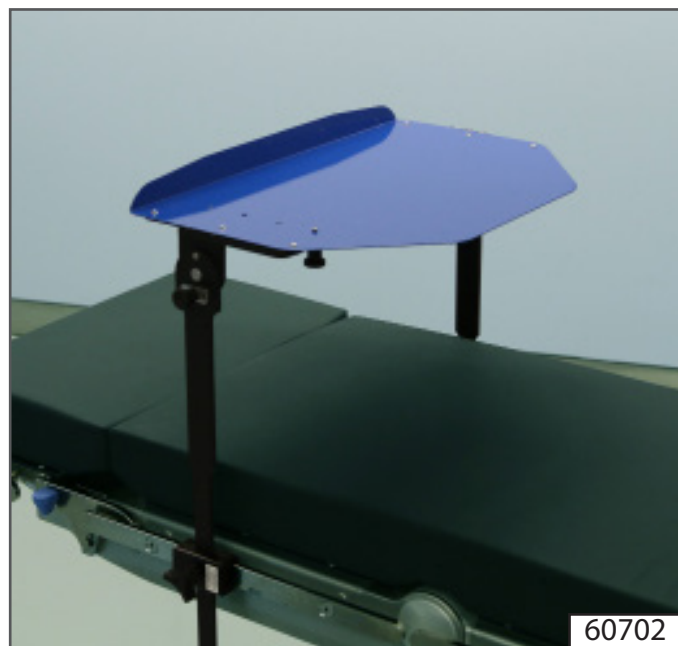
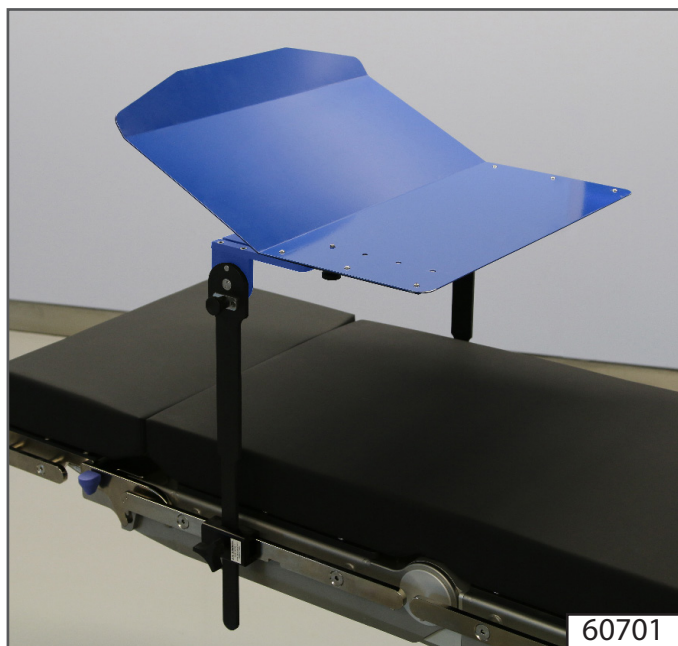


Instructions for use:

FaceGuard™

Dual Angle Head Shield / Instrument Tray #60701
Flat Head Shield / Instrument Tray #60702
Combo Dual-Angle and Flat Trays #60703

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



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



CONTENTS

INTENDED USE.....	2
WARNINGS & CAUTIONS	2
PRODUCT COMPONENTS	2-3
INSTRUCTIONS FOR USE	4-6
STORAGE & CLEANING.....	7
REPLACEMENT PARTS & SERVICE....	7
DISCLAIMER.....	7
CE LABEL.....	8
EXPLANATION OF SYMBOLS.....	8

Rev. 14 6/1/23



INTENDED USE

The intended use of FaceGuard™ Patient Head Shield and Instrument Tray is to protect the patient during the surgical procedure from unintended contact with instruments, surgical team members and/or robotic arms, etc. It may also act as an anesthesia screen and table-mounted instrument holder.

WARNINGS and CAUTIONS

WARNING - PERSONAL INJURY HAZARD:

- Read and understand all instructions presented in this manual before attaching/removing FaceGuard.
- Before positioning FaceGuard over the patient, users must complete training on proper use of FaceGuard.
- DO NOT use if FaceGuard components, rail clamps, or OR table side rails are damaged.
- ALWAYS inspect all parts of FaceGuard components before use.
 - DO NOT use if any part or component of FaceGuard has visible damage, especially tray slides or locking mechanism, as this could hinder quick access to the patient in an emergency.
- DO NOT lean on FaceGuard tray, it is not meant to support more than 10 lb | 4.5 kg.
- ALWAYS ensure clamps are tightened.

WARNING - INFECTION HAZARD:

- ALWAYS ensure components are cleaned and dried prior to use.
- DO NOT submerge. DO NOT heat sterilize.
- DO NOT use if there are cracks/chips in finish, which may tear clinician's gloves.

PRODUCT COMPONENTS

PART NUMBER ON EACH PHOTO

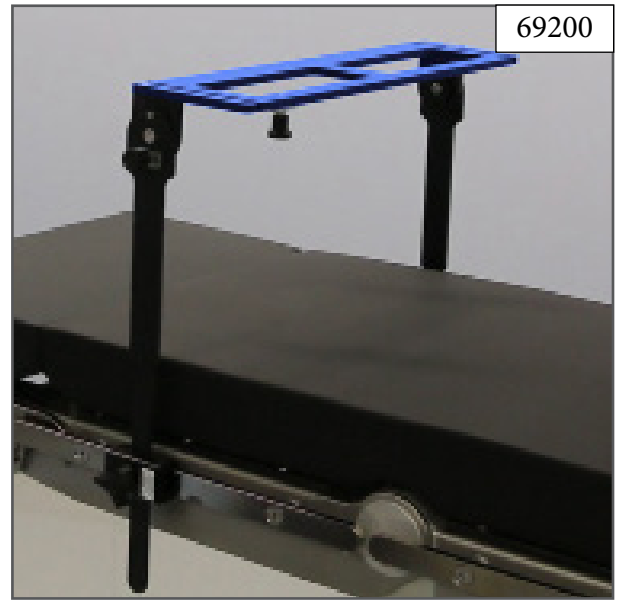
- #69200 FaceGuard Frame
- #69202 Flat Head Shield / Instrument Tray
- #69201 Dual-Angle Head Shield / Instrument Tray

Required for use:

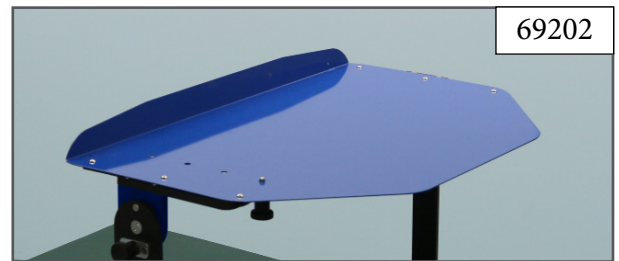
- FaceGuard Frame
AND
- Flat Tray (sold as item #60702)
for supine and prone positions
OR
Dual-Angle Head Tray (sold as item #60701)
for Trendelenburg position
- (Also available for sale as #60703 with one frame
and both trays.)

Other devices required for use:

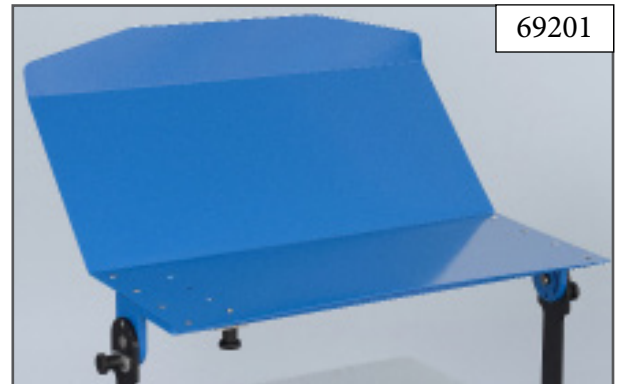
- Compatible rail clamps for your OR table
accessory rail type.



69200



69202

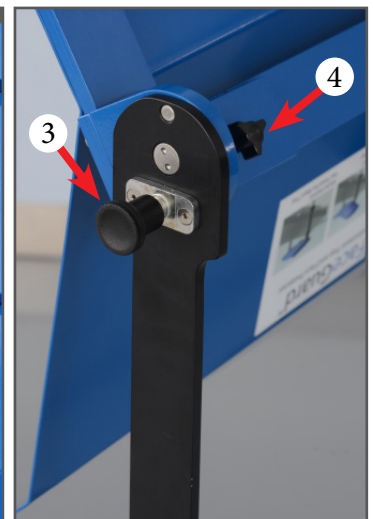
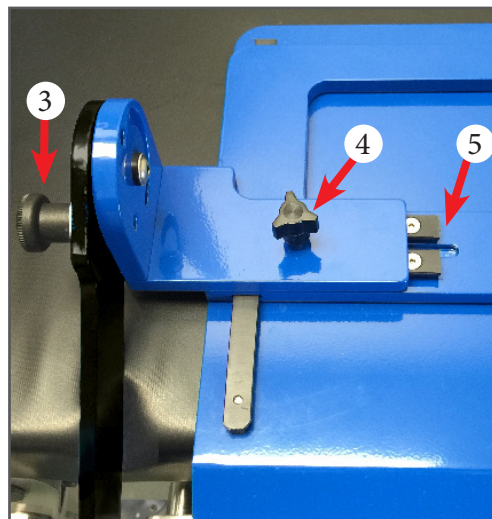
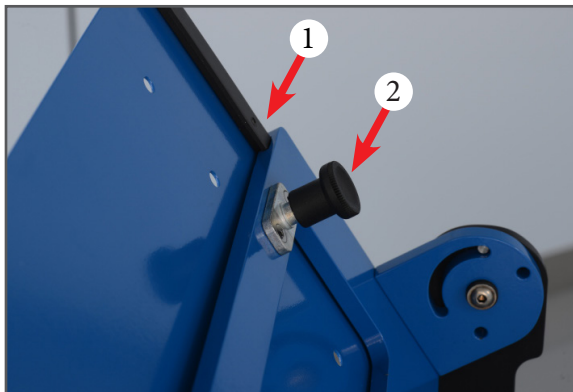


69201

CRITICAL PART IDENTIFICATION

NUMBER CODE FOR EACH PART


1. Tray Slide
2. Tray Spring Pin
3. Leg Spring Pin
4. Width-Adjustment Knob
5. Width-Adjustment Slide




INSTRUCTIONS FOR USE

Step 1 - Attach FaceGuard to OR Table

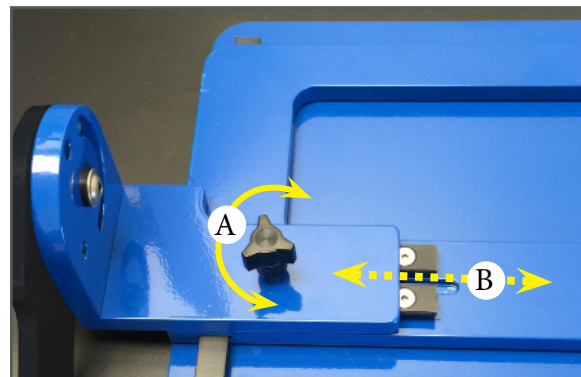
1. Mount rail clamps to the table accessory rails.
2. Adjust width for your OR table accessory rails
 - Loosen the small Width-Adjustment Knob, on the underside of the frame. (A)
 - Slide the frame until the legs are at the appropriate width. (B)
 - Legs must be at 90° to the frame when secured in rail clamps, with no bowing.
3. Slide both legs into clamps simultaneously; two-person installation required. (C)

 **CAUTION** - Maintain a safe distance between tubes and the underside of the tray.

 **CAUTION** - Maintain full control of the device until the clamps are secured. (D)

4. Tighten both rail clamps.
5. Tighten the width-adjustment knob securely to lock the width for your OR table. **Do not over-tighten the knob.**

NOTE: If using FaceGuard on only one table model, you may set the width once and keep it locked in that position to skip steps 1.2 and 1.5 regarding width-adjustment.

