



CSA Medical CryoSpray Ablation System Second Generation CryoAblation Device Service Pack

Key Goals and Accomplishments

Improved Reliability
Improved Safety Record

Approach and Tools

Structured Problem Solving & Continuous Improvement Programs (CAPAs)
Critical Parameter / Tolerance & Stack-Up Analysis
Risk Management & Failure Modes & Effects Analysis
Statistical Experiment Design (DOE)
Test Planning, Protocols, Execution and Reports
Post-Launch Surveillance & Trend Analysis

Results and Recognition

Service pack implementation increased reliability from 0.9 years to 12.6 years

Enhanced cryogen decompression tube improved venting and patient safety

Reduced number of field complaints after Service Pack

Successful FDA inspections and ISO audits

