

Instructions for use:

ArmGuard™ Patient Arm Protector

ArmGuard Classic Sled Kit

#40004

Includes:

#40140 ArmGuard Standard Sled x 2

#40240 ArmGuard Bariatric Sled x 2



Alternative Language IFUs:

www.da-surgical.com/ifu



Instructional videos:

www.da-surgical.com/instructional-videos



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INTENDED USE

ArmGuard Patient Arm Protector is intended to secure the arm at the side of a patient during surgery without “tucking,” protect the arm from contact with other accessories, control medial compression, and provide immediate visual and physical access to the IV and monitor lines in the case of emergencies without having to un-tuck the arm.

WARNINGS and CAUTIONS

WARNING - PERSONAL INJURY HAZARD:

- Read and understand all instructions presented in this manual before attaching/removing ArmGuard.
- Before positioning the patient using ArmGuard, users must complete training on proper use of ArmGuard.
- DO NOT use if ArmGuard components are damaged.
- ALWAYS inspect all ArmGuard components before use.
 - DO NOT use if VELCRO® Brand fastener* (from now on, referred to as Velcro) on sled or padded arm protector 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 if patient, with arm(s) at side, is wider than OR table plus horizontal support of ArmGuard sled(s). Patient arm(s) should rest within the horizontal cradle of the sled, NOT on hard surface of sled's upright edge.
- DO NOT use when table is articulated in lateral tilt.

WARNING - INFECTION HAZARD:

- DO NOT reuse ArmGuard single-use pads.
- ALWAYS ensure sleds are cleaned and dried prior to use.
- DO NOT submerge sleds. DO NOT heat sterilize sleds.

PRODUCT COMPONENTS

NUMBER CODE ON EACH PART

1. ArmGuard Sled
(Kit includes Bariatric and Standard Sleds)
2. ArmGuard Pack padded arm protector - required for use
(Available in STANDARD or BASIC - see details below)
3. ArmGuard Width Extender - required for use with high-BMI patients
(Available in two sizes - see details below)



ArmGuard Bariatric Sleds (*left*)

- longer under-mattress extension for use with Width Extender for larger patients
- model #40240

ArmGuard Standard Sled (*right*)

- model #40140



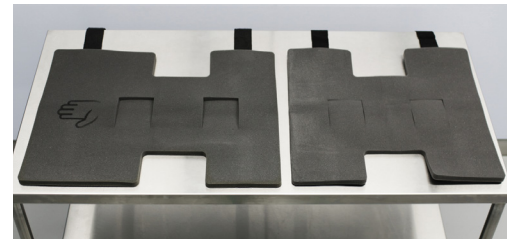
ArmGuard STANDARD (*left*)

- each Pack contains two (2) padded arm protectors, 24 in | 61 cm long, to fully enclose and protect patient's fingers
- model #40401 (single pack), model #40412 (case of 12 packs)



ArmGuard BASIC (*right*)

- each Pack contains two (2) padded arm protectors, 20 in | 51 cm long
- model #40103 (single pack), model #40101 (case of 12 packs)



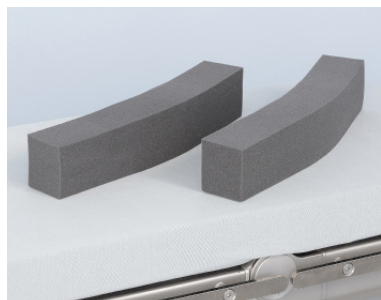
ArmGuard Width Extender

- each Pack contains two (2) Width Extender Pads for table mattresses up to 3 in | 7.6 cm
- model #40206 (single pack), model #40203 (case of 12 packs)



ArmGuard XL Width Extender

- each Pack contains two (2) Width Extender Pads for table mattresses up to 4 in | 10.2 cm
- model #40207 (single pack), model #40204 (case of 12 packs)



INSTRUCTIONS FOR USE

Step 1 - Select the appropriate ArmGuard Packs based on patient anatomy and surgeon preference:

- ArmGuard STANDARD - for all patients to fully enclose and protect the patient's hands and fingers.
- ArmGuard BASIC - for patients with shorter arms or to leave patient's hand exposed.

