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PRODUCT GUIDE & USER MANUAL

Operon® Imaging Extension Unit

OZ 7520175: 36" Extension without Support Leg

OZ 7521275: 44" Extension with Support Leg

Operon® Pediatric Table Accessory

OZ 7520304 & OZ 7520375

for D-Series Tables





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GENERAL PRECAUTIONS

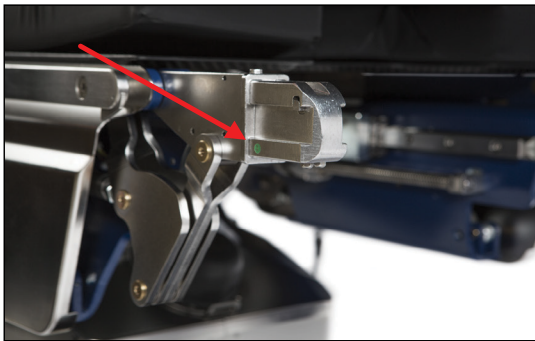
WARNING STATEMENTS

! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 484-720-6054 OR TECHSUPPORT@QFIX.COM.

! WARNING ! DO NOT USE TABLE OR ACCESSORIES IF DAMAGE IS APPARENT OR DEVICE CANNOT BE SECURELY TIGHTENED. CHECK FOR DAMAGE OR WEAR PRIOR TO EACH USE.

ADDITIONAL WARNINGS

- DO NOT use 44" Extension without Support Leg.
- DO NOT use 36" Extension in Reverse Orientation of the Table.
- To prevent the accessory from falling and patient injury, make sure the green dots are visible on the side after installation, indicating that the accessory is securely installed and engaged.



- Proper installation of the Operon® Imaging Extension requires two persons using the accessory cart.
- Proper installation of the Operon Pediatric Table requires two persons.
- DO NOT use the Operon Imaging Extension Unit or the Operon Pediatric Table with any other Table than an Operon D-Series surgical Table.

SERIOUS INCIDENTS

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

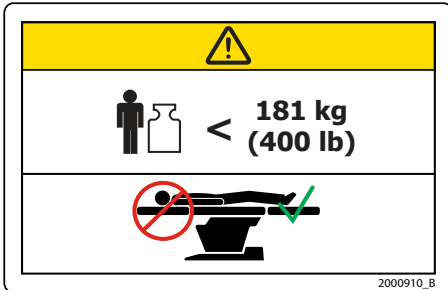
LOAD RATING

- DO NOT exceed 181 kg (400 lb) with 36" Extension.
- DO NOT exceed 340 kg (750 lb) with 44" Extension with the Support Leg.
- DO NOT exceed 340 kg (750 lb) with 44" Extension with the Support Leg in Reverse Orientation.
- DO NOT exceed 34 kg (75 lb) with Pediatric Table Accessory.
- DO NOT exceed 34 kg (75 lb) with Pediatric Table Accessory in Reverse Orientation.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

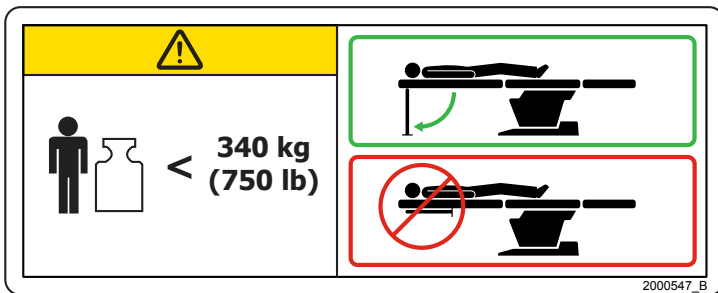
Refer to Qfix.com for a listing of symbols and their definitions.



LOAD RATING—OZ 7520175 (36" EXTENSION)

Attach to back end of seat section ONLY.

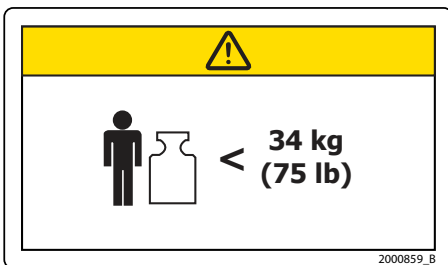
Do NOT exceed 181 kg (400 lb) uniformly distributed load.



LOAD RATING—OZ 7521275 (44" EXTENSION)

Do NOT exceed 340 kg (750 lb) uniformly distributed load.

Engage support leg before use.



LOAD RATING—OZ 7520304 & OZ 7520375 (PEDIATRIC TABLE)

Do NOT exceed 34 kg (75 lb) uniformly distributed load.

INTENDED USE

The 36" and 44" imaging extensions are intended for to support a patient during radiologic and surgical procedures when used together with the Operon® D-Series Surgical Tables (Models D 750, D 752, D 760, D 770, D 820, D 830, D 850 and D 860).

The pediatric extensions are intended to support and position a patient during surgical procedures when used together with the Operon D-Series Surgical Tables (Models D 750, D 752, D 760, D 770, D 820, D 830, D 850 and D 860).

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

Patient Target Groups

Patients undergoing general medical or surgical procedures involving diagnostic imaging.

Intended Users

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

OPERATING INSTRUCTIONS

INSTALLATION OF 44" EXTENSION & 36" EXTENSION ACCESSORIES

- Ensure that the Table's floor locks are engaged. (See Fig 1)
- Inspect the Table and the accessory for any wear or damage before installation.

! WARNING ! PROPER INSTALLATION OF THE IMAGING EXTENSION UNIT ACCESSORY REQUIRES TWO PERSONS.



Figure 1

Installing to the Seat Section (off the Leg Spars) Normal Orientation

1. SLIDE the Table to the FOOT.
2. Remove Leg Section of the Table. (See Fig 2)
3. Level Leg Spars hitting the "LEVEL" button on the Table Pendant.
4. Attach Imaging Extension to the Leg Spars. It will click into place. When Extension is attached to the Leg Spars, a gap is created between the Extension and the Table Seat Section. (See Fig 3)
5. Remove the Seat Pad to install the Imaging Extension Filler Plate (OZ 7522675). (See Fig 4)

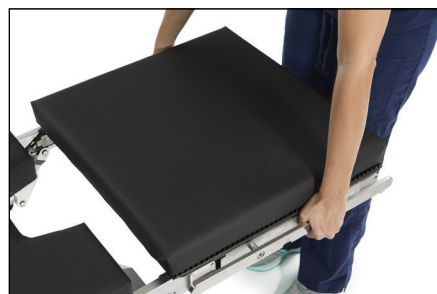


Figure 2

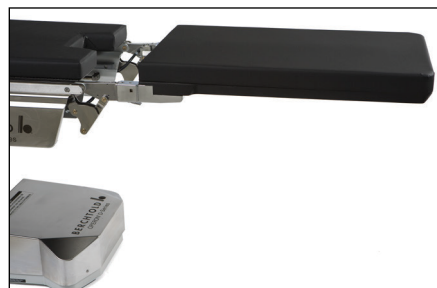


Figure 3



Figure 4

OPERATING INSTRUCTIONS

6. Reattach the Seat Pad to the Table. (See Fig 5)



Figure 5

7. Attach the Imaging Extension Filler Pad to fill the gap. (See Fig 6)

! NOTE ! Imaging Extension Filler Plate with Pad needs to be ordered separately. It is not part of the standard package.



Figure 6

8. Remove the Head Section of the Table.

OPERATING INSTRUCTIONS

Installing to the Back Section in Reverse Orientation for 44" Extension ONLY. (See Fig 7)

! WARNING ! DO NOT USE 36" EXTENSION IN REVERSE ORIENTATION.

1. SLIDE the Table all the way to the head.
2. Level back spars by hitting "LEVEL" button on the Table Pendant.
3. Attach the Imaging Extension.
4. REVERSE orient the Table by turning the large profile base of the Table towards anesthesia.
5. Hit the REVERSE orientation button on the Hand Pendant.
6. Detach Head and Back Section.
7. Replace the Back Section with the 44" Imaging Extension.

! NOTE ! When Extension is attached to the Leg Spars, a gap remains in the Seat Section. (See Fig 8) A Perineal Filler Plate with Pad (OZ 7519975) may be used to fill the gap.



Figure 7



Figure 8

8. To install the Perineal Filler Plate, remove the Seat Section and attach the Perineal Filler Plate with Pad. (See Fig 9)

! NOTE ! Perineal Filler Plate is not part of the standard package and should be ordered separately.



