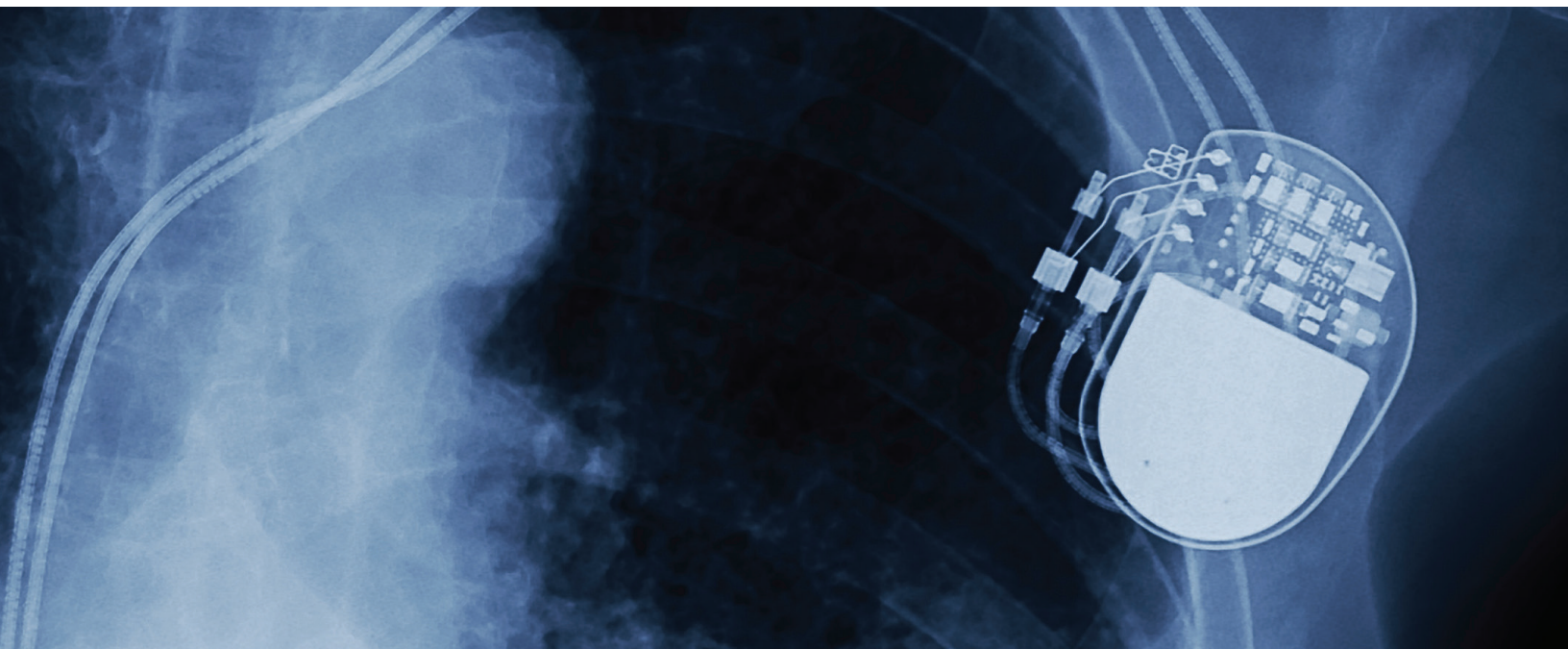




ENHANCING ELECTRODE PROPERTIES WITH **LASER RESTRUCTURING**

An advanced surface engineering technique improves the performance of implantable electrodes



The materials that go into medical devices—particularly implantable electrical devices—have to strike a unique balance of properties. Once you consider biocompatibility and all the required physical and mechanical properties, there are very few metals that will make the grade. In fact, for electrode materials, you won't get much further than platinum and gold. And while innovative new alloys do occasionally emerge, there are usually limited opportunities to solve engineering problems by turning to entirely new materials.

A more accessible innovation strategy in this space involves getting more out of materials that have an established track record in implantable medical devices—and a history of FDA approvals.

That's where surface engineering comes into play. An emerging set of surface modification techniques can extend the capabilities of well known metals and alloys. These techniques range from very simple to highly advanced. In this paper we'll focus on laser restructuring, an advanced technique that improves the properties of medical device materials, particularly those used for implantable electrodes.

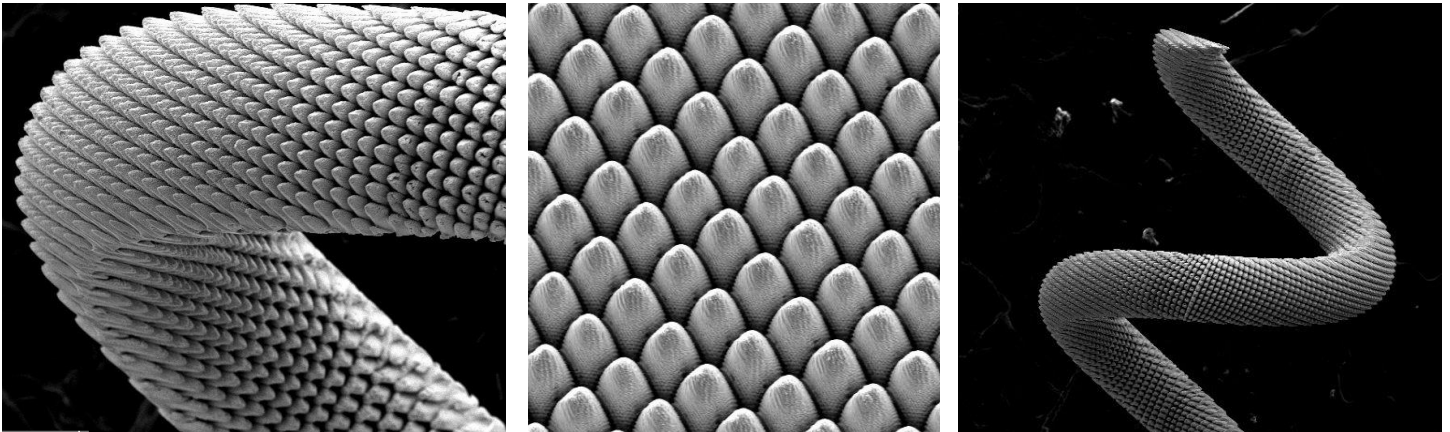
This patented technology uses carefully-controlled laser pulses to create minuscule structures on the metal substrate surfaces. These structures increase the surface area of the metal substrate, improving key electrical properties without affecting other mechanical or physical properties. The process also offers a more economical and high-performing alternative to the coating technologies currently used to boost electrical properties.

WHAT IS LASER RESTRUCTURING?

As its name suggests, laser restructuring subjects metal components to short pulses of a high-energy laser. A typical process, for example, subjects the substrate to hundreds of thousands of pulses from a 10-watt laser whose power we carefully adjust to meet the application requirements. Laser restructuring is not primarily ablative; instead, the process shifts the position of the surface atoms to build up the desired structures.

The feature size of the structures spans a range from nanoscale to macroscale, depending on the application requirements. Typically, the surface topology consists of macro-, micro- and nano-sized features in a tiered arrangement: The nano-structures present as spherical globules atop a hill-like microstructure atop a ridged macrostructure. In electrode applications, which is the most common use today, feature sizes across the tiers might range from as little as 0.01 μm to as much as 50 μm . A typical distance between the ridge-like tiers might be 20 μm .

If the process sounds simple enough, the reality is more complex. A deep understanding of metal surface characteristics and careful development of material-specific process parameters are needed to achieve a fine-grained control of the feature shape and size distribution. In particular, the size and distribution of the various features are governed by the wavelength and duration of the laser pulses.



Pulse Technologies uses scanning electron microscopes to examine laser restructured surfaces.