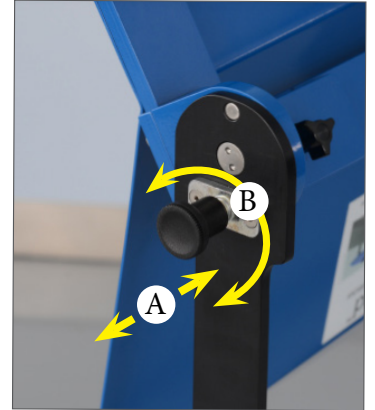


INSTRUCTIONS FOR USE (continued)

Step 2 - Set Tray Position

1. Ensure instrument tray is perpendicular to the legs for clinical use, as it may be pivoted to parallel with the tray for easy storage.

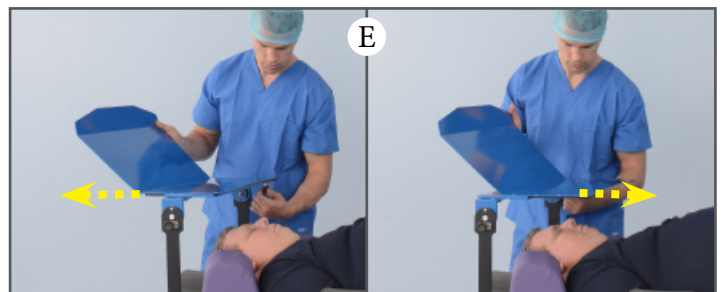
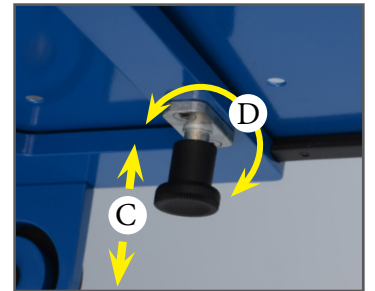
- Pull the Leg Spring Pin knobs out to disengage the Leg Spring Pins from the restraining holes. (A)
- Turn the knobs 90° to lock the pins in the open position. (B)
- Swing the legs into the desired position and rotate the knobs back 90° to release the pins. (B)
- The unlocked pins will re-seat with an audible “click” when they align with the new restraining holes.



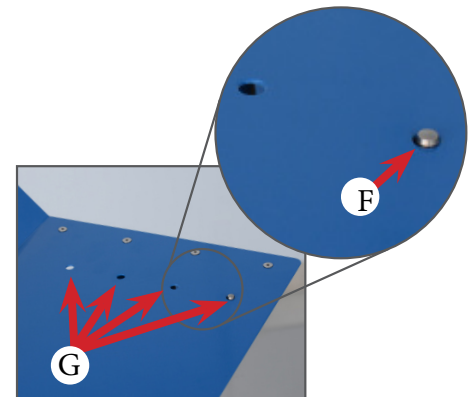
CAUTION - If you have moved the legs to the full stop position and the pins have not re-seated, turn the knobs to unlock the pins. They should snap into place.

2. Adjust tray to desired position over the patient’s head.

- Pull the Tray Spring Pin knob out to disengage the pin from the restraining hole. (C)
- Turn the knob 90° to lock the pin open. (D)
- Slide the tray into the desired position. (E)
- Rotate the knob back 90° to release the pin. (C)
- The unlocked pin will re-seat with an audible “click” when aligned with one of desired restraining holes.



