Total Hip Replacement Acetabular Components for Cemented Application

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CE 2797

QIN4301 Rev. AC

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

Labeling 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	Standard
Caution (See instructions for use for operator awareness)	ISO 15223-1
Consult instructions for use or consult electronic instructions for use	ISO 15223-1
Do not re-use	ISO 15223-1
Sterilized using irradiation	ISO 15223-1
Sterilized using hydrogen peroxide	N/A
Sterilized using ethylene oxide	ISO 15223-1
Sterilized using Aseptic processing techniques (Aseptic fill)	ISO 15223-1
Non-sterile	ISO 15223-1
Do not resterilize	ISO 15223-1
Single sterile barrier system	ISO 15223-1
Double sterile barrier system	ISO 15223-1
Single sterile barrier system with protective packaging inside	ISO 15223-1
Single sterile barrier system with protective packaging outside	ISO 15223-1
Use-by date	ISO 15223-1
Date of manufacture	ISO 15223-1
Legal manufacturer	ISO 15223-1
Authorized representative in the European Community	ISO 15223-1
Catalogue number	ISO 15223-1
Batch code	ISO 15223-1
Serial number	ISO 15223-1

Symbol		Standard
MR Safe		ASTM F2503
MR Conditional		ASTM F2503
MR Unsafe		ASTM F2503
Do not use if package is damaged		ISO 15223-1
Medical device		ISO 15223-1
Quantity		N/A
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician		N/A
Contains hazardous substances		ISO 15223-1
Temperature limit		ISO 15223-1
Keep dry		ISO 15223-1
Keep away from sunlight		ISO 15223-1
Patient identification		ISO 15223-1
Date (of Implantation)		ISO 15223-1
Health care center or doctor		ISO 15223-1
Patient information website		ISO 15223-1
Unique Device Identifier		ISO 15223-1
Contact by Phone		N/A
Open Here		N/A
Open Here		ISO 7000

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MT +31 20 796 5693
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TR 00800 142 064 866
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VN 122 80297

English

Total Hip Replacement Acetabular Components for Cemented Application

The advancement of total hip replacement has provided the surgeon with a means of restoring mobility and reducing pain with the use of implanted prosthetic devices. While these devices have proven to be largely successful in obtaining these goals, they are manufactured from metal, plastic, or other biomaterials. Any total hip replacement system, therefore, cannot be expected to withstand the same activity and loads as that of normal healthy bone. The system will not be as strong, reliable or durable as a natural human hip joint and does not have an infinite lifetime. The surgeon must warn patients about the device limitations.

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

A. The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the implant. Total joint prostheses require careful seating 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, chemical dependence or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
   2. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Description

STRYKER Total Hip Replacement Acetabular Components are intended for cemented fixation within the prepared acetabulum. The acetabular components are used in conjunction with any appropriately sized STRYKER Stems and femoral heads of compatible head size to help achieve total reconstructive replacement of the hip joint.

THR Acetabular Components: The total hip replacement acetabular components include the EXETER X3 RimFit Cups and EXETER CONTEMPORARY Flanged Cups. The EXETER X3 RimFit Cups and EXETER CONTEMPORARY Flanged Cups are assemblies that contain polyethylene cup, radiopaque wire, and cement spacer components. EXETER X3 RimFit Cups have an outer flange in either oversized or reduced configuration, radiopaque wire to help easily identify the cup position on an x-ray, and four factory-assembled cement spacers which assist to ensure a minimum cement mantle thickness of 2mm or 3mm upon cemented implantation. EXETER CONTEMPORARY Flanged Cups have an oversized outer flange, radiopaque wire to help easily identify the cup position on an x-ray, and four factory-assembled cement spacers which assist to ensure a minimum cement mantle thickness of 2mm or 3mm upon cemented implantation. Refer to product label for cement mantle sizing. STRYKER THR Acetabular Components are compatible (except specific mention) with all STRYKER Heads of the same diameter.

Materials:

The EXETER X3 RimFit Cups and EXETER CONTEMPORARY Flanged Cups are manufactured from materials that meet the following standards:

EXETER® X3® RimFit® Cup (6309-3-24X, 6309-3-6XX)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Stainless Steel Alloy (ASTM F1586)	Carbon	≤0.08	1.25 – 1.56	5.01 – 7.98
	Manganese	2.00 – 4.25		
	Phosphorus	≤0.025		
	Sulfur	≤0.01		
	Silicon	≤0.75		
	Chromium	19.5 – 22.0		
	Nickel	9.0 – 11.0		
	Molybdenum	2.0 – 3.0		
	Nitrogen	0.25 – 0.50		
	Niobium	0.25 – 0.80		
	Copper	≤0.25		
	Iron	Balance		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	14.1 – 29.3	90.2 – 93.9
Acrylic Resin (PMMA) (ASTM D788)	Acrylic Resin (PMMA)	100	0.289 – 0.350	1.12 – 1.85

