2017-10-12
ZJ-S 379/2017

Urgent Field Safety Notice

Microdot Droplet Pen Needle 4mm x 32G28G, type 810, catalogue number 8065.

FSCA – ZJ-S 379/2017

Type of action: advice given by MANUFACTURER regarding the use of the device.

Date: 2017-10-12.

Notice in connection with instruction for use (IFU) and lack of steps regarding correct removal and putting on the protective caps and measures to correct the problem.

Details of affected devices:

Pen needles are sterile, single use needles intended for use with pen injector device for the subcutaneous injection of insulin. Pen needles are used by consumers, caregivers and healthcare professionals. The product is a medical device of the IIa class as per MDD.

The notice concerns the Microdot Droplet Pen Needle 4mm x 32G28G, type 810, catalogue number 8065. Shelf boxes of 200 pcs.

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VAT: PL7321880362 • REGON: 472350579 • District Court for Lodz-Srodmiescie in Lodz, XX Commercial Department of the National Court Register, KRS: 0000256309, share capital: 2,934,421.10 PLN (paid in full)

Description of the problem:

The Field Safety Notice concerns instruction for use (IFU) and lack of steps regarding correct removal and putting on the protective caps.

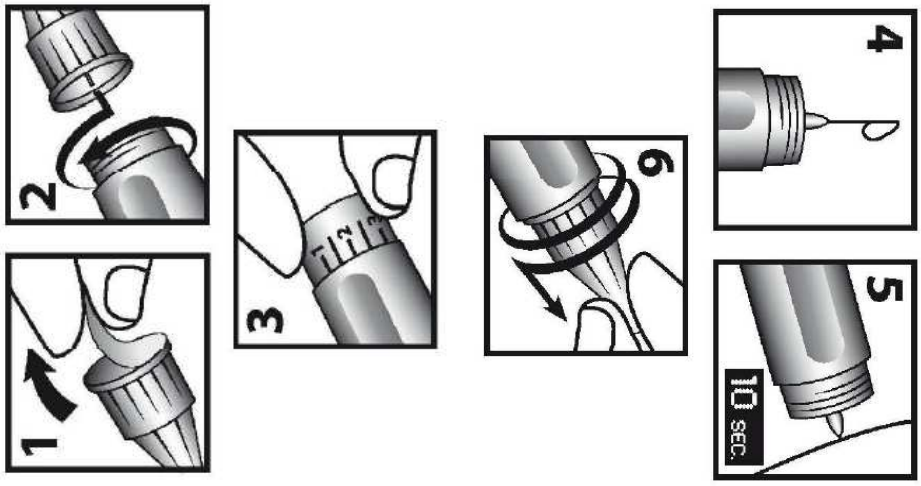
On 2017-07-28 Cambridge Sensors Ltd. has informed HTL-STREFA S.A. about notification from a patient: "The alleged fault with the needles is that they are described by the patient as "bent and unsafe to use"."

The notification concerns Microdot Droplet Pen Needle 4mm x 32G, lot number: X46J1, catalogue number: 8065.

The defect reported by the customer cannot be generated on pen needle assembly line due to the optical control stations which detect and reject such a defect – a non-conforming product. Final control is conducted at the end of the process.

The most likely cause of the defect was incorrect removal of the cap or multiple recapping by the user.

The current IFU shows 6 steps of use of the device. The step related to correct removal of the inner and outer cap is not included.



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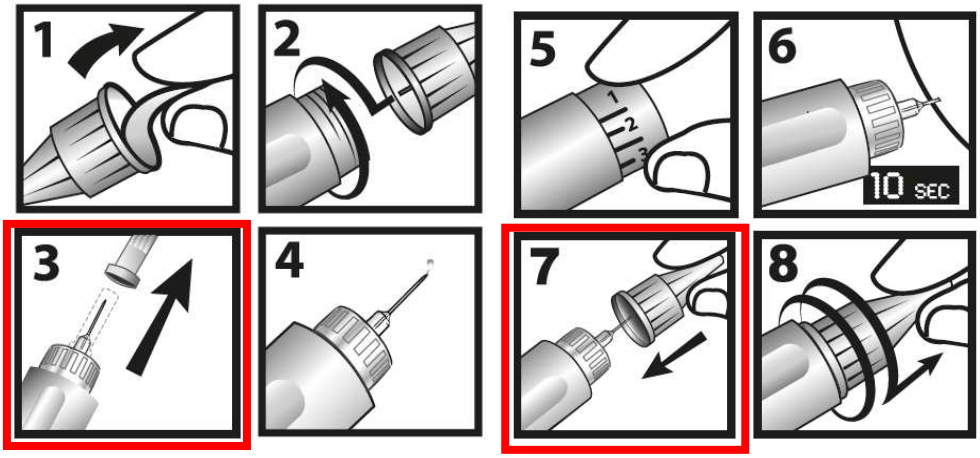
Advise on action to be taken by the user:

Within corrective actions there will be added two additional steps (step 3 and step 7) to IFU, explaining how to remove and put on the caps correctly:



Within immediate corrective actions there will be a leaflet included to next shipments, containing the IFU with new steps included.

HTL-STREFA S.A. will introduce changes in the packaging, IFU and a description of use of the device to allow to correct removal of the needle caps.

The users are requested to pay attention to the way they remove and put on protective caps according to instruction for use on the packaging and in the leaflet.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where potentially the boxes have been transferred. All potential users should be properly informed about updated IFU in regards to the steps explaining how to remove and put on the caps correctly.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The notice will be forwarded to the Notify Body of HTL-STREFA S.A.

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HTL-STREFA S.A. has informed HPRA (Irish Competent Authority) about the complaint and provided all relevant information.

Corrective actions to the complaint are conducted within KDK-87/2017. The changes of artwork and IFU will be implemented in CC-315/2017. The actions are planned to be completed by 2017-12-31.

Contact reference person:

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