

A300 WaffleGrip® Trendelenburg Positioning Kit, 10 Pack



A300 contains 10 kits (10 uses)

Each kit contains:

- 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 comprised of 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

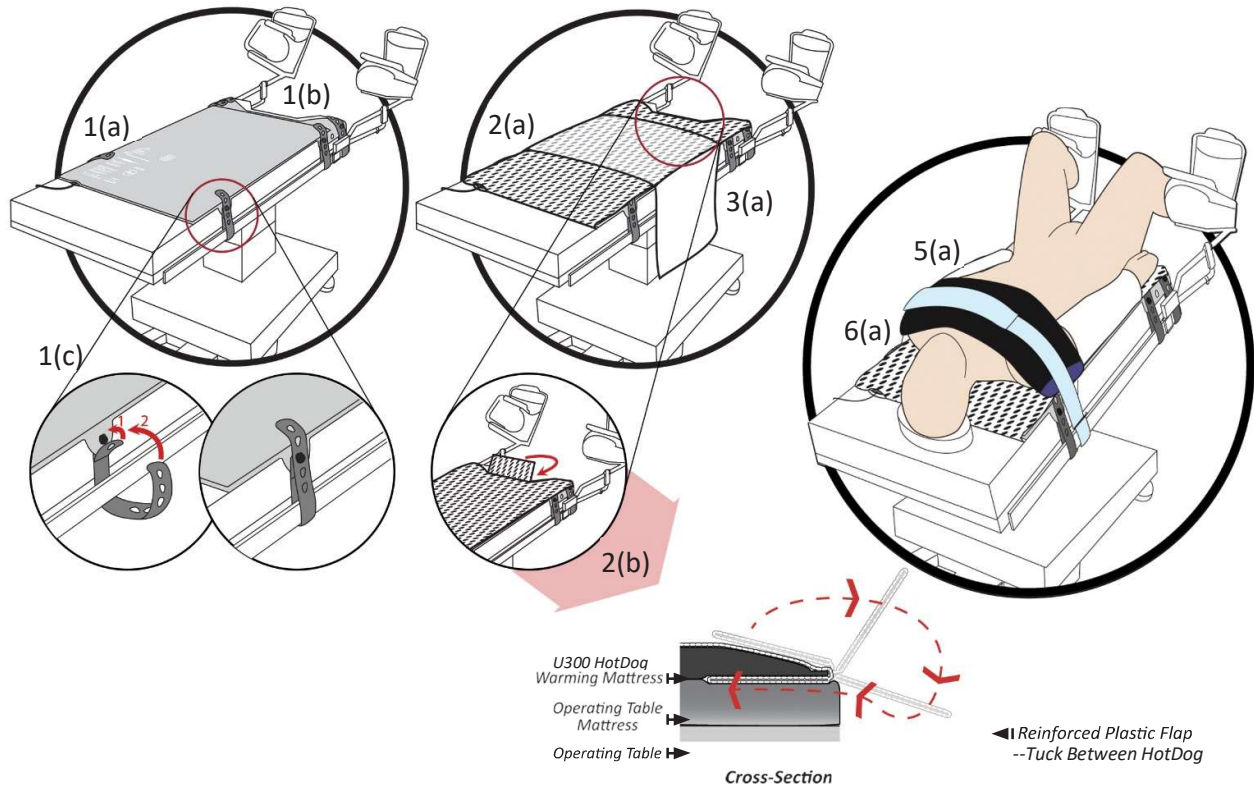
Warnings

- 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

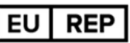
- A waffle pattern may be temporarily visible on skin, but it will dissipate shortly following the procedure.
- Ensure the WaffleGrip remains flat under the patient. If it is rolled or folded, flatten before proceeding.
- Ensure that the U300 HotDog Trendelenburg Warming Mattress is securely strapped 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 the 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. Place the U300 HotDog Warming Mattress on operating table with sensor and cable toward head end (a) as described in the HotDog Warming Mattress IFU. Align the perineal cutout on the warming mattress with that of the operating table (b). Attach Mattress to side rails using **at least 4** straps as shown (c).
2. Place non-slip WaffleGrip over the U300 HotDog Warming Mattress as shown in label and unfold. Feed mattress cable through pad porthole (a). Align sealed fold lines on WaffleGrip with ends of Warming Mattress. The reinforced plastic flap should face the perineal cutout.
IMPORTANT – Tuck reinforced plastic flap between U300 and operating table mattress (see cross-section)(b)]. Flap should not be visible or hang untucked over the perineal cutout. Tuck remaining WaffleGrip (beyond fold lines) under Warming Mattress.
3. Place the Non-Woven Draw Sheet perpendicular across table as shown, with textured WaffleGrip toward the patient (a).
4. Connect the U300 Warming Mattress to the Controller using the A112 blue cable and select temperature to begin warming. See U300 Warming Mattress per IFU (2064) for instructions on operating the Mattress.
5. **IMPORTANT – Patient must be in direct skin contact with WaffleGrip** to prevent slipping in Trendelenburg. Position patient using draw sheet. Align patient's buttocks over tucked end of WaffleGrip (at perineal cutout). Tuck arms using draw sheet as shown or per hospital positioning protocol (a). WaffleGrip is considered a thin barrier as required by the Mattress IFU.
6. 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.
7. At the end of surgery, dispose of WaffleGrip according to local regulations. The device does not pose any potential hazard.

Definition of Product 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		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



Augustine Temperature Management, LLC
15305 Minnetonka Blvd., Minnetonka, MN 55345 USA
www.hotdogwarming.com Ph: 952-465-3500



EMERGO EUROPE
Westervoortsedijk 60 6827 AT Arnhem, The Netherlands



MedEnvoy Global BV
Prinses Margrietplantsoen 33 – Suite 123,
2595 AM, The Hague, The Netherlands

Customer Service Contact Phone: +1-952-465-3500 Email: CS@AugSurg.com

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.

© 2024 Augustine Surgical, Inc. All rights reserved.

P/N 2793EN Rev A (06/2024)