INSTRUCTIONS FOR USE / BUILD MANUAL

CS Universal Spine Extension™ SET (US)*

CSM3031

*CS Universal Spine Extension™ SET (EU) Contains:
CSM3030 CS Universal Spine Extension™ - Table Adaptor (US)
CSM2957 CS Universal Spine Extension™ - Frame
CSM2956 CS Universal Spine Extension™ - Powered Leg

UK: Care Surgical Ltd
Unit 6 Ringtail Road
Burscough, L40 8JY
Tel: 01704 336671

USA: Care Surgical LLC
43 Broad Street
Suite B106, Hudson,
MA 01749, USA
Tel: 866-243-4107

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

Ref: CSM3031 - IFU (Rev.6) 04/2026

Warning: 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 MAX PATIENT WEIGHT AND LOAD DISTRIBUTION OF THE OPERATING TABLE

Contents

1 Instructions for use CS Universal Spine Extension™ SET (EU) CSM3031
1.1 - Indication for use
1.2 - Intended use
1.3 - Authorised user and patients
1.4 - Remaining risk

2 Safety Considerations
2.1 - General Warnings
2.2 - General Battery Warnings
2.3 - Lithium ion batteries Lithium ion battery warnings
2.4 - Lithium ion battery warnings
2.5 - Recommendations
2.6 - Other Warnings / Additional Advisories
2.7 - Safety Feature
2.8 - Emergency disconnection instructions
2.9 - Battery replacement hazards and steps
2.10 - Incident reporting contacts

3 Relevant regulations
3.1 - EU Directives and Regulations
3.2 - UK Regulations
3.3 - Other EU Directives
3.4 - Technical product standards
3.5 - Symbols
3.6 - Product Labelling and On-Product Warnings

4 Product Specification
4.1 - Components and list of features
4.2 - Controls and Indicators
4.2.1 - Remote control
4.2.2 - Control box
4.2.3 - Battery

4.3 - Potential Equalisation Conductor

4.4 - Electromagnetic Compatibility Guidelines
4.4.1 - Intended Electromagnetic Environment
4.4.2 - Essential performance
4.4.3 - Guidance on Adjacent/Stacked Use

Contents

4.4.4 - Replacement parts
4.4.5 - Use of Non-Approved Accessories and Cables
4.4.6 - Recommended Separation Distances for RF Equipment
4.4.7 - Electromagnetic Emissions and Immunity (Manufacturer's Declaration)

5 - Setup and use
5.1 - Before using the CSM3031 CS Universal Spine Extension™ SET (US)
5.2 - Set Up
5.3 - Recommended Accessories Prone Procedures – Instructions & Fitting*
5.3.1 - CSM2714 CS Head Tray Attachment
5.3.2 - CSM2565 CS Prone Plus Head Support System /
CSM2560 CS Prone Head Support System
5.3.3 - CSM2647 CS Universal Arm Support Moulded™
5.3.4 - CSM2709 CS Chest Support
5.3.5 - CSM2717/2719/2723 CS Hip Supports / Large / Small
5.3.6 - CSM2718 CS Thigh Supports
5.3.7 - CSM2821 CS Knee Rings (Pair) and CSM3020 CS Easy Shin Supports™
5.3.8 - Set-Up without Thigh Supports
5.4 - Recommended Accessories for Supine/Lateral Procedures – Instructions & Fitting
5.4.1 - CSM2722-7 CS Supine Top – Base Only +
CSM2966 CS Small Supine Top – Base Only
5.4.2 - CSM2722-2 / -3 CS Supine Tops – 2″ or 3″

6 - Cleaning and disinfection

7 - Repair and disposal
7.1 - CS Universal Spine Extension™ Powered Leg

1 INSTRUCTIONS FOR USE CSM3031

1.1 Indication for Use

The CSM3031 CS Universal Spine Extension™ SET (US) is used in a variety of surgical procedures and is particularly suitable for spine surgery in the prone position. The maximum patient weight of 275 kg (606 lb) allows use across a wide range of patients, subject to prior assessment by specialised personnel.

1.2 Intended Use

The CSM3031 CS Universal Spine Extension™ SET (US) (+ accessories) 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 Authorised User and Patients

Authorised 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 specifications - See 'Maximum Patient Weight' in Section 4 (Product Specification).

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

Follow these safety instructions to help prevent patient fall, injury, and/or damage to the equipment.

2.1 General Warnings

- Read and understand all warnings in these instructions and on the device before use on the patient.
- This device should only be operated by trained persons.
- The procedures 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.
- It is prohibited to make any modifications to this equipment.
- Care Surgical accessories are adapted to the dimensions of the current standard on the market. If products from another manufacturer are to be used, compatibility must be checked and confirmed with the manufacturer in advance to ensure safe use.
- There are no known contraindications to the use of the CSM3031 CS Universal Spine Extension™ SET (US).
- Except when transferring the patient, safety straps must always be used to secure the patient on the support accessories.
- During patient transfer, make sure that the brakes on the CSM2956 CS Universal Spine Extension™ -Powered Leg are locked.
- If the position of the operating table is to be changed, it should first be ensured that the brakes of the Universal Extension™ leg are unlocked.
- Before each use of the device, make sure that all parts are installed correctly, and the device is working properly.
- If the device has been dropped or damaged, make sure that the maintenance department has fully inspected the device and has determined that it is safe to operate before using it.
- The device must only be connected to a supply main with protective earth to avoid the risk of electric shock.
- There is a risk of electric shock with electrical devices. Failure to comply with the operating instructions can result in death or serious injury.
- If the CSM3031 CS Universal Spine Extension™ SET (US) is to be used in the immediate area of high frequency surgical equipment, cardiac defibrillators and cardiac defibrillator monitors, refer to the product manufacturer's instructions to ensure that the equipment functions as intended.
- Incorrect use or handling of the power cable can lead to damage to the power cable. If the power cable or one of its components has been damaged, remove the CSM3031 CS Universal Spine Extension™ SET (US) from operation and contact the responsible maintenance staff.

- Do not expose the device to excessive moisture.

- If liquid is spilled on the electronics, it may result in a hazard. If this occurs, unplug the plug from the socket and take the device out of operation. If liquid is spilled that exceeds the amount normally associated with normal use, proceed immediately as follows:
  - Disconnect the device from its power source.
  - Remove the patient from the device.
  - Clean any liquid spills off the device.
  - Have a service technician completely inspect the device.
  - Do not use the device until it has completely dried and has been tested and found safe to use.

- Be aware of all the crushing hazards:
  - Between CSM3030 CS Universal Spine Extension™ – Table Adaptor (US) and standard rail of the table.
    Between CSM2957 CS Universal Spine Extension™ - Frame and CSM3030 CS Universal Spine Extension™ – Table Adaptor (US).
  - Between CSM2957 CS Universal Spine Extension™ - Frame and connection point to the CSM2956 CS Universal Spine Extension™ - Powered Leg.
  - Between the column and the base of the CSM2956 CS Universal Spine Extension™ – Powered Leg – especially during transport.

- The device is not intended for patient transport.

- If the product is not in use, make sure that:
  All cables are stowed before transport so that they cannot be damaged or pinched.
  All accessories are either fixed to the CSM2957 CS Universal Spine Extension™ - Frame or completely removed before it is disconnected from the operating table / CSM3030 CS Universal Spine Extension™ - Table Adaptor (US) / CSM2956 CS Universal Spine Extension™ - Powered Leg.
  The CSM2956 CS Universal Spine Extension™ - Powered Leg is in the lowest position.

- 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.

- Customers should adhere to all federal, state and / or local laws and requirements regarding the non-hazardous disposal of medical equipment and accessories.
- Do not position the equipment in a way that restricts access to the mains plug or other power disconnection device. The disconnection device must remain easily reachable at all times during use so the equipment can be disconnected from the power supply quickly if necessary
- To isolate the device from all power sources, unplug the mains power cable and disconnect the battery cable from the control box.

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

2.2 General battery warnings

- Handle batteries carefully. Do not short circuit the battery
- Avoid continuous battery discharge when the medical device is not in use, as this may cause lead sulphate formation, which, if left in this state for too long, will irreversibly damage the battery.
- LINAK battery packs may emit flammable gases. Do not expose the battery packs to fire or equipment that emits sparks. Moreover, do not store the battery in a closed environment or incorporate it into a closed structure of an enclosure as this may cause an explosion, fire, equipment damage, or injury.
- Handle tools carefully and do not wear jewellery when handling batteries. A short-circuit of the battery terminals can cause burn injuries, damage or trigger explosions.
- Only connect LINAK batteries to compatible chargers.
- LINAK battery packs contain toxic substances. If the internal battery fluid leaks out and gets onto skin or clothing, make sure it is washed off with clean water. Moreover, if the fluid gets into the eyes, rinse them immediately with clean water and seek medical assistance.
- Do not use or store LINAK battery packs in places where the ambient temperature exceeds 50°C, such as inside a hot automobile, in direct sunlight, or in front of a stove or a source of intense heat. Doing so can shorten the battery life, lower its performance level, cause the battery to leak fluid, explode, cause fire, or be damaged.

2.3 Lithium-ion batteries

- Li-Ion batteries are moving in the direction of minimising the physical size and, at the same time, increasing the capacity. This gives a very compact battery with a high energy concentration. It also increases the risk of thermal runaway (see note below) due to internal short circuits.
- The general use of Li-Ion batteries has increased, and the inherent risk of thermal runaway has led to stricter rules within the transport industry, specifically air transport with tightened restrictions on the quantity, handling, and storage of specific products.
- The OEMs and consumers must recognise that although safe to use, Li-Ion cells always have a very small risk of thermal runaway. The risk could be as little as 1 PPM or even less.
- LINAK currently bases our Li-Ion battery design on cell types with an industry-proven history (e.g. electric cars). The use of well-proven cell technology reduces the risk of thermal runaway, but it does not eliminate it. LINAK has completed activities to reduce this risk, and the complete battery package is approved in accordance with UL.
- An external, internationally recognised expert has also reviewed the design to ensure that it is manufactured according to the latest recommendations. Further to that, we only use cells from well-recognised manufacturers.
- LINAK recommends that when using Li-Ion batteries, the customers should carry out proper risk analysis on their application. The risk analysis must also take into consideration that these productsare not mounted in positions where they are in direct contact with flammable materials.
- LINAK Li-Ion batteries have no greater risk of thermal runaway than other Li-Ion cells from well-recognised manufacturers within the market. Therefore, LINAK cannot take responsibility for any failures that occur due to a failure that is inherent in the nature of Li-Ion batteries.
- If any of the Li-Ion batteries built into LINAK products are found to be defective under warranty, LINAK will provide the OEM with a new product. LINAK explicitly disclaims all other remedies. LINAK shall not in an event be liable under any circumstances for any special indirect punitive incidental or consequential damages or losses arising from any incident related to the inherent risk of thermal runaway in the Li-Ion cell and any use of LINAK products. Moreover, LINAK explicitly disclaims any responsibility for profit loss, failure to realise expected savings, any claim against our customer by a third party, or any other commercial or economic losses of any kind, even if LINAK has been advised of the possibility of such damages or losses.

'Thermal runaway' is overheating of a cell, and it could lead to a small fire and smoke from the cell

2.4 Lithium ion battery warnings

- When using Li-Ion batteries with patient lift control boxes, loss of power might happen due to the battery deep discharge protection. This will only happen in case of continuous battery use despite warnings. In this event, there may be no warning, and the application may not be able to move when expected.
- Do not open the battery housing as damaging the cell or circuitry may develop excessive heat.
- If product caution is not clearly visible at low light intensity, read the product label instructions symbol.
- Defective or damaged Li-Ion batteries are not allowed for transportation.
- For safety reasons, please adhere to the indicated charging and operation temperature.
- In case the battery is too hot, disconnect it, evacuate the room, and wait for 2 hours before taking further steps.
- Disposal of the battery takes place in accordance with local regulations.

2.5 Recommendations

- Do not exceed the storage temperature as it will shorten the product life and performance.
- Allow the battery to settle to room temperature before use.
- If the battery is completely discharged, recharge the battery before storage.
- Always use correct LINAK charger.
- Battery should be replaced after four years at the latest.
- Leave the battery and control box on the CSM2956 CS Universal Spine Extension™ - Powered Leg to prevent it from being lost.

2.6 Other Warnings / Additional Advisories

Do Not:

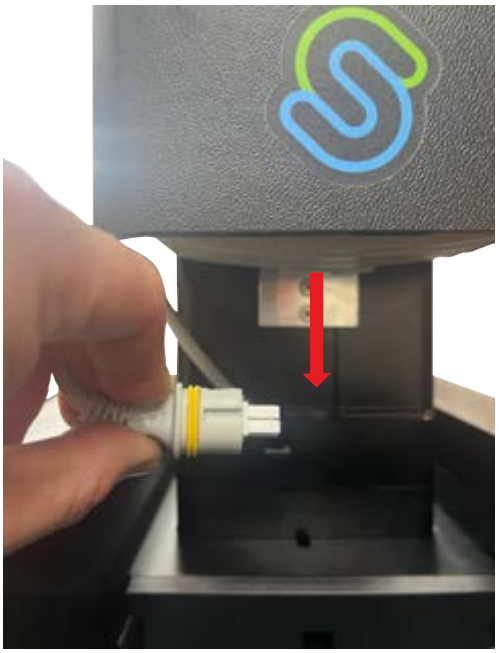
- Heat or burn batteries.
- Expose the batteries to high impact / excessive force.
- Crush or puncture the batteries.
- Use batteries with signs of damage or corrosion.
- Charge or store the batteries near combustible material.
- Exceed IP-ratings.
- Overcharge or fully discharge the batteries.

2.7 Safety feature

Lithium-ion batteries contain several mechanisms to protect themselves from being damaged due to excessive use. In case of overheating, the device will activate a thermal protection. No power output will be available until the temperature is again within normal operating range. Overheating may occur by extensive use at high temperatures or when exceeding the duty cycle (see product label).

2.8 Emergency disconnection instructions.

To disconnect the battery power: Remove the cable from the battery located on the underside of the control box cover



To disconnect the mains power: Remove mains cable from the control box

2.9 Battery replacement hazards and steps.

All battery replacement's should be done by a professional. Only LINAK-approved batteries may be used. Using non-approved batteries may:

- Lack essential thermal protection circuits
- Enter thermal runaway
- Ignite or explode
- Emit flammable gases
- Provide incorrect voltage

2.10 Incident reporting contacts.

In the event of any incident, please contact Care Surgical directly on 866-243-4107 or via email at uk.sales@care-surgical.com.

3 RELEVENT REGULATIONS

The Universal Spine Extension is a Class I medical device that carries both CE and UKCA markings, in accordance with the classifications defined under EU and UK medical device regulations.

All Care Surgical products are manufactured in accordance with the Quality Management System assessment route defined in the ISO 13485 standard. A full list of relevant regulations and directives with which the Universal Spine Extension complies is provided below:

Use only manufacturer-approved parts. Unauthorized replacements void warranty and may cause injury.

Use only: Linak supplied cable (included) or equivalent certified to [IEC 60601-1]

3.1 EU Regulations

The Medical Device is CE marked in accordance with:

- 2017/745 "MDR" EU Medical Device Regulation.

3.2 UK Regulations

The Medical Device is UKCA marked in accordance with:

- (UK) Medical Devices Regulations 2002.

3.3 EMC Testing Standards

The CS Universal Spine Extension has been tested in accordance with the following standards:

Safety tested according to:

- EN 60601-1:2006+A1+A12+A2:2021
- IEC 60601-1:2005 (3rd Edition) + A1:2012 + A2:2020
- EN 60601-1-6:2010 + A1:2015 + A2:2021
- IEC 60601-1-6:2010 A1:2013+A2:2020

EMC tested according to:

- IEC 60601-1-2:2014+A1:2020
- IEC 60601-2-46:2016 (Chapter 202 only - Two operating modes as per Chapter 202.8.101).
- IEC 60601-2-2 in conjunction with IEC 60601-2-46 (Chapter 202.8.102) – Immunity to HF Surgical emissions

3.4 National Deviations

The CS Universal Spine Extension has been tested in accordance with the Standard IEC 60601-1:2005 + A1:2012 + A2:2020 to demonstrate compliance with the following national differences:

Canada National Differences:
- National standard CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

US National Differences:
- National standard AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601- 1:2005/AMD2:2021

Japan National Differences:
- National standard JIS T 0601-1:2023

3.5 Other EMC Directives

The LINK control box used for the CS Universal Spine Extension™ – Powered Leg complies with the following EMC Directives:

EMC Directive 2014/30/EU according to following the standards:
- EN 55011:2016+A1, EN IEC 61000-3-2:2019+A1, EN 61000-3-3:2013+A1+A2,
- EN 61000-4-2:2009, EN IEC 61000-4-3:2020, EN 61000-4-4:2012,
- EN 61000-4-5:2014+A1, EN 61000-4-6:2014,
- EN 61000-4-8:2010, EN IEC 61000-4-11:2020.
-

Low Voltage Directive 2014/35/EU according to the standard:
- EN 60601-1:2006+A1

RoHS2 Directive 2011/65/EU according to the standard:
- EN 63000:2018

3.5 Symbols

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 manufacture of the medical device	EN ISO 15223-1
	Indicates the manufacturers product code	EN ISO 15223-1
	Indicates the device does 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
	Indicates the range of humidity to which the medical device can be safely exposed.	EN ISO 15223-1
	Indicates the temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1
	Indicates a carrier that contains Unique Device Identifier information.	EN ISO 15223-1
	Indicates a medical device that needs protection from light sources.	EN ISO 15223-1
	Indicates the entity importing the medical device into the locale.	EN ISO 15223-1
	Indicates a medical device that has not been subjected to a sterilization process.	EN ISO 15223-1
	To identify equipment meeting the safety requirements specified for Class II equipment.	IEC 60601-1

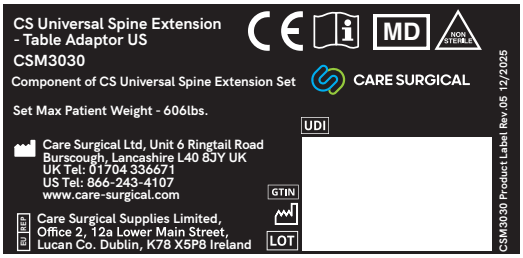
The following symbols are used on the CS Universal Spine Extension™ - Powered Leg CSM2956, where applicable:

MD	Class 1 Medical Device	MDR 2017/745
	Class II equipment (Electrical)	IEC 60417-5172
	Japanese TELEC	
c UL us	Recognised component mark for Canada and the United States	
	Regulatory compliance mark: The Australian Safety / EMC Regulations	
	Electronics scrap	
	PSE diamond mark	
	Direct current	

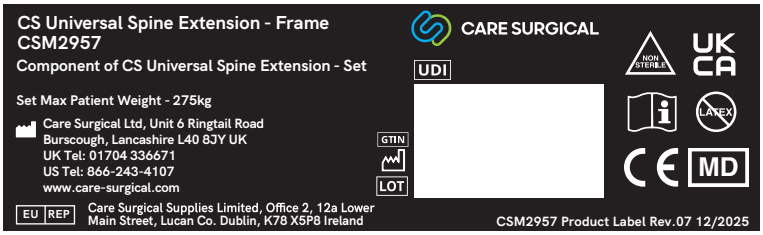
3.6 Product Labelling and On-Product Warnings

3.6.1 Product labelling

1. CSM3030 CS Universal Spine Extension™ - Table Adaptor (US)



2. CSM2957 CS Universal Spine Extension™ - Frame

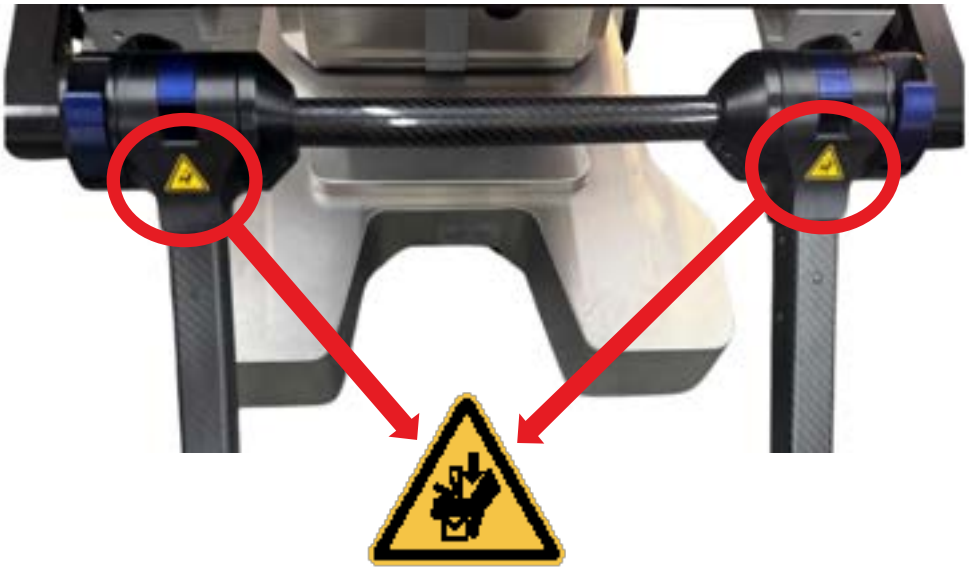


3. CSM2956 CS Universal Spine Extension™ - Powered Leg

3.6.2 Warnings on the product

1. Crushing hazard on the CSM3030 CS Universal Spine Extension™ – Table Adaptor (US) and – Frame CSM2957

2. Crushing hazard on the CSM2957 CS Universal Spine Extension™ - Frame



3. Crushing hazard on the CSM2956 CS Universal Spine Extension™ - Powered Leg

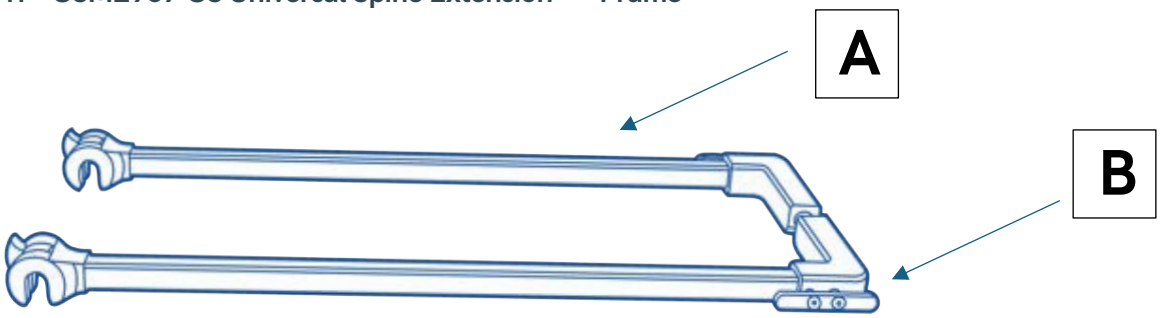
4 PRODUCT SPECIFICATION

Mechanical Specifications	Description
Product Dimensions	**CSM2957 CS Universal Spine Extension™ - Frame** (LxWxH) 1482.5mm x 502.4mm x 77.61mm **CSM3030 CS Universal Spine Extension™ - Table Adaptor (US)** (LxWxH) 226 x 540.5/740.5 x 170mm **CSM2956 CS Universal Spine Extension™ - Powered Leg** (LxWxH) 490x440x568/1133mm
Material	Aluminum alloy, Stainless Steel, Carbon Fibre
Max Patient Weight	**275 kg / 606 lbs.**
Overall Weight of Device	**CSM2957 CS Universal Spine Extension™ - Frame** 7.5 kg / 16.5 lbs. **CSM3030 CS Universal Spine Extension™ - Table Adaptor (US)** 4.5 kg / 9.9 lbs. **CSM2956 CS Universal Spine Extension™ - Powered Leg** 42 kg / 92.5 lbs.
Storage Specifications	**Description**
Storage Temperature	-10 to +40
Operating Temperature	+5 to +40
Storage and Operating Relative Humidity Range	20%-80% - non-condensing
Atmospheric pressure	700 to 1060hPa (rated to be operated at an altitude ≤ 3000 m)
Compatibility Specifications	**Description**
Compatible with:	Compatible with accessories designed for use with standard dual-rail operating table accessories1.25″ (3.2cm) wide and 1.5c″ (3.8cm) tall (with 14.5″/ 36.8cm space between).
To use with:	Recommended for use with: CSM2714 CS Head Tray CSM2709 CS Chest Support CSM2717 CS Hip Supports CSM2718 CS Thigh Supports CSM2647 CS Universal Arm Support™ – Moulded CSM2722-7 CS Supine Top – Base only CSM2722-2 CS Supine Top – 2″ CSM2966 CS Small Supine Top – Base only CSM3048 CS Mayfield/Doro Adaptors
Operating Table Compatibility	Compatible with all operating tables that have EU standard rails and the weight capacity up to 275 kg / 606 lbs.
Transport Specifications	**Description**
Transport Conditions	• Temperature range (-10°C to +40°C). • Humidity limits (20-80% non-condensing). • Do not store in direct sunlight • Do not stack

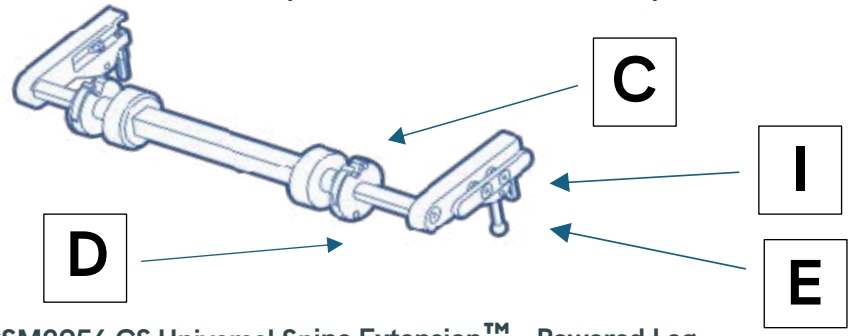
4.1 Components and list of features

Component	Feature
A	Carbon Frame
B	Integrated din rails for accessories
C	Pivot point
D	Width adjustability
E	Clamp lever
F	Connecting point Frame/Powered Leg – allows lateral tilting up to 45°
G	Battery / Control box
H	Brakes (on the left and right)
I	Safety Screw

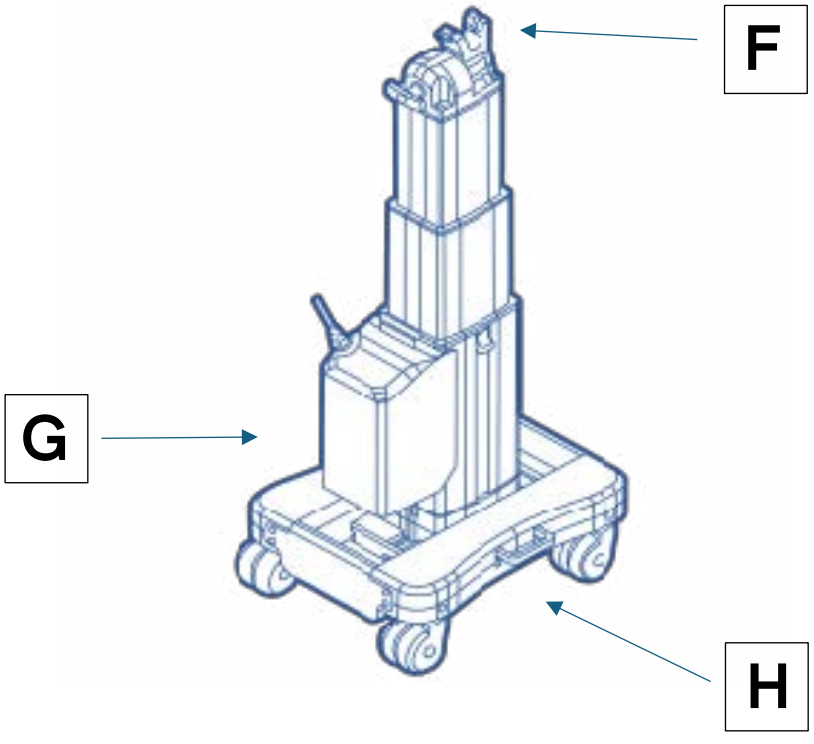
1. CSM2957 CS Universal Spine Extension™ - Frame



2. CSM3030 CS Universal Spine Extension™ - Table Adaptor (US)



3. CSM2956 CS Universal Spine Extension™ - Powered Leg



4.2 Controls and Indicators

4.2.1 Remote

You will find these indicators and controls on the remote:

Battery level indicator

Adjusting the height of the CSM2956 CS Universal Spine Extension™ - Powered Leg

The LED functionality matrix below describes the remote behaviour when the control box is connected to the mains.

LED	Indication of operation
Flashing orange	Charging
No LED Light (when button(s) are pressed)	No charge
Soild orange	Charged (to that percentage)
All lights flashing	Error during charging

The LED functionality matrix below describes the remote behaviour when the control box **is not** connected to the mains.

LED	Indication of operation
No LED Light (when button(s) are pressed)	No charge
Soild orange	Charged (to that percentage)
All lights flashing	Error

4.2.2 Control Box

The control box is equipped with a green LED for indication of mains power connected. When the control box is connected to mains, the LED is green. Connected only to battery, the LED is off.

If the control box makes a beeping noise during remote control, this is to indicate the battery has a low charge. Please plug the product into the mains immediately or at the soonest possible convenience to aviod a dead battery.

Follow these safety instructions to help prevent patient fall, injury, and/or damage to the equipment:

4.2.3 Battery

The LED functionality matrix below describes the battery behaviour when the control box is connected to mains.

LED	Indication of operation
Soild orange	Charging
No LED light	Fully charged
Flashing orange or intermittent lighting	Error during charging

4.3 Potential Equalisation Conductor

The CSM2956 CS Universal Spine Extension™ - Powered Leg features a plug to which you can connect an equipotential cable. This equalises any potential differences when the CSM3031 CS Universal Spine Extension™ SET (US) is used on a patient wearing intravenous, cardiac or other medical devices.

4.4 Electromagnetic Compatibility Guidelines

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

4.4.1 This product is intended for use in an operating room environment by trained healthcare professionals only, within an electromagnetic environment compliant with the IEC 60601-1-2 standard. The product is compatible for use near active high-frequency (HF) surgical equipment. It should not be used within the RF-shielded room of a magnetic resonance imaging (MRI) system.

4.4.2 (b) Essential Performance:

Essential Performance Item	Reason it is Essential	Verification Method
Ability to raise/lower Powered Leg (CSM2956) smoothly	Needed to position patient safely; loss could delay surgery or cause injury	Functional movement test during and after EMC immunity disturbances
Ability to raise/lower Powered Leg (CSM2956) smoothly if the battery goes into hibernation mode	Needed to position patient safely; loss could delay surgery or cause injury	Plugging in the mains cable allows the Powered Leg to operate and bypass the battery hibernation mode
Electrical control responsiveness	Delays or failures could interrupt surgery or cause hazard	Operate controls during RF immunity and ESD tests

4.4.3 (C) Use of this equipment adjacent to or stacked with other equipment should be avoided, as it could result in improper operation. If such use is necessary, this equipment and any other nearby devices should be observed to verify normal operation. Where other electromagnetic equipment is used in proximity, it is recommended that such equipment also complies with IEC 60601-1-2 to minimize the risk of interference or performance degradation.

4.4.4 (D) Replacement Parts:

Component	Length
UK Mains Cable	3.2m
US Mains Cable	3.2m
EU Mains Cable	3.2m
India Mains Cable	3.2m
Aus/NZ Mains Cable	3.2m
Battery Back up cable	0.18m
Handset Cable	0.6m coiled

4.4.5 (E) The use of accessories, transducers, or cables other than those specified or provided by the manufacturer (Care Surgical Ltd) may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, potentially leading to improper operation.

4.4.6 (F) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME Equipment or ME System, including the cables specified by the manufacturer. Failure to maintain this minimum distance may result in degraded equipment performance.

4.4.7

The listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the models should ensure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The listed models use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The listed models are suitable for use in establishments that are not intended for sale to the general public. These professional ME EQUIPMENT and ME SYSTEMS are allowed to meet the requirements for CISPR 11 class A under the following conditions: - they are predominantly intended to be connected (e.g. in hospitals or doctor's offices) to dedicated supply systems (normally fed by separation transformers), or - they have a RATED input power > 20 kVA and are intended to be powered by a dedicated power transformer and connected to it solely by a clearly identifiable power line path.
Harmonic emissions IEC 61000-3-2	Not applicable.	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable.	

The listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the listed models should ensure that they are used in such an environment.

Enclosure Port			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM 1kHz	3 V/m	Mains power quality should be that of a typical commercial or hospital environment.
	385 MHz (18 Hz PM); 27 V/m	27 V/m	
	450 MHz (FM +/-5 kHz deviation 1 kHz sine); 28 V/m	28 V/m	
	710 MHz (217 Hz PM); 9 V/m	9 V/m	
	745 MHz (217 Hz PM); 9 V/m	9 V/m	
	780 MHz (217 Hz PM); 9 V/m	9 V/m	
	810 MHz (18 Hz PM); 28 V/m	28 V/m	
	870 MHz (18 Hz PM); 28 V/m	28 V/m	
	930 MHz (18 Hz PM); 28 V/m	28 V/m	
	1720 MHz (217 Hz PM); 28 V/m	28 V/m	
	1845 MHz (217 Hz PM); 28 V/m	28 V/m	
	1970 MHz (217 Hz PM); 28 V/m	28 V/m	
	2450 MHz (217 Hz PM); 28 V/m	28 V/m	
	5240 MHz (217 Hz PM); 9 V/m	9 V/m	
	5500 MHz (217 Hz PM); 9 V/m	9 V/m	
Proximity magnetic fields IEC 61000-4-39	134,2 kHz; PM 2,1 kHz; 65 A/m	65 A/m	RFID, WPT, and similar equipment should not be used closer than the recommended separation distance of 15 cm from any part of the device, including cables.
	13,56 MHz; PM 50 kHz; 7,5 A/m	7,5 A/m	

The listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the listed models should ensure that they are used in such an environment.

Input a.c. power PORT			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV 100kHz Repetition frequency	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 0,5 kV, ±1 kV; Line-to-line ± 0,5 kV, ±1 kV, ± 2 kV; Line-to-ground (a)	± 0,5 kV, ±1 kV Line-to-line	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF induced by RF fields IEC 61000-4-6	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands b) 80% AM 1kHz	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM Radio Bands	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0°,45°,90°,135°,180°,225°,270°,315° 0% U_T; 0° 0% U_T; 70% 0% U_T; 0%	0,5 Cycles 1 Cycle 25/30 Cycles (50/60Hz) 250/300 Cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the listed models requires continued operation during power mains interruptions, it is recommended that the above listed models are powered from an uninterruptible power supply or battery.

Comment:
a) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
b) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

The listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the listed models should ensure that they are used in such an environment.			
Signal input/output parts PORT			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/bursts IEC 610004-4 (a)	± 1 kV 100 kHz Repetition frequency	± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5 (b)	±2 kV Line-to-ground		Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF induced by RF fields IEC 61000-4-6 (d)	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands c) 80% AM 1kHz	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM Radio Bands	Mains power quality should be that of a typical commercial or hospital environment.
Comment: a) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded. b) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

5 SETUP AND USE

5.1 Before using the CSM3031 CS Universal Spine Extension™ SET (US)

Before each use of the CSM3031 CS Universal Spine Extension™ SET (US), ensure that all necessary accessories are attached and secured and that the CSM3031 CS Universal Spine Extension™ SET (US) is suitable for use. Check all the products do not have any damage and all function as intended. If any of the controls or indicators do not function properly, do not use the CSM3031 CS Universal Spine Extension™ SET (US) and contact Care Surgical Ltd / LLC or your local distributor immediately.

5.1.2 Disconnecting and transporting the device.

Do not lift or carry the Powered Leg assembly. It is intended for transport only on its integrated wheels. Do not attempt to carry the Frame and Adaptor simultaneously.

For safety reasons always ensure a clear pathway.

1. Prepare Area

- Clear obstacles from the pathway.

2. Disconnect System

- Disconnect Frame from Powered Leg
- Disconnect Frame from Adaptor
- Remove Adaptor from operating table:

3. Transport Components

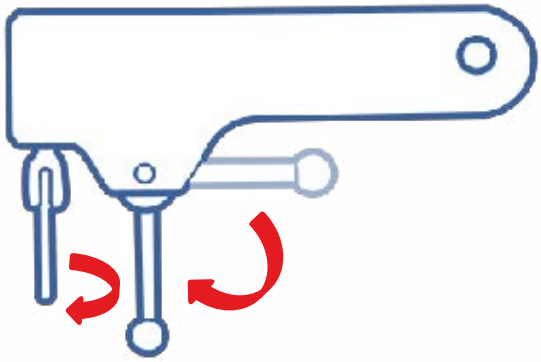
- Carry the frame and adaptor separately
- Wheel the Powered Leg to the new room.

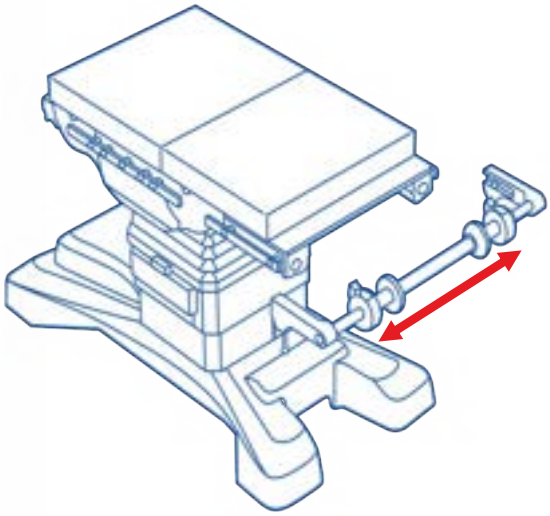
4. Reassemble System

5.2 Set Up

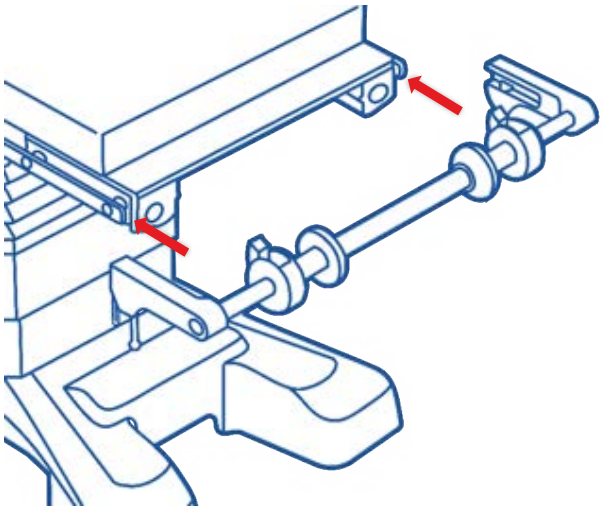
1. To attach the Table Adaptor to the OR table, ensure the adaptor is connected to a table section to avoid damage from the OR table's hinges when adjusted.

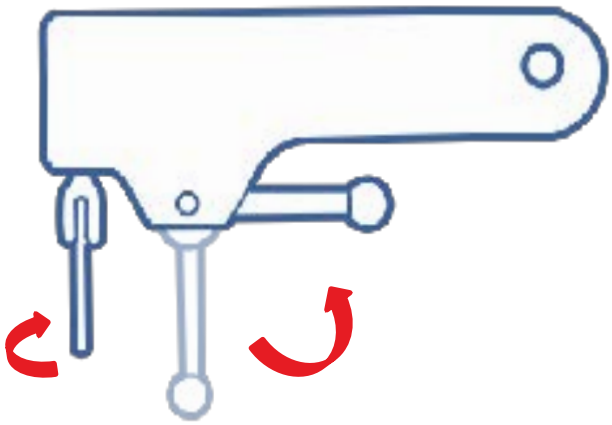
2. Please ensure the blue latches are disengaged to adjust the width of the adaptor to fit the OR table, including din rails. Ensure the levers on the rail clamps are disengaged to attach the adaptor onto the din rails.



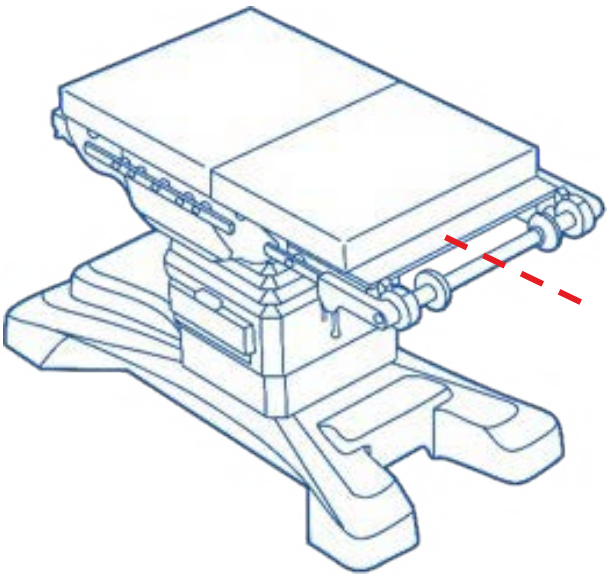


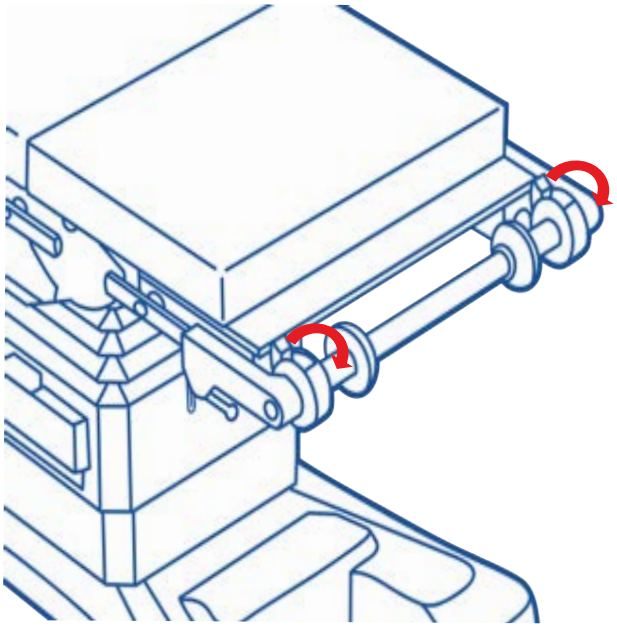
3. Slide the Table Adaptor onto the table's din rails and tighten both clamps to the din rails. Tighten additional safety screws for extra stability.



