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Ultrasonic technology & Surface refinement

Medical Surface Center



Quality does not tolerate compromise

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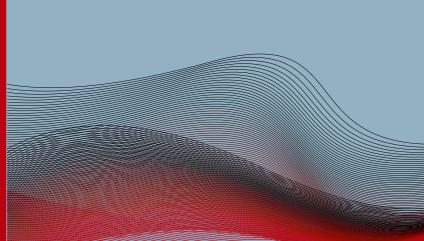
Further information available at www.kks-ultraschall.ch

Cleanliness in the service of health

This is because the medtech industry sets the highest standards for surface quality and functionality and thus on overall quality-of both implants and medical instruments. Concerning implants, for example, cleanliness and biocompatibility of the surface are key factors ensuring optimal human tissue tolerability and thus successful implantation. Every particular process of surface finishing consists of several consecutive steps in order to reach the desired, optimal surface quality. Validated processes guarantee reproducible results in this field.

In our Medical Surface Center, we collaborate with our customers to develop processes adapted to their actual needs and continue our research on new and perfected processes. As a business operating in the field of medtech industry, we are certified in accordance with the international quality management standard DIN EN ISO13485 for medical devices.

The KKS Medical Surface Center represents an economic alternative to expensive in-house facilities and investments. We listen to our customers, focus on their needs and explore their applications. This way, we develop leading technological solutions, improve performance, efficiency and flexibility and thus create true added value.



At the heart of Switzerland, there is a hub of cleanliness. Over the course of a few decades, KKS Ultraschall AG has become an epicenter of ultrasonic cleaning and surface refinement. In 2003, we started offering our entire technological and practical expertise as well as our passion for this field to a global customer base, providing advanced and comprehensive services to customers from a range of different industries - the medtech sector, however, is especially important to us.



REM/EDX



Our scanning electron microscope (SEM) provides high-resolution surface information. Combined with the EDX (energy-dispersive X-ray analysis/spectroscopy), we can thus employ a method of measurement that enables us to carry out the appropriate material analysis of samples.

We employ both methods actively in the areas of Research & Development and Quality Control.

Cleanliness requires quality management

In the health sector, flawed products can cause grave consequences for both patients and manufacturers. As a medtech business, we are always aware of how important impeccable quality is. Our Medical Surface Center features a state-of-the-art quality management system, which we continue to develop even further in collaboration with our customers in order to meet the highest standards of product safety. Of course, we are certified in accordance with the international quality management standards ISO 9001 and ISO 13485 for medical devices.

Quality through innovation and proximity to customers

All processes and technologies are results of our own development, underlining the innovative potential of our business. Our aim is not only to fulfill your needs, but also to enthuse you! Research and development are therefore a priority at KKS. This includes our ongoing efforts to improve processes and products as well as developing new technologies. Thanks to our experience with industry-specific requirements - qualifications and validations - we can rely on a vast pool of knowledge and offer you a corresponding level of support. Furthermore, end-to-end traceability and process documentation is as natural a part of our business as is consistent monitoring of measuring and testing devices or the continuing training of our employees.

Your advantage - strong performance from a single source

- Comprehensive expertise concerning the requirements and regulations of the medtech industry
- Customized applications and systems developed based on in-house experience
- Maximum flexibility due to a high level of in-house manufacturing
- Support and Consulting for the documentation and validation of processes
- Carrying out process/procedure validations

KKS quality management | 5









Order entry via a fully integrated Software solution for tamper-proof, end-to-end recording of target/actual process

Barcode system for optimal process security and data transfer - Labelling

- Identification
- Traceability
- Documentation

State-of-the-art facilities guarantee quality control

Quality control by constant monitoring of processes

Surface analyses via electronic scanning microscopy (SEM) and determination of elements (EDX)

• Our Medical Surface Center as a live test environment and testimonial for processes and technologies • Customer-oriented, environment friendly and economical production with short lead times and sophisticated logistics that is close to the market.

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Tumbling/polishing

- Deburring and rounding of edges
- Descaling, cleaning
- Grinding
- Smoothing, polishing, gloss polishing

Find out more on page 12

Cleanliness due to competence

Laser marking

• Precise and permanent marking of all kinds of materials • Marking on complex geometries

and freeform surfaces

Find out more on page 32

Dark anodizing of titanium & titanium alloys - TioDark™

Ultrasonic cleaning

• Clean surfaces, down to the pores

• Cleaning of the most complicated

geometrics, structured, porous

• Automatic cleaning process

for reproducible results

Find out more on page 8

surfaces, narrow gaps or blind holes • Custom selected cleaning chemicals

- Biocompatible surfaces due to passivating oxide layer
- Unchanged component dimensions
- Excellent characteristics concerning microhardness, fatigue strength, scratch resistance and reduced abrasive wear
- Reduced content of critical alloy elements in the oxide layer
- Ready for easy laser marking

Find out more on page 28

An overview of the treatments we offer

In our Medical Surface Center with its vaste range of processes and services, we ensure your implants and instruments have perfect surfaces.

Color anodizing of titanium and titanium alloys - TioCol™

Laser marking

- Biocompatible surfaces due to passivating oxide layer
- Reduced content of critical alloy elements in the oxide layer
- No change in component dimensions • Application for color-coding of implants
- and instruments • Laser marking possible before or after color anodizing

Find out more on page 24

Electrolytic polishing

Chemical Processes

• Reduction of surface roughness and thus enhanced gloss • Fine deburring of surfaces and edges • Removal of metal impurities ("metallically pure") • Enhancement of corrosion resistance of stainless steel Reduced friction • Reduction in the accumulation of dirt and microorganisms

Find out more on page 22

Dry and wet blasting

• Texturing, mattening, roughening Removal of coatings • Cleaning • Densification of boundary areas of metal components to enhance their fatigue-strength

Find out more on page 14





Pickling and etching

- Pickling removal of oxide layers, targeted removal of materials
- Etching roughening, texturing of implant surfaces
- Fine deburring of surfaces and edges
- Cleaning and activating metal surfaces
 Metallically pure, structured surfaces
- Biocompatible surfaces

Find out more on page 16



Passivating

- Enhancing corrosion resistance
- by strengthening the passive layer
- Removal of metal impurities («metallically pure»)
- Increasing the life span of components
- Biocompatible surfaces due to passivating oxide layer

Find out more on page 20



Ultrasonic cleaning

Core competency cleanliness

Application/use:

Before and after each surface treatment is carried out, cleaning is required. Ultrasonic cleaning has long been established as a reliable fine cleaning process for this purpose. By using ultrasonic waves in combination with aqueous media, we achieve highest levels of cleanliness at relatively short cleaning durations, even for components with complex shapes and delicate components with textured, porous surfaces as well as extremely small grooves and bores. At the same time, ultrasonic cleaning is a thorough, yet gentle-provided optimal parameters are ensured-procedure for cleaning sensitive surfaces down to the pores.

How it works:

The ultrasonic generator creates an alternating electrical field whose energy is transformed into mechanical energy by piezoelectric transducers and transmitted into the cleaning solution. This creates pressure changes in the liquid. Liquids are held together by bonding forces, so called cohesive forces. These act among the individual atoms and molecules of a substance and thus determine the tensile strength of a liquid.

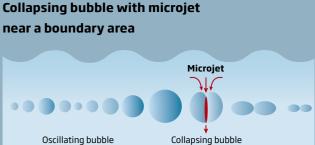
Compression/Expansion



Low-pressure phase, expansion

The pressure changes caused by ultrasonic waves (Expansion and Compression) tear apart the liquid's intermolecular bonds, creating transient and bubble-like cavities (bubbles), which are instantly filled with vapor due to vaporization of the liquid at the boundary of the cavity. During the compression phase, this vapor condensates again.

This creates millions of microscopic cavitation bubbles with oscillating sizes. If a sufficient level of ultrasonic energy is applied, the cavitation bubble can no longer oscillate in a stable fashion and collapses during the following compression phase ("transient cavitation"), creating millions of smaller bubbles or disappearing into the liquid.

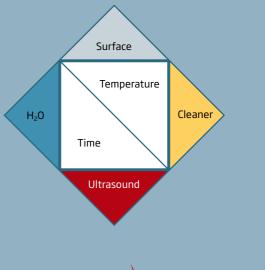


This creates immense localized pressures (shock waves) as well as turbulences and currents. These phenomena are what actually causes the removal of dirt particles from the surface of the component. During this process cavitation bubble implosions occur mainly at the boundary areas between the liquid and the component. The microjets created by the sudden influx of liquid are directed to the surface - precisely where they are required for effective cleaning.

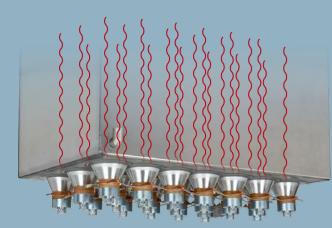
Cleaning factors:

To ensure effective ultrasonic cleaning, a number of parameters must be considered.

First, the material of the components that are to be cleaned determines the nature of the cleaning agent.



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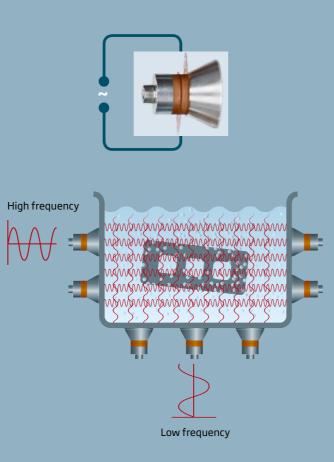
Second: the degree of contamination and the type of cleaning agent determine the temperature and duration of the cleaning step. Third, the ultrasonic parameters depend on how persistant the contamination and how sensitive the material of the component is. Fourth, rinsing the components with water of varying quality is very important to completely remove the cleaning agent and dirt particles from the component's surface. Using demineralized water for the final step ensures the surface is spot-free after drying.

