



Field Safety Notice

Name of the affected product: 3M™ Steri-Drape™ Surgical Drapes, catalogue numbers 1000, 1010, 1020, 1021, 1030, 1033, 1060, 1061, 1061NS, 1071

FSCA-identifier: 2022-10 FSCA Steri-Drape

Type of action: Disposal of affected products

Date: October 13th, 2022

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all customers in impacted European countries of the above-mentioned 3M™ Steri-Drape™ Surgical Drape catalogue numbers 1000, 1010, 1020, 1021, 1030, 1033, 1060, 1061, 1061NS, 1071 of a field safety corrective action.

Description of the problem and potential hazard and risk for the patient/user:

During a recent investigation, 3M confirmed that 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.

Details on affected devices:

The following lots of 3M™ Steri-Drape™ Surgical Drapes are subject to this field safety corrective action:

Catalogue number	Lot number
1000	33HD8F, 33HDDH, 33HFFJ, 33HX4N, 33HXRF, 33HY4P, 33HYA7, 33J5T7, 33J639, 33J6EN, 33J7X8, 33K3DP, 33K3L9, 33K54E, 33K7J8, 33K8KM, 33KXDH, 33LACE
1010	33HHC9, 33HHKA, 33HJNT, 33HLXD, 33HYNH, 33J9CP, 33JATF, 33JFDY, 33JJ9P, 33JMKP, 33JMTJ, 33KE9E, 33KJ63, 33KJEX, 33KLNH, 33KM9K, 33KMLN, 33KNXW
1020	33HD6C, 33HJ3K, 33HLKE, 33H NJ3, 33J43T, 33J5CP, 33J8A7, 33J9RC, 33JD5A, 33JTFX, 33JXRJ, 33K7NF, 33KCX3, 33KL5W, 33KR5C, 33KRDE, 33L6M5
1021	33H9HW, 33HXMD, 33JKD4, 33JKLL
1030	33HFW5, 33HH8Y, 33JRFA, 33KKLW, 33KL53

Catalogue number	Lot number
1033	33H9JH, 33J6KY, 33JCP7, 33JYJ5, 33K6E3, 33KFAC, 33L6E6
1060	33HX3K
1061	33HC74, 33JTNP
1061NS	33J9HM, 33JDFC, 33JE48, 33JKDR, 33K3N3, 33K4AT, 33K5NL, 33KATM, 33KCAF, 33KD7E, 33KE33, 33KNLE, 33L8HN, 33L8TL, 33LDDF, 33LFEA, 33LFNT
1071	33HJ3C, 33HTFH, 33J9CT, 33JED6, 33JJHN, 33K968, 33KTRH

Action to be taken by all customer:

1. Ensure all your internal and external customers are informed about this corrective action.
2. Please inform us if you supplied the affected items to customers outside your home country.
3. Please identify the affected product listed above and immediately cease use of affected models and lots of 3M™ Steri-Drape™ Surgical Drapes.
4. Please discard all remaining affected product listed above per facility procedures.
5. Complete and return by e-mail to meddev.de@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, 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 matter 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
 Mail: meddev.de@mmm.com

Acknowledgement Form – FSN 2022-10 FSCA Steri-Drape

Email completed form to: meddev.de@mmm.com

Please examine your inventory to determine if you have any of the 3M™ Steri-Drape™ Surgical Drapes listed. Note, this corrective action only applies to the affected catalogue numbers and lots listed 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:

Catalogue number	Lot number	Quantity of drapes in inventory that have been disposed
1000	33HD8F, 33HDDH, 33HFFJ, 33HX4N, 33HXRF, 33HY4P, 33HYA7, 33J5T7, 33J639, 33J6EN, 33J7X8, 33K3DP, 33K3L9, 33K54E, 33K7J8, 33K8KM, 33KXDH, 33LACE	
1010	33HHC9, 33HHKA, 33HJNT, 33HLXD, 33HYNH, 33J9CP, 33JATF, 33JFDY, 33JJ9P, 33JMKP, 33JMTJ, 33KE9E, 33KJ63, 33KJEX, 33KLNH, 33KM9K, 33KMLN, 33KNXW	
1020	33HD6C, 33HJ3K, 33HLKE, 33HNJ3, 33J43T, 33J5CP, 33J8A7, 33J9RC, 33JD5A, 33JTFX, 33JXRJ, 33K7NF, 33KCX3, 33KL5W, 33KR5C, 33KRDE, 33L6M5	
1021	33H9HW, 33HXMD, 33JKD4, 33JKLL	
1030	33HFW5, 33HH8Y, 33JRFA, 33KKLW, 33KL53	
1033	33H9JH, 33J6KY, 33JCP7, 33JYJ5, 33K6E3, 33KFAC, 33L6E6	
1060	33HX3K	
1061	33HC74, 33JTNP	
1061NS	33J9HM, 33JDFC, 33JE48, 33JKDR, 33K3N3, 33K4AT, 33K5NL, 33KATM, 33KCAF, 33KD7E, 33KE33, 33KNLE, 33L8HN, 33L8TL, 33LDDF, 33LFEA, 33LFNT	
1071	33HJ3C, 33HTFH, 33J9CT, 33JED6, 33JJHN, 33K968, 33KTRH	

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

Email completed form to: meddev.de@mmm.com

Person completing this form:

Name		Company /Hospital Name	
Signature		City, Country	
Date		Phone	
		E-mail	