

January 20, 2011



Safety Announcement: CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for use with the Blood Volume Monitor

AUDIENCE: Risk Manager

ISSUE: Fresenius Medical Care North America (FMCNA) has announced a voluntary recall of specific lots of CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors (Part Numbers 03-2695-9 and 03-2795-7) for use with the Blood Volume Monitor (BVM), due to reports of arterial line kinks. Kinks may manifest as arterial pressure alarms or be mistaken as access problems and can cause hemolysis. Kinked tubing occurred on specific lots of Part Number 03-2695-9 distributed between August 2010 and November 2010 and specific lots of Part Number 03-2795-7 distributed between August 2010 and November 2010.

The recall includes the following part numbers and lot numbers which were sold in the U.S. and Canada.

Part Number: 03-2695-9 Lot Numbers: 10HR01065, 10HR01083, 10HR01197, 10HR01259, 10JR01019, 10JR01031, 10JR01040, 10JR01058, 10JR01067, 10JR01077, 10JR01239, 10LR01041, 10LR01053, 10LR01061, 10LR01070, 10LR01102, 10LR01111, 10LR01123, 10LR01269, 10LR01282, 10LR01283, 10LR01284, 10LR01285, 10NR01020, 10NR01031, 10NR01041, 10NR01050, 10NR01146, 10NR01157, 10NR01169, 10NR01180

Part Number: 03-2795-7 Lot Numbers: 09JR01174, 09JR01229, 09NR01139, 10KR01801

RECOMMENDATION: Customers who have the affected lots of CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for use with the BVM which are being recalled should discontinue their use immediately and return product to Fresenius Medical Care. Customers with questions may contact Fresenius Medical Care Customer Service Team at 1-800-323-5188 in the USA and 1-888-709-4411 in Canada.

ADVERSE EVENTS:

Any medical device adverse events or quality problems experienced with the use of this product in the USA may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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