B BRAUN
SHARING EXPERTISE

AESCULAP® PATIENT INFORMATION

YOUR NEW ARTIFICIAL TOTAL KNEE JOINT

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 imparied by overloading, disease, and injury which lead to surgical implantation of an artificial knee replacement.

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

In the following pages, a summary was prepared of all the important information for every patient before and after knee surgery. This brochure is intended as supplement to medical advice and consultation 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 maximise recovery.

CONTENTS

I THE KNEE JOINT

STRUCTURE OF 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

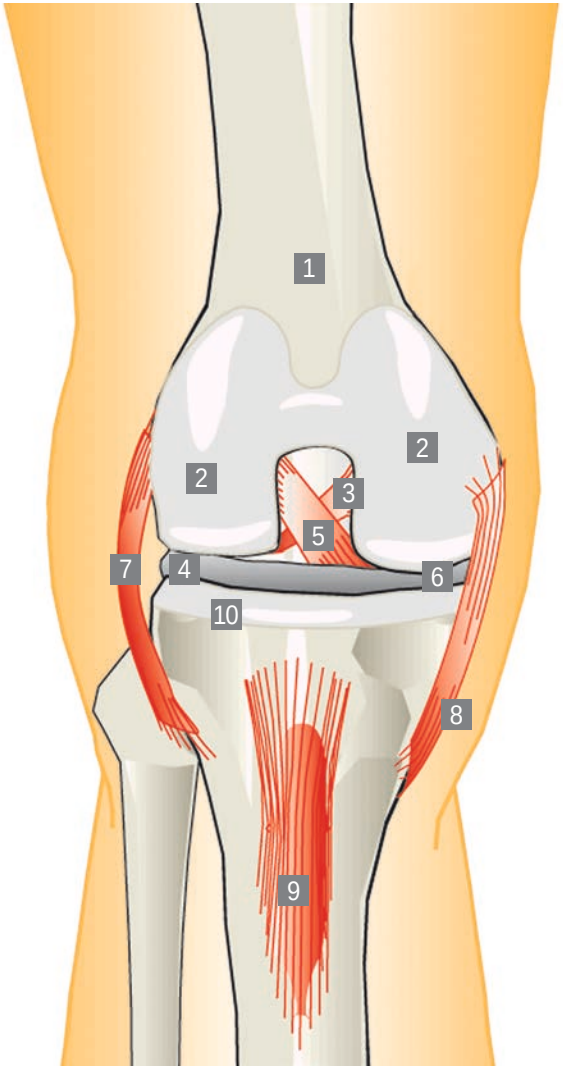
The knee joint is formed by the mobile connection between the lower leg (tibia) and the thigh (femur). In a healthy knee, both the femur and tibia joint are surrounded by a layer of cartilage that acts as a bearing or articulating surface. In addition, the outside and inside edges of the tibia plateau 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 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 stabilisation include the anterior and the posterior cruciate ligaments. The joint also includes the knee cap (Patella), which is a bone encased in the tendon which connects to the quadriceps muscle. The knee cap stabilises 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 movements. Joint fluid ensures 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.



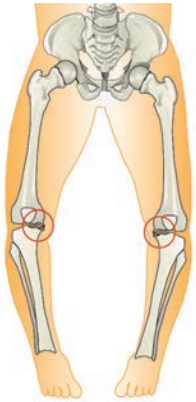
The right knee joint from the front

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

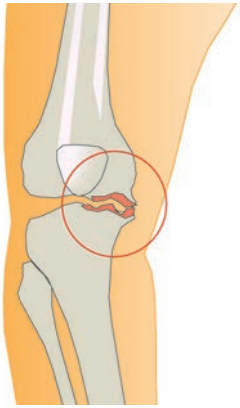
The patella is not shown for clear view of illustration

Osteoarthritis of the knee joint

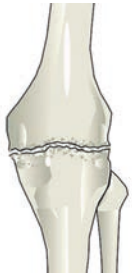
Front View



Frontal View of Right Knee



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



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.

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 it 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 occuring 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 stress acquired with age as a result of leg deformation (bow-leggedness or knock-knee), previous injuries, or inflammation in the knee joint. In many cases, knee osteoarthritis will initially lead to damage of the cartilage menisci, which is then no longer able to sufficiently protect the joint surfaces from the pressure of the 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 point 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 in the knee. As a result, the patient will experience severe 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.

3. Diagnosis and conservative treatment method

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 often adopt an adaptive posture, which leads to abnormal stress 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 excercise 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, following preparations will be made at the hopsital:

- 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

ARTIFICIAL KNEE JOINTS

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

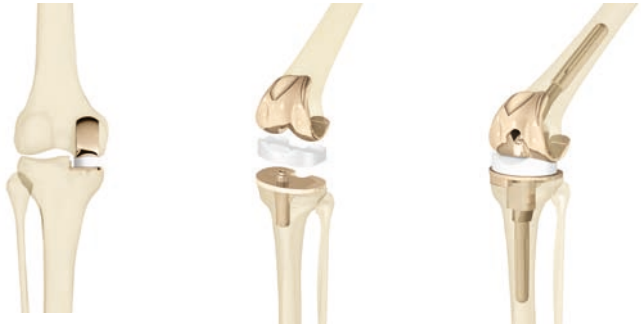
In general, there are two classic types of knee resurfacing treatments, which are known as mobile bearing and fixed bearing knee implant systems. The technical difference between the two systems is the movement of the bearing (meniscus replacement) between the femoral and tibial components.

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.

The following illustrates the different types of resurfacing knee prostheses:



Unicondylar (left), Total Knee Replacement (middle) Hinged Knee Replacement (right)

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 resurfacing of both the sides of the knee, a metal prosthesis caps the natural femoral condyles. The prothesis 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 ligamant 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.

COLUMBUS TOTAL KNEE REPLACEMENT

The Columbus knee arthroplasty system is a bicondylar joint surface replacement with a fixed or rotating gliding surface for primary treatment. It also includes revision components for use in revision surgery.

The Columbus knee endoprosthesis comprises of a CoCrMo femur and tibia component, as well as a UHMWPE meniscus component. Metal components can be cemented or cementless with Plasmapore®. All the CoCrMo components for cemented application are also available in the AS (Advanced Surface) version for people with metal allergies. A gold colored Advanced Surface (AS) made from Zirconium nitride 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 implant components.

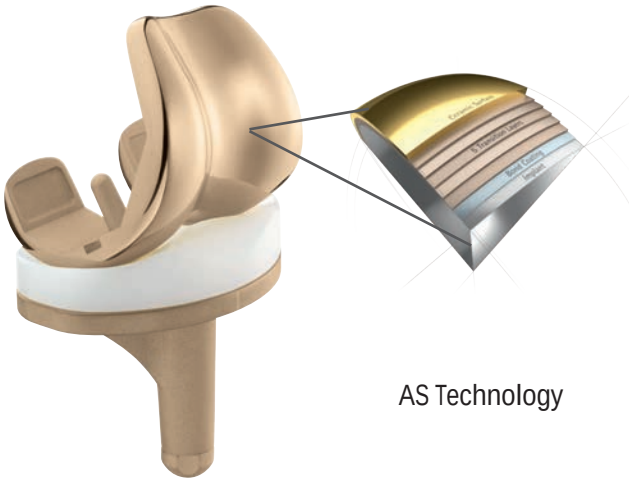
Where required, a UHMWPE patella replacement can also be implanted. There is a left and right knee version for all femur components.

COLUMBUS TOTAL KNEE REPLACEMENT

Metal components are manufactured from CoCrMo alloy according to ISO 5832-4 or ISO 5832-12.

Cementless femur and tibia components
The inner surfaces of the cementless femur and tibia components have an additional coating of a porous pure titanium (Ti) layer (PLASMAPORE®) in conformance with ISO 5832-2.

Cemented femur and tibia components
The inner surfaces of the femur and tibia components are mechanically roughened for cement/implant adhesion. Cement pockets with a depth of 1 mm are provided on the cementing surfaces of the femur and tibia components.



AS Technology

DD

UC

PS

The meniscus components and patella are made from Polyethylene (UHMWPE) according to ISO 5834-2. It includes X-Ray markers made of Stainless steel according to ISO 5832-1 (Patella), Tantalum according to ASTM F560 or ISO 13782 (meniscal components) and Titanium alloy according to ISO 5832-3 (meniscal components).

