ZIMMER BIOMET

Information for Patient

Dear users,

This document includes important information leaflets about the implants you have or may receive.

Please use the Table of Contents below to find the leaflet that matches your implant.

Contents

Patient Information Leaflet – Titanium Interference Screws

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.

What does the implant do?
Reduce pain and restore movement of the knee joint.

Who is the implant for?
Patients who need soft tissue reattachment.
Patients who need to undergo some repair procedures.

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, provided it is approved by your doctor.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff. This information will include:

- 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 your implant functions.

- You are worried about your health after surgery.
- You start to experience pain or swelling, or if you develop a limp.

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction.
- Allergic reaction or sensitivity to toxin or metals in the implant.
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants.
- Blood loss, cut, abrasion or puncture wound.
- Bone death, breakage, removal or absorption around the implant.
- Incomplete bone healing or loss of fixation.
- Implant fracture, loosening, instability or wear.
- Decreased joint movement or flexibility.
- Burn.
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery.

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.

Your implant is intended to serve as a temporary internal fixation device to attach soft tissue to bone during the healing process. Soft tissue healing occurs generally in 6 weeks to 1 year following surgery.

Many factors could influence the function of your implant as a temporary internal fixation device and also influence the soft tissue healing process. These include 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 surgery
- Instructions given to you after surgery regarding the required rehabilitation program, your lifestyle and your physical activity

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor during the soft tissue healing process including the requirement that you cannot put your full weight/load until your doctor has confirmed that soft tissue healing has occurred
- Following the instructions of your doctor regarding your lifestyle and physical activity

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- Soft tissue tear location
- Severity of the soft tissue tear
- 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 implant failure include, but are not limited to:

- Excessive forces put on it.
- Accident or fall.
- Extreme or awkward movements.
- Excessive activity level.
- Excessive weight.
- Not following the recovery instructions provided by your doctor.

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Titanium Interference Screws	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Biomet Orthopedics
Biomet Sports Medicine
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – TOGGLELOC® System

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.

What does the implant do?
Reduce pain and restore function of the repaired/reconstructed site.

Who is the implant for?
Patients who need soft tissue reattachment.
Patients who need to undergo soft tissue repair or reconstruction

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, provided it is approved by your doctor. However, if you have an implant in addition to the sutures, the MR condition of your implant should be confirmed prior to undergoing an MRI scan.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff. Including:

- 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 your implant functions.
- You are worried about your health after surgery.
- You start to experience pain or swelling.

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Discomfort or abnormal sensation due to the presence of the implant

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. Your implant is intended to serve as a temporary internal fixation device to attach soft tissue to bone during the healing process. Soft tissue healing occurs generally in 6 weeks to 1 year following surgery.

Many other factors could influence the function of your implant as a temporary internal fixation device and also influence the soft tissue healing process. These include 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 surgery
- Instructions given to you after your surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor during the soft tissue healing process including the requirement that you cannot put your full weight/load until your doctor has confirmed that soft tissue healing has occurred

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- Soft tissue tear location
- Severity of the soft tissue tear
- 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 tissues. 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Your implant may contain 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
White Polyethylene (PE) Suture	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene $(C_2H_4)_n$: 100%	Not applicable
White/Blue PE Suture	Ultra-High Molecular-Weight Polyethylene (UHMWPE) and Polypropylene (PP)	Ultra-High Molecular-Weight Polyethylene $(C_2H_4)_n$: up to 100% Blue polypropylene monofilament strands The blue dye is [phthalocyaninato (-2)] Copper: <0.5%.	Not applicable
Blue PET Suture	Blue Polyester (PET)	Polyethylene Terephthalatate: >97.3% D&C Blue #6: <0.2% Nu-Sil MED-2174 Elastomer: 1-2%	Not applicable
Suture Loop	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	IDA (PE): 2200/100 Fil UHTPE: 100%	Not applicable
Titanium Suture Button	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136
ZipLoop Suture	UHMWPE/PET/PP	ICF (PET): FP-0500-070-1F-0-0-2-H-NT; 803228-803279- 8% IDA(PE): 2200/100/UHTPE-75; 1296-1- 87% Luxilon (PP): Polypropylene Marlex HGX-030-01; 6120105- 6%	Not applicable

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
		Colorant Batch: 080007PO40	
Stainless Steel Suture Button	316L Stainless Steel	Carbon: 0.030% Manganese: 2.00% Phosphorous: 0.025% Sulfur: 0.010% Silicon: 0.75% Chromium: 17.00 – 19.00% Nickel: 13.00 – 15.00% Molybdenum: 2.25 – 3.00% Nitrogen: 0.10% Copper: 0.50% Cobalt: <0.10% Iron: Balance	ASTM F138

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Biomet Orthopedics
56 East Bell Drive
P.O. BOX 587
Warsaw, Indiana 46581
USA

Biomet Sports Medicine
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USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Refer to the device label for the Legal Manufacturer.

Patient Information Leaflet – TOGGLELOC™ 2.9 and JUGGERLOC™ Soft Tissue Systems

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.

What does the implant do?
Reduce pain and restore function of the repaired/reconstructed site.

Who is the implant for?
Patients who need soft tissue reattachment.
Patients who need to undergo soft tissue repair or reconstruction.

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, and provided it is approved by your doctor. However, if you have an implant in addition to the sutures, the MR condition of your implant should be confirmed prior to undergoing an MRI scan.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

- 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 your implant functions.
- You are worried about your health after surgery.
- You start to experience pain or swelling.

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Bone death, breakage or absorption around the implant
- Bone removal
- Burn
- Cut, abrasion or puncture wound
- Tissue damage or swelling (excess fluid in the tissue)
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer limb length
- Discomfort or abnormal sensation due to the presence of the implant
- Dislocation, disassembly, poor fit of the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Implant fracture, loosening, instability or wear
- Incomplete bone healing or loss of fixation
- Organ failure or dysfunction
- Allergic reaction or sensitivity
- Unexpected blood loss

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.

Information for Patient

Your implant is intended to serve as a temporary internal fixation device to attach soft tissue to bone during the healing process. Soft tissue healing occurs generally in 6 weeks to 1 year following surgery.

Many other factors could influence the function of your implant as a temporary internal fixation device and also influence the soft tissue healing process. These include 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 surgery
- Instructions given to you after your surgery regarding the required rehabilitation program, your lifestyle and your physical activity

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor during the soft tissue healing process including the requirement that you cannot put your full weight/load until your doctor has confirmed that soft tissue healing has occurred

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- Soft tissue tear location
- Severity of the soft tissue tear
- 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 tissues. 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Needle Strand	Blue Ultra-High Molecular-Weight Polyethylene (UHMWPE)	UHMWPE $(C_2H_4)_n$: up to 100%. The blue dye is Chromium-cobalt-aluminium oxide <2.0%	Not Applicable
Passing Differential Strand	UHMWPE	UHMWPE $(C_2H_4)_n$: 100%	Not Applicable
Bone Anchor	High-Tenacity Polyester 500/70 (HTPET)	Polyester $(C_{10}H_8O_4)_n$: 100%	Not Applicable
Titanium Button	Titanium-Aluminium - Vanadium (Ti-6Al-4V) Alloy	Nitrogen: 0.05% Carbon: 0.08% Hydrogen: 0.012% Iron: 0.25%	ASTM F136

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
		Oxygen: 0.13% Aluminium: 5.50-6.50% Vanadium: 3.50-4.50% Titanium: Balance	

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

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TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Refer to the device label for the Legal Manufacturer.

Patient Information Leaflet – PHOENIX™ Ankle Nail System

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.

What does the implant do?
Temporarily stabilizes the joint/bone during the joint fusion/fracture healing process.

Who is the implant for?
Patients with hindfoot conditions that severely affect both ankle and subtalar joints and need a temporary fixation implant to help stabilize the bone during the healing (joint fusion) process.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction
- Damage to blood vessels or excessive bleeding
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Allergic reaction or sensitivity to toxin or metals in the implant
- Dislocation
- Decreased joint movement or flexibility or shorter or longer limb length
- Decrease in bone density
- Discomfort or abnormal sensation due to the presence of the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery

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.

The following is a guide:

Your implant is intended to temporarily stabilize your joint/bone during the joint fusion/fracture healing process. It is intended to function as long as the bone is healing. Joint fusion/healing of the bone usually occurs up to 8-12 months after receiving your

implant. Healing, defined as joint fusion/bone union and or consolidation, marks the end of the implant's functional lifetime. Once your bone has healed, your doctor will decide if the implant should be removed or not.

Failure to achieve joint fusion/bone healing may result in either delayed union (a lengthening of time to bone union/joint fusion) or non-union (failure of the bones/joint to unite). A delayed or non-union will subject the joint fusion site and arthrodesis implant to repetitive stress that may cause eventual bending or breakage of the implant/bone.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 they use during the surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery including the requirement that you cannot put your full weight on your treated bone until your doctor has confirmed bone union

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- Other injuries occurring at the same time or existing injuries
- Severity of your injury
- Complexity of your injury
- Fracture type
- Fracture location
- The condition of your bones
- The condition of your muscles and/or tissues
- Infections
- Other surgeries

These factors can also change depending on your age.

How do I care for my implant?

Your implant is not the same as healthy bone or tissue. 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Ankle Locking Nail	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136
	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene, $(C_2H_4)_n$: 100%	ASTM F648
Offset End Cap	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

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

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TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

For additional copies of this document, please visit: ifp.zimmerbiomet.com.

Patient Information Leaflet – AFFIXUS® Hip Fracture Nail System

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.

What does the implant do?
Temporarily stabilizes the bone after fracture or osteotomy.

Who is the implant for?
Patients who have fractured a bone and need a temporary fixation implant to help stabilize the bone during the healing process.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Decrease in bone strength
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Discomfort or abnormal sensation due to the presence of the implant

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.

The following is a guide:

Your implant is intended to temporarily stabilize your bone during the healing process. It is intended to function for as long as the fracture needs to heal. Healing of the bone usually

occurs up to 8-12 months after receiving your implant. Healing, described as bone union and/or consolidation, marks the end of the implant's functional lifetime. Once your fracture has healed, your doctor will decide if the implant should be removed.

Failure to achieve healing may result in either delayed union (a prolongation of time to bone union) or non-union (the fractured bone does not unite). A delayed or non-union of a fracture will subject the fracture site and implant to repetitive stress that may cause eventual bending or breakage of the implant or re-fracture of the bone.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- Other injuries occurring at the same time or existing injuries
- Severity of your injury
- Complexity of your injury
- Fracture type
- Fracture location
- 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 tissue or bone. 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Nails, End Caps	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?

Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document. To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

For additional copies of this document, please visit: ifp.zimmerbiomet.com.

Patient Information Leaflet – ECHO BI-METRIC Hip System

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.

What does the implant do?
Reduce pain and restore function of the hip.

Who is the implant for?
Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Before having an MRI scan, you must:

- Discuss the scan with your doctor
- Inform the MRI staff that you have an implant
- Show your patient implant card to the MRI staff

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff. This information will include:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Noise

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of first-time total hip implants and 80% of revision total hip implants continue to function at 10 years after surgery. It can be longer or shorter.

Information for Patient

As a guide, based on clinical data, about 92.8% of these implants continue to function ten years after hemi arthroplasty surgery. The lifetime of implants used in hemi arthroplasty is often determined by your health status.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall

- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Femoral Stem	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136
	Porous Coating Titanium-Aluminum-Vanadium (Ti-6Al-4V) Powder	Aluminum: 5.50-6.75% Vanadium: 3.50-4.50% Oxygen: 0.20% Iron: 0.30% Carbon: 0.08% Hydrogen: 0.015% Nitrogen: 0.05% Copper: 0.10% Tin: 0.10% Titanium: Balance	ASTM F1580

Does my implant have special operating instructions?
No, there are no special operating instructions.

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Information for Patient

What should I do if I have a problem?

Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your hip implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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: www.tga.gov.au.

Manufacturer Contact Details:

Biomet Orthopedics
56 East Bell Drive
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TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

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For additional copies of this document, please visit: ifp.zimmerbiomet.com.

Patient Information Leaflet – Metal Femoral Heads (Biomet Orthopedics)

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.

What does the implant do?

Reduce pain and restore function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Organ failure or dysfunction
- Allergic reaction or sensitivity to toxin or metals in the implant
- Damage to blood vessels or excessive bleeding
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Metal debris buildup or abnormal formation of bone in tissues
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Burn
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of femoral heads used in first-time total hip implants continue to function at 10 years after surgery, 92.8% of femoral heads used in partial hip placement continue to function at 10 years after surgery, and 80% of

femoral heads used in revision hip replacement continue to function at 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have as well as its stage
- 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

- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Femoral Heads	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 (up to 68%) **	ASTM F1537

Material Precautions:

* Nickel, classified as skin sensitizer 1: sensitization or allergic reaction to users and/or patients. Classification based on EU legislation for chemical substances.

** 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]

[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.

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.

What should I do if I have a problem?

Please report if you experience unexpected complications, such as pain or swelling, loss of function in your hip implant, or other conditions where you feel unwell, and you think it may be due to your hip implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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: www.tga.gov.au.

Manufacturer Contact Details:

Biomet Orthopedics
56 East Bell Drive
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TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

For additional copies of this document, please visit: ifp.zimmerbiomet.com.

Patient Information Leaflet – TRILOGY® Acetabular System

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.

What does the implant do?

Reduce pain and restore function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

- 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 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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Burn
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Screw thread penetration through hip socket into pelvis

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of first-time hip total implants and 80% of revision hip implants continue to function at 10 years after surgery. It can be longer or shorter.

Information for Patient

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following instructions of your doctor after the surgery

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 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 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight

- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Shell	Tivanium (Ti-6Al-4V 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	ASTM F136
	Hydroxyapatite (HA)	Hydroxyapatite: Balance Limits of specific trace elements: Arsenic (3 ppm max) Cadmium (5 ppm max) Mercury (5 ppm max) Lead (30 ppm max) Total heavy metals (50 ppm max)	Not Applicable
Bone Screw	Tivanium (Ti-6Al-4V 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	ASTM F136
Liners	Ultra-High Molecular Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene (UHMWPE), $(C_2H_4)_n$:100%	ASTM F648

Information for Patient

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

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Information for Patient

Patient Information Leaflet – Replacement Locking Rings

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.

What does the implant do?
Reduce pain and restore function of the hip.

Who is the implant for?
Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

ZIMMER BIOMET

Information for Patient

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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Burn
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Screw thread penetration through hip socket into pelvis

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of first-time total hip implants and 80% of revision total hip implants continue to function at 10 years after surgery. It can be longer or shorter.

ZIMMER BIOMET

Information for Patient

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

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 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 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

ZIMMER BIOMET

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Replacement Locking Ring	Titanium-Aluminum-Vanadium ELI (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

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

ZIMMER BIOMET

Information for Patient

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

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – NEXGEN® All-Polyethylene Patella

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.

What does the implant do?

Reduces pain and restores function of the knee.

Who is the implant for?

Patients who need a knee replacement with an artificial implant as recommended by their doctor.

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 and provided it is approved by your doctor.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant. Inform the MRI staff to visit the Zimmer Biomet eLabeling site for MRI scanning information: labeling.zimmerbiomet.com.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, Organ failure or dysfunction
- Amputation
- Damage to blood vessels
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Noise

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.

As a guide, based on clinical data, about 95% of primary knee implants and 77.3% of revision knee implants continue to function at 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.

Some factors are controlled by your doctor, such as:

- Selecting the proper implant for you
- The technique used during surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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 implant failure include, but are not limited to:

- Excessive forces put on it

- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and compositions:

Components	Material(s)	Material Composition (Range or Maximum)
Patella	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene $(C_2H_4)_n$: 100%

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – TRILOGY® LONGEVITY® Constrained Liner

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.

What does the implant do?

Reduce pain and restore function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

- 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 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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Burn
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 92.5% of constrained acetabular liners used in first-time total hip implants and 72.8% of constrained acetabular liners used in revision total hip implants continue to function at 10 years after surgery. It can be longer or shorter.

Information for Patient

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

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 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 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

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

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Constraining Ring	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136
Constrained Liner	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene $(C_2H_4)_n$: 100%	ASTM F648

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA
TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – ZIMMER® GENDER SOLUTIONS® Patello-Femoral Joint (PFJ) Implant

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.

What does the implant do?
Reduce pain and restore function of the kneecap.

Who is the implant for?
Patients who need knee replacement with an artificial implant as recommended by their doctor.

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 the scan with your doctor.
- Inform the MRI staff that you have an implant. Inform the MRI staff to visit the Zimmer Biomet eLabeling site for MRI scanning information: labeling.zimmerbiomet.com.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?
No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Noise

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 80.35% of patello-femoral joint implants continue to function at 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery
-

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Information for Patient

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Patello-Femoral Joint Implant	Low Carbon Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy	Carbon: 0.14% Chromium: 26.0-30.0% Molybdenum: 5.0-7.0% Nickel: 1.0% Iron: 0.75% Silicon: 1.0% Manganese: 1.0% Nitrogen: 0.25% Cobalt: Balance (up to 64.86%)	ASTM F1537
	Poly (methyl methacrylate) [PMMA]	Poly Methyl Methacrylate $(C_5H_8O_2)_n$: 100 %	Not applicable

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor in first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – Metal Femoral Heads (Zimmer Inc)

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.

What does the implant do?
Reduce pain and restore function of the hip.

Who is the implant for?
Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Allergic reaction or sensitivity to toxin or metals in the implant
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Metal debris buildup or abnormal formation of bone in tissues
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Noise

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of first-time hip implants and 80% of revision hip implants continue to function 10 years after surgery. As a guide, and based on clinical

data, 92.8% of implants used solely for partial arthroplasty of the hip continue to function 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level

- Excessive weight
- Not following the recovery instructions provided by your doctor

What is my implant made of?
If you have any questions about your implant, ask your doctor.

Your implant is made of materials that have been used in implants for a long time. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
VerSys Hip System 12/14 CoCr Femoral Head Zimmer 6 Degree CoCr Femoral Head VerSys Hip System 12/14 Endo Femoral Head VerSys Hip System 12/14 Endo Femoral Head Taper Adapter	Low Carbon Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy	Carbon: 0.14% Chromium: 26.0-30.0% Molybdenum: 5.0-7.0% Nickel: 1.0% Iron: 0.75% Silicon: 1.0% Manganese: 1.00% Nitrogen: 0.25% Cobalt: Balance (up to 64.86%)	ASTM F1537

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may

be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
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TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA
www.zimmerbiomet.com

For additional copies of this document, please visit: ifp.zimmerbiomet.com.

Patient Information Leaflet – TRABECULAR METAL® Modular Acetabular System

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.

What does the implant do?

Reduce pain and restore function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

- 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 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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup or abnormal formation of bone in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Burn
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Screw thread penetration through hip socket into pelvis

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, about 95% of first-time hip total implants and 80% of revision hip implants continue to function at 10 years after surgery. As a guide, based on

clinical data, about 92.5% of constrained acetabular liners used in first-time total hip implants and 72.8% of constrained acetabular liners used in revision total hip implants continue to function at 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following instructions of your doctor after the surgery

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 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 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall

- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Trabecular Metal Modular Shell	Tantalum (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	Not Applicable
	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?

No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw, Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

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Patient Information Leaflet – ZIMMER BIOMET® 12/14 CoCr Femoral Head and Freedom Head

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.

What does the implant do?

Reduce pain and restore function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

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, and provided it is approved by your doctor.

Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant. Inform the MRI staff to visit the Zimmer Biomet eLabeling site for MRI scanning information: labeling.zimmerbiomet.com.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or dysfunction
- Damage to blood vessels
- Blood loss, cut, abrasion or puncture wound
- Bone death, breakage, removal or absorption around the implant
- Incomplete bone healing or loss of fixation
- Implant fracture, loosening, instability or wear
- Dislocation, disassembly, poor fit of the implant
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Tissue damage or swelling (excess fluid in the tissue) around joints or implants
- Metal debris buildup in tissues
- Allergic reaction or sensitivity to toxin or metals in the implant
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Burn
- Noise

How long will my implant last?

Information for Patient

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. All implants may need to be replaced at some point.

Zimmer Biomet 12/14 CoCr Femoral Heads: As a guide, based on clinical data, about 95% of first-time hip implants and 80% of revision hip implants continue to function at 10 years after surgery. As a guide, and based on clinical data, 92.8% of implants used solely for hemi arthroplasty of the hip continue to function 10 years after surgery. It can be longer or shorter.

Zimmer Biomet 12/14 CoCr Freedom Heads: As a guide, based on clinical data, about 92.5% of constrained acetabular liners used in first-time total hip implants and 72.8% of constrained acetabular liners used in revision total hip implants continue to function at 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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?

Information for Patient

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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Femoral Head	Low Carbon Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy	Carbon: 0.14% Chromium: 26.0-30.0% Molybdenum: 5.0-7.0% Nickel: 1.0% Iron: 0.75% Silicon: 1.0% Manganese: 1.00% Nitrogen: 0.25% Cobalt: Balance up to 64.86	ASTM F1537

Information for Patient

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer, Inc.
1800 W. Center Street
Warsaw Indiana 46580
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – MS-30® Cemented Hip Stems, MS-30® Distal Centralizers and MS-30® Proximal Positioners

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.

What does the implant do?

Reduce pain and improve function of the hip.

Who is the implant for?

Patients who need a hip replacement with an artificial implant as recommended by their doctor.

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 the scan with your doctor.
- Inform the MRI staff that you have an implant. Inform the MRI staff to visit the Zimmer Biomet eLabeling site for MRI scanning information: labeling.zimmerbiomet.com.
- Show your patient implant card before to the MRI staff.

*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 may have.

Information for Patient

What to do if I need help or want advice?

You should always follow the information provided by your doctor and other medical staff including:

- 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:

- You have questions about how your implant functions.
- You are worried about your health after surgery.
- You start to experience any pain, swelling or begin to limp.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Bone fracture, perforation
- Cardiovascular and circulatory complications with their potential, fatal consequences (complications to heart and blood vessels)
- Cement-related hypotension (low blood pressure related to the use of cement)
- Corrosion of metal implants (breakdown of metal due to chemical reactions in the body)
- Damage of surrounding soft tissues
- Death
- Disassembly of implant components
- Dislocation, subluxation
- Elevated concentration of metal
- Osteolysis, resorption, osteonecrosis (progressive deterioration of the bone around the implant)
- Pain
- Peripheral neuropathies (nerve injuries)
- Poor function
- Wear (of the implant)
- Other complications associated with surgery in general, e.g. with medication, instruments used, blood loss, anesthesia, and/or urological complications.
- Aggravation of conditions involving other joints or the back due to intraoperative trauma, differences in leg lengths, femoral

ions
- Heterotopic bone formation (abnormal formation of bone within soft tissue)
- Impingement (unintended contact between the implant components, soft tissues and/or bones of the joint) and altered range of motion
- Implant breakage, damage
- Implant subsidence, migration
- Infections
- Inflammatory and/or hypersensitive reactions
- Instability
- Limb length discrepancy
- Loosening of components

medialization or weakening of the muscles.
- Although there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors, any condition that causes chronic damage to tissues may be oncogenic.

Information for Patient

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. All implants may need to be replaced at some point.

As a guide, based on clinical data, the lifetime for this implant is as follows:

- About 95% of primary total hip implants continue to function at 10 years after surgery.
- About 80% of revision total hip implants continue to function at 10 years after surgery.

For information on the partial joint replacement products for hips, please refer to the applicable documentation, including the Information for Patient (IFP), of the compatible femoral heads intended for partial replacement surgery of the hip.

As a guide, based on clinical data, about 92.8% of these implants continue to function 10 years after first-time partial replacement surgery. The lifetime of these implants is often determined by health status of the patient.

Many factors could influence the length of healing time and overall performance of your implant. These include 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
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have and its stage
- 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 implant failure include, but are not limited to :

- Excessive forces placed on it
- Accident or fall
- Extreme or awkward movement
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

What is my implant made of?

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

The implant materials are stated in the table below. They are Protasul®-S30 and Sulene®-PMMA. These materials are metal and plastic. They have been used in implants for a long time and meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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-S30	Iron: 57.34 – 67.00 Chromium: 19.50 - 22.00 Nickel: 9.00 - 11.00 Manganese: 2.00 - 4.25 Molybdenum: 2.00 - 3.00 Niobium: 0.25 - 0.80 Silicone: 0.75 max Nitrogen: 0.25 - 0.50	5832-9	F1586	Nickel, classified as *skin sensitiser 1** Sensitisation or allergic reaction to users and/or patients

Information for Patient

Material Name	Composition in weight%	ISO	ASTM	Material Precaution
	Copper: 0.25 max Carbon: 0.08 max Phosphorus: 0.025 max Sulfur: 0.01 max			
Sulene-PMMA	Acrylic terpolymer (Poly Methyl Meth Acrylate (PMMA) $(CH_2C(CH_3)(CO_2CH_3))_n$ (CAS # 9011-14-7), Poly Styrene (PS) $(CH_2CH(C_6H_5))_n$ (CAS # 9003-53-6), Poly Ethyl Acrylate (PEA) $(C_5H_8O_2)_p$ (CAS # 9003-32-1)): 100	N/A	F3087	None

* Classification based on applicable EU legislation for chemical substances

The MS-30 Cemented Hip Stem 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your hip implant or other conditions where you feel unwell, and you think it may be due to your hip implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice” within this document.

To report a problem, contact your doctor in first instance. You may also contact:

- 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: www.tga.gov.au.

Information for Patient

Manufacturer Contact Details:

Zimmer GmbH
Sulzerallee 8
8404 Winterthur, Switzerland

TEL: +800 135 79135

www.zimmerbiomet.com

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

Patient Information Leaflet – NEXGEN® COMPLETE KNEE SOLUTION TRABECULAR METAL® Primary Patella

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.

What does the implant do?

Reduce pain and restore function of the knee.

Who is the implant for?

Patients who need a knee replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

- 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 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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or burn
- Bone death, breakage, loss or absorption around the implant
- Incomplete bone healing or loss of fixation
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Implant fracture, loosening, instability or wear
- Implant dislocation, disassembly or poor fit
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Allergic reaction or sensitivity
- Tissue damage or swelling (excess fluid in tissue) or buildup of metal particles in tissue

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.

As a guide, based on clinical data, about 95% of primary knee implants and 77.3% of revision knee implants continue to function at 10 years after surgery. It can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

What is my implant made of?

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

Information for Patient

The implant is made of materials that have been used in implants for a long time. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Components	Material(s)	Material Composition (Range or Maximum)
Patella	Tantalum (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
	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene, $(C_2H_4)_n$: 100%

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

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

ZIMMER BIOMET

Information for Patient

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

Manufacturer Contact Details:

Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

ZIMMER BIOMET

Information for Patient

Patient Information Leaflet – NEXGEN® COMPLETE KNEE SOLUTION CRUCIATE RETAINING (CR) AND LEGACY® KNEE POSTERIOR STABILIZED (LPS) TRABECULAR METAL® Monoblock Tibias

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.

What does the implant do?
Reduce pain and restore function of the knee.

Who is the implant for?
Patients who need a knee replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff. This information will include:

- 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 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?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or burn
- Bone death, breakage, loss or absorption around the implant
- Incomplete bone healing or loss of fixation
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Implant fracture, loosening, instability or wear
- Implant dislocation, disassembly or poor fit
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Allergic reaction or sensitivity
- Tissue damage or swelling (excess fluid in tissue) or buildup of metal particles in tissue

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.

As a guide, based on clinical data, about 95% of primary knee implants and 77.3% of revision knee implants continue to function at 10 years after surgery. It can be longer or shorter.

ZIMMER BIOMET

Information for Patient

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control some factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have, as well as its stage
- 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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

ZIMMER BIOMET

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component	Material(s)	Material Composition (Range or Maximum)
Tibia	Tantalum (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
	Ultra-High Molecular-Weight Polyethylene (UHMWPE)	Ultra-High Molecular-Weight Polyethylene $(C_2H_4)_n$: 100%

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your implant, or other conditions where you feel unwell, and you think it may be due to your implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice?” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA
www.zimmerbiomet.com

Patient Information Leaflet – NEXGEN® COMPLETE KNEE SOLUTION TRABECULAR METAL® Augments

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.

What does the implant do?
Reduce pain and restore function of the knee.

Who is the implant for?
Patients who need a knee replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?
MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?
Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?
No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or burn
- Bone death, breakage, loss or absorption around the implant
- Incomplete bone healing or loss of fixation
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Implant fracture, loosening, instability or wear
- Implant dislocation, disassembly or poor fit
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Allergic reaction or sensitivity
- Tissue damage or swelling (excess fluid in tissue) or build up of metal particles in tissue

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.

NexGen Complete Knee Solution Trabecular Metal Augments used with NexGen Complete Knee Solution Legacy Constrained Condylar Knee System (LCCK):

As a guide, about 95% of first-time knee implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e.

revision knee implant) about 77.3% of the knee implants continue to function at 10 years. However, it can be longer or shorter.

NexGen Complete Knee Solution Trabecular Metal Augments used with NexGen Complete Knee Solution Rotating Hinge Knee (RHK):

As a guide, about 90% of first-time rotating hinge implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e. revision knee implant), about 77.3% of the rotating hinge knee implants continue to function at 10 years. However, it can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

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?

Information for Patient

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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Trabecular Metal Augments	Tantalum (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	Not Applicable

Information for Patient

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Locking Bolts/Screws	Titanium-Aluminum-Vanadium (Ti-6Al-4V) 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	ASTM F136

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your knee implant or other conditions where you feel unwell, and you think it may be due to your knee implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer Trabecular Metal Technology, Inc.
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USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – TRABECULAR METAL® Tibal Cone Augments

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.

What does the implant do?

Reduce pain and restore function of the knee.

Who is the implant for?

Patients who need a knee replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or burn
- Bone death, breakage, loss or absorption around the implant
- Incomplete bone healing or loss of fixation
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Implant fracture, loosening, instability or wear
- Implant dislocation, disassembly or poor fit
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Allergic reaction or sensitivity
- Tissue damage or swelling (excess fluid in tissue) or buildup of metal particles in tissue

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.

Trabecular Metal Tibial Cone Augments used with NexGen Complete Knee Solution Legacy Constrained Condylar Knee System (LCCK):

As a guide, about 95% of first-time knee implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e.

revision knee implant) about 77.3% of the knee implants continue to function at 10 years. However, it can be longer or shorter.

