HEIDENHAIN

Issue 02

Klartext Medical

HEIDENHAIN Controls in the Medical Technology Sector

dynamic + precision

EFFECTIVELY COMPENSATING FOR THREATS TO PRODUCTION

PROCESS RELIABILITY FOR MEDICAL PRODUCTS

Dynamic Precision — efficient production of precise components

Klartext

***Medical* Issue 02**

Editorial

Dear Klartext Reader,

Perfect surfaces, extremely high levels of precision and high-efficiency production are absolute requirements for medical technology products, the quality of which significantly affects the health and quality of life of patients. HEIDENHAIN controls of the latest generation have been designed to ideally fulfill such demands.

With the machining of medical technology workpieces, controls surpass the limits of seemingly contradictory needs, and maximum processing speed no longer needs to be bought with a compromise in accuracy or surface quality, or vice verse. The **Dynamic Precision** range of functions effectively solves this problem, and improves the performance capability of modern machine tools.

This edition of Klartext offers an overview of the most important **Dynamic Precision** functions, outlining their benefits for the medical technology sector. In two reports, users make the most of the high potential of HEIDENHAIN controls for the production of implants and medical tools, and also face the challenge of manufacturing unique pieces in serial production.

Read and enjoy, with best wishes from the Klartext staff!

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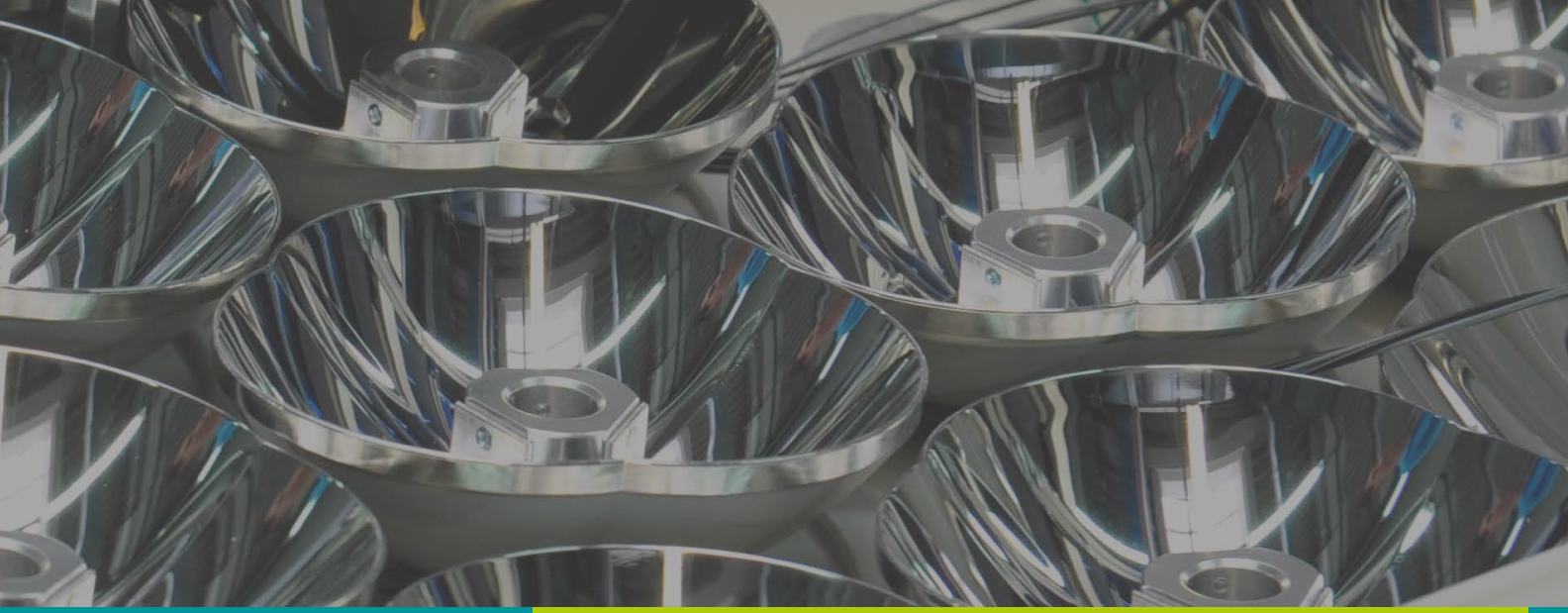

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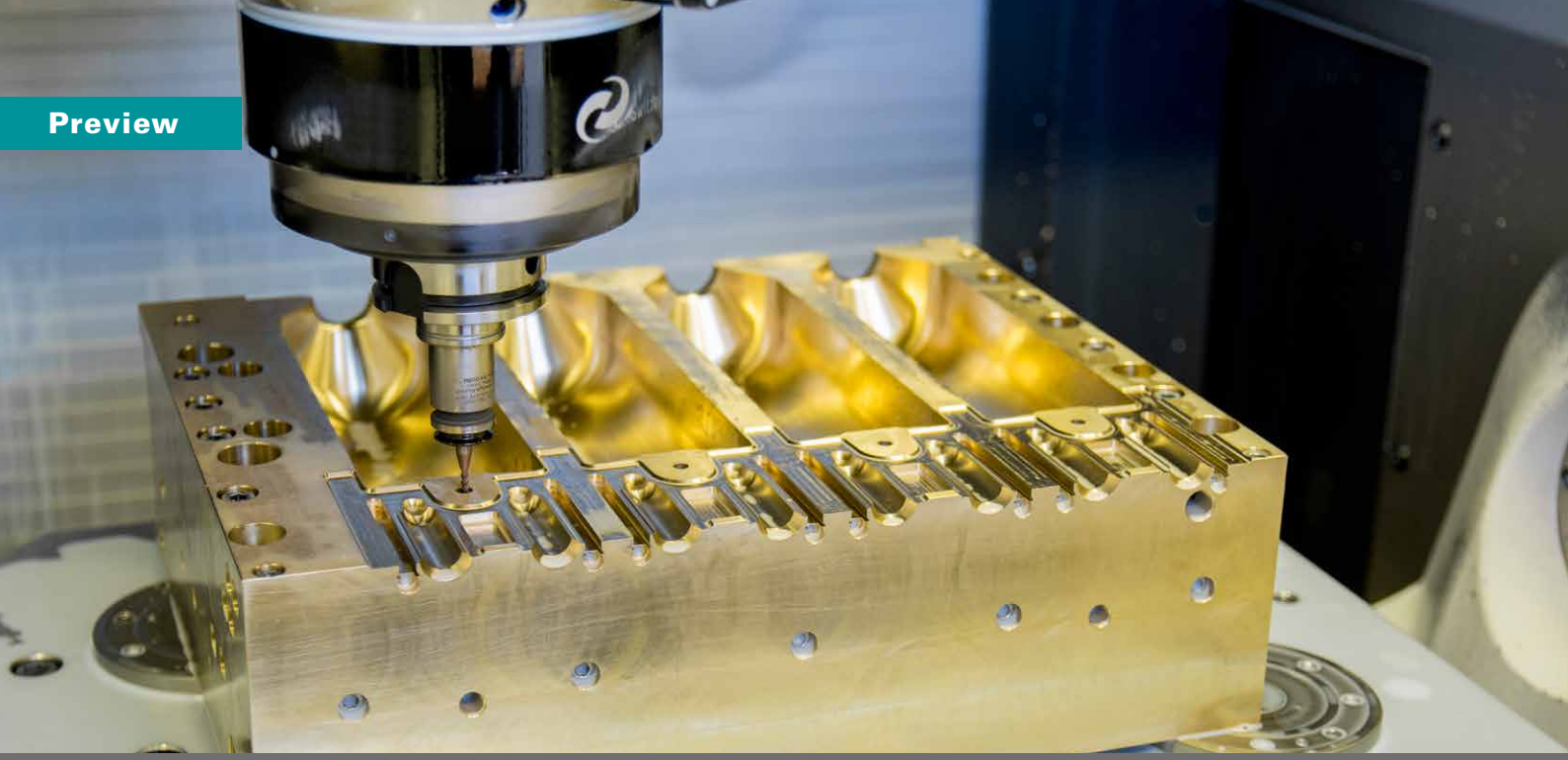


Medical Technology—Just Machining?

Special demands for a sophisticated market

The question of health is central with all products in the medical technology sector, and these therefore also affect the preservation or recovery of the quality and joy of life. It's no wonder then that patients, doctors and therapists demand maximum standards for such products. This in turn has fundamental consequences for the manufacturers of medical technology products, in particular during production machining. Such companies are active in a highly specific production sector, where simple cutting tasks are rapidly transformed into highly complex production processes.

The machining of medical products is characterized by fluctuating batch volumes and an almost unlimited diversity of variants. The serial production of unique parts has gained in importance in the dental sector, whereby the inherent level of diversity with medical instruments has led to small batch runs. Hip and knee joints on the other hand are produced as part of cost-efficient, process-oriented serial manufacturing. Such production methods go hand-in-hand with high demands in terms of surface quality, contour precision and dimensional accuracy.

International regulations must also be complied with, straining production processes with non-value-creating tasks such as extensive documentation obligations, wide-ranging validation requirements and detailed regulations concerning processes. These regulations make their own implementation a factor playing a role in competitive capability, in addition to quality and productivity. The aim of the medical technology sector is therefore to effectively implement regulations within the production process, but without sacrifices in terms of productivity. As a result, the medical technology industry specifies production equipment used by suppliers that complies with these demands.

TNC controls provide highly practical solutions for precise and economic machining, ranging from unique parts to volume production. Perfect contours and faces without the need for reworking, for example, are an elemental precondition for high levels of economy with single-part production. TNC controls achieve efficiency in volume production with the precise, reproducible production of all workpieces.

And for this purpose they have a variety functions and options, that from simulation to running production all have a single aim—to control the production process directly on the control while considering real machine kinematics and compensating for negative influences. Dynamic and thermal errors are thus reduced, as are errors caused by tool mold deviations, being automatically compensated for in the process and documented.

As such, TNC controls comply with the demands of production as well as international regulations for constant product quality, under consideration and documentation of all known factors of influence on workpiece accuracy. Operators of TNC controls have the spectrum of production-relevant parameters for medical technology products under control at all times, enabling machining of highest quality!

Premium cutting quality—with the TNC 640 high-end control.

Keeping a Tight Grip on Complex Processes

Customized TNC functions for medical technology

HEIDENHAIN TNC controls provide many advantages for the demanding medical technology production sector. Their functions bring together high-precision machining and the complex compliance with standards and regulations, within the framework of an efficient production process. A consistently high surface quality, the reliable compliance with tight tolerances, high machining speeds and the documentation and validation of complex processes during production runs all play a part in this.

dynamic + precision

High precision, short cutting times and optimum faces on a bridge.

Dynamic Precision: Rapid, productive and economical

In the field of qualitative, precision-oriented medical technology, dynamic errors frequently limit factors of productivity, economic viability and efficiency. They prevent an improvement of machine dynamics to achieve more rapid processing, or else leave behind visible surface errors and tangible deviations in workpiece geometry. Dynamic errors generally increase when the speed of NC program execution increases, and accelerating the machining process undermines the level of accuracy and surface quality.

Dynamic Precision functions aim at the time-efficient production of precise workpieces with high surface quality, and also effectively reduce dynamic errors. The functions thus enable greater accuracy at the same speeds, or higher speeds with identical precision, and in many cases both factors can be increased. High precision with rapid machining also means improvements in productivity, and unit costs are reduced without compromises to contour accuracy and surface quality. **Dynamic Precision** achieves greater levels of economy in the single-part and small batch sector in particular, and is therefore especially interesting for the medical technology industry.

With its **CTC** function (Cross Talk Compensation), HEIDENHAIN provides a control option for compensating these acceleration-induced position errors at the tool center point (TCP). Thanks to CTC, it was possible to reduce mean error by up to 80% as measured by a grid encoder. This enables jerk to be increased and processing time to be significantly shortened.

The **AVD** function (Active Vibration Damping) suppresses dominant low frequency oscillations (installation oscillations or elasticity in the drive train) to enable rapid and vibration-free milling. This reduces machining times without impairing the surface quality of the workpiece.

The **PAC** (Position Adaptive Control), **LAC** (Load Adaptive Control) and **MAC** (Motion Adaptive Control) options enable machine parameters to be modified depending on the axis positions (PAC), the momentary weight with linear axes or mass inertia with rotary axes, and the momentary frictional forces (LAC) and input quantities such as speed, servo lag and drive acceleration (MAC).

Dynamic Precision functions can be used singly or in combination. They effectively reduce dynamic errors with machine tools, improve dynamic machine behavior and achieve higher levels of rigidity on the TCP, thus enabling milling to the limits of what is technologically possible, regardless of the age of the machine, its load and machining position.

KinematicsOpt: The perfect calibration of machine kinematics

Machine components are subjected to relatively significant fluctuations in temperature with single parts and small batch runs. This means that if the real machine was modified during machining due to thermal influences, then the kinematic transformation chain would need to be adapted accordingly. HEIDENHAIN controls provide operators with support for this complex task with its KinematicsOpt software option. The function not only recalibrates, but also saves all data with modifications to the kinematic configuration, meaning that not only previous configurations can be simply restored later, but documentation obligations in the medical technology field are also simply implemented.

