Fresenius Medical Care

P R E S S – R E L E A S E

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Fresenius Medical Care North America Initiates Voluntary Recall of CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for use with the Blood Volume Monitor

FOR IMMEDIATE RELEASE – January 14, 2011 – Waltham, MA – 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. The kinking may develop prior to or during use and may not be apparent until after the blood tubing warms. The most commonly affected location is in the pre or post cuvette tubing segments, entering or leaving the BVM module. The kinks are not always visible because they may occur in the tubing behind the BVM module door.

Kinking is a partial obstruction of the bloodline caused by a bend or narrowing of the tubing that results in a restriction of blood flow. Kinks may manifest as arterial pressure alarms or be mistaken as access problems. Kinking is likely to result in inadequate or incomplete hemodialysis treatment which may result in the need for medical intervention, lengthening of the dialysis treatment and/or additional dialysis.

Fresenius has not received any reports of hemolysis associated with the defective devices. However, kinking can cause hemolysis. Hemolysis is the breakdown of red blood cells, which may result in serious injury and or death.

There have been reports of re-needling when operators mistakenly concluded that an access problem existed. There is also the possibility for the inappropriate administration of tissue plasminogen activator (tPA) if operators mistakenly conclude there is an access problem.

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.

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.

The recall was initiated on November 19, 2010 after Fresenius Medical Care received complaints of kinked tubing on the CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for use with the BVM. The FDA has classified this action as a Class I recall.

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

Patient safety and the quality of our products are Fresenius Medical Care's first priorities. Fresenius Medical Care investigated and determined the root cause to be a design change affecting the tubing dimensions. 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 2009 and November 2010. The design problem has been corrected.

All 190,080 units of Part Number 03-2695-9 and 10,032 units of Part Number 03-2795-7, CombiSet True Flow Series™ Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for use with BVM, that were recalled were distributed in the United States and Canada.

Fresenius Medical Care has provided written notification of the recall with confirmation of receipt to all US and Canadian customers and is arranging for the return of affected products. 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.

Fresenius Medical Care has notified the U.S. Food and Drug Administration (FDA) and Health Canada, and is working with them to coordinate recall activities. Clinic Managers, Unit Administrators and/or distributors with questions may contact Fresenius Medical Care Customer Service Team at 1-800-323-5188 in USA (7am-6pm CST, 5 days per week, with after-hours emergency support) and 1-888-709-4411 in Canada.

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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About Fresenius Medical Care
Fresenius Medical Care (NYSE: FMS) is the world's leading company devoted to patient-oriented renal therapy. Through more than 2,700 clinics in North America, Europe, Latin America, Asia-Pacific and Africa, we provide kidney dialysis treatments to approximately 210,000 patients worldwide. We are also the world's leading maker of dialysis products such as hemodialysis machines, dialyzers and related disposable products. Chronic kidney failure is a condition that affects about 1.9 million individuals worldwide. For more information about the company's more than 1,800 U.S. dialysis facilities, visit www.ultracare-dialysis.com (in English and Spanish). For more information about Fresenius Medical Care, visit www.fmc-ag.com or www.fmcna.com