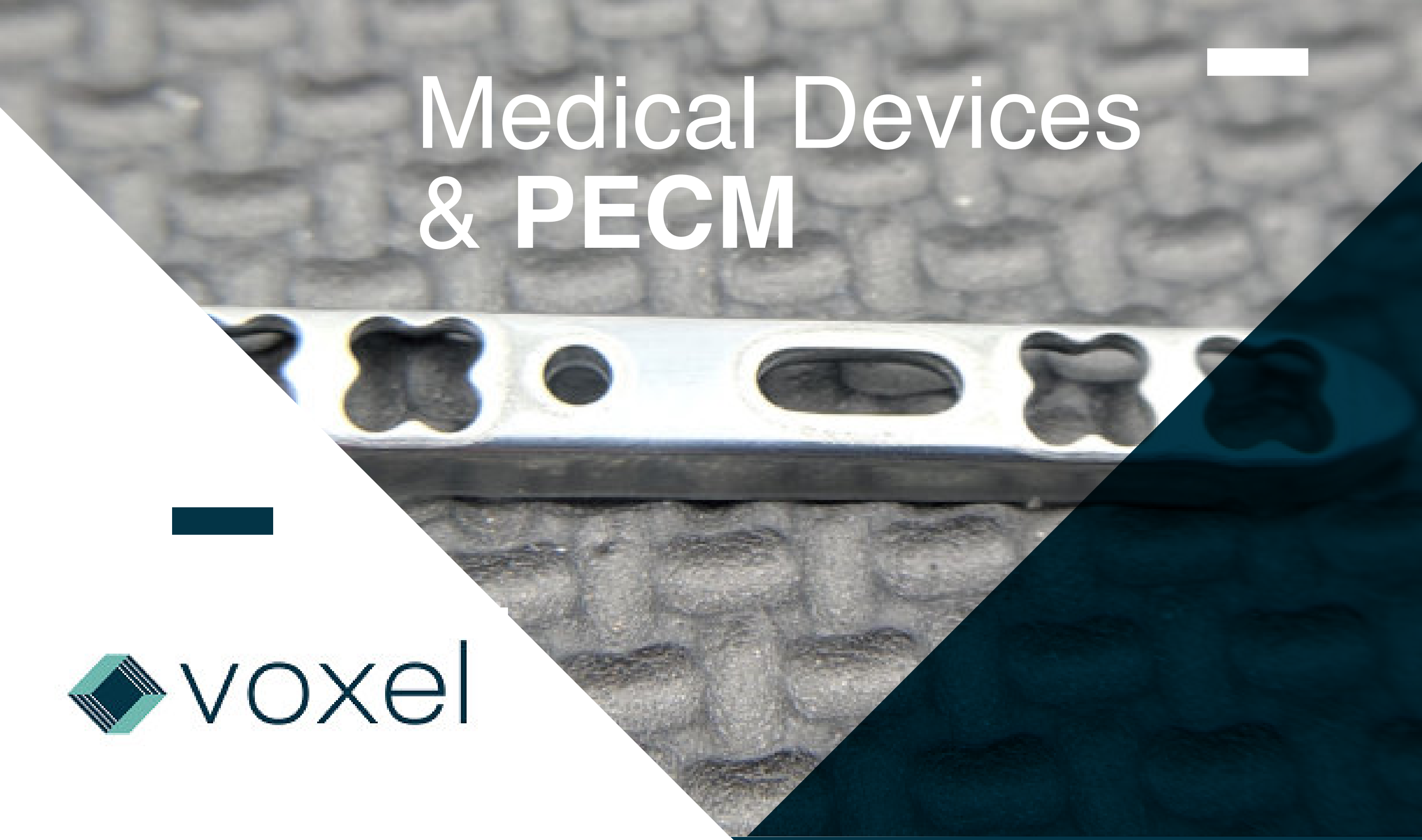
Medical Devices & **PECM**



voxel

Executive Summary

*Orthopedic, trauma, and surgical-instrument programs increasingly depend on hard, difficult-to-machine alloys where surface condition governs performance. The **recast layers, heat-affected zones,** and **burrs** left by conventional machining drive the fatigue-validation burden on implants, the reprocessing and reuse-reliability burden on reusable instruments, and a long chain of secondary finishing, inspection, and scrap on both. **Pulsed electrochemical machining (PECM) removes material through electrochemical dissolution rather than mechanical cutting or thermal erosion, producing burr-free, recast-free surfaces on cobalt-chrome, hardened stainless, and Nitinol in a single operation, at production volume.** Voxel operates PECM in production today as a qualification-ready, drop-in sub-supplier that closes the difficult-alloy special-process gap, to AS9100D and ISO 9001:2015.*

1

PECM is well suited for orthopedic components in Nitinol and CoCr, where surface condition and feature fidelity influence fixation and fatigue performance. From bone staples to complex fixation geometries, PECM enables controlled finishing while preserving material integrity.

2

PECM also supports cardiovascular components that rely on precise internal geometries and smooth flow paths. It enables uniform finishing of internal features and intricate metallic structures in high-performance device materials.

