COOK MEDICAL
1025 ACUFF ROAD, P.O. BOX 4195
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November 28, 2017

URGENT: MEDICAL DEVICE RECALL

ATTENTION:
Risk Management/Recall Administration
Our records indicate that you may have received some of the affected products listed below.

Description of the Problem:

Cook Medical is initiating a voluntary recall of the products listed below. During testing of the non-coring needle we have identified that the non-coring needle provided with the Cook Vital-Port® Vascular Access System (Vital-Port) may cut or dislodge a core or sliver of material from the Vital-Port septum when the non-coring needle is inserted into the Vital-Port. This needle is used on the initial implant of the Vital-Port. Vital-Port products that have been successfully placed in patients are not impacted by this recall.

There have been no adverse event reports from septum leakage or a silicone sliver pushed into the patient associated with these products to date.

Potential adverse events that may occur are unwanted side effects from silicone cores or slivers that may embolize into the patients' bloodstream. In addition, medications may leak from the port, resulting in inadequate delivery of the medication and potential injury to the surrounding tissues.

Details on Affected Products:

PRODUCT FAMILY	CATALOG IDENTIFIER	GPN	INTENDED USE	LOT NUMBER
Vital-Port Vascular Access System Titanium Power Injectable Single-Chamber Systems	IP-7110 IP-S7010 IP-S7110 IP-S9010 IP-S9110	G20254 G26434 G26436 G26438 G26440	Vital-Port Vascular Access System Power Injectable Port (Single-Chamber Port): The devices are intended for use in patient therapy requiring repeated vascular access for infusion therapy, power injected diagnostic techniques using contrast media, and blood infusion/withdrawal. For the power injection of contrast media, the maximum recommended infusion rate is 5mL/sec using media with a maximum viscosity of 11.8 cP.	All Lots
Vital-Port Vascular Access System Standard, Petite and Mini Titanium and MRI Single-Chamber Systems	IP-5112-N IP-5112-NC IP-5116 IP-5116-N IP-5118-N IP-5118-NC IP-6018 IP-6113 IP-7112 IP-9112 IP-S5016 IP-S5018 IP-S5116 IP-S5116-MPIS-NT IP-S5116-N IP-S5116W IP-S5116W-MPIS-NT IP-S5118 IP-S5118-N	G46543 G26539 G26468 G46544 G46545 G26540 G26510 G26424 G19803 G19769 G26469 G26507 G26470 G50864 G46546 G26472 G26489 G26509 G46547	Vital-Port Vascular Access System (Single-Chamber Port): The devices are intended for use in patient therapy requiring long-term vascular access for infusion therapy and/or blood sampling	All Lots

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	IP-S6010 IP-S6012 IP-S6013 IP-S6018 IP-S6110 IP-S6112 IP-S6113 IP-S6113-MPIS-NT IP-S6118 IP-S6118-MPIS-NT IP-S7012 IP-S7112 IP-S9012 IP-S9112	G26430 G26458 G26431 G26511 G26432 G26449 G26433 G50860 G26513 G50861 G26435 G26437 G26439 G26441		
Vital-Port Vascular Access System Standard and Petite Titanium Dual-Chamber Systems	IP-S1021 IP-S1121 IP-S7029 IP-S7129 IP-S7129-MPIS-NT	G26428 G26429 G26502 G26504 G50863	Vital-Port Vascular Access System (Dual-Chamber Port): The devices are intended for use in patient therapy requiring long-term vascular access for infusion therapy and/or blood sampling. Two independent port chambers and a dual lumen catheter allow simultaneous or separate infusion and/or withdrawal	All Lots

Action to Be Taken:

1. Examine inventory immediately to determine if you have affected products and quarantine affected products.
2. Return the affected products to Cook Medical with a completed copy of the Acknowledgement and Receipt Form to receive a product credit. Unaffected product that is returned will not be credited.
3. **Even if you do not have affected products on hand**, you must still complete the Acknowledgement and Receipt Form and send it via fax (812.339.7316) or email (FieldActionsNA@CookMedical.com).
4. Complete and return the Acknowledgement and Receipt Form attached to this letter **within 15 days**.
5. Report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern time), or email CustomerRelationsNA@CookMedical.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:
Online at: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
Call the FDA at: 1-800-FDA-1088

Transmission Of This Notice:

This notice must be shared with appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.

Cook Medical

[redacted]

Rita A. Harden
Global Director, Communications
Customer Support and Delivery