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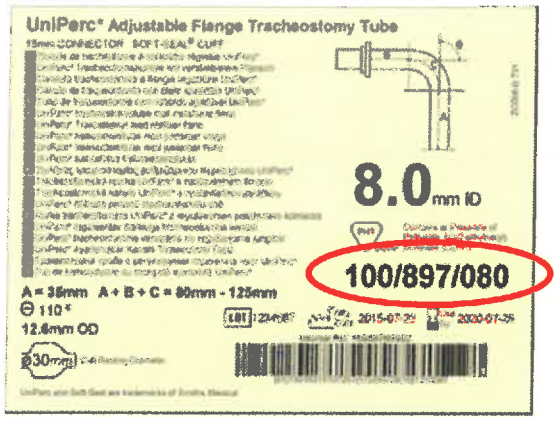
URGENT MEDICAL DEVICE RECALL

Affected Device: UniPerc® Adjustable Flange Tracheostomy Tube Kit

Type of Action:	Removal
Date:	August 7, 2017
Attention:	Distributors of, and Clinicians who use, the UniPerc® Adjustable Flange Tracheostomy Tube kit, product reorder number 100/897/080, lot number 3308971



Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall for one lot of the UniPerc® Adjustable Flange Tracheostomy Tube Kit. A total of 89 units are included in this recall. Model and lot number information of affected product in your possession can be found on the Urgent Medical Device Recall Response Form accompanying this notice.

REASON FOR RECALL:

Smiths Medical became aware that one lot of the 8.0mm UniPerc® Adjustable Flange Tracheostomy Tube kit, product reorder number 100/897/080 CZ, lot number 3308971, contains a 9.0mm sized obturator instead of the correct 8.0mm sized obturator. As a result, the 9.0mm obturator cannot physically be inserted into the 8.0mm tracheostomy tube due to the incompatible dimensions of the tracheostomy tube and the obturator. This may result in a delay in the surgical placement of the tracheostomy tube.

RISK TO HEALTH:

A delay in the surgical placement of the tracheostomy tube has the potential to result in serious injury to the patient. The severity of potential injury to the patient would depend on the patient's condition and the

amount of time the surgical procedure is delayed, which is dependent on local availability of a kit with a correctly sized obturator.

Tracheostomy tubes are placed surgically in a patient that is intubated with an endotracheal tube and, therefore, has a protected airway. During preparation, the clinician ensures the obturator moves freely and can be easily removed from the tracheostomy tube prior to placement in the patient so the issue is readily apparent.

Smiths Medical has not received any reports of deaths or serious injuries related to this issue.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS RECALL:

1. Locate the affected UniPerc® Adjustable Flange Tracheostomy Tube kit(s) in your possession by referring to the attached Urgent Medical Device Field Recall Response Form. This form provides the specific number(s) of UniPerc® Adjustable Flange Tracheostomy Tube kit(s) your organization purchased. The lot number of these devices can be found on the yellow device label attached to the shelf carton box and on unit package.

2. Determine the number of affected devices in your possession and complete the Urgent Medical Device Field Recall Response Form attached to this letter within 10 days of receipt and send it to Smithsunipercrecall@stericycle.com. The form must be returned even if you do not have any of the affected UniPerc® Adjustable Flange Tracheostomy Tube kit(s) in your possession. Product credit will be processed once the Urgent Medical Device Field Recall Response Form is received.

3. All affected devices must be returned to Stericycle for processing. Pre-paid shipping labels are included with this notice. Package the affected devices and include a copy of the completed Urgent Medical Device Field Recall Response Form inside EACH BOX of returned devices so that you will obtain proper credit for returned devices. Make sure boxes are sealed and labeled with your facility name prior to shipping devices to Stericycle.

4. If you have distributed potentially affected devices to your customers, please immediately notify your customers of this Recall.

If you have any questions regarding this notification, please contact Stericycle via email at Smithsunipercrecall@stericycle.com.

Please report any issues with these products to Smiths Medical's Global Complaint Department via email at globalcomplaints@smiths-medical.com.

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

Sincerely,

[redacted]

Christine Thomas
Vice President Quality Systems, Regulatory and Compliance
Smiths Medical
fieldactions@smiths-medical.com

Enclosure: Attachment 1 – Recall Response Form

ATTACHMENT 1

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URGENT MEDICAL DEVICE FIELD RECALL

RESPONSE FORM

Affected Device:

UniPerc® Adjustable Flange Tracheostomy Tube Kit

Product Number 100/897/080 CZ; Lot Number 3308971

Please assist us in making this Recall Notification process as efficient and convenient for you as possible by completing and returning this form via email to Smithsunipercrecall@stericycle.com within 10 calendar days of receipt of this Urgent Medical Device Recall Notice. This will serve as confirmation that you have received and understand the notification, and will allow us to ensure that we have reached all customers who may be affected by this voluntary recall. Please return this response form even if you do not have any potentially affected product.

Facility Name
Address
Zip code, city, Country

According to our records, you have received the following UniPerc® Adjustable Flange Tracheostomy Tube kits affected by this recall:

Product Number	Product Description	Lot Number	Quantity Purchased	Quantity to be Returned
100/897/080 CZ	UniPerc® Adjustable Flange Tracheostomy Tube Kit	3308971		
		Totals		

Name and title (Please print)	Signature	Date
Email Address	**Telephone Number**	