Shockwave Therapy Machine for Cellulite - Official Clinical Overview & Technical Datasheet

EXECUTIVE SUMMARY

The Shockwave Therapy Machine for Cellulite represents a paradigm shift in non-invasive aesthetic medicine, utilizing focused acoustic wave technology to mechanically remodel fibrotic septae, restore dermal elasticity, and reduce subcutaneous adipose tissue irregularity. Unlike energy-based devices that rely on thermal or optical mechanisms, this platform delivers high-peak-pressure acoustic pulses that disrupt the fibrous bands responsible for the characteristic dimpled appearance of cellulite (Nurnberger-Muller Grade II-III). This datasheet provides a comprehensive clinical architecture overview, technical performance registry, and regulatory compliance summary for procurement and clinical integration.

CLINICAL ARCHITECTURE & DESIGN

The device operates on the principle of electroacoustic generation: a high-voltage discharge across a coaxial electrode within a water-filled chamber creates a rapid plasma expansion, generating a planar shockwave. This wave is focused via a parabolic acoustic lens, concentrating energy at a precise focal depth of 5–15 mm below the dermal surface—targeting the interface between the hypodermis and the superficial fascia. The handpiece incorporates a sealed water coupling membrane to ensure impedance-matched energy transfer without epidermal trauma. A closed-loop pressure feedback system dynamically adjusts output to compensate for tissue density variations, ensuring reproducible fluence across treatment zones.

KEY INDICATIONS & CAPABILITIES

Primary Indication: Reduction of cellulite appearance (edematous fibrosclerotic panniculopathy) on buttocks, thighs, and flanks. Secondary indications include focal adipose tissue softening and improvement of local microcirculation. Clinical capabilities: radial and focused shockwave modes; adjustable pulse repetition rate (1–15 Hz); maximum positive pressure output up to 5.5 MPa; energy flux density range 0.01 – 0.35 mJ/mm ² . Device supports pre-programmed clinical protocols for six skin phototypes (Fitzpatrick I-VI) and three cellulite severity grades.

COMPLIANCE & STANDARDS

The system is manufactured under ISO 13485:2016 certified quality management system and complies with IEC 60601-1 (Medical electrical equipment – General requirements for basic safety and essential performance), IEC 60601-2-58 (Particular requirements for the basic safety and essential performance of lens removal equipment and vitrectomes – referenced for shockwave safety), and Medical Device Regulation (EU) 2017/745 Class IIa. CE marked. FDA 510(k) cleared for aesthetic soft tissue treatment.

TECHNICAL SPECIFICATIONS

Parameter	Specification
Technology Type	Electroacoustic focused shockwave (F-ESWT)
Focal Depth Range	5 mm / 10 mm / 15 mm selectable
Peak Positive Pressure	Up to 5.5 MPa (adjustable)
Energy Flux Density	0.01 – 0.35 mJ/mm²
Pulse Repetition Rate	1 – 15 Hz (preset or manual)
Pulse Count Per Session	500 – 5,000 (programmable)
Handpiece Coupling	Sealed water membrane, disposable tip covers
Cooling System	Passive air + conductive gel (no TEC required)
User Interface	10.1-inch capacitive touchscreen, preset protocols
Power Supply	100–240 V AC, 50/60 Hz, 250 VA
Dimensions (W x D x H)	380 mm x 420 mm x 950 mm (movable cart)
Weight	32 kg (cart integrated)

CLINICAL PROTOCOLS

Recommended treatment regimen: 6–8 sessions at 7-day intervals. Per-session parameters: 1,500–2,500 pulses per treatment zone (40 × 40 cm grid), energy flux density 0.15 mJ/mm² (low) to 0.30 mJ/mm² (high), frequency 8–10 Hz. Technique: slow overlapping longitudinal passes (1 cm/s) followed by circular passes, maintaining perpendicular handpiece-to-skin orientation. Coupling gel mandatory. Clinical endpoint: visible reduction in skin dimpling (≥ 25% improvement on Cellulite Severity Scale) after three sessions, maintained at six-month follow-up. No anesthetic required; mild erythema resolves within 2 hours.