Howmedica Osteonics INSIGNIA™ HIP STEM

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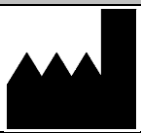
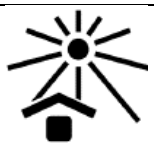
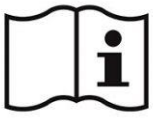
QIN 4441 REV AUS1.0

Refer to product label for CE mark status and Legal Manufacturer. The CE mark is only valid if also found on the product label

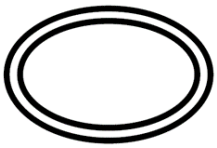
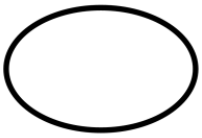
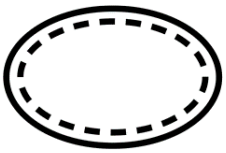
Labelling Symbols Glossary

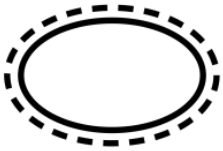
The following is a list of symbols that may be used on Stryker medical device labelling. Refer to individual product labels for applicable symbology for each product.

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized European Representative	Indicates the Authorized representative in the European Community.	ISO 15223-1	5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1	5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.7
	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	ISO 15223-1	5.2.2
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1	5.2.3

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1	5.2.4
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1	5.2.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1	5.2.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1	5.2.8
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1	5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1	5.3.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1	5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
 ifu.stryker.com	Consult instructions for use	Indicates an instruction to consult an electronic instructions for use (eIFU). This symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or any other appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1	5.4.3.A.15
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
	MR conditional	Indicates an item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503	N.A
	MR safe	Indicates an item that poses no known hazards resulting from exposure to any MR environment.	ASTM F2503	N.A

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
	MR unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503	N.A
	Prescription only	Requires prescription for sale in the United States and is used in place of the statement below: Caution: Federal law restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner.	21 CFR Part 801.109	N.A
	Medical Device	Indicates the item is a medical device	ISO 15223-1	5.7.7
	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1	5.2.12
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1	5.2.11
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	ISO 15223-1	5.2.13

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1	5.2.14
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1	5.7.10
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine-disrupting properties	ISO 15223-1	5.4.10
	Patient identification	Indicates the identification data of the patient	ISO 15223-1	5.7.3
	Date (of Implantation)	To identify the date that information was entered, or a medical procedure took place	ISO 15223-1	5.7.6
	Health care center or doctor	To indicate the address of the health care center or doctor where medical information about the patient may be found	ISO 15223-1	5.7.5

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Clause
	Patient information website	Indicates a website where a patient may obtain additional information on the medical product	ISO 15223-1	5.7.4
	Open Here	To identify the location where the package can be opened and to indicate the method of opening it.	ISO 7000-3079	N.A

Stryker Symbols

Symbol	Symbol Title	Explanatory Text
	Sterilized using hydrogen peroxide	Indicates a medical device that has been sterilized using hydrogen peroxide.
	Contact by Phone	Indicates an instruction to dial telephone number(s). The symbol is accompanied by the available telephone number(s).
	Open Here	To identify the location where the package can be opened and to indicate the method of opening it.
	QTY	Quantity

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VN 122 80297

English

INSIGNIA™ HIP STEM

Description
Howmedica Osteonics Corp. Insignia™ Hip Stem is a collared stem that is intended for cementless use in primary applications where there is adequate bone stock. It features a plasma-sprayed Hydroxyapatite coating over plasma-sprayed Titanium in the proximal region and a plasma-sprayed Hydroxyapatite coating over grit blast in the distal region and collar underside. See package label for specific product features and the surgical protocol for additional procedural information and product information.

Materials
The devices are manufactured from materials that meet the following standards:

Product	Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Insignia Hip Stems 7000-55XX XX=00-11	Ti-6Al-4V ELI (ASTM F136)	Nitrogen	0.05 Max	70.6-218	92.9-93.3
		Carbon	0.08 Max		
		Hydrogen	0.012 Max		
		Iron	0.25 Max		
		Oxygen	0.13 Max		
		Aluminum	5.5-6.5		
		Vanadium	3.5-4.5		
		Titanium	88.48-91		
	Cp Ti Coating (ASTM F1580)	Oxygen	≤0.4	4.83-14.3	6.12-6.35
		Iron	≤0.5		
		Carbon	≤0.08		
		Hydrogen	≤0.05		
		Nitrogen	≤0.05		
		Titanium	98.92-100		
	HA (ISO 13779-2:2018)	Hydroxyapatite	≥45	.604-1.45	.620-.794
		Amorphous Calcium Phosphate	≤55		
		Other Crystalline Calcium Phosphates	≤30		
		Calcium Oxide	≤5		
Insignia Hip Stems 7000-66XX XX=00-11	Ti-6Al-4V ELI (ASTM F136)	Nitrogen	0.05 Max	74.0-222	93.2-93.4
		Carbon	0.08 Max		
		Hydrogen	0.012 Max		
		Iron	0.25 Max		
		Oxygen	0.13 Max		
		Aluminum	5.5-6.5		
		Vanadium	3.5-4.5		
		Titanium	88.48-91		
	Cp Ti Coating (ASTM F1580)	Oxygen	≤0.4	4.83-14.3	6.01-6.08
		Iron	≤0.5		

		Carbon	≤0.08		
		Hydrogen	≤0.05		
		Nitrogen	≤0.05		
		Titanium	98.92-100		
	HA (ISO 13779-2:2018)	Hydroxyapatite	≥45	.601-1.45	.610-.757
		Amorphous Calcium Phosphate	≤55		
		Other Crystalline Calcium Phosphates	≤30		
		Calcium Oxide	≤5		

See the surgical technique for the components, which are compatible for the specific hip system.

Compatibility

- Howmedica Osteonics Insignia Hip Stems are compatible with Howmedica Osteonics V40 Taper Femoral Heads made from the following material: CoCr, LFIT CoCr, Alumina, and BIOLOX delta.
- Howmedica Osteonics Insignia Hip Stems are compatible with Howmedica Osteonics C-Taper Femoral Heads made from the following material when used with the Howmedica Osteonics V40 Taper Adapter Sleeve: Alumina, BIOLOX delta.
- Howmedica Osteonics Insignia Hip Stems are compatible with Howmedica Osteonics Universal Taper BIOLOX delta Femoral Heads when used with a Howmedica Osteonics V40 Taper Universal Adapter Sleeve.
- Howmedica Osteonics Insignia Hip Stems are compatible with Howmedica Osteonics Unitrax Unipolar Heads when used with the Unitrax V40 monolithic adapter.
- Howmedica Osteonics Insignia Hip Stems cannot be used with femoral heads with an offset greater than +12mm. This is indicated with a visual check (√) on the trunnion of the stem.

Hip Arthroplasty Indications for US and Rest of World:

1. Painful, disabling joint disease of the hip resulting from: noninflammatory degenerative joint disease (including osteoarthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
2. Revision of previous unsuccessful femoral head replacement, hip arthroplasty or other procedure.
3. Correction of functional deformity.
4. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Insignia Hip Stems with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indication specific to use of Insignia Hip Stems with compatible ADM and MDM Acetabular Components:

- When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks

Insignia Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Indications for Australia:

1. noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
2. correction of functional deformity.

Additional indication specific to use of Insignia Hip Stems with compatible ADM and MDM Acetabular Components:

- When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks

Insignia Hip Stems are intended for cementless use only and are intended for total arthroplasty procedures.

Contraindications

1. Any active or suspected latent infection in or about the hip joint.
2. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
3. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis
4. Skeletal immaturity
5. Known or suspected sensitivity and/or allergy to any material in the device

Warnings

In using this system, the surgeon should be aware of the following:

- In selecting patients for total joint replacements, the following factor is of extreme importance to the eventual success of the procedure: The patient's weight. The heavier the patient, the greater the load on the prosthesis. As the loads on the prosthesis increase, the chance a patient will suffer adverse reactions increases, including but not limited to failure of fixation, loosening, fracture and dislocation of the device and can lead to a decreased service life. The effect of these loads will be accentuated when a small sized prosthesis is used in larger patients. Overweight or obese patients impose greater loads on the prosthesis. As obesity is a clinical diagnosis, we leave it to the surgeon to make the diagnosis based on his/her own clinical judgment. However, the World Health Organization (WHO) defines "overweight" as a BMI equal to or more than 25, and "obesity" as a BMI equal to or more than 30.
- Do not substitute another manufacturer's device, except if identified in Compatibility section above, for any component of the HOWMEDICA OSTEONICS Total Hip System. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Modular Junctions: Mate modular components firmly to prevent dissociation. Machined taper surfaces must be clean, dry and firmly mated to ensure proper seating and assembly. Repeated assembly/disassembly or failure to clean, dry and firmly mate the components could compromise the taper lock and contribute to wear/corrosion and significant clinical consequences to the patient. (See Adverse Effects below).
- Modular heads and femoral components must be from the same manufacturer to prevent mismatch of tapers. Scratching of modular heads and tapers must be avoided.
- Do not impact (hammer) directly on the ceramic head. Howmedica Osteonics Ceramic Heads must not be used if dropped or damaged in use.
- Patient post-operative pain. Inherent to all joint replacement is the risk that a patient will develop post-operative pain; pain is a commonly reported symptom regardless of the device implanted. The clinical literature reveals numerous potential causes of pain not directly related to the implant performance including, but not limited to, prior history of trauma and natural disease progression.
- For patients who present with pain following implantation of any orthopaedic implant system, the physician should consider all potential causes of the symptoms identified in the clinical literature, including infection, soft tissue impingement, and possible adverse local tissue reactions associated with wear debris, metal ions or corrosion. Accurate diagnosis of the source of pain and directed, timely intervention is essential to ensuring effective treatment of pain.
- This is a single-use device and should never be reused. Reuse of a single-use device may result in a myriad of risks including, but not limited to:

    - Contaminants leading to infection
    - Material fragments, debris, corrosion byproducts or unintended foreign objects leading to inflammatory response
    - Biologic Contaminants (non-pathological) leading to inflammation.
- Additionally, although the device may appear undamaged, previous use may have created nonvisible damage that could result in loss of device functionality such as:
    - Fractured device
    - Assembly issues
- See the "Information for Patients" Section for more information.

Precautions

- Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure, limitations of the device, instruments and implant characteristics, prior to performing surgery.
- Appropriate selection, placement, positioning, and fixation of these components are critical factors which affect implant service life. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and pre-operative level of health, as well as the surgeon's experience and familiarity with the device.
- Strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- Use caution when handling any sharp-edged orthopaedic device.
- Periodic, long-term follow-up is recommended to monitor the position and condition of the prosthetic components, as well as the condition of the adjoining bone. Avoid handling hydroxyapatite coated regions, as it may compromise the effectiveness of the device.
- Single-use devices cannot be explanted and subsequently reimplanted as the physical forces exerted by these actions may compromise the physical integrity, dimensions and/or surface finishes of the devices. Also, sterility cannot be assured for reused devices as cleaning and re-sterilization procedures have not been verified.
- Do not allow coated surfaces to contact cloth or other fiber-releasing materials.
- Protect polished bearing areas and machined taper surfaces from contact with hard or abrasive surfaces.
- Avoid handling hydroxyapatite coated regions, as it may compromise the effectiveness of the device.
- Surgeons should warn patients with metallic implants of the potential risks of undergoing a Magnetic Resonance Imaging (MRI) scan. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects. In addition, the presence of a metallic implant can produce an image artifact that may appear as a void region or geometric distortion of the true image. If the image artifact is near the area of interest, it may make the MRI scan uninformative or may lead to inaccurate clinical diagnosis or treatment.

Magnetic Resonance Imaging (MRI) Safety Information

The Insignia Hip Stem has been evaluated for safety and compatibility in the MR environment. Non-clinical testing demonstrated that the devices listed above are MR Conditional. A patient with the listed device can be safely scanned in an MR scanner meeting the following conditions:

Device Name	Insignia Hip Stem
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	2,310 Gauss/cm (23 T/m)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole Body
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)

Scan Duration	2 W/kg whole-body average SAR for 15 minutes of continuous RF scanning. Under the scanning conditions defined above, these devices are expected to produce a temperature rise of less than 4.1 ºC after 15 minutes of continuous scanning. *
MR Image Artifact	The presence of this implant may produce an image artifact. In nonclinical testing, the image artifact caused by the device extends approximately 84 mm from the device when imaged with a gradient echo pulse sequence using a 3.0 T/128 MHz MR system.

* Nonclinical testing of Insignia Hip Stem in a worst-case implant system configuration demonstrated maximum temperature rise of 2.0 ºC when scanned for 1 hour in Normal Operating Mode.

This MRI information is also available at https://www.stryker.com/us/en/joint-replacement/MRI.html.

Adverse Effects

1. While the expected life of joint replacement devices is difficult to estimate, it is finite. These devices are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices but cannot be evaluated in vivo, the devices cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
2. Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations. Muscle and fibrous tissue laxity can also contribute to these conditions.
3. Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
4. Fatigue fracture of femoral stems has occurred in a small percentage of cases. Stem fracture is more likely to occur in heavy, physically active patients, or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
5. Intraoperative fissure, fracture, or perforation of the femur or trochanter can occur due to impaction of the component into the prepared femoral canal. Postoperative femoral fracture can occur due to trauma, the presence of defects, or poor bone stock.
6. Polyethylene particles and metal particles from mechanisms other than wear. Very small particles from metal and polyethylene components can be shed from non-articulating surfaces during normal use and over time. Although most of these particles stay in the relevant joint (e. g. contained in the synovium) or are trapped by surrounding scar tissue, microscopic particles can migrate throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. The long-term effects, if any, from these particles, are unknown. The long-term effects have been theorized to include:
   - **Cancer:** There is presently no scientific evidence that links metallic or polyethylene particles with cancer. However, the possibility cannot be ruled out.
   - **Lymphadenopathy and Accumulation in Other Tissues/Organs:** There have been a few reports of the accumulation of particles in lymph nodes (proximal and distal). Although no medical complications or disease process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
   - **Systemic Disease:** It is possible that some long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of

particles and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long term effect.

7. Non-metallic wear debris. Wear debris is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third-body wear. With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
8. Metal wear debris. Metal wear debris, metal ions and corrosion of metal implants. Generation of metal wear debris, metal ions and/or corrosion occurs whenever two surfaces are in contact, and at least one surface is metal. There have been reports in the literature of cases of adverse local tissue reactions associated with wear and/or corrosion at modular junctions formed by modular heads (stem/head interface). Local joint chemistry and/or other patient-specific conditions including, but not limited to infection may affect the potential for *in vivo* corrosion and its possible clinical consequences.
9. Metal debris and corrosion by-products. Modular junctions may release metal debris and/ or metal ions due to fretting, galvanic corrosion, crevice corrosion, or other processes. There are several factors involved in these processes, including forces across a junction, which are not fully understood. These corrosion products or metal debris may affect the tissues surrounding the implant and adversely affect the duration of service life. There have been reports of patients developing adverse local tissue reactions (including, but not limited to, tissue necrosis, pseudotumors, cysts and fluid accumulations, metallosis and aseptic lymphocyte dominated vasculitis associated lesions), elevated metal ion levels in the blood and/or urine and hypersensitivity/allergic reactions associated with corrosion and/or wear-related debris in the implant vicinity. Affected patients may present with symptoms similar to those associated with infection, including pain (most likely during weight-bearing) and swelling at the local joint site. These reactions should be carefully monitored and may result in early revision surgery. Medical literature describes systemic reactions to by-products arising from contemporary metal on metal articulating bearing surfaces. While there are no metal on metal bearing interfaces in this system, it could be theorized that similar systemic reactions may arise from fretting and corrosion arising from any metal interface.
10. Although rare, sensitivity/allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
11. Undesirable shortening or lengthening of the limb.
12. Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders, gastrointestinal disorders, vascular disorders including thrombus, bronchopulmonary disorders including emboli, myocardial infarction, or death.
13. Peripheral neuropathies, nerve damage, circulatory compromise, and heterotopic bone formation may occur.
14. Infection can lead to failure of the joint replacement.
15. Adverse effects may require medical intervention including reoperation, revision, arthrodesis of the involved joint, Girdlestone, or amputation of the limb.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

Patient Selection

- Proper implant selection is critical to the stability and longevity of the femoral stem implant in hip arthroplasty. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and pre-operative level of health, as well as the surgeon's experience and familiarity with the device. Longevity and stability of the implant may be affected by these factors.
- The smaller sized femoral stem implants are intended for use in patients with smaller intramedullary femoral canals. Their geometry has been reduced to accommodate the anatomy of the smaller intramedullary femoral canal, which thereby decreases their fatigue-strength and load- bearing characteristics. Therefore, patients with high physical activity levels, poor bone quality, or who are overweight are not candidates for the smaller femoral implant stem.

- Patients with high-activity level and/or higher weight patients are at greater risk for implant complications or failures. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.
- The surgeon must evaluate each situation carefully based upon the patient's clinical presentation before making any decisions regarding the selection of the implant.

