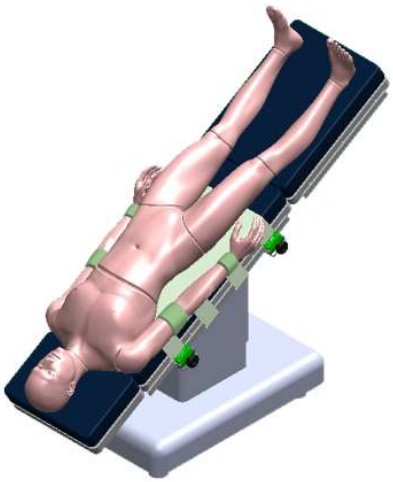
Innovative Medical Products™

Positioned to Perform

Instructions For Use

TrenMAX®

TRENDELENBURG POSITIONING GEL SHEET



Catalog Number **415**

Doc Title **IFU-IMP-0004**

Version **2**

Intended Use/Intended Users: TrenMAX® is a medical device used to position a patient in Trendelenburg or Reverse Trendelenburg with little to no movement while holding the patient's arms to their side and allowing access for the OR personnel. Surgeons are the intended users.

Target Patient Group: Any patient that must be in Trendelenburg or reverse Trendelenburg position that weighs between 100 and 370 pounds and exhibits normal spine curvature.

Contraindications: Patients who should not be placed in Trendelenburg or reverse Trendelenburg should not use TrenMAX®. Examples include:

- Patients with spinal cord injuries may not be suitable candidates for the Trendelenburg position, as it can lead to changes in blood pressure and autonomic dysreflexia.
- Severe Lower Extremity Edema: In cases of severe lower extremity edema, the Trendelenburg position may not be effective and can potentially worsen the edema.
- Patients with unstable fractures should not be placed in Trendelenburg or reverse Trendelenburg as it can exacerbate the instability or cause further injury.

Warnings/Precautions

- Do not use device in a manner that doesn't follow these instructions for use
- Untrained personnel - review and understand the IFU
- Incorrect set up – follow IFU
- Single use

Risks:

- Hook and Loop Failure
- Clamp Failure
- Pooling of body fluids between the legs and lower back.
- Oils / lotions on patient skin may create poor contact with Phase 4 Gel®.

Complaints and Adverse Events: For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country.

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Product Identification:

Part No	Product Name	GTIN
415	TrenMax® Pad	00696588006277

Consumables: Not Applicable

Disposal of unit:
If a device is being returned for repair or disposal, please contact Innovative Medical Products at sales@IMPmedical.com. If the device is not being returned, instruments are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state, and local regulations.

Acceptable Accessories:

Part No	Product Name	GTIN
415-215	TrenMAX® Clamp	00696588006291
415-EXT	TrenMAX® Extensions	00696588006086
415-ABX	TrenMAX® Arm Board Extension	00696588002972

Symbol Glossary

Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified. The manufacturer's catalog number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
⚠	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.	ISO 15223-1:2016
CE	Complies with European Directives.		
	Consult instructions for use		ISO 15223-1:2016
	Date of manufacture	The date must be presented in the following format: YYYY-MM-DD	FDA 21 CFR 801
	Keep Dry		ISO 15223-1:2016
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
MD	Medical device		ISO 15223-1:2016

Symbol	Title	Description	Standard
LATEX	Not made with natural rubber latex		Manufacturer defined
SN	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

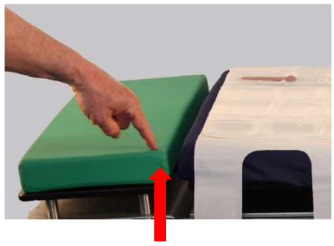
1. Remove contents from the package and place green straps on back table.

2. **With Stirrups**

Open the TrenMAX® Positioning Gel Sheet and position the distal edge approximately 3 inches (76mm) from the peroneal cutout of the OR table pad leaving space on the side rail to attach the stirrups.

Without Stirrups

Open the TrenMAX® Positioning Gel Sheet and position the sheet on the proximal edge of the Center Pad (next to the Head Pad) of the OR table.



Head Pad

3. Position the (4) white straps between the OR table and the side rail.

4. Lift gel sheet exposing the black hook material and attach the white strap to the lower black hook.

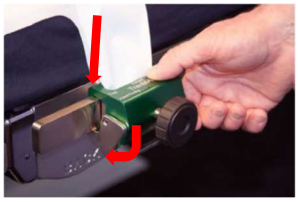
5. Attach all four (4) straps on one side.

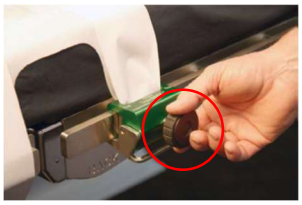
6. Attach all four (4) straps on the opposite side by pulling and tensioning the strap indenting the table pad, then pull the white strap up and attach to the lower black hook. Proceed to the other side and tension those straps.

Lower the top flap on both sides.

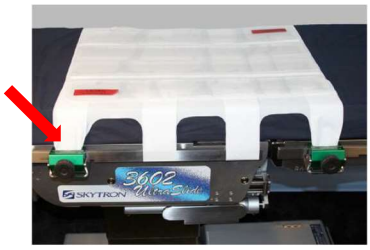
7. On the opposite side from the patient transfer, attach the TrenMAX® Clamp over the proximal strap, by attaching clamp over one side of the strap and then the other.

8. Seat the Clamp jaws over the strap and side rail while holding the pivot bar, then seat the pivot bar over the side rail and tighten knob.





9. Attach another TrenMAX® Clamp to the distal strap on the same side.

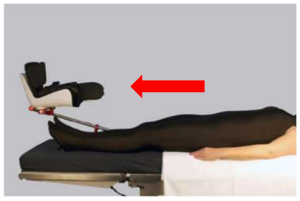


10. Remove the caution stickers before transferring the patient.

11. Then transfer the patient on the side of the OR table *without* the clamps, using a draw sheet.

12-A **With Stirrups**

Move the patient towards the end of the OR table with the draw sheet for robotic procedures.

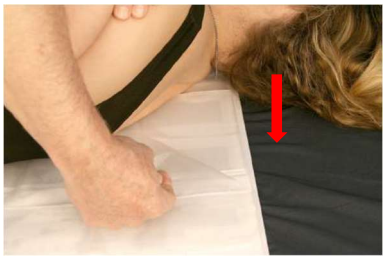


Attach the stirrups then the TrenMAX® Clamps to the distal and proximal white straps, and remove the draw sheet

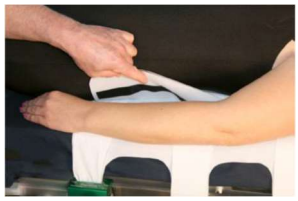
12-B **Without Stirrups**

Attach the remaining two TrenMAX® Clamps to this side of the OR table, remove draw sheet.

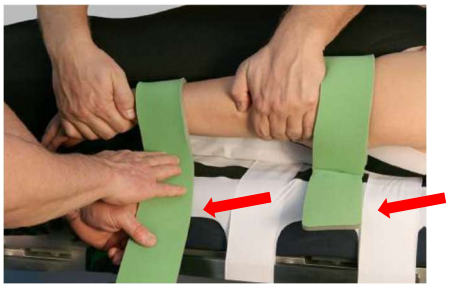
13. Lift the patient's shoulder and peel the protective plastic sheet off gel sheet. Repeat on the other shoulder.



14. Lift the gel sheet and hook and attach the green foam arm strap to the upper black hook, positioning the two (2) straps proximal and distal to the elbow.



15. Loop the green foam arm strap over the arm and attach it to the black hook material on the lower gel sheet.

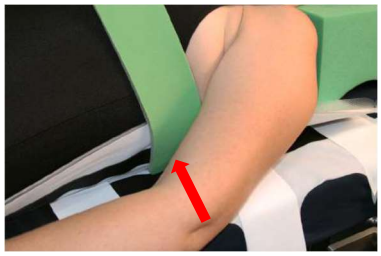


16. Attach all four (4) green foam arm straps in the same fashion. For ease of use, attach the strap over the biceps first on each arm.

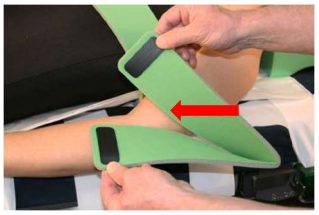
Bariatric Option ~ Biceps "Arm Only" Strap

Arm Extension Straps For Obese Patients

1. Lift the gel sheet with the hook material, then attach the green foam arm strap to the upper black hook on biceps of arm region.



2. Open the extensions and remove the black hook from one end.



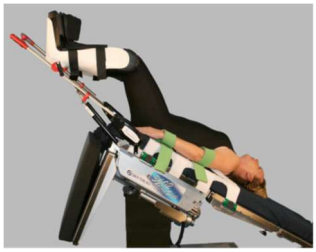
3. Place this black hook next to the other existing black hook and attach the extension strap to the green foam arm strap.

4. Attach the extension strap to the bottom black hook.

Instructions for Use Continued:

17. Proceed to positioning the patient in Trendelenburg

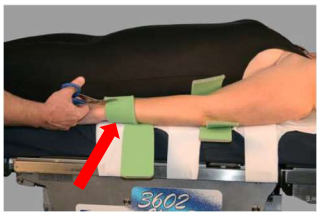
With Stirrups



Without Stirrups

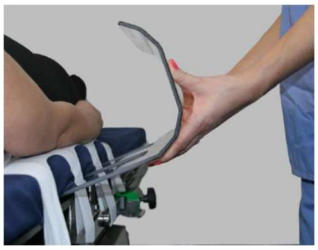
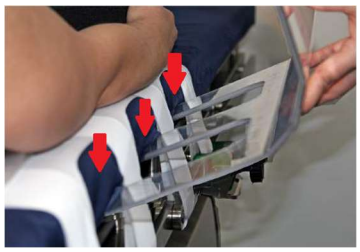
18. Upon conclusion of the procedure:

Cut the (4) green foam arm straps, then transfer the patient to the stretcher.



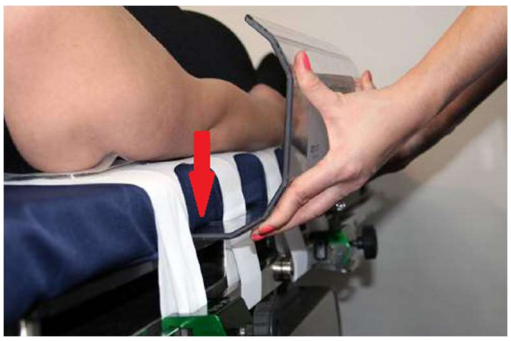
Armboard Extension Instructions

1. Insert the TrenMAX® Armboard at an angle which will clear any possible underside stitching of the table pad. Ensure that the board extensions are inserted between the white straps.

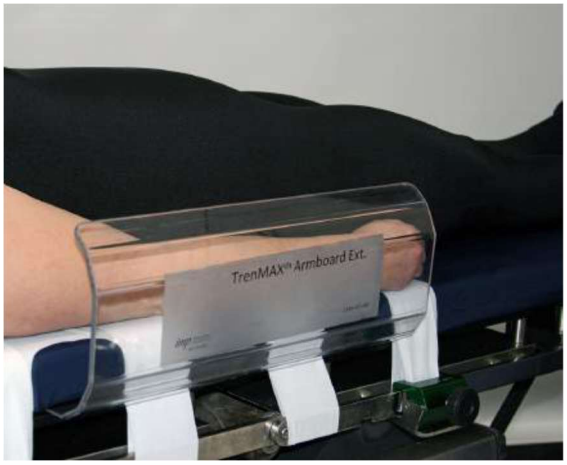



2. While inserting the Armboard, an assistant may be required to hold the patient's arms to slightly roll the patient away from the edge

