URGENT MEDICAL DEVICE RECALL NOTIFICATION

AutoPlex® System

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

June 13, 2016

Dear AutoPlex® System Customer,

The purpose of this letter to advise you that Stryker Instruments is voluntarily recalling the following AutoPlex® System Product Numbers/Lot numbers:

For purposes of being able to readily locate recalled product within your inventory, we are providing two methods for identifying the affected AutoPlex® Systems: 1. By Sterilization Lot Number listed on the corrugated shipper and plastic bag (See Fig. 1) and/or 2. By Manufacturing Lot Number listed on the individual blister packs (See Fig. 2).

Product Number	Product Description	Sterilization Lot Numbers	Manufacturing Lot Numbers
0605-683-000	AUTOPLEX W/VERTAPLEX AND 11G NDL	16071012	16063012
0605-687-000	AUTOPLEX W/VERTAPLEX	16041012, 16047012, 16111012	16036012, 16039012, 16102012
0605-887-000	AUTOPLEX W/O NDL. INTL	N/A (Please use Manufacturing Lot Number).	16022012, 16040012, 16050012, 16057012, 16069012, 16078012, 16104012, 16112012, 16124012
0607-687-000	AUTOPLEX W/VERTAPLEX HV	16021012, 16022012, 16025012, 16025022, 16026012, 16026022, 16027012, 16027022, 16028012, 16028022, 16033012, 16041012, 16048012, 16048022, 16049012, 16049022, 16049032, 16053012, 16056012, 16056022, 16060012, 16061012, 16063012, 16063022, 16070012, 16070022, 16074012, 16088012, 16092012, 16098012, 16100012, 16104012, 16104022, 16105012, 16106012, 16107012, 16109012, 16109022, 16113022, 16113032, 16118012, 16118022	16015012, 16016012, 16017012, 16018012, 16019012, 16020012, 16021012, 16022012, 16025012, 16036012, 16039012, 16041012, 16042012, 16043012, 16047012, 16048012, 16049012, 16053012, 16054012, 16055012, 16056012, 16062012, 16063012, 16064012, 16077012, 16081012, 16095012, 16096012, 16097012, 16098012, 16099012, 16100012, 16103012, 16106012, 16109012, 16110012

Reason for Voluntary Recall: The valve on the AutoPlex® System's injection assembly may become blocked, resulting in a cement backflow towards the injector handle.

Risk to Health: There is a potential for a delay in surgery if additional cement needs to be prepared for the injection procedure.

Product Description: The AutoPlex® System is used for mixing bone cement and delivering the bone cement percutaneously.

Instruments

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Fig. 1 Corrogated shipper & plastic bag label. Part and lot numbers are circled.

Fig. 2 Blister pack label. Part and lot numbers are circled.

Actions to be taken by the Customer/User:

1. Immediately review the Recall Notification.
2. Check all stock areas and/or operating room storage to determine how many AutoPlex® Systems are at your facility. Quarantine and discontinue use of the affected AutoPlex® Systems.
3. Complete the Business Reply Form (BRF) even if you don't have any affected product on hand. Fax the completed, signed BRF to Stryker Instruments at 866-521-2762, or scan and email a copy to jennifer.olson@stryker.com.

   Note: Your signature indicates that you have received and understand the notification and have quarantined all unused affected product. Please keep a copy of this completed form for your records
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 this form indicates that affected product is on hand, then Stryker Instruments will schedule your facility to receive replacement product upon receipt of the form.
6. If this form indicates that affected product is on hand, a FedEx shipping label will also be emailed to the email address provided below to return the affected product to Stryker Instruments.

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 online, or by fax or phone. Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm Fax: (800) FDA-0178 Phone: (800) FDA-1088

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.

For questions regarding this recall, please contact Stryker Instruments:

Jennifer Olson
269-389-2644
jennifer.olson@stryker.com