



20 November 2015

«Hospital\_Name»  
«Users\_Name» - «Department»  
«Customer\_Address»  
«Zip\_Code», «City»  
«Country»

Re: URGENT Field Safety Notice RETURN, velox CD™, 20 November 2015

Dear «Users\_Name»,

Transluminal Technologies has decided to issue a Field Safety Corrective Action (FSCA) regarding the lot of velox CD™ vascular closure devices designated #TT039672. Per this FSCA, all product from this lot is to be returned to Transluminal Technologies.

This FSCA is being issued to prevent possible risks to patients due to observed performance deficiencies during clinical use. Specifically, vascular closure implants were observed to deploy incompletely, with intraluminal material (e.g. Footplate) delivered without proper tethering to extraluminal material (e.g. Plug). In the cases observed, no evidence of arterial occlusion was detected and hemostasis was achieved through application of manual compression. If the observed malfunction were to occur during continued use of the product however, the potential exists for either vessel occlusion or arterial bleeding.

Per your order #XXXXXX dated DD MONTH 2015, Transluminal sent «QUANTITY» units of P/N TT41001-01 on DD MONTH 2015 to your facility. Please provide an accounting of all product expended and disposed of either clinically or for training/investigatory efforts. Please identify and quarantine all other units of lot #TT039672, ensuring that they are not distributed to end users or released from control in any way. This quarantine will ensure that all affected product remains in control.

Once quarantined, please return the affected product to Transluminal Technologies. In your return documentation, please confirm that all remaining (unexpended) units are accounted for, and that no units have been distributed to any end user beyond those inoperable units from clinical and investigatory efforts. We request that this return occur within 10 days of this notice.

Please communicate this notice to all those who need to be aware within your organization.

Transluminal requests that you respond to this Field Safety Notice with confirmation that the product referenced has been quarantined, and with return shipment information once return has been initiated.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew Keary", with a long horizontal flourish extending to the right.

Matthew Keary  
Quality, Transluminal Technologies