



FIELD SAFETY NOTICE FSN 002-2021

BATCH RECALL - URGENT

Product concerned : Evolution and Advance crutches

Evolution crutches	Ref 200 000 (grey) Ref 200013 (blue) Ref 200014 (red) Ref 200017 (turquoise) Ref 200018 (anise)
Advance crutches	Ref 200913 (blue) Ref 200915 (purple) Ref 200917 (turquoise) Ref 200916 (orange)

Products delivered from 24 April to 30 May 2021 (months concerned APRIL and MAY)

Product Batch Numbers concerned :

7001 8002 8011 8013 9001 9003 9007

Dear Valued Customers,

Despite strength testing performed in accordance with ISO 11334-1, we have found an unusually high rate of handle breakage on our Evolution and Advance crutches.

An initial analysis suggests that in extreme cases of use, especially when the user presses very hard on the front of the handle and not in the middle of the handle as is usual, the handle may break. This can happen in some very rare cases.

It seems to be established that this abnormal fragility is the consequence of the use of a plastic material with characteristics slightly different from that usually used and which was out of stock at our usual supplier.

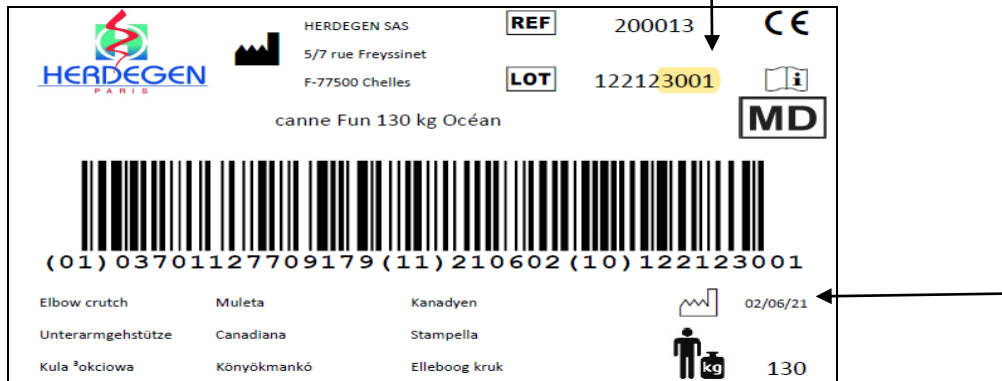
As a precautionary measure, we have therefore decided to recall the batches manufactured with this material. They are listed below :

7001 8002 8011 8013 9001 9003 9007

These numbers can be identified on the labels stuck on the crutch and on the box.
Please refer to the scheme below



The batch number is indicated on the box or on the crutch in the upper right corner of the label by 4 digits



Month and year of production batch in the lower right corner of the UDI label

We therefore ask you to :

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

We remain at your disposal for further information:
qualite@herdegen.fr or by phone 0248269880.

Yours sincerely,

Enrique APARICIO, Quality Manager