

## PRODUCT SAFETY ALERT

DATE ISSUED: June 12, 2015

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

DEVICES: JET FLOW<sup>®</sup> HEMODIALYSIS CATHETERS (JF1420SL, JF1428SL, JF1428SLG, JF1432SL, JF1432SLG, JF1436SL, JF1436SLG)

SUMMARY OF PROBLEM AND SCOPE: Jet Medical<sup>®</sup>SA has become aware of the potential for holes developing in the extension tubing of the silicone catheters. The holes leak when the catheter is being accessed or pressurized during a treatment. The timeframe of when the holes are discovered are immediately post insertion to after several months of usage or longer.

The investigation determined that during the insertion procedure engaging the extension line clamp over the guidewire may damage the inside of the tubing. A crack in the tubing on the inside can propagate over time and eventually travel through thickness of the tubing 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 removed and replaced the device prior to continuing the dialysis treatment.

CONCLUSION OF THE HEALTH RISK ASSESSMENT: The conclusion reached is there is minimal risk to the patient. The hole in the extension tubing leaks when the device is being pressurized 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 number of complaints with sales, is <0.01%.

INSTRUCTIONS FOR IMPLANTING PHYSICIANS: During the insertion of the device **DO NOT** clamp over the guidewire-damage to the tubing may occur.

CONTACT INFORMATION: If you have questions about this communication please email questions to [complaints@jetmedical.net](mailto:complaints@jetmedical.net).