Allergan
an AbbVie company

Allergan Malaysia Sdn Bhd (831025-D), Level 5-02, Block A, PJ8, No 23 Jalan Barat, Seksyen 8, 46050, Petaling Jaya.
Tel: 603 7957 3885 Fax: 603 7957 3141

Date:

Dear Customer / Distributor,

Purpose of this letter:

- 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 applicators) due to the observance of a slightly increased rate of Paradoxical Hyperplasia (PH) 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) surface applicators (CoolSmooth and CoolSmooth Pro) or the CoolSculpting® Elite system and associated family of Elite applicators.

Reason for the Voluntary Recall:

The safety profile of CoolSculpting® is well characterized. Paradoxical hyperplasia (PH) is a rare adverse event associated with cryolipolysis that is defined as a 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® and CoolSculpting® Elite labeling as a rare side effect 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® 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.

Risk to Health:

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.

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Actions to be taken by the Customer/User:

Effective immediately, healthcare providers should cease use of these parallel plate applicators. All affected products should be quarantined and returned to **Biomed Global, No.21-1, Jalan 4/62A, Bandar Menjalara, Kepong, 52200 Kuala Lumpur** as described in the attached business response form.

The recalled products include

Name	Part Numbers/ Catalog Numbers
CoolCore Applicator	BRZ-AP1-063-000
CoolCurve Applicator	BRZ-AP1-062-000
CoolCurve + Applicator	BRZ-AP1-064-000
CoolMax Applicator	BRZ-AP1-080-000
CoolFit Applicator	BRZ-AP1-066-000

Healthcare providers with questions regarding this announcement should contact Medical Information via email at medinfo.sea@abbvie.com

Sincerely,

Electronically signed by: Paul Venables Reason: Management Approval Date: May 31, 2022 23:42 GMT+8

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Paul Venables
Country Manager,
Allergan Aesthetics -Singapore/Malaysia/Philippines