Spinal Surgery Top

Owner's Manual

Available Translations:

- English (en-US)
- Spanish (es-ES)
- French (fr-FR)
- German (de-DE)
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REF 5943, 5943I

NW0678 Rev P
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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 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 NW0646 Advanced Control Base Owner's Manual.

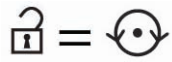
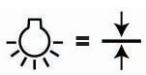
NOTE: *This device is intended for use by trained personnel only. To schedule an in-service, please contact your domestic Mizuho OSI sales representative or call **1-800-777-4674** inside the USA or **+1-510-429-1500** outside the USA.*

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.*

The following symbols are used on this product and/or in this manual:

Symbol	Meaning
EC REP 5.1.2 Authorized representative in the European Community[1]	This symbol indicates an authorized representative in the European Community.
CH REP CH-Rep symbol[7]	This symbol indicates the authorized representative in Switzerland.
CE CE marking[6]	This symbol indicates the product is in conformity with European Community harmonization legislation.
UK CA UKCA marking[8]	This symbol indicates the product is in conformity with the requirements of the relevant Great Britain (UK) legislation.

Symbol	Meaning
 5.7.7 Medical Device[1]	This symbol indicates a medical device.
 3082 Manufacturer[2]	This symbol indicates the Manufacturer of the device.
NOTE:	This symbol indicates a comment or instruction of importance.
 0434B Caution[2]	This CAUTION symbol indicates a potentially hazardous situation, which if not avoided could result in minor or moderate injury.
 W001 General warning sign[3]	This WARNING symbol indicates a potentially hazardous situation, which if not avoided could result in serious injury or death.
 WEEE symbol[5]	This symbol indicates proper disposal instructions. See Section 1.2 for more information.
 2493 Catalog number[2]	This symbol indicates a product number.
 2498 Serial number[2]	This symbol indicates a serial number.
 M002 Refer to instruction manual/ booklet[3]	This symbol indicates that you need to read the manual before use.
 1641 Consult instructions for use[2]	This symbol indicates that you need to refer to the instructions for use.
 5019 Protective earth; protective ground[4]	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.
 5840 Type B applied part[4]	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.

Symbol	Meaning
	This symbol represents a Fault Indicator.
	This symbol identifies the 180° 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.
 5008 "OFF" (power)[4]	This symbol indicates POWER OFF.
5007 "ON" (power)[4]	This symbol indicates POWER ON.
	This symbol represents the Battery Status of the Advanced Control Base.
 5569 Locking, general[4]	This symbol represents a locked state.
 5570 Unlocking, general[4]	This symbol represents an unlocked state.
	This symbol informs the user that Unlocking the lock may cause movement.
	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.
	This symbol identifies the Foot-End of the Table.

Symbol	Meaning
	This symbol identifies a Small Hip Pad.
	This symbol identifies a Regular (Medium) Hip Pad.
	This symbol identifies a Large Hip Pad.
	This symbol identifies the Left Combination Contoured Hip/Thigh Pad.
	This symbol identifies the Right Combination Contoured Hip/Thigh Pad.
	This symbol identifies the Hip Pads.
	This symbol identifies the Left Thigh Pad.
	This symbol identifies the Right Thigh Pad.

[1] Standard symbol from "ANSI/AAMI/ISO 15223- 1: Medical devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements."

[2] Standard symbol from "ISO 7000 Graphical symbols for use on equipment."

[3] Standard symbol from "ISO 7010: Graphical symbols -- Safety colours and safety signs -- Registered safety signs."

[4] Standard symbol from "IEC 60417 Graphical Symbols for use with Equipment."

[5] Symbol from "Directive 2012/19/EU."

[6] Symbol from Regulation (EC) No 765/2008.

[7] Symbol from "Medical Device Ordinance of 1 July 2020; SR 812 213."

[8] Symbol from "The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulation 2019, Schedule 33."

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 Spinal Surgery 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 electrical 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 13).

WARNING: The Spinal Surgery 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.

WARNING: Do not perform any service or maintenance work on the device while it is in use with a patient. Servicing the device while in use may cause injury to the patient.

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 Spinal Surgery 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 Spinal Surgery Top and Advanced Control Base, refer to the instructions for use provided by the manufacturer of those devices.*

NOTE: *(European Union) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

1.1 Trademarks

GentleTouch® and OrangeAid® are registered trademarks 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, part of Black Forest Medical Group.

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

Velcro® is a registered trademark of Velcro Industries.

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

The Spinal Surgery Top includes Mizuho OSI Tempur-Pedic® Medical Pads. The material used in the manufacture of the Mizuho OSI pads has viscoelastic properties and is temperature sensitive, becoming softer where the patient's body makes the most contact with the surface and remaining firm in the areas where less body contact is made. Pressure is distributed evenly over the entire surface area. The pads are 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 Spinal Surgery Top discussed in this manual, there are several optional accessories available, including Cervical Management Systems and the Wilson Plus™ Radiolucent Frame. 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.*

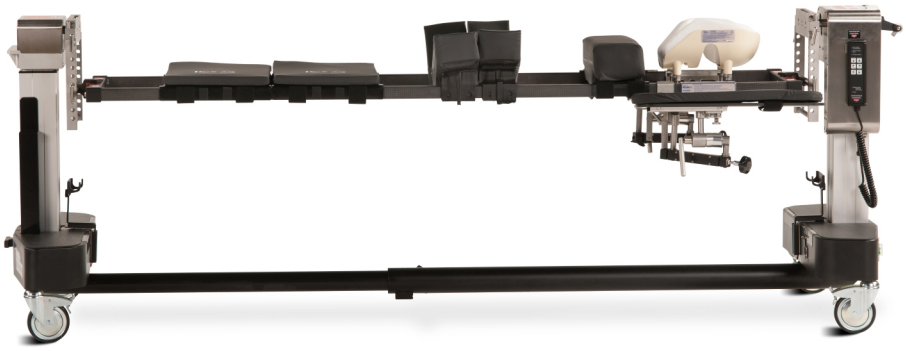


Figure 1: Spinal Surgery Top with Standard Components Mounted on the Advanced Control Base

2.2 Intended Use

The Spinal Surgery 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 prone position. The Spinal Surgery Top mounted on the Base is intended for use during surgical procedures, including radiographic imaging during such procedures. The Spinal Surgery Top mounted on the Base should not be used for patient transport.

The Spinal Surgery 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 Spinal Surgery 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 and radiology technicians.

2.4 Training Requirements

Before using the Modular Table System, the user must read the 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:

NW0678 Spinal Surgery Top Owner's Manual

NW0677 Radiolucent Imaging 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 professional, or the device.

2.5 Conditions of Use

The Spinal Surgery 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 Spinal Surgery 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 product design life is 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. The product's functionality depends on many factors, including but not limited to frequency of use, maintenance and servicing, and how it's used. Therefore, Mizuho OSI recommends that the table undergo authorized preventative maintenance and repair throughout its lifetime. Contact Mizuho OSI Service for product end-of-life disposal instructions (see Section 13). For product warranty information, see Section 13.5.

NOTE: *Expected end-of-life for Tempur-Pedic® Medical Pads is three (3) years or sooner, based on use and care.*

2.7 Specifications

The Spinal Surgery Top has the following specifications:

- Maximum patient load of the table top is 500 lbs (227 kg)
- Table top width is 17 inches (43.2 cm)
- Table top length is 84 inches (213.4 cm)
- The carbon fiber frame has a radiolucent equivalency of less than one (1) millimeter of aluminum.
- Operating environment – 68 °F (20 °C), relative humidity 50%
- Class 1 Equipment
- This table top mounted on the Base is not suitable for use with flammable anesthetic gas mixtures.

2.8 Shipping and Storage

If required to be transported, the Spinal Surgery 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 Spinal Surgery 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 provided should be used to protect the table top and all components and accessories stored on the Equipment Cart.

3 Component Identification

3.1 Spinal Surgery Top

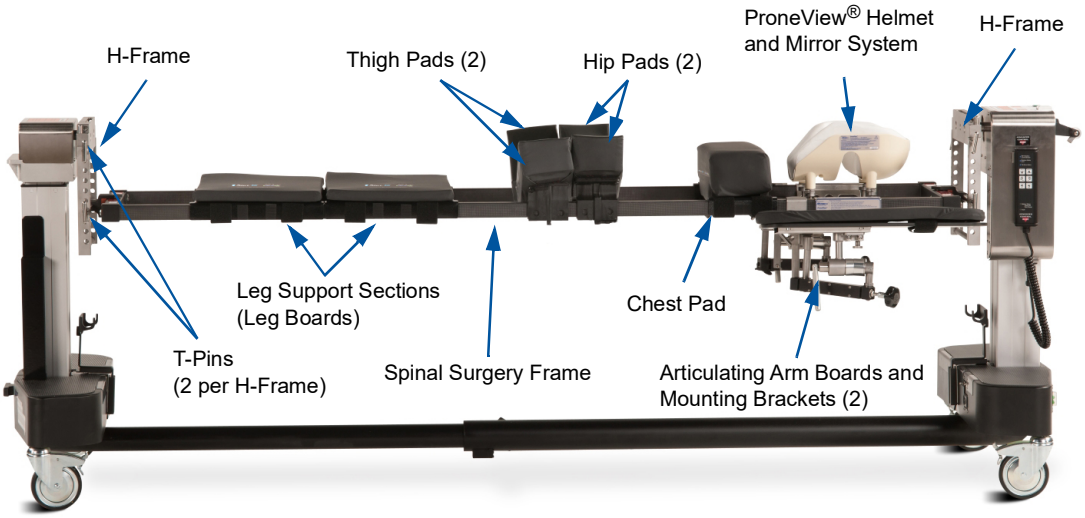


Figure 2: Spinal Surgery Top with Components Mounted

3.2 Additional Standard Components

3.2.1 Face Plate

The Face Plate, which provides the platform for using a GentleTouch® Pillow, may be used to support the head when the patient is prone.



Figure 3: Face Plate Mounted on Spinal Surgery Top

3.2.2 Leg Sling

NOTE: *Using either the Leg Sling or the Leg Boards is at the discretion of the surgeon.*

The Leg Sling may be used in place of the two (2) Leg Boards to support the patient's legs when positioned prone on the open frame. The Leg Sling may be used to accommodate taller patients or in cases where more flexion is desired as it allows the patient's knees to be lowered below the spinal frame. It is recommended that the Thigh Pads not be used with the Sling as the increased hip flexion may increase pressure on the anterior aspects of the thighs (Figure 4).

CAUTION: Failure to ensure there is no pressure on the patient's anterior thighs when using the Leg Sling may result in harm to the patient.

The four (4) straps of the sling consist of a double-sided hook closure that allows for infinite adjustment along the length of the strap.

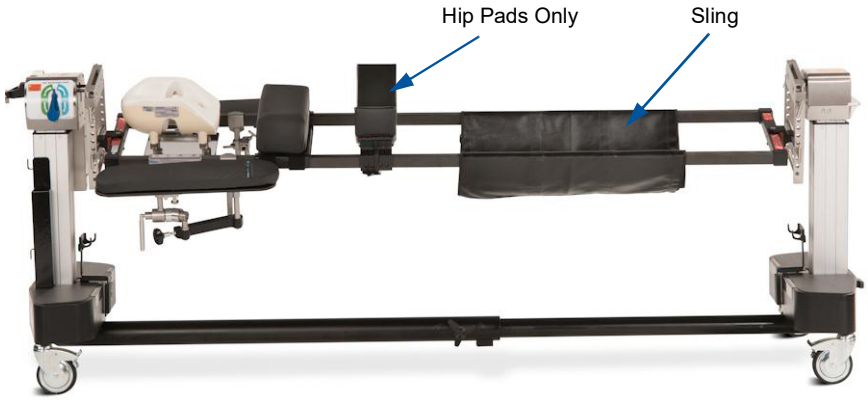


Figure 4: Use of Sling with Hip Pads on the Spinal Surgery Table

3.2.3 Safety Straps

Safety straps are provided to secure the patient safely to the table and during the 180 Degree Rotation sequence as discussed in this manual. The following Safety Straps are provided as standard components to the table top (Figure 5):

- One (1) Buttocks Strap
- One (1) 60-inch Safety Strap
- Four (4) 90-inch Safety Straps



Figure 5: Buttocks Strap and Safety Straps

3.2.4 Cervical Traction Vector Adjuster

The Cervical Traction Vector Adjuster is designed to provide adjustability of the angle of pull of cervical traction as well as to maintain alignment of the traction rope when skull tongs or a head halter is used. It helps guide the cervical traction line (rope) to the Pulley System on the Advanced Control Base.

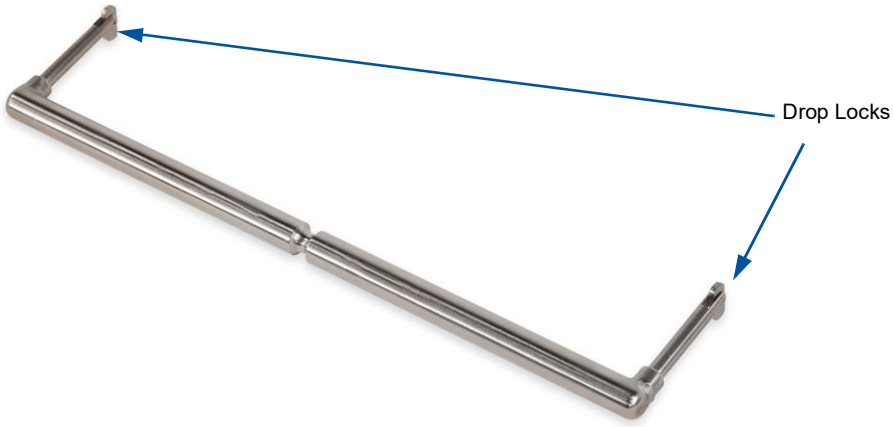


Figure 6: Cervical Traction Vector Adjuster

3.3 Hip and Thigh Pad Options

For the Spinal Surgery Top, there are two options of hip and thigh pads from which to choose:

- Tempur-Pedic® Comfort 8-Piece Pad Set
- Tempur-Pedic® Comfort Combination Hip/Thigh Pad Set

3.3.1 Tempur-Pedic® Comfort 8-Piece Pad Set

This set includes Small, Medium/Regular, and Large Hip Pads (Figure 7), and Left and Right Thigh Pads. The appropriately sized Hip Pads should be chosen such that they support the patient while allowing abdominal fallout.

For individuals weighing 350 pounds (159 kg) or less, take into consideration the patient's girth and weight when selecting the Pad size.

For individuals weighing more than 350 pounds (159 kg), it may be necessary to purchase an additional set of Large Hip Pads so that two sets can be used together to support the patient properly.

CAUTION: The choice of the proper pads used for any particular patient is the responsibility of the surgeon.

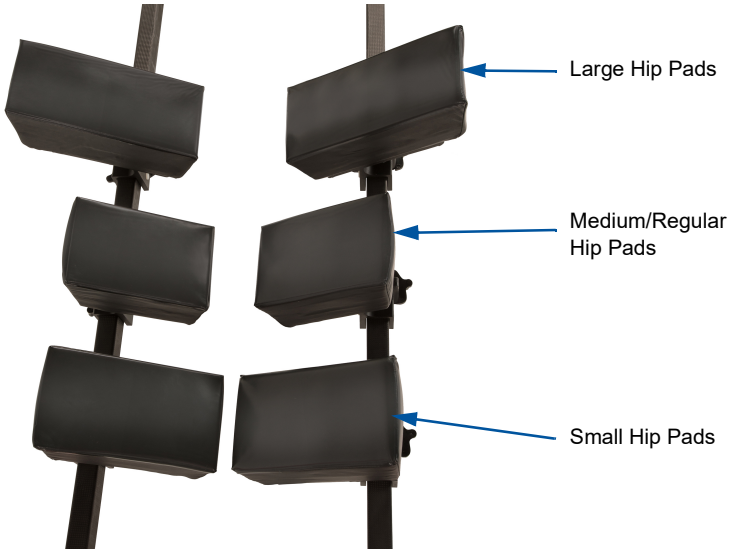


Figure 7: Small, Medium and Large Hip Pads Shown on Spinal Surgery Top for Comparison

3.3.2 Tempur-Pedic® Combination Hip/Thigh Pads

The footprint of each Combination Hip/Thigh Pad is similar to a Medium/Regular Hip Pad and a Thigh Pad (Figure 8).

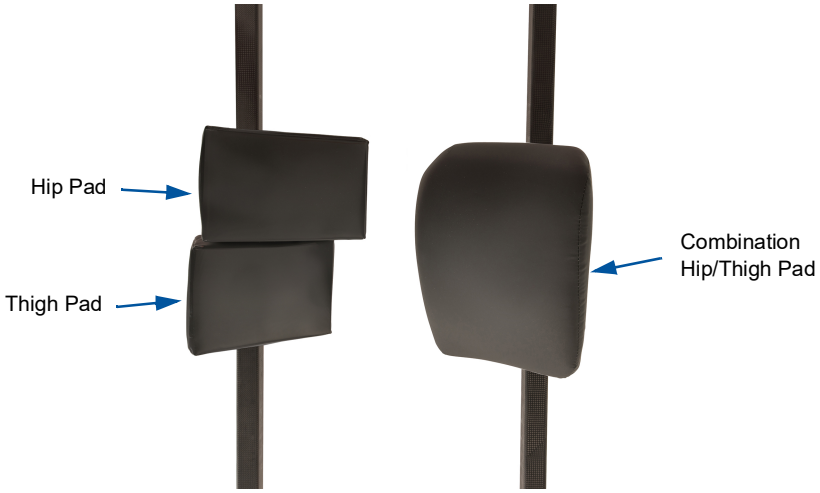


Figure 8: Comparison of Combination Hip/Thigh Pad to Medium/Regular Hip Pad and Thigh Pad

3.4 Arm Board Options

For the Spinal Surgery Top, there are two options of arm boards from which to choose:

- Articulating Arm Boards
- Translating Arm Boards

3.4.1 Articulating Arm Boards

To install the Articulating Arm Boards:

1. Slide the Arm Board Bracket onto the Spinal Surgery Top at the desired position and tighten the T-Handle. The Arm Board Brackets may be placed in front of or behind the ProneView® Mirror System or the Face Plate as needed to accommodate correct position of the patient's arms.
2. Repeat this process with the second Arm Board Bracket.
3. Place the Arm Board Assembly into the Bracket and tighten the T-Handle to secure the Arm Board Assembly in place (Figure 9).

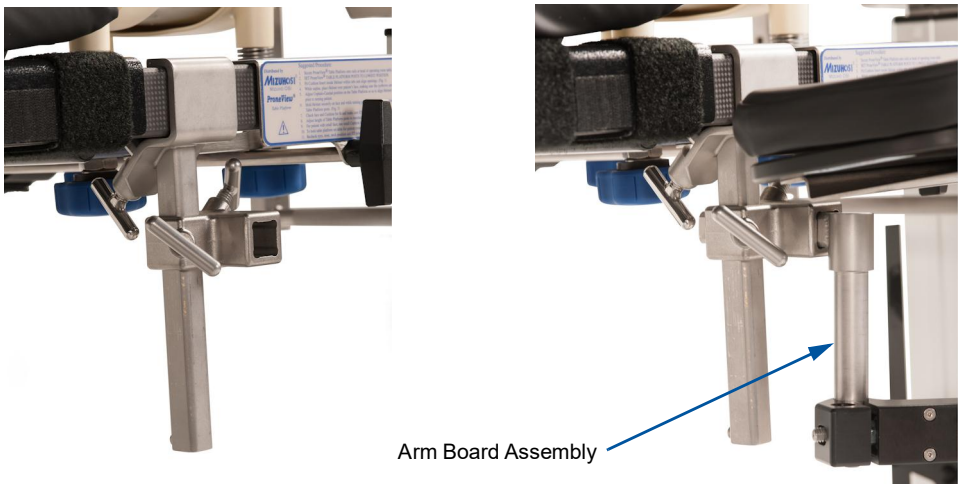


Figure 9: Arm Board Bracket Mounted and Arm Board Assembly Attached

4. Adjust the Articulating Arm Boards as needed. Using the handles, knobs, and pulls shown in Figure 10, they may be translated, raised, lowered, pivoted, or angled to properly support the patient's arms.

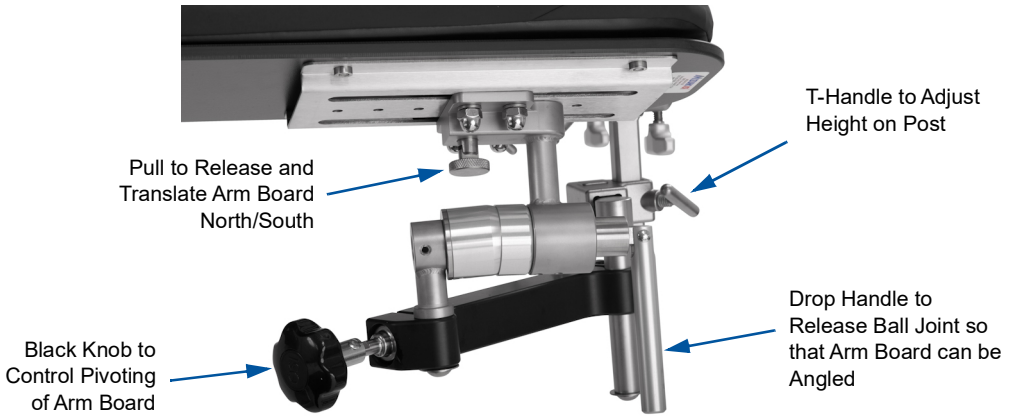


Figure 10: Articulating Arm Board Functionality

3.4.2 Translating Arm Boards

To install the Translating Arm Boards:

1. Slide the Arm Board Bracket onto the Spinal Surgery Top at the desired position and rotate the T-Handle clockwise to secure in place. The Arm Board Brackets may be placed in front of or behind the ProneView® Mirror System or the Face Plate as needed to accommodate correct position of the patient's arms.
2. Repeat the process with the second Arm Board Bracket.
3. Place the Translating Arm Board Assembly into the Bracket and tighten the T-Handle clockwise to secure the Arm Board Assembly in place (Figure 11).

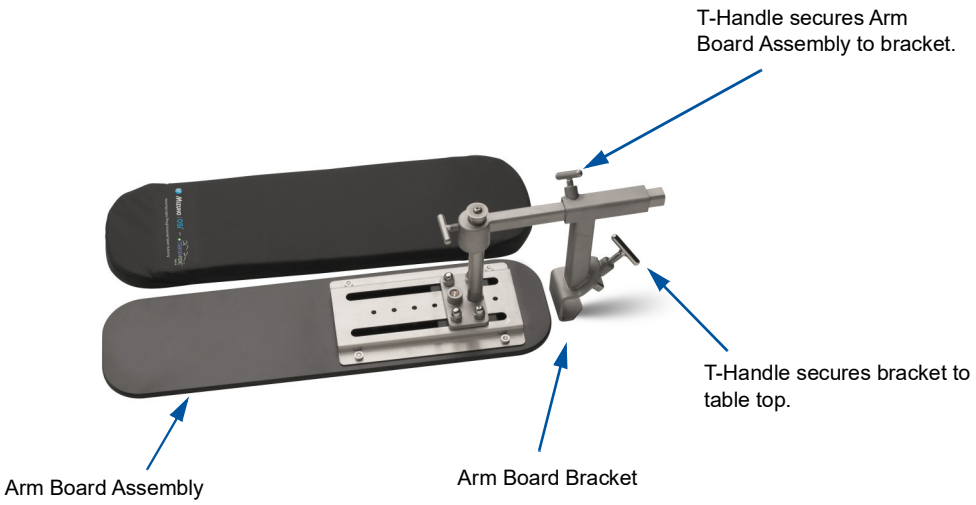


Figure 11: Translating Arm Board

3.5 Model Number and Serial Number

The REF product number and a SN serial number for the Spinal Surgery Top are located on the end of the frame.

