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PRODUCT FSCA: Potential breach of sterile packaging of Needle Passer Components

28 July 2014

AdVance® XP Male Sling System, Model Number / Product Reference 720163-01 and 1008202

Dear Sir or Madam,

As a result of routine periodic product shelf life testing, AMS has identified that the sterile barrier of some samples of packaging of the Needle Passer components supplied with the AdVance® XP Male Sling System, may have potentially been breached and therefore not consistently meet the three (3) year shelf life stated on the product label. Further testing confirms that the packaging of the Needle Passers continues to meet the requirements for the one (1) year shelf life.

The AdVance® XP Male Sling system contains the following components:

Component	Product 720163-01	Product 1008202	Components status
Needle passers (2)	200517-01	1008175	Affected
Male sling (1)	200478-01	1008176	Not affected
Percutaneous needle (1)	310153-01	310153-01	Not affected
Retractor ring(1)	72403263	72403263	Not affected
Blunt stay hooks (8)	72403615	72403615	Not affected

During implant procedures of the AdVance® XP Male Sling, the two Needle Passers (left and right sides), are used by the Surgeon to assist transobturator passage while the placing and positioning the Sling. These tools are disposable and indicated for one-time-use only. There is a potential for an increased risk of patient infection due to breach in the sterile barrier of the Needle Passer components.

As a cautionary measure, AMS is informing all affected customers via a Field Safety Notice (FSN) to:

1. Return all AdVance ® XP Male Sling System product in stock. As the product is supplied as a packaged system, the recommendation applies to the entire packed product.
    a. Immediately quarantine and prevent from use any stock exceeding nine (9) months from the date of manufacture*.
    b. Where the customer has patient cases scheduled within the next two (2) months and there is AdVance® XP product available in inventory that is within nine (9) months from the date of manufacture*, the customer may decide to proceed to use this product as indicated.

    *The date of manufacture can be found on the carton of the by the symbol shown below:

2. Please return the signed copy of the Acknowledgement form attached to this letter using fax or scan and email to AMS contact detailed below.

3. AMS will make arrangements for the return of affected product following receipt of the completed Acknowledgement form attached to this letter.

AdVance® XP Male Sling System product will be available for order from AMS from 1st August 2014.

AMS conclude this incident constitutes a reportable event in accordance with MEDDEV 2.12-1 rev 8 and, in addition to the information provided in this letter, we enclose a Manufacturer's Field Safety Corrective Action Report (FSCA), and a copy of the Customer FSN.

Please do not hesitate to contact me if you require further information.

Regards,

Mario Wijker
Sr. Director Regulatory Affairs
American Medical Systems