



October 3, 2022

Subject: URGENT Product Recall - 3M™ Steri-Drape™ Surgical Drapes, Catalog Numbers 1000, 1000NS, 1000NSD, 1010, 1010NS, 1010NSD, 1020, 1020NS, 1021, 1021NS, 1030, 1030NS, 1033, 1060, 1060NS, 1061, 1061NS, 1071

Dear 3M Health Care Distributor:

As a valued 3M partner, we wanted to make you aware of our recent decision to conduct a voluntary recall of select models and lots of **3M™ Steri-Drape™ Surgical Drapes** distributed between October 29, 2021 – August 25, 2022. Reference **Attachment 1** for list of products affected.

During a recent investigation, 3M confirmed the liner on the adhesive component of the affected drapes is difficult to remove without damaging the product and may render the product unusable. Additionally, 3M has observed an increase in reported adhesive related skin injuries for these affected lots. Although the acceptance criteria for the device was met upon product release, the adhesive component may not meet 3M's performance criteria throughout product shelf life. 3M requests customers cease use of the product and quarantine it for destruction/disposal.

Actions Requested:

1. Immediately discontinue distribution of affected models and lots of 3M™ Steri-Drape™ Surgical Drapes. Reference **Attachment 1** for list of models and lots.
2. Determine if any stock of the affected models and lots remain in inventory.
3. Complete the **Distributor Acknowledgement Form** with the following:
 - Acknowledge that you have read and understood this letter *whether or not you have any 3M™ Steri-Drape™ Surgical Drapes in stock at your facility*; and
 - Indicate if you have any product in stock and dispose of this material per facility policy.
 - Email the completed form to 3MFieldSafetyAction@montage72.com.
4. Notify any of your customers who have purchased this product using the **Customer Letter** and **Customer Acknowledgement Form** provided.
5. To request credit, contact 3M Health Care Customer Helpline at 1-800-228-3957, option 7 or by email to 3MFieldSafetyAction@montage72.com.

This voluntary recall only applies to the affected models and lots of 3M™ Steri-Drape™ Surgical Drapes in **Attachment 1** and does NOT apply to other 3M drapes. If you have additional questions or need to report an adverse event, contact the 3M Health Care Customer Helpline at 1-800-228-3957, option 7.

Reporting to the FDA MedWatch Serious Injury Reporting Program may be completed:

- **Online:** By completing and submitting the report online at: <https://www.accessdata.fda.gov/scripts/medwatch/>
- **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

We apologize for any inconvenience this may cause you. Thank you for your cooperation.

Sincerely,

Harry Janiski, Vice President of Quality
3M Medical Solutions Division
3M Center, 270-5N-01, St. Paul, MN 55144



3M™ Steri-Drape™ Surgical Drapes Recall
 Distributor Acknowledgement Form

Email completed form to: 3MFieldSafetyAction@montage72.com

Please examine your inventory to determine if you have any of the 3M™ Steri-Drape™ Surgical Drapes listed in **Attachment 1**. Note, this voluntary recall only applies to the affected catalog numbers and lots listed in Attachment 1 and does NOT apply to any other 3M drape products.

- Acknowledge that you have read and understood this letter and will complete the actions requested.
- We have examined our inventory and identified and disposed of the following number of 3M™ Steri-Drape™ Surgical Drapes:

Catalog Number (REF #)	Quantity of drapes in inventory that have been destroyed/ discarded
1000	
1000NS	
1000NSD	
1010	
1010NS	
1010NSD	
1020	
1020NS	
1021	

Catalog Number (REF #)	Quantity of drapes in inventory that have been destroyed/ discarded
1021NS	
1030	
1030NS	
1033	
1060	
1060NS	
1061	
1061NS	
1071	

- We have examined our inventory and **do not** have the affected 3M™ Steri-Drape™ Surgical Drapes in stock.

Email completed form to: 3MFieldSafetyAction@montage72.com

Person completing this form:

Name (Print)		Company Name	
Signature		City, State	
Date		Phone	
		E-mail	



Attachment 1. 3M™ Steri-Drape™ Surgical Drapes Manufactured between October 26, 2021 – August 15, 2022

Catalog Number	Generic Descriptor	Affected Lots									
1000	Small Towel Drape	33HD8F	33HFNY	33HYA7	33J7ML	33JTE3	33K4YY	33K8KM	33KXKH	33LC4T	
		33HDDH	33HFTH	33HYLK	33J7X8	33JTPP	33K54E	33K8Y7	33L8CR	33LCHH	
		33HDK3	33HTJR	33J5L5	33J89T	33JW5A	33K5CH	33K95A	33L8WC	33LCNA	
		33HDR6	33HTNP	33J5T7	33J8LE	33JWAR	33K5N9	33K9J6	33L97L	33LD68	
		33HDXN	33HTYL	33J639	33JK67	33K35Y	33K63K	33K9NX	33L9CD	33LJD4	
		33HECP	33HW9C	33J6EN	33JKCL	33K3DP	33K7CM	33KA3R	33L9LD	33LJJY	
		33HEM4	33HWMN	33J6KE	33JKLR	33K3L9	33K7J8	33KA7X	33L9XD		
		33HF3E	33HX4N	33J6R5	33JL35	33K444	33K7WC	33KADW	33LACE		
		33HFAM	33HXRF	33J763	33JLDA	33K4D4	33K88L	33KX6W	33LAKN		
33HFFJ	33HY4P	33J7ED	33JLJ4	33K4JP	33K8H6	33KXDH	33LATP				
1000NS	Small Towel Drape	33HP4H	33KCDK								
		33HPDN	33KCP4								
		33HPLM	33KY37								
		33HPWP	33KYDK								
		33J478	33KYNY								
		33J8MT									
		33J948									
		33JLMY									
		33JLWL									
33K6FN											
1000NSD	Small Towel Drape	33HCR7	33KAY7								
		33HD4C	33KC8K								
		33J4J6									
		33J4NF									
		33JRKR									
		33JRYN									
		33JT7E									
		33K6D6									
		33KAH8									
33KAMP											



Catalog Number	Generic Descriptor	Affected Lots												
1010	Large Towel Drape	33HAET	33HJH7	33HLXD	33J37F	33JATF	33JHAC	33JN8N	33KF3N	33KJNK	33KNAJ	33KTEM	33L6XH	33LFJ9
		33HAPR	33HJNT	33HMAD	33J3EL	33JC94	33JHJ4	33JNNF	33KF83	33KK5D	33KNN4	33L4D6	33L7AM	33LFPM
		33HAYX	33HK4K	33HMJH	33J3NC	33JCK8	33JJ4H	33JPHR	33KFRC	33KKC4	33KNXW	33L4K4	33L7FX	33LH6E
		33HC8R	33HKD8	33HMWA	33J44N	33JCMJ	33JJ9P	33JPKT	33KFY9	33KLHM	33KP63	33L4X5	33L7XL	
		33HCEX	33HKHT	33HN5C	33J9CP	33JD45	33JJF7	33JPWT	33KH7R	33KLNH	33KPJY	33L5C7	33L878	
		33HH47	33HKPP	33HND4	33J9FN	33JDF6	33JJT9	33KDER	33KHCM	33KLWJ	33KPYP	33L5P5	33LDF8	
		33HHC9	33HKRT	33HNWM	33J9TH	33JDPK	33JM5W	33KDMN	33KHLJ	33KM9K	33KRC5	33L5X3	33LDPJ	
		33HHKA	33HL59	33HYNH	33JA7C	33JDT4	33JMDH	33KDY5	33KHX3	33KMJH	33KRPW	33L64A	33LED4	
		33HHTA	33HL9X	33HYTN	33JADN	33JFDY	33JMKP	33KE9E	33KJ63	33KMLN	33KT57	33L6D7	33LETX	
		33HJA9	33HLLW	33J33L	33JAMH	33JFHJ	33JMTJ	33KEL3	33KJEX	33KN3J	33KT9N	33L6N4	33LF49	
1010NS	Large Towel Drape	33HR7D	33JEM5	33JYM4	33L44T									
		33HR94	33JEYA	33JYXH	33LLC5									
		33HRET	33JWHK	33KD6N										
		33HRWK	33JWLX	33KKET										
		33HT5X	33JWRH	33KKMT										
		33HTDY	33JX5M	33KL65										
		33J4XP	33JXFA	33KLAR										
		33J583	33JXPK	33L34N										
		33J5FA	33JY6E	33L3JN										
		33JEF8	33JYEM	33L3LT										
1010NSD	Large Towel Drape	33JE6A												
		33JR86												
		33JRFK												
		33KD3C												



Catalog Number	Generic Descriptor	Affected Lots
1020	Small Drape with Adhesive Aperture	33H9T5 33HFXP 33HNXX 33J7YJ 33JD5A 33JRNA 33JYMH 33KAXL 33KL5W 33KWEX
		33HA9D 33HH8C 33HY4Y 33J8A7 33JE49 33JTFX 33K3AE 33KC8P 33KLMN 33KWT5
		33HC7R 33HHKC 33HYCP 33J97T 33JEEM 33JTNV 33K3N7 33KCJT 33KM4C 33KXRH
		33HCJN 33HJ3K 33J3LW 33J9JR 33JEP8 33JW4L 33K6CJ 33KCX3 33KN54 33KYA3
		33HCPL 33HK5H 33J43T 33J9RC 33JFAJ 33JWD4 33K7CL 33KE37 33KNAX 33KYKA
		33HD6C 33HKJH 33J4E7 33JA5D 33JFJX 33JWLR 33K7NF 33KHXA 33KR5C 33KYWT
		33HDYW 33HKPA 33J4M7 33JAED 33JPDM 33JXEM 33K9A3 33KJAA 33KRDE 33L3YR
		33HEDM 33HLKE 33J5CP 33JC7L 33JPPC 33JXRJ 33K9JW 33KJL5 33KRR5 33L6EW
		33HELH 33HLWT 33J798 33JCHH 33JR3D 33JY7J 33K9R5 33KJWK 33KTNC 33L6M5
		33HF3X 33HNJ3 33J7KC 33JCPY 33JRRC 33JYFL 33K9YW 33KKMY 33KW4K 33L7RH
1020NS	Small Drape with Adhesive Aperture	33HPA7 33KEAT
		33HPMC 33KFCA
		33HRTD 33KFMN
		33JHA8 33KH4C
		33JHNK 33L47C
		33JJAJ 33L55C
		33K44C 33LJL7
		33K4DT
		33K5J8
33K5TD		
1021	Small Drape with Incise Sheet	33H9HW
		33HXMD
		33JKD4
		33JKLL
		33KPXJ



Catalog Number	Generic Descriptor	Affected Lots
1021NS	Small Drape with Incise Sheet	33HT9W 33HWN8 33J5T9 33JL66 33JLLW 33JMKR 33JN4N 33K7Y7 33K888
1030	Medium Drape with Adhesive Aperture	33HFW5 33HH8Y 33JRFA 33JTD4 33KKLW 33KL53
1030NS	Medium Drape with Adhesive Aperture	33JPRN 33JPWY 33JR98 33KLEY 33KLME



Catalog Number	Generic Descriptor	Affected Lots
1033	Medium Drape with Wide Adhesive Aperture	33H9JH 33J6KY 33JCP7 33JRD4 33JYJ5 33K6E3 33KFAC 33KHKL 33L6E6 33LAXJ
1060	Medium Drape with Incise Film	33HT6E 33HWFM 33HWMF 33HX3K 33K9TF 33KA3T 33KA95
1060NS	Medium Drape with Incise Film	33J7AA 33JPE6 33J7JY 33JPM8 33J7W8 33K8HC 33J8AX 33K966 33J8JR 33K9FK 33JM8K 33JMKC 33JMW3 33JN9L 33JNHN



Catalog Number	Generic Descriptor	Affected Lots												
1061	Medium Drape with Incise Film and Pouch	33HAEY	33KFNC											
		33HC74	33KFY5											
		33HCHP	33KHK3											
		33JHYT	33KHWN											
		33JJ8X	33KJ7L											
		33JJHM	33KJJ7											
		33JTNP	33KJTC											
		33JW4J	33KYY7											
		33JWDD	33L4L6											
33JWLT														
1061NS	Medium Drape with Incise Film and Pouch	33HCPF	33HKJJ	33HPWN	33J5ER	33JC6Y	33JHA7	33JYNF	33K7JL	33KEKL	33KRNF	33L97A	33LF6E	
		33HD5K	33HLFP	33HR5W	33J5PJ	33JCHF	33JKDR	33K3A3	33K7X9	33KF3M	33KTNL	33L9WX	33LFEA	
		33HDAN	33HLXW	33HRF9	33J643	33JCR8	33JKMK	33K3N3	33K89R	33KFAH	33KW4L	33LA8J	33LFNT	
		33HDXM	33HM9X	33HRRM	33J6DF	33JD59	33JKYM	33K43M	33KATM	33KN4W	33KWEW	33LAJY	33LH67	
		33HEDT	33HMHE	33HX8N	33J6KR	33JDFC	33JLD4	33K4AT	33KCAF	33KNCR	33KWR5	33LAY6	33LHCW	
		33HELW	33HMWN	33J3LR	33J9AK	33JE48	33JLKN	33K5FA	33KCJ3	33KNLE	33KXX6	33LCYM	33LJ9Y	
		33HEXM	33HNLK	33J438	33J9HM	33JEET	33JXF6	33K5NL	33KCY5	33KNYE	33KY84	33LDDF	33LJJ6	
		33HJRY	33HNW9	33J4CX	33J9R6	33JEMN	33JXMY	33K64F	33KD7E	33KPHW	33KYHP	33LDN3		
		33HJXT	33HP9A	33J4LN	33JA7J	33JEYL	33JY79	33K6AE	33KE33	33KR3A	33L8HN	33LDYL		
		33HK99	33HPJF	33J4WC	33JAE8	33JFK6	33JYDR	33K79D	33KE9D	33KRAF	33L8TL	33LEDD		
		1071	Urological Drape	33HJ3C										
33HTFH														
33J9CT														
33JED6														
33JJHN														
33K968														
		33KTRH												