

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 a 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 – Use of a 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 °F)

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

Hernia – When an organ, like an intestine, pushes through a weak spot in the muscle or tissue. This may cause a lump to form on the body (hernia)

Implanted electrical devices – Electrical devices implanted in the body such as cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids, implanted defibrillators, neurostimulators, etc

Intrauterine device (IUD) – Small device made of a tiny, soft piece of plastic or metal that a doctor puts into a woman's uterus to help prevent pregnancy

Infections – Septic conditions, empyema, acute inflammations, systemic or local infections

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 toward 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® device is FDA-cleared in adults aged 22 years or older for:

- Strengthening, toning, and firming of the abdomen, buttocks, and thigh muscles
- Stimulating healthy muscles to improve or help muscle performance; CoolTone® induces muscle contractions to enhance muscle function and may, therefore, be considered a method of muscle training
- Relaxation of muscle spasms, preventing or slowing muscle weakness due to lack of use, increasing blood flow to a specific area, retraining muscles, and maintaining or increasing the range of motion
- Use under medical supervision with other therapies for treating certain medical diseases and conditions
- Stimulating leg muscles for rehabilitation therapy

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 the 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.

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 active, metal, electrical, or electronic implants or devices such as cardiac pacemakers, implanted hearing aids, defibrillators, neurostimulators, or drug pumps.
- CoolTone® should be used with caution in persons with Graves disease; in women with an intrauterine device (IUD); and in patients with a hernia in or near the treatment site, active bleeding problems, or a seizure disorder.

- If you have an IUD and experience symptoms such as severe abdominal pain, cramping, spotting, or heavy bleeding develop during or after treatment, seek medical care right away.

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

Women who are close to their period may find that their period starts earlier or cramping becomes stronger with CoolTone® treatments. For this reason, it is best to avoid treatment during this time of the month.

Other medical reasons:

- Fever
- Application over uterus during menstruation
- Application over areas with active, metal, or electronic implants; defibrillators; neurostimulators; or drug pumps
- Implanted defibrillators
- Implanted neurostimulators
- Drug pumps
- Cancer
- Bleeding disorders
- Infections
- Epilepsy
- Recent surgery
- Lung problems
- Pregnancy
- Patients with cardiac demand pacemakers

What should my physician warn me about?

The CoolTone® procedure has not been studied in children, individuals who are pregnant or lactating, or patients with any of the above conditions. CoolTone® is not recommended on certain parts of your body: the heart, head, neck, mouth, areas of new bone growth, or places with poor blood flow or reduced feeling.

Do not use CoolTone® on skin that is swollen, infected, irritated, or has rashes. Applying it over scarred skin may raise your risk of burns. If you have or may have heart problems, tell your healthcare provider before using CoolTone®. If you have a condition not listed above, inform your CoolTone® healthcare provider as you may not be an appropriate candidate for CoolTone® treatment. Talk to them about any questions or concerns you may have before 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.

- Severe abdominal pain, cramping, spotting, or heavy bleeding in women with IUD that develop during or after treatment. Monitor for these symptoms and seek medical advice if these occur.

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 treatments. As an alternative to utilizing strengthening, toning, and firming devices, other means/modes may include 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 the CoolTone® Product Support line at 1-888-935-8471.

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

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