Intact Vascular
150 Strafford Avenue, #303
Wayne, PA 19087

URGENT – FIELD SAFETY NOTICE

March 19, 2013

<Study Coordinator>
<Hospital Address>

Cc: <Investigator>

Affected Product: Intact Vascular *Tack-IT Endovascular Stapler System®*
Lot Number DS-9707
Clinical Study TD-009, Prospective, Multicenter Tack Optimized Balloon Angioplasty (TOBA) Study for Femoropopliteal Arteries Using the *Tack-IT Endovascular Stapler®*

Dear <Coordinator>,

We have received a single report of a crack in the distal catheter tip of the *Tack-IT Endovascular Stapler System®* during clinical use. There have been no reported adverse events related to this event, and the cause of this crack is currently under investigation. Although there was no patient injury and 115 clinical cases have been completed without this incident, until the cause can be determined and in the interest of patient safety, do not use product from Lot Number DS9707. Segregate units from this lot number to ensure they are not used. Do not return product to Intact Vascular at this time.

Our records indicate that you have the following units in your possession:

Catalog Number	Lot Number	Quantity
1006-04	DS-9707	< >

Please complete the attached Response Form within 24 hours to acknowledge your receipt and understanding of the requirements of this Field Safety Notice. In addition, please send a copy of your Device Accountability Log. You may reply by email directly to me at [redacted]@intactvascular.com or by fax to 484-253-1047, Attention Quality Assurance.

Please continue to conduct screening and clinical follow-up per protocol. Monitoring visits will proceed as planned.

Ensuring patient safety and providing high quality product is of the utmost importance. Be assured that determining the solution to this event and providing additional product to you is the highest priority for Intact Vascular. The date additional product will be available cannot be determined until the investigation is completed.

We appreciate your prompt attention to this matter, and we apologize for any inconvenience this may cause. If you have any questions about the requirements of this notice, the progress of the failure investigation, or the conduct of the clinical study, please do not hesitate to contact me directly at [redacted] or by email at [redacted]@intactvascular.com.

Sincerely,

[redacted]

[redacted]
Vice President, Regulatory Affairs and Quality Assurance

Intact Vascular
150 Strafford Avenue, #303
Wayne, PA 19087
T: 484.253.1048
Cell: [redacted]
[redacted]@intactvascular.com

RESPONSE FORM
FIELD SAFETY NOTICE

Affected Product: Intact Vascular *Tack-IT Endovascular Stapler System*®
Lot Number DS-9707
Clinical Study TD-009, Prospective, Multicenter Tack Optimized Balloon Angioplasty (TOBA) Study for Femoropopliteal Arteries Using the Tack-IT Endovascular Stapler®

This acknowledges my understanding of the Field Safety Notice dated March 3, 2013 and the product Lot Number DS9707 has been segregate as requested to ensure it is not used. Do not return the product to Intact Vascular and do not use the product until notified by Intact Vascular.

Intact Vascular
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Please examine your inventory, record the unit number and quantity of lot number 9707 in your possession in the table below, and sign and date this form.

Catalog Number	Lot Number	Unit Number	Quantity
1006-04	DS-9707		
1006-04	DS-9707		

Email this completed form and a copy of the Device Accountability Log to [redacted] at [redacted]@intactvascular.com or send by fax to 484-253-1047, Attention Quality Assurance.

Name: _____

Signature: _____

Date: _____

Phone: _____

Email: _____