Instructions for Use

REF **Schure Spine Frame 800-0235**

Replacement Parts:

Schure Spine Frame Crank Handle 800-0277

Schure Spine Frame Pad Set 508-0472

Disposable Laminectomy Arm Cradles 508-0373

Disposable Richards Slotted Headrests, Extended 508-1340

Schure Spine Frame Straps 512-0049

INTENDED USE

Schure Spine Frame is used as a platform to do simple spine surgeries. The intended users of this device are medical professionals within hospitals and surgery centers.

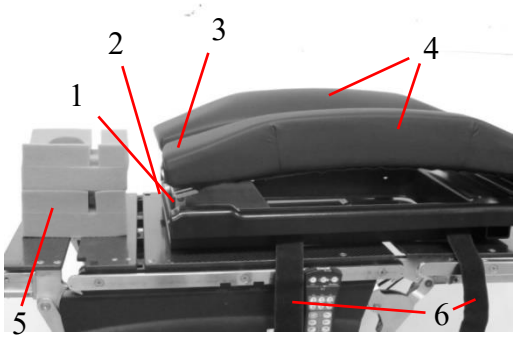
INSTRUCTIONS

Become familiar with features of patient positioning device before use with patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

COMPONENT OVERVIEW

Schure Spine Frame is used as a platform to do simple spine surgeries. Its arches create desired lordosis needed to open inter-vertebral spaces.

1. *Buttons*
2. *Hole for Crank*
3. *Cranial End*
4. *Schure Spine Frame Pads: 508-0472*
5. *Disposable Richards Slotted Headrest, Extended: 508-1340*
6. *Schure Spine Frame Straps: 512-0049*



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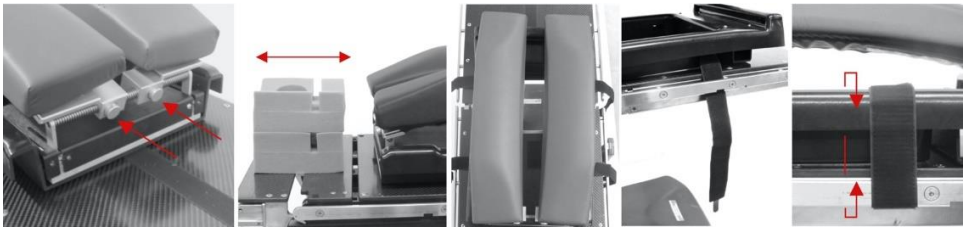
Latest Revision: 2022-01

SET UP FOR FLEX FRAME OR JACKSON TABLE

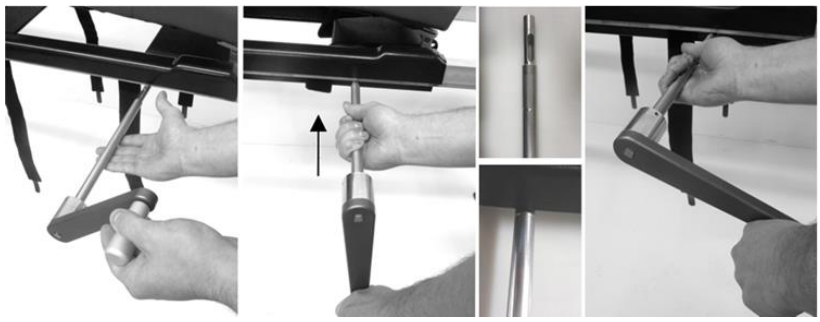
1. *Lower head end of Schure Spine Frame onto rails and slide to desired location*
2. *Ensure hook and loop straps are in between rails*
3. *Lower frame completely onto rails*
4. *Bring hook and loop straps around rails and secure to Schure Spine Frame*

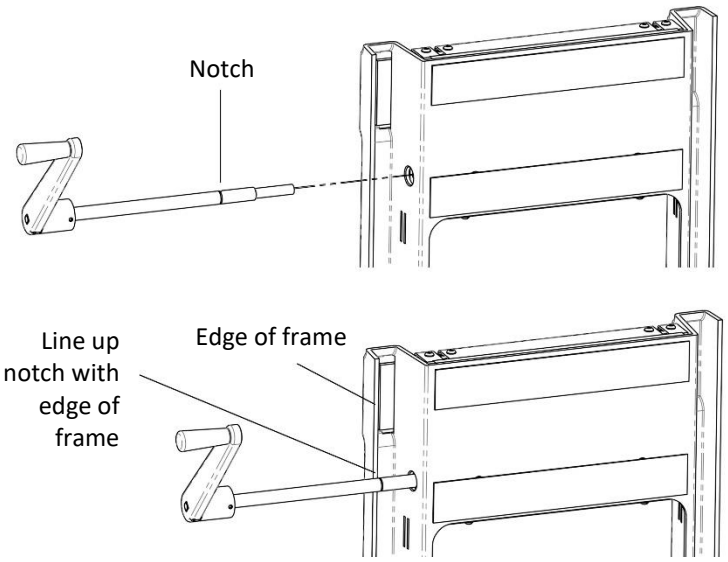
SET UP FOR SURGICAL TABLE/FLAT SURFACE



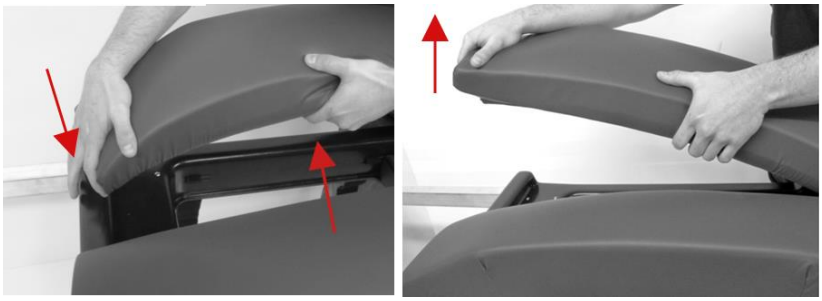
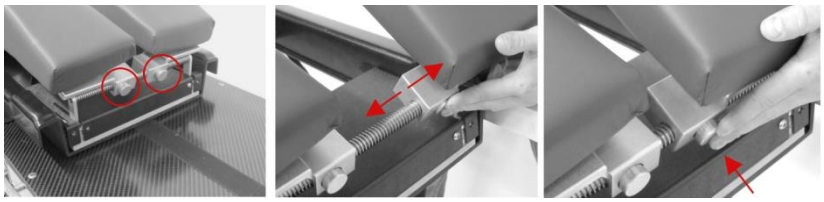
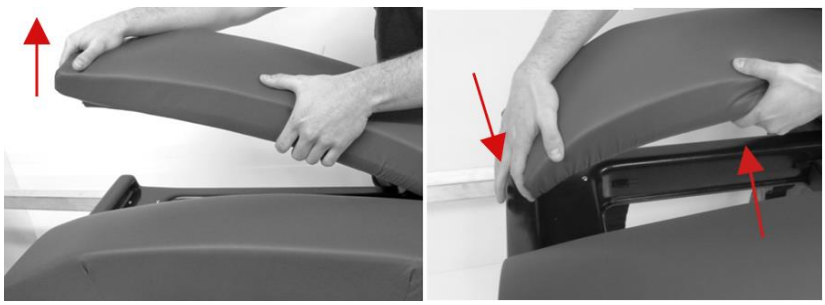
1. *Place frame on surgical table with buttons facing head end of surgical table*
2. *Ensure enough room for head positioner*
3. *Ensure frame is centered between surgical table rails*
4. *Place hook and loop straps through surgical table rails*
5. *Bring hook and loop straps around rails and secure back to Schure Spine Frame*

DEVICE CONTROLS TO ADJUST PAD HEIGHT

1. *Insert Crank Handle (800-0277) into Schure Spine Frame by supporting Crank Handle Rod with one hand and holding handle with other. Ensure square insert is lined up properly. If needed, rotate handle to adjust.*	

