

«Contact_Name_»
«Customer_Name_»
«Address_1»
«Address_2»
«Town_»
«Postal_code_»
«Country_»

URGENT Field Safety Notice: RA 2014-144

20th April 2015

Description: Stryker CBC II Wound Drains and Ambulating Bulb

Product Code: Various – Please refer to the attached list

Lot Number: Various – Please refer to the attached list

Dear Customer,

Please find attached details of a Product Field Action that has been initiated by Stryker Instruments concerning the above referenced subject devices. This advice has been issued to ensure that users are aware of important information concerning the devices listed above.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. You are required to read the attached Field Safety Notice and then sign and return the Customer Response Form confirming that you have completed the actions requested by the manufacturer. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.



Name: Mark Fielding
Position: Product Complaints Specialist UK
Telephone: 01635 262 427
Fax: 01635 262 464
E-mail: mark.fielding@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'Mark Fielding', with a stylized flourish at the end.

Mark Fielding
Quality Assurance and Regulatory Affairs

URGENT Field Safety Notice: RA 2014-144

20th April 2015

Description: Stryker CBC II Wound Drains and Ambulating Bulb

Product Code: Various – Please refer to the attached list

Lot Number: Various – Please refer to the attached list

Dear Customer,

Stryker Instruments initiated a voluntary Field Safety Corrective Action for the above referenced devices.

Product Description

The CBC II Wound Drains are single-use, sterile devices that are used in conjunction with the Stryker CBCII ConstaVac Blood Conservation System. The CBCII is a closed blood recovery system used post-operatively to collect, filter, and allow for reinfusion of autologous blood.

The Ambulating Bulb is a single-use, sterile wound drainage device that is used in conjunction with the Stryker CBCII ConstaVac Blood Conservation System. The Ambulating Bulb is intended for the express purpose of collecting wound drainage in an ambulatory environment.

Please see Figures 1-5 below for product images.

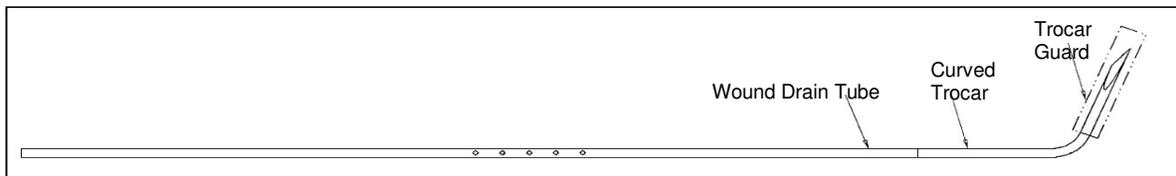


Figure 1. Diagram of a Curved Trocar with Wound Drain

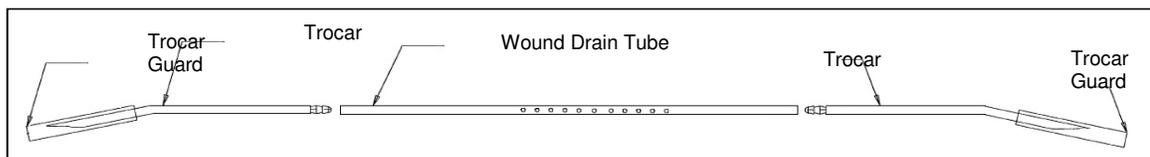


Figure 2. Diagram of a Double Trocar with Wound Drain

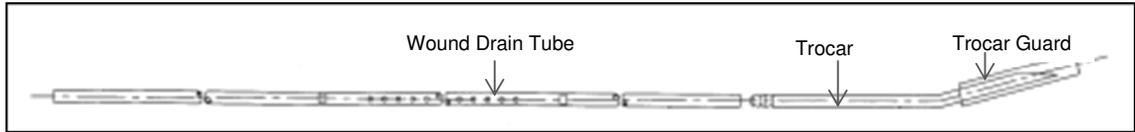


Figure 3. Illustrates the Wound Drain with Single Trocar and the Round Drain with Single Trocar.

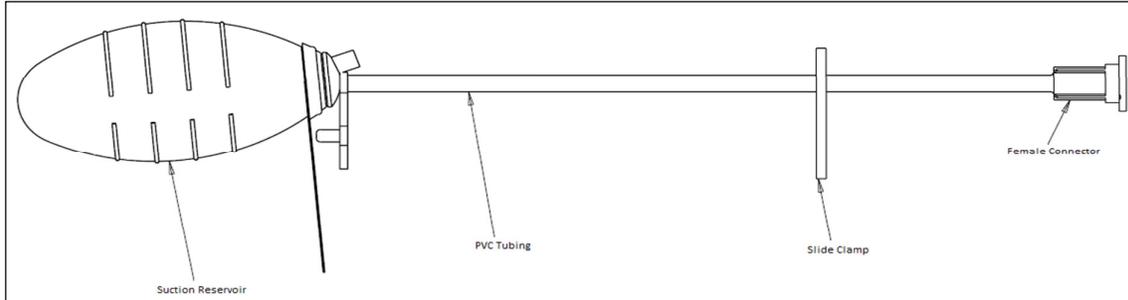


Figure 4. Diagram of the Ambulating Bulb showing its main components.

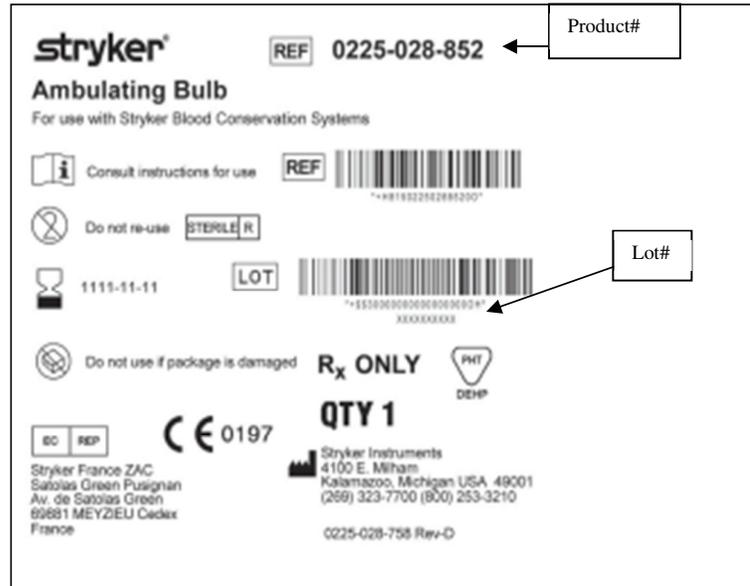


Figure 5. Example of the product package label.

Reason for Voluntary Recall

During an evaluation as a result of updated standards, these legacy products underwent bubble emission testing and visual inspection. Results of these activities indicated a potential for a sterility breach in the form of tears and abrasions in the packaging.

Risk to Health

Although no complaints have been received, there is the potential for patient infection due to the wound drain outer packaging being potentially punctured during shipment resulting in the patient being exposed to unsterile equipment if the inner package is placed in the sterile field.

Although no complaints have been received, there is the potential for patient infection due to the packaging being potentially punctured during shipment resulting in the patient being exposed to an unsterile ambulating bulb.

Actions Required

1. Immediately check your internal inventory and quarantine any subject devices.
2. Circulate this Field Safety Notice internally to all interested / affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
5. Complete the attached customer response form and return to Mark Fielding by fax (01635 262 464) or by e-mail (mark.fielding@stryker.com).
 - a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.
 - b) Upon receipt of a completed response form a Stryker Representative will be in touch to arrange collection and replacement of subject devices.
6. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - a) Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,



