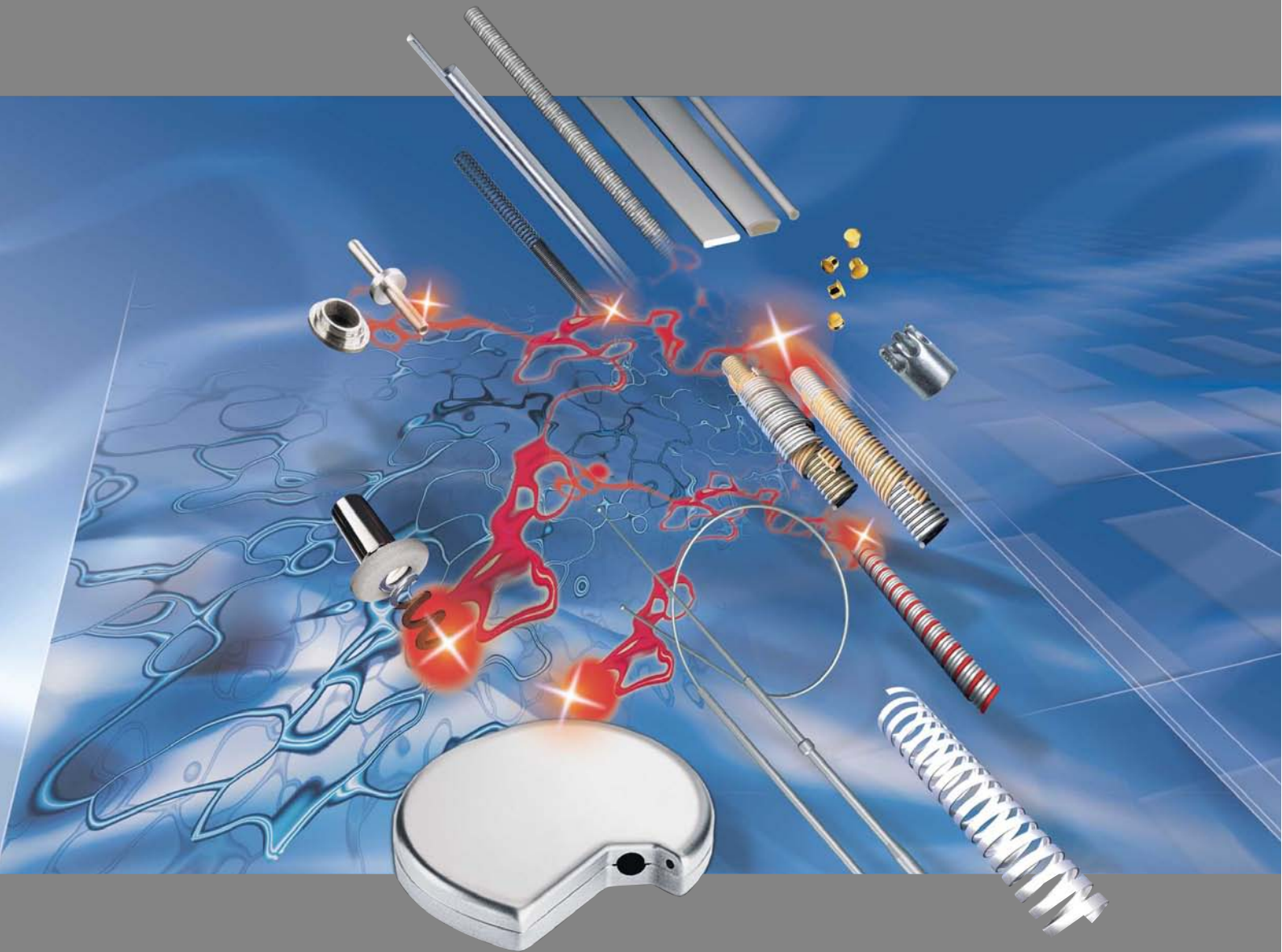


Heraeus



Medical Components

W. C. Heraeus

W. C. Heraeus – Medical Components Division



When Wilhelm Carl Heraeus successfully melted Platinum in 1856, no thought had been given to electro-stimulation of the heart. Who knew that this ingenious pioneer accomplishment more than 150 years ago would contribute not only to manufacturing techniques in chemistry and physics, but also in improving the quality of human life? Today Heraeus is a privately held group of companies with operations in more than 30 countries across the globe, servicing all industries as their precious metals and technology partner.