4 Inspection

4.1 Acceptance and Transfer

1. Upon receipt of your Spinal Surgery 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 Spinal Surgery Top, visually inspect all accessible areas and all movable parts for possible damage that may adversely affect the proper operation of the Spinal Surgery 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 13).

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 11.3) on your Spinal Surgery 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 Spinal Surgery Top Components

5.1 Standard Components

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.

NOTE: *If a part needs repair, contact Mizuho OSI Service (see Section 13).*

Table 1: Standard Components for Spinal Surgery Top

Component	Description
REF **5840-830** **Spinal Frame**	The Spinal Frame is an open frame platform on which the standard components may be mounted.
REF **5840-370** **H-Frame (2)**	The two (2) H-Frames provided with the Spinal Surgery 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 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 **D28705CE** **Reusable ProneView® Adjustable Mirror Platform and Helmet for the Spinal Surgery Top**	The Mirror Platform provides support for the ProneView® Helmet and allows for the patient's eyes to be viewed from three (3) sides when positioned prone. The reusable ProneView® Helmet is part of the ProneView® System and is mounted on the adjustable posts of the mirror, supporting the disposable cushion insert provided in the Patient Care Kit. The posts have 2.5-inch (6.4 cm) of adjustment to allow for positioning the patient's head with a neutral neck position.
REF **5840-277** **Face Plate (Patient Head Support)**	The Face Plate provides the platform for using a GentleTouch® Pillow, an option used to support the head when the patient is positioned prone.
REF **5840-580** **Single Chest Support Plate**	The Single Chest Support Plate mounts on the open frame and provides the platform on which the Tempur-Pedic® Medical Chest Pad is attached. This is utilized to support the patient's upper body when positioned prone on the Spinal Table Top.
REF **5840-7569** **Tempur-Pedic® Medical Single Chest Pad**	The Single Chest Pad is made of TEMPUR® material, and when properly positioned, the top edge of the pad should rest at the bottom of the patient's supra-sternal notch.
REF **5840-24** **Leg Board with Pad (2)**	The two (2) Leg Boards, when used together, provide support for the patient's legs when positioned prone on the open frame. The 1-inch (2.5 cm) pad is made of TEMPUR® material.
REF **5840-450** **Leg Sling**	The Leg Sling may be used in place of the two Leg Boards to support the patient's legs when positioned prone on the open frame. The Leg Sling may be used to accommodate taller patients or in cases where more flexion is desired.

Table 1: Standard Components for Spinal Surgery Top *(Continued)*

Component	Description
REF **5840-45** **Buttocks Strap**	The Buttocks Strap rests across the patient's lower gluteal area when positioned prone to secure him/her in place on the Hip and Thigh Pads and open frame.
REF **5840-43** **60-inch Safety Strap**	The 60-inch Safety Strap is used to secure the patient in place when positioned on the table.
REF **5840-44** **90-inch Safety Strap (4)**	The four (4) 90-inch Safety Straps are primarily used to secure the patient during the 180 Degree Rotation sequence. They may also be used to secure the patient in place when positioned on the table if additional safety straps are desired.
REF **5840-389** **Cervical Traction Vector**	The Cervical Traction Vector helps guide the cervical traction line (rope) to the Pulley System on the Advanced Control Base.
REF **5943-3000** **Spinal Surgery Top Cover**	The Spinal Surgery Top Cover serves as a dust cover when it is in storage.
REF **5808PV-2** **Spinal Surgery Top ProneView® Patient Care Kit**	The Patient Care Kits are single-use pad covers intended to prevent cross-contamination and protect the equipment. Three (3) ProneView® Patient Care Kits are included with the Spinal Surgery Top.

5.2 Hip and Thigh Pad Options

The following hip and thigh pad options are available for use with the Spinal Surgery Top. Hip/Thigh pads are required for use with the Spinal Surgery Top, but the choice of specific pad set option is at customer's preference.

Table 2: Hip and Thigh Pads for Spinal Surgery Top

Pad Option	Description
REF **6956 Tempur-Pedic® Comfort 8-Piece Pad Set**	This pad set is comprised of two Small Hip Pads, two Regular Hip Pads, two Large Hip Pads, and Left and Right Thigh Pads. The Pads are made of TEMPUR® material. This pad set is one of two options meant for use with the Spinal Surgery Top.
REF **6956-5 Tempur-Pedic® Comfort Hip Pad, Small (2)**	The Small Hip Pads are intended for use on smaller patients as the size of allows them to fit closer together, providing additional support. The Pads are made of TEMPUR® material.
REF **6956-4 Tempur-Pedic® Comfort Hip Pad, Regular (2)**	The Regular (or Medium) Hip Pads are intended for use on average sized patients, providing appropriate support to the pelvic area. Overall stature should be assessed when choosing the Pad size as weight limits may be misleading given variations in individual's height and frame. The Pads are made of TEMPUR® material.
REF **6956-3 Tempur-Pedic® Comfort Hip Pad, Large (2)**	The Large Hip Pads are intended for use on larger patients, designed to fit further apart to allow for appropriate abdominal fallout. The Pads are made of TEMPUR® material.
REF **6956-7 Tempur-Pedic® Comfort Thigh Pad, Left**	The Left Thigh Pad is intended for use on the patient's left side when lying prone. It is used in conjunction with the Hip Pad to provide additional support on the open frame. The Thigh Pad should abut the Hip Pad when positioned on the spinal frame. It is recommended that the Thigh Pad be removed when using the Leg Sling.
REF **6956-6 Tempur-Pedic® Comfort Thigh Pad, Right**	The Right Thigh Pad is intended for use on the patient's right side when lying prone. It is used in conjunction with the Hip Pad to provide additional support on the open frame. The Thigh Pad should abut the Hip Pad when positioned on the spinal frame. It is recommended that the Thigh Pad be removed when using the Leg Sling.
REF **5939 Tempur-Pedic® Combination Hip/Thigh Pad Set**	The Combination Hip/Thigh Pads may be used in place of the Regular/Medium Hip Pads and Thigh Pads and are made of TEMPUR® material. This pad set is one of two options meant for use with the Spinal Surgery Top.

5.3 Arm Board Options

The following arm board options are available for use with the Spinal Surgery Top. Arm boards are required for use with the Spinal Surgery Top, but the choice of a specific arm board is at customer's preference.

Table 3: Arm Boards for Spinal Surgery Top

Arm Board	Description
REF **5579 Articulating Arm Board with Pad and Arm Board Mounting Bracket (2 required)**	The Articulating Arm Boards provide support for the patient's arm when positioned prone on the Spinal Surgery Top. When in place, the Arm Board can be translated, articulated, raised, lowered and laterally adjusted depending on the positioning needs of the patient. The Ball Joint controls the articulation of the Arm Board, which may be required for positioning a patient with decreased shoulder or arm range of motion. The 1-inch (2.5 cm) pad is made of TEMPUR® material.
REF **5376 Translating Arm Board (2 required)**	The Translating Arm Board provides support for the patient's arms when positioned prone on the Spinal Surgery Table. When in place, the Arm Board can be translated, raised, or lowered, depending on the positioning needs of the patient. The 1-inch (2.5 cm) pad is made of TEMPUR® material.

5.4 Spinal Surgery Top Patient Care Kits

Each individual Spinal Surgery Top ProneView® Patient Care Kit includes the following:

- ProneView® Cushion Insert
- Chest Pad Cover
- Pair of Hip Pad Covers
- Pair of Thigh Pad Covers
- Pair of Foam Arm Cradles

WARNING: Patient Care Kits are single use-only. Discard after use. Re-use of any component in the Patient Care Kit may result in cross contamination.

The components should be used as described in the Patient Care Kit instructions for use, which are included in each packaged kit. The Spinal Surgery Top ships with three (3) individual Spinal Surgery Top ProneView® Patient Care Kits. A case of six (6) individual kits is provided when ordering REF 5808PV.

The ProneView® Patient Care Kit works with the provided ProneView® Helmet and Mirror System. The system is designed by the manufacturer to support the patient's head while in a prone position. Additionally, the position of the patient's facial alignment with the ProneView® Helmet can be readily viewed while he/she is in the prone position.

NOTE: *Remove the Patient Care Kit components from the packaging and visually inspect the components. The ProneView® Cushion Insert should be opened sixty (60) minutes prior to use and the Arm Cradles should be opened twenty (20) minutes prior to use for complete expansion of the foam.*

NOTE: *The Spinal Surgery Top Adjustable Mirror Platform is a rectangular shaped device with a square shaped mounting post pattern. The Spinal Surgery Top Adjustable Mirror Platform is mounted directly onto the rails of the Spinal Surgery Top, and secured in place with a rod.*

Each Spinal Surgery Top GentleTouch® Patient Care Kit includes the following:

- 7-inch (17.8 cm) GentleTouch® Face Pillow
- Chest Pad Cover
- Pair of Hip Pad Covers
- Pair of Thigh Pad Covers
- Pair of Foam Arm Cradles

The components should be used as described in the Patient Care Kit instructions for use, which are included in each packaged kit. A case of six (6) individual kits is provided when ordering REF 5808.

NOTE: *Remove the Patient Care Kit components from the packaging and visually inspect the components. The GentleTouch® Face Pillow and the Arm Cradles should be opened twenty (20) minutes prior to use for complete expansion of the foam.*

6 Installing the Spinal Surgery Top on the Advanced Control Base

NOTE: *This device is intended for use by trained personnel. Prior to installing a table top, ensure 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 Spinal Surgery Top, the user must have read the NW0646 Advanced Control Base Owner's Manual and have a thorough understanding of the Base's functionality.*

6.1 Preparing 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, unlocking 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 12).
8. Confirm the 180 Degree Rotation Lock indicator light is illuminated (Figure 12).
9. Confirm the Tilt Drive Status indicator light is illuminated (Figure 12).



Figure 12: Head-End Assembly with Indicator Lights Illuminated

NOTE: *If the Tilt Drive Status indicator light is not illuminated, synchronization of the Lateral Roll 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 Spinal Surgery Top

NOTE: *The Spinal Surgery 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 Left/Right Lateral Roll and Trendelenburg/Reverse Trendelenburg.*

NOTE: *Only Mizuho OSI Bases and accessories have been tested and approved for use with the Spinal Surgery Top. Other manufacturers' products have not been tested for proper performance when used with the Spinal Surgery Top, and therefore are not endorsed for use by Mizuho OSI. Use of other manufacturers' 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.

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 end of the H-Frame with the posts on the bottom of the Crossbar (Figure 13), and secure it in place with a T-Pin (Figure 14).

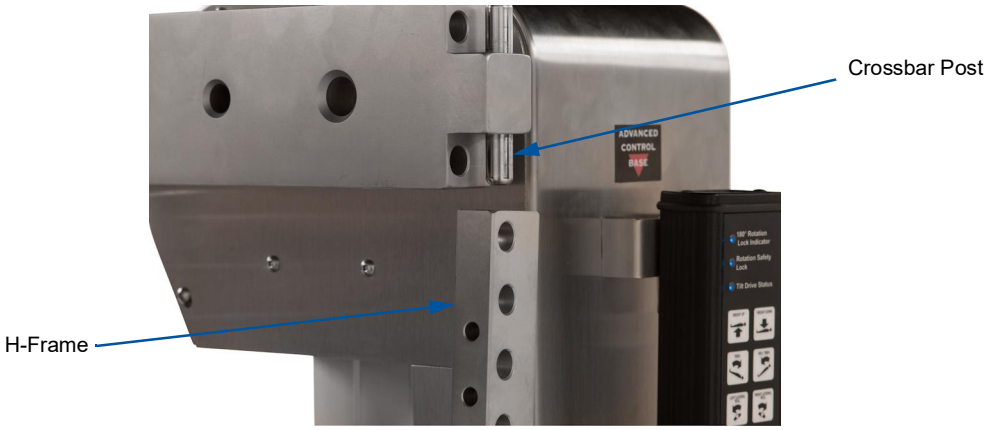


Figure 13: Attaching H-Frame to the Crossbar

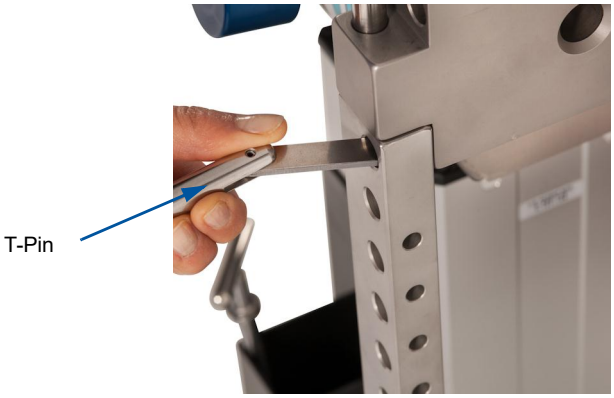


Figure 14: Inserting T-Pin to Secure H-Frame to Crossbar

3. Pass the T-Pin completely through the Crossbar such that the Drop Lock is visible and pivots freely on the opposite side (Figure 15).

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.*

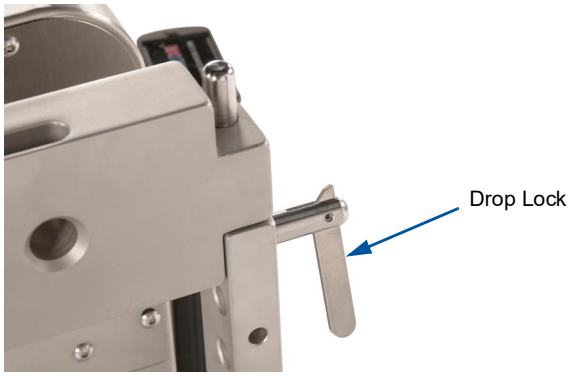


Figure 15: T-Pin Drop Lock Visible after Proper H-Frame Installation

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 end of the H-Frame with the posts on the bottom of the Crossbar (Figure 13), and secure it in place with a T-Pin (Figure 14).
6. Pass the T-Pin completely through the Crossbar such that the Drop Lock is visible and pivots freely on the opposite side (Figure 15).

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 16: 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 17).

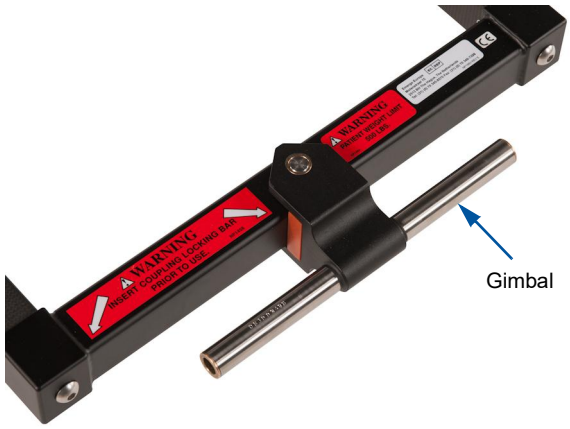


Figure 17: Gimbal on One End of Spinal Surgery Top

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 prone (Figure 18). The specific procedure to be performed and the surgeon's preference should also be considered when choosing the appropriate mounting hole.

WARNING: The Spinal Surgery 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. Failure to do so may make the patient unstable during lateral rotation.

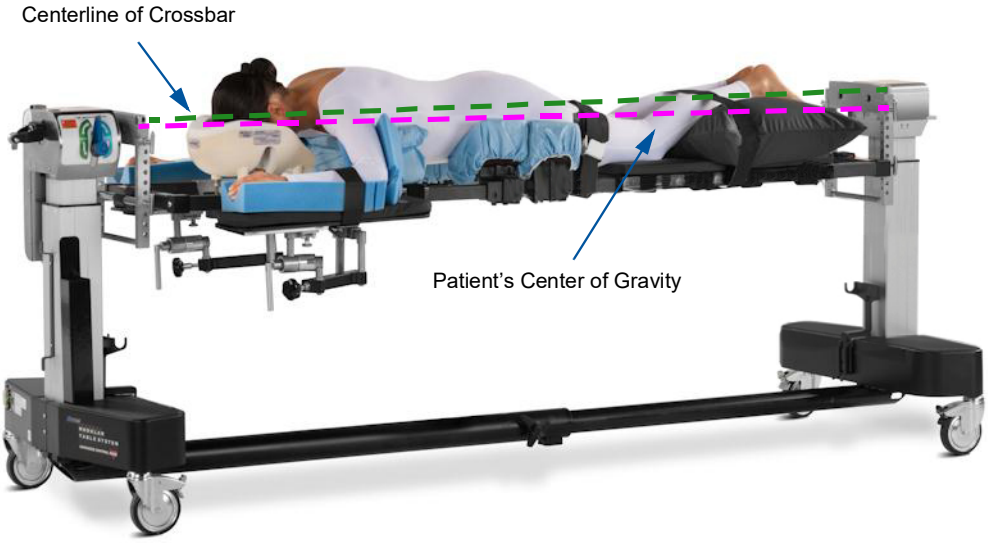


Figure 18: Patient's Center of Gravity Shown in Relation to Centerline of Crossbar

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 the device.



Figure 19: Attaching the Table Top to the H-Frame

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 (Figure 19).

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 workers, or the table.

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

13. The table top is now properly mounted to the Advanced Control Base (Figure 20).



Figure 20: Spinal Surgery 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).*

7 Spinal Surgery Table Prone Patient Positioning

NOTE: *This device is intended for use by trained personnel. Prior to set-up and use of the Spinal Surgery Top and Advanced Control Base, ensure 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: *Upon installing the Spinal Surgery Top on the Advanced Control Base, the Table is ready for the installation of the patient components required for prone positioning prior to patient transfer. Components have been designed specifically to mount on the carbon-fiber frame while safely supporting the patient and not damaging the frame.*

NOTE: *Only Mizuho OSI Bases and accessories have been tested and approved for use with the Spinal Surgery Top. Other manufacturers' products have not been tested for proper performance when used with the Spinal Surgery Top, and therefore are not endorsed for use by Mizuho OSI. Use of other manufacturers' 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.



Figure 21: Spinal Surgery Top with Components Mounted

The following instructions provide the recommended steps for set-up. Final determination of patient positioning and set-up is at the discretion of the surgeon and surgical team.

1. Confirm the Spinal Surgery Top and Advanced Control Base are prepared for set-up (see Section 6). When the patient is positioned prone, his/her head is oriented toward the Head-End of the table.
2. Confirm that the four (4) Caster Locks are locked.
3. Open the following: the Patient Care Kit, either the ProneView® Cushion Insert or GentleTouch® Face Pillow, and the package of Arm Cradles, and set aside. (See Section 5.4 for appropriate preparation time for Patient Care Kits prior to patient use.)
4. To install the ProneView® Mirrored Platform, place the adjustable platform over the rails of the Spinal Surgery Top and secure it in place with the rod (Figure 22). Ensure that the adjustable posts are in the lowest position in preparation for patient transfer to the Spinal Surgery Top.



Figure 22: Installation of the ProneView® Mirror Platform

5. Place the ProneView® Cushion Insert into the ProneView® Helmet and within the tabs provided at the chin end of the ProneView® Helmet. Adjust the Cushion Insert openings to be centered relative to the ProneView® Helmet openings (Figure 23).



Figure 23: ProneView® Helmet with Cushion Insert

6. If using the Face Plate, release the Velcro® straps on both sides, and orient the Face Plate over the Spinal Frame in the desired location. Slide the Face Plate over the Frame until it sits on the Frame, and secure with the Velcro® straps (Figure 24).
7. Place the GentleTouch® Pillow on the Face Plate (Figure 24).

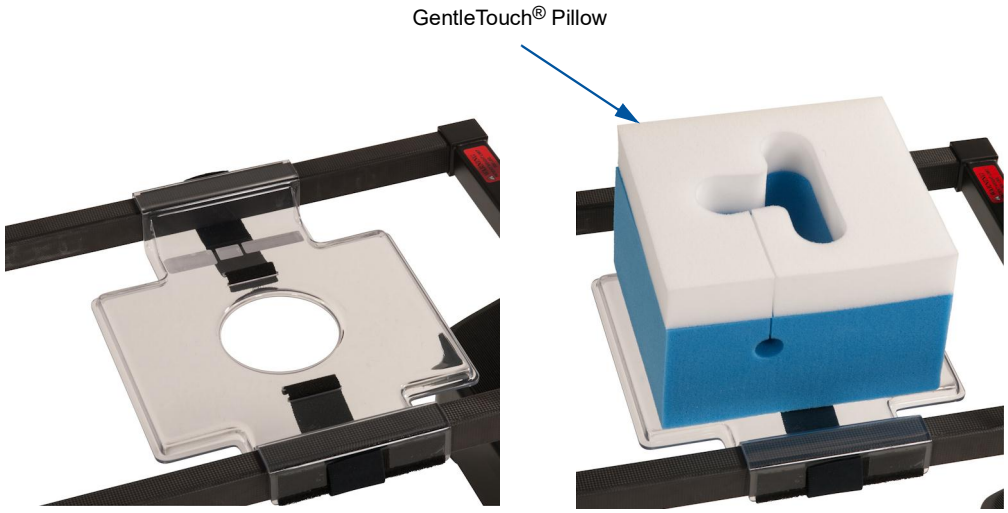


Figure 24: Face Plate Alone and with GentleTouch® Pillow

8. Install the Arm Board Brackets and Arm Board Assembly as follows:
   a. Slide the Arm Board Bracket onto the Spinal Surgery Top at the desired position and tighten the T-Handle. The Arm Board Brackets may be placed in front of or behind the ProneView® Mirror System or the Face Plate as needed to accommodate correct position of the patient's arms.
   b. Repeat this process with the second Arm Board Bracket.
   c. Place the Arm Board Assembly into the Bracket and tighten the T-Handle to secure the Arm Board Assembly in place (Figure 25).

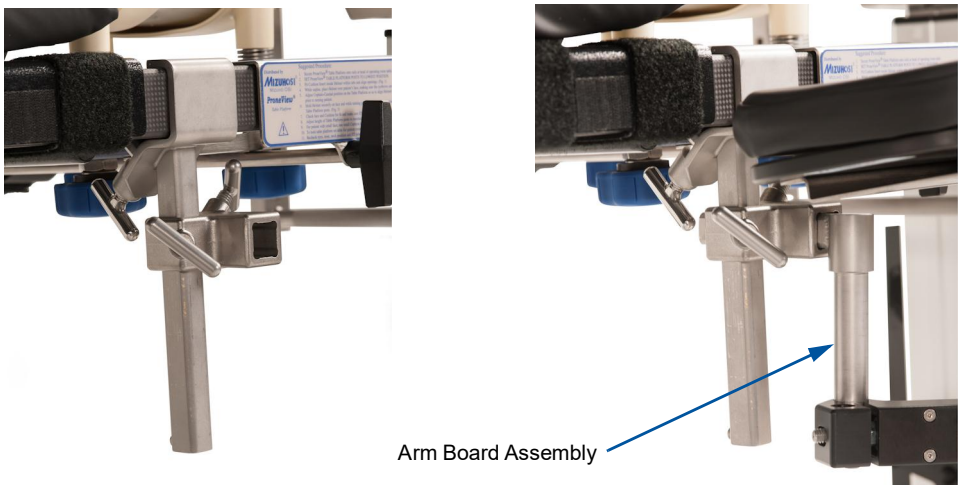


Figure 25: Arm Board Bracket Mounted and Arm Board Assembly Attached

9. Attach the Chest Support Plate by releasing the Velcro® straps on both sides and orienting the Chest Support Plate above the rails of the Spinal Surgery frame in the desired location. Slide the Chest Support Plate over the Frame until it sits on the Frame, and secure with the Velcro® straps.

