Allergan
Aesthetics
an AbbVie company

2 June 2022

Urgent Field Safety Notice

Commercial Name: CoolSculpting System parallel plate Applicators: CoolCore, CoolCurve, CoolCurve+, CoolMax, and CoolFit applicators

FSCA Identifier: FSCA-22-001-CS

Type of Action: Return of product

Dear Customer,

The purpose of this letter is to advise you that ZELTIQ Aesthetics, Inc. (ZELTIQ) is voluntarily discontinuing and recalling CoolSculpting® parallel plate applicators (CoolCore, CoolCurve, CoolCurve+, CoolMax, and CoolFit) due to the observance of a slightly increased rate of Paradoxical Hyperplasia (PH) associated with these applicators during a recent analysis of data from the 2019-2021 timeframe.

This voluntary discontinuation and recall does not affect the CoolSculpting® control units, cooling cup applicators (CoolMini, CoolAdvantage, CoolAdvantage Petite, and CoolAdvantage Plus) or surface applicators (CoolSmooth and CoolSmooth Pro).

Details on affected devices:

The following products (all serial numbers) are included in the scope of this FSCA:

Applicators	PN
CoolMax	BRZ-AP1-080-000
CoolCore	BRZ-AP1-063-000
CoolCurve	BRZ-AP1-062-000
CoolCurve+	BRZ-AP1-064-000
CoolFit	BRZ-AP1-066-000

Description of the problem:

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The safety profile of CoolSculpting® is well characterized. Paradoxical hyperplasia (PH) is a rare adverse event associated with cryolipolysis that is defined as visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment and may require surgical intervention for correction. PH is described in the CoolSculpting® labeling as a rare adverse event occurring in approximately 1 out of 3,000 treatments (0.033%).

ZELTIQ closely monitors PH reporting rates. The historical and overall rate of PH for CoolSculpting® parallel plate applicators since launch in 2010 to 2021 is within the predicted frequency. In a recent analysis of reported complaints during the 2019 to 2021 timeframe, however, the data showed an increase in the rate of PH with the CoolSculpting® parallel plate applicators (approximately 1 out of 1,000 treatments), which is at the upper limit of the predicted frequency.

The overall risk to health is considered low based on the frequency of occurrence and the treatment required for correction of PH. As noted above, the reported rate of PH with parallel plate applicators is approximately 1 out of 1000 treatments. The condition will not resolve on its own and may require surgical intervention for correction.

Advice on action to be taken by the user:

Effective immediately, healthcare providers should cease use of these parallel plate applicators and quarantine them prior to return. All affected products should be returned to Kühne & Nagel (Baumlimattstrasse 12, 4313 Mohlin, Switzerland) for which details will be provided after return of the business response form.

Transmission of this Field Safety Notice:

This notice needs to be distributed to all those who need to be aware within your organisation. If any such devices have been transferred outside of your organisation, please provide these details to the manufacturer and forward a copy of this Field Safety Notice.

Please maintain awareness on this notice until such time that all affected applicators in your organization have been returned.

Please report all device-related incidents to the Allergan Aesthetics and the national Competent Authority, if appropriate, as this provides important feedback.

Contact Information:

For adverse event reporting, medical information questions or to speak to our Product Support team, please contact us as follows:

Adverse event reporting: coolsculpting.intlsupport@allergan.com
Medical Information: medinfo.ch@abbvie.com
Technical Product support: Sebastiaan.Deruijter@allergan.com
Logistical Product Support: braun_sabrina@allergan.com

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.