The Medical Components Division of W. C. Heraeus will provide you with the solutions you need for all of your medical component demands. You will find that the pioneering spirit of Wilhelm Carl Heraeus is still very much alive in our organization today. Our committed teams world wide are equipped to take on your most challenging projects, presenting you with the solutions you need to improve all areas of your business.

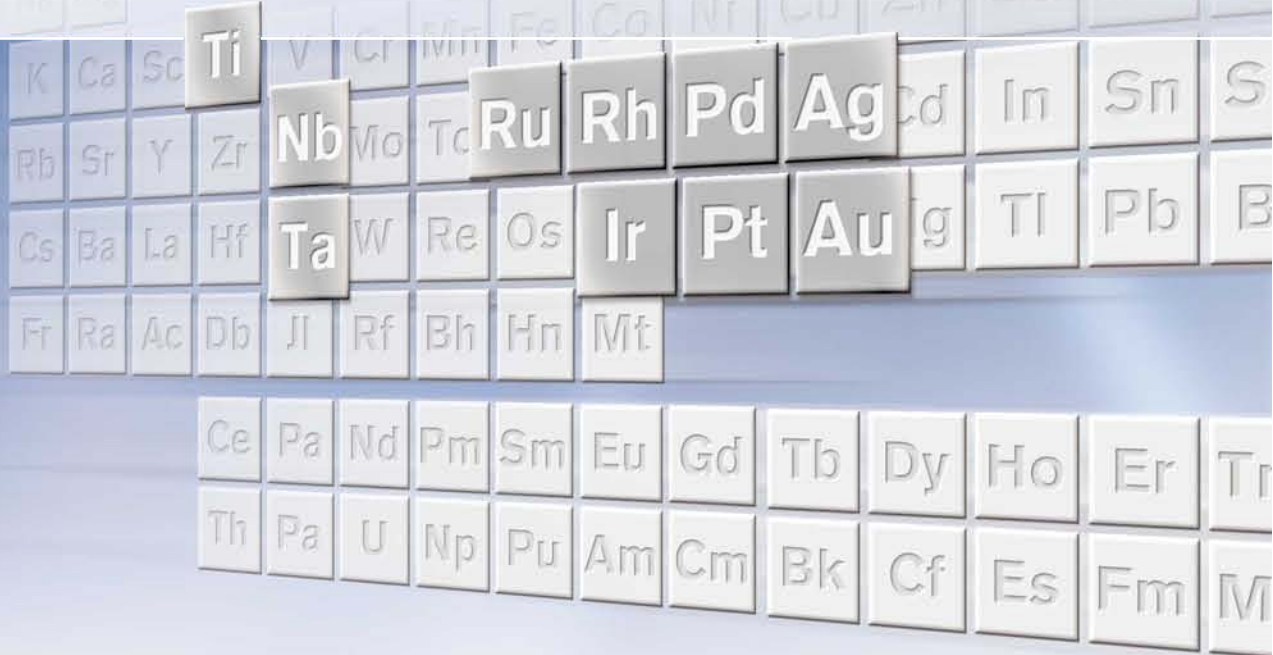
With four production sites, two in the US and two in Europe, Heraeus is well represented at the heart of the medical device industry. From the development

of new components to new materials and technologies, our convenient locations allow us to provide you with exceptional service.

Our modern production facilities will supply you with only the most innovative, high quality products available.

We are responsive to your ever-changing demands, and we are dedicated to exceeding even your highest expectations. As your partner, we will do everything it takes to contribute to your success while striving together to achieve world-class performance.

Materials



Biocompatibility, high strength, long fatigue life and corrosion resistance are only a few of the criteria that must be considered when selecting from the complete portfolio of advanced metals and alloys that Heraeus offers:

Precious Metals:

- Platinum
- Platinum Iridium Alloys (90/10, 80/20, 70/30)
- Platinum Tungsten
- Gold
- Silver
- Rhodium
- Ruthenium

Refractory Metals

- Tantalum
- Tantalum Tungsten
- Niobium
- Niobium Zirconium
- Tungsten
- Titanium
- Titanium 6/4 (Ti6Al4V)

Other Alloys

- Stainless Steel (316L, 304)
- Nickel Chrome
- Cobalt Chrome
- MP35N®
- Nitinol

Specialty Materials

From chemical refining, to melting, to wire and tube drawing, Heraeus has the capability to monitor the entire material cycle in house, thus allowing optimum control over the material characteristics of your products.

The ability to control the material process is crucial to manufacturing high strength and ultra fine wires or thin foils out of critical materials such as Pt30Ir, Pt8W, and Rh.

Alloy Development

Due to our sophisticated metallurgical laboratories and material controls, Heraeus excels in developing alloys for your new application and device requirements.

Wires, Tubes, Strips and Rods



By drawing and rolling our own wires, tubes, profiles and ribbons, we can guarantee high precision dimensions, well controlled mechanical properties, and superior surface conditions.

Wires

The fine wire drawing for most of our materials can be as small as 10 μm (0.0004") diameter. For example very thin Pt 8W wires are produced in high volumes for both medical and electronic applications. Our capabilities include special materials like Tantalum, Niobium, and Nitinol.

Profiles

Should your profile always be round? The answer is no. In fact, many applications benefit from flattened, oval, or tapered ribbon profiles. This allows you to design smaller, more flexible devices.

With our profile rolling, we can provide maximum flexibility in designing the best shape for different applications.

Clad Materials

If there is not just one material or alloy that fulfils your requirements, we are able to design clad wires, profiles and tubes. For example, we can place a metal of high electrical conductivity into the core with a shell of another alloy, which produces the required mechanical strength. Furthermore, this can be coated or clad with a precious metal for optimum biocompatibility, improved electrochemical resistance, or to create a diffusion barrier.

Tubes

Tubes are critical to many machining and micro component products. We offer fine tube drawings, which range

in wall thickness from very thick to very thin, such as 25 μm (0.001"). Our typical tube diameters range from 6 mm (0.24") down to 0.1mm (0.004").

Strips and Foils

Our high precision rolling technology enables us to offer ultra thin sheet, strip and ribbon materials. Platinum Iridium 80/20 and 90/10 ribbons with a thickness of only 10 μm (0.0004") are used to produce electrodes for neuro-stimulation. We can also produce mammography x-ray filters from Rhodium, which is very brittle, with a thickness of just 25 μm (0.001"). Outstanding cleanliness and process control throughout the entire production process guarantees that your filters are free from any defects.

Implantable Housings



Through various manufacturing techniques, we process initial strips of metal into finished implantable housing components in accordance with customer specifications. Our devices are used in several medical device industries, including:

- Cardiovascular – pacemakers and defibrillators
- Neuro-stimulation
- Power sources – capacitors and batteries
- Implantable medical pumps



Manufacturing Techniques

By using different manufacturing and tooling techniques, we are able to produce many different cases out of materials such as Titanium (Grade 1, 2, 6Al/4V), Aluminium and Stainless Steel, which range significantly in design, profile, height, etc. We have the machinery and know-how to utilise basic stage tooling for projects with smaller volumes, and more advanced progressive tooling concepts for higher volume parts. We have both mechanical and hydraulic presses of varying tonnage located in our facility, which offers us even more control over our processes. We also have an on-site tool room and a staff of tool and die makers, which gives us the option to manufacture all critical tooling components in house.

Lip Shape

We developed a superior manufacturing process to create a lip, or an integrated weld ring, on a case half, making it a snap to assemble with the mating case. By bringing this to the market, we have reduced the assembly time and costs experienced by our customers.

Quality System

All data from hand-held measuring equipment is directly imported into our paperless process database. Our measurement capabilities include CNC, touch probe and vision systems.

Coils, Stylets, Core Wires and Assemblies



Micro-invasive procedures require a number of different wire based instruments that are key to smooth and easy handling by the surgeon. For leads, stylets, guide wires, and catheters, we offer a variety of wire products, including coils, core wires, ground mandrels, complete stylets and other such assemblies.

Coil Winding

Our coil winding capabilities cover more or less the complete range of coil constructions in the medical device industry, from multifilar lead coils to micro coils for aneurism treatment.

Guidewire and Catheter Coils

- Clean cut coil ends
- Multiple and tapered diameters
- Wire diameters >0.018 mm (0.0007")
- Coil diameters down to 0.08 mm (0.003")
- Shaped wire coils
- Varying stiffness (droop) in close wound coils for unifilar and multifilar coils
- Coils for strengthening and reinforcing catheters and tubing
- Double helix aneurism coils

Drive Cables

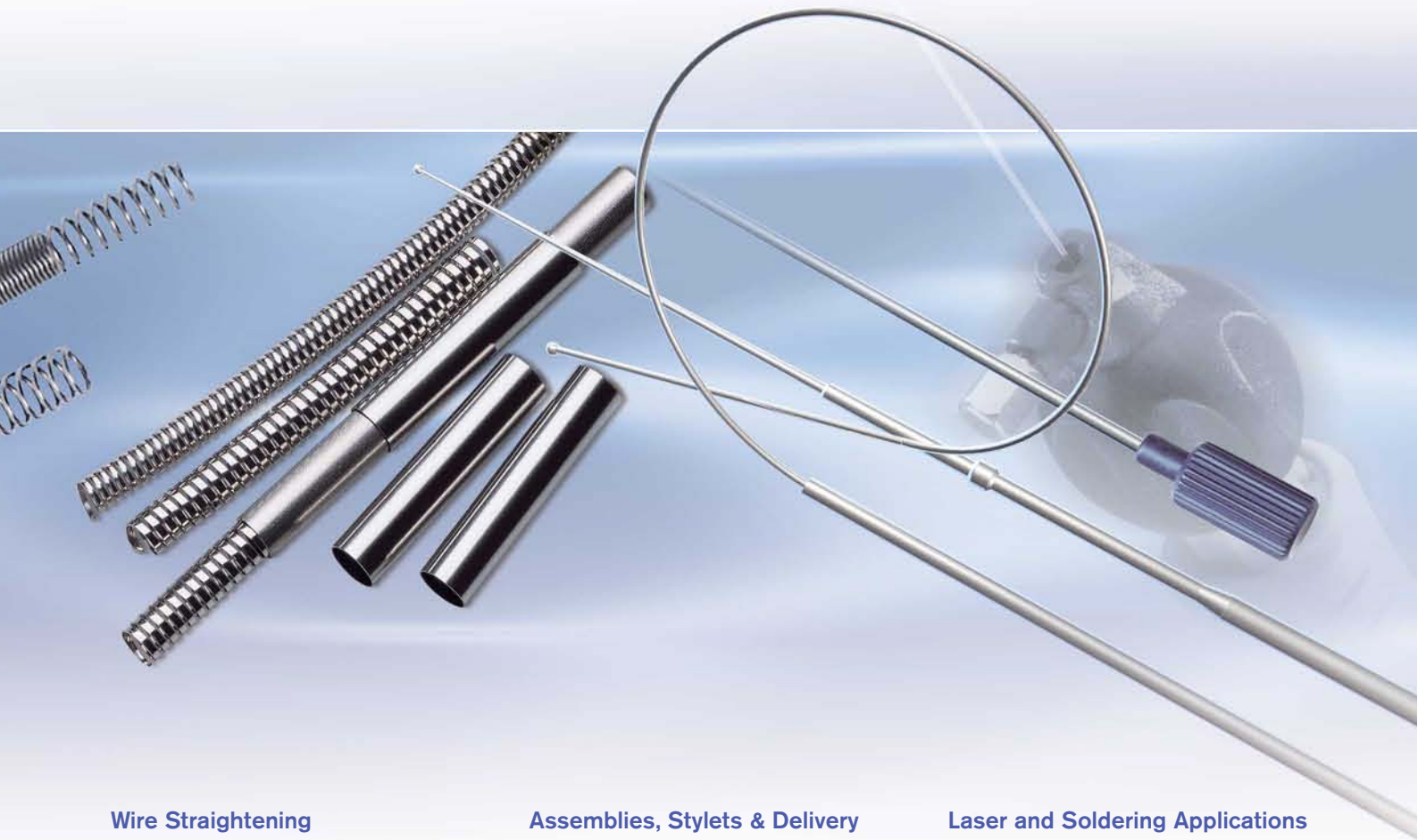
- Drive cables and assemblies with high torsional stiffness and column strength for rotating surgical devices

