# CordAlign™ Precision Wand: Technical Description

*Integrating Imaging, Alignment, and Automated Delivery for Safer Dupuytren Treatment*

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## 1. Device Name and Model Variants

**Primary Device Name: CordAlign™ Precision Wand (CPW)**

**Configurations Covered in This Description:**

1. **CPW-S (Standalone Configuration)**
    - Integrated micro-display
    - Onboard processing
    - Fully portable, self-contained unit
2. **CPW-C (Connected Configuration)**
    - No onboard display
    - Operates via Bluetooth/WiFi connection to iPad, iPhone, or PC
    - Offloads processing and visualization to companion software

Both configurations share identical core functionality, safety controls, and UCP hardware.

## 2. Intended Use and Indications for Use

### 2.1 Intended Use

The CordAlign™ Precision Wand (CPW) is intended to assist clinicians in performing **ultrasound-guided injections** by providing real-time visualization, automated geometric alignment, and controlled micro-dose delivery of medication into subcutaneous structures, specifically Dupuytren cords.

### 2.2 Indications for Use

The device is indicated for:

- Ultrasound-guided injection of enzymatic medication into **Dupuytren cords** in the palm.
- Guidance in aligning the injection pathway with the cord centerline to reduce off-target placement and tissue injury.
- Real-time display of cord geometry, depth, and alignment cues to support safe needle positioning.

### 2.3 Future/Secondary Intended Use (Optional for Pre-Submission)

The CPW platform may be adapted for precision vascular access, facilitating injection or catheter placement into **small or difficult-to-access veins and arteries**.

## 3. Device Description

### 3.1 Overview

The CPW is a **miniaturized handheld instrument** combining:

- Ultra-high-frequency (UHF) ultrasound imaging
- Automated tissue boundary detection
- Centerline alignment guidance
- Controlled micro-dose syringe actuation

Its purpose is to unify imaging, geometric alignment, and injection delivery into one device, eliminating the need for separate probes, needles, and syringes.

### 3.2 Core Components

Each CPW includes:

1. **UHF Ultrasound Cord-Position (UCP) Detector**
    - 20–30+ MHz linear array for near-microscopic resolution
    - Superficial imaging optimized for 3–15 mm depth
2. **Needle Alignment Channel**
    - Fixed geometric coupling between ultrasound beam and needle trajectory
3. **Micro-Dose Auto-Syringe Delivery Mechanism**
    - Precision actuator for controlled enzymatic injection
    - Disposable sterile cartridges
4. **AI-Enabled Guidance Module**
    - Real-time image interpretation
    - Centerline detection
    - Alignment verification
    - Depth safety checks
5. **Clinician Confirmation Interface**
    - Ensures injections occur only after explicit human approval

### 3.3 AI-Guided Delivery for Multi-Injection Procedures

Dupuytren treatment often requires **multiple enzyme injections spaced 5–10 mm apart**, following the geometry and tension-bearing distribution of the cord. Because these injections must each enter the cord's narrow central axis, freehand ultrasound frequently results in variable placement, inconsistent weakening, or off-target enzyme deposition.

The CPW architecture supports a structured, reproducible multi-injection workflow. As the clinician advances the wand along the cord, the system continuously analyzes UHF ultrasound frames to determine cord boundaries, depth, and centerline location, while simultaneously tracking previously completed injections. The AI module identifies recommended sequential injection sites, verifies proper spacing, and ensures alignment accuracy before the micro-dose actuator is enabled.

This approach transforms multi-injection delivery from a manual, skill-dependent task into a **standardized, geometry-driven process** that improves consistency of weakening along the treated cord segment.

## 4. Configurations

### 4.1 CPW-S: Standalone Model (Integrated Display)

**Description**

A fully self-contained unit with:

- Integrated micro-display (1–2 inches)
- Local processor for image rendering + AI inference
- Onboard battery and controls
- Visual alignment cues shown directly on the device

**Advantages**

- Fully portable, no external equipment required
- Useful in operating rooms, field medicine, ambulatory clinics

**Regulatory/Design Considerations**

- Higher thermal and power management requirements
- Slightly increased device size
- Software validation must include graphics rendering and UI logic

**4.2 CPW-C: Connected Model (No Display; Recommended for Miniaturization)**

**Description**

A minimalistic wand that offloads processing and visualization to an external device (iPhone, iPad, PC).

