

Safety Notice

Medical Devices

Sedeo Pro Manual Elevating Legrest

Priority 2 – Warning

HPRA Safety Notice: SN2021(06)

Issue Date: 01-07-2021

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Sunrise Medical HCM	V42479

ISSUE
<p>The Health Products Regulatory Authority (HPRA) is issuing this Safety Notice to raise awareness of the risk of finger entrapment with the Sedeo Pro manual elevating legrest used on Ibis wheelchairs. While the Sedeo Pro manual elevating legrest is commonly used with the Ibis wheelchair (previously known as the Handicare Ibis), please note that the Sedeo Pro manual elevating legrest can be sourced individually as a spare part and therefore may be attached to an Ibis at any stage during its life cycle, even though not originally supplied with this type of legrest.</p> <p>An incident involving finger entrapment has the potential to result in injury needing medical intervention and the HPRA is aware of incidents of this nature in Ireland.</p> <p>The manufacturer has updated the Instructions for Use for this device to highlight the potential risk should the leg rest not be used in line with manufacturer’s guidelines and HC21, the sole distributor in Ireland, is affixing pinch point stickers to warn users further of the potential risk of moving parts.</p> <p>Please refer to the accompanying customer communication letter and Appendix to the IFU for further information on moving parts associated with these legrest.</p>

ACTION OR RECOMMENDATIONS

The HPRA advises that:

If you are a distributor/ supplier for a healthcare facility:

- 1 Check inventory for Ibis wheelchairs that have the Sedeo Pro manual elevating legrest fitted (see Fig.1).

Fig.1



- 2 While identifying the affected legrest, please note that the Sedeo Pro manual elevating legrest can be sourced individually as a spare part and therefore may be attached to an Ibis at any stage during its life cycle even though not originally supplied with this type of legrest. Please exercise caution if you are manually examining the device for identification.
- 3 Check Ibis wheelchairs to see if the Sedeo Pro manual elevating legrest has been affixed with pinch point stickers as shown in the attached customer communication letter.
- 4 Should Ibis wheelchairs fitted with a Sedeo Pro manual elevating legrest not have pinch point stickers affixed, please contact your customer service provider/ HC21 to support the completion of the action to affix pinch point stickers for the devices in your possession.
- 5 Forward a copy of this Safety Notice to all relevant personnel within your organization and to any other organizations/ persons to which/whom these devices have been transferred.

If you are a user/ caregiver:

- 6 Inspect your device to identify whether your Ibis wheelchair contains the Sedeo Pro manual elevating legrest. As the legrest can also be supplied as a spare part, this legrest could have been fitted on your Ibis wheelchair at a later date. Please exercise caution if manually examining the device for identification.

- 7 Inspect your device to ensure pinch point stickers have been affixed and you have been provided with a copy of the updated Instructions for Use of the device. Please contact your supplier/service provider should your Sedeo Pro Manual elevating legrest not have any pinch point stickers.
- 8 Inspect the device for moving parts and familiarize yourself with safe use of device by following the instructions captured in the IFU of the device.
- 9 Please report any adverse events/ incidents associated with these devices to the manufacturer and to the HPRA.

TARGET GROUPS

Physiotherapists/ Occupational therapists Clinical/ Biomedical Engineers Hospital managers Care home staff/ managers Nursing and Midwifery managers and staff	Hospital purchasing/ procurement staff Community care managers Hospital risk managers Loan store managers Accident and Emergency departments
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BACKGROUND

Sunrise Medical has informed the HPRA of incidents of finger entrapment in Ireland associated with the use of the Sedeo Pro Manual Elevating legrest.

Sunrise Medical has identified that in some cases, user/ caregiver finger(s) can become trapped and/or crushed between moving parts, which may result in acute injury requiring urgent medical intervention. Sunrise Medical states that this might occur if users interacting with moving parts of the elevating legrest fail to follow instructions and do not exercise adequate caution. Moreover, users might not be aware of the pinch points related to the moving parts and the addition of pinch point stickers, aims to raise this awareness.

Sunrise Medical has also updated the owner's manual to increase awareness regarding the risk of finger entrapment when using the Sedeo Pro Manual Elevating legrest. The updated Instructions for use along with the pinch point stickers aim to reduce the risk of finger entrapment.

The HPRA is issuing this notice to highlight these updated instructions and the affixation of pinch point stickers.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION (amend as required)

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

Sunrise Medical HCM, Noord-Brabant, Helmond 5705 CI, Netherlands	Telephone: +31653692634 E-mail: enquiries@sunmed.co.uk Website: sunrisemedical.co.uk
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Enquiries to the **distributor** should be addressed to:

HealthCare21, Unit 5 WestPoint Buildings,
WestPoint Business Park, Ballincollig, Co. Cork,
P31 XK11

Telephone: +353214875055
E-mail: service@hc21.ie
Website: www.healthcare21.eu

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