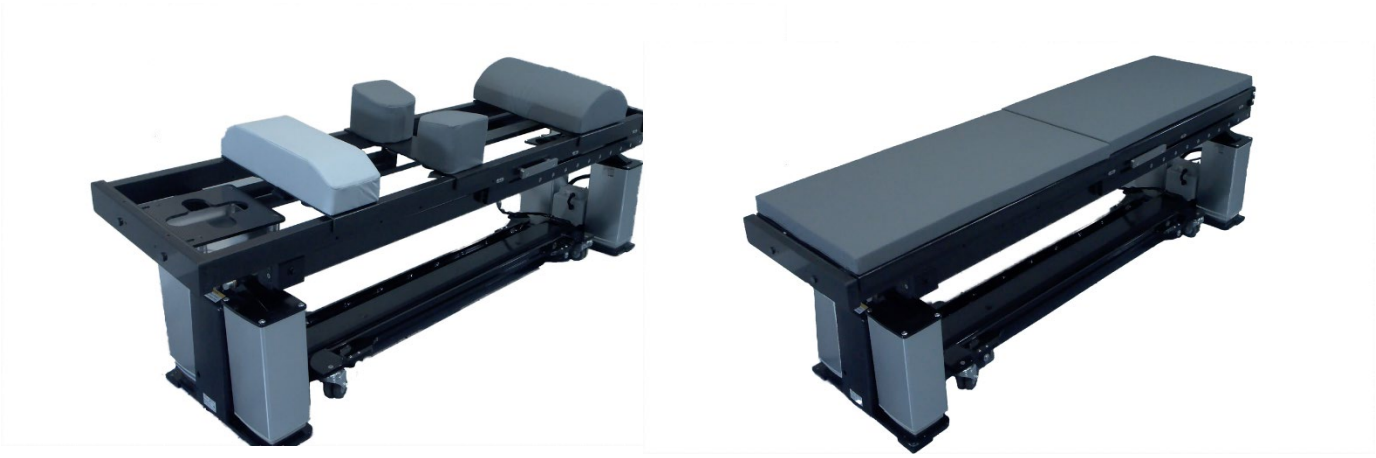
FusionMAX™ Spine Table System

Owner's Manual



Patents Pending

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SURGIX

Version 1 issued 9/2022

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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.

Carefully observe and comply with all warnings, cautions, and instructions placed on the equipment or described in this manual.

WARNING: This device is intended for use by trained personnel only. To schedule an in-service, please contact Surgix Medical Technologies.

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

In this manual, the following symbols are used:

Symbol	Meaning
EC REP	This symbol indicates an Authorized Representative in the European Community.
	This symbol indicates the Manufacturer of the device.
NOTE:	This symbol indicates a Comment or Instruction of Importance.
	This symbol is to signify CAUTION. It is intended to alert the user to consult the documentation for safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	This WARNING symbol, when used in this manual or on product labels, is intended to alert the user of important operation, maintenance, or safety instructions. Be sure to read and comply with all precautions and warnings.
	This symbol indicates proper disposal instructions.
(PN)	This symbol indicates a product number.
SN	This symbol indicates a serial number.
	This symbol, when used in this manual or on product labels, indicates that the user must read the owner's manual before use for safe operation.
	This symbol indicates that the user is advised to refer to the owner's manual before use for safe operation.
	This symbol, when used in this manual or on product labels, indicates a Protective Earth (Ground) Terminal.

Symbol	Meaning
	This symbol, when used in this manual or on product labels, indicates alternating current (AC).
	This symbol, when used in this manual or on product labels, indicates direct ---- current (DC).
	This symbol, when used in this manual or on product labels, indicates that there is a finger pinch point on the product.
	This symbol, when used in this manual or on product labels, warns against an electrical shock hazard. Be sure to observe and comply with all warnings.
	This symbol indicates a medical device that can be broken or damaged if not handled carefully.
	This symbol, when used in this manual or on product labels, indicates that information is given regarding the recommended temperature limits during transport and storage.
	This symbol, when used in this manual or on product labels, indicates that the medical device should be protected from moisture. The humidity specifications for transport and storage are listed in Section 2.8.
	This symbol, when used in this manual or on product labels, warns that during transport there should be no stacking of containers on the product.
	This symbol indicates single use only.

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

 **WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. Grounding reliability can only be achieved when this equipment is connected to an equivalent three (3)-prong receptacle marked "Hospital Only" or "Hospital Grade."**

 **WARNING:**  **This symbol indicates an external ground post 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 device from possible electrical hazards, an external ground wire connection is required between**

the external ground post and protective earth ground when the device is in use under battery power or not connected to a protective earth ground.

 **WARNING: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.**

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment

 **WARNING: Electrical Shock Hazard. The power supply/control module is located on the Table base. No user serviceable parts are inside. Refer servicing to qualified personnel. Unplug the wall connector prior to contact with any cables connected to the power supply.**

Disconnect the power supply plug prior to cleaning any surfaces near the power supply/control module.

 **WARNING: Use of the FusionMAX™ Table in its home position with patients and patient support equipment weighing more than 600 lbs. (272.2 kg) could result in damage to the Table, possible injury to the patient, or harm to the healthcare professional.**

 **WARNING: Use of the FusionMAX™ Table in a cantilevered position with patients and patient support equipment weighing more than 500 lbs. (226.8 kg) could result in damage to the Table, possible injury to the patient, or harm to the healthcare professional.**

 **WARNING: When patient exceeds 500 lbs. (226.8 kg), do not raise Table Platform above 32 inches (81.3 cm).**

 **WARNING: The FusionMAX™ Table can achieve lateral tilt positions that could cause patient injury risk due to falling. A patient restraint strap or securement consistent with facility guidelines must be used.**

 **WARNING: There are possible pinch points under the operating platform of the Table when the Table is in motion. Care should be taken to ensure that patient and caregiver body parts are clear of the marked areas when the Table is in motion. Pinch points are marked with this label:**

WARNING: Before and after each use, inspect the Table, components, and accessories for possible damage, excessive wear, or non-functioning parts. Carefully inspect all accessible areas, joints, and all moving parts for possible damage or non-function. Damaged or defective parts should not be used or processed. Contact Surgix Medical Technologies for repair or replacement (see Section 12).

WARNING: The FusionMAX™ Table should not be operated in an oxygen-rich environment nor in the presence of flammable anesthetics, volatile substances, or other explosive gases, liquids, or atmospheres.

WARNING: The FusionMAX™ Table must not be used for patient transport. The wheels must be raised (Table in Locked state) when the patient is on the Table, mounting the Table, or dismounting the Table. Using the wheels (unlocking the Table) when a patient is on the Table may result in possible injury to the patient or harm to the healthcare professional.

WARNING: No modification of the FusionMAX™ Table or its components is allowed. Any modification to the equipment will void the warranty and may result in damage to the Table, possible injury to the patient, or harm to the healthcare professionals.

WARNING: All personnel with access during procedures to the Table motion controls must be trained in the safe and proper use of the Table. For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled using the ON/OFF Switch on the Fixed Control Panel, located at the Foot-End of the Table.

WARNING: When the Table is placed in Cantilever position, the patient weight rating drops from 600 lbs. (272 kg) to 500 lbs. (227 kg).

CAUTION: After unpacking your Table, inspect it thoroughly for damage. If you suspect a problem, do not use the Table. Please contact Surgix Medical Technologies.

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.

NOTE: *If the integrity of the AC power source is in doubt, the equipment shall be operated from its internal electrical power source (battery).*

1.1 Trademarks

FusionMAX™, OpenFrame™, and FlexFrame™ are registered trademarks of Surgix Medical Technologies.

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

Mayfield® is a registered trademark of SM USA, Inc. and used by lntegra LifeScience Corporation under license

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

ProneView® is a registered trademark of Dupaco, 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 and batteries must be disposed of in accordance with local regulations or returned to Surgix Medical for proper disposal. Please contact Surgix Medical Technologies at customerservice@surgixmedical.com for further information regarding this requirement.

2 Introduction

2.1 General Description

The FusionMAX™ Spine Table (the FusionMAX™ or the Table) is a specialty surgery table developed and designed to provide unrestricted access to the patient, enhanced safety, and improved ease of use. The classification of the device is Class I equipment/internally powered. The FusionMAX™ allows for precise surgeon-controlled positioning and imaging ability. The standard configuration of the FusionMAX™ Table includes two operating surfaces or platforms: the Supine and the Prone Platforms. These platforms are easily interchanged to suit the clinical situation.

The Prone Platform is intended for procedures that require the patient to be in the prone position. The Prone Platform has an open configuration top and is intended to allow for abdominal fallout, thereby reducing pressure on the vena cava and blood pooling during surgery. The Prone Platform can be used with several different positioning devices to stabilize the patient in the desired position.

The Supine Platforms and Pads are intended for procedures that require the patient to be in the supine or lateral position. The Supine Platforms have two solid, carbon fiber operating surfaces to facilitate clear imaging. The Supine Platforms Pads are made of specialized foam and are intended to be a comfortable resting surface for the patient.

The FusionMAX™ Table has four electrically powered table functions, which are controlled by means of the Hand Pendant. The four functions are: Height (up/down), Lateral Tilt (left/right), Trendelenburg/Reverse Trendelenburg, and Translation/Cantilever. Powered wheels used to lock and unlock the Table in the operating location are also controlled by the Hand Pendant.

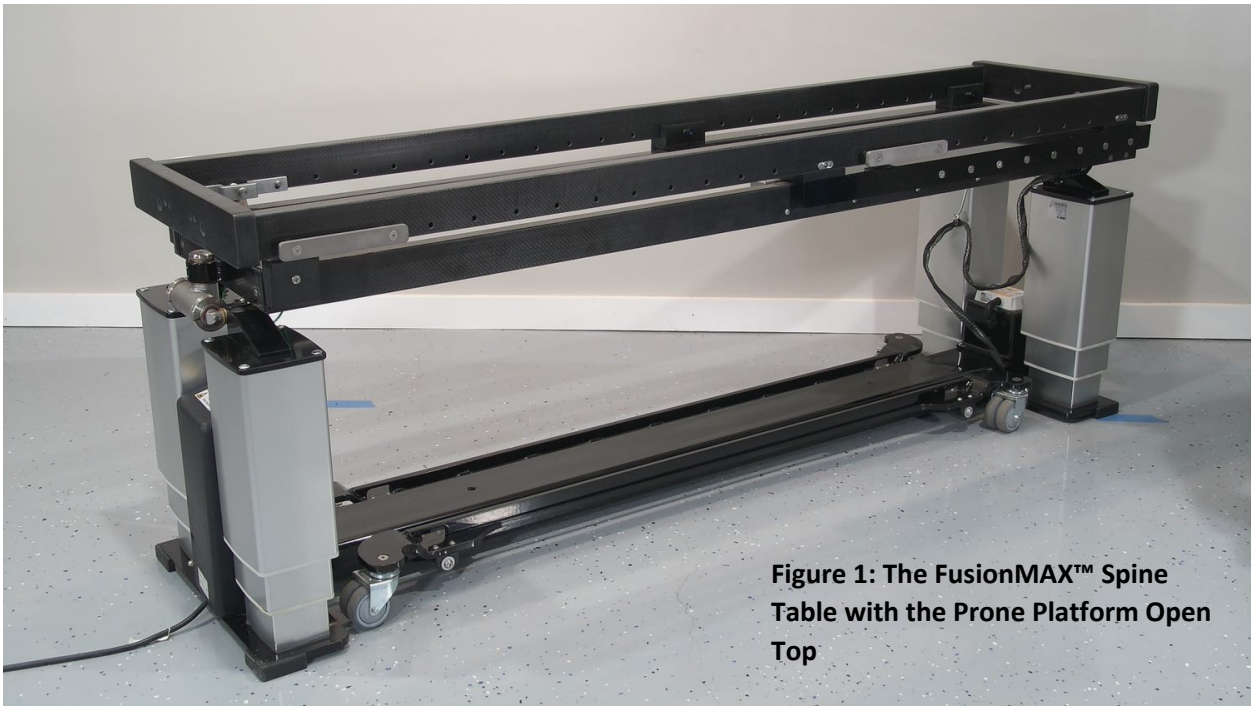


Figure 1: The FusionMAX™ Spine Table with the Prone Platform Open Top

2.2 Intended Use

The FusionMAX™ Table is a mobile surgery table designed for temporary support (<24 hours) and positioning of a patient in a prone, supine, or lateral position. The Table is intended for use during surgical procedures, including radiographic imaging during such procedures. The Table is not intended for use in patient transport.

The FusionMAX™ Table provides a platform designed to support and position adult and pediatric patients with body weight less than ?pounds (?kg) when used in the home position and ?pounds (?kg) when used with the tabletop translated to a cantilevered position.

2.3 User Profile

The FusionMAX™ Table is suitable for use by health care professionals, including but not limited to surgeons, radiologists, anesthesiologists, circulating nurses, surgical technicians, biomedical technicians, and radiology technicians.

2.4 Training Requirements and Description

Before using the FusionMAX™ Table, the user must read this FusionMAX™ Spine Table Owner's Manual. (PN?)

It is required that personnel using the FusionMAX™ Table receive training by the distributor or someone qualified by the medical facility to provide this training.

 **WARNING: Failure to ensure training prior to use of this device may cause harm to the patient, health care professional, or the device.**

2.5 Conditions of Use

The FusionMAX™ Table may be used several times throughout the day and night in medical facilities, e.g., hospitals and outpatient surgery/imaging centers. The FusionMAX™ Table 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's service lifetime is defined as 10 years. At the time of delivery, your product fulfills existing regulations and standards. However, despite proper use, routine inspection, prescribed service, maintenance, and repairs, the product is subject to aging and wear. Therefore, the manufacturer cannot guarantee the product's safety after five (5) years and recommends your product be taken out of service. For product warranty information refer to Section 12.4 of this manual

2.7 Specifications

The FusionMAX™ Table has the following specifications:

- The dimensions of the top frame are 80 3/8 x 20 inches (204 x 50 cm)
- The weight of the Table is 450lbs (204kg) without accessories, 500lbs (226kg) with accessories
- The shipping weight of the Table is ? to ? lbs. (? To ?kg)
- The Table features motorized retractable wheels
- The Table features adjustable, industry standard side rails
- The Table is equipped with the following controls:
    - Two (2) 5 function backlit hand controls that include ? preset positions
    - One (1) 5 function Fixed Control Panel
- The Table height range is 24 to 40 inches (60 to 101cm)
- The Table has 21 inches (53.3cm) of cantilevered longitudinal motion
- The lateral tilt range is ±20 degrees
- The Trendelenburg/reverse Trendelenburg range is ±10 degrees
- The maximum patient load is lbs. (?kg), or ?lbs. (?kg) when cantilever is employed

2.8 Shipping and Storage

If required to be transported, the FusionMAX™ Spine Table must be transported using the appropriate shipping crate. Unpacking instructions are included with the original shipping crate. Shipment of the FusionMAX™ Spine Table without the appropriate shipping crate will void the product warranty.

When not in use, the FusionMAX™ Table must be stored in a clean, dry environment

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

Ambient temperature 15◦F (-10◦C) to 120◦F (50◦C)

Relative Humidity from20% to 80% at 85◦F

Barometric pressure 20.7 to 31.3 in Hg (700 to 1060 in hPa)

If the Table is exposed to temperatures below 15◦F (-10◦C) for an extended amount of time, the battery will not function until returns to an above freezing temperature.

When in storage, to ensure that the battery is always fully charged and ready for use, connect the Table to AC power which matches the ratings on the Ratings Label, located on the ouside of the head-end of the Table (Figure 44).

2.9 Glossary of Terms

Head-End Columns	The two Head-End Columns are lifting columns that are controlled by either the Hand Pendant or the Fixed Control Panel at the Foot-End of the Table. The power cord and grounding plug are located at the head end of the table between the Head-End Columns.
Foot-End Columns	The two Foot-End Columns are lifting columns that are controlled by either the Hand Pendant or the Fixed Control Panel at the Foot-End of the Table. An important Manufacturers label is located at the Foot-End of the Table.
Fixed Control Panel	The Fixed Control Panel is located at the Foot-End of the Table, between the Foot-End Columns. It serves as a back-up control system to the two (2) Hand Pendants and allows for (Owner's Manual Guided) troubleshooting of the Table
Center Beam	The Center Beam of the Table runs along the ground and connects the Head-End and Foot-End Columns. It provides stability and houses the wheels mechanism that locks and unlocks the Table.
Unlocked	The Table is considered in an Unlocked state when the wheels are employed (lowered). In this state, the full weight of the Table is supported by the wheels and the Table can be transported.  **WARNING: The Table should NOT be used as a patient transport device.**
Locked	The Table is considered to be in a Locked state when the wheels are fully disengaged (raised). In this state, the wheels are not in contact with the ground and the full weight of the Table is supported by the feet of the Table.
Table Feet	There are four Table Feet, one under each of the four lifting columns. The feet can be adjusted to account for inconsistencies of the floor.
Left Side of the Table	Refers to the left side of the Table (as you stand at the Head-End and look to the Foot-End).
Right Side of the Table	Refers to the right side of the Table (as you stand at the Head-End and look to the Foot-End).
Lower the Table	Refers to lowering the height of the tabletop.
Raise the Table	Refers to raising the height of the tabletop.
Motorized Cantilever	The FusionMAX™ Table features 21 inches (53.3cm) of Motorized Cantilever. Under continuous activation of the Motorized Cantilever button on a Hand Pendant, the tabletop will slide toward the Head-End of the Table at a slow, controlled rate for a maximum travel of 21 inches (53.3cm).  WARNING: When the Table is placed in Cantilever position, the patient weight rating drops from ? lbs. (? kg) to ? lbs. (? kg).
Hospital Grade Outlet	Refers to specially designated outlets (receptacles) that include additional grounding reliability, assembly integrity, strength, and durability. A hospital grade outlet in the United States may be indicated by a green colored dot on the face of the outlet.

3 Component Identification

3.1 Table Orientation

The FusionMAX™ Table is described as having a Head-End and a Foot-End (Figure 2). When the components are set up and the patient is positioned, the patient's head is oriented towards the Head-End of the device and his/her feet are oriented towards the Foot-End of the device. It should be noted that the FusionMAX™ Table features 21 inches (53.3 cm) of motorized cantilever toward the Head-End of the Table.

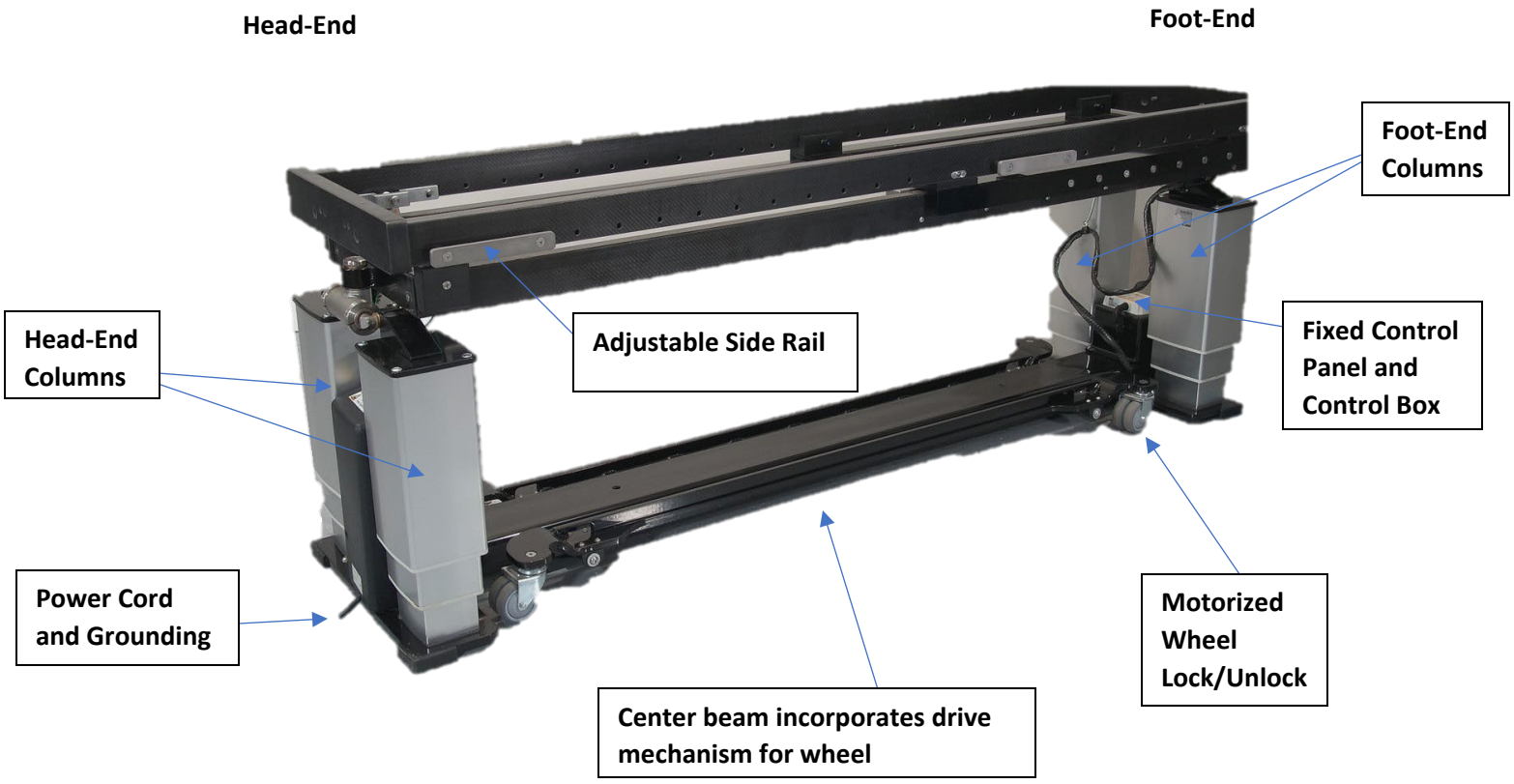


Figure 2: FusionMAX™ Table Base

An important safety label located at the Foot-End of the Table is the Safe Working Load (SWL) Label.

WARNING: Use of the FusionMAX™ Table with patients and patient support equipment weighing more than ? lbs. (? kg) could result in damage to the Table, possible injury to the patient, or harm to the healthcare professional.

WARNING: When the cantilever is extended on the FusionMAX™ Table, use of the Table with patients and patient support equipment weighing more than ? lbs. (? kg) could result in damage to the table, possible injury to the patient, or harm to the healthcare professional.

The center beam of the base is not intended to be used for storage. The tabletop can be raised and lowered during normal use. Storing anything on or around the center beam and under the Table can cause damage to the stored item or to the Table itself.

WARNING: Not for storage. Do not store anything on or around the center beam of the base.

The FusionMAX™ Table Standard Offering includes two easily interchangeable operating platforms: the Supine Platforms and the Prone Platform.

The Supine Platforms and Pads are intended for procedures that require the patient to be in the supine or lateral position. The Supine Platforms have a solid, carbon fiber operating surface to facilitate clear imaging. The Supine Platforms Pads are made of specialized foam and are intended to be a comfortable resting surface for the patient.

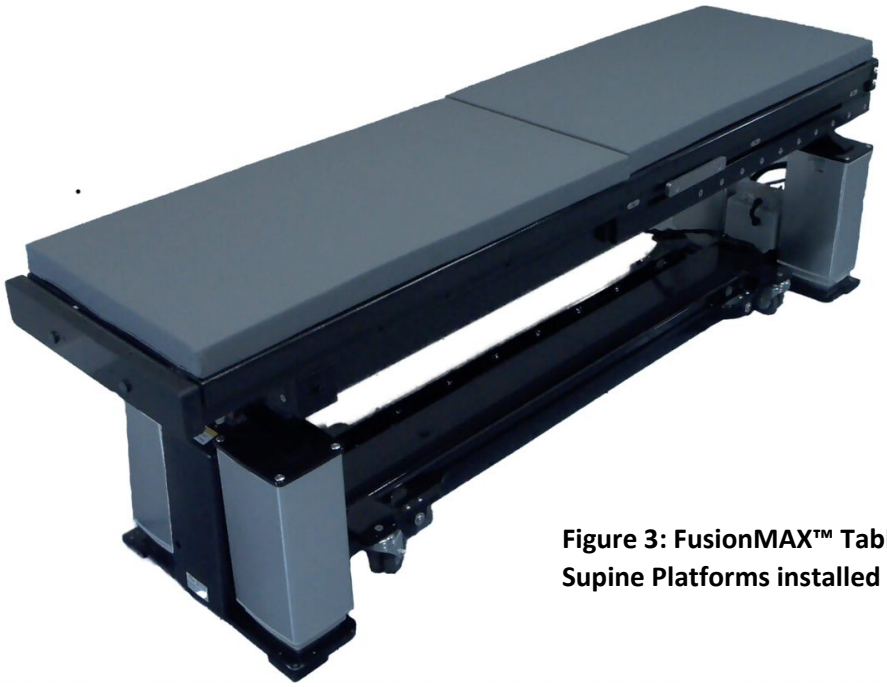


Figure 3: FusionMAX™ Table with Supine Platforms installed

The Prone Platform is intended for procedures that require the patient to be in the prone position. The Prone Platform has an open configuration top and is intended to allow for abdominal fallout, thereby reducing pressure on the vena cava and blood pooling during surgery. The Prone Platform can be used with several different positioning devices to stabilize the patient in the desired position.

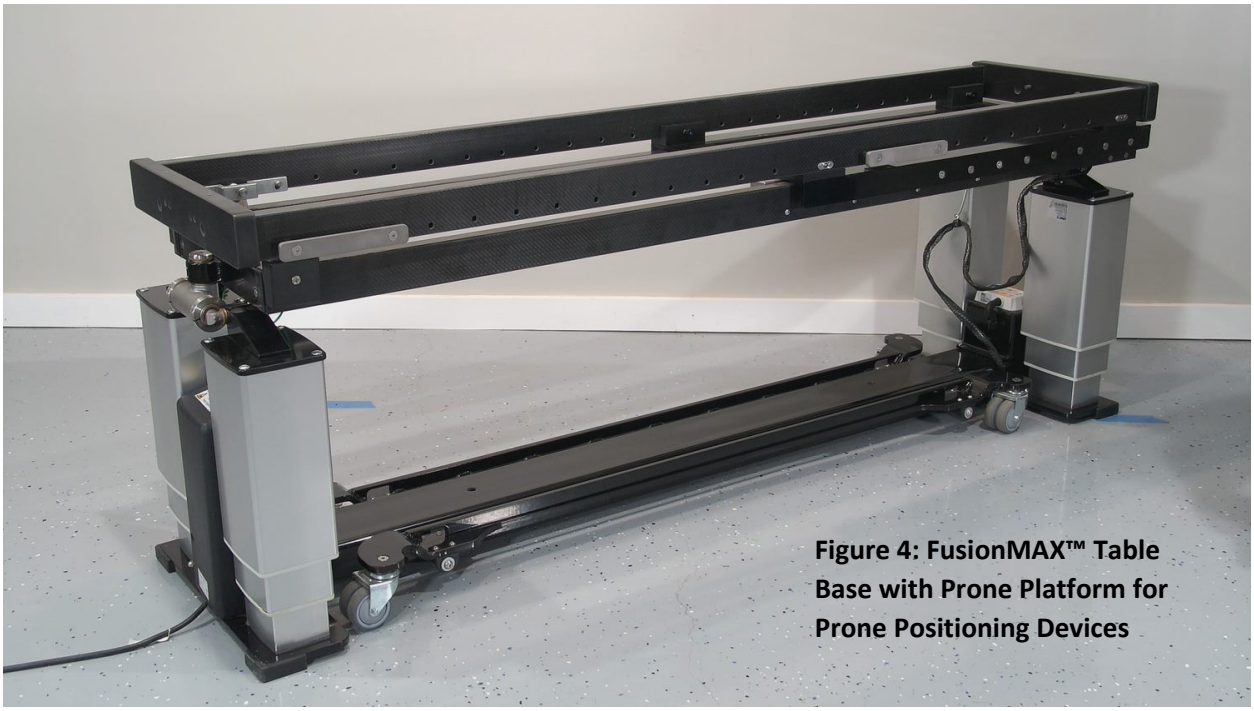


Figure 4: FusionMAX™ Table Base with Prone Platform for Prone Positioning Devices

3.2 Model Number and Serial Number- need new sticker

PLACE STICKER PIC HERE

In addition to the REF product number and SN serial number, the following information is provided on the Manufacturer's Label:

- Address and contact information of Manufacturer, Domico
- Address and contact information of Distributor, Surgix Medical Technologies

NOTE: *Additional product information may be found on the Manufacturer's Label.*

4 Basic Operation

4.1 Grounding and Power

This FusionMAX™ Table must be grounded. In the event of electrical malfunction or breakdown, grounding provides a path of least resistance for electrical current and reduces the risk of electric shock. This product is equipped with a cord that has an equipment-grounding conductor and a grounding plug. The plug must be plugged into an appropriate outlet that is properly installed and grounded in accordance with all local codes and ordinances. Make sure that the product is connected to an outlet with the same configuration as the plug.

To disconnect the Table from electrical power, remove the plug from the outlet. Be sure that access to the plug is not obstructed in a way that would prevent a user from disconnecting the Table from power.

The FusionMAX™ Table is equipped with a backup battery that is intended to power the Table in the event of mains power failure. The backup battery is not to be used as the primary power source. The Table should be plugged into hospital grade mains power whenever in use.

It is recommended that the battery be replaced after three (3) years (four years maximum), dependent on the pattern of use (frequent and high-powered discharges reduce the battery life). The battery must be replaced only with the manufacturer's defined replacement. Failure to replace with the original equipment may result in voiding the product warranty and may harm the patient, staff, or the device.

If the Table is to remain unused for a period greater than three (3) months, it is recommended to remove the battery.

WARNING: **This symbol indicates an external ground post 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, or when the Table is in use under battery power. Failure to ensure ground may cause harm to the patient, healthcare workers, or the Table.**

To confirm Table grounding from the plug to the metal Table, use the ground post located on the base at the Head-End of the Table (see Figure 6). Connect tester to the ground post and the plug.

Figure 6: Grounding Plug located at Head-End of Table

4.2 Hand Pendant Controls

Table motions are controlled by the Hand Pendants or by the Fixed Control Panel, located at the Foot-End of the Table.

> **NOTE:** *The Table features two Hand Pendants. One is intended to be used by anesthesia. The other can be sterile draped and placed in the sterile field, providing the surgeon direct control over the Table.*

To prevent accidental motion, the Table will only respond to commands from one source at a time. In the event that two controls are simultaneously activated (either both Hand Pendants or a Hand Pendant and the Fixed Control Panel), the Table will not move until both controls are released. After both have been released, the controls (Hand Pendants and Fixed Control Panel) will function normally.

To prevent accidental motion, all controls (both Hand Pendants and the Fixed Control Panel) enter a sleep mode after 30 seconds of non-use. To reactivate a Hand Pendant (or the Fixed Control Panel) press any button once and release. The hand control will re-illuminate to signify that it is now active. All Table controls will now function normally.

The table below describes the motion of the Table that corresponds to each of the buttons Shown in Figure 7. Note that the nine(9) control buttons on the Fixed Control Panel (see figure 9) are identical to those of the Hand Pendants in both appearance and function. The only exception is that the three preset buttons (NEUTRAL, CERVICAL, and TRANSPORT) are not included on the Fixed Control Panel. Troubleshooting with the Fixed Control Panel is covered in section 4.3.

Control Button	Function	Control Button	Function
Height Up	Raise Table (max. height is 38 inches / 96.5cm)	Height Down	Lower table (min. height is 22 inches / 55.9cm)
Trendelenburg	Lower Head-End to lowest position AND raise Foot-End to highest position (max. angle is 12◦) When transitioning from a reverse Trendelenburg position to a Trendelenburg position, the Table will pause at flat before continuing movement toward Trendelenburg	Reverse Trendelenburg	Lower Foot-End to lowest position, AND raise Head-End to highest position (max. angle is 12◦) When transitioning from a Trendelenburg position to a reverse Trendelenburg position, the Table will pause at flat before continuing movement toward reverse Trendelenburg
Tilt Left	Lateral tilt the Table to the left (max. angle is 20◦) When transitioning from a tilt right position to a tilt left position, the Table will pause at flat before continuing movement toward tilt left	Tilt Right	Lateral tilt the Table to the right (max. angle is 20◦) When transitioning from a tilt left position to a tilt right position, the Table will pause at flat before continuing movement toward tilt right
Cantilever Extended	Extended cantilever. Tabletop will move toward the Head-End of the Table (max. travel is 21 inches / 53.3cm)	Cantilever Retract 	Retract cantilever. Tabletop will move from an extended position until it returns to normal position. **WARNING: The Table will emit a beeping noise as the tabletop retracts to warn user of a pinch point at the Foot-End of the Table**
NEUTRAL	The Table will move to home position. Table is locked, flat and level at 28.5 inches (72.4cm) in height. Cantilever is fully retracted	CERVICAL	The Table will move to a cervical starting position. Table is locked, flat and level at 25 inches (63.5cm) in height. Cantilever is fully extended
TRANSPORT 	The Table will move itself into storage transport position. Table is UNLOCKED, flat and level at max. height of 38 inches (96.5cm) **WARNING: The Table is NOT TO BE USED AS A PATIENT TRANSPORT DEVICE.**	WHEELS	The wheels move up and down. When the wheels move down, they engage the floor, and the Table is UNOCKED. When the wheels move up, the base engages the floor, and the Table is LOCKED. See section 4.2.1

NOTE: *Before each use, or at a minimum of once per day, lower the table all the way down to maintain accurate alignment of the four columns*

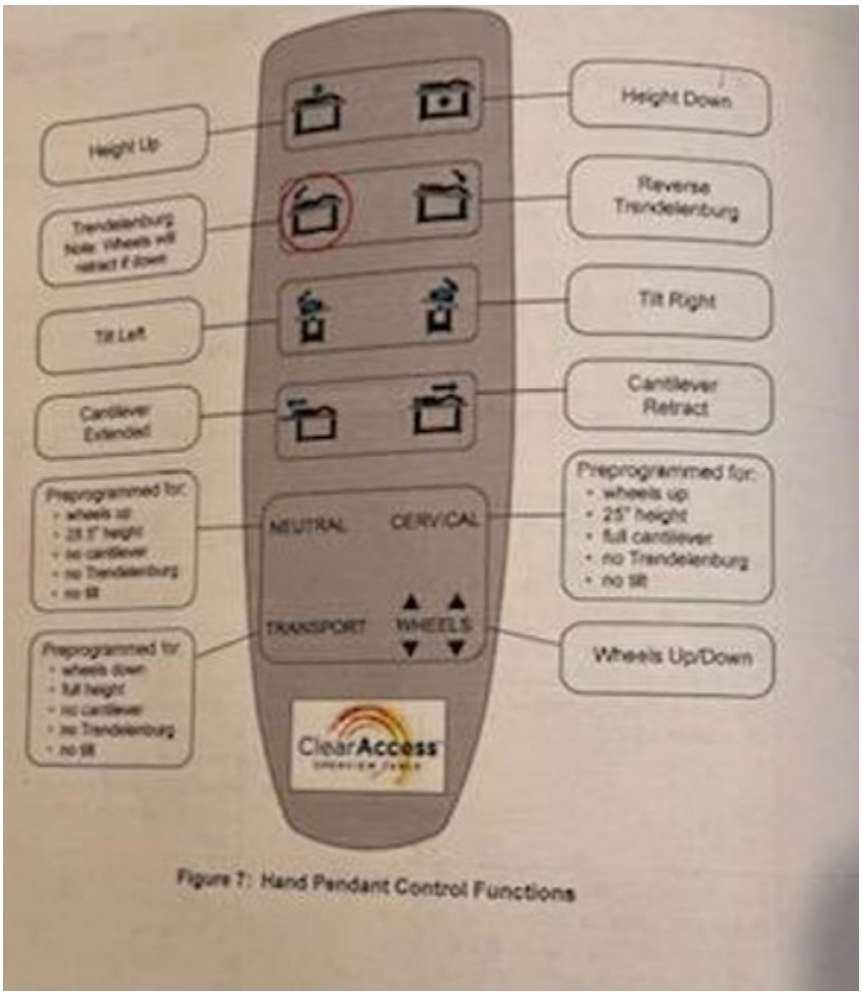


Figure 7: Hand Pendant Control Functions

If desired, the user can disable all controls on the Table with the ON/OFF switch, located at the Foot-End of the Table (see Figure 8)

Figure 8: ON/OFF Switch enables/disables all controls to the Table. The ON/OFF Switch is shown in the ON position (controls enabled).

WARNING: All personnel with access during procedures to the Table motion controls must be trained in the safe and proper use of the Table. For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled using the ON/ OFF Switch on the Fixed Control Panel, located at the Foot-End of the Table.

4.2.1 Floor Locks

The Table can be locked and unlocked by pressing the WHEELS button on either Hand Pendant or the Fixed Control Panel. The table must be LOCKED during use. To LOCK/UNLOCK the Table:

1. Press any button on the Hand Pendant to activate it from sleep mode. Note that the Hand Pendant illuminates to indicate that it is activated.

2. Press the WHEELS button once firmly and then release.

- If LOCKING the Table from an unlocked state: the wheels of the Table will raise up slowly, gradually placing the base of the Table on the ground. The Table will emit a beeping noise to warn caregivers to keep feet, hands, and equipment clear of the Table as it lowers.

WARNING: There is a pinch point between the Table base and the floor as the Table is lowered to the floor. Be mindful of caregiver toes and equipment cables before lowering the Table to the floor.

- If UNLOCKING the Table from a locked state: the wheels will lower to the ground slowly, gradually lifting the Table.

NOTE: *The initial motion of the wheels is very subtle. To prevent confusion, press the WHEELS button only once and release.*

- When unlocking the Table, if the user pushes the WHEELS button again before the Table is unlocked, this action will arrest the downward motion of the wheels. The next time the user presses the WHEELS button, the wheels will retract (locking the Table), and the Table will beep.

- To unlock, simply wait until the beeping stops (indicating the Table is fully locked again), then press the WHEELS button once and release.

- Observe that the WHEELS button light on the Fixed Control Panel (see Figure 9) will illuminate immediately after the Table receives the UNLOCK command, signifying that the Table is engaging the wheels and unlocking the Table.

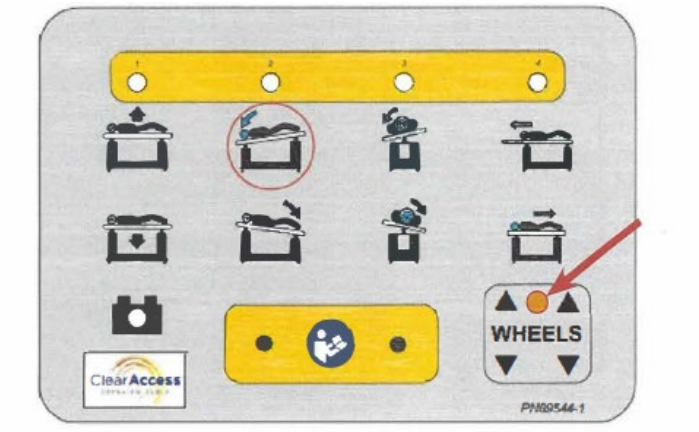


Figure 9: The WHEELS light on the Fixed Control Panel at the Foot-End of the Table

4.2.2 Auto Lock and Disabled Lock

The FusionMAX™ Table is not to be used for patient transport. Use of the FusionMAX™ Table as a patient transport device may cause an unsafe situation that could result in injury to the patient or healthcare professional. Accordingly, two important safety features are incorporated into the control system of the table: **Auto Lock** and **Disabled Unlock**.

4.2.2.1 Auto Lock

If the Table is unlocked and a user attempts to manipulate the Table (raise, lower, tilt left or right, Trendelenburg or Reverse Trendelenburg, cantilever), the Table will Auto Lock itself. Before completing the command (raise, lower, tilt left or right, Reverse Trendelenburg, cantilever), the Table will lock itself. To do so, it will lower to the ground, emitting a beeping noise to warn nearby personnel of a pinch hazard between the base of the Table and the floor.

The one exception to Auto Lock is Trendelenburg. If the Table is unlocked and a user presses the Trendelenburg button, the Table will Auto Lock itself while simultaneously moving into Trendelenburg position. This exception is to accommodate for an emergency situation that requires movement of the patient into Trendelenburg immediately.

4.2.2.2 Disabled Unlock

If the Table is in a position that includes tilt, Trendelenburg, reverse Trendelenburg, or height above 30 inches (76.2 cm), the Table will not UNLOCK. The Unlock function is Disabled when the Table is in a position that would be unstable if the Table were unlocked. If the Table is in such a position and a user presses the WHEELS button to unlock the Table, the Table will emit an error beep and will not unlock.

To unlock the Table, the user should remove all angulation (tilt and Trendelenburg/Reverse Trendelenburg) and reduce height to a safe level. The simplest and fastest way to accomplish this is to press and hold the NEUTRAL button until the Table stops moving. Once the table has reached the NEUTRAL preset position, it is in a safe position to be unlocked. Press the WHEELS button once firmly and release to proceed with unlocking the Table.

4.3 Troubleshooting

The FusionMAX™ Table has four (4) lifting columns that control height, tilt, and Trendelenburg. Each of these columns has a duty cycle of 10%. A 10% duty cycle is defined as two (2) minutes of continuous operation within a 20-minute period. Exceeding this duty cycle could damage the columns.

Below is a highlighted list of problems with troubleshooting suggestions, beginning with the simplest.

4.3.1 The Table will not Unlock

Verify that the Table is flat and level. The Table must be flat and level before it can be unlocked. If a user attempts to unlock the Table when the table is in Trendelenburg, reverse Trendelenburg, or lateral tilt, the Table will emit an error beep. To correct, press and hold the NEUTRAL button on the Hand Pendant, returning the Table to a safe position to be unlocked. Once the Table is flat and level, press the WHEELS button once firmly and release. Note that the LED over the WHEELS button on the control panel illuminates immediately, while the Table gradually unlocks.

4.3.2 The Table is Unresponsive to Hand Pendant Control

1. Verify that the Hand Pendant is activated. A Hand Pendant will automatically enter sleep mode if left unused for 30 seconds. To reactivate a Hand Pendant, press any button. The Hand Pendant will illuminate and should function normally.

2. Verify that the ON/OFF Switch /Figure 8) at the Foot-End of the Table is in the ON position. If the ON/OFF Switch is switched to the OFF position, all controls for the Table (both Hand Pendants and the Fixed Control Panel) are disabled. Switch the ON/OFF Switch to the ON position and activate a Hand Pendant by pressing any button on the Hand Pendant. The Table and Hand Pendant should function normally.

3. Verify that the Table has power. Look for a green power indicator at the Head-End of the Table (Figure 10). If the light is extinguished, the control box is not receiving power. No power to the control box is the result of a depleted battery and the Table not connected to mains power. Plug the Table into mains power consistent with the Ratings Label and activate a Hand Pendant by pressing any button on the Hand Pendant. The Table and Hand Pendant should function normally.

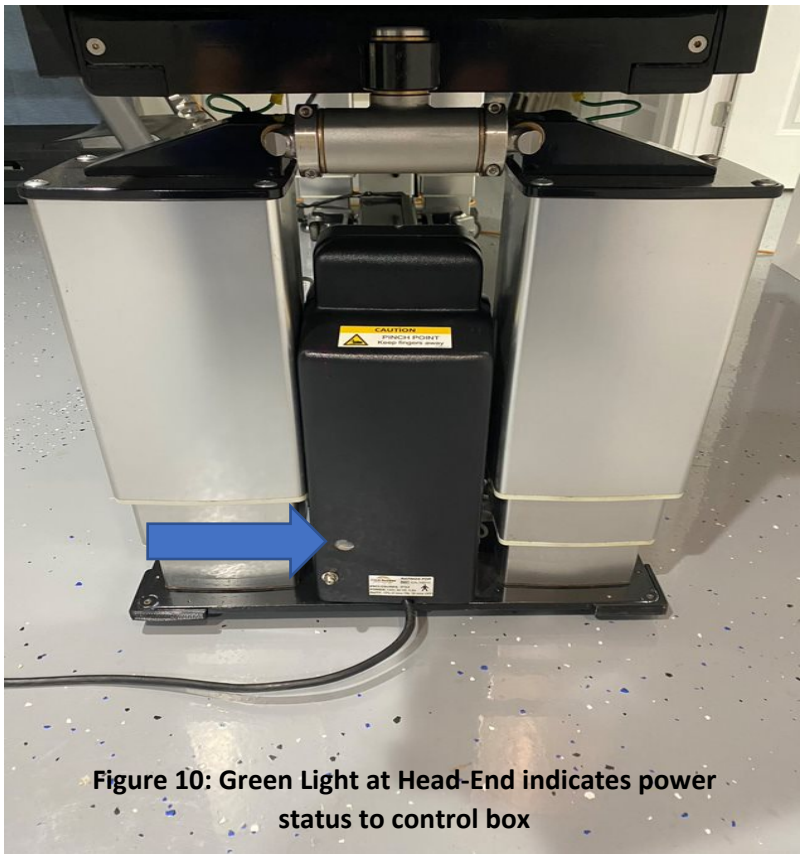


Figure 10: Green Light at Head-End indicates power status to control box

4. Investigate the status of the columns and reset the columns if necessary. To protect the Table from damaging itself, each of the four columns is equipped with a safety sensor. If any of the columns is out of synchronization, a safety switch will disable the controls of the Table (an error beep noise will sound with each attempt to manipulate the Table) until the affected column is reset (see the "Manual Reset Procedure" in Section 4.3.3)

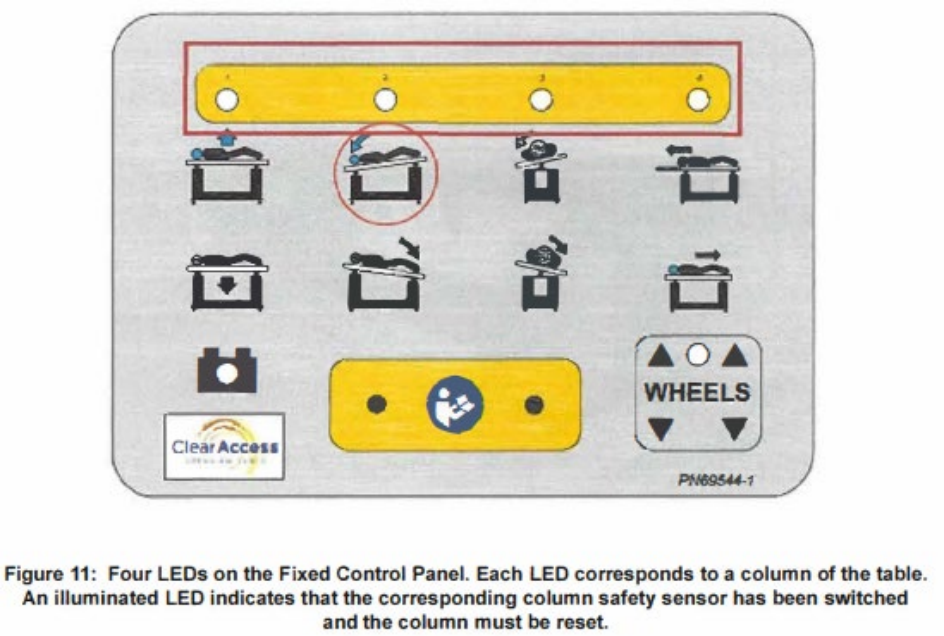


Figure 11: Four LEDs on the Fixed Control Panel. Each LED corresponds to a column of the table. An illuminated LED indicates that the corresponding column safety sensor has been switched and the column must be reset.

4.3.3 Manual Reset Procedure

If Table Height/Trendelenburg/Tilt functions do not operate and a long beep sounds when any of these buttons are pressed, the Table columns need to be reset. To reset the columns, the controls must be put into Manual Mode. This can be done via the Fixed Control Panel located at the Foot-End of the base ONLY. The handsets will not operate when the Table is in Manual Mode.

NOTE: *The button functions on the Fixed Control Panel change when in Manual Mode (see diagram below) and DO NOT correspond to the normal pictured functions on the label.*

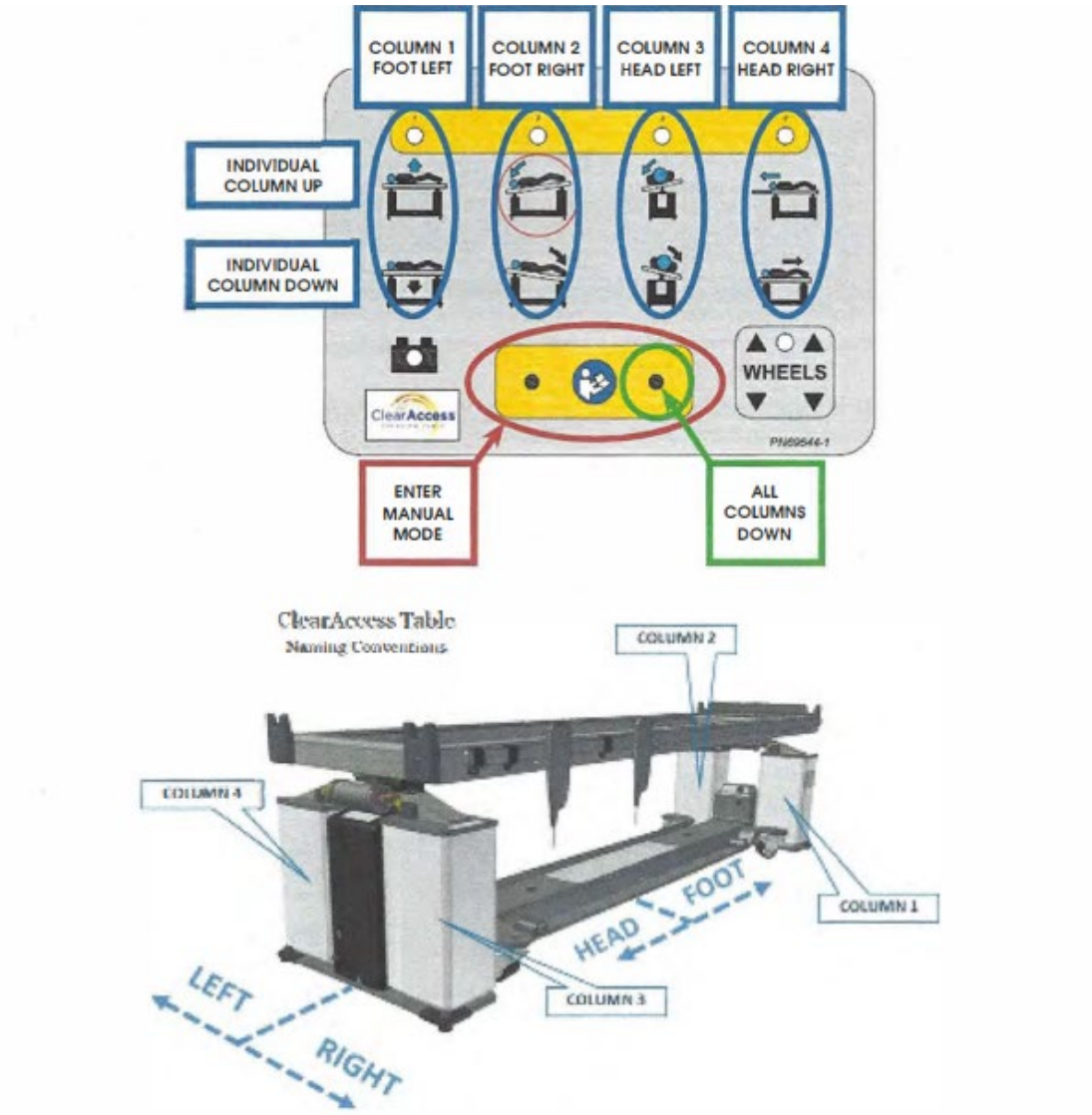


Figure 12: Enter Manual Mode by pressing both buttons in the yellow field simultaneously. While in Manual Mode, the Fixed Control Panel buttons no longer correspond to the normal pictured functions on the label.

