



Finest Tubes for Medical Devices



○ Who we are

A Cirtec Company

For over 30 years, Cirtec Medical has been partnering with medical device manufacturers, providing product design, development and contract manufacturing services. We specialize in the areas of neuromodulation, cardiac rhythm management, implantable drug delivery, ventricular assist devices and minimally invasive surgical devices. Our facilities are FDA-registered, ISO 13485 certified, with Class 7&8 cleanrooms.

For more information visit: www.cirtecmed.com



Cirtec Medical Headquarters | Brooklyn Park | MN USA

Vascotube is based in Baden-Württemberg, Germany, between Karlsruhe and Stuttgart. At the edge of the Black Forest is situated the heart of Germany's automotive, mechanical and medical industry. As part of that regional cluster in a globalised environment, we stick to the old watch making tradition of fine precision workmanship and the "Quality made in Germany" approaches to our products.

Vascotube is specialized in implantable high quality tubing and serves the medical industry. Most of our customers are based in Europe and the United States, including some of the best known medical companies in the world.

Together, with our combined experience and production know-how, we can bring quality, high-end technical products and solutions to meet the critical needs of our customers.



Vascotube GmbH | Goethestraße 38 | D-75217 Birkenfeld

○What we do

To give our customers the quality they expect, we have concentrated on the production of high quality tubing. Simply: we do not do anything else.

We are dedicated to quality tubing and the specific requirements of working and forming Nitinol and other demanding materials as Tantal and Magnesium.

The staff at Vascotube has more than twenty five years of experience in the field of high quality medical tubing. They have been at the core of the development of nitinol components since 1986. Developing and devising technical procedures to produce medical tubing for over 15 years.

Since 2004, Vascotube is certified ISO 13485, the European Quality control management standard for the production of medical products. We have passed numerous client audits and value the fact that most of our customers have to meet FDA regulations.

Quality control is done through all production steps and can be provided in an elaborated IT based documentation. All products are passing an intensive and documented quality control before shipping. Traceability can be guaranteed for a period of more than 30 years.



○Manufacturing

Vascotube starts the production process from the ingot bars. We order to our quality specifications at certified melters. We have a very selected array of qualified suppliers. All incoming material will pass a broad quality and specification control.

Vascotube has a “all in-house” philosophy. To realize new processes and to implement new production methods, we are developing and building own drawing benches. We use mainly in-house built machinery and produce our own tooling.

This is one of the reasons why we can push the diameter, surface smoothness, wall tolerances and concentricity of our tubes to higher levels, not reached by our competitors.

We rely on experienced workmanship and do long term training and qualification. All production staff that has joined Vascotube since the beginning is still with us. Experienced people and broad documentation of all production steps guarantee a long term reliability of our product capability to our customers.



○ Specifications

Surface

Surface roughness of the finished tube is one of the most critical specifications for the quality and the lifecycle of your finished device.

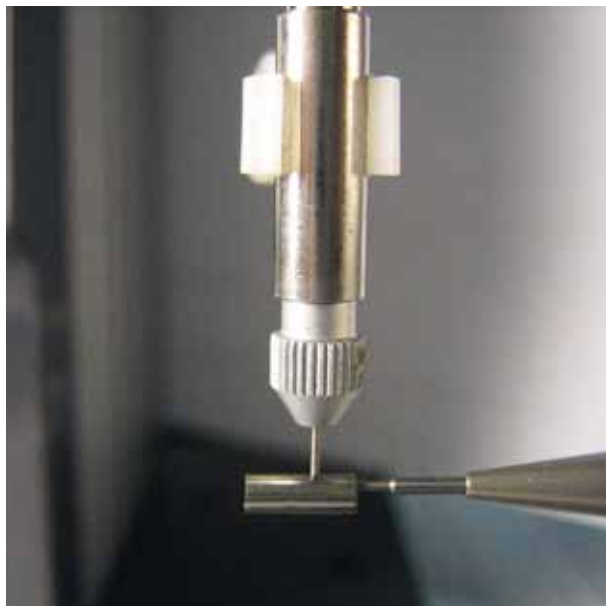
Surface defaults cannot be removed by electro polishing of the finished stent. Cracks and deformations will remain. With our unique tube production technology we are able to avoid cracks and obtain a better inner surface. We are leading in high quality OD and ID surfaces. On the OD we are able to produce roughness up to $0,1\mu\text{m}$ (Ra). For the ID we are able to achieve roughness as low as $0,2\mu\text{m}$ (Ra) as drawn, with a thin oxide layer.

