

A301 WaffleGrip® Trendelenburg Positioning + BackSaver® Slide Sheet Kit, 10-Pack



A301 contains 10 kits (10 uses)

Each kit contains:

- 1 BackSaver Slide Sheet
- 1 WaffleGrip Anti-Slip Layer
- 1 WaffleGrip Draw Sheet

Instructions for Use

Device Description

The WaffleGrip Trendelenburg Positioning System uses friction to securely hold a patient in steep Trendelenburg position and must be used with a HotDog Warming Mattress. It also allows heat from the HotDog Warming Mattress to reach the patient, if the Mattress is set to warm.

WaffleGrip is single-use and must be discarded following completion of the surgical procedure.

Indications for Use

WaffleGrip is a single-use device to secure the patient on the table during surgical procedures utilizing the steep Trendelenburg position while also accommodating underbody warming. WaffleGrip is intended to be used by healthcare professionals in accordance with these instructions for use. The use environment is a professional healthcare facility.

Target Patient Groups

The patient population is adult patients for whom the steep Trendelenburg position is determined to be necessary by the healthcare professionals. There is no weight limit.

Intended Use

WaffleGrip is intended to position and secure patients in the steep Trendelenburg position during surgical procedures.

Contraindications

- None

Warnings

- Ensure that the patient's skin is in direct contact with the WaffleGrip surface throughout the procedure.
- Do not use lubricants, oils, or powders on the patient's skin in contact with WaffleGrip. If necessary, clean skin with alcohol before use. A decrease in friction will reduce securement capability and could result in unintended patient movement.
- Not designed for use in reverse Trendelenburg.
- Do not use at a Trendelenburg angle greater than 45°.
- California Proposition 65 Warning: The medical devices and products mentioned in this IFU may contain chemicals including Urethane, which is known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information go to, www.p65warnings.ca.gov

Precautions

- A waffle pattern may be temporarily visible on skin, but it will dissipate shortly following the procedure.
- Ensure the WaffleGrip remains flat under the patient. If it is rolled or folded, flatten before proceeding.
- Do not tilt the OR table until the BackSaver Slide Sheet has been removed.
- Ensure that the U300 HotDog Trendelenburg Warming Mattress is securely strapped to the table before placing the WaffleGrip kit. Refer to the HotDog Warming Mattress IFU for details.
- This device should not be disposed of with general waste at end of life. Follow local regulations for disposal. The device does not pose any potential hazard.

- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the country in which it occurred.

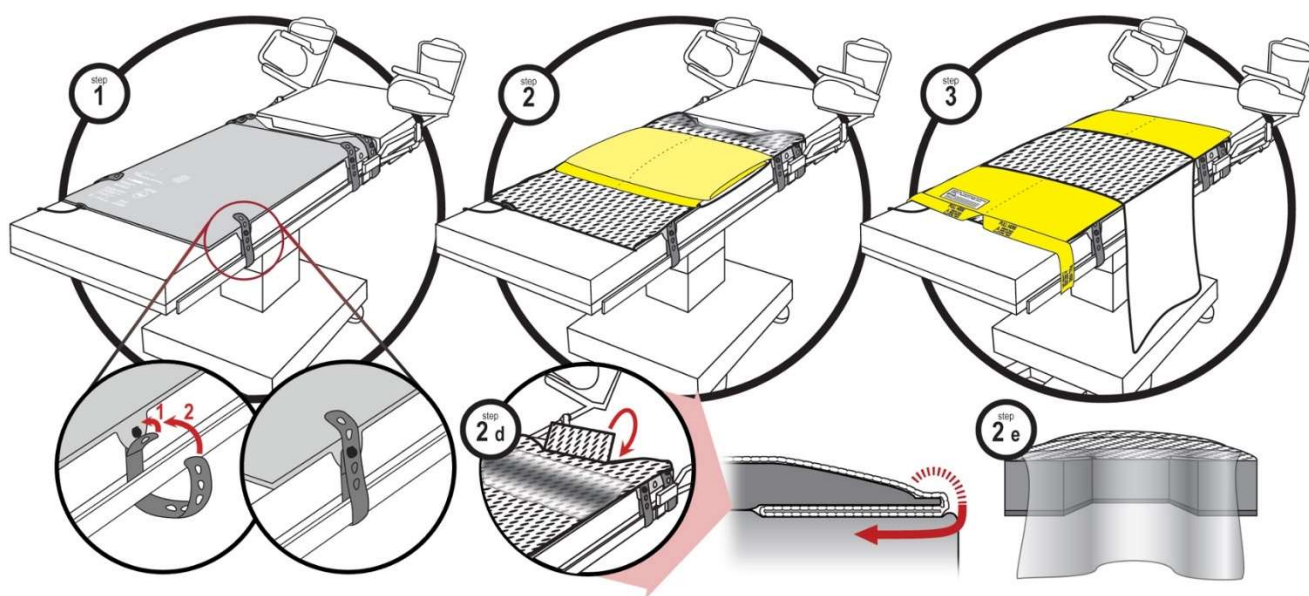
Set-up and Use

1. Secure U300 HotDog Trendelenburg Warming Mattress to the Operating Table

- Place U300 Mattress on operating table with sensor and cable toward head end.
- Align the perineal cutout on the Warming Mattress with that of the operating table.
- Attach Mattress to side rails using at least 4 straps, as shown in step 1.

2. Align and Secure WaffleGrip Positioning System.

- Place folded A301 Kit on the U300 Mattress as shown in step 2 and unfold non-slip WaffleGrip layer.
- The sealed lines on WaffleGrip should be aligned with the edges of the U300 Mattress
- Feed Mattress cable through pad porthole and fold excess WaffleGrip material under U300 Mattress.
- IMPORTANT**— at the perineal end, **Tuck reinforced plastic flap between U300 and operating table mattress** [see cross-section 2d]. Flap should not be visible or hanging amongst perineal cutout. Tuck remaining WaffleGrip layer (beyond fold lines) under U300 Mattress.
- Ensure that the perineal drape (2e), the plastic material at the perineal end, is draped and hanging over the perineal cut-out to prevent fluids from leaking under the U300 Mattress. **IMPORTANT:** if the plastic is under the patient, it could impact WaffleGrip performance, and the patient could move in Trendelenburg.



3. Align and position the BackSaver® Slide Sheet

- Unfold the yellow BackSaver Slide Sheet over the WaffleGrip layer.
- Tuck the head-end of the BackSaver Slide Sheet under the U300 Mattress.
- Ensure that the pull tabs are hanging off the side of the operating table for easy removal.
- Position the draw sheet in the center of the U300 Mattress with the grip side facing up.

4. Initiate Patient Warming

- Connect the U300 Mattress to the HotDog Controller using A112 blue cable. Select temperature and start warming.
- See Warming Mattress IFU (2064) for instructions on operating HotDog patient Warming Mattress.

