

stryker

URGENT Medical Device Recall

Nasopore | Otopore

Attn: Materials Manager, OR Director, Risk Manager

March XX, 2025

RA2025-38888970

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling all lots of Nasopore and Otopore nasal dressings distributed between 21OCT2022- 31OCT2024.



Catalog Number	Description	GTIN	Lot Numbers
5400-010-000	Otopore Cylinder Standard	07613327301663	See Appendix A
5400-010-000ITL	Otopore Cylinder Standard	07613327359510	
5400-010-004	Nasopore Standard 4cm	07613154340798	
5400-010-004ITL	Nasopore Standard 4cm	07613327359435	
5400-010-008	Nasopore Standard 8cm	07613154340804	
5400-010-008ITL	Nasopore Standard 8cm	07613327359503	See Appendix B
5400-020-000	Otopore Cylinder Firm	07613327301670	
5400-020-000ITL	Otopore Cylinder Forte	07613327359466	
5400-020-004	Nasopore Firm 4cm	07613154340811	
5400-020-004ITL	Nasopore Forte 4cm	07613327359459	
5400-020-008	Nasopore Firm 8cm	07613154340828	See Appendix C
5400-020-008ITL	Nasopore Forte 8cm	07613327359428	
5400-020-100	Otopore Square Firm	07613327301656	
5400-020-100ITL	Otopore Square Forte	07613327359497	
5400-020-108	Nasopore FD	07613327117226	
5400-020-108ITL	Nasopore FD	07613327117226	See Appendix D
5400-030-004	Nasopore Ex Firm 4cm	07613154340835	
5400-030-004ITL	Nasopore Forte plus 4cm	07613327359442	
5400-030-008	Nasopore Ex Firm 8cm	07613154340842	
5400-030-008ITL	Nasopore Forte plus 8cm	07613327359473	
5400-212-004S	Nasopore 4cm Standard 2PK	07613327500387	See Appendix D
5400-222-004S	Nasopore 4cm Firm 2PK	07613327500479	

Product description

Nasopore is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.

Otopore® is intended for single use as a means of a temporary wound dressing in the outer ear after ear surgery.

Product issue

There is a potential for blister seals on the product to present a bubble on the seal area of the packaging. This seal acts as a sterile barrier and, in this event, indicates that the sterility seal has been breached. Two complaints have been identified for this non-conformance. There have been no reports of illness or injury.

Potential risks

There is a potential for products with a breached sterility seal to be exposed to excessive pathogens, resulting in a possible increased risk of infection that may require medical intervention.

Patient Follow up

NasoPore and OtoPore products are consumed in clean but non-sterile environments. Therefore, there is no concern if a patient has been exposed to this product, as there is no increased risk of infection or injury.

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Commented [MC1]: Please check IFU to see if it is mentioned nasal trauma



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 <xxxxxx@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.
 - 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 Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 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 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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Business Reply Form

Nasopore | Otopore
March xx , 2025

Please choose the most appropriate option below and complete this form. Email the completed form to XXXXXXXXXX@stryker.com.
RESPONSE IS REQUIRED.

☐ I, the customer, choose to return the following product(s) for replacements:

Catalog Number	Description	Affected Lots	Qty on Hand*	
			EA	PACKS
5400-010-000	Otopore Cylinder Standard			
5400-010-000ITL	Otopore Cylinder Standard			
5400-010-004	Nasopore Standard 4cm			
5400-010-004ITL	Nasopore Standard 4cm			
5400-010-008	Nasopore Standard 8cm			
5400-010-008ITL	Nasopore Standard 8cm			
5400-020-000	Otopore Cylinder Firm			
5400-020-000ITL	Otopore Cylinder Forte			
5400-020-004	Nasopore Firm 4cm			
5400-020-004ITL	Nasopore Forte 4cm			
5400-020-008	Nasopore Firm 8cm			
5400-020-008ITL	Nasopore Forte 8cm			
5400-020-100	Otopore Square Firm			
5400-020-100ITL	Otopore Square Forte			
5400-020-108	Nasopore FD			
5400-020-108ITL	Nasopore FD			
5400-030-004	Nasopore Ex Firm 4cm			
5400-030-004ITL	Nasopore Forte plus 4cm			
5400-030-008	Nasopore Ex Firm 8cm			
5400-030-008ITL	Nasopore Forte plus 8cm			
5400-212-004S	Nasopore 4cm Standard 2PK			
5400-222-004S	Nasopore 4cm Firm 2PK			

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

Form completed by:

Facility Name			
Facility Address			
Printed Name		Title	
Email		Phone	
Signature		Date	

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			

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Appendix A

Otopore Cylinder Standard (5400-010-000)			
2023011112	2023020334	2023072413	2024032615

Nasopore Standard 4cm (5400-010-004)			
2022101814	2023021412	2023082413	2024022915
2022102413	2023022133	2023090613	2024031915
2022111413	2023050913	2023091912	2024032215
2023011613	2023051213	2023103115	2024040214
2023012413	2023071713	2023110812	2024052915
2023012713	2023080812	2023112018	2024062412
2023020912	2023081112	2024011613	2024080912

Otopore Cylinder Standard (5400-010-000ITL)			
2023022132	2023112213	2024020515	2024032013

Nasopore Standard 4cm (5400-010-0041TL)		
2022111414	2023051712	2023090114
2023011013	2023052415	2023110315
2023011913	2023061615	2023112314
2023020113	2023062132	2024011912
2023020333	2023062615	2024020813
2023020612	2023062915	2024080117
2023050414	2023070433	2024082216

Nasopore Standard 8cm (5400-010-008)							
2022100514	2023011113	2023012412	2023041712	2023052212	2023062714	2023110214	2024011112
2022100616	2023011612	2023012712	2023050812	2023053012	2023062914	2023110714	2024012912
2022101733	2023011712	2023021014	2023050912	2023061516	2023070314	2023111312	2024013112
2022101815	2023011912	2023021414	2023051212	2023061614	2023091914	2023111512	2024020712
2022102412	2023012312	2023041212	2023051713	2023062614	2023092112	2023112212	2024021215
2024030612	2024031112	2024042412	2024042514	2024073114	2024080116	2024080913	2024082014

Nasopore Standard 8cm (5400-010-008ITL)							
2022092712	2022112912	2023020613	2023042612	2023090412	2023112814	2024021414	2024032612
2022092912	2022113012	2023020712	2023050512	2023090612	2023112914	2024021512	2024040215
2022093014	2022120112	2023020812	2023051012	2023090714	2023113014	2024021612	2024040414
2022100432	2022120212	2023020913	2023051512	2023091312	2023120114	2024021912	2024041614
2022101212	2022120532	2023022112	2023051616	2023091414	2024010914	2024022112	2024041712
2022102114	2022120533	2023030614	2023052312	2023092214	2024011012	2024022212	2024051312
2022102612	2022120632	2023030712	2023052414	2023092732	2024011214	2024022312	2024051412
2022102714	2022120512	2023030812	2023052516	2023100314	2024011512	2024022714	2024052914
2022103132	2022120733	2023030912	2023060114	2023100414	2024011612	2024022712	2024052912
2022110712	2022120732	2023031012	2023060116	2023100932	2024011712	2024022814	2024053012
2022110812	2022120612	2023031412	2023060612	2023101712	2024011714	2024022812	2024060415
2022110332	2022120714	2023031612	2023060512	2023101914	2024011913	2024022914	2024060514
2022110912	2022120912	2023031714	2023060712	2023102415	2024012212	2024022912	2024061214
2022111032	2022121212	2023032012	2023061915	2023102514	2024012214	2024030112	2024061212
2022111012	2022121332	2023032112	2023062014	2023103114	2024012512	2024030614	2024061712
2022111033	2022121432	2023032312	2023062112	2023110112	2024012312	2024030714	2024061714
2022111432	2022121312	2023032732	2023062314	2023110314	2024012612	2024031212	2024062413
2022111412	2022121532	2023032832	2023062732	2023110612	2024013014	2024031312	2024062512
2022111433	2022121533	2023033132	2023062814	2023110732	2024020114	2024031414	2024070232
2022111612	2022121632	2023040332	2023071712	2023110813	2024020514	2024031514	2024070114
2022111632	2023011012	2023040433	2023072412	2023111414	2024020812	2024031912	2024070112
2022111712	2023013012	2023040532	2023080813	2023111614	2024020815	2024032012	2024070812
2022111732	2023013112	2023041314	2023081113	2023111714	2024020912	2024031914	2024070912
2022111812	2023020112	2023041912	2023082412	2023112016	2024020914	2024032114	2024080114
2022111832	2023020212	2023042415	2023083032	2023112315	2024021312	2024032214	2024080512
2022112615	2023020312	2023042512	2023090115	2023112712	2024021412	2024032614	2024080915
2024081214	2024081212	2024081612	2024082112	2024090632	2023050415		

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Appendix B

Otopore Cylinder Firm (5400-020-000)							
2023011815	2023021312	2023081413	2023102413	2024031115			

Otopore Cylinder Forte (5400-020-000)(TL)							
2023050112	2023060615	2023061912	2023072432	2023080832	2023081712	2023082213	2023101115
2023101614	2023103013	2024031417	2024043013	2024050612	2024052715	2024060315	2024070814

Nasopore Firm 4cm (5400-020-004)							
2022100314	2023013132	2023042514	2023081512	2023110114	2024011514	2024032512	2024082612
2022102514	2023021012	2023050216	2023082811	2023110614	2024011814	2024042914	
2023011332	2023021512	2023060214	2023090514	2023111616	2024021213	2024052812	
2023012632	2023030814	2023062214	2023091813	2023112112	2024030412	2024073012	

Nasopore Forte 4cm (5400-020-004)(TL)							
2022102012	2023011714	2023011714	2023051614	2023081812	2023110914	2024012614	2024030716
2022111514	2023012014	2023012014	2023052314	2023083116	2023112414	2024020714	2024031214
2023010914	2023020214	2023020214	2023062733	2023100914	2023112912	2024021514	2024031814
2023011214	2023051112	2023051112	2023080112	2023101214	2024010912	2024022014	2024032816
2024042314	2024051314	2024052212	2024060512	2024061114			

Nasopore Firm 8cm (5400-020-008)						
2022101214	2023011115	2023021612	2023061932	2023101632	2024011532	2024051512
2022101314	2023011212	2023031312	2023062612	2023110232	2024021914	2024072631
2022101414	2023011314	2023031414	2023062812	2023113034	2024022731	2024081312
2022101914	2023011615	2023042413	2023072433	2023120732	2024030431	2024082614
2023010912	2023011814	2023050212	2023091112	2023121532	2024031932	2024082812
2022101214	2023011115	2023021612	2023061932	2023101632	2024011532	2024051512
2023011015	2023021313	2023051014	2023091212	2023121832	2024050814	

Nasopore Forte 8cm (5400-020-008)(TL)						
2022101912	2023030914	2023070715	2023073132	2023090512	2023101012	2023110832
2022102614	2023031015	2023070712	2023080132	2023090712	2023101014	2023111314
2022110714	2023032932	2023071132	2023080232	2023090814	2023101133	2023110932
2022110814	2023042614	2023071133	2023080233	2023091214	2023101114	2023111332
2022110914	2023050113	2023071134	2023080332	2023091314	2023101314	2023111333
2022111014	2023050312	2023071135	2023080732	2023091416	2023101313	2023111514
2022111114	2023050412	2023071232	2023080733	2023091514	2023101615	2023111632
2022111715	2023061414	2023071233	2023080932	2023091815	2023101612	2023112132
2022111814	2023061933	2023071432	2023080833	2023091916	2023101832	2023112012
2022113014	2023061913	2023071433	2023081132	2023092014	2023101814	2023112215
2022120214	2023062114	2023071733	2023081432	2023092114	2023101812	2023112233
2022120514	2023062712	2023071832	2023081412	2023092533	2023102012	2023112332
2022120614	2023062912	2023071833	2023081713	2023092733	2023102314	2023112317
2022120712	2023063012	2023071932	2023081532	2023100212	2023102412	2023112714
2022120914	2023063014	2023072032	2023081632	2023100215	2023102614	2023113032
2022121214	2023062932	2023072132	2023082112	2023100232	2023102532	2023113033
2022121412	2023070312	2023072033	2023082116	2023100532	2023103015	2023113016
2023013114	2023070432	2023072434	2023082212	2023100533	2023103012	2023120433
2023020115	2023070412	2023072532	2023082415	2023100511	2023110132	2023120432
2023020314	2023070414	2023072512	2023082914	2023100514	2023110332	2023120412
2023020615	2023070512	2023072533	2023082912	2023100614	2023110216	2023120414
2023021714	2023070514	2023072732	2023083014	2023100612	2023110632	2023120532
2023030612	2023070612	2023072832	2023083114	2023101032	2023110833	2023120614
2023030714	2023070614	2023070715	2023090414	2023101132	2023110815	2023110832

For reporting any serious adverse events or product quality problems contact Stryker at 1-800-253-3210, ext. 5555 8:00 A.M. to 7:00 P.M. (Eastern Time), Monday – Friday or by email at inst.stryker.cs@stryker.com. In addition to contacting Stryker, healthcare professionals and consumers may report any potential quality problems or adverse reactions, or events associated with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by fax or phone. Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm Fax: (800) FDA-0178 Phone: (800) FDA-1088.

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Appendix B cont.

