CERAMIC LINER: The Equator Plus™ Ceramic Liner is made up of a pre-assembled ceramic insert of either BIOLOX® forte (ISO 6474) or delta*, and a metal (CoCr - ISO5832-6) taper ring and should be treated as a single component. The Ceramic Liners are designed for use with the ceramic Femoral Heads.

Bone Screw: The titanium (ISO 5892-3) 6.5mm cancellous-type Bone Screw is an accessory available if additional fixation of the exterior shell is required. The screws are available in various lengths, and are intended for fixation into cancellous bone only.

FEMORAL HEADS: Femoral Heads are available in a range of sizes in either metal or ceramic. The Femoral Heads are designed to mate with the M-COR® Femoral Necks and articulate against the Equator Plus™ Liners.

CoCr Femoral Heads: The metal Femoral Heads are manufactured from Cobalt Chrome (CoCr - ISO5832-6). The CoCr Femoral Heads may be used to articulate against UHMWPE liners, but are not compatible for use with Ceramic Liners.

Ceramic Femoral Heads: The ceramic Femoral Heads are manufactured from either BIOLOX® forte (ISO 6474) or delta. The Ceramic Femoral Heads may be used to articulate against Equator Plus™ UHMWPE or ceramic liners. The 28mm heads are not compatible for use with Cobalt Chrome femoral necks tapers.

BIOLUX® forte / delta is a registered trademark of CeramTec AG, Germany

SYSTEM COMPATIBILITY

1. Components of the Mipro modular hip replacement systems are only to be used with approved components. Any misuse will negate the responsibility of Mipro for performance of the resulting mixed component implant.

2. Mipro instruments are to be used for the insertion of Mipro hip replacement systems. Any misuse may result in damage to either the instrument or the implant.

3. The proximal taper of the M-COR™ Femoral Neck is a standard 12/14 taper. This taper will mate with ceramic (ISO 6474) or CoCr (ISO 5832-6) femoral heads with a compatible female 12/14 taper. Mipro systems have been tested to be compatible with femoral head sizes of 28, 32 and 36mm with offsets ranging from -4 to +7mm. Use of heads outside this range may lead to interference, reduced range of motion or fatigue failure.

4. The CoCr Femoral Heads are not compatible for metal-on-metal articulation.

5. Do not use other manufacturers’ bone screws for Equator Plus™ Exterior Shell fixation due to potential screw/liner interference.

POTENTIAL ADVERSE EFFECTS

1. Dislocations, either single or multiple subluxations, decreased range of motion, or shortening/lengthening of limbs caused by incorrect component positioning, loosening of implants, and penetration of the bone by the implant or instruments due to excessive reaming, impingement and/or calcification.

2. Wear of the UHMWPE articulating surfaces, possibly initiated by patellae of cement, metal or other debris, may shorten the useful life of the prosthesis.

3. Fractures of the pelvis or femur. Fracture of the acetabulum is usually due to excessive reaming or too large a prosthesis being implanted in weakened or previously implanted bone. Fracture of the femur can be caused by a defect in the femoral cortex, due to misdirected reaming, or prior pathology such as screw holes or osteoporosis.

4. Intraoperative fracture of the femur can be caused by a defect in the femoral cortex, due to misdirected reaming, or prior pathology such as screw holes or osteoporotic or brittle bone. Excessive reaming or insertion of the stem component too tightly or forcefully can cause fractures.

5. Infection, which can occur immediately post-operatively or later as deep wound sepsis.

6. Neutrophils have been reported from injury to the sciatic, femoral or lateral cutaneous nerve of the thigh. Direct injury to the nerves during surgery, or stretching of the nerves from retraction during the operation can cause nerve damage, which may be permanent or temporary.

7. Cardiac complications include, wound haematoma, deep vein thrombosis and pulmonary embolism. Platelets dysfunction and Heparin-induced thrombocytopenia syndrome (HITS) needs early exclusion.

CONTRAINDICATIONS FOR USE

Contraindications may be relative or absolute, and need to be taken into consideration when evaluating the situation and prognosis in each case. Alternative management techniques to hip replacement need to be taken into consideration, such as non-operative treatments, femoral or acetabular osteotomy, arthrodesis, hemi-arthroplasty, bipolar arthroplasty and resection arthroplasty.

Patients' general physical condition that would exclude surgery or anaesthesia on a medical basis, e.g. cardiac, renal, hepatic and haematological disease.

Any active or suspected latent infection in or about the hip joint.

Patients' physical condition that would eliminate bony support of the implanted prosthesis, e.g. devascularised bone, gross osteoporosis, cancer, femoral osteotomy revision, infection of bone.

