Important Information: Please read prior to use in a clinical setting. The surgeon should be familiar with the operative technique and all the information in this insert.

Description: The TriboFit® Hip System consists of the TriboFit® Acetabular Shell, TriboFit® Acetabular Buffer™ component, TriboFit® Modular Femoral Heads and Neck Adaptors and TriboFit® Resurfacing Heads. The TriboFit® Hip System is intended to help reconstruct the human hip joint in primary or revision hip arthroplasty. The implants and instruments are available in a variety of sizes to satisfy anatomical requirements and to help assist the surgeon during implantation. Except for possibly the femoral stem or resurfacing heads, all the components are designed for cementless implantation.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description:

TriboFit® Acetabular Buffer: This device is made of medical grade polycarbonate-urethane. The device is designed for use with or without the metal TriboFit® Acetabular Shell. The Buffer component is designed to articulate against the TriboFit® cobalt chrome modular femoral head or resurfacing component of a diameter designed to be within the tolerances to the size cavity of the Buffer component. The labelled outer diameters of the Buffer components are 6 mm more than the appropriate sized TriboFit® Modular Femoral Head or Resurfacing component. Do not use any other femoral head components with the TriboFit® Acetabular Buffer component. Never let stainless steel components come into continuous physical contact with any of the TriboFit® components.

TriboFit® Acetabular Shell: This component is provided in a range of outer diameter sizes and several inner diameters that match the TriboFit® Acetabular Buffer sizes. The outer surface is hydroxyapatite coated with a Supravit® coating. The appropriate Shell, if one is used, will be labelled 6 mm larger than the selected TriboFit® Acetabular Buffer component.

TriboFit® Modular Femoral Head and Resurfacing Components: The modular femoral heads and resurfacing heads are available in different sizes designed to mate with the appropriately sized TriboFit® Acetabular Buffer components.

Neck Adaptor Components: The Neck Adaptors are available in different sizes and are offered in three different neck lengths: short, medium and long for use with the modular femoral heads for equalizing leg length. The Neck Adaptor components are intended for use only with the TriboFit® Femoral Modular Heads and a titanium alloy or cobalt-chrome stem with a 12/14mm tapered neck that has the same indications for use as the TriboFit® components, such as the Furlong® H-A.C. femoral components with a Supravit® hydroxyapatite coating. Whenever using the Furlong H-A.C. femoral component with the TriboFit® Total Hip components; read and follow the instructions for use and surgical technique provided by the manufacturer.

The metal components of the TriboFit® Hip System can only be used in combination with the TriboFit® Acetabular Buffer.

The characteristics specific to each component are detailed on the product outer label.

Indications: The TriboFit® Hip Replacement System is indicated for, but not limited to the following conditions:

1. Severely painful and/or disabled hip joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia
2. Avascular necrosis of the femoral head
3. Acute traumatic fracture of the femoral head or neck
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement
5. Certain cases of ankylosis

Note: This system is to be used only under the control and supervision of an accredited orthopaedic surgeon. The medical team has a responsibility to determine the necessity for the implantation of this device, keeping in mind, the indications and contraindications for the product. The medical team should carry out a full and adequate consultation with the patient before surgery, explaining the risks and consequences of the surgical procedure and the longevity of the implant and any factors affecting its use. Implant the device using an appropriate operative technique and implement a suitable post-operative regime with appropriate follow up, monitoring for any adverse effects of surgery. Patients receiving hip joint replacements should be advised before surgery that the longevity of the implant depends upon their weight and level of activity.

Contra-indications: The device should not be implanted in patients with an active infection or insufficient bone stock or quality to support the prosthesis or provide adequate fixation. Further contraindications may be, but are not limited to the following conditions:

1. Severe deformities
2. Severe Osteoporosis
3. Tumours
4. Systematic and metabolic disorders
5. Obesity
6. Drug and/or alcohol addiction
7. Rapid joint destruction or bone absorption apparent on radiographic imaging
8. Skeletally immature patients or cases where a loss of abductor musculature, poor bone stock or poor skin coverage around the hip joint exists
9. Patients incapable of producing synovial fluid, such as those with Sjogren's Syndrome
10. Active infection
11. Acetabular bone incapable of being press-fit or cut to support fixation

Patients with any of the following conditions are not ideal candidates for surgery and should only be operated upon with precaution: obese or severely overweight patients, excessive loading through arduous activity, lack of mental faculties to understand postoperative recuperative regime, alcohol or drug abuse, a history of falls or disabilities. Smaller sized implants are intended for patients with smaller bone and regular Body Mass Index and may be inappropriate for use in other patients. Whenever surgery can be delayed on patients with a Body Mass Index of 25 or more, it is advisable that a programme of weight reduction be undertaken prior to implantation of an artificial hip. The surgeon should discuss all aspects of the surgery and the implant with the patient and transfer the information contained in this Instructions For Use to them, with the surgeon explaining and answering all question before surgery takes place. Allergies and other reactions to implant materials although rare should be considered and ruled out pre-operatively. The patient should be advised of all surgical risks including the risk of cardiovascular disorders, tissue reactions,

hematoma and infection. X-ray templates should be used to estimate implant sizes, placement, leg length and joint alignment. All packages and implants should be thoroughly inspected for possible damage prior to surgery and not used if they are.

Intra-operative: The surgeon is responsible for the operative technique used for implanting the product. Read and follow the TriboFit® System operative technique provided by the company, (and available on request). The metal Shell should definitely be used with the Buffer component whenever the quality of bone stock in the acetabulum is of poor quality such as during a revision, whenever cysts exist, or when severe osteoporosis exists. Use any available trial for any test fit and to check the range of motion. Not using the appropriate size of implant, adequately seating the components, or inappropriate assembly of the components, etc., may result in dislocation, subsidence, fracture or loosening of the components. Prior to closing perform a full range of motion to confirm positioning and leg length restoration, check for implant stability and lack of impingement, and assure that the femoral head will move or spin inside the Buffer component.

Implants MUST NEVER, be re-used once in contact with a patient since the fatigue strength and mechanical properties of the implant may be impaired from previous use.

Post-operative: Patients should be advised by the surgeon about the post-operative recuperative regime and be given suitable directions or warnings. Standard surgical practices should be followed in regard to patient handling, post-operative therapy, weight-bearing, unassisted physical activity and protection from trauma to the operative site. The incidence and severity of complications are usually greater in surgical revisions than primary operations.

Adverse effects:

1. Loosening of any or all of the components from each other or the bone
2. Bending or breakage of the components or bone
3. Dislocation or subluxation
4. Device-generated noise, clicking, or motion sensation perceived by the patient
5. Foreign body reaction to the materials used or to wear debris created
6. Osteolysis
7. Bone resorption, remodelling, or excessive calcification around the prosthesis such as by osteophyte, ectopic, or heterotopic bone formation; deformity
8. Infection
9. Loss of or restriction in motion or function of the hip; pain
10. Leg length discrepancy
11. Other complications associated with hip surgery

While the expected life of hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body to help with the potential restoration of mobility and/or the reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to withstand the loads of normal healthy bone indefinitely.

Storage & Handling: Components of the TriboFit® Hip Replacement System are supplied sterile having been sterilized by gamma irradiation. The components should be stored in their original boxes in a clean and dry

atmosphere at room temperature, protected from direct sunlight. If the inner packaging becomes wet, is damaged or opened, do not use. The metallic prosthesis can, at the discretion of the clinician, be re-sterilized disassembled using a validated steam autoclave process, but NOT by Ethylene Oxide gas. Never try to re-sterilize the TriboFit® acetabular Buffer component. Do not use any product after the expiry date (year-month) shown on the product packaging.

Exposed articular surfaces must be neither marked nor come into contact with metallic or hard objects prior to final implantation. Touching the articular surfaces, the hydroxyapatite coating or the taper on the stem must be avoided. If they are damaged in any way the device should not be implanted, but returned to the manufacturer. A femoral head should be fitted immediately after removing the protective cap on the stem taper. Joint prostheses must never be treated mechanically nor modified. Visibly damaged, scratched, improperly handled implants and implants that have already been used must not be implanted under any circumstances as the functionality, integrity and/or sterility of that device may have been adversely affected and therefore cannot be assured.

Post-operative follow up: The patient should be instructed to inform his surgeon without delay of the slightest change in his operated joint. Early detection of an impending complication may allow the surgeon to initiate timely and effective treatment. It is advisable that the surgeon systematically monitors every patient.

MRI safety: Non-clinical testing has shown that the metal components of the TriboFit® Hip System are MRI Conditional. The non-metallic components are non-magnetic. A patient with any of these devices can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less and a maximum spatial gradient magnetic field of 720-Gauss/cm or less.

Non-clinical testing has indicated that MRI-related heating is negligible at 3-Tesla. Image quality may be compromised if the area of interest is in the vicinity of, or relatively close to, the implanted device. Testing has also shown that both MRI and CT scans create artefact that interferes with the ability to detect the location of the Buffer component. Additional information is available upon request.

Device Lifetime: The lifetime of this device is strongly dependent upon the patients' weight / activity level and on the operational technique, and the device is subject to wear and tear through normal use.

Complaints: Any healthcare professional who has problems associated with the use of the TriboFit® Hip System should contact JRI ORTOPAEDICS LTD:

TriboFit® Hip System – Acetabular Shell, Neck Adaptors and Heads:-

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www.jri-ltd.co.uk

TriboFit® Hip System – Acetabular Buffer:-

Active Implants (Israel) Ltd.
43 Hamelacha Street
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Netanya, Israel 42504
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The European Authorised Representative for the TriboFit® Hip System Acetabular Buffer:-

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