smiths medical

URGENT: FIELD SAFETY NOTICE

Missing Languages in Instructions for Use in Bivona® TTS™ Adjustable Neck Flange Hyperflex™ Tracheostomy Tube

13th March 2025

Dear Valued Customers:

Smiths Medical is issuing this Urgent Field Safety Notice to notify you of instructions that were missing certain languages with the following Bivona® Tracheostomy products listed within this notification. This letter details the issue and the required steps for you to complete.

Issue:
Smiths Medical has identified that the Instructions for Use (P/N 10018848-001) for the Bivona® Tracheostomy products were not fully printed for the following languages: Cesky (cs), Dansk (da), Suomi (fi), Greek (el), Magyar (hu), Norsk (no), Polski (pi), Turkce (tr).

Potential Risk:
The potential risk of not having a fully printed Instructions for Use (IFU) in the required language of the countries could lead to a delay of therapy if a physician is not familiar with the device and could not follow the instructions in the languages already provided. To date, Smiths Medical has received zero (0) reports of serious injury or death.

Table 1: Affected Products(s)

Affected Product SKU	Affected IFU Part Number	Description	Lot #'s
67HA60	P/N 10018848-001	TTS TRACHEOSTOMY TUBE 6.0MM TIGHT TO SHFT ADJUST HYPERFLEX	4329099, 4346846, 4379963, 4389672, 4385525, 4424824, 4424825, 4426133
67HA70	P/N 10018848-001	TTS TRACHEOSTOMY TUBE 7.0MM TIGHT TO SHFT ADJUST HYPERFLEX	4335547, 4335548, 4346849, 4354816, 4346850, 4354819, 4346851, 4362645, 4362647, 4362646, 4367943, 4371704, 4371706, 4381834,4381836,4385530, 4385531, 4385532, 4389676, 4393468
67HA80	P/N 10018848-001	TTS TRACHEOSTOMY TUBE 8.0MM TIGHT TO SHFT ADJUST HYPERFLEX	4346853, 4346854, 4346859, 4362652, 4362651, 4362653, 4373561, 4362655, 4385534, 4385533, 4385540, 4389682, 4393469, 4393471, 4393472, 4408014
67HA90	P/N 10018848-001	TTS TRACHEOSTOMY TUBE 9.0MM TIGHT TO SHFT ADJUST HYPERFLEX	4346861, 4346860, 4346863, 4367938, 4346862, 4376188, 4376187, 4393474

Smiths Medical Action:
Smiths Medical is sending this notification to all Bivona® customers who received affected product. Smiths Medical is also providing replacement Instructions for Use for affected customers within this communication

Customer Required Actions
Please complete the following actions listed below:

1. Check all inventory locations within your institution for the affected product listed in Table 1 and replace the Instructions for Use (P/N 10018848-001) with the one attached to this communication.
2. Share this notification with all potential users of the devices to ensure they are aware of this notification and proposed mitigation. If the devices are used at another location, please ensure this communication is delivered there.
3. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.
4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further inquiries, please contact Smiths Medical using the information provided below:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about product replacement and/or credit.

Your country regulatory agency has been notified of this action

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Andy Mathein
Vice President of Quality

See below:
Customer Response Form

Attached: Instructions For Use P/N 10018848-001

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

Missing Languages in Instructions for Use in Bivona® TTS™ Adjustable Neck Flange Hyperflex™ Tracheostomy Tube

13th March 2025

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it by email to *EMEA-FSN@icumed.com* . If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to EMEA-FSN@icumed.com).

☐ I have **NO** affected product (complete and return this form to EMEA-FSN@icumed.com)

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.