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Smiths Medical ASD, Inc.
5700 W 23rd Avenue
Gary, IN 46406

URGENT FIELD SAFETY NOTICE

For Bivona® Inner Cannula

Affected Devices:	Bivona® Inner Cannula
Type of Action:	Field Safety Corrective Action – Safety Alert
Date:	17 April 2015
Attention:	Risk/ Safety Managers, Clinicians, Nursing, Emergency Departments, Respiratory Therapy, and other users of these devices
Details on affected devices:	**All Product Reorder Number and Lot Numbers** See Attachment B for list of Reorder and Lot Numbers

Dear Valued Customer:

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of additional information for the safe and effective use of Bivona® Inner Cannula. Smiths Medical is voluntarily taking this action with the knowledge of relevant Regulatory Agencies.

Smiths Medical has become aware of the potential for compression of the inner cannula to occur as a result of handling or certain cleaning methods used with inner cannulae. Compression can result in a shorter overall length. Use of an inner cannula which is too short may lead to a build-up of secretions within the end of the tracheostomy tube which may cause infection or occlusion. Smiths Medical has received a small number of customer reports regarding this issue, with no reports of permanent injury.

Bivona® Inner Cannulae are constructed of a soft and flexible material (ePTFE) and should be handled and cleaned with care, and according to the Instructions for Use ("IFU"). If difficulty is experienced when inserting the inner cannula into the tracheostomy tube, do not use excessive force as this may cause compression of the inner cannula. If this occurs, discard the damaged inner cannula and use a new one.

To clean the inner cannula, follow the cleaning process as outlined in the IFU. Do not resterilize or use brushes, autoclaves, dishwashers, vigorous or aggressive cleaning methods, or any solution to clean the inner cannulae (other than sterile water or saline). If you are unable to remove secretions following the cleaning instructions in the IFU, then discard the used inner cannula and use a new one. Patients who have thick, tenacious, or large volumes of secretions may require more frequent inner cannula replacements, if you are unable to easily remove secretions using the cleaning methods described in the IFU.

We are in the process of reviewing and revising our Instructions for Use and will provide you with information on the revised IFU upon release.

Advice on Action to be Taken by the User:
Subject to this Field Safety Notice, Smiths Medical is requesting its customers acknowledge receipt and understanding of this information.

1. Complete and return the attached Confirmation Form (see Attachment A) by Fax to 1-866-305-9874 or by E-Mail to bivonaic@smiths-medical.com within 7 days of receipt of this Notice.

Transmission of this Field Safety Corrective Action
This notice shall be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this safety alert.

Customers should report any issues with these products to Smiths Medical's Global Complaint Department at 1-866-216-8806 or globalcomplaints@smiths-medical.com.

If you should have any questions regarding this information, please contact your local sales representative or Smiths Medical's Customer Service Department.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may have caused.

Sincerely,

Cheryl Stadler
Quality Systems Manager
Smiths Medical ASD, Inc.

Enclosures: Attachment A – Confirmation Form
Attachment B – List of Affected Devices

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ATTACHMENT A

URGENT FIELD SAFETY NOTICE- CONFIRMATION FORM
For Bivona® Inner Cannula

17 April 2015

Customer Account No. _____

Please complete and return this Form by fax to 866-305-9874 or by sending an electronic copy via email to bivonaic@smiths-medical.com

☐ **YES** – I have read and understand the Urgent Medical Device Safety Alert for Bivona® Inner Cannula	
☐ **NO** – I do not understand the Urgent Medical Device Safety Alert for Bivona® Inner Cannula and wish for someone to contact me	
Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: ( )

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ATTACHMENT B

PRODUCT NAME/DESCRIPTION, REORDER NUMBER, & LOT NUMBER

Product Name/ Description	Reorder No.	Lot No.
Bivona® Inner Cannula, 7.0mm	BRC270	2263224, 2289250, 2312819, 2347367, 2397658, 2651074, 2675970, 2696150, 2723918, 2759081, 2783472, 2844997, 2885873, 2892500
Bivona® Inner Cannula, 7.5mm	BRC275	2263225, 2312820, 2378348
Bivona® Inner Cannula, 8.0mm	BRC280	2263226, 2312821, 2378349, 2618720, 2687741, 2715862, 2759082, 2771720, 2817842, 2844998, 2882377, 2885874, 2892501, 2899448
Bivona® Inner Cannula, 8.5mm	BRC285	2263227, 2347368
Bivona® Inner Cannula, 9.0mm	BRC290	2263228, 2347369, 2521425, 2618721, 2696149, 2759083, 2805411, 2822622, 2844999, 2892502, 289449
Bivona® Inner Cannula, 7.0mm	BRCA70	2263229, 2347370, 2378350, 2651077, 2651079, 2663115, 2899450, 2927992
Bivona® Inner Cannula, 7.5mm	BRCA75	2187719, 2347371, 2447185, 2478194, 2508399, 2521426, 2618722, 2749985, 2771698, 2771699
Bivona® Inner Cannula, 8.0mm	BRCA80	2263230, 2347372, 2378351, 2447186, 2478195, 2500377, 2521427, 2533974, 2618724, 2618725, 2805254, 2805268, 2817844, 2822606, 2822607, 2822623, 2845000, 2892503
Bivona® Inner Cannula, 8.5mm	BRCA85	2263231, 2347373, 2378352, 2447197, 2478196, 2500378, 2565938, 2618726, 2749984, 2749986, 2845001, 2892504, 2899452, 2915187, 2927994
Bivona® Inner Cannula, 9.0mm	BRCA90	2181117, 2347374, 2478197, 2533979, 2583018, 2651075, 2651076