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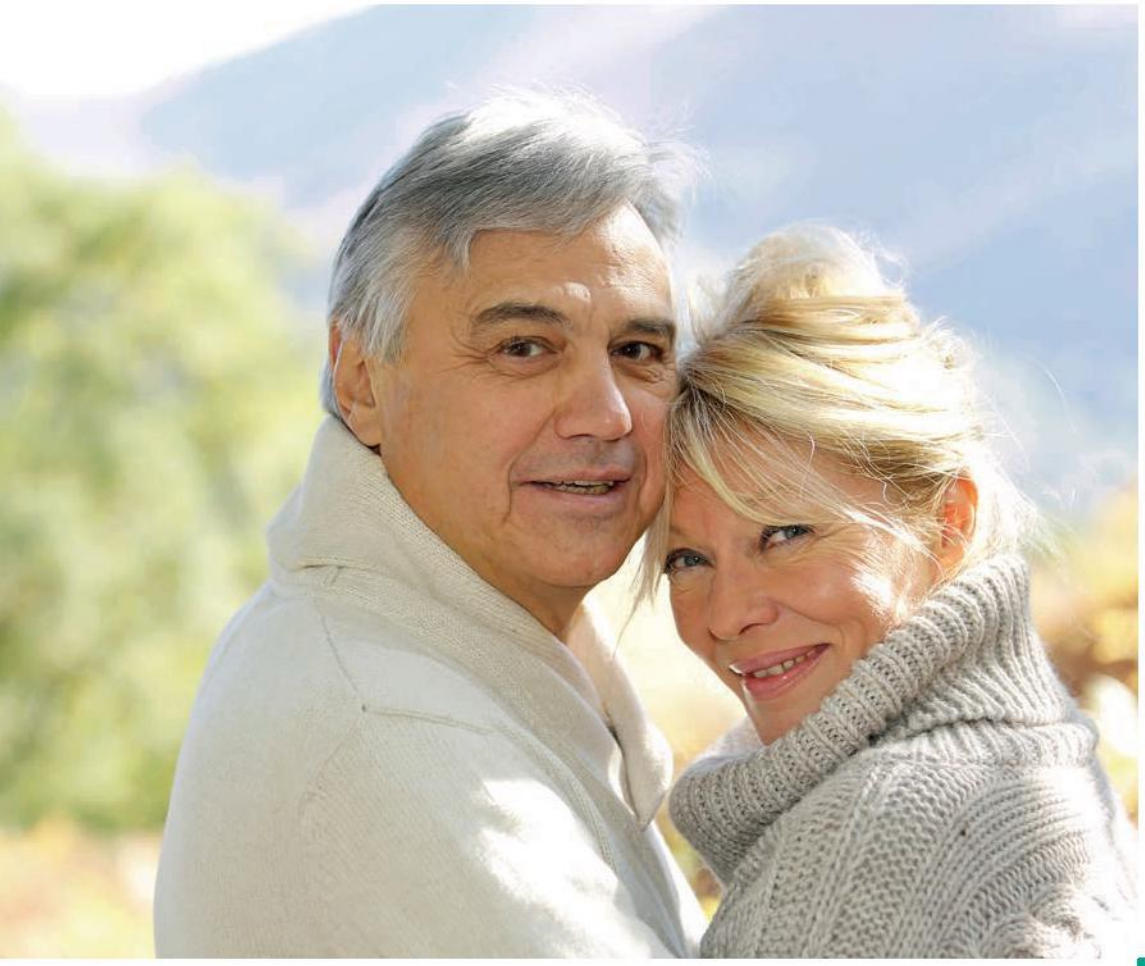
SHARING EXPERTISE



ORTHOPAEDIC SURGERY

AESCULAP® PATIENT INFORMATION

HIP JOINT REPLACEMENT

PATIENT INFORMATION(1)

WHAT MATERIALS DOES YOUR BODY COME INTO CONTACT WITH?

MATERIALS AND SUBSTANCES

The artificial hip joint is made of medically suitable implant materials (2). Hip stems and acetabular cups are made of titanium, cobalt-chromium-molybdenum or stainless steel alloys. Hip prosthesis heads are made of cobalt-chromium alloy or ceramic and cup inserts are made of polyethylene or ceramic. You can obtain information on the implanted materials from your doctor with your arthroplasty passport.
If parts of your artificial hip joint are anchored with bone cement, the manufacturer of the bone cement will provide you with the corresponding patient information.

HOW LONG DOES YOUR ARTIFICIAL HIP JOINT LAST?

EXPECTED LIFETIME

The product lifetime depends on numerous factors in addition to the quality of the implant. These factors include: how, how often and how intensely a patient moves and how much strain is placed on their joint. The patient's age and body weight as well as the condition of their musculoskeletal system and any diseases affecting it also play an important role. The outcome of the surgery is also important. This affects the position, alignment and anchoring of the implants in the bone.
Issues that could make a revision surgery on the hip joint necessary include: Infection, wear, loosening, change of position or crack in one of the parts or a dislocation of the joint. The time before another operation becomes necessary varies in each individual case for the above reasons.

What do we know about the survivorship of artificial hip joints?

From implant registries we know that on average approx. 95 % of all hip joints have not had to be replaced after 10 years, after 15 years the figure is still above 90 % (3).

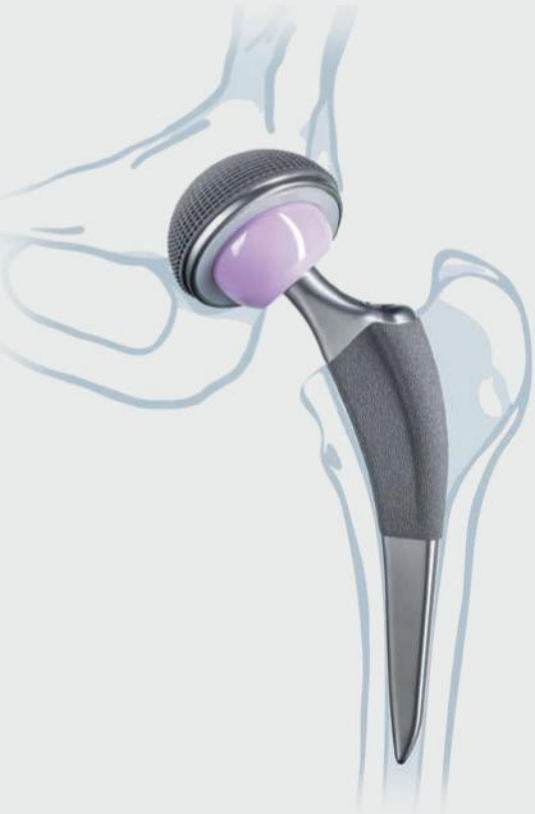
How was your artificial hip joint tested?

Implants have been tested by the manufacturers according to the standards that apply to them (4). These include strength, wear and range of motion tests.

The requirements of these standards subject to stress testing include:

- A load of 1,200/2,300 N (depending on the size of the implant) for 5 million load changes in the stem test.
- A load increased up to 5,340 N for more than 10 million load cycles in the neck test.
- A load of 14,000 N for 10 million load cycles in the head test (ceramic).
- 5 million simulated steps with a maximum force of 3,000 N in the wear test.

In case of small implants, restrictions may be given in order to achieve the same high safety range for all implants. Your doctor will tell you about these restrictions.



What can you do to improve the lifetime of your artificial hip joint?

Discuss this individually with your doctor and during rehabilitation. Appropriate mobility and muscle training after surgery is very important. The following should be avoided in your everyday life and especially in the first few months after the implantation of your artificial hip joint:

- Abrupt and jerky or impulsive movements
- Endurance sports, frequent climbing of stairs
- Excessive and long periods of standing
- Crossing your legs
- Sitting in deep seating furniture, such as sofas and armchairs
- Heavy and disproportionate weight gain
- Lifting heavy loads
- Flexing the hip by more than 90°
- Other people putting their weight on the hip joint

Drug or medication abuse or alcohol addiction can slow the healing process and jeopardise the success of the operation.

What do you have to keep in mind?

An artificial joint is fundamentally inferior to a healthy natural joint. It replaces the joint function and load after a joint disease with painful joint wear through suitable implant components. For this reason, please read the information on the survivorship of the artificial hip joint.

When should you visit your doctor?

You should have regular follow-ups with your doctor to ensure long term success. These will be recorded on your arthroplasty passport. If you experience pain or a change in your perception of your hip joint, consult your doctor.

WHAT YOU AND YOUR DOCTOR SHOULD LOOK OUT FOR!

INTERACTIONS WITH ENVIRONMENTAL CONDITIONS

Interactions during MRI scans

Metal implants can become warm during an MRI scan (imaging procedure). The treating doctor must be informed of the artificial hip joint and take the implant into consideration during an MRI scan. Show your arthroplasty passport!

Warning!
The implant has not been evaluated for safety and combability in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. Scanning a patient who has this implant may result in patient injury.

Security checks

The metal components of your implant will be detected by a security check, for example at an airport. Show your implant card!

DO YOU HAVE ANY FURTHER QUESTIONS?

If you have any questions regarding your diagnosis, therapy and prognosis, please contact your doctor.
We will also be happy to answer questions about your implant directly.

Any serious incident that occurs in Austrlia in **relation to the device should be** reported to B. Braun and to the Ther**apeutic** Go**ods** A**dministration (https://www.tga.gov.au/).**

(1) Patient information in accordance with Regulation (EU) 2017/745, art. 18, in conjunction with your individual implant card.
(2) ISO 5832-3, ISO 5832-9, ISO 5832-12, ISO 6474-1, ISO 5834-2, Highly Crosslinked PE, Plasmapore®, calcium phosphate surfaces.
(3) National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 15th Annual Report 2018. Surgical data to 31 December 2017; Swedish Hip Arthroplasty Register. Annual Report 2017. Gothenburg, 2018; Nasjonal Register for Leddproteser, Rapport Juni 2018. Norway.
(4) ISO 7206, ISO 14242.