Instructions for Use

maxx orthopedics

LIBERTAS™ | Hip Replacement System

maxx orthopedics

Maxx Orthopedics
2460 General Armistead Ave,
Suite 100, Norristown,
PA 19403, U.S.A.

MXO-00153 Rev. G Effective Date: 14FEB2022

℞ Only

⚠ **CAUTION:** FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

1. Device Name: Libertas™ Hip Replacement System:

Libertas™ Hip Replacement System consists of individually packed components i.e. Modular Shell, HXLPE Modular Liner, Modular Femoral Head, Uncemented Femoral Stem and Cemented Femoral Stem.

2. Device Description:

A Total Hip Replacement System is composed of individually packaged components i.e. Modular Shell (Acetabular cup), Modular Liner (Acetabular Liner), Modular Femoral Head, and Uncemented Femoral Stem or Cemented Femoral Stem.

2.1. Modular Shell:

The Modular Shell is made from Titanium alloy (Ti6Al4V- Extra Low Interstitials (ELI) (ASTM F136 / ISO 5832-3). It is provided occluded with screw-hole occluders. The surgeons can remove these during surgery if additional fixation of the Modular Shell with bone screws is desired. It is intended for press-fit, uncemented fixation within prepared acetabulum. The Modular Shell is available in a range of sizes. The outer surface of the Modular Shell is coated with commercially pure titanium. Inner surface is designed for use with Modular Liner of matching size.

The following individually packaged accessories are used with the Modular shell.

- **Bone Screw:** Bone Screw is made from Titanium alloy ELI (ASTM F136 / ISO 5832-3). Bone Screw has 6.5 mm cancellous-type threads and is available in various lengths. It is available if additional fixation of the Modular Shell is required. The Bone Screws are intended for fixation into cancellous bone only.
- **Apical Hole Occluder:** Exterior Shell Apical Hole Occluder is made up of Titanium alloy ELI (ASTM F136 / ISO 5832-3). It is designed to occlude the apical hole of the Modular Shell which mates with instrumentation during Implantation.

2.2. Modular Liner:

The Modular Liner is available in following material [i.e. HXLPE (Highly Cross- Linked Ultra-High Molecular Weight Polyethylene) (ASTM F648 / ISO 5834-2) and Vitamin E containing HXLPE]. The Modular Liner is available in a range of sizes and is designed for use with the Modular Shell and Modular Femoral Head.

Refer to "Surgical technique document MXO-00148" for specific instructions for implantation of the Modular Shell, Modular Liner, Bone Screw and Apical hole Occluder.

2.3. Modular Femoral Head:

The Modular Femoral Head is available in two different materials [i.e., a. cobalt chromium alloy (ASTM 1537 / ISO 5832-12) and b. Biolox® delta (High-purity alumina ceramic compound ISO 6474-2)]. The Modular Femoral Head is available in a range of different sizes and offsets. The Modular Femoral Heads have a 12/14 taper and are designed to articulate against the Modular Liner and also to mate with a Femoral Stem.

Refer to "Surgical technique document MXO-00147" and Surgical technique document MXO-00150" for specific instructions for implantation of the Modular Femoral Head.

2.4. Femoral Stem:

Femoral stems are available in two designs, Uncemented and Cemented.

2.4.1 Uncemented Femoral Stem:

The Uncemented Femoral Stem is made from Titanium alloy ELI (ASTM F136 / ISO 5832-3) and is coated with Hydroxyapatite below the resection line. The Uncemented Femoral Stems are available in various sizes and 3 different neck angles. The 12/14 taper of the Uncemented Femoral Stem is designed to mate with the Modular Femoral Head. The Uncemented Femoral Stem is intended for press-fit, uncemented use only.

Refer to "Surgical technique document MXO-00147" for specific instructions for implantation of the Uncemented Femoral Stem.

2.4.2 Cemented Femoral Stems:

The Cemented Femoral Stem is made from high nitrogen stainless steel (ASTM F1586 / ISO 5832-9). The 12/14 taper of the Cemented Femoral Stem is designed to mate with the Modular Femoral Head. The Cemented Femoral Stem is intended for cemented use only.

The following individually packaged accessories are used with Cemented Femoral Stem.

- **Centralizer:** The Centralizer is made from Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648 / ISO 5834-2). It is used during fixation of the cemented stem and is available in two designs: winged and non-winged.
- **Cement Restrictor:** The Cement Restrictor is made from Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648 / ISO 5834-2). It is used to restrict bone cement in the medullary cavity during surgery and is available in two sizes: Small and Medium.
- Refer to "Surgical technique document MXO-00150" for specific instructions for implantation of the Cemented Femoral Stem, Centralizer and Cement Restrictor.

2.4.3 Taper Uncemented Femoral Stem:

The Taper Uncemented Femoral Stem is made of titanium alloy ELI (ASTM F136 / ISO 5832-3) and is coated with titanium below the resection line. The Taper Uncemented Femoral Stem are available in various sizes and 3 different neck angles. The 12/14 taper of the Taper Uncemented Femoral Stem is designed to mate with the Modular Femoral Head. The Taper Uncemented Femoral Stem is intended for press-fit, Uncemented Use Only.

Refer to surgical Technique Document MXO-LH00016 for specific instructions for implantation of the Taper Uncemented Femoral Stem

2.4.4 Collared Uncemented Femoral Stem:

The Collared Uncemented Femoral Stem is made of titanium alloy ELI (ASTM F136 / ISO 5832-3). The Collared Uncemented Femoral Stems are available in various sizes and 3 different neck angles. The 12/14 taper of the Collared Uncemented Femoral Stem is designed to mate with the Modular Femoral Head. The Collared Uncemented Femoral Stem is intended for press-fit, uncemented use only.

Refer to surgical technique for specific instructions for implants of the Collared Uncemented Femoral Stem

3. Indications:

- The Libertas™ Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components.

3.1 Total hip replacement is indicated for the following conditions:

3.1.1 Non-inflammatory degenerative joint diseases including osteoarthritis, post traumatic arthritis and avascular necrosis.

3.1.2 Rheumatoid arthritis.

3.1.3 Congenital hip dysplasia.

3.1.4 Acute traumatic fracture of the femoral head or neck.

3.1.5 Certain cases of Ankylosis.

3.1.6 Dislocation of the hip.

3.1.7 Correction of functional deformity.

3.1.8 Revision of failed joint reconstruction or treatment.

3.1.9 Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur.

Note:

- The Modular Shell and Uncemented Stem are intended are intended for pressfit, uncemented use only.
- The Cemented stem is intended for cemented use only.

4. Contraindications:

4.1 Active local or systemic infection.

4.2 Poor bone quality or Bone stock that is inadequate for support or fixation of the components.

4.3 Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.

4.4 Any condition that may interfere with the survival of the implants such as Charcot's disease, or Paget's disease.

4.5 Skeletally immature patients.

4.6 Metabolic disorder which may impair bone formation.

4.7 Patients having sensitivity to the implant materials

5. Warnings and Precautions:

5.1 Improper selection, placement, positioning, alignment and fixation of the implant components may results in unusual stress conditions which may lead to failure of the components. Proper implant selection must consider design, fixation and environmental variables including: Patient weight, age, bone quality and size, activity level and preoperative level of health.

5.2 Conditions such as obesity or being overweight, active sports participation, high levels of patient activity, alcohol or drug addiction tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement.

Note: WHO (World Health Organization) defines "overweight" as a BMI (Body Mass Index) greater than or equal to 25, and "obesity" as a BMI greater than or equal to 30.

