ZIMMER BIOMET

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 is the implant comprised of?

The implant includes components designed to be implanted in, and replace parts of, the natural shoulder “ball-and–socket”. The implants are implanted by your doctor during a shoulder replacement surgery.

The Sidus® Stem-Free Shoulder consists of two implant components:

- a component (anchor) placed under the spherical head of the upper arm bone, made of Titanium alloy (Ti-6Al-4V)
- a component (head) placed on top of and locked to the anchor, made of Cobalt-chrome alloy (Co-28Cr-6Mo), and replaces the natural spherical head of the upper arm bone. This restores the ball from the “ball-and-socket” joint.

What does the implant do?

- Improves the function of the shoulder.
- Reduce pain.

Who is the implant for?

- Patients who need a shoulder implant for the first time.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant is MR Conditional: This means it can undergo MRI, but only 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.

*And if approved by your doctor.

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?

You should 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 (side effects)

Contact your doctor if:

- You have questions about how the implant function
- You are worried about your health after surgery
- You start to experience pain or swelling

What are the possible issues?

There may be issues that can shorten the life of the implant and lead to early replacement. They may include (but are not limited to this list):

- Peripheral neuropathies (nerve injuries)
- Infections
- Damage of surrounding soft tissues
- Wear (of the implant)
- Heterotopic bone formation (abnormal formation of bone within soft tissue)
- Hypersensitive reactions (exaggerated immune system response to implant material)
- Inflammatory reactions
- Osteolysis, resorption (progressive deterioration of the bone around the implant)
- Dislocation, subluxation and/or joint instability
- Vascular complications (complications to blood vessels)
- Corrosion of metal implants (breakdown of metal due to chemical reaction in the body)
- Loosening of components (loosening of the implant's fixation to the bone)
- Disassembly of implant components
- Implant breakage, damage
- Pain
- Poor function
- Bone fracture, perforation
- Impingement and altered range of motion
- Other complications associated with surgery in general, e.g. with medication, instruments used, blood and/or anaesthesia

How long will my implant last?

If the implant is 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 a human body. However, all implants may need replacement at some point.

The following is a guide to how long your shoulder implant may last:

- primary shoulder hemiarthroplasty (replacement of the head of the upper arm bone) around 86% last for at least 10 years
- primary total shoulder arthroplasty replaces both head of the upper arm bone and the socket side of the shoulder joint (glenoid) around 91% for at least 10 years

Many factors could have an effect on how long your implant lasts. An implant might last longer or (considerably) shorter due to surgical and / or patient specific circumstances and characteristics.

Some factors are controlled by your doctor, such as:

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

You can control other factors, such as:

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

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have as well as its stage
- The condition of your bone
- The condition of muscles and / or tissue
- Infections
- Further surgeries

These factors can also change as you get older.

How do I care for my implant?

An implant is not the same as normal healthy bone. An implant has some limitations which you should take into account. These limitations can impact your lifestyle. An implant can break early if you put too much demand on it. An implant can also become damaged or loose if it is put under too much stress. It can fracture, dislocate and wear out, if it is put under too much stress.

Here are some reasons why your implant might fail early (but not limited to this list):

- Excessive forces placed on it
- Accident or fall
- Extreme arm and shoulder movement
- Activity level
- Excessive weight
- Not following the recovery program

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 (ISO 5832-3, ISO 5832-12, ASTM F1537, ASTM F136).

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.

Material Name	Composition in weight %	ISO	ASTM	Material Precaution
Protasul-21WF (Heads)	Cobalt 58.72-68.85 Chromium 26.0-30.0 Molybdenum 5.0-7.0 Nickel 1.0 max Iron 0.75 max Manganese 1.0 max Carbon 0.15-0.25 Silicon 1.0 max Nitrogen 0.25 max Oxygen 0.02 max Boron 0.007 max	5832-12	F1537	Nickel, classified as *skin sensitizer 1** Sensitization or allergic reaction to users and/or patients Element cobalt is classified as a carcinogen, mutagen and toxic to reproduction (CMR) 1B substance, specifically carcinogen 1B, reprotoxin 1B and mutagen 2
Protasul-64WF (Anchors)	Titanium: 88.52-91 Aluminum: 5.5-6.5 Vanadium 3.5-4.5 Iron: 0.25 max Oxygen: 0.13 max Carbon: 0.08 max Nitrogen: 0.05 max Hydrogen: 0.012 max	5832-3	F136	None

*Classification based on applicable EU legislation for chemical substances

The humeral head components of the Sidus Stem-Free Shoulder implant contain 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.

[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.

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 comparable for patients with such implants as for patients without implants. The research further shows negligible effects on fertility.

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

The humeral head components of the Sidus Stem-Free Shoulder implant contain nickel. This can cause allergic reactions if it comes in direct contact with the skin for a long period of time.

If you think that you are allergic to nickel, tell your doctor before the surgery. Also tell your doctor if you have any allergic reactions after surgery.

Does my implant have special operating instructions?

No, there are no special instructions.

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
- The local distributor
- The competent authority
- The ministry of health
- The local delegated agency

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

Manufacturer Contact Details

Zimmer Switzerland Manufacturing GmbH
Sulzerallee 8
8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
Fax +41/ (0)52 262 01 39
www.zimmerbiomet.com

For additional copy of this document, please visit:

http://ifp.zimmerbiomet.com

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Symbols Glossary:

	Indicates the medical device manufacturer as defined in EU Directive 90/385/EEC, 93/42/EEC and 98/79/EC.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
MD	Indicates the item is a medical device.
UDI	Indicates a carrier that contains Unique Device Identifier information.

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