



Degania Silicone Ltd., 15130, Israel
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E-mail: ds@ds-il.com Web: www.degania-medical.com

URGENT FIELD SAFETY NOTICE UPDATE 09/02/2018

Attention to Customer:

02-Sept-2018

**Covidien AG
Weg naar Zwartberg 239, hall 5
Opplabbeek 3660
Belgium**

Dear Valued Customer,

On June 21st, 2018 we issued a field safety notice regarding the voluntary recall of the Temperature Sensor Catheters distributed to your facility. This voluntary recall was identified after a review of our customer complaints. We conducted an investigation and found a defect in the temperature sensor. Manufacturing of the product was stopped, and shipment discontinued based on the suspected lots provided by the supplier. Following verification that the raw sensor lots still available within Degania Silicone were manufactured outside of the suspect date range and that the root cause was identified, lots quarantined, and process corrected, we began production and shipment again in June 2018.

Status of Root Cause Investigation: The root cause of the temperature discrepancy has been identified by the supplier as chips that were ground to a sharp point during the grinding process, which may create a condition of mechanical weakness allowing the chip to break during handling or subsequent manufacturing processes. The Supplier identified this issue during routine QC inspection. On 26 Feb 2017 the Supplier QC inspection identified one unit with a sharp point and on 28 Feb 2017 identified six additional units with a sharp point. During this time there were several new operators and the Supplier identified new operator training as a contributing factor to the QC findings of sharp points. Operators were retrained on 1 March 2017. To bracket the timeframe, the Supplier took a one month buffer prior to the inception of the new hires and a two month buffer following the retraining. The inspection records from May 2017 through August 2018 were reviewed and there were no QC failures for sharp points from May 2017 through August 2018. The supplier root cause analysis is complete and the effectiveness of the actions taken at the supplier was verified as effective by us.



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Subsequent Report of Patient event: On 13 August 2018 we received a complaint with a reported incorrect temperature reading. The report documents a patient death. The product in this complaint was manufactured in February 2018. This manufacture date is outside of the scope of this recall. This product in this complaint will not be returned to us as it was discarded at the point of use. The investigation into this complaint is not yet completed. However, at this time, there is no information to indicate that this complaint is related to the recall and the investigation has not identified a need to expand the recall based on this specific event. We will update you once this investigation is completed. The relevant Authority and the FDA have been notified of this event.

Scope of Recall: During a recent visit of the Supplier we identified that the initial bracketing of the affected lots was based on shipment dates rather than the manufacturing dates. Additional manufactured lots will be added to the scope of the recall. Please find attached the list of additional involved lots in the below Table 1.

Status of manufacturing: Following the customer complaint on 13 August 2018, described above, shipment of the product was suspended (15 August 2018) while we gathered additional information on the patient event. We plan to resume shipment of product by September 03. Only product produced from sensor batches that were manufactured after May 2017 will be shipped. This is based on the root cause analysis and bracketing of manufacturing dates within the scope of the recall.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient and customer satisfaction.

Sincerely, Q Medical Devices

Andrew Holman, President

A handwritten signature in black ink, appearing to read "Andrew Holman", is positioned to the right of the typed name.



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Table 1

Recall extension – list of the lots

Lot #	Degania PN	Covidien PN	Part name	MNF date	Expiry date	Date supplied	Quantity, pcs
S17003430	102201101280TY	90055T	TSC CATHETER CLEAR 12FR STERILE	19-06-17	19-05-22	16-11-17	1080
S17002986	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	31-05-17	30-04-22	16-11-17	1080
S17005116	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	02-08-17	02-07-22	20-09-17	1440
S17007031	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	09-10-17	09-09-22	16-11-17	1080
S17003446	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	20-06-17	20-05-22	13-09-17	1080
S17005114	102201101280TY	90055T	TSC CATHETER CLEAR 12FR STERILE	01-08-17	01-07-22	18-12-17	1080
S17006363	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	08-09-17	08-08-22	11/01/18 10/04/18	1440
S17007599	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	28-10-17	28-09-22	18-12-17	720
S17002076	102201101280TY	90055T	TSC CATHETER CLEAR 12FR STERILE	24-04-17	24-03-22	16-10-17	1440
S17007623	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	28-10-17	28-09-22	06-02-18	720
S17007780	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	10-11-17	10-10-22	23-04-18	720
S17000335	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	21-02-17	21-01-22	20-06-17	360
S17006814	102201100880TY	90053T	TSC CATHETER CLEAR 8FR STERILE	30-09-17	30-08-22	06-02-18	360
S17002987	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	31-05-17	30-04-22	16-11-17	720
S17006676	102201101280TY	90055T	TSC CATHETER CLEAR 12FR STERILE	26-09-17	26-08-22	11-01-18	720
S17007806	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	10-11-17	10-10-22	06-02-18	720
S17005115	102201100880TY	90053T	TSC CATHETER CLEAR 8FR STERILE	01-08-17	01-07-22	11-01-18	360
S17008017	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	24-11-17	24-10-22	26-02-18	360
S17002083	102201101480TY	90056T	TSC CATHETER CLEAR 14FR STERILE	24-04-17	24-03-22	29-08-17	720
S17002090	102201101680TY	90051T	TSC CATHETER CLEAR 16FR STERILE	24-04-17	24-03-22	20-07-17	1080
S18001346	102201101880TY	90052T	TSC CATHETER CLEAR 18FR STERILE	26-02-18	26-01-23	13-04-18	1080
S17000333	102201101880TY	90052T	TSC CATHETER CLEAR 18FR STERILE	21-02-17	21-01-22	29/05/17 14/06/17	720
S17007771	102201101280TY	90055T	TSC CATHETER CLEAR 12FR STERILE	10-11-17	10-10-22	11-01-18	720
Total:							19800

UPDATED URGENT FIELD SAFETY NOTICE

Mon-a-Therm™ Foley catheters with temperature sensors

October, 2018

Medtronic Reference: FA835

Attention: Risk Management Director and Materials Management Director

Dear Valued Customer:

The purpose of this letter is to advise you of an update to our August, 2018, communication related to Degania Silicone's voluntary recall of specific production lots of Mon-a-Therm™ Foley catheters with temperature sensors. The attached communication from Degania Silicone details the specifics of this expanded lot number recall.

Required Actions:

1. Please review the attached Urgent Field Safety Notice Update 09/02/2018, from Degania Silicone.
2. Please immediately discontinue use, and quarantine, the additional affected item codes and lots listed below.
3. Please return affected product as indicated below.
4. Complete the Recalled Product Return Form even if you do not have inventory.

Item Code	Description	Affected Lot Numbers		
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002986	S17002987	S17008017
		S17006363	S17007806	S17002090
		S17007623		
90052T	TSC CATHETER CLEAR 18FR STERILE	S18001346	S17000333	
90053T	TSC CATHETER CLEAR 8FR STERILE	S17006814	S17005115	
90055T	TSC CATHETER CLEAR 12FR STERILE	S17003430	S17002076	S17007771
		S17005114	S17006676	
90056T	TSC CATHETER CLEAR 14FR STERILE	S17005116	S17007599	S17000335
		S17007031	S17007780	S17002083
		S17003446		

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased from a distributor	Complete all fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating “no inventory”	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

If you are aware of any incidents related to this issue or if you have any questions, please contact your Medtronic representative immediately to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at 01 511 1400.