5.3 The load on the implanted components will be more when small sized components is used in larger patients.

5.4 Conditions such as severe osteoporosis or poor bone stock, metabolic disorders or systemic pharmacological treatments leading to progressive, deterioration of solid bone support for the implant (e.g., Diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.), history of general or local infections, severe deformities leading to impaired fixation or improper positioning of the implant, tumors of the supporting bone structures, allergic reactions to implant materials (e.g., bone cement, metal, polyethylene), congenital dysplasia of the hip which may reduce the bone stock available to support the acetabular cup components in total hip replacement, tissue reactions to implant corrosion or implant wear debris, and disabilities of other joints (e.g., knees and ankles) tend to adversely affect the fixation of hip replacement implants.

5.5 Do not use implants and trials of other manufacturers with Libertas™ implants.

5.6 The devices are designed for single use only. Never re-implant the Hip components, even if the implants appear undamaged. Do not reuse, reprocess, or resterilize. Reuse can potentially compromise device performance and patient safety. If component is reused, there are chances of infection, loosening or revision surgery.

5.7 Always use trial components for trial purposes. Trials should not be assembled with any components intended for permanent implantation.

5.8 Do not alter or modify implants in any way.

5.9 Mate modular components firmly to prevent dissociation.

5.10 Do not allow coated surfaces to contact cloth or other fiber releasing

materials.

5.11 Protect polished bearing areas, machined taper surfaces and coated surfaces from contact with hard or abrasive surfaces.

5.12 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.

5.13 Cemented Femoral Stems are indicated only for use with bone cement.

5.14 Bone cement should not be used with Uncemented Femoral Stems.

5.15 Do not use if package is open or damaged.

5.16 Use the device before the 'Use By' date specified on the package.

5.17 Never use a metal hammer on the Biolox® delta Modular Femoral Head. Use only the plastic head impactor provided for this purpose.

6. Handling Instructions for Biolox® delta Modular Femoral Head:

Biolox® delta Modular Femoral Head products must be handled with care. When Biolox® delta Modular Femoral Heads are taken by hand, gloves must be used to avoid possible contamination of the product. The customer has to ensure that no damage to the Biolox® delta Modular Femoral Head is caused by the handling. A Biolox® delta Modular Femoral Head that is damaged in any way must not be used. A Biolox® delta Modular Femoral Head that has fallen on the floor must not be used. Contact of the Biolox® delta Modular Femoral Head with metal or with other Biolox® delta Modular Femoral Head must be avoided under all circumstances in order to prevent possible surface contamination with metal or damage to the Biolox® delta Modular Femoral Head. Do not use any product with a contaminated surface or other Damage.

7. MR Safety Information:

The Libertas™ Hip Replacement System has not been evaluated for safety and compatibility in MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. Scanning a patient who has this device may result in patient injury. Surgeon should warn the patients with metallic implants of potential risk of undergoing Magnetic Resonance Imaging (MRI) Scan.

8. Adverse Effects:

8.1 Early or late infection.

8.2 Sensitivity/Allergic reactions.

8.3 Change in position of the component.

8.4 Loosening of the component.

8.5 Wear or fracture of the polyethylene components.

8.6 Fatigue fracture of the femoral stem.

8.7 Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation.

8.8 Intraoperative perforation, fissure, or fracture of the femur, acetabulum or trochanter.

8.9 Subluxations or dislocation of the hip joints.

8.10 Lengthening or shortening of the affected extremity.

8.11 Serious complications including, but not limited to cardiovascular disorders such as thrombosis, pulmonary embolism, and myocardial infarction.

8.12 Haematoma and/ or delayed wound healing.

8.13 Pneumonia and/ or atelectasis.

8.14 Trochanteric avulsion from excessive muscular tension, weight-bearing, or inadvertent intraoperative weakening of the trochanter.

8.15 Aggravation of problems in the ipsilateral or contralateral knee and ankle joints due to leg length discrepancy, femoral medialization and/or muscular deficiency.

8.16 Post-operative femoral or acetabular fracture can occur due to trauma or excessive loading, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery, intraoperative reaming procedures, or bone resorption.