Concentricity

This specification has a great influence on the laser cutting process. Vascotube is able to reach concentricity tolerances up to $0,01\text{ mm}$ in regular production batches.

Wall tolerance

The tolerances on wall thickness for our tubes can be asked as narrow as $\pm 0,0075\text{ mm}$. Vascotube guarantees these tolerances, not only for a single tube, but for entire production batches. This attribute has significant influence on the lifecycle of your device and the performance in fatigue testing.



○Inspection

Vascotube produces tubing exclusively for the medical device industry. The vast majority of our tubes are going to be parts of FDA class III medical devices, such as stents and heart valve frames.

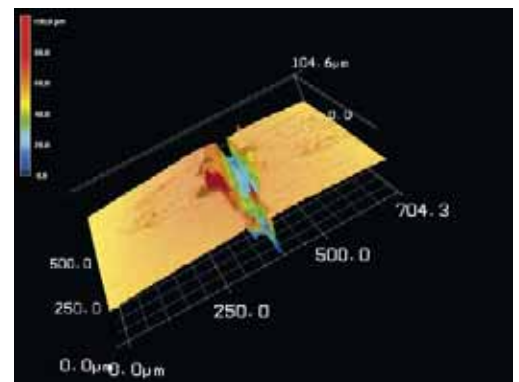
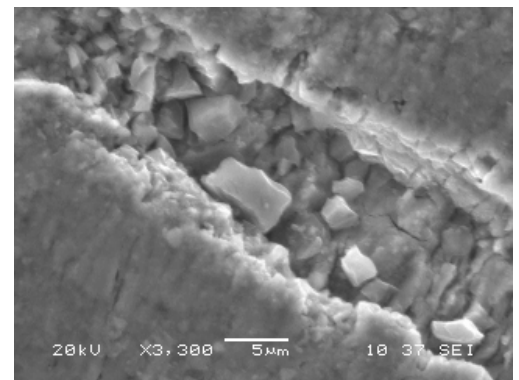
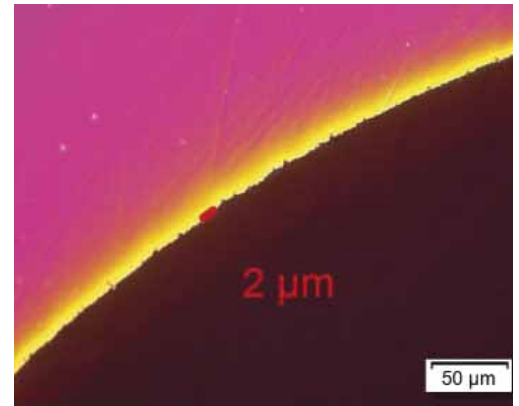
We do value this fact: we carry numerous in process inspections at all different process steps. We have invested in sophisticated inspection and analysis equipment to be able to look beyond the first sight. We make cross-sections of every lot that we produce and hold retention samples of every lot that we ship.

Quality control and inspection equipment include:

SEM Scanning Electron Microscope, EDX analyze unit, 3D Laser Confocal Microscope 1000x, Metallurgical Microscope 2000x, Endoscope, Stereo Light Microscopes 20x and 40x, Zeiss Microscope 120x, DSC Differential Scanning Calorimetry, Af-Tester, Eddy Current Testing, Zwick Tensile Test equipment, Laser Micrometer, Surface Roughness measurement unit, Mahr Wall thickness measurement.

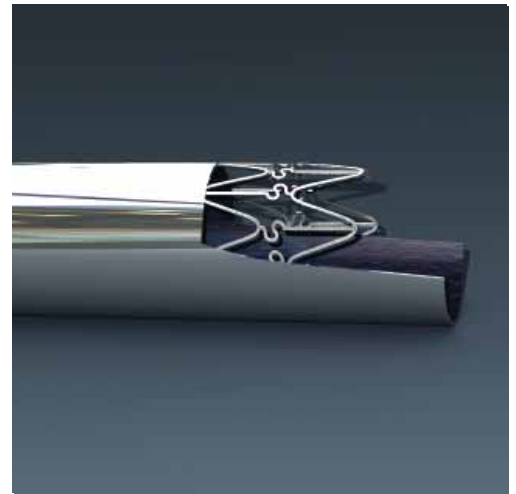
Quality inspection process is managed in a specialized IT system. Each article gets its own specified inspection plan. The measuring equipment is directly linked to the IT system. The data are stored in a change recorded IT environment and are related to the unique production lot number. We save all data on our two parallel secured servers and do hold copies in a separate location.

Due to our specialization on the medical device industry we are certified ISO 13485, the medical device standard, for more than 12 years now. We have passed a high number of audits from notified bodies, as well as from customers, including renowned US medical device companies.



○R&D

For providing fast feedback to our customers' research and development departments, we offer a special service to quickly satisfy the need for tubes in this area. To support your development activities, we strive for an extremely short turnaround and typically will be able to deliver the tubes within 2 weeks. This service is intended for situations where the outer diameter and wall thickness are needed and small quantities are sufficient. As for all our tubes, certificates will be provided for R&D tubes as well. If you would like to receive a quote for a R&D production, please send an email to info@vascotube.com specifying the outer diameter, wall thickness as well as the desired quantity. Please note, that the service is offered to a max. of 10 m for tubing with an outer diameter of at least 5 mm. For tubing with an outer diameter of less than 5 mm max. 20 m can be provided. For larger quantities or more specific mechanical parameters, we would be glad to provide a regular quotation for you.



○Fast Tubes List

The Fast Tubes List is designed as a service to the research and product development department of our clients. We aim to give you the possibility of a fast respond to your tube needs and your clients' needs with your own overview of material that we can send you in a matter of two days. We provide a CofC with the tubes on this Fast Tubes List. The CofC will give you full information about the ingot, the material and the measurements of the tube. We have conceived the list to be able to ship small quantities, one or two tubes. It is not designed to meet production quantity requirements. The material is aimed for your development needs. We apply the regular price for small quantities and have decided to add no extra "fast charge". We do not offer the service of cutting the tubing. We deliver at least one tube within our standard length of 700 to 2500 mm.

You can find the Fast Tubes List on our website www.vascotube.com/fast-tubes-list, which is updated on a daily basis.



○ Nitinol tubing for medical devices

Medical devices require high quality surface on Nitinol tubing. The technology and tube making processes developed by Vascotube, have been perfected over many years of practice. Using our experience, combined with new technologies and custom made machinery, we have been able to develop a drawing process that avoids the need of slurry cleaning, chemical cleaning, or mechanical removal operations on the inner surface of the drawn tube. Our process allows us to attain a roughness value of Ra 0,1 μm .

In the last years we have pushed the feasibility of dimensions to seize up to an outer diameter of 0.59 inches and down to 0.004 inches, thus achieving to keep the high quality inner surface of our tubes.

Concentricity tolerances are up to 0,01 mm

Wall tolerances are narrow as $\pm 0,0075$ mm



○ Nitinol | ASTM F 2063

– flexible, superelastic and biocompatible

Nitinol is a unique material. No other material exhibits the mechanical shape memory superelasticity and the thermal shape memory effects. Fields of applications are peripheral stents, cardio stents and other medical devices for the human body. We deliver tubes with the mechanical properties, the requested tolerances and the appropriate surface quality for stent use.

All our tubes are made according to customer's specifications.

