# <FINAL TEMPLATE> <Modify country specific contact information>



## **URGENT FIELD SAFETY NOTICE/ DEVICE RECALL**

COMMERCIAL NAME: StarClose SE Vascular Closure System FS CA-Identifier: February 10, 2017 Type of Action: Device Recall

#### Attention: Risk Manager or Health Care Professional

Dear Valued Abbott Vascular Customer:

Abbott Vascular has initiated a voluntary field action regarding specific lots of the StarClose SE Vascular Closure System. Our records indicate that affected lots have been shipped to your account.

Product from the identified lots may exhibit difficulty or failure to deploy the StarClose SE Clip. Potential risks associated with this event include prolonged procedure times, use of another device or manual compression to achieve hemostasis. There have been no long term or irreversible patient effects reported.

This action does not affect patients having successfully undergone cardiac or endovascular procedures using the StarClose SE Vascular Closure System.

#### How does this issue occur?:

Exchange sheath material variation with a higher sheath split force may result in difficulty or failure to deploy the device.

What action is Abbott Vascular asking you to take?:

- Please reference the attached list of affected part numbers and lot numbers
- The use of devices from these lots should cease immediately
- Please review your inventory, complete the attached Effectiveness Check Form
- Return all unused identified products to Abbott Vascular
- Share this notification with other relevant personnel in your organization

#### What is Abbott Vascular doing?:

Abbott Vascular has already implemented corrective actions to ensure ongoing product performance and has ceased distributing any product built before the corrective actions. Abbott Vascular will work with you to replace returned units with similar product, pending availability. The appropriate regulatory agencies have been notified of this action.

We regret any inconvenience this may cause you and appreciate your patience. Abbott Vascular is committed to providing high quality products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Abbott Vascular Representative or Customer Service department on xxxx xxxxxx.

Sincerely,

[Name] GM / Country Manager



### URGENT FIELD SAFETY NOTICE / DEVICE RECALL February 10, 2017

Green Sheath ( Part Number 14679-02)           50831K1           50903K1           50908K1           50911K1           50921K1           50924K1           50929K1           50929K1           51002K1           51002K1           51002K1           51002K1           51002K1           51002K1           51010K1           51029K1           51029K1           51029K1           51029K1           51029K1           51103K1           5112041           5112041           5112041           5112041           5120141           5120141           6011641           601141           601141           6011941           6011941           6031041           6031541           6032241           6032241           6042941           6042941           6051341           6051341           6051941           6051941           6051941	StarClose SE VCS, International
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<Modify country specific contact information>

URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

COMMERCIAL NAME: StarClose SE Vascular Closure System FS CA-Identifier: February 10, 2017 Type of Action: Device Recall

## Effectiveness Check Form

Customer Account #	ŧ	
Account Name		
Address		

(Information required for regulatory effectiveness check)

After reviewing your inventory of StarClose SE Vascular Closure System, please check one box in the section below. If affected inventory was identified, please contact Customer Services to obtain a Returned Goods Authorization (RGA) number. After signing this form, please return the form and any identified products to Abbott Vascular.

A thorough search for all affected products has been completed and no affected units remain in inventory. No devices will be returned.
Affected StarClose SE Vascular Closure Systems have been identified and are being returned.
RGA Number:

Customer Name/ Title (print)

Signature

Date

#### This form is to be returned to Abbott Vascular

- □ If returning product, call Abbott Vascular Customer Service XXX XXX XXXX to receive RGA number. Record RGA number above.
- □ Fax this completed form to XXX XXX XXXX or scan an e-mail to XXXXXXXXXXXXXXX
- □ Return a copy of this completed form with the returned product.

