



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: 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 Synapse Medical Customer Service department on 01 8624600

Sincerely,

Brendan McConnell
National Sales Manager – Synapse Medical
Mobile: +353-(0)87-6206885

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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 _____

(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.

<input type="checkbox"/> A thorough search for all affected products has been completed and no affected units remain in inventory. No devices will be returned.
<input type="checkbox"/> Affected StarClose SE Vascular Closure Systems have been identified and are being returned.

Customer Name/ Title (print)

Signature

Date

This form is to be returned to Synapse Medical

Brendan McConnell - **National Sales Manager – Synapse Medical**
Email: bmccconnell@synapsemedical.ie or Fax: 01 8624606