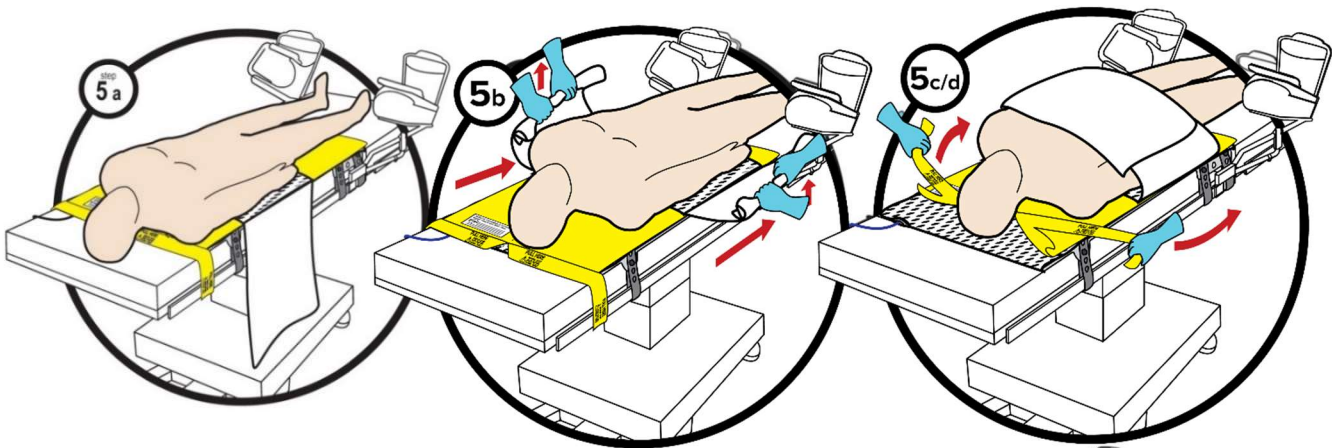
5. Maneuver and Position the Patient

- During prep, the patient should lie on top of the yellow BackSaver Slide Sheet and the draw sheet.
- After induction, to reposition the patient lower on the table, use the draw sheet to slightly raise the patient from the table while moving the patient down the table over the yellow BackSaver Slide Sheet. Follow institutional protocols for supporting the legs, head, and neck.
- Once the patient is properly positioned for lithotomy, place draw sheet ends over the patient for yellow BackSaver Slide Sheet removal.
- REMOVE the Slide sheet by pulling on the two tabs at the head end. Be sure to completely remove the yellow BackSaver Slide Sheet, which will tear down the perforation in the middle.



IMPORTANT—BackSaver Slide Sheet must be removed prior to tilting the table or serious injury may result.

- Check the draw sheet and WaffleGrip anti-slip layer remains flat under the patient after repositioning.
- Secure arms with the draw sheet as shown or per hospital positioning protocol.
 - Align ends of draw sheet between patient's torso and arm, then wrap arms to secure.
 - Tuck excess material **between the U300 Mattress and operating table mattress** to hold in place.



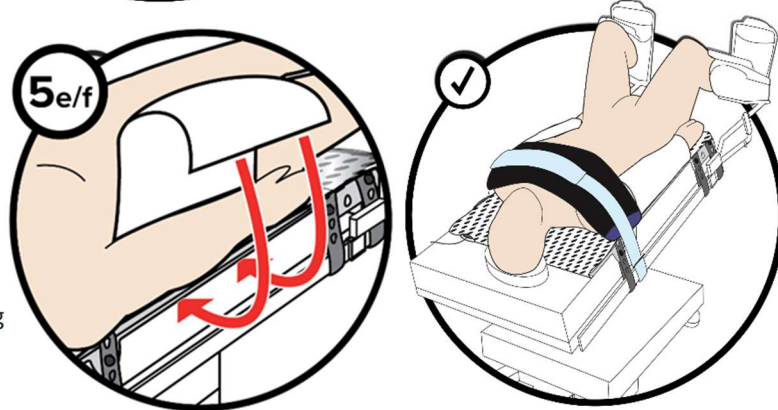
IMPORTANT – The patient must be in direct skin contact with WaffleGrip to prevent slipping in Trendelenburg.

✓ Optional: You can also use a B500 HotDog Universal Warming Blanket folded across the patient's chest. Use a hospital-provided strap to secure the blanket. Strap not included.

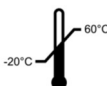
✓ See separate instructions for HotDog Patient Warming Blankets.

USE ONLY AS INDICATED

Reminder: A waffle pattern may be temporarily visible on skin, but it will dissipate shortly following procedure.



Definition of Symbols

	Medical Device		Unique Device Identifier		Conforms to European Medical Device Regulation 2017/745
	Consult the electronic instructions for use on the website at the URL provided.		Reference Number		Medical Device restricted to sale by or on the order of a physician
	Non-Sterile		Natural Latex Free		Single Use
	See IFU for Warnings and Precautions		Manufacture Location		EU Authorized Representative
	MDR Importer		Manufacture Year		Lot Number
	Keep Dry		Transport and storage humidity range 20-80%		Transport and storage temperature range - 20°C–60°C
	Separate treatment from general waste at end of life. See Precautions for details.				



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HotDog is a trademark of Augustine Temperature Management, registered in the U.S. Patent & Trademark Office. Devices are protected by some or all of the following patents: (US Patents 10, 575,784; 10,765,580; 10,959,675; 10,980,694; 10,993,866; 11,103,188).

Other patents are pending.

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