Corin

Paragon™

Instructions for use

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This "Instructions for Use" contains information on how to use the Corin Paragon™ Hip Stem.

IMPORTANT: *The manufacturer recommends that all personnel responsible for handling and implanting the devices read and understand this information before use. The implantation of a joint prosthesis requires knowledge of anatomy, biomechanics and reconstructive surgery of the musculoskeletal system and may be performed only by a qualified surgeon. The surgeon must be acquainted, prior to surgery, with the specific operative technique of the product available from the manufacturer. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery.*

The patient must be properly informed about the device and the information contained in the present instructions for use.

Caution:

1. *The Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician.*
2. *This device should only be used in a sterile operating room of an accredited hospital by appropriately credentialed orthopaedic surgeons.*
3. *Please contact the company for product inquires and surgical techniques.*

For Glossary of product label symbols, please consult the table in Section 11.

1. Device Description

The Paragon™ Hip System is a cementless monoblock bi-planar femoral component of a joint replacement prosthesis intended to be used in Total or Partial Hip Replacement surgery. The stem is to be used in conjunction with a compatible Femoral Head component that articulates with either a compatible acetabular component in Total Hip arthroplasty surgery or with the native acetabulum in Partial Hip hemiarthroplasty surgery.

For Total Hip Replacement surgery the Paragon™ Hip System is compatible with OMNI and Corin components listed in Table 1. The femoral head diameter is selected to match the acetabular component of the surgeon's choosing. The femoral head component must have the standard 12/14 taper that connects to the tapered trunion on the Paragon™ femoral stem component.

The Paragon™ Hip System is available in a range of sizes with various offset options including Standard, High Offset and Coxa Vara. Each size and offset is available in either collared or non-collared options. The collared stems have the same function and intended use of non-collared stems but provide those surgeons who prefer it, a more definitive reference point relative to the osteotomy line when inserting the stem into the intra-medullary canal of the patient's femur. The addition of the collar on the stem does not alter the indications for use and their selection for use is at the choice of the surgeon.

Each femoral stem variant is manufactured from titanium alloy (ASTM F 136). The stem is available with a Hydroxyapatite (ASTM F 1185) coating.

Table 1: Compatible Components List

OMNIlife science Acetabular Cups
Apex Modular Acetabular Shell, 46-66mm, no hole, flared, A-E Insert
Apex Modular Acetabular Shell, 46-70mm, 3 hole, flared, A-F Insert
Apex Interface Acetabular Shell, 46-66mm, no hole, Hemi, A-E Insert
Apex Interface Acetabular Shell, 46-70mm, 3 hole, Hemi, A-F Insert
OMNIlife science Acetabular Inserts
Apex Modular Acetabular Shell, 48X-58X, 48-58mm dia, C-E liner (41-48mm), no hole
Apex Modular Acetabular Shell, 48X-58X, 48-58mm dia, C-E liner (41-48 mm), 3 holes
Apex Modular Acetabular Insert, A-F/28-36, 0 degree
Apex Modular Acetabular Insert, A-F/28-36, 10 degree
Apex-LNK Acetabular Insert, A-F insert/28-40, 0 Deg
Apex-LNK Acetabular Insert, A-F insert/28-40, 10 Deg Hood
OMNIlife science Femoral Heads
Apex Modular Femoral Head 28mm, BIOLOX® delta (-3.5, 0 and +3.5mm)
Apex Modular Femoral Head 32mm, BIOLOX® delta (-4, 0, +4 and +7mm)
Apex Modular Femoral Head 36mm, BIOLOX® delta (-4, 0, +4 and +8mm)
Corin Trinity Femoral Heads
Trinity BIOLOX® delta Modular Head 28mm (Short, Medium, Long)
Trinity BIOLOX® delta Modular Head 32mm (Short, Medium, Long, Extra Long)
Trinity BIOLOX® delta Modular Head 36mm (Short, Medium, Long, Extra Long)

2. Materials

Each femoral stem variant is manufactured from titanium alloy (ASTM F 136). The stem is available with a Hydroxyapatite (ASTM F 1185) coating.

3. Intended use and intended performances of the implant

The Paragon™ Hip Stem is intended for use in hemiarthroplasty and total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

They are intended to be used by appropriately qualified surgeons, who must practice in accordance with current advancements in scientific data and surgical techniques.

The use of The Paragon™ Hip Stem is intended to elicit the below clinical benefits to the indicated patients:

- *Significant decrease in Pain*
- *Increase in hip mobility*

4. Indications for use

The Paragon™ Hip System is intended for use as the femoral component of a primary total hip replacement. This femoral hip stem is intended for uncemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate:

1. Degenerative osteoarthritis of the hip.
2. Inflammatory arthritis of the hip.
3. Secondary arthritis of the hip, such as may follow trauma (e.g. fracture of the femoral neck, or fracture and/or dislocation of the hip or acetabulum), or congenital conditions (e.g. developmental dysplasia of the hip).