520 Hinton Pond Road, STE 128,
Knightdale, NC 27545

info@voxelinnovations.com

984-464-0701

www.voxelinnovations.com

www.voxelinnovations.com

At-a-Glance:
PECM & MedTech Features

PECM delivers consistent, unique value for Medtech applications.

Maintaining consistent internal geometries, ultra-smooth surfaces, and predictable performance across tens of thousands of patient-critical components requires a process that **eliminates thermal distortion, taper, and geometry drift** across production runs.

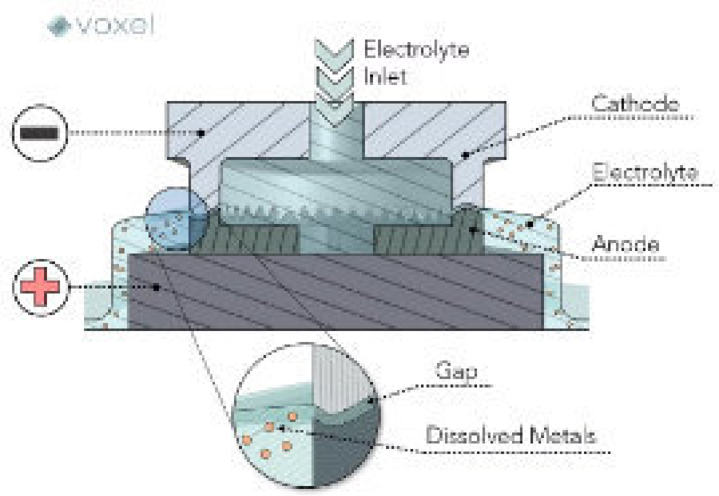
Voxel's PECM can act as a unique solution to these medical manufacturing challenges.

PECM removes metal atom-by-atom, generating uniform internal surfaces and feature architectures in Nitinol, CoCr, stainless steels, titanium, and other conductive materials used throughout orthopedic and cardiovascular implants with high scalability.

PECM enables:

- Burr-free, recast-free surfaces on threads, edges, and fixation features
- Below 0.2 μm Ra surface finishes on Nitinol, CoCr, and hardened stainless
- Consistent edge and surface condition across repeated cleaning and sterilization cycles
- Repeatable geometry across tens of thousands of parts with minimal tool wear

PECM **BASICS**



Unlike other material removal technologies such as electrical discharge machining (EDM), PECM is based on the principles of electrolysis. The machining operation involves a tool (the cathode) in the inverse shape of the desired workpiece (the anode).

As the tool moves towards the workpiece surface, it machines the workpiece into the complementary shape of the tool. This occurs as a pulsed DC current is applied, allowing for high precision and superior surface quality. At the same time, an electrolyte is pumped between the cathode and anode at high speed, removing dissolved metal and heat.

The result is an operation capable of producing a burr-free 3D shape with minimal tool wear in alloys that are difficult or impossible to machine through traditional methods. As PECM can produce parts in parallel with excellent repeatability, it is well-suited to high-volume and/or high-value production.

The PECM process has **4** factors:

- The **cathode**, or tool
- The **anode**, or workpiece
- The **electrolytic fluid,** and
- **The pulsed voltage**

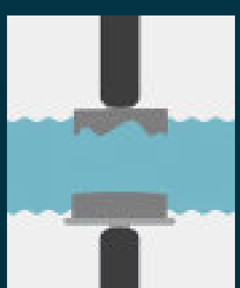
voxel

www.voxelinnovations.com

Material Compatibility

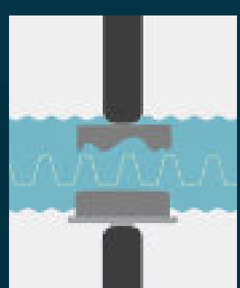
PECM can most conductive materials, including but not limited to:

4140	**Copper**	**M4 Tool Steel**	**Stainless 17-4**
A2 Tool Steel	**Ferrium C64**	**MarM247**	**Stainless 304**
Al MMCs	**GaSb**	**Molybdenum**	**Stainless 316**
Aluminum 6061	**Germanium**	**MP35N**	**Stainless 440C**
Aluminum 7075	**Haynes 230**	**NdFeB**	**Ti Grade 2**
AMZ4	**Inconel 625**	**Nickel**	**Ti64**
Brass	**Inconel 718**	**Nitinol**	**TiAl**
Bronze	**Inconel 738**	**Nitronic 60**	**Vit105**
CMSX-4	**Inconel 740h**	**Pyrowear 53**	
Cobalt Chrome	**InSb**	**Rene N-5**	



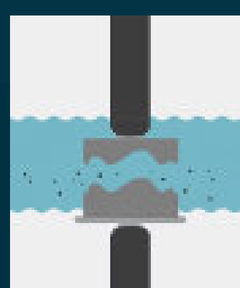
STEP 1

Cathode and anode are set up, and electrolyte is pumped between the two parts.



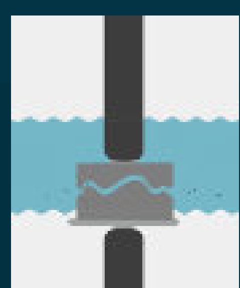
STEP 2

As the two pieces move together, a pulsed DC current is applied to the anode and cathode.



