Abbott Laboratories (S) Pte Ltd
1 Maritime Square,
HarbourFront Centre, #11-22
Singapore 099253

Tel : +65 6270 0760
Fax : +65 6270 2920

# 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.

**Indications**
The StarClose SE Vascular Closure System is indicated for the percutaneous delivery of an extravascular clip for closure of femoral artery access sites following catheter-based procedures.

**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.

**Advisory to Healthcare Professionals:**

- 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.

**Reporting of Adverse Event**
Healthcare Professionals are advised to report any adverse events and/or suspected adverse reactions associated with the use of these devices to the Abbott Vascular representative or to Abbott Laboratories (S) Pte Ltd at Tel: 6270 0760 or Fax: 6270 2920. Alternatively, you may also report any adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group at Tel: 6866 3538, Fax: 6478 9069, or report online via www.hsa.gov.sg/ae_online. Events

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that are reported to Abbott Laboratories (S) Pte Ltd will be investigated and subsequently reported to HSA.

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 at +65 6270 0760.

Sincerely,

[redacted]

**Marietta Nicolson**
Country Manager



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February 10, 2017

| 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.

☐ 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***



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

- If returning product, call Abbott Vascular Customer Service at +65 6270 0760 to receive RGA number. Record RGA number above.
- Return this completed form to the Abbott Vascular Sales representative or fax it to +65 6270 2920
- Return a copy of this completed form with the returned product.