Pacing and Defibrillator Lead Coils

- Multifilar, pitched or tight wound
- Offsets and tapers
- "J" coils
- Coated wire coils
- Components for implantable electric stimulators

Pre-Coated Wire and Laser Ablation

We are able to wind precision coils from pre-coated wire. And we can perform an automated stripping process to remove the coating in predetermined areas. The stripping is integrated into a coiling system. The Materials we have stripped include ETFE, hydrophilic coatings and other Teflon[®] materials.



Wire Straightening

We straighten wires made of 1.4310 (AISI302), 1.4301 (AISI304), 1.4335 (AISI316L), mp35n®, NiTi etc., and cut them to precise length. This is a common first step in stylet and core wire production.

Centerless Grinding

CNC controlled centerless grinding allows us to produce many different cylindrical, conical and spherical shapes, with and without flat faces as small as 30 µm (0.0012") in diameter.

Ball Welding

With our optical SPC controlled ball welding operations, we have efficient methods for creating a ball at the tip of the wires.

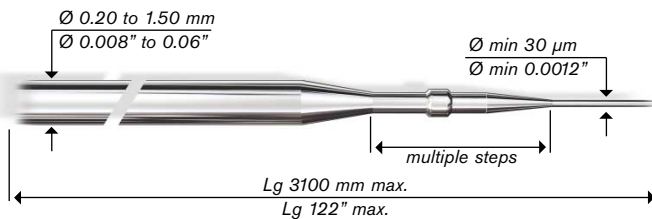
Assemblies, Stylets & Delivery System

Our assembly lines allow us to produce many complex wire components. For stylets, we weld aluminum or plastic handles to the end and shape the tip according to your requirement. For active devices we assemble wire, coil and tube with the necessary machined components for the handle in order to provide you with a complete delivery system.

Laser and Soldering Applications

Comprehensive laser welding and soldering are an important part of assembly work. It is often important that this type of work is completed in a strictly controlled clean room environment. Our services include:

- Spot welding
- Orbital welding
- Coils to coils, including coils of different materials
- Coils to hypo-tubes
- Component to component
- Ball tipping



Electrodes



A good example of how our various technologies contribute to one high-tech component is an electrode used in cardiac or neurological stimulation. The following processes contribute to a product which has optimized stimulation as well as improved sensing characteristics:

- Wire, tube, rod & strip
- Coiling
- Tip grinding
- Micro machining
- EDM & laser cutting
- Shape sintering
- Micro porous coating

The shapes of these electrodes are as manifold as the applications, which include standard tips and rings, helices

for active fixation leads, shock coils for defibrillators, miniature size electrodes for left heart stimulation, and ribbon electrodes for neurological stimulation.