IMPROVE ELECTRICAL PROPERTIES

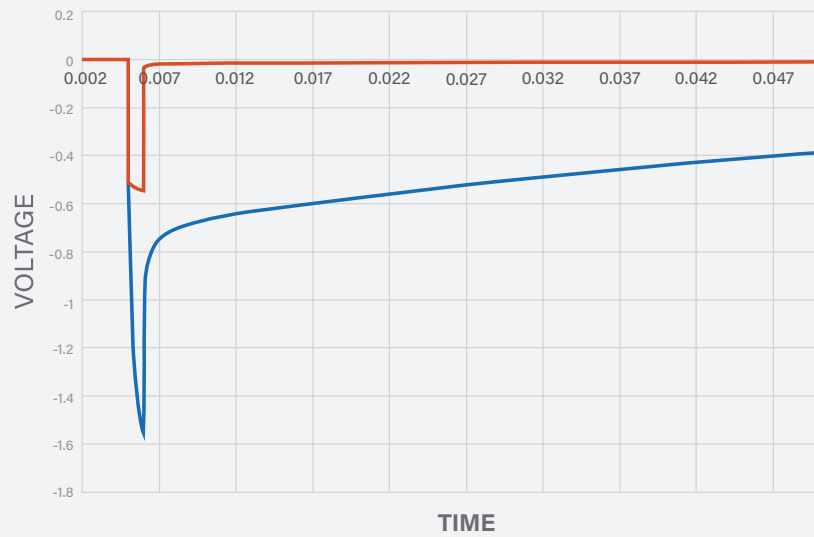
The driving force behind laser restructuring is the desire to enhance the electrical properties of electrodes. By increasing the surface area that comes in contact with human tissue, laser restructuring boosts the electrode's capacitance and reduces polarization. As a result of the capacitance and polarization enhancements:

- Energy efficiency rises, which translates to either a smaller package size for a given battery life or increased battery life for a given package size. This improved energy efficiency has resulted in pacemaker and neural-electrode packages that are 30% smaller without a reduction in battery life.
- Signal-to-noise ratio improves, which makes it possible to sense electrical signals—such as cardiac P and R waves—with lower capture thresholds.
- Charge transfer efficiency increases, increasing charge transfer at a given voltage.

