

# Medical Devices & PECM



## ***Medical Device manufacturing is increasingly defined by its invisible geometries....***

*...Such as micro-scale surface textures that guide osseointegration, internal flow paths that shape hemodynamics, and miniature features that determine fatigue life, clot risk, and long-term implant stability.*



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.

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## At-a-Glance: PECM & MedTech Features

PECM delivers consistent, unique value for Medtech applications.

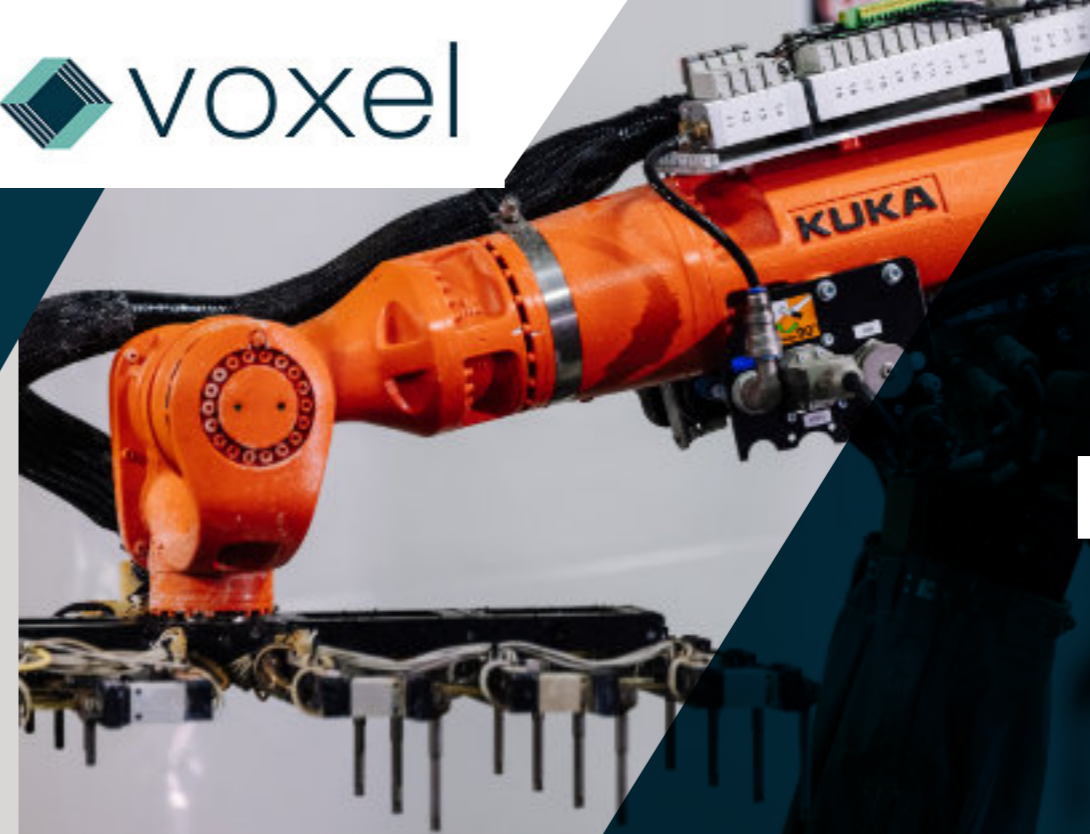
Maintaining consistent internal geometries, ultra-smooth surfaces, and predictable performance across tens of thousands of patient-critical components requires a process that **eliminates thermal distortion, taper, and geometry drift** across production runs.

