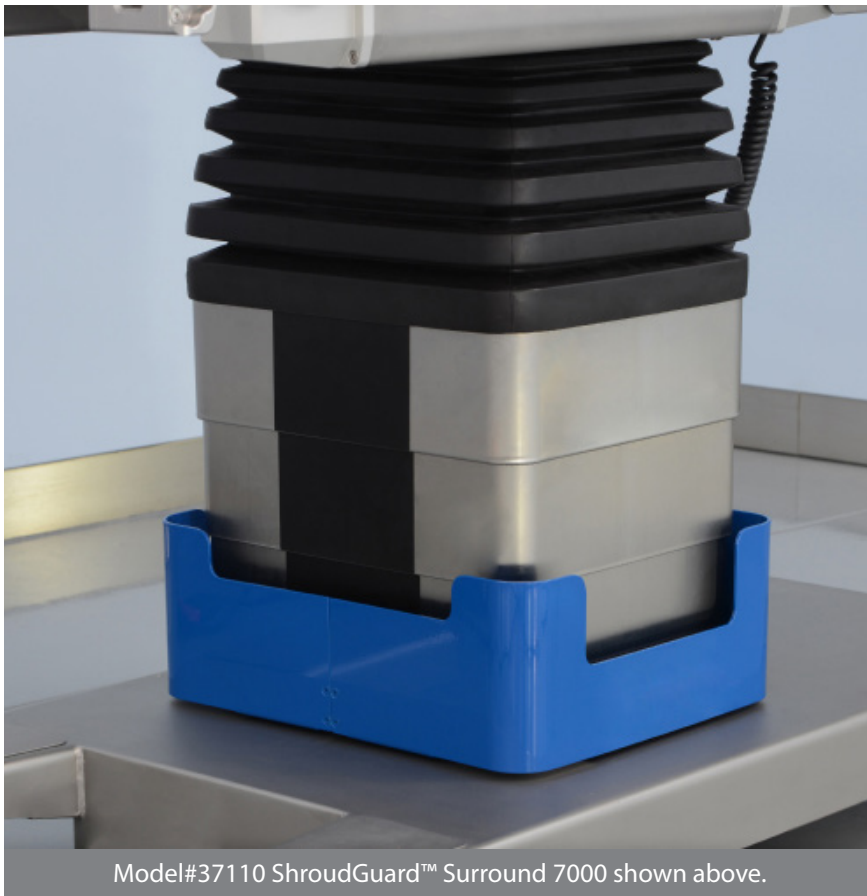


Instructions for use:

ShroudGuard™

OR Table Pedestal Protector



Model#37110 ShroudGuard™ Surround 7000 shown above.

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- 37110 ShroudGuard™ Surround 7000
- 37303 ShroudGuard™ Surround MPB3

- OR Table Pedestal Protector for Trumpf® 7000/7000dv
- OR Table Pedestal Protector for Merivaara Promerix™ and Promerix™ B3

Discontinued models:

- 37120 ShroudGuard™ Surround Titan
- 37210* ShroudGuard™ Surround 3085
- 37212* ShroudGuard™ Surround 4085
- 37214* ShroudGuard™ Surround 5085 NL
- 37216 ShroudGuard™ Surround OT1200
- 37217* ShroudGuard™ Surround 5085
- 37220 ShroudGuard™ Surround CMAX
- 37221 ShroudGuard™ Surround CMAX3
- 37222 ShroudGuard™ Surround for CMAX BP
- 37224 ShroudGuard™ Surround OD850

- OR Table Pedestal Protector for Trumpf® Titan®
- *OR Table Pedestal Protector for STERIS® Amsco 3080, 3085
- *OR Table Pedestal Protector for STERIS® 4085, 4095
- *OR Table Pedestal Protector for STERIS® 5085, 5095 - no latch
- OR Table Pedestal Protector for STERIS® OT1200
- TOR Table Pedestal Protector for STERIS® 5085, 5095
- OR Table Pedestal Protector for STERIS® CMAX®
- OR Table Pedestal Protector for STERIS® CMAX® 3
- OR Table Pedestal Protector for STERIS® CMAX® 2 with black plastic
- OR Table Pedestal Protector for Berchtold® Operon® D850

* Contact D. A. Surgical at CustomerService@da-surgical.com or 001 (800) 261-9953 for alternate source of protection for these table models.

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INTENDED USE

ShroudGuard is a device in the form of a fence/surround intended to protect the pedestal/cladding of an operating table from direct physical damage. It is a multi-piece shield/guard which clips together around the perimeter of the base of the pedestal. This is a reusable device.

INDICATION FOR USE


ShroudGuard should only be used with the appropriate corresponding model of OR table.

WARNINGS and CAUTIONS

WARNING - PERSONAL INJURY HAZARD:

- Read and understand all instructions presented in this manual before attaching/removing ShroudGuard.
- Take care to prevent pinching of clothing or skin when connecting the closure mechanism.

WARNING - INFECTION HAZARD:

-  • ALWAYS ensure ShroudGuard is cleaned and dried prior to use.
- DO NOT submerge. DO NOT heat sterilize.

WARNING - EQUIPMENT HAZARD:

- DO NOT use if ShroudGuard is damaged or if shroud cladding on OR table is significantly bent.
- ShroudGuard is not intended to protect table/shroud from C-arm damage.
- ShroudGuard may not protect table/shroud from damage in every situation, care should still be taken when placing extra equipment on table pedestal base and articulating table in extreme positions.

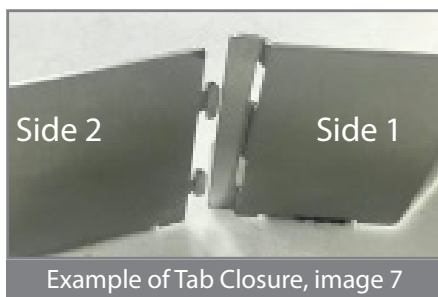
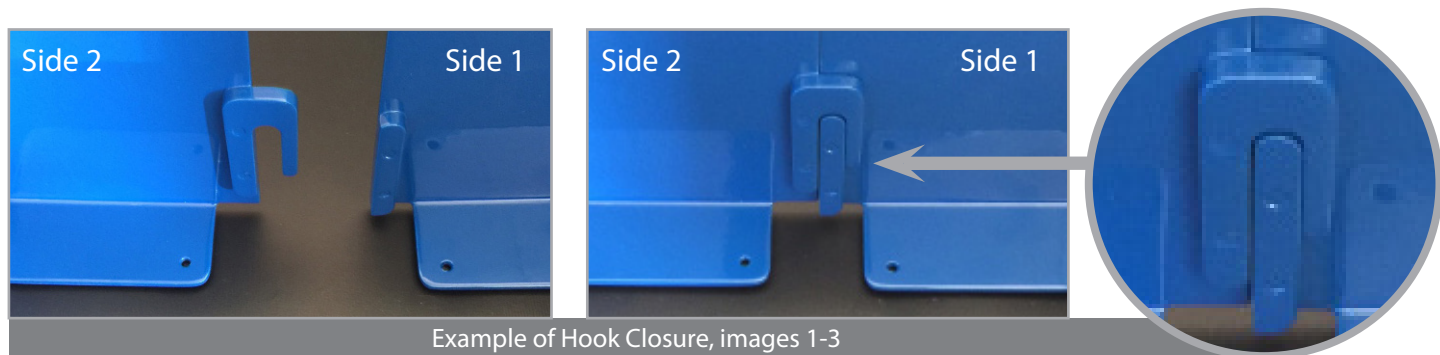
INSTRUCTIONS FOR USE

Step 1 - Verify device and prepare for installation

- A. Compare model number and name on UDI label on the ShroudGuard to the listing on the cover of this IFU to ensure you have the correct version for your OR table make and model.
- B. Inspect ShroudGuard for damage, warping, bends, dents, or missing rubber bumpers (as applicable) before use.
- C. Raise table to full height, with table surface parallel to the floor.

Step 2 - Install

- A. Verify proper orientation of ShroudGuard, based on the shape of your table base and/or any labeling or controls on your table shroud cover.
- B. Carefully place side 1 around table shroud.
- C. Carefully lower side 2 into place, aligning the hooks or tabs with the pin or slots on side 1. Secure ShroudGuard with the applicable closing mechanism as shown below. (Closing mechanism may differ depending on ShroudGuard model number.)
 - 1. Hook Closures: secure as shown in images 1-6 below.
 - 2. Tab Closures: secure as shown in images 7-13 below and on next page.

