



**Field Safety Notice**  
**CONMED Corporation**  
**AirSeal® Access Ports**

May 20, 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, arrhythmias (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:

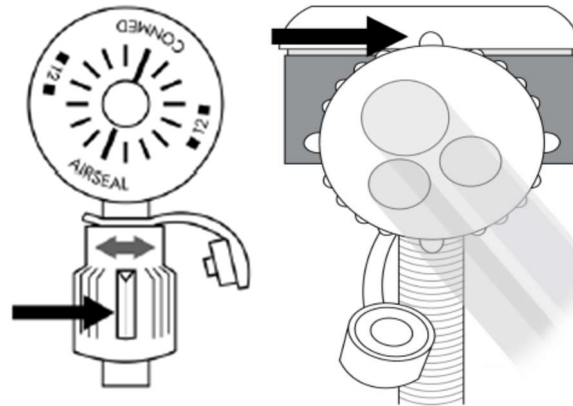
A replacement AirSeal disposable should be available prior to the procedure in order to minimize potential delays. Before initiating insufflation, the user should ensure the tubing is properly connected between the AirSeal tube set and Airseal Access Ports. If the connection cannot be securely tightened 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-DIS-IFU, Rev. B 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](http://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](mailto: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,

A handwritten signature in blue ink that reads 'Kavita Amin'.

Kavita Amin  
Regulatory Affairs Manager and Recall Coordinator

**Attachments:**

AirSeal Access Port IFU: AS-DIS-IFU, Rev. B

**Appendix A****AirSeal® Access Ports  
Customer Reply Form**

|                                                 |                            |
|-------------------------------------------------|----------------------------|
| <b>1. Field Safety Notice (FSN) information</b> |                            |
| 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                        |

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

|                                                                           |                                                                                          |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| <b>3. Customer action undertaken on behalf of Healthcare Organisation</b> |                                                                                          |
| <input type="checkbox"/>                                                  | 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*                                                                     |                                                                                          |

|                                                 |                                                                  |
|-------------------------------------------------|------------------------------------------------------------------|
| <b>4. Return acknowledgement to sender</b>      |                                                                  |
| Email:                                          | accessports2026@conmed.com                                       |
| Customer Helpline:                              | 1-800-448-6506                                                   |
| Postal Address:                                 | ATTN: Khinthandar Lwin<br>525 French Road<br>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

|                                                 |                            |
|-------------------------------------------------|----------------------------|
| <b>1. Field Safety Notice (FSN) information</b> |                            |
| 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)                         |                            |

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

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

|                                                         |                                                                                   |                                      |
|---------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------|
| <b>4. Distributors/Importers (Check all that apply)</b> |                                                                                   |                                      |
| <input type="checkbox"/>                                | *I confirm the receipt, the reading and understanding of the Field Safety Notice. |                                      |
| <input type="checkbox"/>                                | 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 \*