

25. August 2023

FIELD SAFETY NOTICE
for Distribution Partners of
Hamilton Medical In2Flow Nasal cannulas
Reference #: FSCA 2023-08-04

Recipients: Distribution partners of Hamilton Medical AG.

Dear Distribution Partner,

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.

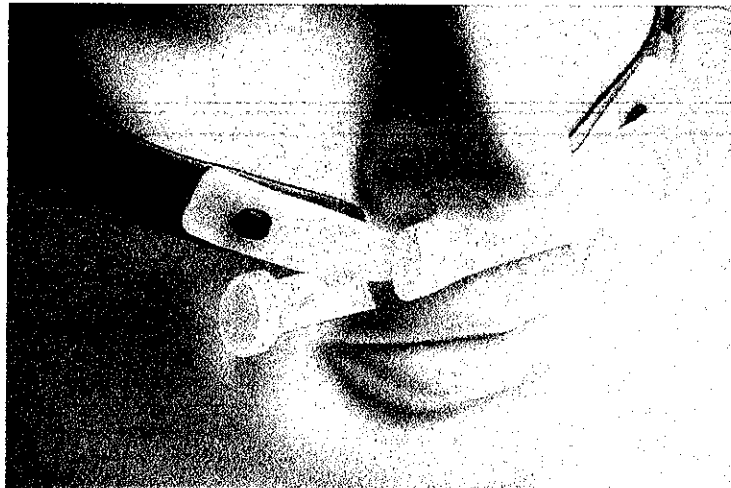


Figure 1: An In2Flow Nasal cannula size M is shown. The plug became detached from the opposite side of the tubing. (This is an example; sizes S and L are also affected.)



Manufacturer: Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

Contact: Hamilton Medical AG
Technical Support
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CH-7013 Domat/Ems
Switzerland
Tel. +41 58 610 10 20
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We appreciate your support in this matter and sincerely regret any inconvenience you may experience because of the issue described above.

Failure effect:	In case the plug becomes detached from the In2Flow Nasal cannula during high flow therapy desaturation of the patient with SpO ₂ < 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 O ₂ 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: <ol style="list-style-type: none">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 SpO ₂ , at all times. (As indicated in the Instructions for Use, Document 10083250/02.)
Additional actions to be taken by distribution partners:	<ul style="list-style-type: none">• Distribution partners are requested and obliged to notify the local authorities if Hamilton Medical AG has not already done so. The report to the local authorities must be made in accordance with your local regulations, but no later than 10 working days after the receipt of this safety notification. Please contact vigilance.med.global@hamilton-medical.com if you have any further questions regarding reportability. The evidence, that the local authorities have been informed, must be filed in the prepared TASK 2 of ky2help.• Translate the End-Customer FSN to your local language, where applicable, and send it to the affected end-customers immediately.• Collect the confirmation sheets from end customers. File the documents locally. This must be completed by 04. October 2023.• If the end customer does not respond promptly, the distribution partner must send and document at least three attempts to obtain feedback from the end customer. If the end customer does not provide a response, document internally, and no further action needs to be taken with respect to this end customer.


Confirmation — For Hamilton Medical's Distribution Partners

Field Safety Notice

Reference #: FSCA 2023-08-04

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 all affected end customers have been informed of this Field Safety Notice and that all signed confirmations are archived locally.

Name: MAHALIA ABDULWAH
Company: STAR MEDIK SDN BHD
Country: MALAYSIA
Date: 05/09/23
Signature: 

Sign this confirmation sheet.

Complete and attach the document "Confirmation - For Hamilton Medical's Distribution Partners" to TASK 1 in ky2help no later than 45 calendar days after receipt of the Field Safety Notice.