

## Urgent Recall Notice

### AMS 700 Accessory Kit - Lightning Bolt Keith Needles

October 15, 2014

Dear Valued Customer,

This letter is to inform you that AMS' supplier has issued a recall of certain lots of Lightning Bolt Keith needles supplied in AMS 700 Accessory Kits. Based on this, AMS is recalling AMS 700 Accessory Kits which contain these lots of needles.

The supplier made the decision to issue this recall after an internal investigation that was requested by AMS. The investigation identified a potential nonconformity that may lead to a bent or broken Keith Needle when used with the Furlow tool.

The supplier recall is restricted to the lots of AMS 700<sup>®</sup> Accessory kits listed in the table below.

Item/part number
72401850
Serial/lot
861173001 – 899085001

A broken or bent Keith Needle may result in the physician having to switch to suitable alternative needles. There is no increase to patient safety risk as a result of this issue.

Although AMS has not identified any increase in patient or healthcare provider harm resulting from this issue, AMS has decided to recall all potentially impacted lots of the AMS 700 Accessory kits containing recalled Lightning Bolt Keith Needles. As a replacement, AMS is supplying AMS 700 Accessory Kits with straight Keith Needles as they come available for shipment.

To assist us with this recall action and help ensure affected products have been removed from circulation, please do the following

- Check your inventory for items/parts and serial/lots related to this recall.
- Record your inventory findings using the enclosed Product Recall Acknowledgement Form.
- Return the completed Product Recall Acknowledgement Form using one of these methods:
  - Fax to 0800 0322 307
  - Scan and email to [EMEA-CustomerRelations@ammd.com](mailto:EMEA-CustomerRelations@ammd.com)
- Contact AMS Customer Service to:
  - Obtain a Return Authorization number where a courier shipping account number will be provided for your use in shipping affected product to AMS.
  - Request credit to your account or a full refund, if needed.
- Package all affected products and send them to:  
DSV Solutions NV c/o AMS  
Kennedy Industriepark  
21-B-9042 Eddastraat  
Gent, 9042  
Belgium

If you have any questions or require additional information please contact AMS Customer Service at:

- Telephone: 0800 0322 308
- Fax: 0800 0322 307
- Email: [EMEA-CustomerRelations@ammd.com](mailto:EMEA-CustomerRelations@ammd.com) / [CSUK@ammd.com](mailto:CSUK@ammd.com)

- Mail to: American Medical Systems Europe B.V.  
Haarlerbergweg 23G  
1101 CH, Amsterdam Zuid-Oost  
The Netherlands
- Business Hours: 8:00 AM – 5:00 PM CET Monday through Friday

AMS is committed to supporting the best procedures and outcomes, and providing the safest and most effective treatment options. AMS appreciates your cooperation in this matter and regrets any inconvenience this has caused for you.

Sincerely,

Ginger Glaser  
Vice President, Regulatory Affairs

Enclosure: Medical Device Recall Acknowledgement Form

## Acknowledgement Form – Urgent Recall Notice

### AMS 700 Accessory Kit - Lightning Bolt Keith Needles

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 0800 0322 308 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
72401850		
72401850		
72401850		

- 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 0800 0322 307
2. Scan and e-mail to [EMEA-CustomerRelations@ammd.com](mailto:EMEA-CustomerRelations@ammd.com)