Radiolucent Imaging Top

Spinal Top 5943

REF 5927

Owner's Manual

This manual is supplied in the following versions:

- English (EN)
- Spanish (ES)
- French (FR)
- German (DE)
- Italian (IT)
- Portuguese (PTBR)
- Danish (DA)
- Japanese (JA)
- Chinese (ZH)
- Multilingual (ML)

REF NW0677 Rev E

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Table of Contents

1 Important Notices

CAUTION: To ensure safe operation of the equipment, please READ THESE INSTRUCTIONS COMPLETELY and keep this manual readily available for future reference.

CAUTION: Trained personnel must also read the REF NW0646 Advanced Control Base Owner's Manual in its entirety to properly and safely operate the equipment.

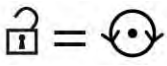
Carefully observe and comply with all warnings, cautions and instructions placed on the equipment or described in this manual and in the REF NW0646 Advanced Control Base Owner's Manual.

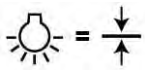
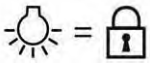
NOTE: *This device is intended for use by trained personnel only. To schedule an in-service, please contact your domestic Mizuho OSI sales representative or call 1-800-777-4674 inside the USA or +1-510- 429-1500 outside the USA.*

NOTE: *The application techniques outlined in these instructions are the manufacturer's suggested techniques. The final disposition of each patient's care as related to the use of this equipment rests with the attending surgeon.*

In this manual, the following symbols are used:

Symbol	Meaning
EC REP	This symbol indicates an authorized representative in the European Community.
	This symbol indicates the Manufacturer of the device.
NOTE:	This symbol indicates a comment or instruction of importance.
	This CAUTION symbol indicates a potentially hazardous situation which if not avoided could result in minor or moderate injury.
	This WARNING symbol indicates a potentially hazardous situation which if not avoided could result in serious injury or death.
	This symbol indicates proper disposal instructions. See Section 1.2 for more information.
REF	This symbol indicates a product number.
SN	This symbol indicates a serial number.

Symbol	Meaning
	This symbol indicates that you need to read the manual before use.
	This symbol indicates that you need to refer to the instructions for use.
	This symbol indicates an external ground stud that is required for use when the AC power cable is not connected to a protective earth ground hospital grade AC outlet in your operating room or facility.
	This symbol indicates this equipment is an applied part TYPE B in accordance with IEC 60601-1 and is generally suitable for applications involving external or internal contact with the patient, excluding the heart. The patient circuit is connected to protective earth and this equipment should be connected only to hospital grade AC outlets with a protective earth ground.
	This symbol represents a Fault Indicator.
	This symbol identifies the 180º Rotation Lock.
	This symbol identifies the Rotation Lock.
	This symbol indicates rotation in either of two directions.
	This symbol indicates rotation in one direction.
	This symbol identifies the Tilt Drive Status.
	This symbol indicates the Table Weight Limit.
	This symbol indicates POWER OFF.
	This symbol indicates POWER ON.
	This symbol represents the Battery Status of the Advanced Control Base.
	This symbol represents a locked state.
	This symbol represents an unlocked state.
	This symbol informs the user that Unlocking the lock may cause movement.

Symbol	Meaning
	This symbol informs the user that the Tilt Drive is centered when the light is on.
	This symbol informs the user that the mechanism is locked when the light is on.

WARNING: Proper preoperative and intra-operative procedures must be followed to prevent venous stasis and pooling, pressure sore development, neuropathy, improper electro surgical tissue grounding, hypertension, and hypothermia.

WARNING: Use of the Radiolucent Imaging Top with patients weighing more than 500 lbs (227 kg) could result in damage to the table, possible injury to the patient, or harm to the healthcare workers.

WARNING:  **This symbol indicates an external ground stud that is required for use when the AC power cable is not connected to a protective earth ground hospital grade AC outlet in your operating room or facility. To protect the patient, hospital staff and the table from possible electrical hazards, an external ground wire connection is required between the external ground stud and protective earth ground when the table is in use under battery power or not connected to a protective earth ground.**

WARNING: Medical electric equipment needs special precautions regarding Electro-magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

WARNING: Before and after each use, inspect the table top, components, and accessories for possible damage, excessive wear, or non-functioning parts. Carefully inspect all critical, accessible areas, joints, and all moving parts for possible damage or non-function. Damaged or defective parts should not be used or processed. Contact Mizuho OSI Service for repair or replacement (see Section 10).

WARNING: The Radiolucent Imaging Top in conjunction with the Advanced Control Base should not be operated in the presence of flammable anesthetics, volatile substances, or other explosive gases, liquids, or atmospheres.

CAUTION: As outlined in the AORN Recommended Practices for Positioning a Patient in the Perioperative Setting, following the positioning of the patient, an assessment of the patient's alignment, tissue perfusion and skin integrity should be completed. All contact points of the patient with the table pads should be monitored during the procedure.

CAUTION: No modification of the Radiolucent Imaging Top, the Advanced Control Base, or their components is allowed. Any modification to the equipment may result in damage to the table, possible injury to the patient, or harm to the healthcare workers.

NOTE: *If high-frequency surgical equipment, cardiac defibrillators or cardiac defibrillator monitors are to be used with the Advanced Control Base, refer to the instructions for use provided by the manufacturer of those devices.*

1.1 Trademarks

GentleTouch® and OrangeAid® are registered trademarks of Mizuho OSI.

Wilson Plus™ is a trademark of Mizuho OSI.

ProneView® is a registered trademark of Dupaco, Inc.

Tempur-Pedic® and TEMPUR® are registered trademarks of Tempur-Pedic® North America, Inc.

O-arm® is a registered trademark of Medtronic, Inc.

DORO® is a registered trademark of pro med instruments GmbH.

Mayfield® is a registered trademark of Schaerer Mayfield USA, Inc.

Velcro® is a registered trademark of Velcro Industries.

1.2 Disposal of Components

In accordance with the European Union Waste Electrical and Electronic Equipment (WEEE) Directive, all electrical components, batteries and carbon composite components must be disposed of in accordance with local regulations or returned to Mizuho OSI for proper disposal. Please contact Mizuho OSI Service at **1-800-777- 4674** inside the USA or **+1-510-429-1500** outside the USA for further information regarding this requirement.

2 Introduction

2.1 General Description

The Radiolucent Imaging Top is one of three interchangeable tops offered as part of the Modular Table System. The gimbaled Radiolucent Imaging Top may be used with the REF 5803 / 5803I / 5803J Advanced Control Base. When mounted on the Advanced Control Base through the use of H-Frames and T-pins, the Radiolucent Imaging Top is designed to support and position a patient undergoing various surgical and radiographic procedures.

The Radiolucent Imaging Top includes a 2" (5 cm) thick Mizuho OSI Tempur-Pedic® Medical Pad. The material used in the manufacture of the pads contains viscoelastic properties and is temperature sensitive, which becomes softer where the patient's body makes the most contact with the surface and remains firm in the areas where less body contact is made. Pressure is distributed evenly over the entire surface area.

The pad is radiolucent and is not made with natural rubber latex. The benefits of using Mizuho OSI Tempur-Pedic® Medical Pads are improved pressure management, reduced shear forces, and enhanced patient comfort when used in ambient temperatures. In accordance with AORN recommendations, it is important to limit skin exposures to lower ambient temperatures, protect the patient by initiating passive warming interventions (e.g. applied forced-air warming systems, blankets, drapes, and reflective composites), and to maintain an ambient room temperature of 20° to 25°C.

In addition to the standard components of the Radiolucent Imaging Top discussed in this manual, there are several optional accessories available, including Cervical Management Systems and the Wilson Plus™ Radiolucent Frame. In order to obtain a thorough understanding of these products and their applications to perform certain surgical procedures, refer to the Owner's Manual for each specific product.

NOTE: *This manual is intended to be used solely for the devices identified and is not a substitute or replacement for the Owner's Manuals of the other devices discussed in this manual.*

Figure 1: Radiolucent Imaging Top with Safety Strap Mounted on the Advanced Control Base

2.2 Intended Use

The Radiolucent Imaging Top used in conjunction with the Advanced Control Base creates an electrically powered mobile operating table designed for temporary (<24 hours) support and positioning of a patient in a supine or lateral position. The Radiolucent Imaging Top mounted on the Base is intended for use during surgical procedures, including radiographic imaging during such procedures. The Radiolucent Imaging Top mounted on the Base should not be used for patient transport.

The Radiolucent Imaging Top when mounted on the Advanced Control Base provides a platform designed to support and position adult and pediatric patients with body weight up to 500 lbs (227 kg).

2.3 User Profile

The Radiolucent Imaging Top in conjunction with the Advanced Control Base is suitable for use by health care professionals, including but not limited to surgeons, radiologists, anesthesiologists, circulating nurses, surgical technicians, biomedical technicians, and radiology technicians.

2.4 Training Requirements

Before using the Modular Table System, the user must read the REF NW0646 Advanced Control Base Owner's Manual. Depending on the table top(s) used, the user must also read the corresponding Owner's Manual listed below:

REF NW0677 Radiolucent Imaging Top Owner's Manual

REF NW0678 Spinal Surgery Top Owner's Manual

It is recommended that personnel using the Modular Table System receive training by either Mizuho OSI or by someone qualified by the medical facility to provide this training.

WARNING: Failure to ensure proper training prior to use of this device may cause harm to the patient, healthcare worker, or the device.

2.5 Conditions of Use

The Radiolucent Imaging Top in conjunction with the Advanced Control Base may be used several times throughout the day and night in medical facilities; e.g. hospitals, and outpatient surgery/imaging centers. The Radiolucent Imaging Top with the Advanced Control Base will be used in an operating room or other treatment room, and may be rolled between rooms. It shall not be used for patient transport.

2.6 Product Lifetime

The device's service lifetime is defined as ten (10) years. At the time of delivery, your product fulfills existing regulations and standards. However, despite proper use, routine inspection, prescribed service, maintenance and repairs, the product is subject to aging and wear. Therefore, Mizuho OSI cannot guarantee the product's safety for more than ten (10) years after date of manufacture and recommends your product be taken out of service. For product warranty information, refer to Section 10.5 of this manual.

2.7 Specifications

The Radiolucent Imaging Top has the following specifications:

- Maximum patient load of the table top is 500 lbs (227 kg)
- Table top width is 21.5 inches (54.6 cm)
- Table top length is 84 inches (213.4 cm)
- The carbon fiber table top has a radiolucent equivalency of less than one (1) millimeter of aluminum.
- Operating environment: 68 Degrees F (20 Degrees C), relative humidity 50%, atmospheric pressure 75-105 kPa
- Class 1 Equipment
- This table top is not suitable for use with flammable anesthetic gas mixtures.

2.8 Shipping and Storage

If required to be transported, the Radiolucent Imaging Top must be transported using the appropriate packaging. Unpacking instructions were included with the original packaging and should be included on the outside of the packaging if the table top or components must be transported.

When not in use, the Radiolucent Imaging Top, the standard components, and any optional accessories should be stored in a clean, dry environment.

The following conditions are required of the shipping and/or storage environment:

- Ambient temperature -4 °F (-20 °C) to 122 °F (50 °C)
- Relative humidity from 10% to 95%, non-condensing
- Atmospheric pressure from 75 to 105 kPa

If the table top is stored on the Advanced Control Base, the table cover provided serves as a dust cover and should be used. If the table top is stored on the Equipment Cart, the Equipment Cart Cover should be used to protect the table top and all components and accessories stored on the Equipment Cart.

3 Component Identification

3.1 Radiolucent Imaging Top

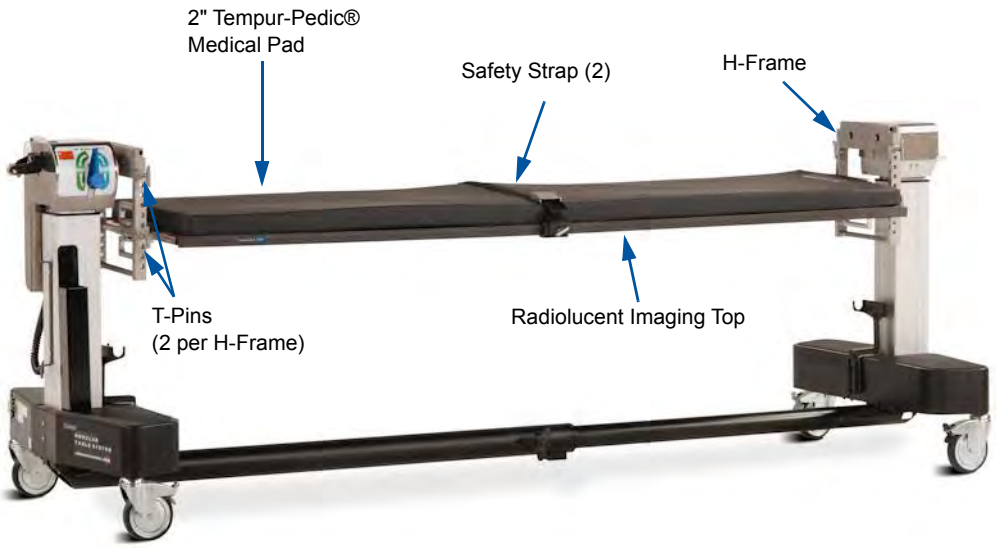


Figure 2: Radiolucent Imaging Top with Safety Strap

3.2 Model Number and Serial Number

The REF product number and a SN serial number for the Radiolucent Imaging Top are located on the end of the table top.

4 Inspection

4.1 Acceptance and Transfer

1. Upon receipt of your Radiolucent Imaging Top, remove it from the shipping packaging. Remove any protective packaging. Visually inspect all surfaces for freight damage.

NOTE: *Any freight damage must be reported to the freight carrier immediately upon delivery. It is the responsibility of the recipient to make freight damage claims.*

2. Read the model number and serial number on the frame.

4.2 Pre-Procedure/Post-Procedure

Before and after each use of the Radiolucent Imaging Top, visually inspect all accessible areas and all movable parts for possible damage that may adversely affect the proper operation of the Radiolucent Imaging Top. Examine the patient restraints for any sign of wear or damage. Examine the covers of all pads for tears or other damage which might cause the pads to trap fluids or other contaminants. Damaged or defective products should not be used or processed. Contact Mizuho OSI Service for repair or replacement (see Section 10).

WARNING: Failure to inspect the device before and after each use and failure to replace damaged components may cause harm to the patient, healthcare professional, and/or the device.

4.3 Preventative Maintenance

A Preventative Maintenance (PM) check (see Section 9.3) on your Radiolucent Imaging Top is required at least once every year.

To obtain the PM checklist, call Mizuho OSI Service at 1-800-777-4674 inside the USA or +1-510-429-1500 outside the USA. PM checks may only be performed by trained service personnel. The PM checklist will only be provided to service personnel with proper training.

5 Radiolucent Imaging Top Components

The Radiolucent Imaging Top consists of the following standard components. Use proper lifting and carrying techniques when moving components and accessories due to their weight and size.

To place an order for components, contact Mizuho OSI Sales Operations at 1-800-777-4674 inside the USA or +1-510-429-1500 outside the USA. At the prompt, select Option 1.

5.1 Standard Components

REF **5840-726** **Imaging Table Top Assembly** 	The Imaging Table Top Assembly consists of the gimbaled table top itself, complete with the 2" (5 cm) Tempur-Pedic® Medical Pad.
REF **5840-370** **H-Frame (2)** 	The two (2) H-Frames provided with the Radiolucent Imaging Top allow the top to be mounted onto the Crossbars of the Base.
REF **5840-361** **T-Pin (4)** 	Two (2) T-Pins are used to secure the H-Frames to each of the Crossbars. The other two (2) T-Pins are used to mount the table top to the respective H-Frame located at the Head-End and Foot-End.

REF **5855-550** **Patient Safety Strap (2)** 	The Patient Safety Strap is used to secure the patient in place when positioned on the table.
REF **5927-3000** **Radiolucent Imaging Top Cover**	The Radiolucent Imaging Top Cover serves as a dust cover when the top is in storage.

6 Installation and Setup

NOTE: *This device is intended for use by trained personnel. Prior to installing a table top, ensure that personnel have been trained. To schedule an in-service, please contact your domestic Mizuho OSI sales representative or call* ***1-800-777-4674*** *inside the USA or* ***+1-510-429-1500*** *outside the USA.*

NOTE: *Before using the Radiolucent Imaging Top, the user must have read the* REF *NW0646 Advanced Control Base Owner's Manual and have a thorough understanding of the Base's functionality.*

6.1 Preparation of the Advanced Control Base

To prepare the Advanced Control Base for installation of the table top, complete the following steps:

1. Roll the Base to where it will be used, and orient the Head-End Column toward the anesthesiologist work station.
2. If the Base has been in its retracted configuration, unlock the Retracting Knob and pull the Head-End and Foot-End Columns in opposite directions until the unit is fully expanded. Lock the Retracting Knob.
3. Lock the four (4) Casters of the Base.
4. Plug the Power Cord of the Advanced Control Base into a properly grounded receptacle. Refer to the manufacturer's label at the Head-End of the Base for input voltage requirements. If the AC power cable is not connected to an outlet with a protective earth ground, then the external ground stud should be connected to a protective earth ground.
5. Connect the Hand Pendant to the port on the Head-End.
6. Toggle the Power Switch to the On position.
7. Confirm the Rotation Safety Lock switch is illuminated (Figure 3).
8. Confirm the 180 Degree Rotation Lock indicator light is illuminated (Figure 3).
9. Confirm the Tilt Drive Status indicator light is illuminated (Figure 3).

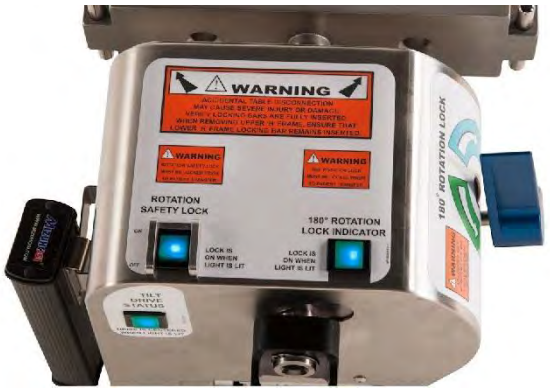


Figure 3: Head-End Assembly with Indicator Lights Illuminated

NOTE: *If the Tilt Drive Status Indicator light is not illuminated, synchronization of the Lateral Tilt Function may be required. Refer to the Advanced Control Base Owner's Manual for instructions on how to synchronize and center the tilt drive.*

6.2 Installing the Radiolucent Imaging Top

NOTE: *The Radiolucent Imaging Top must have gimbals to be used with the* REF *5803 / 5803I / 5803J Advanced Control Base. Gimbaled table tops allow for proper rotation of the top when in extreme lateral tilt and Trendelenburg/Reverse Trendelenburg.*

NOTE: *Only Mizuho OSI base(s) and accessories have been tested and approved for use with the Radiolucent Imaging Top. Other manufacturers' products have not been tested for proper performance when used with the Radiolucent Imaging Top, and therefore are not endorsed for use by Mizuho OSI.*

WARNING: Use of components not manufactured by Mizuho OSI may result in harm to the patient, the table top, the device, or the healthcare professional.

To install a table top:

1. Remove the H-Frame from the H-Frame Storage Bracket located on the Head-End Column, and remove a T-Pin from the Quiver.
2. Install the H-Frame to the Head-End Crossbar by aligning the holes on the bottom of the H-Frame with the posts on the Crossbar (Figure 4), and secure it in place with a T-Pin (Figure 5).