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

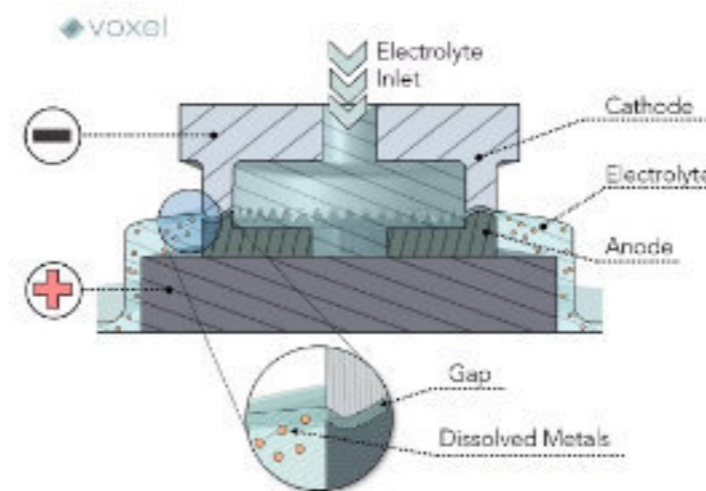
PECM removes metal atom-by-atom, generating uniform internal surfaces and feature architectures in Nitinol, CoCr, stainless steels, titanium, and other conductive materials used throughout orthopedic and cardiovascular devices, with high scalability.

### PECM enables:

- **Micron-level channel uniformity** without taper, burrs, or HAZ
- **<.2µm Ra internal surface finishes** on nitinol, CoCr and stainless
- **Repeatable multi-channel arrays** for thermal flow paths
- **Minimal tool wear**, supporting consistency across production



# 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:

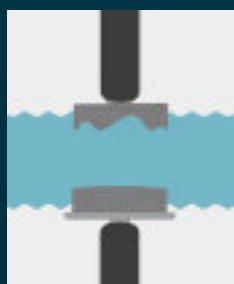
- The **cathode**, or tool
- The **anode**, or workpiece
- The **electrolytic fluid**, and
- **The pulsed voltage**



## Material Compatibility

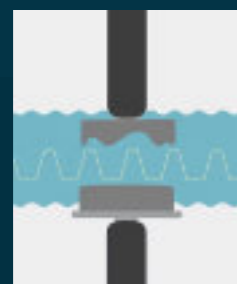
PECM can most conductive materials, including but not limited to:

- |               |              |               |                |
|---------------|--------------|---------------|----------------|
| 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      |                |



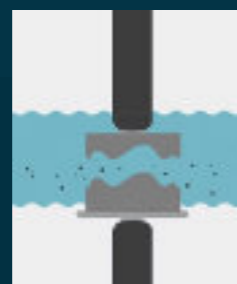
STEP 1

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.



## 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

3500-7000mm<sup>2</sup> 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 50 $\mu$ m, with no maximum. .075mm (.003in) has been achieved in 2D blind or through features, minimum feature size is a wall of <25 $\mu$ m

### ✔ Slot Channel

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

### ✔ Surface Finish

.005 $\mu$ m Ra to .4 $\mu$ m 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: 50 $\mu$ m (.002in) minimum; Bottom: 20 $\mu$ m (.0008in) minimum
- Minimum inside 90 corner radius, pocket bottom: 15-25 $\mu$ m possible; 25-50 $\mu$ m is more typical
- Minimum outside 90 corner radius, pocket top: 50 $\mu$ m standard
- Internal: 150 $\mu$ m (.006) minimum is most common, although 75 $\mu$ m (.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 .1-2 $\mu$ m/s  
Feature of 2+mm: speeds of 15-30+  $\mu$ m/s  
More NRE yields more opportunity to improve speeds

### ✔ Depth Tolerance

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

Orthopedic and cardiovascular device 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**.

Cardiovascular disease remains a leading global health burden [1], and projected growth in orthopedic procedures such as total knee arthroplasty indicates substantial long-term volume expansion even under conservative modeling assumptions [2].

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 “near-surface physicochemistry that influences protein adsorption and platelet adhesion on blood-contacting materials” [6,7]. **When these attributes drift across production runs, the outcome can translate into tangible risks to durability, sterility and biological response.**

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 cardiovascular devices, surface-blood interactions are clinically sensitive. Blood-contacting materials initiate protein adsorption events that influence platelet adhesion and activation [6]. Reviews of hemocompatibility emphasize that surface morphology, roughness, and chemistry are central to thrombus-related performance and downstream complication pathways [7]. Experimental studies further demonstrate that platelet adhesion depends on microstructure size and flow conditions, underscoring that “roughness” represents a multi-parameter microgeometric environment rather than a single scalar value [8].

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  $\mu\text{m}$  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].

