

13. Place Clark clamp on table rail on non-operative side. Place adjustable arm board into Clark clamp parallel to table. This is used to support non-operative arm during surgery.

14. Ensure medial border of scapula hangs off Slide Pad to allow easier access to anterior portal for arthroscopic procedures.

15. Position Headset Pad to ensure patient's head rests in middle of Pad.

Intubation

The black Intubation Tree is used to hold tubing during surgery and can be rotated out of the way when not in use. Procedures depend on whether preference for intubating is with the Intubation Pad or the Surgical Headset.

If using the Intubation Pad

The Intubation Pad is inserted into headset Forward Slide Collar prior to patient loading. Hex bar shaft of Intubation Pad fits into Forward Head Adjustment Collar. Tighten in place so pad runs continuous with Slide Pad. For very tall patients the Intubation Pad may be raised with a gap between pads.

1. To position for intubation, after the initial positioning, lower patient to supine using Lift System Release Handle.

2. During intubation the patient's arms can be secured by placing arms alongside the body inside the lateral supports. For wider patients Extended Lateral Supports are an optional accessory.

3. Patient is intubated as on a regular O.R. table. Pillows can be placed under the neck on the headset.

4. Once patient is anesthetized, remove arms from inside Lateral Supports. Anesthetist will control head as patient is raised to sitting position.

5. Intubation pad is removed and replaced with Surgical Headset which is adjusted to attain ideal head positioning by adjusting height (Vertical Adjustment Knob,) head angle (Ball and Socket Knob,) and forward translation (Headset Forward Slide Knob.) To remove Intubation Pad the anesthetist must control the patient's head. Loosen Double Ball and Socket and tilt pad back as far as possible. Loosen Forward Slide Knob and remove Intubation Pad, replace with Surgical Headset, adjust position and tighten headset.

Once positioning is complete, patient's head is secured in place using TENET's Face Mask. The Face Mask provides pressure to the forehead and chin to secure the head in place during surgery. This head positioning ensures the head and airways will be in a neutral position throughout the surgical case. Face mask attaches into two clips on each side of the Surgical Headset. Position mask and tighten mask by pulling straps.

If using Surgical Headset:

1. Lower Surgical Headset so pad is behind patient's neck. Loosen Forward Slide Knob and slide Surgical Headset as far back as possible. Lower patient to supine and the head will slide down headset to the center of the pad.

2. Ball and Socket can be loosened to allow the anesthetist to manipulate Surgical Headset for optimal positioning. Anesthetist is also free to use any usual techniques for intubation including use of pillows under head and shoulders.

3. Once anesthetized, control patient's head while raising to a sitting position. Place Face Mask on patient and tighten straps. Adjust head position as required.

4. Once positioned the patient can be draped. When an anesthetic block is used the Drape Bar attaches to the Surgical Headset and keeps the drape off the patient's face.

5. Positioning is not generally adjusted during the surgery, but can be adjusted under the drape if necessary. Extra care must be taken to ensure pressure is not created on patient's head or neck structures during adjustments.

6. Following the procedure, remove draping.

7. Release Face Mask and lower headset pad behind patient's neck.

8. Use Lift System Release Handle to slowly lower patient to supine position.

9. Remove Lateral Support from transfer side before moving patient from the Beach Chair to a stretcher.

10. TENET Medical Engineering's SPIDER Limb Positioner can be used to intra-operatively position the operative arm during surgery. When using the T-MAX, the SPIDER is attached to the Attachment Bar on the back of the T-MAX Beach Chair.

For additional information please see SPIDER Limb Positioner and Beach Chair Shoulder Bar Instructions for Use.

Cleaning

Wipe pads with mild detergent/disinfectant following each case.

Avoid moisture contact on Hex Shaft of T-MAX.

Dry off Hex Shaft after use.

Disposable foam masks should be discarded after each surgery.

Storage

The T-MAX is stored on its own cart for transportation and storage. To place T-MAX on cart, move Headset forward. Lift T-MAX by the Lift System Release Handle and place Lift System Release Handle over front hook on cart. Bottom of cylinders rest against cylinder rests. Intubation pad goes between slide pad and knee bolster. Arm board post sits on side storage hook on cart. Clamp post at bottom of cart holds both Square Rail Clamps. Knee Bolster is wedged between Lateral Supports and tightened in place.

All TENET Medical Engineering products have a standard 12 month parts and labour warranty against manufacturing defects.

For further information please contact:

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TENET Medical Engineering

T-MAX Beach Chair

Instructions for Use

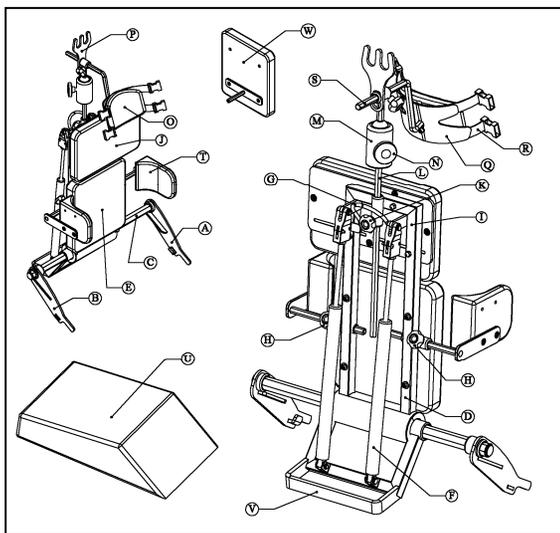
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Device Description

TENET's T-MAX Beach Chair provides ideal access, adjustability, and stability for Beach Chair shoulder procedures. It is designed to fit over the rails of most O.R. tables. On most tables the head section is removed and the T-MAX is placed over the rails. Some tables require the leg section to be lowered and the table to be turned around.