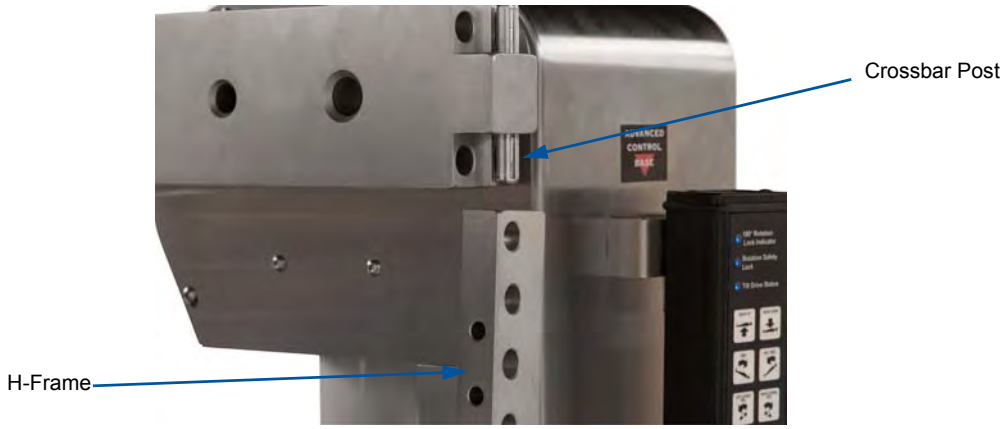


Figure 4: Attaching H-Frame to the Crossbar

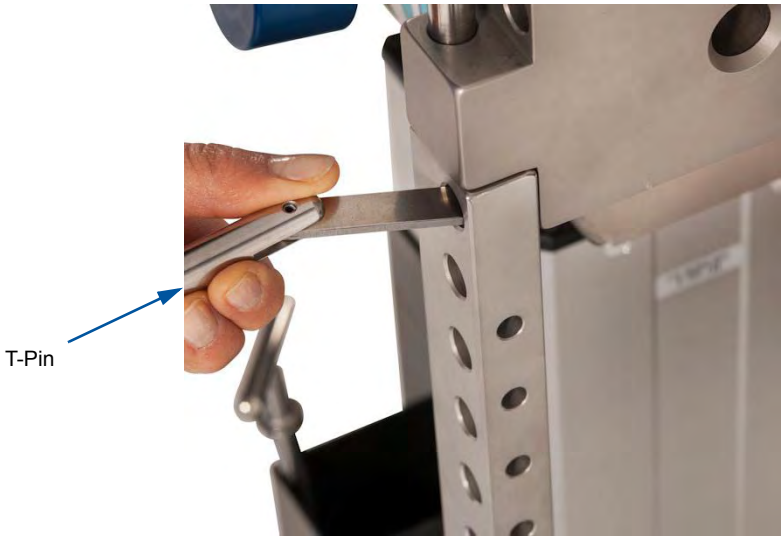


Figure 5: Inserting T-Pin to Secure H-Frame to Crossbar

3. Pass the T-Pin completely through the Crossbar such that the Drop Lock is visible and pivots freely on the opposite side (Figure 6).

NOTE: *When the T-Pin is installed properly with the Drop Lock visible and pivoting freely, the T-Pin cannot be accidentally removed when pulled.*

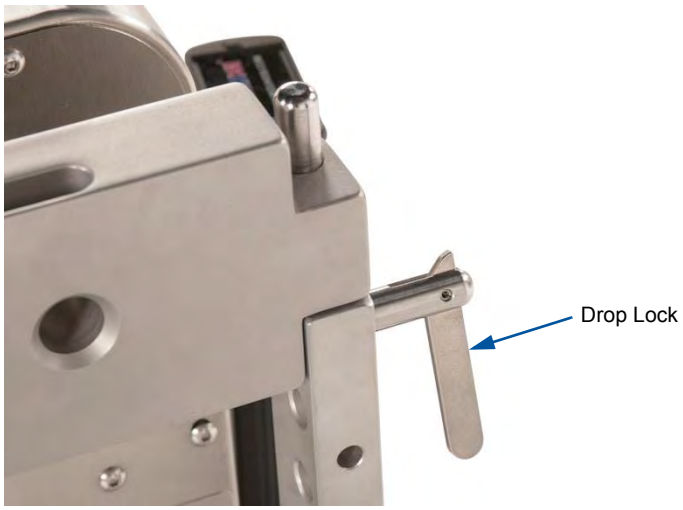


Figure 6: T-Pin Drop Lock Visible after Proper H-Frame Installation

WARNING: Failure to install the T-Pin properly with the Drop Lock visible and pivoting freely may result in harm to the patient, healthcare professional, or this device.

4. Remove the H-Frame from the H-Frame Storage Bracket located on the Foot-End Column, and remove a T-Pin from the Quiver.
5. Install the H-Frame to the Foot-End Crossbar by aligning the holes on the bottom of the H-Frame with the posts on the Crossbar (Figure 4), and secure it in place with a T-Pin (Figure 5).
6. Pass the T-Pin completely through the Crossbar such that the Drop Lock is visible and pivots freely on the opposite side (Figure 6).

NOTE: *When the T-Pin is installed properly with the Drop Lock visible and pivoting freely, the T-Pin cannot be removed when pulled.*

WARNING: Failure to install the T-Pin properly with the Drop Lock visible and pivoting freely may result in harm to the patient, healthcare workers, or the device.

WARNING: T-Pins extended through the Crossbars and table top supporting the patient should never be removed with the patient on the table top. Removing these T-Pins may result in harm to the patient, healthcare workers, or the device.

Figure 7: H-Frame Properly Installed on Foot-End Crossbar

7. The Head-End Column has a Slide Assembly that adjusts to accommodate Trendelenburg and Reverse Trendelenburg. Fully retract the Slide Assembly to allow adequate space for a table top to be installed.
8. With an H-Frame properly secured to each of the Columns, a gimbaled table top may now be mounted to the H-Frame (Figure 8).

Figure 8: Gimbal on One End of Radiolucent Imaging Top

9. Selection of the appropriate mounting hole position on the H-Frame is determined by the patient's size such that his or her center of gravity is at or below the center of rotation of the Crossbar when supine (Figure 9). The specific procedure to be performed and the surgeon's preference should also be considered when choosing the appropriate mounting hole.

WARNING: The Radiolucent Imaging Top should be mounted to the Advanced Control Base such that the patient's center of gravity is at or below the center of rotation of the Crossbar when prone. Failure to do so may make the patient unstable during lateral rotation.

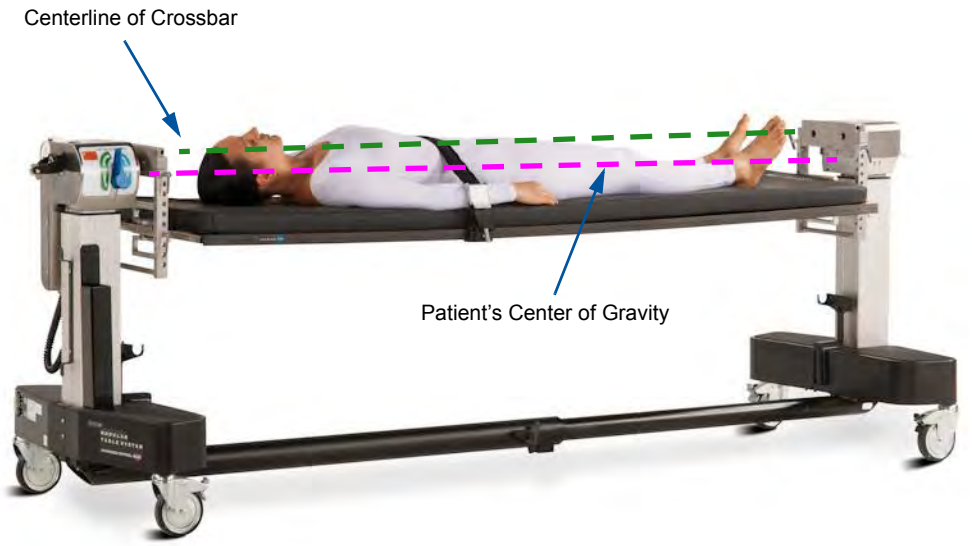


Figure 9: Patient's Center of Gravity Shown in Relation to Centerline of Crossbar

WARNING: Patient must be placed within four (4) inches (10 cm) of the Centerline of the table top. Placement of the patient too far left or right from the centerline could result in unintended rotation of the table.

10. With the assistance of two people, lift the table top into place, aligning it with the selected mounting holes in each H-Frame.
11. Secure the table top to the Foot-End H-Frame first with the use of a T-Pin. Pass the T-Pin completely through the H-Frame and the coupling device such that the Drop Lock is visible on the outside of the H-Frame and pivots freely.

NOTE: *When the T-Pin is installed properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame with the Drop Lock visible and pivoting freely, the T-Pin cannot be removed when pulled.*

WARNING: Failure to install the T-Pin properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame with the Drop Lock visible and pivoting freely, may result in harm to the patient, healthcare professional, or this device.

12. To secure the table top to the Head-End H-Frame, confirm that the H-Frame and the Slide Assembly are pulled away from the Foot-End as appropriate to accommodate the length of the table top. Pass the T-Pin completely through the H-Frame and the coupling device such that the Drop Lock is visible on the outside of the H-Frame and pivots freely.

NOTE: *When the T-Pin is installed properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame, with the Drop Lock visible and pivoting freely, the T-Pin cannot be removed when pulled.*

WARNING: Failure to install the T-Pin properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame with the Drop Lock visible and pivoting freely at both the Head-End and Foot-End of the table, may result in harm to the patient, healthcare professionals, or the table.

NOTE: *The Head-End and the Foot-End of the table top are usually mounted at the same hole in the respective H-Frames. An exception to this process may exist when extreme Trendelenburg is needed.*

WARNING: Failure to follow these instructions for securing the H-Frames to the Crossbars and mounting a table top may result in harm to the patient, healthcare professionals, or the device.

13. The table top is now properly mounted to the Advanced Control Base (Figure 10).

Figure 10: Radiolucent Imaging Top Properly Installed on the Advanced Control Base

NOTE: *Perform all steps of the Function Check before every use of the Advanced Control Base. (See the Advanced Control Base Owner's Manual for more information.)*

6.3 Patient Transfer to Radiolucent Imaging Top

6.3.1 Table Positioning and Safety Check

1. If imaging devices will be used, trial position the equipment as it will be used. If necessary, relocate the Radiolucent Imaging Table in the room. Unlock the Casters and, with the assistance of a second person, move the Radiolucent Imaging Table. When the table is located where it will be used, lock the four (4) Casters.

