



Date: 27 September 2018

URGENT FIELD SAFETY NOTICE

Commercial name of the product: Mölnlycke® Procedure trays
Type of action: Device destruction
Attention: Theatre Manager
Details of affected devices: For more details – see attached list of affected devices

Dear Customer,

At Mölnlycke, patient safety is our highest priority. We are writing to inform you about a Field Safety Corrective Action (FSCA) informed by supplier Medtronic regarding three components manufactured by the legal manufacturer Degania Silicone Ltd.

Medtronic is performing a FSCA on three components included in some of the Mölnlycke® Procedure trays that are provided to you. The reason for this is because the legal manufacturer, Degania Silicone Ltd., has detected that specific production lots of three types of Mon-a-Therm™ Foley catheters have defective temperature sensors.

In line with Medtronic FSN, Mölnlycke has decided to request that all affected components included in Mölnlycke® Procedure trays will be discarded according to the below instruction. If you have any affected Mölnlycke® Procedure trays in your inventory from the list, we ask you to follow the instructions below.

What you need to do

1. Please use the attached list to identify and isolate all affected, unused Mölnlycke® Procedure trays at your facility.
2. Please complete the attached confirmation form and **e-mail/fax** back per its instructions. Even if you no longer have any concerned Mölnlycke® Procedure tray, Mölnlycke needs to be sure all customers are aware of the situation. Mölnlycke will provide a **Scrapping Confirmation** form upon receiving the signed **FSN confirmation** form.
3. At the point of use, the user is required to remove the affected components from the Mölnlycke® Procedure tray, **discard it** followed by updating the **Scrapping Confirmation** form with the relevant information. Once all affected trays have been utilized, and all components are discarded, please **sign** and **email/fax** back the form per its instructions.
4. When complete and signed scrapping confirmation is received by Mölnlycke, Mölnlycke will contact you regarding compensation for the affected components scrapped.
5. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly.
6. If you are a distributor, please inform your customers by sending them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly and return the confirmation form to you.

In addition Mölnlycke appreciates your help in collecting data on product complaints and/or incidents related to the concerned products. Please, follow the reporting procedures established by your facility.

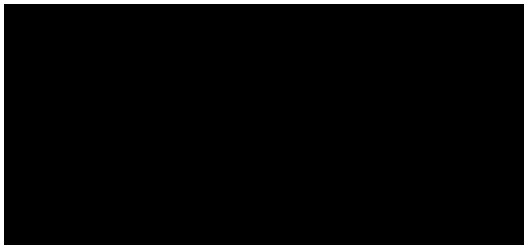
Any questions?

Please contact your local Mölnlycke Customer Care or Account Manager if you have any questions or concerns regarding this FSN. You may also contact:

Vigilance: Linda Magnusson (vigilance@molnlycke.com) or +46 31 352 3733

Mölnlycke confirms that this FSN has been notified to the appropriate Regulatory Agencies.
Thank you for time and attention, and Mölnlycke apologies for any inconvenience.

Sincerely,



CONFIRMATION FORM**PLEASE COMPLETE AND RETURN THIS FORM TO:**

Linda Magnusson, Global Product Complaints Manager
 Mölnlycke Health Care,
 Box 130 80, SE-402 52
 Gothenburg, Sweden

E-mail: vigilance@molnlycke.com
 Fax +46 31 722 34 00

Ref – 2018-09 (01)

Product code	Batch/LOT	Quantity Quarantined (trays)

I have read this Field Safety Notice, understand the actions required and have acted accordingly.

If you are a distributor: I return the completed confirmation form and by that ensure that the end users have received the Field Safety Notice and acted accordingly.

PLEASE COMPLETE ALL SECTIONS

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

SERVICE/ DEPARTMENT : _____

CITY : _____ POSTCODE / ZIP : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

