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BioBall
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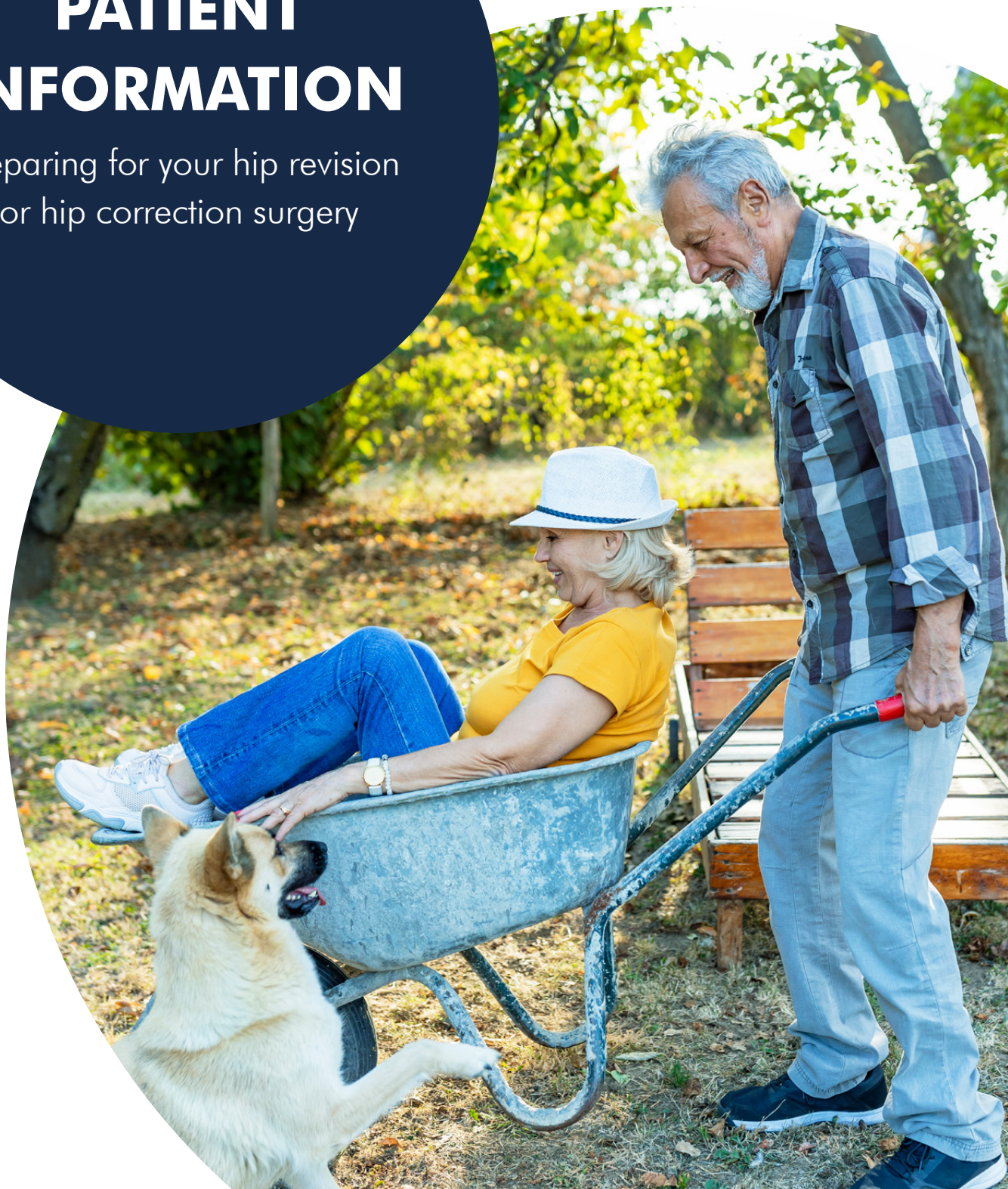
The BioBall® System

PATIENT INFORMATION

Preparing for your hip revision or hip correction surgery



ENGLISH

Dear patient,

Hip problems can significantly impact your quality of life. They keep you from enjoying your favourite hobbies, force you to change your everyday routines, make housework and gardening more difficult, and generally impair your mobility. Whether these issues are the result of an accident, a pathological change in the hip, or simple wear and tear, the goal in treatment is to alleviate your pain, re-establish your freedom of movement, and help you return to an active, pain-reduced life.

Your treating physician will guide you through the process and provide detailed information along the way. Now that your physician has recommended hip replacement surgery, which uses an artificial hip joint to help restore hip function, you and your loved ones will want to prepare as thoroughly as possible.

This brochure is designed to help you prepare for the upcoming operation by giving you information about the condition and explaining the treatment process.

Your Chief Physician
Dr. med. Elke Johnen

St. Joseph Hospital, Clinic for Orthopaedics and Trauma Surgery, Berlin Tempelhof, Germany

If you have any questions regarding your condition, treatment options, follow-up, or any other related topic, please contact your treating physician or care team.

