

**IMPORTANT NOTIFICATION TO USERS OF
SUPERA VERITAS® PERIPHERAL VASCULAR SYSTEM
21 March 2012**

Device Brand Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Peripheral Vascular System (6F and 7F)

Device Common Name: Stent Delivery System (SDS)

Model/Lot Numbers: All

Intended Use: For palliative treatment of biliary strictures produced by malignant neoplasms and peripheral vascular use following failed percutaneous transluminal angioplasty (PTA)

Reason for the User Notification: IDEV has received reports of a rare event in which the catheter tip was pulled off during use. IDEV thoroughly investigated these reports and has determined that failure to adhere to the Instructions for Use appears to be the root cause of these events. Specifically, if the thumb slide on the catheter handle is not retracted and locked prior to catheter withdrawal, per the Instructions for Use, the catheter tip may catch on the introducer sheath and may be pulled off the catheter body. Removal of the detached tip may be necessary, as determined by the physician. To date, the company is not aware of these incidents occurring when the Instructions for Use are followed and, no injuries have been reported.

What precautions can you take?

Before using this device, users should be familiar with the operation of the device through training and careful review of the Instructions for Use. Specifically, familiarization and adherence to Step 5: Post Stent Placement/Deployment is essential. A summary of that section is presented here:

Following release and placement confirmation of the SUPERA® Biliary Stent, the SDS should be withdrawn by first retracting the Thumb Slide into the proximal most position on the Handle to bring the Catheter Tip flush with the Outer Sheath. (See Figure 1)

The System Lock must then be rotated to the right to secure the Thumb Slide and Catheter Tip in the closed position. Using fluoroscopy, the SDS is withdrawn over the guidewire through the introducer sheath and out of the body. (See Figure 2)

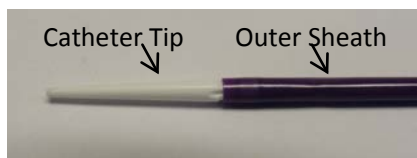


Figure 1. Closed Catheter Tip position

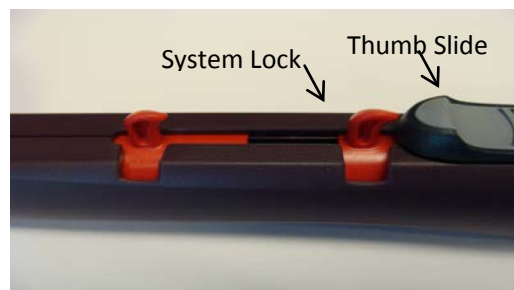


Figure 2. Secured Thumb Slide

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