HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Lifeguard LG20, LG50, LG55

Priority 2 – Warning

HPRA Safety Notice: SN2020(08) **Issue Date: 24 June 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
ArjoHuntleigh	V43461

ISSUE
Following a number of reports of side weld breakage, ArjoHuntleigh have updated the Instructions For Use (IFU) for the Lifeguard LG20, LG50 & LG55. The manufacturer has issued a Field Safety Notice (FSN) for users of this device in order to inform all users of this issue and subsequent IFU update. The manufacturer has indicated that the failure mode has not yet resulted in any injury. The IFU has been updated to include the following caution: "*Do not use the safety sides to move the Lifeguard trolley. Only use the push bar handles to operate the Lifeguard trolley*" Please see the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Read the accompanying FSN carefully.

2	Follow the instructions in the FSN to identify whether you have affected devices in use at your facility or in the home / community setting and download a copy of the updated IFU.
3	Acknowledge receipt of the FSN if you have not already done so.
4	Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
5	Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	Clinical Directors
Supplies Managers	Purchasing Managers
Risk Managers	Clinical/Biomedical Engineers
All Nursing Staff	Public and Private Nursing Homes
Relevant Wards	Medical Device Distributors

BACKGROUND

The Lifeguard® LG20, LG50 & LG55 are patient trolleys intended for use in trauma, patient examination and imaging, treatment, transport and recovery. Following the receipt of reports in relation to weld breakage, ArjoHuntleigh have updated the IFU.

ArjoHuntleigh has indicated that as long as the device is used according to the IFU and labelling, users of this device are not exposed to any additional risk to health. The IFU includes a "Care and Preventive Maintenance" section and the procedures in this section should be always be followed.

The HPRA is issuing this Safety Notice to raise awareness of this issue. Please see the accompanying manufacturer's FSN for further information.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Arjo IrelandEA House, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	Telephone: E-mail: Website:	+44 (0) 28 9050 2003 fieldactions.uki@arjo.com www.arjo.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie