Cc: Chairmand Medical Board and relevant Head of Department

URGENT MEDICAL DEVICE RECALL NOTIFICATION

PRODUCT: Color Cuff® Disposable Tourniquet Cuffs

ATTENTION: OR DIRECTOR, RISK MANAGER, MATERIALS MANAGER

Cc Chairman Medical Board and relevant Head of Department

November 6, 2019

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling four specific lots of Color Cuff Disposable Tourniquet Cuffs.

Product Number	Description	GTIN	Affected Lots
5921-018-135	Color Cuff - Disposable 18X3, 1BLA, 1PRT Quick	37613154599258	60180348 60180373
5921-018-235	Color Cuff - Disposable 18X3, 1BLA, 2PRT Quick	37613154599296	60180374 60181194

Risk to Health:
A loss of vascular occlusion may lead to operative site blood loss/hemorrhage or in exceedingly rare situations other major complications.

Reason for the Voluntary Recall:
There is a potential for the cuff to leak air leading to a loss of vascular occlusion.

Product Description:
The Stryker Disposable Tourniquet Cuff is indicated for use in surgical procedures that require the temporary occlusion of blood flow in a patient's extremities during surgical procedures to produce greater visualization of the operative field.

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

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

Actions to be taken:

1. Immediately review this Recall Notification and the Business Reply Form.
2. Immediately check all stock areas and/or operating room storage for affected products. Quarantine and discontinue use of any Color Cuff Disposable Tourniquet Cuffs identified in this Notification.
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. Return the completed BRF via fax (866-521-2762) or email to [redacted]

   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 copies of this Notification and the BRF to all affected locations, for each location to complete and return. Even if you have distributed all product to another location, please complete a BRF and indicate each location that received product.
5. If the BRF for your facility indicates that recalled product is currently on hand, a shipping label will be provided which should be used to return recalled product. Upon receipt of the recalled product, a credit will be applied 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.

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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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