

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.

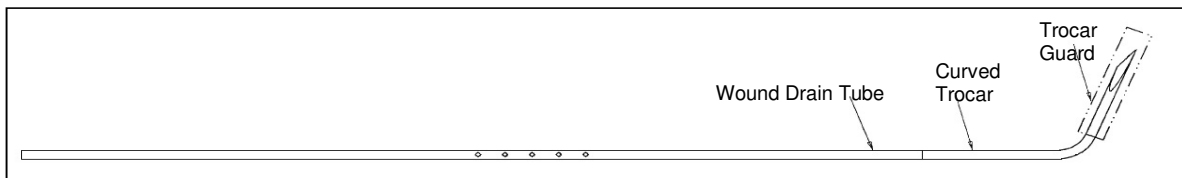


Figure 1. Diagram of a Curved Trocar with Wound Drain

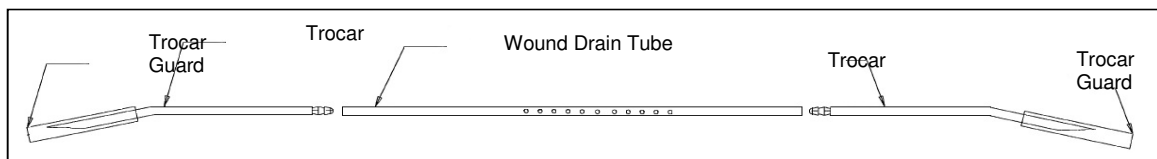


Figure 2. Diagram of a Double Trocar with Wound Drain

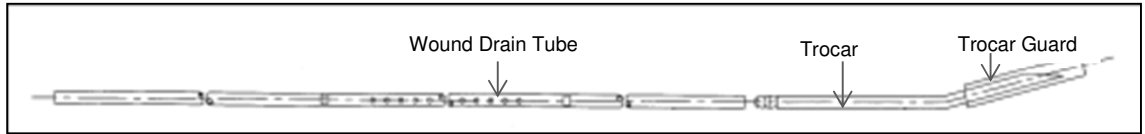


Figure 3. Illustrates the Wound Drain with Single Trocar and the Round Drain with Single Trocar.

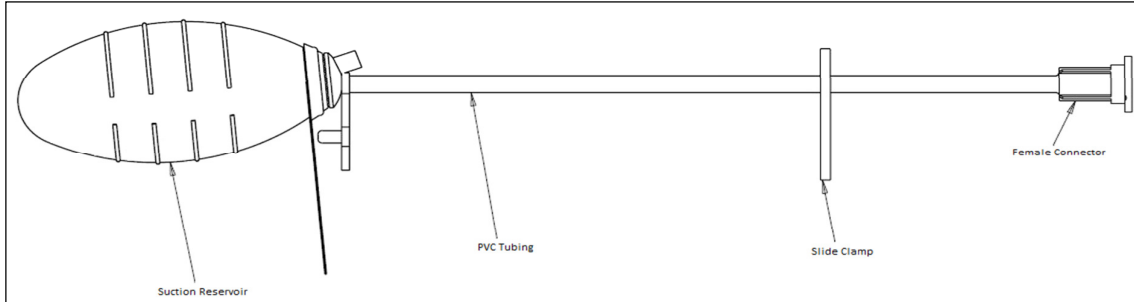


Figure 4. Diagram of the Ambulating Bulb showing its main components.

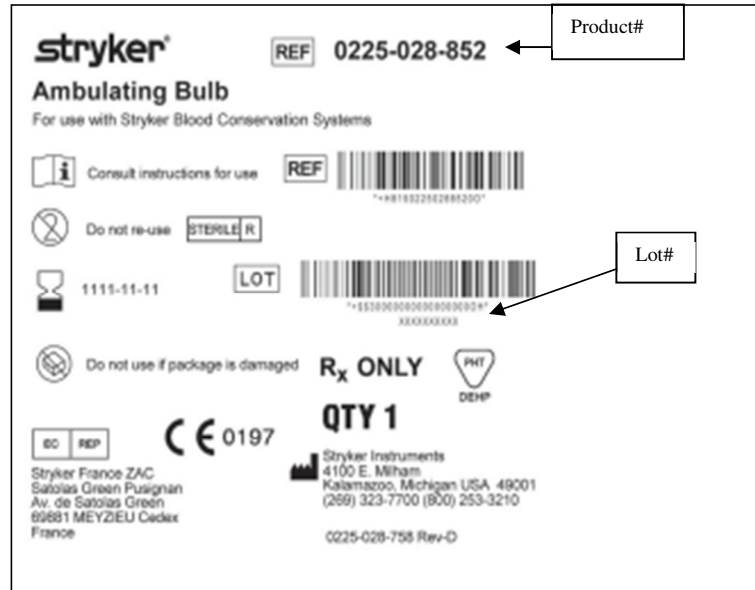


Figure 5. Example of the product package label.

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							
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	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	
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	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.