

25. August 2023

FIELD SAFETY NOTICE
for End-Customers using
Hamilton Medical In2Flow Nasal cannulas
Reference #: FSCA 2023-08-04

Recipients: Health care facilities using In2Flow Nasal cannulas from Hamilton Medical AG.

Dear End-Customer,

This Field Safety Notice (FSN) provides information on a Hamilton Medical In2Flow Nasal cannula issue which was reported to Hamilton Medical AG by users.

Hamilton Medical AG is informing about a potential health risk when using the In2Flow Nasal cannula after receiving reports that the plug became detached from the soft part as shown in Figure 1.

Failure description: Several complaints were received 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 may lead to 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 are also affected.)

Failure 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.

- Affected devices:** Hamilton Medical AG In2Flow Nasal cannula of all sizes and all lot numbers are affected.
Product numbers of affected devices:
In2Flow Nasal cannula, size S: 10076606
In2Flow Nasal cannula, size M: 10076605
In2Flow Nasal cannula, size L: 10076604
- Patient risks:** If health care staff does not detect and solve the issue within a short period of time (minutes), this might result potentially in prolonged O2 desaturation and thus in serious deterioration in state of health of patients.
- Required user actions if failure occurs:** In case desaturation is identified, perform as required:
1. Keep monitoring patient's O2 saturation and act accordingly.
 2. Check if plug of In2Flow Nasal cannula became detached.
 3. If the plug is still in place, check for other reasons for O2 desaturation.
 4. If the plug became detached, exchange the affected In2Flow Nasal cannula, and use a new In2Flow Nasal cannula.
- Preventive actions:** Use additional independent monitoring devices, including pulse oximeters measuring SpO2, at all times. (As indicated in the Instructions for Use, Document 10083250/02.)
- Actions to be taken by End-Customers:** Please sign the enclosed/attached sheet to confirm that, as an End-Customer, you have received and duly noted this FSN.

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

Manufacturer:	Hamilton Medical AG Via Crusch 8 CH-7402 Bonaduz Switzerland	Contact:	Hamilton Medical AG Technical Support Parc Industrial Vial 10 CH-7013 Domat/Ems Switzerland Tel. +41 58 610 10 20 Email: techsupport@hamilton-medical.com
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Please inform all users and make this information physically visible for the team members.

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

Confirmation — For HAMILTON MEDICAL In2Flow Nasal cannula End-Customers

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By signing this document, I confirm that I have received and understood the current FSN, stating that the plug may become detached from the In2Flow Nasal cannula causing leakage, which may result in degraded high flow support and oxygen delivery. This may lead to patient SpO2 desaturation.

By signing this document, I confirm that I have received and duly noted the FSN and will follow the instructions provided in this FSN.

Name:

Healthcare Facility:

Country:

Date:

Signature:

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

Note:

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