Sheffield Medical Products Ltd.
636 Abbey Lane, Sheffield
S11 9NA, England, UK
Tel: +44(0)114 346 3063
Fax: +44(0)114 275 0662
e-mail: info@sheffield-medical.co.uk
www.sheffield-medical.co.uk

TOTAL HIP JOINT REPLACEMENT FOR CEMENTED APPLICATIONS

FOR THE ATTENTION OF THE OPERATING SURGEON

Total hip replacement provides the surgeon with a means of restoring mobility and reducing pain with the use of implanted prosthetic devices. While these devices have proven to be largely successful in obtaining these goals, they are manufactured from metal, plastic or other materials. Any hip replacement system, therefore, cannot be expected to withstand the same amount of activity and loads that normal healthy bone can withstand. The system will not be as strong, reliable or durable as a natural human hip joint and does not have an infinite lifetime. The surgeon must warn patients about device limitations.

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

a) The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by selection of the correct size, shape and design of the implant. Total joint prostheses require careful seating and adequate bone support.

b) In selecting patients for total joint replacement, the following factors can be extremely important to the eventual success of the procedure:

1) **The patient's weight**. An overweight or obese patient will produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when small sized prostheses have to be used because of the patient's bone size.
2) **The patient's occupation or activity**. If the patient is involved in an occupation or activity which includes significant impact loads, (walking, running, lifting or twisting), the resultant forces can cause failure of the fixation, the device or both. High levels of physical activity over the years can also accelerate the normal wear process that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations. (See the PRECAUTIONS section for more information).
3) **A condition of senility, mental illness, chemical dependence or alcoholism**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other omplications.
4) **Foreign body sensitivity**. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Materials:

The materials used in the manufacture of these implants have beean carefully selected and are certified to ASTM and/or ISO Standards. Some of the alloys needed to produce orthopaedic implants contain metallic components that may be carcinogenic in tissue culture or whole organisms under particular circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may prove to be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such a phenomenon, in spite of the millions of implants in use.

Label Information:

The product label provides information regarding specific material(s), from which the device has been manufactured, the expiry date of sterile devices, the specific method of sterilisation, the individual LOT / Batch number, the specific device reference / part number, taper fit size and size of the implant if applicable.

Indications: The indications for total hip arthroplasty include:

1) non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed;
5) treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

Sheffield Medical Products Ltd.
636 Abbey Lane, Sheffield
S11 9NA, England, UK
Tel: +44(0)114 346 3063
Fax: +44(0)114 275 0662
e-mail: info@sheffield-medical.co.uk
www.sheffield-medical.co.uk

Contraindications (relative or absolute):

1) overt infection;
2) distant foci of infections, (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
4) skeletally immature patients;
5) cases where there is a loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint which would make the procedure unjustifiable.

Conditions presenting potentially increased risk of failure include;

1) uncooperative patient or patient with neurological disorders, incapable of following instructions;
2) osteoporosis;
3) metabolic disorders which may impair bone formation;
4) osteomalacia;
5) obesity;

Warnings:

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the service life of the implant. The surgeon should be thoroughly familiar with the surgical procedure, instrumentation and implant characteristics, prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and condition of the prosthetic components, and condition of the adjoining bone.

Attention Warning

AEON Cemented Hip - CDH has a weight limit of 56kg and must not be used with heads of more than +4mm offset. Cemented Application: Care should be taken to assure complete support of all parts of the device embedded in bone cement in order to prevent stress concentration, which may lead to failure of the procedure. Complete removal of bone chips, bone cement fragments and metallic debris from the articulating surface of the implant is necessary prior to closure.

Modular Femoral Head:

A range of SMPL modular femoral heads is available. Components should only be used with other compatible components of the AEON hip system, with the corresponding taper connections. Implant components from other manufacturer MUST NOT be used together with those of another manufacturer, since compatibility of mating parts cannot be assured **except for product combinations specifically approved for use with SMPL devices.**

JRI Orthopaedics Ceramic, HNStSt, Cobalt Chrome, HNStSt Bipolar & HNStSt Physiological Femoral heads are approved for use with the AEON hip stem. Care must therefore be taken to use heads with the same taper angle and diameter.

The modular head component must be firmly seated on the femoral component to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head/neck interface could compromise the critical locking of the taper. Complete cleaning of the male taper, complete removal of any debris and any traces of body fluid, is necessary prior to application of the femoral head to ensure a stable interface.

Acetabular Cups:

A range of SMPL 28mm acetabular cups with several outside diameters is available.

Implant components from one manufacturer MUST NOT be used together with those of another manufacturer, since compatibility of mating parts cannot be assured The SMPL **modular heads** are to articulate with SMPL **acetabular cups** ONLY **except for the 28mm diameter ceramic head range from JRI**

Sheffield Medical Products Ltd.
636 Abbey Lane, Sheffield
S11 9NA, England, UK
Tel: +44(0)114 346 3063
Fax: +44(0)114 275 0662
e-mail: info@sheffield-medical.co.uk
www.sheffield-medical.co.uk

Orthopaedics. Other approved modular head from JRI Orthopaedics are to articulate with JRI Orthopaedics acetabular cups ONLY. Approved combination details are contained in the AEON hip system Operative Procedure.

Care must therefore be taken to use cups and heads with the same articulation diameter.

Ultra-High-Molecular-Weight Polyethylene, (UHMWPE): Polyethylene Wear: As would be expected, wear of the polyethylene articulating surface of the acetabular component has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to relatively early revision surgery.

Precautions:

Information for patients: The surgeon must advise patients of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive ctivity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as ell as damage to the bone, making successful revision surgery more difficult. The surgeon must caution patients to limit activities and protect the replaced joint from unreasonable stresses and follow the instructions of the surgeon with respect to follow-up care and treatment. The surgeon must warn patients of surgical risks and inform them of possible adverse effects. The surgeon should warn patients that the device does not replicate the flexibility, strength, reliability or durability of a normal healthy oint, that the implant can break or become damaged as a result of strenuous activity or trauma and that the device has a finite life and may need to be replaced in the future. Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Instrumentation:

Specialised instruments are available and must be used to assure the accurate implantation of the prosthetic components. While rare, intraoperative fracture or breaking of instruments can occur. Instruments, which have experienced extensive use or excessive force, are more susceptible to fracture. Instruments should be examined for wear or damage prior to and post surgery.

Re-use:

An implant should never be reused. While it may appear undamaged, a used implant may have acquired defects, which would reduce its service life. Furthermore, implants must not be re-sterilised.

Handling:

Handling of implants is important, the highly polished portion of the implant should not come into contact with hard surfaces. Implants should not be bent, notched or scratched, as all of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.

Storage:

Sterile implants should be stored in their unopened original packaging. Store at room temperature.

Adverse Effects:

1) With all joint replacements, asymptomatic, localized progressive bone resorption, (osteolysis), may occur around or remote from the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Osteolysis can lead to future complications necessitating the removal and replacement of

Sheffield Medical Products Ltd.
636 Abbey Lane, Sheffield
S11 9NA, England, UK
Tel: +44(0)114 346 3063
Fax: +44(0)114 275 0662
e-mail: info@sheffield-medical.co.uk
www.sheffield-medical.co.uk

prosthetic components. (See **Important Clinician Information** section for more information).

2) Although rare, sensitivity / allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has also been reported and may occur as the result of surgical trauma.
4) Dislocation and subluxation of implant components can result from improper positioning or migration of the components as well as inappropriate patient activity. Muscle and fibrous tissue laxity can also contribute to these conditions.
5) Implants can loosen or migrate due to trauma or loss of fixation.
6) Infection can lead to failure of the joint replacement.
7) Fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment and/or duration of service, singularly or in combination.
8) Fracture of the femur can occur while seating the femoral stem component into the prepared femoral canal.

Intraoperative and early postoperative complications can include:

1) femoral or acetabular perforation, or fracture;
2) femoral fracture while seating the device.
3) damage to blood vessels;
4) temporary or permanent nerve damage resulting in pain, numbness or a degree of paralysis of the affected limb;
5) undesirable shortening or lengthening of the limb;
6) cardiovascular disorders including venous thrombosis, pu lmonary embolism or myocardial infarction or death;
7) haematoma;
8) delayed wound healing;
9) infection.

Late postoperative complications can include:

1) trochanteric avulsion, (tearing away of soft tissue from the bone), as a result of excess muscular tension, early weight bearing or inadvertent intraoperative weakening;
2) trochanteric non-union due to inadequate reattachment and/or early weight bearing;
3) aggravated problems of the affected limb or contralateral extremity caused by length discrepancy, excess femoral medialisation or muscle deficiency;
4) femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
5) periarticular calcification or ossification, with or without impediment to joint mobility;
6) the following, singularly or in combination can lead to and/ b or cause decreased range of motion; improper selection or positioning of components, femoral impingement and/or periarticular calcification;
7) progressive bone resorption and osteolysis.

Important Clinician Information

Bone Resorption and Osteolysis. Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodelling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localised foreign-body reaction to particulate debris, (e.g., cement, metal, UHMWPE), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of

Sheffield Medical Products Ltd.
636 Abbey Lane, Sheffield
S11 9NA, England, UK
Tel: +44(0)114 346 3063
Fax: +44(0)114 275 0662
e-mail: info@sheffield-medical.co.uk
www.sheffield-medical.co.uk

adhesion, abrasion and fatigue. It has been hypothesised that particulate debris generated by articulation of the components of a prosthesis migrate from the synovial cavity and into the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by size, distribution and amount of particulate debris as well as the rate of debris generation and patient related factors. The phagocytic action has been demonstrated in vitro to release of cytokines and cellular mediators. (IL-1, IL-2, IL-6, PGE2, TNFα) These mediators have been shown to modulate osteoclastic bone resorption. Since osteolysis is frequently asymptomatic, the patient's normal periodic radiographic examination is a good way to help detect and minimise any serious future complication. However, radiographs may not completely define the extent of osteolysis.The presence of local lesions which are progressive may necessitate replacement of the prosthetic component(s).

Magnetic Resonance Imaging, MRI:

The AEON system components have not been tested for safety in the MRI environment. However, a review of similar products listed at www.mrisafety.com, has shown that equivalent devices can be considered to be safe for post operative clinical evaluation using MRI Equipment.

Supply

These products are delivered sterile and have been exposed to a gamma radiation dose of between 25 and 35 kGy from a cobalt 60 source or Ethylene Oxide. Products should only be accepted if received in the original factory packaging. The packaging of all sterile products should be examined prior to use for possible compromise of the sterile packaging. Products with damaged packaging must not be re-sterilised.