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URGENT FIELD SAFETY NOTICE - PRODUCT REMOVAL

Stryker Advanced Cement Mixer System

Attn: Materials Manager, Risk Manager, OR Director

Recall Number: RA2023-3361855

Xxxx August 2023

This notification is to inform you of an increase in reported events of disassembly for specific lots of the Stryker Advanced Cement Mixer (ACM) System.

Catalog number	GTIN	Product description	Lot number
0206512000	04546540039415	BreakAway Femoral Nozzle	Refer to Appendix A
0206530000	04546540857880	180Gram Cement Cartridge with Breakaway Femoral Nozzle	
0306563000	04546540055408	ACM Kit w/ Femoral Breakaway Nozzle	
0306564000	04546540899071	ACM Kit w/ Femoral Breakaway Nozzle & Solid Blades	
0306573000	04546540055415	ACM Kit w/ Femoral Breakaway Nozzle & Prox. Med. Press.	
0306703000	07613327051285	ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Press.	
0306705000	04546540055422	ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Med. Press.	

Product description

The Stryker ACM System allows the user to mix bone cement with a constant high vacuum through the process. It is transferred directly from the mixing bowl to the application cartridge while under vacuum. The cartridge containing the cement is attached to an applicator tip and delivered using a cement gun.

Product issue

There is potential for the BreakAway Femoral Nozzle (*Figure 1*), the applicator tip connecting the cement cartridge, to disassemble from the system during use.

Potential risks

Disassembly may lead to the potential for user annoyance and delay in cement application. Intervention and/or additional post-operative care may be necessary in the event parts fall into the surgical site during a procedure to prevent serious injury

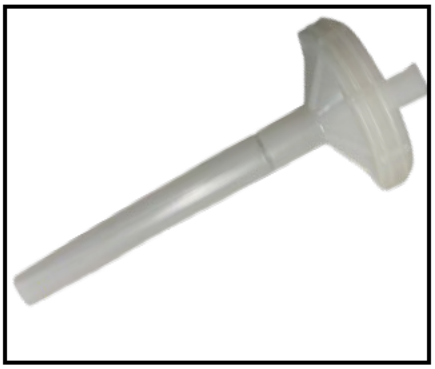

Figure 1. Break-Away Femoral Nozzle

Actions needed

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.
We therefore request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.

2. Sign and return the enclosed Business Reply Form by email to <xxx@stryker.com> to confirm receipt of this notification/documenting product disposition.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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 eliminate the need for us to send further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.

3. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details so that we can inform the recipients appropriately.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.121 and EU 2017/745, 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 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 and your expectations, remain on the market.

Sincerely,

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Appendix A

75 Serial Numbers across seven product numbers are listed below.
Distribution dates for products in scope range from 11/10/2022 – 5/10/2023.

BreakAway Femoral Nozzle (0206512000)	180Gram Cement Cartridge with Breakaway Femoral Nozzle (0206530000)
22314012	22332012
22336012	22333012
	22355012
	22356012
	23052012

ACM Kit w/ Femoral Breakaway Nozzle (0306563000)				
22305012	22321012	22336012	22354012	23005012
22306012	22322012	22337012	22355012	23009012
22307012	22323012	22340012	22356012	23010012
22308012	22325012	22341012	22357012	23011012
22311012	22326012	22342012	22361012	23012012
22315012	22327012	22346012	22362012	23013012
22316012	22332012	22347012	22363012	23014012
22318012	22333012	22348012	22364012	23015012
22319012	22334012	22351012	23003012	23017012
22320012	22335012	22353012	23004012	23018012
				23019012

ACM Kit w/ Femoral Breakaway Nozzle & Solid Blades (0306564000)	ACM Kit w/ Femoral Breakaway Nozzle & Prox. Med. Press. (0306573000)	
22305012	22313012	22348012
22336012	22314012	22349012
	22315012	22350012
	22343012	22353012

ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Press. (0306703000)	ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Med. Press. (0306705000)	
23010012	22306012	22341012
	22307012	22342012
	22340012	23017012

Business Reply Form

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Stryker Advanced Cement Mixer System

Recall Number: RA2023-3361855

XX August 2023

Please complete and sign this form. Email the completed form to <xxx@stryker.com> by <MMM DD YYYY>.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Lot number(s)	Quantity on hand*
0206512000	BreakAway Femoral Nozzle		
0206530000	180Gram Cement Cartridge with Breakaway Femoral Nozzle		
0306563000	ACM Kit w/ Femoral Breakaway Nozzle		
0306564000	ACM Kit w/ Femoral Breakaway Nozzle & Solid Blades		
0306573000	ACM Kit w/ Femoral Breakaway Nozzle & Prox. Med. Press.		
0306703000	ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Press.		
0306705000	ACM Kit w/ Femoral Breakaway Nozzle, Restrictors & Prox. Med. Press.		

*If all devices have been used and none remaining for return, please indicate 0 (zero) for quantity on hand.

Form completed by:

Facility Name			
Facility Address			
Printed Name		**Title**	
Email		**Phone**	
Signature		**Date**	

If you have further distributed any affected product, please indicate to whom:

Facility Name		**Contact Person**	
Full Address			

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____Signature_____Date :