Bones Made Of Titanium

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Substantial legal requirements result in more complex functional specifications for the implant manufacturers: From the design - including the materials — through production, the complete process chain must be documented and validated. CNC-controlled high-tech machines support the prosthetics manufacturers, and permit high-quality products to be manufactured despite the continuing pressures of high cost.

The idea for a new medical implant normally arises to meet a practical need. It is a long process before the implant can be produced in quantity — it takes approximately 12 to 18 months from the first drawing, including the design and job planning, through the completed, approved implant.

“After receiving a request for a new product from an orthopedist, we first design and develop a prototype”, explains Hans-Joachim Mahr, production manager at implantcast Corp. in Buxtehude, Germany. “The CNC controller assumes an important function for the transfer of the CAD/CAM data to the actual production. It supports the idea and the virtual model in a workpiece that the orthopedist can then hold in his hands for the first time.”

Artificial bones made of titanium are mainly manufactured using the stock-removal process. The production of hip implants runs on DMG turning-milling centers equipped with the Siemens CNC Sinumerik 840D sl **(Figure 1)**.

Each implant has an associated, specially-tailored set of instruments required for the implantation. This includes a surgical rasp used to prepare the bone **(Figure 2)**.

The fast data processing of the 840D sl is a particular advantage for the standard implants produced in quantity. implantcast also offers, for particularly complicated applications such as cancer patients, the manufacturing of patient-specific implants. In this case, the implants and instruments are cut perfectly to the associated bone structure with the help of a CT or MRI picture. For this single-part production, implantcast uses the comprehensive setup functions of the Sinumerik for fast machine setup.

The CNC user interface has, on all levels, self-explanatory icons that can be configured as popular keys. Many intelligent functions are available to assist the measuring of tools and workpieces. These measuring functions can be used both for the setup and process measurement, that is, the overall quality assurance during the machining. The ‘Sinumerik Operate’ user interface also integrates simple swivel commands that simplify the machine setup. The Cycle 800 swivel cycle is characterized by its easy handling, despite its high-level functionality. The swivel functions are available both for the swiveling in a machine axis and also in an axis of the workpiece coordinate system. The CNC immediately handles any required

coordinate transformation.

Irrespective of the one-off or quantity run, the highest demands are placed on each individual medical engineering workpiece. It is obvious that no letdown may be permitted from rigorous quality and precision standards. Furthermore, the manufacturer is responsible for validating the complete production process, which means that even prototype construction must satisfy the same conditions as the subsequent volume runs.

Artificial Hip Sockets in Twelve Standard Sizes

The number of artificial bone implants is continually increasing. Operations, such as the use of a replacement hip made of titanium, also belong to the standard daily program in orthopedic surgery today. In 2010, one million artificial hip and knee joints were implanted in the USA. Forecasts expect this number to exceed 4 million by 2030. This large number, however, does not obviate the fact that the highest demands are placed on each individual medical implant, whether a one-off or production run.

Standard implants are now available in various sizes as required for the physique of the patient. The NC programming that defines the functions for machining the workpiece, and consequently includes all associated details concerning the form and technology, is very fast. “Thanks to the user-friendly ‘Sinumerik Operate’, we save a significant amount of time,” explained Axel Robiller, manager of the stock removal department at implantcast. “One reason is that the human-machine interface (HMI) has the familiar Windows style.” The Sinumerik 840D sl provides a comprehensive range of powerful turning and milling cycles. Because all operator functions and cycles are supported with animated elements, the operator intuitively knows how the function is to be used without needing to consult the instruction manual. Dynamic vector graphics can be used when the animated elements do not suffice to explain the purpose of the individual input values, such as the parameterization of complex cycles. These graphics reflect the current input values with their proportional representation.

Work Economically & Efficiently Despite the Complexity

At EMO 2011 in Hanover, Germany, Siemens will present dual-channel production of bone rasps on machines with two slides. This allows turning-milling centers, such as the DMG CTX alpha 450TC to be operated more effectively, because the complete programming functionality is available in both channels. The ‘Programsync’ function synchronizes the machining channels, whether or not the programs have been programmed in DIN/ISO, standard cycles, or ShopTurn — the proprietary Siemens software.

The increasing complexity of the turning-milling machines and the possible production programs also increase the risk of programming errors that, under some circumstances, can cause machine damage. For this purpose, the Sinumerik 840D sl offers a simulation program that shows the stock removal process in virtual 3D. In addition to the complete representation of the cutting actions, the expected

machining time corresponding to the programmed technology values is displayed before the production of a single workpiece.

A short machining time, however, is critical for the economy of quantity production. The turning-milling center with the Siemens 840D sl used at implantcast, with cross slides for Y and B axes, permits five-axis simultaneous machining **(Figure 3)**, and significantly reduces the processing time. The implants are manufactured in a single operation, with parallel machining on the main and counter spindles. For the complete machining, the Sinumerik 840D sl provides turning-milling functions that can be used in combination. The complete scope of all milling functions is available here — from the cycle technology to the simultaneous free surface machining.

Simple Parts Do Not Exist

Bone rasps are an example of very complex workpieces. Their basic form represents a significant challenge in machining, namely, a rasp body with many rasp teeth located on the contoured outer surfaces. The Sinumerik MDynamics technology package ensures the required surface quality at high machining speed. Even for difficult materials, the “Advanced Surface” motion control produces milling results that meet the stringent requirements placed on medical implants and instruments.

Each individual part is subjected to a comprehensive quality control. Sensing probes check the accuracy of the contour and the peak-to-valley height and scan the surface for even the smallest damage. To check the material structure, X-ray examinations are also made on some parts. Only when all these hurdles have been overcome are the implants passed to the internal department at implantcast for sterile packaging and subsequent shipping.

A Patient Stands at the End of Each Process Chain

A patient with bone prosthetics receives a prosthesis pass. This document allows the complete manufacturing process of the prosthesis to be reconstructed at any time. Whereas in other industry sectors, such as automotive or food processing, products must have trackability. This tracking requirement in the orthopedic world is specific to each individual patient’s medical implant. This is a major challenge, considering implantcast produces approximately 3,000 items, each week.

Despite the extensive use of highly sophisticated technology, at the end of the process chain there is a suffering patient who must be helped. The difference between the manufacturer of turned, milled, and ground parts used in the medical technology, and one that produces parts for machinery construction, makes itself apparent.

“The patient whose prosthesis is in the package would need to wait one day longer for his/her operation if we did not act immediately”, explains Mahr. For such very late requests, and these are not infrequent, it is quite possible that he will personally start the prosthesis on its journey to a patient in need.

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