Mark Fielding
Quality Assurance and Regulatory Affairs

RA 2014-144: Affected Products

| Product # | Lot Number | | | | | | | |
|---------------------|------------|----------|----------|----------|----------|----------|----------|----------|
| 0215-015-000 | 10090012 | 10272012 | 11110012 | 11264012 | 12044012 | 12249012 | 13144012 | 14035012 |
| | 10104012 | 10292012 | 11126012 | 11269012 | 12051012 | 12264012 | 13176012 | 14057012 |
| | 10123012 | 10320012 | 11143012 | 11287012 | 12081012 | 12297012 | 13217012 | 14088012 |
| | 10141012 | 10334012 | 11146012 | 11298012 | 12116012 | 12339012 | 13247012 | 14167012 |
| | 10158012 | 10344012 | 11146022 | 11318012 | 12139012 | 12353012 | 13266012 | 14168012 |
| | 10187012 | 11005012 | 11159012 | 11337012 | 12152012 | 13003012 | 13276012 | 14213012 |
| | 10208012 | 11041012 | 11194012 | 11346012 | 12159012 | 13008012 | 13294012 | 14253012 |
| | 10228012 | 11048012 | 11213012 | 12011012 | 12179012 | 13105012 | 13312012 | 14265012 |
| | 10236012 | 11075012 | 11244012 | 12023012 | 12228012 | 13119012 | 13338012 | |
| Product # | Lot Number | | | | | | | |
| 0215-015-200 | 10074012 | 10280012 | 11110012 | 11271012 | 12066012 | 12349012 | 13225012 | 14022012 |
| | 10105012 | 10294012 | 11138012 | 11298012 | 12080012 | 13016012 | 13260012 | 14070012 |
| | 10118012 | 10315012 | 11151012 | 11346012 | 12091012 | 13077012 | 13268012 | 14163012 |
| | 10155012 | 10319012 | 11185012 | 11356012 | 12181012 | 13115012 | 13303012 | 14169012 |
| | 10215012 | 10344012 | 11189012 | 12025012 | 12275012 | 13120012 | 13323012 | 14195012 |
| | 10242012 | 11025012 | 11264012 | 12053012 | 12290012 | 13148012 | 13346012 | 14246012 |
| | 10252012 | 11033012 | | | | | | |
| | | | | | | | | |
| Product # | Lot Number | | | | | | | |
| 0215-018-000 | 10076012 | 10284012 | 11108012 | 11280012 | 12110012 | 12334012 | 13158012 | 14020012 |
| | 10095012 | 10292012 | 11117012 | 11298012 | 12131012 | 12338012 | 13182012 | 14050012 |
| | 10103012 | 10295012 | 11125012 | 11305012 | 12143012 | 12339012 | 13191012 | 14056012 |
| | 10112012 | 10307012 | 11136012 | 11308012 | 12153012 | 12348012 | 13220012 | 14059012 |
| | 10125012 | 10319012 | 11143012 | 11339012 | 12158012 | 12352012 | 13227012 | 14076012 |
| | 10133012 | 10335012 | 11145012 | 11343012 | 12160012 | 13011012 | 13238012 | 14083012 |
| | 10137012 | 10342012 | 11146012 | 11356012 | 12164012 | 13035012 | 13239012 | 14147012 |
| | 10160012 | 10356012 | 11157012 | 12012012 | 12181012 | 13050012 | 13261012 | 14165012 |
| | 10175012 | 11010012 | 11161012 | 12019012 | 12188012 | 13059012 | 13262012 | 14169012 |
| | 10188012 | 11014012 | 11187012 | 12030012 | 12242012 | 13078012 | 13274012 | 14174012 |
| | 10205012 | 11026012 | 11204012 | 12051012 | 12255012 | 13091012 | 13281012 | 14189012 |
| | 10222012 | 11032012 | 11221012 | 12053012 | 12262012 | 13099012 | 13298012 | 14190012 |
| | 10228012 | 11043012 | 11230012 | 12055012 | 12277012 | 13106012 | 13323012 | 14231012 |
| | 10237012 | 11053012 | 11249012 | 12061012 | 12292012 | 13113012 | 13324012 | 14233012 |
| | 10252012 | 11069012 | 11251012 | 12065012 | 12303012 | 13138012 | 13340022 | 14245012 |
| | 10266012 | 11088012 | 11265012 | 12081012 | 12313012 | 13144012 | 13351012 | 14280012 |
| | 10273012 | 11103012 | 11269012 | 12091012 | 12317012 | 13155012 | 14017012 | 14344012 |

