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Urgent Field Safety Notice

Name of the affected product: Coban 2 and Coban 2 Lite (compression layers only)
FSCA-identifier: FSN 2016-02 FSCA Coban 2
Type of action: device destruction / advice given by manufacturer regarding the use of the device

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Date: February 15th, 2016

Attention: 3M Customers

3M is conducting a Field Safety Corrective Action (FSCA) for compression bandages Coban 2 and Coban 2 Lite.

Details on affected devices:
The following products are in scope of this FSCA:

	Reference	ID number	Lot number
Coban 2	20024	DH888822474	2018-12AQ
Coban 2 Lite	20724	DH888822441	2017-12AP
Coban 2 Lite	20724	DH888822441	2018-01AS

Description of the problem:
During printing of the foil used as the primary packaging for the products, the printing plates for Coban 2 and Coban 2 Lite were mixed up. As a result, the foil pouch of Coban 2 shows "Coban 2 Lite" as product name and the foil pouch of Coban 2 Lite shows "Coban 2" as product name. The compression bandage, the outer carton packaging, the corresponding instructions for use as well as the colour codings (purple for Coban 2 and green for Coban 2 Lite) are all correct.

Coban 2: The product in the pouch, IFU and primary cartons are all correct, only the pouch label is incorrect

Correct pouch label:

Incorrect pouch label with Lite underneath Coban 2 and incorrect ABPI value:

Coban 2 Lite : The product in the pouch, IFU and primary cartons are all correct, only the pouch label is incorrect

Correct pouch:

Incorrect pouch: missing the word Lite under Coban 2 and incorrect ABPI value

Potential hazard and risk for the patient:
The potential hazard is that the products are used according to the name on the pouch foil (disregarding the IFU, the colour coding and primary carton) and the wrong bandage would be applied to a patient.
If **Coban 2** is used by mistake for a patient requiring moderate compression, a reduced blood circulation in the extremity is a possible consequence, which could lead to local necrosis or complete ischemia.
If **Coban 2 Lite** is used by mistake for a patient requiring regular compression, the compression efficacy might not be sufficient. This would be noticed by the health care provider and corrected with the next bandage change.

Action to be taken by the user:

For Coban 2:

- Read and distribute this information
- Identify and quarantine the devices of the concerned batch (2018-12AQ)
- Dispose these devices
- Fill in confirmation form A and send it back to the manufacturer

For Coban 2 Lite:

- Read and distribute this information
- Use Coban 2 Lite as is, referring to the label of the carton, the IFU and to the green colour coding on the pouch and in core of the bandage
- Fill in confirmation form B and send it back to the manufacturer

Transmission of this Field Safety Notice:

Please pass this notice immediately on to all everybody and all departments who might use or order the concerned products. Moreover, 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 apologize for any inconvenience this situation may cause.

Contact reference person:
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 A - for Coban 2 Compression Layer

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

Field Safety Corrective Action for **Coban 2**, FSN 2016-02 FSCA Coban 2, dated February 15th, 2016
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 organization or to any department where the affected product has been distributed.

We checked our storage locations and identified/isolated the following affected products:

Product references	*Lot Number*	*Identified quantity of rolls*
Coban 2, reference 20024	**2018-12AQ**	

Note: don't leave cells blank, but mention "none" in case no rolls were identified at your site.

Certificate of Destruction

We hereby certify that all items listed in the table above have been destroyed on site.

Name:

Position:

Signature:

Date:

Hospital/Institute:

Confirmation Form B – for Coban 2 Lite Compression Layer

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

Field Safety Corrective Action for **Coban 2 Lite**, FSN 2016-02 FSCA Coban 2, dated February 15th, 2016
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 organization or to any department where the affected product has been distributed.

Name:

Position:

Signature:

Date:

Hospital/Institute: