American Medical Systems
10700 Bren Road W
Minnetonka, MN 55343 USA
visitams.com

Urgent Recall Notice

AdVance™ XP

October 15, 2014

Corrective Action – Return of Medical Device to AMS

Attention: Physician, Health Care Professional, Nurse, Risk Manager

Subject: Potential to breach sterile packaging of Needle Passer Components

This letter is to bring to your attention important information regarding the AdVance™ XP Male Sling Systems, Model number / Product Reference 720163-01.

During routine periodic packaging testing, AMS identified that in simulated extreme shipping and handling situations the sterile barrier packaging of the Needle Passer components supplied with the products listed above may potentially be compromised. It is important to note that we have received no complaints of packaging breaches and we have not observed any breach in products that have undergone routine shipping and handling. However, because AMS cannot rule out a situation in which a product undergoes extreme conditions during the shipping and handling process, and because any packaging breach would result in non-sterile product and potentially lead to a patient infection, we are recalling all affected lots of needle passers.

During implant procedures of devices, the two Needle Passers (left and right sides), are used by the surgeon to assist transobturator passage while placing and positioning the mesh sling. These tools are disposable and indicated for one-time-use only. The implantable mesh components are not affected by this issue.

This notice needs to be passed on to all those who need to be aware within your organization or to departments where the potentially affected devices may have been transferred where appropriate. Please maintain awareness on this notice and resulting action for an appropriate period to enable corrective actions to be completed.

AMS confirms that the United States Food and Drug Administration and other relevant National Authorities or Regulatory Agencies are being advised of this Action.

AMS as a cautionary measure recommends the following actions:

1. Check your inventory for items/parts related to this recall and complete the Acknowledgment Form.
2. Return the signed copy of the Acknowledgement Form attached to this letter via fax, or scan and email to AMS customer service contact detailed.
3. Contact AMS to make arrangements for the return of affected product. AMS will provide a FedEx account number to facilitate the return.

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4. Return all AdVance™, AdVance™ XP, Monarc™ C and Monarc™ Plus product in stock. As the product is supplied as a packaged system, the action applies to the entire packed product.

AMS recognizes the inconvenience that this may cause and will work to urgently replenish your inventory with replacement product upon availability. AMS expects new device systems with improved packaging will be available for order during the month of November.

AMS is committed to supporting the best procedures and outcomes, and providing the safest and most effective treatment options. If you have any questions, or require more information, please contact American Medical Systems Customer Service as detailed on the attached Acknowledgement Form.

Sincerely,

Ginger Glaser
Vice President, Global Regulatory Affairs
American Medical Systems

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Acknowledgement Form – Urgent Recall Notice
AdVance™ XP, AdVance™, Monarc™ C & Monarc™ Plus

October 15, 2014

Customer information	
Customer name	
Customer number	

Please check one of boxes below indicating the action you have taken.

☐ I have checked inventory for the products listed in the recall letter and have identified and quarantined the affected product. I have contacted AMS Customer Service at 1-800-328-3881 (x 6469) to obtain a Return Authorization number to facilitate the return of the affected product.

Please list the affected product that will be returned to AMS in the table below. Product Lot Number information is found on the product label.

REF/ Product Number	Lot Number	Quantity

☐ I have checked inventory for the products listed in the Urgent Recall Notice and was not able locate any of the affected products.

Customer performing action	
Printed name	
Title	
Signature	
Signature / date	
Phone number	
Fax number	
E-mail address	

Please return the signed copy of this form using one of the following methods:

1. Fax to 952-516-5904
2. Scan and e-mail to AMSrecalls@americanmedicalsystems.com