



Product Description

Intended Use: The EPD is intended to assist in the support and positioning of a patient during epidural procedure and other spinal anesthetic procedures. This device is intended for use by trained professionals in a hospital or clinical setting.



IMPORTANT! This instruction Manual contains important information for the user of the product. All who use this product should review and completely understand its contents. Remember to keep this instruction guide in a place where it is always available to those using the product.

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Safety Instructions

Before using, be sure that:

- You have read the instructions and understand all warnings, precautions, and safety labels.
- A doctor or clinician authorized by the state must ensure that the patient's health and physical condition are appropriate for the treatment being applied when the patient is using this device and treatment must be performed under the direction of a licensed clinician.
- Personnel using this device are informed of the correct operation and use.
- All components have been inspected for damage, are fully functional, and properly lock.

Warnings:

- Patient weight not to exceed 600 lbs. (272 kg)
- This is NOT a standalone support, patient transport, or patient lifting device.
- This device is NOT intended for use with accessories other than those specified in this manual.
- Never leave patient unattended. Have a hand on patient at all times while using this device.
- Patient must be seated on stationary bed, exam table or gurney while using this device.
- The Foot Rest Tray should be in a low position, below the level of a patient's feet, prior to rolling the device up to a patient.
- Use only on dry surfaces. Ensure casters do not slide.
- Allow only patients and authorized staff in treatment area. KEEP ALL CHILDREN AWAY FROM TREATMENT AREA.
- Contact Pivotal Health Solutions if service to device is needed (1-800-743-7738).



Never leave patient unattended during use.



Under no circumstances should the EPD be modified. Contact Pivotal Health Solutions for more information.

Definitions & Precautions

Warnings and Precautions throughout this manual and on the device are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment.

The definitions of these symbols are as follows:

	Caution: Text with a “CAUTION” indicator explains safety information to prevent potential injury.
	Pinch Point: Indicates space between manually adjustable moving and stationary parts where body parts may become caught, leading to minor injury.
	Indicates to refer to the user manual instructions.
	Indicates the product is a medical device.
	Indicates device manufacturer.



CAUTION: Patient weight not to exceed 600 lbs. (272 kg)

There are two sections to the EPD, the top half is considered the EPD and the bottom is called the LDS (see picture below). The Serial Label is located on the LDS base:

Point of Reference:



Assembly

Your EPD Box Includes

1

LDS Base

1



2

EPD

2



3

Face rest pillow

Sternum pillow

One (1) box of 25 Sani- Cover® medical grade
face rest covers

EPD manual and EPD instructional video

3



Assembly STEP 1 Place the EPD into the LDS base	
Assembly STEP 2 Tighten EPD Lock handle	
Assembly STEP 3 Place face rest pillow on Velcro fasteners	
Assembly STEP 4 Place sternum pillow on Velcro fasteners	
Assembly STEP 5 Your EPD device is now fully assembled.	

