

Introduction

Before beginning your CoolTone® treatment, please review this important information. Results and patient experience may vary. This is not meant to cover all aspects of the CoolTone® treatment. Please contact your healthcare provider for additional details.

Glossary of terms

- Active applicator** - Applicator currently running magnetic field
- Active bleeding disorder** - Inability to form blood clots which results in blood that does not stop flowing after several minutes
- Contouring** - To enhance shape or structure
- Contraction** - muscle becoming shorter and/or tighter
- Drug pump** - Medical device that stores and pumps medication into the body
- Electrical activity** - Energy that affects the body in forms of electricity or electrical current
- Electromagnetic stimulation** - Uses magnetic field to stimulate muscles
- Epilepsy** - Sudden sensory disturbance and loss of consciousness due to abnormal electrical activity in the brain
- Erythema** - Appearance of red area on the skin
- Fever** - Body temperature that is higher than normal 98.6°C
- Firm** - Feeling of solid structure
- Graves' disease** - Condition with overactive thyroid gland that results in swelling of neck and eyes
- Hemorrhagic conditions** - Abnormal bleeding disease
- Implanted electrical devices** - Electrical devices implanted in the body such as cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids, implanted defibrillators, neurostimulators, etc
- Involuntary** - Occurring without your control
- Joint or tendon pain** - Feeling of discomfort or pain in the joint or tendon several hours after a treatment and resolution within several days
- Magnetic field** - Area defined by a magnetic force being exerted on a moving charged particle
- Malignant tumor** - Tumor that grows and invades surrounding tissues
- Menstruating/Menstruation** - Discarding of blood during monthly cycle in women
- Muscle spasm** - Feeling of contraction of the muscle
- Muscles** - Fibrous tissue throughout the body that helps move arms, legs, and other parts of the body
- Muscular pain** - Feeling of pain in the muscle
- Noninvasive** - Not requiring the introduction of instruments into the body
- Pulmonary insufficiency** - Problem with blood flow through the pulmonary valve towards the heart
- Seizure disorders** - Abnormal electrical activity in the brain
- Sensation** - A physical feeling
- Strengthen** - Make stronger
- Tone** - The continuous and passive contraction of muscle during a resting state

What is it?

The CoolTone® procedure is a body contouring procedure that applies noninvasive electromagnetic stimulation onto the muscles. The procedure involves repeatedly contracting muscle tissues by passing electric currents through applicators that are in contact with the specific body area. The CoolTone® procedure is FDA-cleared for improving abdominal tone, strengthening the abdominal muscles, and development for firmer abdomen. Also, the CoolTone® procedure strengthens, tones, and firms the buttocks and thighs.

What does it do?

The CoolTone® noninvasive body contouring treatment uses magnetic muscle stimulation to strengthen, tone, and firm the muscles of the abdomen, buttocks, and thighs. The technology penetrates below the fat layer to strengthen and tone muscles in the treated area. Results can vary from person to person.

How is it used? What does it feel like?

The CoolTone® System is a prescription-use-only device and may only be used by or on the order of a physician. Your practitioner will discuss your individual treatment plan for your needs. A strap covers the applicator, and you may be dressed in a thin layer of clothing. Depending on the selected body area of treatment, one or two applicators may be applied over the targeted area.

The electromagnetic stimulation is delivered through the applicator and a practitioner may adjust the intensity of the magnetic muscle stimulation as tolerated by you. During treatment, you will feel a series of involuntary deep muscle contractions over the targeted area that will last for a few seconds followed by a period of rest.

What will it accomplish?

The CoolTone® procedure improves abdominal tone, strengthens the abdominal muscles, and develops firmer abdomen. Also, the CoolTone® procedure strengthens, tones, and firms the buttocks and thighs. Results and patient experience may vary.

Are there any reasons I should not get the CoolTone® procedure?

Yes, there are reasons why you may not be able to get the CoolTone® treatment. You should inform your physician of your entire medical history. If you have one of the following conditions, inform your CoolTone® healthcare provider as you may not be an appropriate candidate for CoolTone® treatment.

- CoolTone® should never be placed over areas with metal, electrical, or electronic implants/devices like cardiac pacemakers, implanted hearing devices, implanted defibrillators, implanted neurostimulators, drug pumps, or hearing aids.
- CoolTone® should be used with caution in persons with Graves' disease, active bleeding disorders, or seizure disorders.

Are there any reasons I should not get the CoolTone® procedure? (continued)

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

Other medical reasons:

- Fever
- Application over menstruating uterus
- Application over areas of the skin that lack normal sensation
- Metal or electronic implants in the treatment area
- Implanted defibrillators
- Implanted neurostimulators
- Drug pumps
- Malignant tumor
- Hemorrhagic conditions
- Epilepsy
- Recent surgical procedure
- Pulmonary insufficiency
- Pregnancy

What should my physician warn me about?

The CoolTone® procedure has not been studied in children, those who are pregnant or lactating, or patients with any of the above conditions. CoolTone® should not be used in the heart or head areas, areas of new bone growth, 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. If you have a condition not listed above, inform your CoolTone® healthcare provider as you may not be an appropriate candidate for CoolTone® treatment.

The safety and effectiveness for the treatment of areas other than the muscles within the abdominal, buttock, and thigh areas have not been established.

What are possible side effects?

The following effects can occur in the treatment area during and after a treatment. These effects are temporary and generally resolve within days or weeks. These effects may include but may not be limited to:

- **Muscular pain:** Feeling of pain in the muscle several hours after a treatment and resolution within several days
- **Temporary muscle spasm:** Feeling of contraction of the muscle several hours after a treatment and resolution within several days
- **Temporary joint or tendon pain:** Feeling of discomfort or pain in the joint or tendon several hours after a treatment and resolution within several days
- **Local erythema or skin redness:** Appearance of red area on the skin several days after a treatment and resolution within several weeks.

What other treatments are available to me?

There are a variety of medical devices available in the United States that may be used for muscle strengthening, toning, and firming treatment. As an alternative to utilizing strengthening, toning, and firming devices, other means/modes may include specific exercise protocol. You may discuss these treatments with your physician.

When should I notify my physician?

Be sure to report to your physician for (1) any side effect that lasts for more than two weeks and (2) any other symptom that causes you concern. You may also contact CoolTone® Product Support line at 1-888-935-8471.

For more information or further questions about the CoolTone® procedure, visit www.CoolSculpting.com or call 1-888-935-8471.



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