



COOL CONFIDENCE PROGRAM

Please see Important Safety Information on the last page.



What is Paradoxical Hyperplasia?

Paradoxical Hyperplasia (or PH) is characterized by the gradual development of a visibly enlarged tissue volume, of varying size and shape, in the CoolSculpting treatment area 2 to 5 months after treatment. This is distinguished from temporary swelling and will not resolve on its own.

Over 11 million CoolSculpting treatments have been performed worldwide. Paradoxical Hyperplasia (PH) is a rare¹ side effect of cryolipolysis with a reported rate of **1 in 3000** CoolSculpting treatments.

The Cool Confidence Program

CoolSculpting is an FDA cleared **noninvasive procedure** used to freeze and eliminate unwanted fat.

In the rare event of a confirmed PH case, you will be eligible for financial assistance of **up to \$7,500** for the corrective procedure.² A PH diagnosis meets the characteristics of PH that Allergan Aesthetics has established.

To find out if you are eligible, your healthcare provider must **contact CoolSculpting Product Surveillance** prior to the corrective procedure. To submit a claim, your provider must provide the appropriate **documentation** to confirm PH.

¹ "Rare" can be defined as when the frequency falls between 1/1000 and 1/10,000. Council for International Organizations of Medical Sciences (CIOMS). Guidelines for preparing core clinical-safety information on drugs. 1999.

² The patient will directly receive financial compensation of up to \$7,500 once the executed release is received.

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Patient was treated with CoolSculpting® Elite on her abdomen and flanks. Results may vary.

PRODUCTS COVERED

The Cool Confidence program applies to **CoolSculpting®** and **CoolSculpting® Elite** treatments, provided that the treatments are performed as intended by appropriately qualified and licensed healthcare providers in accordance with current and accepted medical practices and in accordance with the current CoolSculpting and CoolSculpting Elite User Manuals found in CoolNet®.

EVENTS COVERED

- Paradoxical Hyperplasia

EVENTS NOT COVERED

- Lack of results or dissatisfaction with treatment results
- Adverse events other than those listed in the "Products Covered" section
- Experiences related to other manufacturers' devices
- Patients who have previously participated in the Cool Confidence Program

Where applicable, financial assistance will be issued upon receipt and verification of the patient's warranty general release.

Allergan Aesthetics has the right to request photographs, treatment documents, and other documents deemed acceptable by CoolSculpting in order to participate in the Cool Confidence Program and confirm a PH diagnosis.



† Patient was treated on abdomen and flanks with CoolSculpting Elite. Results may vary.



coolsculpting®

For more information, ask your provider about
CoolSculpting and the Cool Confidence Program

[COOLSCULPTING.COM](https://www.coolsculpting.com)

Uses

CoolSculpting® and **CoolSculpting® Elite** are FDA-cleared for the treatment of visible fat bulges in the submental (under the chin) and submandibular (under the jawline) areas, thigh, abdomen, and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll), and upper arm. It is also FDA-cleared to affect the appearance of lax tissue with submental area treatments. **CoolSculpting®** and **CoolSculpting® Elite** are not treatments for weight loss.

Important Safety Information

These procedures are not for everyone. You should not be treated with **CoolSculpting®** or **CoolSculpting® Elite** if you suffer from cryoglobulinemia, cold agglutinin disease, or paroxysmal cold hemoglobinuria.

Tell your doctor if you have any medical conditions including recent surgery, pre-existing hernia, and any known sensitivities or allergies.

During the procedure you may experience sensations of pulling, tugging, mild pinching, intense cold, tingling, stinging, aching, and cramping at the treatment site. These sensations lessen as the area becomes numb. Following the procedure, typical side effects include temporary redness, swelling, blanching, bruising, firmness, tingling, stinging, tenderness, cramping, aching, itching, or skin sensitivity, and sensation of fullness in the back of the throat after submental or submandibular area treatment.

Rare side effects may happen in 1 to 10 out of 10,000 **CoolSculpting®** and **CoolSculpting® Elite** treatments (between 0.01% to 0.1%). One such rare side effect is a visible enlargement in the treated area, which may develop 2 to 5 months after treatment, will not resolve on its own, and may require surgical intervention for correction.

Please see full Important Safety Information for **CoolSculpting®** and **CoolSculpting® Elite** on [CoolSculpting.com](https://www.coolsculpting.com).

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