

Your new artificial hip joint

Patient information leaflet

Introduction



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, Berlin Tempelhof

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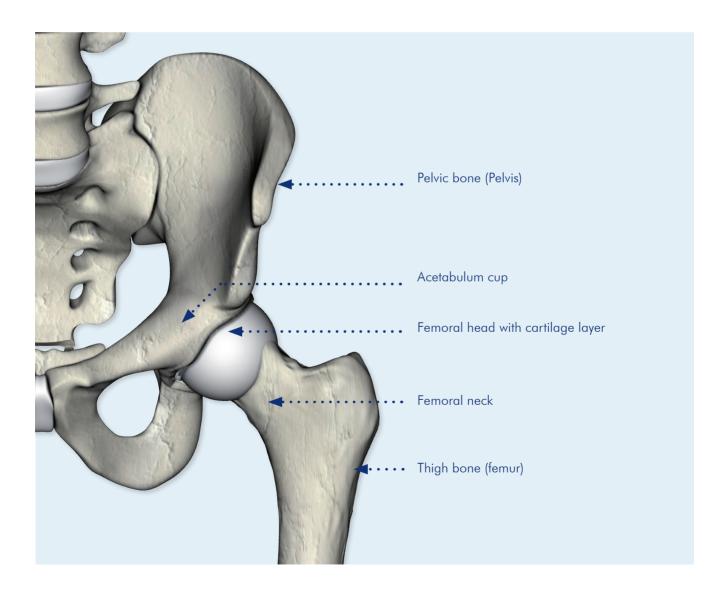
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1. The natural hip joint

Anatomical structure

The hip joint is the largest joint in the human body, and the one under the most stress. When we walk, the load-bearing areas of the hips can experience pressure loads more than double our 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, which runs together with the pelvic bone. The acetabulum is composed of the iliac bone (Os ilium), the pubic bone (Os pubis) and the ischium (Os ischii). A thick, protective cartilage layer (hyaline cartilage) covers the joint connecting the acetabulum 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. The artificial hip joint

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, leaving bone 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 endoprostheses 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. These include:

- 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

- Rheumatoid arthritis (chronic polyarthritis)

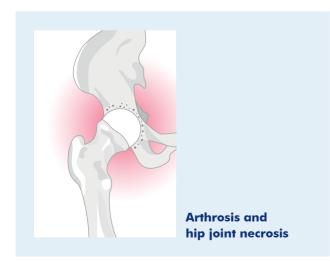
Inflammatory changes to the hip joint (e.g. due to rheumatic diseases or bacteria spread through the bloodstream) can also lead to permanent destruction of the joint structure

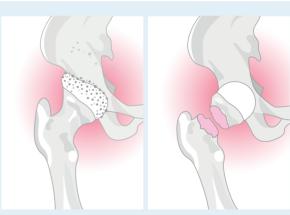
- Malformation / Deformity of the hip joint (hip dysplasia)

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





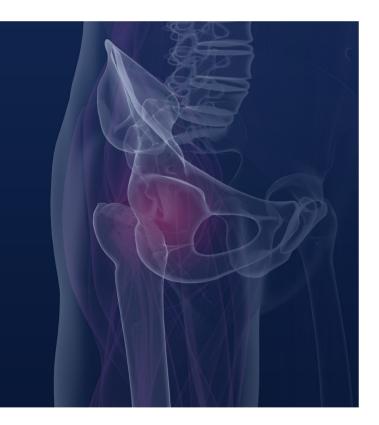
Hip dysplasia-related arthrosis

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 Chap. 6).

3. Implants

The last 25 years have seen significant advances in hip replacement surgery. 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 endoprostheses not only allow joint reconstruction, but can also restore pain-reduced movement in the human hip.

Endoprostheses 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 endoprostheses have a long lifespan (duration of implantation). At present, an average service life of between 15 and 20 years is presumed for all protheses, regardless of model. In some cases, this can even be significantly higher.

There are a variety of factors that can affect the progression and success of implantation. These may include skeletal disorders (e.g. osteoporosis, tumours, bow legs 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.

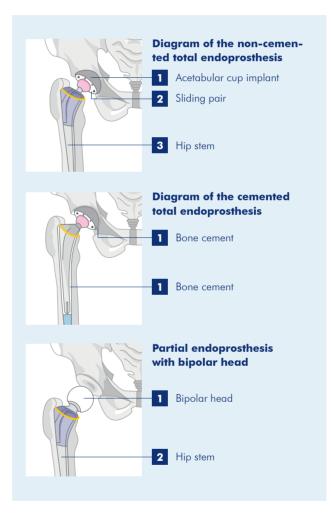
Restoration options

We distinguish between two types of endoprosthetic components: cemented and non-cemented. This refers to how the implants are fixed into position. Using a mixture of the two is known as hybrid restoration.

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 promote bone growth; over time, this creates a secure connection.

Cemented prostheses are implanted using cement, which prevents bone-implant contact. As such, cemented cups do not have a coating - their surfaces are smooth. Each prosthesis component is available in a variety of diameters / dimensions, which makes it possible to adjust to the patient's individual anatomical situation.