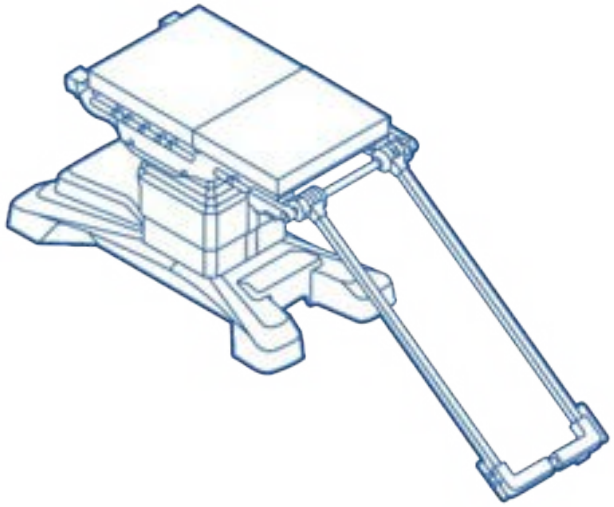


4. Centralise the Table Adaptor to the table and close the blue latches.

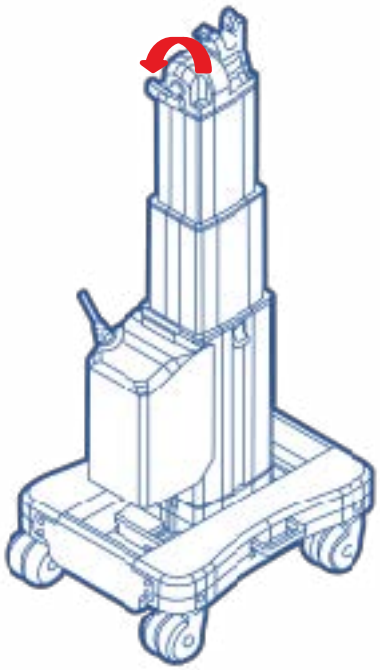


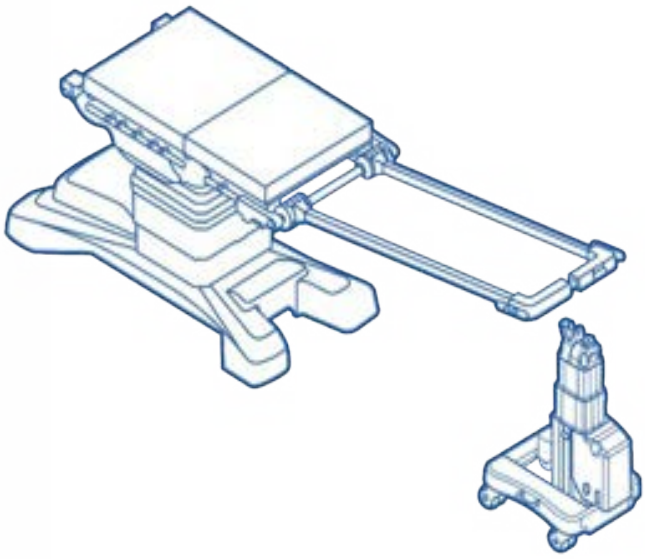


5. To attach the Frame to the adaptor place the closed head end of the frame on the floor and step through the frame holding the collar ends.Open the blue levers and place onto the adaptor, once in position, close the blue lever.

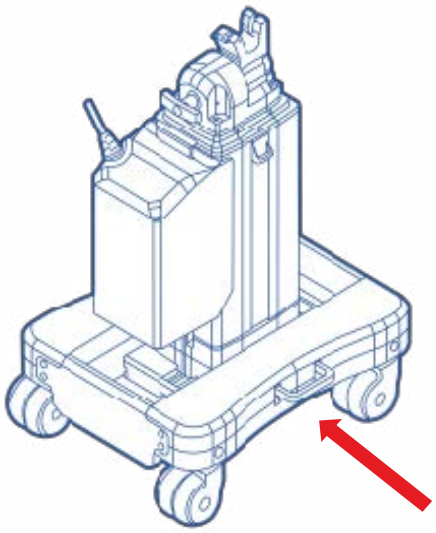


6. To attach the frame to the Powered Leg; Slightly loosen the pivot shaft on the powered leg by turning the handle. Place the head end of the frame into the pivot shaft - ENSURE the leg is aligned straight with the frame to allow the coupling to engage. For the best possible flexibility, the battery should face towards the anaesthetist.



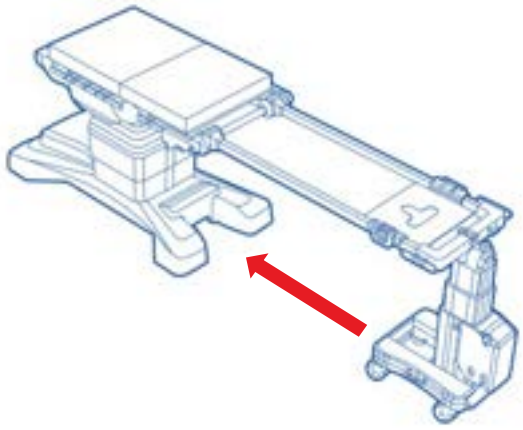


7. For safety reasons, the brakes of the Powered Leg should always be engaged during patient transfer and during procedures on the patient



8. When trending or laterally tilting the operating table, release the brakes on the Powered Leg to allow it to move freely with the table and prevent tipping

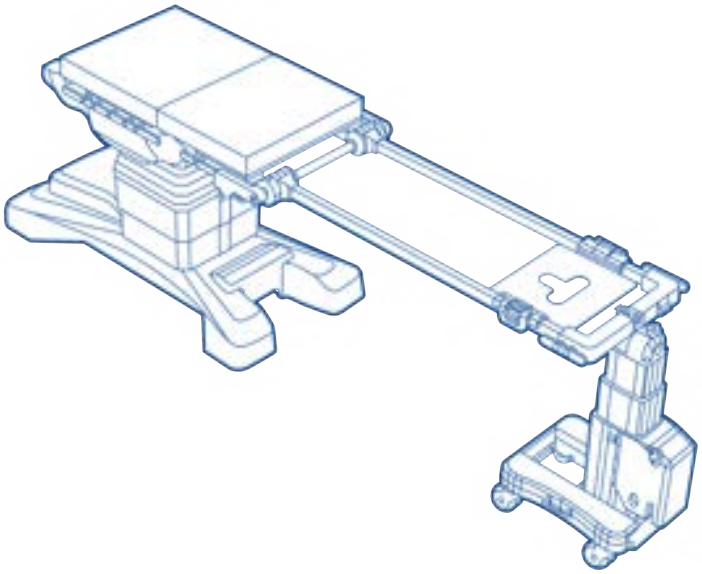
9. When the table and frame are LEVEL make sure that the base of the Powered Leg is positioned as close as possible to the operating table. This ensures that the column has sufficient leeway and avoids tipping over in the case where the operating table trends, and the brakes on the powered leg are locked.



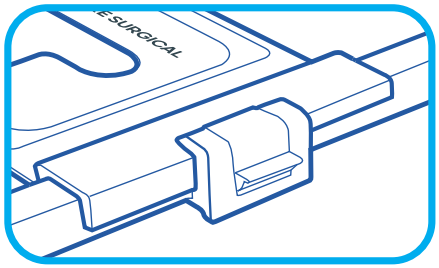
10. Make sure that Powered Leg is at the same height as the operating table and the CSM2957 CS Universal Spine Extension™ - Frame in a horizontal position before moving or turning the patient.

5.3 Recommended Accessories Prone Procedures – Instructions & Fitting*
(If using for lateral or supine procedures go to 5.4)

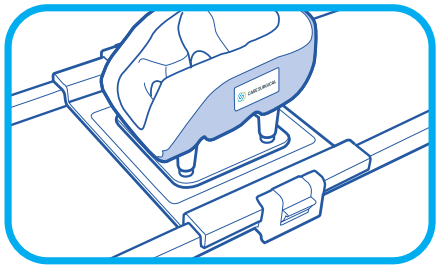
5.3.1 CSM2714 CS Head Tray Attachment



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

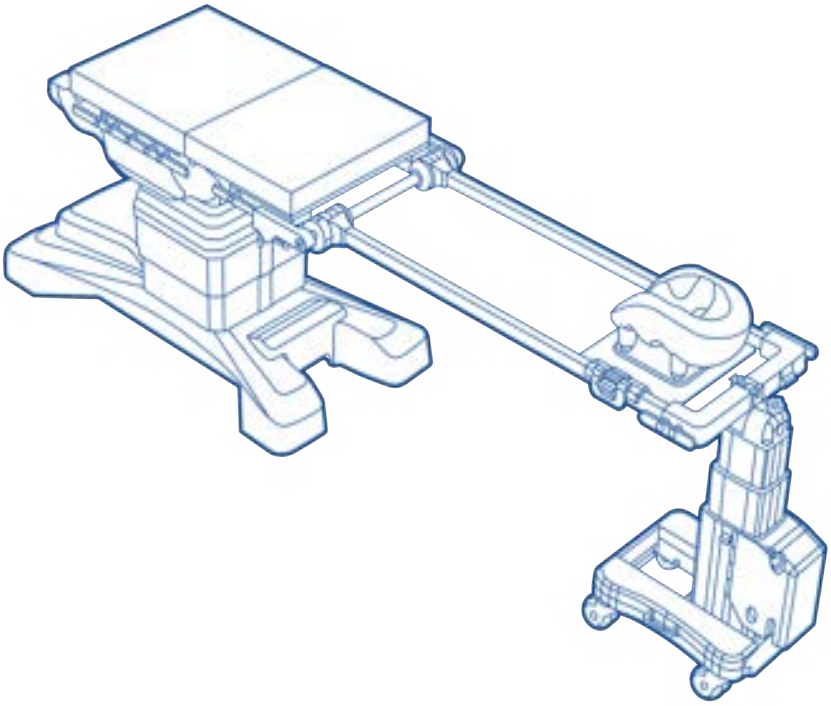


2 Snap the locking clip shut to secure the attachment in position

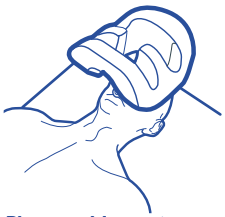


3 Place prone head support in the centre of the attachment

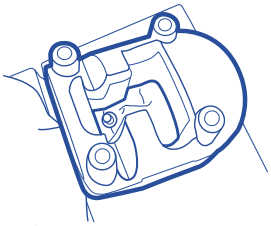
5.3.2 CSM2565 CS Prone Plus Head Support System™ / CSM2560 CS Prone Head Support System™



