SIS MEDICAL
Swiss | Interventional | Systems

SIS Medical AG
Hungerbüelstrasse 12a
CH-8500 Frauenfeld

Frauenfeld, 5. June 2026

Subject: Important voluntary recall request for OPN NC 400-015-004 LOT 220237
Reference Number: FSA260601 – Field Safety Notice

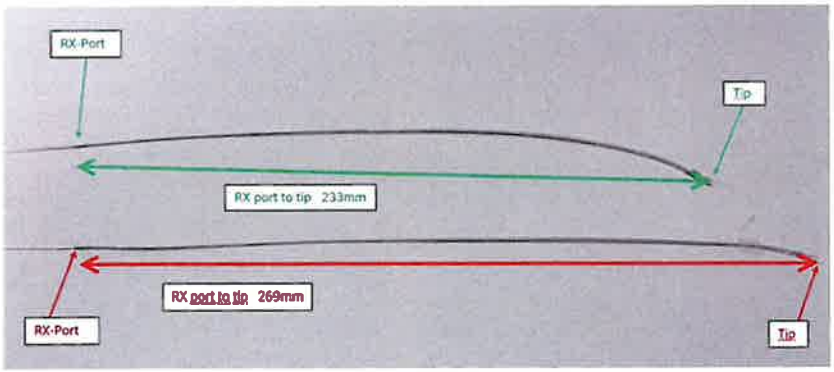
Dear valued Customer,

SIS Medical has identified a potential issue affecting the below mentioned medical device.

Device: OPN NC 400-015-004
LOT: 220237
UDI-DI: 07640142570639

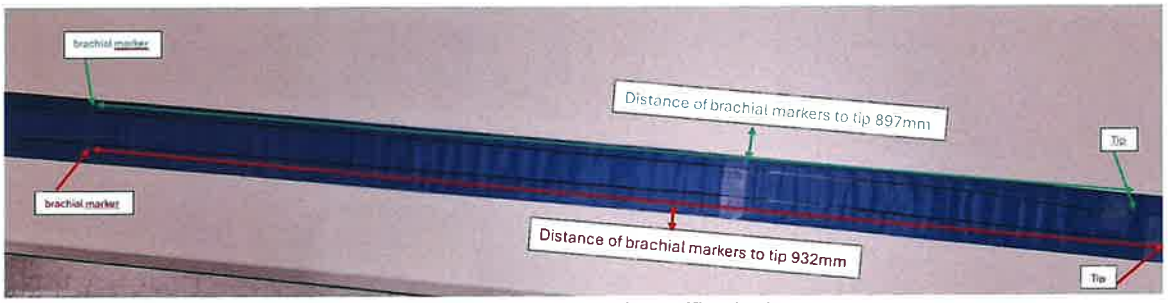
Description of the issue:

As part of a root cause analysis it has been identified that **one product** of **OPN NC 400-015-004 LOT 220237** was manufactured with an incorrect distance from the tip of the catheter to the RX port (Picture 1) and brachial marker (Picture 2). However, the total usable length of the catheter is within its specifications (Picture 3).

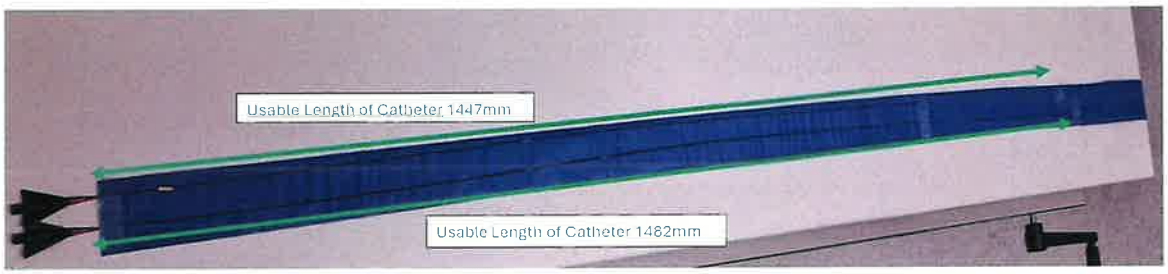


Picture 1: Distance RX-port to tip (out of specification)

SIS Medical AG
Hungerbüelstrasse 12a | CH-8500 Frauenfeld
Phone +41 52 245 09 90 | Fax +41 52 245 09 91
info@sis-medical.com | www.sis-medical.com



Picture 2: Distance between tip and brachial marker (out of specification)



Picture 3: Usable Length (within specification)

Important Note/preliminary risk assessment:

The deviation in dimensions is not expected to have a clinically relevant impact based on the following considerations:

- In clinical practice, the brachial marker is used as a guidance aid to indicate when the catheter tip exits the guiding catheter. A length deviation between brachial marker and catheter tip may potentially result in an initial misalignment between the expected and the actual tip position, but the appropriate positioning of the balloon across the lesion before inflation is performed by means of the balloon location markers under fluoroscopy or intravascular imaging. Moreover, balloon performance (e.g. inflation, compliance behavior, RBP) is not affected by the aforementioned dimensional deviations.
- In clinical practice, the RX-port is used to perform guidewire exchanges when needed. A length deviation between RX-port and catheter tip is not expected to become apparent during clinical procedures, as physicians visually recognize the RX-port. Potential guidewire exchanges are not affected by the aforementioned dimensional deviations.
- From a clinical perspective, a potential relevance of the dimensional deviation cannot be completely excluded when the device is used in combination with 900 mm guiding catheters. However, based on current clinical practice, 1000 mm guiding catheters represent the predominant configuration used during procedures. Therefore, the probability of encountering a clinically relevant impact due to the dimensional deviation is considered low. In addition, final device positioning and treatment decisions are always verified under fluoroscopic and/or intravascular imaging guidance, which further mitigates potential risks associated with the dimensional deviation.

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Overall, the clinical performance of the balloon is not affected, and the aforementioned dimensional deviations are expected to have no clinically significant impact.

Furthermore, to date, zero complaints/incidents have been reported related to this issue. Therefore, also no serious injuries or deaths have been reported.

As a precautionary measure, SIS Medical AG is initiating this voluntary Field Safety Corrective Action (FSCA).

Please take the following actions immediately:

1. Identify all affected products in your inventory.
2. Quarantine and discontinue use of affected devices.
3. Inform all relevant personnel within your organization.
4. Confirm receipt of Field Safety Notice letter and fill and sign the attached product recall form.
5. If affected products have been distributed to other organizations, forward this Field Safety Notice to those customers and provide reception notes to us accordingly.
6. For the return of the products, please contact our Customer Service department info@sis-medical.com

Replacement
All returned products will be replaced free of charge.

We regret any inconvenience caused and thank you for your support in implementing this measure in the interest of patient safety and product quality.

If you have any questions or would like to coordinate the return shipment, please do not hesitate to contact us at any time.

Kind regards

SIS Medical AG

SIS Medical AG
Hungerbüelstrasse 12a | CH-8500 Frauenfeld
Phone +41 52 245 09 90 | Fax +41 52 245 09 91
info@sis-medical.com | www.sis-medical.com

FSA-ID: FSA260601

Product Recall

Customer	

Product Identification			
Product Name	REF	LOT	UDI
OPN NC	400-015-004	220237	07640142570639

Acknowledgement

Please acknowledge a.s.a.p. and return this page duly signed by mail: ra@sis-medical.com

- ☐ **Receipt** of this form
- ☐ **Any** health care professional within the affected organization that needs to be aware of the FSCA has been informed
- ☐ **Inform** SIS Medical AG on all relevant communication sent to the National Competent Authority

Note: the information you provide will be used to track the effectiveness of this Field Safety Action.

Date:	Customer Signature:

FSA-ID:	FSA260601

Consolidation

We confirm that

- ☐ all areas (in house and at customers) where affected products could be stored have been checked and the products were removed to a safe place, if appropriate
- ☐ all hospitals affected by the FSCA were identified and informed, if appropriate
- ☐ all not used products will be returned to SIS Medical AG

REF Number	Lot Number / UDI	Quantities			
		Total Received	Used Qty	Return Qty	Date

Comment:

☐ **Attachment (tick, if appropriate; indicate # of pages) _____**

Date:	Customer Signature:

FSA-ID:	**ID**

Instructions

To guarantee a proper and fast handling of this withdrawal, please follow these instructions:

1. Acknowledgement (Page 1)
   Acknowledge receipt and initiated actions as shown in the acknowledgement section to SIS Medical AG: ra@sis-medical.com

2. Consolidation (Page 2 and attachments, if appropriate)
   Complete this form, fill in the total quantity used and quantities of products that will be returned to SIS Medical AG.

3. Return of Products and original Documentation (Pages 1-3 and attachments, if appropriate)
   Return all available products with the original of this form to

   SIS Medical AG
   Attn. QA/RA
   Hungerbüelstrasse 12c
   CH-8500 Frauenfeld
   Switzerland

   Please make sure that the products are returned a.s.a.p.

4. Questions
   Questions on this Field Safety Action can be sent to: ra@sis-medical.com

Thank you in advance for your assistance.

SIS Medical QA/RA:
Produkte in Quarantäne eingelagert und Listen aktualisiert (Dat./Vis.):