

Snuggle Warm® Patient Warming Blanket

- en** Instructions for Use
- fr** Mode d'emploi
- de** Gebrauchsanleitung
- it** Istruzioni per l'uso
- es** Instrucciones de uso
- pt** Instruções de Utilização
- nl** Gebruiksaanwijzing
- sv** Bruksanvisning
- da** Brugervejledning
- no** Bruksanvisning
- fi** Käyttöohjeet
- el** Οδηγίες χρήσης
- ja** 取扱説明書
- cs** Návod k použití
- hu** Használati útmutató

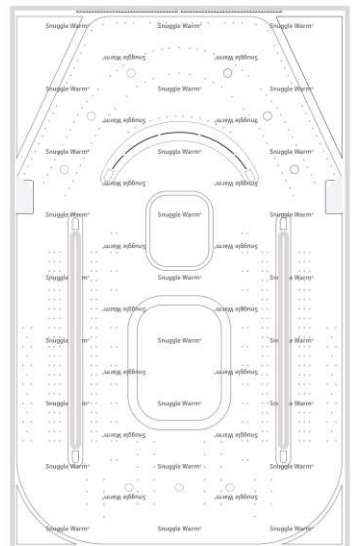
- pl** Instrukcja użycia
- et** Kasutusjuhend
- lt** Naudojimo instrukcijos
- tr** Kullanım Talimatları
- ro** Instrucțiuni de utilizare
- ru** Инструкция по эксплуатации
- zh** 使用说明。中文部分请参考包装中所附产品中文说明书。
- ko** 사용 지침
- ar** إرشادات الاستخدام
- be** Інструкцыі па выкарыстанні
- bn** ব্যবহারের
- id** Petunjuk Penggunaan
- th** ข้อแนะนำการใช้

Patent No. US 9,969,127

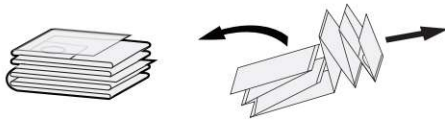


Manufacturer:
Smiths Medical ASD, Inc.
 6000 Nathan Lane North
 Minneapolis, MN 55442 USA
 Tel: 1 800 258 5361 (US/CA)
 Tel: +1 614 210 7300

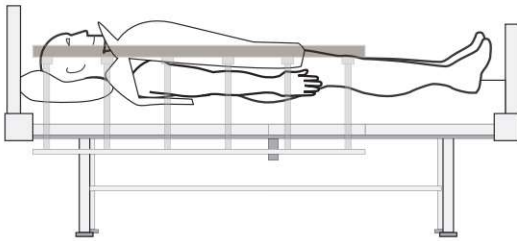
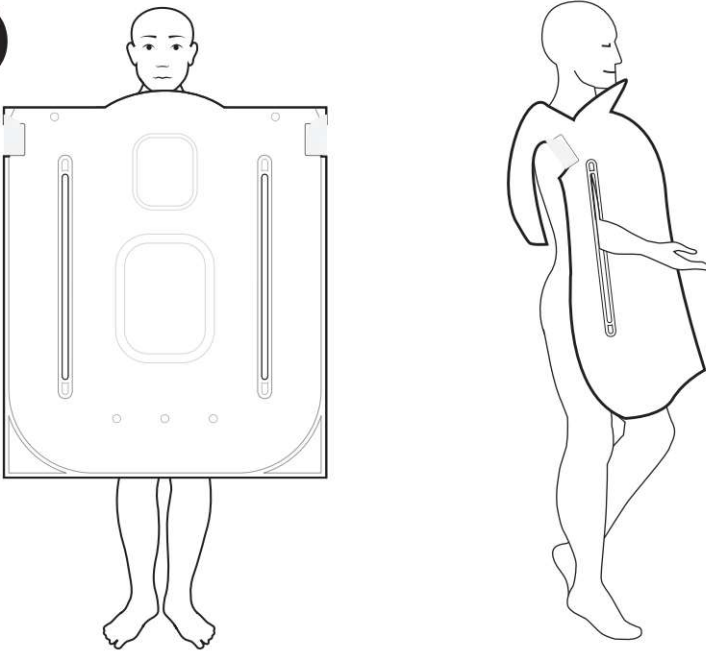
EC REP European Representative:
Smiths Medical Czech Republic a. s.
 Olomoucká 306, Hranice 1 - Město,
 753 01 Hranice, Czech Republic
 Tel: +44 (0)1233 722100



