URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# FMI 14018 - Ireland

To: Director of Orthopedic dept/Physicians/Gynecologist
Risk Manager/Hospital/ Clinic Administrator
Director of Biomedical Engineering

RE: **Achilles EXPII Systems with Incorrect power cords shipped - Potential for Electric Shock - Ireland**

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.
Please retain this document for your records.

Safety Issue

Certain Achilles EXP II systems were shipped with European Power Cords to non-European countries where three pin plugs are required for protective earth connection.

This issue could lead to an electric shock. There have been no reported injuries as a result of this issue.

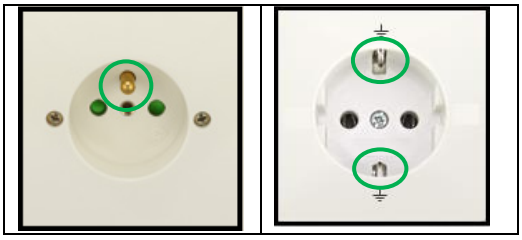
Safety Instructions

You may continue to use your system after following the instructions below:

- Inspect the power cord set used on your Achilles EXP II system and ensure its compatibility with your wall socket.
- Use the European plug shown in Figure 1 only with the two wall sockets shown in Figure 2. The protective earthing connection will not be established with any other socket.
- Do not use any adapters with your plug or wall socket.
- If you have a Europe plug and a wall socket other than that shown in Figure 2, discontinue use of your system. Your power cord set will be replaced with the correct power cord. Destroy the incorrect power cord to ensure it is not used.

Figure 1: **European Plug**
(shipped with systems)

Figure 2: **Use European Plug ONLY with these Wall Sockets**



Affected Product Details

Achilles EXPII Systems with power cords.

Product Correction

GE Healthcare will send you the correct replacement power cord set at no cost to you.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Kate Worland – T: +44 7717 857755; Email: kate.worland@ge.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken GEHC Ref# 14018-Ireland.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:
Recall14018@ge.com

You may obtain this e-mail address through the QR code below: