

**Urgent Field Safety Notice****Name of the affected product: 3M™ Universal Electrosurgical Pad, reference number 9130****FSCA-identifier: FSN 2016-10 FSCA 3M Universal Electrosurgical Pad****Type of action:** destruction of concerned batchesDate: October 28th, 2016

Attention: 3M Customers

3M is conducting a Field Safety Corrective Action (FSCA) for 3M™ Universal Electrosurgical Pad.

Details on affected devices:

The following products are in scope of this FSCA:

Catalog Numbers	Lot Numbers	Expiration Dates
9130	2019-02DT	02-2019
	2019-03DU	03-2019

Description of the problem:

This Field Safety Corrective Action follows confirmation of a single user report of an unintended material (process liner) in the product. The presence of a process liner may prevent or impede the safe return of electrosurgical current following Electrosurgical Unit (ESU) activation. While there is only a remote possibility of the pads containing the process liner, 3M is requesting your prompt assistance for this FSCA.

Potential hazard and risk for the patient:

This defect has the potential to increase the risk of a patient burn directly under the pad or at an alternate site of the body due to increased impedance at the pad application site.

Action to be taken by the user:

- Read and distribute this information
- Identify and quarantine the devices of the concerned lots
- Dispose these devices
- Fill in the confirmation form and send it back to the manufacturer
- Notify your customers down to the user level about this FSCA.

Transmission of this Field Safety Notice:

Please pass this notice immediately on to everybody and all departments in your organisation who might use or order the concerned products. Moreover, please ensure that the information is provided to any customer where the concerned products potentially have been delivered to.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this situation may cause.

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

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

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH - Health Care Business
Carl-Schurz-Strasse 1
41453 Neuss, Germany
Mail: mcobbers@mmm.com
Tel.: +49-2131-144792

Confirmation Form – FSN 2016-10 FSCA 3M Universal Electrosurgical Pad

Please complete and return this form by e-mail to: 3M Deutschland GmbH, Dr. Marie Isabel Cobbers,
eMail: mcobbers@mmm.com, Fax: +49-2131 14124792

Please examine your stock immediately to determine if you have the following lots of the product:

- 3M™ Universal Electrosurgical Pad, Catalog Number 9130 in Lots 2019-02DT and 2019-03DU

If you have any product of the concerned lots, isolate and dispose the concerned products.

Please indicate your response by completing the following information:

We have examined our inventory, isolated and disposed the following amount of the concerned lots of the product:

Catalog Numbers	Lot Numbers	Expiration Dates	Check Mark <input type="checkbox"/>	Number of pouches
9130	2019-02DT	02-2019		
	2019-03DU	03-2019		

We have examined our inventory and do not have the above specified 3M products.

We hereby confirm that we received and understood the information about the Field Safety Corrective Action and that the notice has been passed to all those who need to be aware within our organisation or to any department where the affected product has been supplied to.

Person completing this form:

(Name)

(Signature)

(Date)

(Customer Name)

(City, State)

(Phone)

(email)