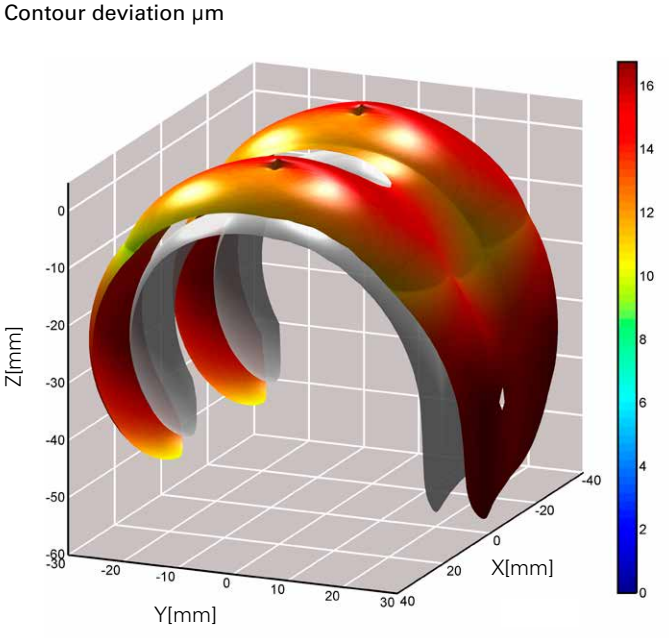
KinematicsOpt combines special probing cycles, enabling these to be completely integrated into TNC controls and called as specific options. The principle is simple enough—the position of a precise calibration sphere is measured at various rotary axis settings with a triggering 3-D touch probe, the TS 740 for example. The operator then receives a log stating actual accuracy during tilt at the current point in time. If desired, KinematicsOpt also automatically optimizes the measured axes simultaneously, and requisite modifications to the machine data are also automatically implemented. Operators need no detailed knowledge about the kinematic configuration of the machine and can recalibrate their milling machines in just a few minutes.

If the calibration sphere is permanently mounted on the machine table, then this procedure can even be performed as an automated step between the individual machining processes. This makes it possible to achieve a consistently high level of quality, both in series and single-part production, and testing and validation processes that are obligatory for medical technology can be carried out with significantly shorter interruptions to production processes, and with less effort.

3D-ToolComp: Machining with real cutter radii

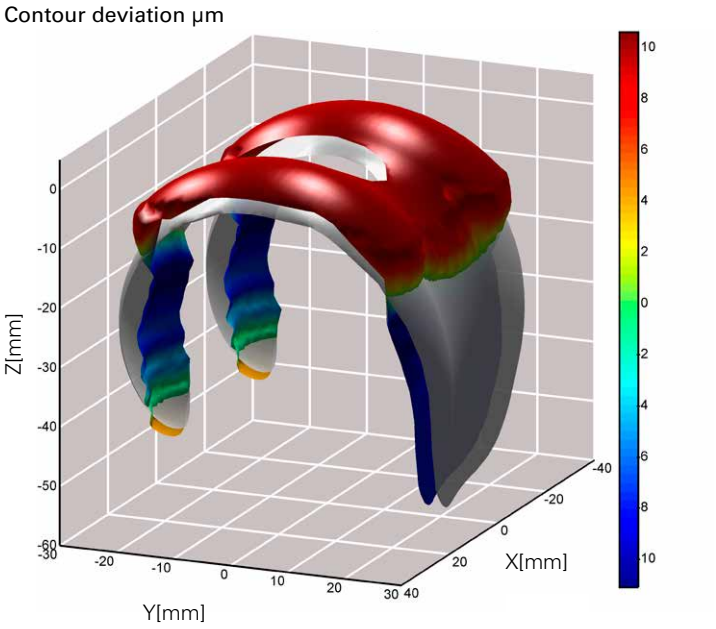
Despite high levels of precision in tool manufacturing, spherical cutters in particular have no uniform geometry, and the radius of each tool usually deviates individually from the ideal circular interpolation. This is a serious deficiency for high-precision machining, as the contact point between the cutter radius and the workpiece calculated by the control does not correlate with the actual radius—this being the case with each newly loaded cutter.

3D-ToolComp is a powerful option for three-dimensional tool radius compensation. A compensation-value table is used to define angle-dependent delta values that describe the tool deviation from the ideal circular form. The TNC then corrects the radius value defined for the tool's current point of contact with the workpiece. In order to precisely determine the point of contact, the NC program must be created by the CAM system with surface-normal

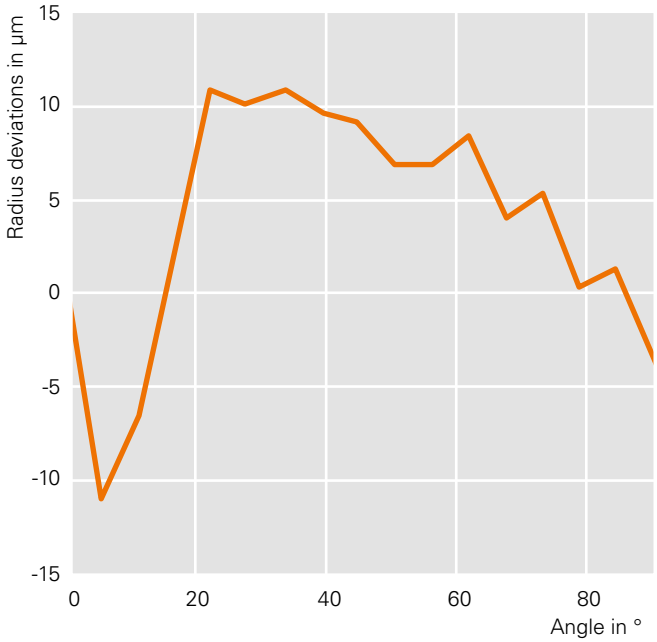


Impact of rotary axes: Position error of the A axis in + y (Y0A 0.017; Z0A 0.0044; X0C -0.005; Y0C 0.003), form deviations magnified by a factor of 500

The KinematicsOpt TNC function measures rotary and swivel axes simply and quickly with the help of a calibration sphere. The kinematics table compensates for possible deviations, and with a protocol if specified by the customer.



Tool form deviation impacts the level of contour precision at various contact angles (form deviations magnified x 500).



Radius deviations on a ball cutter.

blocks (LN blocks). These surface-normal blocks specify the theoretical center point of the radius cutter, and also tool orientation relative to the workpiece surface.

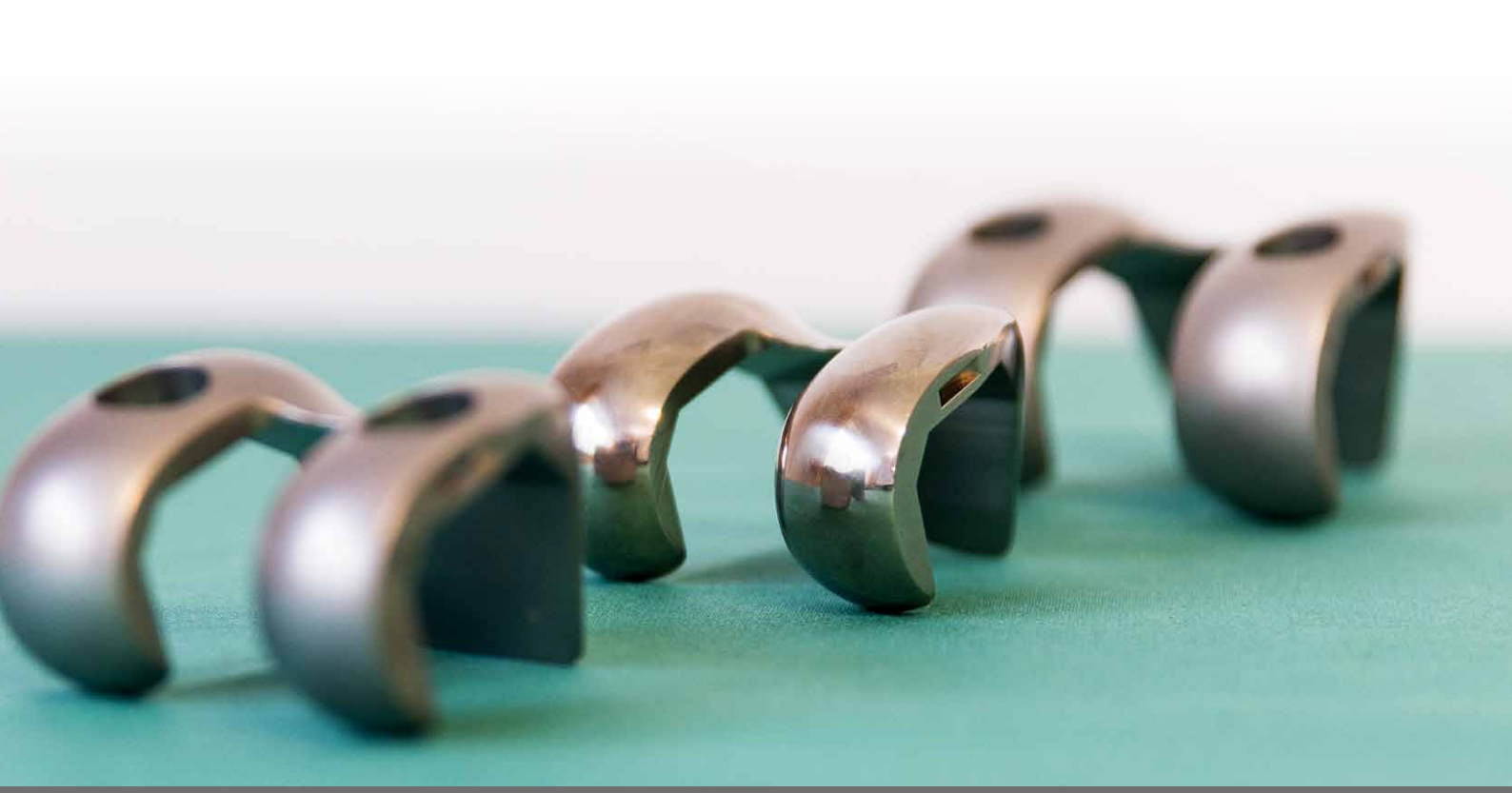
Compensation is implemented automatically by the TNC-controlled machine tool. The tool form is measured for this purpose with a laser system and a specific cycle, to enable the TNC control to directly utilize this data and also list it in a compensation table, meaning that machine operators do not need to perform tool compensation again in the NC program. The TNC control handles the variable influences automatically via tool form deviations, and thus fulfills an important factor for reliable machining processes in accordance with currently valid medical technology specifications.

