



<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Bair Hugger™ Warming / Cooling Blankets, Model 63500

FSCA-identifier: FSN 2018-01 FSCA Blanket 63500

Type of action: Isolation and disposal of the device

Date: January 25th, 2018

Attention: 3M Health Care Business Customers

Dear Customer,

3M is conducting a Field Safety Corrective Action (FSCA) for 3M™ Bair Hugger™ Warming / Cooling Blankets, Model 63500.

Details on affected devices:

The following lots are in scope of this FSCA:

R10359
R10361
R10362
R10363
R10364

The vast majority of Bair Hugger™ blankets are not affected by this recall. The lots referenced above were distributed after October 26, 2017.

Description of the problem:

During a recent investigation, 3M confirmed that the affected blankets are more susceptible to unintended occlusion of airflow resulting in partial or limited inflation during use.

Potential hazard and risk for the patient:

If blankets are only partially inflated during use in surgery, the potential exists for incomplete warming therapy to be given to a patient.

Action to be taken by the user:

- 1) Please immediately identify if you have product from the affected lots listed above, remove from your inventory and **DO NOT USE or DISTRIBUTE**.
- 2) Follow the instructions on the attached **Confirmation Form**, complete the form and return it to 3M (meddev.de@mmm.com) as indicated on the confirmation form.
- 3) Notify any of your departments or customers who may have received the affected lots.
- 4) Please **dispose** of all affected product as per your facility protocol.

Once 3M has received your completed form and if you have indicated that you had any remaining product from the affected lots, we will provide you with replacement products.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. Moreover, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this situation may cause.

Contact reference person:

If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany



Confirmation Form – FSN 2018-01 FSCA Blanket 63500

Please examine your stock immediately to determine if you have any 3M™ Bair Hugger™ Warming / Cooling blankets, model 63500 with the lot numbers listed in the table below and complete this form.

Please indicate in the table below how many full (unopened) cases and/or individual blankets from partial (opened) cases of each listed lot you have and fill in your contact information. If you do not have inventory of the affected lots, please indicate in the second checkbox below. Email this form to Dr. Marie Isabel Cobbers via meddev.de@mmm.com

We have examined our inventory, identified the following products and have completed the table below with the quantity.

3M™ Bair Hugger™ Warming / Cooling Blanket, model 63500

Affected Lot	Count of Full (Unopened) Cases	Count of Individual Blankets from Partial (Open) Cases
R10359		
R10361		
R10362		
R10363		
R10364		

We have examined our inventory and do not have the specified 3M products subject to recall.

We hereby confirm that we have received and understood the information about the Field Safety Corrective Action and that the notice has been passed to all those who need to be aware within our organisation and/or to any department or third party organisation where the affected product has been supplied to.

By signing below, we certify that we will fully dispose of the affected product.

Contact Information:

Name		Facility/Company Name	
Signature		Facility/Company Address	
Date		Phone	