10. Attach the Mizuho OSI Tempur-Pedic® Medical Chest Pad to the Support Plate by aligning the Velcro® on the bottom of the Chest Pad with the Velcro® on the Support Plate (Figure 26). With ideal positioning, the Chest Pad should support the patient such that the load is borne predominantly by the sternum. When the patient is positioned correctly, the top edge of the pad should rest below the patient's anatomical landmark, the supra-sternal notch.

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



Figure 26: Chest Pad Correctly Mounted to Spinal Surgery Frame

11. To install the Hip Pads:
    a. Assess which of the three sizes – Small, Medium/Regular, or Large – is appropriate for the patient. The Hip Pads should support the patient and allow for abdominal fallout.
    b. For individuals weighing 350 pounds (159 kg) or less, take into consideration the patient's girth and weight when selecting the Pad size.
    c. For individuals weighing more than 350 pounds (159 kg), it may be necessary to purchase an additional set of Large Hip Pads so that two sets can be used together to support the patient properly.

CAUTION: The choice of the proper pads used for any particular patient is the responsibility of the surgeon.

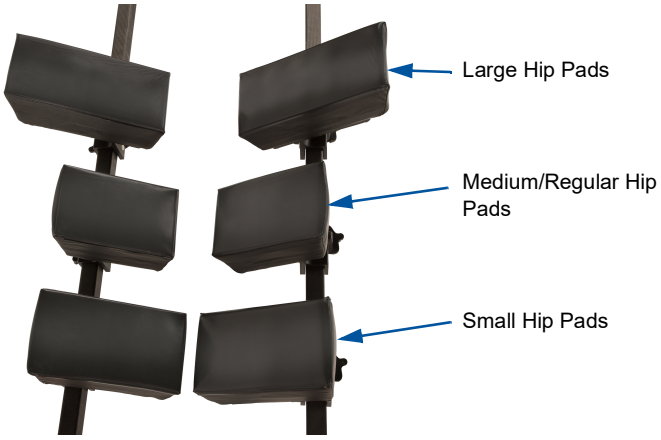


Figure 27: Comparison of Small, Medium/Regular, and Large Hip Pads

12. Once the appropriate Hip Pads are selected, attach each Pad by opening the Locking Lever on the bottom of the Bracket, placing it directly over the Spinal Surgery Top, and sliding it into place (Figure 28). The Hip Pads are not side-specific. Lock the Locking Lever to secure the Pad to the frame (Figure 29).



Figure 28: Pad with Locking Lever Open



Figure 29: Pad with Locking Lever Locked

NOTE: *When positioned correctly, the patient's anatomical landmark, the iliac crest, is centered on the Hip Pad.*

CAUTION: Failure to ensure the patient is positioned correctly on the Hip Pad may result in harm to the patient or the device.

13. Attach the Thigh Pads. The Thigh Pads are labeled right and left specific to be oriented to the patient's right and left side when lying prone on the Spinal Surgery Top. When installed correctly, the arrow on the bottom of the Thigh Pad Bracket will point toward the Foot-End of the Base. Similar to the Hip Pad, open the Locking Bracket, orient the Thigh Pad and Bracket over the rail of the Spinal Surgery Top, lower into place, and close the Locking Bracket. The Thigh Pads should be mounted on the Top such that they abut the Hip Pads (Figure 30).



Figure 30: Hip and Thigh Pads Correctly Installed

14. Attach the Leg Boards with the 1-inch (2.5 cm) Tempur-Pedic® Medical Pad. Release the Velcro® straps on the sides of the Leg Board. Place the Leg Board over the rails of the open frame and slide into place (Figure 31). Secure with the Velcro® straps. Repeat this process with the second Leg Board. Ensure that the two Leg Boards abut each other (Figure 32).



Figure 31: Leg Board Placed over Rails



Figure 32: Leg Boards Properly Installed

15. The Leg Sling may be used in place of the Leg Boards to support the legs on the Spinal Surgery Top. Use of the Leg Sling allows for a greater degree of hip and knee flexion by allowing the patient's knees to be lowered below the spinal frame. When the sling is used, it is recommended that the thigh pads not be used.
16. To install the Leg Sling:
    a. Place the Leg Sling over the frame at the Foot-End of the Spinal Surgery Top.
    b. Feed the four (4) straps through their respective buckles on the opposite side of the Leg Sling and secure. The hook end of the strap may be folded over onto the loop portion of the strap to allow for greater adjustability. The strap may also be folded over itself again to shorten it, thereby raising the sling and decreasing the hip flexion angle of the patient if desired.
17. Place two (2) to three (3) REF 6946 or REF 6947 Tempur-Pedic® Medical pillows in the Leg Sling approximately where the patient's lower legs will rest to achieve the desired amount of flexion (Figure 33). Pillows may also be used with the Leg Boards.



Figure 33: Leg Sling with Hip Pads Only and Pillows

NOTE: *When the patient is positioned with the pillows and the Leg Sling, ensure that there is no pressure on the patient's anterior thighs. To achieve the desired position, you may need to reposition the patient's legs or adjust the pillows.*

CAUTION: Failure to ensure that there is no pressure on the patient's anterior thighs when using the Leg Sling may result in harm to the patient.

18. Place the Patient Kit Covers on the Chest, Hip, and Thigh Pads. Smooth the surfaces (Figure 34).



Figure 34: Spinal Surgery Top with Patient Care Kit

19. Trial position the imaging equipment if it will be used. If necessary, re-locate the Spinal Surgery Table in the room. Unlock the Casters and, with the assistance of a second person, move the Spinal Surgery Table. When the table is located where it will be used, lock the four (4) Casters.

NOTE: *The Spinal Surgery 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 transfer of the patient to the table.*

20. Conduct a safety check prior to transferring the patient to the table.
21. Confirm the four (4) Casters are locked.
22. 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.
23. 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.
24. 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 on the Head-End Column and Hand Pendant must be illuminated 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.

25. Remove the Arm Board Assembly from the Arm Board Bracket on the patient transfer side of the table top. Alternatively, if using the Articulating Arm Board, you may articulate the Assembly below the table and out of the way such that it does not interfere with the patient transfer.

26. Position the patient bed or stretcher so the patient's anatomical landmarks are aligned with the support pads on the Spinal Surgery Top. It may be necessary to re-position a pad or component on the frame to align with the patient's anatomical landmarks.
27. The height of the patient bed or stretcher should be level with the top of the Hip Pads. To assist the patient transfer process, you may choose to use the Hand Pendant to tilt the table toward the patient bed or stretcher by depressing the **Left or Right Lateral Roll** button.
28. Lock the patient stretcher or bed. Confirm that the four (4) Casters of the Advanced Control Base are locked.
29. Place the ProneView® Helmet with Cushion Insert on the patient's face. Ensure that the patient's eyes are visible. With the assistance of others, log-roll the patient onto the Spinal Surgery Table while supporting the patient's head, torso, and legs.
30. After log-rolling the patient to a prone position and onto the adjustable Mirror Platform on the Face Plate, verify that there is adequate clearance between the patient's nose and the mirror, and verify that the endotracheal tube is not kinked.

CAUTION: Failure to confirm the positioning of the patient and patient tubes may cause harm to the patient.

31. Continue to support the patient on the table until the safety straps are in place. DO NOT leave the patient unattended on the Table.

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

32. Remove the patient bed or stretcher while supporting the patient on the Table.
33. Using the Hand Pendant, depress either the **Left** or **Right Lateral Roll** button until the Table is level side to side and the Tilt Drive Status indicator is illuminated.
34. Install the Arm Board on the patient transfer side of the table (Figure 23). Position the patient's arms in the Arm Cradles and on the Arm Boards. Final positioning of the patient's arms should be completed after confirming the patient's orientation on the Chest, Hip, and Thigh Pads.
35. Confirm that the patient's face is seated in the Cushion (Figure 35). The eyes should be visible in the mirror, and the neck should be in a neutral position. Raise the height of the ProneView® Helmet until a neutral neck position is achieved by turning the posts on the mirror platform. The available height adjustment range is 2.5 inches (6.4 cm).

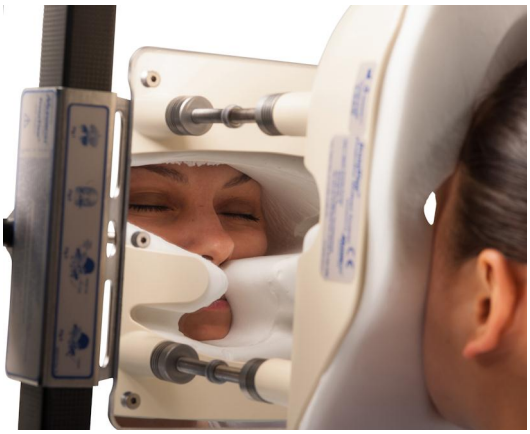


Figure 35: Patient Positioned Properly in ProneView® Helmet

36. Visually confirm the placement of the Chest Pad. When positioned correctly, the edge of the pad should rest at the patient's anatomical landmark, the supra-sternal notch (Figure 36). Breasts should be down and lying flat, with the nipples oriented towards the Foot-End of the table. The Patient Kit Chest Pad Cover should be smooth against the patient's skin. Ensure that the patient's skin is smooth and positioned flat against the cover. If necessary, re-position the Chest Pad. While lifting and supporting the patient, release the Velcro® straps of the Chest Pad, move to the desired location, re-secure the Velcro® straps, and smooth the Chest Pad Cover. The patient should then be lowered back onto the Chest Pad (Figure 37).

NOTE: *With ideal positioning, the Chest Pad should contact the patient such that the load is borne predominantly by the sternum.*

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

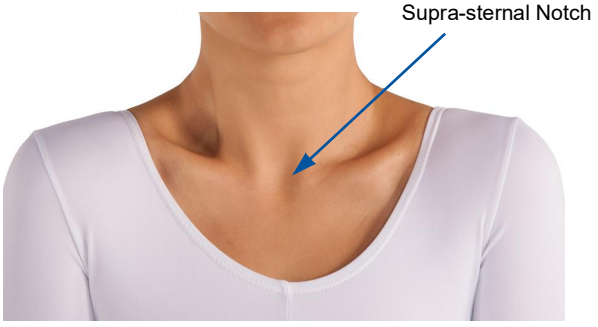


Figure 36: Example of Patient's Supra-sternal Notch



Figure 37: Proper Upper Body Patient Positioning

37. Visually confirm the placement of each Hip Pad. When positioned correctly, the patient's anatomical landmark, the iliac crest should be centered on the Pad. The Patient Kit Hip Pad Cover should be smooth against the patient's skin. Ensure that the patient's skin is smooth and flat against the Patient Kit Hip Pad Cover. If necessary, re-position the pad. To re-position, the patient should be lifted and supported, the Locking Bracket of the pad opened, and the pad moved. Lock the Bracket, smooth the Hip Pad Cover, and then lower the patient back onto the pad. Confirm correct placement of the pads such that each of the patient's iliac crests is centered on its respective Hip Pad (Figure 38).
38. Visually confirm the Thigh Pads are abutting the Hip Pads. Re-position the Thigh Pads if necessary. Visually check and ensure that the Patient Kit Cover is smooth against the patient. Ensure the patient's skin is smooth and flat against the Patient Kit Thigh Pad Covers.

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

39. Visually confirm that the position of the Leg Boards provides support to the patient's legs such that they are extended and the knees are supported in the middle of the upper Leg Board. 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. Re-position the Leg Boards if necessary (Figure 38).

CAUTION: Failure to ensure that the patient is positioned correctly on the Leg Board may result in harm to the patient or the device.

40. If using the Leg Sling, ensure that there is no pressure on the patient's anterior thighs. Reposition the patient's legs or adjust the pillows to achieve the desired position.
41. Place the Buttocks Strap across the lower gluteal area of the patient such that it surrounds both hips and the buttocks. A blanket may be used under the Buttocks Strap to protect the patient from direct contact with the strap. Confirm that the Buttocks Strap is positioned low on the gluteal area and is secured snugly around the buttocks. Ensure that the patient does not directly contact the frame of the table. Use foam or gel padding as needed to pad the area between the patient and the rails of the frame.

42. Apply the 60" Safety Strap over the patient's lower legs and around the table top. Secure the Safety Strap in place with use of the buckle. A 90" Safety Strap may be secured around the patient's torso, Chest Pad, and table top if desired. Secure the Safety Strap in place with use of the buckle.

NOTE: *The placement and location of the straps are at the discretion of the surgeon and vary by procedure.*



Figure 38: Proper Lower Body Patient Positioning 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.*

43. Position the patient's arms and adjust the Arm Boards as needed. Support the arms in the foam Arm Cradles. The V of the Cradle should rest against the inside of the patient's elbow. Translate, raise, lower or articulate the Arm Board as needed and then secure in place (Figure 39).

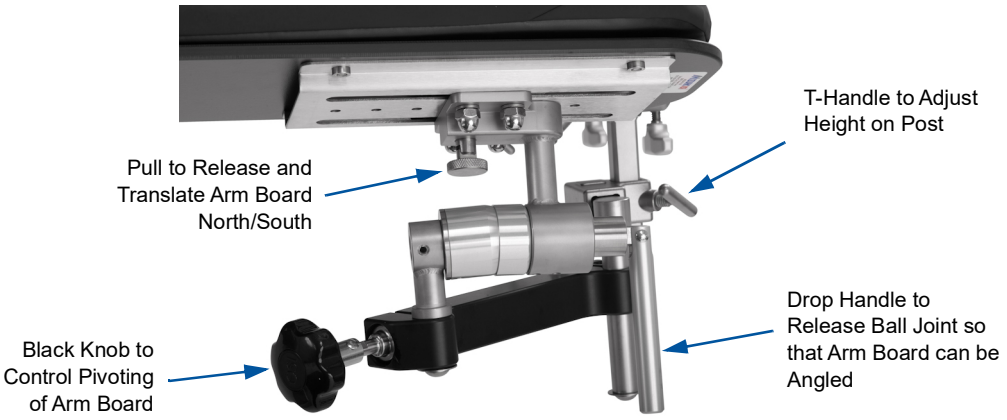


Figure 39: Articulating Arm Board Functionality

44. Confirm that all of the T-Handles and the Drop Handle are tightened. Confirm that the patient's arms are positioned so that there is no more than 90 degrees flexion at the shoulder and no more than 90 degrees flexion at the elbow. Use the Velcro® Arm Board straps provided to secure the arms (Figure 37).

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



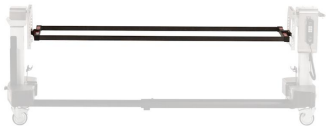
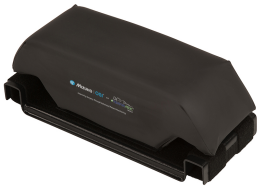
Figure 40: Final Prone Patient Positioning

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 Table using the Height Up/Down, Trendelenburg/Reverse Trendelenburg, and Left/Right Lateral Roll functions to ensure that the patient or the table does not interfere with other equipment. Failure to do so may cause harm to the patient or device.

45. Confirm that the patient is in their final position. An optional accessory, the Retractor Adapter, provides 6 inches (15.2 cm) of side rail and is required for mounting ancillary equipment onto the carbon fiber frame (see Section 10). To install the Retractor Adapter, place the Bracket over the rail of the Spinal Surgery Top at the desired location and slide it into place. Adjust the positioning of the side rail as needed and tighten the T-Handle to secure it in place. Ensure that the patient does not come in contact with the Retractor Adapter at its designated location. Use foam or gel padding as needed to pad the area between the patient and the Adapter.

7.1 Components Used for Prone Patient Positioning

Spinal Surgery Top  REF **5840-830**	**H-Frame (2)**  REF **5840-370**	**T-Pin (4)**  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 required):** *Option 1*  REF **5579**	**Translating Arm Board (2 required):** *Option 2*  REF **5376**

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



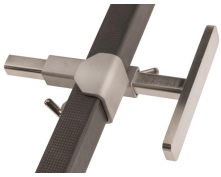
REF **5864**
Modular Equipment Cart and Cover

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

8 180 Degree Rotation

The Modular Table System is designed to allow for 180 Degree Rotation of a patient through the use of the Spinal Surgery Top in conjunction with the Radiolucent Imaging 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 5943 / 5943I Spinal Surgery Top, the REF 5927 Radiolucent Imaging Top and the REF 5803 / 5803I / 5803J Advanced Control Base is required prior to use and patient transfer.*

CAUTION: Failure to follow the instructions detailed in this manual, the REF 5927 Radiolucent Imaging 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 41). 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 41: Spinal Surgery Top Prepared and Stored on the 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) 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 the Radiolucent Imaging Top Owner's Manual for more information.)
9. Transfer the patient to the Radiolucent Imaging Top using the standard drawsheet method (Figure 42).



Figure 42: 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-Frame installed at both the Head-End and the Foot-End. Secure the table top to the H-Frames by inserting T-Pins (Figure 43). 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 the T-Pins are properly installed may cause harm to the patient, healthcare personnel, and/or the device.



Figure 43: 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 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 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 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 their 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 44). 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 Pads 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 44).



Figure 44: 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 uppermost 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.
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 45).

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 45).



Figure 45: 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 Drop Locks are visible and pivot freely.
   - Four (4) T-Pins in place in the Foot-End H-Frames. Ensure 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 himself 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 himself 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 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 the patient's face is properly seated in the pillow, with the eyes, nose, and mouth visible.



Figure 46: 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 47). 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 47: 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 47). 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 coupling 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, and 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, 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 48: 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. Should a level position be desired, depress the **Reverse Trendelenburg** button on the Hand Pendant until the desired position is achieved.



Figure 49: Final Prone Patient Positioning Following 180 Degree Rotation

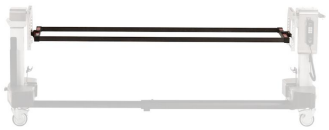
12. The patient is now correctly positioned prone and secured in place with Safety Straps.

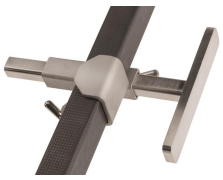
NOTE: *Due to the open nature of the Spinal Surgery Top and the long duration of many spinal procedures, the use of forced air warmers, fluid warmers, and blankets should be considered to help prevent hypothermia. Blankets may be placed over the feet up to the gluteal area and across the shoulders and 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 interfere with other equipment. Failure to do so may cause harm to the patient or device.

8.7 Components Used for 180 Degree Rotation

Spinal Surgery Top  REF **5840-830**	**Radiolucent Imaging Top**  REF **5927**	**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**
Optional Accessory  REF **5864** **Modular Equipment Cart and Cover**	**Optional Accessory**  REF **6946 Standard** REF **6947 Queen** **Mizuho OSI Tempur-Pedic® Medical Positioning Pillows**	*Option 1:* **Spinal Surgery Top ProneView® Patient Care Kit**  REF **5808PV**
Option 2: **Spinal Surgery Top GentleTouch® Patient Care Kit**  REF **5808**	**Optional Accessory**  REF **5888** **Retractor Adapter**	

9 Cervical Management with the Spinal Surgery Table

Several cervical management options exist for use with the Spinal Surgery Table. The Cervical Traction Vector Adjuster is a standard component provided with the Spinal Surgery Top while the REF 5979-1 Cervical Management Base Unit and REF 5873 Coupler II are optional accessories.

9.1 Cervical Traction Vector Adjuster

The Cervical Traction Vector Adjuster is designed to facilitate adjusting the angle of pull of cervical traction as well as to maintain alignment of the traction rope when skull tongs or a head halter is used.

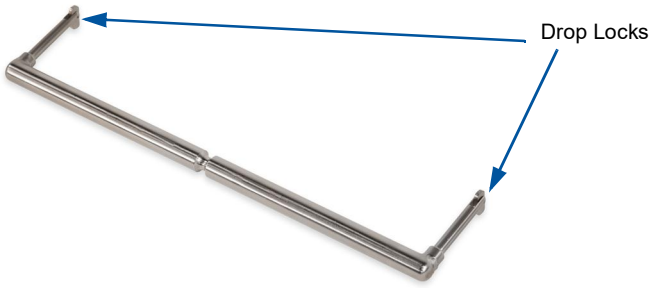


Figure 50: Cervical Traction Vector Adjuster

To use the Cervical Traction Vector Adjuster:

1. Align the Drop Locks of the Cervical Traction Vector Adjuster, and slide them into the mounting holes located on the front of the H-Frame mounted on the Head-End Crossbar.

NOTE: *The mounting holes chosen depend on the surgeon's preference, based on the angle at which he or she chooses to orient the traction rope.*

2. Attach the traction rope to the desired traction weight to be used.
3. Pass the traction rope over the Traction Pulley Assembly and thread through the Pivot Shaft of the Head-End Crossbar (Figure 51).

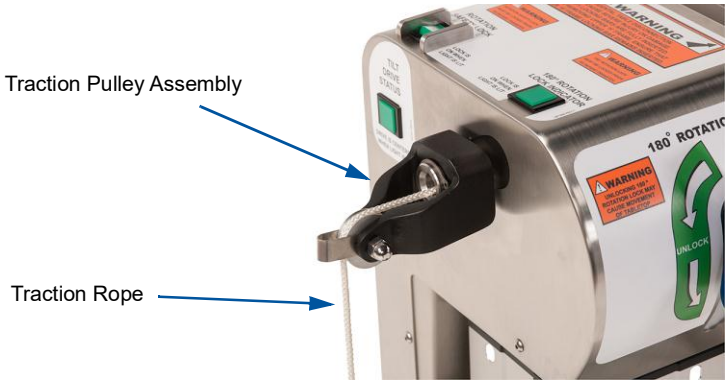


Figure 51: Traction Rope Threaded over the Traction Pulley Assembly

4. Run the rope behind and under the Cervical Traction Vector Adjuster and connect it to the patient traction device (Figure 52).

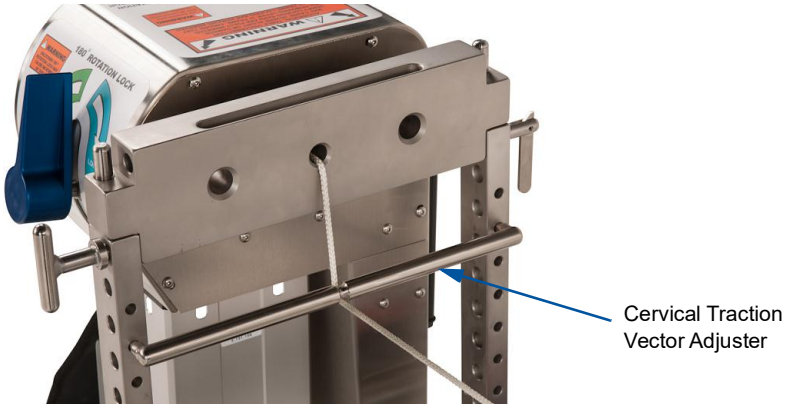


Figure 52: Proper Alignment of Rope with Cervical Traction Vector Adjuster

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



Figure 53: Proper Setup of Cervical Traction Vector Adjuster with Weight

To remove the Cervical Traction Vector Adjuster:

1. Hold the Drop Locks in a horizontal position and remove them from the front of the Head-End H-Frame.
2. Ensure the Cervical Traction Vector Adjuster is cleaned properly (see Section 11.1) and return it to its storage location on the lower rung of the Equipment Cart.

9.2 Coupler II

The Coupler II is designed to support the use of a skull clamp in posterior cervical cases when used on the Spinal Surgery Top. A pair of Spinal Top Adapter Brackets is also required to use the Coupler II on the Spinal Surgery Top.

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

The following instructions provide the recommended steps for setup. Final determination of patient positioning and setup is at the discretion of the surgeon and the surgical team.

To prepare the Coupler II for mounting on the Spinal Surgery Top:

1. Ensure that the knob that secures the Coupler Crossbar in place is loosened prior to advancing the Crossbar so that the Crossbar advances freely. Align the Crossbar with the opening in the Main Assembly and slide the Crossbar through the Yoke until it is centered. Tighten the Knob securing the Crossbar in the Yoke. Refer to the Mizuho OSI Owner's Manual provided with the Coupler II for detailed information on the Coupler II Main Assembly.
2. Attach a Spinal Top Adapter Bracket to each end of the Crossbar. Orient the C-shaped openings of the Brackets so that they face the same direction. This will allow the Coupler II to more easily mount on the Spinal Surgery Top. Tighten the oversized T-Handles to secure the Brackets on the Crossbar (Figure 54).

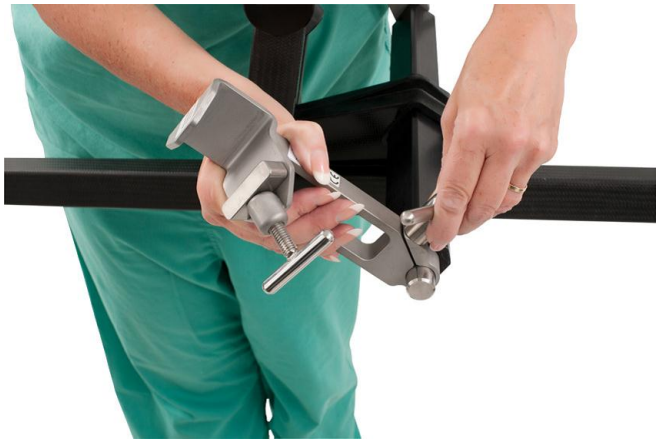


Figure 54: Tightening of Oversized T-Handles

To mount the Coupler II on the Spinal Surgery Top:

1. Ensure that the T-Handles adjusting the C-shaped openings of the Brackets are completely unscrewed. Support the Coupler II and approach the Spinal Surgery Top from below. Raise the Assembly until the Spinal Top Adapters can be slid into place on the rails of the Top (Figure 55).



Figure 55: Attaching Coupler II to the Spinal Surgery Top

2. Tighten the T-Handles on each Bracket, securing each Bracket to the Spinal Surgery Top.
3. With the Coupler II Assembly mounted on the Spinal Surgery Top, adjustments can be made to the location of the Assembly on the Top and to the position of the Adapter to which the skull clamp or horseshoe headrest is connected.
4. To re-locate the Coupler II Assembly along the Top, loosen the T-Handles securing the Brackets and slide the Assembly on the frame toward the Head-End or the Foot-End of the Advanced Control Base until the desired location is reached. Tighten the T-Handles.
5. Confirm that the Advanced Control Base with the Spinal Surgery Top installed is prepared for setup (see Section 6).
6. Prior to use, ensure that the Coupler II is assembled properly and correctly mounted on the Spinal Surgery Top by confirming the following:
   a. All T-Handles securing the Adapter Brackets are tightened.
   b. The teeth of all the starbursts are aligned and fully engaged, and the corresponding knobs can be turned to loosen or tighten as required.

7. The Coupler II is now prepared for an Aluminum DORO® or Mayfield® Skull Clamp to be attached (Figure 56). A radiolucent Skull Clamp may also be attached with use of the appropriate adapter.



Figure 56: Coupler II Installed on Spinal Surgery Top

9.3 Cervical Management Base Unit

The Cervical Management Base Unit is designed for use with the 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 set-up, cleaning, and maintenance.*

To mount the Cervical Management Base Unit:

1. Lift the Cervical Management Base Unit, and place the top of the Table Adapter Assembly over the top of the Head-End Crossbar and lower it into place (Figure 57).



Figure 57: Mounting the Cervical Management Base Unit on the Crossbar of the Advanced Control Base

2. Align the Cervical Management 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 (Figure 58).



Figure 58: Orienting Table Adapter Assembly, with Traction Pulley Centered on the Crossbar

4. 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 top or the Crank Handle at the base 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.
5. Confirm that the Advanced Control Base with the Spinal Surgery Top already installed is properly prepared for setup (see Section 6).
6. Prior to use, ensure that all teeth of the starburst are aligned and the corresponding knobs are properly tightened.
7. The Cervical Management Base Unit is now prepared for the attachment of an Aluminum DORO® or Mayfield® Skull Clamp. The Swivel Adapter can be positioned by releasing the Drop Handle and moving the Ball Joint until the Swivel Adapter is in the desired location (Figure 59). 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.



Figure 59: Cervical Management Base Unit Mounted on Crossbar

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.*

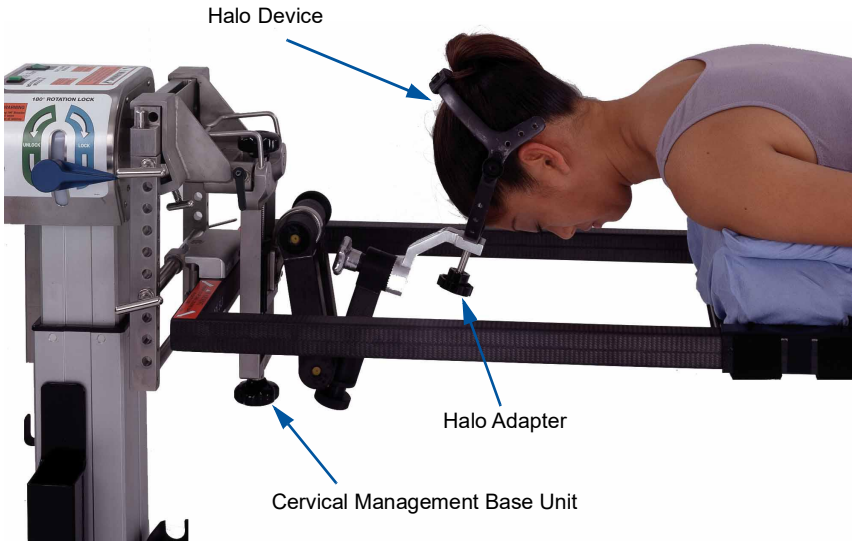


Figure 60: Halo Device Attached to the Cervical Management Base Unit

9.4 180 Degree Rotation with Cervical Management Base Unit

NOTE: *The surgeon decides if the patient is to be rotated from supine to prone while positioned with a Skull Clamp mounted to the Cervical Management Base Unit.*

NOTE: *A thorough understanding of the use of the Spinal Surgery Top, the Radiolucent Imaging Top, the Advanced Control Base, and the 180 Degree Patient Rotation Procedure, as well as the Cervical Management Base Unit, is required prior to use and patient transfer. For complete instructions on preparing the Spinal Table System for a 180 Degree Patient Rotation, refer to Section 8.*

CAUTION: Failure to follow the instructions detailed in Section 8 may cause harm to the patient, healthcare professional, or device.

1. Mount the Cervical Management Base Unit on the Advanced Control Base and position it to support a patient positioned supine on the Radiolucent Imaging Top. (Refer to the Cervical Management Base Unit Owner's Manual for details on setup.)
2. Transfer the patient to the Radiolucent Imaging Top.
3. Attach the Skull Clamp to the patient and to the Cervical Management Base Unit.
4. Set up the Spinal Surgery Top with the pads and components to support the patient in the prone position as outlined in Section 8.1. Store the Spinal Surgery Top on the Modular Equipment Cart until needed.
5. At the time the rotation will be performed, 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.

6. 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-Frame installed at both the Head-End and the Foot-End. Secure the table top to the H-Frames by inserting T-Pins. 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.
7. Confirm that each component and pad is aligned with the corresponding anatomical landmarks on the supine patient as outlined in Section 7. Adjust the position of the components or pads as necessary to ensure proper placement and support of the patient when rotated.
8. 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.
9. Remove the Pivoting Arm Boards mounted on the Radiolucent Imaging Top and remove the Universal Side Rail Adapters prior to beginning the rotation sequence.
10. The surgeon confirms orientation of the Cervical Management Base Unit by ensuring the T-Handles of the Table Adapter Assembly, Knobs of the Transitional Arms, Drop Handle of the Swivel Adapter, and Locking Lever of the Horizontal Slide are secure and the patient is positioned properly for the 180 Degree Rotation.
11. Complete the 180 Degree Rotation as instructed in Section 8.
12. Immediately following the completion of the 180 Degree Rotation, the surgeon should support the patient's head and Skull Clamp as needed until final patient positioning on the pads and components is achieved.

NOTE: *Height adjustment of the Yoke Assembly Slide may be required to maintain the desired position when using the Trendelenburg or Reverse Trendelenburg function of the Advanced Control Base.*

CAUTION: Failure to adjust the height of the Yoke Assembly Slide to maintain the desired position when using the Trendelenburg or Reverse Trendelenburg function of the Advanced Control Base may cause harm to the patient, healthcare professional, or device.

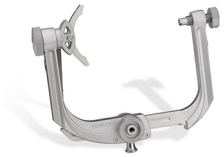
13. The surgeon verifies that the T-Handles of the Table Adapter Assembly, Knobs of the Transitional Arms, Drop Handle of the Swivel Adapter, and Locking Lever of the Horizontal Slide are secure following the rotation and the patient is positioned for the procedure.
14. Complete final positioning of the patient per the instructions in Section 8.
15. If the patient's arms are to remain at his/her sides, ensure the arms are safely positioned and secured in place.

CAUTION: Failure to ensure the patient is supported and positioned properly as outlined in Section 7 may result in harm to the patient, healthcare professional, or device.

16. The patient has been rotated from supine on the Radiolucent Imaging Top to prone on the Spinal Surgery Top with a skull clamp in place utilizing the Cervical Management Base Unit.

9.5 Cervical Management – Components and Optional Accessories

Traction Vector  REF **5840-389**	**Optional Accessory**  REF **5873** **Coupler II**	**Optional Accessory**  REF **5846** **Spinal Top Adapter Brackets (1 pair) – for use with Coupler II**
Optional Accessory  REF **5873-300** **Radiolucent DORO® Adapter for Coupler II**	**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 **5880-09** **Supine Operating Top, Short**	**Optional Accessory**  REF **5879** **Cervical Management Base Unit, Supine Operating Top, & Anterior Extension Positioner**

Optional Accessory  REF **6910-1001** **DORO® Skull Clamp, Aluminum** REF **6910-4004** **DORO® Skull Clamp, Radiolucent, Spinal Frame**		

10 Spinal Surgery Top Optional Accessories

Many optional accessories are available for use on the Spinal Surgery Top.

