WORKPIECE

Bone Screw

In surgery, bone fractures are often stabilized directly with bone screws. They connect bones and bone fragments in all parts of the body. In this way, what belongs together grows back together. These medical products are manufactured from special, biocompatible materials in sophisticated production processes. Process and material are subject to the highest requirements.

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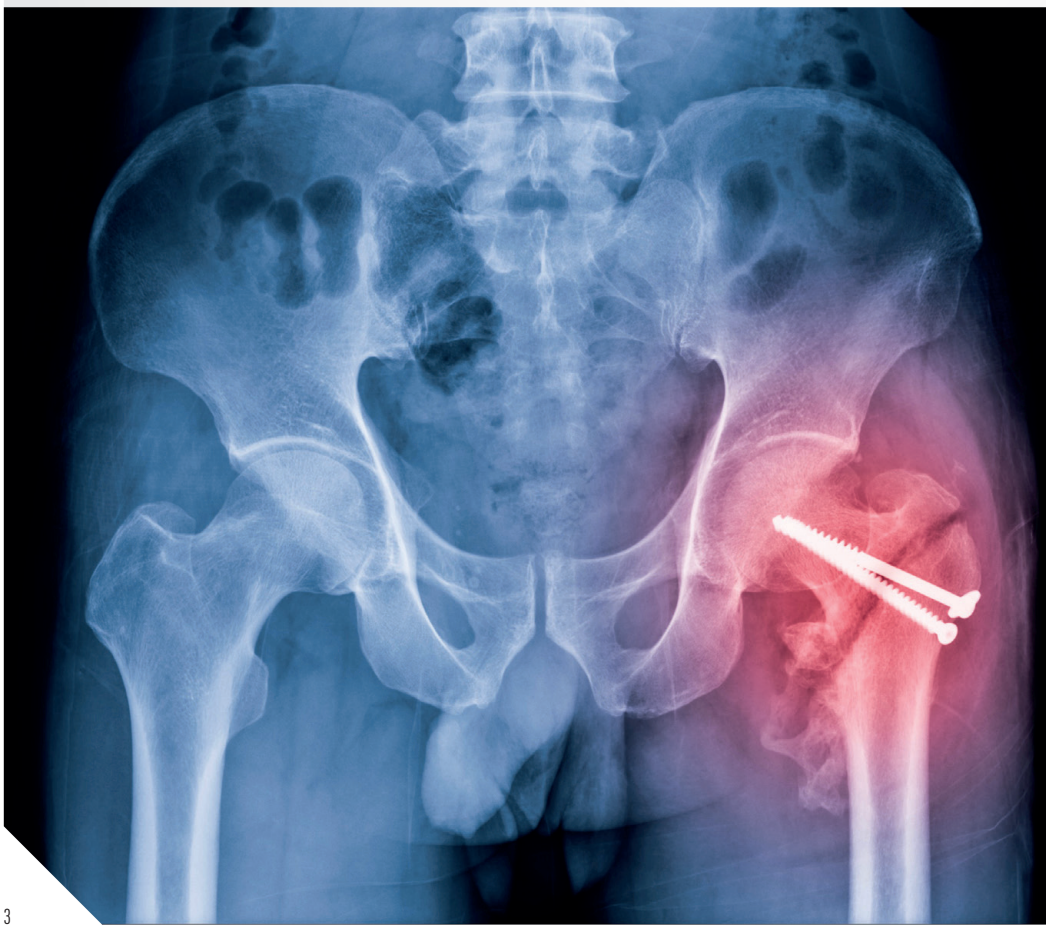
Bones are among the most resistant components in the human body and are extremely resilient despite their low weight. However, if literally "supernatural", i.e. too great, forces act on the body, fractures can occur. They are usually located in the area of the arms and legs or the hands and feet. In the worst case, however, the spine or even the bones of the skull can be affected. A fracture is understood to be a complete or incomplete interruption of the bone tissue. Two or more fragments are formed and the stabilizing function is lost.

Fractures can be classified according to the course of the fracture line, the number of bone fragments and many other criteria like the AO classification. If fractures are not treated properly, bony overgrowth of the fracture gap may occur and pseudarthrosis (a so-called false joint) may develop as a late indication.



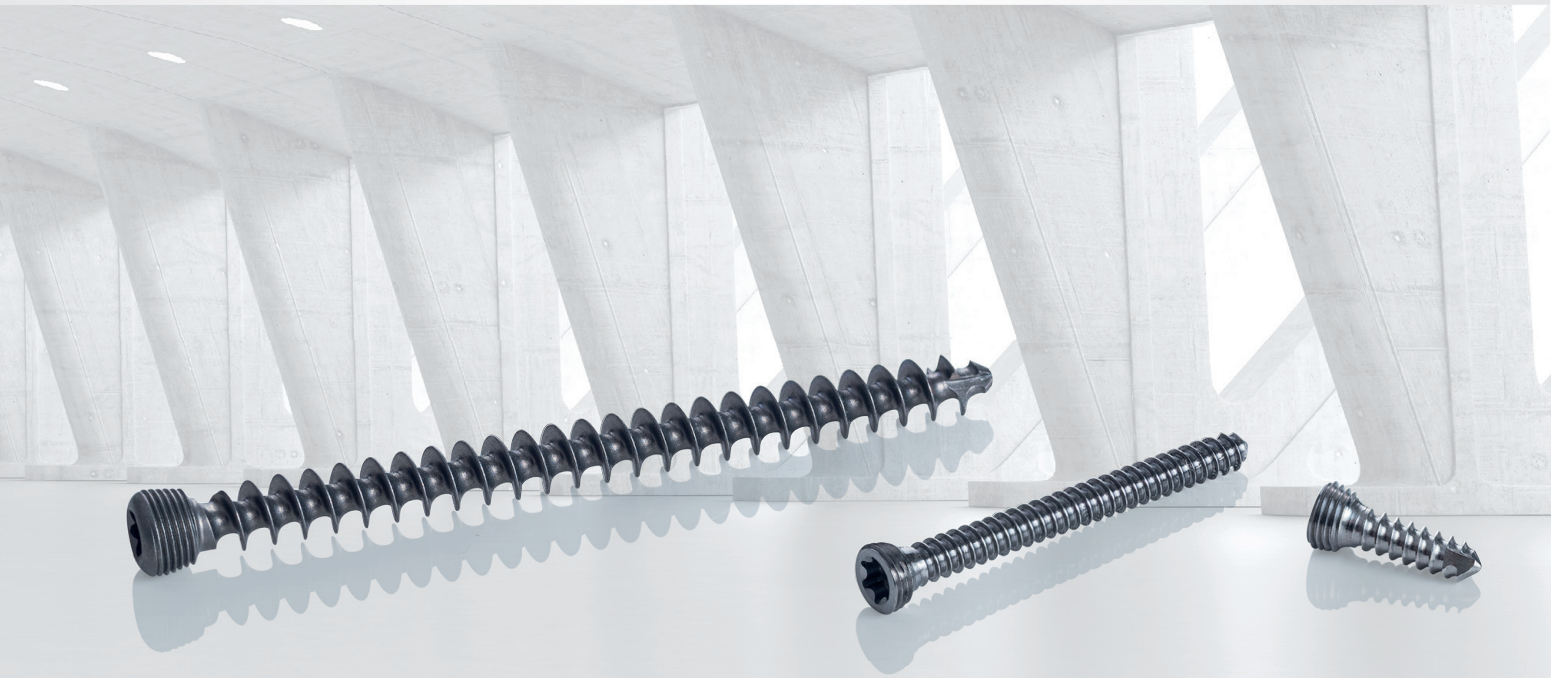
Bone screws become necessary when a fracture would not heal properly without additional fixation. These medical devices can be used in various anatomical regions of the body. However, bone screws are frequently used for fractures close to the joints – such as the hip.

(Picture: ChooChin – shutterstock.com)

In many cases, it is sufficient to fix a fracture with the help of a traditional plaster splint and to pave the way for self-healing. If this is not sufficient, a surgical intervention becomes necessary. During the operation, so-called bone screws are often used to stabilize the fracture.

There are no limits to the variety. Bone screws are available in any size and shape and made of different materials. This sounds like simple standard parts: However, due to the regulations and quality requirements in medical technology, their production is very demanding.

DMG MORI has been developing and implementing innovative CNC technologies for customers in the medical technology sector for many decades. These solutions are created through the existing expertise at the DMG MORI Medical Excellence Center in cooperation with customers and suppliers. The team of experts designs application-oriented manufacturing solutions with which bone screws can also be produced efficiently.



Bone screws are the most commonly used fixation aid and can be used independently or in conjunction with other aids. (Picture: DMG MORI)

SCREWS AND THEIR USAGE

When bone fractures do not heal properly without assistance, bones and bone fragments require stabilization to help them grow together. In this case, bone screws are used. They are used in numerous anatomical regions, but especially for fractures close to the joints, such as the hip.

