Instructions for use:

TrenGuard™

Trendelenburg Patient Restraint

Dynamic Patient Support Frame

Alternative Language IFUs:
www.da-surgical.com/ifu

Instructional videos:
www.da-surgical.com/instructional-videos

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Rev. 9 6/8/23

D. A. SURGICAL

INTENDED USE

TrenGuard Trendelenburg Patient Restraint is a patient positioning system for surgical procedures utilizing the Trendelenburg Position.

The product is intended to keep patients static and fixed in place during the time that they are positioned in the Trendelenburg position, up to 40-degrees, to prevent patients from sliding on the surgical table.

WARNINGS and CAUTIONS

⚠ **WARNING - PERSONAL INJURY HAZARD:**

- Read and understand all instructions presented in this manual before attaching/removing TrenGuard.
- Before positioning the patient using TrenGuard, users must complete training on proper use of TrenGuard.
- DO NOT use if TrenGuard components, rail clamps, or OR table side rails are damaged.
- DO NOT attach TrenGuard Patient Support Frame to the removable headrest / head section of an operating room table.
- ALWAYS inspect all TrenGuard components before use.
  - DO NOT use if VELCRO® Brand fastener* (from now on, referred to as Velcro) on frame or pillows appears worn, peeling, or damaged in any manner.
  - DO NOT use if any component has visible damage or wear.
- DO NOT use with patients weighing more than 550 lb | 250 kg.
- DO NOT use in reverse Trendelenburg.
- DO NOT use when table is articulated in lateral tilt without using additional positioning equipment.

⚠ **WARNING - INFECTION HAZARD:**

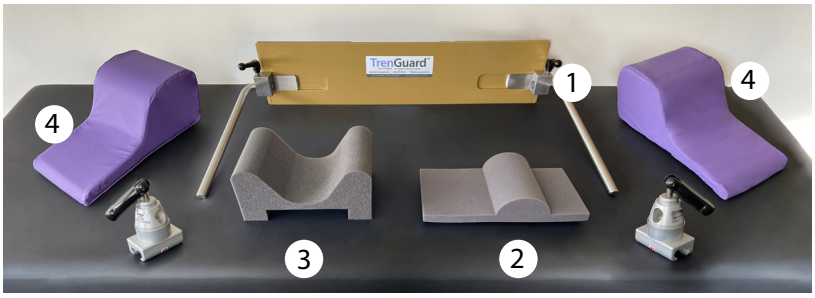
- DO NOT reuse TrenGuard single-use components.
- ALWAYS ensure reusable components are cleaned and dried prior to use.
- DO NOT submerge. DO NOT heat sterilize.

PRODUCT COMPONENTS

NUMBER CODE ON EACH PART

1. TrenGuard Dynamic Patient Support Frame
2. Cervical Notch Bolster (“bolster”)
3. Head Stabilizer
4. Lateral Stabilizing Pillows*

All components are required for use.



*HYBRID Reusable Lateral Stabilizing Pillows shown.

Other devices required for use:

- OR table rail clamps which accept 5/8” diameter (1.6 cm) round mounting posts and are weight-rated for > 550 lb | 250 kg.
- We recommend Schure™ Socket 800-0006 (or equivalent for non-U.S. table rails).

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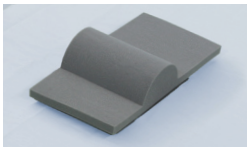
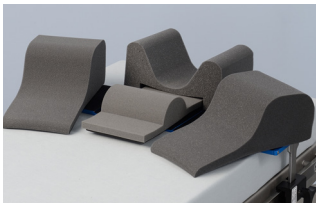
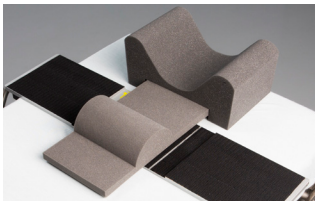
PRODUCT COMPONENTS (continued)

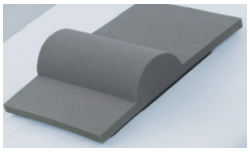
TrenGuard 450 Packs
are intended for patients
weighing 90-450 lb | 41-204 kg.

