Field Safety Notice
CONMED Corporation
AirSeal® Access Ports

June 24, 2026

Dear Risk Manager/ Safety Coordinator/Purchasing Agent:

CONMED Corporation is sending this communication to provide you with important information concerning the Instructions for Use (IFU) for the AirSeal® Access Ports. This communication affects the catalog numbers listed below for customers who received devices manufactured from 14 June 2024 to 12 Jan 2026. The Lot numbers impacted as a result of this Field Safety Notice is from 202406144 through 202601124.

CONMED is ***not*** requesting users to return, remove or dispose any of the *Airseal Access Ports* from the market.

Table 1: Catalog number impacted

Catalog No.	Device Identifier	Device Name
iASB5-150	10845854045695	AirSeal® 5 mm Smooth Access Port and Obturator with Blunt Tip, 150mm Length
iASB12-120	10845854045725	AirSeal® 12 mm Access Port and Obturator with Blunt Tip, 120mm Length
iASB12-100	10845854045602	AirSeal® 12mm Access Port and Obturator with Blunt Tip, 100mm Length
iAS8-120LP	10845854045657	AirSeal® 8mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 120mm Length
iAS8-100LP	10845854045718	AirSeal® 8mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 100mm Length
iAS5-75LP	10845854046388	AirSeal® 5mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 75mm Length
iAS5-120LP	10845854045657	AirSeal® 5mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 120mm Length
iAS5-100LP	10845854045626	AirSeal® 5mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 100mm Length
iAS12-150LPI	10845854052006	AirSeal® 12mm Access Port and Palm Grip Obturator with Bladeless Optical Tip, 150mm Length
iAS12-120LPI	10845854045688	AirSeal® 12mm Access Port and Low Profile Obturator with Bladeless Optical Tip, 120mm Length
iAS12-100LPI	10845854045640	AirSeal® 12mm Access Port and Palm Grip Obturator with Bladeless Optical Tip, 100mm Length

Reason for the Notice:
CONMED has received an increase in reports of overpressure alerts with AirSeal Access Ports, which in some cases have resulted in delay of treatment. During a review of complaint data, CONMED identified that a previous manufacturing process update may, under certain conditions, contribute to overpressure alerts. In response, the Instructions for Use (IFU) were clarified to ensure proper device tightening.

In the event of an overpressure condition, AirSeal® is designed to respond automatically via a built-in venting system, which activates when the pressure exceeds the set point by more than 3 mm Hg for more than 3 seconds. When the “overpressure” alert is displayed there is a higher-than-expected pressure within the system between the AirSeal® iFS and the AirSeal® access port but does not represent higher-than-expected pressure within the patient.

Risk to Health:
When the “overpressure” alert is displayed there is a higher-than-expected pressure within the system between the AirSeal® iFS and the AirSeal® access port but does not represent higher-than-expected pressure within the patient. The reported incident may result in the loss of pneumoperitoneum due to the system venting gas to compensate for the overpressure. Loss of pneumoperitoneum may result in loss of field of view, which may lead to iatrogenic injury, more complex or converted procedures, and/or delay of treatment.

Although the erroneous overpressure alerts on the device resulting from the issue described above are not indicative of the actual patient cavity pressure, the overpressure alarm should nevertheless be taken seriously when a true overpressure condition occurs within the patient. *Potential risk associated with a true overpressure could include air embolism, arrythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, more complex procedures, and potentially death. CONMED has received no reports of patient or user injury or death associated with these overpressure alerts.*

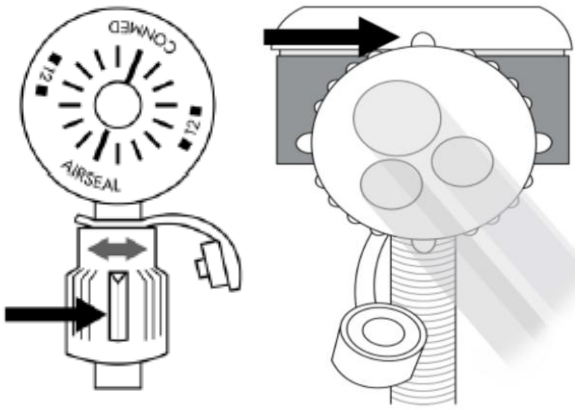
Actions to be taken by the Users:
A replacement AirSeal disposable should be available prior to the procedure in order to minimize potential delays. Before initiating insufflation, the user should ensure the tubing is properly connected between the AirSeal tube set and Airseal Access Ports. If the connection cannot be securely tightened and the “overpressure” alert cannot be resolved, please replace the affected device.

Detailed instructions on how to connect the AirSeal tube set and Airseal Access Ports are as follows:

Remove the manifold plug from the side of the cannula on the AirSeal Access Port and connect the distal end of the Tri-Lumen Filtered Tube Set with Activated Charcoal Filter to the cannula manifold and tighten.

Note: *If the AirSeal Tube Set and Access Port are not appropriately tightened, the pressure reading on the device may not reflect the pressure experienced by the patient. A secure connection can be visually confirmed when one of the white fins on the Tube Set bullseye connector aligns directly to the top of the Access Port (Fig. 15). Looking straight into the bullseye of the Access Port while the Tube Set is connected, one of the fins on the connector piece of the Tube Set should sit directly vertical to the Access Port (Fig. 16).*

The figures below were added to the updated Instructions for Use to illustrate proper setup. **The prior Instructions for Use did not include these figures.**



Please review your inventory of AirSeal® Access Ports and place a copy of the enclosed Instructions for Use, Part No. AS-DISP-IFU, Rev. F with any inventory in your possession with an active expiration date.

Please dispose of any other Instructions for Use in your possession. Clarification of the IFU is meant to assist all customers when using the AirSeal® Access Ports correctly.

Copies of the corrected Instructions for Use are also available electronically for each of the AirSeal® Access Ports at **eifu.conmed.com/eifu**. If you have provided these devices to other facilities or distributors, or you are a distributor, please forward this information as appropriate. It is imperative that all end users of these devices receive this notice.

Please do not return any devices as this is a Field Safety Notice. CONMED is not requesting to remove, dispose or return any of the affected devices. Please complete Appendix A or B and return it with acknowledgement

Please respond to this Field Safety Notice that this letter has been read and understood by using Appendix A for Health Care providers and Appendix B for Importers and Distributors.

The appropriate international competent authorities have been notified of this action.

Follow up:
If you have any questions or requests, please contact the Field Action Support Team at 1-800-448-6506 (8:00am to 7:00pm ET, Monday through Friday) or email accessports2026@conmed.com.

If further information relevant to this issue becomes necessary CONMED will communicate as such. CONMED is dedicated to providing safe and reliable products to our customers and their patients. We are committed to manufacturing products of the highest quality, and we sincerely apologize for any inconvenience this may cause you or your staff.

Sincerely,

Kavita Amin
Regulatory Affairs Manager and Recall Coordinator

Attachments:
AirSeal Access Port IFU: AS-DISP-IFU, Rev. F

Appendix A

AirSeal® Access Ports
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	Pre-filled by manufacturer
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	AirSeal® Access Ports
Product Code(s)	iASB5-150
	iASB12-120
	iASB12-100
	iAS8-120LP
	iAS8-100LP
	iAS5-75LP
	iAS5-120LP
	iAS5-100LP
	iAS12-150LPI
	iAS12-120LPI
	iAS12-100LPI
Batch/Serial Number (s)	N/A

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
Print Name*	Customer print name here
Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email:	accessports2026@conmed.com
Customer Helpline:	1-800-448-6506
Postal Address:	ATTN: Khinthandar Lwin 525 French Road Utica, NY 13502 USA
Deadline for returning the customer reply form*	30 days from receiving the notice

Mandatory fields are marked with *

Appendix B

AirSeal® Access Ports
Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	Pre-filled by manufacturer
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	AirSeal® Access Ports
Product Code(s)	iASB5-150
	iASB12-120
	iASB12-100
	iAS8-120LP
	iAS8-100LP
	iAS5-75LP
	iAS5-120LP
	iAS5-100LP
	iAS12-150LPI
	iAS12-120LPI
	iAS12-100LPI
Batch/Serial Number (s)	

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to sender	
Email:	accessports2026@conmed.com
Distributor/Importer Helpline:	1-800-448-6506
Postal Address:	ATTN: Khinthandar Lwin 525 French Road Utica, NY 13502 USA
Deadline for returning the distributor/importer reply form*	30 days from receiving the notice

4. Distributors/Importers (Check all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have informed the identified customers of this Field Safety Notice	Date of communication:
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

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