EXETER® X3® RimFit Cup (6309-4-05X, 6309-4-06X)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Stainless Steel Alloy (ASTM F1586)	Carbon	≤0.08	1.50 – 1.56	6.00 – 6.97
	Manganese	2.00 – 4.25		
	Phosphorus	≤0.025		
	Sulfur	≤0.01		
	Silicon	≤0.75		
	Chromium	19.5 – 22.0		
	Nickel	9.0 – 11.0		
	Molybdenum	2.0 – 3.0		
	Nitrogen	0.25 – 0.50		
	Niobium	0.25 – 0.80		
	Copper	≤0.25		
	Iron	Balance		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	19.7 – 24.1	91.7 – 92.7
Acrylic Resin (PMMA) (ASTM D788)	Acrylic Resin (PMMA)	100	0.289 – 0.350	1.34 – 1.35

EXETER® X3® RimFit® Cup (7309-2-2XX, 7309-2-8XX)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Stainless Steel Alloy (ASTM F1586)	Carbon	≤0.08	0.997 – 1.56	4.08 – 9.07
	Manganese	2.00 – 4.25		
	Phosphorus	≤0.025		
	Sulfur	≤0.01		
	Silicon	≤0.75		
	Chromium	19.5 – 22.0		
	Nickel	9.0 – 11.0		
	Molybdenum	2.0 – 3.0		
	Nitrogen	0.25 – 0.50		
	Niobium	0.25 – 0.80		
	Copper	≤0.25		
	Iron	Balance		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	9.71 – 36.4	88.4 – 95.0
Methyl methacrylate/methyl acrylate-based polymer	Methyl methacrylate/methyl acrylate-based polymer (PMMA)*	100	0.281 – 0.341	0.891 – 2.56

*****_Note: The manufacturer has stated that the exact formulation is proprietary information._

EXETER® X3® RimFit® Cup (7309-3-2XX, 7309-3-6XX)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Stainless Steel Alloy (ASTM F1586)	Carbon	≤0.08	1.25 – 1.56	5.10 – 8.23
	Manganese	2.00 – 4.25		
	Phosphorus	≤0.025		
	Sulfur	≤0.01		
	Silicon	≤0.75		
	Chromium	19.5 – 22.0		
	Nickel	9.0 – 11.0		
	Molybdenum	2.0 – 3.0		
	Nitrogen	0.25 – 0.50		
	Niobium	0.25 – 0.80		
	Copper	≤0.25		
	Iron	Balance		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	13.6 – 28.7	89.9 – 93.8
Methyl methacrylate/methyl acrylate-based polymer	Methyl methacrylate/methyl acrylate-based polymer (PMMA)*	100	0.281 – 0.341	1.11 – 1.86

*****_Note: The manufacturer has stated that the exact formulation is proprietary information._

EXETER® X3® RimFit® Cup (7309-4-05X, 7309-4-06X)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
Stainless Steel Alloy (ASTM F1586)	Carbon	≤0.08	1.50 – 1.56	6.13 – 7.14
	Manganese	2.00 – 4.25		
	Phosphorus	≤0.025		
	Sulfur	≤0.01		
	Silicon	≤0.75		
	Chromium	19.5 – 22.0		
	Nickel	9.0 – 11.0		
	Molybdenum	2.0 – 3.0		
	Nitrogen	0.25 – 0.50		
	Niobium	0.25 – 0.80		
	Copper	≤0.25		
	Iron	Balance		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	19.2 – 23.6	91.5 – 92.5
Methyl methacrylate/methyl acrylate-based polymer	Methyl methacrylate/methyl acrylate-based polymer (PMMA)*	100	0.281 – 0.341	1.34

*****_Note: The manufacturer has stated that the exact formulation is proprietary information._

EXETER® CONTEMPORARY Flanged Cups with Cement Spacers (6309-4-24X, 6309-4-25X, 6309-4-35X, 6309-4-64X, 6309-4-65X, 6309-4-84X, 6309-4-85X, 6309-4-86X for MS0112)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
316L Stainless Steel Alloy (ASTM F138)	Carbon	≤0.030	0.959 – 1.35	3.25 – 4.90
	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		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	18.2 – 40.0	93.2 – 95.8
Acrylic resin (PMMA) (ASTM D788)	Acrylic resin (PMMA)	100	0.363 – 0.382	0.916 – 1.85

