SoftWave therapy

Understand the technology, its cleared uses and the questions to ask.

THE KEY POINT

SoftWave is a branded acoustic-wave technology. Suitability depends on the exact device, intended use, diagnosis and care plan.

What is SoftWave?

FDA describes the OW100S as a pulsed acoustic-wave device. Its applicator delivers unfocused pressure pulses through a coupling membrane and gel. It is a device-based approach, not an injection of cells or PRP. [30]

Why might someone discuss it?

A person seeking a noninvasive approach for a suitable problem may want to discuss whether the specific device and intended use fit their goals. A diagnosis and a comparison with established care come first. [30,31]

SoftWave and shockwave are related

Shockwave is the wider technology category. Brand, wave generation, energy and treatment protocols matter. Research on another device should not automatically be presented as evidence for a SoftWave protocol. [18,19,30]

Education only. Individual care requires a qualified clinician. Clinical review pending.

Evidence, benefits & tradeoffs

What FDA cleared

FDA records for OW100S and OrthoGold 100 identify relief of minor muscle aches and pains, temporary increase in local blood circulation, and activation of connective tissue as intended uses. [30,31]

What this does not establish

Those intended uses do not establish cartilage regrowth, a cure for arthritis, or proven stem-cell activation in patients. Ask for human evidence for the exact outcome being proposed. [30,31]

Condition-specific evidence

ESWT research and guidance vary by diagnosis and device. NICE guidance for Achilles and calcific shoulder problems does not establish that a specific SoftWave protocol works for every tendon condition. [18,19]

RISKS TO DISCUSS

The older OW100-US instructions list potential effects such as temporary increased pain, redness, swelling, bruising or reduced sensation. Ask the clinician to review the actual device's current instructions and explain health conditions, medicines or treatment sites that require precautions or make treatment unsuitable. [43]

Compare the alternatives

Ask about appropriate rehabilitation, activity changes, medicines, other procedures or no procedure today. Technology should support a clear care plan, with goals and a review date.

Education only. Individual care requires a qualified clinician. Clinical review pending.

Make the conversation count

1. Which SoftWave model and applicator would be used?
2. What is my diagnosis, and does the proposed use match the device labeling?
3. Which human studies support this protocol and expected outcome?
4. What personal risks or device-specific exclusions apply?
5. How many sessions are proposed, and what is the complete cost?
6. How will we assess results and decide whether to continue?

Why evaluation matters

Persistent symptoms can justify a clinical assessment. There is no universal deadline to start SoftWave, and an inquiry does not determine candidacy.

The RegenLuma approach

RegenLuma aims to explain the exact technology, its evidence and its limits. Device availability, treating clinicians, services and pricing will be confirmed before treatment is offered.

Education only. Individual care requires a qualified clinician. Clinical review pending.

Sources & your notes

Read the original resources for context. These sources support education; they do not endorse RegenLuma or determine your eligibility for treatment.

[30] U.S. Food and Drug Administration: SoftWave OW100S (OW100S-US): K213120 clearance and indications (October 12, 2022)

[31] U.S. Food and Drug Administration: OrthoGold 100: K210451 clearance and indications (May 5, 2021)

[18] NICE (United Kingdom): Shockwave therapy for Achilles tendinopathy (HTG426) (2016 guidance; current resource)

[19] NICE (United Kingdom): Shockwave therapy for calcific shoulder tendinopathy (HTG645) (2022 guidance; current resource)

[43] SoftWave / MTS Medical (manufacturer): OrthoGold100 OW100-US instructions for use: older model-specific safety information (January 9, 2019; not a substitute for the current actual-device IFU)

Notes for my visit