UNICONDYLAR

KNEE REPLACEMENT SYSTEM (iUni® G2)

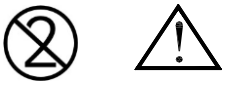
Instructions for Use

FOR CEMENTED USE ONLY

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

THE restor3d® UNICONDYLAR KNEE REPLACEMENT SYSTEM (iUni® G2) 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 Unicondylar Knee Replacement System (iUni® G2) is composed of individually packaged femoral and tibial components and single use sterile instruments (iJigs®). Using data from a patient's imaging study (either CT or MR scans), a patient-specific implant is designed to fit the anatomy of the specific patient. The system allows for the placement of a cemented metallic device to treat severe pain and/or disability due to knee osteoarthritis or trauma.

The femoral component is manufactured from a cobalt chromium molybdenum (CoCrMo) alloy. The tibial component is comprised of a CoCrMo alloy tray with an ultra-high molecular weight polyethylene (UHMWPE) insert. The outlines of all tibial components are personalized to match the patient's tibial anatomy.

The Unicondylar iJigs® consist of single-use, sterile instruments packaged in double-layer Tyvek® pouches. Each instrument set is designed specifically for one patient. The iJigs® are made of Polyamide material and may be fitted with stainless steel bushings and guide clips.

Indications for Use

The restor3d® Unicondylar Knee Replacement System (iUni® G2) is intended for use in one compartment of the osteoarthritic knee to replace the damaged area of the articular surface in patients with evidence of adequate healthy bone sufficient for support of the implanted components.

Candidates for unicondylar knee replacement include those with:

- Joint impairment due to osteoarthritis or traumatic arthritis of the knee
- Previous femoral condyle or tibial plateau fracture, creating loss of function
- Valgus or varus deformity of the knee
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

This implant is intended for cemented use only.

Contraindications

The following conditions are contraindications for unicondylar knee replacement.

- Active or recent local or systemic infection
- 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 unjustified
- Severe instability due to advanced loss of osteochrondral structure.
- Absence of collateral ligament integrity
- Severe (>15º) fixed valgus or varus deformity

Warnings and Precautions

- **The unicondylar knee components are for single use only. Do not reuse. If resterilization of the instruments (iJigs®) is needed, the following parameters are recommended as they have been validated for a Sterility Assurance Level of 1x 10^{-6}. Only uncontaminated components which do not require cleaning may be re-sterilized.**

Method	Cycle	Temperature	Exposure Time
Steam	Gravity	270°F (132°C)	3 minutes

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

- **The presence of metallic implants may interfere with MRI scans. The iUni® G2 Unicondylar Knee Replacement System has not been evaluated for safety and compatibility in the MR environment. The iUni® G2 Unicondylar Knee Replacement System has not been tested for heating or migration in the MR environment.**
- **Implants and components from different manufacturers should never be used together.**
- **Due to the patient specific nature of this implant system, 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 system labeling should be carefully inspected to ensure it matches patient identification.**
- **The iJigs® are specific to a condyle (i.e. – handed). An iJig for one condyle should not be used for a different condyle.**
- **The iJigs® 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.**
- **Before using the iUni® Knee Replacement System components inspect them for damage or defects.**

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 of the supporting bone
- Allergic reactions to the implant materials (e.g., nickel) or bone cement
- Tissue reaction to implant corrosion or wear debris
- Disabilities of other joints (e.g., hips, ankles)
- Inflammatory arthritis
- Fixed deformity
- Flexion-contracture of more than 10 degrees
- ACL insufficiency

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

IF OR WHEN THE SURGEON DETERMINES THAT UNICONDYLAR KNEE REPLACEMENT IS THE BEST MEDICAL OPTION AND DECIDES TO USE THIS DEVICE IN A PATIENT WITH ANY OF THE PRIOR NOTED PHYSICAL CONDITIONS, THE SURGEON MUST INFORM THE PATIENT ABOUT THE STRENGTH LIMITATIONS OF THE IMPLANT MATERIALS AND THE NEED TO REDUCE OR ELIMINATE ANY RISKY BEHAVIOR 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 post-operative 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® iUni® G2 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 ensure it matches the patient identification.

The iUni® Unicondylar Knee Replacement System is created 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 iUni component is being revised and where pre-existing data is not sufficient to reproduce an appropriate implant system a new scan may be required.

Preoperative

THE SURGEON SHOULD DISCUSS ALL ASPECTS OF THE SURGERY INCLUDING ALL PHYSICAL AND MENTAL LIMITATIONS PARTICULAR TO THE PATIENT AND THE IMPLANT WITH THE PATIENT BEFORE SUGERY. 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 unicondylar implant 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

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 patient-specific surgical cutting and placement guides (iJig® Instrumentation), provided with the implants, is required 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 the post-operative protocol is important. Accepted post-operative 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 instructions regarding postoperative therapies and activities. 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 observed and evaluated to detect deterioration.

Adverse Events and Complications
The following are the most frequent adverse events after knee arthroplasty: misalignment of the prosthetic components, 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, pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, fracture of the femur or tibia.

How Supplied
The iUni® G2 unicondylar knee components, both CoCrMo and UHMWPE, are supplied individually packed and STERILE. The iJig® Instrumentation System is also supplied STERILE. The individual pouches are labeled with the patient information. This information and the expiration date should be checked prior to opening any components. If the patient information is incorrect or the expiration date has passed, DO NOT USE THE DEVICE OR ANY COMPONENTS. Open the pouches using standard aseptic techniques. DO NOT USE IF THE STERILE BARRIER SEEMS TO BE COMPROMISED OR THE PACKAGE IS DAMAGED.

Caution: Do not re-sterilize implant components. The iUni® G2 is for single use only. The risk of reuse could compromise performance or sterility.

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 VHP	Sterilized Using Vaporized Hydrogen Peroxide
STERILE EO	Sterilized Using Ethylene Oxide
	Manufacturer