

June 24, 2019

**URGENT FIELD SAFETY NOTICE**

COOPERSURGICAL TRANSWARMER® WARMING INFANT TRANSPORT MATTRESS  
P/N 20421

Dear Valued CooperSurgical Customer,

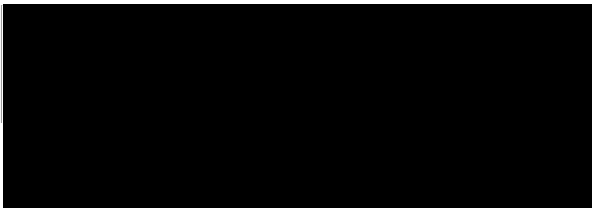
CooperSurgical is issuing a Field Safety Notice for 77 lots its TRANSWARMER® Warming Infant Transport Mattress (TRANSWARMER Mattress) distributed between January 4, 2017 to May 10, 2019 (see **Table 1** on Page 2). The mattress is used to provide warmth during transport of infant within the hospital, or between hospitals.

CooperSurgical has updated the IFU in April 2019 to clarify that use of the TRANSWARMER Mattress with other heat producing devices, such as an incubator, is prohibited. **Such use could lead to serious health consequences, such as skin burns.** Please reference the updated version of the IFU included in this mailing for details on proper use of the product moving forward.

Please complete the enclosed **Acknowledgement and Receipt Form** and return it to CooperSurgical, so that we can document receipt of this letter and track customer responses to ensure patient safety.

The relevant regulatory authorities have been notified of this field safety notice. We sincerely apologize for any inconvenience caused by this safety notice. CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at: +001.203.601.5200 ext. 3300 with any questions regarding this notice.

Sincerely,



| Affected Lots |       |       |
|---------------|-------|-------|
| IJ780         | IJ920 | IK147 |
| IJ782         | IJ924 | IK162 |
| IJ785         | IJ933 | IK164 |
| IJ789         | IJ946 | IK171 |
| IJ794         | IJ948 | IK178 |
| IJ796         | IJ957 | IK184 |
| IJ804         | IJ962 | IK201 |
| IJ807         | IJ973 | IK214 |
| IJ817         | IJ976 | IK238 |
| IJ824         | IJ982 | IK252 |
| IJ832         | IJ985 | IK258 |
| IJ834         | IJ999 | IK265 |
| IJ841         | IK007 | IK270 |
| IJ853         | IK009 | IK276 |
| IJ865         | IK015 | IK298 |
| IJ874         | IK028 | IK318 |
| IJ878         | IK038 | IK322 |
| IJ884         | IK041 | IK330 |
| IJ886         | IK053 | IK332 |
| IJ892         | IK060 | IK339 |
| IJ895         | IK066 | IK353 |
| IJ897         | IK095 | IK361 |
| IJ900         | IK102 | IK378 |
| IJ902         | IK107 | IK384 |
| IJ909         | IK127 | IK390 |
| IJ917         | IK135 |       |

**Table 1:** Product Code: 20421, Distributed: January 4, 2017 to May 10, 2019

**Acknowledgement and Receipt Form: Response is required**

Please complete this form and return it via email: [recall@coopersurgical.com](mailto:recall@coopersurgical.com) or fax to **+001.203.601.9870 ATTN: Product Surveillance.**

Customer Account #: \_\_\_\_\_ Account Name: \_\_\_\_\_

Street Address: \_\_\_\_\_ Town, State, Zip Code: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Email address: \_\_\_\_\_

I have read and understood the instructions provided in the June 24, 2019 notice.

Yes \_\_\_\_ No\_\_

Any adverse events associated with this correction? Yes \_\_\_\_ No \_\_\_\_

If yes, please explain:

\_\_\_\_\_

**Please check the box below for confirmation:**

We have received the current version of the Instructions-for-Use (IFU) included in this mailing.

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **+001.203.601.5200 Ext. 3300** or email us at [recall@coopersurgical.com](mailto:recall@coopersurgical.com). Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch or the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

**Acknowledgement and Receipt Form: Response is required**

Please complete this form and return it via email: [recall@coopersurgical.com](mailto:recall@coopersurgical.com) or fax to +001.203.601.9870 ATTN: Product Surveillance.

**FOR DISTRIBUTORS ONLY:**

Customer Account #: \_\_\_\_\_ Account Name: \_\_\_\_\_

Contact Name/Title: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Email address: \_\_\_\_\_

**Please complete the appropriate information below if applicable.**

I have read and understand the safety alert instructions provided in the June 24, 2019 letter.  
Yes \_\_\_ No \_\_\_

I have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_ (Specify date and method of notification)

**Or**

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: \_\_\_\_\_ Date: \_\_\_\_\_

PLEASE E-MAIL COMPLETED RESPONSE FORM TO [recall@coopersurgical.com](mailto:recall@coopersurgical.com) OR FAX  
+001.203.601.9870 ATTN: Product Surveillance