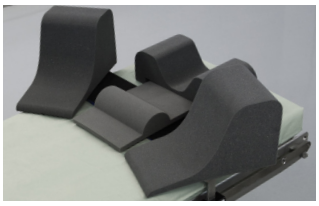

450 bolster
for visualization

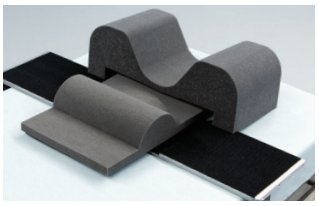

TrenGuard 450 CLASSIC Pack
order #55101 (case of 12 ea. 55103)


TrenGuard 450 HYBRID Pack
order #55201 (case of 12 ea. 55104)*

TrenGuard 600 Packs
are intended for high-BMI patients
weighing up to 550 lb | 250 kg.

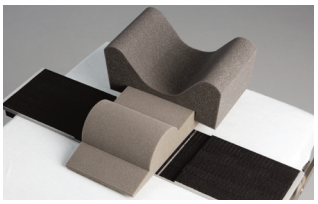

600 bolster
for visualization

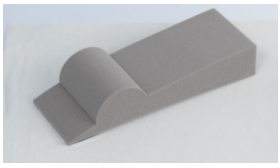

TrenGuard 600 CLASSIC Pack
order #56101 (case of 12 ea. 56203)


TrenGuard 600 HYBRID Pack
order #56201 (case of 12 ea. 56202)*

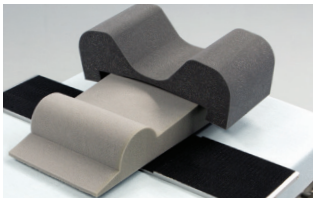
TrenGuard Wedge Packs are intended for use when a decreased range of cervical motion impedes proper extension of the neck or positioning the bolster in the region of the cervical concavity is hindered by adipose tissue. Wedge Packs are available in HYBRID and CLASSIC versions of 450 and 600 Packs or as Wedge-only for last-minute substitution.

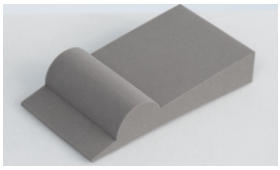

TrenGuard 450 CLASSIC Wedge Pack
order #55301 (case of 12 ea. 55303)


TrenGuard 450 HYBRID Wedge Pack
order #55401 (case of 12 ea. 55461)*


TrenGuard 450 Solo Wedge Pack
order #54612 (case of 12 ea. 54600)


TrenGuard 600 CLASSIC Wedge Pack
order #56302 (case of 12 ea. 56502)


TrenGuard 600 HYBRID Wedge Pack
order #56401 (case of 12 ea. 56481)*


TrenGuard 600 Solo Wedge Pack
order #54812 (case of 12 ea. 54800)

***ALL HYBRID Packs require:**


TrenGuard 450 HYBRID Reusable Lateral Stabilizing Pillows
order #55251 (each)


TrenGuard 600 HYBRID Reusable Lateral Stabilizing Pillows
order #56251 (each)

INSTRUCTIONS FOR USE

Step 1 - Select the appropriate TrenGuard Pack, based on patient weight and anatomy:

- 41 kg to 204 kg - use 450 CLASSIC or HYBRID
- 205 kg up to 250 kg - use 600 CLASSIC or HYBRID

If patient has decreased cervical range of motion or adipose tissue that prevents extension of the neck or hinders positioning the bolster in the region of the cervical concavity, use:

- 41 kg to 204 kg - use 450 CLASSIC Wedge or HYBRID Wedge
- 205 kg to 250 kg - use 600 CLASSIC Wedge or HYBRID Wedge

NOTE: TrenGuard may not be appropriate for patients who have severe kyphosis, have obstructions preventing direct contact with the neck, may not present with a discernible cervical notch, or have any other known conditions that would prevent them from lying flat on their back with the bolster in the cervical notch.

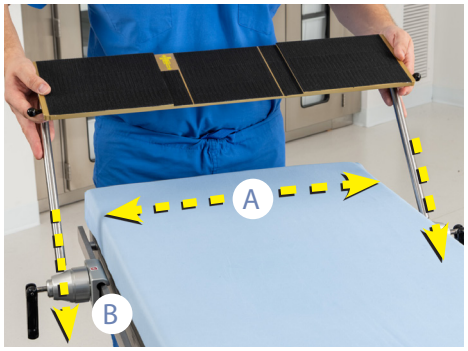
Step 2 - Open Pack and Inspect ALL Components

- Open pack at least 10 minutes prior to use.
- TrenGuard Packs may occasionally lose their seal and inflate. They remain suitable for patient use.
- If components do not appear fully inflated after 10 minutes, open new pack.
- Inspect all components to verify all are present and undamaged.
  - DO NOT use TrenGuard frame, or any other component, if Velcro appears worn, peeling, or damaged in any manner.
  - Confirm that rail clamps are free of defects and in good working order.
  - Ensure HYBRID Reusable Lateral Stabilizing Pillows are clean, dry, and in good working order.

Step 3 - Install Frame

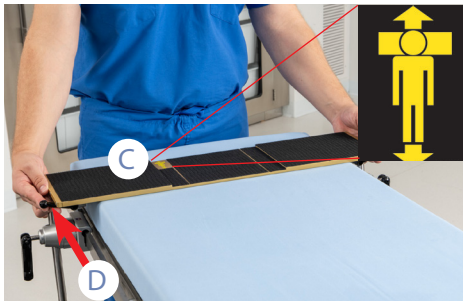
1. Fully open socket-style rail clamps and mount on the rails of the torso section of surgical table with the clamp opening angled toward the head of table.

   ⚠ NOTE: Do not mount clamps on head section.



2. Holding the mounting posts and frame plate (as shown at right) and adjust the distance between the posts (A) to center the frame plate across the width of the table as you insert the posts into the rail clamps (B).
   - Stand at the head of the table and install the frame before the patient is transferred. The swivel posts allow the frame to be positioned out of the way during patient transfer.
   - **NOTE:** Insert both posts into clamps at the same time for ease of installation.
   - Do not tighten clamps or lock black levers, for ease of adjustment during patient positioning later.

3. Refer to label on frame for proper orientation (C). Ensure the frame is centered across the table and the black levers are toward the foot end of table (D).



4. Avoid clashing with the anesthesia tube 'tree' by placing it off to one side under the mattress at the head of the table.

5. Cover Velcro with a lint-free towel or other protective covering to prevent scratching patient skin during transfer.

NOTE: If using an under-patient device (ex. warming, grounding, gel pads, air-assisted transfer device), ensure the full surface of TrenGuard Patient Support Frame is in contact with it or the Frame is free from the device so that TrenGuard is level with the mattress.

INSTRUCTIONS FOR USE (continued)

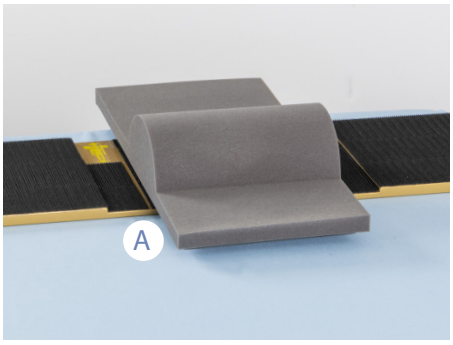
Step 4 - Transfer patient to table

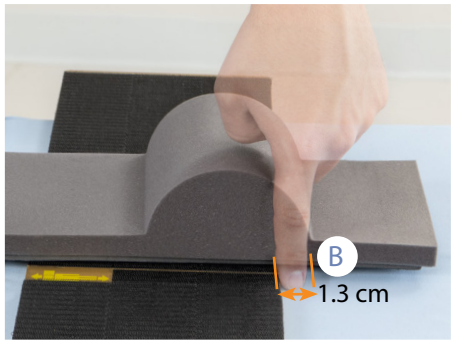
Transfer patient onto table in the usual manner and position as appropriate for procedure.

Step 5 - Attach Cervical Notch Bolster to Frame

1. Remove towel covering Velcro on the frame.
2. Place the bolster onto the depression in the frame, centered (A).
3. Ensure the short extension is toward the foot of the table and the curved portion extends over the frame (B) by a finger thickness (at least 0.5 in | 1.3 cm).

   NOTE: Long extension of the bolster pad assists in supporting patient's head.
4. Press the bolster firmly to the support frame to ensure full contact of Velcro.

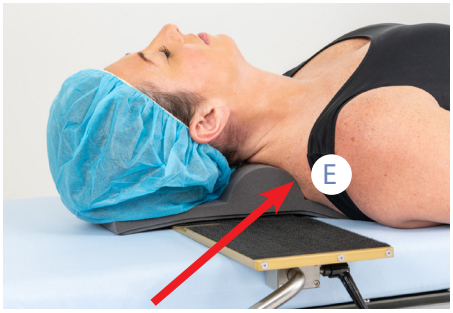




Step 6 - Adjust Frame and Bolster Position

1. Lift patient's head.
2. Slide the TrenGuard Dynamic Patient Support Frame toward the patient (C) until the curve of the bolster is placed securely against the trapezius muscle, in direct contact with skin.

   NOTE: Ensure the clamps remain toward the head of the table with the frame plate toward the foot of the table, as shown (D).
3. Lower patient's head.
4. Visually confirm that the leading edge of the curve is nesting into the cervical notch, secure against the trapezius muscle in direct contact with skin (E).
5. If the bolster is not properly positioned, lift the head and slide the frame further forward to snug the curved portion against the trapezius muscle (see 2, 3, and 4 above).



Step 7 - Securely tighten both rail clamps and lock posts in place

⚠ 1. Hand-tighten rail clamps (F) to secure the frame onto OR table.
2. Turn black levers (G) inward to lock the angle of the posts.

   NOTE: Locks will maintain appropriate angle of posts for use in extreme Trendelenburg.

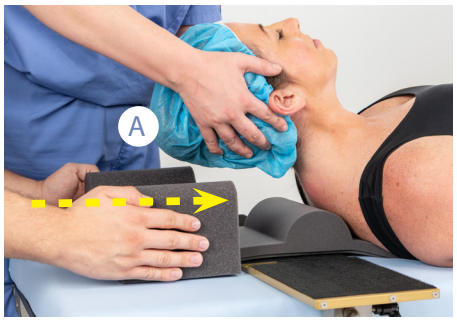
   If black levers are in unlocked position and they collide with the frame, remove frame, turn it around so the label on frame is aligned with how the patient is positioned.

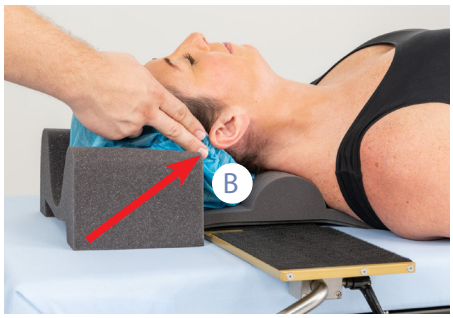
INSTRUCTIONS FOR USE (continued)

Step 8 - Place Head Stabilizing Pillow

Lift head and slide pillow under the occiput (A).

⚠ **WARNING** - DO NOT compress patient's ears (B), to avoid risk of pressure injury, maintain 2-finger space (1.0 in | 2.6 cm)





Step 9 – Install Lateral Stabilizing Pillows

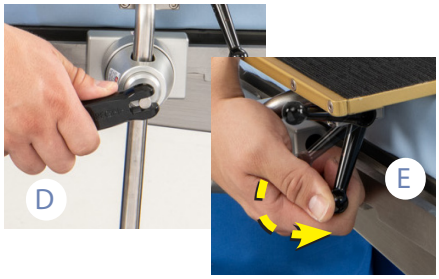
1. Lift the Shoulder.
2. Angle the pillow (C) to avoid contact with the hook and loop fastener, and position pillow under the shoulder.
   - Maintain an initial gap of a hands-width (2 in | 5 cm) between pillow and patient's shoulder.
   - Soft, non-structural Lateral Stabilizing Pillows control body mass shift during the transition from supine to extreme Trendelenburg.
3. Lower the shoulder to engage Velcro on pillow to the frame.
4. Repeat on other side.

