



FREQUENTLY ASKED QUESTIONS: COOLSCULPTING® AND PARADOXICAL ADIPOSE HYPERPLASIA (PAH)

This document is provided by Allergan Aesthetics to CoolSculpting healthcare providers to assist with questions about CoolSculpting and Paradoxical Adipose Hyperplasia.

Adverse Event reporting to Allergan Aesthetics is important to further understand the benefits and risks of CoolSculpting. Any possible Adverse Events must be reported to Product Support at 1-888-935-8471 between 6 AM and 5 PM PT or via email at CoolSculpting.support@allergan.com.

If you have additional questions, please contact your sales representative, medical affairs professional, or the Allergan Aesthetics Medical Information team at gmi@abbvie.com or 1-800-678-1605 Option #2.

What is CoolSculpting and how does it work?

CoolSculpting was first cleared by the FDA in 2010 for the noninvasive reduction of subcutaneous fat. CoolSculpting applies controlled cooling to the treated area, which leads to subcutaneous adipocyte cell death. The process for adipocyte death includes an inflammatory response that typically lasts 2 to 3 months, which is around the time you can start seeing results.¹ More than 11 million treatments have been delivered worldwide,² with more than 100 scientific publications providing clinical information on how CoolSculpting can be used to achieve patients' aesthetic body contouring goals.³

What are the possible CoolSculpting adverse events?

During the CoolSculpting procedure, patients may experience sensations of pulling, tugging, and mild pinching at the treatment site, as well as intense cold, tingling, stinging, aching, and cramping. Immediately following the CoolSculpting procedure, there are several possible adverse events that can occur in the treatment area. These include redness, firmness, transient blanching, and bruising as well as tingling and stinging in the treatment area. In the weeks following CoolSculpting treatment, patients may also experience redness, bruising, swelling, tenderness, cramping, and aching as well as itching, increased skin sensitivity, tingling, and numbness. When treating the submental and submandibular areas, fullness of the back of the throat after treatment may also be experienced.

What are the rare CoolSculpting adverse events?

A number of rare adverse events have been reported with CoolSculpting. These include Paradoxical Adipose Hyperplasia, late onset pain, severe pain, freeze burn, vasovagal symptoms, subcutaneous induration, hyperpigmentation, hernia, treatment area demarcation, as well as cold panniculitis.

What is Paradoxical Adipose Hyperplasia?

Paradoxical Adipose Hyperplasia, also known as 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.⁴ Paradoxical Adipose Hyperplasia is a known and rare CoolSculpting adverse event that was first described in a clinical publication (*JAMA Dermatology*) in January 2014.⁵

Indications

The CoolSculpting® procedure is FDA-cleared for the treatment of visible fat bulges in the thigh, abdomen and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll), and upper arm in patients with a Body Mass Index (BMI) of ≤ 30 and in submental and submandibular areas in patients with a BMI of ≤ 46.2. It is also FDA-cleared to affect the appearance of lax tissue with submental area treatments.

See Important Safety Information for CoolSculpting® on the back.



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How common is Paradoxical Adipose Hyperplasia?

Per the CoolSculpting User Manual, Paradoxical Adipose Hyperplasia is considered a rare adverse event. "Rare" can be defined as when the frequency falls between 1/1000 and 1/10000.⁶

Does Paradoxical Adipose Hyperplasia only occur with CoolSculpting?

There are case reports and case series that have been published since the first report of Paradoxical Adipose Hyperplasia published in 2014.⁵ The majority of these have been associated with CoolSculpting. There has also been a recent case report of Paradoxical Adipose Hyperplasia following use with another device utilizing a different modality for noninvasive fat reduction.⁷

Are there any known risk factors for the development of Paradoxical Adipose Hyperplasia?

The pathophysiology of Paradoxical Adipose Hyperplasia is not currently understood, and the predisposing risk factors are not known.

Does Paradoxical Adipose Hyperplasia resolve on its own?

There is currently no reported literature that suggests that Paradoxical Adipose Hyperplasia resolves on its own.

How can Paradoxical Adipose Hyperplasia be treated?

Surgical intervention, such as liposuction, may be required for correction of Paradoxical Adipose Hyperplasia.

Important Safety Information

CoolSculpting® is contraindicated in patients with cryoglobulinemia, cold agglutinin disease, or paroxysmal cold hemoglobinuria.

Ask your patient about any medical conditions including recent surgery, pre-existing hernia, and any known sensitivities or allergies.

During the procedure patients may experience sensations of pulling, tugging, mild pinching, intense cold, tingling, stinging, aching, and cramping at the treatment site. These sensations subside 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 also occur. Paradoxical hyperplasia (visibly enlarged tissue volume in the treated area) may develop 2-5 months after treatment and requires surgical intervention for correction.

As with any medical procedure, a consultation should be done by a licensed healthcare professional to determine if the patient is a candidate for treatment. Consult the CoolSculpting® System User Manual for a complete list of Contraindications, Warnings, Precautions, and potential side effects. Treatment applications that deviate from the guidelines are not recommended.

References: **1.** Coleman SR, Sachdeva K, Egbert BM, Preciado J, Allison J. Clinical efficacy of noninvasive cryolipolysis and its effects on peripheral nerves. *Aesthetic Plast Surg.* 2009;33(4):482-488. **2.** Data on file, Allergan, 2021; 11+ Million CoolSculpting® Cycles. **3.** Data on file, Allergan, October 5, 2017; Number of CoolSculpting® Publications. **4.** Data on file, Allergan; COM1 User Manual (BRZ-101-TUM-EN2-L). **5.** Jalian HR, Avram MM, Garibyan L, Mihm MC, Anderson RR. Paradoxical adipose hyperplasia after cryolipolysis. *JAMA Dermatol.* 2014;150(3):317-319. **6.** Council for International Organizations of Medical Sciences (CIOMS). Guidelines for preparing core clinical-safety information on drugs. 1999. **7.** Agochukwu-Nwubah N, Mentz H. Paradoxical adipose hyperplasia after noninvasive radiofrequency treatment: A novel report and review. *J Cosmet Dermatol.* 2020;19(4):866-868.