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 1000002562 – 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 1000002562 – 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 1000002562 – 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.*