



07-Feb-2017

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,

Abbott Vascular Deutschland GmbH - Betriebsstätte Wetzlar



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| StarClose SE VCS, International Green Sheath (Part Number 14679-02) |
|---|
| 50831K1 |
| 50903K1 |
| 50908K1 |
| 50911K1 |
| 50921K1 |
| 50924K1 |
| 50929K1 |
| 51002K1 |
| 51008K1 |
| 51016K1 |
| 51026K1 |
| 51029K1 |
| 51103K1 |
| 5111741 |
| 5112041 |
| 5112441 |
| 5112741 |
| 5120141 |
| 5120441 |
| 6010641 |
| 6011141 |
| 6011441 |
| 6011941 |
| 6012241 |
| 6031041 |
| 6031541 |
| 6032241 |
| 6032941 |
| 6041941 |
| 6042141 |
| 6042641 |
| 6042941 |
| 6051141 |
| 6051341 |
| 6051941 |
| 6052441 |
| 6061541 |
| 6100341 |



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Effectiveness Check Form

Customer Account # _____
 Account Name _____
 Address _____

 Phone _____
 (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 XXXXXXXXXXXX
 - Return a copy of this completed form with the returned product.