BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

BioPro® Bipolar Head

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

PRODUCT HANDLING – BIPOLAR HEAD

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage, which may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labeling for correct Cat. No. and size. When removing the implant from it's packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

DESCRIPTION

The BioPro Bipolar Head consists of three factory-assembled parts: a cobalt chromium outer shell, a UHMWPE liner, and a UHMWPE retention ring. The outer shell has a highly polished spherical outer surface for articulating with the acetabular joint socket. The liner has a hemispherical inner surface for articulating with the spherical head component of the BioPro femoral stem (22mm or 28 mm, depending on bipolar head size). The retention ring provides a locking function to resist dislocation of the femoral head from the bipolar head.

INDICATIONS FOR USE

The BioPro Bipolar Head is intended for use in combination with a PSL femoral stem for primary or revision hemi-arthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other treatments or devices for these indications have failed.

CONTRAINDICATIONS

Absolute contraindications include:

- Infection or sepsis or osteomyelitis;
- bipolar head is not for use with an acetabular shell or liner.
- Insufficient bone structure or quality which may affect the stability of the implant;
- Rapid joint destruction or bone absorption;
- Skeletal immaturity;
- Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity;
- Alcoholism or other addictions;
- Sensitivity to the implant materials;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Obesity that can produce loads on the prosthesis, which can lead to failure of the fixation of the device or the device itself;

Relative contraindications include:

- Uncooperative patient or a patient with neurological disorders and incapable of following instruction;
- Metabolic disorders which may impair bone formation or bone quality;
- Distant foci of infections.

WARNINGS AND PRECAUTIONS

While total hip arthroplasty and hemi-arthroplasty components are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

In using joint replacement implants, the surgeon should be aware of the following:

- The correct selection of the modular implant components is extremely important. The potential for success in joint replacement is increased by the selection of the proper size, shape and design of the implant. Joint replacement prostheses require careful seating and adequate bone support,and should be restricted to limited functional stress. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery.
- In selecting patients for joint replacement surgery, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when a small prosthesis must be used.
2. The patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device or both.
3. A condition of senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.
4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
5. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.

- The correct handling of the implant is extremely important. Care must be taken to protect mating surfaces and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
- Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.
- A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have small defects and internal stress patterns, which may lead to failure. Use only new prosthesis of the current design.
- Resterilization of the device is not recommended.
- The modular head and neck components must be firmly seated to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head or neck components could compromise a critical locking action. The head or neck components should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.
- Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, bone cement or other detritus that may cause a third body wear problem. Range of motion should be checked for impingement or instability.
- Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity levels permissible. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture and/or wear of the prosthesis implant. Early load-bearing should be carefully controlled. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.
- Range of motion is decreased with the use of the skirted +10.5mm offset head.

ADDITIONAL CONSIDERATIONS FOR CERAMIC HEADS

Femoral Heads are only for use with BioPro™ System femoral stems. No other ceramic heads should be used with these hip stems. Other considerations for the ceramic heads include the following:

- The ceramic head must not be sterilized on the hip stem.
- The ceramic heads should not be resterilized.
- The stem cone and head bore should be dry and free of contamination.
- The ceramic head should not be implanted if the head, or the cone of the stem, are possibly damaged.

- The ceramic head should be placed on the stem neck gently while keeping the head and neck in alignment, and then firmly attached by sharply hitting the head with a soft plastic hammer.
- Ceramic heads are contraindicated for use with anything other than an UHMWPE cup or a metal backed UHMWPE cup.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects of the BioPro Hip System are similar to those occurring with any hip arthroplasty and include the following:

- Dislocation or subluxation due to improper positioning or muscle and fibrous tissue laxity.
- Loosening or migration of components due to trauma and/or loss of fixation.
- Accelerated wear of the polyethylene articulating surfaces of acetabular components. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prostheses, and leads to early revision surgery to replace the worn components.
- Histiocytic granuloma formation and osteolysis around the implant due to wear debris.
- Fatigue fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation, extreme duration of service, or obesity.
- Urological complications, especially urinary retention and infection.
- Dislocation, wear, dissociation, or fracture of the acetabular cup liner due to neck-liner impingement.
- Dislocation of the bipolar head from the acetabulum due to soft tissue laxity and/or femoral component impingement at extremes of joint motion.
- Wear, erosion, or abrasion of the acetabular cartilage and/or underlying bone secondary to articulation of the bipolar head in the acetabulum, which may result in pain and/or disability.
- Other complications associated with general surgery, drugs or ancillary devices used, blood, etc.

Intraoperative and early postoperative complications can include:

- Femoral perforation;
- Fracture of the femur while press-fitting the femoral stem component;
- Damage to blood vessels;
- Temporary or permanent neuropathies;
- Undesirable shortening or lengthening of the limb;
- Traumatic arthrosis of the knee from Intraoperative positioning of the extremity;
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- Hematoma;
- Delayed wound healing;
- Infection

Late postoperative complications can include:

- Trochanteric avulsion as a result of excessive muscular weakening;
- Trochanteric non-union due to inadequate reattachment and/or early weight bearing;
- Aggravated problems of the knee or ankle of the affected limb or contralateral extremity by leg length discrepancy, too much femoral medialization, or muscle deficiency;
- Femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- Periarticular calcification or ossification, with or without impediment to joint mobility;
- Inadequate range of motion due to improper selection or positioning of components, by femoral impingement and periarticular calcification;
- Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues;
- Infection.

STERILIZATION:

The re-usable instruments provided must be thoroughly cleaned and sterilized per BioPro's validated cleaning and sterilization method prior to use.

MR SAFETY INFORMATION

BioPro Biopolar and Femoral Heads have not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Sterilized with ethylene oxide gas.

Caution: Do not use if package is open or damaged. **This is a single use device.**

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