Instructions for use:

TrenGuard® TrueFit™

Trendelenburg Patient Positioner

TrueFit Dynamic Patient Support Frame





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Rev. 3 10/19/26

DAS™

INTENDED USE

TrenGuard Trendelenburg Positioner 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.

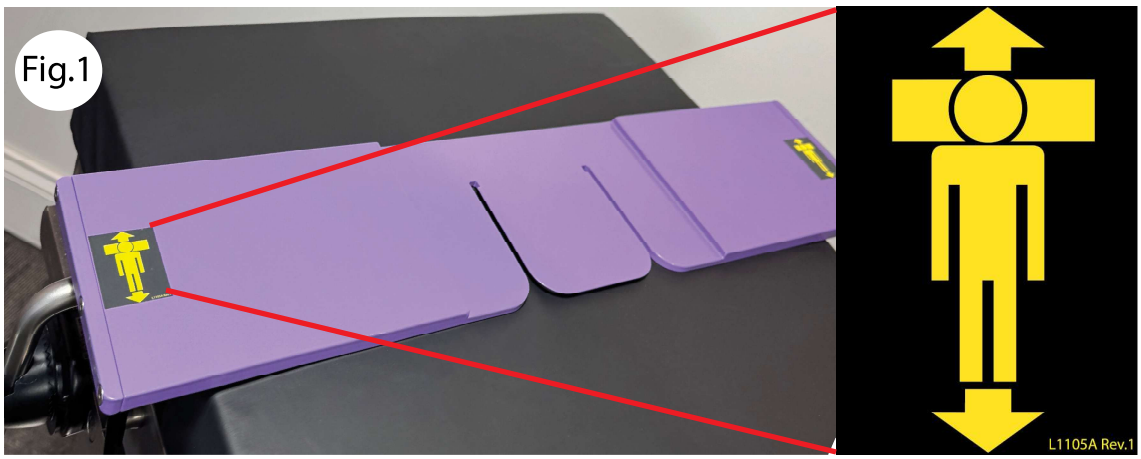
WARNINGS and CAUTIONS

⚠ **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. Schedule a no-charge in-service at customerservice@da-surgical.com or 800-261-9953.
- 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 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.
- ⚠ **ALWAYS reference the on-device labels for proper frame orientation relative to the table and patient (reference Figure 1 below).**
- **The central slot of the frame must aim toward the foot end of the OR Table.**
- ⚠ DO NOT use frame in reverse orientation
- DO NOT use when table is articulated in lateral tilt without using additional positioning equipment.

WARNING - INFECTION HAZARD:

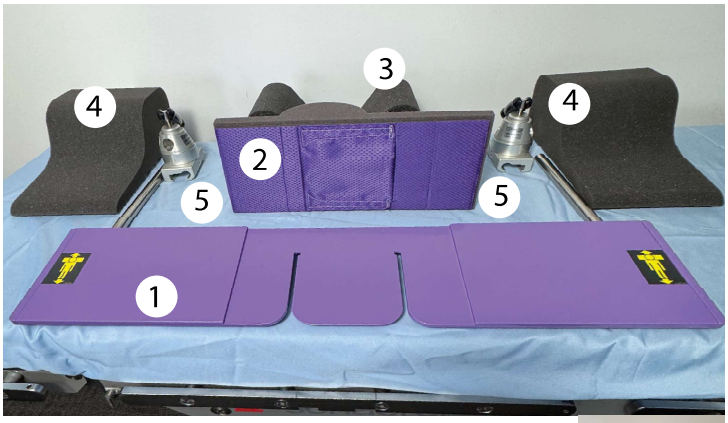
- DO NOT reuse TrenGuard single-use components.
- ALWAYS ensure reusable components are cleaned and dried prior to use.
- DO NOT submerge. DO NOT heat sterilize.



PRODUCT COMPONENTS

NUMBER CODE ON EACH PART

1. TrenGuard TrueFit Dynamic Patient Support Frame
2. Cervical Notch Bolster ("bolster")
3. Head Stabilizer
4. Lateral Stabilizing Pillows
5. Rail Clamps (Not included in pack)
   All components are required for use.



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 Clark Socket, Schure Socket, or equivalent clamps.



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



TrenGuard TrueFit 450 CLASSIC Pack
order #55701 (case of 12 ea. 55703)
Available in 600 size
order # 56701 (case of 12 ea. 56703)



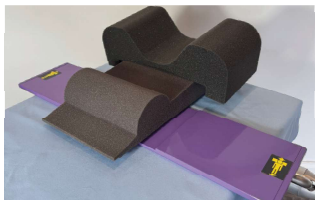
TrenGuard TrueFit 450 HYBRID Pack
order #55702 (case of 12 ea. 55704)*
Available in 600 size
order # 56702 (case of 12 ea. 56704)

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. Bolster and Wedge Packs are available in HYBRID and CLASSIC versions of 450 and 600 Packs or as Bolster or Wedge-only for last-minute substitution.

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



TrenGuard TrueFit 600 CLASSIC Wedge Pack
order #56801 (case of 12 ea. 56803)
Available in 450 size
order # 55801 (case of 12 ea. 55803)



TrenGuard TrueFit 600 HYBRID Wedge Pack
order #56802 (case of 12 ea. 56804)*
Available in 450 size
order # 55802 (case of 12 ea. 55804)

***ALL TrueFit HYBRID Packs require TrueFit Hybrid Lateral Pillows:**

TrenGuard TrueFit 450 HYBRID Reusable Lateral Stabilizing Pillows
order #55751 (each)



TrenGuard TrueFit 600 HYBRID Reusable Lateral Stabilizing Pillows
order #56751 (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.
- Keep label from uninflated pack and notify customerservice@da-surgical.com or 800-261-9953 of the serial number.
- Inspect all components to verify all are present and undamaged.
  - DO NOT use TrenGuard frame, or any other component, if it appears damaged in any way
  - Confirm that rail clamps are free of defects and in good working order.
  - Confirm the stitching pattern is intact and free from an fraying or loose stitches. (Fig. 2)

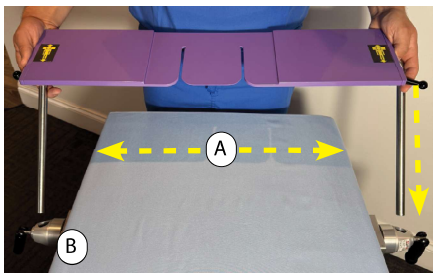
Step 3 - Install Frame



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.

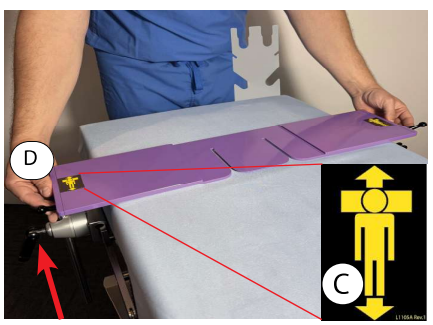
⚠
- NOTE: Do not mount clamps on head section of OR table.

2. Holding the mounting posts and frame plate (as shown at right), 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.



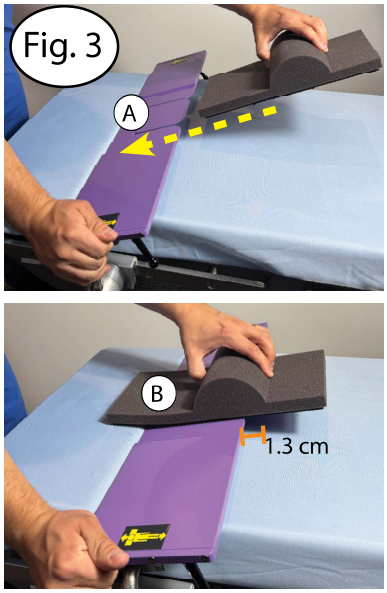
NOTE: If using an under-patient device (ex. warming, grounding, gel pads, air-assisted transfer device), ensure the full surface of TrenGuard TrueFit Dynamic Patient Support Frame is in contact with it or the Frame is free from the device so that TrenGuard is level with the mattress.

INSTRUCTIONS FOR USE (continued)

Step 4 - Transfer patient to table (note: you may install the bolster before patient transfer)

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

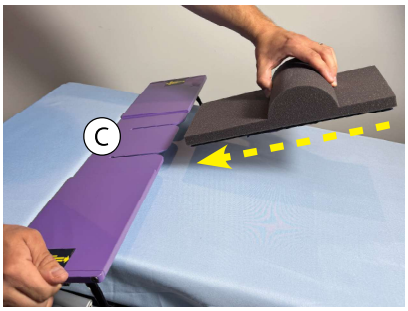
Step 5 - Attach Cervical Notch Bolster to Frame

