

ENDOFIT™

The Femoral Hip Stem



CE 0434

Drug Mfg. Licence
issued by DCGI, India

SUSHRUT-ADLER GROUP





Sushrut™ Global Headquarters, Hinjewadi, Pune, India



The Adler® EndoFit femoral hip stem design is a dual tapered, highly polished stem, based on a design that has proven itself clinically over more than three decades^{1,2,3} of highly successful use.

Cemented stems in hip replacement surgery have been in use since the pioneering years of Sir John Charnley. Widespread clinical experience and extensive failure investigations have created a wealth of knowledge related to manufacturing and metallurgical requirements for these critical devices.

Adler's commitment to patient safety ensures that all current international learning in this area is incorporated into the design, metallurgy and manufacturing of the EndoFit stem.

The use of high-nitrogen stainless steel, variously referred to as Ortron-90^{4,5} or Rex734^{4,5}, adoption of closed-die forging as the manufacturing method as opposed to high-risk investment casting⁶ for this application and exacting control of microstructure and mechanical properties are all Indian firsts, but only to be expected, considering what Adler® stands for and represents, the **highest possible commitment to patient safety**.

The EndoFit™ Femoral Hip Stem

The polished dual-tapered EndoFit™ stem is based on the highly successful loaded taper principle⁷ with biomechanical characteristics that have been proven over more than three decades of successful clinical use².

12/14 Taper

Precise control of taper angle, form and finish ensured by 100% inspection using precision measurement technology guarantee taper characteristics that minimise fretting at the bore-taper interface

Highly Polished Stem

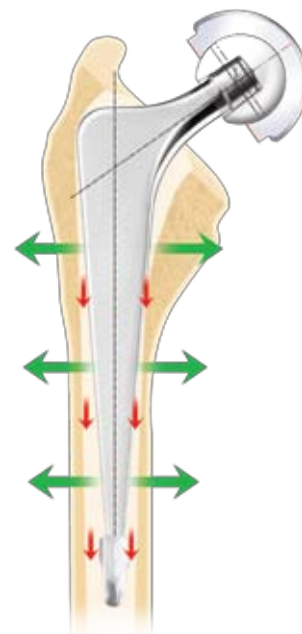
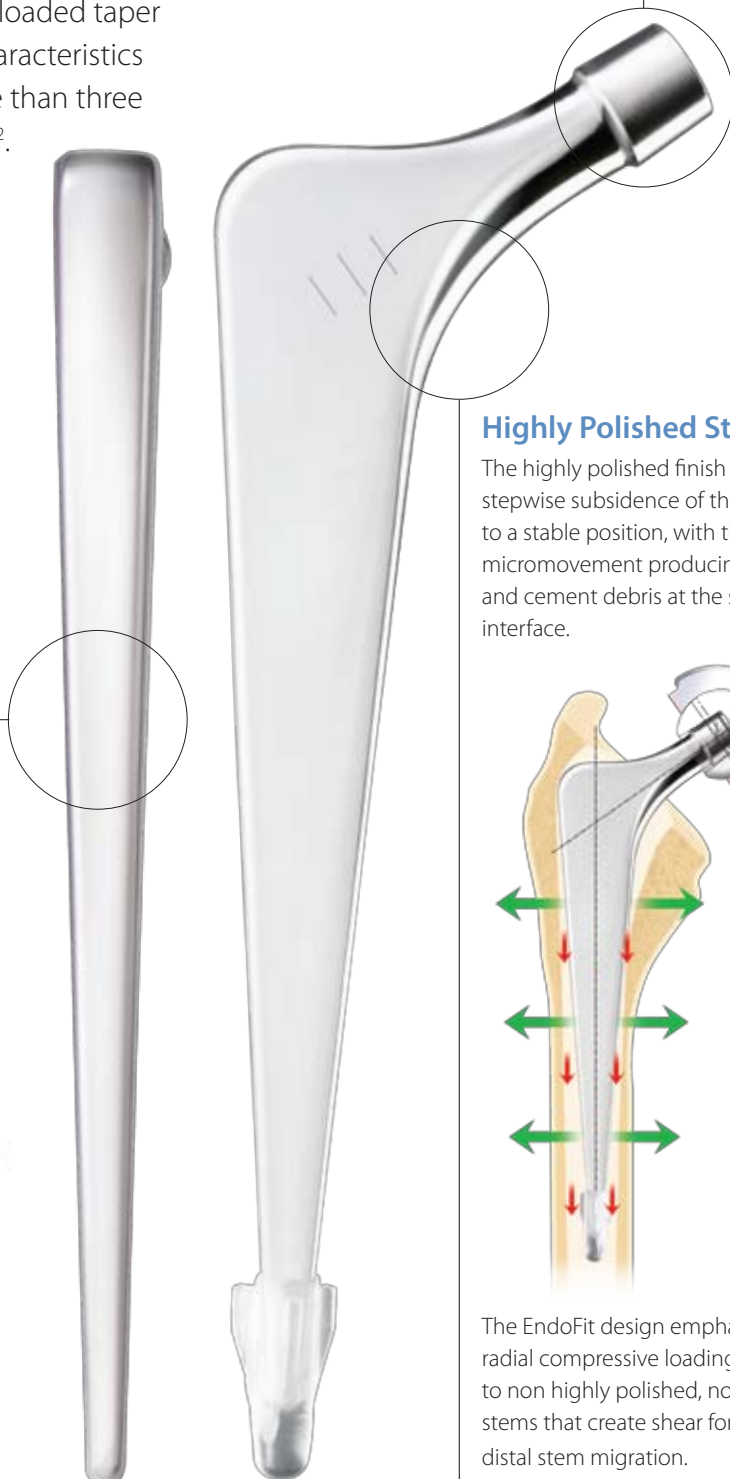
The highly polished finish allows stepwise subsidence of the stem to a stable position, with the associated micromovement producing less metal and cement debris at the stem-cement interface.

Dual Taper Stem Geometry

The dual tapered stem geometry enables the EndoFit stem to become lodged as a wedge in the cement mantle during axial loading, reducing peak stresses in the proximal and distal cement mantle.

Non-winged Centraliser design

An air-filled distal centralizer, provided in three diameters, facilitates subsidence of the stem to a stable position without creating excessive stresses in the distal cement mantle⁷.



The EndoFit design emphasizes radial compressive loading as opposed to non highly polished, non dual tapered stems that create shear forces with distal stem migration.

Femoral Stems - Implant Survivorship

Direct measurements of hip joint forces using telemeterized hip joint prosthesis^{8,9} have confirmed peak hip joint forces between 2.5-3.5 times body weight. Severe internal cyclic stresses are produced in femoral stems as a result of these force magnitudes. Stem breakages through fatigue failure have been extensively reported^{6,10,11}. Detailed failure investigations have clearly identified implant related factors^{6,11} responsible for mechanical failures of femoral stems. The most critical factors are elaborated below.

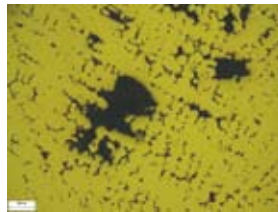
Choice of Material

Extensive experience with failures of hip stems have confirmed that cast cobalt-chromium alloy, cast stainless steel (316 series) and forged stainless steel (316 series) lack the necessary fatigue strength for femoral stem use⁶. The alloy of choice for cemented femoral stems today is a high-nitrogen stainless steel with the typical composition 21Cr-10Ni-2.5Mo. Various referred to as Ortron-90^{4,5} or Rex 734^{4,5}, this alloy, complying with the requirements of ASTM F-1586 / ISO 5832-9 provides greater static and fatigue strength and superior corrosion and corrosion fatigue resistance as compared to stainless steel 316LVM^{4,5}.

