



INDICATION

- The radiofrequency energy only delivery components of the Thermage system and accessories are indicated for use in:
 - Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
 - Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; and
 - Non-invasive treatment of wrinkles and rhytids.
- The simultaneous application of radiofrequency energy and skin vibration by the Thermage system and accessories are indicated for use in:
 - Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
 - Non-invasive treatment of periorbital wrinkles and rhytids;
 - Non-invasive treatment of wrinkles and rhytids;
 - Temporary improvement in the appearance of cellulite;
 - Relief of minor muscle aches and pains;
 - Relief of muscle spasms; and
 - Temporary improvement of local circulation (blood circulation).

IMPORTANT SAFETY INFORMATION

- Do not undergo a Thermage treatment if you have a cardiac pacemaker or other active implants. Inform your doctor if you have this condition or are in doubt.
- The most common adverse effects include:
 - Surface Irregularities: Frequently, surface irregularities are not evident immediately post-treatment, but may appear up to 1 or more months post-treatment.
 - Altered Sensation: "Numbness," "tingling," or "temporary paralysis" that typically resolves in a short period of time, but may persist up to several weeks.
 - Burns, Blisters, Scabbing, and Scarring: The procedure may produce heating in the upper layers of the skin, causing burns and subsequent blister and scab formation. There is a possibility of scar formation.
 - Lumps / Nodules: lumps or nodules under the skin may occur primarily in the neck area that usually resolve within 1 or 2 weeks without chronic or long term complications.
 - Pigment Changes: Hyperpigmentation (darkening of the skin) that normally resolves within several months.
 - Edema: Swelling may occur and typically resolves within 5 days, but can persist up to several weeks.
 - Mild to Moderate Pain: Typically, the discomfort is temporary during the procedure and localized within the treatment area.

Talk to your doctor for more information about Thermage.