Otopore Cylinder Forte (5400-020-008ITL) Continued							
2024011132	2024022012	2024032116	2024041715	2024051532	2024061012	2024070214	2024080712
2024011114	2024022115	2024032714	2024041732	2024051612	2024061112	2024070312	2024080714
2024011533	2024022214	2024032712	2024041816	2024051614	2024061132	2024070314	2024080814
2024011632	2024022632	2024032814	2024041814	2024051732	2024061232	2024070416	2024080812
2024011633	2024022314	2024032914	2024041831	2024051714	2024061315	2024070532	2024081314
2024011615	2024022612	2024040312	2024041914	2024052115	2024061312	2024070414	2024081414
2024011732	2024022831	2024040314	2024042215	2024052112	2024061412	2024070932	2024081512
2024011833	2024022614	2024040232	2024042414	2024052214	2024061414	2024070815	2024081412
2024011832	2024022931	2024040416	2024042516	2024052432	2024061812	2024070514	2024081514
2024012232	2024022933	2024040331	2024042614	2024052314	2024061912	2024071631	2024081914
2024012234	2024030114	2024040514	2024042912	2024052316	2024061914	2024071731	2024081912
2024012233	2024030531	2024040932	2024043012	2024052414	2024062016	2024071831	2024082114
2024011916	2024030631	2024040814	2024043015	2024052711	2024062014	2024071931	2024082315
2024012332	2024030514	2024040812	2024050112	2024052714	2024062114	2024072231	2024082712
2024012432	2024030731	2024041031	2024050114	2024052932	2024062415	2024072331	2024082715
2024012415	2024030814	2024041132	2024050214	2024052815	2024062514	2024072431	2024082814
2024012433	2024031132	2024041232	2024050212	2024053014	2024062732	2024072531	2024090232
2024012532	2024031114	2024041012	2024050314	2024053112	2024062614	2024071012	2024090332
2024012932	2024031332	2024040914	2024050312	2024053114	2024062612	2024072913	2024090331
2024012933	2024031315	2024040912	2024050613	2024060312	2024062714	2024071512	2024090432
2024012915	2024031432	2024041014	2024050615	2024060314	2024062712	2024071112	2024090431
2024020116	2024031416	2024041631	2024050712	2024060413	2024062812	2024073112	2024090532
2024020612	2024031832	2024041114	2024051432	2024060614	2024070332	2024080214	2024090932
2024021314	2024032032	2024041112	2024051415	2024060712	2024070432	2024080514	2024090931
2024021614	2024032015	2024041612	2024051516	2024051532	2024070212	2024080615	2024091034

Appendix C

Otopore Square Firm (5400-020-100)					
2022101016	2023021716	2023062115	2023082113	2024022114	

Otopore Square Forte (5400-020-100ITL)						
2023021715	2023100214	2023102315	2024012414	2024022615	2024041015	2024052114
2023072513	2023100515	2023102615	2024012914	2024030515	2024041714	2024052415
2023082114	2023101015	2023111515	2024020117	2024030815	2024042214	2024060412
2023082915	2023101312	2024010813	2024021315	2024031314	2024050713	2024072912
2023092532	2023101815	2024011115	2024021615	2024040515	2024051414	2024081415

Nasopore FD (5400-020-108)					
2023011317	2023021717	2023030932	2023040317	2023083017	2023102517
					2024020517
					2024080717

Nasopore FD (5400-020-108ITL)					
2023012017	2023032817	2023042017	2023091117	2023111417	2023120517
2023020732	2023041117	2023062017	2023092017	2023112017	2024010817
2023031717	2023041417	2023082317	2023103117	2023112817	2024011217
					2024011817
					2024012417

Appendix D



Nasopore Ex Firm 4cm (5400-030-004)								
2023012514	2023050514	2023080912	2024020214					

Nasopore Forte plus 4cm (5400-030-004ITL)								
2023071933	2023102714	2024012314						

Nasopore Ex Firm 8cm (5400-030-008)								
2023012515	2023012715	2023022012	2023050814	2023072632	2023102312	2023102612	2024032514	2024040212

Nasopore Forte plus 8cm (5400-030-008ITL)								
2022092714	2023020633	2023032433	2023050915	2023052514	2023062216	2023082814	2023101112	2024031812
2022092914	2023020814	2023032814	2023051114	2023053115	2023062032	2023090618	2023101714	2024042212
2022101332	2023020915	2023033016	2023051215	2023060914	2023082215	2023100312	2023102014	2024042312
2022121932	2023021416	2023050115	2023052214	2023061412	2023082312	2023100412	2024030414	2024061814
2022122032	2023022032	2023050515	2023052412	2023061514	2023082514	2023100912	2024030512	2024062814

Nasopore 4cm Standard 2PK (5400-212-004S)								
2024011914								

Nasopore 4cm Firm 2PK(5400-222-004S)								
2024021212			2024052813					