Technology:

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Cleaning facilities for ultrasonic cleaning, both manual and automatic, consist of at least one rinsing tank and one drying chamber. Advanced cleaning facilities such as those used for medical products consist of at least two cleaning tanks and a number of rinsing tanks. The latter are filled only with water of different

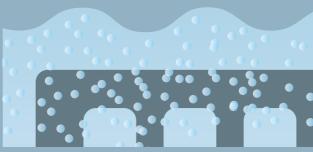
quality, or even only with demineralized water (highest quality), which is constantly reconditioned. Depending on the required amount of ultrasonic power, the ultrasonic cleaing tanks are equipped with multiple transducers at the bottom and/or the sides of the tank.



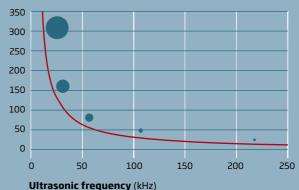
The ultrasonic generators supply the transducers with two different frequencies of ultrasound for DUALfrequency ultrasonic cleaning, or MIX-frequency ultrasound cleaning in case of a tank equipped with transducers on multiple sides.

This way, we can clean components of different materials and with varying levels of contamination very effectively and flexibly. The application and combination of both high and low ultrasonic frequencies is derived





High frequencies for small bores and delicate structures.



The resonance radius of the cavitation bubbles as a function of ultrasound frequency

from the physical behaviour of the cavitation bubbles depending on the ultrasonic frequency. Low frequencies create large cavitation bubbles, whose implosion produces shockwaves releasing a high amount of energy. High frequencies, however, create bubbles with a smaller radius, whose implosion releases a lower amount of energy. This is why persistant and heavy contamination can be effectively removed with low frequency ultrasound. The surfaces of sensitive materials, however, are at risk of incurring cavitation damage.

For these, we use higher frequency ultrasound, which causes less cavitation damage. It also produces higher streaming velocities, which is especially effective in the removal of small and less persistant particles.

Tumbling and polishing



For quality without compromise

Application/use:

The medtech industry sector sets the highest standards and accepts no compromises, especially concerning the surface quality of implants. The tumbling and polishing processes of our Medical Surface Center guarantee optimal results for the processing of products/components (e.g. during deburring, rounding, polishing of implants and instruments) as well as a high level of dimensional and shape accuracy. Furthermore, tumbling and polishing are often indispensable steps of the pretreatment for electrochemical surface finishing processes.

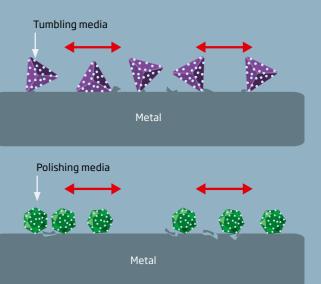
How it works:

Tumbling is an abrasive procedure for surface treatment used mainly for metal components. These are placed in a recipient as bulk material together with abrasive media. The abrasive media usually consist of a polymer or ceramic base, into which hard, abrasive particles are embedded. Moving these abrasive media over the surface of the component removes material. The component is deburred and finely smoothened while oxide layers and microscopic distortions are removed, which could otherwise disturb further processing. For the final finish, polishing, which removes far less material, is used. By selecting the appropriate tumbling methods and polishing pastes, any pits or microcracks still existing after tumbling are eliminated. The result: a very smooth, shiny surface.

Technology:

A rotating or vibrating movement of the recipient creates a relative movement between component and abrasive media. This causes removal of material from the component, especially at its edges. Geometry and size as well as the desired surface quality of the components to be processed determine whether a centrifugal, a drag finishing or a vibratory system is employed.

By choosing the appropriate geometry and size of abrasives, we can apply finishing to both the inside and outside of components in an optimal manner. We mostly use centrifugal disc machines at high rotational speed for polishing, which often follows tumbling. The polishing media are selected specifically according to the material of the component which is to be processed. The size and content of the abrasive or polishing media determine the aggressiveness, wear and the resulting surface quality of the components. We can rely on many years of experience in mechanical surface finishing of stainless steel and titanium implants, which allows us to always ensure optimal process conditions.



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Dry and wet blasting

Always first class surfaces

Application/Use:

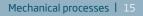
Blasting techniques are important methods for the finishing of surfaces. Regardless of which technique is applied - our Medical Surface Center always achieves first class results by using the appropriate blasting technology, blasting chamber and blasting media. The processes can be abrasive in order to texturize surfaces or to remove coatings, surface irregularities and contaminations. We employ blasting media to roughen the surface of cement-free implants, what facilitates osseointegration. However, we can also use media which cause a densification of material in the boundary areas (plastic deformation). This significantly enhances the fatigue-strength of metal components. Furthermore, wet blasting enables us to create surfaces on which fingerprints, e.g. on medical instruments, are not visible.