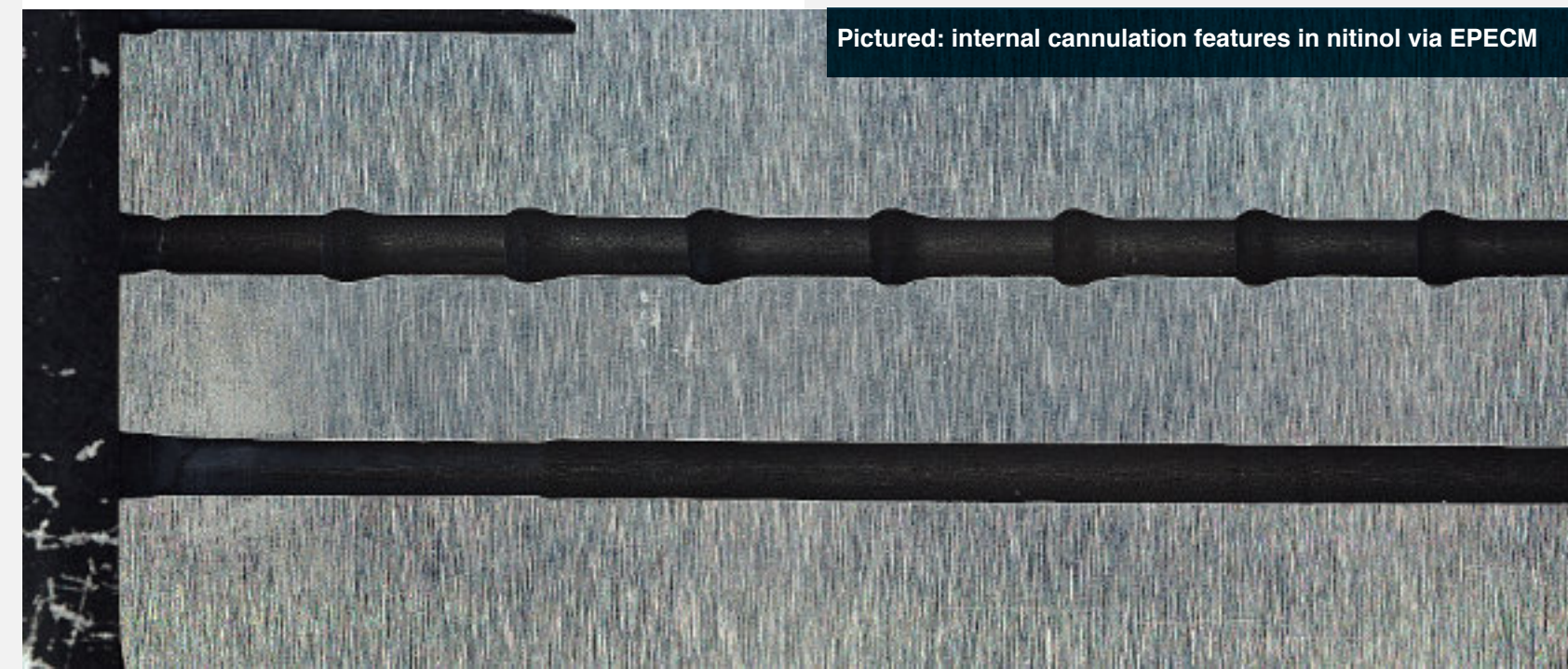
**Cobalt-chromium** alloys provide high strength and wear resistance but are characterized as difficult-to-machine materials associated with rapid tool wear and shortened tool life [16]. Manufacturing-route selection in CoCr implants influences microstructure and downstream corrosion resistance and biocompatibility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

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

complex near-surface states when processed by 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 cardiovascular manufacturing.

Osseointegration literature frames implant performance as dependent on surface topography and chemistry [3]. Hemocompatibility reviews link thrombosis initiation to early protein adsorption events influenced by surface morphology and chemistry [6,7]. Experiments confirm, "...microstructured roughness modulates platelet adhesion under flow conditions" [8].

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  $\sim 1,20 \mu\text{m}$  Ra under specific conditions, while less favorable parameter combinations yield roughness near  $\sim 2,1 \mu\text{m}$  [23,24]. Such sensitivity to process windows becomes operationally significant at scale.

**Additive manufacturing** introduces further process-chain expansion. Studies of NiTi stent structures show substantial roughness reduction following polishing (e.g., from  $6,64 \mu\text{m}$  to  $0,45 \mu\text{m}$  in reported cases), accompanied by dimensional effects that must be controlled [25]. Internal-channel finishing remains particularly challenging; discussions of electrochemical finishing in AM internal channels emphasize that initial roughness often exceeds  $\sim 5 \mu\text{m}$  Ra and that uniform finishing of curved internal surfaces is difficult for certain mechanical approaches [28]. ■

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

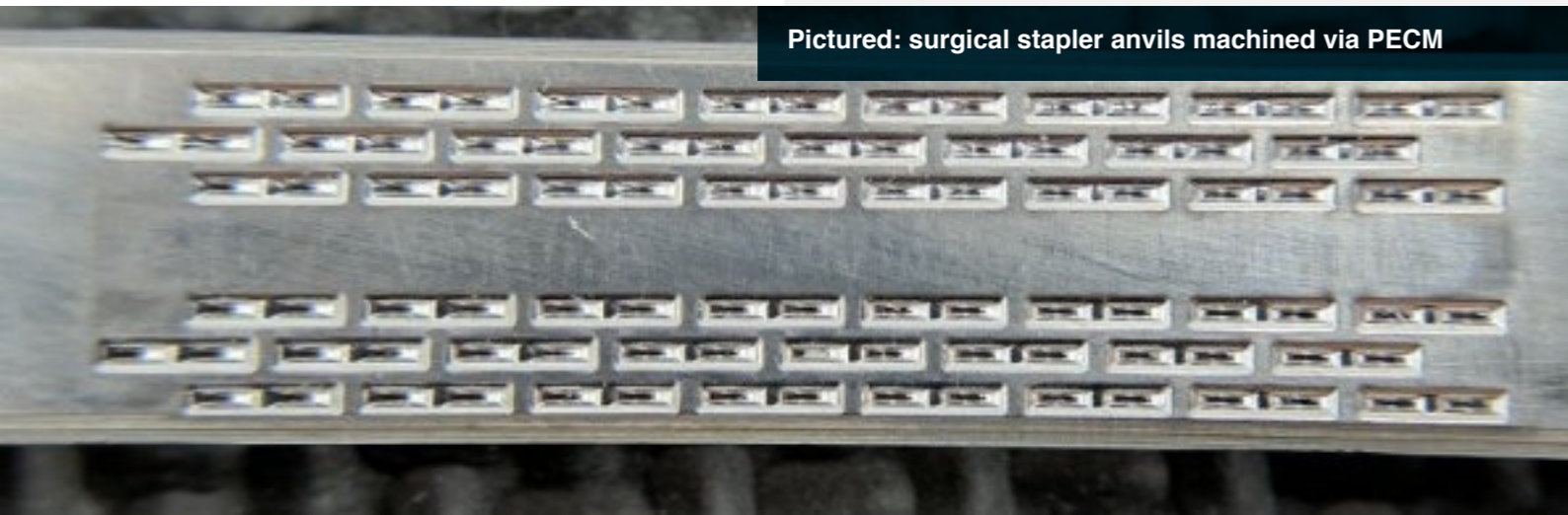
Our applied R&D enables machining of challenging **features, materials, and surface conditions** impractical or impossible with legacy processes.

### ☑ 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.





## 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:

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# 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>](<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>](<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>](<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/10.1016/j.prostr.2019.12.032>)  
[<https://doi.org/10.1007/s11837-017-2728-5>](<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/10.1016/j.actbio.2024.04.018>)  
[<https://doi.org/10.1039/d1ma00367d>](<https://doi.org/10.1039/d1ma00367d>)

[8] Platelet Adhesion to Micro-Structured Surfaces Under Flow | Journal of Biomechanics  
[<https://doi.org/10.17106/jbr.35.49>](<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/10.3389/fmats.2024.1431992>)  
[<https://doi.org/10.1007/s00170-018-2818-8>](<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>](<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>](<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>](<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>](<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.2024.08.045>)  
[<https://doi.org/10.1016/j.procir.2022.06.017>](<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>](<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>](<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.ijmactools.2022.103908>](<https://doi.org/10.1016/j.ijmactools.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>](<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.ijeos.2025.101101>](<https://doi.org/10.1016/j.ijeos.2025.101101>)

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

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