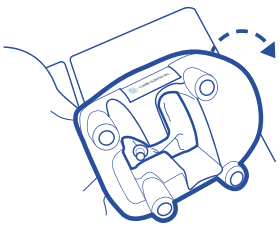
1 With patient supine, disconnect ET tubing



2 Place cushion onto patient's face

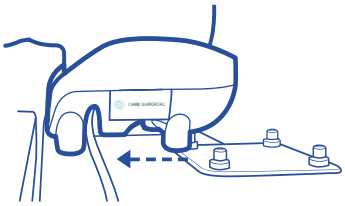


3 Place helmet over cushion



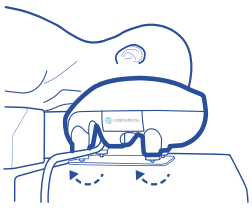
4 Turn patient to prone position

5 Re-connect ET Tubing



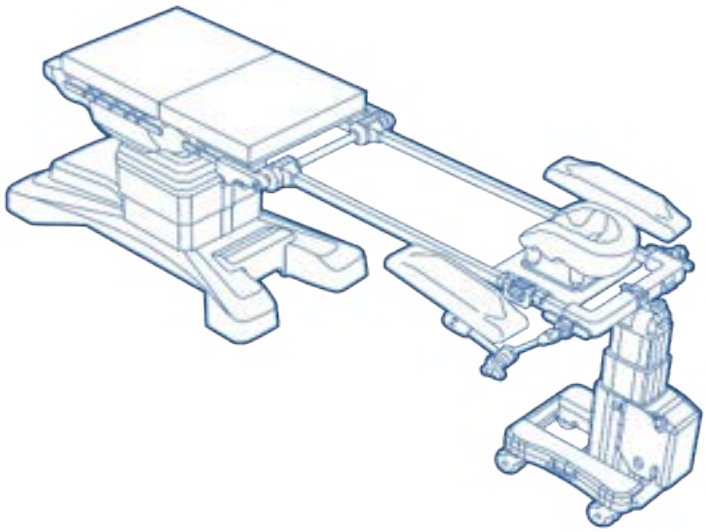
6 Lift helmet & locate onto mirror's cogs

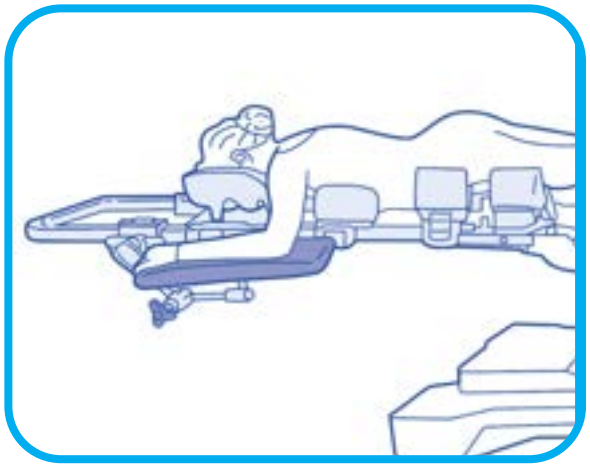
7 Check the face is correctly positioned in cushion

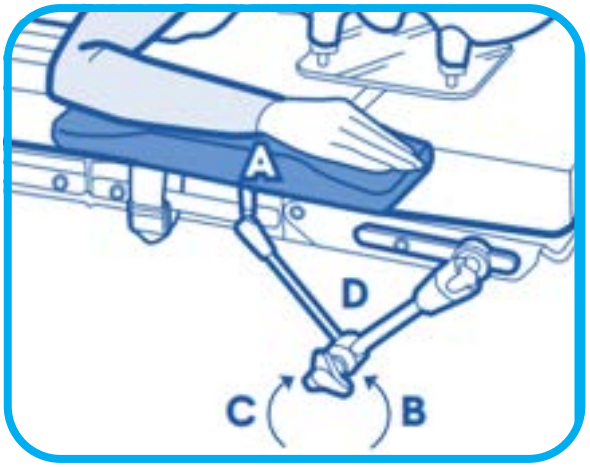


8 Adjust cogs to obtain neutral neck line

5.3.3 CSM2647 CS Universal Arm Support Moulded™

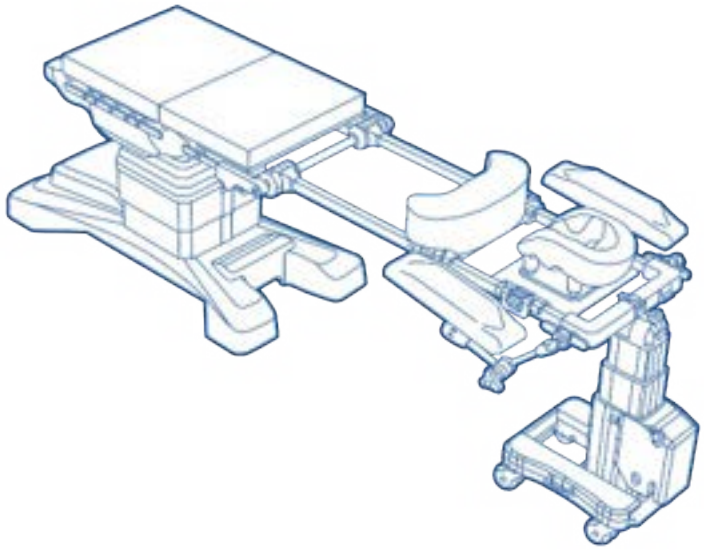




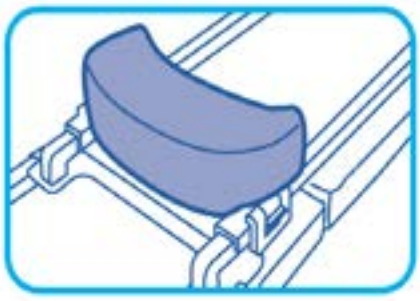


1. Hold the Universal Arm Support with one hand via the anterior segment (A) and manipulate the central clamping handle (D) with the other hand.
2. To release turn the central handle (D) counter clockwise (B) as far as necessary.
3. Move the Universal Arm Support into the desired position.
4. Turn the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

5.3.4 CSM2709 CS Chest Support



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

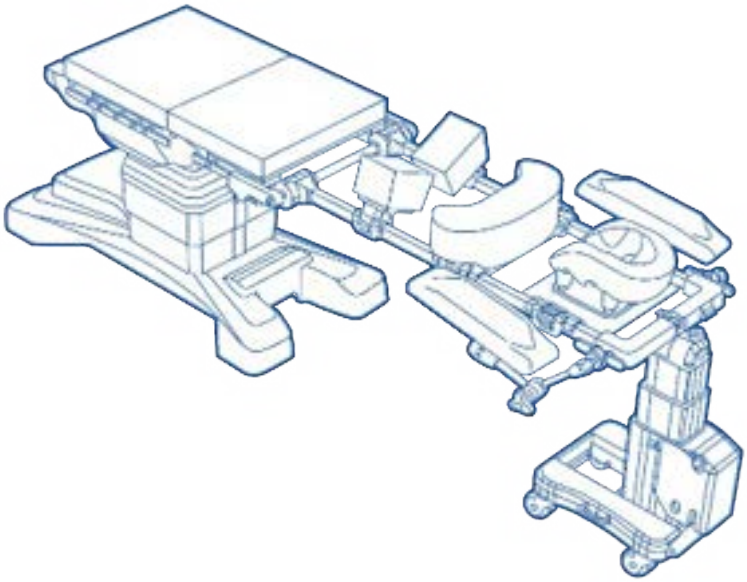


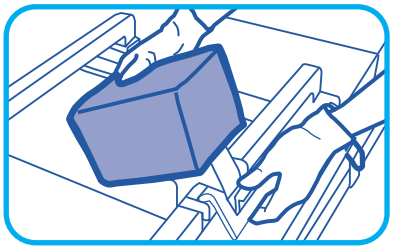
2 Snap the locking clip shut to secure the support in position

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)

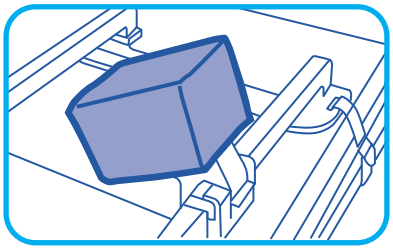
For male patients, the chest support should be positioned directly under the nipples.
For female patients, move the chest support towards the head to allow easier positioning of the breast.
These products will support a patient weight of up to 250kg. Do not exceed the weight capacity of the operating table.

5.3.5 CSM2717/2719/2723 CS Hip Supports / Large / Small

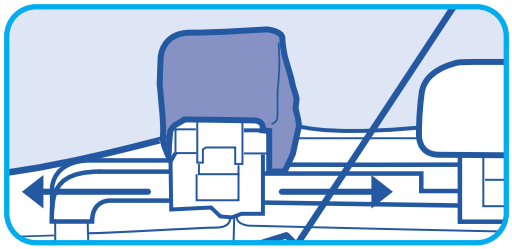




1 Place the supports on the frame so that the brackets are over the bars



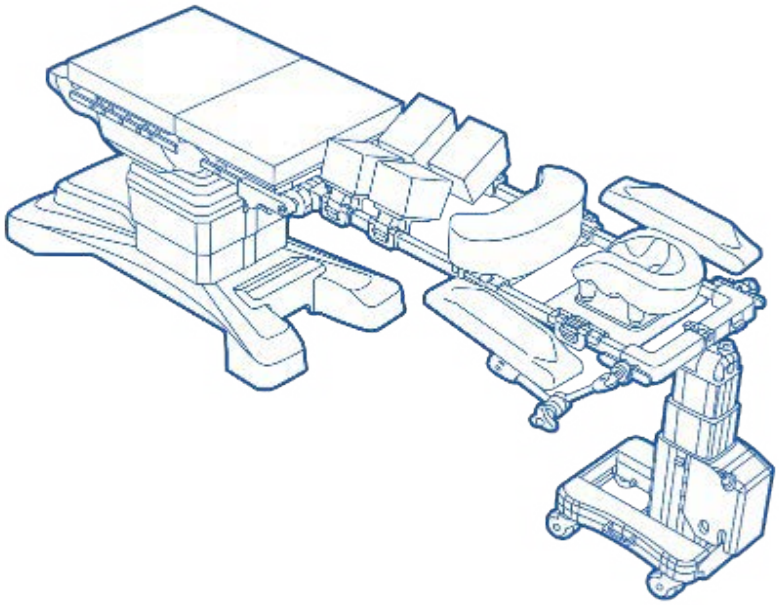
2 Snap the locking clip shut to secure the support in position

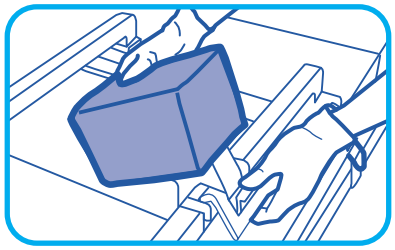


3 To adjust the position of the supports, release the clip(s), raise the patient's chest or hips, slide the supports to the correct position, lock the clip(s)

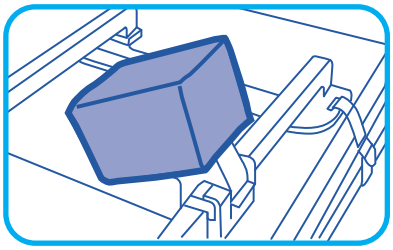
Ensure the iliac crest is in the centre of the hip pads. Do not exceed the weight capacity of the operating table.
Compatible with rail sizes that measure 1.25" (3.2cm) wide and 1.5" (3.8 cm) tall
Refer to the label on the support to ensure it is placed in the correct position on the table.

5.3.6 CSM2718 CS Thigh Supports

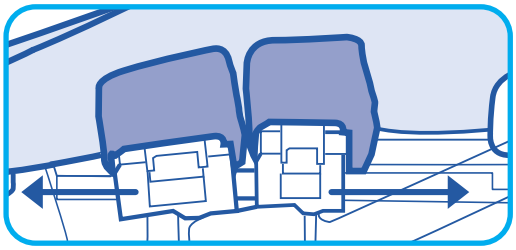




1 Place the supports on the frame so that the brackets are over the bars



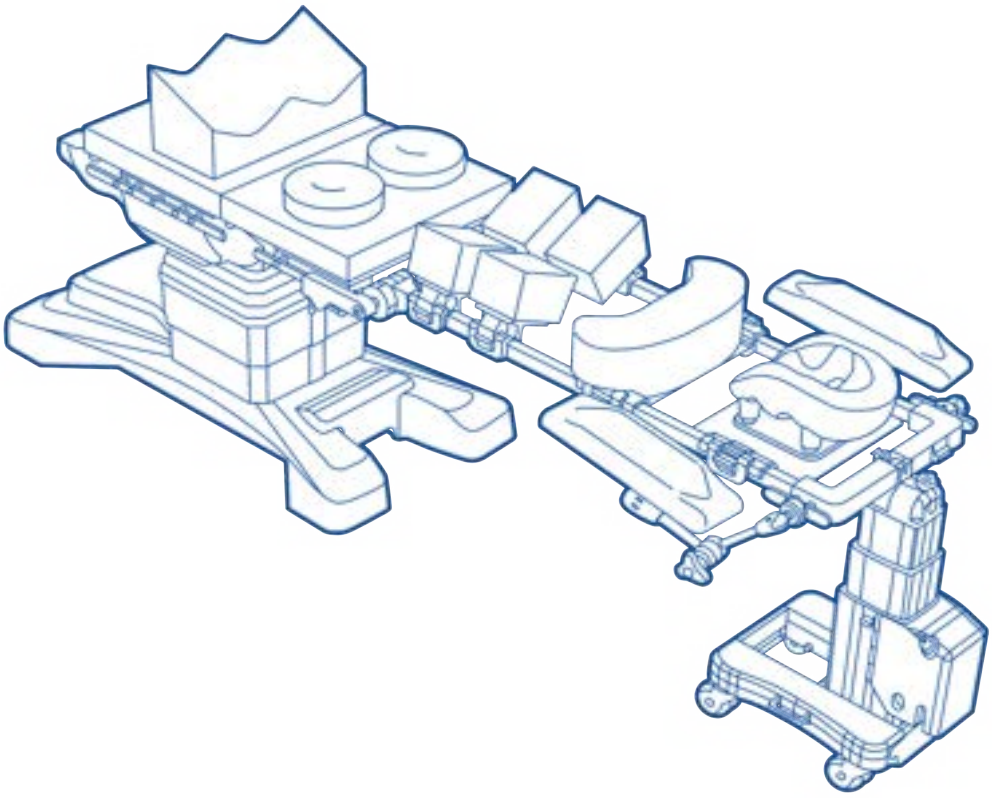
2 Snap the locking clip shut to secure the support in position

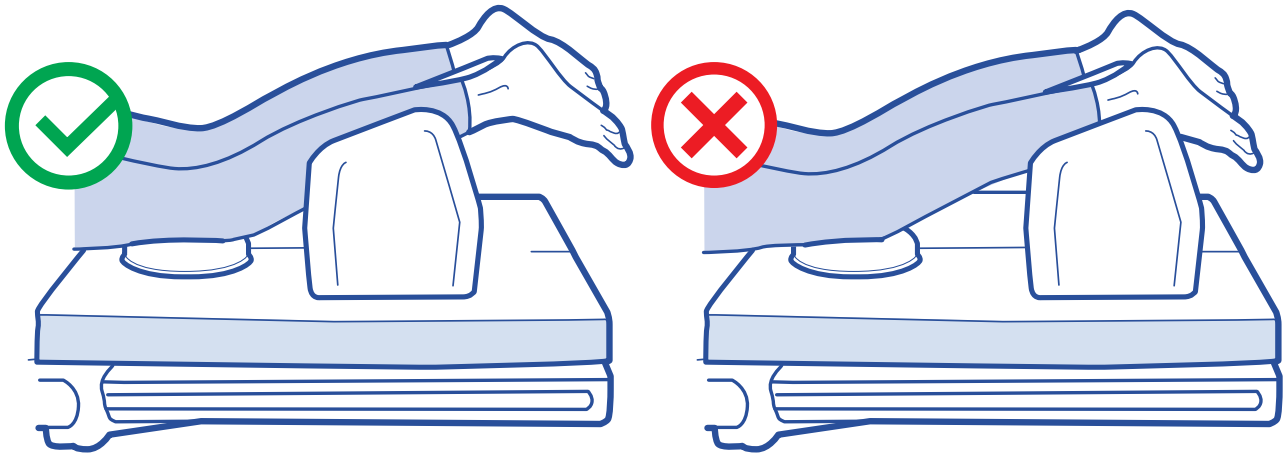


3 To adjust the position of the supports, release the clip(s), raise the patient's chest or hips, slide the supports to the correct position, lock the clip(s)

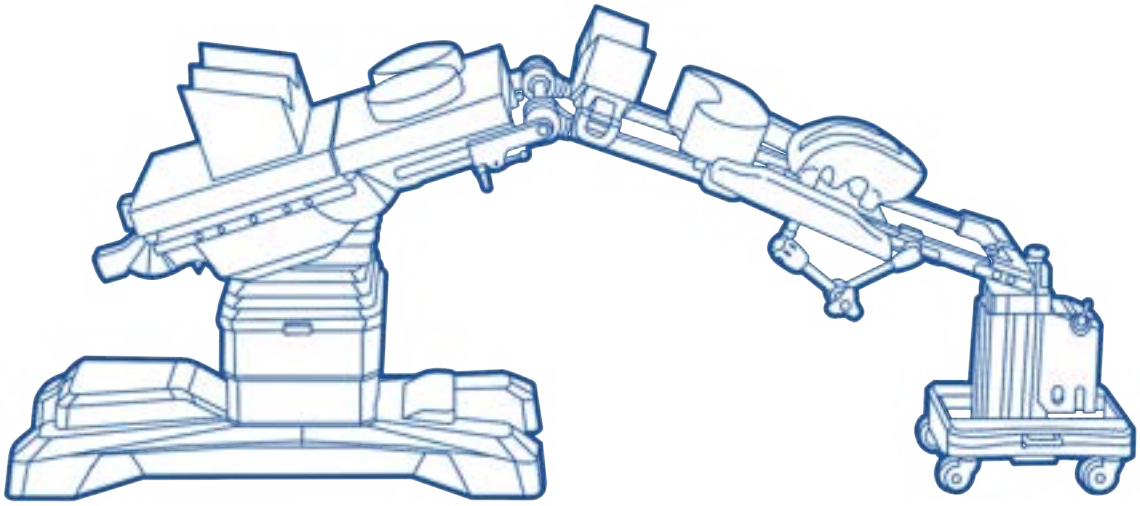
Ensure the iliac crest is in the centre of the hip pads. Do not exceed the weight capacity of the operating table.
Compatible with rail sizes that measure 1.25″ (3.2cm) wide and 1.5″ (3.8 cm) tall
Refer to the label on the support to ensure it is placed in the correct position on the table.

