iTotal® Identity™ Cruciate Retaining 3DP Porous Total Knee Replacement System

Instructions for Use

CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

THE restor3d® iTotal® Identity™ CRUCIATE RETAINING 3DP POROUS TOTAL KNEE SYSTEM IS INTENDED FOR USE ONLY BY MEDICALLY TRAINED PHYSICIANS.

IF THERE ARE ANY QUESTIONS CONTACT restor3d, INC. AT +1.781.345.9001 OR YOUR LOCAL SALES REPRESENTATIVE OR DISTRIBUTOR.

Important Information: Please read before use.

Refer to https://www.restor3d.com/resources/instructions-for-use/ for an electronic version of this IFU.
For a printed copy or to have an electronic copy e-mailed to you call +1.781.345.9001

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Device Description

The iTotal® Identity™ Cruciate Retaining (CR) 3DP Porous Total Knee Replacement System (KRS) is a tricompartmental semi-constrained knee prosthesis composed of three components: a Femoral Component, a Tibial Component, and a Patellar Component. The product design incorporates a bone preserving approach for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. The joint restoring design provides for more natural kinematics by maintaining the patient specific femoral sagittal curves, preserving the patient specific femoral offset, preserving the medial and lateral joint lines and having a patient specific fit. It is intended for use in those patients whose condition cannot be appropriately or effectively addressed using a device that treats only one or two compartments of the knee (i.e. a unicompartmental, bicompartmental, or patellofemoral prosthesis).

Using patient imaging (CT scans), a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The treatment allows for the placement of an uncemented metallic device designed from the patient's natural bone geometry. The femoral component is additively manufactured from a cobalt chromium molybdenum ("CoCrMo") alloy. The tibial tray component is additively manufactured from titanium ("Ti6Al4V") alloy. The tibial inserts are manufactured and offered in either ultra-high molecular weight polyethylene (iPoly®) or highly cross-linked ultra-high molecular weight Vitamin-E enriched polyethylene (iPoly® XE). The patellar component is manufactured and offered in ultra-high molecular weight Polyethylene (iPoly®) with a porous Ti6Al4V metal backing. The femoral, tibial, and patellar implants are additively manufactured using proprietary TIDAL Technology™, which allows biological fixation without the need for bone cement. The iTotal® Identity™ CR 3DP Porous KRS is designed for use without cement, but may be used with a cemented technique if necessary.

The iTotal® Identity™ CR 3DP Porous KRS implants are supplied with disposable, patient-specific instrumentation (iJig®) designed for use with the system. These patient-specific guides are pre-navigated to fit the contours of the patient's femoral and tibial anatomies and to facilitate a simpler surgical technique. Each set of instruments is designed for one time use, specifically for one patient. The iJig® instrument set is manufactured from biocompatible nylon material and supplied sterile along with the implants.

The iTotal® Identity™ CR 3DP Porous KRS is compatible with cemented iTotal® Identity™ CR implants. Cemented and uncemented implants may be used together for a hybrid technique.

Indications for Use

The iTotal® Identity™ CR 3DP Porous KRS is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

This system is intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

The CS (cruciate sacrificing) insert option should be utilized when additional anterior-posterior constraint is desired.

Contraindications

The following conditions are absolute contraindications for cruciate retaining total knee replacement.

- Active or recent local or systemic infection.
- Insufficient bone stock on the femoral or tibial surfaces.
- Skeletal immaturity.
- Loss of bone or musculature, osteoporosis, neuromuscular or vascular compromise in the area of the joint to be operated to an extent that the procedure is unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).
- Severe instability due to advanced loss of osteochondral structure or the absence of collateral ligament integrity.
- Severe (>15º) fixed valgus or varus deformity.
- Metal sensitivity (e.g., nickel).

Warnings and Precautions

- **The iTotal® Identity™ knee components are for single use only. Do not reuse. If re-sterilization of the metal implants (femoral component and tibial tray) or instruments (iJigs®) is needed, the following parameters are recommended as they have been validated for a Sterility assurance Level of $1x10^{-6}$. Do not re-sterilize UHMWPE or iPoly® XE components. Only uncontaminated components which do not require cleaning may be re-sterilized.**

Method	Wrap	Cycle	Temperature	Exposure Time	Drying
Steam	Double-Wrap*	Pre-Vacuum	270°F (132°C)	4 minutes	20 minutes

*****Wraps used during the steam sterilization process are to be FDA cleared wraps. Use Manufacturer's instructions.

The adequacy of any sterilization process should be suitably tested and validated for each facility's sterilization equipment.