Patients' mental or neurological condition that could or would impair the patient's ability or willingness to cooperate during the post-operative course, during the initial healing period and long term, e.g. mental illness, senility, general neurological disease, drug or alcohol abuse.

Patients' physical condition that tends to excessively stress or load well-implanted prostheses, e.g. obesity, myopathies, deformities.

1. Patients’ mental or neurological condition that could or would impair the patient’s ability or willingness to cooperate during the post-operative course, during the initial healing period and long term, e.g. mental illness, senility, general neurological disease, drug or alcohol abuse.

2. Contraindications may be relative or absolute, and need to be taken into consideration, such as non-operative treatments, femoral or acetabular osteotomy, arthrodesis, hemi-arthroplasty.
1. Myositis ossificans occurs especially in patients with early loosening and low-grade infection, as well as in patients with Paget's disease, ankylosing spondylitis and hypertrophic arthritis. Prophylactic measures such as non-steroidal anti-inflammatory therapy and/or radiotherapy also need to be considered carefully for these patients.

2. All instruments and prostheses sizes need to be present and checked in the operating environment before commencing surgery. All packaging needs to be checked for external damage and extra components are recommended to be available in case any are dropped or other errors occur.

3. Implants should be handled with great care. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.

4. Trials should be used to confirm preoperative templating.

5. Trial prosthesis components should be used for trial purposes only.

6. Hip prosthesis components should never be re-implanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections, which could lead to failure.

7. Do not modify or alter the implants in any way.

8. Proper assembly technique and seating of ceramic heads and ceramic liners are critical to the success of ceramic hip systems. It is important that the surgical team understand that the ceramic head can be assembled to the mating component only once. The surgical technique must be strictly followed.

9. Implant and other complications may result from failure to follow and observe the listed warnings.

10. Implants should be stored in clean, dry conditions and should not be exposed to direct sunlight, ionizing radiation, and extremes of temperature or particulate contamination.

**WARNINGS AND PRECAUTIONARY INFORMATION**

It is imperative for the operating surgeon to take an active role in the medical management of their patients. The surgeon should thoroughly understand all aspects of the surgical procedure, instruments and limitations of the devices. Care in patient/implant selection, and the use of proper surgical procedures and techniques are the responsibility of the surgeon and surgical team. Adequate surgical training should be completed before inserting any prosthesis. The surgical technique must be strictly followed.

**Postoperative Care**

1. Willingness and the ability of the patient to cooperate with the post-operative regime, which excludes heavy labour, active sports or any activity which places heavy, abrupt or percussive forces on the hip replacement.

2. Loosening, cracking or fracture of implants and other complications may result from failure to follow and observe the listed warnings.

3. Patient monitoring, including periodic x-rays are recommended for comparative evaluation with immediate postoperative x-rays are recommended for comparative evaluation with immediate postsurgical x-rays are recommended for comparative evaluation with immediate postoperative x-rays.

4. Mental attitude or disorders resulting in a patient's failure to adhere to the surgeon’s orders may delay post-operative recovery and/or increase the risk of adverse effects including implant fixation failure.

5. Caution: Following insertion of a tightly implanted prosthesis the patient may feel little or no pain in the early post-operative period and must be cautioned to comply with the post-operative regimen.

**STERILIZATION**

All implants are supplied sterile in protective packaging to a sterility assurance level of 10⁻⁶. Metal and ceramic components have been sterilized using a minimum dose of 25 kGy of gamma irradiation (ISO 11137). Polyethylene components have been sterilized using Ethylene Oxide (EtO) (ISO 11135). Products that have been exposed to gamma radiation bear a red dot indicator. Products exposed to EtO bear a green dot indicator on the outer tray. All implants are for single use only and should not be resterilized.

**PACKAGE AND LABELING**

The dual tray packaging system protects the implant during transportation and storage, and allows for aseptic handling of the implant in the surgical environment. Packaging should be inspected for signs of damage or tampering prior to using the implant. Any implants with damage packaging where the sterile barrier may have been compromised should not be used. Expiry date should also be confirmed prior to using the implant. Damaged or out of date stock should be returned to the supplier or manufacturer.

**INFORMATION FOR USA ONLY**

1. Federal Law (USA) restricts these devices to sale by, or on the order of, a physician.

2. Equator Plus™ BIOLOX forte / delta Liners are not available for use in the USA.

3. BIOLOX delta Ceramic Femoral Heads are not available for use in the USA.

**ADDITIONAL INFORMATION**

For further information on Mipro US, Inc. products contact us via email at info@miprous.com.

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