Stem Microstructure: Influence of manufacturing technology

Early fatigue failures are strongly influenced by⁶

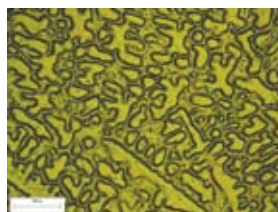
- Grain Size
- Metallurgical microcleanliness of the material, typified by the population of inclusions within the material structure
- Typical metallurgical characteristics associated with the use of investment casting as a manufacturing method that include:
 - Interdendritic segregation
 - Shrinkage and gas porosity
 - Large non-metallic inclusions (impurities)



Microporosity, associated with early fatigue failure, seen at 50x magnification of a typical "investment cast" femoral stem



Large Globular Oxides (inclusions) associated with early fatigue failure - seen at 100x magnification of a typical "investment cast" femoral stem



Interdendritic segregation, associated with easy fatigue crack propagation - seen at 100x magnification of a typical "investment cast" femoral stem



Large grain size associated with early fatigue failure - seen in a typical "forged 316L" femoral stem

The Adler® EndoFit™ Stem-Built to Last

Adler's choice of material for the EndoFit™ Femoral Stem - high nitrogen stainless steel complying with ASTM F-1586/ISO 5832-9 ensures that the implant possesses the mechanical properties (fatigue strength) necessary to assure long term protection against mechanical failure.

Adler's choice of forging as the manufacturing technology ensures metallurgical characteristics such as grain size and microcleanliness, critical parameters that directly influence long term implant survivorship.



EndoFit forgings are based on European expertise gained through years of experience in forging hip stems.



Grain size - seen at 100x magnification of the EndoFit™ femoral stem forged from high nitrogen stainless steel.



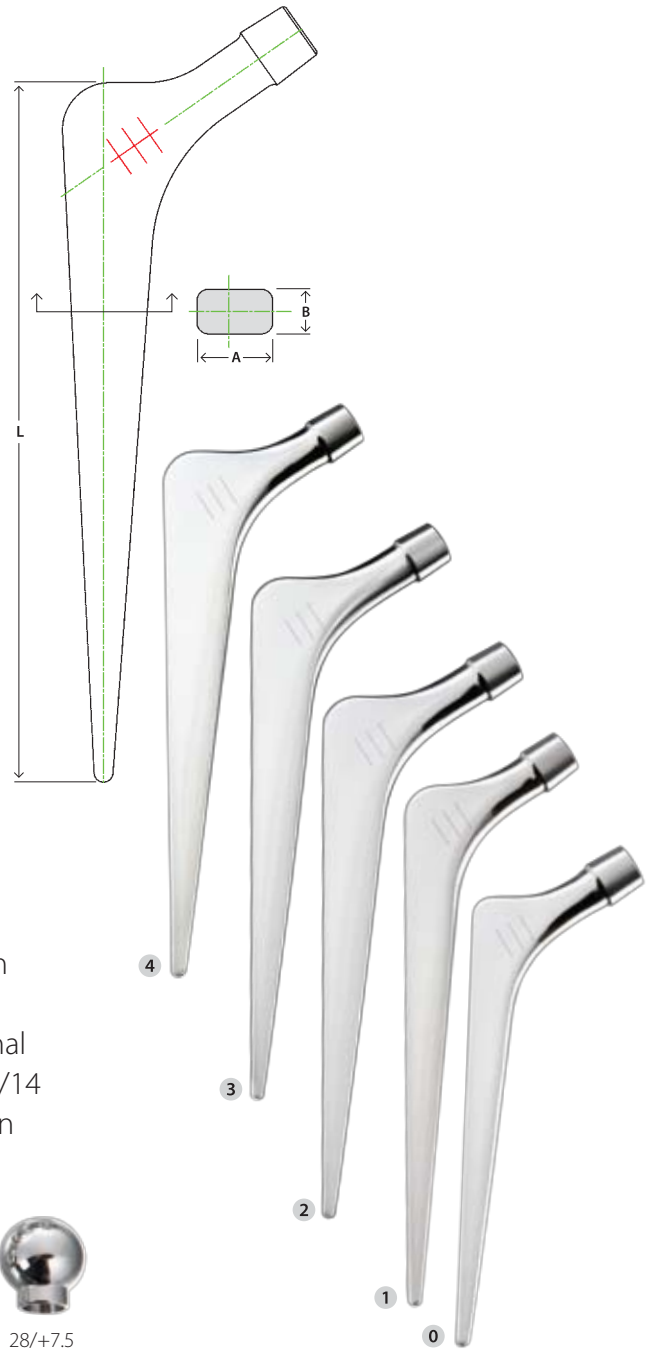
The choice of "forging" as a manufacturing technology also provides EndoFit™ femoral stems with a "grain flow" orientation (similar to the trabecular orientation of the proximal femur) best designed to resist the severe stresses encountered in its intended application