Grid encoders

Grid encoders such as the HEIDENHAIN KGM 282 are suitable for dynamically testing the path behavior of CNC-controlled machine tools. With grid encoders, circular interpolation tests can be run out for example with radii from 115 mm down to 1 µm, and at tool feed rates to 80 m/min. Contact-free scanning also permits free-form tests over any contours in two axes.

In this way, the grid encoder captures any movements in a plane, and outputs measured values for both axes separately. The benefits on the one hand are contact-free measuring, i.e. without frictional impact, and on the other, errors resulting from the machine's geometry have no influence on the results of circular interpolation tests with very small radii.

Functions



A New Start in Medical Technology

The cost-efficient production of single parts and small batches

For a young company, successfully starting up in the medical technology branch with the production of implants and surgical tools is challenging, but also fascinating. LEX Feinmechanik GmbH is proof that this is possible, and places its trust in machining centers from GF Machining Solutions and the HEIDENHAIN iTNC 530 control.

In an interview, junior director Martin Lex explains how his grandfather's former workshop now functions as a hub of innovation for dental technology. An idea for a tool here came about 30 years ago that enabled the practical implementation of a dental impression in silicone, and many years later, life was again injected into this historical work location—initial products for medical technology were created step-by-step. It rapidly became clear that an up-to-date machine park and CAD/CAM systems were needed, and with suitable light engineering expertise and contacts in the sector, the father and son team founded their new company LEX Feinmechanik GmbH in 2006, adding a new production hall in 2007.

A successful restart with the right machine

The start was made with the purchase of a Mikron UCP 600 Vario from GF Machining Solutions, along with an iTNC 530. Martin Lex: "The machine proved reliable from the very beginning—it fits right in with our spectrum of components." With 5-axis simultaneous machining, the machine produces knee prostheses, bone plates, surgical instruments and much more. Customers supply drawings and data, that are then transformed into executable machining programs with the Hypermill CAD/CAM system. The transition from the CAD/CAM system to the HEIDENHAIN control works perfectly: Program generation utilizes HEIDENHAIN cycles, e.g. for boring, drilling and tapping which facilitates subsequent cutting data optimization, and with smaller modifications also avoids looping back over the CAD/CAM system.

Martin Lex places value on consistency with the machine and control.

Rapid task implementation with the TNC

"With the iTNC we really appreciate the ability to clearly structure the programs, which makes orientation in long machining programs simpler," stated Martin Lex. None of the LEX operators wants to do without the simulation of machining programs directly on the control. Only in realistic conditions are tool-related problems, such as deviations in circular transitions, detected in good time prior to the machining process. The HEIDENHAIN control also gets the thumbs up for its simple probing cycles that facilitate setup work.

Typical machining materials are titanium alloys and stainless steel, but also plastics. The surface quality and homogeneity of the surfaces are subject to high quality stipulations, and milling the free formed surfaces should be visually perfect—particularly important for operating theaters. The target of high production efficiency prohibits mechanical reworking, and exploiting the potential of the iTNC 530 and Mikron machines to the full is vital. If required, further processing with glass bead blasting and passivating can be then be performed.

Efficient, flexible production with simple automation

Small runs of 10 to 100 units and many single parts and prototypes are not the ideal preconditions for cost efficient production, and special effort is needed to make production processes flexible and efficient at the same time. In ideal cases, the first machining run should produce acceptable parts. Driven by increased demand, LEX Feinmechanik made the decision to purchase a second machining center from GF Machining Solutions: A Mikron HPM 450U with integral pallet changer. This adds a practical automation solution to the already high levels of precision and dynamics, intended to simplify the production of highly diverse parts with good utilization factors, and with unmanned night shifts in the future.

"The components also run distinctly longer," said Lex. The iTNC 530 has proved its worth as an especially reliable control system, functioning perfectly with the Mikron machining center automation. The pallet changer system is programmed solely with the HEIDENHAIN iTNC 530, with Mikron using the reliable conversational text functions for pallet management, allowing rapid familiarization for machine operators. The control ensures that the corresponding presets and zero shifts are activated for each pallet.

An added safety feature for automated production is the Mikron-specific Cycle 307 for example. The calibration cycle compensates for temperature-related deviations in the rotary swivel axis, and precisely determines the pivot point in the C axis.

Mastering challenges through closeness to customers and integrated technology

As a small-sized company, LEX Feinmechanik has enough flexibility to give its customers direct support, and as a consequence, many medical components produced feature specific characteristics. Optimizations frequently mean that a large number of prototypes are necessary, and also require much time. A direct contact to clients shortens both routes and time periods, so that in some cases LEX Feinmechanik is able to back up product design with its own manufacturing expertise. "We often achieve the quality demanded in very short time periods," stated the Managing Director.

LEX Feinmechanik has certainly achieved a successful start in the medical technology field. In addition to technical challenges, certifications were also required such as the ISO 9001 initially, followed by the ISO 13485, which meant relatively high effort for a small company. The courage of a new start has been rewarded by increasing interest from the medical technology sector, and has also led to the purchase of a new, high-performance machining center from GF Machining Solutions.

LEX Feinmechanik GmbH

LEX Feinmechanik GmbH is a family-owned company situated near Lake Chiemsee in the foothills of the Bavarian Alps between Munich and Salzburg. The production spectrum consists of implants, surgical instruments as well as components and devices for human medicine.

+ www.lex-feinmechanik.de

GF Machining Solutions GmbH

+ www.gfms.com/de

Implants and surgical instruments demand extraordinary quality levels.

TNC Sets Standards with Medical Products

Leitner AG provides the high quality demanded by its customers

A quick look around the workshop confirms that this subcontractor is a medical technology specialist: White floors, ultra-clean workstations and measuring devices positioned tidily on the workbenches. Daniel Müller, owner and Managing Director of Leitner AG in Busswil, Switzerland, places much importance on highly motivated employees, providing them with ideal working conditions. Leitner cost-efficiently produces medical products with maximum quality using nine Mikron high-speed machining centers from GF Machining Solutions, equipped with HEIDENHAIN iTNC 530 controls.

Several obstacles must be overcome for medical technology suppliers. "Regulatory directives in the medical technology sector are very stringent," explained Daniel Müller, Managing Director of Leitner AG. His customers are globally renowned manufacturers of surgical instruments and implants that demand maximum quality, and this means on the one hand that Leitner must supply perfect components, and on the other, the company needs to cope with the wide range of administrative tasks, as all processes must be documented and also be traceable.

The subcontractor Leitner produces prototypes and small series from 5 to 50 pieces. Projects often run over a period of one or two years because instruments are repeatedly tested by doctors and subsequently optimized. Sometimes though, rapid production is needed if an order comes in at short notice. "We have to be highly flexible," explained Müller, "and we have to consistently find intelligent solutions so that we can be not only quick but really accurate as well."

