



URGENT: MEDICAL DEVICE RECALL
3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, Single Use Rolls

January 28, 2010

Dear 3M Health Care Distributor,

3M is voluntarily recalling specific lots of 3M™ Micropore™ Surgical Tape 1" x 1-1/2 yard, **Single Use Rolls** (CAT#1530S-1). 3M has received complaints from hemodialysis centers that the **Single Use Rolls** are not consistently performing in dialysis procedures. If the tape does not perform, the dialysis needle may loosen and could then dislodge.

In the interim, please offer 3M™ Micropore™ Surgical Tape, 1" by 10 yard rolls (CAT#1530-1) as a substitution until supply of single-use rolls is available. 3M™ Micropore™ Surgical Tape in 1" x 10 yard rolls (CAT#1530-1) is **NOT** included in this product recall effort.

Action Required:

1. 3M Health Care is requesting its distributors to check existing inventory to determine if you have any of the affected lots of 3M™ Micropore™ Surgical Tape 1530S-1 in your warehouse and place affected lots in quarantine.
2. Notify your customers down to the user level and have them return any affected lots to you, OR provide them with the enclosed customer letter (Attachment 1) which will instruct them how to contact 3M for recovery of the recalled lots.
3. Fill out the enclosed Product Recall Form for all lots you have in house and/or that you recover from your customer(s) and fax the completed form to 3M Health Care at 1-800-772-2547. Upon receipt of the completed form, 3M will issue a Return Authorization, arrange for pickup and notify you of the carrier and details.
4. Provide 3M with a summary of your recall activities since FDA will be requesting this information from 3M. See Attachment 2.

*******It is important to notify 3M whether your facility has the affected product or not.*******

If you have any questions, please contact the 3M Customer Helpline 1-800-228-3957 (8:30a.m. - 7:00p.m. EST).

We apologize for any inconvenience this situation may have caused you.

Sincerely,

Kathryn Foran
Regulatory & Quality Manager
3M Skin & Wound Care Division
Phone: 651-736-4989, Fax: 651-733-2009
Email: kwforan1@MMM.COM

2 Attachements

3M™ Micropore™ Surgical Tape (CAT#1530S-1), one inch, Single Use Rolls
DISTRIBUTOR Product Recall Form

MEDICAL DEVICE RECALL – RESPONSE REQUIRED
(PLEASE RESPOND EVEN IF YOU DO NOT HAVE THE PRODUCT IN STOCK)

Lot numbers containing “2014”, and lot numbers beginning with “2015-01” followed by two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW

Lot number examples: **2014-XX ZZ** or **2015-01 ZZ**

Please fax completed form to 3M Health Care at 1-800-772-2547.

Consignee Mailing Address:

Facility Name: _____

Mailing Address: _____

City/State/Zip Code: _____

Please examine your stock immediately to determine if you have any 3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, single use rolls, with lot numbers containing “2014”, and/or lot numbers beginning with “2015-01” with the following two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW. **If you do not have any of the affected lots, please check the first box below.**

Upon receipt of this completed form, 3M will issue a Return Authorization, arrange for pickup and notify you of carrier and details. Once the shipment has been received at our Regional Return Center, 3M will provide you a credit for the returned product.

Please check one of the two boxes below:

- We do **not** have 3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, **Single Use Rolls**, in our inventory.
- We have examined and identified 3M™ Micropore™ Surgical Tape (CAT#1530S-1) with **lot numbers containing “2014”, and lot numbers beginning with “2015-01” with the following two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW** in our inventory.

We will be returning _____ (# of boxes) affected boxes of product.

Person completing this form: _____ (Print)

_____ (Sign) _____ (Date)

_____ (Dept/Title)

_____ (Phone)

_____ (Fax)

**Attachment 1: Example Customer letter and
Customer Product Recall Form**



URGENT: MEDICAL DEVICE RECALL
3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, Single Use Rolls

January 28, 2010

Dear 3M Health Care Customer,

3M is voluntarily recalling specific lots of 3M™ Micropore™ Surgical Tape 1" x 1-1/2 yard, **Single Use Rolls** (CAT#1530S-1). 3M has received complaints from hemodialysis centers that the **Single Use Rolls** are not consistently performing in dialysis procedures. If the tape does not perform, the dialysis needle may loosen and could then dislodge.

