
Urgent Field Safety Notice

Commercial name: COOLTECHNOLOGY (trademark cooltech)

FSCA-identifier: reference MEDDEV2.12_HTP_02 (04/07/2019)

Type of action: advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users or others

Date: 10th July, 2019

Attention: High Technology Products, SLU customer (cooltech device)

Details on affected devices:

Identifier: COOLTECHNOLOGY device (trademark cooltech)

Reference: 521007

Company: High Technology Products, SLU (cocoon medical)

Description of the problem:

Paradoxical adipose hyperplasia has been included in the latest version of the cooltech's User Manual with reference number 1000002288 – 20190704 – v2.2 as a new side effect (categorized as infrequent). This action is based on the clinical evaluation updating performed by High Technology Products, SLU (HTP) where the most recent publications regarding side effects of cryoadipolysis as a part of the state of the art were analyzed. This new user manual is aligned with the "consent form" model previously shared by HTP with its customers on March 2018, where Paradoxical adipose hyperplasia was already included.

Through this notification, High Technology Products is going to send to all its customers the most recent version of the cooltech's user manual with reference number 1000002288 – 20190704 – v2.2 and the "consent form" with the addition of the side effect: Paradoxical adipose hyperplasia with the updated occurrence frequency. (reference 1000002562 – 20190704 – v2.2).

High Technology Products takes this opportunity to share with its customers that this problem is NOT considered an incident representing a serious risk to public health.

Advise on action to be taken by the user:

The user of the cooltech device when receiving the corresponding updated material 1) user manual for cooltech device reference 1000002288 – 20190704 – v2.2 and 2) "consent form" (reference 1000002562 – 20190704 – v2.2) should:

- *Revise the received material, eliminate the old versions of both user manual and "consent form" and start using the new material with the above-mentioned references.*

HIGH TECHNOLOGY PRODUCTS, SLU

(cocoon medical)

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08005, Barcelona, Spain

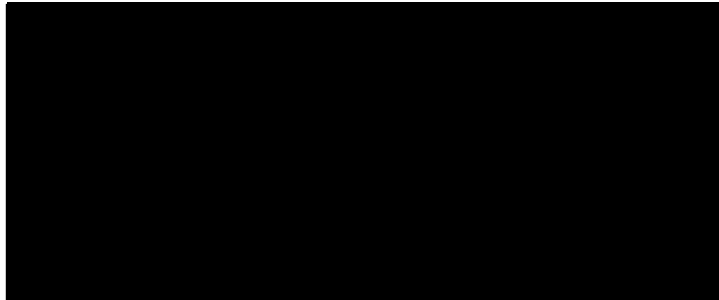
Tel. +34 934 588 506

www.cocoonmedical.com

- *Send to its official distributor and/or the manufacturer (High Technology Products, SLU) and acknowledgment of receipt of the information with specific confirmation of its application.*

Transmission of this Field Safety Notice:

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



The undersign confirms that this notice has been notified the appropriate Regulatory Agency

High Technology Products, SLU (cocoon medical) reiterates its commitment to the continuous improvement of its products and processes and we wish to continue having your trust.

