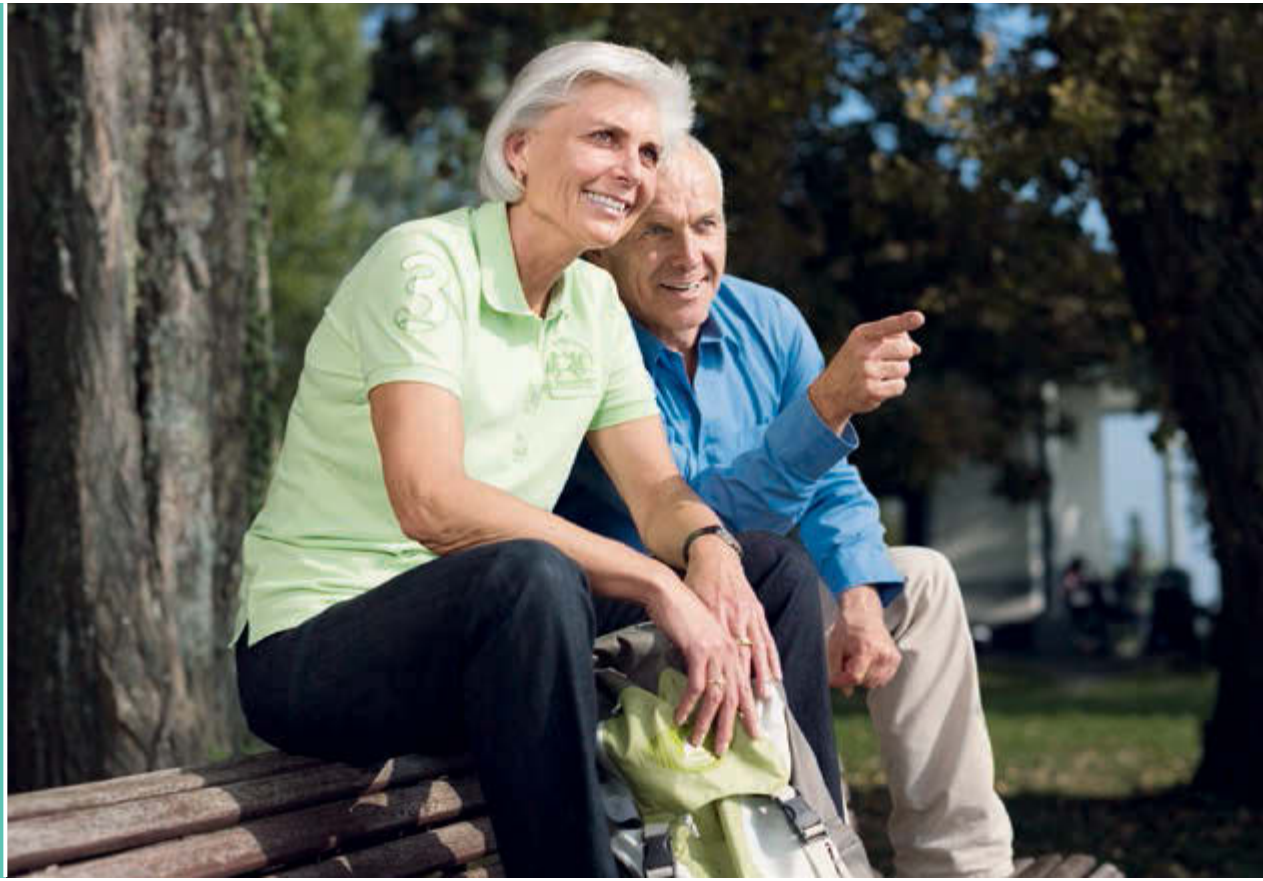
Aesculap Patient Information

Your new artificial knee joint



B BRAUN
SHARING EXPERTISE

Dear Patient,

The knee joint receives the most stress compared to other joints in the body. The natural structure of the knee joint enables a wide range of motion patterns. The knee joint function can be impaired by overloading, disease, and injury which lead to the surgical implantation of an artificial knee replacement to achieve the desirable quality life that was previously experienced.

The implantation of a knee endoprosthesis is one of the most common orthopaedic surgical procedures.

In the following pages, a summary was prepared of important information for every patient before and after knee surgery. This brochure is intended as supplement to medical advice and consultations with your physician, and help you find answers to questions about knee surgery.

The medical professionals at your hospital will advise and provide you with intensive care during the process, as well as do everything they can to support you during this relevant time and recovery process. Being well prepared, and having a support system will help enable you to maximize recovery and enjoy movement for an active lifestyle.

Contents of the brochure

I The knee joint

The knee joint, along with its' ligaments and muscles, is the largest joint in the human body. It allows us to stand, remain upright, and above all it allows us to walk. Our knees ensure our ability to move and provide us with stability.

1. Knee structure and knee mechanics

Knee structure

The knee joint is formed by the mobile connection between the tibia and the femur. In a healthy knee, both the femur and tibia joint are surrounded by a layer of cartilage that acts as a bearing or articulating surface. In addition, the outside and inside edges of the tibia plateau contain a crescent shaped menisci that are made of cartilage. The articulating surface of the joint absorbs pressure in the joint, and protects the joint surfaces of both the femur and tibia.

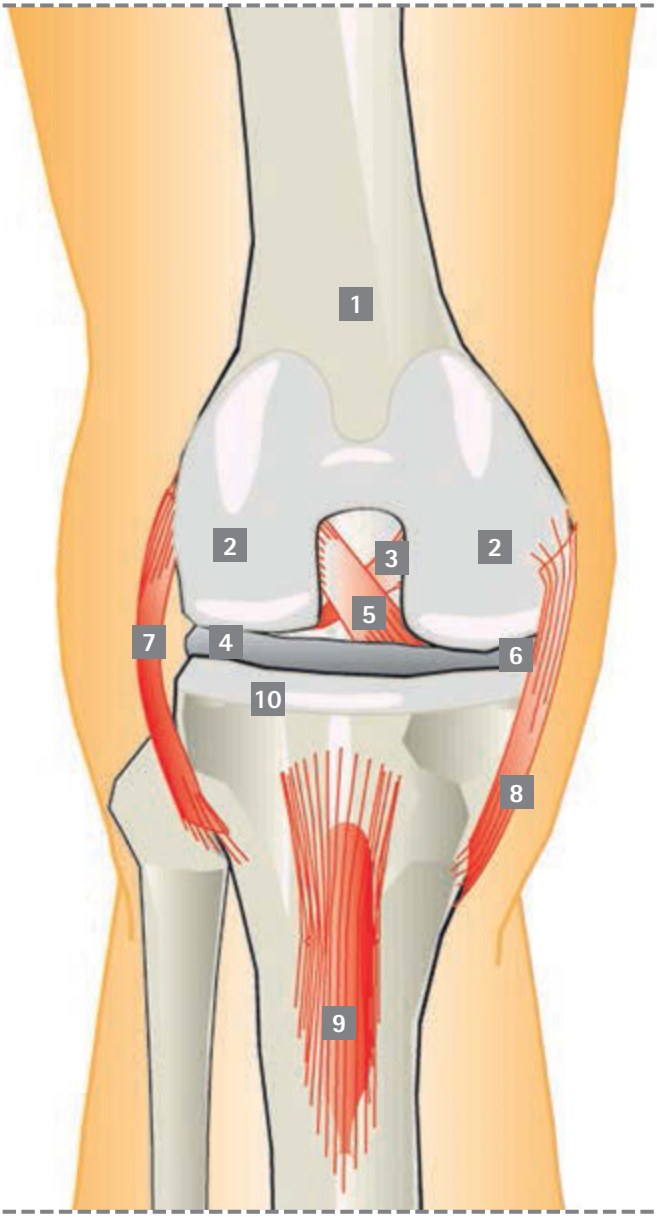
The stability of the knee joint is the result of a complex system of ligaments. There are both medial and lateral ligaments that provide stability for the knee joint. An additional source of stabilization include the anterior and posterior cruciate ligaments. The joint also includes the kneecap (patella), which is a bone encased in the tendon which connects to the quadriceps muscle. The kneecap stabilizes the knee joint from the front during movement.

Knee mechanics

Joint fluid is found in the joint space and acts as a lubricant to help reduce friction on the articulating surface of joints during movement. Joint fluid insures the various parts of the knee work together. If any part of the knee joint is affected by disease, the entire system will be affected.

The knee joint has a sliding joint axis that can be moved in five different directions. This essentially means rolling and sliding movements of the femur over the tibia. For example, when the knee is bent, slight outward and inward rotations are made possible. When the knee is fully extended, these movements are blocked by the ligaments for stability.

Structure of the knee joint



The right knee joint from the front

1 *Femur*
2 *Femoral condyles with cartilage coverage*
3 *Posterior cruciate ligament (PCL)*
4 *Lateral meniscus*
5 *Anterior cruciate ligament (ACL)*
6 *Medial meniscus*
7 *Lateral collateral ligament*
8 *Medial collateral ligament*
9 *Patellar tendon*
10 *Tibial plateau with cartilage coverage*

The patella is not shown to for clear view of illustration.

I The knee joint

Osteoarthritis of the knee joint

Front View

Frontal View of Right Knee

Pronounced bow-leggedness can lead to the development of osteoarthritis of the medial joint space.

Osteoarthritis of the knee joint

Left image:

Frontal View of Knee

The joint space has narrowed, because the cartilage has worn away. This causes the bones, femur condyles and tibia plateau, to be pushed together.

Right image:

Side View of Knee

Wear affects not only the femoral condyles and the tibia plateau, the dorsal (backside) surface of the patella will also experience wear.

2. Reasons for knee replacement

Nowadays, knee replacement is one of the most common surgical orthopaedic procedures being performed, and is considered a standard procedure.

The knee joint is under great daily stress since if bears the weight of the entire body. Therefore, an intact cartilage layer on the femoral condyles and tibial plateau is required for smooth and pain-free movement in the knee joint.

Several factors can lead to the erosion of or damage to the protective cartilage layer:

Pain associated with wear and tear of the knee joint, known as osteoarthritis, is the most common and frequently occurring condition. Osteoarthritis can be a result of age related wear of the joint, which can lead to pain and restricted movement.

Other causes of wear include congenital or improper stresses acquired with age a result of leg deformations (bow-leggedness or knock-knee), previous injuries, or inflammations in the knee joint.

In many cases, knee osteoarthritis will initially lead to damage of the cartilage menisci, which are then no longer able to sufficiently protect the joint surfaces from the pressure of body weight. As a consequence, the joint surfaces of the femoral condyles and the tibial plateau are subsequently affected. The protective cartilage layer begins to erode at the points of greatest stress, until it is completely worn away and the bone is exposed. Since cartilage is not supported by blood vessels, this is in contrast to numerous other body tissues. This means it has a low capacity to heal itself after injuries or disease related disorders. Once the cartilage is worn away, the joint cartilage will not grow back. Therefore, any movement in the joint will be painful. In such cases, the synovial membrane produces a large amount in the tissue, which is only slightly lubricating, and leads to join effusion or water on the knee. As a result, the patient will experience sever pain.

An artificial knee replacement will be necessary if the knee was damaged to the extent that joint-preserving surgery is no longer an option.

I The knee joint

3. Diagnosis and conservative treatment methods

In a current clinical scenario, surgeons use X-ray imaging, which illustrates the condition of the bone, as well as various clinical evaluation methods to learn restrictions in the knee joint during natural movement.

Wear and tear of the knee joint manifests itself through pain while walking and in situations of stress on the joint. As a result of this pain, a person suffering from this condition will adopt an adaptive posture, which leads to abnormal stresses and changes to the muscle and tendon structures.

At first, joint replacement can be avoided through a targeted conservative treatment process. Initially, medications may be prescribed to alleviate pain, and then next through therapeutic exercise or physical therapy to treat current limitations in movement.

However, the pain often reaches a level where daily activity is affected to the point where the quality of life is significantly reduced, and disruption in sleep also occurs.

After surgery confirmation at the hospital, the following preparations will be made at the hospital:

- Consultations
- Date of surgery
- Appointment for X-rays
- Selection and review of suitable prosthesis
- Pre-operative planning and sizing based on X-rays

II Implants

1. Development

There have been significant advances in knee replacement surgery in the past 20 years. As a result, advanced implant systems made from high quality materials, are being implanted using modern surgical techniques by surgeons today. Modern knee replacement implants adapt better to the bone situation and therefore allow for the best possible reconstruction of the joint.

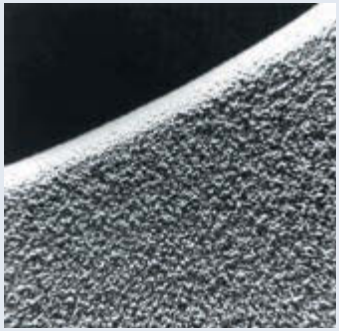
An endoprosthesis attempts to imitate the original bone anatomy as close as possible, however it can never be viewed as an exact equivalent replacement. Due to this limitation, an implant is not intended to last forever. There are also various revision systems available for potential implant replacement.

2. Anchorage options and materials

The prosthesis components can be anchored with bone cement or cement-free. A combination of both procedures is called a hybrid procedure.

Aesculap AG manufactures implants for fixation with bone cement, made from a high quality cobalt-chrome alloy. Prosthesis components for cement-free implantation are made from the same basic material. However, these implants have an additional rough surface made from titanium and are covered with a layer that promotes bone growth. This surface coating ensures a bond between the bone and the implant.

Your surgeon will decide which implants are used, and if the implants will be cementless or cemented. These decisions will vary based on bone condition, level of patient activity, as well as any other additional parameters.



Plasmapore®
The microporous titanium surface coating for cement-free knee implants.

3. Metal sensitivity

When implants are used, the implant replaces the normal joint function. Implants are foreign to the body and may trigger a reaction. A reaction which may occur is a sensitivity or allergy to metals. These reactions can include eczema, swelling, and effusions. Contact allergies to cobalt, nickel, and chrome are relatively common and occur in 13 % of the population.[1] In recent decades, allergic reactions following the implantation of a prosthesis have been diagnosed more frequently than was previously assumed.

Metal ion barriers

The job of a modern knee implant is not just to fulfil its function, but also to ensure biological tolerance.

Aesculap AG has developed a unique surface for people with metal allergies. This innovative technology has all the advantages of a standard implants but also includes a barrier effect against metals that can trigger allergies.

The high quality, gold colored Advanced Surface (AS) is applied to the standard implant through a physical vapor process. A total of seven layers are applied to seal the metallic parts of the metal implant components.

The gold top layer is made from zirconium nitride, a material known for being well tolerated by the human body.

Improved resistance to wear

A knee prosthesis is subjected to high stresses on a daily basis. Nevertheless, the artificial joint has to be stable for several years. Reducing wear at the implant contact surfaces is very important in artificial knee joints, as material friction can lead to early wear of the components affected and is a common cause of prosthesis replacement. The AS surface quality can help to reduce wear. The ceramic, very hard AS surface substantially reduces wear and means a longer lifespan can be expected from an AS-coated knee prosthesis.

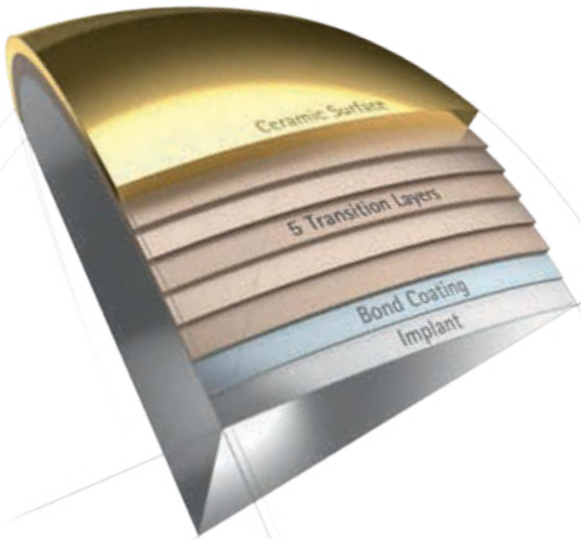
This new coating can be applied to all Aesculap knee implants.

[1] Schäfer T, Böhler E, Ruhdorfer S, Weigl L, Wessner D, Filipiak B, Wichmann HE, Ring J. Epidemiology of contact allergy in adults. Allergy. 2001 Dec;56(12):1192-6.

[2] Grupp TM, Giurea A, Miehlke RK, Hintner M, Schilling C, Schwiesau J, Kaddick C. Biotribology of a new bearing material combination in a rotating hinge knee articulation. Acta Biomater. 2013 Jun;9(6):7054-63. doi: 10.1016/j.actbio.2013.02.030. Epub 2013 ,Feb 26.

II Implants

AS Advanced Surface Technology



Advantages of the AS Advanced Surface Technology:

- Sophisticated 7-layer coating
- Prevention of allergic reactions[1]
- Reduced wear[2]
- Stability and improved scratch resistance[1]

[1] Reich J, Hovy L, Lindenmaier HL, Zeller R, Schwiesau J, Thomas P, Grupp TM. Präklinische Ergebnisse beschichteter Knieimplantate für Allergiker. Orthopäde. 2010 Mai;39(5):495-502.

[2] Grupp TM, Giurea A, Miehlke RK, Hintner M, Schilling C, Schwiesau J, Kaddick C. Biotribology of a new bearing material combination in a rotating hinge knee articulation. Acta Biomater. 2013 Jun;9(6):7054-63. doi: 10.1016/j.actbio.2013.02.030. Epub 2013 ,Feb 26.

4. Artificial knee joints

The artificial knee joint replaces the worn parts of the knee joint and has a similar form to the human knee.

In general, there are two classic types of knee resurfacing treatments, which are known as mobile bearing and fixed bearing knee implant systems. The technical difference between the two systems is the movement of the bearing (meniscus replacement) between the femoral and tibial components.

The mobile bearing can rotate on the metal plate of the tibial components. In contrast in a fixed bearing system, the artificial bearing is firmly clicked into the metal components and is therefore fixed.

Both types have proven valuable in recent decades and have been proven equally reliable and functional. Both systems offer good mobility, allow the knee to be bent to a significant degree, and offer sufficient stability.

Depending on the extent to which the knee joint has been damaged by osteoarthritis, different types of prosthesis can be considered. Below the differences between resurfacing and hinged knee prosthesis are illustrated:

- Unicompartmental resurfacing
- Complete resurfacing
- Hinged knee endoprosthesis

II Implants

5. Unicompartmental resurfacing

In this case, one side of the knee joint is worn (usually the medial side), and the other part of the joint, the ligaments and the knee cap are still functional. The prosthesis is only implanted on one of the femoral condyles, this is known as a sled prosthesis.

When the knee articulates, the unicompartmental femoral implant slides on artificial cartilage, which is implanted together with a metal base on the corresponding side of the tibial plateau. Stability is ensured by the preserved cruciate collateral ligaments.

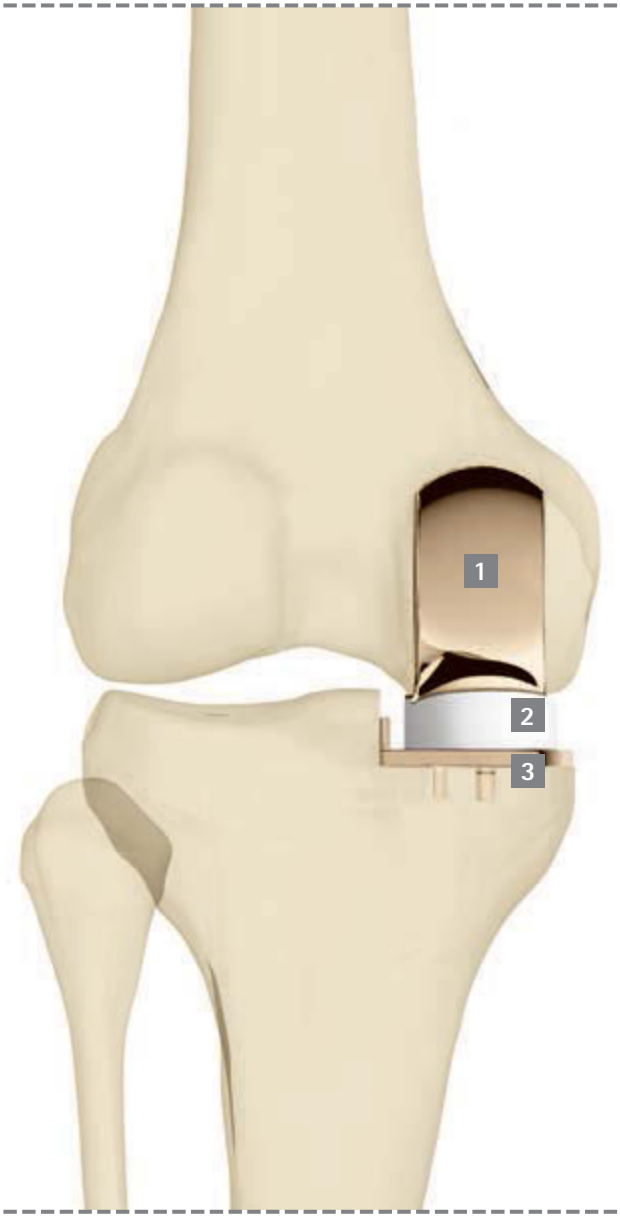
The surgery therefore only replaces the damaged medial or lateral joint surface. The area of the patellar bearing and the non-damaged (or only slightly damaged surface), are preserved during the operation.

Example: univation® X

univation® X combines the advantages of a unicompartmental knee implant and minimally-invasive surgical techniques. The design of the prosthesis ensures that as much bone as possible is preserved.

- *Bone-saving implant fixation*
- *Available in both mobile or fixed bearing system*
- *Extra flat implant design for minimally invasive surgical techniques*

Unicompartmental resurfacing



1 Unicompartmental femoral implant

2 Polyethylene bearing surfaces

3 Metal tibial plateau or base plate

II Implants

6. Complete resurfacing

More than one part of the knee joint (medial and lateral) are damaged by osteoarthritis and must be replaced. The collateral ligaments are completely preserved.

During a resurfacing of both sides of the knee, a metal prosthesis caps the natural femoral condyles. The prosthesis is made to mirror the natural geometry of the femoral condyles. The tibia is also capped with a metal prosthesis and an artificial meniscus as the bearing surface.

The anterior curciate ligament is removed during the operation. In addition, there are prosthesis variants that take on the function of the posterior cruciate ligament as well. Your surgeon will decide which option is preferred based on the present situation.

1 Femoral implant

2 Mobile or fixed polyethylene bearing

3 Tibial metal plateau

4 Implant keel

Example: e.motion®

e.motion® is a mobile bearing endoprosthesis system with implant options offering free axial rotation through the entire range of movement and uniform load distribution. The very fine size gradation allow for personalized adaption to anatomical circumstances.

Example: Columbus®

The Columbus® knee endoprosthesis system is a modern system of standard care with a complete resurfacing based on a fixed platform.

II Implants

7. Hinged knee endoprosthesis

In the event of advanced bone loss, severe deviations in the axis of the leg or unstable collateral ligaments, a so-called hinged knee endoprosthesis must be implanted. In such cases, the prosthesis has to take on the function of the ligaments as well.

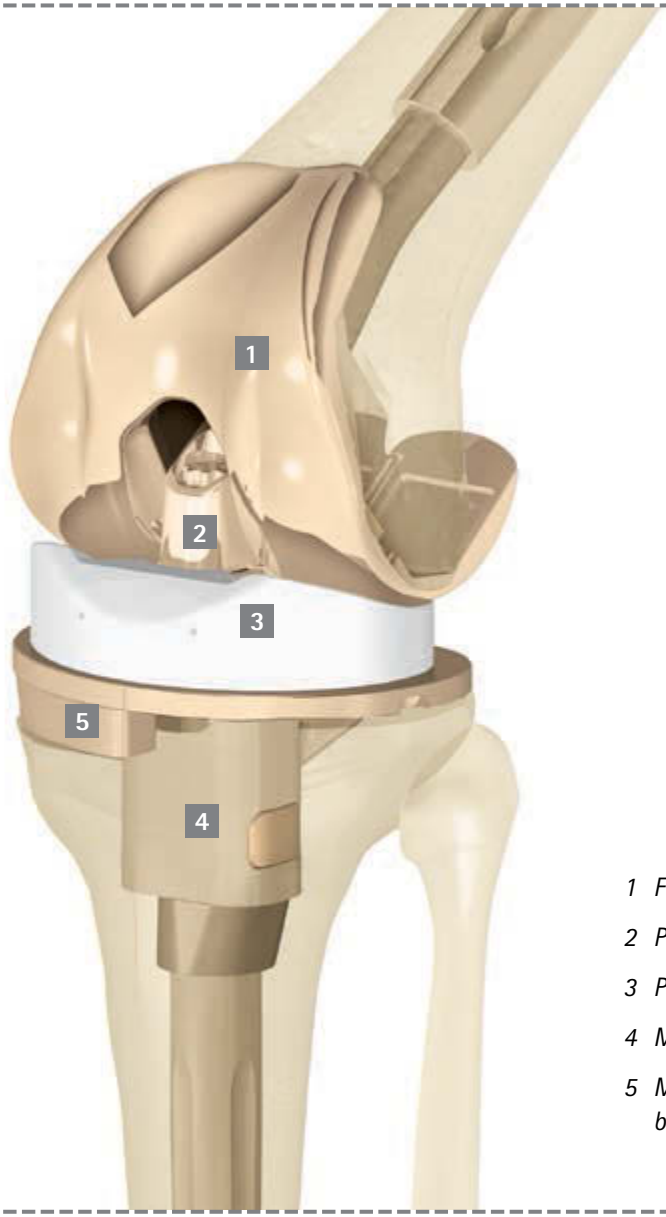
This artificial joint is comprised of a femoral and a tibial part. Each component possesses a long stem, which is fixed into the femur and tibia during the surgery.

In contrast to a simple resurfacing, these two components are connected through an axis, which offers the required stability.

Example: EnduRo

EnduRo is a hinged knee endoprosthesis with a rotating meniscus component. The wide range of implant components enables specific treatment to be adapted based on the individual patient, for partially or fully damaged collateral ligaments.

Total hinged joint replacement



1 *Femoral implant with stem extension*

2 *Prosthesis axis*

3 *Polyethylene bearings*

4 *Metal tibial plateau with stem extension*

5 *Metal augment for the configuration of additional bone defects*

III The surgical intervention

1. Preparations for the operation

Allergies

Inform your surgeon in advance prior to your surgical procedure of any known allergies. It is important to inform your doctor to all allergies which include, but are not limited to drug reactions, synthetic substances, and metal allergies.

Other illnesses

If you are receiving medical treatment for other illnesses, you should inform your surgeon prior to the operation. This will insure the surgical team can make the necessary arrangements in advance of your treatment.

Anaesthetic

In addition to a general anaesthetic, there is also generally the possibility that a local anaesthetic (spinal anaesthetic) or peripheral nerve block ("pain catheter") may be administered. The decision as to which form will be used, will be determined by the anesthesiologist in charge, and will generally be based on any concomitant diseases.

2. Important tools

Normally you will be admitted to the hospital one day prior to the surgery. When someone is admitted to the hospital, the question of what is needed for the hospital stay always arises. The following list may help when preparing for your stay.

Personal necessities:

- *Toiletries*
- *Pyjamas*
- *Bath robe*
- *Clothes for sport or free time*
- *Flat, non-slip shoes*
- *Trainers and slippers*
- *Required medications*
- *Books, magazines*
- *Contact details of family and friends*
- *Small amount of cash*

Clinic requirements:

- *X-rays*
- *Examination file*
- *Referrals*
- *Health insurance card*
- *Allergy record*
- *If applicable, Marcumar card*
- *Detailed list of medications including dosages, quantity, and times of medication administration*
- *Implant passport of prior operations (e.g. hip operations or heart pacemakers)*

III The surgical operation

3. The day of admission to the hospital

Generally, a patient is admitted to the hospital on the day before the operation. After your personal information has been recorded, you will be taken to the ward. The anesthesiologist will discuss the anesthesia with you and confirm if you are taking other medications, or have any other illnesses. The nurses and caregivers will be there to answer any other questions.

Due to the anaesthetic, you may not eat after a certain time. If necessary, you will receive a sedative or mild sleeping pill before the operation.

4. The surgical procedure

Access to the joint

After the anesthesia is administered, and preparations are complete, the knee to be operated on will be washed, and an incision will be made in the skin. The soft tissue and muscles under the skin will be gently moved aside and the knee joint will be exposed. The damaged cartilage, misshapen bone, and the meniscus will then be removed.

The surgical incision will always be made from the front, but there are various procedures with differing skin incision points and different soft tissue preparation. Less invasive procedures are becoming increasingly popular nowadays, as they preserve individual muscle and tendon structures. However, it is not the length of the visible skin incision that is important, but rather the careful handling of the soft tissue under the skin.

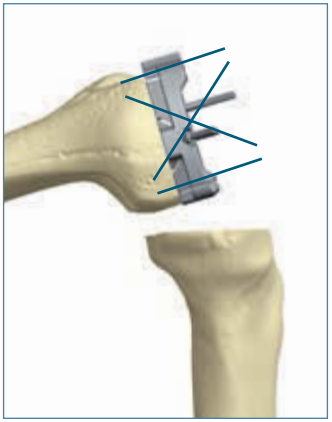
Under normal circumstances the surgery lasts between 90 and 120 minutes depending on the individual case.

III The surgical operation

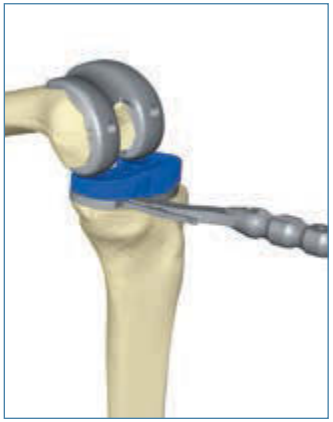
Course of the operation

I. *Preparation of the tibia*

II. *Measurement and adjustment of the joint space*



III. *Preparation of the femur*



IV. *Sample positioning of the size specific implant*

V. *Preparation of the shaft for the tibial implant*

VI. *Implant of the final tibia implant*

Implant of the final femur implant

Insertion of the bearing

Resurfacing

I. The femur and tibia bone is prepared using the adapted molds to fit the prosthesis. For this purpose, the tibia is prepared with a saw, at a right angle to the axis of the leg.

II. Then, the joint space is measured, taking the soft tissue (joint capsule and ligaments) into consideration. If a shortening of the ligaments in the joint occurred for example, this can be corrected in order to make the knee joint more stable.

III. The size of the femur will be determined, and it will be prepared for the prosthesis with a saw.

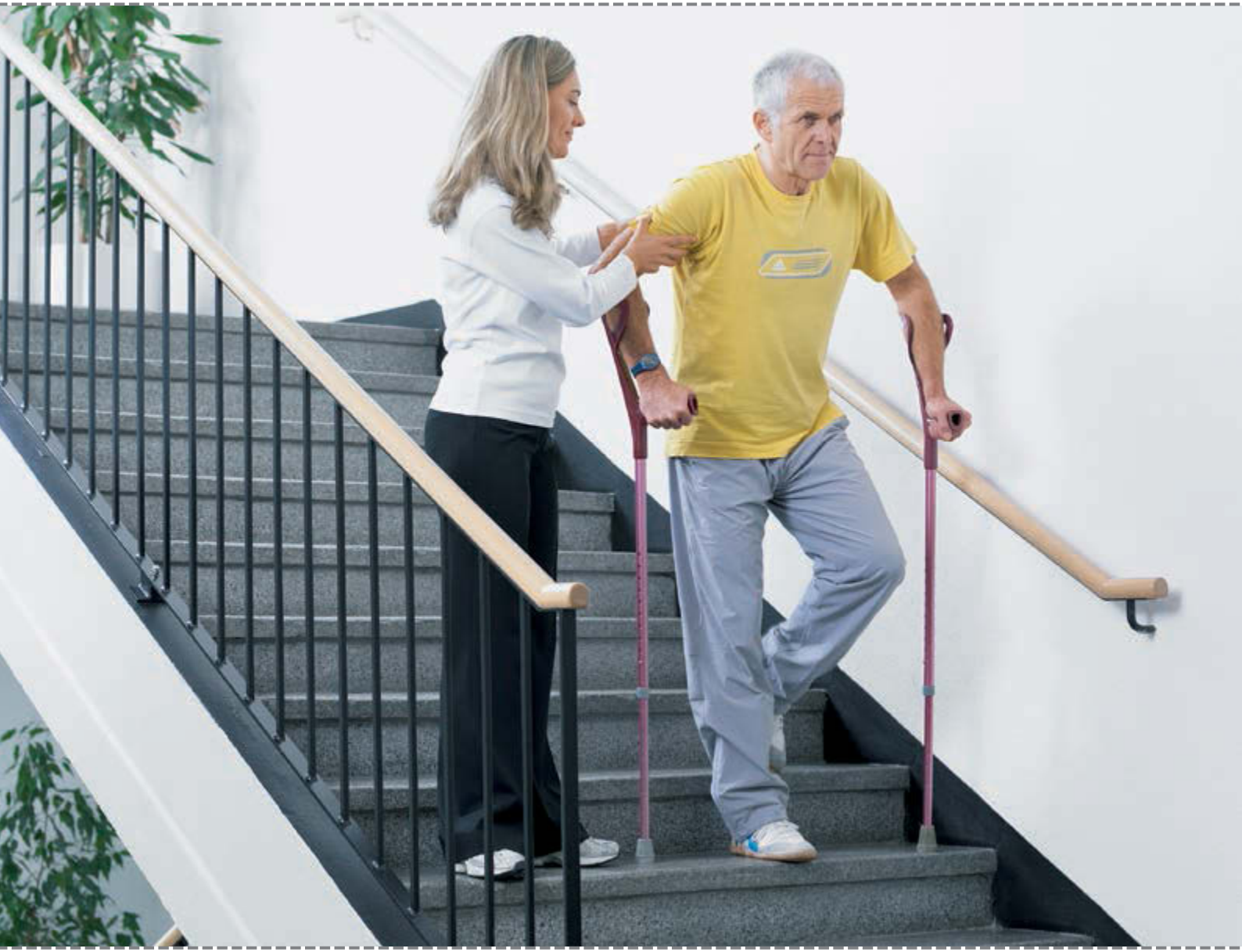
IV. Once the implant bed is created accordingly, the correct fit and good mobility of the knee joint will be trialed and tested using sample prostheses.

V. After confirmation that the prosthesis is an exact fit, the anchoring points in the bone will be drilled or cut.

VI. In the final step, the original prosthesis are positioned and fixed.

The functionality of the new joint is then checked and the incision in the knee is gradually sutured. Tubes are inserted into the wound to allow for wound drainage.

IV After the operation



1. First steps

Generally, weight will be put on your new artificial joint one or two days after the surgery, under the instruction of medical personnel. At the hospital, you will learn to bend and stretch your joint again with the help of a physiotherapist. You can make your first attempt at walking with the help of crutches. Little by little, additional therapeutic measures will be added and you will learn how to walk and the best way to climb stairs and to sit down.

2. Rehabilitation

After approximately 5-10 days, you will be discharged from the hospital to rehabilitation, where they are specialized in treating patients like you with artificial knee joints. The goal is for you to gradually build up to putting your full weight on the artificial joint and prepare you for normal daily activities and everyday routines. Your mobility will be improved through intensive exercises and your muscles built up accordingly. The subsequent treatment can take place on either an outpatient or inpatient basis at a rehabilitation facility. The nature and scope of the activities will be planned together by you and the social services at the hospital.

3. Follow-ups

Follow-up visits should be held at regular intervals to ensure long term success. X-rays are used to assess the integration of the prosthesis components in and to the bone, as well as joint functionality.

V Living with an artificial knee joint

1. Daily life

The long term success of the knee replacement is influenced by the follow-up care and your behaviour after the surgery. After the rehabilitation, you will return to regular daily life with all the normal stresses on the joint. Approximately six to eight weeks after the operation, your muscles will be built up again and be strong enough that you will contribute to the stability of the joint. You must therefore avoid putting a lot of stress on the prosthesis during this time.

2. The prosthesis passport

This is an important part of travel, especially at the security gates in airports, as body scanners can detect metal components in the body. The passport states that you have an implant, and identifies and documents the components that have been implanted in you through the attached stickers. Your follow-up appointments are also recorded in the document. Keep the passport in a secure place or carry it with you.

3. Tips and tricks

Even in the hospital, you will learn how to use your joint again with light physiotherapy exercises. These exercises, such as swimming (with front crawl kick or side stroke) or walking on a well-built path, should also become habitual later, once you have left the hospital. You can even go for short bike rides (on flat terrain).

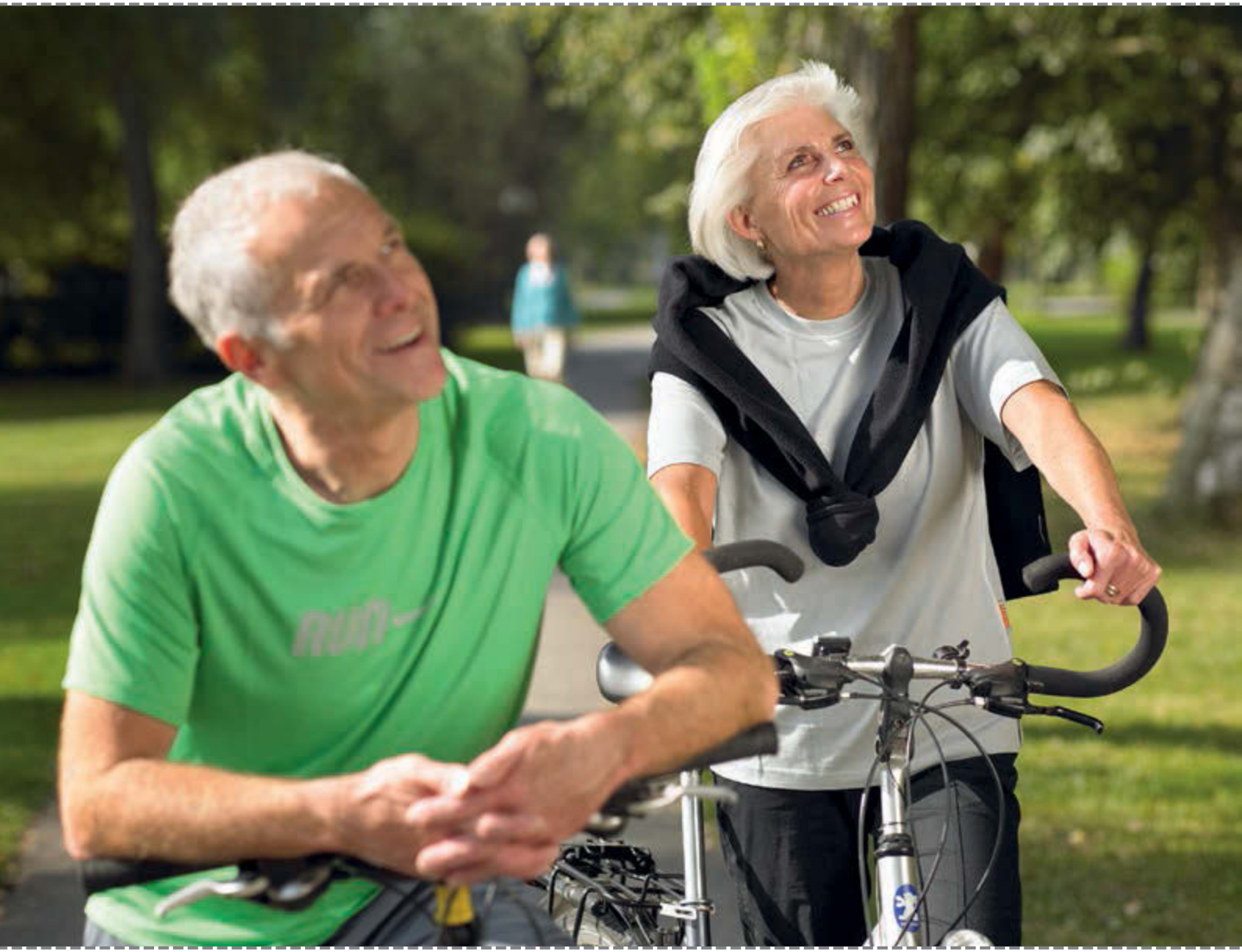
You should avoid:

- Abrupt, jerky, or impulsive movements
- Sports that require quick acceleration and sudden stops (tennis, alpine skiing, mountaineering etc.)
- Excessive and long periods of standing
- Crossing your legs
- Extreme bending, e.g. when crouching or kneeling
- Heavy and over-proportional weight gain
- Lifting heavy loads

Recommendations for making daily life easier:

- Good, flat and non-slip footwear
- Regular gait
- Shoes with Velcro or elastic laces
- Removing tripping hazards, e.g. carpet edges, objects lying around

V Living with an artificial knee joint



4. Sport

Once the prosthesis components have been engrafted into the bone, a high level of stability is achieved. However, an artificial joint is not like a natural joint so there are restrictions, especially with sport. Sport is positive in every respect, but „moderation" should always be of paramount importance.

Simple pushing movements, such as jumping from a higher level, or jerky stresses that occur in rapid, repetitive cycles or which require a wide range of movement, should preferably be avoided.

Sports that are suitable:

- Cycling
- Swimming
- Hiking
- Nordic walking
- Cross-country skiing
- Gymnastics
- Dancing (standard or Latin dancing)

Sports that are less suitable:

- Ball games and team sports such as football, handball, basketball etc.
- Martial arts
- Squash
- Tennis
- Alpine skiing

The information given here is not a blanket recommendation and can vary from patient to patient. Your age, your sporting experience and your general state of health affect the overall situation. If you have any further questions, please contact the doctor treating you directly.

VI Aesculap AG – an introduction to the manufacturer

The name Aesculap is synonymous with surgical expertise. With over 140 years of experience, Aesculap continues setting standards in surgery up to the present day. Worldwide it connects the knowledge of its approximately 11,500 employees, of whom approximately 3,480 work at the company's headquarters in Tuttlingen, and develops products and solutions for all core surgical processes.

Whether it's surgical instruments, suture material, microneedles, implants or sterile containers – through consistent research and development Aesculap strives for innovations that make medical advances possible.

Aesculap joint implants are products with the quality standard: Made in Germany. In this manner, the names e.motion®, Columbus® and VEGA System® stand for leading knee endoprosthesis systems that have been used in more than 300,000 implants.

As part of the B. Braun Group, which is still run as a family business today, the Aesculap division combines tradition and modernity through its comprehensive wealth of experience gathered from its more than 40 years in the joint endoprosthesis industry.

As the largest German manufacturer of orthopaedic implants, Aesculap is committed to close cooperation with doctors and hospitals and aims to continue developing high standards of patient safety.

Its production site in Tuttlingen is one of the most modern joint implant manufacturing sites in Europe, where the components for artificial hip and knee prostheses, spinal implants, and screws, plates and nails for bone fractures are manufactured. The production line at the Tuttlingen site has its own, state-of-the-art biomechanics laboratory where the implants are subjected to a wide range of stress tests - well beyond the regulatory standards.

Through Sharing Expertise, Aesculap gives its partners a promise to share medical knowledge, experience and healthcare information through dialogue, and to use this information effectively and constantly expand upon it.

As a German quality manufacturer, Aesculap offers you the opportunity to take a look behind the scenes of implant manufacture during an Aesculap patient day, and to experience the high quality standards for yourself.

Further information can be found on the B. Braun website: **www.bbraun.com**

Notes

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