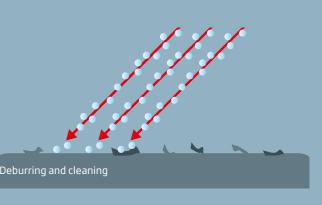
How it works:

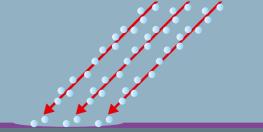
Using compressed air, a stream of blasting media is propelled under high pressure aginst the component through a nozzle. In this process, we distinguish between fine (e.g. glass beads at low pressure) and coarse (e.g. corundum at medium pressure) blasting. Ceramic or metal beads and high pressures are used mostly for the densification of component material. The blasting media can also be applied to the component via a high-pressure water jet. This allows producing especially finely blasted surfaces.

Technology:

We employ both dry and wet blasting technology in systems operating manually and automatically. During wet blasting, the mixture of blasting medium and water is regulated automatically, which ensures consistent processing conditions.



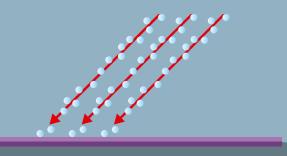








Roughening/texturizing



Densification/shot peening





Intensive cleaning and activation

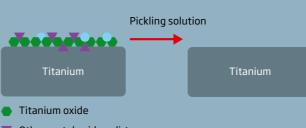
Application/use:

Pickling, which we also offer in our Medical Surface Center, is a necessary step in the passivation of stainless steels whenever their natural passive layer consisting of chromium oxide is highly contaminated and compromised. This rarely occurs during the manufacturing of implants and medical instruments, which thus usually do not require pickling. Titanium and titanium alloys, however, need to be pickled if electrochemical processes such as, for example, color anodizing - or a specific material removal are to be carried out.

How it works:

Pickling is a chemical process during which the metal oxide layer is dissolved. In most cases, only hydrofluoric acid achieves this effect. We use a variety of pickling solutions, which contain hydrofluoric acid mixed with other acids and substances. Depending on the material, its surface condition and the desired extent of material removal, we use different pickling solutions under defined conditions.

Dissolving the titanium oxide layer

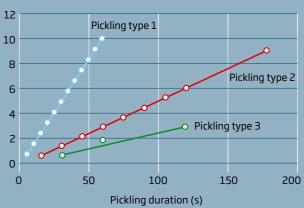


Other metal oxides, dirt

Blasting particles

The extent of material removal depends on the duration of pickling and the type of pickling solution used in this process. After pickling is completed, the clean and oxide-free titanium surface provides ideal conditions for the creation of clear and bright colors in the anodizing process TioCol[™] (find out more on page 24).

Titanium components are pickled using the immersion technique. The components are immersed in the pickling solution, either inside a chemically resistant basket or attached to a rack, and are constantly moved. After the predefined pickling duration the parts are immediately rinsed with water. Since a new titanium oxide layer forms immediately on titanium under normal oxygen conditions, all required electrochemical processes are carried out as soon as pickling and rinsing have been completed.



Removal of titanium relative to pickling duration and type of pickling

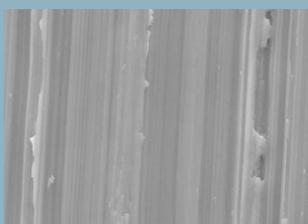
Technology:



Optimal stability due to roughness

Application/use:

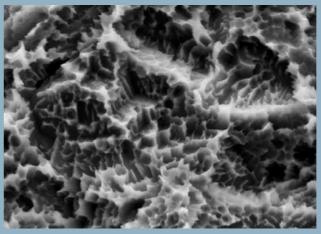
By etching titanium in our Medical Surface Center, we create a highly roughened component surface, which facilitates osseointegration in medical implants. Etching is a key surface finishing step especially for dental



Surface before etching process × 10000



Surface after etching process × 2500



Surface after etching process, highly magnified $\times\,10\,000$

implants, where it is often used in combination with corundum blasting. The blasting first creates a macro structure, on which a microstructure is created subsequently by means of etching.

How it works:

Etching is a chemical process which dissolves the metal oxide layer and strongly attacks the titanium base material chemically. Any corundum particles, which may have remained in the surface from the previous blasting process, are now permanently removed. The etching solutions we use are acid mixtures. We determine which kind of microstructure is created on the surface in this process through the selection of the types of acids used, their concentration and ratios, the etching temperature and the etching duration.

Technology:

We use the immersion process for etching titanium implants. These are fixed to specific holders, immersed in the acid mixture and immediately rinsed with water after the predefined etching duration. This process can involve either only one acid mixture, or a number of acid mixtures can be used consecutively. The etching process can be carried out both manually and automatically.





Active corrosion protection

Application/use:

All stainless steel alloys used in the medtech sector must be resistant to corrosion caused by all ambient media and bodily fluids/tissues. In order to restore the natural passive layer of stainless steel, which is damaged during the manufacturing of implants and medical instruments made from this material, we subject these components to the passivation process in our Medical Surface Center.

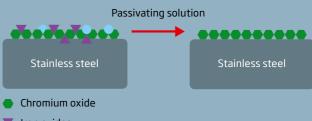
How it works:

The chromium contained in stainless steel reacts spontaneously with atmospheric oxygen at the surface of the component, forming a chromium oxide layer with a thickness of 3 to 5 nanometers. This protects the base material from corrosive destruction (passive layer). During the manufacturing process of the components, this passive layer is contaminated and/or damaged in a variety of ways. The iron released by this creates rust and thus causes surface defects, which can lead to a fractures of implants or instruments. A surface treatment commonly known as passivation becomes indispensable. In a chemical context, passivation refers to the formation of an oxide layer - in the case of stainless steel, this is chromium oxide. By using an oxidizing acid, such as nitric acid, a new oxide layer can be created quickly and reliably. At the same time, nitric acid also removes the exposed iron and any other metal impurities from the surface and facilitates the formation of chromium oxide. If the natural passive layer is highly contaminated and disturbed, it is helpful to subject the component to pickling prior to passivation in order to create a metallically pure surface. In this case, it is always necessary to passivate with nitric acid. If the passive layer is undamaged and if only traces of other metals are present on the surface of the component, these can be removed with other acids as well. Citric acid is highly effective for this, especially in removing iron from the surface by forming an iron-citrate complex and thus avoiding the formation of rust. However, citric acid does not facilitate the formation of a chromium



We passivate stainless steel components using an immersion process. The components are placed in baskets made from a material resistant to nitric and citric acid and immersed in the passivation acid for the required passivation duration. Acid concentration, temperature and passivation duration are pursuant to the processes NITRIC-2 and NITRIC-4 for nitric acid and CITRIC 1, CITRIC 2 and CITRIC 3 for citric acid, as described in the standards ASTM-F86, ASTM A967-05 and ASTM A380-06. After the components have been passivated, they are rinsed intensively with water of high quality (osmosis water, deionized water) and dried immediately. Asides from the immersion process, we also carry out wipe passivation, for example if already assembled medical instruments contain components which are not stable against passivating acids. In this case, the exposed stainless steel area is passivated through wiping.

Chemical treatment to prevent corrosion: chromium oxide forms passive layer



Iron oxides Dirt

oxide layer. Treatment with citric acid and/or citric acid formulations thus constitutes an acidic cleaning process. However, it is also widely referred to as passivation. Titanium does not require chemical passivation, since it already forms a stable oxide layer spontenously. In the case of superficial contaminations with other metals, especially for components with titanium plasma coating, a treatment with nitric or citric acid may be appropriate.

Technology:

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Electrolytic polishing

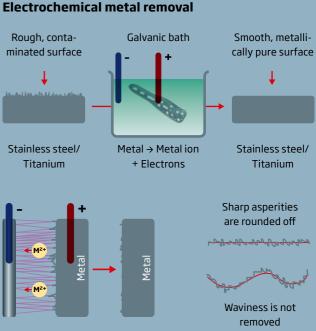
Intensive cleaning and passivation

Application/use:

Electrolytic polishing reduces surface roughness. Roughness peaks and sharp edges are reduced faster with this process. Another effect is fine deburring on the entire surface area, which reduces the capacity of dirt and germs to adhere to the component. In our Medical Surface Center, we treat surgical instruments as well as implants using this method. Due to the resulting smooth surface, temporary implants can be removed more easily after bone regeneration. Electrolytic polishing also increases the strength, corrosion resistance and thus the durability of components which are subject to mechanical stress, since it allows removing stress cracks and structural changes from the surface. Furthermore, removing microroughness creates a glossy surface.



Electrolytic polishing is an electrochemical process. The components, which are to be treated this way, are immersed in an electrolyte solution and contacted electrically to the anode. A DC voltage is applied, causing electrical field lines between the cathode and the anode (i.e. the parts to be treated). These are preferencely directed to the roughness peaks of the components surface, thus creating a high local field strength at the peaks. Electrolytic polishing is therefore a process during which material is removed preferencely at the peaks. Due to the chemical properties of the electrolyte, the metal dissolves and is removed from the surface, and remains in the electrolyte. This rounds off sharp asperities. Surface waviness, however, remains after the electrolytic polishing process and may even become more visible. Chromium, in turn, which is important for the passivity of stainless steel, is dissolved less efficiently and accumulates on the surface, forming a dense chromium oxide layer on the component by reacting with atmospheric oxygen as well as oxygen being formed at the anode. This increases its corrosion resistance. Accordingly, this is sometimes referred to as electrolytic passivation. Electrolytic polishing also re-



For the electrolytic polishing process, we attach the components to a titanium rack, which is immersed in the electrolyte and connected to the anode. Electrolytic polishing can be carried out with a predefined current density. The duration of the treatment determines how much material is removed. Alternatively, the process can be carried out with a given voltage and duration, with the advantage that the surface area of the components does not need to be known. However, in this case the required voltage and duration must first be determined in preliminary tests. Since electrolytic polishing requires field lines to form between the surface of the component that is to be treated and the cathode, unexposed areas (e.g. cavities) can only be treated with additional cathode arrangements. We perform electrolytic polishing of stainless steel and titanium in different electrolytes with different electrolytic polishing parameters.

moves any contaminations with other metals, which is the reason it can also be understood as electrolytic cleaning.