CAUTION - Visually inspect that the spring pin is in a restraining hole prior to draping the tray. (F)
There are four pre-set restraining holes. (G)

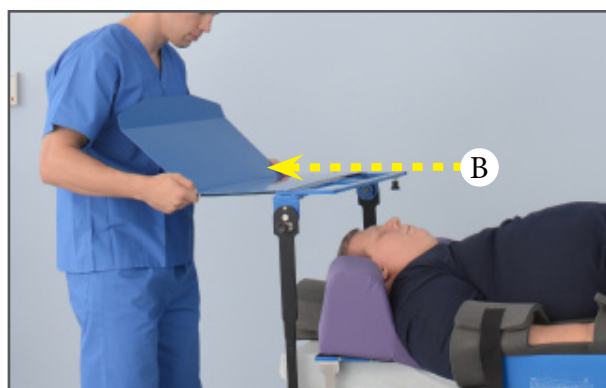


GETTING FULL ACCESS IN AN EMERGENCY - Removing the tray

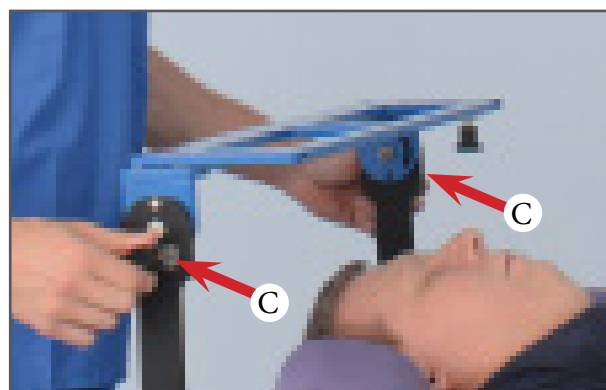
1. Locate the Tray Spring Pin under the frame. (A)
2. Pull the knob out and turn 90° to lock open.



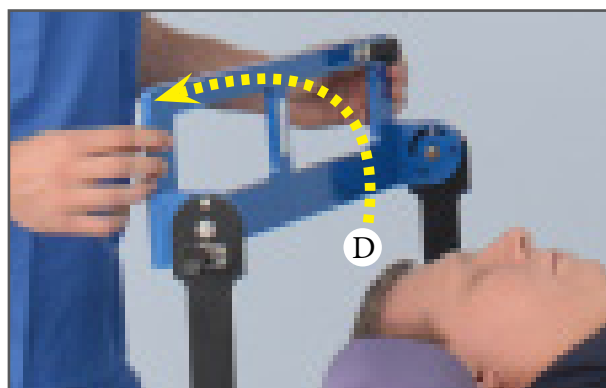
3. Use both hands to slide the tray off the frame. (B)



4. Pull out and turn both Leg Spring Pins (left and right sides) 90° to lock open. (C)



5. Lift the leading edge of the frame 90° into vertical position to provide full access to the patient's face. (D)



CLEANING and STORAGE

Follow the hospital's cleaning, hygiene, and disinfection protocol for table accessories. 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 FaceGuard in a secure location to prevent damage. FaceGuard has legs that swivel to allow a configuration that is easier for storage. Take care not to drop device.

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 FaceGuard Patient Head Shield and Instrument Tray is 5 years under normal use.

Always inspect all components before use. Look for signs of warping or cracks/chips in finish which may impact performance.

If unsure of usable condition of FaceGuard, 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 FaceGuard Patient Head Shield and Instrument Tray.

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 FaceGuard properly.

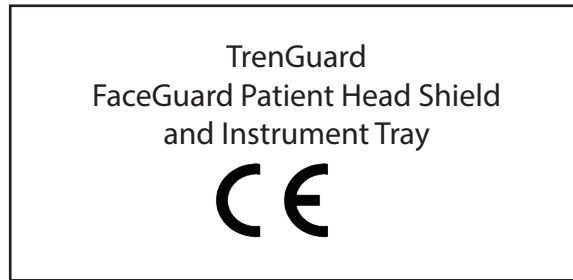
Contact D. A. Surgical for training options.

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



EXPLANATION OF SYMBOLS

 MD	MEDICAL DEVICE		
	INDICATES A POTENTIAL RISK		CONSULT INSTRUCTIONS FOR USE
 LOT	BATCH CODE / LOT NUMBER	 SN	SERIAL NUMBER
	MANUFACTURER		DATE OF MANUFACTURE
	CONFORMITY MARK	 EC REP	AUTHORIZED REPRESENTATIVE IN EUROPEAN COMMUNITY