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

10.1 Optional Accessories

Table 4: Optional Accessories for Spinal Surgery Top

Accessory	Description
REF **5888** **Retractor Adapter**	The Retractor Adapter provides six (6) inches (15.2 cm) of side rail and is required for mounting ancillary equipment onto the carbon fiber spinal frame.
REF **5840-620** **Dual Chest Pads (1 pair)**	The Dual Chest Pads may be used in place of the standard single Chest Pad. They are right and left specific, provide increased lateral support, and provide a larger surface area for contact with the patient. They may also provide a better option for a patient with breast implants.
REF **5321G** **Wilson Plus™ Radiolucent Frame for SST**	The Wilson Plus™ provides a convenient and stable method of maintaining patients in a flexed position for lumbar procedures.
Levó™ Head Positioning System	The Levó™ Head Positioning System is a modular accessory that provides head support and positioning when the patient is prone for cervical and other spinal procedures, See Section 10.2.3 for more information.
REF **7887-100 Prone**	Includes Levó™ Arm, Levó™ Lateral Base, and Levó™ Prone Platform.
REF **7887-200 Cervical**	Includes Levó™ Arm, Levó™ Dual Motion Base, Levó™ Control Handles, Tempur-Pedic® Contoured Chest Pad, Raised Chest Support Plate, and QuickConnect Skull Clamp Adapter (compatible with Aluminum Mayfield® or DORO® Skull Clamp).
REF **7887-300 Standard**	Includes Levó™ Arm, Levó™ Dual Motion Base, Levó™ Prone Platform, Levó™ Control Handles, Tempur-Pedic® Contoured Chest Pad, Raised Chest Support Plate, and QuickConnect Skull Clamp Adapter (compatible with Aluminum Mayfield® or DORO® Skull Clamp).
REF **7887-400 Premium**	Includes Levó™ Arm, Levó™ Dual Motion Base, Levó™ Prone Platform, Levó™ Control Handles, Levó™ Z Tower, Tempur-Pedic® Contoured Chest Pad, Raised Chest Support Plate, and QuickConnect Skull Clamp Adapter (compatible with Aluminum Mayfield® or DORO® Skull Clamp).

Table 4: Optional Accessories for Spinal Surgery Top *(Continued)*

Accessory	Description
REF **5979-1** **Cervical Management Base Unit**	The Cervical Management Base Unit is designed for use specifically with the Mizuho OSI Modular Table System and mounts on the Head-End Crossbar of the Advanced Control Base. The Cervical Management Base Unit is required to allow positioning of a patient on the Spinal Surgery Top or the Radiolucent Imaging Top in both anterior and posterior cervical procedures as appropriate and uses a Skull Clamp for cranial stabilization or support. An aluminum Skull Clamp Adapter comes standard with this accessory.
REF **5880-09** **Supine Operating Top, Short**	The Supine Operating Top is designed to mount directly on the Spinal Surgery Top and allows for supine patient positioning. The use of this accessory increases the flexibility in patient positioning for supine cervical procedures on the open spinal frame.
REF **5879** **Complete Cervical Management Set**	The Complete Cervical Management Set consists of REF 5979-1 Cervical Management Base Unit; REF 5880-09 Supine Operating Top, Short; and REF 5879-2 Anterior Extension Positioner with Bladder (used on the Radiolucent Imaging Top). These accessories allow for a wide variety of anterior and posterior cervical procedures on the Spinal Surgery Top.
REF **5979-300** **Radiolucent DORO® Adapter for Cervical Management Base Unit**	The Radiolucent DORO® Adapter for the Cervical Management Base Unit is required to attach a radiolucent DORO® Skull Clamp.
REF **5979-200** **Radiolucent Mayfield® Adapter for Cervical Management Base Unit**	The Radiolucent Mayfield® Adapter for the Cervical Management Base Unit is required to attach a radiolucent Mayfield® Skull Clamp.
REF **5873** **Coupler II**	The Coupler II is designed for use specifically with the Spinal Surgery Top and mounts to the frame utilizing the Spinal Top Adapter Brackets (REF 5846). The Coupler II provides another Cervical Management option to allow for positioning of a patient on the spinal frame, utilizing either a skull clamp or horseshoe headrest for cranial stabilization or support.
REF **5873-300** **Radiolucent DORO® Adapter for Coupler II**	The Radiolucent DORO® Adapter for Coupler II is required to attach a radiolucent DORO® Skull Clamp to this device.
REF **6910-1001** **DORO® QR3 Aluminum Skull Clamp**	The Aluminum Skull Clamp provides rigid cranial stabilization when required for cervical spine surgery. This skull clamp can be used with the Levó™ Head Positioning System, the Cervical Management Base Unit, or the Coupler II using the respective aluminum skull clamp adapter that comes standard with each system..
REF **6910-4004** **DORO® Skull Clamp, Radiolucent, Spine Frame**	The Radiolucent Spine Frame model of the DORO® Skull Clamp provides a radiolucent option for rigid cranial fixation when required for cervical spine surgery. This clamp is designed with a slimmer profile, allowing for a better fit within the Spinal Frame. This skull clamp can be used with the Levó™ Head Positioning System, the Cervical Management Base Unit, or the Coupler II using the appropriate radiolucent skull clamp adapter.
REF **6910-3006-2** **Titanium Adult Skull Pins for DORO®**	These skull pins are compatible with the Radiolucent DORO® Skull Clamp.

Table 4: Optional Accessories for Spinal Surgery Top *(Continued)*

Accessory	Description
REF **6910-3006-00 Stainless Adult Skull Pins for DORO®**	These skull pins are compatible with the Aluminum DORO® Skull Clamp.
REF **5864 Modular Equipment Cart with Cover**	The Modular Equipment Cart is used to store the Spinal Surgery Top along with all components and optional accessories. The Cover serves as a dust cover when the equipment is in storage. See Section 10.2.4 for more information.
REF **6946 Mizuho OSI Tempur-Pedic® Medical Positioning Pillow, Standard size**	This standard size Tempur-Pedic® pillow may be used to provide additional support while maintaining proper positioning of the patient's legs while on the Spinal Surgery Top.
REF **6947 Mizuho OSI Tempur-Pedic® Medical Positioning Pillow, Queen size**	This queen size Tempur-Pedic® pillow may be used to provide additional support while maintaining proper positioning of the patient's legs while on the Spinal Surgery Top.

10.2 Use and Installation

10.2.1 Dual Chest Pads

To install the Dual Chest Pads:

1. Open the Locking Lever on the Pad Bracket, orient the Bracket over the rail of the Spinal Surgery Top, slide it into place, and lock the lever.

NOTE: *The Dual Chest Pads are right- and left-specific pads that are labeled accordingly. The pads must be oriented toward the patient when the patient is positioned prone. Confirm the pads are applied to the appropriate side of the Spinal Surgery Top.*



Figure 61: Dual Chest Pad Set

2. When positioned correctly, the Dual Chest Pads will contact the patient so that the top edges of the pads are parallel to the patient's landmark, the supra-sternal notch.
3. Ensure that the lateral support section encompasses the patient's chest wall and is inferior to the brachial plexus.

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

10.2.2 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 5321G) may be used in place of the chest, hip, and thigh pads for positioning on the Spinal Surgery Top (Figure 62). 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 62: 5321G Wilson Plus™ Radiolucent Frame Mounted on the Spinal Surgery Top

10.2.3 Levó™ Head Positioning System

The Levó™ Head Positioning System is a modular accessory, designed to mount on the Spinal Surgery Top, that provides head support and positioning when the patient is prone for posterior cervical procedures, as well as other spinal procedures not requiring a skull clamp for head stabilization. The L System is designed to provide enhanced support and control while reducing setup time. It includes an Arm that uses an electromechanical lock and release mechanism, allowing for simultaneous adjustment of all arm joints. The unique features provided by this system allow for controlled pre-operative and intra-operative head positioning adjustment.

There are four pre-configured bundles to choose from:

- Package 1: Prone (REF 7887-100)

  The Prone Package provides a system that easily positions the patient's head for non-cervical prone spine cases using an enhanced range of motion provided by the Levó™ Arm. This package includes the Arm and Prone Platform for head support, compatible with either ProneView® Helmet or GentleTouch® face pillows.

- Package 2: Cervical (REF 7887-200)

  The Cervical Package provides the primary components needed to effectively use the system for prone cervical cases. This package includes the Arm, QuickConnect adapter, and Control Handles, allowing for efficient patient positioning and intraoperative adjustments.

- Package 3: Standard (REF 7887-300)

  The Standard Package provides a system that supports both cervical cases when a skull clamp is needed, as well as other prone spine procedures that only require the Prone Platform to support the head.

- Package 4: Premium (REF 7887-400)

  The Premium Package includes all positioning modules, including the Z Tower, which provides fine controlled vertical motion. This configuration offers ultimate versatility by providing all platforms and adjustment interface options.



Figure 63: Levó™ Head Positioning System (Standard Package; Components for Prone Spine Procedures)



Figure 64: Levó™ Head Positioning System on Spinal Surgery Top (Cervical Package Components)

10.2.4 Equipment Cart and Cover

The Equipment Cart provides a convenient storage method for all components of the Spinal Surgery Top. It is designed to allow easy access to all components and prevent damage while stored. It also has the capacity to store the Radiolucent Imaging Top, which also mounts on the Advanced Control Base (Figure 65). The Equipment Cart also comes with a cover to further protect the table top and components while in storage (Figure 66).



Figure 65: Equipment Cart



Figure 66: Equipment Cart with Cover

11 Cleaning, Storage and Maintenance

11.1 Cleaning and Disinfecting

NOTE: *Clean and disinfect the Spinal Surgery Top after each use.*

11.1.1 Table Top

The exterior surface should be regularly wiped clean with a mild detergent solution and wiped dry with a soft lint-free cloth. This includes the table pad and table top.

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 Spinal Surgery Top. Never subject the Spinal Surgery Top to an equipment washing machine.

Blood or other fluids, etc., if allowed to remain on the table for a long period of time, will require special cleaning to remove.

NOTE: *Use of iodophors will cause staining.*

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 and damage to the surface of the device.*

11.1.2 ProneView® Helmet and Mirror System

Clean the ProneView® Helmet and Mirror after each use by spraying and wiping with a germicidal cleaner then wiping dry, or washing with anti-bacterial soap and water, rinsing, then wiping dry.

NOTE: *Do not autoclave the ProneView® Helmet or Mirror Platform.*

11.1.3 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.

11.2 Storage

When not in use, the Spinal Surgery 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.

11.3 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 within 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.

12 Removal and Replacement

12.1 Mounting Brackets on Pads

To remove mounting brackets on hip, thigh, or chest pads:

1. Use the appropriate tool to remove the four screws on the reverse side of the pad.

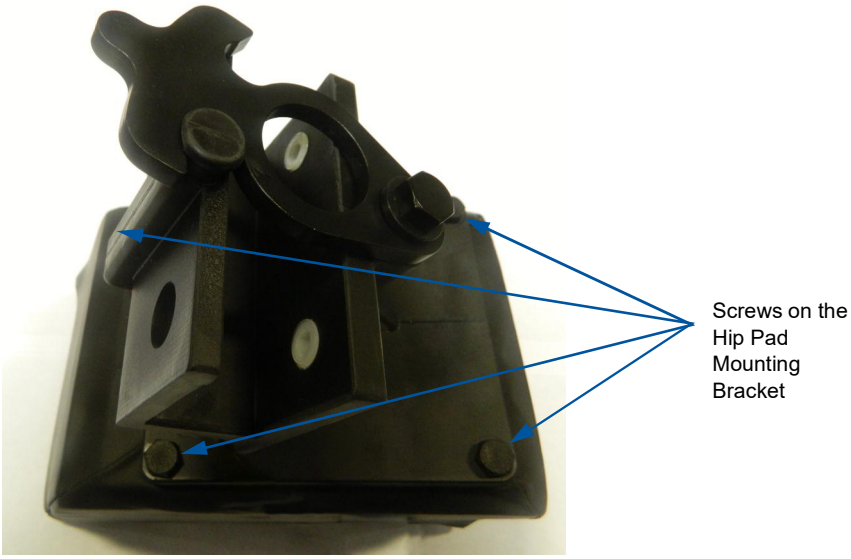


Figure 67: Location of Screws on the Hip Pad Mounting Bracket

2. Replace if required, and reassemble in reverse order.

13 Technical Support

13.1 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 within 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**.

13.2 Order Replacement Parts

If unable to identify 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 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 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 order is for Replacement Parts (RP).

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

13.4 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, and include the Certificate of Decontamination with the shipment.

The part will be evaluated and the 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.

13.5 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.