2. Push Crank Handle inward until fully engaged. Make sure notch on Crank Handle lines up with edge of frame indicating that it is fully inserted. *3. Use crank to adjust frame extension and pad height. Rotate clockwise to extend frame (reduce height) and rotate counterclockwise to retract frame (increase height)* *Note: Do not rotate handle past extension limits.*	

LATERAL ADJUSTMENT OF PATIENT SUPPORTS

1. With supports fully extended, slightly flex carbon fiber support by pushing upwards in center of support with one hand, while pushing down on cranial end with other hand. Lift support upwards until end of support disengages from slot in frame.	
2. While carbon fiber support is free, push button to adjust supports laterally, then release button.	
3. Reinsert support by flexing support upwards in center and pushing down on cranial end. Insert free end into slot on frame.	

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Loading Patient Important Notes

- *Note: Techniques detailed in this manual are only manufacturers suggestions. Final responsibility for patient care with respect to this device remains with attending physician.*
- *Optional Recommended –Place moisture absorbing/friction reducing covers over supports*
- *Prior to transferring patient, crank spine frame to highest setting. After transferring patient, lower to desired level.*
- *Position patient to reduce nerve contact and subsequent injury*
- *Additional support must be provided to head, arms and legs*

REMOVAL AND STORAGE

1. *Remove hook and loop strap from Spine frame and unwrap from rail*
2. *Remove from table and store*

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Length: 30”+/- 0.5” (76 cm +/- 1 cm)*
- *Width: 19”+/- 0.5” (48 cm +/- 1 cm)*
- *Depth: 7.5”+/- 0.5” (19 cm +/- 1 cm) (Minimum no pad) & 10”+/- 0.5” (25 cm +/- 1 cm) (Maximum no pad)*
- *Device Weight: 27 +/- 0.5 lbs. (69 +/- .22 kg)*
- *Range of Motion: 7.5” (19 cm) lateral adjustment*
- *Attaches to rail of surgical table at any point on rail*
- *Single-person installation*
- *Removable hand crank*
- *Stores on Schure Spine Frame Dolly*
- *Compatible with Jackson table and any other surgical table that has side rails*
- *3/4 of Spine Frame is radiolucent—just be sure to turn mechanics (where buttons and crank handle is inserted) are on opposite end of surgical procedure*

GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 500 lb. (227 kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model)*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *If damaged in shipping, call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Product is maintenance-free, check product condition before next use*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to +86°F (-20°C to 30°C)*

DISPOSAL

- ***General** - Prevent infection by cleaning and disinfecting product before disposal*
- ***Packaging** - Dispose packaging material via household waste according to national requirements*
- *SchureMed accepts back used or retired products - or dispose of product in accordance with national requirements*

PRODUCT USE WARNINGS

WARNING!

Maximum load should not exceed appropriate proportion of a patient weighing 500 lbs. (227 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.

WARNING!

Hazard resulting from incorrect use. Strictly follow Instructions for Use with your surgical table system.

WARNING! *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.*

CLEANING RECOMMENDATION

Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning and disinfection procedure.

WARNING!

Adhere to standards for blood-borne pathogens from Occupational Safety and Health Administration. Use recommended protective clothing, gloves, masks and eye protection to clean accessory.

CAUTION

Strictly read/follow manufacturer's directions for cleaning fluids. DO NOT use cleaners containing phenolics.

1. *Remove major contaminants from accessory with disposable materials. Follow appropriate bio-hazard waste disposal procedures.*

2. *Apply cleaning fluid liberally to entire accessory and wipe with clean, lint-free cloth until all moisture and cleaning fluid is removed from accessory*
3. *Let accessory dry*

USER NOTICE
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

UDI Basic UDI-DI: 081001460F0030DR

eIFU Language Versions
To download and print the Instructions for Use, please go to http://www.schuremed.com/schuremed-eifu.

Symbol Glossary

Symbol	Title	Symbol Description
	Manufacturer	Indicates the medical device manufacturer.
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the european community.
	Use-by Date	Indicates the date after which the medical device is not to be used.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
SN	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
MD	Medical Device	Indicates the item is a medical device.
UDI	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
CE	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.

Manufacturer
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CE MD

EC REP **Authorized Representative**
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands