Medtronic

URGENT FIELD SAFETY NOTICE

CPFA Coupled Plasma Filtration Adsorption™ in Patients with Septic Shock

27 April 2018

Medtronic reference: FA815

Attention: Risk Management Director, Safety Officer, OR and ICU Materials Management, ICU Medical Directors

Dear Valued Customer:

The reason you are receiving this letter is that you are a current user of either the LYNDA™ (Product Code: IB0590000) or the Amplya (Product Code IBAXXX700 (Amplya equipment) IB0600000 (Amplya kit)) Acute Multitherapeutic System™ and CPFA Coupled Plasma Filtration Adsorption™ therapy is a treatment that can be performed on these systems.

The purpose of this letter is to advise you of the early termination of the COMPACT-2 (COMbining Plasma-filtration and Adsorption Clinical Trial 2) clinical trial. On October 23, 2017, GiViTI, a not-for-profit research organization within the Mario Negri Research Institute, terminated the study early due to observed higher mortality rates in septic shock patients receiving CPFA therapy compared to patients receiving standard care.

The COMPACT-2 investigators are analyzing their data to better understand the reasons for the observed results and intend to publish the study results after their independent assessment is complete. All study sites have been notified by GiViTI of the study's early termination and their recommendation to not use CPFA for treating patients with septic shock. Pursuant to this recommendation from GiViTI and the extended timeline associated with the rigorous collection of patient data, Medtronic is informing all clinicians who might be using or contemplating the use of CPFA therapy for patients in septic shock that this treatment is **not** recommended.

As a result of the COMPACT-2 study findings in septic shock patients, Medtronic will add the following warning statement in CPFA User Manuals and Instructions for Use:

> **WARNING:** In a clinical study, higher early mortality (within 72 hours of randomization) was observed in septic shock patients receiving CPFA Coupled Plasma Filtration Adsorption™ therapy compared to patients receiving standard care. Septic shock patients often have clinical characteristics (hemodynamic instability, coagulation disorders) that increase the risk of extracorporeal treatment. Based on the preliminary data from this study, CPFA should not be used in patients with septic shock.

If results of the independent assessment being conducted by the COMPACT-2 investigators suggest that the observed early mortality can be attributed to specific patient conditions at the time of treatment or other factors, we will update the labeling accordingly. Until then, please inform your staff of this warning statement.

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This Field Safety Notice is specific to the use of CPFA in septic shock patients. Medtronic has not received any reports suggesting potential harm in other patient indications for which the product is approved. Please complete the attached Acknowledgement form and return it using the contact details at the bottom of the form.

If you choose to return any unused CPFA product related to this notification, please complete the Product Return Form and ship to the address noted on that form. Medtronic will issue a credit for the products returned in connection with this notification.

The Competent Authority of your country has been notified of this action.

Thank you for your attention to this notification. We are committed to ensuring unsurpassed patient safety and customer service through transparent communication. If you have any questions regarding this communication, please contact your Medtronic representative .

Sincerely,

Asim Nigam
Sr. Quality Systems Director
Renal Care Solutions, Medtronic

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Field Safety Notice

Acknowledgement and Receipt Form—Response is Required

CPFA Coupled Plasma Filtration Adsorption™ in Patients with Septic Shock

Please complete this form in its entirety.

Date: _____

Name of Person Completing this Form: _____ Title: _____

Direct Phone #: _____ Email _____

Account Name:	
Primary Account #:	
Account Street Address:	
Postal Code + City:	

I have read and understand the information provided and acknowledge receipt of the Field Safety Notice regarding CPFA Coupled Plasma Filtration Adsorption™ in patients with septic shock by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

_____ _____ _____

Name: (print) **Signature:** **Date:**

If you have any questions regarding this Field Safety Notice, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

rs.bellcoproductcomplainthandling@medtronic.com or via fax to +39 0535 29177

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PRODUCT RETURN FORM

CPFA Coupled Plasma Filtration Adsorption™ in Patients with Septic Shock

PLEASE COMPLETE THIS FORM IF REQUESTING CREDIT

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

Account Name:

Primary Account #:

Account Street Address:

Postal Code + City:

Reference Code/Product Description	Lot/Serial Number	Qty (Each)

PLEASE EMAIL OR FAX THIS PRODUCT RETURN FORM TO:

rs.bellcoproductcomplainthandling@medtronic.com or via fax to +39 0535 29177

PLEASE RETURN PRODUCT TO:

Due Torri Warehouse
Via Maceri Superiore 16/A
40061 Minerbio Bologna Italy