EXETER® CONTEMPORARY Flanged Cups with Cement Spacers (6309-4-2XX, 6309-4-25X, 6309-4-35X, 6309-4-64X, 6309-4-65X, 6309-4-84X, 6309-4-85X, 6309-4-86X for TS2270 per D06502)

Material Description	Substances in Materials	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
316L Stainless Steel Alloy (ASTM F138)	Carbon	≤0.030	0.959 – 1.35	3.25 – 4.90
	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		
X3® UHMWPE (ASTM F648)	Ultra-High Molecular Weight Polyethylene	100	18.2 – 40.0	93.3 – 95.9
Methyl methacrylate/methyl acrylate-based polymer	Methyl methacrylate/methyl acrylate-based polymer (PMMA)*	100	0.354 – 0.372	0.893 – 1.81

*****_Note: The manufacturer has stated that the exact formulation is proprietary information._

Definition of the term "Balance": After the determination of the quantitatively lesser alloying elements within a metal material, the balance represents the quantity of the remaining main element. The balance is typically the element that makes up the greatest weight percentage of a material's composition.

Label Information

The product label provides information regarding the characteristics specific to each device (including the specific material(s) from which the product is manufactured). See product label for information regarding the specific product referenced in this package insert.

Indications for the US and Rest of World

Exeter X3 RimFit Cups

The indications for use for total hip arthroplasty include:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less

likely to achieve satisfactory results.
4. Where bone stock is of poor quality or inadequate for other reconstructive techniques, such as cementless fixation, as indicated by deficiencies of the acetabulum.

Stryker's EXETER X3 RimFit Cup is intended for cemented use only.

Exeter Contemporary Flanged Cups (not available for sale in the United States)
The indications for use for total hip arthroplasty include:
1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Stryker's EXETER CONTEMPORARY Flanged Cup is intended for cemented use only.

Indications for the EU, EMEA, and Australia

Exeter X3 RimFit Cups
The indications for use for total hip arthroplasty include:
1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Stryker's EXETER X3 RimFit Cup is intended for cemented use only.
Exeter Contemporary Flanged Cups
The indications for use for total hip arthroplasty include:
1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. correction of functional deformity;
3. revision procedures where other treatments or devices have failed

Stryker's EXETER CONTEMPORARY Flanged Cup is intended for cemented use only.

Contraindications

Exeter X3 RimFit Cups
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 postoperative care.
3. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the cement mantle around the prosthesis.
4. Skeletal immaturity.
5. Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Exeter Contemporary Flanged Cups
1. active infection or suspected latent infection in or about the hip joint;
2. bone stock that is inadequate for support or fixation of the prosthesis
3. skeletal immature
4. any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability,

prosthesis fixation failure, or complications in postoperative care

Warnings

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

- In selecting patients for total joint replacements, the following factors can be 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 s 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 IMPACT** directly on the integral cement spacer.
- 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.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- Use caution when handling any sharp-edged orthopaedic device.
- Howmedica Osteonics Corp. strongly advises against the use of another manufacturer's femoral head or stem component with any HOWMEDICA OSTEONICS Acetabular System Component. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Intentional removal of an acetabular component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.
- Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in service life of the prosthetic implant. The surgeon must 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 condition of the prosthetic components, as well as the condition of the adjoining bone.
- 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.
- Ultra-High-Molecular-Weight Polyethylene (UHMWPE) Polyethylene Wear. As would be expected, wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip 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 may shorten the useful life of the prosthesis, and lead to relatively early revision surgery to replace the worn prosthetic components. For the EXETER CONTEMPORARY Flanged Cup and EXETER X3 RimFit Cup with the oversized flange configuration, care must be taken if the flange is trimmed. Refer to surgical protocol for appropriate method. Never implant a cup that has been incorrectly trimmed.
- Avoid excessive verticalization, which may accelerate bearing wear.

- See the ″Information for Patients″ Section for more information.
- 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
- The EXETER X3 RimFit Cups and EXETER CONTEMPORARY Flanges Cups devices contain the following substance 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 devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

Precautions

- Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure and limitations of the device, instruments, and implant characteristics prior to performing surgery.
- Appropriate selection, placement, positioning, and fixation of the total hip 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. 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.
- 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.
- 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.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- 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.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.
- 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 EXETER X3 RimFit Cups and EXETER CONTEMPORARY Flanged Cups have been evaluated for safety and compatibility in the MR environment. Non-clinical testing has demonstrated that the devices listed above are MR Conditional. A patient with these listed devices can be safely scanned in an MR scanner meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 2,310 gauss/cm (23 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system.
- Evaluation was performed using a quadrature body coil only

Under the scan conditions defined above, these devices are expected to produce a temperature rise of less than 4.1 ºC after 15 minutes of continuous scanning.

In non-clinical 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 MRI system.

