Femoral Component for Hip Prosthesis: M-Vizion™

PRODUCT DESCRIPTION

A hip prosthesis for total hip replacement consists of:

• A femoral stem made of metal.
• A modular femoral head made of metal or ceramic.
• An acetabular component.

A hip prosthesis for partial hip replacement consists of:

• A femoral stem made of metal.
• A femoral head that can be:
  • An Unipolar head.
  • A Bipolar head.

The M-Vizion™ femoral stem is composed of a Proximal Body, a Distal Stem and a Locking Screw.

The Proximal Body is made out of Titanium alloy (Titanium Aluminum Nitride, Ti-6Al-7Nb) coated with Titanium plasma spray under the neck.

Distal Stem made out of Titanium alloy (Titanium Aluminum Nitrid, Ti-6Al-7Nb).

Locking Screw made of Titanium alloy (Titanium Aluminum Nitrid, Ti-6Al-4V) extensively coated with Titanium (TiN).

The cementless acetabular components consist of a metal cup and a liner (either fixed or mobile, depending on cup type) that is made of ultra-high molecular weight polyethylene (UHMWPE), or Highcross highly crosslinked ultra-high molecular weight polyethylene (XKHUHMPE). Cementless acetabular components that may be associated with the M-Vizion™ stem are: Versafitcup CC Trio, Versafitcup DM, Maptic system, Maptic DM.

All the components of the prosthesis are supplied in single-use individual packages.

The M-Vizion™ stem can be combined with the Medacta heads (12/14): CoCr, Endohed or with the MecaCer BIOX® forte or MecaCer BIOX® delta femoral heads. Please refer to the Medacta head package insert for more information about ball heads.

INTENDED USE / INDICATIONS

The hip prosthesis M-Vizion™ is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

• Severely painful or/and disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.

• Arvacus necrosis of the femoral head.

• Acute traumatic fracture of the femoral head or neck.

• Failure of previous hip surgery: joint re-construction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

CONTRAINDICATIONS

Total or partial hip replacement is contraindicated in the following cases:

• Acute, systemic or chronic infection.
• Skeletal immaturity.
• Muscular, neurological or vascular deficiency of the affected limb.
• Bone destruction, or loss of bone characteristics that may compromise the stability of the implant.

• Pathologies that may compromise the functionality of the implant in any way.
• Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications.

It is the surgeon’s responsibility to ensure that the patient has no known allergy to the materials used.

WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied as well as the proper use of the instrumentation specially designed and supplied for that range of implants. The trial instrumentation must be used to ascertain the choice of sizes and verify the functionality of the joint. The label shows the size of the taper cone. The surgeon should check the instrumentation fit before assembly.

The M-Vizion™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of M-Vizion™ in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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RISK FACTORS

The following conditions, individually or together, may cause excessive loading of the affected limb, exposing the patient to greater risk of a hip arthroplasty failure:

• Obesity.
  • Hard physical labor.
  • Intensive sporting activity.
  • High level of activity.
  • Probability of falling.
  • Alcoholism or drug addiction.
  • Other handicaps which could compromise the outcome of the operation.

The following conditions, individually or together, will make fixation of the hip prosthesis challenging:

• Advanced osteoporosis or insufficient bone stock.
• Metabolic disorders or systemic medications leading to gradual loss of bone support for the prosthesis (e.g. diabetes mellitus, treatment by steroids, immunosuppressives, etc.).
• History of disseminated systemic or local infections.
• Significant deformations preventing correct fixation or placement of the prosthesis.
• Tumours of the supporting bone structures.
• Allergic reactions to the prosthesis materials (e.g. cement, metal, polyethylene).

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