Figure 9

9. Reattach the Seat Pad to the Table. (See Fig 10)



Figure 10

OPERATING INSTRUCTIONS

10. Ensure the green dots are visible for the secure attachment on the 36" or 44" Extension. (See Fig 11)

! WARNING ! DO NOT DISENGAGE THE SUPPORT LEG IF THE PATIENT IS ON THE TABLE.

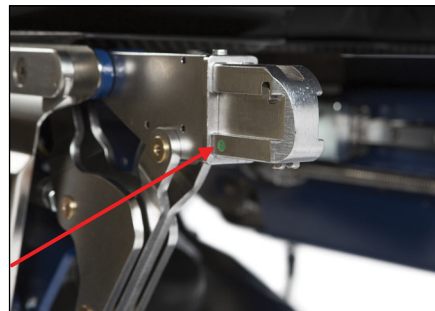


Figure 11

44" Extension Support Leg Adjustment and Setup

1. Pull the latch shown while holding the Leg to release. (See Fig 12)
2. Make sure the Leg is in the proper position, perpendicular to the floor and touching the floor to support the Extension's weight and then secure the Knob as shown.



Figure 12

Removal of Imaging Extension Unit from Table

1. Remove all accessories from the Imaging Extensions if any.
2. Pull the latch on the Support Leg to release the Leg. (See Figure 13)
3. Take the Leg completely under the Extension and loosen the Knob. Extend Leg all the way to the end of the Extension and secure the Knob. (See Figure 13)
4. With help of a second personnel, release the latches under the Extension and remove the accessory carefully. (See Figure 14)



Figure 13

! WARNING ! A MINIMUM OF TWO PERSONS ARE NEEDED TO REMOVE THE ACCESSORY.



Figure 14

OPERATING INSTRUCTIONS

INSTALLATION OF PEDIATRIC TABLE ACCESSORY

- Ensure that the Table's floor locks are engaged. (See Fig 15)
- Inspect the Table and the accessory for any wear or damage before installation.

! WARNING ! PROPER INSTALLATION OF THE OPERON PEDIATRIC TABLE REQUIRES TWO PERSONS.



Figure 15

Installing to the Seat Section (off the Leg Spars) Normal Orientation

1. SLIDE the Table to the FOOT.
2. Remove Leg Section of the Table. (See Fig 16)
3. Level Leg Spars hitting the "LEVEL" button on the Table Pendant.
4. Attach Pediatric Table to the Leg Spars. It will click into place. When Extension is attached to the Leg Spars, a gap is created between the Extension and the Table Seat Section. (See Fig 17)
5. Remove the Seat Pad to install the Imaging Extension Filler Plate (OZ 7522675). (See Fig 18)

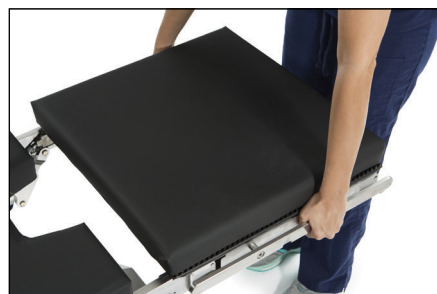


Figure 16



Figure 17



Figure 18

OPERATING INSTRUCTIONS

6. Reattach the Seat Pad to the Table. (See Fig 19)



Figure 19

7. Attach the Extension Filler Pad to fill the gap. (See Fig 20)

! NOTE ! Extension Filler Plate with Pad needs to be ordered separately. It is not part of the standard package.



Figure 20

8. Remove the Head Section of the Table.

Installing in Reverse Orientation (See Fig 21)

1. SLIDE the Table all the way to the Head.
2. Detach Head and Back Section.
3. Level the table by hitting “LEVEL” button on the Hand Pendant.
4. Replace the Back Section with the Pediatric Table.

! NOTE ! When Pediatric Table is attached to the Leg Spars, a gap remains in the Seat Section. (See Figure 22) A Perineal Filler Plate with Pad (OZ 7519975) may be used to fill the gap.

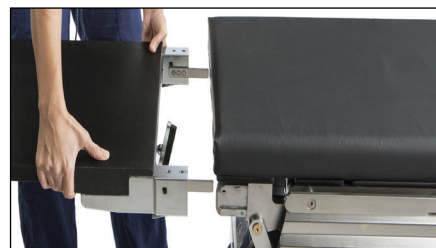


Figure 21

5. REVERSE orient the Table by turning the large profile base of the Table towards anesthesia.
6. Hit the REVERSE Orientation button on the Hand Pendant.



Figure 22

OPERATING INSTRUCTIONS

11. Remove the Seat Section Pad and attach the the Perineal Filler Plate with Pad. (See Fig 23)

! NOTE ! Perineal Filler Plate is not part of the standard package and should be ordered separately.

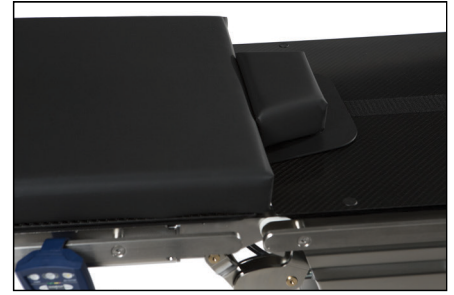


Figure 23

12. Reattach the Seat Pad to the Table. (See Fig 24)

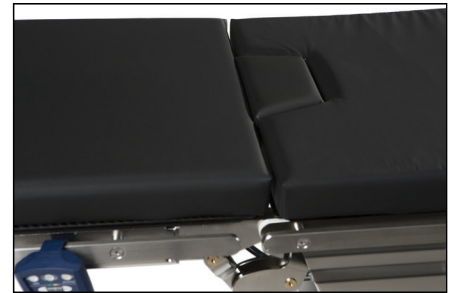


Figure 24

13. Ensure the green dots are visible for the secure attachment of the Pediatric Table Accessory. (See Fig 25)

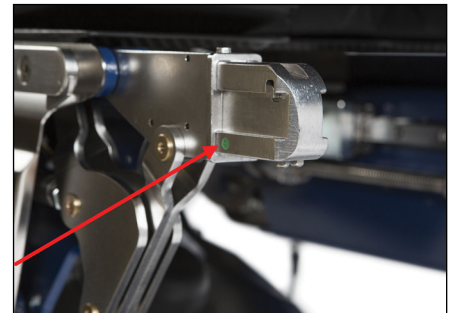


Figure 25

OPERATING INSTRUCTIONS

Removal of Pediatric Table Accessory from OR Table

1. Remove all accessories from the Pediatric Table, if any.
2. With help of a second personnel, release latches (see Figure 26) under the Pediatric Table and remove the accessory carefully.

! WARNING ! A MINIMUM OF TWO PERSONS ARE NEEDED TO REMOVE THE ACCESSORY.

! WARNING ! PATIENT MUST BE REMOVED FROM THE TABLE BEFORE ANY ATTEMPT TO REMOVE THE PEDIATRIC TABLE. CHECK TABLE AND ACCESSORIES FOR DAMAGE OR WEAR PRIOR TO EACH USE.

! WARNING ! DO NOT USE IF ANY DAMAGE IS APPARENT OR DEVICE CANNOT BE SECURELY TIGHTENED.



Figure 26

MAINTENANCE

CLEANING THE SYSTEM

The Imaging Extension Unit and the Pediatric Table Accessory can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe the surface.

DISINFECTING THE SYSTEM

The following cleaning materials have been tested and found to be appropriate for cleaning the surfaces of the Imaging Extension Unit and the Pediatric Table Accessory. To disinfect the surface refer to specific instructions from the cleaning agent manufacturer.

- Water
- 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution
- Soap and Water

CLEANING AND DISINFECTING THE PADS

Thoroughly clean and disinfect the device after each use with a quaternary ammonium disinfecting/cleaning solution following the manufacturer's recommendation for achieving low-level disinfection.

ROUTINE INSPECTION

Check for dents or damages on the connections of the Imaging Extension.

Check for any dents or damages on the connections of the Pediatric Table.

Check for dents or damages on the Support Leg of the Imaging Extension (if installed) and make sure the latches and the telescopic movement of the Leg are functioning smoothly.


Ensure the Operating Table connection point to the Imaging Extension has not been damaged or bent before installing any accessories.


Ensure the operating Table connection point to the Pediatric Table has not been damaged/bent before installing any accessories.

Check pads for any debris, discoloration or tear. Reprocess pad to remove debris (bio-material) and replace pad if it is discolored or torn.



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