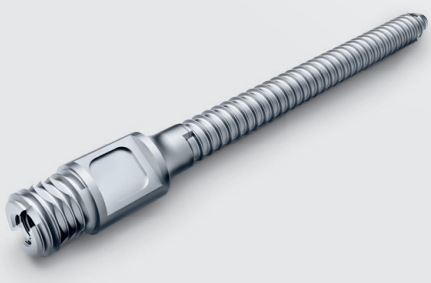
Bone screws are the most frequently used fixation aids in orthopedic surgery – either independently in the form of cannulated screws or in conjunction with other implants, for example plates or nails. These different applications lead to a wide variety in size, shape and materials.

The sizes of bone screws vary and always depend on the body region in which they are used. In the area of the skull, hand or foot, their diameter is between ø 1.5 and 2.3 mm. The length here is a few millimeters. In the upper and lower extremities, on the other hand, bone screws with a length of several centimeters are used. Their diameter then ranges from ø 2.7 to 4.5 mm. In the hip and pelvic region, the length of inserted bone screws is even up to 12 cm – with a diameter of ø 6.5 to 7.3 mm.

In addition to their dimensions, medical bone screws also differ in their shape. For example, there are locking screws with head thread and round-head screws without head thread, cannulated (cannulated) and non-cannulated screws, self-tapping and non-self-tapping as well as fully threaded and partially threaded screws.

Here, for example, a distinction can be made between cancellous bone screws and cortical screws. A **cancellous bone screw** is a surgical screw that has a high thread and a spiral tip compared to a **cortical screw**. They are usually self-tapping and have a slender core and high flanks. The corticalis screw has a lower thread compared to the cancellous screw. Corticalis screws are usually not self-tapping. They have a strong core and low flanks.

The thread form also depends on the issue into which the screw is to be inserted. In addition, there are special types of bone screws, including pedicle screws in the spine or sliding screws as part of femoral nail systems. In addition to the type, bone screws also differ in their «drive types». The most common are hexagon socket, cross recess, square and hexagonal.



There are fractures that do not heal properly without help. Thanks to bone screws, what belongs together grows together. (Picture: DMG MORI)

MATERIALS

For a long time, metal bone screws were the only option on the market. However, these require additional surgery for removal after the fracture has healed. Nowadys, numerous other materials exist, such as magnesium or plastics, which have the special property of resorbability. This means that the patient is spared an additional surgical removal with such a bone screw. Currently, a bone screw can consist of the following materials:

The most common materials for such screws are implant steel and titanium alloys. They are characterized by excellent stability and are generally biocompatible. Biocompatible refers to materials that, as a rule, do not have a negative effect on the human metabolism. Only a small proportion of the population may experience incompatibilities or allergic reactions.

Generally speaking, implants made of implant steel or titanium alloy must be removed in a second operation as soon as the fracture has healed completely. This is mandatory for children and adolescents, as they are still growing. In adult patients, they can remain in the body under certain circumstances, provided the implants do not cause any discomfort. However, the decision on this is individual and must be made between the patients concerned and the treating physician.

Further advanced metallic materials for implants are magnesium and magnesium alloys. Their greatest advantage is that they are continuously resorbed, i.e. absorbed, by the human body and ultimately degraded while the fracture is allowed to heal completely. Subsequent surgery to remove the material is therefore unnecessary.

It should be noted here that magnesium is flammable and almost impossible to extinguish once it has been ignited. For this reason, plants that process this material must be equipped with suitable safety precautions. These include, for example, argon extinguishing systems, regular cleaning of the plant and dust extraction systems. The operating personnel must also be specially protected with appropriate protective equipment. DMG MORI also offers this technical solution. The world's first production of magnesium screws was realized on DMG MORI lathes (SPRINT 20|8).

In addition to metals, there are other innovative materials such as plastics (polymers), which like magnesium can be absorbed by the human body, or biocompatible ceramic materials. Even screws made of bone material from donor bones are used. They identify the implant as the body's own and become its own bone tissue over time.

It should be noted that screws made of resorbable polymers are much less stable than metals. For this reason, they are not suitable for all applications and are preferred in cases where rather low loads are to be expected. The bioceramic screws exhibit the highest biocompatibility and are allergologically harmless. They consist of calcium phosphate and can be absorbed by the body. The calcium supports bone healing. Screws made of bone are considered grafts because the material used to manufacture them is obtained from human donor bones – primarily from the hard, middle part of the femur. The great advantage is the excellent biological compatibility and the ingrowth of the transplant into the patient's bone.

PRODUCTION

The majority of the requires bone screws are machined. Lathes with bar loaders are most common for this purpose. The bar stock is usually delivered in three meter long bars and loaded directly into the bar feeder. Bars for the production of knob screws require specific quality requirements in order to achieve good part quality later on. The lathe then independently loads the material into the machine starts machining. After OP10/OP20, the finished screws can be unloaded via a conveyor belt and made available for further machining.

Important points in the production are a burr-free manufacturing of the products as well as the guarantee of the so-called self-holding in the screw head. Special technologies are required for this. In addition, thread whirling plays a major role. For the SPRINT and MULTISPRINT series, DMG MORI therefore offers a patented unit for external thread whirling. Its direct drive has 8 Nm torque, 2 kW power and a speed range of 1,500 to 4,000 min^{-1}. The unit enables machining up to a di-ameter of ø 15 mm and with adjustable angle (+/- 15°).

Since the screws exist in a wide variety of lengths, parameterized programs are usually created. In their simplest form, they allow a quick change from one length to another. This simplifies program management, process validation and the effort required for changes. DMG MORI has appropriate know-how in this form of programming and has already successfully implemented various manufacturing solutions.

The machines are operated with oil or water-based emulsion when machining titanium and implant steel. Both coolants require approval before they can be used in medical manufacturing. This approval is usually obtained by means of a cytotoxic test.

After machining, the screws are subjected to various processing steps. These include, for example, sandblasting, fine vibratory grinding, anodizing (titanium) or electropolishing (implant test steel), laser marking (new with QR code) and final packaging. In some cases, the screws are sterilized and packaged immediately. Often, sterilization takes place shortly before the surgical procedure by means of steam sterilization. In many scenarios, bone screws are stored in trays in the hospital and cleaned and sterilized as required.

Bone screws made of non-metallic materials are shaped by other processes. Common processes are injection molding, pressing and extruding. This is followed by a sintering process. Machining usually does not follow – however, the same post-treatments as for machining are used.

Quality

In the field of medical technology, the highest quality is indispensable, so that companies in this sector must have a corresponding quality management system in accordance with DIN EN ISO 13845. The products must be manufactured and approved in accordance with certain regulations and specifications. Serial products are manufactured in validated processes and randomly checked before they come into contact with patients. If processes cannot be validated, they must be subjected to 100 percent testing. Every bone screw, for example, is subjected to a visual inspection. A wide variety of quality control procedures are available.

Regulatory requirements

Regulatory requirements in medical technology are becoming increasingly stringent, presenting manufacturing companies with major challenges. One of the requirements is DIN EN ISO13485. It includes the necessary guidelines for a comprehensive quality management system in the design and manufacture of medical devices. Added to this is the introduction of the new EU Medical Device Regulation.

Since May 2021, all players involved in medical devices, from the manufacturer to the end user, must comply with the new regulations. The regulation replaces the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). Requirements for the product, but also for the organization, are raised to a new level by these regulations.

Core contents of the Medical Device Regulation for manufacturing companies and manufacturers:

+ Certification by an inspection body
+ Designation of a responsible body
+ Introduction of the UDI system (Unique Device Identification)
+ Obligation to use the European database Eudamed
+ Obligation of manufacturers for post-market surveillance
+ Clinical evaluation for all medical devices

SPRINT 32 | 8 from DMG MORI – the perfect solution for all requirementsand the screw production of today and tomorrow.

(Picture: DMG MORI)

MEDICAL EXCELLENCE BY DMG MORI

As a full-liner in the field of medical technology, DMG MORI, together with the DMG MORI Medical Excellence Center, can look back on many successfully implemented projects. Thanks to its wide-ranging product portfolio and years of industry expertise, DMG MORI designs optimal manufacturing solutions for its medical technology customers. In specially established DMG MORI Medical Excellence Centers – the largest of which is located at DECKEL MAHO Seebach – the machine tool manufacturer's experts implement innovative turnkey solutions for both industry giants and smaller companies and suppliers, enabling quality oriented, fully automated and thus economical production.

The services offered by the DMG MORI Medical Excellence Center include the technological elaboration of the entire process as well as the consideration of all regulatory requirements up to the CE approval of such a system. This extends to support during validation, for example by providing templates. Through early involvement in customer projects already during development, DMG MORI engineers can incorporate their expertise into the design of machines and components in order to design ever more efficient manufacturing solutions.

DMG MORI is more than a machine supplier. Our success in the medical sector is based on our ability to recognize trends, our network, and our experience.

Horst Lindner
Head of DMG MORI
Medical Excellence Center