HUMAN MED®
water-jet assisted medical technologies

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

Field Safety Notice

Date: October 17, 2024
To: Users and customers of Human Med AG

Product name:	Single-use Biofill infiltration cannula 2.5 mm
FSCA- Ref:	2024-012
Article no.:	1580107-5
LOT no:	**24-20198, 23-19612**
Date of manufacture:	**21.08.2024, 04.03.2024**
Manufacturer:	**Human Med AG**

Reason for the Field Safety Notice:

During a routine sample inspection, it was discovered that some cannula tips in the afore-mentioned batches may not have been manufactured to specifications. This could affect the formation of the fan-shaped spray pattern required for infiltration.

Potential hazard:

The cannula tubes are designed so that the fluid directed through the WAL applicator hits the deflection surface in the cannula tip as a focused jet, where it is dispersed into a flat, fan-shaped spray as it exits the cannula.

For the cannula tubes that were not manufactured to specification, it is possible that the fluid does not hit the deflection surface and instead exits the cannula as a concentrated jet.
An unnoticed jet stream could pose a potential risk, especially when treating small body areas such as the face. Nerve damage caused by the jet stream cannot be ruled out.

Measures:

Before using the aforementioned cannula, you must check the spray pattern as instructed in the user manuals for the body-jet (Chapter 4.4) and body-jet evo (Chapter 5.1.3) devices. The spray should exit as a flat, fan-shaped pattern, as shown in Figure 1, not as shown in Figure 2.

If the spray does not exit in a flat, fan-shaped pattern, do not use the cannula. Sort it out and dispose of it properly. Please confirm on the confirmation form (Attachment 1) that the faulty cannula has been correctly disposed of and send it to your distributor or to the email address provided below. For reimbursement of the original purchase price, please contact your distributor.

For any questions, please contact:

Ms. Carina Buck, phone +49 (385) 39570-25, mobile: +49 (151) 57828292
E-Mail: buck@humanmed.com

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Figure 1

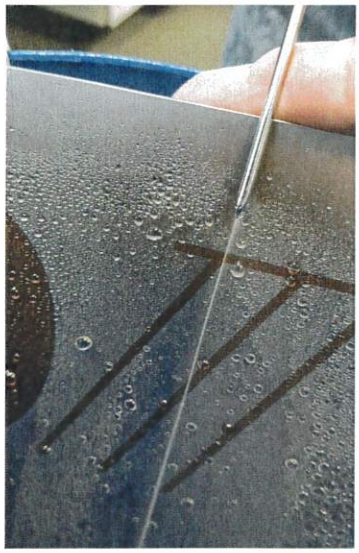
Figure 2

Thank you for your understanding and please excuse any inconvenience this may cause.

Best regards,

Bianca Tomuschat
Quality Management Representative

Attachment 1

Dear Human Med Team,

I hereby confirm that I have read and understood your **Field Safety Notice dated 10/17/2024** regarding the

Single-use Biofill Infiltration Cannula 2.5 mm, REF 1580107/1580107-5

LOT-No. 24-20198 and 23-19612

I further confirm that I have taken the following actions with the affected cannulas, if necessary:

☐ Disposed of

Date:	
Clinic or practice:	
Address:	
Surname, first name:	
Signature:	

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Field Safety Notice

Date: October 17, 2024
To: Distributors of Human Med AG

Product name:	Single-use Biofill infiltration cannula 2.5 mm
FSCA- Ref:	2024-012
Article no.:	1580107-5
LOT no:	**24-20198, 23-19612**
Date of manufacture:	**21.08.2024, 04.03.2024**
Manufacturer:	**Human Med AG**

Reason for the Field Safety Notice:

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Potential hazard:

The cannula tubes are designed so that the fluid directed through the WAL applicator hits the deflection surface in the cannula tip as a focused jet, where it is dispersed into a flat, fan-shaped spray as it exits the cannula. For the cannula tubes that were not manufactured to specification, it is possible that the fluid does not hit the deflection surface and instead exits the cannula as a concentrated jet. An unnoticed jet stream could pose a potential risk, especially when treating small body areas such as the face. Nerve damage caused by the jet stream cannot be ruled out.

Measures:

Do not continue to deliver the concerned products to your users and customers. If the concerned products are still in your warehouse, dispose of them properly.

Please make sure to forward the field safety notice for users and customers (Attachment 1) to the ones who you have supplied with the concerned product. Please confirm with the confirmation form (Attachment 2) that you have read and understood this field safety notice and that all users and customers have been informed accordingly. Send the completed and signed form via email to the address provided below.

For any questions, please contact:

Ms. Carina Buck, phone +49 (385) 39570-25, mobile: +49 (151) 57828292,
E-Mail: buck@humanmed.com

Thank you for your understanding and please excuse any inconvenience this may cause.

Best regards,

Bianca Tomuschat (Quality Management Representative)

Attachment 2

Dear Human Med Team,

I hereby confirm that I have read and understood your **Field Safety Notice dated 10/17/2024** regarding the

Single-use Biofill Infiltration Cannula 2.5 mm, REF 1580107/1580107-5

LOT-No. 24-20198 and 23-19612

I further confirm that I have forwarded the Field Safety Notice for Users and Customers to my users and customers.

I also confirm that I have taken the following actions with the affected cannulas:

☐ Disposed of

Date:	
Company:	
Address:	
Surname, first name:	
Signature:	