



Degania Silicone Ltd., 15130, Israel  
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## **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 21<sup>st</sup>, 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
<b>Total:</b>							<b>19800</b>