



بمقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 10 dated 30/1/24 Regarding NCMDR Field Safety Notice of Surgical Razor from (mfr: 3M Health Care).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ dgpa_dc Email: dg-padc@moh.gov.om



لتقدم بثقة
Moving Forward
with Confidence



Circular No. 10/2024

18 -07-1445 H

30 -01-2024

Field Safety Notice of Surgical Razor from 3M Health Care.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19893
Product	3M™ Surgical Clipper Blade Assembly 3M™ Specialty Blade Assembly 3M™ Surgical Clipper
Description	Surgical Razor.
Manufacturer	3M Health care.
Local agent	Muscat pharmacy & Stores LLC.
The affected products	3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690 used with 3M™ Surgical Clipper Catalog Number 9661L.
Reason	An additional caution statement to customers using the above-named products to reduce the risk of burns.
Action	1. Please continue to use the product as intended, following the additional caution statement provided in the attachment. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



Field Safety Notice

Name of the affected product: 3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690 used with 3M™ Surgical Clipper Catalog Number 9661L

FSCA-identifier: 2024-01 FSCA Clipper

Type of action: Communication of additional warning

Date: January 16th, 2024

Attention: 3M Healthcare Customers

Dear Customer,

3M is notifying all customers and users of the above-named products of a field safety corrective action.

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

This corrective action has been initiated to communicate an additional caution statement to customers using the above-named products. By applying this additional caution, the safe usage of the products will be ensured. This additional caution statement is provided below:

Caution - To reduce the risk of burns, which if not avoided may result in minor injury:

- Do not use on injured skin.
- Do not leave clipper running unused in air without applying to skin for more than 1 minute as blade temperature may exceed 41°C (105.8°F).
- Do not leave the clipper blade applied to the same location on the patient's skin for longer than 1 second as potential injury may occur; continuous motion of the clipper during use is required.

Note: If clipper is left running unused in air for 10 minutes without applying to skin, the Model 9690 blade maximum temperature may reach 60°C (140°F) and the Model 9660 blade maximum temperature may reach 77°C (170.6°F).

Details on affected devices:

The additional caution statement applies to all 3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690. See attachment on page 3 for the named products.

Action to be taken by all customers:

1. Ensure all your internal and external customers are informed about this corrective action.
2. If you are a distributor, send this FSN to all affected customers and future customers of the blades until the instruction for use will be updated.
3. Please inform us if you supplied the affected items to customers outside your home country.
4. Continue to use the product as intended, following the additional caution statement above.
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.

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.

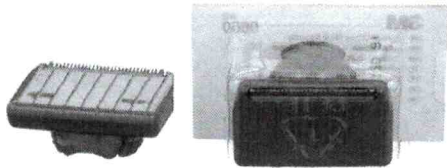
Contact reference person:

If you have questions, please contact your local 3M representative.

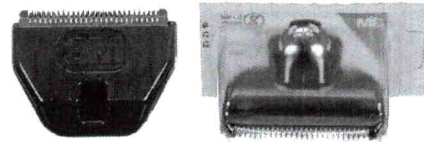
The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Manager Regulatory and Vigilance
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: meddev.de@mmm.com

Attachment



Catalog Number 9660



Catalog Number 9690



Catalog Number 9661L with 9660 blade

Acknowledgement Form – FSN 2024-01 FSCA Clipper

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

Please evaluate and confirm that the 3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690 used with 3M™ Surgical Clipper Catalog Number 9661L are used as described in the additional product caution.

Caution - To reduce the risk of burns, which if not avoided may result in minor injury:

- Do not use on injured skin.
- Do not leave clipper running unused in air without applying to skin for more than 1 minute as blade temperature may exceed 41°C (105.8°F).
- Do not leave the clipper blade applied to the same location on the patient's skin for longer than 1 second as potential injury may occur; continuous motion of the clipper during use is required.

Note: If the clipper is left running unused in air for 10 minutes without applying to skin, the Model 9690 blade maximum temperature may reach 60°C (140°F) and the Model 9660 blade maximum temperature may reach 77°C (170.6°F).

- I have read and understood this field safety notice, informed all relevant people and acknowledge the additional product caution.

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

Person completing this form:

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