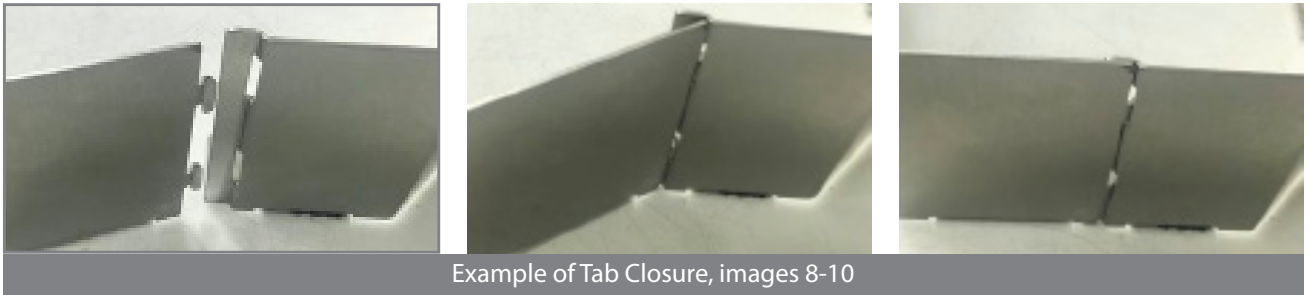


INSTRUCTIONS FOR USE (continued)

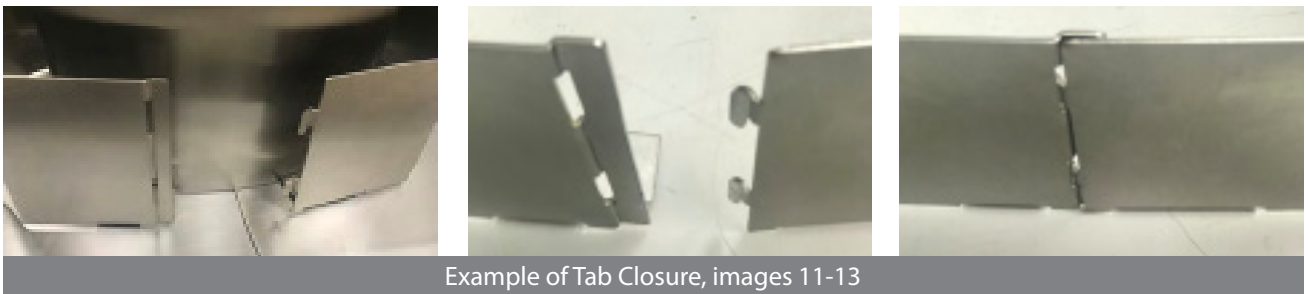
Step 2 - Install (continued)

3. Tab Closures (continued)

- a. Connect straight tabs into slots of first.



- b. Swing halves together and connect angled tabs into slots.



- E. If ShroudGuard model uses a Swing Latch Lock, swivel the latch into closed position and confirm it is snug and secure.
(Swing Latch design may differ, depending on ShroudGuard model number.)



Step 3 - Test

- A. Carefully lower the OR Table to its lowest setting while checking to make sure that the ShroudGuard is in the proper position and will not make contact with the table shroud.

NOTE: Use caution when articulating OR Table in extreme positions to ensure ShroudGuard does not interfere with under-table components or cables.

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. Allow to dry.



DO NOT submerge.
DO NOT heat sterilize.

After disinfecting and drying, store ShroudGuard in a secure location to prevent damage or place back into service on appropriate OR table. 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 ShroudGuard OR Table Pedestal Protector 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 ShroudGuard, 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 ShroudGuard OR Table Pedestal Protector.

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 ShroudGuard properly.

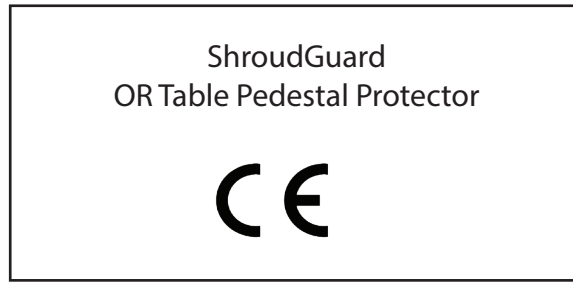
Contact D. A. Surgical for training options.

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




D. A. SURGICAL










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EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

EXPLANATION OF SYMBOLS

 <p>MEDICAL DEVICE</p>	
 <p>INDICATES A POTENTIAL RISK</p>	 <p>CONSULT INSTRUCTIONS FOR USE</p>
 <p>BATCH CODE / LOT NUMBER</p>	 <p>SERIAL NUMBER</p>
 <p>MANUFACTURER</p>	 <p>DATE OF MANUFACTURE</p>
 <p>CONFORMITY MARK</p>	 <p>AUTHORIZED REPRESENTATIVE IN EUROPEAN COMMUNITY</p>