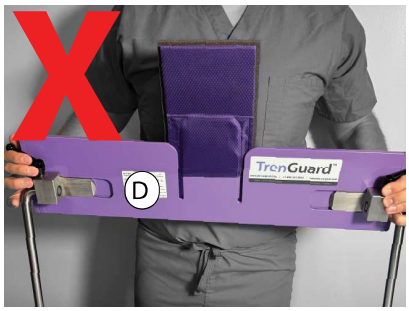


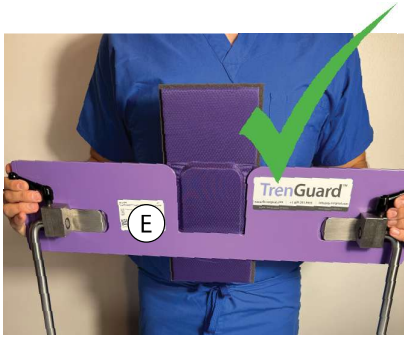
1. Lift the end of the frame as indicated (Fig. 3).
2. Slide the open end of the pouch onto the central slot of the frame (A).
3. Ensure the pouch is fully engaged on the frame and cannot slide on any further (B). The bolster is designed to protude slightly past the leading edge of the frame- approx. 1.3 cm.

   NOTE: Long extension of the bolster pad assists in supporting patient's head.
4. Pull the bolster firmly from the long end to ensure it is fully engaged with the frame.

⚠ **Note: Slide the bolster onto the frame in the direction shown. The pouch must fully engage on the central slot of the frame.(C)**
Note: (D) Shows the underside of the frame and what incorrect placement of the bolster looks like.
(E) Shows the underside of the frame and what proper placement of the bolster looks like.

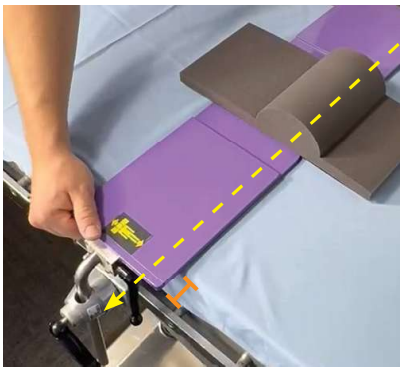


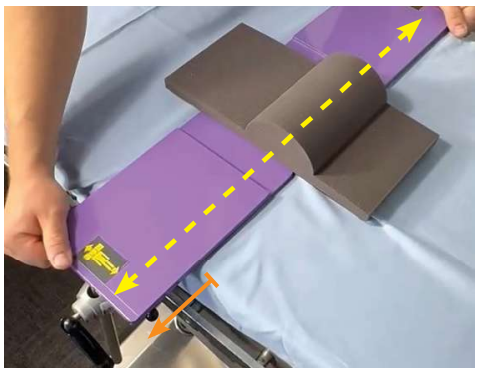




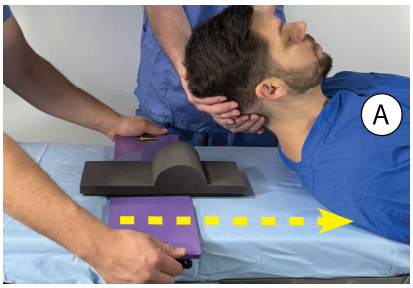
CENTERING OF FRAME

NOTE: If the patient is not fully centered on the table, the frame can be moved side to side.
1. Lock the frame and clamps before adjusting.
2. Grab the frame and adjust side to side to fully center the bolster under the patient.



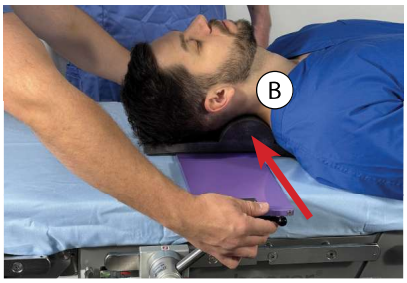


Step 6 - Adjust Frame and Bolster Position



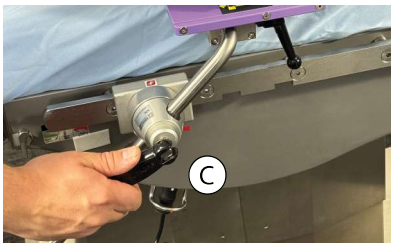
1. Lift patient's head.
2. Slide the TrenGuard TrueFit Frame toward the patient (A) until the curve of the bolster is placed securely against the trapezius muscle, in direct contact with skin.
3. Lower patient's head.

⚠ 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 (B).



5. If the pad is not properly positioned, lift the head and slide the frame forward to snug the curved portion against the body at the trapezius muscles (see steps 2, 3, and 4).

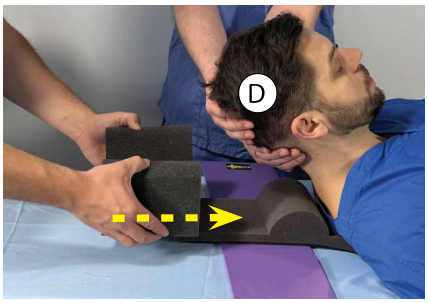
Step 7 - Securely tighten both rail clamps

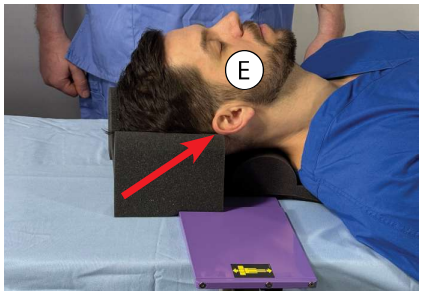


⚠ Hand-tighten rail clamps to secure the frame onto OR table for secure patient positioning (C).

Step 8 - Place Head Stabilizing Pillow

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





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

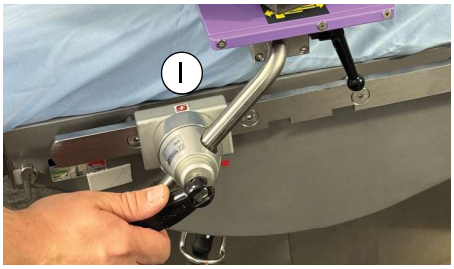
Step 9 – Install Non-Slip Lateral Stabilizing Pillows

Note: Ensure the frame is dry before placing the lateral pillows.



Shown with Disposable Velcro Free Lateral Stabilizing Pillows

1. Lift the Shoulder.
2. Tilt pillow to avoid contacting frame and position pillow under the shoulder (F).
   - For high BMI patients, maintain an initial gap of 3-finger widths (2 in | 5.08 cm) between pillow and patient's shoulder. For low-BMI patients, approximately two finger-widths (1.5 in | 3.81 cm) is acceptable.
   - Soft, non-structural Lateral Stabilizing Pillows control body mass shift during the transition from supine to extreme Trendelenburg.
3. Lower the shoulder to engage non-slip material on pillow to the frame. The thin part of the lateral pillow should be partially under the patient, while also maintaining contact with the frame.
4. Repeat on other side.

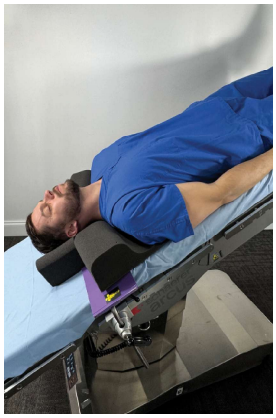


Step 10 - Confirm installation

1. Re-confirm that the rail clamps are tightened (I).
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.

⚠ NOTE: To remove the bolster after the procedure, or in an emergency, push on the back of the bolster with both thumbs until the pouch releases from the frame.

CLEANING and STORAGE

Follow the hospital's cleaning, hygiene, and disinfection protocol for table accessories and Frame. 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.

⚠ DO NOT submerge.
DO NOT heat sterilize.

After disinfecting and drying, store TrenGuard TrueFit Dynamic Patient Support Frame and HYBRID Reusable 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 TrueFit Dynamic Patient Support Frame is 3 years. Useful Life of HYBRID Pillows is 1 year or 500 uses, whichever occurs first. All other components are single-use only.

Always check integrity of the Inlay on TrenGuard TrueFit Dynamic Patient Support Frame before use, ensuring it is unbent.

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 Positioner.

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 Positioner
CE

D. A. Surgical
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Newbury, OH 44065
USA
www.da-surgical.com
customerservice@da-surgical.com

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Westervoortsedijk 60,
6827 AT Arnhem, The
Netherlands

UK REP Anetic Aid Ltd. 44
New Lane, Havant,
Hampshire, PO9 2NF

CH REP OZG AG Mülibodenstrasse
3, 8172 Niederglatt,
Switzerland

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	US	DATE OF MANUFACTURE COUNTRY OF ORIGIN SYMBOL
CE	CE MARKING OF CONFORMITY	EC REP	AUTHORIZED REPRESENTATIVE IN EUROPEAN COMMUNITY
UK REP	AUTHORIZED REPRESENTATIVE IN UK COMMUNITY	CH REP	AUTHORIZED REPRESENTATIVE IN SWISS COMMUNITY