- **Implants and components from different manufacturers should never be used together.**
- **Due to the patient specific nature of this implant, it 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 implant must be carefully inspected to ensure that it matches the patient.**
- **The guides and trials are for use to fit the components and must never be left implanted.**
- **Do not alter or modify the implants in any way.**
- **Avoid drilling multiple holes in the tibia which may affect the compressive strength of the tibia.**
- **Avoid notching, scratching or striking the device during preparation and insertion.**
- **Using bio-contamination controls can minimize the potential for deep sepsis.**
- **Surgeons should determine based on disease state and patient risk if a new scan should be taken to assess potential changes in anatomy if the surgery has not been performed within 6 months following the initial scan.**

Cleaning Instructions

In the event of an iJig® being dropped and contaminated, perform the following cleaning steps before steam re-sterilization:

1. Prepare a cleaning bath with an enzymatic detergent such as Steris Prolystica 2X Concentrate Enzymatic Pre-soak and Cleaner or equivalent at the concentration and temperature specified by the detergent manufacturer

2. Completely submerge instruments in an enzyme solution for 5 minutes.

3. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams and any other hard to access areas. Actuate any moving mechanisms to free trapped blood and debris.

4. Remove instruments from the cleaning solution. Rinse in running (tap) water for 3 minutes or until all traces of cleaning solution are removed, whichever is longer. Thoroughly and aggressively flush lumens, holes or other hard to access areas.

5. Repeat Steps 2, 3 and 4.

6. Rinse instruments in purified water for 3 minutes or until rinse stream is clean of blood or soil, whichever is longer. Thoroughly and aggressively flush lumens, holes or other hard to access areas.

7. Visually inspect each device for remaining soil to ensure device is visibly clean. If soil remains repeat steps 2 thru 6.
    a. Blood from patient may stain instruments. However, these cleaning instructions pertain to patient specific devices which are not intended to be used on other patients. The device in question is intended to be used on the same patient in which it has potentially come in contact with prior to cleaning.

8. Dry instruments immediately after final rinse.

9. Proceed to steam sterilization steps previously outlined.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity which may place the patient at higher risk for failure of the knee replacement:

- Obesity.
- Heavy manual labor.
- Active participation in sports.
- High levels of activity by the patient.
- History or likelihood of falls.
- Drug or alcohol abuse.
- Other disabilities.

In addition to the above risks, the following physical conditions, alone or in combination, tend to adversely affect the fixation and add to the risk of failure of the knee replacement:

- Marked osteoporosis or poor bone stock.
- Progressive bone deterioration due to metabolic disorders or systemic pharmacological treatment.
- History of recurrent systemic chronic infection, general or local infections.
- Severe deformities of the joint that could lead to impaired function or improper placement of the implant.
- Tumors or defects in the supporting bone.

- Allergic reactions to the implant materials including the bone cement.
- Tissue reaction to implant corrosion or wear debris.
- Disabilities of other joints (e.g., hips, ankles).

The incidence of implant failure may be higher in paraplegics, and patients with cerebral palsy or Parkinson's Disease.

IF OR WHEN THE SURGEON DETERMINES THAT TOTAL KNEE REPLACEMENT IS THE BEST MEDICAL OPTION AND DECIDES TO USE THIS DEVICE IN A PATIENT WITH ANY OF THE ABOVE CONDITIONS, THE SURGEON MUST INFORM THE PATIENT ABOUT THE STRENGTH LIMITATIONS OF THE IMPLANT MATERIALS AND THE NEED TO REDUCE OR ELIMINATE ANY ABOVE CONDITION WHEN POSSIBLE.

The pre and post-operative care and management of the patient must be carried out with all existing conditions considered, including any mental attitudes or disorders. A patient's failure to adhere to the surgeon's postoperative instructions may delay recovery and/or increase the risk of adverse effects, including fixation failure or implant failure.

Excessive physical activity or trauma to the joint during recovery may contribute to premature failure of the replacement by causing a shift in position, fracture or increased wear of the implants. The functional life expectancy of this knee implant is not known at this time. The patient should be informed that factors such as weight and activity level may significantly affect wear and subsequent device life.

General Information

Surgeons are offered training on the restor3d® iTotal® Identity™ CR 3DP Porous design concept and surgical implantation technique. The training may include a review of the surgical indications, design approach, surgical implantation methods via surgical technique, live surgery videos, and surgical observations. On request, restor3d® also provides hands on training via bioskills labs.