Shown with HYBRID Reusable Lateral Stabilizing Pillows

Step 10 - Confirm installation

1. Re-confirm that the rail clamps are tightened (D) and the posts are locked (E).
2. Confirm pillows are secured to frame.

⚠ DO NOT tilt table until verifying components are secure.



Step 11 – Conduct Patient Tip Test

⚠ **CAUTION: ALWAYS perform this important step prior to draping.**

1. Move the OR table to the maximum degree of Trendelenburg anticipated for the procedure.
2. Hold the position for a 5 second count.
3. Return the table to level.

⚠ **CAUTION: ALWAYS repeat steps 6-10 when patient needs to be repositioned.**

CLEANING and STORAGE

Follow the hospital's cleaning, hygiene, and disinfection protocol for table accessories and Velcro. Use hospital-grade cleaners, such as Quaternary Ammonium Compound ("Quats") Germicidal Surface Disinfection/Deodorizing/Cleaning Wipe or similar to dampen and wipe-down reusable components.

Pay particular attention to areas where fluid migration could occur. Lint and fiber particles may be removed from Velcro with a TrenGuard Cleaning Brush (model #9106).

⚠ DO NOT submerge.
DO NOT heat sterilize.

After disinfecting and drying, store TrenGuard Dynamic Patient Support Frame and HYBRID Reusable Lateral Stabilizing Pillows in a secure location to prevent damage. Store at room temperature. Avoid exposing TrenGuard components to extreme temperatures.

REPLACEMENT PARTS and SERVICE

D. A. Surgical warrants that our products will be free from manufacturing defects for a period of 12 months following delivery to the end user.

Useful Life of TrenGuard Dynamic Patient Support Frame is 3 years with periodic maintenance of hook fastener.

Useful Life of the HYBRID Lateral Stabilizing Pillows is 1 year or 500 uses, whichever occurs first.

All other components are single-use only.

Always check integrity of the Velcro on TrenGuard Dynamic Patient Support Frame and HYBRID Reusable Lateral Stabilizing Pillows before use. If Velcro begins to peel, creep, or appears worn, the Velcro must be replaced.

If foam pillows do not fully inflate after 10 minutes, open a new pack and contact D. A. Surgical for a replacement.

If unsure of usable condition of TrenGuard, contact D. A. Surgical immediately at CustomerService@da-surgical.com or 001 (800) 261-9953.

DISCLAIMER

D. A. Surgical assumes no liability arising from misuse or misapplication of TrenGuard Trendelenburg Patient Restraint.

It is the sole responsibility of the user and staff to determine applicability of the device for its use, and to study and thoroughly understand these instructions for use and to use TrenGuard properly.

Contact D. A. Surgical for in-service options.

D. A. Surgical reserves the right to make changes without notice in design, specifications, and models.

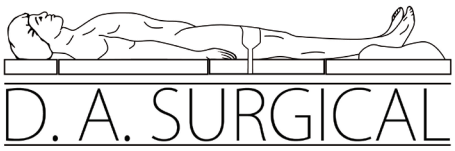
NOTICE

Report any serious incident that has occurred in relation to this device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CE LABEL

TrenGuard
Trendelenburg Patient Restraint

CE



D. A. SURGICAL

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EC REP

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EXPLANATION OF SYMBOLS

MD — MEDICAL DEVICE	CONSULT INSTRUCTIONS FOR USE
INDICATES A POTENTIAL RISK	DO NOT REUSE
LOT — BATCH CODE / LOT NUMBER	SN — SERIAL NUMBER
MANUFACTURER	DATE OF MANUFACTURE
CE — CONFORMITY MARK	EC REP — AUTHORIZED REPRESENTATIVE IN EUROPEAN COMMUNITY