Specification Guide

Syncera
Powered by smith&nephew

LEGEND

Uncemented Femoral Hip Stem

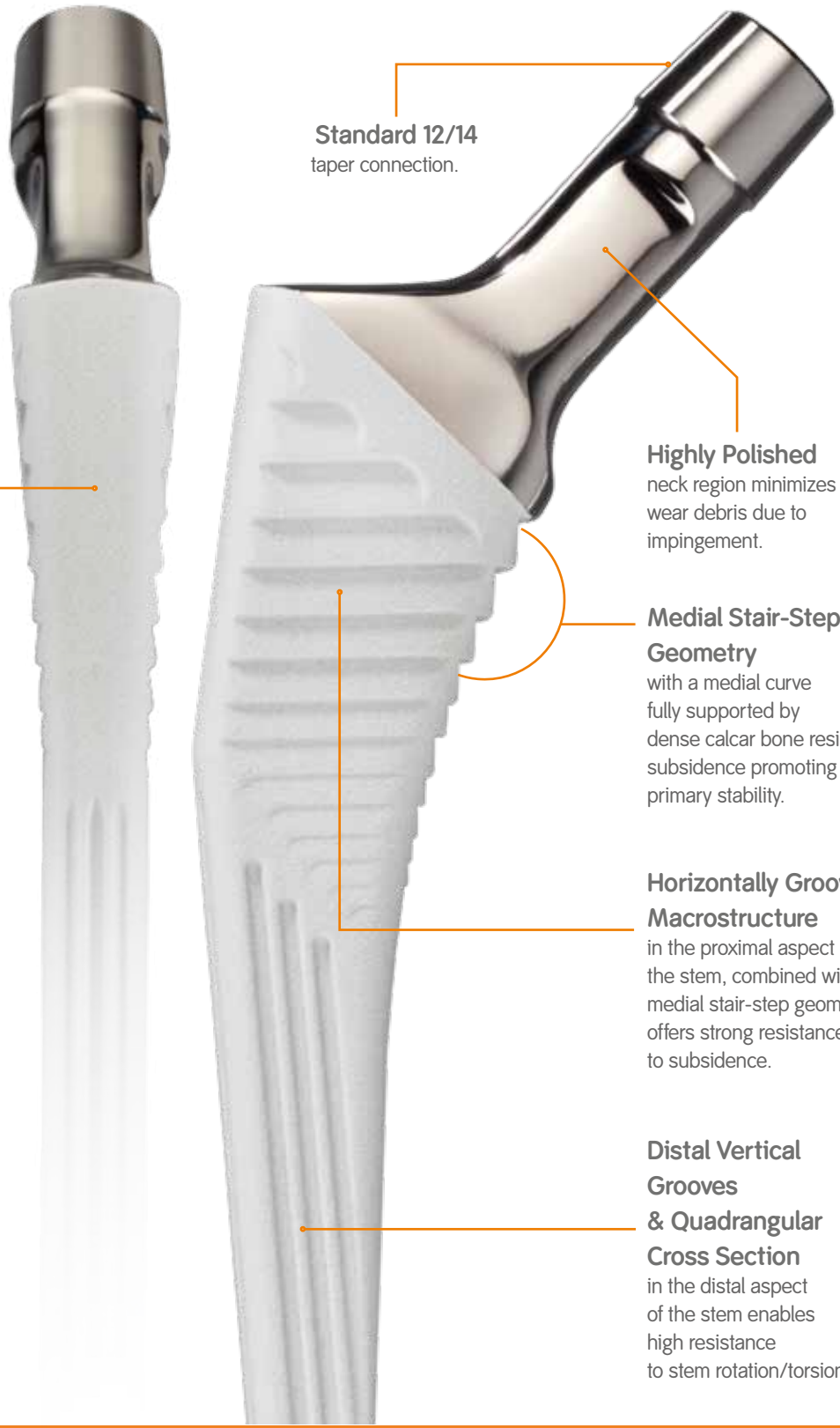
Table of Contents

LEGEND◇ Uncemented Femoral Hip Stem

The LEGEND Uncemented Femoral Hip Stem is designed to provide excellent primary mechanical stability and secure long term fixation within the femur through biological integration. These goals are achieved through a combination of long-proven features that have stood the test of time to provide positive results[1,2] for over two decades.

Thigh pain after cementless stem fixation is a known complication with an incidence of 10-30% with various cementless designs. Thigh pain is directly influenced by primary axial and torsional stability. Based on a proven design philosophy that emphasizes primary stability combined with a narrow distal tip, the LEGEND stem is designed to minimize the possible incidence of post-operative thigh pain in patients.

Philosophy and Design Rationale



Standard 12/14
taper connection.

Highly Polished
neck region minimizes wear debris due to impingement.

Metaphyseal Flare
in both A-P and lateral views. Straight and symmetrical geometry resists axial and torsional loosening forces reinforcing primary mechanical stability.

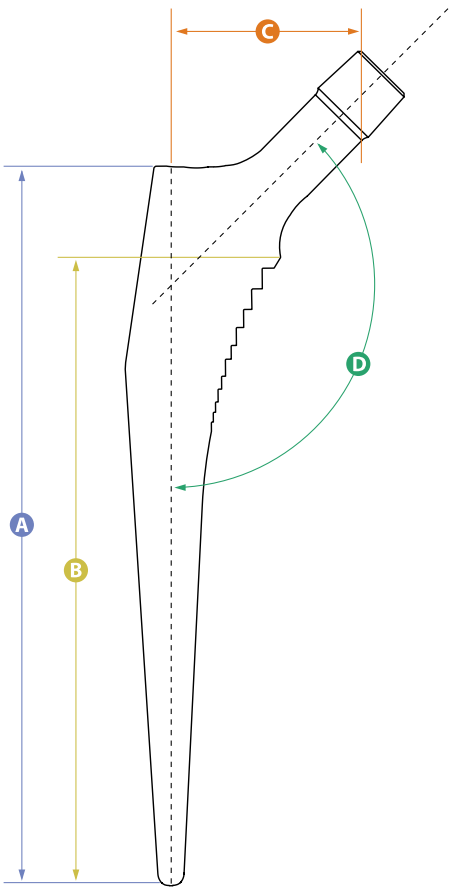
Medial Stair-Step Geometry
with a medial curve fully supported by dense calcar bone resists subsidence promoting primary stability.

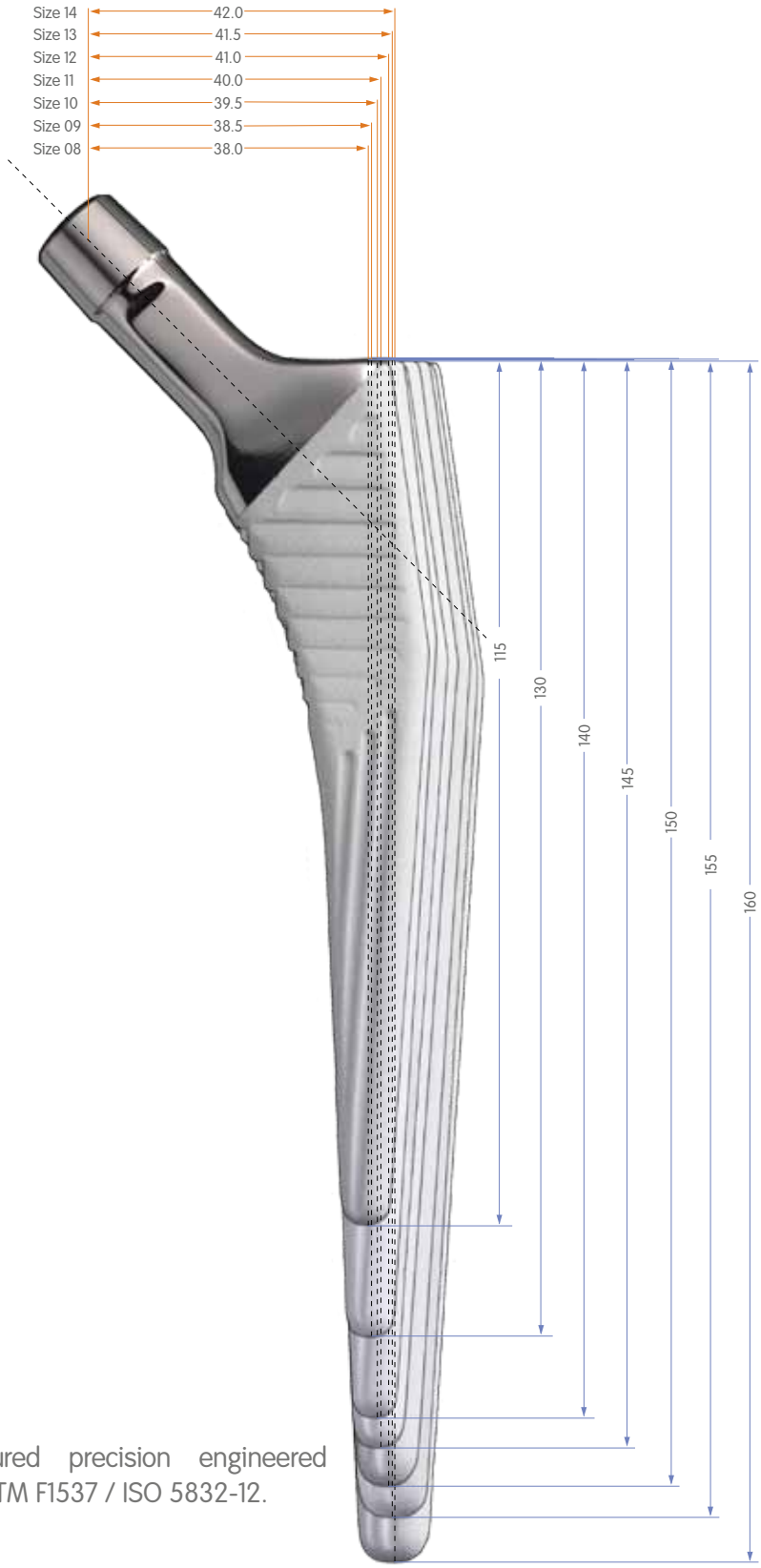
Horizontally Grooved Macrostructure
in the proximal aspect of the stem, combined with medial stair-step geometry offers strong resistance to subsidence.

Distal Vertical Grooves & Quadrangular Cross Section
in the distal aspect of the stem enables high resistance to stem rotation/torsion.

Illustrations not to scale.

Implant Sizing





Standard - Collarless

Size	Stem Length, mm-A	Stem Length, mm-B	Offset, mm-C	Neck Shaft Angle-D
8	115.0	95.0	38.0	135°
9	130.0	110.0	38.5	135°
10	140.0	120.0	39.5	135°
11	145.0	125.0	40.0	135°
12	150.0	130.0	41.0	135°
13	155.0	135.0	41.5	135°
14	160.0	140.0	42.0	135°

ADLER® Modular Heads, COCR

ADLER Modular Heads are manufactured precision engineered from Cobalt-Chrome alloy conforming to ASTM F1537 / ISO 5832-12.

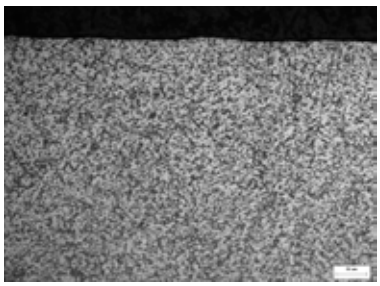
Illustrations not to scale.

LEGEND◇ Technology for Implant Survivorship

LEGEND stems are manufactured from forged titanium alloy (Ti-6Al-4V). Each batch of raw material is certified to comply with the stringent ELI grade that limits oxygen content, enhancing resistance to fatigue failure. The low elastic modulus of the material reduces distal stem rigidity, reducing the potential for distal load transfer, thereby, stress shielding of proximal bone.

Titanium alloys are known to be sensitive to processing parameters as they possess a high resistance to deformation and require high forging loads. Thus, titanium alloy forgings produced with inadequate controls can lead to potential mechanical failure through cracking[12].

Adequacy of forging parameter control is typically evidenced through the microstructure of the forged stem which should be equivalent to one of the acceptable microstructures as defined by ETTC criteria and specified by the International Standard, ISO 20160.



Example of Acceptable Microstructure.

Example of Unacceptable Microstructure.

Safety of LEGEND stems are assessed through microstructural examination and each batch of LEGEND forgings is certified for compliance with ISO 20160 requirements.

This is in addition to Adler Mediequip validation of the forging process to certify its capability to consistently produce forgings complying with stringent quality requirements. A range of checks is carried out to assure forging quality.

- **Material analysis** assuring chemical composition complying with Ti-6Al-4V ELI specified in ASTM F136.
- **Mechanical testing** assuring minimum strength requirements specified in ASTM F136.
- **Microstructure analysis** assuring acceptability of microstructure as per ISO 20160 specified requirements.
- **Hydrogen content analysis** assuring compliance with ASTM F136 specifications.
- **Assessment of uniformity of grain size** assuring that the forged implant has the right properties to maximize resistance to fatigue loads.
- **Grain flow report** assuring that material flow in the forging is in the most appropriate direction favourable to resist loads imposed on the implant while in service.
- **Dye Penetrant Testing** assuring absence of surface imperfections that could impair implant life.

As a further measure of safety, in addition to the forging process validation, all the parameters verified during the validation process, with the exception of “grain flow” which is a destructive one-time test, are verified for every single batch of forgings produced.

Illustrations not to scale.

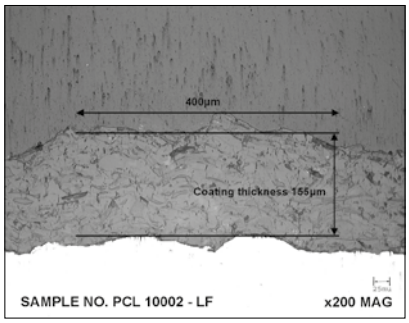
The Hydroxyapatite Coating

Adler Mediequip controls a wide range of critical aspects related to the LEGEND® hydroxyapatite coating with an emphasis on delivering implants capable of long term survivorship[1,2] demonstrated by the design philosophy.

Hydroxyapatite coated implants have been in clinical use for more than two decades and have found increasing acceptance due to the ability of HA to directly bond with the host bone to achieve earlier and greater fixation strength.

LEGEND stems are fully coated with a 155µm thick plasma sprayed hydroxyapatite coating on a pre-prepared surface that is corundum blasted to achieve closely controlled surface characteristics.

Achieving desired clinical results with a HA coating is directly related to coating properties, with the stability and adherence of the coating strongly influencing performance[4]. These are influenced by a host of factors, including, preparation of the titanium stem prior to the coating process[6,7], control of the HA (hydroxyapatite) powder used[8,9,11], and coating process parameters[10,11] employed. These factors, in turn, influence key properties of the coating that directly influence the biological behavior of the coated surface.



The plasma spray process used on LEGEND stems has been validated and certified for its capability to consistently produce coatings of average thickness 155µm with coating porosity ≤ 5% with a mean coating adhesion strength (Adler Mediequip internal specification) that is significantly higher[10] than the strength specified in the International Standard ISO 13779-2. The coating microstructure image shown alongside, from the LEGEND Coating Validation File, demonstrates a coated LEGEND Size 8 stem with a coating thickness of 155µm and coating porosity < 2%.

Further, Adler Mediequip controls a host of critical parameters for each batch of coated stems, elaborated in the table below.

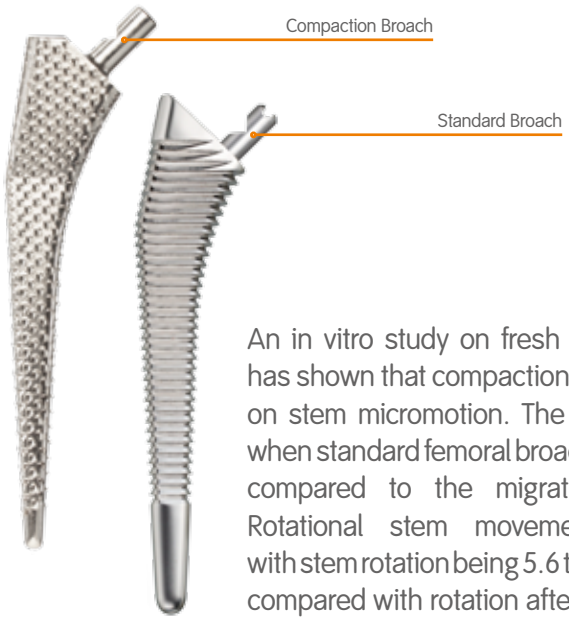
Critical parameter	Requirement / Reference	Adler Mediequip Controls
Preparation of LEGEND stem prior to coating	Corundum blasting to achieve specified surface roughness[6,7].	• Corundum blasting process validated for consistency.
Hydroxyapatite Powder	Powder purity, Powder Crystallinity, Absence of Powder Contamination.	• Every lot of HA powder used tested by XRD* for compliance with ASTM F1185 specifications. • Heavy Metals Analysis carried out on every lot of powder and certified compliant to ASTM F1185 specifications.
	Particle Size distribution - particle size and shape (spheroidal) [8, 9,11] significantly affect coating properties.	• Every lot of HA powder tested using Laser Particle Sizing for particle size, form and distribution within specifications.
Hydroxyapatite Coating	Coating Composition: Ca:P ratio between 1.67 – 1.76, specified in ISO 13779-2.	• Controlled by XRD* on a coated test plate for each batch of coated stems XRD analysis certifies Ca:P ratio, maximum non-HA phases and coating crystallinity.
	Coating Purity – max allowable non HA phases is 5%, specified in ISO 13779-2.	
	Coating Crystallinity > 45%, specified in ISO 13779-2.	
	Coating Adhesion Strength, min. 15 MPa, specified in ISO 13779-2.	• Validated for significantly higher value through Coating Validation Study[10].

* X-ray Diffraction

Illustrations not to scale.

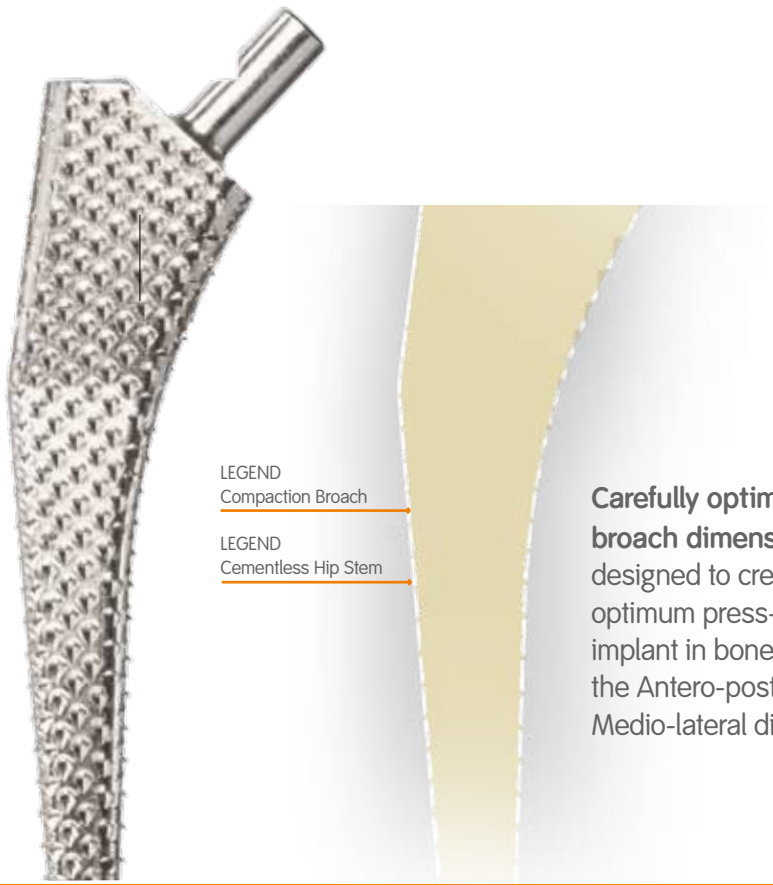
LEGEND◇ Compaction Broaching

Femoral component loosening is a major complication in hip arthroplasty and the key role played by instrumentation, especially femoral preparation and broaching in preventing loosening is critical.



An in vitro study on fresh frozen anatomic specimen femurs[3] has shown that compaction broaching has a very high influence on stem micromotion. The magnitude of axial stem migration when standard femoral broaches were used was 3.9 times higher compared to the migration after compaction broaching. Rotational stem movement was even more significant with stem rotation being 5.6 times higher after standard broaching compared with rotation after compaction broaching.

LEGEND compaction broaches are designed to compress and compact cancellous bone without bone destruction in order to create an excellent cancellous bone bed for the implant.



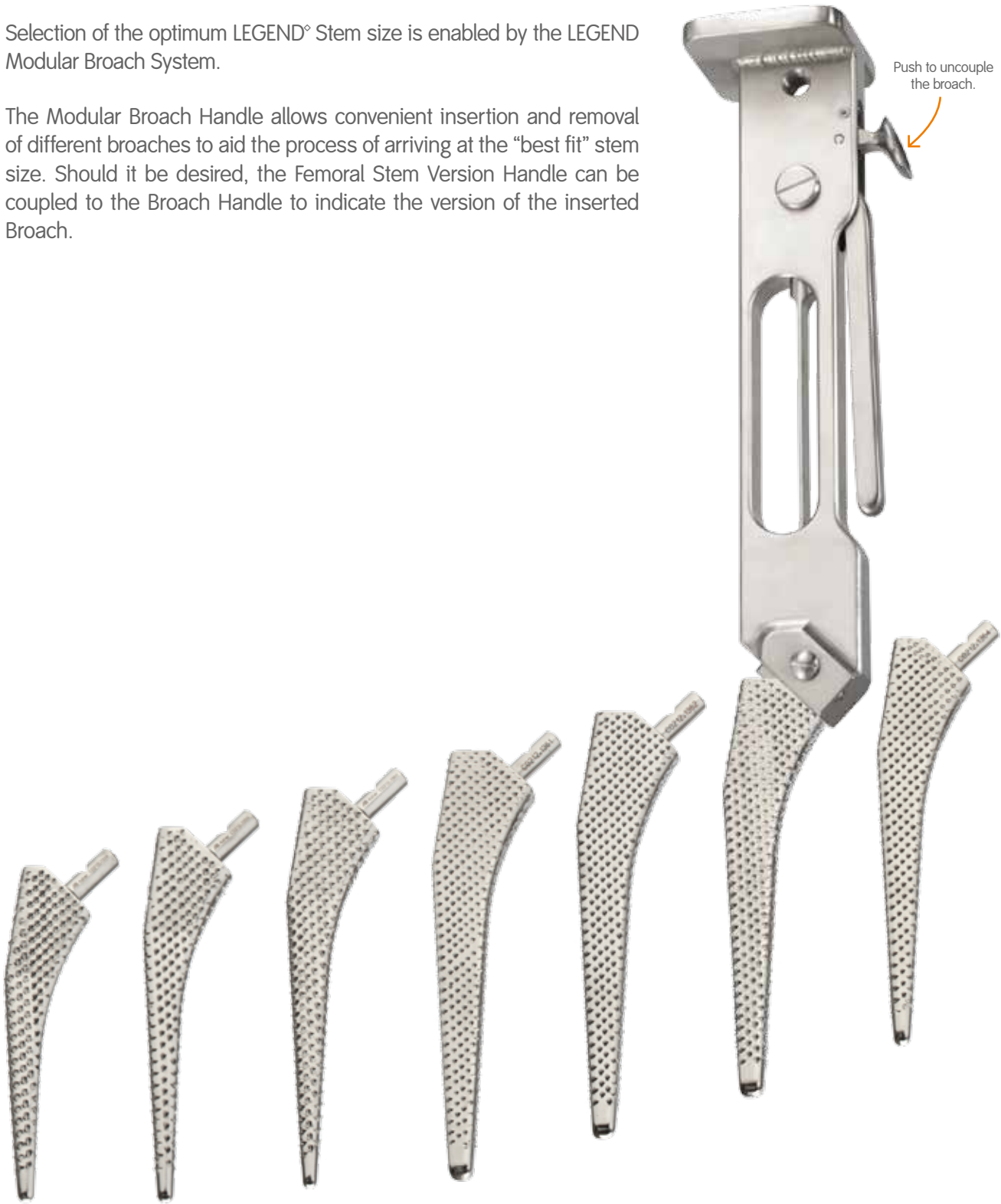
Carefully optimized broach dimensions designed to create an optimum press-fit of the implant in bone, both in the Antero-posterior and Medio-lateral dimensions.

Illustrations not to scale.

Instrumentation Stem Preparation

Selection of the optimum LEGEND® Stem size is enabled by the LEGEND Modular Broach System.

The Modular Broach Handle allows convenient insertion and removal of different broaches to aid the process of arriving at the “best fit” stem size. Should it be desired, the Femoral Stem Version Handle can be coupled to the Broach Handle to indicate the version of the inserted Broach.

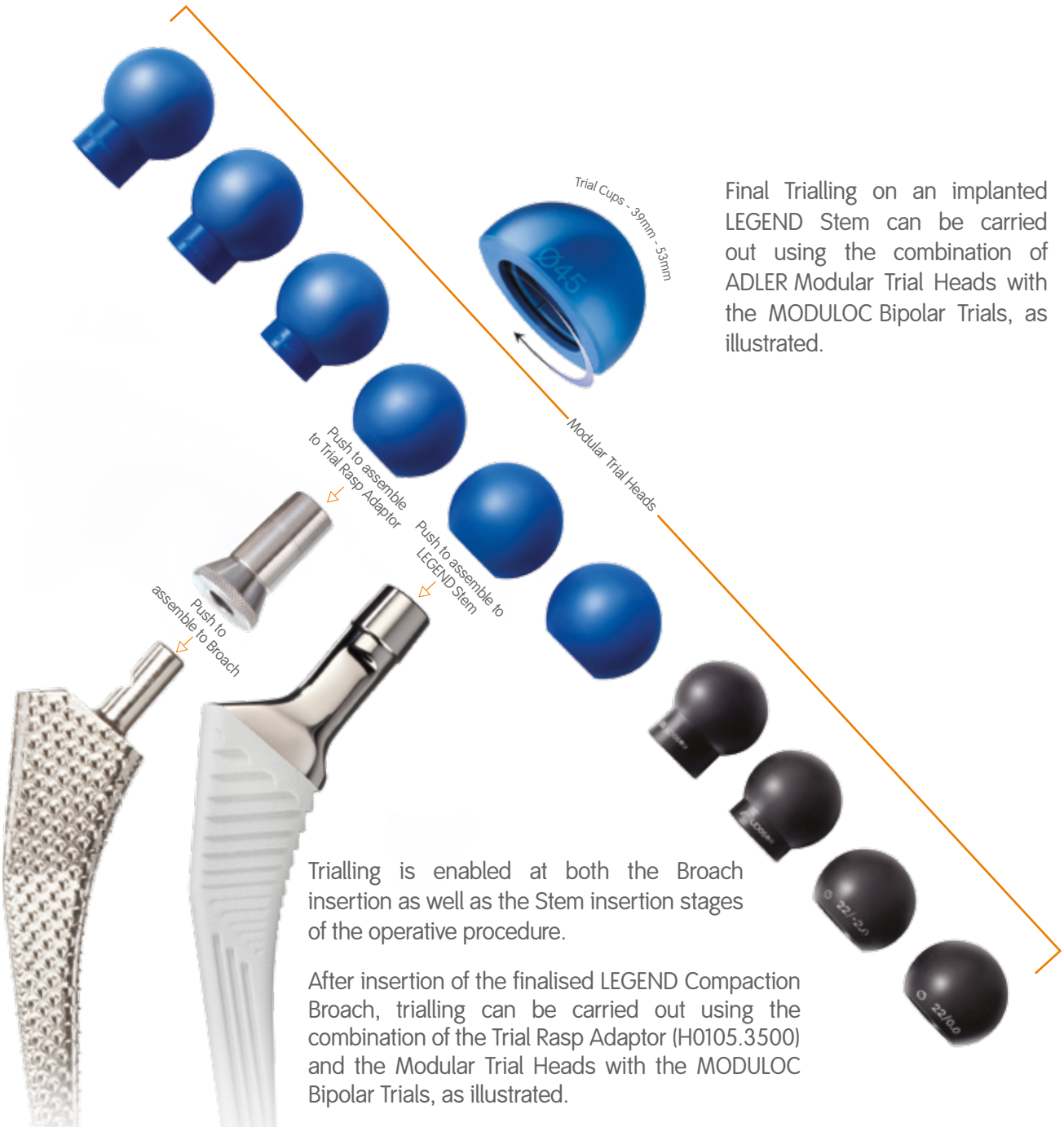


Illustrations not to scale.

Instrumentation Stem Insertion

Trial Reduction

LEGEND® Cementless Hip system is compatible with ADLER® Modular Heads and the MODULOC® Bipolar Cup System. LEGEND Broaches and Stems can be used with ADLER Modular Head trials and MODULOC Bipolar Cup trials to enable trialling either after LEGEND Broach insertion or after implantation of definitive LEGEND Stems.



Final Trialling on an implanted LEGEND Stem can be carried out using the combination of ADLER Modular Trial Heads with the MODULOC Bipolar Trials, as illustrated.

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

After insertion of the finalised LEGEND Compaction Broach, trialling can be carried out using the combination of the Trial Rasp Adaptor (H0105.3500) and the Modular Trial Heads with the MODULOC Bipolar Trials, as illustrated.

Illustrations not to scale.

Catalogue Section Instruments

Aluminium Case, 2-Part, 600 X 275 X 95, ADLER°.

D0101.2107

Tray - LEGEND° Instrument Set.

D0102.1708

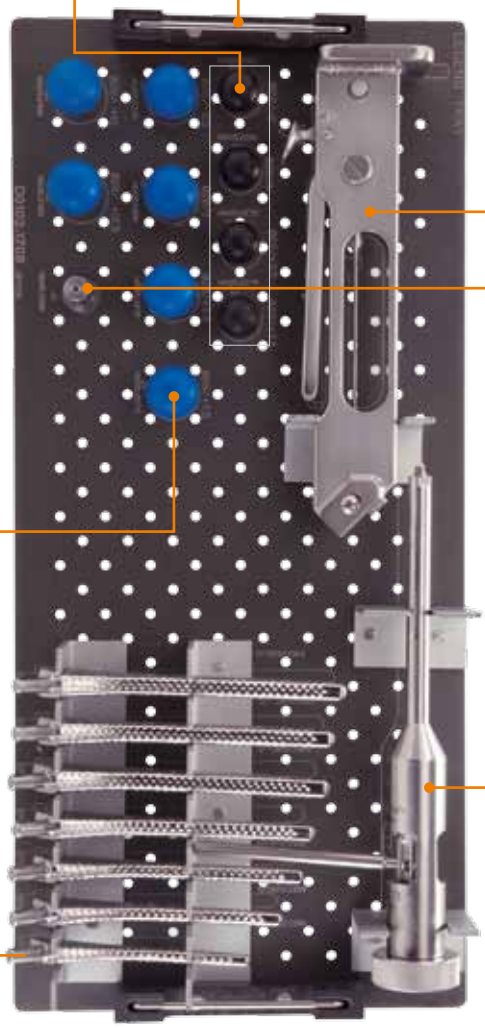
Modular Trial Heads, ADLER.

Ø 22 mm

Code	NL (mm)
H0105.2275	+7.5
H0105.2235	+3.5
H0105.2200	0.0
H0105.2120	-2.0

Ø 28 mm

Code	NL (mm)
H0105.2925	+12.5
H0105.2900	+10
H0105.2875	+7.5
H0105.2835	+3.5
H0105.2800	0.0
H0105.2735	-3.5



Broach Handle, LEGEND Cementless Hip Stem.

H0101.0403

Trial Rasp Adaptor, LEGEND/ENDOFIT°.

H0105.3500

Inserter, LEGEND Cementless Hip Stem.

H0102.17

Broach with Trial, LEGEND Cementless Hip Stem, 135°.

Code	Size
C0212.1358	08
C0212.1359	09
C0212.1360	10
C0212.1361	11
C0212.1362	12
C0212.1363	13
C0212.1364	14

Illustrations not to scale.

Catalogue Section Implants

LEGEND®
Cementless Hip Stem, 135°, Collarless

Size 08	Size 09	Size 10	Size 11	Size 12	Size 13	Size 14
H0212.1358	H0212.1359	H0212.1360	H0212.1361	H0212.1362	H0212.1363	H0212.1364

ADLER® Modular Heads, COCR

Code	Size
A1607.2120	ADLER Modular Head, COCR, 22/-2 to be used with MODULOC® Cup
A1607.2200	ADLER Modular Head, COCR, 22/00 to be used with MODULOC Cup
A1607.2235	ADLER Modular Head, COCR, 22/+3.5 to be used with MODULOC Cup
A1607.2735	ADLER Modular Head, COCR, 28/-3.5 to be used with MODULOC Cup
A1607.2800	ADLER Modular Head, COCR, 28/00 to be used with MODULOC Cup
A1607.2835	ADLER Modular Head, COCR, 28/+3.5 to be used with MODULOC Cup

References

1. G. Hallan, S. A Lie, O. Furnes, L. B. Engesaeter, S. E. Vollset, L. I. Havelin. Medium and long-term performance of 11516 uncemented primary femoral stems from the Norwegian arthroplasty register. *J Bone Joint Surg (Br) 2007;89-B:1574-80.*
2. Jean-Pierre Vidalain. Twenty year results of the cementless Corail stem. *International Orthopaedics (SICOT) (2011) 35:189-194.*
3. Keerati Chareancholvanich, Craig A. Bourgeault, Andrew H. Schmidt, Ramon B. Gustilo, William D. Lew. In Vitro Stability of Cemented and Cementless Femoral Stems With Compaction. *Clin Orthop Rel Res (2002);394:290-302*
4. Y. C. Tsui, C. Doyle, T. W. Clyne. Plasma sprayed hydroxyapatite coatings on titanium substrates Part I: Mechanical properties and residual stress levels. *Biomaterials 19 (1998):2015-2029.*
5. Hugh U. Cameron, Lorence Trick, Bruce Shepherd, Alan Turnbull, Douglas Noiles, Timothy McTighe. An International Multi-center Study on Thigh Pain in Total Hip Replacements. *A Scientific Exhibit at the 1990 AAOS meeting, New Orleans, Louisiana.*
6. S. Amada and T. Hirose. Influence of grit blasting pre-treatment on the adhesion strength of plasma sprayed coatings: fractal analysis of roughness. *Surface and Coatings Technology. Vol. 102:132-137.*
7. Y. C. Yang and E. Chang. The bonding of plasma sprayed hydroxyapatite coatings to titanium: effect of processing, porosity and residual stress. *Thin Solid Films (2003) vol. 444:260-275.*
8. ASTM F 1185 - Standard Specification for Composition of Hydroxylapatite for Surgical Implants.
9. P. Cheang and K. A. Khor. Thermal Spraying of hydroxyapatite (HA) coatings: Effect of powder feedstock. *J Mater. Process Tech. (1995) vol. 48:429-436.*
10. Data on file with ADLER.
11. M. P. Taylor. Assessment of plasma-sprayed hydroxyapatite coatings. PhD Thesis, University of Birmingham, Birmingham, 1994.
12. J. Adamus. Forming of the titanium implants a nd medical tools by metal working. *Arch Mat Sc Engg (2007) vol.28:5:313-31.*

Illustrations not to scale.

Important Information on Adler Mediequip Cementless Femoral Hip Stems and Modular Heads.

Instructions for use for Adler Mediequip Cementless Total Hip Replacement Prosthesis
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 judgment 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

LEGEND® Cementless femoral hip stems and ADLER CoCr 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

LEGEND cementless hip stems are manufactured from forged Titanium-Vanadium alloy (ASTM F-136 ELI/ISO 5832-3), fully coated with Hydroxyapatite (ISO 13779) and are available in multiple sizes to suit patient anatomy. LEGEND stems are internally certified for taper compatibility with ADLER CoCrMo Modular Heads. LEGEND Femoral Stems should not be combined with Stainless Steel Modular Heads.

Each system component is individually packaged in secure inner/outer packaging with an outer protective box and individually labeled.

ADLER CoCr Modular Heads feature a 12/14 internal taper, certified for taper compatibility with all ADLER cementless femoral hip stems and are manufactured from Cobalt-Chrome alloy (CoCrMo - ISO 5832-12/ASTM F1537)

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.
- Sensitivity to Implant Materials.

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.
- Nerve damage, haematomas and wound-healing impairment.
- Periarticular calcification with joint pain and restricted movement.
- Cardiovascular Accident such as stroke.
- Femoral or acetabular perforation, or fracture.
- Femoral fracture while seating the device.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction or death.
- Progressive bone resorption and osteolysis.
- Trochanteric non-union due to inadequate reattachment and/or early weight bearing.
- Implant migration due to trauma or loss of fixation.

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.
- Re-use of any implant is prohibited as it including risk of infection / disease.

Intra-operative

ADLER cementless femoral hip 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/or 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 to ensure the use of only compatible taper combinations.

Caution

Selection of the ADLER Cocr Modular Head neck length as well as the selected ADLER cementless femoral hip stem is performed with the aid of trial implants provided in the corresponding ADLER Instrumentation Set. The correct use of these components is clearly described in the relevant product literature corresponding with the femoral hip stem being implanted.

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 prior 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.

The warnings and precautions mentioned above cover all the relevant warnings and precautions and clinically relevant information, as consistent with the clinical data.

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, radiosterilized (gamma sterilization, 25 kGy min.)/ ETO sterilized (Ethylene Oxide) protective packages.
- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the "sterile" sticker that seals the outer box is intact, the sterility indicator button is of the right colour indicating a properly sterilized implant (red in case of Gamma Irradiation and Green in case of ETO sterilization) and that the implant is within the sterility period indicated on the label.
- 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.

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.

For non-metal components

If packaging appears to be damaged, non-metal components should not be re-sterilized and used.

For metal components only

ADLER recommends that if the packaging appears to be damaged, metal components should not be re-sterilized and used. If the packaging appears to be damaged and metal components are to be used however, then the device must be cleaned and re-sterilized prior to implantation, according to the following Instructions:

Cleaning (metal components only)

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. 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 cannulated, 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.

Re-Sterilization (metal components only)

If packaging of a metal component appears to be damaged and the metal component is to be used, the following parameters to re-sterilize the metal component following cleaning 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.

Storage Conditions

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

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. Adler Mediequip's responsibility will be limited to the delivery of implants in sterilised condition. The surgeon has to take care of complications due to inaccurate diagnosis, improper 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 on 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 Mediquip Pvt. Ltd. or from ADLER customer service at the address on the product package or through email to ***info@adlermediequip.com.***

DMN-XII-2014-34-0a

Manufactured by
ADLER MEDIEQUIP PVT. LTD.
Sushrut House, Survey No. 288, Next to MIDC Hinjewadi Phase II,
At Mann, Tal. Mulshi, Pune 411 057, India. Tel: +91(0)20 66520700
Fax: +91(0)20 66520800 e-mail: info@adlermediequip.com Internet: www.adlermediequip.com

CE 0434