



URGENT MEDICAL DEVICE FIELD NOTIFICATION Action Required

Date:

Customer Name:

Re: SureFlex™ Reusable Fibers and Reusable Stripper and Cleaver Accessories

Dear Sir/Madam:

As a customer of the SureFlex™ Reusable Fibers and/or the Reusable Stripper and Cleaver Accessories, we are providing you with this notice.

It was determined that validation data related to cleaning instructions and sterilization methods and the methods defined in instructions for use (IFU) for the SureFlex™ Reusable Fibers and the Reusable Stripper and Cleaver Accessories do not meet the new guidance on qualifying reusable products.

AMS has evaluated the potential clinical impact of this issue and we have concluded that improper cleaning and sterilization of the product could result in potential for cross-contamination and potentially lead to exposure to micro-organisms that could lead to an infection. To date, there have been no related complaints reported to AMS.

All model numbers for the SureFlex™ Reusable Fibers are affected:

SureFlex™ Reusable Fibers	
Sureflex 150 Lithotripsy Fiber, 5x, Blue	Model R-LLF150TG
Sureflex 200 Lithotripsy Fiber, 5x, Blue	Model R-LLF200TG
Sureflex 273 Lithotripsy Fiber, 5x, Blue	Model R-LLF273TG
Sureflex 365 Lithotripsy Fiber, 5x, Blue	Model R-LLF365
Sureflex 550 Lithotripsy Fiber, 5x, Blue	Model R-LLF550
Sureflex 910 Lithotripsy Fiber, 5x, Blue	Model R-LLF910
200µM Lithotripsy Fiber - Reusable	Model 8013046
365µM Lithotripsy Fiber - Reusable	Model 8013056

For the SureFlex™ Reusable Fibers, which have not been used in your inventory, and are within the 3 year shelf life, AMS will be offering to exchange the SureFlex™ Reusable Fiber with the SureFlex™ Single Use Fiber. In order to receive the exchange, the product must be returned to AMS in the unopened original packaging. Instructions regarding product exchange are listed in the attached acknowledgement form.

If the SureFlex™ Reusable Fibers inventory has been used, and has not been discarded, AMS asks that you discard the device or return the used device to AMS directly. Instructions regarding product return are listed in the attached acknowledgement form.

All models numbers for the Reusable Stripper and Cleaver Accessories are affected:

Reusable Stripper and Cleaver Accessories	
Fiber Stripper, 150µm, Autoclavable	Model 80-10001-003
Fiber Stripper, 200µm, Autoclavable	Model 80-10002-003
Fiber Stripper, 273µm, Autoclavable	Model 80-10003-003

Fiber Stripper, 365µm, Autoclavable	Model 80-10005-003
Fiber Stripper, 550µm, Autoclavable	Model 80-10011-003
Fiber Stripper, 910µm, Autoclavable	Model 80-10008-003
Fiber Cleaver	Model 0010-0760
1X1 Cleaving Tiles	Model 80-10007-001
Tool, Stripper W/BLD, 10S, Nonautoclavable	Model 80-10001-001
Tool, Stripper W/BLD, 10S, Autoclavable	Model 80-10001-002
Tool, Stripper W/BLD, 12S, Nonautoclavable	Model 80-10002-001
Tool, Stripper W/BLD, 12S, Autoclavable	Model 80-10002-002
Tool, Stripper W/BLD, 14S, Nonautoclavable	Model 80-10003-001
Tool, Stripper W/BLD, 14S, Autoclavable	Model 80-10003-002
Tool, Stripper W/BLD, 18S, Nonautoclavable	Model 80-10005-001
Tool, Stripper W/BLD, 18S, Autoclavable	Model 80-10005-002
Tool, Stripper W/BLD, 44S, Nonautoclavable	Model 80-10008-001
Tool, Stripper W/BLD, 44S, Autoclavable	Model 80-10008-002
Tool, Stripper W/BLD, 28S, Nonautoclavable	Model 80-10011-001
Tool, Stripper W/BLD, 28S, Autoclavable	Model 80-10011-002
Stripper, 0.6mm Disposable EndoStat Fiber	0010-0751
Stripper, 0.4mm Disposable EndoStat Fiber	0010-0752
Stripper, 0.3mm Disposable EndoStat Fiber	0010-0754
Stripper, 0.2mm Disposable EndoStat Fiber	0010-0755

For the accessory products that have not been used in your inventory, AMS will be extending a credit to you for the purchase price. In order to receive the credit, the product must be returned to AMS. Instructions regarding product credit are listed in the attached acknowledgement form.

If the inventory has been used, and has not been discarded, AMS asks that you discard the devices or return the used device to AMS directly. Instructions regarding product return are listed below in the attached acknowledgement form.

Please review and complete the acknowledgement form attached for additional instructions regarding the affected product.

AMS apologizes for any inconvenience this may cause you. If you have any questions about this notification, please do not hesitate to contact us via email FAsureflex@ammd.com or phone at 0800 0322 308 or your local customer service organization.

Thank you for your prompt attention to this matter.

Please remember to report any complaints to Customer Service at 0800 0322 308 or your AMS Sales Representative.

Sincerely,

Jennifer Mascioli-Tudor
 Director, Quality Assurance – Prostate Health
 American Medical Systems

ACKNOWLEDGEMENT FORM Action Required

Re: SureFlex™ Reusable Fibers and Reusable Stripper and Cleaver Accessories

Customer Name:

Customer Address:

Please check boxes below that apply and complete the information requested:

I have read and acknowledge AMS' notice. I do not have any existing SureFlex™ Reusable Fibers or Reusable Stripper and/or Cleaver Accessories in my inventory.

I have read and acknowledge AMS' notice. I have inventory of the SureFlex™ Reusable Fibers (falls within the 3 year shelf life) and/or Reusable Stripper and Cleaver Accessories that have not been used. I will contact Customer Service to request either 1) *an exchange of the SureFlex™ Reusable Fiber for the SureFlex™ Single Use Fiber* or 2) *a credit for the purchase price for the Reusable Stripper and Cleaver Accessories*. I understand that in order to obtain the exchange and/or credit, the SureFlex™ Reusable Fibers and/or the Reusable Stripper and Cleaver Accessories **must be returned to AMS**.

Please indicate number of devices for return:

- SureFlex™ Reusable Fibers: _____
 Reusable Stripper: _____
 Reusable Cleaver: _____

I have read and acknowledge AMS' notice. I have inventory of SureFlex™ Reusable Fibers and/or Reusable Stripper and Cleaver Accessories that have been used.

I have discarded the device(s).

Please indicate number of devices discarded:

- SureFlex™ Reusable Fibers: _____
 Reusable Stripper: _____
 Reusable Cleaver: _____

I will return the device(s) to AMS to discard. Please contact Customer Service at 0800 0322 308 to obtain a return product authorization number.

Please indicate number of devices for return:

- SureFlex™ Reusable Fibers: _____
 Reusable Stripper: _____
 Reusable Cleaver: _____

For any questions please contact Customer Care at 0800 0322 308 or your AMS Sales Representative.

Name (Customer Representative)

Title

Signature

Date

Please copy for your records and then RETURN the COMPLETED FORM to AMS.

Fax: 0800 0322 307

Email: FAsureflex@ammd.com