Technology:

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Color anodizing TioCol™

Increased safety due to color coding

Application/use:

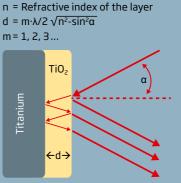
The "color coding" of implants and medical instruments made from titanium and titanium alloys is extremely helpful for surgeons both before and during surgery. Different types and sizes of osteosynthesis products, such as screws, wires, plates or intramedullary nails, are much more easily distinguishable if these have different colors.

In our Medical Surface Center, we achieve this coloring through color anodizing with the TioCol[™] process. Color anodized titanium implants show excellent biocompatibility regardless of color. A further positive side effect of the TioCol[™] treatment is a reduction in the release of alloying elements from titanium alloys. Implants and instruments with a TioCol[™] surface can be laser marked before or after the treatment with excellent results.

Color codes
 SZM
 SSN
 S7N
 60H
 62H
 65H
 67H
 70H

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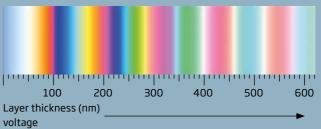


Incoming light ray with wavelength λ

Reflected light ray

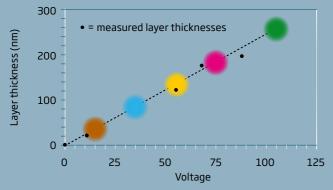
How it works:

The TioCol[™] process creates colors with a titanium oxide layer, which causes an optical interference effect. Incoming light is reflected at the surface of the oxide layer as well as at the bottom of the layer, which is colorless in itself. Due to the overlap of the reflected light waves (interference), however, the layer appears colored. Different layer thicknesses create different colors.





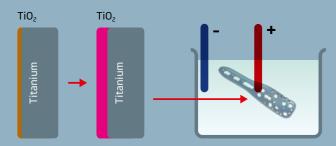
26 | Electrochemical processes



Under normal environmental conditions, titanium spontaneously forms a titanium oxide layer on its surface, which is about 5 nanometers thick. This protects the base material from extended corrosive destruction (passivation). The thickness of this layer can be increased in various ways. With TioColTM, we create a titanium oxide layer with a thickness of up to 300 nanometers using an electrochemical process.

Technology:

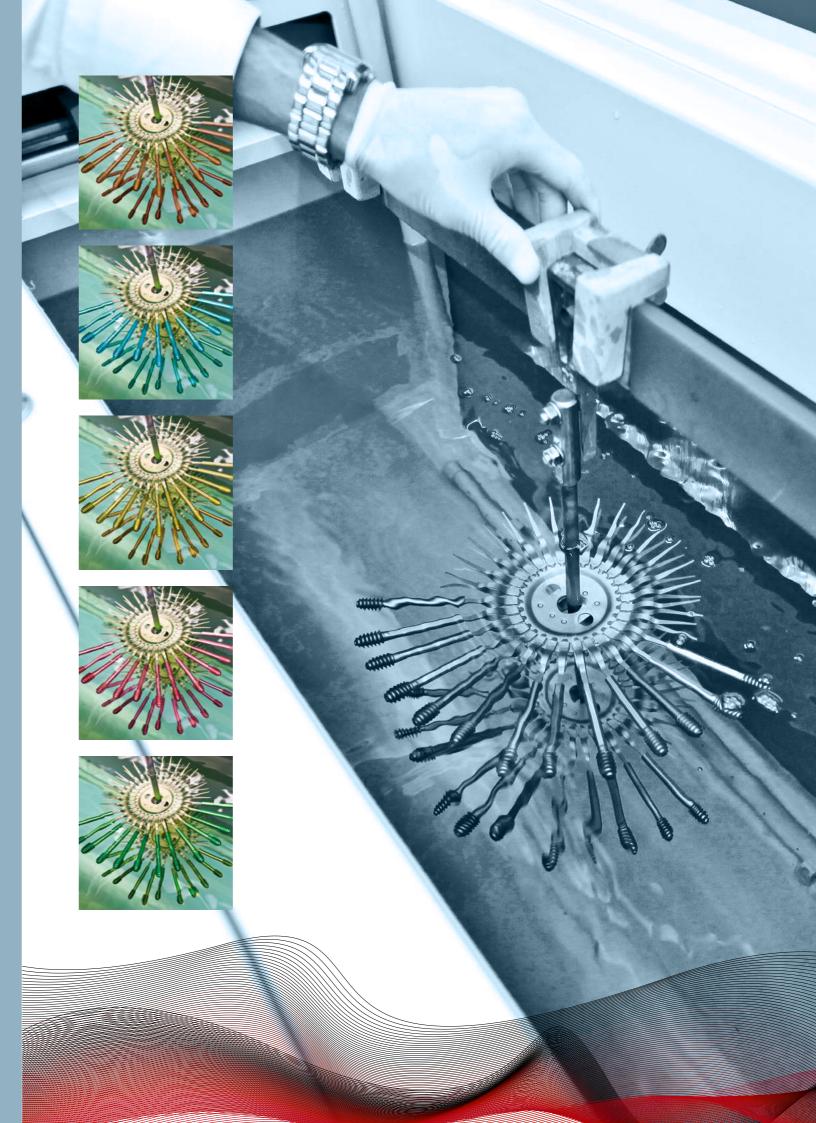
Depending on the requirements, we first subject the implants to a pretreatment (mechanical pretreatments, cleaning, pickling). During the TioColTM anodizing process, the color specific thickness of the titanium oxide layer (TiO₂) is reached electrochemically by applying an electrical DC voltage.



In order to do so, we attach the implants to a rack, which is immersed in an aqueous electrolyte and connected to the anode. During this process, there is a linear relation between the thickness of the oxide layer (specific interference color) and the electrical voltage applied, whose increase - depending on the type of titanium and titanium alloys - has a gradient of 2,4 to 2,5 nm/V.

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Dark anodizing – TioDark™

Where maximum hardness is required

Application/use:

If hard and scratch-resistant surfaces are required for implants and instruments made from titanium and titanium alloys, we recommend the dark anodizing process TioDark™ offered by our Medical Surface Center to our customers. This process increases the components' fatigue-strength and reduces frictional wear. The layer created by this process shows excellent biocompatibility. TioDark™ meets the criteria for cytotoxity (ISO 10933-3/5), hemocompatibility testing (ISO-10993-4) and HET-CAM-testing (ISO 10993-4/10). Furthermore, dark anodizing prevents the release of critical alloying elements. TioDark™ surfaces can be laser marked with optimal results. Due to their dark grey color and the pleasant haptic properties, they also provide an interesting contrast to TioCol™ surfaces.

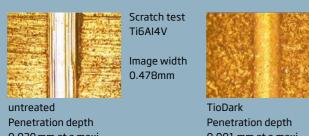




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How it works:

The dark grey color produced by the TioDark[™] process is created by a combination of optical interference and absorption effects when light penetrates the oxide layers. Under normal environmental conditions, titanium spontaneously forms a titanium oxide layer with a thickness of about 5 nanometers. The oxide layer thickness created by TioDark[™] is significantly higher than this and surpasses that created by TioCol[™] as well.



0.020 mm at a maximum force of 30 N

Technology:

cleaning).

0.001 mm at a maximum force of 30 N

Surface hardness, scratch-resistance and fatigue strength (4-point-bending test) of the treated components are significantly increased compared to untreated components. Friction is also significantly reduced compared to other hard surfaces.

The TioDark[™] treatment modifies the passivating

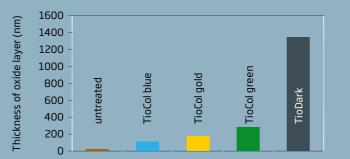
AMS 2488). Depending on the requirements, the

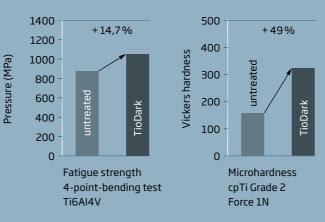
components which are to be treated are first subjected to pretreatment (e.g. mechanical pretreatment and