UPLIFT ADDRESS IF APPLICABLE: _____

SIGNATURE : _____

DATE : _____

TABLE A - PRODUCT CODES AND MDD CLASS

Country	Product	LOT	Product Name	Material group code	Material group description	Date of Manufacture (date of confirmation)	Expiry date	MDD Class	Number of trays per TRP	Quantity produced (PCS)
SE	97001883-14	17448267		P12036	Cardiovascular Other	06.11.2017	28.04.2020	III	1	64
SE	97001883-14	17448268		P12036	Cardiovascular Other	06.11.2017	28.03.2020	III	1	64
SE	97001883-14	17466680		P12036	Cardiovascular Other	16.11.2017	28.04.2020	III	1	64
SE	97001883-14	17470296		P12036	Cardiovascular Other	02.12.2017	28.04.2020	III	1	64
SE	97001883-14	17470297		P12036	Cardiovascular Other	30.11.2017	28.04.2020	III	1	64
SE	97001883-14	17470298		P12036	Cardiovascular Other	30.11.2017	28.04.2020	III	1	64
SE	97001883-14	17471100		P12036	Cardiovascular Other	23.11.2017	28.04.2020	III	1	15
SE	97001883-14	17485950		P12036	Cardiovascular Other	18.12.2017	28.04.2020	III	1	58
SE	97001883-14	17487532		P12036	Cardiovascular Other	07.12.2017	28.04.2020	III	1	35
SE	97001883-14	17488584		P12036	Cardiovascular Other	05.12.2017	28.04.2020	III	1	21
SE	97001883-14	18079657		P12036	Cardiovascular Other	12.03.2018	28.07.2020	III	1	21
SE	97001883-14	18169121		P12036	Cardiovascular Other	19.04.2018	28.07.2020	III	1	57
SE	97001883-15	18204566		P12036	Cardiovascular Other	23.05.2018	28.10.2020	III	1	53
SE	97001883-15	18260297		P12036	Cardiovascular Other	18.07.2018	28.11.2020	III	1	54
ES	97016814-03	17503581		P12036	Cardiovascular Other	15.12.2017	28.05.2020	IIB	2	24
ES	97016814-03	18061826		P12036	Cardiovascular Other	14.02.2018	28.10.2020	IIB	2	26
ES	97016814-03	18085413		P12036	Cardiovascular Other	26.02.2018	28.08.2020	IIB	2	24
ES	97016814-03	17520205		P12036	Cardiovascular Other	09.03.2018	28.05.2020	IIB	2	24
ES	97016814-03	18139773		P12036	Cardiovascular Other	26.03.2018	28.08.2020	IIB	2	24
NO	97025727-06	18028339		P12033	CABG	09.01.2018	28.09.2020	IIB	2	30
NO	97025727-06	18155631		P12033	CABG	16.04.2018	28.02.2021	IIB	2	28
NO	97025727-06	18181630		P12033	CABG	03.05.2018	28.03.2021	IIB	2	24
NO	97032094-09	17459779		P12036	Cardiovascular Other	07.11.2017	28.03.2020	IIB	1	39
NO	97032094-09	17504034		P12036	Cardiovascular Other	11.12.2017	28.04.2020	IIB	1	53
NO	97032094-09	18021525		P12036	Cardiovascular Other	16.01.2018	28.05.2020	IIB	1	58
NO	97032094-11	18111591		P12036	Cardiovascular Other	15.03.2018	28.06.2020	IIB	1	48
NO	97032094-11	18173858		P12036	Cardiovascular Other	25.04.2018	28.09.2020	IIB	1	48
NO	97032094-11	18218587		P12036	Cardiovascular Other	25.05.2018	28.09.2020	IIB	1	48
DK	97035335-05	17465648		P12036	Cardiovascular Other	14.11.2017	28.04.2019	III	1	14
DK	97035335-05	18041236		P12036	Cardiovascular Other	24.01.2018	28.07.2019	III	1	10
ES	97040889-00	17518414		P12034	Valve open heart surgery	21.12.2017	28.05.2020	IIB	2	54
ES	97040889-00	18037591		P12034	Valve open heart surgery	19.01.2018	28.05.2020	IIB	2	42
ES	97040889-00	18055308		P12034	Valve open heart surgery	31.01.2018	28.07.2020	IIB	2	60
ES	97040889-00	18176305		P12034	Valve open heart surgery	30.04.2018	28.01.2021	IIB	2	62
NO	97042597-04	17459148		P12036	Cardiovascular Other	06.11.2017	28.04.2020	IIB	1	6
NO	97042597-04	17459147		P12036	Cardiovascular Other	06.11.2017	28.04.2020	IIB	1	64
NO	97042597-04	17492349		P12036	Cardiovascular Other	07.12.2017	28.04.2020	IIB	1	49
NO	97042597-04	18020697		P12036	Cardiovascular Other	11.01.2018	28.11.2019	IIB	1	5
NO	97042597-04	18048526		P12036	Cardiovascular Other	22.01.2018	28.11.2019	IIB	1	64
NO	97042597-04	18076066		P12036	Cardiovascular Other	21.03.2018	28.11.2019	IIB	1	63
SE	97046023-05	17459509		P12040	Valve replacement (TAVI)	06.11.2017	28.07.2020	IIB	2	16
SE	97046023-05	18149106		P12040	Valve replacement (TAVI)	05.04.2018	28.11.2019	IIB	2	8
DK	97049933-07	17471080		P12124	Plastic surgery Others	23.11.2017	28.10.2019	IIB	2	20
DK	97049933-07	18014212		P12124	Plastic surgery Others	05.01.2018	28.01.2020	IIB	2	26
DK	97049933-07	18132934		P12124	Plastic surgery Others	12.04.2018	28.05.2020	IIB	2	20
DK	97049933-07	18160484		P12124	Plastic surgery Others	19.04.2018	28.05.2020	IIB	2	10
NO	97050935-01	17518584		P12062	Breast procedures	01.01.2018	28.09.2019	IIB	1	2
DK	97051278-05	17505096		P12024	MIS Anti-reflux	18.12.2017	28.09.2019	IIB	2	28
DK	97051278-06	18064336		P12024	MIS Anti-reflux	15.03.2018	28.09.2019	IIB	2	10
DK	97051278-06	18247943		P12024	MIS Anti-reflux	21.06.2018	28.11.2019	IIB	2	20
DK	97053143-08	17450640		P12032	Femoral	07.11.2017	28.03.2020	IIB	2	52
DK	97053143-08	17484385		P12032	Femoral	04.12.2017	28.02.2020	IIB	2	22
DK	97053143-08	17486296		P12032	Femoral	09.12.2017	28.02.2020	IIB	2	12
DK	97053143-08	18041185		P12032	Femoral	25.01.2018	28.07.2020	IIB	2	18
DE	97060166-06	17449275		P12050	Craniotomy	07.11.2017	28.06.2021	III	2	22
DE	97060166-06	18040886		P12050	Craniotomy	23.01.2018	28.05.2022	III	2	18
DE	97062751-04	17453831		P12030	Aortic bypass	18.11.2017	28.10.2019	IIB	1	43
DE	97062751-04	17492288		P12030	Aortic bypass	16.12.2017	28.04.2020	IIB	1	17