Use and Implantation
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
- The Surgical Protocol provides additional procedural information.
- Specialized instruments are available and should be used to ensure accurate implantation of prosthetic components.
- To preserve the integrity of the actual implants and their sterile packaging, use the recommended trial components for size determination, trial reduction and range-of-motion evaluation.
- Proper selection, placement, and fixation of the implant components are critical factors affecting implant service life. The durability of prosthetic implants is affected by many biologic, biomechanic and other extrinsic factors that limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

Information for Patients
- The surgeon must warn patients of surgical risks and inform them of possible adverse effects. The surgeon must warn patients that the implant does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint, that the implant can break or become damaged for numerous reasons, including as a result of strenuous activity or trauma, and that the implant has a finite service life and may need to be replaced in the future.
- The surgeon must warn patients of the limitations of the reconstruction and the need to protect the implant from full weight bearing until adequate fixation and healing have occurred. The surgeon must advise the patient to limit activities and protect the implant from strenuous activity, trauma or impact loading, and to follow the surgeon's instructions regarding activity level, follow-up care, and treatment.
- The surgeon must advise patients that the implant cannot be expected to withstand the same activity levels and loads as a normal healthy joint, and that the implant will not restore function to the level expected with normal healthy bone. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the implant, or both. The surgeon must advise the patient against having unrealistic functional expectations.
- The surgeon must warn patients that strenuous activity, trauma or impact loading affecting the implant have been implicated in failure of the implant by loosening, fracture and/or wear of the implants. Many factors, including loosening of the implant components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other surgical procedures have also been associated with transient bacteremia. To help minimize the risk of infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures. Surgeons should advise the patient to inform their doctors/dentists If they have an artificial joint replacement so that a decision can be made regarding antibiotic prophylaxis for such procedures.

Additional information for the patient can be found here: patientinfo.stryker.com

How Supplied:
- These components have been sterilized by gamma radiation. Refer to the package label for the sterilization method.
- Do NOT resterilize.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is not sterile.
- If the package is opened, but the product is not used, the product must not be resterilized and must therefore be discarded or returned to the supplier.

- Use caution to prevent contamination of any components.
- Discard ALL nonsterile or contaminated products.
- Device should not be used after the expiry date displayed on the label as packaging has not been validated beyond this date.
- Single use devices cannot be explanted and subsequently reimplanted as the physical forces exerted by these actions may compromise the physical integrity, dimensions and/or surface finishes of the devices. Also, sterility cannot be assured for reused devices as cleaning and re-sterilization procedures have not been verified.

Transport & Storage Information
The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging. Do not remove the device from the packaging until it is planned to be used. Store the device in standard hospital environmental conditions unless specific requirements are defined and described on the product label.

Expected Lifetime
The expected lifetime of the device is based upon analysis of non-clinical mechanical testing models that were designed to meet a minimum of at least 10 years of simulated use. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

Safe Disposal
If a device is being returned for evaluation, please contact your local Stryker representative for shipping/handling information. If the device is not being returned to Stryker, implant components are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state and local regulations. As part of the disposal process, verify that the implant in its entirety has been explanted from the surgical site.

List of abbreviations used in labelling

Term	Abbreviation	Term	Abbreviation
Alpha Code	ALPH CDE	Neck	NK
Angle	ANG	Offset	OFFST
Degree	DEG or °	Outer Diameter	OD
Diameter	DIA	Right	RT ►
Extra Deep	XDP	Screw Holes	SCR HLS
Extra Large	XLGE	Side	SDE
Extra Small	XSM	Size	SZE
Head	HD	Small	SM
Height	HT	Standard	STD
Inner Diameter	ID	Stem	STM
Insert	INSR	Taper	TPR
Large	LGE	Thickness	THKNS
Left	◄ LFT	Type	TYP
Length	LNTH	With	W/
Medium	MED	Without	W/O

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

CE Disclaimer
Refer to product label for CE Mark Status and Legal Manufacturer. The CE mark is only valid if also found on the product label.

Trademark Statement
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Patient Implant Card Instructions (for Health Care Professionals)
Healthcare providers are responsible for completing the following information on the provided Patient Implant Card. Once complete, that Patient Implant Card should be given to the patient.
· Name of the patient
· Date of implantation
· Name and address of surgical centre
· Type of implant in native language