



Medical Device Safety Notification – First Notice

11 January 2024

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.

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 3MFieldSafetyAction@montage72.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 the 3M Health Care Customer Helpline at 1-800-228-3957, option 7.

Reporting to the FDA MedWatch Serious Injury Reporting Program:

- **Online:** By completing and submitting the report online at:
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,

A handwritten signature in black ink that reads "Harry Janiski".

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



Attachment 1

 A purple 3M 9660 blade, shown both as a standalone component and in its original retail packaging. The blade is rectangular with a series of fine teeth along its top edge.	 A black 3M 9690 blade, shown both as a standalone component and in its original retail packaging. The blade is rectangular with a series of fine teeth along its top edge.
Catalog Number 9660	Catalog Number 9690

 A white and purple 3M 9661L trimmer, shown vertically. It has a purple handle with a white grip and a purple head with a silver blade. The 3M logo is visible on the handle.
Catalog Number 9661L with 9660 blade



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:

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- 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: 3MFieldSafetyAction@montage72.com

Person completing this form:

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

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11 January 2024

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 Risk Manager Director of the Department of Surgery, Materials Management:

As a valued 3M customer, we wanted to make you aware 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:

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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.

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** are being asked to take the following actions.



Actions Requested:

- Ensure this safety notification is passed to all those who need to be aware within your organization or to any department where the affected product has been transferred.
- Continue to use the product as intended, following the additional caution statement above.
- Complete the attached **Customer Acknowledgement Form** acknowledging that you have read and understood this letter and the additional caution statement.
- Email the completed form to 3MFieldSafetyAction@montage72.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 the 3M Health Care Customer Helpline at 1-800-228-3957, option 7.

Reporting to the FDA MedWatch Serious Injury Reporting Program:

- **Online:** By completing and submitting the report online at:
www.accessdata.fda.gov/scripts/medwatch/
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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,

A handwritten signature in black ink that reads "Harry Janiski".

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



Attachment 1

 A purple 3M 9660 blade and its retail packaging. The blade is purple with a silver-colored cutting edge. The packaging is white and purple, featuring the 3M logo and product information.	 A black 3M 9690 blade and its retail packaging. The blade is black with a silver-colored cutting edge. The packaging is white and black, featuring the 3M logo and product information.
Catalog Number 9660	Catalog Number 9690

 A white and purple 3M 9661L trimmer. The trimmer has a white body with purple accents and a purple 9660 blade attached to the head. The 3M logo is visible on the handle.
Catalog Number 9661L with 9660 blade



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

Customer Acknowledgement Form

Please evaluate and confirm 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:

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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).

If you have additional questions, please contact the 3M Health Care Customer Helpline at 1-800-228-3957, option 7.

- ☐ I have read and understood this product safety information and acknowledge the additional product caution.

Email the completed form to: 3MFieldSafetyAction@montage72.com

Person completing this form:

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