Development and Production of
Human-Implants and Surgical Instruments
HumanTech Germany is the Humantechology Manufactury of the Hutzel Group.

For a Better Life

Precision turning at Hutzel DrehTech is our core competence, in which we have acquired many years of experience and know-how in the field of Medical Device manufacture as well as the manufacture and testing of implants and instruments. We have within a short period become a global market level manufacturer.

HumanTech Germany is a company which is fully dedicated to the highly functional use and manufacturing of implants and instruments in the medical field. We develop through research and innovation new technologies and are constantly seeking improved solutions.

We develop and produce ourselves in Germany all of our implants and instruments, both today and as well as in the future. Made in Germany is for us a special quality seal of which we are proud. Our HumanTech competence team operates in all parts of the world creating in-depth market analysis, and are advised and supported by the expertise of renowned surgeons.

Everything from one source - research, development, production and sales. This will avoid unnecessarily distribution costs and as manufacturer, we are the direct point of contact for our customers.
Human-Implants and surgical instruments
directly from manufacturer
The experience of three generations and motivated employees, this combined with a highly developed technological focus, forms the cornerstone of our success. An on-going program of training underpins a high standard of individual responsibility and independence in our workforce, simultaneously encouraging team spirit. Every employee identifies himself with the quality of our products – from the planning stage to delivery.

Our complete range of human implants and instruments are manufactured exclusively in Germany in our own manufacturing facilities. For us „Made in Germany“, really means Made in Germany - in all areas of production.
For us, the term “Medical Parts” stands for fully machined world-class-quality products and product groups. Whether small batches or long runs, here efficiency and reliability are a matter of fact.

**Everything from one Source**

Our objective: Taking existing potential and turning it into concrete products and processes. We produce medical devices from prototype to finished ready-to-assemble products, in all machineable materials, including titanium, tantalum, zirconium, stainless steel and Peek.

Our on-site secondary machining operations consists of grinding, lapping, honing, bore drilling, assembly, sand-, ball- and ceramic blasting, laser inscribing, anodizing, super-finishing and polishing. We produce every implant completely within our facilities. Upmost confidentiality is guaranteed and your advantage is that: everything comes from source.
Another crucial advantage in our company is the final surface treatment which takes place in the own production areas. Modern machines offer a variety of opportunities to modify surfaces, to combine materials and to change surface properties.

**Complete Final Processing**

Our portfolio includes a wide range of technologies for surface treatment of human implants and surgical instruments. These include passivation, anodizing, barrel finishing, blasting, super finishing, polishing, plating and laser inscribing.
Precision Machinery

- 140 lathes
- 20 grinding machines
- 3 machining centers
- 5 transfer machines
- 5 lapping machines
- 1 polishing machine
- 2 superfinsihing machines
- 4 honing machines
- 1 deep-hole drilling machine
- 5 switching ring machines
- 3 thread rolling machines
- 8 blasting machines
- 6 vibratory grinding machines
- 1 water jet deburring machine
- 1 YAG Laser
- 1 anodizing/passivating
- 1 rapid prototyping
- 1 packaging machine
- 9 cleaning machines
- 8 inspection automates
- 4 assembly robots
- 1 hotsealing machine
- 1 sterilization
- 2 cleanrooms
For us, quality management means more than simply certification in compliance with various quality standards.

The pillars of our quality management are a team of highly qualified employees, preventive quality controls, the use of top-quality materials and machines. We guarantee compliance with the most ambitious quality targets through the use of documented, effective quality assurance systems. These fulfill the exact requirements stated in ISO/TS 16949, ISO 13485, ISO 9001, ISO 14001 as well as different international standards and the Medical Device Directive 93/42/EEC.
We guarantee that all employees are able to continually relate and respond to all customer needs and product requirements, by developing integral, detailed specifications and by pursuing the continuous improvement process (CIP / Kaizen) in every area of the organization.

HumanTech was the first company which applied these QM methods, derived originally from the automotive industry for the development and production processes and is integrated into the medical technology sector.

**Highest Quality Standards**

The newest technology of our measurement equipment makes it possible for us to reach our high standard in product quality, which is another very important element of our success.
Along with product development, a number of additional applications have been offered with the support of some of the most modern design software available:

- Simulation of the function and load capability of instruments and implants using FEM
- Application of simulation methods in current development and technology projects
- Validation of prototypes in close coordination with a university research lab

Fit for future

Stress analysis and lifetime assessment
Excessive stress on mechanical human implants can cause bone atrophy. That may cause bacterial inflammation and in the worst case scenario, even lead to implant failure. A structural mechanical analysis of these models are made, using the finite element analysis method, providing information on the material, design, type, number and position of required implants. Within the framework of the model building process, various prototype test series are combined and expanded with the design and the FEM method.

