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September 2010

Urgent Field Safety Notice

Affected Product Part Numbers (all Lot Numbers):

External Sterilizable Defibrillation Hard Paddle: PN: 3009166-XX for use with LIFEPAK 12 and 20/20e

External Sterilizable Defibrillation Hard Paddle: PN: 804507-XX for use with LIFEPAK 9 and 9P

Sterilizable Pediatric Paddle attachments: PN: 800418-XX

Discontinued Use and Changes of sterilization recommendations

Medtronic Ref: FA412

Dear Physio Customer,

In November 2008, we sent a letter to your facility regarding a change in sterilization methods and guidelines for External Sterilizable Defibrillation Paddles and Pediatric Paddle attachments used with LIFEPAK®9, LIFEPAK 9P, LIFEPAK 12, LIFEPAK 20 or LIFEPAK 20e defibrillator/monitors. This communication is an update to that letter.

In the November 2008 letter, we indicated the need to limit sterilization cycles for External Sterilizable Paddles and Pediatric Paddle attachments. These products were designed and introduced twenty years ago, prior to the introduction of current cleaning and sterilization standards. While there have been no design or manufacturing changes to these products since their introduction, current standards are more stringent than those in place in 1990. Our most recent testing results have not sufficiently demonstrated these products can meet current cleaning and sterilization standards. It is important to note that there have been no reports of infection with these products using current recommendations. Also, no complaints have been received and there have been no patient or user-related events due to damage or corrosion of paddles. However, Physio-Control has made the decision to discontinue our production and distribution of External Sterilizable Paddles, so they will no longer be available for sale.

We will continue to distribute Pediatric Paddle attachments; however we can no longer recommend their use as a sterilizable product.

Our records show your facility was included in our November 2008 mailing or your facility has purchased External Sterilizable Paddles or Pediatric Paddle attachments after November 2008. If you no longer have these accessory items, you are not affected.



External Sterilizable Paddles
Part Number label: 3009166-03



Pediatric Paddle attachment
Part Number Label: 800418-00 thru 800418-05

For customers who have an immediate need for external defibrillation within a sterile field and would like assistance from Physio-Control, please call [INSERT LOCAL SUPPORT TELEPHONE NUMBER]

The Competent Authority of your country has been notified of this action. This notice needs to be passed to all those who need to be aware within your organization.

Physio-Control is committed to making sure customers are fully supported. If you have any questions regarding this product update, please call [INSERT LOCAL SUPPORT TELEPHONE NUMBER]

Sincerely,

[INSERT LOCAL NAME]
[TITLE]