CORDERA™ Hip System
Instructions for Use
FOR CEMENTLESS USE ONLY

CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. THE CORDERA™ HIP SYSTEM IS INTENDED FOR USE ONLY BY MEDICALLY TRAINED PHYSICIANS.

IF THERE ARE ANY QUESTIONS CONTACT CONFORMIS, INC. AT +1.781.345.9001 OR YOUR LOCAL SALES REPRESENTATIVE.

Important Information: Please read before use.

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DEVICE DESCRIPTION

The CORDERA™ Hip System is an uncemented, primary total hip replacement composed of femoral and acetabular components. The system can be used with or without a pre-operative CT scan that is used to design patient-specific instruments. All components are provided sterile.

The femoral component consists of a standard monoblock femoral stem body and neck, which mates with a standard femoral head. The stem and neck are manufactured as one piece and hence are not modular. The proximal neck surface with a 12/14 taper is highly polished and transitions to hydroxyapatite coating in the main stem body and is indicated for uncemented press fit fixation only. The femoral head is designed to connect to the femoral stem neck. All femoral heads are polished and have a 12/14 taper to match the femoral stem. The femoral heads are available in either cobalt chromium alloy (CoCr) or ceramic (Biolox® Delta).

The acetabular component consists of a standard size shell with standard screw hole placement, a mating polyethylene liner, and cancellous screws. The acetabular component is designed for uncemented use; initial implant fixation is achieved through press-fit design. The 6.5mm diameter cancellous screws with low profile head fits through the acetabular shell screw holes and are driven using a 3.5mm hex drive recess. The acetabular component has matching circumferential scallops on the shell and liner that rotationally secure the liner in the shell and allow for dialing the liner in a desired orientation. The liner is provided with an impactor made of a biocompatible nylon material.

If utilizing a pre-operative CT scan, the CORDERA™ Hip System is supplied with disposable, patient-specific instrumentation (iJigs) and reference models designed for use with the system. These patient-specific guides and reference models are pre- navigated to fit the contours of the patient's femoral and acetabular anatomies and to facilitate a simpler surgical technique. Each set of instruments and reference models are designed for one-time use, specifically for one patient. The iJig® instrument set and reference models are manufactured from biocompatible nylon material, and it may include titanium temporary fixation screws.

The CORDERA™ Hip System is supplied with disposable, Stage 1 and Stage 2 reamers. These reamers are designed to work with the patient-specific iJig® instrument set. Each set of Stage 1 and Stage 2 reamers are selected to work with the acetabular component supplied for the patient. The reamers are manufactured from biocompatible stainless-steel material.

INDICATIONS FOR USE

The CORDERA™ Hip System may be used with iJigs that are designed from a patient's pre-operative CT scan, which must include certain necessary anatomic landmarks that are clearly identifiable. The

CORDERA™ Hip System is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The CORDERA™ Hip System includes standard hip replacement components, and if selected, may use patient-specific single use instrumentation.

The CORDERA™ Hip System implants are intended for cementless fixation using an anterior or posterior surgical technique.

CONTRAINDICATIONS

The following conditions are contraindications for total hip replacement:

1. Active or recent local or systemic infection.
2. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
3. Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
4. Charcot's or Paget's disease.
5. Ceramic heads are contraindicated in revision surgery when the femoral stem is well fixed and is not being replaced.
6. Poor quality femoral bone stock which may compromise the proximal fixation of the femoral stem.
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
8. Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.
9. Metal sensitivity

WARNINGS AND PRECAUTIONS

- Use only Conformis Hip System femoral heads with CORDERA™ Hip System femoral stems. The taper size of the femoral head MUST be matched to the taper size of the femoral stem.
- Firmly seat the femoral head component to prevent loosening. Thoroughly clean and dry taper prior to attachment of the femoral head component to avoid crevice corrosion and improper seating.
- Implants, trials, and iJigs from different manufacturers or implant systems should never be used together.
- Due to the patient-specific nature of the iJigs, they should never be used for a patient other than the patient for whom it has been ordered. Prior to use, the serial number on the iJigs should be carefully inspected to ensure it matches the patient identification. Confirm that the iJigs have the same serial number.

- Hip prosthesis components should never be reused. Even though the implant appears undamaged, the implant may have developed microscopic imperfections which could lead to failure.
- Acetabular screws are to be fully seated in the cup to assure stable fixation and to avoid interference with the acetabular liner component.
- Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis. When a pre-operative CT scan is utilized, the recommended patient-specific maximum screw length should not be exceeded.
- Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
- Always use trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, etc., as the corresponding components to be permanently implanted. The guides and trials are for use to fit the components and must never be left implanted.
- Do not alter or modify implants in any way.
- Avoid notching, scratching, or striking the device during preparation and insertion.
- Do not use bone cement for fixation of a hydroxyapatite coated prosthesis.
- Using bio-contamination controls can minimize the potential for deep sepsis.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the total hip replacement:

1. Obesity or excessive patient weight.
2. Heavy labor.
3. Active sports participation.
4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities, as applicable.
8. Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection or slow wound healing, the surgeon should carefully consider the advisability of hip replacement in the diabetic patient.

CAUTION: The following conditions singularly or concurrently, tend to adversely affect the fixation of hip replacement implants:

1. Marked osteoporosis or poor bone stock.
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., including but not limited to diabetes mellitus, steroid therapies, immunosuppressive therapies).
3. History of general or local infections.
4. Severe deformities leading to impaired fixation or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to implant materials (e.g., metal, polyethylene).
7. Congenital dysplasia of the hip which may reduce the bone stock available to support the acetabular cup prosthesis in total hip replacement.
8. Tissue reactions to implant corrosion or implant wear debris.
9. Disabilities of other joints (i.e., knees and ankles). The incidence of implant failure may be higher in paraplegics, and patients with cerebral palsy or Parkinson's Disease.

WHEN THE SURGEON DETERMINES THAT TOTAL HIP REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR IMPLANT FIXATION, AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the hip replacement by causing a change in position, fracture, and/or increased wear of the implants. The functional life expectancy of prosthetic total hip implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect the functional life expectancy of the device.

GENERAL INFORMATION FOR USE

Preoperative

THE SURGEON SHOULD DISCUSS ALL PHYSICAL AND MENTAL LIMITATIONS PARTICULAR TO THE PATIENT AND ALL ASPECTS OF THE SURGERY AND THE PROSTHESES WITH THE PATIENT BEFORE SURGERY. The discussion should include the limitations and possible consequences of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight.

The preoperative planning and surgical techniques for implantation of the CORDERA™ Hip System evolved from the surgical experience gained during the development of many hip prostheses. Surgeons should not begin the clinical use of any hip prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Critical appraisals of such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures are available from Conformis.

Correct handling of an implant is important. The CORDERA™ Hip System implant should be used without nicks, scratches, or other alterations. These can produce defects and stresses which may cause eventual failure of the implant.

The CORDERA™ Hip System may be based on patient-specific data which may be subject to change depending on patient condition. It is up to the medical provider to determine if the patient's anatomy may have changed sufficiently to require an additional scan.

In those cases where a CORDERA™ Hip System component is being revised and where pre-existing data is not sufficient to produce an appropriate implant system, a new scan may be required.

Intraoperative

The iJigs are patient-specific. DO NOT USE IJIGS FOR ANY PATIENT OTHER THAN THE ONE FOR WHOM IT HAS BEEN DESIGNED

It is recommended that femoral head components at least one size larger and one size smaller than were preoperatively determined be available at surgery to accommodate intraoperative selection of the appropriate size.

Protective covers should be left on until the components are ready to be implanted. **Do not use components if they have been dropped or have impacted a hard surface. Damage to the component may not be visible, but could cause early failure of the prosthesis. Before implanting a femoral head, the male taper on the femoral stem should be wiped clean of any blood, bone chips or other foreign materials. Foreign material between the head and the femoral stem taper may impede proper seating of the head on the stem. This could affect the performance of the femoral head or the locking mechanism between the femoral head and the femoral stem.** Do not allow the coated portion of hydroxyapatite coated prosthesis to come in contact with cloth or other fiber releasing materials.