4. Displaced intracapsular femoral neck fractures where there is a high risk of non-union or avascular necrosis and bone collapse.
5. Avascular Necrosis of the femoral head.

5. Known contra-indications to date

Absolute Contraindications include:

1. Infection or sepsis or osteomyelitis.
2. Insufficient bone structure or quality which may affect the stability of the implant.
3. Rapid joint destruction or bone absorption.
4. Skeletal immaturity.
5. Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity.
6. Alcoholism or the other addictions.
7. Sensitivity to the implant materials.
8. High levels of physical activity e.g. competitive sports, heavy physical labour.
9. Obesity that can produce loads on the prosthesis, which can lead to failure of the fixation of the device or the device itself.

Relative Contraindications include:

1. Uncooperative patient or a patient with neurological disorders and incapable of following instruction.
2. Metabolic disorders which may impair bone formation or bone quality.
3. Distant foci of infections.

6. Undesirable side effects and possible complications

The possible adverse effects of the prosthesis are similar to those occurring with any hip replacement and include the following:

1. Dislocation or subluxation due to improper positioning or muscle and fibrous tissue laxity.
2. Loosening or migration of components due to trauma and/or loss of fixation.
3. Accelerated wear of articulating surfaces. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prosthesis, and leads to early revision surgery to replace the worn components.
4. Histiocytic granuloma formation and osteolysis around the implant due to wear debris.
5. Fatigue fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation or extreme duration of service.
6. Urological complications, especially urinary retention and infection.
7. Other complications associated with general surgery, drugs or ancillary devices used such as blood etc.

Intraoperative and early postoperative complications can include:

1. Femoral perforation.
2. Fracture of the femur while seating the femoral stem component.
3. Damage to blood vessels.
4. Temporary or permanent neuropathies.
5. Undesirable shortening or lengthening of the limb.
6. Traumatic arthrosis of the knee from Intraoperative positioning of the extremity.
7. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
8. Hematoma.
9. Delayed wound healing.
10. Infection

Late postoperative complications can include:

1. Trochanteric avulsion as a result of excessive muscular weakening.
2. Trochanteric non-union due to inadequate reattachment and/or early weight bearing.
3. Aggravated problems of the knee or ankle of the affected limb or contralateral extremity by leg length discrepancy, too much femoral medialisation, or muscle deficiency.
4. Femoral fracture by trauma or excessive loading particularly in the presence of poor bone stock.
5. Periarticular calcification or ossification, with or without impediment to joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components, by femoral impingement and periarticular ossification.
7. Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues.

7. Warnings and cautions

While total hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

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

1. The correct selection of the femoral stem implant and accessories is extremely important. The potential for success in total joint replacement is increased by the selection of the proper size, shape and design of the implant. Total joint prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress. The surgeon is to be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery.
2. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:
    a. *The patient's weight. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when small prostheses must be used.*

b. *The patient's occupation or activity. 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 device or both.*

c. *A condition of senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.*

d. *Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.*

e. *Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.*

3. The maximum offset of the femoral head should not exceed +8mm for all stem sizes.
4. The correct handling of the implant is extremely important. Care must be taken to protect mating surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
5. A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have small defects and internal stress patterns, which may lead to failure. Use only new prosthesis of the current design.
6. Do not resterilise – Single use only.
7. Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, bone cement or other detritus that may cause a third body wear problem. Range of motion should be checked for impingement or instability.
8. Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity levels permissible. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture and/or wear of the prosthesis implant. Early load-bearing should be carefully controlled. The patient should be advised to report to their treating surgeon any related pain, decrease in range of motion, fever and unusual incidences.
9. Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.

a. Pre-operatively

The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contra-indications for this type of implant.

As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors are present that will affect the correct conduct of the operation and the postoperative period. The surgeon must also check that the quality of the bone is satisfactory enough to support the implantation.

An appropriate range of implant sizes must be available at the time of the operation.

b. Intra-operatively

The Paragon™ HA Hip Stem is intended for cementless use only.

The correct selection of the type and size of the implant appropriate to the patient and the positioning of the implant are extremely important. The use of trial implants may allow for the proper size selection of the implants. Frequent radioscopic checks allow the position of the prosthesis to be checked.

The prostheses must not be used if their functional surfaces have been damaged or have undergone shock, abrasion, or other deterioration.

Coated implants must be handled with care and be used according to the recommendations of the surgical technique to avoid deterioration of the coating. Do not cement coated implants.

In case of revision, special care must be taken not to damage the components that are not removed.

Always remove all surgical debris prior to closure.

If there is a reason to believe that a serious incident has occurred in relation to the device, please report it to the national authority and to the manufacture.

c. Post-operatively

It is recommended that a regular postoperative follow-up is undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider the action to be taken. Normal wear of the implant in respect of the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or a deterioration in the characteristics of the implant.

A suitable rehabilitation program must be designed and implemented specific to the patient.

d. Information to be conveyed to the patient

The following information should be provided to the patients:

- *Undesirable side-effects and complications.*
- *Precautions to take in daily life to guarantee maximum implant survival.*
- *The fact that their weight and level of activity can affect the life span of the prosthesis.*
- *Information about exposure to MRI conditions.*
- *That they must inform the surgeon of any change in performance (mobility, pain etc.).*
- *That they must report any serious incident occurred in relation to the device to the national authority and the manufacturer.*
- *The overall qualitative and quantitative information on the materials and substances to which patients can be exposed and precautions related to these materials (possible sensitisation, allergic reaction or CMR substances).*
- *The implant card filled with requested information.*
- *That updates on this information will be available on the website given on the implant card.*

e. MRI safety information

The Paragon™ Hip System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Paragon™ Hip System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

8. Storage and handling

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage, which may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labelling for correct catalogue number (REF) and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visible damage.

This implant is part of a system and should be used only in combination with the Apex Interface™ Acetabular System, the Apex Modular Femoral Heads manufactured by OMNIlife science (OMNI) and the Corin Trinity BIOLOX® delta Femoral Heads. All implants must be stored in dry conditions and protected from exposure to sunlight, the extremes in temperature and contamination by particles.

9. Packaging and sterilisation

The implants are supplied sterile. The Paragon™ HA Hip stems are sterilised by gamma irradiation delivered from a cobalt60 source. The expiration date for sterilisation and integrity of the packaging must be checked. An implant whose packaging is open or damaged or whose expiration date has passed must not be used.

Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Do not re-sterilise. For single use only.

Re-Use and Damage Prevention

1. This device is for single use only. While it may appear undamaged imperfections may exist that would reduce the service life of the prosthesis.
2. Re-use of a taper connection may reduce the locking strength between the femoral stem taper and the modular femoral head internal taper and cannot guarantee an exact fit. Therefore only new and unused components may be combined.

Some instruments may be supplied sterile.

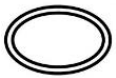
- *For handling and sterilisation of non-sterile ancillary instruments, refer to the ancillary instruments' instructions.*
- *For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.*

10. Implant retrieval and handling

In case of retrieval of the implant from the patient, the retrieved implant should be handled according to appropriate and validated hospital procedures to facilitate the safe disposal of the device and its accessories. These procedures should consider infection, microbial and physical hazards.

11. Interpretation of terms and symbols

GLOSSARY OF PRODUCT LABEL SYMBOLS			
Caution: The key for the following symbols is for reference only – some symbols listed may not apply. Please see main product label affixed to product for applicable symbols.			
Symbol	**Symbol title**	**Symbol description**	**Reference and Standard**
	Manufacturer	Indicates the medical device manufacturer	ref. 5.1.1 in ISO 15223-1[1]
	Use-by date	Indicates the date after which the medical device is not to be used.	ref. 5.1.4 in ISO 15223-1[1]
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ref. 5.1.5 in ISO 15223-1[1]
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ref. 5.1.6 in ISO 15223-1[1]
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ref. 5.1.7 in ISO 15223-1[1]
	Sterilised using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ref. 5.2.3 in ISO 15223-1[1]
	Sterilised using irradiation	Indicates a medical device that has been sterilized using irradiation.	ref. 5.2.4 in ISO 15223-1[1]

Symbol	Symbol title	Symbol description	Reference and Standard
	Do not resterilise	Indicates a medical device that is not to be resterilised.	ref. 5.2.6 in ISO 15223-1[1]
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ref. 5.2.7 in ISO 15223-1[1]
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ref. 5.2.8 in ISO 15223-1[1]
	Double sterile barrier system	Indicates two sterile barrier systems	ref. 5.2.12 in ISO 15223-1[1]
	Do not re-use	Indicates a medical device that is intended for one single use only.	ref. 5.4.2 in ISO 15223-1[1]
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ref. 5.4.3 in ISO 15223-1[1]
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ref. 5.4.4 in ISO 15223-1[1]

Symbol	Symbol title	Symbol description	Reference and Standard
	Medical Device	Indicates the item is a medical device	ref. 5.7.7 in ISO 15223-1[1]
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	ref. 5.7.10 in ISO 15223-1[1]
	Not made with natural rubber latex	Indicates that the device is not made with natural rubber latex	21 CFR 801.437
	Prescription use only	Indicates that Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
	MR Conditional	Indicates there are certain conditions associated with the safety of the device in the MR environment	ref 7.4.6 in ASTM F2503-20[2]
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties	ref. 5.4.10 in ISO 15223-1[1]

[1]: EN ISO 15223-1:2021 — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.

[2]: ASTM F2503-20 Standard practice for Marking Medical Device and other items for safety in the Magnetic Resonance Environment.

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This "Instructions for Use" has been approved by the U.S. Food and Drug Administration