STEP 3

The flowing electrolyte removes heat and waste products from the gap.



STEP 4

The workpiece is machined into the complementary shape of the cathode tool.

STEP 5

Part is complete with no need for secondary process, burr removal or polishing.

voxel

www.voxelinnovations.com

PECM vs. **Legacy Processes**

Design agency is limited by heat and/or contact-based material removal processes.

Conventional processes have inherent limitations, including…

Burrs & Tool Vibration

Contact-based machining introduces cutting forces that create **burrs, edge rollover,** and **vibration-driven surface damage**, notably on thin features and tight internal geometries.

Heat-affected Zones / Recast Layers

Thermal processes leave **HAZ, microcracks,** or **recast layers** that alter material properties, reducing fatigue or corrosion resistance.

Limited Repeatability

Repeatability degrades as tools wear and get replaced. **Dimensional drift, inconsistent finishes,** and **increased inspection** affect high-volume production.

Manufacturers are forced to compromise new designs to meet these limitations.

WHY CHOOSE PECM?

The unique properties of Voxel's pulsed electrochemical machining technology allow it to avoid many of the aforementioned issues:

- ☑ Non-contact machining produces **no burrs** or **tool vibration**, allowing machining of sensitive areas
- ☑ Non-thermal machining leaves **no HAZ** or **recast layers**, leaving **superfinished surfaces**
- ☑ PECM allows **part-to-part/ feature-to-feature repeatability**, significantly less tool wear

PECM IS FUNDAMENTALLY DIFFERENT

By utilizing electrochemistry instead of contact or heat, PECM removes material atom-by-atom, allowing smoother surface finishes, higher tolerances and improved repeatability– enabling manufacturers to explore new designs into production.

Process Specs

☑ Cut Surface Area

3500-7000mm2 in slower cuts; 1750-3500 in faster cuts. Larger surfaces may require multiple operations or higher-amperage equipment while smaller surfaces can potentially be run in-parallel

☑ Wall Thickness

Less than 50μm, with no maximum. .075mm (.003in) has been achieved in 2D blind or through features, minimum feature size is a wall of <25μm

☑ Slot Channel

•Top: 50μm (.002in) minimum
•Bottom: 20μm (.0008in) minimum
•Slot: 30 to 50μm
•Internal: 150μm (.006) minimum is most common, although 75μm (.003in) has been achieved in an ideal case

☑ Surface Finish

.005μm Ra to .4μm Ra, depending on the material

☑ Durability

Cathodes will have a lifetime exceeding thousands of parts

☑ Aspect Ratio

No minimum, capable of exceeding 300:1, depending on the feature size and electrode fabrication method

☑ Corners & Radii

•Top: 50μm (.002in) minimum; Bottom: 20μm (.0008in) minimum
•Minimum inside 90 corner radius, pocket bottom: 15-25μm possible; 25-50μm is more typical
•Minimum outside 90 corner radius, pocket top: 50μm standard
•Internal: 150μm (.006) minimum is most common, although 75μm (.003in) has been achieved in an ideal case

☑ Process Speed

Tends to be a step change in speed with geometry size, depending on the ability to flow electrolyte through the part's features.
Minimum blind feature (e.g. a slot): .5mm, speeds of .1-2μm/s
Feature of 2+mm: speeds of 15-30+ μm/s
More NRE yields more opportunity to improve speeds

☑ Depth Tolerance

Depends on parallelism of the workpiece. Generally, the depth can be controlled to +/- 5μm or less

voxel

Industry **Outlook**

Orthopedic, trauma, and surgical-instrument manufacturing is increasingly shaped by two simultaneous forces: **rising procedural demand and accelerating product-iteration cycles**, alongside **heightened expectations for repeatable microgeometry, surface integrity, and traceable quality systems**.

Projected growth in orthopedic procedures such as total knee arthroplasty indicates substantial long-term volume expansion even under conservative modeling assumptions [2], and rising procedure volumes drive parallel demand for the reusable instruments used to deliver them.

Many of the performance-governing attributes in these device categories are not macroscopic dimensions. They reside in microtopography that mediates bone response around implants [3], in surface condition that governs fatigue initiation under cyclic loading [4,5], and in edge and surface integrity that determine cutting performance and reuse reliability in reprocessed instruments. **When these attributes drift across production runs, the outcome can translate into tangible risks to durability, sterility, and device performance.**

Device geometry is simultaneously becoming more complex as manufacturers are expected to scale. Porous lattices, microfeatures, thin struts, and internal passages are increasingly common in orthopedic and cardiovascular designs. Additive manufacturing has expanded geometric possibility, but scaling friction persists: as-built surfaces are often too rough or too variable for functional requirements [19]; internal and occluded surfaces are difficult to finish uniformly [18,28]; and quality control of hidden features frequently requires computed tomography when conventional inspection methods cannot access the features of interest [21].

The combined constraints (challenging materials, internal geometry, clinical sensitivity to surface state, inspection burden, and post-processing intensity, etc.) are continuously compounding. The result is a **widening gap between what can be designed, what can be validated, and what can be produced repeatably at volume.**

Market Demand & **Scale Pressures**

Medical device manufacturing does not scale in the same manner as general industrial production. Demand growth often coincides with product proliferation across sizes, anatomies, patient populations, and delivery-system variants, as well as heightened compliance expectations.

Cardiovascular disease continues to account for a dominant share of global mortality, with heart disease and stroke as leading contributors [1]. **This macro-level burden drives sustained volume pressure for a variety of interventional and implantable technologies**. Orthopedics reflects a parallel trajectory: demographic aging and extended life expectancy increase throughput requirements for joint reconstruction and fixation. Conservative projections of total knee arthroplasty in the United States alone estimate substantial increases in procedure volume by 2050 [2].

From a manufacturing perspective, the key variable is not geography but the shape of the demand curve: increasing volume over time, often accompanied by increasing product mix complexity. Devices are not manufactured solely to dimensional print; they are manufactured to clinical function mediated by surface state and microgeometry. As programs transition from pilot builds to validated production, repeatability and inspectability of performance-governing features (often small, internal, and difficult to rework) become central challenges.

Consequences of **Manufacturing Variability**

In implantable medtech, variability is physiological as well as economic. Nominally identical designs can behave differently in-vivo if near-surface condition, microtopography, or local stress concentrators vary across builds.

In orthopedic implants, **osseointegration** depends not only on bulk material selection but also on micro- and nano-scale surface characteristics, chemistry, and physical parameters [3]. Manufacturing variability in surface generation (whether from tool wear, finishing inconsistency, or uncontrolled local texture) introduces variability at the bone–implant interface.

In reusable surgical instruments, variability is a service-life problem. Instruments must retain cutting performance and dimensional integrity across repeated use, cleaning, and sterilization. Recast layers and heat-affected zones left by machining can seed corrosion pitting under repeated autoclave cycles, while burrs and edge rollover degrade both cutting performance and cleanability. Surface condition is therefore not a single scalar value but a multi-parameter driver of reuse reliability, and manufacturing variability in that surface translates directly into variability in instrument service life.

Durability under cyclic loading reinforces the importance of surface integrity. In fatigue-critical metallic components, surface roughness and near-surface defects serve as stress concentrators and crack initiation sites. **Reviews of additively manufactured Ti64 link fatigue variability directly to characteristic surface roughness and porosity** [5], and experimental studies treat roughness as a primary variable affecting fatigue strength [4]. Surface integrity drift therefore represents a potential lifetime-performance deviation.

Geometric **Complexity**

Modern orthopedic and cardiovascular devices are increasingly governed by internal, occluded, or micro-scale features rather than solely by external tolerances.

Orthopedic designs incorporate porous architectures and microfeatures to encourage bone in-growth and modulate stiffness. Cardiovascular designs depend on thin struts, small radii, and smooth internal transitions that influence deployment mechanics and flow fields. As geometry becomes smaller and more complex, constraints tighten simultaneously in both tool access and measurement access.

Additive manufacturing (AM) alleviates certain tool-reach limitations but introduces new challenges. Reviews of multiscale characterization for AM components note that internal defects, porosity, surface irregularities, and residual trapped powder can remain inaccessible to traditional inspection methods [21]. Internal-channel roughness in AM components often exceeds ~5 μm Ra due to phenomena such as balling, powder adhesion, and staircasing [28]. **Design freedom therefore relocates finishing and inspection burdens rather than eliminating them.**

Material **Challenges**

Orthopedic and cardiovascular manufacturing is frequently constrained by materials that are clinically valuable yet difficult to machine.

Nitinol's superelastic and shape-memory behavior make it indispensable in minimally invasive devices, yet machining reviews emphasize phase transformation during cutting, excessive tool wear, and sensitivity of surface integrity to machining parameters [12,13].

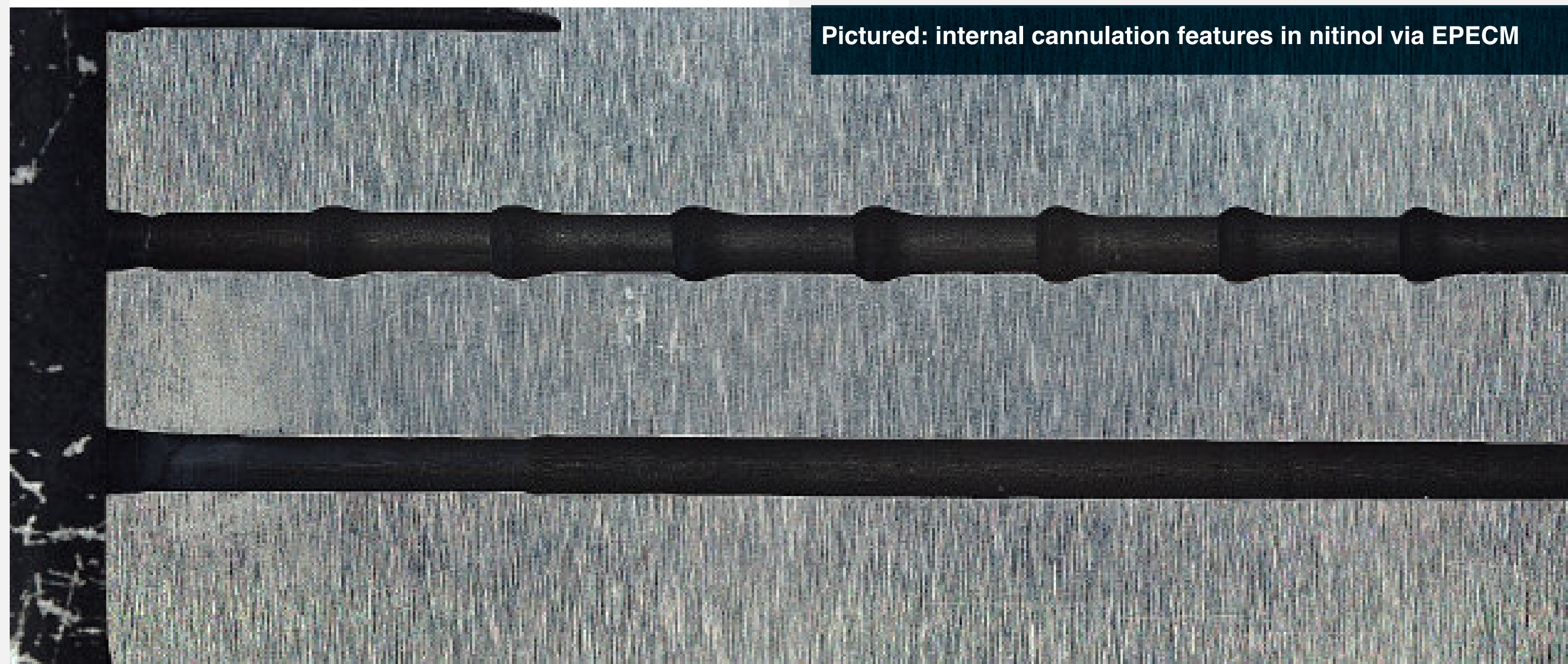
Cobalt-chromium alloys provide high strength and wear resistance but are characterized as difficult-to-machine materials associated with rapid tool wear and shortened tool life [16]. Manufacturing-route selection in CoCr implants influences microstructure and downstream corrosion resistance and biocompatibility [17].

Titanium alloys offer corrosion resistance and biocompatibility but exhibit low thermal conductivity and chemical reactivity, contributing to tool wear, surface degradation, and dimensional instability during machining [15].

Even **stainless steels** such as 316L, commonly used in cardiovascular applications, develop complex near-surface states when processed by

Manufacturing-Induced Surface Degradation and Its Impact on Turbomachinery Performance

	CNC / Micro-Machining	EDM / Laser	Additive Manufacturing	PECM
Heat-Affected Zones / Recast Layers	Low	High	High	Low
Surface Roughness Variability	Medium	Medium	High	Low
Micro-burrs & Edge Deformation	Medium	Low	Medium	Low
Feature-to-Feature Dimensional Drift	Medium	Medium	High	Low
Postprocessing Access Limitations (Internal Features)	High	Medium	High	Low
Impact on Cooling Effectiveness & Pressure Loss	Medium	High	High	Low
Impact on Component Durability	Medium	High	High	Low


Pictured: internal cannulation features in nitinol via EPECM

laser methods. Fiber laser cutting studies treat outcomes as integrated surface-integrity packages including roughness, heat-affected zones (HAZ), recast layers, dross, and subsurface hardness variation [22].

Surface **Integrity**

Surface integrity (encompassing roughness, micro-defects, residual stress, and damage layers) represents a unifying risk vector across orthopedic and instrument manufacturing. Osseointegration literature frames implant performance as dependent on surface topography and chemistry [3]. For fixation implants, surface condition governs fatigue initiation under cyclic loading [4,5]; for reusable instruments, it governs edge retention, corrosion resistance across sterilization cycles, and cleanability. In both cases, the defects machining leaves behind, recast, heat-affected zones, and burrs, are the surface-integrity risks that matter most.

Fatigue-critical metallic components further reinforce this constraint. Reviews and experimental studies of additively manufactured Ti-6Al-4V correlate **fatigue performance with roughness and porosity** [4,5]. Reviews of as-built AM roughness document wide variability in Ra values depending on process parameters and technology, including ranges extending well beyond single-digit micrometer levels [19].

As geometry becomes more complex, roughness distribution becomes non-uniform across orientation and feature accessibility. Internal surfaces and occluded regions are particularly challenging to finish and verify uniformly [18,28].

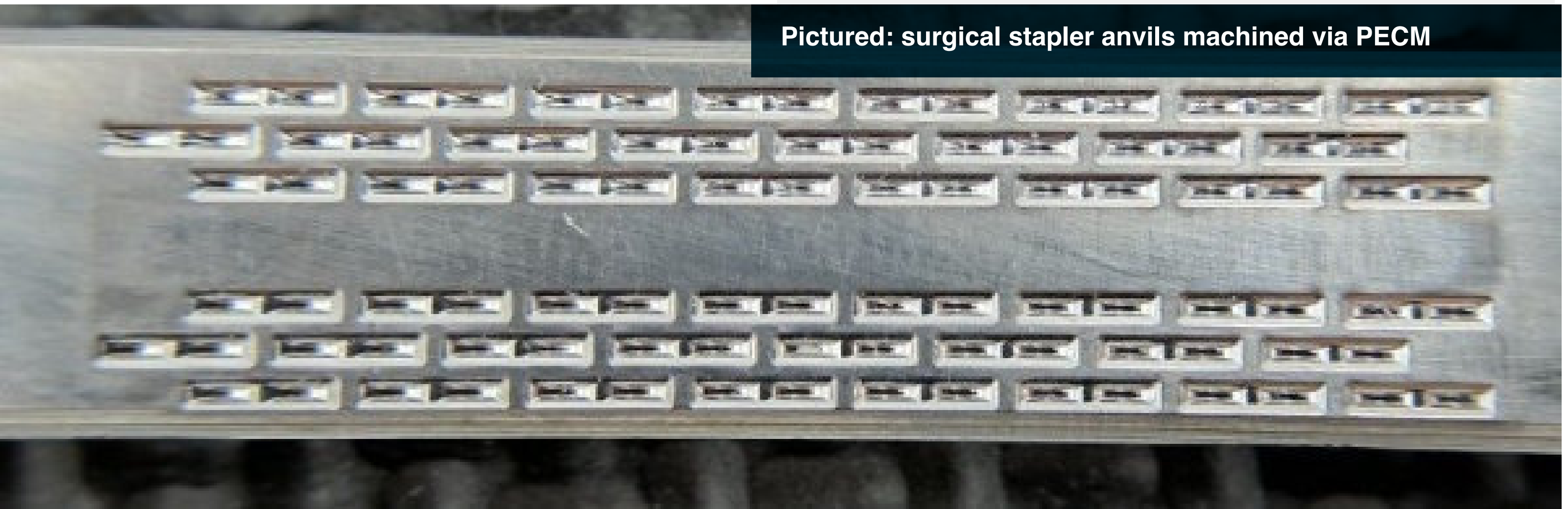
Production **Bottlenecks**

As device complexity increases, process chains lengthen. Reviews of post-processing for additively manufactured metallic components describe surface finishing as a technological bottleneck, particularly for internal and hard-to-access surfaces [18]. Broader analyses of AM process chains emphasize the need for well-understood post-processing to achieve functional surface integrity [20].

Inspection presents a second bottleneck. Internal geometries often require X-ray-based inspection modalities when tactile or optical approaches cannot access features of interest [21]. In production environments, CT-based inspection raises questions of scan time, detection thresholds, calibration, and operational cost.

Laser-based processes illustrate throughput–surface tradeoffs. Studies of laser-cut Nitinol stents report optimized surface roughness values below ~1,20 μm Ra under specific conditions, while less favorable parameter combinations yield roughness near ~2,1 μm [23,24]. Such sensitivity to process windows becomes operationally significant at scale.

Additive manufacturing introduces further process-chain expansion. As-built surfaces typically require substantial secondary finishing to reach functional roughness, accompanied by dimensional effects that must be controlled. Internal and curved surfaces remain particularly challenging; electrochemical finishing of internal features is difficult for mechanical approaches to reach uniformly [28], which is precisely where a single-operation, non-contact PECM finish removes the bottleneck.



Pictured: surgical stapler anvils machined via PECM

Working With **Voxel**

Voxel is a uniquely specialized contract manufacturer deploying critical parts in production environments via PECM with applied R&D.

☑ Driven by Co-Development

Voxel embeds with our customers throughout the product lifecycle, creating value through **IP, licensing,** and **production contracts.**

☑ Unique Capabilities

Our applied R&D enables machining of challenging **features, materials,** and **surface conditions** impractical or impossible with legacy processes.

☑ Production-Ready Success

Voxel's PECM-based processes are engineered for **repeatability** and **parallelization**, supporting the transition from early development to reliable, high-volume production with minimal process rework.

Voxel is not organized around selling a process or executing to a fixed print, but to work **alongside** engineering teams as manufacturing constraints are discovered, challenged and rewritten via continued, applied R&D. We engage early-on when materials, internal features, or surface requirements are still fluid, creating unique **partnerships** from qualification to production and beyond.

At our core is Voxel's proprietary application of PECM: continuously advanced through applied R&D and feedback. By vertically integrating electrolyte chemistry, cathode design, tooling and process control, we enable unique **internal geometry machining, superfinished surfaces** and **material machining** methodology**.**

voxel

Implementation and Economics

Voxel enables new design, engineering, and even economic opportunities for its customers.

☑ Full-Sequence Economics

Single-operation finishing removes secondary steps, labor, and scrap rather than managing them.

☑ Supply Resilience

A US-based, drop-in or dual-source finishing option with no capital outlay on your side.

☑ Defined Qualification Pathway

Feasibility, trials, first-article and CPK valication, then documented production ramp-up.

For sourcing and program teams, the economics of PECM are best measured across the full production sequence, not a single per-part quote. Conventional difficult-alloy parts accumulate cost after machining: deburring, recast and HAZ removal, polishing, passivation, added inspection, and scrap on high-value blanks. **Because PECM produces a finished surface in a single operation, those secondary steps, and their associated labor, cycle time, and yield loss, are removed rather than managed; the as-machined part can be the finished part.**

Consolidating finishing into one qualified operation also reduces supply risk. Many special-process finishing steps sit with a single qualified supplier; a qualified PECM operation provides a US-domiciled, drop-in or dual-source option for that step, with no capital outlay required on the customer side. PECM equipment carries a capital barrier well above conventional CNC, which is why most programs source it rather than build it.

Qualification follows a defined path: feasibility review, PECM trials and inspection, first-article and process-capability validation, then production ramp with documented controls. Voxel operates to AS9100D and ISO 9001:2015.

Partnership **Roadmap**

1 Engagement
Start a conversation about your goals and challenges; share relevant examples.

2 Discovery & Qualification
Assess project fit by reviewing geometry, materials, and production targets.

3 Solution Shaping
Define a clear manufacturing path via transparent discussion of requirements and risk.

4 Proposal & Negotiation
Review detailed scope, pricing, and assumptions; refine terms for alignment.

5 Commitment
Formalize partnership, assign resources, and establish communication channels.

6 Feasibility
Validate manufacturability via PECM trials, inspection, and parameter tuning.

7 Repeatability
Demonstrate consistent part quality across multi-part runs with documented controls.

8 Scalability
Prepare tooling, capacity and throughput for cost-effective, high-volume production.

9 Ramp-Up
Launch initial production runs: optimizing for speed, quality and delivery assurance.

10 Full Production
Deliver reliable, efficient supply while supporting long-term improvement & growth.

voxel

www.voxelinnovations.com

Contact our Team

WHY VOXEL?

Voxel integrates our **PECM technology** with **unique process expertise** to enable **repeatable**, production-rate manufacturing of complex metal parts for critical industries.

WHY NOW?

Engaging with Voxel early creates **leverage**: our applied R&D and production teams can influence geometries, surfaces, and material strategies, ultimately enabling **higher-performance parts**, **smoother qualification** and a more **direct path to production**.

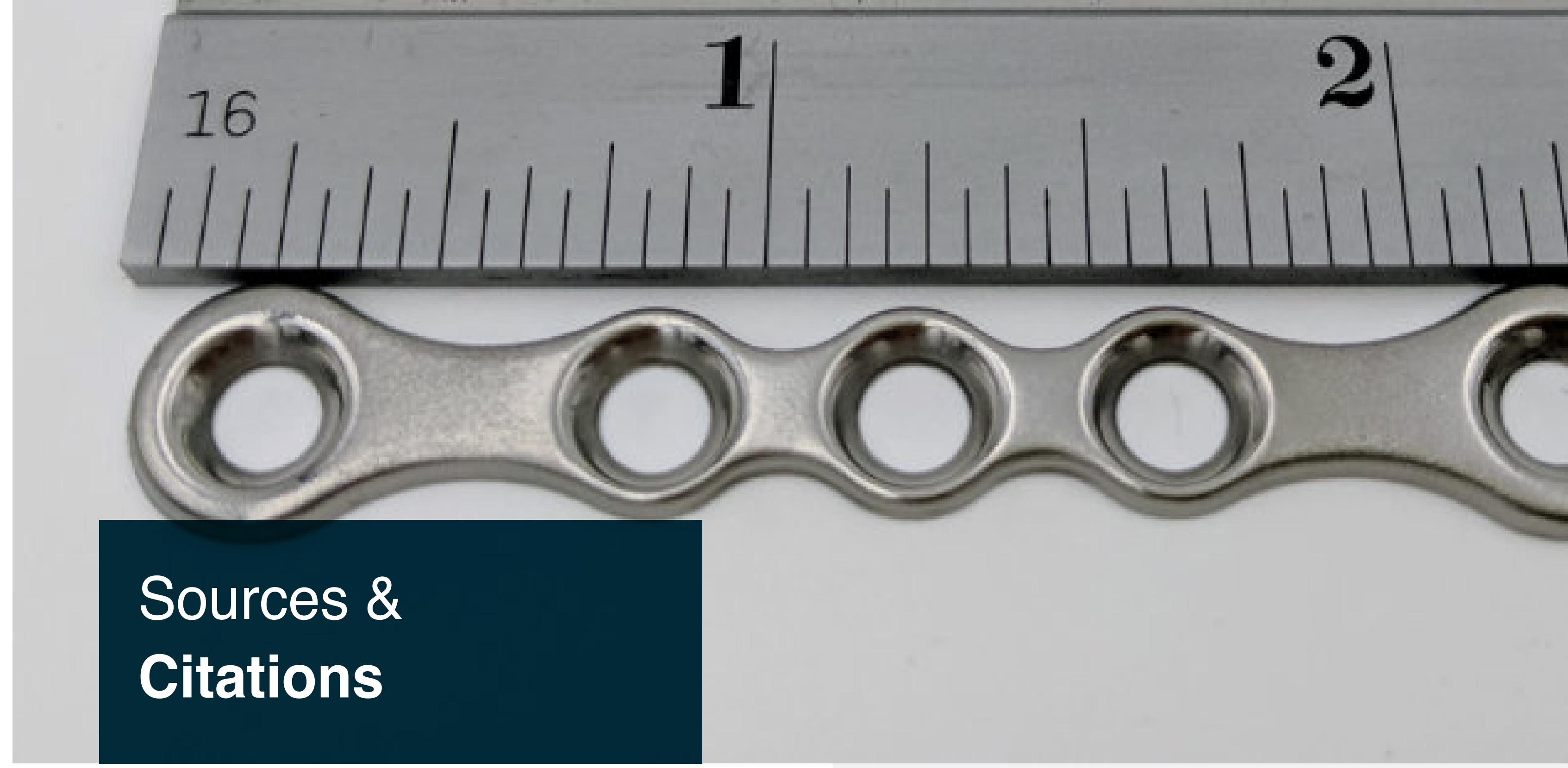
GET IN TOUCH WITH OUR ENGINEERS:

520 Hinton Pond Road STE 128
Knightdale, NC 27545

984-464-0701

info@voxelinnovations.com

www.voxelinnovations.com



Sources & Citations

[1]Global Burden of Cardiovascular Diseases and Risk Factors, 1990–2019 | Journal of the American College of Cardiology
https://doi.org/10.1016/j.jacc.2020.11.010

[2]Projected Increase in Total Knee Arthroplasty in the United States | Osteoarthritis and Cartilage
https://doi.org/10.1016/j.joca.2017.07.022

[3]Osseointegration in Relation to Implant Surfaces | Clinical Implant Dentistry and Related Research
https://doi.org/10.1111/cid.12742

[4] [5]Surface Roughness and Fatigue Performance of Additively Manufactured Ti-6Al-4V | Structural Integrity Procedia; JOM
https://doi.org/10.1016/j.prostr.2019.12.032
https://doi.org/10.1007/s11837-017-2728-5

[6] [7]Surface–Blood Interactions and Hemocompatibility of Implant Materials | Acta Biomaterialia; Materials Advances
https://doi.org/10.1016/j.actbio.2024.04.018
https://doi.org/10.1039/d1ma00367d

[8]Platelet Adhesion to Micro-Structured Surfaces Under Flow | Journal of Biorheology
https://doi.org/10.17106/jbr.35.49

[9] [10]Machining of NiTi Shape Memory Alloys – Process and Surface Integrity | Frontiers in Materials; International Journal of Advanced Manufacturing Technology
https://doi.org/10.3389/fmats.2024.1431992
https://doi.org/10.1007/s00170-018-2818-8

[11]Surface Roughness Ranges for Finishing Processes | International Journal of Scientific & Engineering Research

[12]Machining of Titanium Alloys – Surface Integrity and Tool Wear | Arabian Journal for Science and Engineering
https://doi.org/10.1007/s13369-021-05420-1

[13]Machinability of Cobalt-Based and CoCrMo Alloys | Procedia Manufacturing
https://doi.org/10.1016/j.promfg.2017.07.150

[14]Manufacturing Processes of Cobalt-Chromium Implants and Biocompatibility Implications | Journal of Biomedical Materials Research Part B
https://doi.org/10.1002/jbm.b.35431

[15]Surface Integrity of 316L Cardiovascular Stents by Fiber Laser Wet Cutting | International Journal of Advanced Manufacturing Technology
https://doi.org/10.1007/s00170-018-03252-2

[16] [17]Process Chain and Surface Topography Studies for Laser-Cut Nitinol Stents | Procedia CIRP
https://doi.org/10.1016/j.procir.2024.08.045
https://doi.org/10.1016/j.procir.2022.06.017

[18]Surface Characteristics of NiTi Stents After SLM and Electrochemical Polishing | International Journal of Advanced Manufacturing Technology
https://doi.org/10.1007/s00170-023-12734-x

[19]Surface Roughness of As-Built Metal Additive Manufacturing Parts – Review | Metals (MDPI)
https://doi.org/10.3390/met15101069

[20]Post-Processing of Additively Manufactured Metallic Alloys – Review | International Journal of Machine Tools and Manufacture
https://doi.org/10.1016/j.ijmachtools.2022.103908

[21]Multiscale CT/X-Ray Microscopy for Additive Manufacturing Inspection | Journal of Nondestructive Evaluation
https://doi.org/10.1007/s10921-025-01231-8

[22]Electrochemical Polishing Effects on Laser-Cut NiTi Stents | International Journal of Electrochemical Science
https://doi.org/10.1016/j.ijoes.2025.101101

[23]Fundamentals and Developments in Electropolishing | International Journal of Machine Tools and Manufacture
https://doi.org/10.1016/j.ijmachtools.2019.01.001

[24]Electrochemical Finishing of Internal Channels in AM Components | CIRP Annals
https://doi.org/10.1016/j.cirp.2025.04.066