



16 Jan 2024

3M Malaysia Sdn. Bhd.
Company Registration No.
196701000267 (7251-V)
Level 8, Block F, Oasis Square,
No. 2 Jalan PJU 1A/7A,
Ara Damansara,
47301 Petaling Jaya, Selangor,
Malaysia.
Phone +603 7884 2888
Web www.3M.com.my

Medical Device Safety Notification – First Notice

Subject: 3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690 used with 3M™ Surgical Clipper Catalog Number 9661L

Dear Valued 3M Health Care Distributor:

This letter is to inform you of our recent decision to notify all users of 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** about an added caution statement regarding the use of the product. 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 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).

This safety notification has been initiated to disclose maximum potential temperature of the clipper blades during use and the conditions for safe contact to be in compliance with the IEC 60601-1 standard and further reduce the potential for injury. There have been no changes to design or composition of these products that prompted this notification, or a trend in complaints of alleged burns related to the products identified. Since release of a redesigned clipper handle in 2016, 3M has received one unconfirmed complaint of eight instances of alleged blade overheating and at least one minor contact burn.



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Distributors are being asked to take the following actions:

- Notify all customers who have purchased 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** since October 2018 using the **Customer Letter and Customer Acknowledgement Form** provided.
- Customers may continue to use the products as intended, following the additional caution statement above.
- 3M is updating the instructions for use (IFU). Continue to provide the **Customer Letter and Customer Acknowledgement Form** to all new customers until 3M notifies you of the updated IFU.
- Complete the **Distributor Acknowledgement Form** acknowledging that you have read and understood this letter and have notified customers who purchased the products.
- Email the completed form to 3M Customer Service Representative via this email (3msupport.my@mmm.com).

This safety notification only applies to 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** and does NOT apply to any other 3M Surgical Clipper products. Reference **Attachment 1** for pictures of the affected products. If you have additional questions or need to report an adverse event, contact 3M Customer Service Representative (3msupport.my@mmm.com).

Note: **3M™ Specialty Blade Assembly, Catalog Number 9690** has not been supplied in Malaysia

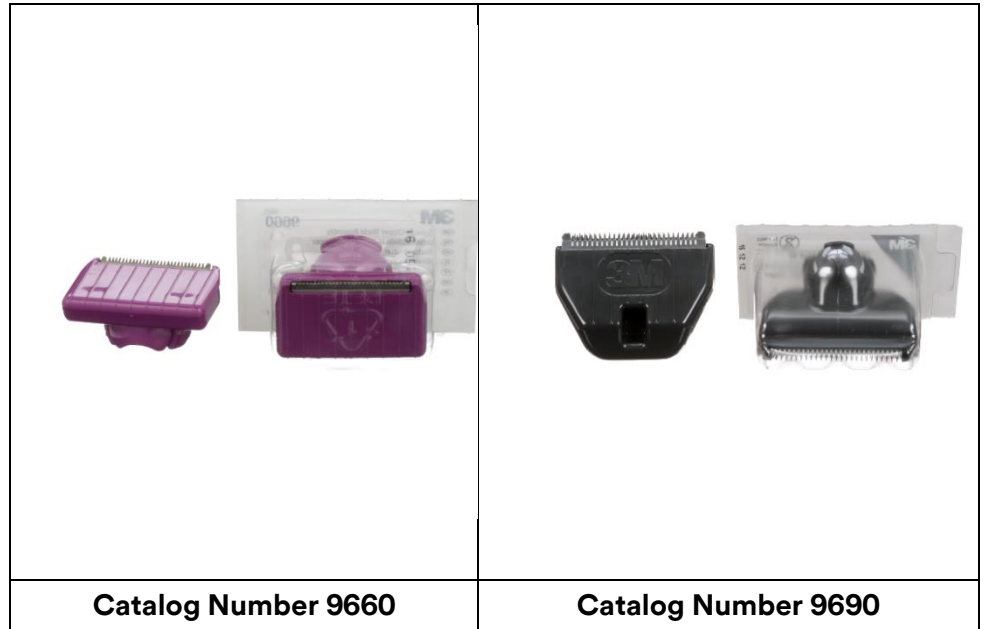
We apologize for any inconvenience this may cause you. Thank you for your cooperation.

Sincerely,

Kulveen Singh Bali
Manager
3M HCBG Quality Compliance (Asia)

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Attachment 1





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3M™ Surgical Clipper Blade Assembly Catalog Number 9660 and 3M™ Specialty Blade Assembly, Catalog Number 9690 used with 3M™ Surgical Clipper Catalog Number 9661L

Distributor Acknowledgement Form

All customers who have purchased 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** were notified of the additional caution statement using the **Customer Letter and Customer Acknowledgement Form** provided.

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).

Acknowledge that you have read and understood this letter and have completed the actions requested.

Email the completed form to: 3msupport.my@mmm.com

Person completing this form:

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