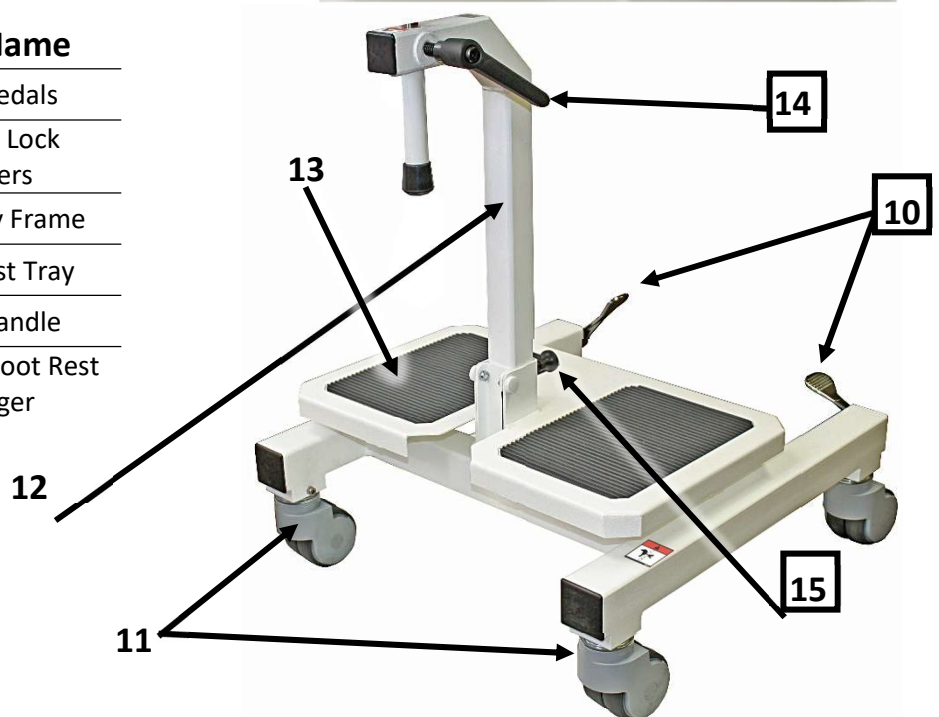
Parts



#	Part Number	Part Name
1	EPD214	Arm Rest
2	EPD204	Torso Bracket
3	EPD207	Torso Knob
4	EPD216	Valley Cam Lever
5	EPD224 or EPD213*	Sternum Pillow*
6	EPD208	EPD Sternum Knob
7	EPD212	Face Rest Pillow
8	EPD203	EPD Body



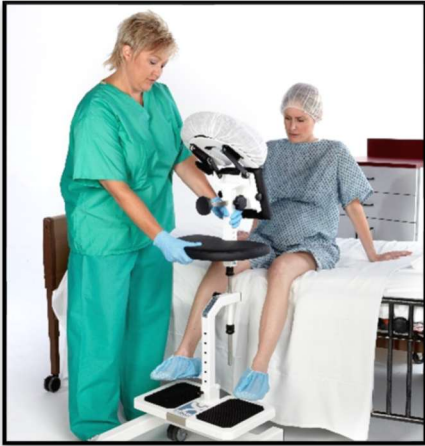
#	Part Number	Part Name
10	LDS1011/1010	Foot Pedals
11	LDS1009	4 Total Lock Casters
12	LDS1004	LDS Body Frame
13	LDS1003	Foot Rest Tray
14	E7097	Lock Handle
15	LDS1008	Indexing Foot Rest Plunger



OPERATION

Note to user: If a serious incident occurs, report the incident to Pivotal Health solutions. (See section with Manufacturer Contact Information for contact details). If the incident occurs in the EU, also report any serious incident to the Competent Authority of the Member State in which the user and/or patient is established.

- 1) Have patient sit squarely on bed or gurney. Before moving EPD to patient, lower the Foot Rest Tray to a position below the patient's feet and then roll the EPD in front of patient.



- 2) Lock casters by pushing downward on BOTH brake levers.



- 3) Adjust top section of EPD to desired height by turning the lock handle counterclockwise to loosen. The height of the EPD should be slightly below the level of the patient's head. Lock the EPD into place by turning lock handle clockwise.

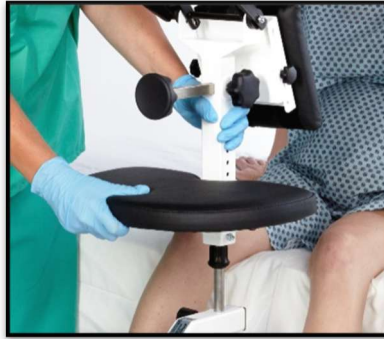
PRECAUTIONS



Ensure the patient is in a seated position before moving the EPD towards the patient.



Always use Sani-Cover Disposable Face Rest Covers.



- 4) Have patient lean slightly into EPD with face resting on face rest and arms placed on arm rest.