WARNING: This procedure should be performed by trained personnel only. Severe damage to the Table can result with improper manipulation of the Table while in Manual Mode.

Enter Manual Mode by pressing and holding the two (2) center bottom buttons in the yellow field simultaneously. A series of 19 long beeps should be heard for a period of approximately 10 seconds. The series of long beeps is followed by a series of short beeps. The short beeps indicate the Table is in Manual Mode. Release the two buttons. If no beeps can be heard, the timing of the simultaneous button press was not close enough to invoke the Manual Mode function and must be tried again.

Once the Table is in Manual Mode (short beeps), reset the columns by pressing the right button in the central yellow field (see Figure 12 -ALL COLUMNS DOWN). Press and hold this button to bring all four (4) columns down simultaneously. Continue to hold the button until all four (4) columns are all the way down and the Table exits Manual Mode (the short beeps stop). The Table should now function normally.

NOTE: *Once entering Manual Mode, the Table will remain in Manual Mode for 30 seconds. If no other buttons are pressed, the Table will exit Manual Mode automatically Since the columns were not reset properly, the Table will remain in an error state and columns will not function. To correct, enter Manual Mode and reset the columns as described above.*

5 Inspection

5.1 Acceptance and Transfer

1. Upon receipt of your FusionMAX™ Table, remove it from the shipping crate. Remove any protective wrapping or 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 Manufacturer's Label (Figure 5) and confirm the power requirements on the Ratings Label (Figure 44)

3. Perform Function Check (see Section 6).

5.2 Pre-Procedure/Post -Procedure

Before and after each use of the FusionMAX™ Table, visually inspect all accessible areas, electrical cords, and all movable parts for possible damage that may adversely affect the proper operation of the FusionMAX™ Table. 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 Surgix Medical Technologies for repair or replacement (see Section 12).

5.3 Recommended Regular Inspections (Monthly or Local Standard)

- Check for damage to the power, hand control cables, and all visible wiring.
- Visually inspect components for obvious damage that could cause problems during operation.
- Check the Control Box Cover to ensure:
    - No damage to the ground test point.
    - Control Box has not been dislodged from its proper position as evidenced by examining all edges and seams and verifying good alignment of cable chain.

5.4 Recommended Periodic Inspections (Yearly or Local Standard)

• Check for damage to the power, hands control cables, and all visible wiring.

• Visually inspect components for obvious damage that could cause problems during operation.

• Check all mechanical functions using the hand control. Check for abnormal noises.

• Replace any missing or illegible labels.

• Check that all fasteners are present and fastened securely.

• Check table grounding.

• Clean unusual buildup of dirt on the Table and/or parts of the table not normally cleaned on a regular basis

5.5 Maintenance

The battery should be replaced every three (3) years.

No other specific maintenance tasks are required.

It is recommended to perform a Preventative Maintenance (PM) check on your FusionMAX™ Table (see Section 10.3).

To obtain the PM checklist, call Surgix Medical Technologies at 1-800-231-4651.

6 Function Check

Perform all steps in this procedure before using the FusionMAX™ Table. If the Table does not pass any of the function checks, refer to the Troubleshooting information in Section 4.3. If the Table still does not pass the specified function check, contact Surgix Medical Technologies 1-800-231-4651.

For a complete definition of terms used in this procedure, please refer to the Glossary of Terms in Section 2.9.

1. Plug the Power Cord into a properly grounded receptacle. Refer to the Ratings Label at the Head-End of the Table for input voltage requirements (Figure 44).
2. 2. Select one Hand Pendant and activate it by pressing any button on the Hand Pendant once. Observe that the Hand Pendant illuminates to indicate that it has been activated.
3. 3. If the Table is unlocked, lock it by pressing the WHEELS button on the Hand Pendant once firmly and releasing. Keep hands, feet, and equipment clear, and observe that the Table is lowering itself to the ground. The Table will emit a steady beep to warn of a pinch point between the Table base and the ground.
4. Once the Table is locked, cycle through the motions of the Table in the following sequence. Refer to Figure 7 for the capitalized functions listed below:

   a. Press and hold the NEUTRAL button to bring the Table to its home position to begin the function check. When the Table stops moving, it should be flat, level, and at a height of approximately 28.5 inches (72.4 cm).

   b. Press and hold the HEIGHT UP button until the Table stops moving. The Table should remain flat and level as the height of the Table increases to approximately 38 inches (96.5 cm).

   c. Press and hold the HEIGHT DOWN button until the Table stops moving. The Table should remain flat and level as the height of the Table decreases to approximately 22 inches (55.9 cm). d. Press and hold the TRENDELENBURG button until the Table stops moving. The Head-End columns of the Table should remain in the same position from the previous step, while the Foot-End columns should extend to their maximum height. The angle of Trendelenburg should be approximately 12 degrees.

   e. Press and hold the REVERSE TRENDELENBURG button until the Table stops moving. The Head-End columns should extend to their maximum height, while the Foot-End columns simultaneously retract to their minimum height. The angle of reverse Trendelenburg should be approximately 12 degrees

NOTE: *As the Table moves from Trendelenburg to reverse Trendelenburg, it will pause momentarily when it is level, before continuing motion to reverse Trendelenburg.*

f. Press and hold the NEUTRAL button to return the Table to the home position described in step (a) above.

g. Press and hold TILT LEFT until the Table stops moving. The left side of the Table should lower uniformly while the right side of the table rises uniformly. The angle of lateral tilt should be approximately 20 degrees to the left.

h. Press and hold TILT RIGHT until the Table stops moving. The right side of the table should lower uniformly while the left side rises uniformly. The angle of lateral tilt should be 20 degrees to the right.

NOTE: *As the Table moves from lateral tilt left to lateral tilt right, it will pause momentarily at flat before continuing motion to full lateral tilt right.*

i. Press and hold the NEUTRAL button to return the Table to the same home position described in step (a) above.

j. Press and hold the CANTILEVER EXTEND button until the Table stops moving. The Table's operating platform should move slowly toward the Head-End of the Table. When fully extended, the operating platform will have traveled 21 inches (53.3 cm) in the direction of the Head-End.

k. Press and hold the CANTILEVER RETRACT button until the Table stops moving. The Table's operating platform should return to the same home position described in step (a) above. As the operating platform returns to the home position, keep hands, feet and equipment clear of the system and observe the warning beep

5. Battery Status Check:

To Test the Battery:

a. Unplug the Table from the mains voltage.
b. Check battery indicator light on the control panel on the Table.
   - Charged= solid amber
   - Low Voltage= blinking amber
   - No voltage= no light

Battery Indicator Light

Figure 13: Battery Indicator Light

NOTE: *The battery must be brought back to a fully charged state after any significant use of battery power. It is recommended to leave the Table plugged in when not in use.*

NOTE: *The power plug must be removed from the supply for the battery indicator light to indicate battery level.*

7 FusionMAX™ Spine Table Standard Components

In addition to the Hand Pendant and the Power Cord, the following standard patient positioning components and accessories are shipped with the (PN) FM-10011 FusionMAX™ Spine Table Standard Offering. Pictures of the individual components and instructions for use are provided in Section 8.

> **NOTE:** *Use proper lifting and carrying techniques when moving components and accessories due to their weight and size.*

(PN)FM-10011 FusionMAX™ Table Base	FusionMAX™ Table Base, patient rating ?lbs/?kg (static) or ?lbs/?kg (dynamic), motorized cantilever, electronic wheel locks, two(2) hand controllers, back-up battery, ?sq ft operational foorprint
(PN)? Supine Platforms	Two(2) removable solid carbon fiber operating platforms with locking mechanisms
(PN)? Prone Platform	Removable solid carbon fiber surface
(PN)? Supine Pads	Two(2) 35x19x2in (88.9x48.2x5.1cm) comfort pads with Velcro® attachment to supine platforms
(PN)FM-10041 Head Support Tray	Plexiglass head support tray, non-adjustable
(PN)FM-10027 FusionMax™ Head Rest Support	Head Rest Support can be used inside or outside the prone platform
(PN)? OpenFrame™ Spine Platform	FusionMAX™ Prone Pads including chest and pelvic support systems with pads
(PN)? Knee Support	Carbon Fiber platen with locking mechanism and comfort pad
(PN)FM-10016 Ankle Support	Carbon Fiber Platen with locking mechanism and comfort pad

7.1 FusionMAX™ Table Disposable Kits

The FusionMAX™ Table should be used with the following disposable kits:

(PN)FF-30017 FlexFrame® Disposable Kit (case of 20)

(PN)OF-40024 OpenFrame® Disposable Kit (case of 20)

(PN)FM-10042 Leg Management Disposable Kit (case of 20)

WARNING: Disposable Kits are single use-only ②**. Discard after use. Re-use of any component in a Disposable Kit may result in cross contamination.**

The components should be used as described in the Disposable Kit instructions that are included in each kit.

NOTE: *Remove the Disposable Kit components from the packaging and visually inspect the components.*

NOTE: *The Disposable Kits are not standard components of the FusionMAX™ Table. They are sold separately.*

8 Setup of the FusionMAX™ Spine Table

WARNING: This device is intended for use by trained personnel. Prior to set-up and use of the FusionMAX™ Table, ensure personnel have been trained. To schedule an in-service, please contact Surgix Medical Technologies.

To prepare the FusionMAX™ Table for patient positioning, complete the following steps:

1. Utilizing either Hand Pendant, press and release the WHEELS button to unlock the Table (Figure 7).
2. With the assistance of a second person, move the Table to where it will be used. One person should be located at the Head-End and the other person at the Foot-End. Care should be taken to control the Table when tilting.

WARNING: If an unlocked Table is pushed at too fast of a rate, it may be difficult to stop or turn. Ensure the area around the FusionMAX™ Table system is clear of obstructions during transport or actuation, as impact of the tabletop with a stationary object may cause damage to the Table. If an impact does occur, the Table must be visually inspected for damage and a Function Check must be performed (see Section 6). If damage is discovered or the Table does not successfully complete the Function Check, call Surgix Medical Technologies (see Section 12).

3. To properly position the Table in the operating room, consider the following:
    a. If the surgery will involve the use of motorized cantilever, the Table should be positioned to account for the 21 inches (53.3 cm) of travel toward anesthesia
    b. If ancillary imaging equipment will be used (e.g., C-arm or O-arm®), position the Table such that the imaging equipment can easily access the target site
4. Plug the Power Cord into a properly grounded receptacle. Refer to the Ratings Label at the Head-End of the base for input voltage requirements (Figure 44).
5. Using the Hand Pendant, press and release the WHEELS button to lock the Table (Figure 7).
6. Complete a Function Check with the Hand Pendant (see Section 6).

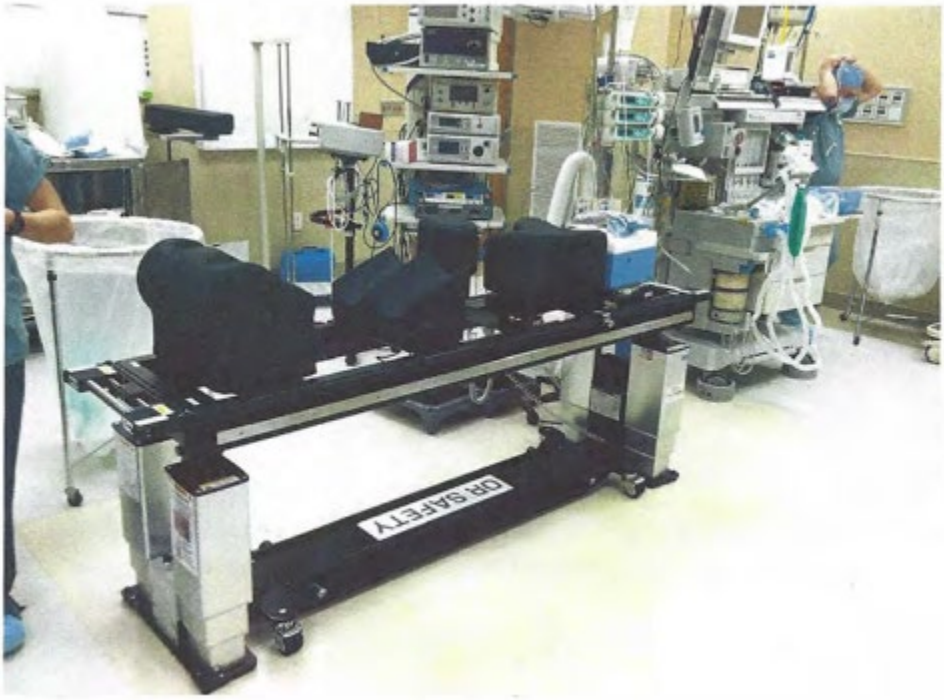


Figure 14: ClearAccess® Openview Table placed for surgery in the operating room

Once the FusionMAX™ Table is placed in the operating room and locked, it is necessary to complete the set-up of additional, patient-specific components prior to patient transfer.

WARNING: Use of components not manufactured by Surgix Medical Technologies may result in harm to the patient, the tabletop, the device, or the healthcare professional.

8.1 FusionMAX™ Prone Patient Positioning

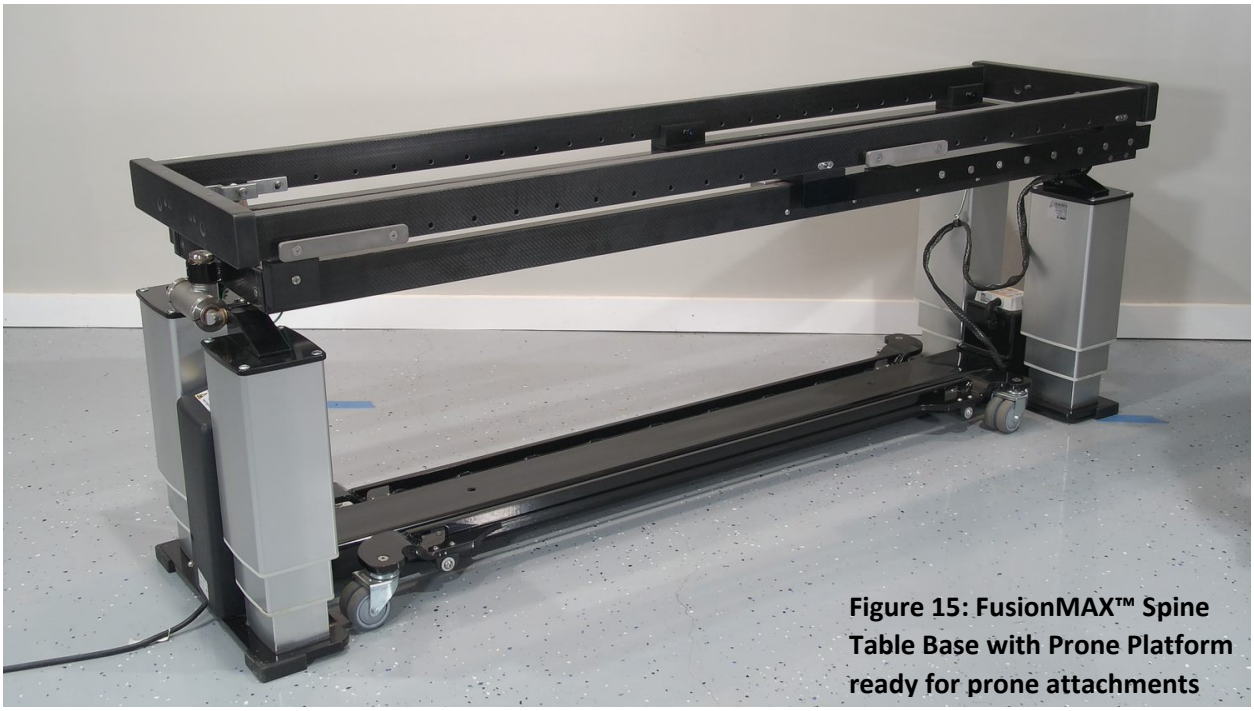


Figure 15: FusionMAX™ Spine Table Base with Prone Platform ready for prone attachments

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 FusionMAX™ Spine Table is prepared for set-up (see Section 8). When the patient is to be in the prone position the appropriate prone components should be installed onto the FusionMAX™ Prone Platform.
2. Confirm that the Table is locked.
3. Install preferred FusionMAX™ Head Supports (Head Support Tray or Head Rest Support: see Figures 16 and 17)

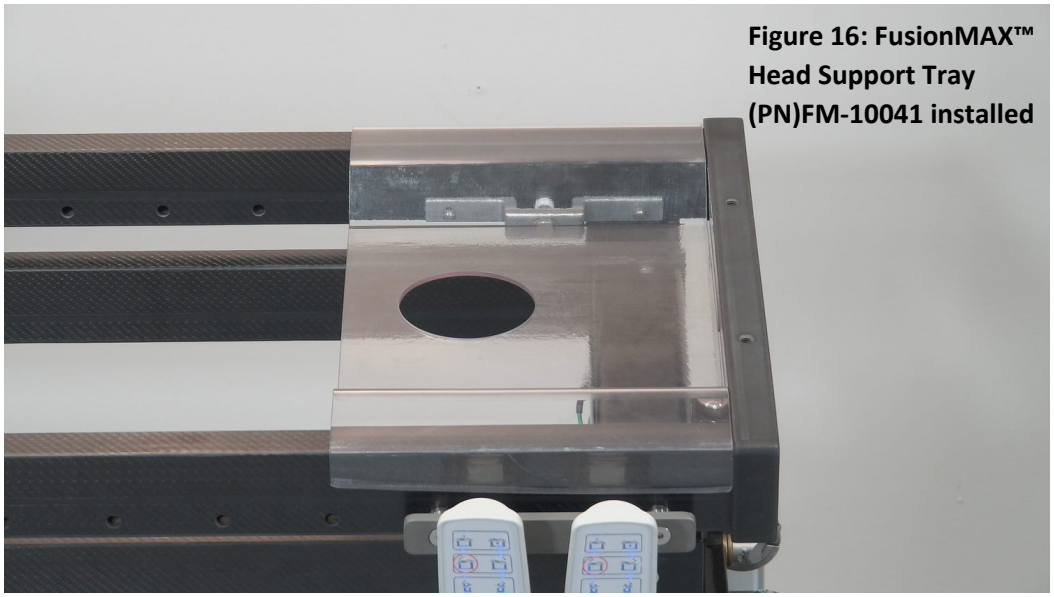


Figure 16: FusionMAX™ Head Support Tray (PN)FM-10041 installed

Figure 17: FusionMAX™ Head Rest Support (PN)FM-10027 installed inside and outside the frame

a. To install the FusionMAX™ Head Support Tray (PN)FM-10041 press the Head Tray onto the rails of the Prone Platform until fully seated (Figure 16). Adjust forward and backward as necessary.

b. To install the FusionMAX™ Head Rest Support (PN)FM-10027 position the support at the head of the bed with the black side face up. Insert the two posts into the holes in the Prone Platform. The Head Rest Support can be positioned either inside or outside the Prone Platform (Figure 17).

c. To lock Head Support into place, tighten the black knobs located under the Prone Platform.