| Product # | Lot Number | | | | | | | |
|--------------|------------|----------|----------|----------|----------|----------|----------|----------|
| 0215-018-200 | 10082012 | 10266012 | 11089012 | 11222012 | 12047012 | 12240012 | 13121012 | 14034012 |
| | 10099012 | 10289012 | 11109012 | 11231012 | 12059012 | 12256012 | 13145012 | 14072012 |
| | 10105012 | 10309012 | 11122012 | 11241012 | 12072012 | 12283012 | 13156012 | 14083012 |
| | 10118012 | 10319012 | 11129012 | 11252012 | 12080012 | 12319012 | 13194012 | 14164012 |
| | 10134012 | 10323012 | 11136012 | 11271012 | 12125012 | 12332012 | 13235012 | 14170012 |
| | 10168012 | 10342012 | 11143012 | 11305012 | 12144012 | 12349012 | 13260012 | 14234012 |
| | 10180012 | 11012012 | 11151012 | 11337012 | 12152012 | 13015012 | 13275012 | |
| | 10217012 | 11035012 | 11168012 | 11355012 | 12157012 | 13039012 | 13317012 | |
| | 10229012 | 11052012 | 11188012 | 12004012 | 12178012 | 13057012 | 13343012 | |
| | 10256012 | 11070012 | 11199012 | 12027012 | 12198012 | 13086012 | 14016012 | |
| Product # | Lot Number | | | | | | | |
| 0215-019-000 | 10095012 | 10312012 | 11060012 | 11186012 | 11346012 | 12115012 | 12349012 | 13262012 |
| | 10109012 | 10321012 | 11067012 | 11192012 | 11356012 | 12157012 | 13017012 | 13277012 |
| | 10127012 | 10347012 | 11088012 | 11220012 | 12003012 | 12193012 | 13023012 | 13347012 |
| | 10189012 | 10355012 | 11097012 | 11230012 | 12009012 | 12206012 | 13044012 | 14020012 |
| | 10195012 | 11011012 | 11117012 | 11269012 | 12026012 | 12235012 | 13063012 | 14030012 |
| | 10274012 | 11039012 | 11136012 | 11286012 | 12031012 | 12290012 | 13145012 | 14039012 |
| | 10285012 | 11059012 | 11178012 | 11335012 | 12060012 | 12310012 | 13254012 | 14066012 |

| Product # | Lot Number |
|--------------|------------|
| 0215-019-200 | 14122012 |

| Product # | Lot Number | | | | | | | |
|--------------|------------|----------|----------|----------|----------|----------|----------|----------|
| 0215-031-000 | 10074012 | 10231012 | 10337012 | 11122012 | 11348012 | 12172012 | 13081012 | 14044012 |
| | 10104012 | 10263012 | 11012012 | 11185012 | 12053012 | 12237012 | 13126012 | 14147012 |
| | 10147012 | 10279012 | 11055012 | 11216012 | 12082012 | 12318012 | 13163012 | 14153012 |
| | 10153012 | 10309012 | 11110012 | 11252012 | 12116012 | 12331012 | 13211012 | |
| Product # | Lot Number | | | | | | | |
| 0215-032-000 | 10098012 | 10279012 | 11017012 | 11131012 | 12033012 | 12275012 | 13128012 | 14063012 |
| | 10165012 | 10343012 | 11122012 | 11159012 | 12137012 | 13025012 | 13343012 | 14105012 |

| Product # | Lot Number | | | | | | | |
|--------------|------------|----------|----------|----------|----------|----------|----------|----------|
| 0225-015-000 | 10083012 | 10349012 | 11224012 | 12151012 | 13092012 | 13196012 | 14034012 | 14246012 |
| | 10125012 | 11014012 | 11257012 | 12286012 | 13119012 | 13248012 | 14127012 | 14263012 |
| | 10162012 | 11059012 | 12039012 | 12341012 | 13135012 | 13274012 | 14165012 | |
| | 10273012 | 11108012 | 12075012 | 13010012 | 13172012 | 13326012 | 14177012 | |
| | 10309012 | 11160012 | 12080012 | 13065012 | 13191012 | 14021012 | 14231012 | |

| Product # | Lot Number | | | | | | | |
|--------------|------------|----------|----------|----------|----------|----------|----------|----------|
| 0225-018-000 | 10081012 | 10272012 | 11060012 | 11223012 | 12074012 | 13002012 | 13254012 | 14167012 |
| | 10123012 | 10295012 | 11104012 | 11259012 | 12115012 | 13022012 | 13290012 | 14174012 |
| | 10138012 | 10321012 | 11124012 | 11284012 | 12201012 | 13053012 | 13318012 | 14252012 |
| | 10162012 | 10334012 | 11137012 | 11320012 | 12250012 | 13060012 | 13345012 | |
| | 10182012 | 10341012 | 11143012 | 11361012 | 12293012 | 13095012 | 14031012 | |
| | 10228012 | 11007012 | 11188012 | 12018012 | 12317012 | 13138012 | 14085012 | |
| | 10245012 | 11043012 | 11207012 | 12046012 | 12340012 | 13221012 | 14149012 | |
| Product # | Lot Number | | | | | | | |
| 0225-019-000 | 10111012 | 11018012 | 11273012 | 12296012 | 13066012 | 13175012 | 14029012 | 14143012 |
| | 10131012 | 11115012 | 12237012 | | | | | |
| Product # | Lot Number | | | | | | | |
| 0225-028-852 | 10097012 | 10281012 | 11087012 | 11178012 | 12066012 | 12335012 | 13234012 | 14178012 |
| | 10105012 | 10298012 | 11095012 | 11189012 | 12101012 | 12348012 | 13248012 | 14197012 |
| | 10130012 | 10312012 | 11105012 | 11206012 | 12108012 | 12353012 | 13263012 | 14254012 |
| | 10162012 | 10322012 | 11115012 | 11229012 | 12138012 | 13046012 | 13302012 | 14260012 |
| | 10172012 | 10337012 | 11130012 | 11269012 | 12156012 | 13086012 | 13319012 | |
| | 10195012 | 10340012 | 11139012 | 11313012 | 12159012 | 13095012 | 14029012 | |
| | 10205012 | 11003012 | 11146012 | 11337012 | 12199012 | 13108012 | 14052012 | |
| | 10238012 | 11013012 | 11147012 | 12016012 | 12248012 | 13143012 | 14058012 | |
| | 10251012 | 11048012 | 11151012 | 12040012 | 12261012 | 13171012 | 14155012 | |
| | 10272012 | 11055012 | 11160012 | 12041012 | 12289012 | 13221012 | 14164012 | |

RA 2014-144: PFA Acknowledgement Form

Description: Stryker CBC II Wound Drains and Ambulating Bulb

Product Code: Various – Please refer to the attached list

Lot Number: Various – Please refer to the attached list

I acknowledge receipt of the Field Safety Notice for RA 2014-144 and can confirm that:

| We have not located any of these devices in our inventory: (please delete if not applicable) | | | |
|---|-------------------|------------|-----|
| We have located the following devices which require replacement: | | | |
| Product Description | Product Reference | Lot Number | Qty |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| We have further distributed subject devices to the following organisations: | | | |
| Facility Name | | | |
| Facility Address | | | |

| | | | |
|---|--|----------------|--|
| Please sign and return this form to acknowledge receipt of product notice. | | | |
| Name of Hospital / Organisation | | Department | |
| Contact Name | | Address | |
| Contact Title | | | |
| Contact Signature | | E-mail Address | |
| Contact Phone No. | | Date | |

**PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO MARK.FIELDING@STRYKER.COM.**