- 5) Adjust face rest to desired position.



- 6) Adjust arm rest by pulling out indexing plunger pin and sliding into position. Release to lock.

PRECAUTIONS



The chest support may be removed from the device by loosening both the torso knob and sternum knob.



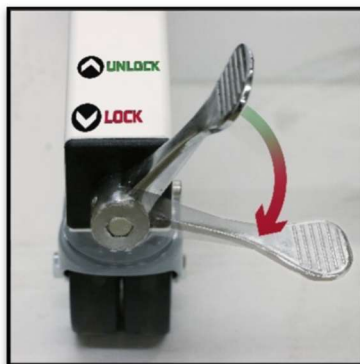
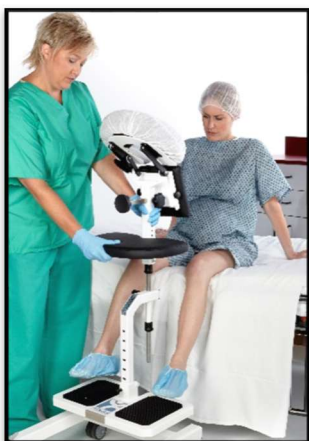
- 7) Adjust foot rest using the indexing foot rest plunger.



- 8) Adjust chest support by loosening the sternum knob counterclockwise and tightening by turning clockwise.



9) After procedure, have patient lean back into a normal sitting position.



10) Unlock casters by lifting up on brake lever and roll EPD out of the way.

Technical Specifications

EPD Specifications		LDS Specifications (base)	
• Weight	12 lbs. (5 kg)	• Weight	42 lbs. (19 kg)
• Load Rating	600 lbs. (272 kg)	• Foot Plate Size	20" x 12"
• Arm Rest Range	32" – 43"	• Foot Plate Range	10.5" x 19.5"
• Arm Rest Size	16.5" x 10"	• Width	20.5"
• Chest Piece Range	5.5"-10"	• Length	23"
• Chest Piece Depth	3"	• Shipping Weight	50 lbs. (22 kg)
• Chest Piece Size	8" x 8"	• Shipping Box	29" x 26" x 21"
• Shipping Weight	42 lbs. (19kg)		
• Shipping Box	36.5"x38.5"x50"		

Additional information:

Patents: US 6,758,447,B2 and D455,495

Expected Life: The product has an approximate expected life time of 10 years when correctly handled, serviced and inspected in accordance with these instructions.

Design and Quality: Pivotal Health Solutions is certified in accordance with ISO 13485, the standard for the medical device industry.

Product changes: Pivotal Health Solutions, Inc. reserves the right to make product changes without prior notice. Contact your Pivotal Health Solutions representative for advice and information about product upgrades.

Cleaning and Care



CAUTION: DO NOT use alcohol-based cleaning agents.

DO NOT use cleaning agents that contain phenol or chlorine, since these can damage aluminum and plastic materials. The device should not be exposed to running water.

IMPROPER CLEANING WILL CANCEL THE WARRANTY

To clean: Use any non-corrosive hospital approved disinfectant that does not contain the chemicals listed above. As requirements vary by state, please consult your state's guidelines. Please use the type of non-corrosive cleaner that suits the use of the device in your facility. Examples include, but are not limited to: Sporidicin®.



Accessories

Part Number FRC 03-3110: Sani-Cover® Medical Grade, Latex-Free Disposable Face Rest Covers.

Sani-Covers® are designed to fit on the arm rest in addition to face rest.

Box of 25 covers: FRC 03-3110

Case of 8 Boxes: FRC 03-3110-CASE



Warranty and Manufacturer

<http://www.phsmedicalsolutions.com/customer-service/warranty.aspx>

Note to user: If a serious incident occurs, report the incident to Pivotal Health solutions. (See section with Manufacturer Contact Information for contact details). If the incident occurs in the EU, also report any serious incident to the Competent Authority of the Member State in which the user and/or patient is established.

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