December 5, 2012

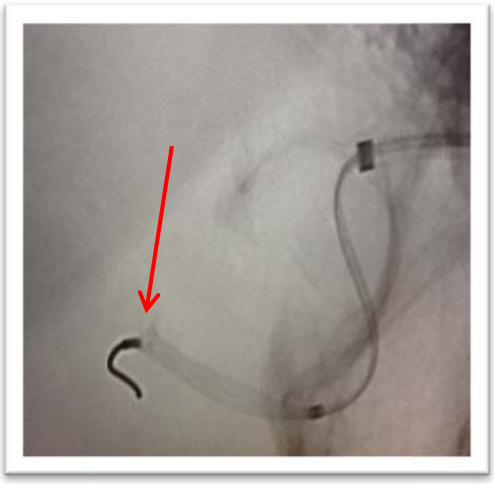
Re: Use of Pipeline™ Embolization Device

Dear Pipeline Device Users,

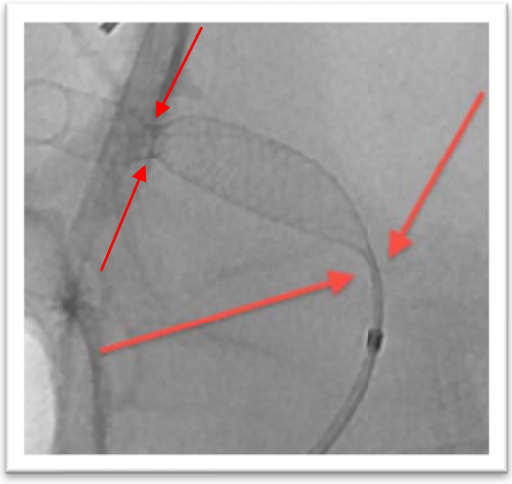
Since commercialization of the Pipeline Embolization Device (PED), Covidien has conducted postmarket surveillance of the clinical use of our PED system. Our current postmarket data continues to demonstrate morbidity and mortality rates in alignment with those noted in the PUFS (Pipeline for Failed Aneurysm) trial that was the clinical basis for US commercial approval of the device. Rates of major neurologic complications or death in the PUFS clinical trial were 5.6% (2.8% for morbidity and 2.8% for mortality). With over 15,000 PED devices implanted to date, the rate of overall morbidity and mortality are 2.6% and 1.6% respectively.

While data collected during the postmarket surveillance period indicate that the PED continues to be a safe and effective option for the endovascular treatment of complex aneurysms, as with all medical devices when used outside controlled clinical trials, several important learning points around surgical technique and treatment have been observed. As always, patient selection and device use following the guidelines outlined in the product Instructions for Use (IFU) are critical. Through postmarket surveillance, we have observed two specific implant delivery related complaints (believed to occur due to anatomic variations of individual patients) that we want to bring to your attention: 1) the PED might not readily disengage from the capture coil, and 2) the PED might not completely open and appose the vessel wall.

Retained in capture coil



Incomplete opening of the PED



Covidien has worked closely with experienced physician proctors at neurological centers to evaluate the anatomic variations that can contribute to deployment difficulties and identify steps to reduce the possibility of the above conditions occurring.

We have discovered that these situations occur most often in procedures where the PED is being delivered in areas of significant tortuosity or restrictive anatomy. If significant resistance is encountered during PED delivery (e.g., prompting the use of a torque device to advance the system), difficulties in obtaining full disengagement from the capture coil or incomplete expansion of the device may occur.

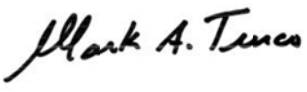
PED educational programs and training materials detail these potential delivery issues, and the appropriate steps to take if encountered. Early identification of delivery challenges, together with complete device removal can minimize the risk for complications associated with manipulation while attempting device release or full vessel wall apposition.

In order to minimize the risk of possible delivery related complications, Covidien recommends adherence to the following guideline identified in the product IFU: “Caution: If excessive resistance is noted during the use of the Pipeline Embolization Device or microcatheter at any time during the procedures, discontinue the delivery of the Pipeline Embolization Device and identity the cause of the resistance. Advancement of the Pipeline Embolization Device against resistance may result in device damage or patient injury.” The treating physician should evaluate the utility and associated risk of repeat deployment with a replacement device.

Covidien is committed to providing you with the most up-to-date and relevant information with respect to the use of the PED. We will continue to monitor the use of PED and develop additional clinical evidence through our ongoing retrospective and prospective registries. In addition, we are continually advancing our training programs by engaging leaders in the field to reinforce techniques and appropriate patient selection.

If you have any questions, please contact me or Fred Gunderman, Director, Professional Affairs and Clinical Education Covidien Vascular Therapies, (949) 837-3700 ext. 1139.

Sincerely,



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