medCOMP

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URGENT FIELD SAFETY NOTICE-DEVICE RECALL

June 14, 2016

Product: PRO-PICC and PRO-LINE DEVICES
Catalog Codes and Lot Numbers: See attached list

Dear Customer,

Medcomp has received reports of the purple luer (hub/end cap) cracking/breaking. This has occurred during flushing of the device prior to insertion or within a few days post insertion. **No patient injuries have been reported.** Medcomp' health risk assessment concluded this type of failure to be low risk to the patient.

If the device has been implanted and is functioning removing the device is unnecessary. To prevent patient injury should the luer of an implanted device crack the extension clamp should be engaged and remain closed and an end cap in place until the device can be removed. Repeated over tightening of luer lock connections, syringes, and caps could lead to potential connector failure.

Our records indicate that you have received the affected product. **Further distribution or use of any remaining product should cease immediately.**

The failure mode has been thoroughly investigated, root cause has been determined, and corrective actions taken. All products manufactured from January 2016 include the corrective action and no complaints have been received for any of these devices.

Instructions: Medcomp is requesting the return of all un-used affected product. Please review your inventory for the affected product and immediately remove from your stock. In addition you will need to contact all facilities/end users who have purchased the affected product and request the return of any product in their inventory.

Contact your Medcomp customer service representative for a Returned Goods Authorization (RGA) number if necessary.

CONTACT INFORMATION: If you have questions about this communication please contact Medcomp at 215-256-4201 between 8AM-5PM EST, email questions to complaints@medcompnet.com or fax questions to 1-215-256-9191.

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Affected Product for FSCA

Code	Description	Lot #
MR17034101	4F Single Lumen Pro-PICC CT	MHDF380
		MHDV550
		MHDW040
MR17034102	4F Single Lumen Pro-PICC CT	MHDV780
		MHDF390
MR17034105	4F Single Lumen Pro-PICC CT	MHCP720
		MHDA120
		MHBW420
		MHDH570
		MHDT050
MRCTP41010	4F Single Lumen Pro-PICC CT	MBZB540
MRCTP41024	4F Single Lumen Pro-PICC CT	MHCB360
		MHDF160
MRCTP41028	4F Single Lumen Pro-PICC CT	MHBT530
		MHDG800
MRCTP41029	4F Single Lumen Pro-PICC CT	MBZL510
MR17035101	5F Single Lumen Pro-PICC CT	MHCP410
		MHDR260
		MHDV540
		MHDZ830
MR17035101-KR	5F Single Lumen Pro-PICC CT	MHDQ720
MR17035102	5F Single Lumen Pro-PICC CT	MHDM820
		MHDW340
		MHDR340
		MHFN540
MR17035102-KR	5F Single Lumen Pro-PICC CT	MHDQ730
MRCTP51028	5F Single Lumen Pro-PICC CT	MHDR250
MR17035105	5F Single Lumen Pro-PICC CT	MHFK770
MR17036201	6F Dual Lumen Pro-PICC CT	MHDK210
		MHDP560
MR17036201-KR	6F Dual Lumen Pro-PICC CT	MHCA030
MR17036202	6F Dual Lumen Pro-PICC CT	MHBZ620
		MHCF140
MRCTP62028	6F Dual Lumen Pro-PICC CT	MHBY570
MR28035101	5F Single Lumen Pro-Line CT	MHCS010
		MHFC220
		MHDD630
MR28036201	6F Dual Lumen Pro-Line CT	MHBS800
		MHCA600
		MHDQ000
MR28036221	6F Dual Lumen Pro-Line CT	MHDQ010