URGENT MEDICAL DEVICE RECALL

November 10, 2026

Dear Valued McKesson Customer:

Intersurgical has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Recall regarding specific lot(s) of their 22mm Smoothbore Breathing Systems. This notice has been issued because during the manufacture of these products, Tetrahydrofuran (THF) solvent is used to bond the soft connectors onto the Smoothbore tube. Following reports from markets outside the U.S. of soft connectors disconnecting from the tube, an investigation and testing of internal stock found that some products were manufactured with too little solvent to ensure a secure connection. As a result, the affected lots are being voluntarily recalled. Affected product first shipped May 23, 2025.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Intersurgical at **(800) 828-9633.**

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
1182077	5191000	CIRCUIT, BREATH EXHALATION VALVE W/MONITIR 22MM 1.8M (25/CS)	32520670 32522190 32522802
1279862	5805000	BREATHING SYS, SMTHBORE BILEVEL W/MONIT LINE/SWIVL 22MM (35/	32516315 32517877
1279864	5191850	BREATHING SYS, SMTHBORE EXHALATION VLV W/MONIT LINE 22MM(25/	32521551 32521655
1228711	5183000	CIRCUIT, BREATHING UNIVERSAL ADLT 22MM (20/CS)	32527207
1189083	5804000	CIRCUIT, BOARD SMOOTH BILEVEL ADLT/PED 22MM 1.8M LNG (30/CS)	32508034 32509327 32510909 32516895 32518659 32519175 32525543

McKesson Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.

2.) A copy of the Urgent Medical Device Recall from Intersurgical has been included for reference.

3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
- **Please note**: Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
- **Please place a new order for replacement product if there is an immediate need**.

4.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,
McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc. November 10, 2026
Medical Device Recall Reply Form: RC-2026-271
Intersurgical - 22mm Smoothbore Breathing Systems

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

☐ I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			1182077	5191000	CIRCUIT, BREATH EXHALATION VALVE W/MONITIR 22MM 1.8M (25/CS)
			1279862	5805000	BREATHING SYS, SMTHBORE BILEVEL W/MONIT LINE/SWIVL 22MM (35/
			1279864	5191850	BREATHING SYS, SMTHBORE EXHALATION VLV W/MONIT LINE 22MM(25/
			1228711	5183000	CIRCUIT, BREATHING UNIVERSAL ADLT 22MM (20/CS)
			1189083	5804000	CIRCUIT, BOARD SMOOTH BILEVEL ADLT/PED 22MM 1.8M LNG (30/CS)

*Return Affected lot numbers only

*** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

☐ I am on a McKesson truck route, please schedule a delivery professional pick up.

☐ Please send my UPS/Return label by **Email**. Number of UPS Parcels to be returned: _____

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and trust

Intersurgical Inc.
2055 Executive Drive, Indianapolis, IN 46241, USA
Phone: (800) 828-9633 support@intersurgicalinc.com www.intersurgical.com

URGENT MEDICAL DEVICE RECALL

November 3, 2026

Dear Valued Customer,

The purpose of this letter is to notify you that Intersurgical Inc. is voluntarily recalling specific lots of its 22mm Smoothbore Breathing Systems, as identified below.

During the manufacture of these products, Tetrahydrofuran (THF) solvent is used to bond the soft connectors onto the Smoothbore tube. Following reports from markets outside the U.S. of soft connectors disconnecting from the tube, an investigation and testing of internal stock found that some products were manufactured with too little solvent to ensure a secure connection. As a result, the affected lots are being voluntarily recalled.

Potential risk: If a connector disconnects from the Smoothbore tube during use, this could result in a loss of ventilation or compromised ventilation, which may cause the patient to desaturate until ventilation is manually re-initiated. Depending on the individual patient, the specific situation and the time to re-initiate ventilation, loss of ventilation could potentially lead to organ failure, brain damage or death caused by hypoxia. The probability of this occurring has been estimated as remote (1 in 100,000 to 1 in 1,000,000 products); however, we believe it is essential to address the issue promptly to reduce the risk of any potential patient harm.

