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<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Surgical Clipper Professional, Model 9681
FSCA-identifier: FSN 2018-02 FSCA Clipper 9681
Type of action: Communication of an additional warning advice

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Date: February 9th, 2018

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all users of the **3M™ Surgical Clipper Professional, Model 9681**, of an added product warning, stressing the importance of following proper clipper charging practices as documented in the Model 9681 Clipper instructions for use. Current charging instructions recommend leaving the clipper body in the drop-in charger in between uses.

Details on affected devices:
All devices of model 9681 distributed after January 1st, 2016 are affected by this corrective action.

Description of the problem and potential hazard and risk for the patient/user:
Failure to follow proper charging practices can result in lithium-ion battery degradation, characterised by excessive heat during operation or failure to properly charge. In rare circumstances, battery degradation has been associated with battery venting, which is a rapid release of battery energy. 3M has received two reports of battery venting resulting in minor burn injury.
3M is adding the following product warning to emphasise the importance of following proper charging practices:

Warning: *To avoid potential battery degradation, charge the clipper after each use and store in the drop-in charger stand when not in use.*

Action to be taken by the user:
All users of the **3M™ Surgical Clipper Professional, Model 9681** are being asked to take the following actions:

- Ensure all users within your facility are following proper clipper charging practices as documented in the Model 9681 Clipper instructions for use and emphasised in the new product warning.
- Immediately evaluate Model 9681 clipper units within your facility. **Discontinue use and dispose of** any Model 9681 clippers if proper charging practices were not maintained, or that exhibit the following criteria:
    a) Any clipper that has no remaining charge (i.e., clipper motor does not run when the "ON" button is pushed), or that fails to charge.
    b) Any clipper that is uncomfortably hot-to-the-touch during use.
- Complete and return the enclosed **Confirmation Form**, indicating the number of clipper units requiring disposal and your understanding of the new product safety warning.

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
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Confirmation Form – FSN 2018-02 FSCA Clipper 9681

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

Please examine your inventory immediately to determine if you have any **3M™ Surgical Clipper Professional, Model 9681** that exhibit any of the following criteria:

a) Any clipper that has no remaining charge (i.e., clipper motor does not run when the “ON” button is pushed), or that fails to charge.

b) Any clipper that is uncomfortably hot-to-the-touch during use.

Immediately discontinue use of any units that exhibit these criteria and **dispose of** per your facility policy.

Please record the number of Model 9681 clipper units that are being disposed of.

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☐ I would prefer to receive ☐ replacement product ☐ credit for Model 9681 clipper units that are being disposed of

☐ **I have read and understood this product safety communication and acknowledge the new product warning**

By signing below, I confirm that I have disposed of all identified affected clippers within my facility.

Contact Information:

Name		Facility/Company Name	
Signature		Facility/ Company Address	
Date		Phone	