Patella

III THE SURGICAL INTERVENTION

1. Preparation for the surgery

Allergies

Inform your surgeon in advance prior to your surgery of any known allergies. It is important to inform your doctor about 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 all 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

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
- ☐ Casual Clothes
- ☐ 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
- ☐ Detailed list of medications including dosages, quantity, and times of medication administration
- ☐ Implant passport of prior operations (e.g. hip operations or heart pacemakers

3. The day of admission to the hospital

Generally, a patient is admitted to the hospital on the day of 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.

4. The surgical procedure

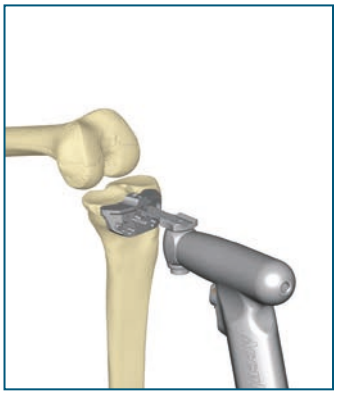
Access to the joint

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.

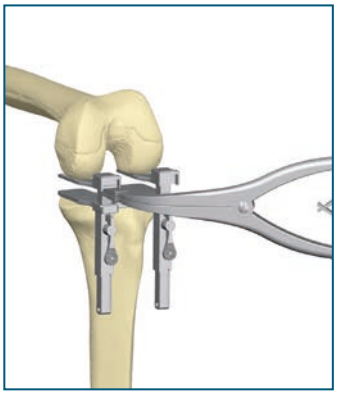
The surgical incision will always be made from the front, but there are various procedures with different skin incision points and different soft tissue preparation. Less invasive procedures are becoming increasingly popular nowadays, as they preserve individual muscle and tendon structures. However, 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 60-90 minutes depending on the individual case.

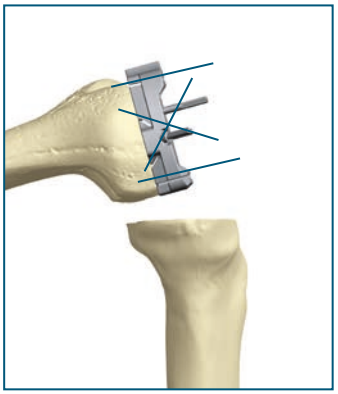
Course of the operation



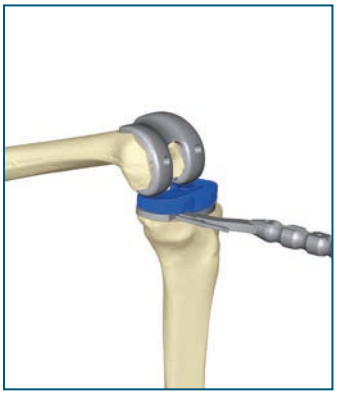
I. Preparation of the tibia



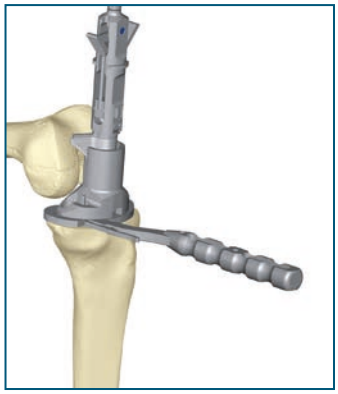
II. Measurement and adjustment of the joint space



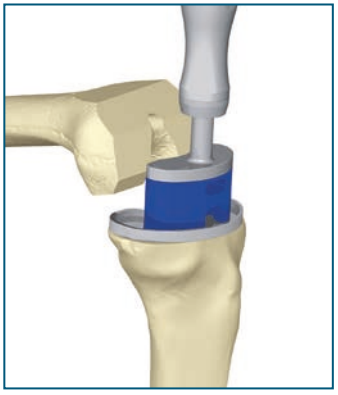
III. Preparation of the femur



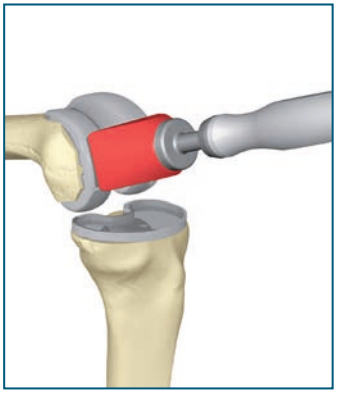
IV. Sample positioning of the size specific implant



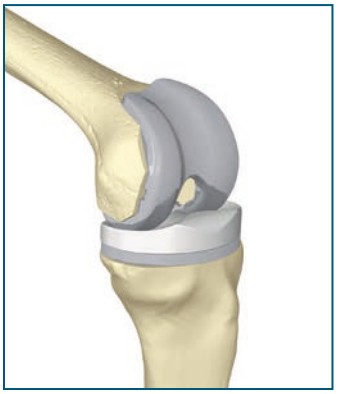
V. Preparation of the shaft for the tibial implant



VI. Implant of the final tibia implant



Implant of the final femur



Insertion of the new bearing

Preparation and Implantation

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 occured 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 prosthesis.

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 a 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 personnal. At the hopsital, 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 3-5 days, you will be discharged from the hospital and in some cases moved to rehabilitation, if available. The goal is for you to gradually be able to put your weight on the artificial joint and prepare you for normal daily activities and everyday routine. Your mobility will be improved through intensive excercise and your muscles built up accordingly. The subsequent treatment can take place on either an outpatient or inpatient basis at the rehabilitation facility. The nature and scope of the activities will be planned together by you and the medical staff at the hospital.

3. Follow-ups

Follow-up visits should be held at regular intervals to ensure long term success. In some instances X-rays are used to access 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 stress on the joint. Approximately 6-8 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.

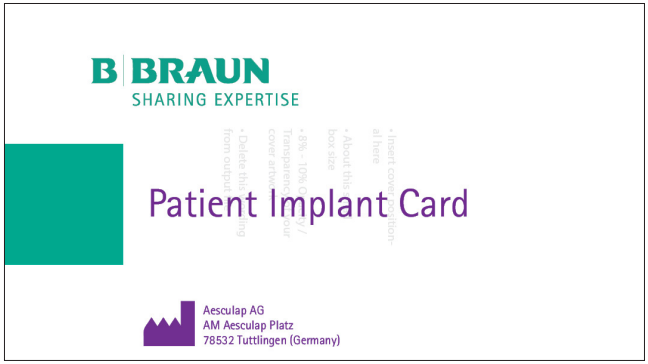
2. Patient Implant Card

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 ID card states that you have an implant, it 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 ID card in a secure place or carry it with you.

Side Effects & Risks

As with any surgery, there are side effects and risks associated with the procedure which may include:

- Loosening, wear, and breakage of implant components
- Misalignment of joints
- Bony changes including bone loss
- Joint dislocation
- Infection
- Blood clots in the leg or lungs
- Heart attacks or strokes
- Allergy reactions to the implant
- Implant fracture
- Blood vessel or nerve damage
- Skin or muscle sensitivity or scarring
- Wound and bleeding complications
- Joint stiffness
- Loss of knee mobility or functionality and/or inability to perform everyday physical tasks



3. Tips and tricks

Even in the hopsital, you will learn how to use your joint again with light physiotherapy exercises. Once you have left the hospital, exercises such as swimming (with free style or side stroke) or walking on a well-built path, should become habitual. 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, mounterring etc.)
- Excessive and long periods of standing
- Crossing your legs
- Extreme bending, eg. 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

4. Sport

Once the prosthesis components have been ingrown 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 sports. Sport activities are positive in every respect, but "moderation“ should always be of paramount importance.

Simple pushing movements, such as jumping from a higher level or jerky stress 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
- Light gym work
- 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 are unsure of which activities are suitable, please consult your doctor.

With normal use and activity, a knee replacement can last up to 10 years.

Excessive activity or obesity may accelerate wear and could cause knee replacement to loosen and become painful.

By adopting the right lifestyle for you, there is no reason why your knee should not provide you with a good quality of life.

