

New Mandatory for Co-Op Advertisements*

All advertisements must include the abbreviated Important Safety Information if the ad makes a claim (in words or imagery) relating to the use, benefits, efficacy, or safety of CoolSculpting® or CoolTone™.



What is a Claim?



Examples of CoolSculpting® claims include:

Discussion of what CoolSculpting® does:

- Freezes away unwanted fat
- Uses cryolipolysis technology to eliminate fat cells in the treated area

Mention of CoolSculpting® benefits:

- Little to no downtime
- Reduces unwanted or stubborn fat
- FDA-cleared, safe, and effective
- Results may be seen as early as 1 to 3 months after treatment
- Treated fat cells, once eliminated, are gone for good
- Up to 20-25% fat reduction in the treated area

REQUIRED ABBREVIATED IMPORTANT SAFETY INFORMATION

CoolSculpting® is FDA-cleared to treat visible fat bulges in 9 areas of the body. Some common side effects include temporary numbness, discomfort, and swelling.



For both:

Showing Before and After photos (benefits)

Including imagery of a patient being treated with CoolSculpting® or CoolTone™ (use)

Examples of CoolTone™ claims include:

Discussion of what CoolTone™ does:

- Conditions and strengthens muscle fibers
- Tones, firms, and strengthens treated muscles
- CoolTone™ is a great, nonsurgical way to tone, firm, and strengthen your abs, buttocks, and thighs

Mention of CoolTone™ benefits:

- FDA-cleared, safe, and effective
- Tones treated areas (abs, buttocks, and thighs)
- Firms and strengthens treated muscles
- Results typically seen after 4 treatments over a 2-week period

REQUIRED ABBREVIATED IMPORTANT SAFETY INFORMATION

CoolTone™ is FDA-cleared to strengthen, tone, and firm the abdomen, buttocks, and thighs. Common side effects include muscle, joint, or tendon pain, muscle spasm, and skin redness.

*See CoolSculpting® Rewards Program guide for additional information.

CoolSculpting® 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.

CoolSculpting® 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.

CoolTone™ Indications

The CoolTone™ device is indicated for improvement of abdominal tone, strengthening of the abdominal muscles, and development for firmer abdomen. CoolTone™ is also indicated for strengthening, toning, and firming of buttocks and thighs.

CoolTone™ Important Safety Information

CoolTone™ treatment is contraindicated in placing the active applicator over metal, electrical, or electronic implants/devices in the treatment area like cardiac pacemakers, cochlear implants, intrathecal pumps, implanted defibrillators, implanted neurostimulators, drug pumps, or hearing aids.

CoolTone™ is also contraindicated in placing the active applicator over menstruating uterus, over areas of the skin that lack normal sensation, and in patients with fever, malignant tumor, hemorrhagic conditions, epilepsy, recent surgical procedure, pulmonary insufficiency, or pregnancy.

CoolTone™ should be used with caution in patients with Graves' disease, active bleeding disorders, or seizure disorders.

Women who are close to menstruation may find that it comes sooner, or cramping is increased or intensified with CoolTone™ treatments, therefore, it is recommended to not undergo treatment during this time of the month.

CoolTone™ should not be used in the heart or head areas, areas of growth plate, over the carotid sinus nerves, or over the neck or mouth. CoolTone™ should not be applied over swollen, infected, inflamed areas or skin eruptions. Caution should be used for patients with suspected or diagnosed heart problems.

Ensure that persons with pacemakers are not present in vicinity of the device during treatment.

Common adverse effects may include, but may not be limited to muscular pain, temporary muscle spasm, temporary joint or tendon pain, and local erythema or skin redness.

Consult the CoolTone™ User Manual for a complete list of Contraindications, Warnings, Precautions, and potential side effects. Treatment applications that deviate from the guidelines are not recommended.