NOTE: *The FusionMAX™ Head Rest Support (PN)FM-10027 can be left in place/stored inside the Prone Platform during Supine Platform use in cases where a cranial stabilization base unit will not be utilized.*

NOTE: *For information Regarding the correct set up and use of the FlexFrame™ Spine Platform (PN)FF-30011U, please refer to the FlexFrame™ Owner's Manual.*

Figure 18: FusionMAX™ Prone Platform with the FlexFrame™ Spine Platform (PN)FF-30011U installed

4. Install the appropriate OpenFrame™ Chest Support platen with desired pad (Part numbers ?& ?).
    a. Place chest support on Prone Platform rails and press down until fully seated.
    b. Adjust to desired location
5. The OpenFrame™ Chest support is locked to the table using rubberized grips located on the underside of the support platform. It is also equipped with a rubberized pad to prevent sliding when weight is applied (Figure 20).

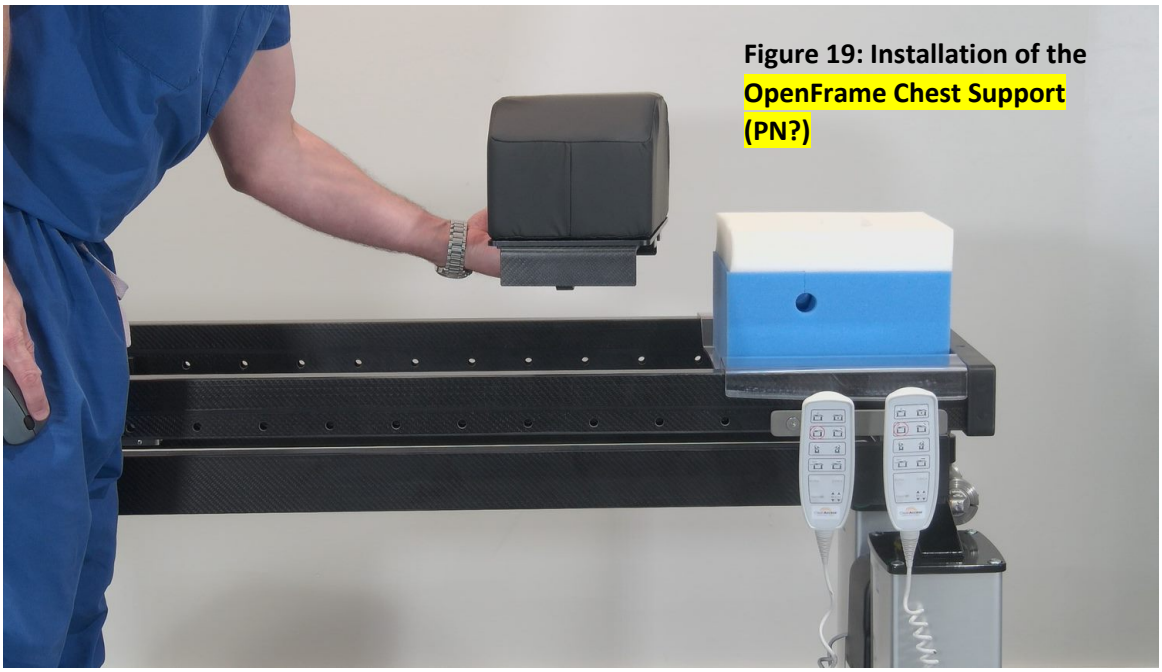


Figure 19: Installation of the OpenFrame Chest Support (PN?)

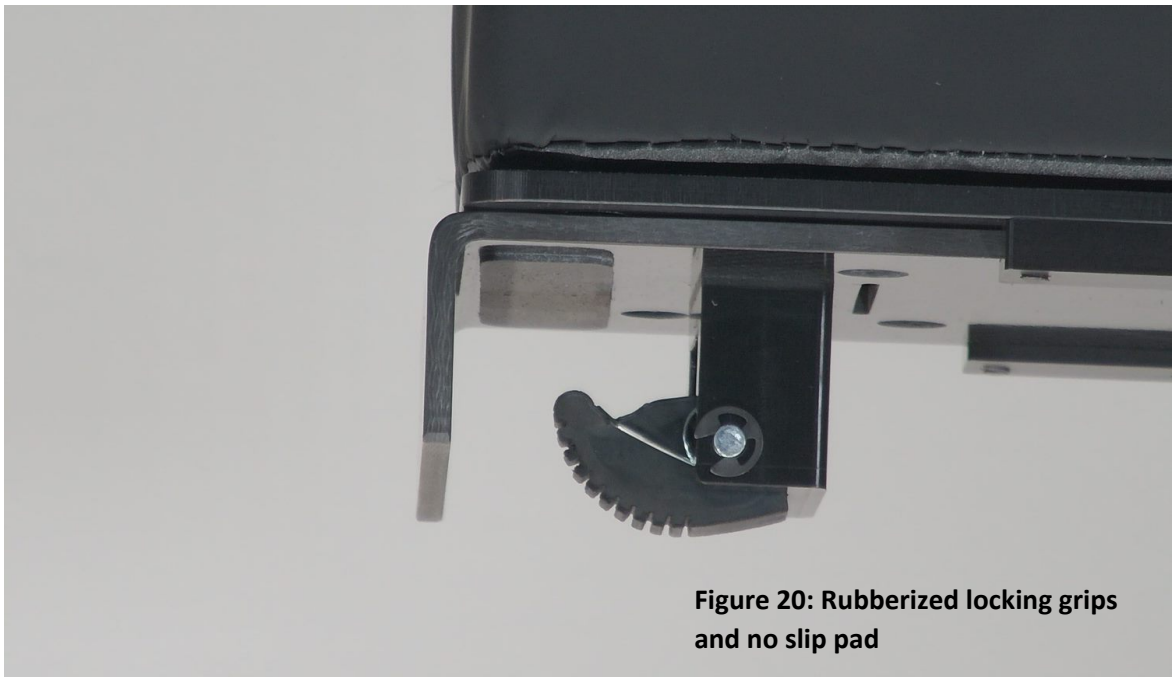


Figure 20: Rubberized locking grips and no slip pad

6. To remove the chest support, grasp the support from the outside edges and pull straight up. You will meet resistance until the locking mechanism disengages from the Prone Platform.
7. The chest pad can be removed from the support platen for cleaning or in case of damage. To remove chest pad:
    a. Pull up on tab located on underside of the chest pad to disengage lock (Figure 21).
    b. Slide chest pad left or right (this will be dependent upon which direction you place the pad down) to open slots on the support platen and lift pad from platen (Figure 22).

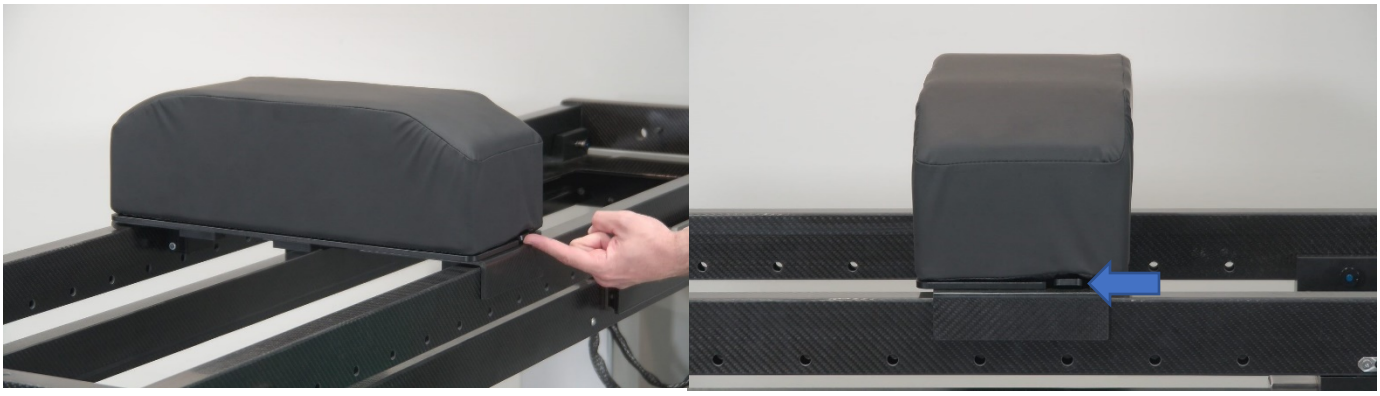


Figure 21: Release tab for Chest Pad

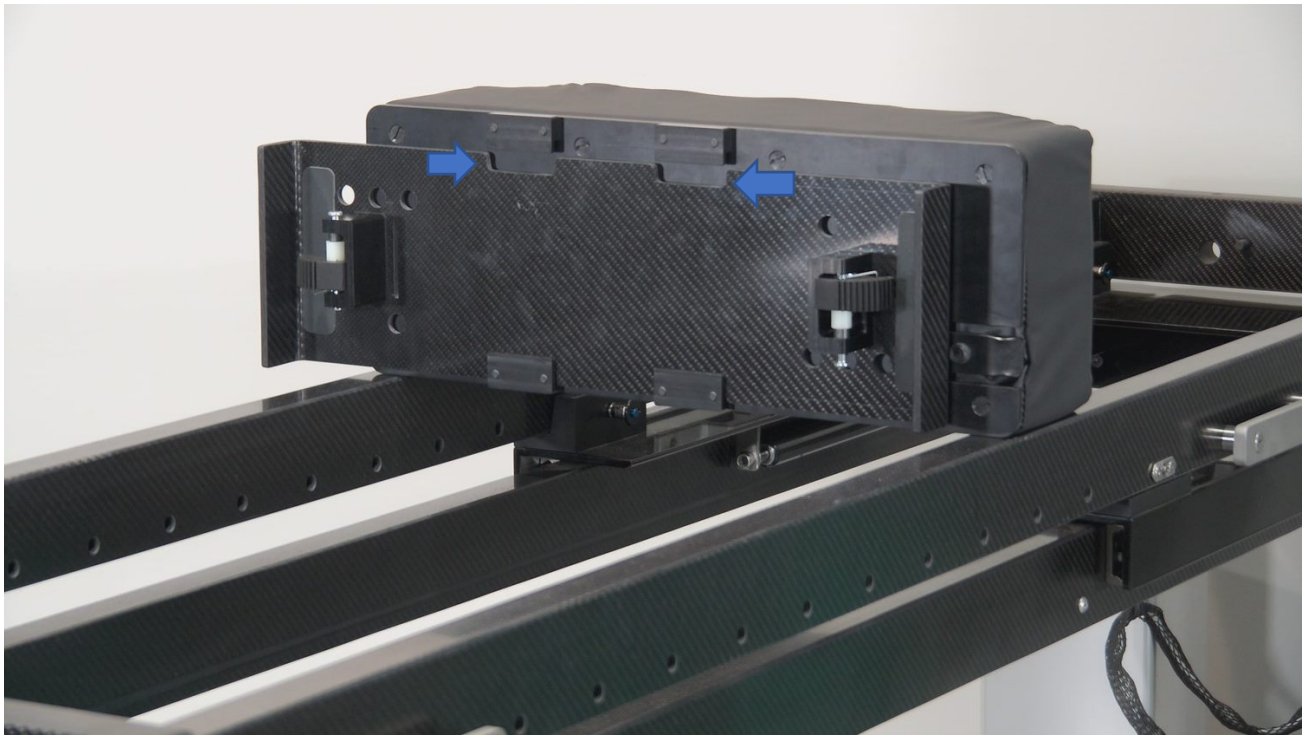


Figure 22: Chest Pad aligned with open slots for removal

8. Install the OpenFrame™ Pelvic Support with desired pad (PN? & ?).
    a. Place OpenFrame™ Pelvic Support on Prone Platform rails and press down until fully seated (Figure 23).
    b. Adjust to desired location

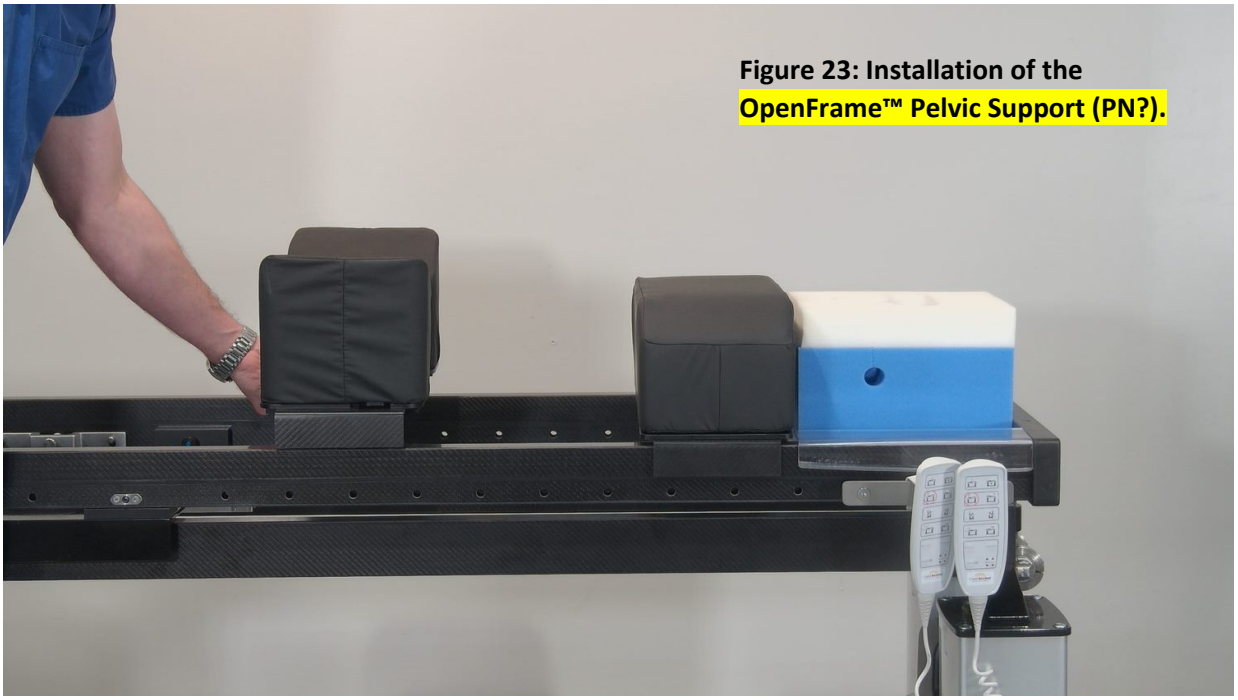


Figure 23: Installation of the OpenFrame™ Pelvic Support (PN?).

9. The OpenFrame™ Pelvic Support is locked to the table using rubberized grips located on the underside of the support platform. It is also equipped with a rubberized pad to prevent sliding when weight is applied (Figure 20).
10. To remove the Open Frame™ Pelvic Support , grasp the support from the outside edges and pull straight up. You will meet resistance until the locking mechanism disengages from the Prone Platform.
11. The pads on the Pelvic Support have three adjustable distances. To adjust the pads in or out:
    a. Pull up on the tab located on the underside of each pelvic pad.
    b. Adjust each individual pelvic pad in or out to desired location.
    c. Pad will seat into one of three slots in the pelvic platen (Figure 24).

