stryker

URGENT FIELD SAFETY NOTICE - PRODUCT REMOVAL

Spetzler™-Malis® Bipolar Forceps

Attn: Risk Manager, OR Director, Materials Manager

Recall Number: RA2023-3390730

September, 2023

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling 56 specific lots of Disposable Spetzler-Malis Bipolar Forceps.

Distribution dates: 09NOV2022 – 05JUN2023

Catalog number	Description	GTIN	Affected Lots
6760-180-005	18CM SM DISP BAYONET 0.5MM TIP	7613327300192	200507002
6760-180-015	18CM SM DISP BAYONET 1.5MM TIP	7613327300376	201119005, 201210009
6760-200-005	20CM SM DISP BAYONET 0.5MM TIP	7613327300284	201105002
6760-230-005	23CM SM DISP BAYONET 0.5MM TIP	7613327300253	200507007, 200515006, 201203014
6760-230-010	23CM SM DISP BAYONET 1.0MM TIP	7613327300291	200507008
6760-230-015	23CM SM DISP BAYONET 1.5MM TIP	7613327300246	200507009
6770-180-005	18CM IM DISP BAYONET 0.5MM TIP	7613327299908	200525007, 200806005, 200910009
6770-180-010	18CM IM DISP BAYONET 1.0MM TIP	7613327300260	200515007, 200731007, 200924011, 201001028
6770-180-015	18CM IM DISP BAYONET 1.5MM TIP	7613327300321	200515008, 200525009, 200626006, 200731008, 200806007
6770-200-005	20CM IM DISP BAYONET 0.5MM TIP	7613327300185	200924012, 201001029, 201022005, 201029006
6770-200-015	20CM IM DISP BAYONET 1.5MM TIP	7613327300352	200731010, 201008012
6770-230-005	23CM IM DISP BAYONET 0.5MM TIP	7613327300161	200515009, 201008013, 201015011, 201126013
6770-230-010	23CM IM DISP BAYONET 1.0MM TIP	7613327300222	200507015, 200515010, 201008014
6780-200-005	20CM SLM DISP BAYONET 0.5MM	7613327300277	201008016, 201015014, 201029008, 201210016
6780-200-010	20CM SLM DISP BAYONET 1.0MM	7613327300369	200525011, 200806012, 201015015
6780-200-015	20CM SLM DISP BAYONET 1.5MM	7613327300314	200525012, 200716010, 200731013, 200806013, 200924017
6780-230-005	23CM SLM DISP BAYONET 0.5MM	7613327300307	201015016, 201029011, 201105009
6780-230-010	23CM SLM DISP BAYONET 1.0MM	7613327300178	200525014, 201015017, 201112017
6780-230-015	23CM SLM DISP BAYONET 1.5MM	7613327300239	200423023, 200525015, 200806014, 201015018

Product description

The Disposable Spetzler-Malis Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue. The forceps are manufactured in various lengths and tip sizes and are bayonet-style, including a cord at the proximal end, which allows for connection to a standard bipolar electrosurgical generator. The system, when used with Malis Bipolar forceps, aids in coagulating, grasping, and manipulating tissue.

Product issue

An error was identified on the expiration date of the product label. The shelf life for the products impacted is 36 months (3 years) however the product label represents a 54 month (4.5 year) shelf life. It has been confirmed that Stryker's distribution system had the correct shelf life indicated therefore all distributed devices were shipped and delivered to customers with good shelf life remaining.

Potential risks

Sterility and performance cannot be assured after the product expiration date of the product, which results in potential for pathogen exposure possibly causing inflammatory reaction or infection or performance degradation which may include unplanned electrical energy discharge if impacted product is used while expired.

Actions to be taken

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 <jamie.harvey@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: Jamie Harvey
Position: RAQA Senior Post-Market
Email: jamie.harvey@stryker.com

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,

Business Reply Form

Account number:
Account name:
Account Address:

Spetzler™-Malis® Bipolar Forceps

September, 2023

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6770-230-010	23CM IM DISP BAYONET 1.0MM TIP		
6780-200-005	20CM SLM DISP BAYONET 0.5MM		
6780-200-010	20CM SLM DISP BAYONET 1.0MM		
6780-200-015	20CM SLM DISP BAYONET 1.5MM		
6780-230-005	23CM SLM DISP BAYONET 0.5MM		
6780-230-010	23CM SLM DISP BAYONET 1.0MM		
6780-230-015	23CM SLM DISP BAYONET 1.5MM		

*If all devices have been used and no affected devices are available for return please enter 0 (zero).

Form completed by:

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

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

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

Product(s) Distributed		**Quantity Distributed**	
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 :