DE	97062751-04	17503854		P12030	Aortic bypass	16.12.2017	28.05.2020	IIB	1	7
DE	97062751-04	18036694		P12030	Aortic bypass	23.01.2018	28.05.2020	IIB	1	36
DE	97062751-04	18125730		P12030	Aortic bypass	21.03.2018	28.09.2019	IIB	1	28
DE	97062751-04	18212402		P12030	Aortic bypass	30.05.2018	28.06.2020	IIB	1	16
DE	97062752-04	18048766		P12032	Femoral	23.01.2018	28.05.2020	IIB	1	6
DE	97074670-04	17466745		P12030	Aortic bypass	22.11.2017	28.02.2020	IIB	2	34
DE	97074670-04	17502843		P12030	Aortic bypass	22.12.2017	28.04.2020	IIB	2	38
DE	97074670-05	18038659		P12030	Aortic bypass	05.02.2018	28.05.2020	IIB	2	18
DE	97074670-05	18084490		P12030	Aortic bypass	21.03.2018	28.05.2020	IIB	2	16
GB	97079349-02	17493395		P12033	CABG	08.12.2017	28.11.2019	III	1	21
GB	97079349-02	18061223		P12033	CABG	14.02.2018	28.11.2019	III	1	19
GB	97079350-01	18013266		P12030	Aortic bypass	04.01.2018	28.03.2020	III	2	4
GB	97079351-01	17504959		P12040	Valve replacement (TAVI)	18.12.2017	28.03.2020	III	2	2
GB	97079351-01	18033740		P12040	Valve replacement (TAVI)	18.01.2018	28.11.2019	III	2	4
GB	97079352-01	17492292		P12033	CABG	07.12.2017	28.11.2019	III	1	18
CL	97080950-00	17503678		P12036	Cardiovascular Other	15.12.2017	28.07.2020	III	4	36
CL	97080950-02	18198196		P12036	Cardiovascular Other	17.05.2018	28.09.2020	III	4	64
CY	97084410-02	18155958		P12033	CABG	13.04.2018	28.02.2021	IIB	2	6
DK	97088030-00	17452575		P12029	Laparoscopy others	10.11.2017	28.05.2020	IIB	2	28
DK	97088030-00	17521494		P12029	Laparoscopy others	10.01.2018	28.08.2020	IIB	2	60

DE	97074670-04	17502843		Aortic bypass	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	RE
DE	97074670-05	18038659		Aortic bypass	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
DE	97074670-05	18084490		Aortic bypass	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079349-02	17493395		CABG	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079349-02	18061223		CABG	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079350-01	18013266		Aortic bypass	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079351-01	17504959		Valve replacement (TAVI)	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079351-01	18033740		Valve replacement (TAVI)	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
GB	97079352-01	17492292		CABG	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	RE
CL	97080950-00	17503678		Cardiovascular Other	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	RE
CL	97080950-02	18198196		Cardiovascular Other	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	DEEPC	AV
CY	97084410-02	18155958		CABG	P61371	Cardiothoracic surgical	A collection of various sterile cardiothoracic surgical instruments, dressings, and materials intended to be used	WITHOUT NRL	SOFTX	AV
DK	97088030-00	17452575		Laparoscopy others	P44096	Laparoscopic surgical	A collection of various sterile surgical and endoscopic instruments (e.g., trocars, sleeves, cannulae), possibly	WITHOUT NRL	SOFT	AV
DK	97088030-00	17521494		Laparoscopy others	P44096	Laparoscopic surgical	A collection of various sterile surgical and endoscopic instruments (e.g., trocars, sleeves, cannulae), possibly	WITHOUT NRL	SOFT	AV