We have supply agreements with leading melters and we are able to supply tighter specifications than ASTM F 2063, e.g. on inclusion size.

Dimensions / Tolerances

OD	OD Tolerances	WT	WT Tolerances
> 0,800 mm	± 0,005 mm	0,050 - 0,120 mm	± 0,0075 mm
0,810 - 2,800 mm	± 0,010 mm	0,130 - 0,260 mm	± 0,010 mm
2,810 - 6,000 mm	± 0,015 mm	0,270 - 0,400 mm	± 0,013 mm
6,010 - 12,00 mm	± 0,020 mm	0,410 - 0,600 mm	± 0,020 mm
12,010 - 15,00 mm	± 0,030 mm	0,600 - 1,000 mm	± 0,030 mm

Notes:

Tolerances may vary depending on the wall thickness / outer diameter ratio. For other tolerances, please contact us.



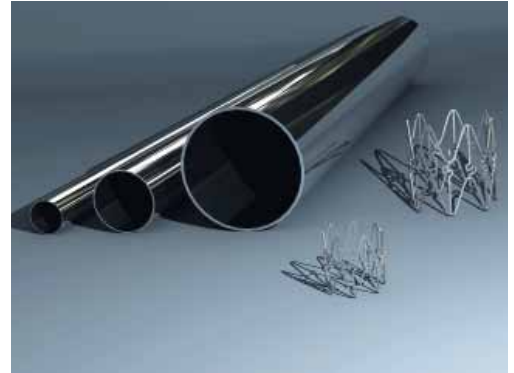
○MP35N | ASTM F 562

Heat Treatment

Tantalum exhibits high reactivity towards interstitial elements like hydrogen, nitrogen and oxygen. Also it may react with hydrocarbons. Its recrystallization temperature varies between 900° C and 1450° C. Vacuum and dry inert gases are most suitable as heat treatment atmospheres. The duration of the heat treatment may depend on the equipment, the process and the experience with the material. Lubricants should be completely removed prior to the heat treatment. If not, they may react with the tantalum and cause embrittlement of the material.

Surface

Under atmospheric conditions, Tantalum is covered by a stable, tight oxide layer. Although Tantalum is a reactive element, this layer is the reason for the high corrosion resistance and the high biocompatibility. In its manufacturing process, Vascotube® applies only appropriate tooling, lubricants and custom heat treatment equipment. Favorable to the manufacturing process is the excellent formability of the material.



○Titanium | ASTM F 67

Heat Treatment

Titanium has a great thermodynamical affinity towards interstitial elements like hydrogen, oxygen, nitrogen and carbon. For heat treatment protective atmospheres like high vacuum or inert gases are suitable. The annealing temperatures range from 600° C to 800° C. The duration depends on the equipment, the type of process and the experience with the material. Organic residues such as lubricants should be completely removed prior to annealing. If they react with Titanium, hydrogen may be formed embrittling the material.

Surface

Under most conditions, Titanium and its alloys are covered by a thin but even oxide layer. If destroyed, the material exhibits fretting corrosion. Vascotube® processing sequence includes high quality tooling, lubricants and heat treatment equipment.



○Magnesium

Biocompatible degradable materials

Stents aim to support revascularization procedures by mechanically preventing vessel recoil.

Taking in account all positive effects, permanent implants still pose the risk of interaction between a non-absorbable stent and surrounding tissue, leading to physical irritation, long-term endothelial dysfunction, or chronic reactions. Over the long lifecycle of the implant, there is a risk of stent fracture.

To overcome these shortcomings, stent technology has looked towards the development of temporary implants composed of biocompatible materials which mechanically support the vessel during the period of risk for recoil, and then are completely degraded by the body.

With the Know How in the forming of difficult materials, Vascotube® has been producing tubes from biocompatible degradable materials, starting with pure magnesium tubes some years ago.

We work with partners in the medical research to bring these materials to the required specification for medical stent use. We are proud to give our technical input to help to create together with our customers an advanced medical device that will help patients all over the world.



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