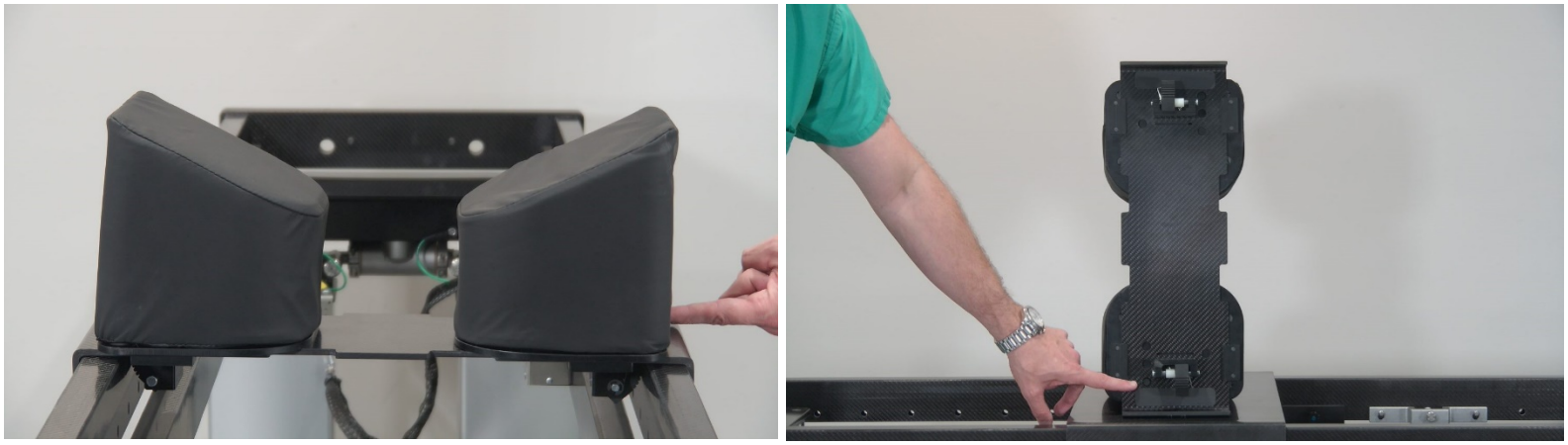


Figure 24: Adjusting the pelvic pads

12. To remove/exchange the pelvic pads from the Pelvic Support platen:
    a. Pull up on tab located on the underside of each pelvic pad.
    b. Adjust each individual pelvic pad toward the center until the pad is even with the notch in the Pelvic Support platen.
    c. Lift up on pad to remove.
13. Install the Knee Support (PN?) onto the Prone Platform.
    a. Place the Knee Support on the Prone Platform Rails and press down until fully seated.
    b. Adjust to desired location.
14. To remove the Knee Support, grasp the support from the outside edges and pull straight up. You will meet resistance until the locking mechanism disengages from the Prone Platform.
    a. The knee support pad is attached to the knee support platen with Velcro©.
15. Install the Ankle Support (PN)FM-10016 onto the Open Frame™.
    a. Place the Ankle Support on the Prone Platform Rails and press down until fully seated.
    b. Adjust to desired location
16. To remove the Ankle Support, grasp the support from the outside edges and pull straight up. You will meet resistance until the locking mechanism disengages from the Prone Platform.
    a. The ankle support pad is attached to the ankle support platen with Velcro©.

Figure 25: The Prone Platform with Chest Support, Pelvic Support, Knee Support and Ankle Support attached.

17. A Leg Sling (PN)FM-10033 may also be used in place of the Knee Support and Ankle Support. In order to use the Leg Sling:
    a. Remove both the Knee Support and the Ankle Support from the Prone Platform.
    b. To install an adjustable Leg Sling, place the sling over the Foot-End section of the Prone Platform. Feed the four straps through their respective buckles on the opposite side of the sling and secure. The sling should be adjusted for each patient. The straps on the sling consist of a double-sided hook and loop closure that allows for continuous adjustment along the length of the strap. 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 be folded over itself again to shorten, thereby raising the sling, and decreasing the degree to which the patient's hips are flexed. If the double-sided hook and loop closure is worn from repetitive use or misuse, replacement of the sling is required (Figure 26).
    c. Place two (2) or three (3) medical pillows in the sling approximately where the patient's lower legs will rest to achieve the desired amount of knee flexion and support.

Figure 26: Leg Sling installed on Prone Platform.

18. The Adjustable side rail of the FusionMAX™ Table allows for the attachment of arm boards to support the patient's arms and/or table attachments in the prone or supine position. To use the side rails:
    a. Remove the side rail locking mechanism (Figure 27) from the side rail.

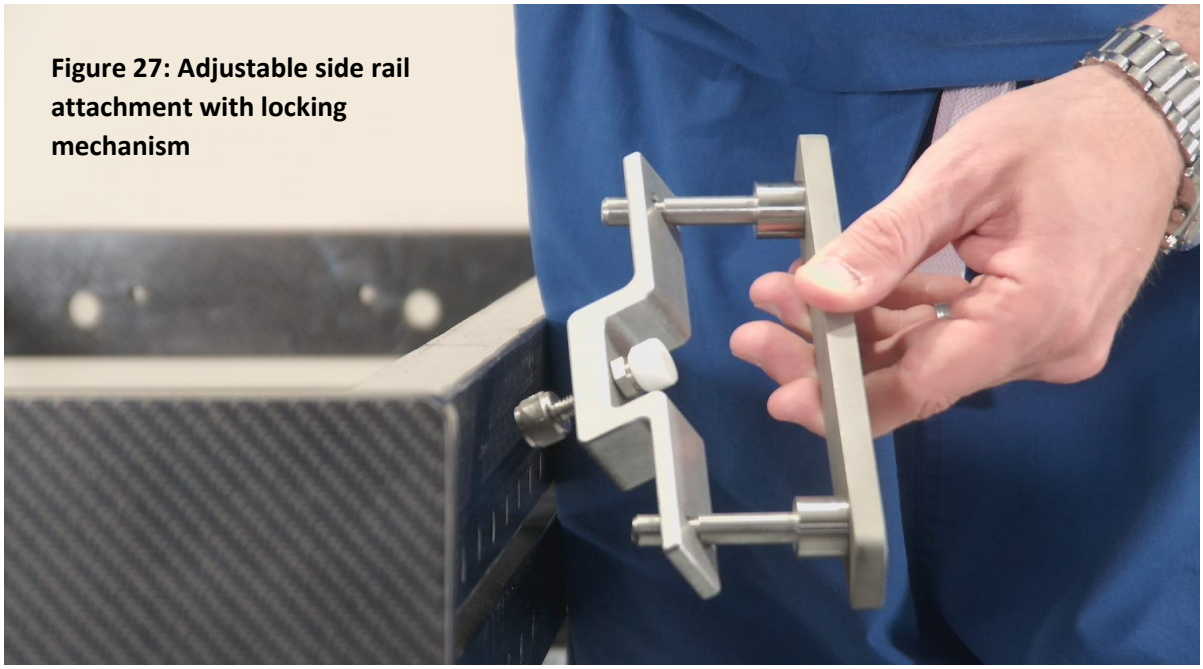


Figure 27: Adjustable side rail attachment with locking mechanism

    b. Insert the side rail into the holes on the Prone Platform where needed (Figure: 28).
    c. Place the side rail locking mechanism inside the Prone Platform and over the pegs making sure that the pegs are seated into the slots on the locking mechanism. Tighten the silver knob on the locking mechanism until side rail is secure (Figure 28).

Figure 28: Installation of FusionMAX™ Adjustable Side Rails

19. For the prone position, the arm board used must allow for the patient's arms to be positioned such that there is no more than 90 degrees flexion at the shoulder and no more than 90 degrees flexion at the elbow. To facilitate positioning of the patient's arms in the prone position, the FusionMAX™ Arm Boards (PN FM-10026) can be used. In order to use the FusionMAX™ Arm Boards:

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.

a. Engage the socket of the Arm Board onto the side rail of the FusionMAX™ Table, as shown in Figure 29.

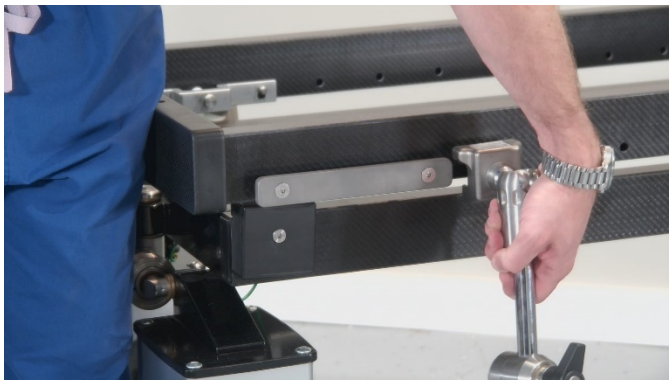


Figure 29: Engaging Arm Board onto the Side Rail

b. Lock the socket in place by firmly hand-tightening the locking screw, as shown in Figure 30.

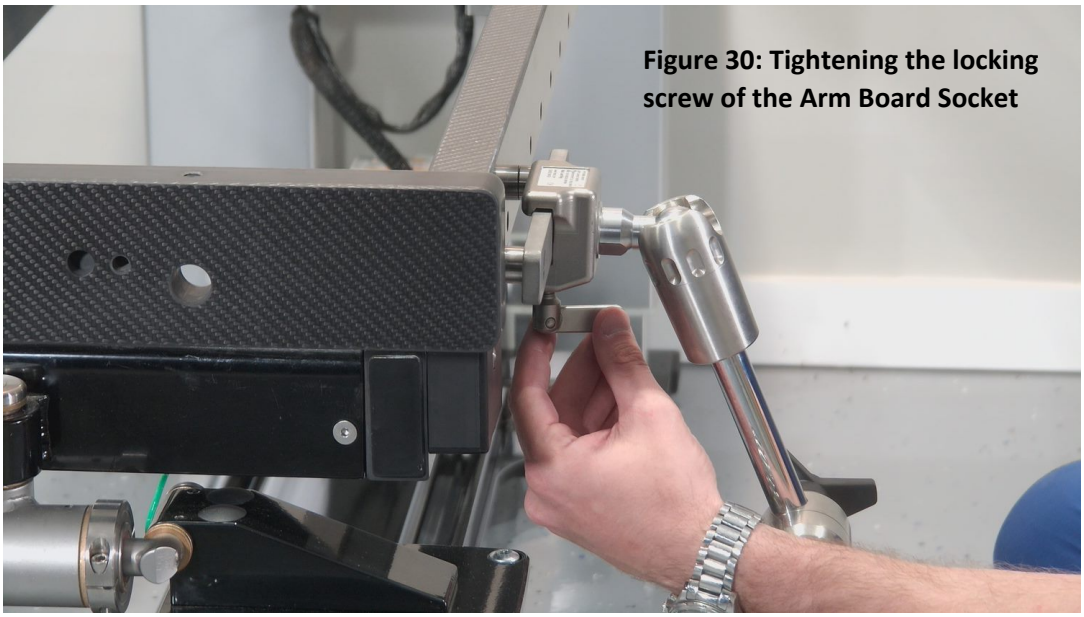


Figure 30: Tightening the locking screw of the Arm Board Socket

c. To position the Arm Board, grasp the Arm Board with one hand, while releasing the large black locking knob with the other. To release the locking knob, turn it counterclockwise (Figure 31).

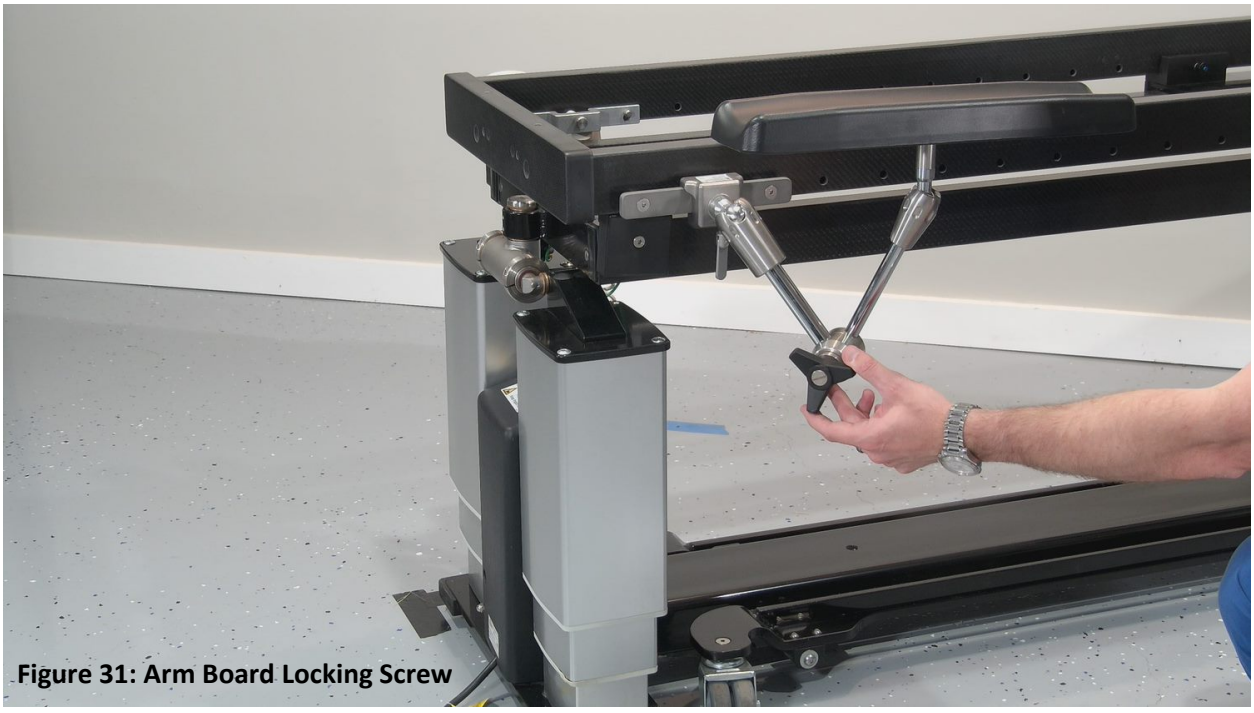


Figure 31: Arm Board Locking Screw

d. Once the locking knob has been fully released, the Arm Board will move smoothly in any direction. Move the Arm Board to the desired position, taking into account the position of the support arms and possible interference with other equipment or healthcare professionals.

 **WARNING: It is important to maintain positive control of the Arm Board and the patient's arm while adjusting the position of the Arm Board by releasing the locking knob. If the Arm Board and the patient's arm are not supported when the locking knob is released, the Arm Board and the patient's arm could fall, which may result in harm to the patient, the device, or the healthcare professional.**

e. When the Arm Board and support arms are in the desired positions, firmly tighten the locking knob by turning it clockwise until the Arm Board is rigid. Verify that the Arm Board is secure by pushing downward on the Arm Board. It should resist downward movement. If it does not, support the Arm Board with one hand and further tighten the locking knob with the other.
f. Place the patient's arm on the Arm Board, taking care to nest the forearm in the cradle of the Arm Board pad. Secure the patient's arm to the Arm Board with belts, Velcro® straps, or tape, in accordance with the institution's practice.

 **WARNING: If the patient's arm is not properly secured to the Arm Board, it could slip from the Arm Board, which may result in harm to the patient.**

g. Verify that there is no more than 90 degrees flexion at the shoulder and no more than 90 degrees flexion at the elbow. If adjustment of the patient's arm is required, repeat steps 10c through 0e above, taking care to maintain control of the patient's arm and the Arm Board during adjustment.

20. If using the ProneView® Mirror and Helmet System, place the Adjustable Mirror Platform with the ProneView® Helmet on the on the FusionMax™ Head Support. Ensure that the adjustable posts are in their lowest position in preparation for patient transfer. Fit 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.
21. If using a face pillow, place the pillow on the FusionMax™ Head Support.
22. Place the appropriate pad covers and arm board cushioning on the OpenFrame™ Chest and Pelvic pads, Knee Support, Ankle Support, and arm boards.
23. Trial position the imaging equipment if it will be used. If necessary, re-locate the FusionMAX™ Table in the room. Unlock the Table by using the Hand Pendant, and with the assistance of another person move the Table. When the Table is located where it will be used, lock the Table using the Hand Pendant.

NOTE: *The FusionMAX™ Spine Table is not for patient transport. The location of the Table relative to the imaging equipment must be confirmed prior to the patient being transferred to the Table.*

24. Position the patient bed or stretcher so the patient's anatomical landmarks are aligned with the support pads on the FusionMAX™ Table. It may be necessary to re-position a pad or component on the frame to align with the patient. Target landmarks for the pads are as follows:
    a. The Standard Chest Pad should be aligned so the top edge of the pad is at the patient's supra-sternal notch. Patient load should be borne by the superior aspect of the chest on the sternum. If the Heart Shaped Chest Pad is being used, position the indentation of the pad three finger widths below the supra-sternal notch. (Check on pad options here)
    b. The Pelvic Pads should be positioned such that the iliac crest is centered on the pad.
    c. The Knee Support should be positioned with the patient's knees resting fully in the middle of the support.
    d. The Ankle Rest should cradle the patient's ankles and provide separation of the feet.
25. The height of the patient bed or stretcher should be level with the top of the Chest Pad. 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 LATERAL TILT.
26. Lock the patient stretcher or bed. Confirm that the FusionMax™ Table is locked.
27. If using the ProneView® System, place the ProneView® Helmet with Cushion Insert on the patient's face. Ensure the patient's eyes are visible. With the assistance of others, log-roll the patient onto the FusionMax™ Table while supporting the patient's head, torso, and legs.