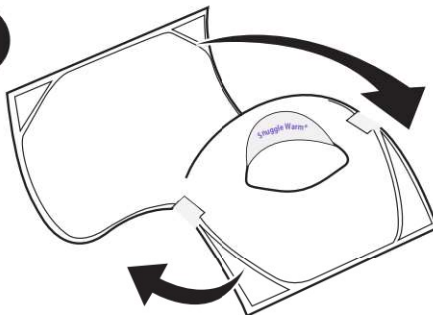
1

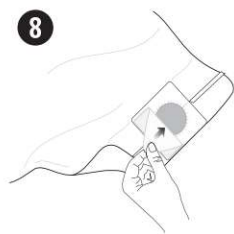
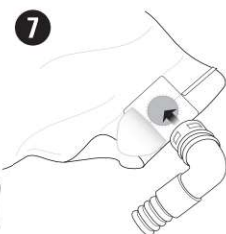
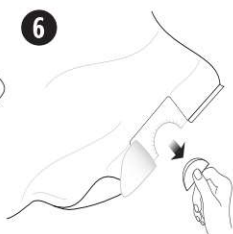
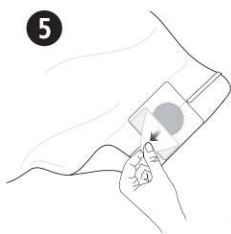
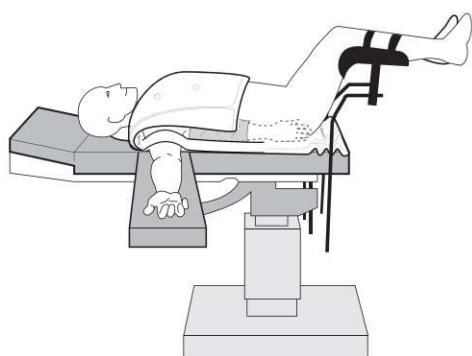
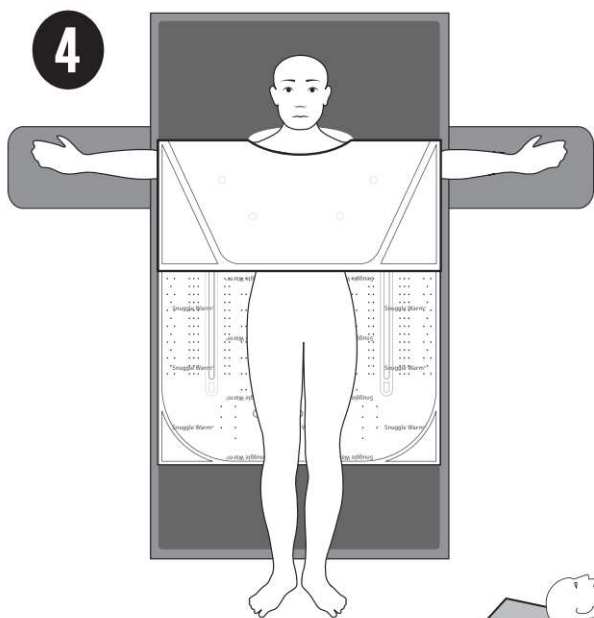


2



3





WARNING

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in serious injury or death to the patient.

Description

The **Snuggle Warm**® Convective Warming Blanket is a disposable, single use blanket that is placed on the patient and is connected to a convective warmer. The convective warmer generates heated air that is distributed throughout the blanket for patient temperature management.

The **Snuggle Warm**® blanket meets Consumer Products Safety Commission's flammable fabric regulation, 16 CFR 1610.

Intended use: Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.

Indications for Use

The **Snuggle Warm**® Patient Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause the patient to become too warm or too cold. The **Snuggle Warm**® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

Contraindications

- Thermal injury may occur if convective warming therapy is applied to lower extremities during aortic cross-clamping procedures.
- Thermal injury may occur if convective warming therapy is applied to ischemic limbs.

Requirements

Compatible convective warmers require the following for use with **Snuggle Warm**® convective warming blankets: (fpm = feet per minute. mpm = meters per minute.)

Minimum Flow Rate	Maximum Flow Rate	Low Temp	High Temp	Minimum Hose Diameter	Maximum Hose Diameter
1541 fpm 470 mpm	2500 fpm 762 mpm	Ambient	113° F 45° C	2.625 in 66.675 mm	3.125 in 79.375 mm

CAUTION: Using a non-Level 1® convective warming device with the Snuggle Warm® blanket without the proper Level 1® Hose Adapter connector may affect the Snuggle Warm® blanket performance.*

*Use Appendix A to select the proper Level 1® Hose Adapter.

Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

Warnings

- Monitor patient's body core temperature, vital signs, and observe cutaneous response at regular intervals to prevent thermal injury. If erythema or instability in vital signs is evident, decrease the temperature setting or discontinue use of convective warming therapy.
- Monitor the patient's breathing closely to prevent suffocation injury when the patient's nose or mouth is near the convective warming blanket (or the plastic drape when present).
- Cover all open wounds that may come into contact with the convective warming blanket to prevent airborne contamination.
- To prevent thermal injury, do not use the highest temperature setting when treating patients who have poor perfusion.
- Use only one convective warmer and one hose. Use of multiple convective warmers in multiple inlet ports of the same convective warming blanket may cause damage to the blanket and thermal injury to the patient.
- To prevent thermal injury, do not allow the patient's body or extremities rest on the active hose inlet.
- Do not place objects onto the convective warming blanket that will obstruct air flow. Items on the blanket may produce localized pressure on the patient's skin, reducing cutaneous blood flow and may cause thermal injury.
- Always place the perforated side of the convective warming blanket – the side with the small holes – toward the patient. Incorrect blanket positioning may impact therapy.
- Do not use a convective warming blanket over transdermal medications as this may lead to increased drug delivery that may result in patient injury or death.
- Do not sterilize convective warming blankets. Sterilizing blankets may damage the blanket and may cause thermal injury to the patient.
- No free-hosing. The hose nozzle must be connected to the blanket. Do not treat patients with the hose alone as thermal injury may occur.
- Do not use a non-Level 1® convective warmer and Snuggle Warm® blanket without the proper Level1® Hose Adapter* as patient therapy may be affected.

*Use Appendix A to select the proper Level 1® Hose Adapter.

Note: When using a Level 1® Convective Warmer System, a hose adapter is not needed.

Disposal Information

Dispose of the convective warming blankets in a safe manner according to local guidelines for disposal of medical waste.

Level 1, Snuggle Warm, Level 1 design mark and Smiths Medical design mark are trademarks of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark office and certain other countries. ©2014, 2017, 2018, 2019 Smiths Medical. All rights reserved.