Patient Information

The BioBall® System

1. Your natural hip joint

Anatomical structure

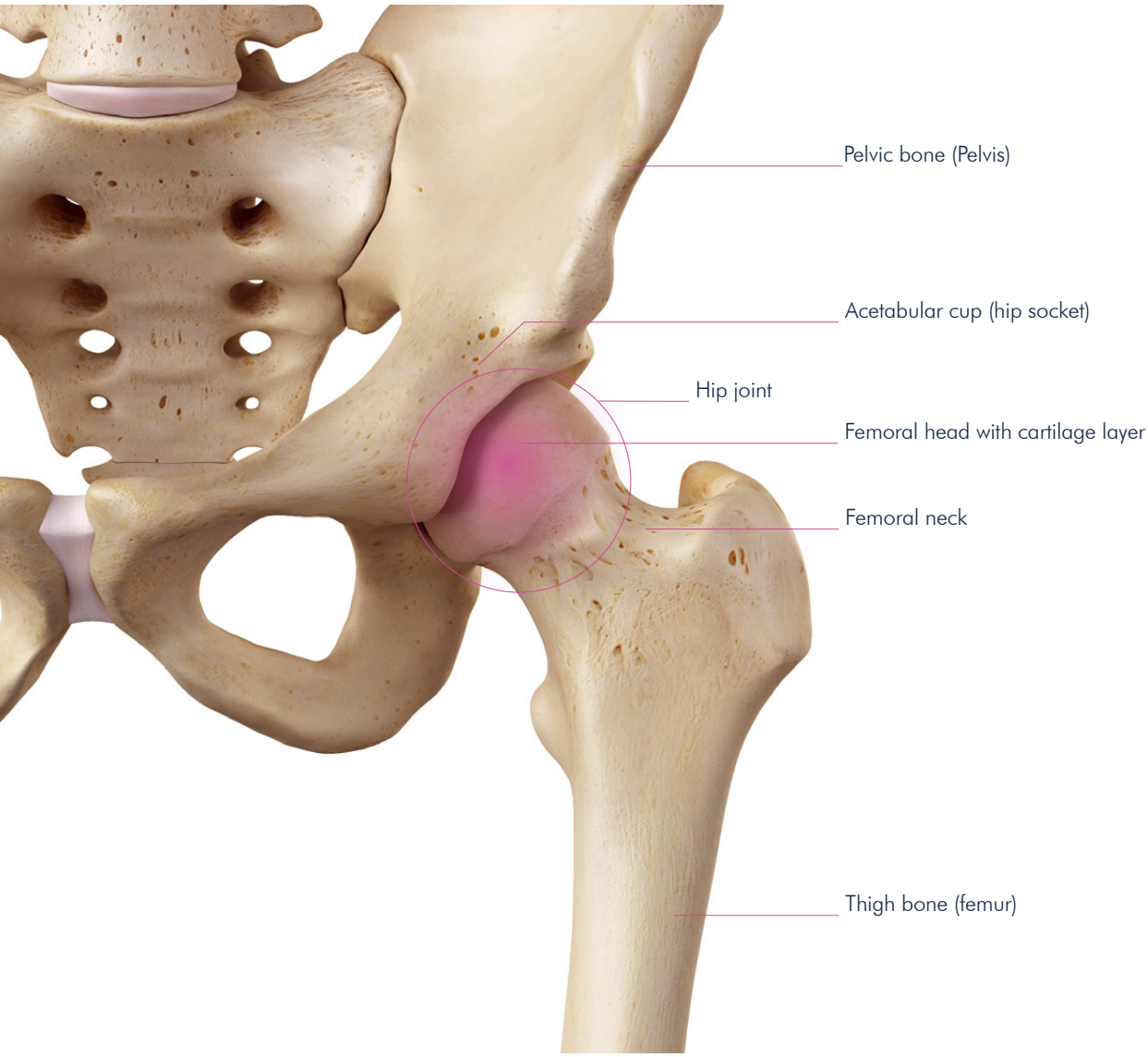


Illustration of the hip joint

The **hip joint** is the largest joint in the human body, and the one under the most stress. During walking, your hip joint may experience forces that are two or more times your body weight. Most healthy hip joints can withstand this pressure throughout the person's entire life.

The hip joint connects the **pelvis** to the **thigh bone**. The spherical head of the thigh bone sits in the **acetabular cup** (the hip socket), which runs together with the pelvic bone.

A thick, protective cartilage layer (hyaline cartilage) covers the joint connecting the acetabular cup and the head of the femur. This **cartilaginous layer** allows sliding movement of the leg in all directions and distributes the forces acting on the joint. The hip joint moves with the help of muscles and tendons. A network of very strong ligaments provides stability when moving.

2. Why an artificial hip joint may be needed

Indications that make an artificial hip joint necessary

The hip joint is involved in many different forms of bodily movement, which is why it is especially prone to wear and tear. The sliding layer of cartilage wears down over time, leavingbone rubbing against bone. Eventually, this results in painful changes to the shape of the femoral head and cup.

Artificial hip joints are always used in cases where the patient's own hip functionality is permanently impaired, and pain is restricting the patient's mobility. Hip prostheses are implanted with the goal of helping the patient return to an active lifestyle with minimal pain and the greatest possible range of motion.

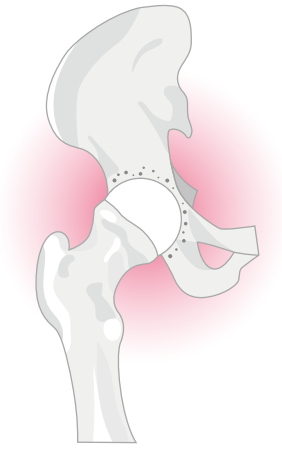
There are many reasons why doctors may recommend artificial hip joints:

Arthrosis

Arthrosis refers to degenerative changes to the joints due to pathological wear of the joint cartilage

Femoral head necrosis

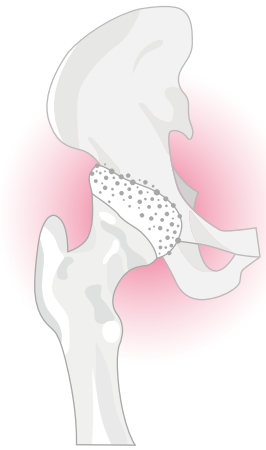
Diseases in the area of the femoral head which disrupt blood supply, causing the femoral head tissue to die off



Arthrosis and hip joint necrosis

Rheumatoid arthritis (chronic polyarthritis)

Inflammatory changes to the hip joint (e.g., due to rheumatic diseases or bacteria spread through the bloodstream) can also lead to permanent destruction of the joint structure



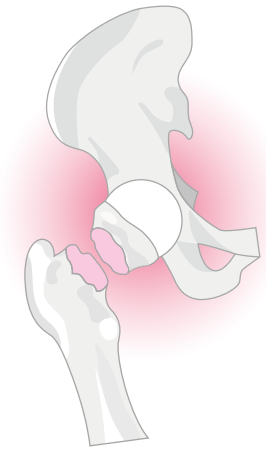
Hip dysplasia-related arthrosis

Malformation / Deformity of the hip joint (hip dysplasia)

Congenital and acquired malformations or deformities of the hip joint cause pathologically improper load distribution, leading to impaired hip joint mobility and pain when putting weight on the joint – eventually also at rest

Injuries to joint structures

e.g. femoral neck fractures in the elderly



Femoral neck fracture

How do I know if I need an artificial hip joint?

Once you begin experiencing limitations in your range of pain-free motion, diseases of the hip joint will need to be taken into consideration as a possibility. In everyday life, this type of pain may develop while climbing stairs, walking longer distances, or sitting for extended periods. Activities involving additional stress on the joint, such as housework or gardening, are no longer painless. Even prolonged sitting or lying down may trigger periods of latent pain. The joint itself may be painful, you may feel it in your groin, or it may radiate down your thigh to your knee.

Besides pain, reduced joint mobility or freedom of movement may be signs of pathological changes to the hip joint.

When is an artificial hip joint a good choice?

The symptoms and issues mentioned develop gradually over time. Most people hardly notice them at first, as they occur only sporadically. Even when painful symptoms increase, they can often be alleviated for many years using conservative treatments such as pain medication or physical applications.

Once other solutions no longer achieve the desired effect, patients may elect to have an artificial hip put in. Your treating physician and physiotherapist will work closely with you throughout the decision-making process, providing detailed information on the goals of the procedure and the results you can expect.

All operations are associated with some level of risk, so it is important to weigh expectations and goals against those risks.

For example, even after successful surgery, patients may experience allergic tissue reactions, long-term local nerve damage, or infections. The implant can also loosen inside the body and shift out of place or trigger a rejection response.

You as a patient can help influence the success of the procedure by adapting your everyday life to fit the prosthesis (see chapter 7 ▸ Tips for everyday living with a prosthesis).

3. Hip replacement surgery

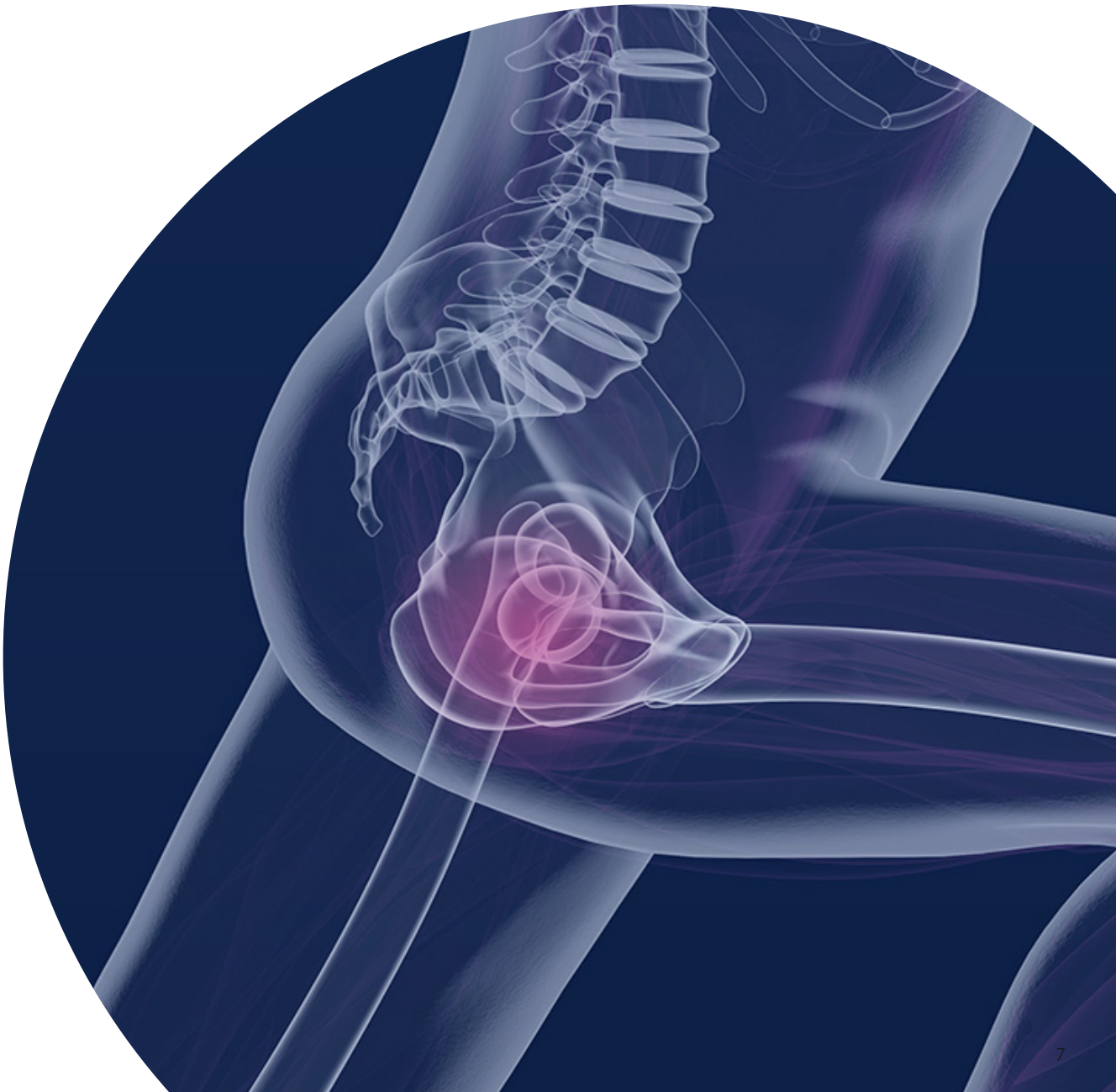
Introduction to hip replacements

Hip replacement surgery has been performed since the 1970s and has been continuously improved ever since. Today, surgeons have access to sophisticated implant systems made of high-quality materials, which are implanted using modern surgical procedures. Implants are becoming easier and easier to adapt to fit individual bone situations and joint loading profiles. As a result, today's hip prostheses not only allow joint reconstruction, but can also restore pain-reduced movement in the human hip.

Hip prostheses attempt to imitate the initial anatomical circumstances as closely as possible, though they can never be viewed as a 100% equivalent replacement. This also means that implants are not intended to last forever.

However, thanks to the high quality of the materials used and the exceptional precision with which they are manufactured, hip prostheses have a long lifespan (duration of implantation).

There are a variety of factors that can affect the progression and success of implantation. These may include skeletaldisorders (e.g. osteoporosis, tumours, bowlegs or knock knees), organic impairments and metabolic disorders. Over-/underweight, excessive alcohol/drug use, smoking, and excessive physical stress (through heavy labour or certain types of sport) can all affect implants as well (see ▸ Factors interfering with success).



What is a hip prosthesis?

A hip prosthesis is an **artificial implant** used to replace a damaged or diseased hip joint. It is typically composed of four main components **Stem – Head – Inlay – Cup** that work together to restore normal hip function and reduce pain. The following sections explain each of these four components in more detail:

Cup

The cup (acetabular cup) replaces the natural socket of the hip joint.

It is fixed into the pelvic bone and holds the inlay and head.

Often made of metal, it can have a special coating that helps the bone grow onto it for long-lasting stability.

Inlay

The inlay (or liner) is placed inside the cup.

It creates a smooth surface between the head and the cup, ensuring the artificial joint moves smoothly.

Inlays are typically made of polyethylene, ceramic, or metal, depending on the desired wear resistance and durability.

Head

The head is the round ball attached to the top of the stem.

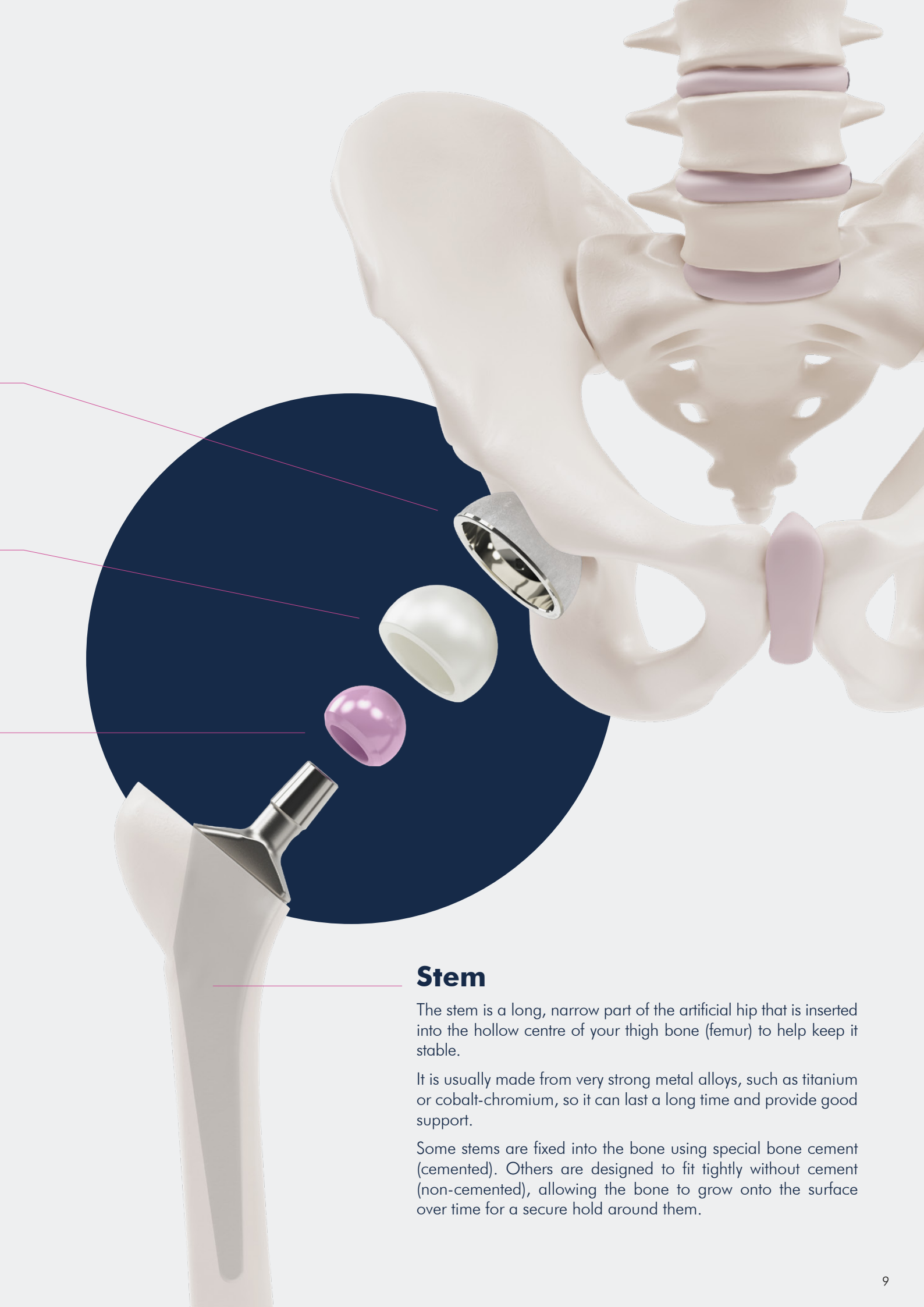
It replaces the natural femoral head and fits into the inlay of the cup, allowing smooth movement.

Heads are made of metal or ceramic and come in different sizes to suit individual needs.

BiPolar Head

(mainly in hip fractures)

A bipolar head is a special type of prosthesis head, mainly used in partial hip replacements, often for hip fractures. It has a metal shell (usually cobalt-chromium alloy) with an inner inlay made of polyethylene or ceramic. Inside this inlay, a smaller head (metal or ceramic) moves, creating two points of motion: one inside the shell and one in the patient's natural hip socket. It is often used when the patient's own socket is still intact.



Stem

The stem is a long, narrow part of the artificial hip that is inserted into the hollow centre of your thigh bone (femur) to help keep it stable.

It is usually made from very strong metal alloys, such as titanium or cobalt-chromium, so it can last a long time and provide good support.

Some stems are fixed into the bone using special bone cement (cemented). Others are designed to fit tightly without cement (non-cemented), allowing the bone to grow onto the surface over time for a secure hold around them.

Treatment options in hip replacement surgery

Partial and total hip replacement

When joint damage requires surgical intervention, either a partial hip replacement or a total hip replacement may be performed, depending on the extent of the damage and the patient's condition.

In medical terms, these are called partial endoprosthesis (PEP) and total endoprosthesis (TEP).

Partial Endoprosthesis (PEP)

- Replaces only the damaged part of the joint.
- Example: replacing the femoral head while keeping the natural socket.
- **Possible advantages:** may be less invasive and can sometimes allow quicker recovery.
- **Possible disadvantages:** in some cases, a total hip replacement may still be needed later if the joint deteriorates further.

Total Endoprosthesis (TEP)

- Replaces the entire joint.
- Example: replacing stem, femoral head and socket.
- **Possible advantages:** may be more durable and can improve function in severe cases.
- **Possible disadvantages:** usually involves a bigger surgery and recovery may take longer.

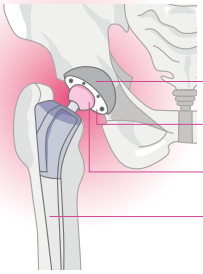
Cemented vs. non-cemented hip replacement

We distinguish between two main types of hip implants: cemented and non-cemented. This refers to how the implant is fixed in the bone. Sometimes, a combination of both methods is used – this is called a hybrid fixation.

Non-cemented prostheses are implanted directly into the bone without cement. The prosthesis has a special surface that comes in direct contact with the bone and is designed to encourage bone growth. Over time, this creates a secure connection between the implant and the bone.

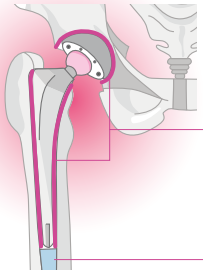
Cemented prostheses are implanted using bone cement, which prevents bone-implant contact. Because of this, cemented prostheses do not have a coating, their surfaces are smooth.

Each prosthesis component is available in different sizes, so it can be adapted to your individual anatomy. Which implant and which type of fixation are right for you depends on your personal situation, the condition of your bone, and your level of activity. Your physician will decide this together with you.



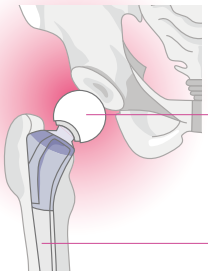
Non-cemented hip prosthesis

1. Cup
2. Inlay
3. Head (ceramic or metal)
4. Hip stem



Cemented hip prosthesis

1. Bone cement
2. Cement stopper



Hip prothesis with bipolar head (in natural hip socket)

1. Bipolar head
   (Outer head: Cobalt-Chromim,
   Inlay: polyethylene or ceramic,
   Inner head: metal or ceramic)
2. Hip stem

Hip revision surgery

Primary surgery vs. revision surgery

- **Primary surgery**
  Primary hip replacement surgery involves replacing the natural hip joint with an artificial implant for the first time. It is typically recommended when conservative treatments have failed to relieve pain or restore mobility.
- **Revision surgery**
  Hip revision surgery refers to replacing some or all components of an existing artificial hip joint. Revisions may be necessary in the following cases:
  - **Wear and tear**
    Even with normal use, materials can degrade over time, potentially loosening the prosthesis within a few years.
  - **Bone conditions**
    Poor biological conditions of the bone tissue, osteoporosis, or deterioration due to peripheral diseases may compromise implant stability.
  - **Accidents and overloading**
    Trauma, joint overuse, or lifting heavy loads can lead to loosening or damage.

Patients are advised to avoid activities that may overload the joint or cause sudden shocks (e.g. high-impact sports) to prolong the implant's lifespan (see ▸ Factors interfering with success).

In **some revision surgeries**, only certain parts of the artificial hip need to be replaced. For example, if the **cup or inlay in the hip socket becomes loose** but the stem in the thigh bone is still firmly fixed, only the socket parts (cup, inlay or head) may need to be changed while the stem can stay in place. In such cases, the **BioBall® Adapter System** may be used. With the help of a small adapter (connector), the surgeon can attach a new head to the existing stem, which can make the surgery less extensive and may reduce strain on the bone.

What is the BioBall® System?

The BioBall® System is **a modular hip implant system** made up of an **adapter** and a **matching head,** which can be either ceramic or metal. Different sizes and shapes are available so the implant can be adjusted to fit each patient's needs.

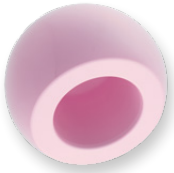
It is mainly used **in revision surgeries** when the stem in the thigh bone is still firmly fixed and does not need to be removed. In some cases, it can also be used during first-time hip surgery to make adjustments during the operation.

Hip revision surgery with the BioBall® System

In many hip revision surgeries, **the head needs to be replaced** while the stem in the thigh bone is still firmly in place and does not need to be removed. However, the connection between the stem and the hip head has already been used and may no longer hold a new head securely. In these cases, an **adapter is needed** – the BioBall® Adapter to create a stable connection for the new head without removing the stem.

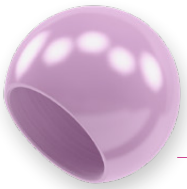
How does it work?

The BioBall® Adapter **connects the new hip head** (made of ceramic or metal) **to your already implanted stem**. This way, the stem can stay in place. At the same time, your surgeon can make small adjustments to restore your hip movement as naturally as possible.