 **WARNING: Frequently monitor the patient's neck, head, eyes, nose, and mouth to ensure that a safe position is maintained, and the endotracheal tube is not kinked or displaced. Failure to do so can lead to serious adverse consequences, including blindness and failure to ventilate.**

 **WARNING: Failure to maintain neutral neck position can result in neck damage and/or chin abrasions. Skin contact with the materials in this product or compression during prolonged cases can result in erythema.**

28. DO NOT leave the patient unattended on the Table until after safety straps are in place.
29. Remove the patient bed or stretcher while supporting the patient on the Table.
30. If using the ProneView® Helmet, confirm that the patient's face is seated in the Cushion Insert. 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 of the mirror. There is 1 inch (2. 5 cm) of adjustment available.
31. Visually confirm the placement of the Chest Pad. When positioned correctly, the notch in the center of the Heart Shaped Pad should rest three (3) finger widths below the patient's anatomical landmark, the supra-sternal notch. The Standard Chest Pad should be aligned so the top edge of the pad is at the patient's supra-sternal notch. Breasts should be down and lying flat with the nipples oriented towards the Foot-End of the

Table. The Disposable 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, move the Chest Pad to the desired location. The patient should then be lowered back onto the Chest pad with care.

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

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

32. 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. Confirm that the patient's arms are positioned so there is no more than 90 degrees flexion at the shoulder and no more than 90 degrees flexion at the elbow.

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

33. Visually confirm the placement of the Pelvic Pads. When positioned correctly, the patient's anatomical landmark, the right and left iliac crests, should rest in the center of the respective right, and left Pelvic Pads. The Disposable Kit Pelvic Pad Cover should be smooth against the patient's skin. Ensure that the patient's skin is smooth and flat against the Disposable Kit Pelvic Pad Cover. If necessary, re-position the Pad.

 **WARNING: Failure to ensure that the patient is positioned correctly on the Pelvic Pad may result in harm to the patient or the device.**

34. Visually confirm the position of the Knee Support and Ankle Support. The patient's knees should rest in the center of the Knee Support. The Ankle Rest should cradle the patient's ankles and provide separation of the feet.

 **WARNING: Failure to ensure that the patient is positioned correctly on the Knee Support or Ankle Support may result in harm to the patient.**

35. Place a buttocks strap (PN)FM-HS across the lower gluteal area of the patient. 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 that it

surrounds both Pelvic Pads, 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.

36. Apply a restraining Safety Strap over the patient's lower legs.

NOTE: *Due to the open nature of the FusionMAX™ Table 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.*

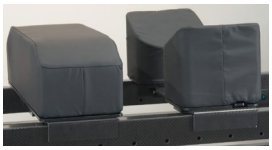
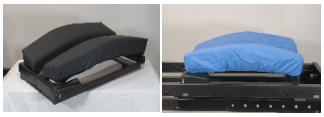
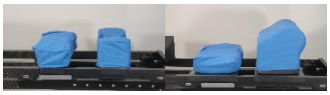
 **WARNING: Proper pre-operative and intra-operative procedures must be followed to prevent venous stasis and pooling, pressure sore development, neuropathy, improper electrosurgical tissue grounding, hypotension, and hypothermia.**

 **WARNING: Use care and monitor the patient when changing the position of the FusionMAX™ Table (Height Up/Down, Trendelenburg/reverse Trendelenburg, and Lateral Roll) to ensure that the patient or Table do not interfere with other equipment. Failure to do so may cause harm to the patient or device.**

37. Confirm that the patient is in the final position.
38. Should any retractors be required, they may be attached directly to the Adjustable Side Rail on the FusionMAX™ Table.

NOTE: *All non-Surgix Medical Technologies accessories, including retractors, should be assessed by the user.*

8.1.1 Components Used for Prone Positioning

FusionMAX™ Table Base  **(PN)? FusionMAX™ Table Base with neither operating platform**	**Prone Platform**  **(PN)? Prone Platform must be installed onto FusionMAX™ Table Base for use**	**Head Rest Support**  **(PN)FM-10027 Support for the patient's head while in the prone position**
Arm Board  **(PN)FM-10026 FusionMAX™ Arm Board**	**OpenFrame™ Spine Platform**  **(PN)? Chest Support Frame(left) and Pelvic Support Frame(right)**	**Knee Support**  **(PN)? Reusable Knee Support**
Head Support Tray  **(PN)FM-10041 Head Support Tray**	**Optional Accessory**  **(PN)FM-10017 Reusable Thigh Pad**	**Optional Accessory**  **(PN)FM-10016 Reusable Ankle Rest**
Optional Accessory  **(PN)FF-30011U FlexFrame™ Spine Platform** **(PN)FF-30017 FlexFrame™ Disposable Kit**	**Optional Accessory**  **(PN)FM-10033 Leg Sling**	**Optional Accessory**  **(PN)OF-40024 OpenFrame™ Disposable Kit** **(PN)FM-10042 Leg Management Disposable Kit**

8.2 FusionMAX™ Table Supine Patient Positioning

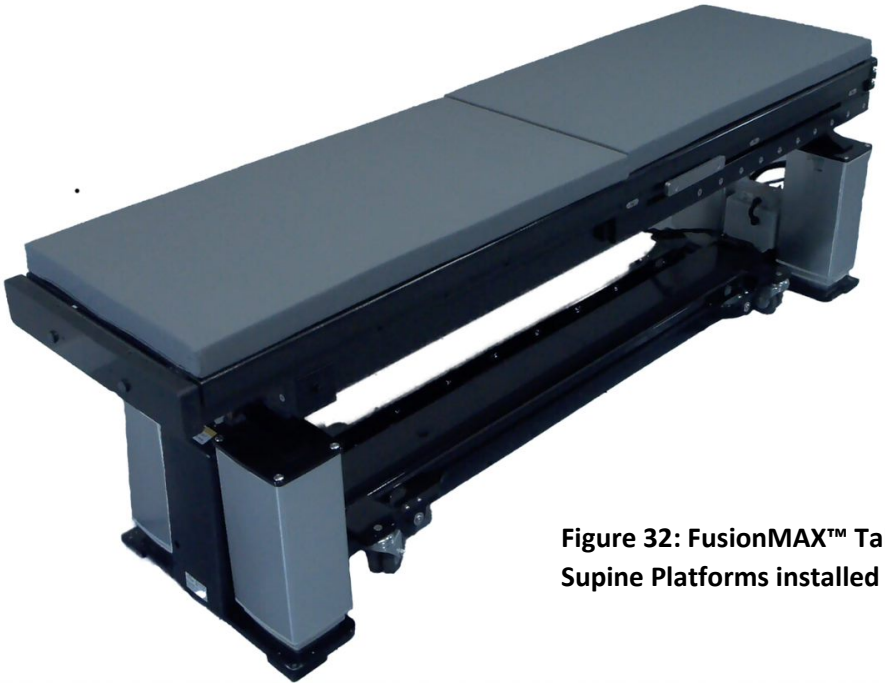


Figure 32: FusionMAX™ Table with Supine Platforms installed

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 FusionMAX™ Table is prepared for set-up (see Section 8). When the patient is to be in the supine or lateral position, the Supine Platforms should be installed onto the Table Base, as shown in Figure 26.
    a. Remove all prone positioning pads and devices and store appropriately.
2. Place the two(2) Supine Platforms on the Table base.
    a. To install the Supine Platforms place one end of an individual Supine Platform on the Prone Platform rails at an angle.
    b. Line up the edge of the Supine Platform with the edge of the Prone Platform Rails and lower platform into place until fully seated. The Supine Platform is locked to the table using rubberized grips located on the underside of the support platform. It is also equipped with a rubberized pad to prevent sliding when weight is applied
    c. Repeat with the second Supine Platform at the opposite end of the Table.

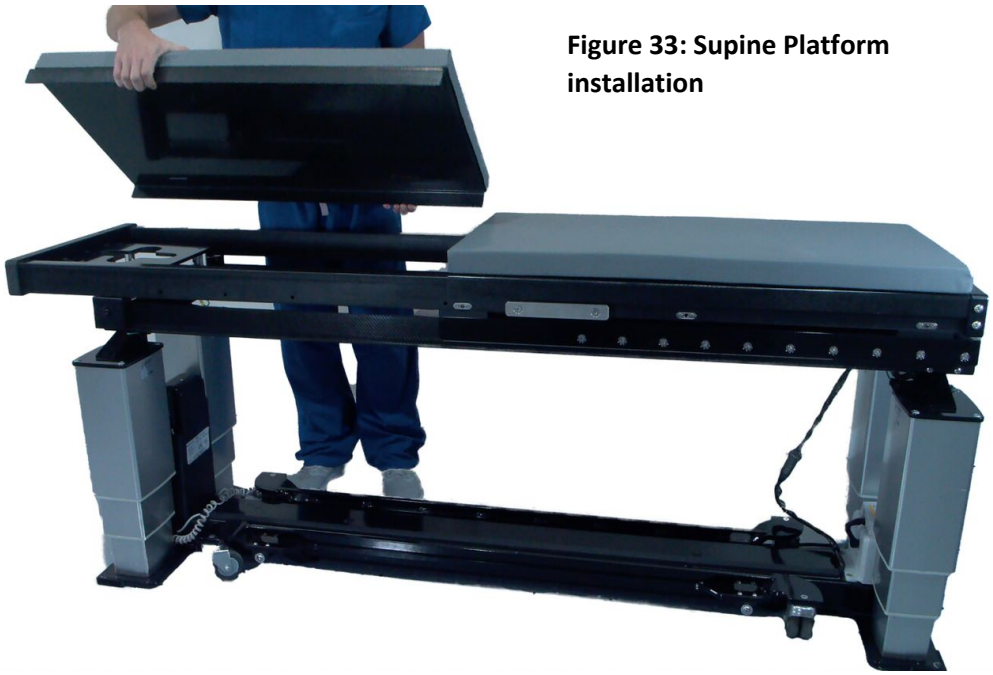


Figure 33: Supine Platform installation

3. Confirm that the Table is locked.
4. Trial position the imaging equipment if it will be used. If necessary, re-locate the FusionMAX™ Table in the room. Unlock the Table by using the Hand Pendant, and with the assistance of another person move the Table. When the Table is located where it will be used, lock the Table using the Hand Pendant.
5. To remove the Supine Platforms, grasp the support from the outside edges and pull straight up. You will meet resistance until the locking mechanism disengages from the Prone Platform.
   NOTE: *The FusionMAX™ Spine Table is not for patient transport. The location of the Table relative to the imaging equipment must be confirmed prior to the patient being transferred to the Table.*
6. Position the patient bed or stretcher so that the patient is aligned with the tabletop. The height of the patient bed or stretcher should be level with the top of the table pad.
7. Lock the patient stretcher or bed. Confirm that the FusionMAX™ Table is locked.
8. Transfer the patient in a supine position using a standard drawsheet method.
9. Accessories such as the FusionMAX™ Arm Board, Clark Socket with Cross Arm Support, Rail Mounted IV Pole, Drape Rod, and Universal Foot Board can be mounted on the side rail.
10. Secure the patient with restraining safety straps.

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/hypertension, and hypothermia.

WARNING: Use care and monitor the patient when changing the position of the FusionMax™ Table (Height Up/Down, Trendelenburg/reverse Trendelenburg, and Lateral Roll) to ensure that the patient or Table do not interfere with other equipment. Failure to do so may cause harm to the patient or device.

8.2.1 Components Used for Supine Patient Positioning

FusionMAX™ Table Base	Supine Platforms and Pads	Arm Board
		
(PN)? FusionMAX Table Base with Prone Platform	(PN)? Supine Platform (PN)? Supine Pads	(PN)? FusionMax™ Arm Board

8.3 Cranial Stabilization with the FusionMAX™ Spine Table

The FusionMAX™ Spine Table can accommodate a variety of procedures that require cranial stabilization and/or traction. These include but are not limited to:

1. Posterior Cervical Procedures utilizing a Mayfield® or DORO® skull clamp.
2. Cranial Procedures utilizing a Mayfield® or DORO® skull clamp.
3. Posterior Procedures utilizing rope traction.
4. Anterior Cervical Procedures utilizing rope traction.

NOTE: *All non-Surgix Medical Technologies, including the various types of cranial stabilization systems discussed in this section, should be assessed by the user.*

NOTE: *The Rope Traction Device (PN)FM-10020 is not a standard component of the FusionMAX™ Spine Table. It is sold separately.*

NOTE: *Cranial stabilization systems, such as the ones shown in Figure 34 Are not manufactured by Surgix Medical Technologies. The correct selection and use of such equipment is the responsibility of the user.*

Figure 34: Example Aluminum Base Unit

8.3.1 Posterior Cervical Procedures utilizing a Mayfield® or DORO® Skull Clamp

The FusionMAX™ Table can accommodate the standard base units of most cranial stabilization systems (see Figure 34) to support posterior cervical procedures.

NOTE: *Refer to the manufacturer's instructions for the correct use of the base unit and associated equipment.*

WARNING: All personnel involved in the equipment set up and patient positioning for cranial stabilization cases must be trained in the safe and proper use of the equipment.

WARNING: For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled via the ON/OFF switch on the control box, located at the Foot-End of the Table.

To set up the FusionMAX™ Table for posterior cervical procedures with cranial stabilization:

1. Confirm that the FusionMAX™ Table is prepared for set-up with the Prone Platform installed (see Section 8.1). When the patient is to be positioned using a cranial stabilization system such as a Mayfield® or DORO® skull clamp, the FusionMAX™ head support system is not necessary. If the head support is installed, remove it from the Table and set it aside. The remaining prone components should be attached as described in Section 8.1.
2. Confirm that the Table is locked.
3. For posterior cases utilizing a skull clamp, it will be necessary to install the cranial stabilization base unit into the FusionMAX™ Frame (Figure? GET PICS OF THIS!!!) To mount the base unit to the Table, follow these steps:
    a. Press and hold the EXTEND CANTILEVER button on either Hand Pendant to fully extend the cantilever of the Table. Continue to hold the button until motion stops. DO WE REALLY NEED TO FULLY EXTEND?
    b. Insert the cranial stabilization base unit into the holes at the head of the Prone Platform and tighten black knobs below the Prone Platform until base unit is secure. Attach base unit components per manufacturer instructions as needed.

Insert pics of base unit install here Figure 35

c. For radiolucent side rail base units, attach side rails to both sides of the Head-End Prone Platform. Install radiolucent base unit per manufacturer instructions.

Insert pics of radiolucent install here Figure 36

4. Verify that the entire assembly is secure by tugging outward on the base unit.

WARNING: When the base unit is installed as shown in Figure 35, the cranial stabilization system will support the patient's head from underneath the Prone Platform. DO NOT RETRACT CANTILEVER WHEN IN THIS POSITION. Retracting cantilever could cause the cranial stabilization system to impact the Head-End columns and may result in serious harm to the patient and damage to the equipment.

WARNING: All personnel involved in the equipment set-up and patient positioning for cranial stabilization cases must be trained in the safe and proper use of the equipment.

WARNING: For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled via the ON/OFF switch on the control box, located at the Foot-End of the Table.

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/hypertension, and hypothermia.

8.3.2 Cranial Procedures utilizing a Mayfield® or DORO® Skull Clamp

For cranial procedures, the FusionMAX™ Table can be configured to replicate a general surgery table with a flat, padded surface and the ability to accommodate a standard cranial stabilization base unit off the end of the Table. The FusionMAX™ Table can accommodate the standard base units of most cranial stabilization systems. A benefit of the FusionMAX™ Table for this type of procedure is its low (22 inch/ 55.9 cm) height, possibly enabling a surgeon to sit down during the surgery.

WARNING: Do not put the Table in a cantilevered position when utilizing the set-up described in this section. Cantilevering the Table could result in damage to the Table, possible injury to the patient, or harm to a healthcare professional. (CHECK ACCURACY OF THIS BEFORE KEEPING)

WARNING: All personnel involved in the equipment set-up and patient positioning for cranial stabilization cases must be trained in the safe and proper use of the equipment.

WARNING: For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled via the ON/OFF switch on the control box, located at the Foot-End of the Table.

NOTE: *Cranial stabilization systems, such as the one shown in Figure 34, are not manufactured by Surgix Medical Technologies. The correct selection and use of such equipment is the responsibility of the user.*

NOTE: *Refer to the manufacturer's instructions for the correct use of the base unit and associated equipment.*

1. Confirm that the FusionMAX™ Table is prepared for set-up with the Supine Platform installed (see Section 8.2)
2. Confirm that the Table is locked.
3. Insert the cranial stabilization base unit into the holes at the head of the Prone Platform and tighten black knobs below the Prone Platform until base unit is secure. Attach base unit components per manufacturer instructions as needed.

Insert pics of supine cranial stabilization here figure 37

a. For radiolucent side rail base units, attach side rails to both sides of the Head-End Prone Platform. Install radiolucent base unit per manufacturer instructions.

Install pics of radiolucent here figure 38

4. Verify that the entire assembly is secure by tugging outward on the base unit.
5. The Mayfield® or DORO® skull clamp can be used in accordance with the instructions for use of those devices.

8.3.3 Posterior and Anterior Cases utilizing Rope Traction

The FusionMAX™ Table can be equipped with a Rope Traction Device (PN)FM-10020. The set-up of the Rope Traction Device, illustrated in this section is the same for the Prone Platform and the Supine Platforms.

Pic of rope traction device here figure 39

Be sure to include arrow with rope traction adjustment button

WARNING: All personnel involved in the equipment set-up and patient positioning for cranial stabilization cases must be trained in the safe and proper use of the equipment.

WARNING: The Rope Traction Device (PN)FM-10020 is to be used with the FusionMAX™ Table only. Use of the Rope Traction Device with any other mounting apparatus could result in damage to the Table, possible injury to the patient, or harm to the healthcare professional.

WARNING: For procedures where unintended motion creates a severe risk to the patient, the Table motion hand controls may be disabled via the ON/OFF switch on the control box, located at the Foot-End of the Table.

WARNING: Use of the Rope Traction Device (PN)FM-10020 with more than 100 lbs. (45.3 kg) of traction weight could result in damage to the Table, possible injury to the patient, or harm to the healthcare professional.

NOTE: *The Rope Traction Device (PN)FM-10020 is not a standard component of the FusionMAX™ Table. It is sold separately.*

NOTE: *Other rope traction equipment, such as Gardner Wells Tongs and chin slings, are not manufactured by Surgix Medical Technologies. The correct selection and use of such equipment is the responsibility of the user.*

8.3.3.1 Posterior Cases Utilizing Rope Traction

The following instructions provide the steps for installing the Rope Traction Device on the Prone Platform.

1. Confirm that the FusionMAX™ Table is prepared for set-up with the Prone Platform installed (see Section 8.1).
2. Confirm that the Table is locked.
3. Insert the base of the Rope Traction Device into the vertical slot located on the Head-End of the Table until fully seated.
4. Tighten the Rope Traction Device retaining knob.

Insert pics of rope traction installed here figure 40

5. Verify that the entire assembly is secure by tugging up and outward on the Rope Traction Device.
6. Once the Rope Traction Device is securely installed, the angle of traction can be adjusted by fully depressing the Rope Traction Angle Adjustment (release) button on the Rope Traction Device, moving the traction arm to the desired angle, and releasing the button to lock it in place, as shown in Figure 39.
7. Cantilever the Table as necessary to achieve desired imaging equipment access.

8.3.3.2 Anterior Cases Utilizing Rope Traction

The following instructions provide the steps for installing the Rope Traction Device on the Supine Platforms.

1. Confirm that the FusionMAX™ Table is prepared for set-up with the Supine Platforms installed (see Section 8.1).
2. Confirm that the Table is locked.
3. Insert the base of the Rope Traction Device into the vertical slot located on the Head-End of the Table until fully seated.
4. Tighten the Rope Traction Device retaining knob (Figure 39).
5. Verify that the entire assembly is secure by tugging up and outward on the Rope Traction Device.
6. Once the Rope Traction Device is securely installed, the angle of traction can be adjusted by fully depressing the Rope Traction Angle Adjustment (release) button on the Rope Traction Device, moving the traction arm to the desired angle, and releasing the button to lock it in place, as shown in Figure 39.
7. Cantilever the Table as necessary to achieve desired imaging equipment access.

8.3.4 Optional Accessories Used for Cranial Stabilization

Rope Traction Device

(PN)FM-10020

9 FusionMAX™ Table Optional Accessories

Many optional accessories are available for use on the FusionMAX™ Spine Table.

For more information, please contact Surgix Medical Technologies (see Section 12).

9.1 Optional Accessories

(PN)FM-10020 Rope Traction Device	For use only with FusionMAX™ Spine Table. Maintains alignment of traction rope when cervical traction is utilized
(PN)FF-30011U FlexFrame™	For use on Prone or Supine Platforms
(PN)FF-30017 FlexFrame™ Disposable Kits (case of 20)	Two(2) fabric pad covers, two(2) foam pads per kit, case of 20 kits
(PN)OF-40024 Open Frame™ Disposable Kits (case of 20)	One(1) fabric chest pad cover, two(2) fabric pelvic pad covers per kit, case of 20 kits
(PN)FM-10042 FusionMAX Leg Management Disposable Kits (case of 20)	One(1) fabric ankle rest cover, one(1) fabric thigh pad cover per kit, case of 20 kits

9.2 Use and Installation

9.2.1 FlexFrame™

> **NOTE:** *A thorough understanding of the use of the FusionMax™ Table and FlexFrame™ are required prior to use and patient transfer. For complete instructions on preparing the FlexFrame™, refer to the respective Owner's Manual, which provides detailed information regarding set-up, cleaning, and maintenance.*

The FusionMax™ FlexFrame™ (PN)FF-30011U may be used in place of the Chest and Pelvic Pads for positioning on the Prone Platform. The standalone FlexFrame™ may be used on the Supine Platforms or any flat top surgical table. The FlexFrame™ provides a convenient and stable method of maintaining patients in a flexed position for lumbar procedures. The spinal flexion frame has a patient weight capacity of 675 lbs. (307 kg).

The FlexFrame™ may be used for laminectomy, decompression, or microdiscectomy surgeries. Refer to the FlexFrame™ Owner's Manual for complete instructions on installing the frame.

Figure 41: FusionMAX™ Prone Platform with the FlexFrame™ Spine Platform (PN)FF-30011U installed

10 Cleaning, Storage, and Maintenance

10.1 Cleaning and Disinfecting

10.1.1 Table Exterior

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 tabletop.

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 FusionMAX™ Table. Never subject the FusionMAX™ Spine Table 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. A 5% acetic acid solution or white vinegar and water solution is especially good for this purpose.

> **NOTE:** *The pads for the accessories associated with the FusionMAX™ Table should be stored with care. Flat pads should always be stored in a flat position. Shaped pads should be stored in a location that minimizes risk of puncture or damage.*

DO NOT lift, slide, or carry the FusionMAX™ Table Pads by grabbing the fabric cover. The cover may tear or rip. If the fabric cover is punctured, torn, or ripped, the pad should be replaced.

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.

Clean the pad or the tabletop and wipe dry with a lint free cloth then reposition the pad to flat on the tabletop.

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

10.1.2 Prone Platform Removal

The Prone Platform can be removed from the Table base for cleaning. To remove the Prone Platform, follow the instructions below:

1. Remove all prone pads and head supports from the platform.
2. There are four (4) Prone Platform locking mechanisms located at the Foot-End of the bed (Figure?).

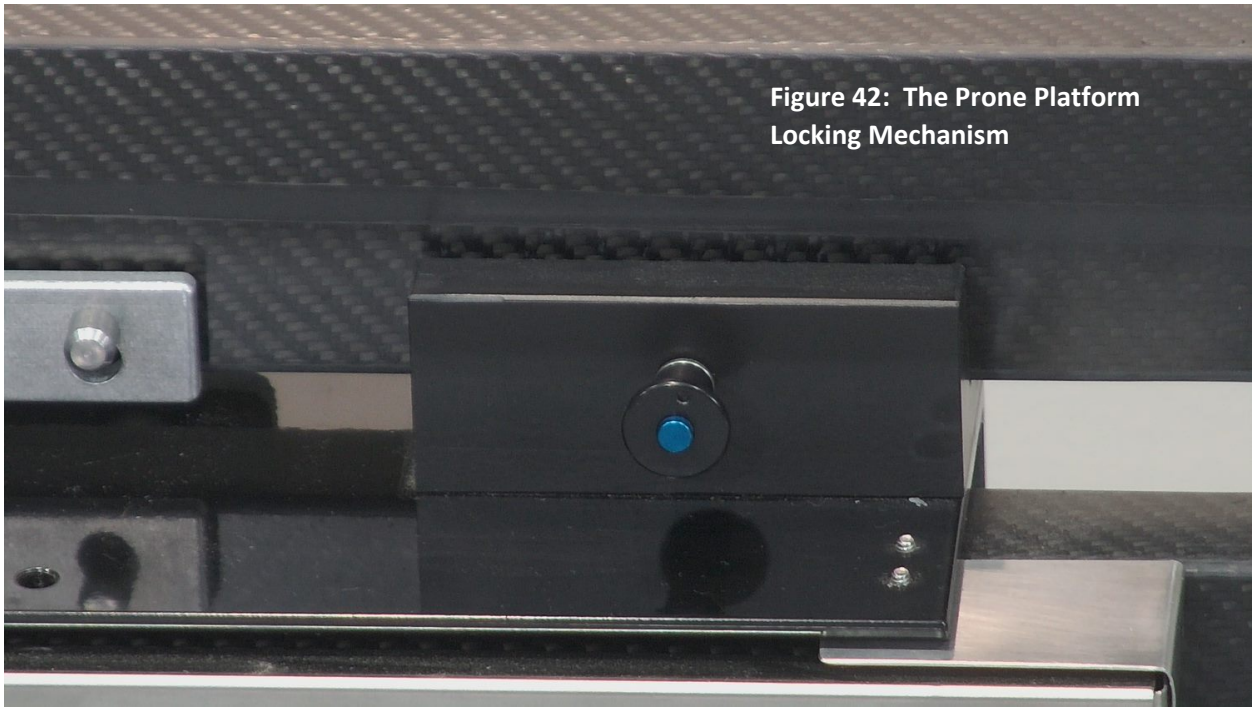


Figure 42: The Prone Platform Locking Mechanism

3. To Release, press the blue button in the center of the pin mechanism while simultaneously pulling the pin until it is completely removed from the locking mechanism.
4. Repeat this for all four (4) locking mechanisms.
5. Lift Prone Platform from the Table Base and clean as needed.
6. After cleaning, replace the Prone Platform and reinsert the pins into the Locking Mechanism.

Figure 43: FusionMax™ Table Base with Prone Platform removed

10.2 Storage

When not in use, the FusionMAX™ Table should be stored in a clean, dry environment.

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

Ambient temperature 15° F (-10°C) to 120° F (50°C)

Relative humidity from 20% to 80% at 85° F

Barometric pressure 20.7 to 31.3 in Hg (700 to 1060 hPa)

When in storage, a table cover serves as a dust cover and should be used. Also, to ensure that the battery is always fully charged and ready for use, store the Table connected to AC power which matches the ratings on the Ratings Label at the Head-End of the Table (Figure 44).

10.3 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 is required. The battery should be replaced every three (3) years.

No other specific maintenance tasks are required.

Preventative Maintenance:

Contact Surgix Medical Technologies for a complete preventative maintenance checklist.

11 Electrical System

11.1 Description

The electrical system provides control of all the Table functions and is comprised of the following:

- Power Cord
- Control Panel
- Control Box
- Power Supply
- Controller Circuit
- Two (2) Hand Pendants
- Four (4) Lifting Columns
- Safety Sensor Assembly
- 100-mm Electromechanical Actuator
- 300-mm Electromechanical Actuator
- Back-up Battery

Electric motor driven lead screw-type actuators	Manipulate the Height, Lateral Tilt, and Trendelenburg functions; are controlled by the Hand Pendant.
Floor Lock buttons	Raise and lower the Table Floor Locks.
Input power requirement for the FusionMAX™ Table	120V, 5A, 60Hz; 230V, 2.5A, 50Hz, as indicated on the Ratings Label (Figure 52).

Figure 44: Ratings information includes (minimum)

- **Part Number**
- **Mains Power Requirement**
- **Duty Cycle**

11.2 Grounding and Power

The FusionMAX™ Table does not have an electrical on/off switch. The ON/OFF switch located on the control box at the foot of the table enables/disables all controls to the table. It does not disconnect power from the table.

The FusionMAX™ Table must be grounded. In the event of electrical malfunction or breakdown, grounding provides a path of least resistance for electrical current and reduces the risk of electrical shock. This product is equipped with a cord having an equipment grounding conductor and a grounding plug. The plug must be plugged into an appropriate outlet that is properly installed and grounded in accordance with all local codes and ordinances. Make sure that the product is connected to an outlet having the same configuration as the plug.

To disconnect the Table from electrical power, remove the plug from the outlet. Be sure access to the plug is not obstructed in a way that would prevent a user from disconnecting the Table from power.

WARNING: This symbol indicates an external ground post 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, or when the table is in use under battery power. Failure to ensure ground may cause harm to the patient, healthcare worker, or the Table.

To confirm Table grounding from the plug to the metal Table, use the ground post located on the base at the Head-End of the Table (see Figure?). Connect tester to the ground post and the plug.

11.3 Safety Sensor Switches

The Table can be manipulated to different heights, degrees of lateral tilt, and degrees of Trendelenburg with the use of the Fixed Control Panel or Hand Pendants. It is important for the lifting columns to remain synchronized throughout such motions. If a column were out of sync with the others, certain motions might cause the out of sync column to damage the table. To prevent such an occurrence, each of the columns is equipped with a primary and secondary safety sensor assembly. The safety sensors are tripped by an unsafe condition and will temporarily disable the controls of the Table. To restore the Table function, follow the "Manual Reset Procedure" in Section 4.3.3.

11.4 Power Cord

The table is equipped with a standard IEC Power Cord with the appropriate hospital grade connector. The Power Cord is connected at the Head-End of the Table. The connection is encased by a black plastic cover. The cover is held in place by the acorn nut that acts as the grounding plug and by a single screw at the top.

11.5 Table Lock System

The FusionMAX™ Table is locked to the floor when its wheels are completely disengaged. The FusionMAX™ Table is unlocked when the wheels are lowered to the ground and the table is supported entirely by the wheels. The movement of the wheels upward (to lock the Table) and downward (to unlock the Table) is driven by the 100-mm electromechanical actuator.

The lock system is operated by pressing and releasing the WHEELS button located on the Fixed Control Panel or on either Hand Pendant.

The Table can be locked and unlocked by pressing the WHEELS button on either Hand Pendant or the Fixed Control Panel. To LOCK/UNLOCK the Table:

- Press any button on the Hand Pendant to activate it from sleep mode. Not that the hand pendant illuminates to indicate that it is activated.
- Press the WHEELS button once and release.
    - If LOCKING the table from an unlocked state the wheels of the Table will raise up slowly, gradually placing the base of the Table on the ground. The Table will emit a beeping noise to warn caregivers to keep feet, hands, and equipment clear of the Table as it lowers.

 **WARNING: There is a pinch point between the Table Base and the floor as the Table is lowered to the floor. Be mindful of caregiver toes and equipment cables before lowering the Table to the floor.**

- If UNLOCKING the Table from a locked state, the wheels lower to the ground slowly gradually lifting the Table.

NOTE: *The initial motion of the wheels is very subtle. To prevent confusion, press the WHEELS button only once and release.*

- When unlocking the table, if the user pushes the WHEELS button again before the Table is unlocked, this action will arrest the downward motion of the wheels. The next time the user presses the WHEELS button, the wheels will retract (locking the Table), and the Table will beep
- To unlock, simply wait until the beeping stops (indicating the Table is fully locked again), then press the WHEELS button once and release.
- Observe that the WHEELS button light on the Fixed Control Panel will illuminate immediately after the Table receives the UNLOCK command, signifying that the Table is engaging the wheels and unlocking the Table.

NOTE: *If the Table is unlocked and a user attempts to manipulate the Table (raise, lower, tilt left or right, Trendelenburg or reverse Trendelenburg, cantilever) the Table will lock itself. To do so, it will lower to the ground, emitting a beeping noise to warn nearby personnel of a pinch hazard between the base of the Table and the floor.*

11.6 Power Supply -AC & DC Operation

The system power supply converts AC power, 120V, 60 Hz or 230V, 50Hz into 24VDC (nominal) operational power

11.7 Battery System

The Table uses a 24V battery. The Battery Indicator Light, located on the Fixed Control Panel at the Foot End of the Table, indicates the status of the battery:

- Charged = solid amber
- Low Voltage = blinking amber
- No Voltage = no light

NOTE: *The power cord must be disconnected from mains voltage for the Battery Indicator Light to indicate the status of the battery.*

The 24V battery is intended to power the Table in the event of mains power failure. The battery is not to be used as the primary power source. The Table should be plugged into hospital grade mains power whenever in use.

It is recommended that the battery be replaced after three (3) years (four years maximum), dependent on the pattern of use (frequent and high-powered discharges reduce the battery life). The battery must be replaced only with the manufacturer's defined replacement. Failure to replace

with the original equipment may result in voiding your warranty and may harm the patient, staff, or the device.

If the Table is to remain unused for a period of greater than three (3) months, it is recommended to remove the battery.

NOTE: *Failure to use an approved Surgix Medical Technologies battery voids the warranty and can cause harm to the Table.*

12 Surgix Medical Technologies Customer Support

12.1 Contact for Customer Support

For customer support please contact Surgix Medical Technologies between the hours of 7AM and 5:30 PM CST Time, Monday through Friday: 888-247-0477.

Alternatively, email: customerservice@surgixmedical.com or fax: 346-510-4823.

For technical support please contact Surgix Technical Support at 346-971-5753.

Alternatively, email: wcarter@surgixmedical.com.

12.2 Technical Support and Return of Parts

Prior to contacting Surgix Medical Technologies and if possible, please photograph or identify the part or part number of interest. The part number or an image of the product will speed the diagnosis of the problem.

In the event that return of a product or part is necessary, please contact Surgix Medical Technologies for a Return Goods Authorization (RGA) number. Decontaminate the product or part and complete the Certificate of Decontamination provided by Surgix Medical Technologies. Return part with RGA number clearly marked on outside of package and include the Certificate of Decontamination with the shipment.

12.3 Sales

For all sales related inquires including in-servicing and product training, please contact your local sales representative or call Surgix Medical Technologies at 888-247-0477.

12.4 Warranty

Surgix Medical Technologies guarantees its products for a period not to exceed one (1) year from date of invoice for defects in material and workmanship, with the exception of products which are misused, altered, or damaged. Defective merchandise will be credited or replaced.

12.5 IFU Information

In case of loss, a link to the electronic copy of the complete IFU can be found at www.surgixmedical.com. A QR code with a direct link to the electronic IFU is located on the table itself (insert location once decided).

13 Appendix

13.1 Electromagnetic Emissions and Immunity

The FusionMAX™ Spine Table was tested in accordance with the applicable standards for electromagnetic emissions and immunity. The below testing certification documents the test specifications from the applicable IEC/EN 60601-1-2:2007 standards. The customer or user of the FusionMAX™ Spine Table should assure that it is used in an appropriate electromagnetic environment.

Insert certificate here