

**FSN 2019-01 – Incorrect maximum user weight on hangtag instruction****Details of the affected devices:**

Affects various adjustable crutches supplied between Jun 2016 – Dec 2018.

10407R-30 Paediatric Crutch	10450-30 Double adjustable elbow crutch - Small
10451-30 Double adjustable elbow crutch - Medium	10452-30 Double adjustable elbow crutch - Adult
10453-30 Double adjustable elbow crutch - Extra-long	10454-30 Double adjustable elbow crutch - Adult

**Description of the issue:**

Following a customer complaint, we have identified that the maximum user weight 160kg (25 stone) advised on the hangtag instruction supplied with the devices was incorrect. The device is safe to use and has passed weight limit tests above 160kg. The correct maximum user weight 127kg (20 stone) is labelled on the device.

**Advice on the actions to be taken:**

An updated instruction can be downloaded from the 'Products section of our website: [www.drivedevilbiss.co.uk](http://www.drivedevilbiss.co.uk) Alternatively, please contact the Drive DeVilbiss Healthcare Ltd Customer Care Dept on 0845 0600 333 and we will provide details for updating the hangtag instruction on affected devices.

**Transmission of this Field Safety Notice:**

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and/or customer base, and/or any organisation where the crutches are used. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this action.

**e-mail feedback form:**

As part of the MHRA vigilance and reporting structure, we are required to feedback that the Field Safety Notice has been acknowledged and the appropriate actions have taken place. Please identify and quarantine all non-conforming devices and arrange for product hangtag instructions to be reworked.

PLEASE USE BLOCK CAPITALS

**Name:**

**Position:**

**Organisation:**

**Signed:**

**Date:**

Following completion, please sign and e-mail this completed form to:

**Mr Roy Smith** Quality and Environmental Manager  
**e-mail:** [quality@drivedevilbiss.co.uk](mailto:quality@drivedevilbiss.co.uk)