

06 February 2025

FIELD SAFETY NOTICE
for healthcare facilities, physicians and end customers
regarding Hamilton Medical In2Flow Nasal cannulas
Reference#: FSCA-2025-02-03
Recall

Recipients: Healthcare facilities, physicians and end customers which have purchased and/or are using Hamilton Medical In2Flow Nasal cannulas.

Affected Product: Hamilton Medical In2Flow Nasal cannulas with a production date dated after 31.12.2022 and till January 2025 of all sizes and all lot numbers:

Name, Size	Part number:
Hamilton Medical In2Flow Nasal cannulas, Size S	10076606
Hamilton Medical In2Flow Nasal cannulas, Size M	10076605
Hamilton Medical In2Flow Nasal cannulas, Size L	10076604

Hereinafter “In2Flow Nasal cannulas” or “Product”.

Time frame: The document “Confirmation — For Hamilton Medical In2Flow Nasal cannula’s Healthcare facilities/End Users” must be returned to local retailers as quickly as possible, but no later than 45 days after receiving the Field Safety Notice.

Dear Sir or Madam,

This Field Safety Notice (FSN) provides information on the **recall** of the In2Flow Nasal cannula.

A. Background

In August 2023, Hamilton Medical AG initiated a Field Safety Corrective Action (FSCA 2023-08-04) to inform distributors/partners and end users (healthcare professionals) on an issue regarding the In2Flow Nasal cannula because of the potential detachment of the plug (see Figure 1).

Description of the issue: Hamilton Medical AG received several complaints where the plug (the one at the opposite side of the tubing) became detached from the In2Flow Nasal cannula, causing leakage due to unintentional disconnection of that part. This may result in degraded high flow support and oxygen delivery, which could lead to a certain level of patient O2 desaturation.



Figure 1: An In2Flow Nasal cannula size M is shown. The plug became detached from the opposite side of the tubing. (This is an example; sizes S and L of the product are also included in the scope of affected products)

Issue effect: In case the plug becomes detached from the In2Flow Nasal cannula during high flow therapy desaturation of the patient with SpO2 < 80% might result.

Patient risks: If health care staff would not detect and solve the issue of detachment within a short period of time, this might result potentially in prolonged O2 desaturation and thus in serious deterioration in state of health of patients.

B. Recall

Even though a decrease in complaints regarding the Product was noticed, it was decided to preferably **recall** the In2Flow Nasal cannulas from the market. Consequently, Hamilton Medical AG is now conducting this new FSCA as a recall (with a new reference).

**Required actions
by healthcare
facilities/end users:**

We kindly ask you to review your stock with the affected Products and to send the Products back to your local distribution partner of Hamilton Medical AG.

Please sign the outer packaging clearly with the word "RECALL".

Please sign the enclosed/attached sheet to confirm that, as Healthcare facility, you have received and duly noted this FSN.

Kindly note that production of the Product has been discontinued. Distribution Partners of Hamilton Medical AG are delighted to support you in looking for and, if feasible, offering alternative devices.

The local distribution partner as approved by Hamilton Medical to conduct all activities around the Hamilton Medical devices is always the first point of contact in this matter.

Manufacturer:	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Contact:	Hamilton Medical AG Vigilance Team Parc Industrial Vial 10 7013 Domat/Ems Switzerland Tel. +41 58 610 10 20 E-Mail: vigilance.med.global@hamilton-medical.com
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Please keep this field safety notice on In2Flow Nasal cannula in your data records (e.g., with the respective ventilators).

We appreciate your support in this matter and sincerely regret any inconvenience you may experience because of the issue described above.

Sincerely,

Vigilance Team
Hamilton Medical AG

**Confirmation — For Hamilton Medical In2Flow Nasal cannula’s
Healthcare facilities/End Users**

Field Safety Notice

Reference #: FSCA-2025-02-03

By signing this document, I confirm that I have received and noted the current FSN. I also confirm that the described Hamilton Medical In2Flow Nasal cannulas have been sent back to the local distribution partner of Hamilton Medical AG.

I herewith also enclose the compiled and signed FSN.

Product:	Number of <u>returned</u> Products:
In2Flow Nasal cannula, size S: 10076606	
In2Flow Nasal cannula, size M: 10076605	
In2Flow Nasal cannula, size L: 10076604	

By signing this document, I confirm that no further Products are in stock and/or used by our Healthcare facility.

Name:

Healthcare Facility:

Role:

Country:

Date:

Signature:

Sign and return this information sheet by email to your Hamilton Medical AG distribution partner.

Note:

The local distribution partner is always the first point of contact in this matter.