Precision via interaction between machine and control

Daniel Müller depends on the high precision levels provided by the combination of Mikron machine and HEIDENHAIN control. A factor contributing to this is the outstanding rigidity of the GF Machining Solutions machining centers, with the TNC control ensuring high-precision contours via highly accurate motion control. Leitner has a firm grip on temperature deviations—the already highly temperature-stable GF machines are housed in an air-conditioned hall. Leitner uses the KinematicsOpt function of the TNC control to simply and quickly measure the rotary and swivel axes with a calibration sphere. The kinematics table compensates for possible deviations, and with a protocol if specified by the customer. In this way, levels of precision can be maintained constantly over long machining periods, as occurring when milling titanium bone plates, a continuous 6-day process. The dimensional change in this case was merely 5 µm.

Machine tool control is the precondition for achieving good quality for Leitner AG, along with specific knowledge and several years of experience. "Put simply, we depend on our modern equipment," confirmed Production Manager Michael Andres. In his opinion, the inherently high dynamics of the high-speed machining centers function ideally with the HEIDENHAIN controls, exploiting this potential to the full.

The technicians develop special fixtures so that workpieces hardly need to be reclamped—a wrist plate for example is

Titanium implants for spinal column applications. Leitner AG achieves perfect surfaces with the iTNC 530 and saves on complex reworking.

Committed technicians: These Leitner AG employees have responsibility for the complete production process, from NC programs to the finished workpiece.

precisely milled in two setups, and only brushing and cleaning are needed afterwards. The quality is simply good. "I have to say the precision we get is simply fantastic," said an enthusiastic Daniel Müller.

"Machine operators are like peak athletes"

Leitner AG places great value on intelligent planning and work preparation. "Even the best planning system can't replace experienced technicians on the machines though," emphasized the Managing Director. He sees his highly qualified employees as peak athletes, and he has to offer them the very best training and competition conditions. He simply gives them the very best controls and machines, and only in this way is it possible to achieve maximum performance in his opinion.

The technicians are keen to work with the HEIDENHAIN controls. "Everything's been intelligently designed," said Michael Andres, "and you know where the functions are straight away." Even though most NC programs are created on the CAM system, Leitner optimizes directly on the control—technicians modify traverse paths, control feed rates and set Q parameters. They also program simple parts directly on the TNC, even when oblique faces are machined, the contours being programmed as if they were flat. The machining plane is simply tilted into the desired position with the PLANE function.

Exploiting potential to become faster

Daniel Müller continuously updates his knowledge and skills. He completed a medical technology study program when he was 45 in order to optimally envisage the tasks of customers, and he's able to identify any possibility to improve efficiency. Leitner is able to improve its machine utilization factor thanks to the integrated pallet changer on the Mikron machining centers from GF Machining Solutions. Production becomes more efficient because one user is able to operate two machines, there are fewer interruptions, and unmanned shifts are made possible due to automatic insertion of the workpieces. Müller praised the appealing price-performance ratio of this automation solution. "It's also worth our while to set up half-shifts as well."

Extensive tests are carried out in the well-equipped measuring room, and are also precisely documented according to customer requirements. Finished parts feature optimum dimensional accuracy as well as optically perfect surfaces. Daniel Müller is convinced that these good results are due to efficient interplay within the process chain, as well as the high level of employee commitment.

Daniel Müller, owner and Managing Director

Leitner AG – precision mechanics for medical technology

Leitner AG has extensive vertical production depth. Ranging from material procurement, cutting, laser welding, measuring and labeling to cleaning, assembly and packaging, Leitner offers its customers the complete value creation chain. With 35 employees and five apprentices, the subcontractor produces instruments and implants for medical technology such as drilling jigs for wrist plates, wrapping arms for hip sockets, bone plates, instruments for dental implants and much more. A wide diversity of materials are used, including stainless steels, titanium alloys, plastics and carbon fiber materials.

+ www.leitner-ag.ch

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Milling more precisely and at the same time more quickly may seem a contradiction. With its **Dynamic Precision** range of features, a TNC control solves this paradox in a very smart way and helps you to more effectively exploit the accuracy potential of your machine tool. The workpieces become more dimensionally accurate, even with very small tolerances and widely differing shapes. And they do so without any compromises in machining speed. Quite the contrary: machine tools with a TNC and **Dynamic Precision** are often even faster than without.

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angle encoders + linear encoders + contouring controls + position displays + length gauges + rotary encoders

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