Note that a femoral stem placed in varus increases the stress on the proximal medial femoral cortex and may lead to loosening of the implant. Increasing the anteversion of an acetabular component in total hip replacement may result in instability and/or dislocation of the joint.

The use of special surgical instruments may be used for the completion of this surgery. The alignment and cutting jigs should be checked prior to use. Bent or damaged instruments should be replaced as they may lead to improper implant position and result in device failure.

Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, etc. Foreign particles at the metal/plastic or ceramic/plastic interface may cause excessive wear. Range of motion should be thoroughly checked for improper mating, instability, or impingement and corrected as appropriate.

Postoperative

Strict adherence by the patient to the surgeon's instructions and warnings is extremely important. Accepted practices should be followed in postoperative care.

The patient should be released from the hospital with complete written instructions and warnings regarding exercises and therapies and any limitations on their activities.

A continuing periodic patient follow-up is recommended. Because of the unknown functional lifetime of the implant, particularly with respect to the maintenance of implant fixation and bearing surfaces, A-P radiographs of the pelvis should be taken at intervals and compared with previous radiographs and correlated with the clinical assessment of the patient. If any radiographic changes are observed, such as the occurrence of radiolucencies, bone resorption, or any changes in the position of an implant, these changes should be closely monitored to determine whether they are static or progressive and the patient treated appropriately.

ADVERSE EVENTS AND COMPLICATIONS

The following are generally the most frequently encountered adverse events and complications in total hip arthroplasty:

1. Early or late postoperative infection.
2. Tissue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergic reactions, or the accumulation of wear debris.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periarticular calcification or ossification which may lead to a decrease in joint mobility and range of motion.
6. Subluxation or dislocation of the hip joint due to implant size or configuration selection, positioning of components and/or muscle and fibrous tissue laxity.
7. Undesirable lengthening or shortening of limb.
8. Fatigue fracture of component can occur as a result of loss of fixation, malalignment, trauma, non-union, or excessive weight/activity, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery, intraoperative reaming procedures, or bone resorption.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion from excessive muscular tension, weight-bearing, or inadvertent intraoperative weakening of the trochanter.
12. Aggravation of problems in the ipsilateral or contralateral knee and ankle joints due to leg length discrepancy, femoral medialization and/or muscular deficiencies.
13. Postoperative bone fracture and pain.
14. Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction.
15. Temporary or permanent nerve and/or blood vessel damage.

HOW SUPPLIED

Components of the CORDERA™ Hip System are packaged and supplied STERILE. The iJig® kit packaging is labeled with the patient information and this information should be checked prior to opening the components. If the patient information is incorrect, DO NOT USE THE DEVICE OR ANY COMPONENTS. Remove from the package using accepted aseptic technique only after the correct size has been determined. **DO NOT USE IF THE STERILE BARRIER APPEARS TO BE COMPROMISED OR THE PACKAGE IS DAMAGED.**

CAUTION: Do not re-sterilize or reprocess components. These components are for single use only. The risk of reuse could compromise performance or sterility.

Reference the "Conformis Reusable Instruments" IFU for sterilization instructions for the hip reusable instruments

MAGNETIC RESONANCE (MR) SAFETY INFORMATION

The CORDERA™ 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 CORDERA™ Hip System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ADDITIONAL INFORMATION

If further information is desired, please contact Conformis, Inc. at +1.781.345.9001.

LABELING SYMBOL DEFINITIONS

℞ ONLY	CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ONTHE ORDER OF A PHYSICIAN.
	Caution. Consult Accompanying Documents
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Do not use if package is open or damaged
	Patient No.
2	Single Use Only.Do Not Reuse.
	Expiration Date. (Use by)
STERILE R	Sterilized Using Gamma Radiation
STERILE EO	Sterilized Using Ethylene Oxide
	Manufacturer
	Consult electronic Instructions For Use (eIFU)