8.17 Bone resorption which may contribute to deterioration of fixation and eventual loosening of the implant.

8.18 Periarticular calcification or ossification which may lead to a decrease in joint mobility and range of motion.

8.19 Traumatic arthrodesis of the ipsilateral knee secondary to intraoperative positioning of the extremity during surgery.

9. Information for patients and surgeon:

9.1 Size Compatibility for Libertas™ Femoral components: Based on bench testing, smaller Uncemented Femoral Stems are not recommended for use with larger Modular Femoral Heads. See additional labeling for the specific Modular Femoral Heads that are contraindicated for use with these stems. Please see the implant compatibility tables in the surgical technique brochures.

9.2 Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure, limitations of the device, instruments and implant characteristics. The surgical technique brochure should be reviewed prior to any surgery.

9.3 Surgeon's experience and familiarity with the device and strict adherence to the indications, contraindications, precautions, and warnings for this product is recommended.

9.4 Periodic, long-term follow up is recommended to monitor the position and condition of the implanted components.

9.5 When the surgeon determines that hip replacement is the best medical option available and decides to use these components in a patient who has any of the above conditions or who is simply young and active, 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.

9.6 The surgeon should discuss all physical and mental limitations particular to the patient and all aspect of the surgery and the components with the patient before surgery. The discussion should include the limitations and possible consequence of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight.

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

10. How supplied:

Modular Shell (occluded with screw hole occluder), Modular Liner, Modular Femoral Head, Uncemented Femoral Stem, Taper Uncemented Femoral Stem, Cemented Femoral Stem, Bone Screw, Apical Hole Occluder, Centralizer and Cement Restrictor components are individually packed and supplied sterile.

10.1. Sterile:

10.1.1 Modular Shell (occluded with screw hole occluder), Modular Femoral Head, Uncemented Femoral Stem, Taper Uncemented Femoral Stem, Cemented Femoral Stem, Bone Screw, Apical Hole Occluder are sterilized with Gamma radiation.

10.1.2 Modular Liner, Centralizer and Cement Restrictor are sterilized with ethylene oxide.

10.1.3 Refer to the package label for the specific sterilization method. Do not use if package is damaged.

10.2. Storage:

10.2.1 Store in cool, dry and dark place

11. Size Compatibility:

Size compatibility for LibertasTM hip components are provided in respective surgical Technique.

12. Disclaimer of warranty and limitations of remedy:

Maxx Orthopedics Inc. has used reasonable care in the design and manufacturing of the product(s) described in this publication. Maxx Orthopedics Inc. and its affiliates have no control over conditions under which this product is used. Therefore, there is no express or implied warranty, including, but not limited to, any implied warranty of merchantability of fitness for a particular purpose, on the products of Maxx Orthopedics Inc. described in this publication. Under no circumstances shall Maxx Orthopedics Inc. and its affiliates be liable for any direct, indirect, incidental or consequential damage of any kind other than expressly provided by specific law. No person has the authority to bind Maxx Orthopedics Inc. to any representation or warranty except as specifically set forth herein.

Description or specifications in the printed matter of Maxx Orthopedics Inc. including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express or implied warranties.

Maxx Orthopedics Inc. will not be responsible for any direct, indirect incidental or consequential damage resulting from reuse, reprocess or re-sterilization of the product.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this disclaimer of warranty and limitations of remedy is held to be illegal, unenforceable or in conflict with applicable law by a court or a competent jurisdiction, the validity of the remaining portion of this disclaimer of warranty and limitations of remedy shall not be affected.

13. Glossary of Symbols:

The Symbol used in labelling are referenced in FDA recognised Standard ISO 15223-1:2016, "Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied --Part 1: General requirements"

Symbols used in labeling

Keep away from sunlight


Keep dry

Consult instruction for use


Use by

Sterilized using ethylene oxide


Caution

Sterilized using Irradiation


Lot number

Do not use if box open or damaged


Reference number

This device to sale by or on the order of a physician


Manufacturer

For single use only do not reuse


Manufacturing date


Do not resterilize