

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		

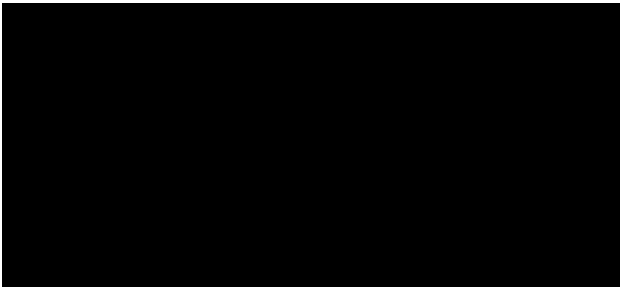
	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification 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 (XXX) XXX-XXXX.

Sincerely,



Medtronic

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
Cathetere Foley con sensore della temperatura 400TM
Sonda Foley con sensor de temperatura 400TM
Foleykatheter med temperatursensor 400TM
Foley-katheter mit temperatursensor
Catheter Foley con sensor de temperatura 400TM
Ballonkatheter med temperaturføler 400TM
Foleyn katetri lämpötila-anturiella 400TM
Καθετήρας Foley με αισθητήρα θερμοκρασίας 400TM
Foleykatheter med temperaturføler 400TM
Foleynho katéter s teplotnim číslom 400TM
Foley hőérzékelős katéter 400TM
Катетер Фолея с датчиком температуры 400TM
Cewnik Foley'a z czujnikiem temperatury 400TM
Isi Sensörü Foley Catheter 400TM

EN 12470-4
Single use
Caution, reuse prohibited
STERILE EO
No Stere
No Steam
No Heat
No Dry
No Radiation
No Chemicals
No Solvents
No Oils
No Greases
No Detergents
No Disinfectants
No Antiseptics
No Lubricants
No Adhesives
No Sealants
No Coatings
No Inks
No Pigments
No Fillers
No Additives
No Impurities
No Contaminants
No Residues
No Leachables
No Extractables
No Degradation Products
No Bioburden
No Endotoxins
No Pyrogens
No Mycotoxins
No Aflatoxins
No Bioterrorism Agents
No Chemical Warfare Agents
No Biological Warfare Agents
No Radiological Warfare Agents
No Chemical Hazards
No Biological Hazards
No Radiological Hazards
No Environmental Hazards
No Safety Hazards
No Health Hazards
No Other Hazards
0473

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Degania Silicone Ltd., Degania Bet 15130, Israel
HR-Drugs-667 B (H)

REF	90056T
SIZE	5-10ml Ch14
Use by	2022 - 12
LOT	\$17008457
	2018 - 01
	12

0110884522000062
(17)221200(10)\$17008457

86380211V Rev 0

Lot number