EndoFit™ Stem Sizing

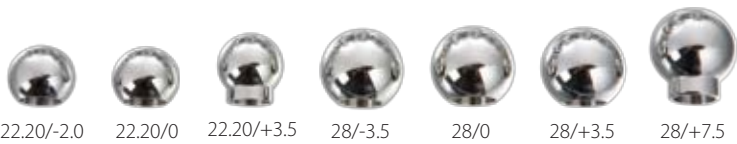
Stem Size	Offset when modular head selected is with					A(mm)	B(mm)	L(mm)
	NL -3.5	NL -2.0*	NL -0.0	NL +3.5	NL +7.5			
0	33.00	34.00	36.00	39.00	42.00	10.80	07.80	127.00
1	35.00	36.00	38.00	41.00	44.00	13.50	09.40	149.00
2	35.00	36.00	38.00	41.00	44.00	16.05	09.40	149.00
3	35.00	36.00	38.00	41.00	44.00	18.00	09.40	149.00
4	35.00	36.00	38.00	41.00	44.00	20.00	09.40	149.00

* applicable only for Modular Head Dia 22mm



Adler® Modular Heads

Adler Modular Heads are precision engineered from high nitrogen stainless steel conforming to ASTM F1586/ISO 5832-9. Extremely tight dimensional controls on diameter, sphericity and the internal 12/14 taper bore are guaranteed through 100% inspection using precision measurement technology.



22.20/-2.0 22.20/0 22.20/+3.5 28/-3.5 28/0 28/+3.5 28/+7.5



EndoFit™ Stem Preparation

Selection of the optimum EndoFit Stem size is enabled by the EndoFit Modular Rasp System.



Push to engage the rasp

The Modular Rasp Handle allows convenient insertion and removal of different rasps to aid the process of arriving at the "best fit" stem size. Should it be desired, the Femoral Stem Version Handle (H0102.16) can be coupled to the Rasp Handle to indicate the version of the inserted Rasp.

The EndoFit Rasp System is built to provide a cement mantle of 2mm.

EndoFit™ Stem Insertion

Trial Reduction

ModuLoc™ Trials are designed for the combination of ModuLoc™ Bipolar Cups, Adler® Modular Heads and EndoFit™ Femoral Stems.

Trialling is enabled at both the Rasp insertion as well as the Stem insertion stages of the operative procedure.

After insertion of the finalised EndoFit™ Rasp, trialling can be carried out using the combination of the Trial Rasp Adaptor (H0103.3500) and the ModuLoc Trial Heads with the ModuLoc Cup Trials, as illustrated.



Final Trialling on an implanted and cemented EndoFit™ Stem can be carried out using the combination of the ModuLoc™ Trial Heads with the ModuLoc™ Cup Trials, as illustrated.

Implant Disassembly

Disassembly of the Bipolar Cup/Head assembly from the femoral stem may be required in certain circumstances that may include:

1. Arthritic changes, acetabular osteolysis or other acetabular changes that prompt a revision surgery to a total hip replacement.
2. Dislocation of the bipolar implant following a post-operative adverse event (accident/trauma) accompanied with damage to the bipolar implant. In such cases, removal of the ModuLoc™ Cup/Adler® Modular Head assembly can be accomplished using the Modular Head Disimpactor (H0103.36). The Disimpactor is a forked instrument that engages with the locator hole provided on all EndoFit™ stems and enables the application of a tensile impact that disengages the taper coupling between the Stem and the Modular Head. Disimpaction forces can be quite large and it is advised that an assistant holds the ModuLoc™ Cup while the Disimpactor is being used.



EndoFit™ /ModuLoc™ Instrumentation



Aluminium Case, 2-Part,
600 X 275 X 160, Adler®

D0101.2102

EndoFit™ Instrumentation

Femoral Taper Reamer
large, small

Large	Small
H0101.09	H0101.091



Modular Rasp Handle
Assembly, EndoFit™

H0101.0402



Box Chisel

H0101.08



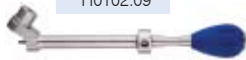
Femoral Trial Stem
Cum Rasp, EndoFit™

Code	Offset (mm)
H0103.0511	36, Size 0
H0103.0521	38, Size 1
H0103.0522	38, Size 2
H0103.0523	38, Size 3
H0103.0524	38, Size 4



Stem Introducer,
Assembly, EndoFit™

H0102.09



Trial Rasp Adaptor,
ModuLoc™

H0103.3500



Impactor for final
tapping, EndoFit™

H0102.14



Lower Tray,
EndoFit™/ModuLoc™
Instrument Set

D0102.1703



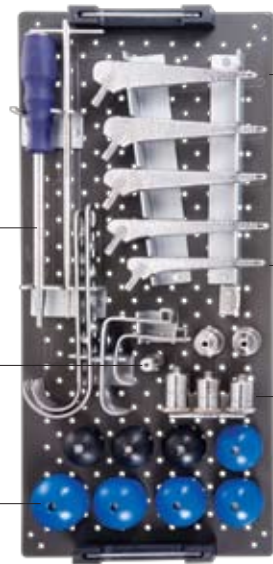
Middle Tray,
EndoFit™/ModuLoc™
Instrument Set

D0102.1702



Upper Tray,
EndoFit™/ModuLoc™
Instrument Set

D0102.1701



ModuLoc™ Instrumentation



Head Gauge Set
for prosthesis

C1304.10



ModuLoc™
Bipolar Cup Impactor

H0102.15



ModuLoc™
Bipolar Cup Press

H0103.10



ModuLoc™
Bipolar Cup Trial

Code	Ø
H0103.0639	39
H0103.0641	41
H0103.0643	43
H0103.0645	45
H0103.0647	47
H0103.0649	49
H0103.0651	51
H0103.0653	53



ModuLoc™
Trial Head

Code	NL(mm)
H0103.3434	-3.5
H0103.3419	-2.0
H0103.3400	+0.0
H0103.3435	+3.5
H0103.3475	+7.5

Hip Replacement General Instruments with EndoFit™/ModuLoc™ Instrument Set



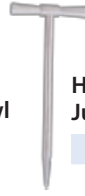
**Charnley Retractor
With Weights, Adler®**

H0103.01



**Diamond
Pointed Awl**

H0101.11



**Head Extractor/
Judet Extractor**

C0902.00



Murphy Skid

H0101.10



**Retractor Ranawat
Pattern, Adler®**

H0103.30



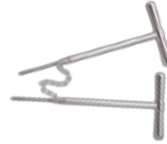
**Right Angle Retractor
(Bent Hohmann), Long, Adler®**

H0103.37



**Right Angle Retractor
(Bent Hohmann), Adler®**

H0103.29



Pin Retractor, Adler®

H0103.03



**Inserter for Cement
Restrictor, Adler®**

H0102.12



**Trochanteric
Elevator, Adler®**

H0103.31



**Modular Head
Disimpactor, Adler®**

H0103.36



**Retractor (Hohmann) Long
Wide Tip 22mm, Adler®**

H0103.02



Intramedullary Canal gauge

Code	Ø (mm)
H0103.3308	08
H0103.3310	10
H0103.3312	12
H0103.3314	14

EndoFit™ Implants

EndoFit™ Stems, Forged High Nitrogen Stainless Steel Dual Taper Highly Polished Stems



**EndoFit™ Stem,
36mm Offset**

H0209.3601



**EndoFit™ Stem,
38mm Offset-Size 1**

H0209.3801



**EndoFit™ Stem,
38mm Offset-Size 2**

H0209.3802



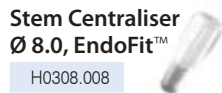
**EndoFit™ Stem,
38mm Offset-Size 3**

H0209.3803



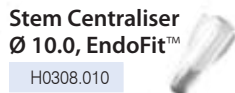
**EndoFit™ Stem,
38mm Offset-Size 4**

H0209.3804



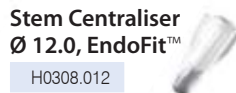
**Stem Centraliser
Ø 8.0, EndoFit™**

H0308.008



**Stem Centraliser
Ø 10.0, EndoFit™**

H0308.010



**Stem Centraliser
Ø 12.0, EndoFit™**

H0308.012



**Stem Centraliser
Ø 14.0, EndoFit™**

H0308.014



**Cement
Restrictor, Adler™**

H0309.01



Adler® Modular Heads, High Nitrogen Stainless Steel



22/-2.0
H0407.2120



22/0.0
H0407.2200



22/+3.5
H0407.2235



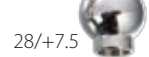
28/-3.5
H0407.2735



28/0.0
H0407.2800



28/+3.5
H0407.2835



28/+7.5
H0407.2875

References:

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Important Information on Adler® Femoral Hip Stems and Modular Heads

For use by an Accredited Orthopaedic Surgeon only

DEVICE DESCRIPTION – General Information

The advancement of partial and total hip replacement has provided surgeons with the means of restoring mobility, reducing pain and correcting deformity in many patients. While the implants used are largely successful in achieving these goals, it must be recognized that implants are manufactured using metals, plastic and ceramic materials. Thus, no hip replacement system should be expected to withstand activity levels and loads as normal healthy human bone. Hip replacement implants would not therefore be as strong, durable or reliable as a natural human hip joint.

Operating surgeons should be aware of the following aspects related to the use of partial/total joint replacement prostheses.

1. Correct prosthesis selection is extremely important: Selection of the proper size, shape and design of the prosthesis significantly influences the potential for success of the procedure. Careful implant seating and adequate bony support are required. Small statured patients with relatively smaller anatomical dimensions may require the use of smaller sized implants. These smaller sized implants may not be appropriate for other patients. Regardless of the endosteal area of the bone, surgeons are encouraged to use their best medical judgement to choose the proper implant size for a given patient.

2. The following factors related to patient selection can be critical to eventual success of the procedure.

a. Patient Weight: Prostheses can be severely loaded due to overweight obese patients. Such overloads can lead to failure of the prosthesis. This can be a major consideration in cases where patients are small statured with small anatomical dimensions that require the use of a small sized implant.

b. Patient occupation or activity: Activities by operated patients that involve substantial walking, running, lifting or other activities that can cause muscle strain can result in forces that can cause failure of the fixation, the device or both. Patient's must be cautioned against unrealistic expectations of function and must bear in mind the fact that joint replacement prostheses do not possess the capability of restoring function to the level expected from normal healthy human bone.

c. Alcoholism, senility, mental illness: Patient's suffering from these conditions, among others, may be led to ignore certain necessary limitations and precautions related to having been implanted with a joint replacement implant, leading thereby to failure or other complications.

d. Foreign body sensitivity: Where sensitivity to materials is suspected, patients should be subjected to appropriate tests prior to material selection or implantation.

Special Note: Patients with renal insufficiency may be sensitive to potential metal ion release. Further, since not much is known about the transport of metal ion release across the placenta, these devices should be used with caution in women of child-bearing age.

Intended Purpose, Indications

Adler® femoral hip stems (EndoFit™/Legend™) and Adler® Modular Heads are indicated for use in total hip/partial hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. A severely painful and/or disabled 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Total or hemi-hip arthroplasty may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for hemi-hip replacement outweighs the risks associated with the age of the patient and if limited demands regarding activity and hip joint loading can be assured. (see WARNINGS AND PRECAUTIONS section) This includes severely crippled patients with multiple joint involvement for whom a gain in hip mobility may lead to an expectation of significant improvement in the quality of their lives.

System Description and Materials

Adler® EndoFit™ femoral hip stems are modular in nature, available in multiple sizes to accommodate the varying needs of femoral anatomy and provided with a 12/14 modular taper cone. Details of the sizes are clearly indicated in the product labeling. Each component is individually packaged in secure inner/outer packaging with an outer protective box and individually labeled.

Adler® EndoFit™ femoral hip stems are manufactured from forged high nitrogen stainless steel, dual certified to ISO 5832-9 and ASTM F1586.

Adler® Modular Heads are manufactured from high nitrogen stainless steel, also dual certified to ISO 5832-9 and ASTM F1586 and carry a internal 12/14 taper closely toleranced and matched to Adler® femoral hip stems.

Contraindications

Contraindications include, but are not limited to the following:

- Acute or chronic infections in the vicinity of the joint or of a systemic nature.
- Accompanying illnesses affecting the function of the joint implant.
- Systemic illnesses and metabolic disturbances.
- Severe osteoporosis or osteomalacia.
- Severe damage to bony structures that stands in the way of stable implantation of the implant components.
- Bone tumours in the area of implant anchoring.
- Bony deformities, axial mal-positioning or bony conditions that rule out implantation of the implant components.
- Obesity and severely overweight patients.
- Expected overloading of the joint implant due to any reason.
- Drug abuse or alcoholism.
- Lack of patient co-operation.

Possible Adverse Effects

A listing of the possible adverse events, includes, but is not limited to the following:

- Early or late loosening, disassembly, bending and/or breakage of any or all of the implant components.
- Foreign body (allergic) reaction to implants, corrosion products and debris including metallosis, tumour formation, staining and/or auto-immune disease.
- Joint dislocations, limited flexibility, post-operative changes in the length of the leg and joint pain.
- Primary and secondary infection.
- Venous thromboses, pulmonary embolisms and cardiac arrest.
- Nerve damage, haematomas and wound-healing impairment.
- Periarticular calcification with joint pain and restricted movement.

Note: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of hip replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS:

Pre-operative

Joint replacement implants manufactured by Adler® Mediequip Pvt. Ltd. should only be used by orthopaedic surgeons experienced with joint replacement surgery.

Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that:

- All necessary implant components are available
- Highly aseptic surgical conditions are present
- The implantation instrumentation is complete and in good working order
- The implant bed is prepared using the appropriate Adler® instruments for the specific replacement procedure being performed
- All informational material concerning the range of implants, instrumentation and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information
- The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed
- In uncertain preoperative situations, especially with implants already in place, prior relevant information has been obtained from the concerned manufacturer

Intra-operative

EndoFit™ femoral stems are available in various sizes and offsets to suit the patient's femoral anatomy. Details of the implant size and offset are explicitly marked on the packaging and on the implants themselves. In addition, the related product literature carries detailed information related to the selection of a particular size and the resultant combinations of offset and leg length resulting from the selection of various Adler® Modular Heads. Always ensure that femoral stems and modular heads are from the same company.

Cautions

Selection of the Adler® Modular Head neck length as well as the EndoFit™ femoral stem is performed with the aid of trial implants provided in the EndoFit™/ModuLoc™ Instrument Set. The correct use of these components is clearly described in the EndoFit™/ModuLoc™ product literature.

Prior to wound closure, all exposed bone cement and bone residue should be removed. Bone cement particles and pieces of bone that find their way into the gliding surfaces of the implant are known to cause abnormal wear that could lead to early failure and the need for revision surgery.

Note: Modular implant components made by different manufacturers may not be compatible with one another. Combining modular implant components of different manufacturers, in the absence of specific manufacturer confirmation, is not permitted.

Post-operative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important:

- Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. The patient must be warned that loosening, bending and/or breakage of the device are complications that may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature.
- The patient must be made to understand that artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved.
- The patient must be explained that an artificial joint can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore joint function again.
- Following joint replacement, the patient will have to submit to regular medical follow-ups.
- The patient must appreciate that the implant cannot be subjected to undue stress through extreme loading, work, and sporting activities.

Sterility and Handling

Correct handling of the implants prior to and during surgery is decisive for the success of joint replacement.

- Implant components are individually packed in correspondingly labelled, radiosterilised (gamma sterilisation, 25 kGy min./) ETO sterilized (Ethylene Oxide) protective packages
- Joint implant components should be kept in the original packaging until shortly before use; check the expiration date and verify the integrity of the sterile package before use.
- Ensure that the surfaces of the implants are not damaged under any circumstances.

Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

For metal components only: If the packaging appears to be damaged and the device needs to be sterilised, the device must be cleaned and sterilized prior to implantation, according to the following instructions.

Cleaning

Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minutes. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is clogged, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Sterilization (metal components only)

If sterilization of metal component is necessary, the following parameters are recommended as they have been validated for a Sterility Assurance Level (SAL) of 10⁻⁶

Method	Cycle	Temperature	Exposure Time
Steam	Pre-vacuum	270°F(132°C)	10 minutes

Note: The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

Re-Sterilization

Re-sterilization of devices supplied in sterile form carries various risks. Various components of joint replacement prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is not recommended.

Storage Conditions

Store in dry place.

Important Information

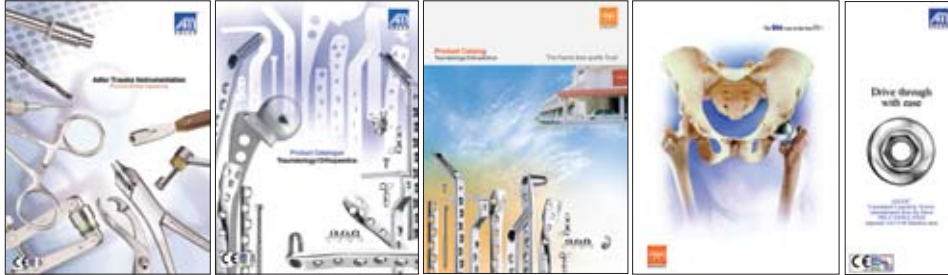
The surgeon bears responsibility for the proper performance of surgical joint replacement and must have mastered the recognised surgical techniques both in theory and in practice. The manufacturer shall not be responsible for complications due to inaccurate diagnosis, selection of implants and surgical technique, limitations of treatment methods or lack of asepsis.

Following mobility and muscle training, special emphasis should be placed on patient information during the postoperative phase. When bone cement or bone structures that transmit forces are damaged, loosening of the components, bone or implant fractures, and other grave complications cannot be ruled out. To recognise such sources of failure as early as possible, the condition of the artificial joint must be checked periodically through suitable measures.

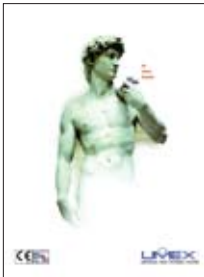
Additional special information about individual joint replacement systems can be obtained from Adler® Mediequip Pvt. Ltd. or from Sushrut®/Adler® customer service at the address on the product package or through email to info@sushrut.com.

Other products from Sushrut®-Adler®

Traumatology



Mini Fixator



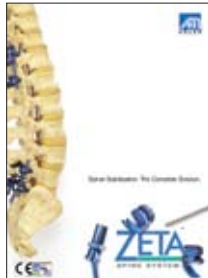
Locked Nailing



Reconstructive



Spine



Manufactured by
ADLER MEDIEQUIP PVT. LTD.



Exclusively marketed by
SUSHRUT SURGICALS PVT. LTD.
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