Correct handling of an implant is important. The restor3d® implant should be used without nicks, scratches or other alterations. These can produce defects and stresses which may become the focal point for the eventual failure of the implant. Prior to use the serial number on the implant should be carefully inspected to insure it matches the patient identification.

The iTotal® Identity™ CR 3DP Porous Knee Replacement System is 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 an iTotal® Identity™ CR 3DP Porous component is being revised and where pre-existing data is not sufficient to produce an appropriate implant system, a new scan may be required.

Preoperative

THE SURGEON SHOULD DISCUSS ALL ASPECTS OF THE SURGERY WITH THE PATIENT BEFORE SURGERY INCLUDING LIMITATIONS OF THE IMPLANT AND ALL PHYSICAL AND MENTAL LIMITATIONS PARTICULAR TO THE PATIENT. The discussion should include the limitations of the knee joint, limitations particular to the patient, possible consequences resulting from these limitations and therefore, the necessity of following the physician's instructions postoperatively, in particular in regards to activity and weight.

Prerequisites for use of the iTotal® Identity™ CR 3DP Porous implants include:

1. Significant arthritic disease of the tibial-femoral surfaces,
2. Stable or re-constructible collateral ligaments,
3. Physiologic or correctable axial alignment,
4. Intact quadriceps and hamstring mechanisms,
5. Suitable patella bone for component if a patella implant is to be used.

Intraoperative

This implant is patient specific. **DO NOT USE THIS IMPLANT FOR ANY PATIENT OTHER THAN THE ONE FOR WHOM IT HAS BEEN DESIGNED.**

It is recommended that other implants be available at the time of surgery. Proper handling of the implant and the guides is essential. The components should only be handled by personnel wearing sterile gloves. If any of the components are dropped or come in contact with a hard surface they may be rendered unusable.

The use of special surgical instruments is suggested for 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.

Proper preparation of the bone surface is critical to the device fixation. Bone excision should be limited to the area directed by the cut guide. Proper placement of the guides is essential to the fit of this device. Care should be taken during the alignment and placement of the guides. Limit the number of drill holes to those indicated to prevent possible mechanical failure.

Prior to closure, the area must be cleared of any extraneous material such as bone chips, cement etc. Foreign material may cause excessive wear to the implant surfaces. Range of motion should be checked to ensure that the implant components are properly mated and there is no instability or impingement in the joint, any corrections should be made as appropriate.

Postoperative

The patient must be made aware that strict adherence to a postoperative protocol is important. Accepted postoperative practices should be followed. The patient should be counseled regarding limitations of activity to protect the joint from unreasonable stresses. The patient should get complete written instructions regarding postoperative therapies and activities as prescribed by the surgeon. Periodic follow-up is recommended. During the follow-up, x-rays should be done at intervals to evaluate any shift in position, loosening, or cracking of components. Any change from the postoperative condition should be evaluated and observed to detect deterioration.

Adverse Events and Complications

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials, or wear debris, cardiovascular disorders and thromboembolic disease, pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, looseness or wear of components, fracture of the patella, femur or tibia.

How Supplied
The iTotal® Identity™ CR 3DP Porous knee components, CoCrMo, Ti6Al4VI, iPoly®, and iPoly® XE, are supplied packaged and STERILE. The patient-specific instrument (iJig®) set are also supplied STERILE. The 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. Open the sterile barrier using standard aseptic techniques. DO NOT USE IF THE STERILE BARRIER APPEARS TO BE COMPROMISED OR THE PACKAGE IS DAMAGED.

Caution: Do not re-sterilize polyethylene components. The iTotal® Identity™ CR 3DP Porous is for single use only. The risk of reuse could compromise performance or sterility

Magnetic Resonance (MR) Environment
The iTotal® Identity™ CR 3DP Porous KRS has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of iTotal® Identity™ CR 3DP Porous KRS in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Additional Information
If further information is desired, please contact restor3d, Inc. at +1.781.345.9001.

Labeling Symbol Definitions

℞ ONLY	Caution: USA Federal Law restricts this device to sale by or on the order of a physician.
	Caution. Consult Accompanying Documents
	Consult electronic Instructions For Use (eIFU)
REF	Model Number
SN	Serial Number
	Do not use if package is open or damaged
	Patient No.
	Single Use Only. Do Not Reuse
	Expiration Date. (Use by)
STERILE | **VH202**	Sterilized Using Vaporized Hydrogen Peroxide
STERILE | **EO**	Sterilized Using Ethylene Oxide
	Manufacturer