

# WHAT IS A CLAIM?

## 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® Elite, CoolSculpting®, or CoolTone®.



Examples of CoolSculpting® Elite claims include:

### DISCUSSION OF WHAT COOLSCULPTING® ELITE DOES:

- Eliminate fat with the most advanced CoolSculpting® system yet\*

\*Treat 2x the stubborn fat at once with dual applicators.

(Note this claim and footnote if used would need to be verbatim.)

- The future of noninvasive fat reduction has arrived

### MENTION OF COOLSCULPTING® ELITE BENEFITS:

- The one and only treatment FDA-cleared to eliminate stubborn fat in 9 different areas
- Innovative, nonsurgical way to contour your body
- Target 2x the stubborn fat at once with new dual applicators
- Reimagined dual applicators can now target 2 areas of stubborn fat at once
- Scientifically proven to eliminate up to 20-25% of treated fat cells for good
- Treatment requires no surgery and little to no downtime, so you can get back to your busy day



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



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

Examples of visual claims include: Showing Before, During, and After photos (benefits), or imagery of a patient being treated with CoolSculpting® Elite, CoolSculpting®, or CoolTone® (use)

### REQUIRED ABBREVIATED IMPORTANT SAFETY INFORMATION

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

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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.

### 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.

If CoolSculpting® /CoolSculpting® Elite and CoolTone® are mentioned on the same advertisement, the mandatory disclaimer is also required:  
The safety and efficacy of CoolSculpting® and CoolTone® in combination have not been evaluated by the FDA.

\*See CoolSculpting® Rewards Program guide for additional information.

### CoolSculpting® and CoolSculpting® Elite Indications

CoolSculpting® and CoolSculpting® Elite are 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  $\leq 30$  and in submental and submandibular areas in patients with a BMI of  $\leq 46.2$ . It is also FDA-cleared to affect the appearance of lax tissue with submental area treatments.

### CoolSculpting® and CoolSculpting® Elite Important Safety Information

CoolSculpting® and CoolSculpting® Elite are contraindicated in patients with cryoglobulinemia, cold agglutinin disease, or paroxysmal cold hemoglobinuria.

See more CoolSculpting®, CoolSculpting® Elite, and CoolTone® Important Safety Information on the reverse side.

### 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.

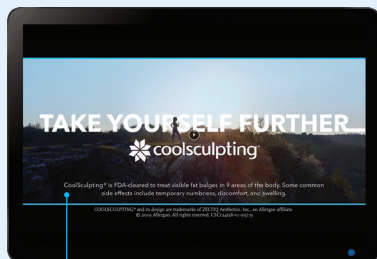
### CoolTone® Important Safety Information

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.

**Examples of advertisements:** How best to incorporate the abbreviated Important Safety Information in CoolSculpting® Elite, CoolSculpting®, and CoolTone® advertisements.



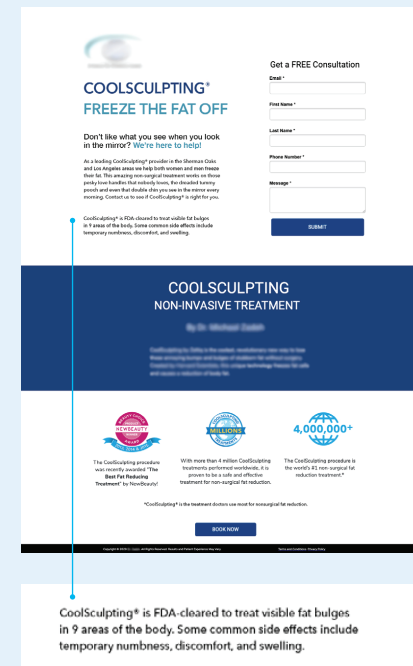
**Static Social Ad Example:** Abbreviated Important Safety Information should be prominent and legible.



**TV/ Video Example:** Abbreviated Important Safety Information can be included as voiceover and/or on-screen text. Copy should be prominent and legible.

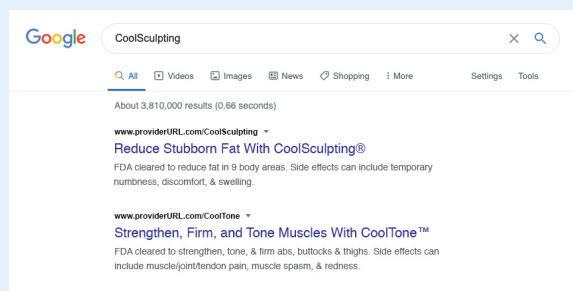


**Full Page Ad Example:** Abbreviated Important Safety Information should be comparable in prominence to the font size as body text.



**Landing Page Example:** With abbreviated Important Safety Information, the font size should be comparable in prominence to the body copy on the page.

**Google Ad Example:** For CoolSculpting® Elite, CoolSculpting®, and CoolTone®, branded co-op paid search ads.



**Radio Commercial Example:** Abbreviated Important Safety Information must be read audibly and intelligibly.

**CoolSculpting® and CoolSculpting® Elite Important Safety Information (continued)**

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 to 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. For a complete list of Contraindications, Warnings, Precautions, and Potential Side Effects, consult the **CoolSculpting®** System User Manual and the **CoolSculpting® Elite** System User Manual. Treatment applications that deviate from the guidelines are not recommended.

**CoolTone® Important Safety Information (continued)**

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.