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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Affected Device:	Bivona® Inner Cannula Tracheostomy Tube
Affected Model Numbers:	BRC270, BRC275, BRC280, BRC285, BRC290, BRCA70, BRCA75, BRCA80, BRCA85, BRCA90 Purchased Prior to August 2018
Type of Action:	Field Safety Corrective Action
Date:	September 11, 2018
Attention:	Users and Distributors of the Bivona® Inner Cannula

Dear Customer,

This Field Safety Notice is being issued to alert you to the release of an updated device Instructions for Use (IFU) for the product models listed above. As of August 2018, this revised IFU has been included with all new shipments of these products. **No return of product is required in response to this Field Safety Notice.**

DESCRIPTION OF ISSUE
As previously indicated in an April 2015 field communication, Smiths Medical became aware of the potential for compression of the inner cannula to occur as a result of handling or certain cleaning methods. Compression can result in a shorter overall length. The revised IFU contains cleaning guidelines that must be followed to ensure device integrity.

RISK TO PATIENT
The 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 could potentially cause infection or occlusion.

REQUIRED ACTIONS
All customers who purchased these affected device models prior to August 2018 should identify any affected product within their possession and refer to the attached IFU for information on device cleaning. Please complete and return the attached Response Form to fieldactions@smiths-medical.com to acknowledge your receipt and understanding of this Field Safety Notice. **You must return a Response Form even if you no longer have affected product in your possession.** If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients copies of this Field Safety Notice and Response Form. No return of product is necessary; this notification is being provided for awareness only.

Sincerely,

Dr. G. Barrett
Vice President, Quality Systems, Regulatory and Compliance
Smiths Medical

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Bivona® Inner Cannula Tracheostomy Tube Instructions for Use (IFU) Update

Please complete this Response Form and return it to **fieldactions@smiths-medical.com** within 10 days of receipt. This form must be completed even of you no longer have affected product in your possession. **No return of product is required in response to this Field Safety Notice.**

☐ I have read and understand the attached Urgent Medical Device Field Safety Notice regarding the release of an updated Instructions for Use (IFU) for the Bivona® Inner Cannula tracheostomy tube	
Facility Name:	Facility Address:
Printed Name:	Signature:
Department:	Date:
Email:	Phone Number: ( )