Security Notice
REF: FSCA-ADV042018

Date: 19 july 2018 Withdraw of

Models: **Elbow crutches Advance :**

Reference	Model	Batch
2009	Elbow crutches Advance bi-matières (all colors)	04-2018
2059	Elbow crutches Canne Advance bi-matières (all colors)	04-2018

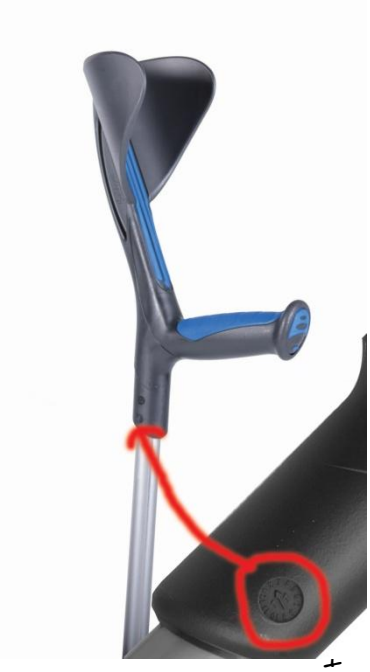
Care of Wholesalers and dealers of elbow crutches Advance.

Dear Sir,

We inform you of a voluntary reminder, with exchange, of a batch of the model of crutches Advance Herdegen, all colours. The problem was not identified in production, but after analyzing a few canes from a limited number of claims, Herdegen SAS detected this problem following a corrective and preventive action plan (CAPA). The root cause is due to an error during production. CAPA ensures that corrective and preventive actions are taken to prevent recurrence. All measures have been taken to ensure production in accordance with the normative requirements for this walking aid, as well as the implementation of new control tools.

It appears that some handles were injected without respecting the usual levels of requirements (fault related to the injection temperature). The handle is likely to become fragile or even break when using the cane. Elbow crutches Advances are class I medical devices that meet the requirements of the CE marking according to the 93/42 directive and in accordance with the ISO 11 334-1 standard. The elbow crutch is a technical aid to overcome a deficiency, temporary or permanent, in terms of mobility. The rupture of the handle can cause imbalance of the patient and its possible fall.

As a precautionary measure, we are recalling the Elbow crutches Advance produced in April 2018, identifiable with the 04/2018 date marking as it is present on the lower part of the handle (see photo).



This letter is addressed to the distributors identified as having received the lot in question. If you sold directly or not some of these canes to other distributors or retailers, send them this information.

Please immediately take inventory of your stock. If you have crutches of the lot indicated above, it is necessary to stop distribution or sale. Herdegen organizes the recall of the products in question.

Please contact Herdegen as soon as possible by returning the enclosed acknowledgment of receipt by e-mail (qualite@Herdegen.fr) so that we can organize the free replacement. ANSM has been informed of this communication.

We apologize for the inconvenience caused by this situation. Do not hesitate to contact your distributor or Herdegen SAS for any question.

Best regards.

Vincent Herdegen
Herdegen SAS
ZI de la Trentaine
77500 Chelles
France

Notice of receipt / reply letter to be completed and returned no later than September 15, 2018.

I confirm that we have inventoried the stock of elbow crutches Advance in our possession. Check below the headings corresponding to your situation and indicate the quantities concerned:

☐ We do not have any elbow crutches corresponding to lot 04/2018:

- ☐ This lot has never been received in our warehouse
- ☐ All elbow crutches from lot 04/2018 have been distributed; indicate : **please indicate how many are concern**:

☐ We have identified elbow crutches corresponding to lot 04/2018; **indicate their number**:

Name of distributor ....
Account number ....
Name of the person answering ....
Function..... ....
Dated..... ....
Signature

Please fill out this form and send it to Herdegen SAS customer service by e-mail to: qualite@Herdegen.fr.

HERDEGEN
PARIS

URGENT: FIELD SAFETY NOTICE

Voluntary Product Recall

Date: July 2018
Catalogue Number: 2009**
For the attention of: • Procurement, Medical Director, Risk Manager, Head of Pharmacy, Medical Device Safety Officer

Description of the problem: Herdegen is conducting a voluntary field safety corrective action for all elbow crutches ADVANCE dated April 2018.

The elbow crutches are being recalled due to risk of breakage. The users must stop using these lots immediately.
Potential hazard and potential risk to patients; as mentioned, there is an increased risk of breakage of the upper part of the crutch.

Action: 1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed below, and quarantine product subject to the recall.

Action: 2. Get in touch with your local supplier who will replace the products for free.

The safety and well-being of patients and healthcare workers is the primary objective for Herdegen and we aim to ensure that only the highest quality product is used by our customers.

We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to solve this matter as quickly and effectively as possible.

Yours sincerely

P. LEVAUX, Export Manager

P.P. Julien Merkel

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