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URGENT: FIELD SAFETY NOTICE

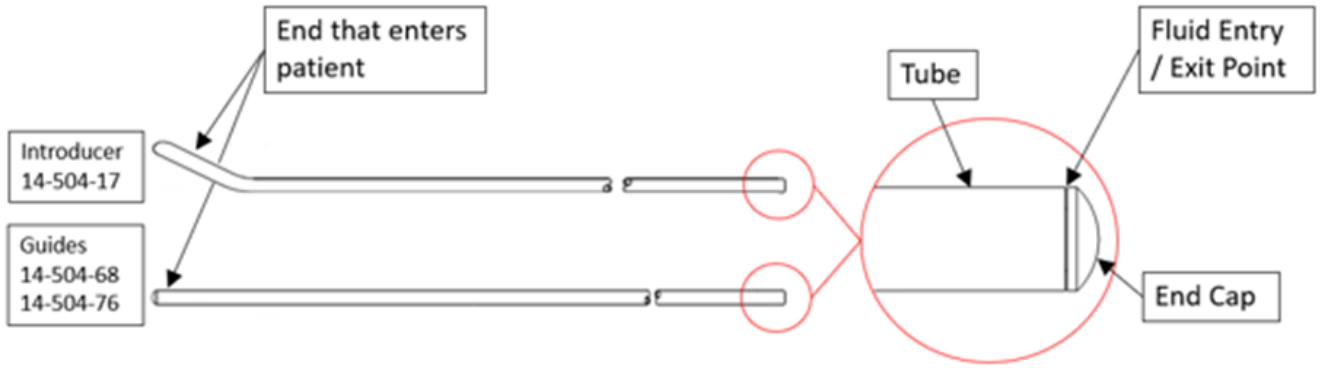
Tracheal Tube Reusable Introducer and Guides

4 November 2024

Dear Valued Customer:

Smiths Medical is issuing this letter to notify you of a potential issue with the Reusable Introducers and Guides. This letter details the issue and the required steps to perform.

Issue:
Smiths Medical has identified a potential for ingress of fluid into the device during reprocessing. The ingress takes place at the rear of the device between the end cap and the tube. This could lead to staining of the device or allowing the fluid to remain in the device. In addition, the Hypochlorite Solution (200ppm) and the 4% Acetic Acid disinfectants recommended in the IFU may be inadequate according to the disinfection standards for this type of device.



Potential Risk
The potential risk of the ingress of the fluid during processing could lead to delay in treatment, which could potentially lead to hypoxia or epistaxis.

The potential risk for inadequate instructions for use associated with disinfection could lead to infection, cross infection or an inflammatory response.

To date, Smiths Medical has received zero (0) complaints or adverse events associated with this issue.

Affected Product

The affected product SKUs are listed in the table below.

Table 1: Affected Product(s)

SKU	Description	Date of Manufacture
14-504-17	Tracheal Tube Introducer Woven Coude Tip 15CH 60cm	28-Sep-2019 through 27-Dec-2022
14-504-68	Tracheal Tube Guide Woven Straight 15CH 70cm	12-Dec-2019 through 24-Dec-2022
14-504-76	Tracheal Tube Guide Woven Straight 10CH 70cm	03-Sep-2019 through 12-May-2022

Please refer to Appendix A for associated lot numbers.

Smiths Medical Actions:

Smiths Medical is sending this notification to all customers who received affected product as listed above.

Smiths Medical no longer distributes any of the affected products. Smiths Medical will provide full credit to affected customers.

Customer Required Actions:

1) Check all inventory locations within your institution for the impacted lot numbers listed in the notification (Appendix A) and discontinue use. Destroy all affected products following your institution's process for destruction. If destroying is not immediately possible at your facility, then the product should be quarantined until disposal.

2) Share this notification with all potential users of the device, to ensure they are aware of this notification. 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, even if you do not have the affected product.

