Information for Patient

Please read the following information carefully.

If you have any questions or are not sure about the information provided below, ask your doctor.

You will receive a patient implant card that holds important information about your implant. If you need medical assistance, show your card to the doctor at your health facility.

Further information can be found at the following website:
https://ec.europa.eu/tools/eudamed
(When European Database on Medical Devices is available)

What does the implant do?

- Reduces pain and restores the function of the knee

Who is the implant for?

- Patients who need a knee implant for the first time
- Patients whose existing knee implant needs to be replaced

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant is MR Conditional. This means it is safe to undergo MRI under special conditions.

Before having an MRI scan, you must:

- Discuss it with your doctor and MRI staff.
- Show them your patient implant card before the scan.

Can I go through a security scanner at airports and other official buildings?

Your implant may cause an alarm at a security scanner. Show your patient implant card to security staff.

How often will I need to visit the doctor?

Your doctor will decide. This will depend on your individual situation, medical history and other medical conditions you have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff. They will tell you what to do after the surgery. Your doctor will also tell you about the risks and possible complications:

- Advice for best recovery after surgery
- Warnings of the general risks related to your surgery and the implant
- Possible complications (adverse effects)

Contact your doctor if:

- You have questions about how your implant functions
- You are worried about your health after surgery
- You start to experience pain or swelling, or if you develop a limp

What are the possible issues?

There may be issues that can shorten the life of the implant and lead to early replacement. These may include, but are not limited to:

- Pain
- Blood clots causing heart or lung problems
- Nerve injuries
- Wound healing issues
- Bone absorbed and broken down around the implant
- Bone fracture around the implant

- Infection
- Swelling
- Implant dislocation
- Implant loosening
- Poor fit of the implant
- Decreased knee movement or flexibility
- Shorter or longer leg length
- Implant fracture
- Implant wear
- Sensitivity or reaction to the metals in the implant (this is rare)

No surgery is risk-free. There are complications such as pain, blood clots, and nerve injuries. The implant can also break. You may also not heal properly after the surgery. Other issues in your bones and tissues can also occur.

Wear and corrosion of an implant can cause “adverse local tissue reaction” (ALTR) or “adverse reaction to metal debris” (ARMD), which can damage surrounding bone and soft tissue and may require early replacement of the implant.

How long will my implant last?

If used under normal conditions and if you follow the detailed instructions from your doctor, the implant can last for a certain lifetime, during which it functions as intended in your body. All implants may need to be replaced at some point.

As a guide, around 95% of first-time knee implants continue to function 10 years after surgery. If your implant needs replaced, around 77% continue to function 10 years after surgery. It can be longer or shorter.

Many factors can affect how long your implant lasts. An implant’s lifetime can be considerably shorter due to surgical and/or patient-specific circumstances and characteristics.

Your doctor controls some factors, such as:

- Selecting the proper implant for you
- The technique used during surgery

You can control some factors, such as:

- Your health
- How active you are
- Lifestyle choices
- Your weight

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have
- The condition of your bones
- The condition of your muscles and/or tissues
- Infections
- Other surgeries

These factors can also change as you get older.

How do I care for my implant?

Your implant is not the same as normal healthy bone and cartilage. Your implant has limitations, which you should keep in mind. These limitations can impact your lifestyle. An implant put under too much stress can break, dislocate, wear out, or be damaged.

Reasons for early implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Activity level
- Excessive weight
- Not following the recovery instructions

Information for Patient

What is my implant made of?

If you have any questions about your implant, ask your doctor.

The implant is made of materials that have been used in implants for a long time. The implant meets international safety and design standards.

Surgical implants are made from different materials. No implant is completely free of side effects when inserted in the human body. For appropriate applications, introducing these materials into the body is acceptable.

Your implant contains nickel. Some people are sensitive to nickel. If you have skin sensitivity to nickel or think you may be allergic to nickel, tell your doctor before your surgery. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and compositions:

Component	Material(s)	Material Composition (%)
Nonporous Femoral Component	Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy	Chromium: 27.00 – 30.00% Molybdenum: 5.00 – 7.00% Nickel: 0.50% * Iron: 0.75% Carbon: 0.35% Silicon: 1.00% Manganese: 1.00% Tungsten: 0.20% Phosphorous: 0.020% Sulfur: 0.010% Nitrogen: 0.25% Aluminum: 0.10% Titanium: 0.10% Boron: 0.010% Cobalt: Balance **

Component	Material(s)	Material Composition (%)
Porous Femoral Component	Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy	Chromium: 27.00 – 30.00% Molybdenum: 5.00 – 7.00% Nickel: 0.50% * Iron: 0.75% Carbon: 0.35% Silicon: 1.00% Manganese: 1.00% Tungsten: 0.20% Phosphorous: 0.020% Sulfur: 0.010% Nitrogen: 0.25% Aluminum: 0.10% Titanium: 0.10% Boron: 0.010% Cobalt: Balance **
	Trabecular Metal	Oxygen: 0.20% Nitrogen: 0.20% Hydrogen: 0.05% Iron: 0.50% Tungsten: 0.20% Molybdenum: 1.00% Silicon: 0.040% Nickel: 0.050% Tantalum: Balance
	Titanium	Nitrogen: 0.05% Carbon: 0.08% Hydrogen: 0.015% Iron: 0.50% Oxygen: 0.40% Titanium: Balance
Nonporous Tibial Plate	Titanium-Aluminum-Vanadium (Ti-6Al-4V ELI) Alloy	Nitrogen: 0.05% Carbon: 0.08% Hydrogen: 0.012% Iron: 0.25% Oxygen: 0.13% Aluminum: 5.50 – 6.50% Vanadium: 3.50 – 4.50% Titanium: Balance

Component	Material(s)	Material Composition (%)
	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene (UHMWPE), (C2H4)n (CAS # 9002-88-4): 100%
Porous Tibial Plate	Titanium-Aluminum-Vanadium (Ti-6Al-4V ELI) Alloy	Nitrogen: 0.05% Carbon: 0.08% Hydrogen: 0.012% Iron: 0.25% Oxygen: 0.13% Aluminum: 5.50 – 6.50% Vanadium: 3.50 – 4.50% Titanium: Balance
	Trabecular Metal	Oxygen: 0.20% Nitrogen: 0.20% Hydrogen: 0.05% Iron: 0.50% Tungsten: 0.20% Molybdenum: 1.00% Silicon: 0.040% Nickel: 0.050% Tantalum: Balance
Vitamin E Articular Surface	Vitamin-E Stabilized Highly-Crosslinked Polyethylene (VEHXPE)	Vitamin E (CAS 10191-41-0): less than 0.3% Ultra-High Molecular-Weight Polyethylene (UHMWPE), (C2H4)n (CAS # 9002-88-4): Balance
Articular Surface (non Vitamin E)	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene (UHMWPE), (C2H4)n (CAS # 9002-88-4): 100%
Vitamin E Patella	Vitamin-E Stabilized Highly-Crosslinked Polyethylene (VEHXPE)	Vitamin E (CAS 10191-41-0): less than 0.3% Ultra-High Molecular-Weight Polyethylene (UHMWPE), (C2H4)n (CAS # 9002-88-4): Balance
Patella (non Vitamin E)	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene (UHMWPE), (C2H4)n (CAS # 9002-88-4): 100%

Component	Material(s)	Material Composition (%)
Stem Extension	Titanium-Aluminum-Vanadium (Ti-6Al-4V ELI) Alloy	Nitrogen: 0.05% Carbon: 0.08% Hydrogen: 0.012% Iron: 0.25% Oxygen: 0.13% Aluminum: 5.50 – 6.50% Vanadium: 3.50 – 4.50% Titanium: Balance

Material Precautions:

* Nickel, classified as skin sensitiser 1: sensitisation or allergic reaction to users and/or patients. Classification based on EU legislation for chemicals.

** This implant contains a metal called cobalt. Cobalt is regulated by EU law when an implant contains it at a concentration above 0.1%.[1]

The regulation of cobalt is for all types of entry into the body. It comes from research where rodents inhaled pure cobalt dust or cobalt oxide dust. This implant is made of a solid alloy that contains cobalt at a concentration above 0.1%. An alloy is a mixture of different metals and chemicals. Solid cobalt-containing alloys are chemically quite different from pure cobalt dust and cobalt oxide dust. Since this implant is made from solid cobalt-containing alloy and placed inside the body, it is not possible to inhale cobalt from it.

There are a few studies where a patient diagnosed with cancer had an implant made from cobalt-containing alloys. This might suggest a possible link between the implant and cancer diagnosis. However, current overwhelming evidence in published studies and a Zimmer Biomet risk assessment do not show that. It shows that cancer risk is negligible and comparable between patients with such implants and those without implants. The research further shows negligible risk to fertility, comparable to patients without implants.

Globally accepted technical standards for joint implants call cobalt-containing alloys proven materials for long-term implants.

Does my implant have special operating instructions?

No, there are no special operating instructions.

[1] EU Medical Device Regulation 2017/745 Annex I GSPR 10.4, referencing CLP regulation 1272 / 2008, where CAS No. 7440-48-4 is designated CMR1B.

Information for Patient

What should I do if I have a problem?

Report any suspected serious incident with your implant.

To do so, you can contact:

- Your doctor
- The manufacturer (see below) or local distributor
- The competent authority / ministry of health / delegated agency in your country

Patients in Australia shall contact the Therapeutic Goods Administration (TGA) at https://www.tga.gov.au

Manufacturer Contact Details:

ZIMMER INC
1800 WEST CENTER STREET
PO BOX 708
WARSAW IN 46580 USA
https://www.zimmerbiomet.com

For additional copy of this document, please visit:
http://ifp.zimmerbiomet.com

Reference: 87-6204-022-99-IFP
Revision: A
Date of Issue: 2022-01-11