stryker
Howmedica
OSTEONICS

TRIATHLON® HINGE KNEE SYSTEM

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

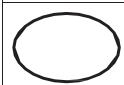
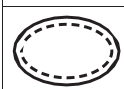
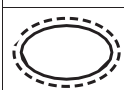
Labelling Symbols Glossary

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

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized Representative in the European Community	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
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1	5.2.4

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	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	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
 https://www.stryker.com/au/en/about/our-locations/australia/ifus/additional.html	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.16
	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
	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

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	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
	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

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	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
	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	Title of Symbol	Description of Symbol
	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

English

TRIATHLON® HINGE KNEE SYSTEM

ATTENTION OPERATING SURGEON

The advancement of total knee replacement has provided the surgeon with a means of restoring mobility, correcting deformity, and reducing pain with the use of implanted prosthetic devices. These devices, while proven successful, are manufactured from metal and plastic materials. No prosthetic device can therefore be expected to withstand activity levels and loads in the same way as would a normal healthy joint. The prosthetic system will not be as strong, reliable, or durable as a natural human knee joint.

In using total knee joint implants, the surgeon should be aware of the following:

A. The correct selection and positioning of the implant are extremely important. Success in total joint replacement requires the selection of the proper size, shape, and configuration implants. Total joint prostheses require careful seating, rigid fixation, and adequate bone support. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic, and other extrinsic factors, which limit their service life. Accordingly, strict adherence to indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service level.

B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:

1. **A condition of senility, mental illness, alcoholism, or chemical dependence.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, hastening failure or other complications**.**
2. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
3. **Orthopaedic history.** The prognosis for success of the procedure is dependent upon the patient's orthopaedic history. Patients who have had multiple previous procedures and/or implants should be carefully counselled regarding their anticipated outcome.
4. **Quality of bone.** Survivorship of the total knee replacement may be affected by weakened bone stock, which may be the result of certain systemic or metabolic diseases such as those treated with steroids, immunosuppressants or chemotherapeutics.

Description

Triathlon® Hinge Knee System is a tricompartmental knee system. The system consists of a bossed femoral component and a stemmed tibial rotating component connected by a set of bushings and an axle. A bumper locks this assembly. This assembly allows for motion through the axle/bushing combination in the flexion/extension plane. The articulation between the cylindrical bearing surfaces on the underside of the tibial rotating component and a tibial insert allows for motion in the rotational plane. The tibial insert is assembled to a tibial stemmed tray which incorporates a longitudinal bore to accept a tibial sleeve. Optional distal femoral and tibial augments are available to fill bone defect.

Materials

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

Triathlon® Hinge Femoral Component (5612-F-X0Y)

Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Cast Co-Cr-Mo (ASTM F75)	Chromium	27.00-30.00	103-126	32-41.3
	Molybdenum	5.00-7.00		
	Nickel	≤0.50		
	Iron	≤0.75		
	Carbon	≤0.35		
	Silicon	≤1.00		
	Manganese	≤1.00		
	Tungsten	≤0.20		
	Phosphorus	≤0.020		
	Sulfur	≤0.010		
	Nitrogen	≤0.25		
	Aluminum	≤0.10		
	Titanium	≤0.10		
	Boron	≤0.010		
	Cobalt	58.7-68.0	146-267	58.7-68.0

Triathlon® Revision Tibial Baseplate (5612-B-X00)

Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Cast Co-Cr-Mo (ASTM F75)	Chromium	27.00-30.00	49.0-51.4	32-41.3
	Molybdenum	5.00-7.00		
	Nickel	≤0.50		
	Iron	≤0.75		
	Carbon	≤0.35		
	Silicon	≤1.00		
	Manganese	≤1.00		
	Tungsten	≤0.20		
	Phosphorus	≤0.020		
	Sulfur	≤0.010		
	Nitrogen	≤0.25		
	Aluminum	≤0.10		
	Titanium	≤0.10		
	Boron	≤0.010		
	Cobalt	58.7-68.0	69.6-109	58.7-68.0

Triathlon® Hinge Insert with sleeve (5612-P-XXX)

Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
UHMWPE Type 1 (ASTM F648) (ISO 5834-1) (ISO 5834-2) Tibial Insert Body	UHMWPE	100	14.8 – 66.9	100
Wrought Co-Cr-W-Ni (ASTM F90) Locking Wire	Carbon	0.05 – 0.15	0.117-0.196	48.1-48.5
	Manganese	1.00 – 2.00		
	Silicon	≤0.40		
	Phosphorus	≤0.040		
	Sulfur	≤0.030		
	Chromium	19.00 – 21.00		
	Nickel	9.00 – 11.00		
	Tungsten	14.00 – 16.00		
	Iron	≤3.00		
	Cobalt	46.4 – 57.0	0.126-0.208	46.4-57.0
UHMWPE Type 1 (ASTM F648) (ISO 5834-1) (ISO 5834-2) Tibial Sleeve Component (5612-5-002)	UHMWPE	100	2.31	100

Triathlon® Hinge Tibial Bearing Component (5612-0-001, 003, 005)

Material Description	Substances in Materials	Increment (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Wrought CoCr Alloy 1 (ASTM F1537)	Carbon	≤0.14	46.4-53.8	31.0-41.1
	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	58.9 – 69.0	77.1-103	58.9 – 69.0

Triathlon® Hinge Bumper (5612-4-000, 003)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
UHMWPE Type 1 (ASTM F648) (ISO 5834-1) (ISO 5834-2)	UHMWPE	100	3.80-3.92	100

Triathlon® Revision Tibial Augment (5612-A-XXX)

Material Description	Substances in Materials	Increment (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
CoCr Alloy 1 (ASTM F1537) Augment Body	Carbon	≤0.14	8.42-31.6	31.0 – 41.1
	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	58.9 – 69.0	12.1-70.4	58.9 – 69.0
CoCr Alloy 1 (ASTM F1537) Locking Screw Body	Carbon	≤0.14	0.631-0.836	31.0 – 41.1
	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	58.9 – 69.0	1.20-1.40	58.9 – 69.0

Triathlon® Revision Tibial Augment (5612-A-XXX)

Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Cast Co-Cr-Mo (ASTM F75) Augment Body	Chromium	27.00-30.00	8.48-32.7	32-41.3
	Molybdenum	5.00-7.00		
	Nickel	≤0.50		
	Iron	≤0.75		
	Carbon	≤0.35		
	Silicon	≤1.00		
	Manganese	≤1.00		
	Tungsten	≤0.20		
	Phosphorus	≤0.020		
	Sulfur	≤0.010		
	Nitrogen	≤0.25		
	Aluminum	≤0.10		
	Titanium	≤0.10		
	Boron	≤0.010		
	Cobalt	58.7-68.0	12.1-69.6	58.7-68.0
CoCr Alloy 1 (ASTM F1537) Locking Screw Body	Carbon	≤0.14	0.631-0.836	31.0 – 41.1
	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	58.9 – 69.0	1.20-1.40	58.9 – 69.0

Triathlon® Hinge Femoral Distal Augment (5612-D-XXX)

Material Description	Substances in Materials	Increment (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
CoCr Alloy 1 (ASTM F1537) Augment Body	Carbon	≤0.14	1.28-7.36	31.0 – 41.1
	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	58.9 – 69.0	1.84-16.4	58.9 – 69.0
CoCr Alloy 1 (ASTM F1537) Locking Screw Body	Carbon	≤0.14	0.883-1.17	31.0 – 41.1
	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	58.9 – 69.0	1.68-1.97	58.9 – 69.0

Triathlon® Bushing and Axle Standard Assembly Pack (5612-3-000)

Material Description	Substances in Materials	Increment (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
CoCr Alloy 1 (ASTM F1537) Axle (5612-3-001)	Carbon	≤0.14	11.3 – 12.8	31.0 – 41.1
	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	58.9 – 69.0	18.3-25.1	58.9 – 69.0
UHMWPE Type 1 (ASTM F648) (ISO 5834-1) (ISO 5834-2) Bushing (5612-2-002)	UHMWPE	100	2.37	100

Compatibility

Howmedica Osteonics Corp.'s Triathlon® Hinge Knee System includes femoral, tibial rotating/bearing, bushing, axle, bumper, tibial baseplate with sleeve, tibial inserts, distal femoral augments, and tibial augment components.

Femoral components (5612-F-X0Y) are designed in right and left configurations and are available in sizes 1 through 6. The femoral components can be used with the bushings and axle (5612-3-000) or bushings (6481-2-110) and axle (6481-2-120), bumper (5612-4-00X), and bearing component (5612-0-00X). The femoral components can be used with the Triathlon® TS stems (5560-S-XXX, 556X-S-0XX), stem extenders (5571-S-0XX), patella components (555X-L-XXX, 555X-G-XXX, 555X-G-XXX-E), femoral cone augments (5549-A-6XX), and Hinge Femoral Distal Augments (5612-D-XXX).

Tibial Baseplate components (5612-B-X00) are available in sizes 1 through 7. The baseplate can be used with the Triathlon® Hinge Inserts with tibial sleeve (5612-P-XXX), and Triathlon® Revision Inserts (5612-X-XXX). The baseplate can be used with the Triathlon® TS Stems (5560-S-XXX, 556X-S-0XX), stem extenders (5571-S-0XX), Tibial Cone Augments (5549-A-XXX), and Revision Tibial Augments (5612-A-XXX).

Triathlon® Hinge Inserts with tibial sleeve (5612-P-XXX) are available in sizes 1 through 7 and in various thicknesses. The Inserts can be used with the Triathlon® Hinge Tibial Bearing Component (5612-0-00X) and Tibial Baseplate (5612-B-XXX).

The optional Revision Tibial Augments (5612-A-XXX) can be used with the Revision Baseplate (5612-B-X00) and the Universal Baseplate (5521-B-X00).

Compatibility of Triathlon Hinge Knee System components when used with MRH/GMRS Femoral component:

Triathlon® Hinge Inserts with tibial sleeve (5612-P-XXX) and Triathlon® Revision Tibial Baseplate (5612-B-X00) can be used with MRH femoral component (6481-1-1XX) when used with Triathlon® Hinge Tibial Bearing Component (5612-0-00X), Triathlon® bushings and axle (5612-3-000) or bushings (6481-2-110) and axle (6481-2-120), and bumpers (6481-2-130/133).

Triathlon® Hinge Inserts with tibial sleeve (5612-P-XXX) and Triathlon® Revision Tibial Baseplate (5612-B-X00) can be used with GMRS small distal femoral component (6495-2-010/020) when used with Triathlon® Hinge Tibial Bearing Component (5612-0-001), bushings (6495-2-105), axle (6495-2-115), and bumper (6481-2-130/133) components.

Triathlon® Hinge Inserts with tibial sleeve (5612-P-XXX) and Triathlon® Revision Tibial Baseplate (5612-B-X00) can be used with the GMRS standard distal femoral component (6495-2-030/040) when used with Triathlon® Hinge Tibial Bearing Component (5612-0-001), Triathlon® bushings and axle (5612-3-000) or bushing (6481-2-110) and axle (6481-2-120), and bumper (6481-2-130/133) components.

The MRH Sleeve (6481-2-140) may be used in place of the sleeve provided with the Hinge Insert (5612-P-XXX) in the compatibilities listed above.

Indications for US and Rest of World:

Rotating Hinge Knee System is intended to be implanted with bone cement for the following condition(s):

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak. And/or
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.
- And/or where segmental resection and replacement of the distal femur is required.

Indications for Australia:

Rotating Hinge Knee System is intended to be implanted with bone cement for the following condition(s):

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak. And/or
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

Refer to the package insert of the devices with which the device listed will be used for a complete list of related indications and contraindications.

Contraindications

Absolute contraindications include:

1. overt infection;

2. distant foci of infections (which may cause hematogenous spread to the implant site);
3. rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
4. skeletally immature patients;
5. cases where there is poor bone stock which would make the procedure unjustifiable.
6. Known or suspected sensitivity and/or allergy to any material in the device.

Conditions presenting an increased risk of failure include:

1. uncooperative patient or patient with neurologic disorder, incapable of following instructions;
2. osteoporosis;
3. metabolic disorders which may impair bone formation or cause bone loss;
4. osteomalacia; and,
5. previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

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.
- Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments, and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- The metal retaining wire on the insert should not be handled or removed, as it is critical to the security of the assembly. Discard any tibial bearing insert if the metal retaining wire appears damaged or mishandled. Tampering with this assembly can result in improper function of the retaining mechanism.
- Use caution when handling any sharp-edged orthopedic device.
- **Cemented application**. Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips, bone cement fragments and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.
- **Prosthetic components**. Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers should not be mixed, since tolerances or materials may be incompatible. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.
- **Metal components**. Some of the alloys utilized to produce orthopedic implants contain metallic

elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon.

- **Alignment of components**. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the limb or joint can cause excessive wear, loosening of the prosthesis and pain leading to earlier-than-desired revision of one or more of the prosthetic components.
- **Polyethylene wear**. As would be expected, wear of the polyethylene surfaces of tibial, bushing and patella components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear likely will shorten the useful life of the prosthesis, and likely will lead to an earlier-than-desired revision to replace the worn prosthetic components.
- Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged. It may have small defects and internal stress patterns which may lead to early failure of the device.
- **Do NOT re-sterilize.**
- Components labeled for "Cemented Use Only" are to be implanted only with bone cement.
- **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 orthopedic 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.
- **Triathlon® Hinge Knee System Femoral Components (5612-F-X0Y) require a 100mm or longer Stem Extension.**
- **Triathlon® Revision Tibial Baseplate Components (5612-B-X00) require a 50mm or longer Stem Extension.**
- **The 50mm Stem Extender cannot be used with the Triathlon® Revision Tibial Baseplate Components (5612-B-X00) when used with a 150mm Triathlon® TS Stem.**
- 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:
    1. Contaminants leading to infection
    2. Material fragments, debris, corrosion byproducts or unintended foreign objects leading to inflammatory response
    3. 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:
    1. Fractured device
    2. Assembly issues
- See the "Information for Patients" Section for more information.
- The Triathlon Hinge Knee System devices listed (Triathlon® Hinge Femoral Component, Triathlon® Revision Tibial Baseplate Triathlon® Hinge Insert, Triathlon® Tibial Bearing Component, Axle, Triathlon® Revision Tibial Augment, and Triathlon® Hinge Femoral Distal Augment) contain the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

- Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical device manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. Refer to the listed device label to determine if the device contains hazardous substances.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
- Surgeons must advise patients of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Surgeons should caution patients to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- Surgeons should warn patients of potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant. The surgeon should warn patients that the device does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint and that the implant can break or become damaged as a result of strenuous activity or trauma.
- Appropriate selection, placement and fixation are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic, and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- **Instruments**. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components.
- While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.
- **Reuse**. An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
- **Handling**. Careful handling of implants is important. The highly polished portion of the implant should not come in contact with hard surfaces. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load. Discard all damaged or mishandled components. Never reuse an implant, even though it may appear undamaged.
- **MR**. 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 Triathlon® Hinge Knee System has not been evaluated for safety in the MR environment. Non-clinical testing demonstrated that the devices listed are MR Conditional. A patient with the listed devices can be safely scanned in an MR scanner under the following conditions. Failure to follow these conditions may result in injury:

Device Name	Triathlon® Hinge Knee System
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	3000 Gauss/cm (30 T/m)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole Body
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	0.5 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	Patients can be scanned at 0.5 W/kg whole-body average SAR for 12 minutes, followed by 18 minutes of wait time. This sequence can be repeated twice in 60 minutes. Under the scanning conditions and sequence defined above, these devices are expected to produce a temperature rise of less than 6.0 ºC.
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 113 mm from the device when imaged with a gradient echo or spin echo pulse sequence using a 3.0 T/128 MHz MR system.

Adverse Effects

- 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 (i.e. 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 for their intended use clearly outweigh the potential risks for any such theoretical long-term effect.

- 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.
- Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported and may be a result of surgical trauma.
- Dislocation and sublaxation of implant components can result from improper positioning and/or migration of the components. Patient activity, trauma and soft tissue laxity including muscle, fibrous tissue and ligaments can also contribute to these conditions.
- Implants can loosen or migrate due to trauma or loss of fixation.
- Infection can lead to failure of the joint replacement.
- While rare, fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment or extreme duration of service.
- Soft tissue imbalance can cause excessive wear and/or failure of the implant.
- Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.)
- Intraoperative fracture of the femur, tibia or patella can occur while preparing the bone sites and/or seating of the implants.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint and/or amputation of the limb.
- **Intraoperative and early postoperative complications can include, but are not limited to**:
  1. deep venous thrombosis;
  2. damage to blood vessels;
  3. temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
  4. a sudden drop in intraoperative blood pressure associated with the use of bone cement;
  5. varus-valgus deformity with resultant limb/prosthesis malalignment;
  6. cardiovascular disorders including, pulmonary embolism or myocardial infarction;
  7. hematoma;
  8. delayed wound healing;
  9. deep wound infection (early or late), a potentially serious complication of any joint replacement which may necessitate removal of the prosthesis and subsequent arthrodesis - appropriate antibiotic prophylaxis and strict adherence to aseptic procedures is mandatory; and,
  10. femoral, tibial or patella bone or component fracture.
- **Late postoperative complications can include, but are not limited to**:
  1. late (or early) loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components. (Clinical experience suggests that particular attention to the items contained in the WARNINGS and PRECAUTIONS sections of this package insert may help minimize the risk of their occurring.);
  2. patellar fracture as a result of excess tension, or inadvertent intraoperative weakening;

3. aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy;
4. periarticular calcification or ossification, with or without impediment to joint mobility;
5. inadequate range of motion due to improper selection or positioning of components, impingement or periarticular calcification, dystrophy; and,
6. bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, all of which have been reported in association with total knee replacement.

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

Important Physician Information

- **Polyethylene Thickness**. Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness of the polyethylene component. In general, thicker inserts are thought to have lower contact stresses than thinner ones. These stresses may affect the wear of the implant components; however, the clinical implications of the theoretical stress differences have not been conclusively established. The physician should consider the trade-off between additional tibial bone resection and the use of a thicker insert. Patient related factors, such as weight, age and activity level should be part of the decision.
- **Component Matching**. There are corresponding tibial widths designed to articulate and conform with the appropriately- sized femoral components. Failure to correctly match components could result in premature failure of the tibial component and contribute to joint laxity.
- **Product Label**. The product label provides information regarding the characteristics specific to each device (including the specific material(s) from which the device is manufactured). See product label for information regarding the specific product referenced in this package insert.
- **Bone Resorption and Osteolysis**. Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence. Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

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, hydrogen peroxide gas plasma, or ethylene oxide. Refer to the package label for the sterilization method.
- Inspect the packaging of ALL sterile products for flaws before opening. In the presence of any flaws, assume the product is not sterile.
- Do NOT re-sterilize.
- Take care to prevent contamination of ANY components.
- Discard ALL nonsterile or contaminated product.
- 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.

Use and Implantation

- Use the recommended trial components for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Care should be taken to remove bone chips, bone cement fragments and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surfaces of the implant.
- Howmedica Osteonics Corp.'s Surgical Protocols provide additional procedural information.
- Consult the product label for specific product compatibility.

Clinical Benefits/Clinical Performance Data

The clinical benefits of the Triathlon® Hinge Knee System include decreased pain and increased function. These claims are supported by a review of the clinical data for the Rotating Hinge Knee System obtained from one or more of the following sources: national joint replacement registries, clinical studies, and/or a review of the clinical literature. These data, in conjunction with supporting bench-top test data and engineering analyses, substantiate that the device performs as intended and remains state of the art for the indications listed.

The expected lifetime of the device is based upon non-clinical 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 orthopedic 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
Depth	DPTH	Right	RT►
Diameter	DIA	Screw Holes	SCR HLS
Distal	DSTL	Side	SDE
Extra Deep	XDP	Size	SZE
Extra Large	XLGE	Small	SM
Extra Small	XSM	Standard	STD
Head	HD	Stem	STM
Height	HT	Taper	TPR
Inner Diameter	ID	Thickness	THKNS
Insert	INSR	Type	TYP
Large	LGE	Width	WDTH
Left	◄ LFT	With	W/
Length	LNTH	Without	W/O
Medium	MED		

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

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademark(s) or service mark(s): GMRS, Howmedica, MRH, Osteonics, Stryker, Triathlon. All other trademarks are trademarks of their respective owners or holders.

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