



**FIELD SAFETY NOTE FSN 002-2021  
BATCH RECALL - URGENT**

Friday 23<sup>rd</sup> July 2021

**Products concerned :** EVOLUTION, FUN and ADVANCE elbow crutches

**Products delivered from 24<sup>th</sup> April to 30th May 2021 (months concerned: APRIL and MAY)**

Dear valued customer,

Despite the abovementioned products successfully passing the resistance and test methods performed in accordance with ISO 11334-1, we have noticed an unusually high rate of handle breakage on our Evolution/Fun and Advance crutches.

An initial analysis suggests that in extreme cases of use, and particularly when the user presses very hard on the front of the handle instead of the middle of the handle as it should be the case in normal use, the handle may break in some very rare cases.

This abnormal fragility appears to be the consequence of the use of a plastic material whose features slightly differ from the ones observed on the raw material normally used, which was out of stock at our regular supplier.

As a precautionary measure, we have therefore decided to recall the batches manufactured with this material. The batches concerned are listed below :

UDI batch numbers :

<b><u>ITEM</u></b>	<b><u>CODE</u></b>	<b><u>UDI BATCH NO.</u></b>
Advance blue + Pivoflex	200913	010370112770694910132119007
Advance blue + Pivoflex and reflector	205913	010370112771073110132119003
Advance turquoise + Pivoflex and reflector	205917	010370112771076210132119003
Advance blue + Pivoflex	200913	010370112770694910132119003
JH 130 Evolution	200000	010370112770193710132119001
JH 130 Evolution	200000	010370112770193710132118013
JH 130 Evolution	200000	010370112770193710132118011
JH 130 Evolution	200000	010370112770193710132118002
Advance blue + Pivoflex	200913	010370112770694910132117001
Evolution/Fun 130 kg turquoise	200017	010370112770922310132117001

These numbers can be identified on the labels stuck on the crutch:

You can find the UDI batch number on the box and on the crutch



The month and year of production are indicated in the lower right corner of the UDI label

We therefore ask you:

- To carry out a pre-market check of your stocks in order to remove potentially defective items from the market, and to arrange for their replacement.
- To contact your customers and/or users and ask them to stop using the devices immediately, and to return them for replacement.

We have informed the French ANSM (Agence nationale de sécurité du médicament et des produits de santé / National Agency for the Safety of Medicines and Health Products) of this batch recall.

We remain at your disposal for any further information you might need via:

- E-mail: [qualite@herdegen.fr](mailto:qualite@herdegen.fr)
- Telephone: +33 248 269 880.

Yours sincerely,

Enrique APARICIO,  
Quality Manager



**FSN ACKNOWLEDGEMENT OF RECEIPT**

PLEASE FILL OUT THIS ACKNOWLEDGEMENT OF RECEIPT AND SEND IT BACK  
before 15/08/2021.

**HERDEGEN FSN 002 2021**

Please tick the box which applies to your situation and indicate the quantities concerned:

- We have read and understood the FSN.
- We confirm that none of the elbow crutches we have received are concerned by this batch recall.
- We have distributed elbow crutches which are concerned by this batch recall. We will contact our customers and/or users in order to ask them to stop using the devices immediately and return them for replacement.

Please indicate the quantity (in pieces) of crutches distributed:      ADVANCE :

FUN :

EVOLUTION :

- We still have elbow crutches in our stock which are concerned by this batch recall.

Please indicate the quantity (in pieces) of crutches to be returned:

- We confirm that we have destroyed all the elbow crutches of our stock which were concerned by this recall for the following batches:

ADVANCE :

FUN :

EVOLUTION :

Company name:

Made by (name and surname):

Signature :

Date:

Please send this acknowledgement receipt filled out and signed to  
the following e-mail address:

[qualite.sav@herdegen.fr](mailto:qualite.sav@herdegen.fr)