ROTOglide® 1st MTP Great Toe System

IFU: Package Insert for Devices Marketed in the USA

CAUTION

United States Federal Law restricts this device to sale by or on the order of a licensed physician.

DEVICE DESCRIPTION

The ROTOglide Great Toe System is a mobile-bearing, uncemented, three component device used for total joint arthroplasty of the first MTP joint. The system includes an anatomic metatarsal component, phalangeal component, and polyethylene mobile bearings.

Implants are made from medical grade Cobalt Chrome per ASTM F1537 with the bone interface surfaces dual plasma coated with commercially pure titanium topped with hydroxyapatite, and conventional polyethylene per ASTM F2759-11.

The ROTOglide Great Toe System implants must only be implanted with the ROTOglide specific instrument sets supplied by Xtremity Solutions.

INDICATIONS

The ROTOglide Great Toe System is indicated for reconstruction of the severely disabled and/or painful first metatarsophalangeal joint due to Hallux Rigidus Grades 3 and 4 resulting from osteoarthritis, rheumatoid arthritis, arthritis secondary to trauma, or failure of prior arthroplasty.

CONTRA-INDICATIONS

Uncorrected hallux valgus (HV) deformities (defined as moderate or severe HV angle deformity, 1st / 2nd intermetatarsal angle > 9° and HV angle ≥ 20°)
Insulin dependent diabetes
Previous, unsuccessful joint preservation surgery
Avascular necrosis
Severe arteriosclerosis
Severe osteoporosis
Heavy impact sports or activities with heavy impact to the toe (e.g., soccer)
A BMI of more than 35
A known allergy, sensitivity or reaction to metal, cobalt or chrome or any implant materials.

WARNINGS & PRECAUTIONS

The correct selection of the implant is extremely important. Potential for successful partial or total joint replacement is increased by the selection of the proper implant. No joint replacements can be expected to withstand the activity levels and loads of normal, healthy bone. Surgeons considering the clinical use of this implant should have a complete understanding of this product. Accordingly, a thorough review of the literature, together with discussions with colleagues using this implant, should always be undertaken, and should also be considered in the decision process.

To determine the optimum size of implant for the patient, the surgeon should first preoperatively size the joint using x-ray templates, followed by physical sizing of the resected metatarsal head and phalanx using the sizers provided in the instrument kits. The thickness of Meniscus to be used should be based on joint kinetics e.g., range of motion, joint lift-off and alignment. Other patient-specific considerations such as patient age, gender, mobility, likelihood of dislocation and soft tissue condition / tension, should also be considered in the decision process. Patients with neurological disorders, mental disorders, conditions requiring chronic corticosteroid use. patient compliance issues or unwillingness to comply with post-operative instructions, may not be ideal for ROTOglide surgery.

PRESS-FIT APPLICATIONS

Tight fixation at the time of surgery is critical to the success of the procedure. The Metatarsal and Phalangeal components must be press-fitted into the bone, which necessitates a precise operative technique and use of specified instruments. An intra-operative fracture of the bone can occur during seating of the prosthesis. Bone stock must be adequate to support the implant device.

IN SELECTING PATIENTS FOR JOINT REPLACEMENTS, THE FOLLOWING CRITERIA SHOULD BE CONSIDERED:

- The patient's weight: An overweight or obese patient (e.g., BMI of >35) can produce loads on the implant which can lead to failure of the device.
- The patient's occupational activity or other strenuous activity such as running, jumping, etc., could impose loads on the implant which could lead to failure of the implant.
- The patients' age. This implant is recommended for patients aged 45 and above.

THE POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Prior to the scheduling of the surgery, the patient must be instructed as to the residual risks inherent to implants and in the surgery being performed. Implants have been known to break or fail, when patients have not been properly instructed, or have failed to follow instructions, and thereby placed heavy and unusual demands upon the implant. It is therefore essential that patients be carefully evaluated as to the existence of alcoholism, mental disorders, senility etc. The possibility of infection: all surgical procedures carry a risk of infection. Certain Degenerative Diseases: In some cases, the progression of degenerative diseases may be so advanced that it may decrease the expectant useful life of the implant.

Implants should never be re-used. Once an implant has been in contact with blood or other bodily fluids or removed from a patient, it must be discarded, for while it may appear in perfect condition, stress produced while implanted in the bone may have compromised the integrity of the implant. Care while handling joint replacement implants must be observed. Implant components must be protected from scratches and surgical debris, on or in the articular surfaces etc.

All instruments should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to the manufacturer.

Loosening of Press-Fit joint replacement implants can occur. Mechanical and / or biological failures may result from improper or defective fixation or stress concentrations of significant intensity. Incorrect positioning of the components could also result in subluxation or dislocation of the joint. Patients should be monitored closely after surgery for any signs of any change in the position of the implant, radiolucencies along the Implant-to-bone interfaces, evidence of bone fracture, bone resorption and bone growth. The devices are produced from chrome cobalt alloy. Metal sensitivity reactions to implants produced from this alloy have rarely been reported: however, it is recommended that patients be screened for metal sensitivity. Osteolysis has been implicated with the use of orthopaedic implant devices. Early or late infection can also lead to the failure of the joint replacement. Implants can also loosen or migrate due to trauma or loss of fixation.

IMPLANT COMPATIBILITY CAUTION

ROTOglide COMPONENTS SHALL NOT BE USED IN COMBINATION WITH ANY OTHER MANUFACTURES' IMPLANT SYSTEMS

Our Metatarsal components are anatomically biased and therefore can only be fitted to the appropriate foot.
e.g., a left metatarsal can only be fitted to a left foot.

The diametric size of meniscus selected for implant, must be complementary to the size of Phalangeal component used:

- Small Phalangeal component must be combined with a Small Meniscus
- Medium Phalangeal component must be combined with a Medium Meniscus
- Large or Extra-Large Phalangeal component must be combined with a Large Meniscus

STERILITY

Implants

THE IMPLANTS ARE SUPPLIED STERILE. DO NOT RE-STERILISE.
THESE ARE SINGLE USE ONLY DEVICES AND EXPLANTED DEVICES SHOULD NEVER BE RE-USED.

Instrumentation

Instruments are supplied clean and "**Non-Sterile**" and ***must be sterilized prior to use***.
Select instruments are supplied "**Sterile**" for **single-use**. The product label will explicitly refer to Gamma sterilization.

INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS

For Instruments Provided Sterile:
Instruments provided sterile are single-use and should not be cleaned or re-sterilized. These are one-time use only devices and used devices should never be re-used.

For Instruments Provided Non-Sterile:

Point of Use

- Immediately remove gross debris after use via initial critical water rinse.
- Disassemble mating components and ***ensure soiling is not left to dry***.
- Remove excess soil with surgical wipes/sponges moistened with critical water.
- Irrigate lumens, blind holes, cavities, serrations and joints with critical water.
- In order to ensure effective cleaning, ***do not allow soil to dry on instruments***.
- A 2% solution of hydrogen peroxide (which bubbles when it encounters blood or protein) may be used to verify removal of protein debris prior to commencing instrument cleaning.

Instrumentation Cleaning

General Instructions

The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies. Point of use initial handling is to be followed by instrument cleaning and then finally instrument sterilization before reuse.

Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling, or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality, and maintenance schedules. In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7 – 9).

During ultrasonic cleaning combine only instruments made of similar metals in order to avoid ion transfer, which may result in etching and pitting.

Ensure rinsing processes remove all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.

Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.).

Manual Cleaning Instructions

Manual Equipment: Ultrasonic cleaner, cleaning brush, enzymatic detergent (neutral pH), running water (tap, critical)

- Pre-rinse under warm running water for a minimum of two (2) minutes to remove gross debris i.e. all visual soiling.
- Completely immerse in an ultrasonic cleaning bath filled with a neutral (pH 7 – 9) enzymatic detergent solution (e.g. Enzol®) prepared according to the manufacturer's instructions.
- Ultrasonically clean for a minimum of ten (10) minutes at or below 35ºC (95 ºF).
- Remove any remaining debris from crevices using a cleaning brush.
- Rinse for at least two (2) minutes under critical running water to remove cleaning residue.
- Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed ***prior to sterilization.***

Cleaning – Automated:

- An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Manual pre-cleaning is recommended in cases of dried-on organic material. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies.
- Arrange instruments in the washer such that all surfaces are exposed to the action of the automated washer.

• Sequencing, number and type of stages may vary among washer manufacturers. Washers may use a single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following: cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse with critical water after use of strong alkaline or acidic cleaning solutions before the final rinse. Use critical water for the final rinse prior to ***drying and sterilization***.

Sterilization:

• Assemble components into their respective tray positions and place lid on tray. Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all instrument surfaces in order to ensure effective sterilization.

• Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States only sterilization wraps cleared for marketing by the Food and Drug Administration (FDA) should be used.

Sterilization Equipment: Pre-vacuum steam autoclave, critical water, sterilization wrap

The appropriate sterilization process and methodology will depend on the process equipment in use, i.e:
steam autoclave sterilization using only FDA approved autoclave equipment.

Perform a pre-vacuum steam cycle as per the following cycle:

Temperature Range	132°C (270°F)
Minimum Exposure Time	4
Drying Time Minimum in Chamber	30

- Ensure autoclave equipment achieves and maintains the proper time, temperature, and pressure.
- Operate equipment in accordance with the equipment manufacturer's instructions.
- When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.
- Use critical water for steam sterilization.

Storage

- Store and transport sterile instruments in such a way as to maintain sterility and functional integrity.
- Store instrument in dry, clean, well-ventilated environments away from floors, ceilings and outside walls.
- If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional covering.
- Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order.
- Do not use instruments if the sterilization wrap is opened, damaged or wet.

WARNINGS

These instructions have not been proven effective for sterilizing instruments contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It should not be assumed that the methods described are effective against such agents.

Cleaning is an essential pre-requisite to ensure effective sterilization. Lumens, blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.

Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.

Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes but is not limited to waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols. Handle sharp instruments with care to avoid injury.

Caustic substances and those containing a chemical make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Instruments with anodized coatings are particularly sensitive to highly alkaline (pH>9) solutions. Exposure to temperatures above 137ºC (279 ºF) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolour or corrode instruments.

Use critical water for final rinsing and steam sterilization cycles. Saline may cause deterioration of instrument surfaces. Corrosion, rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.

Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.

All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Xtremity Solutions Limited products labelled for “single use only” must not be reprocessed. Always clean and sterilize surgical instruments before returning them to Xtremity Solutions or it’s nominated agent/distributor.

PACKAGE INTEGRITY & STORAGE CONDITIONS

Products supplied in the sterile condition: damage to the packaging will threaten the sterility of the products. Sterile boxes should be stored at ambient warehouse conditions, within the recommended range 45°F to 85°F (7° to 29°C) at 30% – 60% RH

MRI SAFETY INFORMATION

MRI (Magnetic Resonance Imaging) and CT (Computer Tomography) may cause distortions in large cobalt-chrome implants such as total hip or knee replacements, due to the mass of these implants. ROTOglide implants with relatively low mass in themselves, have not been specifically tested to safety and compatibility in the MRI Environment, nor has the risk of heating or migration been verified.

This product should be considered MR CONDITIONAL.

A recent publication suggests that between 1.5 – 3.0 Tesla environments, there appear to be no reports of serious injuries to patients. However, it must be noted that there are numerous generations of MRI systems on the market and therefore, we cannot speak for the status of all these machines. Each institution will be responsible for the safety, calibration and safe management of their machines and patients treated within their institutions.

SYMBOL DEFINITIONS

Symbol	Definition	Symbol	Definition
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Catalogue number
	MR Conditional		Batch code
	Non-sterile		Unique device identifier
	Do not re-use		Quantity
	Do not use if package is damaged and consult Instructions for Use		Consult instructions for use
	Do not resterilize		Sterilized using irradiation
	Use-by Date (YYYY-MM-DD)		Date of Manufacture (YYYY-MM-DD)
	Conformité Européene or European Conformity		Manufacturer
MATL	Material		

DISPOSAL

CAT 1: DEVICES REMOVED DUE TO REASONS OTHER THAN THE FAILURE OF THE IMPLANT

In this instance, follow the hospital's established procedure for the safe disposal of contaminated metallic and plastic waste.

CAT 2: DEVICES REVISED OR REMOVED DUE TO THE FAILURE OF THE IMPLANT

These Implants are to be decontaminated using the hospital's established decontamination procedure and implants are to be returned to Xtremity Solutions Inc., at which time QP 68 will come into force.

PRODUCT COMPLAINTS

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any ROTOglide Great Toe System products should notify Xtremity Solutions Inc, or, where applicable, their distributor. In the event of a serious incident, or risk of a serious incident, having resulted in, or that may potentially result in, the death or severe deterioration in the state of health of a patient or user, Xtremity Solutions Inc or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

Address your complaint to your Distributor and Xtremity Solutions Inc. 20 Bailey Circle, Duxbury, MA 02332 by email to george@xtremitysolutionsinc.com

Implants International

MANUFACTURED BY:

IMPLANTS INTERNATIONAL LTD
71 Jay Avenue, Thornaby-on-Tees,
North Riding of Yorkshire,
TS17 9LZ, United Kingdom.

PH: +44 (0) 1642 769080

enquiries@implantsinternational.com
www.rotoglide.com

EUAR Ref: Arazy Group (IRELAND) Ltd
email: ireland@arazygroup.com
tel: +353 21 731 9558

Xtremity Solutions

OWNED AND DISTRIBUTED BY:

XTREMITY SOLUTIONS INC
20 Bailey's Circle Duxbury,
MA 02332, USA.

PH: 1 508 574-6038

www.rotoglide.com