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

Adverse Effects

- While the expected life of total hip replacement components is difficult to estimate, it is finite. These components 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, they cannot be evaluated in vivo. These components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- 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.
- Undesirable shortening or lengthening of the limb.
- Infection can lead to failure of the joint replacement.
- 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.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- 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.
- Acetabular pain may occur due to loosening of the implant.
- Wear of polyethylene components has occurred, and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock.
- 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.
- 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.

- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
- 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 clearly outweigh the potential risks for any such theoretical long-term effect.

Surgeons should warn patients of the above listed potential effects including the finite service life of the device and the need for post-operative protection of the implant.

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

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.

- Do NOT re-sterilize.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume the product is not sterile.
- Use caution 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

- The surgeon must be completely familiar with the implant system and surgical protocol, and complete preoperative planning should be carried out.
- The surgical protocols for total hip replacement acetabular components provide additional procedural information
- The recommended trial components should be used 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.
- All HOWMEDICA OSTEONICS Femoral Heads are compatible with the EXETER CONTEMPORARY Flanged Cup and EXETER X3 RimFit Cup. . For the EXETER CONTEMPORARY Flanged Cup and EXETER X3 RimFit Cup with the oversized flange configuration, the flange may be trimmed by the surgeon in accordance with instructions mentioned in the surgical protocol.

Clinical Benefits/Clinical Performance Data

The clinical benefits of the Exeter Cups include pain reduction and improved mobility. These claims are supported by a review of the clinical data for Exeter Cups 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 remain state of the art for use in primary and/or revision Total Hip Arthroplasty (THA) to alleviate pain and restore hip joint function.

The expected lifetime of the device is based upon 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.

Summary of Safety and Clinical Performance (SSCP)

The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the device identifiers (Basic UDI-DI). To locate the SSCP for the subject devices, refer to the Basic Unique Device Identifier (BUDI) table below.

Device	Basic UDI-DI
EXETER® X3® Rimfit Cup - (6309-2-XXX)	08858251002290SP

- (6309-3-XXX) - (6309-4-0XX)	
EXETER® X3® Rimfit Cup (EO Sterilized) - (7309-2-XXX) - (7309-3-XXX) - (7309-4-XXX)	08858251002289T6
EXETER® Contemporary™ Flanged Cups - (6309-4-XXX)	08858251002291SR

The Eudamed public website is located at https://ec.europa.eu/tools/eudamed. If assistance is needed in locating the SSCP, please contact the manufacturer as directed in these instructions.

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.

CAUTION: THIS DEVICE CANNOT BE USED WITHOUT BONE CEMENT.

IMPORTANT INFORMATION FOR THE OR STAFF
READ BEFORE OPENING STERILE PACKAGE

English

IMPORTANT INFORMATION FOR THE OR STAFF
READ BEFORE OPENING STERILE PACKAGE

The process employed to create DURATION Stabilized UHMWPE requires the use of ***very high strength seals on the inner package. As a result, the blister packages, particularly the inner package, will require significantly greater force to peel open*** than you may be accustomed to.

Please follow these instructions to facilitate opening of DURATION Stabilized UHMWPE sterile packages.

To open the
OUTER BLISTER

With **dry** hands/gloves:
1. Grip the bottom of the blister very firmly.
2. Grip the lid's thumb tab securely.
3. Exerting firm and steady force, slowly pull back the tab to remove the lid.

To open the
INNER BLISTER

With **dry** gloves:
4. Grip the protruding corner of the blister flange firmly with one hand. (Figure 1)
5. Peel the lid's thumb tab with the other hand (as if opening a peel pouch). (Figure 2)

Figure 1

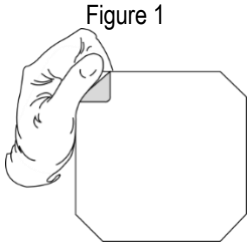
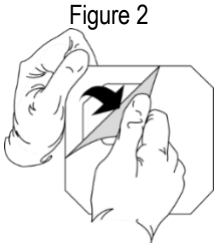


Figure 2



List of abbreviations used in labelling
The following table contains a list of abbreviations that are used on Howmedica Osteonics Corp. product labeling:

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	Taper	TPR
Insert	INSR	Thickness	THKNS
Large	LGE	Type	TYP
Left	◄ LFT	With	W/
Length	LNTH	Without	W/O
Medium	MED		

Caution: Federal Law (USA) 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 trademarks: Duration, Howmedica, Osteonics, Stryker, Exeter, Contemporary, X3, Orthinox. All other trademarks or service marks are trademarks and service marks 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

Note: To download a copy of the instructions for use, visit ifu.stryker.com or call Howmedica Osteonics Corp. toll-free.