

Field Safety Notice

Product name & article: "Toileting Slings", article no 25080, 25085 and 25090

FSCA ID: FSCA 2020-06-10

Action: Product Label Modification

Date: 2020-06-10

To: Human Care's "CUSTOMER"

Products concerned

This field safety notice applies to Human Care's hygiene slings (Toileting Slings), article no. 25080, 25085 and 25090, with production date between 2018-09-11 and 2019-11-14. The article number and the date of manufacturing are stated on the product label.

Problem Description

The illustration in the product label of Human Care's hygiene slings (Toileting Slings), article no. 25080, 25085 and 25090, with production date between 2018-09-11 and 2019-11-14 shows an end-user with arms inside the sling. This illustration is misleading and may cause a health risk to the end-user. The same improper illustration, i.e. end-user with the arms inside the sling, appears in the earlier version of the user-manual.

Hygiene slings have a large opening for the buttocks, which is associated with a risk of slipping. Therefore, it is important that the end-user has his/her arms outside the sling, in order to prevent any slipping from the sling.




The improper illustration
Incorrect use of the sling



The correct illustration
Correct use of the sling

Corrective Actions

The situation with improper product label has been already addressed and products produced after 2019-11-14 carry a label whose illustration shows an end-user with his/her arms outside the sling.

Human Care has reviewed and updated all user-manuals available on the website. All illustrations now show users sitting in the sling with his/her arms outside the sling. The symbol  means that the user-manual must be read before use. The QR code on the label also links to the user-manual on the website.

The link to updated user-manual:

<https://humancare.se/wp-content/uploads/2016/08/99696-user-manual-sling-toileting-REV2.pdf>

Customers who have received slings with a product label with an improper illustration have been receiving self-adhesive labels to be affixed on top of the product's previous label. These self-adhesive labels have an illustration that shows an end-user with his arms outside the sling. Instructions for applying the label have been sent along with the label, which is:

1. Place the product label at a flat surface, with flat material below it for example by putting a book below the label to avoid wrinkles.
2. Insure that the label is clean.
3. Put the sticker over the existing illustration.
4. Ultimate adhesive strength with optimum adhesion after 2 hours after application.
5. After about 8 hours washing machine and tumble dryer safe, according to the instructions of the label and sling manual.

Feedback to Human Care

Human Care hereby requests all customers to confirm that they have received this notice and that the obtained self-adhesive labels have been applied correctly. A form is sent out along with this notice, for easy re-reporting / confirmation to Human Care.

Contact person:

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We are sorry for the inconvenience this may have caused. For questions, please contact Human Care.

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Kamran Kaviani

Chief Quality & Regulatory Affairs Officer

Human Care HC AB