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 the applicable team using the following information:

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 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:

- Appendix A – Impacted Lot Numbers
- Customer Response Form

Appendix A – Impacted Lots

Item	Lot
14-504-17	0003121, 0003122, 0003123, 0003126, 0003127, 0003128, 0003129, 0003131, 0003132, 0003133, 0003134, 0003135, 0003136, 0003137, 0003138, 0003141, 0003142, 0003143, 0003145, 0003146, 0003147, 0003149, 0003150, 0003153, 0003155, 0003157, 0003158, 0003159, 0003160, 0003163, 0003164, 0003166, 0003167, 0003168, 0003171, 0003172, 0003173, 0003174, 0003175, 0003177, 0003178, 0003180, 0003181, 0003182, 0003183, 0003190, 0003191, 0003193, 0003194, 0003197, 0003198, 0003199, 0003200, 0003201, 0003202, 0003203, 0003208, 0003209, 0003211, 0003212, 0003213, 0003214, 0003215, 0003216, 0003217, 0003219, 0003221, 0003224, 0003227, 0003228, 0003231, 0003233, 0003237, 0003238, 0003240, 0003242, 0003243, 0003244, 0003245, 0003246, 0003247, 0003248, 0003249, 0003250, 0003251, 0003252, 0003253, 0003257, 0003258, 0003259, 0003260, 0003261, 0003262, 0003263, 0003264, 0003265, 0003266, 0003268, 0003269, 0003270, 0003271, 0003272, 0003273, 0003274, 0003275, 0003278, 0003279, 0003280, 0003281, 0003282, 0003283, 0003284, 0003285, 0003286, 0003287, 0003288, 0003289, 0003290, 0003291, 0003292, 0003294, 0003296, 0003297, 0003299, 0003302, 0003303, 0003304, 0003305, 0003306, 0003309, 0003312, 0003313, 0003316, 0003317, 0003318, 0003319, 0003320, 0003321, 0003323, 0003324, 0003325, 0003326, 0003327, 0003328, 0003330, 0003331, 0003332, 0003333, 0003334, 0003335, 0003336, 0003337, 0003338, 0003340, 0003341, 0003351, 0003383, 0003384, 0003385, 0003387, 0003390, 0003392, 0003396, 0003397, 0003398, 0003400, 0003401, 0003404, 0003405, 0003406, 0003408, 0003409, 0003410, 0003411, 0003412, 0003413, 0003415, 0003416, 0003417, 0003418, 0003419, 0003420, 0003421, 0003422, 0003426, 0003427, 0003428, 0003429, 0003430, 0003431, 0003432, 0003434, 0003435, 0003438, 0003440, 0003444, 0003445, 0003447, 0003448, 0003450, 0003451, 0003452, 0003453, 0003454, 0003455, 0003458, 0003461, 0003462, 0003463, 0003464, 0003465, 0003466, 0003468, 0003470, 0003471, 0003472, 0003473, 0003474, 0003475, 0003481, 0003482, 0003483, 0003486, 0003487, 0003488, 0003490, 0003491, 0003493, 0003495, 0003496, 0003497, 0003498, 0003499, 0003501, 0003502, 0003503, 0003504, 0003505, 0003506, 0003507, 0003508, 0003512, 0003513, 0003514, 0003515, 0003516, 0003517, 0003518, 0003519, 0003520, 0003521, 0003523, 0003524, 0003525, 0003526, 0003527, 0003528, 0003531, 0003534, 0003536, 0003546, 0003548, 0003552, 0003558, 0003567, 0003572, 0003578, 0003586, 0003596, 0003598, 0003612, 0003616, 0003617, 0003618, 0003620, 0003624, 0003625, 0003630, 0003631, 0003632, 0003641
14-504-68	0003165, 0003184, 0003196, 0003204, 0003206, 0003226, 0003254, 0003256, 0003267, 0003300, 0003307, 0003308, 0003314, 0003322, 0003357, 0003358, 0003359, 0003360, 0003361, 0003362, 0003363, 0003364, 0003369, 0003380, 0003393, 0003394, 0003634, 0003635, 0003643
14-504-76	0003124, 0003130, 0003139, 0003140, 0003144, 0003148, 0003152, 0003161, 0003169, 0003185, 0003205, 0003210, 0003222, 0003232, 0003236, 0003255, 0003276, 0003277, 0003301, 0003315, 0003329, 0003339, 0003367, 0003370, 0003371, 0003372, 0003373, 0003374, 0003375, 0003376, 0003381, 0003391, 0003395, 0003399, 0003403, 0003414, 0003469, 0003476, 0003477, 0003480, 0003484, 0003489, 0003492, 0003500, 0003510, 0003511, 0003522, 0003549, 0003557, 0003619, 0003621, 0003622

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

Tracheal Tube Reusable Introducer and Guides

4 November 2024

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
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	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to Smiths Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

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.

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ADDITIONAL AFFECTED PRODUCT DESTROYED

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction