

URGENT:
FIELD SAFETY NOTICE / PRODUCT RECALL

BlueLavage® LongBoneTip (BL2004.1)

For the attention of: Healthcare professionals, medical device users and distributors

BfArM FSCA reference number: 36965/26

Date of the Field Safety Notice: 07.08.2026

Responsible person: Robin Lüsebrink

Position: Quality Management Representative at UTK Solution GmbH

Affected Product

Article number	Product description	Affected lot numbers
BL2004.1	BlueLavage® LongBoneTip	260118700418 251012700402 251005700401 250824700393 250525700367

Type of Action

Voluntary product recall / field safety corrective action (FSCA). All remaining products from the above-mentioned lots must be immediately blocked from use and returned via the designated return process.

Description of the Product Problem

During internal quality controls, it was determined that a possible assembly error may have occurred in the above-mentioned lots of the BlueLavage® LongBoneTip. In individual cases, the inner tube may be bonded to the outer tube at one point. This unintended connection may subject the tube system to impermissible mechanical stress, creating a risk of tube breakage.

Potential Risks and Possible Consequences

If the tube breaks, a plastic fragment may become detached and remain in the patient's body. Possible consequences include, in particular, tissue injuries, inflammation, and the need for an additional medical intervention to remove a retained fragment. In the internal risk management process, the failure scenario was assessed in terms of severity and probability of occurrence and classified within the unacceptable risk range. Based on this assessment, the recall and further measures were initiated in order to reduce the risk of recurrence to an acceptable level.

Regulatory Authority Information

The competent higher federal authority, the Federal Institute for Drugs and Medical Devices (BfArM), has been informed of this field safety corrective action. The BfArM reference number is 36965/26.

Required Actions for Customers and Distributors

According to our records, you were supplied with one or more of the affected products. Please read this notice in full and carry out the following actions immediately:

1. Immediately check your entire inventory for BlueLavage® LongBoneTips, article BL2004.1, with the affected lot numbers 260118700418, 251012700402, 251005700401, 250824700393 and 250525700367.
2. Remove all affected products from the point of use, block or isolate them, and ensure that any further use is prevented.
3. Complete the enclosed response form in full and confirm receipt and understanding of this Field Safety Notice as well as the quantity currently in your inventory. A response is required even if no affected product remains in your inventory.
4. Return all remaining products from the affected lots. Returned products will be replaced free of charge.
5. If you have forwarded affected products to other facilities, departments or other recipients, immediately forward this Field Safety Notice to those recipients and document the forwarding in the response form.
6. Ensure that this Field Safety Notice remains observed within your organization until all required actions have been completed and the affected products have been fully withdrawn from circulation.
7. Immediately report to UTK Solution GmbH any incidents or adverse events identified in connection with the product problem described and comply with the statutory reporting obligations applicable to you.

Return

A return label is enclosed or will be provided separately.

Response

Please send the fully completed and signed response form to gm@utk-solution.com by 21.08.2026.

Manufacturer Contact

UTK Solution GmbH
Robin Lüsebrink
Sedanstr.16
58507 Lüdenscheid
gm@utk-solution.com

Note for Distributors

Distributors who have further distributed affected products are requested to immediately forward this Field Safety Notice to all affected customers and to document the responses and recall actions in a traceable manner.

We thank you for your support in carrying out this action and apologize for any inconvenience caused. The safety of users and patients, as well as the reliable quality of our medical devices, are of the highest priority for UTK Solution GmbH.

Yours sincerely

UTK Solution GmbH
Robin Lüsebrink
Quality Management Representative

RESPONSE FORM – BlueLavage® LongBoneTip

BfArM reference number: 36965/26

Response deadline: 21.08.2026

Customer number: _____

Customer name: _____

Customer address: _____

Please complete and sign this form in full. Send it back to gm@utk-solution.com.

Note: By signing, you confirm that you have received and understood the Field Safety Notice and have carried out the required actions. Enter 0 (zero) if no stock remains.

Article / Product	Lot No.	Stock on Hand	Quantity for Return
BL2004.1 BlueLavage® LongBoneTip	260118700418		
BL2004.1 BlueLavage® LongBoneTip	251012700402		
BL2004.1 BlueLavage® LongBoneTip	251005700401		
BL2004.1 BlueLavage® LongBoneTip	250824700393		
BL2004.1 BlueLavage® LongBoneTip	250525700367		

Form completed by

Name in block letters		Title / Position	
Signature		Telephone	
Date		E-mail	

Forwarding of Affected Products

If you have forwarded affected products, please provide the recipients and quantities below, where possible:

Forwarded product(s) / lot	Quantity	Facility / Contact person	Full address

I confirm that I have read and understood this Field Safety Notice and acknowledge receipt.

I confirm that all affected products in our possession have been blocked or isolated and will be returned in accordance with the instructions.

I confirm that I have forwarded or will forward this Field Safety Notice to all parties to whom affected products were supplied.

Name: _____ Signature: _____ Date: _____