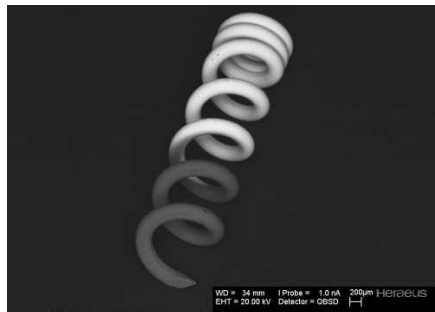
Special Technologies

To manufacture these electrodes we have developed specialized technologies such as grinding a three-face facet or a sharp

conical tip on a helix. Another example is using CNC to cut thin ($10\mu\text{m}$, $0.0004''$ thick) ribbon for custom shaped neurological electrodes. Other processes are EDM and laser cutting for various micro structures, as well as laser welding for more complicated products such as shock coils.

Micro-porous Coating

All types of electrodes can be coated with micro-porous coatings such as TiN, IrOx, Ir, and Pt. They can additionally be covered with isolated layers or oxidation protection. These coatings will ensure that you will receive exactly the characteristics needed to lower the impedance, improve the sensing ability of the device, and direct the stimulating pulse where most effective.



Micro Components



Some advanced applications, including minimally invasive surgery, left heart stimulation, neurological surgery, and interventional cardiology, are only a few areas demanding ever smaller devices and components. The production of such components begins with fine wires, very small tubes, or ultra-thin ribbons, but then in order to reach the desired specifications, we employ special manufacturing techniques including:

- High precision sink and wire EDM
- Micro EDM
- Laser cutting
- Micro stamping
- Micro bending

- Micro coining and cold forming
- Centerless grinding
- Etching

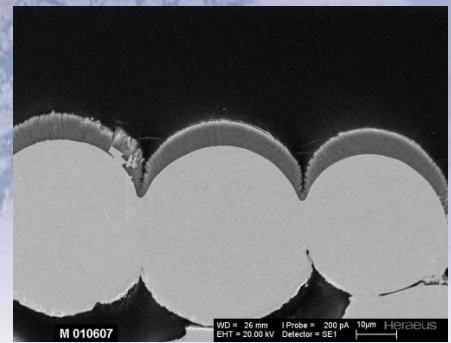
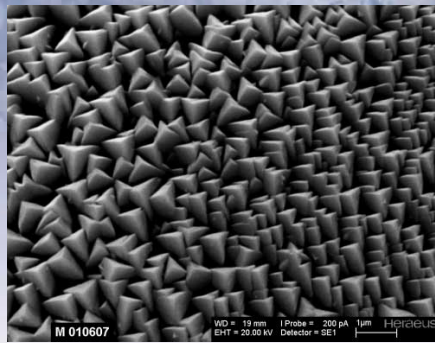
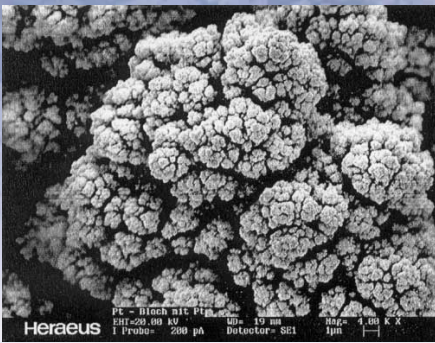
The dimensions of components produced with these processes typically range from 0.1 to 1 mm (0.004" to 0.04"). We can coin wires as small as 0.2 mm (0.008") diameter and cut less than 0.1 mm (0.004") wide holes and slots in tubes of 0.3 mm (0.01") diameter. We structure multiple area electrodes of 10 μm (0.0004") thick platinum foil and cut miniature tungsten weights for accelerometers.

Additional operations, electro-polishing, electro-plating and other similar coatings prepare the parts for soldering and can aid in deburring.

Soldering, as well as laser and resistance welding, is used to build sub-assemblies which make device production more efficient. This allows us to produce components for a large number of micro applications, including:

- X-ray markers
- Stent markers
- Micro contacts
- Structured micro tubes
- Micro coils
- Tungsten Weights

Coating



As additional functionality and miniaturization are progressing with components and end devices, coatings are becoming more critical. We offer a variety of metal coatings, including:

- Evaporation coating
- Magnetron sputtering
- Reactive PVD coating
- Electro plating
- Spray coating

These coatings are applied to all types of substrates, whether it is a selective area or the continuous coating of

- Piece parts
- Micro components
- Flat substrates
- Foils
- Wires

Depending on the product's application, the coating could be dense, porous, and even multi-layered. For example we could apply a micro-porous coating that lowers the impedance, and cover it with a protective layer that prevents oxidation and aging. Another possibility is covering areas of a stimulation electrode with an electrical insulation. Some of our typical coatings are:

- Titanium Nitride (TiN)
- Iridium Oxide (IrOx)
- Porous Platinum
- Platinum
- Gold
- Ruthenium Oxide
- Tantalum Oxide
- Titanium
- Carbon

Coating Development

This list is of course not finalized, but like our technology, it is continually being developed and improved. We have a specialized team that searches for new coatings while simultaneously modifies our existing ones. This includes an ongoing customization of the coating characteristics to fit the specific needs of your component and its application.

Our in-house access to analytical capabilities, such as metallographic cross sectioning, SEM, impedance spectroscopy and other electrochemical analysis tools, help to make the development cycle quicker and more efficient.

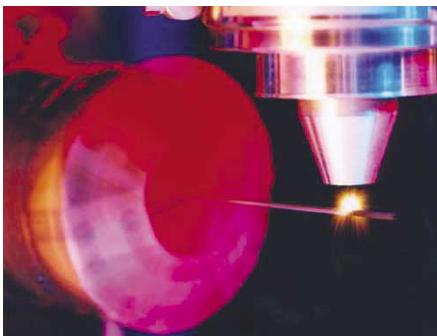
Services



Highly sophisticated production depends greatly on supporting services, which we also offer directly to our customers.

Rapid Prototyping

We have a dedicated staff committed to quick turn prototyping, with the goal of delivering your products within two weeks for our standard technologies. All prototypes are manufactured on production equipment, meaning we have the ability to transfer the prototype product into higher volume stages.



R&D

Our R&D groups not only improve our internal processes, but also work with our customers to develop new materials and technologies, engineer new components, and ultimately apply them to your products. These R&D areas have additional access to powder-metallurgical processes or metal ceramic development.

Analytical Labs

Invaluable for their work are our analytical laboratories, which feature:

- SEM with EDX and GDX
- Auger surface analysis
- Metallography
- XRD Spectroscopy
- Chemical Analysis
- Gas Analysis
- Impedance Spectroscopy
- Cyclovoltametric Measurement
- And others



Quality System

Our service is based on high-quality processes and procedures that have been officially certificated by outside auditors. All of our manufacturing sites are certified according to ISO 9001, and some processes have ISO 13485 certification as well. Individual process controls, reliable product and material traceability, online SPC, and other quality-related factors have led multiple customers to certify us as a Dock-to-Stock supplier for several components.

Production Locations

Germany

W. C. Heraeus GmbH

Medical Components Division
Heraeusstrasse 12 – 14
63450 Hanau, Germany
Phone +49 (0) 61 81 / 35 - 57 92
Fax +49 (0) 61 81 / 35 - 94 48
E-mail: medical@heraeus.com

USA

Heraeus Incorporated

Medical Components Division
280 North Roosevelt Avenue
Chandler, Arizona 85226, USA
Phone +1 (480) 961 58 75
Fax +1 (480) 961 80 28
E-mail: maryw@heraeusmtd.com

Heraeus Vadnais, Inc.

Medical Components Division
1375 Willow Lake Boulevard
St. Paul, Minnesota 55110 USA
Phone +1 (651) 254 26 21
Fax +1 (651) 254 26 10
E-mail: info@heraeus-vadnais.com

Switzerland

Heraeus Materials SA

Medical Components Division
Cossonay-Gare
1305 Penthalaz, Switzerland
Phone +41 (0) 21 / 861 89 13
Fax +41 (0) 21 / 861 89 00
E-mail: daniel.hejda@heraeus.com

The data given here are correct for
December 2004. We reserve the right to
make technical alterations as necessary.