

## **URGENT – Medical Device RECALL Notice**

### **Drive Devilbiss Healthcare Crutches**

**Models: 10400-8, 10400-1, 10401-8, 10401-1,  
10402-8, 10402-1, 10430-8, 10430-1, 10431-8,  
10431-1, 10432-8, 10432-1**

Date: 6-22-2016

Dear Our Valued Customer:

We previously sent you letters dated February 17, 2016, February 25, 2016, and March 11, 2016 (see Exhibit A), concerning a defect involving the tips of certain pairs of the above-listed Drive Devilbiss model crutches. We have not received a response from you with regard to this correction and the associated action steps.

This field correction is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA) and is subject to effectiveness checks.

#### **What is the problem?**

There is a possibility that the crutch tip could fail resulting in the crutch frame tube to push through the crutch tip material.

#### **What is the risk?**

This could expose the crutch frame tube to the walking surface and in some cases may result in a slip or fall.

#### **What units are affected?**

Models: 10400-8, 10400-1, 10401-8, 10401-1, 10402-8, 10402-1, 10430-8, 10430-1, 10431-8, 10431-1, 10432-8, 10432-1

#### **Why are you being contacted?**

According to our records, you have received orders that include the potentially impacted model crutches. *If the product was further distributed, please notify those customers of this recall and either (1) send them a copy of this notice; or (2) create and send them your own notice informing them of this recall and the associated action steps they should take.*

**What actions are required?**

Please follow the instructions listed below:

- 1) Quarantine any stock that has not been inspected already and compare serial numbers of stock to list provided in the accompanying communication.
- 2) **Any product received after 3/7/2016 has been fully inspected and has an approved crutch tip that is free of defect.**
- 3) Contact your customer base that have received these products between 7/2015-12/2015 to see if they are still using these products.
- 4) If the customer is still using the product, instruct them to stop using the crutches. Contact Drive through the email address provided below or contact your Drive sales representative so the return and replacement of this product can be processed through our system.
- 5) Please sign and date the accompanying acknowledgement form, and scan and send it to the e-mail address provided below.

If you have any questions concerning these instructions, please email Drive Devilbiss recall support or contact Jordan Marsh at: [jmarsh@drivemedical.com](mailto:jmarsh@drivemedical.com).