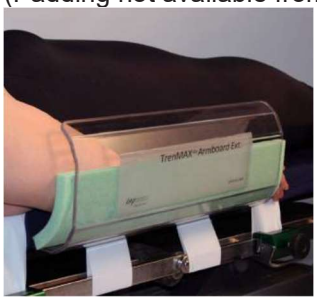
3. Seat the armboard until it makes contact with the patient's arm or the white straps



4. The distal end should cover the wrist and hand



5. Place some padding to protect the patient. The type of padding is at the discretion of the facility. (Padding not available from IMP)

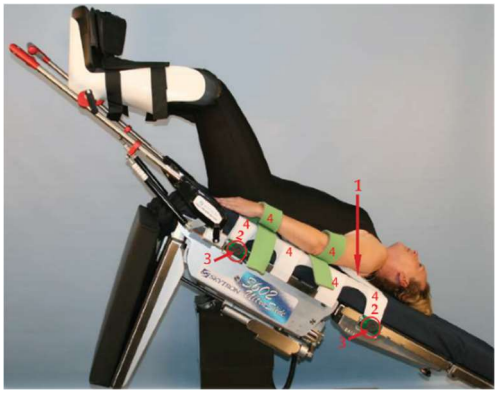


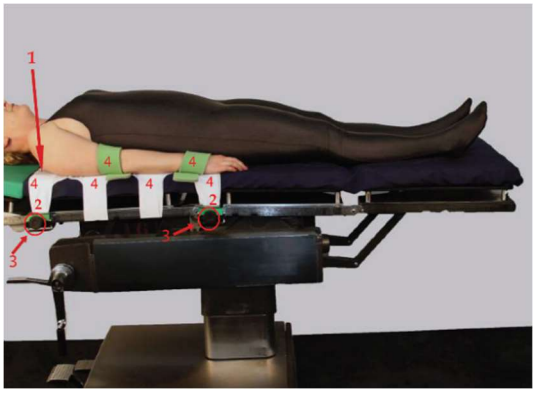
Safety Hook & Loop Strap with Buckle provided with Armboard Extension.

6. Attach safety hook and loop strap. Slide safety strap through the 2 slots on Armboard. Wrap buckle end around table side rail. Feed rounded end through buckle and attach hook end to loop.

Set Up Test Procedure

1. Ensure that the protective plastic sheet has been removed, exposing TrenMAX® Positioning Gel Sheet.
2. Check that the white straps are taut and there are a minimum of 2 TrenMAX® Clamps on each side of the OR table.
3. Ensure TrenMAX® Clamps are tightened with the locking knobs.
4. Check to ensure all hook and loop straps are secure.





Armboard

1. Check that the armboard extensions are between straps
2. As applicable, confirm padding is protecting patient's arm
3. Check armboard safety strap is attached and secured to table side rail

Cleaning Procedure (clamp and armboard)

Wash with a generous application of neutral soap suds and lukewarm water up to 103°F (39°C). Rinse with water and dry. Do not immerse.

Or

Use a diluted bleach solution of 10-parts water to 1-part bleach. Wipe dry with a clean cloth. Do not immerse. Bleach MUST be diluted to the 10:1 ratio.

All chemicals/solutions MUST be diluted to the manufacturer's recommendations. No chemical or solution should be left to dry on the pad surface. After the allotted time has passed to ensure disinfection, the pad surface should be wiped again with a wet cloth to remove the remaining chemical or solution.

DISINFECTING

Use Lysol Brand III I.C. Disinfectant Aerosol Spray by Reckitt Benckiser Inc., per manufacturer's instructions.

Or

Use a diluted bleach solution of 10-parts water to 1-part bleach. Wipe dry with a clean cloth. Do not immerse. Bleach MUST be diluted to the 10:1 ratio.

All chemicals/solutions MUST be diluted to the manufacturer's recommendations. No chemical or solution should be left to dry on the pad surface. After the allotted time has passed to ensure disinfection, the pad surface should be wiped again with a wet cloth to remove the remaining chemical or solution.

Scan for additional documentation

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UDI

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