



Degania Silicone Ltd., 15130, Israel
Tel: +972-4-6755100 Fax: +972-4-6709182
E-mail: ds@ds-il.com Web: www.degania-medical.com

URGENT FIELD SAFETY NOTICE

Urgent- Please bring this letter to the immediate attention of the person(s) responsible for usage of the below product:

Attention to Customer:

21-June-2018

Updated: 26-July-2018

Covidien AG
Weg naar Zwartberg 239, hall 5
Opglabbeek 3660
Belgium

Dear Valued Customer,

The purpose of this letter is to inform you that Degania Silicone is conducting a voluntary recall of the **Temperature Sensor Catheters** distributed to your facility. The details of the lots to be re-called please find in the table #1.

Description of Issue:

The above lots suspected to contain catheters with defective temperature sensor; such parts will show lower body temperature measurement than actual temperature of a patient (~-2°C). Failure to correctly measure patient body temperature can lead to wrong diagnosis and insufficient treatment.

Please immediately follow the Required Customer Actions set forth below.

1. Please forward this information to the immediate attention of the persons responsible for usage of the affected parts. Sub-recall must be initiated by your company to collect any distributed product from the suspected list.
2. Please fill in the attached Recall Response form and indicate the quantity of the affected product in your possession.
3. Promptly return the completed Recall Response form to Degania Silicone by e-mail: **Katia@ds-il.com**



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Any affected product should be returned to our Germany warehouse:

Dietrich Gass oHG
Hauptstrasse 60a
42349 Wuppertal-Cronenberg
Germany
phone.: +49 0202 247 68 15
Contact: Melissa Wagner (mw@degania-silicone.de)

Should you have any questions about this subject, please contact Degania Silicone:

Degania Silicone Ltd.
Degania Bet, 1513000,
Israel
Katia Kayam, Customer complaints Officer
Tel: +972-529532059
E-mail: Katia@ds-il.com

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

Sincerely, Degania Silicone LTD.

Andrew Holman, Managing Director

A handwritten signature in black ink, appearing to read "Andrew Holman".



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Table 1:

Medtronic Material/Part #:	Material/Part Description:	Lot/Serial #	Manufactured Date	Release Qty, pcs
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000191	10-02-17	1800
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000192	13-02-17	2880
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000231	14-02-17	2160
90052T	TSC CATHETER CLEAR 18FR STERILE	S17000279	11-02-17	1800
90052T	TSC CATHETER CLEAR 18FR STERILE	S17000280	15-02-17	360
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000320	18-02-17	2520
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000660	11-04-17	2520
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000808	11-04-17	2520
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000809	21-03-17	1800
90052T	TSC CATHETER CLEAR 18FR STERILE	S17000837	22-03-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000943	20-04-17	2160
90055T	TSC CATHETER CLEAR 12FR STERILE	S17000946	20-04-17	2520
90056T	TSC CATHETER CLEAR 14FR STERILE	S17001226	12-04-17	3600
90055T	TSC CATHETER CLEAR 12FR STERILE	S17001347	20-04-17	1800
90055T	TSC CATHETER CLEAR 12FR STERILE	S17001348	08-04-17	1440
90055T	TSC CATHETER CLEAR 12FR STERILE	S17001349	29-04-17	3240
90051T	TSC CATHETER CLEAR 16FR STERILE	S17001607	19-04-17	1800
90055T	TSC CATHETER CLEAR 12FR STERILE	S17002077	29-04-17	3600
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002082	26-04-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002091	29-04-17	2160
90055T	TSC CATHETER CLEAR 12FR STERILE	S17002197	31-05-17	2880
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002440	09-05-17	3600
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002441	12-05-17	3240
90052T	TSC CATHETER CLEAR 18FR STERILE	S17002452	05-05-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002550	22-05-17	3240
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002558	12-05-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002559	08-05-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002560	11-05-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002561	20-05-17	3600
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002562	20-05-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002563	20-05-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002681	26-05-17	3600
90051T	TSC CATHETER CLEAR 16FR STERILE	S17002682	06-06-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002784	09-06-17	3600

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90053T	TSC CATHETER CLEAR 8FR STERILE	S17002877	27-05-17	720
90053T	TSC CATHETER CLEAR 8FR STERILE	S17002878	31-05-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002883	26-05-17	1440
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002884	02-06-17	3240
90052T	TSC CATHETER CLEAR 18FR STERILE	S17002892	24-05-17	360
90055T	TSC CATHETER CLEAR 12FR STERILE	S17002979	09-06-17	2880
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002982	02-06-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17002983	01-07-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17003219	09-06-17	1800
90051T	TSC CATHETER CLEAR 16FR STERILE	S17003301	13-06-17	1800
90051T	TSC CATHETER CLEAR 16FR STERILE	S17003302	14-06-17	360
90052T	TSC CATHETER CLEAR 18FR STERILE	S17003306	12-06-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17003347	13-06-17	1080
90055T	TSC CATHETER CLEAR 12FR STERILE	S17003350	13-06-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17003351	30-06-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17003391	20-06-17	1080
90055T	TSC CATHETER CLEAR 12FR STERILE	S17003439	01-07-17	1440
90051T	TSC CATHETER CLEAR 16FR STERILE	S17003456	20-06-17	360
90052T	TSC CATHETER CLEAR 18FR STERILE	S17003578	08-07-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17003784	12-07-17	2520
90056T	TSC CATHETER CLEAR 14FR STERILE	S17003785	12-07-17	2160
90053T	TSC CATHETER CLEAR 8FR STERILE	S17003909	08-07-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17003916	12-07-17	3600
90056T	TSC CATHETER CLEAR 14FR STERILE	S17003917	22-07-17	1080
90055T	TSC CATHETER CLEAR 12FR STERILE	S17004190	20-07-17	2520
90056T	TSC CATHETER CLEAR 14FR STERILE	S17004351	24-07-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004376	21-07-17	1800
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004377	21-07-17	1440
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004378	22-07-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004379	22-07-17	360
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004380	24-07-17	720
90053T	TSC CATHETER CLEAR 8FR STERILE	S17004477	27-07-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17004479	29-07-17	1440
90056T	TSC CATHETER CLEAR 14FR STERILE	S17004486	26-07-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004509	29-07-17	1440
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004510	29-07-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004511	29-07-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17004736	02-08-17	1440

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90056T	TSC CATHETER CLEAR 14FR STERILE	S17004746	29-07-17	360
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004771	29-07-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004772	27-07-17	1440
90056T	TSC CATHETER CLEAR 14FR STERILE	S17004877	05-08-17	1800
90051T	TSC CATHETER CLEAR 16FR STERILE	S17004902	02-08-17	1440
90056T	TSC CATHETER CLEAR 14FR STERILE	S17005004	01-08-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005028	04-08-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005029	09-08-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005030	12-08-17	1800
90052T	TSC CATHETER CLEAR 18FR STERILE	S17005046	12-08-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005117	02-08-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005281	14-08-17	2880
90052T	TSC CATHETER CLEAR 18FR STERILE	S17005298	11-08-17	1800
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005529	23-08-17	2880
90053T	TSC CATHETER CLEAR 8FR STERILE	S17005607	18-08-17	720
90055T	TSC CATHETER CLEAR 12FR STERILE	S17005948	23-08-17	1080
90055T	TSC CATHETER CLEAR 12FR STERILE	S17005949	05-09-17	2880
90056T	TSC CATHETER CLEAR 14FR STERILE	S17005956	26-08-17	360
90056T	TSC CATHETER CLEAR 14FR STERILE	S17005957	06-09-17	2880
90056T	TSC CATHETER CLEAR 14FR STERILE	S17005958	06-09-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005979	19-08-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005980	26-08-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005981	28-08-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005982	30-08-17	2880
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005983	01-09-17	3600
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005984	31-08-17	360
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005985	01-09-17	360
90051T	TSC CATHETER CLEAR 16FR STERILE	S17005986	04-09-17	2160
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006206	08-09-17	360
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006333	16-09-17	3600
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006334	08-09-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006687	22-09-17	2880
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006688	23-09-17	1800
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006689	25-09-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006690	29-09-17	3240
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006718	23-09-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006719	23-09-17	2160
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006720	25-09-17	1440

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90051T	TSC CATHETER CLEAR 16FR STERILE	S17006721	28-09-17	1440
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006722	03-10-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006723	26-09-17	720
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006724	06-10-17	1440
90051T	TSC CATHETER CLEAR 16FR STERILE	S17006725	11-10-17	1800
90056T	TSC CATHETER CLEAR 14FR STERILE	S17006926	11-10-17	3240
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007029	11-10-17	360
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007030	12-10-17	2520
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007032	23-10-17	3960
90052T	TSC CATHETER CLEAR 18FR STERILE	S17007065	12-10-17	360
90052T	TSC CATHETER CLEAR 18FR STERILE	S17007171	17-10-17	720
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007334	26-10-17	2880
90051T	TSC CATHETER CLEAR 16FR STERILE	S17007360	17-10-17	360
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007433	26-10-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007434	31-10-17	1080
90051T	TSC CATHETER CLEAR 16FR STERILE	S17007459	31-10-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17007588	04-11-17	2520
90051T	TSC CATHETER CLEAR 16FR STERILE	S17007622	31-10-17	1440
90056T	TSC CATHETER CLEAR 14FR STERILE	S17000373	03-03-17	1080
90056T	TSC CATHETER CLEAR 14FR STERILE	S17008259	12-12-17	1080
90052T	TSC CATHETER CLEAR 18FR STERILE	S17003461	20-06-17	1080
90052T	TSC CATHETER CLEAR 18FR STERILE	S17006731	21-09-17	720
Total:				227,520