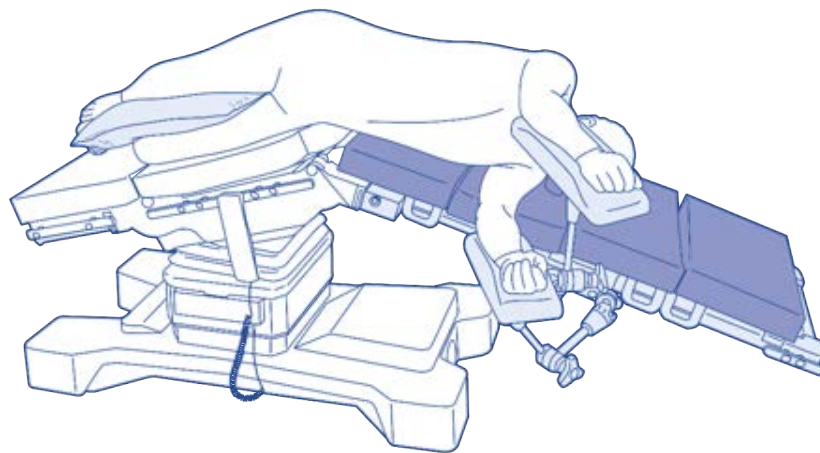
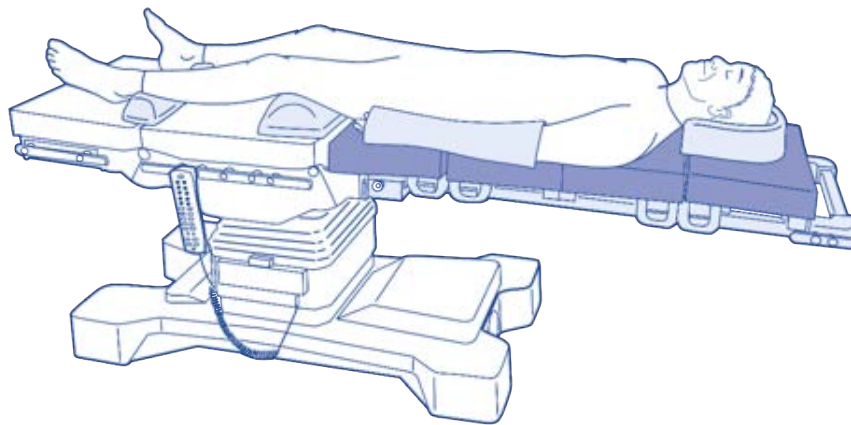
1 Place the attachment on the frame so that the brackets are over the bars.



2 Snap the locking clip shut to secure the attachment in position.



3 Place the CS Supine Top Foam Pad in the centre of the CS Supine Top Base.



*Refer to individual product Instructions for Use for full usage information, instructions, and warnings.



WARNING: The positionings shown here are only examples.
The positioning of patients should always be adapted to the individual circumstances of the patient.