Human Med AG · Wilhelm-Hennemann-Str. 9 · 19061 Schwerin · Germany

2026-06-11

Field Safety Notice

Date: 11 June 2026
To the intention of: Users and customers of Human Med AG
FSCA- Ref.: 2026-003

1. Details regarding the medical device concerned

Device name:	**WAL irrigation and aspiration cannula**
REF no.:	**503001**
Batch no.:	**938823**
Date of manufacture:	**2025-10-27**
Manufacturer:	**Human Med AG**

2. Reason for the Field Safety Notice

This issue was identified following a customer complaint. It was found that, for the afore-mentioned batch, the information on the packaging label does not match the marking on the cannula tube.

Specifically, the label on the packaging indicates the WAL irrigation and suction cannula REF 503001 with a diameter of 3.8 mm and 4 standard suction holes. The marking directly on the cannula tube, however, indicates the cannula variant REF 503002.

The WAL irrigation and suction cannula REF 503002 is a 'RAPID' variant; it has identical dimensions and the same hole geometry as the 'standard' variant REF 503001.Unlike the "standard" variant REF 503001, the suction holes of the "RAPID" variant REF 503002 are specifically designed for indications/treatments requiring more intensive suction.

Due to this discrepancy in the product labelling directly on the product and on the packaging label, clear identification of the cannula cannot be guaranteed, which may lead to misunderstandings regarding the functionality and use of the cannula.

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3. Potential Risk

The use of a 'RAPID' cannula variant exposes the adipose tissue to higher shear forces during suction. If the user fails to recognize that the cannula he is using is a 'RAPID' variant and therefore does not adapt his technique accordingly, this may result in greater tissue trauma than intended. Consequently, increased tissue irritation or injury, haematomas and bleeding may occur.

4. Action required

(1) Prior to use, check the information given on the packaging label of the above-mentioned cannula and on the cannula tube. If the REF numbers do not match, do not use the cannula!

(2) Remove the incorrectly labeled cannula and mark it clearly to prevent further use.

(3) If necessary, inform any internal departments or third parties to whom the affected cannula has been passed on.

(4) Return the incorrectly labeled cannula to Human Med AG or to your supplier. For this, complete the product return form (Attachment 1) and enclose it with your return.

Please confirm receipt of this field safety notice and the return of the above-mentioned cannula using the enclosed confirmation form (Attachment 1) and send it to the email address below.

If you have any questions regarding this safety notice or the measures outlined, please contact our colleague:

Carina Buck
Tel.: 0049 (0)385 39570-25, Mobile: 0049 (0)151 57828292,
Email: buck@humanmed.com

Please contact your supplier for a refund of the original purchase price.

We sincerely apologize for any inconvenience caused and thank you for your understanding.

Kind regards

Bianca Tomuschat
Deputy PRRC (Art. 15 MDR)

Produktrücksendungsfragebogen
Product Return Request Form

BITTE DIESES DOKUMENT AUSSEN AM VERSANDKARTON ANBRINGEN!
PLEASE FIX THIS DOCUMENT TO THE OUTSIDE OF THE TRANSPORT BOX!

Bitte ausfüllen / Please fill out:

Kundeninformationen / Customer information **FSCA-Ref.: 2026-003**

*Rücksendungsdatum / *Return date:

*Kundennummer / *Customer number:

*Adresse / *Address:

*PLZ,Stadt, Land / *Zip code, City, Country:

Firmenname / Company name:

Firmenstempel / Company stamp:

Telefon/ Phone: Email oder Fax / Email or fax:

Produktinformationen/ Product information

*Produktname / *Product name: WAL Spül- und Absaugkanüle

*Artikelnr. / *REF no.: 503001 *Lot-Nr. / Lot no.: 938823

*Menge / *Quantity:

Lieferschein-Nr. / Delivery note no.:

*Grund der Rücksendung / *Reason for product return:

Reklamation / Complaint ☐ Fehlbestellung / Incorrect order ☐

Sonstiges / Others ☑

Kurze Beschreibung /
Short description:

Bei Reklamation / In case of complaint:

☐ Angaben zur Reklamation an / Details on complaint to: complaint@humanmed.com

☑ Das Produkt wurde gereinigt und desinfiziert am / The product has been cleaned and disinfected on:

_____ (Datum / Date)

***Datum, Unterschrift zur Bestätigung, dass das Produkt gereinigt und desinfiziert wurde /**
***Date, Signature to confirm that the product has been cleaned and disinfected** _____

Bei Fehlbestellung / In case of incorrect order:

☐ Das Produkt ist original verpackt. / The product is in its original packaging.

Bitte alle Rücksendungen an / Please send all returns to:

Human Med AG
Wilhelm-Hennemann-Str. 9
19061 Schwerin
- GERMANY –

Wird von Human Med ausgefüllt / To be filled out by Human Med:

Vorgangsnummer / Case number: **F-**

Datum, Unterschrift Empfänger /
Date, Signature of the recipient:

* Pflichtfelder / Mandatory information

Dear Human Med Team,

I hereby confirm that I have read and understood your **Field Safety Notice dated 11 June 2026** relating to the

WAL irrigation and aspiration cannula, REF 503001, LOT 938823

Furthermore I confirm that the affected cannula(s) have been

Quantity: _____ pcs.

☐	Disposed of	Date:

☐	Returned to the supplier	Date:
	Supplier's name and address	

☐	Returned to Human Med AG	Date:

Date:	
Name of the healthcare facility:	
Address:	
Name, first name:	
Signature:	