stryker

URGENT MEDICAL DEVICE RECALL NOTIFICATION

Product: Stryker Instruments - multiple disposable products

ATTN: Risk Manager, Operating Room Director, Materials Manager

November 16, 2017

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling select disposable products that were distributed between October 16, 2017 and November 14, 2017. Please refer to the specific product numbers and descriptions listed in the attached table below.

Product #	Product Description	Lot Number(s)
0206-512-000	Break-Away Femoral Nozzle	17279012
0206-530-000	180-Gram Cement Cartridge with Breakaway Femoral Nozzle	17277012, 17283012
0206-546-000	Femoral Canal Pressurizer without Hub, Medium, Blue	17276012
0206-547-000	Femoral Canal Pressurizer without Hub, Large, Red	17282012
0210-110-100	InterPulse Handpiece with coaxial bone cleaning tip	17283012, 17284012, 17286012
0210-114-100	InterPulse Handpiece with Coaxial High Flow Tip	17278012, 17280012, 17282012, 17283012, 17285012, 17289012, 17292012
0210-118-200	InterPulse Handpiece with Retractable Coaxial Fan Spray Tip	17279012
0210-218-000	InterPulse Irrigation Only Handpiece with Fan Spray Tip	17284012
0306-511-000	11g Verteport Cement Cannula (18/pkg)	17278012
0306-573-000	ACM Kit w/ Femoral Breakaway Nozzle & Prox. Med. Press.	17282012, 17283012, 17297012, 17298012
0506-485-000	PCD Kit: Long 90, 13g Match-Ground w/ Bevel	17277012
0605-887-000	AutoPlex System	17278012
0606-516-000	Revolution 90 Degree Tibial Nozzle	17293012
0606-573-000	Revolution CMS w/ Femoral Breakaway Nozzle & Med. Press.	17290012
0705-115-000	10g/15mm (15/2) iVAS System Kit	17283012
0705-310-000	11g/10mm iVAS System Kit	17277012
0705-315-000	11g/15mm iVAS System Kit	17283012, 17299012
6198-001-514	Intramedullary Brush Standard O.D. 14 mm	17284012

For the purpose 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 and/or 2. By Manufacturing Lot Number listed on the individual blister packs.

Product #	Product Description	Sterilization Lot Number(s)	Manufacturing Lot Number (s)
0607-687-000	AutoPlex System: w/ VertaPlex HV	17278012, 17278022, 17279022, 17282012, 17282022, 17291012, 17291022	17237012, 17240012, 17242012, 17243012, 17244012, 17259012, 17259012

Product Description:
Products are sterile disposable devices. Refer to various product descriptions above.

Reason for the Voluntary Recall:
During routine testing, it was found that bioburden levels were higher than internal acceptable rates; therefore, this voluntary recall is being initiated since the sterility of the products cannot be confirmed.

Stryker Instruments
4100 E Milham Road, Kalamazoo, MI 49001 USA | P 269 323 7700 | F 866 521 2762

Risk to Health:
In addition to the normal risk of infection that any procedure carries, there is an additional potential risk that if an affected product is used in a procedure, an infection may occur which may require medical treatment. To date, there have been no reports of any adverse events or serious injuries.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.
2. Check all stock areas and/or operating room storage to determine if any devices from the affected lots are at your facility.
3. Quarantine and discontinue use of the recalled devices.
4. Complete and sign the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand.

   Note: *Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.*
5. If you have further distributed these products, please forward this letter and the attached BRF to all affected locations. Please indicate each location on the BRF.
6. Return the completed BRF to Stryker Instruments Post Market Regulatory Compliance via fax (866-521-2762) or email (erin.bissonnette@stryker.com).
7. 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.
8. Report any adverse events associated with the use of these devices to Stryker Instruments 1-800-253-3210, including any infections potentially associated with the use of affected product.

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

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BUSINESS REPLY FORM

Product: Stryker Instruments – multiple disposable products

November 16, 2017

Product Number(s)	Lot Number(s)	Quantity on Hand (each)

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Account Name: 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 Quantity Redistributed

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