NOTE: *The Radiolucent Imaging Table is not for patient transport. The location of the table relative to any imaging equipment that may be used needs to be confirmed prior to the patient being transferred to the table.*

2. Conduct a safety check prior to transferring the patient to the table.
3. Confirm the four (4) Casters are locked.
4. Confirm the H-Frames and table top are securely mounted by ensuring the four (4) T-Pins are fully advanced and the Drop Locks are visible and pivot freely.
5. Confirm the 180 Degree Rotation Lock and the Rotation Safety Lock are engaged and the table top is level side to side. Verify that the three corresponding indicator lights – the 180 Degree Rotation Lock, the Rotation Safety Lock, and the Tilt Drive Status – on the Head-End Column are illuminated blue.
6. Verify that the three corresponding indicator lights – the 180 Degree Rotation Lock, the Rotation Safety Lock, and the Tilt Drive Status – on the Hand Pendant are illuminated blue.

NOTE: *All three (3) lights must be illuminated on the Head-End Column and the Hand Pendant before a patient is transferred to the table. If all three (3) lights are not illuminated on the Head-End Column or the Hand Pendant, do not transfer the patient.*

WARNING: Failure to ensure that all three lights on the Head-End Column and Hand Pendant are illuminated prior to patient transfer may result in harm to the patient, device, or healthcare professional.

6.3.2 Patient Transfer for Supine Positioning

1. Position the patient's bed or stretcher such that the patient is aligned with the Radiolucent Imaging Top. The top of the bed or stretcher should be level with the top of the 2" (5.1 cm) Tempur-Pedic® Medical Pad on the table top.
2. Lock the bed or stretcher.
3. Confirm that the four (4) Casters of the Base are locked.
4. Transfer the patient in a supine position to the Radiolucent Imaging Top using a standard drawsheet method.
5. Slide the Safety Strap onto the carbon fiber rail of the Radiolucent Imaging Top and tighten it in place where desired. Secure the patient.

WARNING: Patient must be restrained at all time by a safety strap(s) when positioned on the table.

6. Tempur-Pedic® Medical pillows are an optional accessory, which may aid in final patient positioning.

6.3.3 Positioning for Anterior Spine Surgery Procedures

The Radiolucent Imaging Top may be used for anterior spine procedures when properly set up to support the patient.

1. Upon transferring the patient to the Radiolucent Imaging Top (see Section 6.3.2) and securing with a Patient Safety Strap, ensure that the arms are properly positioned. If arms are to be placed at the patient's side, tuck and support them with padding and a draw sheet.
2. Prep and drape the patient in the standard fashion. This position provides ideal access to the anterior cervical spine or lumbar spine through the abdominal approach which gives exposure to the lumbar-sacral area.
3. For anterior lower lumbar spine procedures, an optional accessory, the REF 973 or REF 974 Inflatable Bladder, may be used under the lower back to provide controlled lumbar spine extension.

6.4 Lateral Patient Positioning

A variety of surgical procedures in the lateral decubitis position may be performed on the Radiolucent Imaging Top.

To set up the Table for a lateral procedure:

1. Ensure that the Radiolucent Imaging Top is coupled to the H-Frame at the fifth or sixth mounting hole below the centerline of the Crossbar for lateral procedures such that the patient's center of gravity lies below the centerline of the Crossbar.

WARNING: The Radiolucent Imaging Top must be coupled to the H-Frame such that the patient's center of gravity lies below the centerline of the Crossbars when the patient is positioned laterally. Failure to do so may make the patient unstable during lateral roll.

2. After the patient is transferred to the Radiolucent Imaging Top in a supine position (see Section 6.3), roll the patient to a lateral position and support the patient until final positioning is achieved.
3. Stabilize and maintain the patient in the lateral decubitus position by means of at least two (2) Patient Safety Straps or a lateral positioning device (see Section 7.4).
4. To attach the Lateral Positioner Set (REF 5300), ensure that three Universal Side Rail Adapters have been attached ready to receive the attachments.
5. To mount the rectangular Positioners, first place the Aluminum Side Rail Sockets on the Universal Side Rail Adapters.
6. Mount the rectangular Positioners on the Aluminum Side Rail Sockets such that one pad is between the scapula, the second is at the sacrum, and the third is over the pubis. Tighten the T-Handles of the Aluminum Side Rail Sockets to secure.
7. Adjust each pad position until it rests against the patient.
8. Tighten the pads in place by turning the Drop Handles.
9. To use the pivoting pubic pad of the Deluxe Lateral Positioner Set (REF 5301), mount a Clark Socket on the Universal Side Rail Adapter. Place the post of the Pubic Pad in the Clark Socket and tighten.
10. To adjust the position of the Pubic Pad, turn the Drop Handles counterclockwise to loosen, pivot to the desired position, and tighten in place by turning the Drop Handles clockwise (Figure 11).
11. Standard positioning aids (pillows, Tempur-Pedic® Medical positioning pads, and foam or gel padding) may be used to provide additional patient stability and comfort.

Figure 11: Deluxe Lateral Positioner Set and Lateral Armboard Mounted on Radiolucent Imaging Top

12. The patient may be laterally rotated to a maximum of 25 degrees in each direction using the Lateral Roll function on the Hand Pendant of the Advanced Control Base.

NOTE: *Do not attempt to rotate the patient in the lateral position more than 25 degrees.*

WARNING: Lateral rotation of a patient in the lateral position by more than 25 degrees may result in the patient being dropped.

7 Optional Accessories

NOTE: *These devices are intended for use by trained personnel. Prior to setup and use of the Radiolucent Imaging Top, the Advanced Control Base, and any of the optional accessories available, ensure that personnel have been trained. To schedule an in-service, please contact your domestic Mizuho OSI sales representative or call **1-800-777-4674** inside the USA or **+1-510-429-1500** outside the USA.*

NOTE: *Only Mizuho OSI table tops and accessories have been tested and approved for use with the Advanced Control Base. Other manufacturers' products have not been tested for proper performance when used with the Base and Radiolucent Imaging Top, and therefore are not endorsed for use by Mizuho OSI. Use or other manufacturer's products may void the warranty.*

WARNING: Use of components not manufactured by Mizuho OSI may result in harm to the patient, the table top, the device, or the healthcare professional.

7.1 Universal Side Rail Adapter

The Universal Side Rail Adapter (REF 6977-959) protects the carbon fiber rail of the table from damage and should always be used when mounting accessories. The Adapter provides 6" (15.2 cm) of side rail for mounting various accessories such as Arm Boards, Retractors, Clark Sockets, and Lateral Positioners.

NOTE: *Use of other manufacturers' side rail adapters on the carbon fiber rail may cause damage to the table top and will void your warranty.*

WARNING: Failure to use the Universal Side Rail Adapter when mounting any accessory may result in damage to the table top, patient, or healthcare professional.

To install the Universal Side Rail Adapter:

1. Open the clamp by rotating the black knob counterclockwise,
2. Place the Adapter in the desired position, with the black knob facing down (Figure 12). Ensure that the notch on the Adapter is fully seated on the carbon fiber rail.
3. Rotate the black knob clockwise to tighten the clamp.

Figure 12: Universal Side Rail Adapter Correctly Attached to Radiolucent Imaging Top

7.2 Pivoting Arm Board

The Pivoting Arm Board (REF 5356 or REF 5357) may be mounted onto the Radiolucent Imaging Top with the use of a Universal Side Rail Adapter to provide support for a patient's arm. The Pivoting Arm Board provides 0 to 180 degrees of adjustment and is available with a 2" (5.1 cm) or 3" (7.6 cm) Tempur-Pedic® Medical Pad.

To install the Pivoting Arm Board:

1. Install a Universal Side Rail Adapter as discussed in Section 7.1.
2. Hold the Locking Lever of the Pivoting Arm Board at the base of the bracket in the open position and over the edge of the Universal Side Rail Adapter.
3. Lower the Arm Board into place and release the Locking Lever (Figure 13).

Figure 13: Pivoting Arm Board Mounted on Radiolucent Imaging Top with Use of Universal Side Rail Adapter

4. To pivot, pull the lever at the distal end of the Arm Board to release the latch, pivot the Arm Board to the desired position, and then release the lever to lock in position (Figure 14).

Figure 14: Pulling the Lever at the Distal End of the Arm Board

7.3 Cross Arm Support

The Cross Arm Support (REF 5857) supports the patient's arm over his or her chest. This accessory comes standard with a 1" (2.5 cm) Tempur-Pedic® Medical Pad.

To install the Cross Arm Support:

1. Install a Universal Side Rail Adapter.
2. Mount a Clark Socket on the Universal Side Rail Adapter.
3. Place the Cross Arm Support upright in the Clark Socket. Turn the Clark Socket handle clockwise to secure the Cross Arm Support upright.

Figure 15: Cross Arm Support

4. Position the Cross Arm Support over, but not in contact with, the patient's chest.
5. Pad and secure the patient's arm to the Cross Arm Support.

7.4 Lateral Positioners

Two sets of Lateral Positioners are available for use on the Radiolucent Imaging Top.

1. Lateral Positioner Set (REF 5300):
   a. This set consists of three (3) Rectangular Pads which can be placed at the scapula, at the sacrum, and over the pubis to support the patient in the lateral position.
   b. Three (3) Aluminum Side Rail Sockets and three (3) Universal Side Rail Adapters are required to mount the Lateral Positioner Set to the Radiolucent Imaging Top.
2. Deluxe Lateral Positioner Set (REF 5301)
   a. This set consists of two Rectangular Pads for supporting the patient between the scapula and at the sacrum, and one pivoting round Pubic Pad for positioning over the pubis.
   b. Two (2) Aluminum Side Rail Sockets, one (1) Clark Socket, and three (3) Universal Side Rail Adapters are required to mount the Deluxe Lateral Positioner Set to the Radiolucent Imaging Top.

7.5 Lateral Arm Board

The Lateral Arm Board Set (REF 5364) consists of two arm Board assemblies with 2" (5.1 cm) Tempur-Pedic® Medical Pads.

To install the Lateral Arm Board Set:

1. Mount a Universal Side Rail Adapter on the carbon fiber rail of the Radiolucent Imaging Top and slide a Clark Socket onto it.
2. Insert the post of the Lateral Arm Board Set into the Clark Socket, and rotate the Clark Socket handle clockwise to secure the post.
3. To adjust the position of the lower Arm Board, release the Drop Handle and pivot the Arm Board into place. Tighten the Drop Handle to secure the Arm Board in its new position.
4. When positioned correctly, the Lateral Arm Board Set should support the lower arm at the same level as the Radiolucent Imaging Top. The upper arm board can be translated toward or away from the patient so that the upper arm is adequately supported (Figure 16).

Figure 16: Proper Positioning of Lateral Arm Board

7.6 Cervical Management Base Unit

The Cervical Management Base Unit (REF 5979-1) is designed for use with the Radiolucent Imaging Top and Spinal Surgery Top to allow for both anterior and posterior cervical procedures.

NOTE: *A thorough understanding of the use of the Cervical Management Base Unit and Advanced Control Base is required prior to use and patient transfer. For complete instructions on preparing the Advanced Control Base and Cervical Management Base Unit, refer to the respective Owner's Manuals, which provide detailed information regarding setup, cleaning, and maintenance.*

To mount the Cervical Management Base Unit on the Advanced Control Base for supine cervical procedures:

1. Place the Cervical Management Base Unit on a stable surface and separate the Table Adapter Assembly from the Cervical Management Base Unit Sub Assembly. Align the Stop Cap of the Horizontal Slide so it can pass through and out of the Table Adapter Assembly and remove the Cervical Management Base Unit Sub-Assembly from the Table Adapter Assembly (Figure 17).

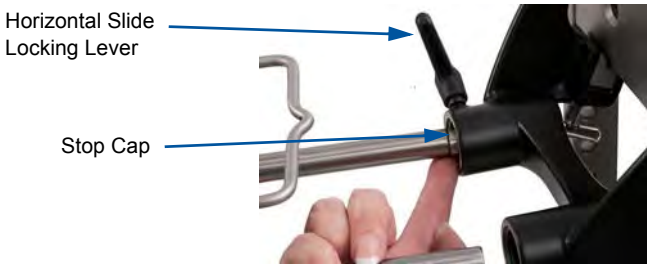


Figure 17: Stop Cap Aligned to Allow for Removal of the Cervical Management Base Unit Sub-Assembly

2. Align the Base Unit so that it is centered on the Crossbar and secure it by tightening the two T-Handles.
3. When mounted correctly, the Adapter Assembly should be securely seated and the Traction Pulley aligned with the center of the Crossbar.
4. Turn the Cervical Management Base Unit Sub-Assembly such that the Crank Handle faces the ceiling and the Black Knob faces the floor. Align the Stop Cap, and re-insert the Horizontal Slide into the Table Adapter Assembly. The Horizontal Slide should move freely back and forth within its range of travel.
5. Tighten the Horizontal Slide Locking Lever when the desired position of the Horizontal Slide is achieved (Figure 18, page 24).

Figure 18: Cervical Management Base Unit Sub-Assembly Rotated and Set Up for Supine Positioning

6. The Cervical Management Base Unit is set up for use with a patient positioned supine on the Radiolucent Imaging Top.
7. With the Cervical Management Base Unit mounted, the following adjustments can be made to the device.
   a. The Horizontal Slide can move freely or be locked in place using the Locking Lever.
   b. The height of the Yoke with Transitional Arms can be raised or lowered by turning the Black Knob at the bottom or the Crank Handle at the top of the assembly.
   c. The Transitional Arms can be articulated by loosening the knobs on the side of the arm and then moving the arms to their desired position.
8. Prior to use, ensure that all teeth of the starburst are aligned and the corresponding knobs are properly tightened.
9. The Cervical Management Base Unit is now prepared for an Aluminum DORO® or Mayfield® Skull Clamp to be attached. The Swivel Adapter can be positioned by releasing the Drop Handle and then moving the Ball Joint until the Swivel Adapter is in the desired location. Tighten the Drop Handle to secure the Swivel Adapter in place. A radiolucent Skull Clamp may also be attached with use of the appropriate adapter.

NOTE: *Skull Clamps and Horseshoe Headrests may be used with the Cervical Management Base Unit. Refer to the specific manufacturer's instructions for use of the Skull Clamp to be attached to the Cervical Management Base Unit.*

NOTE: *If the patient is fitted with a cervical halo, it is possible to attach some halos directly to the Cervical Management Base Unit. Consult with the halo manufacturer for the availability and use of halo adapters.*

7.7 Anterior Extension Positioner

The Anterior Extension Positioner (REF 5879-2) with inflatable bladder can be used on the Radiolucent Imaging Top to achieve hyperextension of the patient's neck (Figure 19).

The pad is oriented such that the inflatable bladder is at the Head-End of the table top. The Tubing with the Bulb Inflater and Air Control Valve extends from the pad and can be accessed from either the Head-End or the Foot-End of the table.

1. Remove the 2-inch (5 cm) standard table pad from the Radiolucent Imaging Top. Place the 5-inch (12.7 cm) pad directly on the Radiolucent Imaging Top and secure it in place with the straps provided.
2. Open the Air Control Valve by turning it counterclockwise.
3. Confirm that the bladder is deflated.
4. Transfer patient to the table.
5. To inflate the bladder of the Anterior Extension Positioner, close the Air Control Valve and compress the Bulb Inflater until the desired degree of neck extension is achieved.
6. To deflate the bladder, open the Air Control Valve. The patient's weight will help expel the air from the bladder.

Figure 19: REF 5879-2 Anterior Extension Positioner Set Up on the Radiolucent Imaging Top

7.8 Head Halter

Use of a Head Halter or Gardner Wells Tongs for cervical management is also an option when using the Radiolucent Imaging Top.

To use:

1. Attach the traction rope to the desired traction weight to be used.
2. Pass the traction rope over the Traction Pulley Assembly and thread through the Pivot Shaft of the Head-End Crossbar.
3. Connect the traction rope to the Head Halter or Gardner Wells Tongs (Figure 20).

NOTE: *The amount of weight or the traction load applied to the patient is at the discretion of the surgeon.*

NOTE: *Refer to the specific manufacturer's instructions for use of the Head Halter or Gardner Wells Tongs device to be attached.*

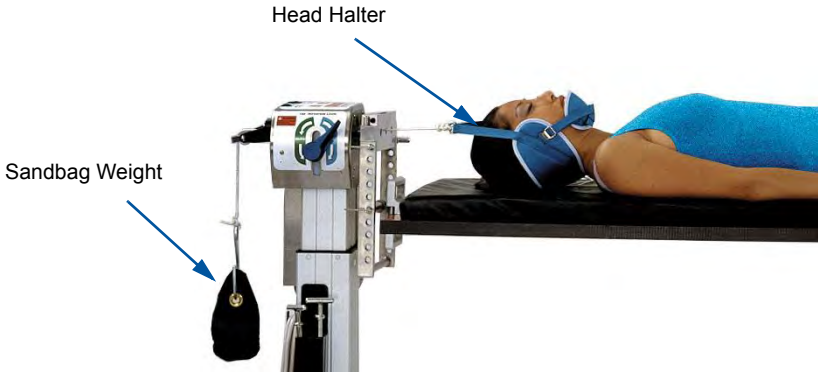


Figure 20: Head Halter Traction

7.9 Wilson Plus™ Radiolucent Frame

NOTE: *A thorough understanding of the use of the Advanced Control Base and Wilson Plus™ Radiolucent Frame are required prior to use and patient transfer. For complete instructions on preparing the Advanced Control Base and Wilson Plus™ Radiolucent Frame, refer to the respective Owner's Manuals, which provide detailed information regarding setup, cleaning, and maintenance.*

The Wilson Plus™ Radiolucent Frame (REF 5319G) may be used for positioning on the Radiolucent Imaging Top or on a General Surgery Table (Figure 21). The Wilson Plus™ provides a convenient and stable method of maintaining patients in a flexed position for lumbar procedures. The spinal flexion frame is constructed of carbon fiber, which allows for unrestricted radiolucency and C-arm integration. The Wilson Plus™ may be used for laminectomy, decompression, or microdiscectomy surgeries.

Figure 21: REF 5319G Wilson Plus™ Radiolucent Frame on the Radiolucent Imaging Top

7.10 Pelvic Reconstruction Kit with Traction Arc

NOTE: *A thorough understanding of the use of the Advanced Control Base and Pelvic Reconstruction Kit with Traction Arc are required prior to use and patient transfer. For complete instructions on preparing the Advanced Control Base and Pelvic Reconstruction Kit with Traction Arc, refer to the respective Owner's Manuals, which provide detailed information regarding set-up, cleaning, and maintenance.*

The Pelvic Reconstruction Kit with Traction Arc (REF 5848), when attached to the Radiolucent Imaging Top, is designed for lower extremity trauma surgical procedures, and can support patients in supine, prone, and lateral positions. Use of the Pelvic Reconstruction Kit with the Imaging Top offers an orthopedic surgical option that provides for skin and skeletal traction during open reduction of the pelvic or acetabular fractures and allows for application of the Kocher-Langenbeck technique.

NOTE: *When the Traction Arc is installed with the Radiolucent Imaging Top on the Advanced Control Base, the lateral tilt (roll) function of the Base is disabled. Height and Trendelenburg adjustments remain active and may be used as needed.*

7.11 Well Hip Fixation Frame

The Well Hip Fixation Frame is attached to the Radiolucent Imaging Top and is used in conjunction with external fixation devices. The device is available in two models: REF 6835-8, designed to work with the Stryker System, and REF 6835-10, designed to work with the Synthes System.

7.12 Tempur-Pedic® Medical Pad Positioning Set

The Tempur-Pedic® Medical Pad Positioning Set (REF 6950) consists of six (6) pads of TEMPUR® construction that can be used to assist in positioning patients. All pads have closed seams, no zippers, and are made with antimicrobial 4-way stretch cover fabric so they can be used in virtually any position.

7.13 Modular Equipment Cart and Cover

The Modular Equipment Cart (REF 5864) may be used to store the Radiolucent Imaging Top, components, and any accessories when not in use. The Equipment Cart Cover provided with the Cart serves as a dust cover and should be used while the products are in storage.

Figure 22: REF 5864 Modular Equipment Cart

7.14 List of Optional Accessories

Optional Accessory	Optional Accessory	Optional Accessory
		
REF 6977-959 Universal Side Rail Adapter	REF 5356 Pivoting Arm Board with 2" Tempur-Pedic® Medical Pad REF 5357 Pivoting Arm Board with 3" Tempur-Pedic® Medical Pad	REF 5857 Cross Arm Support
Optional Accessory	**Optional Accessory**	**Optional Accessory**
		
REF 5301 Deluxe Lateral Positioner Set with Ball Joint (pictured) REF 5300 Lateral Positioner Set	REF 5364 Lateral Arm Board Set with 2" Tempur-Pedic® Medical Pads	REF 5393 Clark Socket

Optional Accessory  **REF 5394** **Aluminum Side Rail Socket**	**Optional Accessory**  **REF 5979-1** **Cervical Management Base Unit**	**Optional Accessory**  **REF 5979-200** **Radiolucent Mayfield® Adapter for Cervical Management Base Unit**
Optional Accessory  **REF 5979-300** **Radiolucent DORO® Adapter for Cervical Management Base Unit**	**Optional Accessory**  **REF 5879-2** **Anterior Extension Positioner**	**Optional Accessory**  **REF 5879 Complete Cervical Management Set** **(Cervical Management Base Unit, Supine Operating Top, & Anterior Extension Positioner)**
Optional Accessory  **REF 6910-3034** **DORO® Skull Clamp, Radiolucent** **REF 6910-3003** **DORO® Skull Clamp, Aluminum**	**Optional Accessory**  **REF 5319G** **Wilson Plus™ Radiolucent Frame for Radiolucent Imaging Top and General Surgery Tables**	**Optional Accessory**  **REF 5864** **Modular Equipment Cart and Cover**

Optional Accessory	Optional Accessory	Optional Accessory
		
REF 6946 Standard REF 6947 Queen Mizuho OSI Tempur-Pedic® Medical Positioning Pillows	REF 6950 Mizuho OSI Tempur-Pedic® Medical 6 pc . Positioning Pad Set	REF 6900-51 Universal Foot Board with Tempur-Pedic® Medical Pad
Optional Accessory	**Optional Accessory**	
		
REF 973 and REF 974 Inflatable Bladder	REF 6835-8 Well Hip Fixation Frame (for use with Stryker System) REF 6835-10 Well Hip Fixation Frame (for use with Synthes System)	

8 180 Degree Rotation

The Modular Table System is designed to allow for 180 Degree Rotation of a patient through the use of the Radiolucent Imaging Top in conjunction with the Spinal Surgery Top and Advanced Control Base. The ability to rotate a patient 180 degrees provides a safe alternative to log rolling when positioning an anesthetized patient prone from a supine position. This feature may also be used intra-operatively during anterior-posterior spinal procedures to re-position the patient from supine to prone without transferring the patient off the table.

NOTE: *A thorough understanding of the REF 5927 Radiolucent Imaging Top, REF 5943 / 5943I Spinal Surgery Top, and the REF 5803 / 5803I / 5803J Advanced Control Base is required prior to use and patient transfer.*

WARNING: Failure to follow the instructions detailed in this manual, the REF 5943 / 5943I Spinal Surgery Top Owner's Manual, and the REF 5803 / 5803I / 5803J Advanced Control Base Owner's Manual may cause harm to the patient, healthcare professional, or device.

8.1 Preparing for the Rotation Sequence

1. Set up the Spinal Surgery Top with the desired components and pads to support the patient in the prone position (Figure 23). Place the Patient Kit Covers on the Chest Pads, Hip Pads, and Thigh Pads. Store the Spinal Surgery Top on the Modular Equipment Cart until needed.

Figure 23: Spinal Surgery Top Prepared and Stored on Modular Equipment Cart

2. Open the individually packaged ProneView® Cushion 60 minutes prior to use. Place the cushion in the Helmet. If using the GentleTouch® Pillow, open the package 20 minutes prior to use. Open the Arm Cradles at least 20 minutes prior to use and set them aside for use during final positioning following the rotation.
3. Set up the Advanced Control Base (see Section 6.1) and conduct the necessary safety check.
4. Confirm the four (4) Casters are locked.
5. Confirm the H-Frames and table top are securely mounted by ensuring the four (4) T-Pins are fully advanced and the Drop Locks are visible and pivot freely.
6. Confirm the 180 Degree Rotation Lock and the Rotation Safety Lock are engaged and the table top is level side to side. Verify that the three corresponding indicator lights – the 180 Degree Rotation Lock, the Rotation Safety Lock, and the Tilt Drive Status – on the Head-End Column are illuminated blue.
7. Verify that the three corresponding indicator lights – the 180 Degree Rotation Lock, the Rotation Safety Lock, and the Tilt Drive Status – on the Hand Pendant are illuminated blue.

NOTE: *All three (3) lights must be illuminated on the Head-End Column and Hand Pendant before a patient is transferred to the table. If all three (3) lights are not illuminated on the Head-End Column and Hand Pendant, do not transfer the patient.*

WARNING: Failure to ensure that all three lights on the Head-End Column and Hand Pendant are illuminated prior to patient transfer may result in harm to the patient, device, or healthcare professional.

8. Mount the Radiolucent Imaging Top on the Advanced Control Base (see Section 6.2).
9. Transfer the patient to the Radiolucent Imaging Top using the standard drawsheet method (Figure 24).

Figure 24: Patient Positioned Supine on the Radiolucent Imaging Top

10. With the patient positioned supine on the Radiolucent Imaging Top, install an H-Frame on the top of both the Head-End and the Foot-End Crossbars. Secure each upper H-Frame in place with a T-Pin. Confirm the H-Frames are securely mounted by ensuring the T-Pins are fully advanced and the Drop Locks are visible and pivot freely.

11. Carefully place the ProneView® Helmet with the Cushion in place over the patient's face. If using the Face Plate, place the GentleTouch® Pillow over the patient's face.

NOTE: *The patient's head must be supported at all times: before, during, and after the 180 Degree Rotation.*

12. Remove the Spinal Surgery Top from the Cart, and with the assistance of others, mount the table top over the patient in the uppermost holes of the upper H-Frames installed at both the Head-End and the Foot-End. Secure the table top to the H-Frames by inserting T-Pins (Figure 25). Confirm that the table top is securely mounted by ensuring the T-Pins are fully advanced and the Drop Locks are visible and pivot freely.

WARNING: Failure to ensure that the T-Pins are properly installed may cause harm to the patient, healthcare personnel, and/or the device.

Figure 25: Spinal Surgery Top Mounted in Preparation for Compression Series

13. Confirm that each component and pad is aligned with the corresponding anatomical landmarks on the supine patient.

8.2 Component Positioning

1. Confirm the placement of the ProneView® Mirror Platform, which should be directly above the patient Helmet, with the adjustable posts aligned. The posts will be fully seated in the Helmet during the compression sequence prior to rotation. If the Face Plate will be used, ensure that the GentleTouch® Pillow is aligned with the Face Plate.
2. If Arm Boards will be used when the patient is positioned prone, confirm that the Arm Board Brackets are secure and ready to accept the Arm Board Assemblies after the rotation.
3. Confirm that the top edge of the Chest Pad is aligned with the bottom of the patient's anatomical landmark, the supra-sternal notch. Breasts should be down, lying flat, and with the nipples oriented towards the Foot-End of the table. Ensure that the Patient Care Kit Cover is smooth.
4. Confirm that the Hip Pads are oriented so that the patient's anatomical landmarks, the iliac crests, will rest centered on each pad. Confirm that the Thigh Pads are abutting the Hip Pads. Ensure that all Patient Care Kit Covers are smooth.
5. Confirm that the Leg Boards will support the patient's knees and legs, and the patient's feet will not be compressed by the Leg Boards.
6. Adjust the position of the components as necessary to ensure proper placement and support of the patient when rotated. Should the Hip or Thigh Pads need adjusting, unlock the Locking Lever on the Bracket, re-position the Pad, confirm the new position by checking the anatomical landmark, and close the Locking Lever to lock in place. When moving the Hip Pad, the Thigh Pad must also be moved to a position abutting the Hip Pad. Ensure that the Patient Care Kit Covers are smooth.
7. If the patient's arms are positioned on Arm Boards while lying on the Radiolucent Imaging Top, remove the patient's arms from the Arm Boards and tuck them to the sides with the draw sheet. Remove the Pivoting Arm Boards mounted on the Radiolucent Imaging Top and remove the Universal Side Rail Adapters.

CAUTION: Failure to ensure that all table accessories and components are removed from the Radiolucent Imaging Top before proceeding with the rotation may result in harm to the patient.

8. Apply the four (4) 90-inch (228.6 cm) Safety Straps around both the Spinal Surgery Top and the Radiolucent Imaging Top. Buckle the Safety Straps loosely in place around the tops, with all buckles oriented on the same side for ease of access (Figure 26). Patient anatomical landmarks for positioning the straps are as follows:
   - The landmark for the Chest Pad is mid-humerus.
   - The landmark for the Hip and Thigh Pad is mid-forearm.
   - The landmark for the upper Leg Board or Sling is mid-femur.
   - The landmark for the lower Leg Board or Sling is mid-tibia.
9. To fill the void between the patient's legs and the Spinal Surgery Top, place pillows over the patient's legs (Figure 26).

Figure 26: Four (4) 90-inch Safety Straps Applied with Pillows Placed over Patient's Legs

NOTE: *A Leg Sling may be used when performing a 180 Degree Rotation to accommodate taller patients or individuals who may require additional hip flexion while in the prone position following rotation.*

10. If rotating using a Leg Sling, place three (3) pillows under the patient's knees and two (2) to three (3) pillows on top of the patient's knees and tibia to fill the void.

8.3 Compression Sequence and Safety Check

NOTE: *The following sequence is intended to be done rapidly to prevent extended compression of the patient. When properly executed, the compression, rotation, and release sequence should take less than thirty (30) seconds. This is desirable to avoid undue extended compression of the patient.*

During the compression and rotation sequence, the anesthesiologist manages and monitors the patient's lines and tubes. Consideration should be given to how the patient's lines and tubes will be managed when determining the direction of rotation.

1. Remove the T-Pins from the upper most hole of the upper H-Frames and support the table top above the patient.

WARNING: Do not remove any Crossbar T-Pins or table top T-Pins located below the patient. Failure to remove the correct T-Pins will result in harm to the patient.

2. Allow the Head-End to lower until the Chest Pad rests on the patient's sternum. If using the ProneView® Helmet System, ensure that the feet of the ProneView® Helmet and the mirror are aligned when lowering the Head-End of the Spinal Surgery Top. There is no compression at the Head-End. Place the T-Pin in the mounting hole of the Head-End upper H-Frame where the table top rests. Ensure that the T-Pin is fully advanced, and the Drop Lock is visible and pivots freely.

NOTE: *When the T-Pin is installed properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame with the Drop Lock visible and pivoting freely, the T-Pin cannot be removed when pulled.*

WARNING: Failure to install the T-Pin properly through one side of the H-Frame, passing completely through the table top mounting tube, and then through the opposite side of the H-Frame with the Drop Lock visible and pivoting freely, may result in harm to the patient, healthcare professional, or this device.

3. Lower the Foot-End of the Spinal Surgery Top until the Hip Pads rest on the patient's iliac crests. This action compresses the legs, so check the position of the pillows and ensure that there is no pressure on the feet. Insert a T-Pin through the nearest mounting hole on the Foot-End upper H-Frame that maintains the position of the table top. Ensure that the T-Pin is fully advanced and the Drop Lock is visible and pivots freely (Figure 27).

NOTE: *Assess the compression of the patient at the chest and iliac crests. Ensure that the Chest Pad rests on the sternum and the Hips Pads are tight against the iliac crests such that compression occurs at this point of contact.*

4. Tighten the four (4) Safety Straps as tightly as possible by hand (Figure 27).

Figure 27: Compression Taking Place at the Foot-End

5. Conduct a count of the 16 critical items to confirm their status prior to rotation. Physically confirm the following 16 items:
   - Four (4) T-Pins in place in the Head–End H-Frames. Ensure that the Drop Locks are visible and pivot freely.
   - Four (4) T-Pins in place in the Foot-End H-Frames. Ensure that the Drop Locks are visible and pivot freely.
   - Four (4) Safety Straps are tight and in place.
   - Four (4) Casters of the Advanced Control Base are locked.

WARNING: Failure to complete all four steps, which detail how to conduct a count of the 16 critical items to confirm their status prior to rotation, ensuring all H-Frames, T-Pins, and Casters are fully engaged and in the locked position, and the Safety Straps are tight and in place, may result in harm to the patient, healthcare professional, or devices.

8.4 Rotation Sequence

Three people are required to complete a 180 Degree Rotation, with one person positioned at the Head-End, one person at the Foot-End, and one person mid-table. After completing the 16-point safety check, the person mid-Table will complete the actual rotation of the table tops by placing one hand on the far side of the Spinal Surgery Top and the other hand on the Radiolucent Imaging Top. He or she will also be responsible for directing the timing of the rotation.

NOTE: *The anesthesiologist may choose to disconnect the patient's intravenous infusions, monitoring devices, and anesthesia prior to the 180 Degree Rotation. If this is not the case, care must be taken to observe and control all lines during the rotation.*

1. At the direction of the person mid-table, the person at the Head-End of the table releases the 180 Degree Rotation Lock by turning the blue handle counterclockwise until the 180 Degree Rotation Lock indicator light is no longer illuminated. He or she then announces "180 Degree Rotation Lock Off".
2. The person mid-table then directs the release of the Rotation Safety Lock verbally on the count of three. The anesthesiologist should confirm control of the tubes and lines attached to the patient. At the completion of the count, the person at the Head-End will toggle the Rotation Safety Lock to the Off position.
3. To control the rotation, the person mid-table always rotates the table tops towards him or herself. After the rotation is complete, the person mid-table and the person at the Foot-End hold the table tops level and in place until both the Rotation Safety Lock and the 180 Degree Rotation Lock are locked as evidenced by the three (3) lights illuminated on the Head-End Column.

NOTE: *The person mid-table must rotate the table tops and the patient 180 degrees towards him or herself without stopping until the complete 180 degree rotation is achieved.*

WARNING: Failure for the person mid-table to rotate the table tops and the patient 180 degrees towards him or herself without stopping until the 180 degree rotation is achieved may result in harm to the patient, healthcare professional, or these devices.

4. The person at the Head-End switches the 180 Degree Rotation Safety Lock On, resulting in the Rotation Safety Lock indicator light illuminating blue. The Head-End person verbally states, "Rotation Safety Lock On." Next, this person locks the 180 Degree Rotation Lock by turning the blue handle clockwise until the 180 Degree Rotation Lock light illuminates. He or she announces, "180 Degree Rotation Lock On." The Tilt Drive Status indicator also illuminates, indicating that the table top is level side to side.
5. The Foot-End and mid-table people should not release their hold on the table tops until the Head- End person provides verbal confirmation of the engagement of the Rotation Safety Lock and the 180 Degree Rotation Lock.

CAUTION: Failure for the people at the Foot-End and mid-table to maintain their hold on the table tops until the Head-End person has provided verbal confirmation of the engagement of the Rotation Safety Lock and 180 Degree Rotation Lock may result in harm to the patient, healthcare professional, or these devices.

6. Once the Rotation Safety Lock and the 180 Degree Rotation Lock are locked and the three (3) blue lights illuminate on the Head-End Column, the anesthesiologist immediately manages the patient's lines and tubes.
7. The surgeon confirms the patient's face is correctly supported by the ProneView® cushion, ensuring that the patient's eyes are visible in the mirror and the neck is in a neutral position. If the neck is not neutral, turn the posts on the platform to adjust the height of the Helmet to achieve the proper position. If using the GentleTouch® Pillow, ensure that the patient's face is properly seated in the pillow, with the eyes, nose, and mouth visible.

Figure 28: Compression Following 180 Degree Rotation

8.5 Removing the Radiolucent Imaging Top

1. Remove the four (4) Safety Straps from around the table tops.
2. Mount the Arm Boards in the Arm Board Brackets.
3. Position the patient's arms and support the arms in the Arm Cradles. The V of the cradle rests against the inside of the elbow. Translate, raise, lower, or articulate the Arm Boards as appropriate and secure them in place. Confirm that all T-Handles and Drop Handles are tight.
4. Confirm the patient's orientation on the Chest Pads, Hip Pads, and Thigh Pads, and then complete final positioning of the patient's arms.
5. With the person at the Head-End and the person at the Foot-End supporting the Radiolucent Imaging Top, remove the T-Pins attaching the top to the upper H-Frame at the Head-End and the Foot-End, and lift the top off the Base and over the patient (Figure 29). This will relieve the compression on the patient. When not in use, store the Radiolucent Imaging Top on the Modular Equipment Cart.

WARNING: When removing the Radiolucent Imaging Top, remove only the T-Pin at the Head-End and the T-Pin at the Foot-End that couple the Radiolucent Imaging Top to the upper H-Frame. Do not remove the T-Pins through the Crossbar or the table top T-Pins located below the patient. Failure to remove the correct T-Pins will result in harm to the patient.

Figure 29: Initial Prone Position Following Removal of Radiolucent Imaging Top

6. Do not leave the patient unattended on the table without Safety Straps in place (Figure 29). At least one person must stay with the patient until the Safety Straps are securely in place.

7. Remove the upper H-Frame at both the Head-End and the Foot-End by removing the T-Pin that couples each upper H-Frame to the Crossbar.

WARNING: When removing the upper H-Frame at the Head-End and the Foot-End, remove only the T-Pin that couples the upper H-Frame to the Crossbar. Do not remove the T-Pins through the lower Crossbar mounting hole or the table top T-Pins located below the patient. Failure to remove the correct T-Pins will result in harm to the patient.

8.6 Final Patient Positioning Following Rotation

1. Visually confirm the placement of the Chest Pad. When positioned correctly, the edge of the Chest Pad should rest at the patient's anatomical landmark, the supra-sternal notch. Breasts should be down, lying flat, and with the nipples oriented towards the Foot-End of the table. Ensure that the Patient Care Kit Cover is smooth against the patient.
2. To re-position the Chest Pad, lift and support the patient, move the pad, smooth the Chest Pad Cover, and lower the patient onto the Chest Pad. Confirm correct placement of the Chest Pad, which ideally should contact the patient such that the load is borne predominantly by the sternum.

WARNING: Positioning the Chest Pad above the supra-sternal notch may apply pressure to the patient's throat or airway. Failure to ensure that the patient is positioned properly on the Chest Pad may result in harm to the patient.

3. Visually confirm the placement of each Hip Pad. When positioned correctly, the patient's anatomical landmark, the iliac crest, is centered on the Hip Pad. Ensure that the Patient Care Kit Covers are smooth against the patient.
4. Should the Hip Pad need to be re-positioned, lift and support the patient, unlock the pad, move it to the desired location, lock the pad, smooth the Patient Care Kit Cover, and lower the patient onto the pad. Confirm correct placement of the pad.
5. Visually confirm that the Thigh Pads are abutting the Hip Pads. Re-position the pads if necessary. Ensure that the Patient Care Kit Covers are smooth against the patient.

CAUTION: Failure to ensure that the patient is positioned properly on the Hip and Thigh Pads may result in harm to the patient.

6. Place a pillow under the patient's tibiae to ensure that the ankles are not hyper-extended and there is no pressure on the patient's feet.
7. Apply the Buttocks Strap, which should rest low on the patient's gluteal area and surround both hips, and secure around the buttocks. Use a blanket under the Buttocks Strap to protect the patient from direct contact with the strap.
8. Ensure that the patient does not directly contact the rail of the top by using gel or foam as needed to pad the area between the patient and the rail.
9. Apply the 60-inch (152 cm) Safety Strap over the patient's lower legs and around the table top and secure in place with the buckle. The strap should be tight enough to secure the legs against the pillows if the table is laterally tilted. Apply and secure a 90-inch (228.6 cm) Safety Strap around the patient's torso, chest pad, and table, if desired, and secure in place with the buckle.

NOTE: *Placement and location of the Safety Straps is at the discretion of the surgeon and may vary by procedure.*

10. Confirm that the patient's arms are supported in the Arm Cradles with the V of the cradle resting against the inside elbow. Ensure that there is no more than 90 degrees flexion at the shoulder and no more than 90 degrees flexion at the elbow. Translate, raise, lower, or articulate the Arm Boards as necessary to achieve the proper positioning. Confirm that all T-Handles and Drop Handles are tight. Use the Arm Board Straps provided to secure the arms in place.

Figure 30: Proper Prone Positioning Following 180 Degree Rotation

WARNING: Failure to ensure proper arm positioning may result in harm to the patient. Hyperextension of the shoulder may cause compression of the brachial plexus resulting in a potential nerve or vascular injury.

11. Following the rotation of the patient from supine to prone, the patient may be in a slight Trendelenburg position (Figure 30). Should a level position be desired, depress the **Reverse Trendelenburg** button on the Hand Pendant until the desired position is achieved (Figure 31).

Figure 31: Final Prone Patient Positioning Following 180 Degree Rotation

12. The patient is now correctly positioned prone and secured in place with Safety Straps.

NOTE: *Due to the open nature of the Spinal Surgery Top and the long duration of many spinal procedures, the use of forced air warmers, fluid warmers, and blankets should be considered to help prevent hypothermia. Blankets may be placed over the feet up to the gluteal area and across the shoulders and arms out of the surgical field to aid in maintaining the patient's body temperature. These devices should be used according to the manufacturer's directions and at the discretion of the surgeon.*

WARNING: Proper pre-operative and intra-operative procedures must be followed to prevent venous stasis and pooling, pressure sore development, neuropathy, improper electrosurgical tissue grounding, hypotension, and hypothermia.

CAUTION: Use care and monitor the patient when changing the position of the Spinal Surgery Top using the Height Up/Down, Trendelenburg/reverse Trendelenburg, and Lateral Roll functions to ensure that neither the patient nor the table interferes with other equipment. Failure to do so may cause harm to the patient or device.

8.7 Components Used for 180 Degree Rotation

Radiolucent Imaging Top  REF **5927**	**Spinal Surgery Top**  REF **5840-830**	**Patient Safety Strap**  REF **5855-550**
H-Frame (4)  REF **5840-370**	**T-Pin (8)**  REF **5840-361**	**ProneView® Helmet and Mirror System:** *Option 1*  REF **D28705CE**
Face Plate: *Option 2*  REF **5840-277** **Patient Head Support**	**Chest Support Plate with Chest Pad**  REF **5840-580 Single Chest Pad Mounting Bracket** REF **5840-7569 Tempur-Pedic® Medical Single Chest Pad**	**Tempur-Pedic® Comfort Hip Pads – Regular (2):** *Option 1*  REF **6956-4**
Tempur-Pedic® Comfort Hip Pads – Small (2): *Option 2*  REF **6956-5**	**Tempur-Pedic® Comfort Hip Pads – Large (2):** *Option 3*  REF **6956-3**	**Tempur-Pedic® Comfort Thigh Pad, Left and Right**  REF **6956-7 – Left** REF **6956-6 – Right**

Articulating Arm Board with 1-inch (2.5 cm) Tempur-Pedic® Medical Pad and Bracket (2)

REF **5579**

Leg Board with Pad (2): *Option 1*

REF **5840-24**

Leg Sling: *Option 2*

REF **5840-450**

Buttocks Strap

REF **5840-45**

60-inch (152 cm) Safety Strap

REF **5840-43**

90-inch (228.6 cm) Safety Strap (4)

REF **5840-44**

Spinal Surgery Top ProneView® Patient Care Kit

REF **5808PV**

Spinal Surgery Top Table Cover

REF **5943-3000**

Optional Accessory

REF **5864**
Modular Equipment Cart and Cover ***(not shown)***

Optional Accessory

REF **5808**

Spinal Surgery Top GentleTouch® Patient Care Kit

Optional Accessory

REF **5888**

Retractor Adapter

Optional Accessory

REF **6946 Standard**

REF **6947 Queen**

Mizuho OSI Tempur-Pedic® Medical Positioning Pillows

9 Cleaning, Storage and Maintenance

9.1 Cleaning and Disinfecting

NOTE: *Clean and disinfect the Radiolucent Imaging Top after each use.*

9.1.1 Table Top

The Radiolucent Imaging Top should be regularly wiped clean with a mild detergent solution and wiped dry with a soft lint-free cloth.

Care should be taken to avoid exposing the table to excessive moisture. Flooding, fogging, or steam cleaning is not recommended.

CAUTION: Never pour any liquid directly onto the Radiolucent Imaging Top. Never subject the Radiolucent Imaging Top to an equipment washing machine.

Blood or other fluids, etc., if allowed to remain on the Radiolucent Imaging Top for a long period of time, will require special cleaning to remove. A 5% acetic acid solution or white vinegar and water solution is especially good for this purpose.

NOTE: *Use of iodophors will cause staining.*

To remove staining or discoloration of plated or stainless steel surfaces, clean with a commercial cleaning compound labeled for stainless steel and then buff the surface by hand.

To disinfect exterior surfaces, use a quaternary ammonium compound according to manufacturer's directions for use. Wipe dry with a soft lint-free cloth.

NOTE: *Failure to thoroughly dry the surface after cleaning and disinfecting may result in rust or damage to the surface of the device.*

9.1.2 Mizuho OSI Tempur-Pedic® Medical Pads

NOTE: *The Mizuho OSI Tempur-Pedic® Medical Pads should always be stored in a flat position. The pads can become stiff in cold temperatures and can crack and break if in a rolled position. It is important that you allow the pads to warm to room temperature before attempting to use or handle. In accordance with AORN recommendations, it is important to limit skin exposures to lower ambient temperatures, protect the patient by initiating passive warming interventions (e.g. applied forced-air warming systems, blankets, drapes and reflective composites), and to maintain an ambient room temperature of 20° to 25°C.*

When handling a Tempur-Pedic® Medical Pad, always grasp by the entire thickness of the pad.

CAUTION: DO NOT lift, slide, or carry Mizuho OSI Tempur-Pedic® Medical Pads by grabbing the fabric cover. The cover may tear or rip.

The pads are intended to be cleaned in place. They do not need to be rotated or removed.

Clean with standard hospital disinfectants labeled for use on table pads. Always dilute and rinse per manufacturer's label instructions. Wipe dry with a lint free cloth. DO NOT soak or autoclave the pads.

NOTE: *The use of bleach or highly concentrated chemicals may discolor the cover and will void the warranty on the pad.*

When cleaning the bottom of the pad or the table top, simply lift one end of the pad, and fold it over onto the other end. Clean the pad or the table top, wipe dry with a lint free cloth then reposition the pad to flat on the table top.

9.2 Storage

When not in use, the Radiolucent Imaging Top should be stored in a clean, dry environment. The following conditions are required of the shipping and or storage environment:

- Ambient temperature -4 °F (-20 °C) to 122 °F (50 °C)
- Relative humidity from 10% to 95%, non-condensing
- Atmospheric pressure from 75 to 105 kPa

When in storage, the table cover provided serves as a dust cover and should be used.

9.3 Maintenance

Cleaning the table surfaces and table pad after each use will assure many years of trouble-free service. All components are lubricated for life at the factory and no other lubrication for the table top is required.

Preventative Maintenance:

Contact Mizuho OSI Service for a complete preventative maintenance checklist.

For detailed repair information or to order replacement parts, call or contact via the web Mizuho OSI Service:

1-800-777-4674, Option 2 (for calls inside the USA)

+1-510-429-1500, Option 2 (for calls outside the USA)

+1-510-429-8324 (Fax)

service@mizuhosi.com

www.mizuhosi.com

Mizuho OSI Service is available from 5 AM to 5 PM Pacific Time, Monday through Friday. Please leave a message after normal business hours.

10 Technical Support

10.1 Contact for Parts and Service

For detailed repair information or to order replacement parts, call Mizuho OSI Service at **1-800-777-4674** (for calls inside the USA) or **+1-510-429-1500** (for calls outside the USA). At the prompt, select Option 2.

A Service line is available from 5 AM to 5 PM Pacific Time, Monday through Friday. Please leave a message after business hours.

Please state slowly your name, phone number, your facility name and city, affected equipment model number, and serial number.

An email message may be left anytime at **service@mizuhosi.com** or through the web site: **www.mizuhosi.com**.

10.2 Order Replacement Parts

If unable to identify a part please telephone, fax, or e-mail Mizuho OSI Service before placing an order. Once the part number is obtained, follow the instructions below to order the replacement part.

If the part is known, please telephone, fax, or e-mail Mizuho OSI Service with the part number and description to obtain price and availability.

To place a Replacement Parts (RP) order please telephone, fax, or e-mail Mizuho OSI Service with the part number, description, price, customer number and method of shipment with the purchase order. Indicate that the order is for Replacement Parts (RP).

10.3 Return Damaged Parts

Identify the part or part number to be returned.

Telephone, fax or e-mail Mizuho OSI Service with the part number and description of the part for return to obtain a Return Goods Authorization (RGA) number.

Complete the Certificate of Decontamination provided by Mizuho OSI Service.

Return part with the RGA number clearly marked on the outside of the package, and include the Certificate of Decontamination with the shipment.

10.4 Send a Part for Repair

If unable to identify a part, please telephone, fax, or e-mail Mizuho OSI Service for assistance.

If the part number is known, please telephone, fax, or e-mail Mizuho OSI Service with the part number and description of problem to obtain a Repair Authorization (RA) number.

Clean/disinfect parts prior to shipping, and complete the Certificate of Decontamination provided by Mizuho OSI Service.

Ship the part with the RA number clearly marked on the outside of the package.

The part will be evaluated and customer will be contacted with the cost of repair, if not covered under table warranty.

After customer approval of repair cost, the part will be repaired and returned to the customer.

10.5 Warranty

Mizuho OSI products come with a one (1) year warranty against manufacturer defect. All expenses for parts and labor for product service calls are covered free of charge for the warranty period, except those products that are misused, altered, or damaged. All Tempur-Pedic® Medical Pads come with a two (2) year warranty against manufacturer defect. Defective merchandise will be credited or replaced.

10.6 European Union EC Representative EC REP

Emergo Europe

Prinsessegracht 20

2514 AP The Hague

The Netherlands