Automated Microneedling Pen (Dermapen) - Official Clinical Overview & Technical Datasheet

DEVICE IDENTIFICATION AND CLINICAL INTENT

The Automated Microneedling Pen (Dermapen) is a precision-engineered, motorized percutaneous collagen induction device intended for professional aesthetic and dermatological applications. Unlike manual roller devices, the Dermapen operates via a high-frequency, vertical reciprocating needle displacement mechanism designed to minimize epidermal trauma while maximizing dermal micro-rupture uniformity. This device is indicated for the treatment of skin texture irregularities, atrophic acne scars, striae distensae, and fine rhytids across Fitzpatrick skin types I through VI.

INTERNAL HARDWARE TOPOLOGY AND ACTUATION MECHANISM

The core actuation assembly comprises a precision-balanced electromagnetic linear motor coupled to a disposable, single-use needle cartridge. The motor delivers an adjustable needle penetration depth ranging from 0.25 mm to 2.5 mm in 0.1 mm increments, with a dynamic frequency range of 30 Hz to 140 Hz (1,800 to 8,400 punctures per minute). The proprietary anti-drag vertical lift technology ensures needles retract vertically without lateral tearing of the stratum corneum, thereby reducing procedural pain and post-inflammatory hyperpigmentation risk. The handpiece integrates a vibration-dampening chassis and an ergonomic lightweight polymer shell for operator fatigue reduction during extended treatment sessions.

EPIDERMAL PROTECTION AND PATIENT SAFETY SYSTEMS

Each sterile, single-use needle cartridge contains 12 to 36 nano-finish surgical-grade stainless steel needles arranged in a linear or circular array depending on model configuration. An integrated skin-contact sensor prevents actuation unless full epidermal contact is established. The device also includes an automatic needle retraction lockout mechanism upon cartridge removal. To further reduce cross-contamination risk, the handpiece and docking station feature antimicrobial-coated contact surfaces compliant with ISO 22196 standards.

TREATMENT ADVANTAGES AND CLINICAL SUPERIORITY

Compared to manual microneedling, the Automated Microneedling Pen offers superior reproducibility of puncture depth, uniform wound healing response, and reduced procedure time by approximately 40-60%. The high-frequency vertical action enables up to 30% less drag force on the epidermis, translating to lower pain scores (mean VAS 2.1 vs. 4.5 for manual rollers in clinical surveys). The device is compatible with topical numbing agents and can be combined with transdermal drug delivery of serums, growth factors, or platelet-rich plasma (PRP) without additional hardware modifications.

SPECIFICATION MATRIX

Parameter	**Specification**
Actuation Mechanism	Electromagnetic linear motor, vertical displacement
Needle Depth Range	0.25 mm – 2.5 mm (adjustable in 0.1 mm steps)
Operating Frequency	30 Hz – 140 Hz (1,800 – 8,400 punctures/min)
Needle Material	Surgical-grade 316 stainless steel,

	nano-finish
Needle Count per Cartridge	12 / 24 / 36 (model dependent)
Power Source	100 – 240V AC, 50/60 Hz, 24V DC adapter
Battery Runtime (cordless models)	Approx. 120 minutes continuous
Handpiece Weight	85 g (without cartridge)
Skin Contact Sensor	Capacitive, enables actuation only on contact
Sterilization Method (Cartridges)	Electron beam, SAL 10^-6
Noise Emission	< 55 dBA at 1 meter
Operating Temperature	+10°C to +35°C

REGULATORY COMPLIANCE AND QUALITY STANDARDS

The Automated Microneedling Pen holds active Medical CE certification under Directive 93/42/EEC (Class IIa) and is FDA 510(k) cleared for over-the-counter use by licensed practitioners in the United States. The device manufacturing facility complies with ISO 13485:2016 (Medical Devices — Quality Management Systems). Needle cartridges are sterile certified via electron beam irradiation to a sterility assurance level (SAL) of 10^-6. Additional compliance includes IEC 60601-1 (electrical safety), IEC 60601-1-2 (electromagnetic

compatibility), and RoHS 2011/65/EU for restricted hazardous substances. Biocompatibility testing for needle materials follows ISO 10993-5 (cytotoxicity) and ISO 10993-10 (irritation and skin sensitization).