VI MATERIAL AND SUBSTANCES INCLUDED IN THE DEVICE

Component	Material	Product Code	Size
Columbus Femur CR cemented	Cobalt chrome alloy (CoCrMo)	NN001K-NN911K	F1 - F8 and F2N - F7N
Columbus AS Femur CR Cemented	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (Crn-CrCN-ZrN)	NN001Z-NN911Z	F1 - F8 and F2N - F7N
Columbus Femur PS Cemented	Cobalt chrome alloy (CoCrMo)	NN161K-NN951K	F1 - F8 and F2N - F6N
Columbus AS femur PS Cemented	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN161Z-NN17Z	F1 - F7
Columbus CR/PS Tibia Cemented	Cobalt chrome alloy (CoCrMo)	NN070K-NN079K	T0 - T5 and T0+ - T4+
Columbus AS CR/PS Tibia Cemented	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN070Z-NN079Z	T0 - T5 and T0+ - T4+
Columbus CRA/PSA Tibia Cemented	Cobalt chrome alloy (CoCrMo)	NN470K - NN479K	T0 - T5 and T0+ - T4+
Columbus AS CRA/PSA Tibia Cemented	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN471Z - NN479Z	T1 - T5 and T1+ - T4+

Component	Material	Product Code	Size
Columbus DD Gliding Surface	Ultra-high, molecular low pressure polyethylene acc. to ISO 5834-2	NN200 - NN255	T0/0+ - T4/4+, T5
Columbus UC Gliding Surface	Ultra-high, molecular low pressure polyethylene acc. to ISO 5834-2	NN400 - NN455	T0/0+ - T4/4+, T5
Columbus PS Gliding Surface	Ultra-high, molecular low pressure polyethylene acc. to ISO 5834-2	NN500 - NN555	T0/0+ - T4/4+, T5
Fixation screw for PS Gliding surface (AS)	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN497Z - NN499Z	10/12, 14/16, 18/20
Patella 3-PEG	Ultra-high ,molecular low pressure polyethylene acc. to ISO 5834-2	NX041 - NX045	P1 - P5
Columbus Tibia Stems	Cobalt chrome alloy (CoCrMo)	NX060K - NX087K	10mm, 12mm, 14mm: 52mm, 92mm, 132mm
Columbus AS Tibia Stems	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NX060Z - NX087Z	10mm, 12mm, 14mm: 52mm, 92mm, 132mm
Columbus Obturator	Cobalt chrome alloy (CoCrMo)	NN261K - NN264K	12mm, 14mm: T0 - T3+, T4 - T5

Component	Material	Product Code	Size
Columbus AS Obturator	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN261Z - NN264Z	12mm, 14mm: T0 - T3+, T4 - T5
Columbus CRA/PSA Tibia Hemi Spacers with screw	Cobalt chrome alloy (CoCrMo)	NN560K - NN596K	T0 - T5
Columbus AS CRA/PSA Tibia Hemi Spacers with screws	Cobalt chrome alloy (CoCrMo) with multilayer coating system made from chromium nitride-chromium carbon nitride-zirconium nitride (CrN-CrCN-ZrN)	NN563Z - NN596Z	T0 - T5

Please Note

Implants partly include metal components, so that metal detectors could respond.
Therefore, please carry yoour patient card with you, especially during Air travel, in order to pass the security checks.
If there are any complications, please contact your hospital.

MRI Warning ⚠

The implant has not been evaluated for safety and compatibility in the MRI environment.

It has not been tested for heating, migration or image artifact in the MRI enviorment.

Scanning a patient who has this implant may result in patient injury.

Incident Reporting

Any serious incident occuring in relation to the device should be reported to B. Braun Australia Pty Ltd and to the Therapeutic Goods Administration.

Phone: 1800 206 045

www.bbraun.com.au

www.tga.gov.au

VII B. BRAUN AESCULAP® AG - AN INTRODUCTION TO THE MANUFACTURER

The name Aesculap® is synonymus with surgical expertise. With over 150 years of experience, Aesculap® continues setting standards in surgery up to the present day. Worldwide it connects the knowledge of its approximately 12500 employees, of whom approximately 3,840 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 devices advances possible.

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

As part of the B. Braun Group, which is still a family business, 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, Germany is one of the most modern joint implant manufacturing sites in Europe, where the components for artificial hip and knee prosthesis, 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.

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

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