Sincerely,



Subu Mangipudi
 Vice President, Quality Assurance
 Respiratory, Gastrointestinal and Informatics
 Medtronic



Samantha Baxter
 Regulatory Affairs Manager
 UK and Ireland

Attachment: Degania Silicone Urgent Field Safety Notice [Update 09/02/2018](#)

Attachment A – List of impacted codes and lot numbers from initial communication

Item Code	Description	Affected Lot Numbers				
90051T	TSC CATHETER CLEAR 16FR STERILE	S17001607	S17002682	S17004509	S17005529	S17006719
		S17002091	S17003219	S17004510	S17005979	S17006720
		S17002440	S17003301	S17004511	S17005980	S17006721
		S17002441	S17003302	S17004771	S17005981	S17006722
		S17002558	S17003391	S17004772	S17005982	S17006723
		S17002559	S17003456	S17004902	S17005983	S17006724
		S17002560	S17004376	S17005028	S17005984	S17006725
		S17002561	S17004377	S17005029	S17005985	S17007360
		S17002562	S17004378	S17005030	S17005986	S17007459
		S17002563	S17004379	S17005117	S17006718	S17007622
		S17002681	S17004380	S17005281		
90052T	TSC CATHETER CLEAR 18FR STERILE	S17000279	S17002452	S17003578	S17007065	S17003461
		S17000280	S17002892	S17005046	S17007171	S17006731
		S17000837	S17003306	S17005298		
90053T	TSC CATHETER CLEAR 8FR STERILE	S17002877	S17002878	S17003909	S17004477	S17005607
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000660	S17000946	S17002077	S17003350	S17004479
		S17000808	S17001347	S17002197	S17003351	S17004736
		S17000809	S17001348	S17002979	S17003439	S17005948
		S17000943	S17001349	S17003347	S17004190	S17005949
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000191	S17002884	S17004486	S17006333	S17007030
		S17000192	S17002982	S17004746	S17006334	S17007032
		S17000231	S17002983	S17004877	S17006687	S17007334
		S17000320	S17003784	S17005004	S17006688	S17007433
		S17001226	S17003785	S17005956	S17006689	S17007434
		S17002082	S17003916	S17005957	S17006690	S17007588
		S17002550	S17003917	S17005958	S17006926	S17000373
		S17002784	S17004351	S17006206	S17007029	S17008259
		S17002883				

Attachment B

Item code

COVIDIEN™
Mon-a-Therm™
Foley Catheter with Temperature Sensor 400TM

Sonde de Foley avec capteur de température 400TM
 Foley-katheter mit Temperatursensor 400TM
 Catetere Foley con sensore della temperatura 400TM
 Sonda Foley con sensor de temperatura 400TM
 Foleykatheter med temperatursensor 400TM
 Foley-katheter met temperatursensor 400TM
 Cateter Foley com sensor de temperatura 400TM
 Balkonkatheter med temperaturføler 400TM

Foleyyn katetri lämpötila-anturi 400TM
 Κάθετήρας Foley με αισθητήρα θερμοκρασίας 400TM
 Foleykatheter med temperatursensor 400TM
 Foleyho kateter s temperatūras sensoru 400TM
 Foley hőérzékelős katéter 400TM
 Катетеры Фолея серии с датчиком температуры 400TM
 Cewnik Foley'a z czujnikiem temperatury 400TM
 Isi Sensörü Foley Catheter 400TM

EN 12470-4
 Single use
 Caution: Sterile
 autoclave
 packaging
STERILE EO
 ISO 15848-2
 ISO 15848-1
 ISO 15848-3
 ISO 15848-4
 ISO 15848-5
 ISO 15848-6
 ISO 15848-7
 ISO 15848-8
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 ISO 15848-100

Mon-a-Therm™ is a Trademark of Covidien Inc.
 © 2011 Covidien - Made in India
Degania Silicone Ltd., Degania Bet 15130, Israel
 HR-Drugs-667 B (H)

REF	900561
SIZE	5-10ml Ch14
Use by	2022 - 12
LOT	S17008457
	2018 - 01
	12

(01)1088452200062
 (17)221280 (10)S17008457

863300021IV Rev 0

Lot number