In the interim, customers affected by this product recall will be offered 3M™ Micropore™ Surgical Tape, 10 yard rolls (CAT#1530-1) as a substitution until supply of single-use rolls is available. 3M™ Micropore™ Surgical Tape in 1" x 10 yard rolls (CAT#1530-1) is **NOT** included in this product recall effort.

Action Required:

1. Please set aside any affected lots and do not use.
2. Complete the enclosed Customer Product Recall Form and fax the completed form to 3M Health Care at 1-800-772-2547. Upon receipt of the completed form, 3M will issue a Return Authorization, arrange for pickup and notify you of the carrier and details.

*******It is important to notify 3M whether you have the affected product or not.*******

If you have any questions, please contact the 3M Customer Helpline 1-800-228-3957 (8:30a.m.-7:00p.m. EST).

We apologize for any inconvenience this situation may have caused you.

Sincerely,

Kathryn Foran
Regulatory & Quality Manager
3M Skin & Wound Care Division
Phone: 651-736-4989
Fax: 651-733-2009
Email: kwforan1@MMM.COM

**3M™ Micropore™ Surgical Tape (CAT#1530S-1), one inch, Single Use Rolls
CUSTOMER Product Recall Form**

**MEDICAL DEVICE RECALL – RESPONSE REQUIRED
(PLEASE RESPOND EVEN IF YOU DO NOT HAVE THE PRODUCT IN STOCK)**

Lot numbers containing “2014”, and lot numbers beginning with “2015-01” followed by two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW

Lot number examples: 2014-XX ZZ or 2015-01 ZZ

Please fax completed form to 3M Health Care at 1-800-772-2547.

Consignee Mailing Address:

Facility Name: _____

Mailing Address: _____

City/State/Zip Code: _____

Please examine your stock immediately to determine if you have any 3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, single use rolls, with lot numbers containing “2014”, and/or lot numbers beginning with “2015-01” with the following two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW. **If you do not have any of the affected lots, please check the first box below.**

Upon receipt of this completed form, 3M will issue a Return Authorization, arrange for pickup and notify you of carrier and details. 3M will send out 3M™ Micropore™ Surgical Tape, 10 yard rolls (CAT#1530-1) as the interim substitution for the affected product.

Please check one of the two boxes below:

- We do **not** have 3M™ Micropore™ Surgical Tape, CAT#1530S-1, one inch, **Single Use Rolls**, in our inventory.
- We have examined and identified 3M™ Micropore™ Surgical Tape (CAT#1530S-1) with **lot numbers containing “2014”, and lot numbers beginning with “2015-01” with the following two-character letters: AA, AB, AC, AD, AE, AF, AH, AI, AL, AN, BW** in our inventory.

We will be returning _____ (# of boxes) affected boxes of product.

Person completing this form: _____(Print)

_____ (Sign)

_____ (Date)

_____ (Dept/Title)

_____ (Phone)

_____ (Fax)

Attachment 2: Distributor Recall Strategy and Report

**3M™ Micropore™ Surgical Tape (CAT#1530S-1), one inch, Single Use Rolls
DISTRIBUTOR Recall Strategy Summary and Report**

E-mail or fax completed form to Karen Rittle: Fax: (651) 737-5320, khrittle@mmm.com

1. RECALLING FIRM	3M Health Care 3M Center St. Paul, MN 55144-1000
2. RECALLING FIRM REGULATORY CONTACT	Karen Rittle, Regulatory Manager 3M Center, 275-5W-06 St. Paul, MN 55144-1000 Tel: (651) 733-0074, Fax: (651) 737-5320 khrittle@mmm.com
2. DISTRIBUTOR	
Provide complete name and address of distributor (include full name of company, full address and telephone number)	(NAME) (STREET ADDRESS) (SECOND ADDRESS) (CITY), (STATE) (ZIP CODE)
3. RECALL STRATEGY	
a. How do you plan to do EFFECTIVENESS CHECKS? (e.g. # of contacts, return/reply cards, response form, follow-up visits or phone calls, etc.)	
b. How do you plan to monitor consignees that are NON-RESPONDING to the recall communication?	
c. Date your firm ceased further distribution of the product(s)?	
d. How do you plan to STORE recall product that is returned? (quarantine, locked storage, etc.)	
4. RECALL EFFECTIVENESS REPORT	
a. How many contacts with the customer did you make?	
b. How many facilities/end-users did you contact?	
c. How many responded?	
d. How many have not yet responded?	
SUMMARY OF RATIONALE TO DISCONTINUE FURTHER CONTACTS	