Trabecular Metal Tibial Cone Augments used with NexGen Complete Knee Solution Rotating Hinge Knee (RHK):

As a guide, about 90% of first-time rotating hinge implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e. revision knee implant), about 77.3% of the rotating hinge knee implants continue to function at 10 years. However, it can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

Some factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have and its stage
- 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?

Information for Patient

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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.

Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Tibial Cone Augments	Trabecular Metal (Tantalum)	Oxygen: 0.20% Nitrogen: 0.20% Hydrogen: 0.05% Iron: 0.50% Tungsten: 0.20% Molybdenum: 1.00% Silicon: 0.040% Nickel: 0.050%	Not Applicable

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
		Tantalum: Balance	

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your knee implant or other conditions where you feel unwell, and you think it may be due to your knee implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

Manufacturer Contact Details:

Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054
USA

TEL: +1-800-348-2759 or +1-800-253-6190 USA
TEL: +800 135 79135 Outside the USA

www.zimmerbiomet.com

Patient Information Leaflet – TRABECULAR METAL® Femoral Cone Augments

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.

What does the implant do?

Reduce pain and restore function of the knee.

Who is the implant for?

Patients who need a knee replacement with an artificial implant as recommended by their doctor.

Can I have an MRI scan?

MRI stands for Magnetic Resonance Imaging.

Your implant has not been tested for safety in a Magnetic Resonance environment. Before having an MRI scan, you must:

- Discuss the scan with your doctor.
- Inform the MRI staff that you have an implant.
- Show your patient implant card to the MRI staff.

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 may have.

What should I do if I need help or advice?

Always follow the information provided by your doctor and other medical staff, including:

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

Additionally, it is advised to always inform your medical practitioner who may be treating you in the future of the presence of your implant.

What are the possible issues?

No surgery is risk-free. Complications may occur as a result of the surgery in general, such as pain, blood clots, nerve injuries or infection. You also may not heal properly after the surgery. Other issues in your bones and tissues can also occur.

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

- Death, organ failure or burn
- Bone death, breakage, loss or absorption around the implant
- Incomplete bone healing or loss of fixation
- Decreased joint movement or flexibility, non-functioning joint or shorter or longer leg length
- Implant fracture, loosening, instability or wear
- Implant dislocation, disassembly or poor fit
- Exposure to drugs that decrease or stop the feeling of pain by putting you to sleep during surgery
- Noise
- Allergic reaction or sensitivity
- Tissue damage or swelling (excess fluid in tissue)
- Buildup of metal particles in tissue

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.

Trabecular Metal Femoral Cone Augments used with NexGen Complete Knee Solution Legacy Constrained Condylar Knee System (LCCK):

As a guide, about 95% of first-time knee implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e.

revision knee implant) about 77.3% of the knee implant continue to function at 10 years. However, it can be longer or shorter.

Trabecular Metal Femoral Cone Augments used with NexGen Complete Knee Solution Rotating Hinge Knee (RHK):

As a guide, about 90% of first-time rotating hinge implants continue to function at 10 years after surgery. If you have had your implant as a replacement to another knee implant (i.e. revision knee implant), about 77.3% of the rotating hinge knee implants continue to function at 10 years. However, it can be longer or shorter.

Many factors could influence the length of healing time and overall performance of your implant. These include 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 surgery
- Instructions given to you after surgery

You can control other factors, such as:

- Your health
- Your weight
- Your activity level
- Your lifestyle choices
- Alcohol and tobacco consumption
- Following the instructions of your doctor after the surgery

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?

Information for Patient

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 implant failure include, but are not limited to:

- Excessive forces put on it
- Accident or fall
- Extreme or awkward movements
- Excessive activity level
- Excessive weight
- Not following the recovery instructions provided by your doctor

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. These materials meet the specifications described in internationally accepted standards that support the safety and design performance of the implants.
Surgical implants are made from different materials. No implant is completely free of side effects when placed 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. If you think you have any allergic reactions after surgery, please contact your doctor.

Materials and Compositions:

Component(s)	Material(s)	Material Composition (Range or Maximum)	ASTM/ISO Standard(s)
Femoral Cone Augments	Trabecular Metal (Tantalum)	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	Not Applicable

Information for Patient

Does my implant have special operating instructions?
No, there are no special operating instructions.

What should I do if I have a problem?
Please report if you experience unexpected complications, such as pain or swelling, loss of function in your knee implant or other conditions where you feel unwell, and you think it may be due to your knee implant. For more information, please see the sections “What are the possible issues?” and “What should I do if I need help or advice” within this document.

To report a problem, contact your doctor at first instance. You may also contact:

- 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 www.tga.gov.au.

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