BioBall® Ceramic Head

BioBall® Metal Head



The BioBall® Heads

Once the adapter is in place, a new femoral head – made of ceramic or metal – is attached.

The BioBall® Adapters

The BioBall® Adapter is a small connector, made of titanium alloy, which is used in hip replacement surgery, especially during revision procedures.

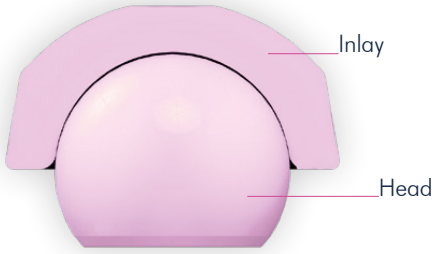
- It attaches securely to the hip stem that is already fixed in your bone.
- Different adapter sizes and angles allow your surgeon to fine-tune leg length, joint stability, and soft-tissue balance.

Head and inlay material options

Together with the inlay inside the cup, it forms a **smooth pair** that allows the hip joint to glide freely in all directions. Different material combinations for the smooth pair are possible, and they can be used in the following ways:

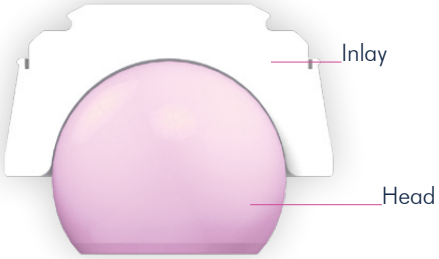
Ceramic head – ceramic inlay

This option is generally regarded as having very low wear and high biocompatibility. The smooth, scratch-resistant surface works well with the body's own fluids, which can help the joint move smoothly. However, with ceramic components a small risk of fracture can never be ruled out entirely.



Ceramic head – polyethylene inlay

Polyethylene is the most commonly used inlay, and doctors have the most experience with it. It can allow smooth motion and may produce fewer wear particles compared to other combinations.



Metal head – polyethylene inlay

This is the most traditional combination and has been used safely for many years. It can provide reliable function and good stability, though over time it may create more wear particles compared to ceramic heads.

The appropriate head and material combination depends on your individual situation, the condition of your hip, age and activities. Your physician will decide together with you which option is most suitable.

4. Before surgery

Before your surgery, your surgeon/medical team will explain the procedure to you.

You will receive:

- **a general description of how the surgery will be performed,**
- **information about possible risks,**
- **and instructions on what you should do before and after the operation.**

It is important that you are also aware of **factors that could affect the success of your surgery** (see ▸ Factors interfering with success). Complications may include implant problems such as dislocation, loosening, or implant failure. These can be caused by different reasons, for example if the bone does not grow firmly around the implant (lack of osseointegration), if the load on the implant changes, or if the cement or surrounding tissue reacts to the implant or its wear particles.

In addition, there are risks that generally come with any surgical procedure, including anaesthesia. If ceramic components are used, a small risk of fracture always remains, even if it is rare.

You will also be informed about what you can do yourself to reduce risks and support the healing process. Your surgeon will explain possible alternative treatment methods and other implant systems that may be suitable.

Your surgeon will explain all **possible risks and side effects** (see ▸ Technical product information) to you, including those related to the implant as well as the general risks of surgery. If you have not received this information or if anything is unclear, please consult your surgeon.

All information discussed with you will be documented by your surgeon in writing.

Your personal diagnosis

Before your surgery, careful planning is carried out with the help of X-rays and computer-assisted sketches. This allows your surgical team to determine the right size and position of your hip prosthesis. Measurements such as leg length and spinal alignment are also checked to ensure the best possible planning and to reduce risks.

In revision surgeries, this planning is especially important because existing implants and bone conditions must be taken into account.

Physical examination

In order for the operation to be successful, the treating physician needs to know the patient's medical history, including any medications the patient takes, any acute infections the patient is experiencing, and any chronic conditions such as diabetes, circulatory disorders, or allergies.

You can also help improve the success of your operation by optimizing your overall condition (see chapter 6 ▸ After surgery and chapter 7 ▸ Tips for everyday living with a prosthesis). Use targeted exercises to strengthen your tendons and muscles. Your physiotherapist will show you suitable exercises. Swimming and cycling are also appropriate. However, excessive exercise can shorten the life of the prosthesis. If you are a smoker, do not use nicotine. These harmful substances stress the cardiovascular system and prolong the healing process. Excessive alcohol consumption may also reduce the useful life of your implant.

Packing list for your hospital stay

To make your hospital stay easier, here are some important things you may want to bring with you. Please check which of these apply to you:

- ◯ Insurance card (public) / Hospital card (private insurance – regular or supplemental)
- ◯ Doctor's referral form
- ◯ Contact information for family doctor or referring physician
- ◯ Medication list and/or medications for your first day
- ◯ Current X-rays (physical or digital copies)
- ◯ Current medical reports
- ◯ Current laboratory results
- ◯ Medical IDs, such as: Marcoumar ID, allergy ID, X-ray ID, pacemaker ID, diabetic ID, antenatal card
- ◯ For dialysis patients only: bring your dialysis medications with you (e.g. phosphate binders)
- ◯ Contact details for your loved ones
- ◯ Pyjamas
- ◯ Bathrobe
- ◯ Toiletries (toothbrush, soap, lotion, etc.)
- ◯ Comfortable, flat, non-slip shoes
- ◯ Loose, comfortable casual clothing
- ◯ Glasses, hearing aid, dentures (if applicable)
- ◯ Reading material or something to pass the time
- ◯ Small amount of cash / bank card for personal needs
- ◯ Earplugs or headphones (optional, for quieter rest)
- ◯ Bag or backpack
- ◯ _____
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Please note that hospital packing lists may vary by region and depend on the specific healthcare system in each country.

5. Day of surgery

Anaesthesia

The operation is performed under general or spinal anaesthesia. Spinal anaesthesia usually has less effect on your overall condition, but it is only suitable if you can tolerate being awake in the operating room. Your anaesthesiologist will meet with you to discuss which form of anaesthesia is best for your individual procedure.

Surgical Procedure

Accessing the joint

The surgeon makes an incision through the skin and tissue to reach the hip joint. In a revision surgery, previously implanted components are exposed so that they can be checked and, if necessary, replaced. In primary surgeries, the patient's natural femoral head is removed to prepare the joint.

Replacing the acetabular cup (if needed)

If the acetabular cup (the cup in the hip socket) is loose or worn, the damaged parts are removed and the bone is carefully prepared for a new cup. The surgeon then places a new prosthesis cup into the pelvis. In some cases, if the existing cup is stable, it may not need to be replaced.

Checking or retaining the prosthesis stem

In many revision surgeries, the stem in the thigh bone is still firmly fixed and does not need to be removed. If it is stable, the surgeon will also check whether it can be used together with a **BioBall® Adapter**. If the stem is suitable, it will remain in place. If a new stem is required, the thigh bone is prepared so that the new stem can be inserted securely. Temporary trial implants may be used to check leg position and stability before the final implant is placed.

In the recovery room

Immediately after surgery, you will be taken to the recovery room, where nurses and anaesthesiologists monitor you closely and give fluids or pain medication if needed. Once your condition is stable, you will be moved back to your hospital room.

Establishing the joint connection with the BioBall® System

This is the key step for using the **BioBall® System**. If the stem is retained, a BioBall® Adapter is attached to the existing stem, and a new head (ceramic or metal) is placed on the adapter. The head is then fitted into the prosthesis cup. The surgeon then checks the function and positioning, often using X-ray imaging during the operation.