For a patient wider than the OR table, select the appropriate Width Extender pads, based on mattress thickness:

- ArmGuard Width Extender - for table mattresses up to 3 in | 7.6 cm.
- ArmGuard XL Width Extender - for table mattresses up to 4 in | 10.2 cm.

Step 2 - Open Pack(s) and inspect ALL components

- Open pack(s) at least 10 minutes prior to use.
- ArmGuard 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 if Velcro on sleds or pads appears worn, peeling, or damaged in any manner.



Step 3 - Transfer patient to table

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

INSTRUCTIONS FOR USE (continued)

Step 4 - Secure Pad to Sled

- A. Choose correct STANDARD pad for right or left side arm.

(BASIC pads, which are shorter, are interchangeable.)

- B. Place ArmGuard sled on table.

- C. Place pad on table, Velcro side up, next to the sled.

- D. Gently pull up the middle two squares.

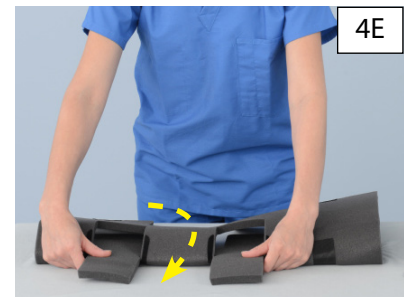
(These are the “adhesion tabs” to be used to fasten the pad to the sled.)

- E. Flip the tabs away from you and place them on table with Velcro side down.

- F. Pick up pad with the ends folded back. Place pad on sled, Velcro-side down.

- G. Place tabs snug against the side of the sled. Secure tabs in position.

(The longest end of the STANDARD ArmGuard pad will aim toward the distal end and patient’s hand. BASIC pads do not have a “long” end.)



INSTRUCTIONS FOR USE (continued)

Step 5 - Place Width Extender

- A. If using Width Extender (for patients with arms that extend past the edge of the OR table mattress), insert it under the arm pad before securing patient's arm.



Step 6 - Slide Sled under table mattress

NOTE: While sliding the sled under the mattress, ensure that the arm pad stays on top of the mattress.



Step 7 - Secure patient's arm

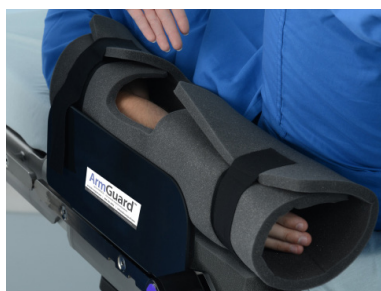
- A. Insert arm.

(The longest end of the STANDARD pad should cover and protect the hand. BASIC pad may leave fingers exposed.)
- B. Wrap pad around arm and secure Velcro on both segments of the pad.

(For the BASIC pad, you may reposition the sled or the pad if you want the pad to envelop the fingers.)

NOTE: Immediate, convenient IV line and port access without the need to un-tuck the patient's arm.

NOTE: Pad is easily re-opened and closed by anesthesia for line access and adjustment, etc.



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), also useful for ArmGuard.



DO NOT submerge.
DO NOT heat sterilize.

After disinfecting and drying, store ArmGuard Sleds in a secure location to prevent damage. Store at room temperature. Avoid exposing ArmGuard 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 ArmGuard Sleds is 3 years with periodic maintenance of hook fastener.

All other components are single-use only.

Always check integrity of the Velcro on ArmGuard Sleds before use. If Velcro begins to peel, creep, or appears worn, the Velcro must be replaced. Contact D. A. Surgical for service options.

If foam pads 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 ArmGuard, 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 ArmGuard.

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 ArmGuard properly.

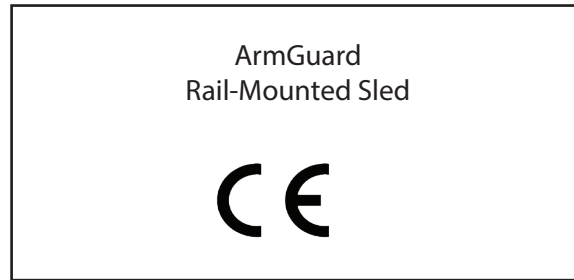
Contact D. A. Surgical for in-service options.

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



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 |