Which implant and which type of fixation are right for you depends on your initial situation, the condition of your bone tissue, and your level of activity; the decision is up to your physician.



Cup restorations

Duo head restorations

Typically used together with a prosthesis stem to treat fractures. The advantage is that there is no need to prepare the intact acetabular bed.



BioBall® Duo Head Bipolar -Femoral head bipolar component

- bipolar head for non-cemented restorations
- The outer shell, inlay and inner head are pre-assembled
- The outer shell and head are made of a forged titanium alloy; the inlay is plastic
- available in 17 different sizes from ø 42 mm to ø 58 mm
- Product is registered in Australia



Bipolar TwinSet™ Cup

- bipolar head for non-cemented restorations
- The outer shell and inlay are pre-assembled, the head is attached during the operation
- The outer shell is made of a titanium forged alloy; the inlay is plastic, and the head is available in either ceramic or a titanium forged alloy
- available in 17 different sizes from ø 42 mm to ø 58 mm

Intended Purpose

Bipolar Heads, in combination with the appropriate system components, serve to restore pain free joint function within the framework of hemiarthroplasty after pathological or accidental defects in the hip joint. Bipolar Heads are inserted into the natural acetabulum.

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
- Allergies to any of the materials used
- Insufficient quality of the natural acetabulu

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 labor, 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

The side effects listed below are among the most common adverse effects of implantation procedures:

- Loosening of the implant system resulting from changed conditions of the load transfer or wearing and fracture of the cement bed
- Tissue reactions, osteolysis, loosening of the implant system and pain due to metal corrosion, fretting or accumulation of abrasive particles or loose cement
- Failure or subsidence of the implant in case of over-loading
- 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 (intra- or periprosthetic 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
- Local tissue reactions, hypersensitivity, allergies and pain
- Migration (bipolar heads)
- Dissociation of the neck and head junction
- Dissociation of modular components
- Noise development (ceramic noise)
- Pseudotumor formation
- Edge loading and stripe wear
- Temporary or permanent nerve damage due to pressure or haematoma
- Wound haematoma and delayed wound healing
- Vascular disorders, including vein thrombosis, pulmonary embolism, and heart failure

- Heterotopic ossification
- Nerve damage as a result of surgical trauma

Bipolar Heads are inserted into the natural acetabulum. This leads to wear and tear of the acetabulum.

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

sive loads (e.g. hard physical labor, certain types of sport)

- Obesity or pre-obesityAlcohol or drug abuse
- Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or exces-

Non-cemented cups

In non-cemented restorations, unlike in duo head restorations, the cup implant is inserted into the pre-prepared acetabulum.

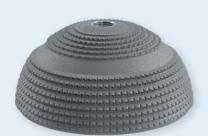
PressFit Cup

is oversized to a defined degree in order to secure it within the pelvis. These are self-contained acetabular systems with a variety of different cup sizes and matching inlays designed to be used with different sliding pairs. The rough surface texture and (in some cases) additional coating help the bone grow onto the implant.



Intended Purpose

The BioBall[®] MaxiMotion[™] Cup System provides primary, trauma and geriatric care for hip diseases and restoration of joint stability. The system is designed for both primary and revision procedures.



EpiCup™ acetabulum Cup

- non-cemented restoration with plastic inlay
- consists of pure titanium and an enlarged surface
- available in 14 different sizes from ø 44 mm to ø 70 mm

Intended Purpose

The non-cemented EpiCup[™] acetabular cups and associated EpiCup[™] inlays from Merete GmbH in combination with the appropriate system components (heads and hip stems), serve to restore pain free joint function of the hip after pathological or traumatic defects of the hip joint.

Screw cup

is screwed into the pelvis.



WM-Cup[™]

- non-cemented restoration with choice of plastic or ceramic inlay
- made of a forged titanium alloy
- available in 12 different sizes from ø 44 mm to ø 62 mm

Intended Purpose

The non-cemented WM-Cup[™] acetabular cups and associated WM-Cup[™] inlays from Merete GmbH, in combination with the appropriate system components (heads and hip stems), serve to restore pain free joint function of the hip after pathological or traumatic defects of the hip joint.

Cemented cups

As with non-cemented restoration, cemented restoration differs from duo head restoration in that the cup implant is inserted into the pre-dissected acetabulum cup - in this case, using cement.



BioBall[®] MaxiMotion[™] Cup

- cemented restoration with plastic inlay and pre-pressed head, available in ceramic or metal
- made of a forged titanium alloy
- available in 12 different sizes from ø 46 mm to ø 68 mm

Intended Purpose

The BioBall[®] MaxiMotion[™] Cup System provides primary, trauma and geriatric care for hip diseases and restoration of joint stability. The system is designed for both primary and revision procedures.

