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Neuss, 08. August 2013

Voluntary Product Recall of selected lots of 3M™ Scotchcast™ Wet or Dry Cast Padding, Catalog Numbers: WDP2 and WDP3

Dear 3M Customer,

3M is conducting a voluntary product recall of selected lots of **3M™ Scotchcast™ Wet or Dry Cast Padding** following a determination that the cast padding material does not consistently repel water. Lack of repellency may result in prolonged cast dry times after exposure to wet conditions. 3M became aware of this issue through health care provider feedback and confirmed it by internal testing. There have been no reports of patient injury associated with this material to date.

3M is voluntarily recalling the product to minimize the potential of skin maceration under a cast exhibiting inconsistent repellency characteristics. This field action involves **3M™ Scotchcast™ Wet or Dry Cast Padding** material only with affected Catalog and Lot Numbers provided in the table below.

3M™ Scotchcast™ Wet or Dry Cast Padding Catalog Number(s)	Lot Numbers
WDP2	793090, 793640 & 796078
WDP3	793098 & 796077

3M™ Scotchcast™ Wet or Dry Cast Padding currently at the end user setting may be used **under dry conditions only** until replacement product is available. Care must be taken to ensure that the change in directions for use is clearly communicated to health care providers using the product as well as patients receiving casts.

This action also does not affect 3M Scotchcast™ Synthetic Cast Padding (MW02, MW03, MW04, and MW06) or 3M™ Scotchcast™ Wet or Dry Cast Padding on hand that contains a Blue Thread down the middle of each roll.

For patients who may have already received a cast containing affected padding material, current patient information handouts provided by 3M include directions for monitoring casts to ensure proper drying. Depending upon office procedures, the health care provider may want to inform patients who have received affected material to avoid wetting the cast and the potential for maceration if the cast is subject to wet conditions. Directions to return product are provided below:

Action Required:

- Examine your inventory and set aside product LOTS subject to recall notice.
- Inform all departments of any affected lots and provide them with a copy of this letter.
- All product lots subject to recall notice should be destroyed on site.
- Fill out the enclosed Product Recall Forms for all lots you have in house and fax the completed form to XXXXXXXXXXX. Upon receipt of the completed form, 3M will issue a credit note for the quantities of products subject to recall notice that have been destroyed.

If you have questions, please contact your respective 3M Representative. We apologize for any inconvenience this situation may cause you or your patients. We look forward to assisting you.

Sincerely,

<Name of local 3M Contact>
<Position>

Please complete this template and return to:

3M Medica
Zweigniederlassung der
3M Deutschland GmbH
XXXXXXXXXXXX
Hammfelddamm 11
41453 Neuss

Phone: XXXX
Fax: XXXX
eMail: XXXX@mmm.com

Customer Product Recall Form

Product recall of 5 lots of the 3M™ Wet or Dry Cast Padding Rolls, your request from 08/08/2013
We hereby confirm that we received the medical device recall form and this notice has been passed to all those who need to be aware within our organization or to any department where the affected product has been transferred.
We furthermore screened our storage locations and identified/isolated the following affected products:

Product references	*Lot Numbers*	*Identified quantity of rolls*
WDP2 - 2 IN X 4 YD WET OR DRY CAST PADDING 20 RLS/BG 4 BG/CS	**793090**	
	793640	
	796078	
WDP3 - 3 IN X 4 YD WET OR DRY CAST PADDING 20 RLS/BG 4 BG/CS	**793098**	
	796077	

Note: don't leave cells blank, but mention "none" in case no rolls were identified at your site.

Certificate of Destruction

We hereby certify that all items listed in the table above have been destroyed on site.

Name:

Position:

Signature:

Date:

Hospital/Institute: