



January 19, 2018

Subject: URGENT MEDICAL DEVICE RECALL of 3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Models 63500 (Lots R10359, R10360, R10361, R10362, R10363, R10364, R10365, R10366) and 63700 (Lot FR10361)

Dear 3M Health Care Customer:

3M is conducting a recall of nine (9) lots of the 3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Models 63500 and 63700.

During a recent investigation, 3M confirmed that that the affected blankets are more susceptible to unintended occlusion of airflow resulting in partial or limited inflation during use. If blankets are only partially inflated during use in surgery, there is potential for incomplete warming therapy to be given to a patient.

The following product and lot numbers are impacted:

Model	Lots
3M™ Bair Hugger™ Full Access Underbody Warming Blanket 63500	R10359, R10360, R10361, R10362, R10363, R10364, R10365, R10366
3M™ Bair Hugger™ Full Access Underbody Warming Blanket 63700	FR10361

The vast majority of Bair Hugger™ blankets are not affected by this recall. The lots referenced above were distributed between October 26 and December 13, 2017.

Actions Required:

- 1) Please immediately identify the affected product listed above, remove from your inventory and **DO NOT USE**.
- 2) Follow the instructions on the attached Customer Product Recall Acknowledgement Form, complete the form and return it to 3M as indicated.
- 3) Please dispose of all affected product per your institutional protocol and document disposal in the recall acknowledgment form.

Once 3M has received your completed form, if you have indicated you have any remaining product from these lots, we will provide replacement product for affected product on hand.

3M Health Care Business

3M Center
St. Paul, MN 55144-1000
651 733 1110

We apologize for any inconvenience this may cause you. If you have questions regarding this matter, please contact the 3M Health Care Customer Helpline at 1-800-228-3957, option #6, Monday through Friday, 7:30 a.m. – 6:00 p.m. Central Daylight Time.

Thank you for your cooperation.

Sincerely,

Michael J. Besser, Division Quality Manger
3M Infection Prevention Division
3M Center, 270-5N-01
St. Paul, MN 55144

Customer Product Recall Acknowledge Form
3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Models 63500 and 63700

Please examine your stock immediately to determine if you have any 3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Models 63500 and 63700 (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 3Mhealthcare@montage72.com.

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

3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Model 63500

Affected Lot	Count of Full (Unopened) Cases	Count of Individual Blankets from Partial (Open) Cases
R10359		
R10360		
R10361		
R10362		
R10363		
R10364		
R10365		
R10366		

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

3M™ Bair Hugger™ Full Access Underbody Warming Blanket, Model 63700

Affected Lot	Count of Full (Unopened) Cases	Count of Individual Blankets from Partial (Open) Cases
FR10361		

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

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

Contact Information:

Name		Company Name	
Signature		Company Address	
Date		Phone	