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PRODUCT SAFETY ALERT

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AUDIENCE: Physicians inserting hemodialysis catheters- interventional Radiologists, Nephrologists, Surgeons

DEVICES: MEDCOMP HEMO-CATH[®] LT AND HEMO-CATH[®]ST HEMODIALYSIS CATHETERS

SUMMARY OF PROBLEM AND SCOPE: Medcomp has become aware of the potential for holes developing in the silicone extension tubing of the Hemo-Cath[®] catheters. The holes leak when the catheter is being accessed or pressurised during a treatment. The timeframe of when the holes are discovered is immediately post insertion up to after several months of use or longer.

The investigation determined that during the insertion procedure, engaging the extension line clamp over the guide wire may damage the inside of the tubing. A crack in the tubing on the inside can develop over time and eventually travel through the thickness of the tubing, eventually developing into a hole that leaks.

Immediate and long-range potential risks to the patients, if a hole develops in the tubing, include the potential for blood loss, air emboli, infection, delays in treatment and a surgical procedure to remove and replace the device prior to continuing the dialysis treatment.

CONCLUSION OF THE HEALTH RISK ASSESSMENT: The conclusion reached is that there is minimal risk to the patient. The hole in the extension tubing leaks when the device is pressurised with a syringe during flushing or during the dialysis treatment. A health care professional would be present and available to take remedial action to prevent permanent injury to the patient. The failure rate, when comparing the number of complaints with sales, is <0.01%.

INSTRUCTIONS FOR PHYSICIANS INSERTING THE IMPLANTS: During the insertion of the device DO NOT clamp over the guide-wire-damage to the tubing may occur.

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.