Product Affected:

Product Code(s):	5018000 5025000 5025310 5026000 5183000 5191000 5191850 5194850 5804000 5805000 5805030
Description:	**REF: 5018000** 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.8m **REF: 5025000** 22mm Smoothbore single heated wire breathing system with water trap, ≥ 1.6m **REF: 5025310** 22mm Smoothbore single heated wire breathing system with water trap and auto-fill chamber, ≥ 1.6m **REF: 5026000** 22mm Smoothbore dual heated wire breathing system, ≥ 1.6m **REF: 5183000** 22mm Smoothbore breathing system with monitoring line and exhalation valve, ≥ 1.6m **REF: 5191000**

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2055 Executive Drive, Indianapolis, IN 46241, USA
Phone: (800) 828-9633 support@intersurgicalinc.com www.intersurgical.com

	22mm Smoothbore breathing system with monitoring line and exhalation valve, single limb, 1.8m **REF: 5191850** 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line and extra limb, ≥ 1.6m **REF: 5194850** 22mm Smoothbore exhalation valve heated wire breathing system with extra limb, ≥ 1.6m **REF: 5804000** 22mm Smoothbore bilevel breathing system with swivel CO_2 leak port, ≥ 1.8m **REF: 5805000** 22mm Smoothbore bilevel breathing system with monitoring line and swivel CO_2 leak port, ≥ 1.6m **REF: 5805030** 22mm Smoothbore bilevel breathing system with swivel CO_2 leak port and Clear-Guard Midi filter, ≥ 1.8m
Product Lots:	**REF: 5018000** 32511811 **REF: 5025000** 32522651 **REF: 5025310** 32526115 **REF: 5026000** 32525551 **REF: 5183000** 32527207 **REF: 5191000** 32520670, 32522190, 32522802 **REF: 5191850** 32521551, 32521655 **REF: 5194850** 32518127 **REF: 5804000** 32508034, 32509327, 32510909, 32516895, 32518659, 32519175, 32525543 **REF: 5805000** 32516315, 32517877 **REF: 5805030** 32505469, 32506841, 32513929, 32514276, 32515579, 32518484, 32519342, 32519468, 32519979, 32522143, 32522415, 32523651, 32525498, 32525628, 32526171, 32526270, 32527299, 32528409

Date product first shipped: 05/23/2025

Intersurgical Inc.
2055 Executive Drive, Indianapolis, IN 46241, USA
Phone: (800) 828-9633 support@intersurgicalinc.com www.intersurgical.com

Recall Instructions:

1. Immediately discontinue use and quarantine any stock with the product/lot numbers described above in this recall notification.
2. Please share this notice with all users of these products within your facility. If you have distributed any of these products, please immediately contact your customers, advise them of the recall situation and have them return their outstanding recalled stock to you.
3. ~~Contact Intersurgical Customer Support at 800-828-9633 for a Return Goods Authorization (RGA) Number and return label. Hours of operation are Monday through Thursday, 8:00 a.m. to 4:00 p.m. EST and Friday 8:00 a.m. to 3:00 p.m. EST.~~
   a. ~~Once you have received the RGA Number, please enter it in the space provided on the **Customer Product Recall Acknowledgement Form:**~~
      i. ~~Return the completed form via email to Intersurgical Inc. at **recalls@intersurgicalinc.com**.~~
      ii. ~~Please ship all product back to Intersurgical using the return label supplied by Customer Support.~~
      iii. ~~The subject line should contain your Company name and RGA number.~~
         1. ~~This will allow us to document your receipt of this letter and the amount of product you have on-hand for return.~~
   b. ~~Intersurgical will credit or replace your product free of charge when the product is received.~~
4. ~~Please note: If you do not have the recalled product in stock, please check the appropriate box on the **Customer Product Recall Acknowledgement Form.**~~
   a. ~~Return the completed form via email to Intersurgical Inc. at **recalls@intersurgicalinc.com**.~~
   b. ~~The subject line should contain your Company name and "Intersurgical Recall".~~
5. ~~Please continue to report to Intersurgical any adverse events involving these products~~.

Intersurgical is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact Customer Support at 1-800-828-9633 or email at recalls@intersurgicalinc.com.

Please note the following: No other product codes or lots are affected by this product recall in the United States. There have been no illnesses or injuries reported to the company to date in connection with this product. The U.S. Food and Drug Administration has been notified of this action.

Intersurgical Inc.
2055 Executive Drive, Indianapolis, IN 46241, USA
Phone: (800) 828-9633 support@intersurgicalinc.com www.intersurgical.com

Sincerely,

Kerrie Campbell

Digitally signed by Kerrie Campbell
Date: 2026.11.03 08:40:59 -05'00'

Kerrie Campbell
Director, Quality Assurance and Regulatory Affairs
D: (315) 491 2812

United States - Intersurgical Incorporated
2055 Executive Drive, Indianapolis, IN 46241
Toll Free: 800 828 9633
QARA@intersurgicalinc.com | www.intersurgical.com