LASER RESTRUCTURING ENHANCES ELECTRICAL PROPERTIES

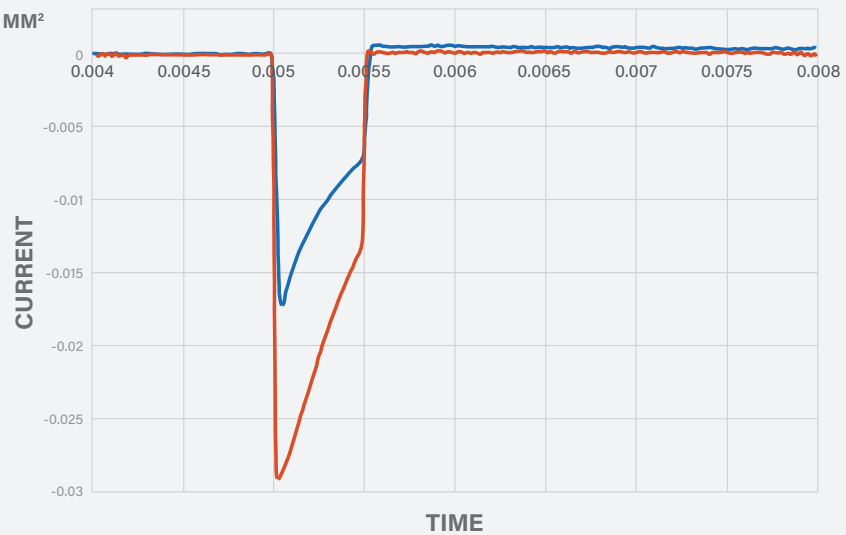
PROXIMAL RING - 16.1 MM²
CONSTANT CURRENT / 1MS 10MA

— Bare Pt20Ir Electrode
 — Surface Restructured Electrode



ACTIVE FIXATION ELECTRODE - 10 MM²
CONSTANT VOLTAGE / 0.5MS 1.5V

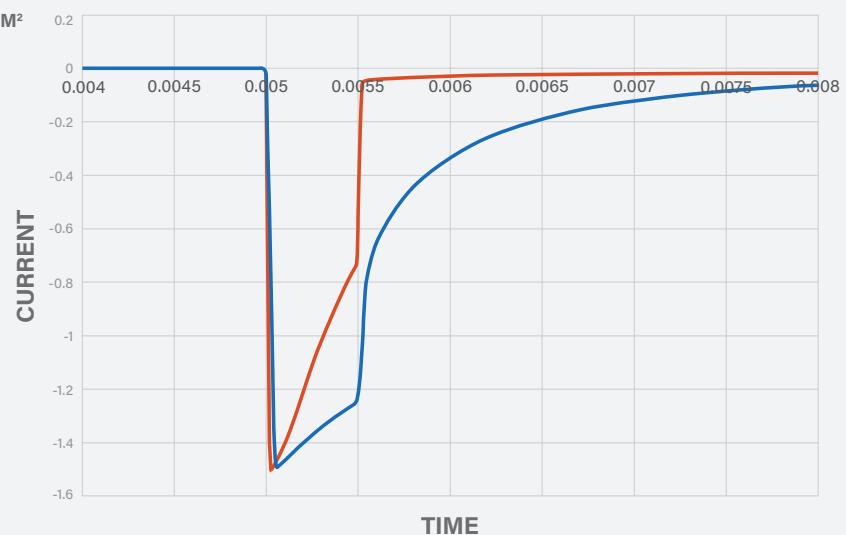
— Restructured Electrode
 — TiN Coated Electrode



Increased current delivery under
 constant voltage stimulation

ACTIVE FIXATION ELECTRODE - 10 MM²
CONSTANT VOLTAGE / 0.5MS 1.5V

— Restructured Electrode
 — TiN Coated Electrode



Acceptable polarization values
 within 100μs post-pulse

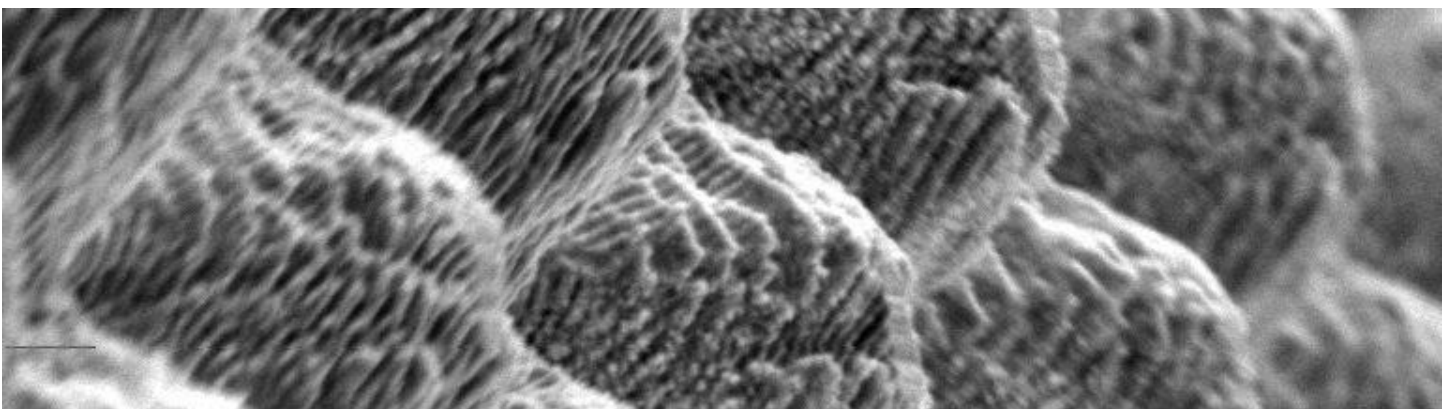
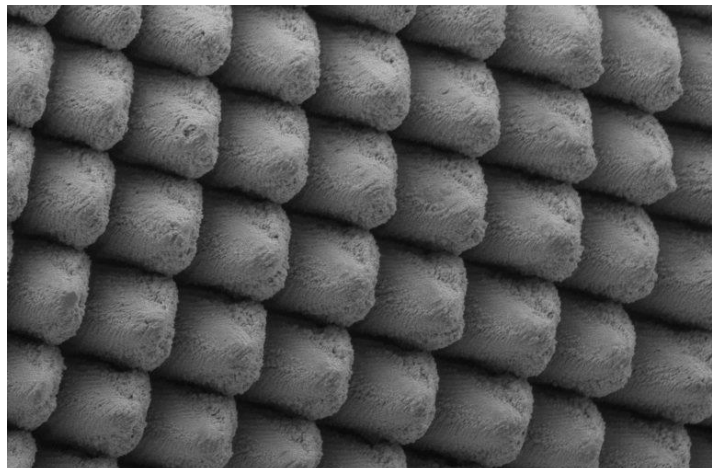
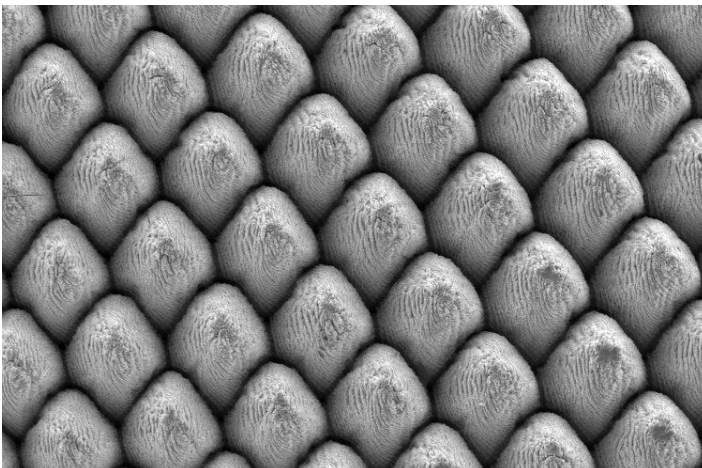
ELIMINATE COATINGS FOR PERFORMANCE AND COST GAINS

