

Aachen, 11.07.2025

## Additional safety instructions for Recall 010 lifecath CT PICC easy

As legal manufacturer of the affected product, we would like to provide you with additional safety instructions. The following products and batches are affected:

Code No.	Batch No.
V021292214	230125GF
	210225GG
V021292414	310125GD
V021292514	260225GD

If a catheter from the affected batches is still in use in one of your patients, you must check the gap dimension between the screw nut and catheter tube to determine whether the catheter was assembled with a screw nut with an internal diameter that is too large.

If the screw nut is too large, a wide gap can be seen between the catheter tube and the screw nut (see Figure 1 (right) and 2).



Figure 1: Comparison of the gap dimensions between the correct screw nut (left) and the faulty screw nut (right)

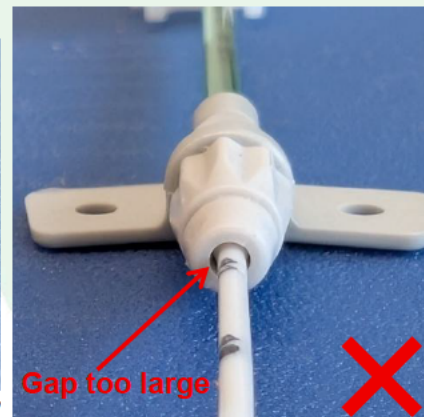
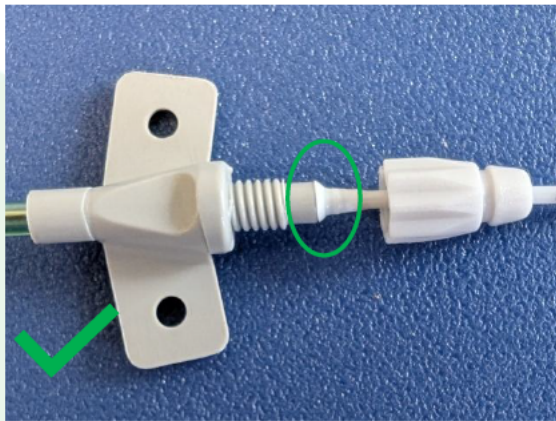


Figure 2: Gap dimension between catheter tube and faulty screw nut

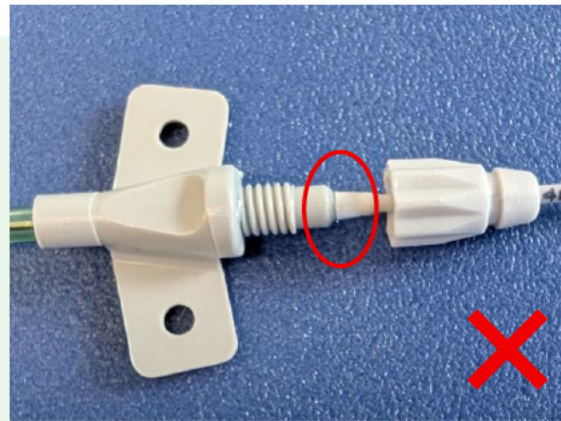
If you are still unsure, you can carefully loosen the nut under aseptic conditions to see whether the catheter tube is properly widened on the pin/plug of the wing.

If this is the case, then it is the correct screw nut (see Figure 3).

Figure 4 shows an insufficiently clamped catheter tube when using a screw nut that is too large.



*Figure 3: Catheter tube sufficiently widened with the correct nut*



*Figure 4: Insufficient widening with incorrect screw nut*

**If it is confirmed that the catheter was assembled with a faulty screw nut, either the extension line or the complete catheter must be replaced with one from a batch number that is not affected by this recall.**

Please acknowledge receipt of this letter and complete and return the attached form, indicating the implementation of the control specified in this safety instructions.

**Additional safety instructions for Recall 010  
lifecath CT PICC easy**

**ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM**

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Please complete and return this form by e-mail to [vigilance@vygon.com](mailto:vigilance@vygon.com)

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<b>Name and address of the institution:</b>	
<b>Full name of the person to contact:</b>	
<b>Function:</b>	
<b>☎ Phone number:</b>	
<b>✉ E-mail:</b>	

**We acknowledge receipt of the above additional safety instructions and that the information contained has been shared with all recipients / end users of above-mentioned products within our organization.**

Signature and date: \_\_\_\_\_