URGENT MEDICAL DEVICE RECALL NOTIFICATION

PRODUCT: Stryker® T4 and T5 Togas

ATTENTION: OR DIRECTOR, RISK MANAGER, MATERIALS MANAGER

March 6, 2018

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling specific lots of various T4 and T5 Togas.

Product Number	Description	Affected Lots	Distribution Dates
0400-710-000	T4 Pullover Toga, (S/M)	17071877	12-19-2017 to 12-28-2017
0400-760-000	T4 Pullover Toga, Large	17061780	12-27-2017 to 2-14-2018
0400-770-000	T4 Pullover Toga, X-Large	17061775, 17061781, 17061784, 17061793, 17102891, 17102916, 17102925, 17113013, 17113083	9-14-2017 to 2-2-2018
0400-820-000	T4 Zipper Toga, (L/XL)	17061810, 17061814, 17071903, 17071918, 17071920, 17071949, 17071960, 17071970, 17071974, 17071997, 17072002, 17072006, 17072016, 17102926, 17102971, 17113133	10-2-2017 to 2-14-2018
0400-820-100	T5 Zipper Toga with Peel-Away Face Shield, (L/XL)	17061816, 17061836, 17061839, 17061853, 17071921, 17072017, 17102948	8-8-2017 to 2-14-2018
0400-830-000	T4 Zipper Toga, Regular	17113204	2-6-2018
0400-850-000	T4 Zipper Toga, X-Large	17061835, 17061838, 17071891, 17071904	12-5-2017 to 1-16-2018

Risk to Health:
There is no additional risk to health.

Reason for the Voluntary Recall:
Raw materials received from the supplier were not within specification leading to a potential for delamination (separation of material layers) to occur.

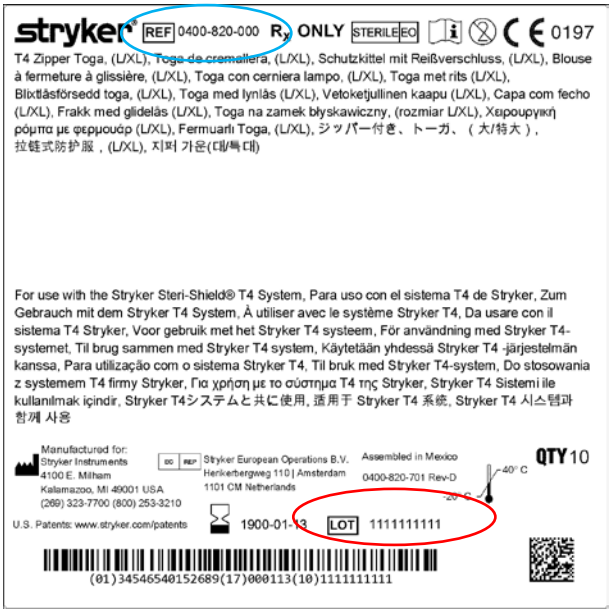
Product Description:
T4 and T5 Togas are components of the Stryker Steri-Shield Personal Protection System and are intended to be worn over any Stryker T4 or T5 Helmet.

Stryker Instruments
4100 E Milham Road, Kalamazoo, MI 49001 USA | P 269 389 4518| F 866 521 2762

Location of Product Number (blue) and Lot Number (red) on the packaging labels:

Package Label

Carton Label



Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.
2. Immediately check all stock areas and/or operating room storage for affected products. Quarantine and discontinue use of any affected T4 and T5 Togas.
3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this Notification and identify how many affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email to kara.spath@stryker.com.
   Note: Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.
4. If you have further distributed this product, please forward this Notification and the attached BRF to all affected locations. Please indicate each location on the BRF.
5. If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you and should be used to return recalled product. Upon receipt of the recalled product, a credit will be issued to your account.

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either by fax or phone, or online. Fax: (800) FDA-0178 Phone: (800) FDA-1088
Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm

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BUSINESS REPLY FORM

Stryker® T4 and T5 Togas

March 6, 2018

Quantity Shipped (Boxes of 10)	Product Number Shipped	Lot Number(s) of Recalled Product Shipped	Quantity On Hand (Each)	Lot Number(s) of Product On Hand

If you don't have any recalled T4 or T5 Togas on hand, please indicate "0" in the "Quantity On Hand" box (above).

1. Immediately review the Recall Notification.
2. Immediately check all stock areas and/or operating room storage to determine how many affected products are at your facility. Quarantine and discontinue use of any affected T4 and T5 Togas.
3. Complete this Business Reply Form (BRF) even if you don't have any affected product on hand. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email to kara.spath@stryker.com.
   Note: Your signature indicates that you have received and understand the notification and have quarantined all unused affected product.
4. If you have further distributed this product, please forward the letter and BRF to all affected locations. Please indicate each location on the BRF.
5. If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you. This shipping label should be used to return recalled product. Upon receipt of the recalled product, a credit will be issued to your account.

Acct: Account #:

Print Customer Name | Customer Title

Contact Phone Number | Customer Signature | Date

Email Address | Fax Number

If you have further distributed any affected product, please indicate to whom below:

Name Address City State Zip

Contact Person Phone Number Part Number(s) and Quantities

Instruments

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