Completion of surgery

At the end of the operation, the surgeon closes the wound using staples or sutures. A drainage tube may be placed to prevent fluid build-up and is usually removed after one to two days.

The length of the surgery varies depending on your individual situation.

6. After surgery

Follow-up treatment – pain therapy and early mobilization

In the first days after surgery, effective pain treatment is very important. Doctors and nurses can use different methods such as pain pumps, catheters, or well-tolerated medications to keep you comfortable. Your wound dressings will also be changed daily.

You will usually begin moving with the help of crutches soon after surgery. In many cases, full weight bearing is already possible, but the exact timing and how long you will need crutches depend on your individual situation. Your doctor will give you personal instructions.

Follow-up treatment – rehabilitation and physiotherapy

After leaving the hospital, most patients continue their recovery with rehabilitation. This can be done either as an inpatient in a rehab clinic or at home with outpatient physiotherapy. Because mobility is reduced right after surgery, the hip, leg, and back muscles need to be strengthened again. Physiotherapy exercises are designed to help you rebuild muscle strength and restore normal movement.

Follow-up visits

After your hip replacement surgery, you should come for regular follow-up examinations as frequently as your surgeon and treating physician recommend. These visits will include a physical examination and a check-up on your mobility and musculature. Your treating physician should also take an x-ray for monitoring purposes.

Check-ups should occur at least once a year.

Make sure to contact your doctor immediately if any new, persistent pain or symptoms develop so that any potential complications can be detected early on.

7. Tips for everyday living with a prosthesis

Getting used to a new prosthesis can take time. New prosthesis users sometimes report mild "weather sensitivity" in their new joint. Others may notice a slight clicking feeling or other sensations in their hip.

The artificial joint contains metal. For this reason, metal detectors can react accordingly. In such cases, your implant card can be used to explain why the detector reacted (see next chapter ▸ The implant card).

Having an artificial hip certainly does not mean you have to avoid all sport and leisure activities. It merely means restricting them to reasonable levels appropriate for the artificial joint. Sports that are easier on the joints, such as biking, swimming, hiking, walking, and golf, are recommended.

Patients whose work involves lifting or carrying heavy loads, bending or squatting for long periods of time, or walking long distances on uneven or slippery surfaces may need to adjust their work activities or, in some cases, consider changing jobs.

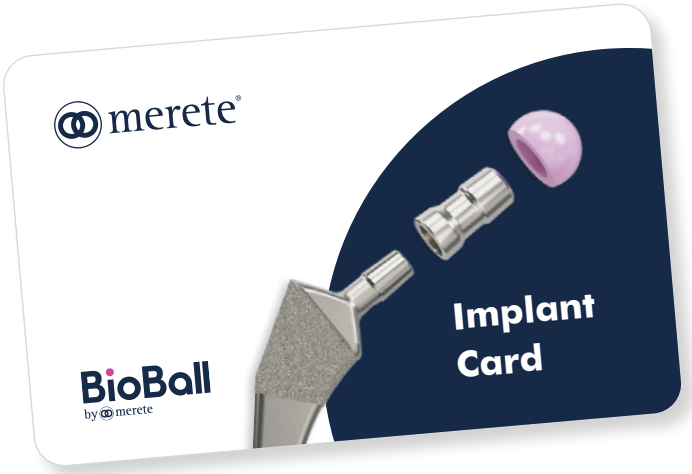
Patients who primarily work seated should find chairs with ergonomically shaped seats, armrests and back supports that facilitate prolonged sitting.

Ball sports such as football, handball, and volleyball put high stress on artificial hips and are therefore generally not recommended.

8. The Implant Card

Implant Cards are documents providing evidence that a joint has been replaced using an implant made of a foreign material (such as metal components). This Implant Card specifies which type of prosthesis was used when and where.

Prosthesis users should always carry this Implant Card with them so that they have proof of their implanted prosthesis. This may be important, for example, in airport security checks, or for some diagnostic procedures, such as MRI magnetic resonance imaging (see ▸ Additional product Information: BioBall® MRI safety information).



Exemplary Implant Card

CAUTION

- Have your Implant Card filled out by your treating healthcare institution / provider before you are discharged from hospital.
- Please arrange regular check-ups with your physician (at least once a year.)
- Please discuss the extent of your sporting activities with your physician.
- Please avoid an extensive increase in weight because the mechanical wear is also dependent on the body weight.
- In case of an infection like nephritis, furuncle etc. please consult your physician immediately, because an artificial joint has no defence against infection.
- Always carry your Implant Card with you.

Explanation of symbols on the Implant Card

	Name of the patient or patient ID. *To be filled by the healthcare institution/ provider.*
	Date of implantation. *To be filled by the health care institution/provider.*
	Name and address of the health-care institution/provider. *To be filled by the healthcare institution/provider.*
	Displays a website where a patient can obtain additional information on the medical device.
DT	Device Type of the implanted medical product

Symbols on the patient label which is stuck on the Implant Card

DT	Device Type
MD	Medical Device Name
UDI	Indicates a carrier that contains Unique Device Identifier Information
REF	Catalogue number
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date after which the medical device may no longer be used
STERILE R	Indicates a medical device that has been sterilized by irradiation
	MR Conditional
Mat	Material of the medical device
Size	Size of the implant
	Manufacturer
CE 0482	CE-Mark

9. FAQs (What do you need to know)

As a patient, I would like to learn about prostheses beforehand. Where can I find more information?

You can find further information in this brochure and on the website **labeling.merete.de**. If you have additional questions, please contact your treating physician.

What is the difference between primary and revision surgery?

Primary surgery is the first time an artificial hip is implanted. Revision surgery usually means replacing parts of an existing implant, for example when only the head needs to be changed but the stem stays in place (see chapter 3 ▸ Hip revision surgery).

What materials are used in hip prostheses?

Hip prostheses are usually made of body-friendly metal alloys (such as titanium or cobalt-chromium), ceramics (such as BIOLOX®), or polyethylene (a durable plastic) (see chapter 3 ▸ What is a hip prosthesis?).

How long does a hip implant last?

Hip implants are designed for long-term use. Many last 15 years or more, but the actual lifetime varies depending on age, activity level, and overall health (see ▸ Technical product information).

What is the BioBall® Adapter used for?

The BioBall® Adapter allows the surgeon to place a new head on an existing hip stem without removing the stem. Depending on your individual situation this can make the surgery less extensive and may reduce invasiveness (see chapter 3 ▸ Hip revision surgery).

Is the BioBall® System right for you?

Not every patient is a candidate for this system. Your surgeon will decide whether it is suitable for you, based on your individual situation, your bone quality, and your overall health and whether a suitable BioBall® Adapter is available for the stem that has already been implanted.

I will need to undergo an MRI for another medical examination in the near future. Will my hip prosthesis affect the MRI?

You should always inform the MRI site that you have a hip prosthesis. Merete hip prostheses can generally be scanned safely in MRI systems, but only under certain conditions (see ▸ Additional product Information: BioBall® MRI safety information).

Are Merete hip prostheses suitable for me as an extreme athlete?

Merete hip endoprostheses are mainly intended for patients with relatively low activity levels. Very intense or extreme sports can shorten the lifetime of an implant (see chapter 6 ▸ After surgery and chapter 7 ▸ Tips for everyday living with a prosthesis).

Can hip prostheses be used in children?

Merete hip implants are generally designed for patients whose bone growth is complete, and therefore they are usually not suitable for children. In exceptional cases, however, the BioBall® System may be used in children if the treating surgeon decides it is appropriate (see ▸ Technical product information).

Who can I contact if serious incidents occur with the implant?

Start by contacting your treating physician directly. You can also report serious incidents to the manufacturer or to the competent authority of the Member State concerned – in Australia, for example, report to the TGA.

> Therapeutic Goods Administration (TGA)
> PO Box 100
> Woden ACT 2606
> Australia
> www.tga.gov.au

And who can I contact in Germany?
It is best to contact the manufacturer's responsible notified body or BfArM.

> Federal Institute for Drugs and Medical Devices (BfArM)
> Waisenhausgasse 36-38a
> 50676 Cologne

What does CE stand for?

The CE mark is the manufacturer's declaration that a product complies with the applicable EU-level requirements. If a notified body has confirmed the conformity of a product, that product must be marked with the CE mark and a four-digit identification number.

10. Glossary of technical terms

Acetabular cup
The artificial part of a hip prosthesis that replaces the natural acetabulum (hip socket).

Acetabulum
The natural "socket" of the hip joint, located in the pelvis. It holds the head of the femur (thigh bone).

Adapter (BioBall Adapter)
A small connector that is attached to an existing hip stem. It enables the surgeon to place a new prosthesis head without removing the hip stem.

Anaesthesiologist
A specially trained doctor who uses anaesthesia to put the patient to sleep during the operation. The anaesthesiologist monitors and adjusts the patient's anaesthesia throughout the entire procedure.

BIOLOX®
A brand of high-quality ceramic material commonly used for prosthesis heads and inlays. It is generally smooth, scratch-resistant, and well tolerated by the body.

Bipolar head
A special type of prosthesis head, mainly used in partial hip replacements. It consists of a metal shell (usually cobalt-chromium alloy) with an inner bearing made of polyethylene or ceramic. Inside this bearing, a smaller head (metal or ceramic) moves, creating two points of motion: one inside the shell and one in the natural hip socket.

Cement stopper (restrictor)
A small device placed inside the thigh bone during a cemented hip replacement. It stops the bone cement from moving too far down the bone canal and helps the cement stay in the right position to secure the stem of the hip implant.

Ceramic
A high-quality, scratch-resistant material used for prosthesis heads and inlays. Ceramic surfaces are very smooth and body-friendly, allowing the joint to glide well.

CE mark
A symbol showing that a product complies with European Union safety and quality requirements.

Cobalt-chromium (CoCr)
A very strong, durable metal alloy often used in prosthesis stems and heads.

Cup see Acetabular cup

Endoprosthesis (hip implant)
A medical term for an artificial hip joint. It replaces parts of the natural hip joint that are damaged or diseased. Depending on the extent of damage, either a partial endoprosthesis (e.g. replacing only the femoral head) or a total endoprosthesis (replacing stem, head and socket) may be used.

Femur
The thigh bone, the longest bone in the human body.

Head (femoral head)
The round ball component of the prosthesis. It connects to the stem and moves inside the cup so the hip can glide smoothly.

Hip replacement
A surgical procedure in which parts of the damaged or diseased hip joint are replaced with an artificial implant.

Inlay (liner)
The insert that sits inside the cup. It creates a smooth surface for the head to move against.

MRI (magnetic resonance imaging)
MRI can be used to visualise pathological changes in soft tissues (heart, abdominal organs, brain), joints and muscles. It uses magnetic fields to make the inside of the body visible layer by layer. Unlike X-rays o CT (computer tomography) scans, the body is not exposed to radiation.

Notified Body

It is an organisation designated by an EU to check that certain medical products meet the legal requirements before they can be marketed. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.

Osseointegration

The process in which bone tissue grows onto the surface of an implant, anchoring it securely in place.

Polyethylene (PE / XPE)

A long-lasting plastic material used to manufacture implants, e.g. inlays inside the cup. It provides a smooth surface for the prosthesis head to move against.

Primary surgery (hip)

The first time an artificial hip joint is implanted.

Prosthesis (implant)

An artificial device that replaces or supports a part of the body. A hip prosthesis is an implant used in hip replacement surgery to restore function and reduce pain. It usually consists of four parts: stem, head, inlay, and cup.

Recovery room

A room or area with special monitoring equipment where the patient recovers until the anaesthesia wears off and they can return to their hospital room.

Revision (hip surgery)

It means the complete or partial replacement of any component of an artificial hip joint.

Stem (prosthesis stem)

The long, narrow part of the prosthesis that is placed inside the femur (thigh bone). It supports the head and connects it securely to the bone.

Titanium alloy

A lightweight metal alloy commonly used for medical implants like stems and other prosthesis parts. The body tolerates titanium alloy well, so it is often used in implants that will remain in the body either temporarily or permanently.

Vivium® (alloy)

A high-nitrogen stainless steel alloy used for certain implants. Its microstructure makes it non-magnetic and well tolerated by the body. It is often used in small screws or highly mobile prostheses.

Additional product information

BioBall® technical product information

General product description

The BioBall® System consists of a titanium alloy BioBall® Adapter which is combined with a fitting BioBall® Metal Head or BioBall® Ceramic Head. The main indication is the revision with well-fitted prosthesis hip stems. The system may also be used for primary interventions in order to make intra-operative corrections. Different adapter geometries and head materials can be used to deal with the individual fitting situation in the case of a revision without having to remove implants that are still firmly embedded. The BioBall® Adapter allows intra-operative correction of neck length as well as antetorsion/retrotorsion and lateralisation/medialisation on in situ stems.

The BioBall® System is a modular system for the surgical care of patients in revision or primary hip surgery with different neck lengths and angle adjustments.

Standard and Offset BioBall® Adapters

- BioBall® Adapters are available in different lengths in Standard and Offset versions
- Made of a titanium alloy
- Can be combined with metal and ceramic heads
- Available for 11 different stem taper geometries
-

BioBall® Heads

- BioBall® Heads are designed for combination with the BioBall® Standard and Offset Adapters
- Available in two different materials (BIOLOX® delta Ceramic and Vivium®)
- Available in 9 different diameters

Materials/chemical composition

Chemical composition TiAl6V4 ELI according to ISO 5832-3

%	Ti	Al	V	Fe	O	C	N	H
Min.	–	5.5	3.5	–	–	–	–	–
Max.	rest	6.5	4.5	0.25	0.13	0.08	0.05	0.012

Chemical composition BIOLOX® delta according to ISO 6474-2

%	Al203	ZrO2+HfO2	HfOs in ZrO2	Additve
Min.	72	24	5	1.51
Max.	76	25.5	–	1.87

Chemical composition Vivium® according to ISO 5832-9

%	C	Si	Mn	P	S	N	Cr	Mo	Ni	Nb	Cu
Min.	–	–	2.00	–	–	0.25	19.50	2.00	9.00	0.25	–
Max.	0.08	0.75	4.25	0.0025	0.01	0.50	22.00	3.00	11.00	0.08	0.25

System compatibility

BioBall® Adapter for stem taper 12/14, 14/16, MSV4 (except Offset 2XL and 3XL), MSZI, MSSY and MS 10/12 can be combined with both BioBall® Metal Heads and BioBall® Ceramic Heads. All other BioBall® Adapters are only approved for combination with a BioBall® Metal Head.

BIOLOX® delta is a registered trademark of CeramTec GmbH.
Vivium® is a registered trademark of Merete GmbH (High Nitrogen Stainless Steel DIN ISO 5832-9).

Intended purpose

The BioBall® Adapters are for use as a spare part in hip revision operations in combination with a BioBall® Head. The BioBall® System (Adapters & Heads) serves to preserve the existing anchored hip stem or total hip endoprosthesis (Hip TEP). The BioBall® Adapter 12/14 can also be used during the primary operation for correcting positioning with only the approved stems of the Merete GmbH.

Intended user

The products may only be used by qualified surgeons in the field of orthopaedics, trauma or reconstructive surgery or surgeons with equal qualification and experience. To ensure the success of the operation, it is essential that the surgeon is familiar with the surgical technique recommended for this system and applies this technique with great care.

Indications

- Bearing couple revisions
- Intraoperative correction of offset, neck length, lateralisation and anteversion/retroversion with anchored prosthesis stem
- BioBall® Adapter 12/14: intraoperative correction of offset, neck length, lateralisation and anteversion/retroversion during primary operation as well

Contraindications

- Acute or chronic infections in the hip joint or the immediate vicinity
- Patients with joint diseases that may be successfully treated with another, joint salvage treatment
- Any comorbidities that could pose a risk to the function or success of the implant, especially severe muscular, nervous, or vascular disorders with specific effects on the limb to be operated upon
- Severely damaged in-situ stem tapers (visible changes in shape, or palpable defects, such as localized wear, abrasion/material loss, or scratches/ridges) or implants which cannot be clearly identified
- Allergies to any of the materials used

Factors interfering with success

- Obesity or pre-obesity
- Local bone tumours
- Osteoporosis or osteomalacia
- Malformations, congenital hip dislocation, severe axial displacement of the knee
- Systemic or metabolic disorders
- Smoking, Alcohol or drug abuse
- Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sport)
- Patients with pathological mental or neurological conditions, or patients who are not capable of following the necessary post-operative care instructions

Possible side effects

- Early or late onset infections
- Dislocation, subluxation, insufficient range of motion, undesired shortening or lengthening of the affected extremities as a result of suboptimal implant positioning
- Bone fractures due to unilateral overuse or weakened bone substance
- Reduced bone density due to stress shielding or bone resorption as a tissue response to abrasion particles
- Tissue reactions, osteolysis and loosening of the implant due to metal corrosion or accumulation of abrasive particles or loose cement
- Corrosion with local tissue reactions or pain
- Aseptic loosening
- Noise development (“squeaking”)
- Corrosion and fretting
- Local tissue reactions and hypersensitivity
- Dissociation of modular components
- Temporary or permanent nerve damage due to pressure or hematoma
- Wound hematoma and delayed wound healing

- Vascular disorders, including vein thrombosis, pulmonary embolism and heart failure
- Heterotopic ossification
- Nerve damage as a result of surgical trauma

With ceramic components, a risk of fracture can never be ruled out entirely. The following factors can increase this risk:

- Obesity or pre-obesity
- Alcohol or drug abuse
- Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sport)

MRI examinations may affect your hip implant. For detailed information on MRI safety see chapter ▸ Additional product information: BioBall® MRI safety information.

Expected lifetime

The expected lifetime of the BioBall® System is 15 years. However, the lifetime in situ is influenced by the physical activity of the patient and his physiology, too.

Precautions and warnings

Use of implants contrary to intended purpose

Risk of injury due to implant failure!

➔ Implants must only be used in accordance with intended purpose.

Combination of BioBall® Adapters with hip stems with neck insertion system

Risk of injury due to premature implant failure!

➔ BioBall® Adapters must not be combined with hip stems that use a neck insertion system.

Use of damaged or defective implants

Risk of injury due to premature implant failure!

➔ Implants with identifiable damage may not be used.

➔ Avoid notches, scratches or bending of the implant in order to preserve its stability.

Use of implant/instrument contrary to intended use

Damage to/destruction of implant/ instrument and injury to patient!

➔ Ensure correct handling of implant/instrument. Do not misuse.

Use of implants which have been previously used

Risk of injury due to premature implant failure!
Risk of sepsis!

➔ Implants are only approved for single use, not repeated use.

Foreign bodies (e.g. cement residues, tissue, bones) between implant components

Risk of injury due to implant failure!

➔ Thoroughly clean any foreign bodies from implant components.

Combination with products from other manufacturers

Risk of injury due to implant failure (e.g. implant loosening, fretting or corrosion)!

➔ BioBall® Adapters may only be combined with stem tapers after taper specifications have been clearly identified and matched.

Combination of implant components of different sizes

Damage to implant components!

➔ Combine only components of the same size.

Combination with over-long heads

Risk of injury due to implant failure!

➔ Impaired component safety due to higher lever forces.

Damage to head

Risk of implant failure!

➔ Never strike the head or the adapter directly with a hammer.

➔ It is advisable to secure the head in place with light hammer blows in an axial direction on the head impactor.

Damage to taper connection

Risk of implant failure!

➔ Ensure careful implantation.

➔ Do not use damaged implants.

Foreign bodies in the taper connection

Risk of implant failure!

➔ Thoroughly clean all foreign bodies from the taper connection.

Breaking of ceramic components

Risk of injury due to implant failure!

➔ When performing revision surgery following breakage of a ceramic component, do not use metal heads.

➔ Replacement component must also be a ceramic head.

Risk of infection due to non-sterile implants!

➔ Do not use implants whose packaging is damaged.

➔ Do not use implants whose expiry date has passed.

Use of soiled implants

Risk of sepsis!

➔ Use only implants without identifiable soiling.

➔ Handle implants only with sterile surgical gloves.

Resterilisation of implants

Risk of injury due to premature implant failure caused by adverse material changes!

➔ Implants delivered sterile by Merete GmbH must not be resterilised and/or repacked.

➔ Products whose expiry date has passed may be returned to Merete GmbH.

Use of instruments with electrical energy

Risk of injury due to implant failure!

➔ Do not damage the surfaces of the implants under any circumstances.

BioBall® MRI safety information

The BioBall® System consists of a titanium alloy BioBall® Adapter which is combined with a fitting BioBall® Metal Head or BioBall® Ceramic Head. The main indication is the revision with well-fitted prosthesis hip stems. The system may also be used for primary interventions in order to make intra-operative corrections. Different adapter geometries and head materials can be used to deal with the individual fitting situation in the case of a revision without having to remove implants that are still firmly embedded. The BioBall® Adapter allows intra-operative correction of neck length as well as antetorsion/retrotorsion and lateralisation/medialisation on in situ stems.

Please share the following MRI safety information with your MRI team:

Non-clinical testing has demonstrated that the Merete Hip Implant System (consisting of cemented or non-cemented hip stem, taper adapter, metal or ceramic head ball, inlay and cup from the materials unalloyed Titanium (ISO 5832-2), TiAl6V4 ELI (ISO 5832-3), Vivium® (ISO 5832-9), CoCrMo (ISO 5832-4/ 5832-12), BIOLOX® delta ceramic (ISO 6474-2), UHMWPE/XPE (ISO 5834-2)) is **MR conditional**. A patient with the entire assembled Merete Hip Implant System can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) at 1.5 Tesla or 3.0 Tesla of 1 W/kg for 15 minutes of scanning. Under the scan conditions defined above, the Merete Hip Implant System is expected to produce a maximum temperature rise of less than 6° C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the Merete Hip Implant System extends at least 1cm and up to approximately 8 cm from the device and exhibits geometric distortion in the image when imaged with a gradient echopulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

Manufacturer

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A PDF of this patient information can be found here:

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