

CUSTOMER ACTION REQUIRED

UPDATED INSTRUCTIONS FOR USE

ULTRA-FLEX MYO/WIRE[®] MONOPOLAR PACING WIRE LOOPED ELECTRODE (M-21 SERIES)

Our records indicate that your location has received the MYO/WIRE[®] Monopolar pacing wire with looped electrode (M-21 Series) from lots 0715A or later. See the attached listing of M-21 series product shipped to you.

The product Instructions for Use have been updated to provide information relative to attachment methods for this product. Historically the Instructions for Use had no instructions for attaching the product. In February 2018 the Instructions for Use were updated with instructions for attaching the M-22 narrow loop configuration but did not state this was only applicable to the M-22 product family and was not appropriate for the M-21 product family. The Instructions for Use have been further updated to clarify the attachment information for each configuration of looped electrodes.

ACTION REQUIRED: Please check your inventory and determine if any of this product is still in your inventory. If you still have inventory, please replace the original Instructions for Use with a copy of the revised Instructions for Use (a copy is included with this notification). It would also be appropriate to make Surgeons who use this product aware of the additional information by making this notice available to them. The Instructions for Use are also accessible on the A&E Medical[™] website at WWW.AEMEDICAL.COM.

There is no need to return or exchange your product. The product is within specifications and fully functional as designed and intended. A&E has had no customer complaints relative to the product's clinical performance. However, to ensure the Instructions for Use are as complete and accurate as possible, we are alerting user who may have product on the shelf to this update in product information. Replacing the Instructions for Use will bring the product current with the most up to date information and provide the best user support possible.

Please confirm your receipt of this notification and the results of your inventory review by completing the attached Acknowledgement Form and emailing it to the address indicated on the form. This confirmation is required by law to demonstrate that the Field Notice has been received and acted upon. We appreciate your support in completing this action.

Should you have any questions regarding this notification, please contact your A&E Medical[™] Sales Representative or A&E Customer Service (800-323-4035). We appreciate your business and again, thank you for taking action on this Field Notice



Dana Rodriguez
Vice President, Regulatory and Quality
June 21, 2019

CUSTOMER NOTIFICATION – ACTION REQUIRED

UPDATED INSTRUCTIONS FOR USE

**ULTRA-FLEX MYO/WIRE® MONOPOLAR PACING WIRE LOOPED ELECTRODE
(M-21 SERIES)**

CUSTOMER ACKNOWLEDGMENT

Customer Name
Address

Customer Contact Person's Name					
Customer Contact Phone Number					
<i>Model Number</i>	<i>Lot Number(s)</i>	<i>Date Shipped</i>	<i>Quantity Shipped</i>	<i>Quantity Currently in Customer's Inventory</i>	

Field Notification received and all affected inventory updated with revised Instructions for Use.

PRINT NAME	
SIGNATURE	
DATE	

Return completed form to: CustomerService@AEMedical.com