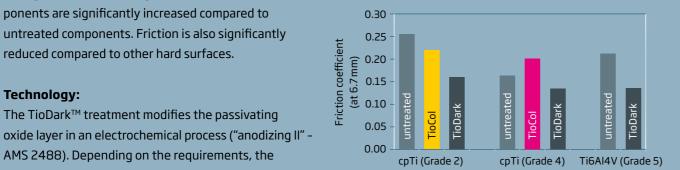
Porous oxide layer

🗲 Titanium

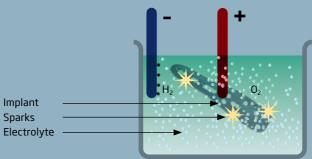
Conversion oxide-layer





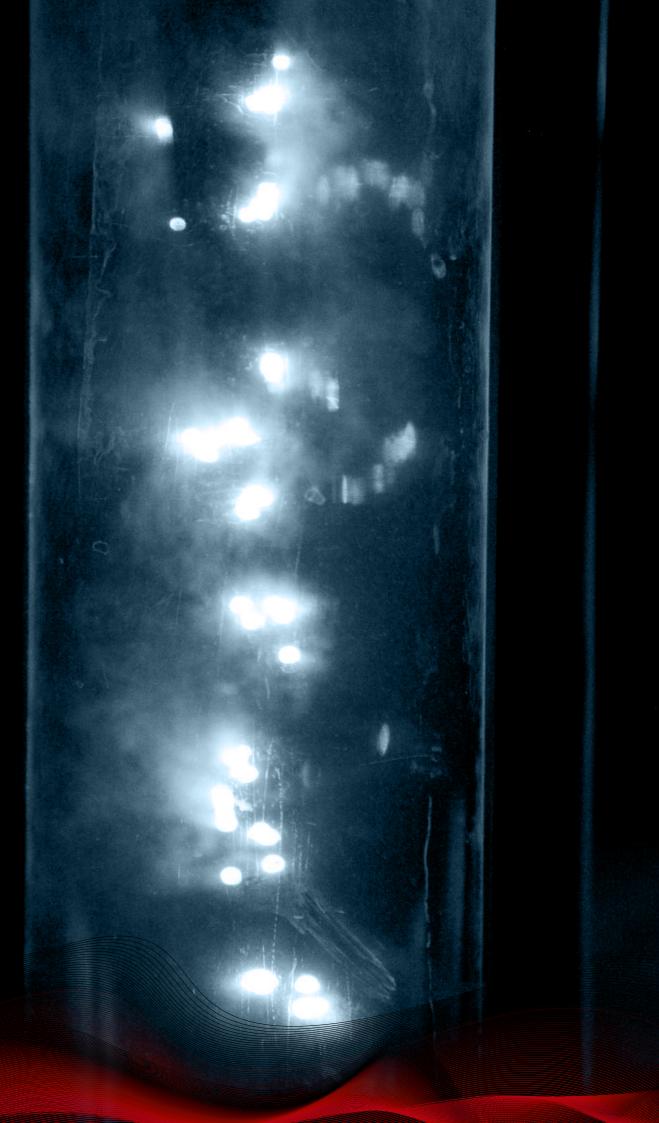


nature of the electrolyte and the kind of executing the process, this produces dielectric breakdowns (sparks) at the implant surface. The conversion layer is 1.0 - 1.5 μ m thick; this thickness is determined from the layer deepness at which the gradient of the oxygen content is decreased to 50%.



During the following anodizing process, the thickness of the oxide layer is significantly increased by applying an DC voltage. In order to do so, we fix the titanium implants to a rack, which is immersed in an aqueous electrolyte and electrically connected to the anode. Due to the





Laser marking

Exact and resistant marking

Application/use:

Laser marking of products has become an integral part of most industries today. This process, offered in our Medical Surface Center as well, is especially important in the medtech sector, where traceability of each implant is crucial. By choosing the appropriate laser parameters, we can mark almost all solid materials.

How it works:

A laser beam is a narrow beam of highly intense, highly coherent monochromatic light. If it is directed at a solid surface, for example that of an implant, different effects can be achieved depending on the material and laser parameters.

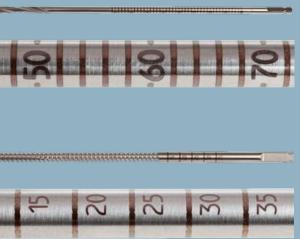


When marking metals, such as stainless steel and titanium, we distinguish between annealing marking and engraving. In the case of marking, the component material at the location where the laser beam hits is heated to a temperature below the melting point, creating so called annealing colors, i.e. oxide layers of varying thickness. The energy applied spreads within the material to the areas surrounding the letters - excessive energy input, however, leads to a visible blurring of the letters. During the process of engraving, on the other hand, the energy input is so high, that part of the base material is vaporized, creating a cut into the surface. Laser marking of stainless steel compromises the chromium oxide layer, causing iron to be released from the base material.

As a result, the components become more prone to corrosion in the marked area. This requires us to passivate stainless steel components again in these areas after marking. Many polymers can be laser marked as well. Depending on the type of polymer, this can be done via engraving, coloring or bleaching, foaming or layer removal. Some polymers, however, require chemical additives in order to mark them. PEEK on the other hand, a polymer widely used in the medtech industry, can be marked very well without the use of additives.

Technology:

We convert the marking desired by the customer into a parameter set using the software of the laser system. There are specific laser parameter sets for each type of application, which we prepare based on routine laser marking of the parts on test components. Furthermore, we create a picture for each component geometry to ensure reproducible positioning of the marking on the components. Stainless steel components are subjected to a so-called secondary passivation after the marking process, using the same acids as in primary passivation, yet with shorter durations. By choosing the right laser parameters, we create high-contrast and durable markings.



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For further information, please visit www.kks-ultraschall.ch

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