**Final Security analyses Guarantee**

The analysis results obtained during this process demonstrate the high quality of the generated models and permit application in almost every field of our medical devices.
In our 3 Cleanroom classifications (1,000, 10,000 and 100,000), which are classified and qualified according to accepted international standards, we conduct the module assembly, visual inspection, cleaning and packaging. Thus we are able to satisfy the diverse and most demanding cleanliness specifications.

**Perfect Cleanroom Method**

Based on a comprehensive hygiene plan, there is a regular monitoring system installed, which includes both the environmental conditions specified for the assembly and visual inspection as well as the requirements for the technical cleanliness for our products. We hereby ensure the highest level quality standard.
The assembly of medical devices requires a high degree of precision and cleanliness during the process. Specially trained personnel, uses limiting sample catalogues and pareto-analyses to monitor the sensitive products with stereo microscopes or other visual inspection systems. This ensures that even the smallest abnormalities are detected and immediately sorted out.

Especially in multi-part products, the assemblies are conducted under controlled conditions. Specially designed mounting devices with Poka-Yoke-adaptations or force-A/way-surveillance systems, enables optimal assembly processes in terms of precision and reproducibility.

100% Human Technology
The importance of product cleanliness and disinfection is ever increasing in complexity. With microbiological cleaning, products are treated for reduction of microscopic organisms in order to gain a reliable base for all following processes. Particle cleaning is absolutely necessary, especially for products produced by machining. Production residues such as greases and oils, for example, are removed. The cleaning processes are validated so that the highest possible level of safety can be achieved.

Medical Cleaning and Sterilization

The sterilization in the autoclave fulfils the most demanding sterilization processes and offers all possibilities of additional options for process improvement according to the latest technology. All sterilization processes are conducted according to a validated method. Evaluating technical cleanliness in accordance with VDA volume 19, entails an analysis of the number of particles of the various size categories contained in the samples. The process allows particles as small as 5 microns (mm) to be detected.
Packaging of medical and pharmaceutical products is subject to variety of complex requirements. Above all, packaging serves as a sterile barrier system, for without this barrier it would be impossible to keep the products sterile and guarantee an appropriate expiration date for use.

In addition, packaging must take into account product characteristics such as geometries and materials and it must also take into account the medical requirements pertaining to on how the product is to be applied.

We use 3D-CAD software to develop packaging systems by modelling optimum product adaptation in the storage, product fixation as well as practical extraction can be displayed.

**Cleanroom Packaging**

All packaging is manufactured and all packaging processes take place under the clean room conditions of class A/B (ISO 5), class C (ISO 7) and class D (ISO 8) and comply with the requirements of MPG, AMG and EN ISO 9001:2008.
Human Tech Germany produces innovative implants and instruments for a wide range of different spine surgeries. The aim is to significantly improve the living conditions of individuals, through the use of our implants. Our compelling product portfolio is used by physicians worldwide, this means, that our implants and instruments are constantly being developed and optimized for an international standard and usage.

**Spine Technology - Made by HumanTech**

Naturally high quality the most important basis for our success. Development and production of all implants and instruments is produced in our own facilities "Made in Germany" and complies invariably with the highest international standards.
Use of VENUS® Spinal Fixation System

Detail: Repositioning Instrument

Stainless steel tray with Implantations Instrument Set

High-precision Implantation Instruments
Our long years of experience in the field of dental implantology and our know-how in development, manufacture and testing of implants and instrument combinations, also guarantees the high-functionality deployment of all HumanTech dental products.

**Dental Technology - Made by HumanTech**

The assortment of RatioPlant product lines RatioPlant, offers a wide range of clinical solutions, as well as reconstructions of individual teeth, screwed or firmly cemented bridges and partial or full dentures. In addition, RatioPlant implants are used in all surgical and bone augmentation procedures. They are made of biocompatible quality titanium and based on their blasted and etched surface on highest level of science.

All HumanTech RatioPlant dental implants and instruments fulfil the highest international standards. We are certified according to DIN EN ISO 13485 / 46001 and Annex II of Directive 93/42 EEC.
**RatioPlant® Classic**
The implants of the HumanTech Classic Line are classic titanium screw-cylinder implants with self-cutting conical threat at the tip.

**RatioPlant® Avantgarde**
The implants of the HumanTech Avantgarde Line are root-analog titanium screw implants, self-cutting with a conical threat at the tip.

**RatioPlant® Single**
The single-piece implant of HumanTech is a titanium screw implant, with self-cutting conical threat at the tip.