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
- Insufficient implant bed which precludes its secure anchoring (e.g. insufficient bone quality that prevents bone ingrowth, or major acetabular defects)
- 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
- 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

The side effects listed below are among the most common adverse effects of implantation procedures:

Loosening of the implant resulting from lack of osseointegration, changed conditions of the load transfer or wearing and fracture of the cement bed and/or tissue reaction of the implant and the associated abrasion products

- Failure or subsidence of the implant in case of over-loading
- Early or late onset infections
- Dislocation, subluxation, insufficient range of motion, undesired shortening or lengthening of the affected extremity 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
- Temporary or permanent nerve damage due to pressure or haematoma
- Wound haematoma 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
- 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)

Stem restorations

Stem implants direct forces into the thigh bones with every step. The prosthesis head is attached to the stem implant. Here, too, we distinguish between cemented and non-cemented restorations.

Non-cemented restorations



Z-Stem[™] hip stem

- non-cemented restoration in which the stem is specially designed to be wedged into the bone
- made of a forged titanium alloy
- can be combined with metal and ceramic heads
- available in 14 different sizes, lengths 129 mm to 191 mm



IntraBlock™ TwinStem™ hip stem

- non-cemented stem with an additional coating in the upper area to ensure good implant-bone contact
- made of a forged titanium alloy
- can be combined with metal and ceramic heads
- available in 8 different sizes, lengths 130 mm to 162 mm

Intended Purpose

The non-cemented hip stems from Merete GmbH, in combination with the appropriate system components (Head/BioBall® System with 12/14 taper by Merete specification), serve to restore pain free joint function of the hip after pathological or traumatic defects of the hip joint.

Cemented restorations



IntraBlock[™] TwinStem[™] hip stem

- cemented stem anchored into the bone using cement
- made of a forged titanium alloy
- can be combined with metal and ceramic heads
- available in 8 different sizes, lengths 130 mm to 162 mm

Intended Purpose

The cemented hip stems from Merete GmbH, in combination with the appropriate system components (Head / BioBall[®] System with 12/14 taper by Merete specification), serve to restore pain free joint function of the hip after pathological or traumatic defects of the hip joint.

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
- Insufficient implant bed which precludes its secure anchoring, especially when the shaft is to be anchored in diaphysis only with concomitant metaphyseal defect
- 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
- Patient's body mass exceeding 65 kg (applies to Z-Stem size 00 and size 01 only)
- 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

The side effects listed below are among the most common adverse effects of implantation procedures:

- Loosening of the implant resulting from lack of osseointegration, changed conditions of the load transfer or wearing and fracture of the cement bed and/or tissue reaction to the implant and the associated abrasion products

- Failure or subsidence of the implant e.g. in case of over-loading
- Implant failure due to corrosion and fretting
- Early or late onset infection
- Dislocation, subluxation, insufficient range of motion, undesired shortening or lengthening of the affected extremity as a result of suboptimal implant positioning
- Dissociation of the modular head/adapter neck junction
- Bone fractures (intra- or peri-prosthetic 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 and allergies to the products of corrosion or wear and cement particles
- Temporary or permanent nerve damage due to pressure or haematoma
- Wound haematoma 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)

Revision

Revision means replacing some or all of the components of an artificial hip joint. Revisions are only necessary if the implant has been in place long enough to wear down, if the biological conditions of the patient's bone tissue are not optimal, or if bone condition has worsened due to peripheral disease. Accidents or joint overloading may make revision procedures necessary as well.

Even with normal use, however, material wear and tear can cause the prosthesis to loosen after just a few years, making its replacement necessary. Overweight, osteoporosis, accidents, overloading and lifting heavy loads can all result in loosening of the prosthesis as well. Therefore, it is important for patients to avoid overloading the joint or playing certain types of sport that could result in shocks.

Adapter head system

Approximately 20% of revision cases involve loosened acetabular cups with hip stems that are still firmly anchored. However, depending on how long the implant has been in place, the stem taper may have already worn down to the point that a new head cannot be attached directly. Adapter-head systems make it possible to avoid having to remove the stem in such cases



BioBall® Adaptor – Femoral head/stem prosthesis

BioBall DELTA™ Ceramic Head – Ceramic femoral head prosthesis

BioBall® Metal Head Vivium – Metallic femoral head prosthesis

- adapter-head system
- made of a forged titanium alloy
- can be combined with metal and ceramic heads
- available in various sizes and lengths
- products are registered in Australia

Intended Purpose

BioBall® Adapters 12/14, 14/16, MS 8/10, MS 10/12, MSZI, MSV4, MST1, MSBG, MSPC, MSSR and MSSY are for use as a replacement part in hip revision operations in combination with a BioBall® head. They serve 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.

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 localised 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

The side effects listed below are among the most common adverse effects of implantation procedures:

- 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 haematoma
- Wound haematoma 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)

Sliding pairs

In non-cemented restorations, the cup inlay and the prosthesis head form the sliding pair, whereas in duo-head restoration, the prosthesis head articulates directly within the cup. This interplay is what makes movement possible, as the femoral head can rotate in all possible directions within the counter bearing.

A wide variety of materials are used to form sliding pairs; they can be used together in the combinations described here.

Ceramic head – ceramic inlay

This sliding pair has the lowest abrasion and the highest degree of biocompatibility. This means that the smooth and scratch-resistant surface is well moistened with the body's own liquids, which allows good gliding behaviour. However, in rare cases (due to a fall, for example), the ceramic may break.

Ceramic head - polyethylene inlay/metal head - polyethylene inlay

Polyethylene is the most commonly used inlay, so medical professionals have the most experience with it. Combining it with a ceramic head allows smoother sliding motion and causes fewer wear particles to form.

4. Before surgery

Your personal diagnosis

Before the operation, a computer-aided planning sketch is created with the help of an X-ray in order to determine the ideal stem size, cup size, head size and position for the patient's individual prosthesis. Measuring leg length and spinal stability helps ensure optimum planning with the lowest possible level of risk.

Physical examination

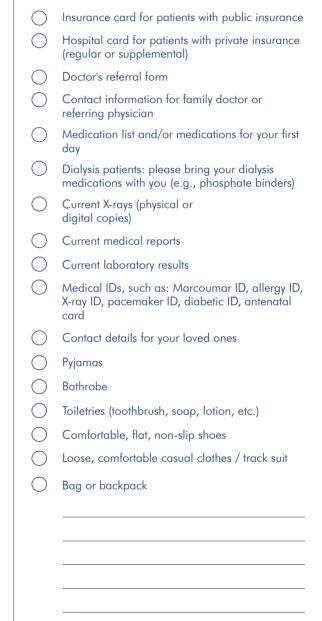
In order for the operation to be successful, the treating physician needs to know the patient's medical history, including any medications the patient takes, any acute infections the patient is experiencing, and any chronic conditions such as diabetes, circulatory disorders, or allergies.



You can also help improve the success of your operation by optimising your overall condition. 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 or tar. 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

We have put together a small list of important things you should bring to the hospital with you:



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5. Day of surgery

Artificial hip surgeries are routine procedures. After anaesthesia, the surgeon accesses and prepares the patient's natural joint and implants the artificial hip. After that, the surgeon closes the wound, and the patient is moved to the recovery room.

Anaesthesia

The operation is performed under general or spinal anaesthesia. Spinal anaesthesia affects patients' overall condition less significantly, but it can only be used in patients who handle the operating room atmosphere well in general. Your anaesthesiologist will meet with you to discuss which form of anaesthesia is best for your individual procedure.

The subsequent surgical steps are nearly identical for cemented and non-cemented hip endoprostheses.

Accessing and preparing the implant bed

The hip joint is accessed by making an incision in the skin down to the hip joint capsule. The hip joint, which is located behind soft tissue, ligaments, and bands of muscle, is exposed. After that, the patient's natural femoral head is separated from the thigh bone and then removed from the natural socket.

Acetabulum cup implantation

To insert the prosthesis cup into the damaged acetabulum, the surgeon removes the damaged cartilage layer in order to create space for the prosthesis cup to be implanted in. The worn acetabulum cup is milled to the correct diameter, and then the surgeon aligns the prosthetic cup and implants it into the patient's pelvis.

Inserting the prosthesis stem into the bone

The patient's thigh bone needs to be prepared as well, so that the prosthesis stem can be inserted. The surgeon uses medullary cavity rasps to expand the inside of the thigh bone to the exact size of the prosthesis being used. The surgeon uses trial implants in order to check correct leg position (and reposition if needed). The non-cemented implantation procedure involves pressing the prosthesis into the cancellous bone (bone marrow) until it is seated firmly.

Establishing the joint connection

The femoral head is attached to the taper of the prosthesis stem and fitted into the prosthesis cup. The surgeon uses imaging technology to re-check joint function and make sure the prosthesis is seated perfectly.

Conclusion of surgery

At the end of the operation, the surgeon closes the wound and then uses staples or suture material to keep the skin closed. The surgeon places drainage tubing while closing the wound in order to prevent seeping blood or wound secretions from building up around the surgical site. These drainage tubes will be removed after a day or two.

The whole operation takes about 60 to 120 minutes in all.

In the recovery room

Immediately after surgery, a specially trained team of nurses and anaesthesiologists monitors and cares for the patient in the recovery room. Infusions and pain medication are administered as needed. The patient is moved back to their hospital room once their overall condition has stabilised.



6. After surgery

Follow-up care – pain therapy

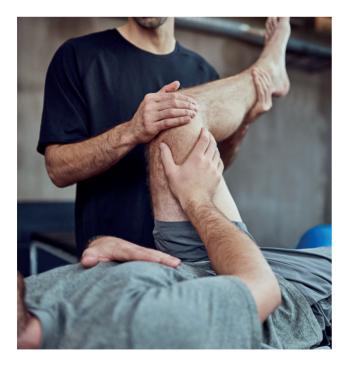
The early stages of post-operative care include extensive pain therapy. Medical professionals have a wide variety of state-of-the-art pain catheters, analgesic pumps, and other well-tolerated medications at their disposal. Doctors and trained nursing staff change the patient's dressings daily.

Non-cemented endoprosthesis recipients are usually mobilised on the second day after the operation, using two crutches with full joint loading for the next 4-6 weeks.

Follow-up care – Rehabilitation / physiotherapy

Most patients undergo follow-up treatment after leaving the hospital. They may do this inpatient at a rehabilitation hospital, or at home on an outpatient basis.

Having had restricted mobility during and immediately after the procedure causes patients' hip, leg, and back muscles to change. Physiotherapeutic methods and exercises are designed to help patients rebuild and normalise their musculature.





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.

6. After surgery

Tips for everyday living with a prosthesis

Getting used to a new prosthesis can take more than a year. 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.

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. We recommend types of sport that are easier on joints, such as biking, swimming, hiking, walking, and golf.



Ball sports such as football, handball, and volleyball are not suitable for artificial hips, as they involve putting alternating loads on the hip joint.

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 will most likely need to change jobs. Patients who primarily work seated should find chairs with ergonomically shaped seats, armrests and back supports that facilitate prolonged sitting.

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 when which type of prosthesis was used where. Postoperative follow-up visits are also recorded here.

Prosthesis users should always carry this Implant Card with them so that they have proof of their endoprosthesis. This may be important, for example, in airport security checks, or for other diagnostic procedures (such as magnetic resonance imaging) partly or wholly incompatible with endoprostheses.



7. What you need to know

FAQs

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

For detailed information about the implant, see the manufacturer's website (www.merete-medical.com).

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 reponsible notified body or BfArM.

Federal Institute for Drugs and MedicalDevices (BfArM)Waisenhausgasse 36-38a50676 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.

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

Merete hip prostheses can be scanned in MRI systems safely under certain conditions. The MR environment must meet certain conditions.

MRI Safety Information/Indications for Use

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 TiAl6V4 ELI (ISO 5832-3), Vivium® (ISO 5832-9), CoCrMo (ISO 5832-4/5832-12), BIOLOX® delta ceramic (ISO 6474-2), PE/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 1 cm and up to approximately 8 cm from the device and exhibits geometric distortion in the image when imaged with a gradient echo pulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

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

Merete hip endoprostheses are designed for patients with relatively low activity levels, as excessive sport can reduce the life of the implants (see Chap. 3 and 6).

Can the endoprostheses be used in children?

Merete hip implants are designed with completed bone growth in mind, so they are not suitable for children.

Glossary of technical terms

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.

Recovery room –

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

Notified Body -

a private testing centre designated by the EU and supervised by the state, which acts on behalf of manufacturers to check the conformity of implants or other products.

Implant -

any artificial product that supports or replaces bodily functions and is intended to remain in the body on a long-term or permanent basis. Common orthopaedic implants include staples, plates, nails, and prosthetics.

MRI –

stands for magnetic resonance imaging (MRI), which 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 with CT (computer tomography), the body is not exposed to radiation.

Polyethylene (PE) -

a long-lasting plastic used to manufacture implants and many other products, such as packaging or pipes. It is one of the most commonly produced plastics in the industry.

Revision –

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

Titanium alloy –

a metallic material containing a large amount of the raw material titanium. The body tolerates titanium well, so it is often used in implants that will remain in the body either temporarily or permanently.

Cup restorations

Duo head restorations

BioBall® Duo Head Bipolar – Femoral head bipolar component

Cup and Head: Vivium® (DIN ISO 5832-9) Inlay: UHMWPE (DIN ISO 5834-2)

Bipolar TwinSet[™] Cup, incl. locking ring

Shell: Vivium[®] (DIN ISO 5832-9) Inlay and locking ring: UHMWPE (DIN ISO 5834-2)



Outer diam.	Head diam.	Ref.
42 mm	28 mm	HM30342
43 mm	28 mm	HM30343
44 mm	28 mm	HM30344
45 mm	28 mm	HM30345
46 mm	28 mm	HM30346
47 mm	28 mm	HM30347
48 mm	28 mm	HM30348
49 mm	28 mm	HM30349
50 mm	32 mm	HM30350
51 mm	32 mm	HM30351
52 mm	32 mm	HM30352
53 mm	32 mm	HM30353
54 mm	32 mm	HM30354
55 mm	32 mm	HM30355
56 mm	32 mm	HM30356
57 mm	32 mm	HM30357
58 mm	32 mm	HM30358



Outer diam.	Ref.		
42 mm	HT00242		
43 mm	HT00243		
44 mm	HT00244		
45 mm	HT00245		
46 mm	HT00246		
47 mm	HT00247		
48 mm	HT00248		
49 mm	HT00249		
50 mm	HT00250		
51 mm	HT00251		
52 mm	HT00252		
53 mm	HT00253		
54 mm	HT00254		
55 mm	HT00255		
56 mm	HT00256		
57 mm	HT00257		
58 mm	HT00258		

Non-cemented cups

PressFit Cup

BioBall[®] MaxiMotion[™] Cup with TPS and BONIT[®], non-cemented

Vivium[®] (DIN ISO 5832-9)

Size	Ref.
Ø 46	HM35346
Ø 48	HM35348
Ø 50	HM35350
Ø 52	HM35352
Ø 54	HM35354
Ø 56	HM35356
Ø 58	HM35358
Ø 60	HM35360
Ø 62	HM35362
Ø 64	HM35364
Ø 66	HM35366
Ø 68	HM35368



BioBall[®] MaxiMotion[™] XPE inlay with BioBall[®] metal head, Ø 28 mm

Head: Vivium® (DIN ISO 5832-9) Inlay: UHMWPE (DIN ISO 5834-2)

Size	Ref.
Ø 46	HM35069
Ø 48	HM35070
Ø 50	HM35071
Ø 52	HM35072
Ø 54	HM35073
Ø 56	HM35074
Ø 58	HM35075
Ø 60	HM35076
Ø 62	HM35077
Ø 64	HM35078
Ø 66	HM35079
Ø 68	HM35080



BioBall[®] MaxiMotion[™] XPE inlay with BioBall DELTA[™] ceramic head, Ø 28 mm

Head: BIOLOX® delta ceramic Inlay: UHMWPE (DIN ISO 5834-2)

Size	Ref.
Ø 46	HM35669
Ø 48	HM35670
Ø 50	HM35671
Ø 52	HM35672
Ø 54	HM35673
Ø 56	HM35674
Ø 58	HM35675
Ø 60	HM35676
Ø 62	HM35677
Ø 64	HM35678
Ø 66	HM35679
Ø 68	HM35680

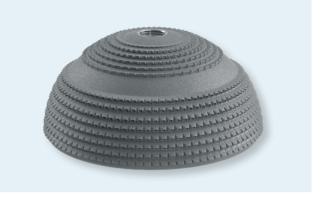


with pre-assembled Ø 28 mm BioBall DELTA™ ceramic head

EpiCup™

Pure titanium grade 2, ISO 5832-2

Size	Ref.
44 mm	HP30144
46 mm	HP30146
48 mm	HP30148
50 mm	HP30150
52 mm	HP30152
54 mm	HP30154
56 mm	HP30156
58 mm	HP30158
60 mm	HP30160
62 mm	HP30162
64 mm	HP30164
66 mm	HP30166
68 mm	HP30168
70 mm	HP30170



EpiCup™ Inlay Standard

Crosslinked UHMWPE, ISO 5834-2



	Ref.
Size	XPE
44/22 mm	HP31103
44/28 mm	HP31104
46/28 mm	HP31105
48/28 mm	HP31106
48/32 mm	HP31107
50/28 mm	HP31108
50/32 mm	HP31109
52/32 mm	HP31110
52/36 mm	HP31111
54/32 mm	HP31112
54/36 mm	HP31113
56/32 mm	HP31114
56/36 mm	HP31115
58/32 mm	HP31116
58/36 mm	HP31117

	Ref.
Size	XPE
60/32 mm	HP31118
60/36 mm	HP31119
62/32 mm	HP31120
62/36 mm	HP31121
64/32 mm	HP31122
64/36 mm	HP31123
66/32 mm	HP31124
66/36 mm	HP31125
68/32 mm	HP31126
68/36 mm	HP31127
70/32 mm	HP31128
70/36 mm	HP31129

EpiCup™ Inlay HighWall

Crosslinked UHMWPE, ISO 5834-2



	Ref.
Size	XPE
44/22 mm	HP31303
44/28 mm	HP31304
46/28 mm	HP31305
48/28 mm	HP31306
48/32 mm	HP31307
50/28 mm	HP31308
50/32 mm	HP31309
52/32 mm	HP31310
52/36 mm	HP31311
54/32 mm	HP31312
54/36 mm	HP31313
56/32 mm	HP31314
56/36 mm	HP31315
58/32 mm	HP31316
58/36 mm	HP31317

	Ref.
Size	XPE
60/32 mm	HP31318
60/36 mm	HP31319
62/32 mm	HP31320
62/36 mm	HP31321
64/32 mm	HP31322
64/36 mm	HP31323
66/32 mm	HP31324
66/36 mm	HP31325
68/32 mm	HP31326
68/36 mm	HP31327
70/32 mm	HP31328
70/36 mm	HP31329

8. Product list

Screw cup

WM-Cup™

WM-Cup: TiAl6V4 ELI (DIN EN ISO 5832-3) Ceramic inlay: BIOLOX® delta Plastic inlay: UHMWPE (DIN ISO 5834-2)

				BIOLOX	® delta ceran	nic inlay XLW	18 Zero	
		F	HF92836	HF92838	HF92840	HF93240	HF93244	HF93644
WM-Cup™			Ø 28 /36	Ø 28 /38	Ø 28 /40	Ø 32 /40	Ø 32 /44	Ø 36 /44
S	HW14436	WM-Cup™ 44 /36	X					
	HW14638	WM-Cup™ 46 /38		X				
Σ	HW14840	WM-Cup™ 48 /40			X	Х		
3	HW15040	WM-Cup™ 50 /40			X	Х		
	HW15244	WM-Cup™ 52 /44					Х	Х
	HW15444	WM-Cup™ 54 /44					Х	Х
	HW15644	WM-Cup™ 56 /44					Х	X
	HW15844	WM-Cup™ 58 /44					X	Х
	HW16044	WM-Cup™ 60 /44					X	Х
	HW16244	WM-Cup™ 62 /44					Х	Х

			MWM II XPE-Inlay Standard					
			HF72836	HF72840	HF73240	HF73244	HF73644	
TM			Ø 28 /36	Ø 28 /40	Ø 32 /40	Ø 32 /44	Ø 36 /44	
WM-C∪p™	HW14436	WM-Cup™ 44 /36	x					
O	HW14640	WM-Cup™ 46 /40		x	x			
Ś	HW14840	WM-Cup™ 48 /40		x	x			
5	HW15040	WM-Cup™ 50 /40		х	x			
>	HW15044	WM-Cup™ 50 /44				x	x	
	HW15244	WM-Cup™ 52 /44				x	x	
	HW15444	WM-Cup™ 54 /44				x	x	
	HW15644	WM-Cup™ 56 /44				x	x	
	HW15844	WM-Cup™ 58 /44				x	x	
	HW16044	WM-Cup™ 60 /44				x	x	
	HW16244	WM-Cup™ 62 /44				x	x	

			MWM II XPE Inlay High Wall				
			HF82836	HF82840	HF83240	HF83244	HF83644
TW			Ø 28 /36	Ø 28 /40	Ø 32 /40	Ø 32 /44	Ø 36 /44
wM-C∪p™	HW14436	WM-Cup™ 44 /36	x				
v	HW14640	WM-Cup™ 46 /40		x	x		
Ś	HW14840	WM-Cup™ 48 /40		x	x		
5	HW15040	WM-Cup™ 50 /40		x	x		
>	HW15044	WM-Cup™ 50 /44				x	x
	HW15244	WM-Cup™ 52 /44				x	x
	HW15444	WM-Cup™ 54 /44				x	x
	HW15644	WM-Cup™ 56 /44				x	x
	HW15844	WM-Cup™ 58 /44				x	x
	HW16044	WM-Cup™ 60 /44				x	x
	HW16244	WM-Cup™ 62 /44				x	x

Cemented cups

BioBall[®] MaxiMotion[™] Cup, cemented

TiAl6V4 ELI (DIN EN ISO 5832-3)

Size	Ref.
Ø 46	HM35146
Ø 48	HM35148
Ø 50	HM35150
Ø 52	HM35152
Ø 54	HM35154
Ø 56	HM35156
Ø 58	HM35158
Ø 60	HM35160
Ø 62	HM35162
Ø 64	HM35164
Ø 66	HM35166
Ø 68	HM35168



Stem restorations

Non-cemented restorations

Hip stem Z-Stem[™] 12/14

TiAl6V4 ELI (DIN EN ISO 5832-3)



Size	Standard CCD: 131°	Lateral CCD: 123°
01	HS15021	HS15121
00	HS15020	HS15120
1	H\$15001	HS15101
2	HS15002	HS15102
3	HS15003	HS15103
4	HS15004	HS15104
5	HS15005	HS15105
6	HS15006	HS15106
7	HS15007	HS15107
8	HS15008	HS15108
9	HS15009	HS15109
10	HS15010	HS15110
11	HS15011	HS15111
12	HS15012	HS15112

IntraBlock[™] TwinStem[™], non-cemented

TiAl6V4 ELI (DIN EN ISO 5832-3) with TPS coating, or with TPS coating and BONIT®



TPS co	pating	TPS coating and BONIT®		
Standard Lateral		Standard	Lateral	
HR35006	HR31006	HR36006	HR37006	
HR35007	HR31007	HR36007	HR37007	
HR35008	HR31008	HR36008	HR37008	
HR35010	HR31010	HR36010	HR37010	
HR35011	HR31011	HR36011	HR37011	
HR35012	HR31012	HR36012	HR37012	
HR35013	HR31013	HR36013	HR37013	
HR35015	HR31015	HR36015	HR37015	

Cemented restorations

IntraBlock™ TwinStem™, cemented

Vivium[®](CrNiMnMo alloy in accordance with DIN ISO 5832-9)



Standard	Lateral
HR33006	HR34006
HR33007	HR34007
HR33008	HR34008
HR33010	HR34010
HR33011	HR34011
HR33012	HR34012
HR33013	HR34013
HR33015	HR3415

8. Product list

Revision

BioBall® Adaptor – Femoral head/stem prosthesis adaptor

Material: TiAl6V4 ELI





Standar	d 14/16						
0							
		BioBall™ A	dapter Syst	tem Standar	d 14/16		
Neck length	M (0)	L (+3.5)	XL (+7.0)	2XL (+10.5)	3XL (+14.0)	4XL (+17.5)	5XL (+21.0)

HM30145

HM30146

HM30147

HM30148

HM30144

Offset 14/16		Ì		
Bi	oBall™ Adapter	System Offse	t 14/16	
Neck length	2XL (+10.5)	3XL (+14.0)	4XL (+17.5)	5XL (+21.0)
Offset (mm)	1.4	1.5	2.0	2.5
Ref.	HM30445	HM30446	HM30447	HM30448

HM30143

HM30142

Ref.

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MS 8/10 Standard

Neck length	Ref.		
S (-3.0)	HM32121		
M (0)	HM32122		
L (+3.5)	HM32123		
XL (+7.0)	HM32124		
2XL (+10.5)	HM32125		

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MS 10/12 Standard

Neck length	Ref.
S (-3.0)	HM30101
M (0)	HM30102
L (+3.5)	HM30103
XL (+7.0)	HM30104
2XL (+10.5)	HM30105
3XL (+14.0)	HM30106

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSZI Standard

Neck length	Ref.
S (-3.0)	HM33121
M (0)	HM33122
L (+3.5)	HM33123
XL (+7.0)	HM33124
2XL (+10.5)	HM33125
3XL (+14.0)	HM33126

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MST1 Standard

Neck length	Ref.		
M (0)	HM36002		
L (+3.5)	HM36003		
XL (+7.0)	HM36004		
2XL (+10.5)	HM36005		
3XL (+14.0)	HM36006		

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSV4 Standard

Neck length	Ref.		
M (0)	HM34122		
L (+3.5)	HM34123		
XL (+7.0)	HM34124		
2XL (+10.5)	HM34125		
3XL (+14.0)	HM34126		

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MS 8/10 Offset

Neck length	Offset (mm)	Ref.
M (0)	1.1	HM32222
L (+3.5)	1.2	HM32223
XL (+7.0)	1.3	HM32224
2XL (+10.5)	1.5	HM32225

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MS 10/12 Offset

Neck length	Offset (mm)	Ref.
M (0)	1.1	HM30202
L (+3.5)	1.2	HM30203
XL (+7.0)	1.3	HM30204
2XL (+10.5)	1.5	HM30205
3XL (+14.0)	2.0	HM30206

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MST1 Offset

Neck length	Offset (mm)	Ref.
M (0)	1.1	HM36022
L (+3.5)	1.2	HM36023
XL (+7.0)	1.3	HM36024
2XL (+10.5)	1.5	HM36025
3XL (+14.0)	2.0	HM36026

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSV4 Offset

Neck length	Offset (mm)	Ref.
M (0)	1.1	HM34222
L (+3.5)	1.2	HM34223
XL (+7.0)	1.3	HM34224
2XL (+10.5)	1.5	HM34225
3XL (+14.0)	2.0	HM34226

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSBG Standard

Neck length	Ref.
M (0)	HM31142
L (+3.5)	HM31143
XL (+7.0)	HM31144
2XL (+10.5)	HM31145

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSSR Standard

Neck length	Ref.
M (0)	HM31152
L (+3.5)	HM31153
XL (+7.0)	HM31154

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSPC Standard

Neck length	Ref.
M (0)	HM31132
L (+3.5)	HM31133

BioBall[®] Adapter – Femoral head/stem prosthesis adaptor MSSY Standard

Neck length	Ref.
S (-3.0)	HM37121
M (0)	HM37122
L (+3.5)	HM37123
XL (+7.0)	HM37124

BioBall® Metal Head Vivium – Metallic femoral head prosthesis

BioBall DELTA™ Ceramic Head – Ceramic femoral head prosthesis



Ref.	Ø	
HM30028	28 mm	
HM30032	32 mm	
HM30033	33 mm	
HM30035	35 mm	
HM30036	36 mm	
HM30038	38 mm	

Material: BIOLOX® delta¹ ceramic

Ref.	Ø
HM50028	28 mm
HM50032	32 mm
HM50036	36 mm
HM50040	40 mm
HM50044	44 mm
HM50048	48 mm

¹ BIOLOX[®] delta is a registered trademark of CeramTec GmbH.

² Vivium[®] is a registered trademark of Merete GmbH (High Nitrogen Stainless Steel ISO 5832-9).

Heads

Ceramic heads

BIOLOX® delta 12/14



Neck length	Ø 28 mm	Ø 32 mm	Ø 36 mm
S	HB51228	HB51232	HB51236
М	HB52228	HB52232	HB52236
L	HB53228	HB53232	HB53236
XL	_	HB54232	HB54236

Metal heads

HipBall™ Premium heads CoCrMo 12/14



Neck length	Ø 28 mm	Ø 32mm	Ø 36 mm
S	HK11228	HK11232	HK11236
Μ	HK21228	HK21232	HK21236
L	HK31228	HK31232	HK31236
XL	HK41228	HK41232	HK41236
2XL	HK51228	HK51232	-
3XL	HK61228	HK61232	-
4XL	HK71228	HK71232	_

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