The incumbent method for enhancing the surface of electrodes involves the use of vacuum-deposited coatings such as titanium nitride (TiN). The coatings have a porous surface that also increases surface area of the electrode to improve electrical properties.

From a performance standpoint, however, coatings don't elevate the electrical properties to the same degree that laser restructuring does. Coatings also create potential biocompatibility issues and a failure point should they delaminate from the electrode substrate.

Coatings for implantable devices also require costly application expertise, vacuum equipment and component preparation. Unlike laser restructuring, which takes place at room temperature, coating processes take place at high temperatures that introduce unwanted thermal stresses into the electrode substrate.

Laser restructuring eliminates these manufacturing hurdles and promises not just improved performance and reduced electrode sizes but lower production costs as well. For those reasons, expect to see this process grow in acceptance for the next generation of cardiac and neural electrodes.



A variety of laser restructured surfaces on platinum and titanium as shown by Pulse's scanning electron microscope.

LASER TEXTURING IMPROVES ADHESIVE BONDING



Another type of laser-based surface treatment can drastically improve adhesive bonding reliability and repeatability. Called laser texturing, this technique uses a CNC laser to etch the surface of metallic substrates that will undergo adhesive bonding. The etched surface, whose features and pattern are carefully controlled, increases the surface area available to the adhesive, improving the bond's tensile strength and fatigue life.

The main use case for this technique has so far been in the UV adhesive bonding of polymer cannulas to metallic subcomponents. Traditionally, the bonding surfaces of the assembly would be mechanically roughened using an abrasive blasting process. This process does have a positive effect on pullout strength of the polymer-to-metal bond. And it's a reliable, well-understood surface treatment process that we employ on many jobs.

Laser texturing, however, goes a few steps further. The textured surfaces can more than double the pullout strength on a typical cannula assembly. The laser texturing also eliminates two pitfalls associated with the semi-manual mechanical roughening process—the debris that must be removed from the bonding surfaces and any operator-induced inconsistencies.