

# URGENT Medical Device Recall

## Nasopore | Otopore | Hemopore

Attn: Materials Manager, OR Director, Risk Manager

February 25, 2025



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

| Catalog Number | Description               | GTIN           | Lot Numbers        |
|----------------|---------------------------|----------------|--------------------|
| 5400-010-000   | Otopore Cylinder Standard | 07613327301663 | See Appendix A & B |
| 5400-010-004   | Nasopore Standard 4cm     | 07613154340798 |                    |
| 5400-010-008   | Nasopore Standard 8cm     | 07613154340804 |                    |
| 5400-020-000   | Otopore Cylinder Firm     | 07613327301670 |                    |
| 5400-020-004   | Nasopore Firm 4cm         | 07613154340811 |                    |
| 5400-020-008   | Nasopore Firm 8cm         | 07613154340828 |                    |
| 5400-020-100   | Otopore Square Firm       | 07613327301656 |                    |
| 5400-020-108   | Nasopore FD               | 07613327117226 |                    |
| 5400-020-208   | Hemopore 8cm              | 07613327117233 |                    |
| 5400-030-004   | Nasopore Ex Firm 4cm      | 07613154340835 |                    |
| 5400-030-008   | Nasopore Ex Firm 8cm      | 07613154340842 |                    |
| 5400-212-004S  | Nasopore 4cm Standard 2PK | 07613327500387 |                    |
| 5400-222-004S  | Nasopore 4cm Firm 2PK     | 07613327500479 |                    |
| 5400-222-208S  | Hemopore 2PK              | 07613327500486 |                    |

### 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.

Hemopore is intended for use in patients undergoing nasal/sinus surgery as a temporary wound dressing. Hemopore functions as a topical hemostatic aid to control mild bleeding by tamponade effect, blood absorption, platelet activation and aggregation. It acts as an adjunct to aid in the natural healing process as a space occupying stent to separate and support tissues. It prevents adhesions and minimizes edema.

### 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 or germs, resulting in a possible increased risk of infection that may require medical intervention.

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](mailto: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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) Fax: (800) FDA-0178 Phone: (800) FDA-1088.

Stryker Corporation or its affiliates own, use or have applied for the following trademarks or service marks: Stryker, OtoPore. All other trademarks are trademarks of their respective owners or holders.

**Stryker Instruments** 1941 Stryker Way Portage, MI 49002 USA

### **Actions to be taken**

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
2. Return the enclosed Business Reply Form (BRF), even if the affected product is no longer in inventory, to the email [Instruments.Recalls@stryker.com](mailto:Instruments.Recalls@stryker.com).
3. Upon receipt of the completed BRF, Stryker will provide a shipping label to return recalled product on-hand.
4. A replacement will be provided upon receipt of the recalled product.
5. Maintain awareness of this communication internally and inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients accordingly.

On behalf of Stryker, we thank you sincerely for your help 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,  
Brooke Thompson | Recall Coordinator | 269-290-0524

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](mailto: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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) Fax: (800) FDA-0178 Phone: (800) FDA-1088.

Stryker Corporation or its affiliates own, use or have applied for the following trademarks or service marks: Stryker, OtoPore. All other trademarks are trademarks of their respective owners or holders.

**Stryker Instruments** 1941 Stryker Way Portage, MI 49002 USA

# Business Reply Form

## Nasopore | Otopore | Hemopore

February 25, 2025

Please choose the most appropriate option below and complete this form. Email the completed form to [Instruments.recalls@stryker.com](mailto:Instruments.recalls@stryker.com). **RESPONSE IS REQUIRED.**

- ☐ No remaining affected products on-hand.
- ☐ 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 |               |              |       |
| 5400-010-004   | Nasopore Standard 4cm     |               |              |       |
| 5400-010-008   | Nasopore Standard 8cm     |               |              |       |
| 5400-020-000   | Otopore Cylinder Firm     |               |              |       |
| 5400-020-004   | Nasopore Firm 4cm         |               |              |       |
| 5400-020-008   | Nasopore Firm 8cm         |               |              |       |
| 5400-020-100   | Otopore Square Firm       |               |              |       |
| 5400-020-108   | Nasopore FD               |               |              |       |
| 5400-020-208   | Hemopore 8cm              |               |              |       |
| 5400-030-004   | Nasopore Ex Firm 4cm      |               |              |       |
| 5400-030-008   | Nasopore Ex Firm 8cm      |               |              |       |
| 5400-212-004S  | Nasopore 4cm Standard 2PK |               |              |       |
| 5400-222-004S  | Nasopore 4cm Firm 2PK     |               |              |       |
| 5400-222-208S  | Hemopore 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           |  |                      |  |

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](mailto: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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) Fax: (800) FDA-0178 Phone: (800) FDA-1088.

Stryker Corporation or its affiliates own, use or have applied for the following trademarks or service marks: Stryker, OtoPore. All other trademarks are trademarks of their respective owners or holders.

**Stryker Instruments** 1941 Stryker Way Portage, MI 49002 USA

## 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 Firm (5400-020-000) |            |            |            |            |
|--------------------------------------|------------|------------|------------|------------|
| 2023011815                           | 2023021312 | 2023081413 | 2023102413 | 2024031115 |

| 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 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 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 |
| 2023011015                      | 2023021313 | 2023051014 | 2023091212 | 2023121832 | 2024050814 |            |

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

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](mailto: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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) Fax: (800) FDA-0178 Phone: (800) FDA-1088.

Stryker Corporation or its affiliates own, use or have applied for the following trademarks or service marks: Stryker, OtoPore. All other trademarks are trademarks of their respective owners or holders.

**Stryker Instruments** 1941 Stryker Way Portage, MI 49002 USA

## Appendix B

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

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

| Hemopore 2PK ( 5400-222-208S) |            |            |
|-------------------------------|------------|------------|
| 2024020221                    | 2024051720 | 2024082321 |

| Hemopore 8cm (5400-020-208) |            |            |            |            |            |            |            |
|-----------------------------|------------|------------|------------|------------|------------|------------|------------|
| 2022093020                  | 2023011632 | 2023041321 | 2023062320 | 2023092220 | 2023112232 | 2024032120 | 2024052420 |
| 2022093021                  | 2023011932 | 2023042120 | 2023062220 | 2023092932 | 2023112420 | 2024032820 | 2024052320 |
| 2022100720                  | 2023012732 | 2023042121 | 2023073120 | 2023101220 | 2023112320 | 2024032920 | 2024060620 |
| 2022100620                  | 2023013033 | 2023050320 | 2023073121 | 2023101221 | 2023120120 | 2024040520 | 2024060720 |
| 2022101320                  | 2023020132 | 2023050220 | 2023081520 | 2023101921 | 2023113020 | 2024040420 | 2024062020 |
| 2022101420                  | 2023020632 | 2023051620 | 2023081521 | 2023101920 | 2023120632 | 2024041820 | 2024062120 |
| 2022101720                  | 2023022033 | 2023051720 | 2023082520 | 2023102721 | 2023121533 | 2024041920 | 2024070420 |
| 2022102120                  | 2023030220 | 2023052620 | 2023082521 | 2023102720 | 2024010532 | 2024042632 | 2024070520 |
| 2022102720                  | 2023030320 | 2023052520 | 2023083120 | 2023110320 | 2024020120 | 2024042520 | 2024071538 |
| 2022102820                  | 2023032420 | 2023060120 | 2023090120 | 2023110220 | 2024020220 | 2024042620 | 2024071738 |
| 2022110220                  | 2023032320 | 2023060220 | 2023090820 | 2023110733 | 2024030820 | 2024050821 |            |
| 2022110320                  | 2023032920 | 2023060820 | 2023090620 | 2023110920 | 2024030720 | 2024050820 |            |
| 2022112932                  | 2023033020 | 2023060920 | 2023091520 | 2023110921 | 2024031420 | 2024051520 |            |
| 2023010433                  | 2023040732 | 2023061520 | 2023091420 | 2023111720 | 2024031520 | 2024051721 |            |
| 2023010932                  | 2023041320 | 2023061620 | 2023092120 | 2023111620 | 2024032220 | 2024052332 |            |

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

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

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](mailto: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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) Fax: (800) FDA-0178 Phone: (800) FDA-1088.

Stryker Corporation or its affiliates own, use or have applied for the following trademarks or service marks: Stryker, OtoPore. All other trademarks are trademarks of their respective owners or holders.

**Stryker Instruments** 1941 Stryker Way Portage, MI 49002 USA