



IMPLANTS  
INTERNATIONAL

## PACKAGE INSERT FOR IMPLANT DEVICES

### FEMORAL & ACETABULAR TOTAL HIP JOINT REPLACEMENT, PROSTHESES FOR PRESS-FIT AND CEMENTED APPLICATIONS

The advancement of partial and total joint replacement in conjunction with the use of Polymethylmethacrylate Bone Cement or as a Press-Fit, has provided the surgeon a means of restoring mobility and reducing pain for many patients. While these devices are largely successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal, healthy bone.

#### INDICATIONS:

- a. Intractable pain and immobility resulting from osteo, traumatic, or rheumatoid arthritis.
- b. For persistent or recurrent pain and physical impairment subsequent to joint replacement or other conventional techniques.
- c. Where bone quality is deficient / inadequate for a more conservative technique, and total reconstruction involving the joint replacement is the considered surgical solution.

#### CONTRA-INDICATIONS:

- a. Presence of osteomyelitis, or any infection in, or in proximity, to the operative joint.
- b. Systemic deficiencies affecting neuromuscular, vascular or skeletal mechanisms secondary to pathological conditions where the affected joint or extremity has been compromised, and its conditions would clearly contra-indicate the surgery.
- c. Rapid joint destruction or bone resorption apparent on roentgenograms.
- d. Elevation of sedimentation rate unexplained by other disease, elevation of W.B.C. count, or more marked shift in differential count. Additional distant foci of infection such as genitourinary, pulmonary, skin or other sites are a relative contra-indication, because hematogenous transmittal to the implant site may occur. The foci of infection should be treated prior to, during and after surgery.
- e. Use of this implant in conditions, or for purposes other than those for which it was originally designed.

#### WARNING:

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.

#### CEMENTED APPLICATION:

Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete pre-closure cleaning (complete removal of bone chips, bone cement fragments, and other debris) of the implant site, is critical to minimise wear of the articulate surfaces of the implant.

#### PRESS-FIT APPLICATION:

Tight fixation at the time of surgery is critical to the success of the procedure. The femoral and acetabular components must press-fit into the bone, which necessitates a precise operative technique and the 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 an implant device.

#### ACETABULAR FIXATION SCREWS:

Perforation of the pelvis with dome fixation screws or rim screws is to be avoided completely. Great care is to be used when determining and selecting the proper length of screws to be used. Perforation of the pelvis with screws that are too long, can rupture blood vessels causing the patient to haemorrhage.

## MODULAR ACETABULAR SHELL / LINER:

Fixation Screws should be fully seated to assure stable fixation of the shell, and to avoid interference with the plastic liner component. Prior to seating the liner component into the shell component (all surgical debris must be cleaned from the interior of the shell. Debris may inhibit the liner from locking into the shell component). Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

## MODULAR FEMORAL HEAD:

The modular head component should be fully seated onto the femoral stem. Failure to properly seat the head onto the stem can lead to disassociation. Debris may inhibit the locking of the components. Modular heads and femoral stems should be from the same manufacturer to prevent mismatching of tapers. Scratching of modular heads and tapers should be avoided.

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

The patient's weight: An overweight or obese patient 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 cement, the implant, or both.  
Prior to the scheduling of the surgery, the patient must be instructed as to the risks inherent to the implant, 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.  
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. The use of Polymethylmethacrylate bone cement can be helpful in securing, supporting and stabilising certain appliances in the bone, but it neither replaces the function of sound bone for support, nor eliminates the need for other post-operative support during healing. The surgeon must insure complete cement support on all parts of the implant embedded in the bone cement to help prevent possible stress concentrations which may lead to failure.

## PRECAUTION:

Implants should never be re-used. Once an implant has been 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, surgical debris, or bone cement on or in the articular surfaces etc.

## ADVERSE EFFECTS:

Loosening of cemented 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 followed closely after surgery for any signs of any change in position of the implant, radiolucenies along the cement-to-implant, and the cement-to-bone interfaces, evidence of cement fracture, or bone resorption. The devices are produced from either titanium alloy, or chrome cobalt alloy. Metal Sensitivity reactions to implants produced from these alloys 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.

## STERILITY

**THESE DEVICES ARE SUPPLIED STERILE. DO NOT RE-STERILISE. IF DEVICE STERILITY IS COMPROMISED, CONTACT THE MANUFACTURER.**

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

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