- CPW sends UHF ultrasound frames + sensor data via BLE/WiFi
- External app performs:
    - AI segmentation
    - Alignment logic
    - Image display
    - Reporting
    - Logging

**Advantages**

- Smallest, lightest wand footprint
- Lower heat generation
- Easier software upgrade cycle
- Leverages existing clinical tablets and mobile devices
- Reduced hardware cost

**Regulatory/Design Considerations**

- Requires cybersecurity assessment for wireless data
- External app must be validated as part of the system
- Must meet connectivity robustness criteria under IEC 60601-1-2

## 5. Principles of Operation

**5.1 Ultrasound Imaging**

- UHF linear array transmits and receives acoustic pulses
- Real-time imaging provides visualization of superficial tissues
- UHF frequencies (20–30+ MHz) offer spatial resolution of **50–150 µm**

**5.2 Cord Identification**

The UCP detector distinguishes a Dupuytren cord from adjacent tissues using:

- Depth (cord lies superficial to tendon)
- Texture (cord is hypoechoic; tendon is fibrillar)
- Shape (elongated fascial band)
- Movement patterns (tendon motion vs. cord stability)

**5.3 Alignment Guidance**

The device computes:

- Cord boundaries
- Cord diameter
- Centerline trajectory
- Needle-to-centerline deviation
- Depth margin of safety

Alignment is shown via:

- **Display model:** real-time screen overlay
- **Non-display model:** LED/indicator cues + app visualization

**5.4 Controlled Injection**

Once alignment is confirmed:

1. Device waits for clinician approval.
2. Micro-dose actuator delivers enzyme into cord centerline.
3. Delivery rate, volume, and pressure are controlled electronically.

**5.5 AI-Guided Multi-Injection Workflow**

When multiple injections are required, CPW uses real-time cord mapping to recommend sequential injection points spaced **approximately 5–10 mm apart**, reflecting collagenase diffusion behavior and clinical best practice. For each proposed point, the AI module verifies:

• centerline alignment
• sufficient spacing from prior injections
• correct depth relative to the fascia and tendon
• absence of risk structures in the needle path

Only when all criteria are met does the device allow the clinician to authorize micro-dose delivery. By coordinating spatial planning, alignment checks, and actuator enablement, CPW provides an integrated method for performing multi-site injections with uniform precision and enhanced safety.

## 6. Engineering Specifications

**6.1 Imaging Specs**

- Frequency: **20–30+ MHz**
- Axial resolution: **75–150 µm**
- Lateral resolution: **150–300 µm**
- Penetration depth: **3–15 mm**
- Aperture width: **10–20 mm**
- Frame rate: **≥ 30 fps**

**6.2 Mechanical Specs**

- Wand mass: **< 150 g**
- Length: **12–15 cm**
- Replaceable sterile injection cartridges
- Medical-grade polymer housing

**6.3 Electrical Specs**

- Rechargeable battery (≥ 3 hrs operation)
- USB-C or inductive charging
- Wireless communication: BLE 5.0 or WiFi-Direct
- Low-noise analog front-end for UHF imaging

## 7. Software Description

**7.1 AI Algorithms**

- Real-time segmentation of cord boundaries
- Centerline mapping
- Needle alignment verification
- Tissue classification (cord vs tendon vs noise)
- Motion compensation
- Multi-injection optimization (spacing, sequential site identification, and coordinated auto-syringe activation).

**7.2 Safety Interlocks**

- Injection lock-out until:
    - Alignment conditions met

    - Depth validated
    - Tissue classification confirmed
    - Injection spacing validated to prevent dosing too close to a previous site

**7.3 Cybersecurity & Data**

- Encrypted communication
- Secure update mechanism
- Optional integration with EMR systems
- No transmission of PHI unless explicitly enabled

## 8. Risk Analysis and Mitigation

**Key Procedural Risks**

- Off-target injection
- Enzyme extravasation
- Tendon/nerve injury
- Needle depth overshoot
- Cord misidentification

**Mitigations**

- Alignment lock-out
- Depth monitoring
- Controlled micro-dose delivery
- Required clinician confirmation
- UHF visualization for improved tissue contrast
- Automatic error and drift detection

## 9. Human Factors & Usability

- Single-hand use
- Ergonomic design for various hand sizes
- Minimal buttons (display model) or no buttons (connected model)
- Clear visual or app-based alignment cues
- Rapid sequential injection capability

Human factors validations will confirm ease of use in:

- multi-injection procedures
- different lighting environments
- various hand anatomies

## 10. Biocompatibility & Sterility

- All patient-contacting components meet **ISO 10993** biological safety standards
- Injection cartridges are sterile and disposable
- Wand is disinfectable between uses (non-immersive)

## 11. Clinical Application Rationale

The CPW system improves Dupuytren injections by:

- Providing **high-resolution UHF visualization**
- Ensuring **consistent and centered needle placement**
- Reducing variability in clinician skill
- Preventing enzyme leakage into surrounding tissues
- Enabling **faster**, **safer**, **more reproducible** multi-site injections

Future development will allow adaptation to **vascular access**, especially where precision is critical (small veins, pediatric vessels, compromised tissue, or cosmetically sensitive areas).

Beyond improving single-point accuracy, the CPW platform standardizes the **multiple-injection method** commonly required for adequate enzymatic weakening of Dupuytren cords. By recommending 5–10 mm spacing, validating each injection site, and ensuring that doses enter the cord's centerline, the system produces a more continuous enzymatic effect along the cord. This reduces the mechanical force required during manipulation and improves the consistency of clinical outcomes. AI-guided multi-injection delivery thus strengthens both the safety profile and the therapeutic predictability of the CPW system.