Indications for Use

The T-MAX Beach Chair is indicated for use during beach chair shoulder procedures.



- A. Fixed Leg
- B. Sliding Leg
- C. Hex Shaft
- D. Lower Frame
- E. Lower Back Pad
- F. Gas Spring Cylinders
- G. Lift System Release Handle
- H. Lateral Support Adjustment Knob
- I. Upper Frame
- J. Slide Pad
- K. Headset Vertical Adjustment Knob
- L. Headset Slide Hex Bar
- M. Double Ball and Socket
- N. Ball and Socket Knob
- O. Headset Pad
- P. Intubation Tree
- Q. Strap Support
- R. Headset Straps
- S. Headset Forward Slide Collar and Knob
- T. Lateral Supports
- U. Knee Bolster
- V. SPIDER Attachment Bar
- W. Intubation Pad
- X. Body Strap (Not Shown)

Warnings

- It is the responsibility of the surgeon to be familiar with the appropriate surgical techniques prior to the use of this product.
- Maximum weight limit for O.R. table must not be exceeded. Most older tables have a 300 lb (136KG) limit. The T-MAX will accommodate patients up to 350 lbs (159KG).
- Review O.R. table instruction manual to ensure operational parameters of table are not exceeded.
- Ensure O.R. table is locked to floor. In most cases this requires the castors to be completely off the floor.
- Never place T-MAX on extended head / foot section of table.
- Secure patient's legs with Body Strap to prevent traveling during positioning.
- Do not use T-MAX without Square Rail Clamps in place (Fig.1).
- Ensure Face Mask is not applying pressure on the patient's eyes and pressure on the face is evenly distributed.
- Do not over tighten straps holding chin in place and ensure there is no pressure on structures under the chin.
- When the patient is lowered, the head will slide down the headset pad. The Face Mask must be released when the patient is raised or lowered.
- To lower patient during an emergency, loosen the Headset Vertical Adjustment Knob (for up and down movement) and release the Face Mask. The patient can then be quickly and safely lowered to a flat position.
- It is the responsibility of the anesthetist to ensure patient's airway, eyes and neck are clear from any pressure and that the positioning will not create any surgical complications.
- Ensure the Face Mask's chin portion is not below the patient's chin and does not contact the neck area.

Precautions

- To ensure the understanding and the safe use of the T-MAX Beach Chair, please read the T-MAX Beach Chair Instructions for Use.
- It is recommended that two people attach T-MAX to O.R. table.
- Ensure O.R. table rail has at least 1" of overlap under back leg tabs.
- Tilt and flexion of O.R. table must be avoided once patient is loaded into T-MAX.
- Non-operative arm can be loosely secured to the arm board to ensure the arm remains in place during procedure.
- Surgical site access should be checked by surgeon prior to administering anesthesia.
- Face Mask should only be tightened when patient is in final sitting position.

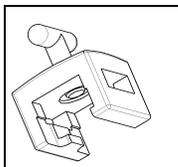


Fig. 1 Square Rail Clamp

Instructions for Use

Please see O.R. Table Fit Guide for details on approved Tables. For O.R. Tables that do not appear on the O.R. Table Fit Guide please contact TENET Medical Engineering (info@tenetmedical.com)

Lower foot section and position O.R. table to allow access to anesthesia equipment. Bend foot section of O.R. table down and place T-MAX over O.R. table rails on main body of table so lower frame abuts O.R. table pad.

1. Place Square Rail Clamps (Fig.1) on O.R. table rails 18" from end of rails.
2. Hook left fixed leg under left rail and slide right sliding leg under right rail. T-MAX legs should be flush against O.R. rails. Slide T-MAX forward onto O.R. table rails as far as possible.
3. Slide Square Rail Clamps over T-MAX legs (Fig. 2). Tighten in place. Square Rail Clamps do not support weight; they prevent T-MAX legs from moving laterally off O.R. table rails.
4. Slide Lower Frame to operative side of table leaving 2-3" (5-7cm) space from frame to side of table.
5. Ensure table pad is securely placed on table. If table is reversed, reverse table pad so it covers cut out in O.R. table.
6. Prior to patient loading, push Slide Pad away from operative side to allow maximum exposure of operative shoulder.
7. Remove Lateral Support from side of table that patient will load from. Lateral Support pads are offset from metal bar to allow positioning for tall or short patients.
8. If Intubation Pad is used, remove Surgical Headset and replace with intubation pad.
9. Position patient's buttocks as close to base of T-MAX Lower Back Pad as possible to prevent patient from sliding down T-MAX during surgery.
10. Insert Lateral Supports and tighten in place.
11. Place Knee Bolster under knees and slide it proximally to wedge patient's back against Lower Back Pad. Pad should sit directly on O.R. table and not on a sheet.
12. Secure the patient with the Body Strap over the patient's legs, the Knee Bolster and table to prevent legs from spreading apart and to secure the patient to table during surgery.

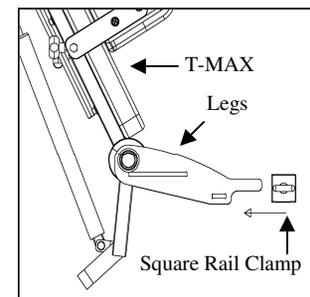


Fig. 2 T-MAX Assembly