5.3.7 CSM2821 CS Knee Rings (Pair) and CSM3020 CS Easy Shin Supports™



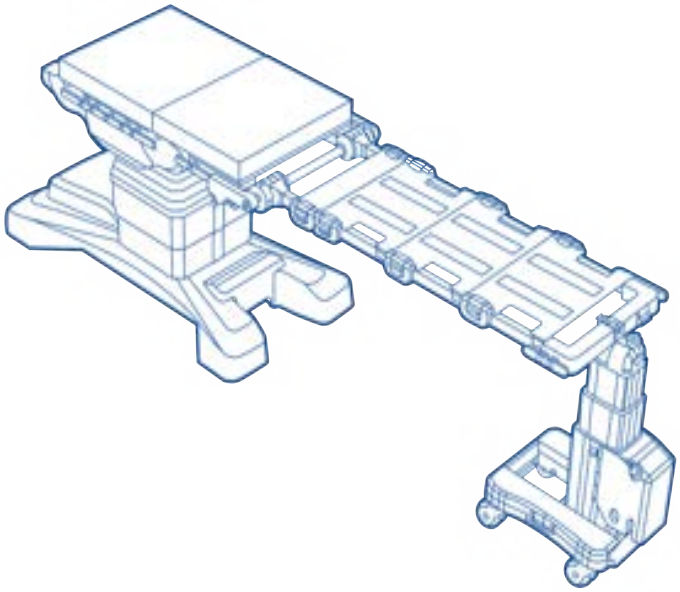


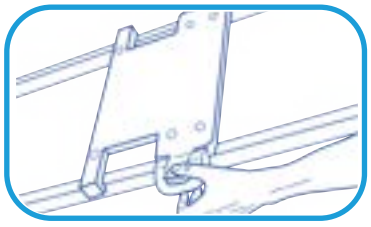
5.3.8 Set-Up without Thigh Supports



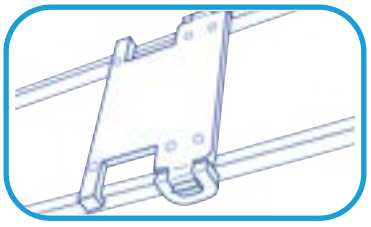
5.4 Recommended Accessories for Supine/Lateral Procedures – Instructions & Fitting

5.4.1 CSM2722-7 CS Supine Top – Base Only + CSM2966 CS Small Supine Top – Base

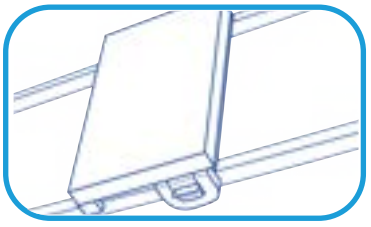




1 Place the attachment on the frame so that the brackets are over the bars.

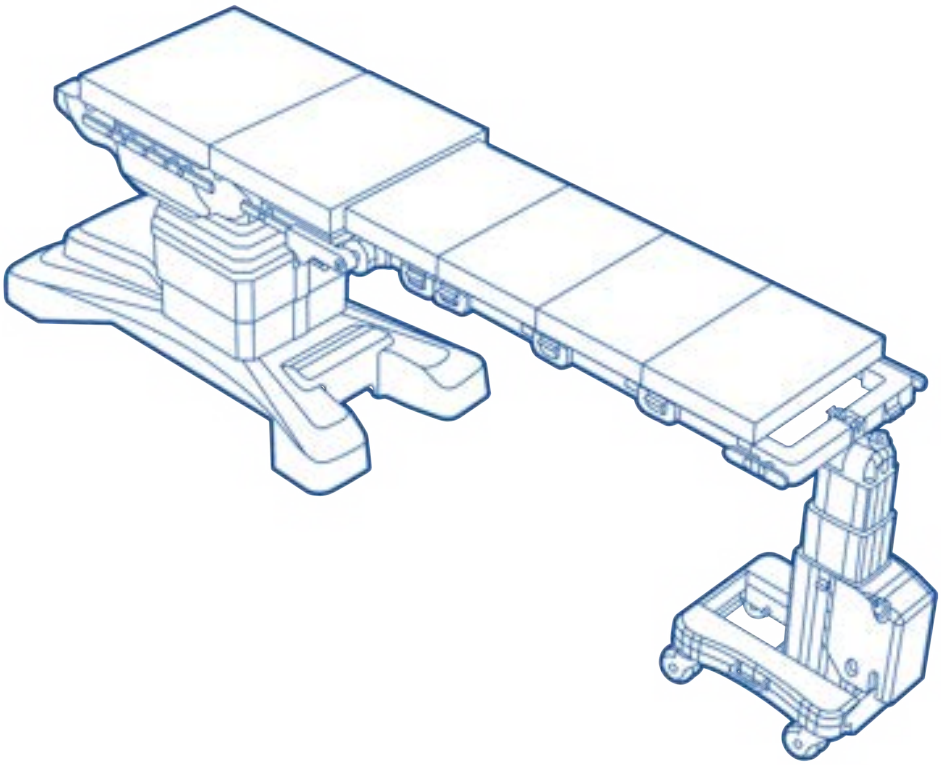


2 Snap the locking clip shut to secure the attachement in position.



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

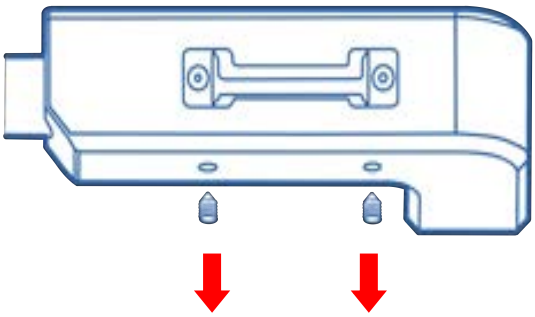
5.4.2 CSM2722-2 / -3 CS Supine Tops – 2″ or 3″



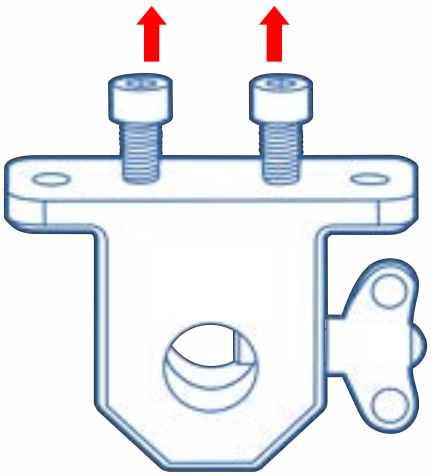
***Refer to individual product Instructions for Use for full usage information, instructions, and warnings.**

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

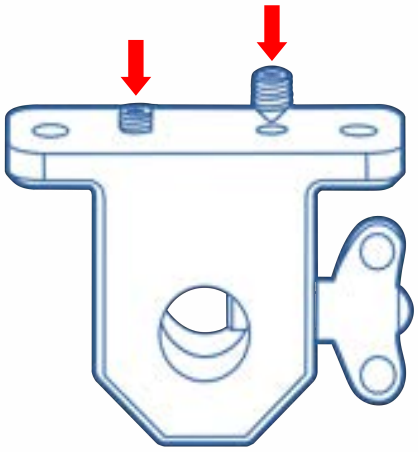
5.5.1 CSM3048 CS Mayfield/Doro Adaptors



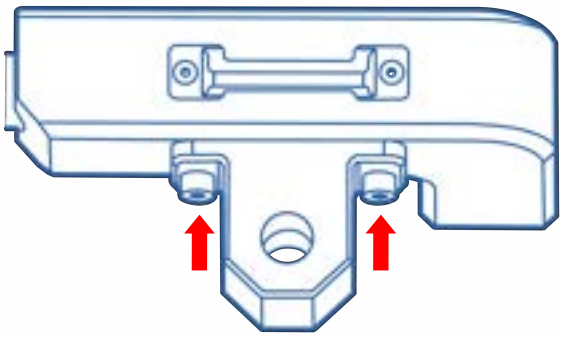
1 Remove the grub screws from underside of the Frame (head end).



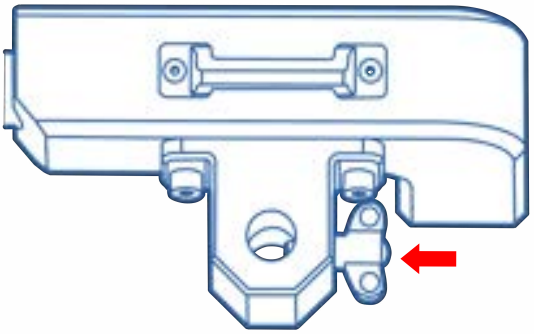
2 Using 6mm allen key, remove bolts from adaptor.



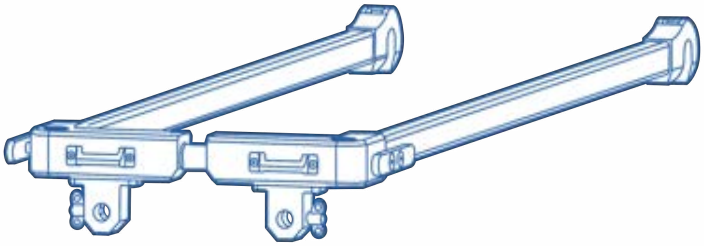
3 Store grub screws in adaptor. Ensure grub screws are not protruding.



4 Bolt the adaptor into the frame (remove wing nut if needed).



5 Reinsert wing nut.



6 CLEANING AND DISINFECTION

The CS Universal Spine Extension™ System should be cleaned between uses on patients/in the operating theatre.

To ensure a long service life for the product, follow the internal regulations and policies regarding cleaning and disinfection, as well as the manufacturer's instructions below:

- There is a risk of electric shock with electrical appliances. Failure to comply with the operating instructions may result in death or serious injury.
- Always wear the appropriate personal protective equipment when cleaning the appliance. Failure to do so may result in injury.
- Do not expose the device or its components to excessive moisture. The patient and or staff could fall, injure themselves or the device could be damaged.
- Do not use harsh cleaning agents, solvents or detergents. The devices could be damaged.
- Do not use iodophors, as these will stain the device.
- If you use a quaternary disinfectant, make sure that you rinse it off immediately. Otherwise, the disinfectant could cause corrosion on painted and coated parts.
- Failure to use cleaning agents and disinfectants in accordance with the manufacturer's instructions may result in damage to the device.
- We recommend that you clean the appliance with detergent and warm water. Do not use excessive liquids or harsh cleaning agents.

7 RELEVANT REGULATIONS

7.1 CSM2956 CS Universal Spine Extension™ - Powered Leg

Only authorised personnel or authorised Care Surgical Ltd / LLC dealers are qualified to repair the CSM2956 CS Universal Spine Extension™ - Powered Leg. If it needs to be repaired under warranty, it must be sent to an authorised service centre. To avoid the risk of malfunction, all drive repairs must only be carried out by an authorised service centre or repairer, as special tools and parts must be used. If a system is opened by unauthorised personnel, there is a risk of subsequent malfunction. To find out who is authorised to repair the device or where it should be sent for repair, please contact Care Surgical Ltd / LLC or the dealer in your country.

The CSM2956 CS Universal Spine Extension™ - Powered Leg or components can be disposed of by separating them into different waste groups for recycling or incineration. When disposing of our product, we recommend that you disassemble it as far as possible and try to recycle it. The CSM2956 CS Universal Spine Extension™ - Powered Leg or components should be disposed of in accordance with the environmental regulations applicable in the respective country.

CSM3031

CS Universal Spine Extension™ SET (US)

CS Universal Spine Extension SET (EU) Contains:
CSM3030 CS Universal Spine Extension - Table Adaptor (US)
CSM2957 CS Universal Spine Extension™ - Frame
CSM2956 CS Universal Spine Extension - Powered Leg

LOT

5 060624 126536

Notes:

CARE SURGICAL

www.care-surgical.com