HIP SYSTEM

150367-0

The following languages are included in this packet:

English (en) only

For additional information please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

HIP SYSTEM
(149856-0)

OUTLINE

HIP GENERAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina
ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

$CaSO_4$	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D

DESCRIPTION

Wright Direct has a variety of hip joint replacement prostheses. The components for these systems include an acetabular shell, acetabular liner, fixation screws, femoral head, and femoral stem. These components can be utilized in a variety of configurations to assemble the final construct. Only components from Wright Direct should be used to prevent mismatch or misalignment of components.

The femoral, acetabular, and cement restrictor components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards. See Table 1.

The implants are single use only devices.

A. GENERAL PRECAUTIONS

Preoperative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery. The surgeon should contact Wright Direct for product-specific surgical techniques.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Patients with high activity levels, poor bone quality, or heavyweight patients may not be candidates for a narrower femoral implant. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as a natural human joint. The patient should not have unrealistic functional expectations for

occupations or activities that include substantial walking, running, lifting, or muscle strain.

Additional conditions presenting increased risk of failure include:
1) uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3) metabolic disorders that may impair bone formation;
4) osteomalacia;
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);
6) pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intraoperative Precautions

Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

Correct selection of the prosthesis is extremely important. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

X-ray templates are used to estimate the size of the product to be used. The anatomy of the patient ultimately determines the size of the product for an individual patient. The

extent of bone preparation is determined intraoperatively by reaming and/or broaching starting at the smallest size and continuing until bleeding cancellous bone is reached. Trial prostheses should be used to evaluate the position of the final implant and the joint range of motion. The final size of the implant selected during surgery may differ from the size originally planned during preoperative assessment or the combination chosen during preliminary trialing.

Non-Cemented Application**.** Adequate fixation at the time of surgery is critical to the success of the procedure. Uncemented femoral stems and acetabular shells must press fit into the host bone, which necessitates precise operative technique and the use of specified instruments. Bone stock must be adequate to support the device.

Postoperative Precautions

The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and possible loosening, fracture and/or wear, and follow the instructions of the physician with respect to follow-up care and treatment. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition, size, and location of the fragment (if known);
    b. The potential mechanisms for injury, e.g., migration, infection;
    c. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

There are inherent risks associated with the use of metallic implants in the MR

environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

Wright Direct Hip Systems have not been evaluated for safety and compatibility in the MR environment. Wright Direct Hip Systems have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright Direct cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

B. ADVERSE EFFECTS for total hip arthroplasty implants can include:

1) Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication.
2) Particulates leading to increased wear rates necessitating early revision.
3) Allergic reactions to materials; metal sensitivity that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).
4) Delayed would healing; Deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.
5) A sudden drop in blood pressure intra-operatively due to the use of bone cement;
6) Damage to blood vessels or hematoma;
7) Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
8) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
9) Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
10) Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
11) Periarticular calcification or ossification, with or without impediment to joint mobility;
12) Trochanteric non-union due to inadequate reattachment and or early weight bearing;
13) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
14) Traumatic arthrosis of the knee from intraoperative positioning of the extremity;

15) Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification;
16) Femoral or acetabular perforation or fracture; femoral fracture while seating the device; femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
17) Undesirable shortening or lengthening of the limb;
18) Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
19) Pain.

C. HANDLING AND STERILIZATION

Implants

Implants are sterilized by gamma radiation, or ethylene oxide. The immediate package label should be consulted for specific method of sterilization. Irradiated implants have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation.

Unless supplied non-sterile, this product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. This is particularly important in handling porous coated prostheses. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

A prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded. Wright Direct does not take any responsibility for the use of implants resterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- Do not sterilize femoral prostheses with femoral heads seated on the stem.
- You must **NEVER** steam sterilize plastic, or metal/plastic implants. If steam sterilization of the metal component(s) is required, proceed as described below.

Instruments

<u>Cleaning</u>

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove any gross contamination.

3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

The minimum recommended steam sterilization conditions for Wright Direct reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79: 2006 Table 5 guidelines[1] and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

1 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006)

For additional information regarding instruments, see Wright Direct's Cleaning and Handling of Wright Direct Instruments.

D. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

HIP FEMORAL SYSTEM

E. INDICATIONS

Intended Use

Wright Direct total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

Wright Direct total hip systems are not intended for use in a metal-on-metal bearing system.

F. CONTRAINDICATIONS

Patients should be warned of these contraindications.

Contraindications include:

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 absorption

apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

G. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

NEVER combine these metals in NON-ARTICULATING contact surfaces:

- Stainless steel (excluding the stainless steel described in ISO 5832-9)/cobalt chrome alloy
- Stainless steel (excluding the stainless steel described ISO 5832-9)/titanium alloy.
- Stainless steel (excluding the stainless steel described ISO 5832-9)/unalloyed titanium.

Do not attempt to seat the implant beyond the envelope of femoral bone preparation. Forcing to seat the implant beyond the prepared femoral bone may increase the chance of bone fracture. In some cases, a portion of the proximal portion of the stem with or without coating may be visible above the proximal resection level.

The smaller sized femoral implants are intended for patients with narrower intramedullary femoral canals. The geometry of these implants is reduced to accommodate the anatomy of the narrower intramedullary femoral canal, which also decreases the fatigue-strength and load-bearing characteristics of the implant.

Other **Modular Components** (Femoral Head and Stems). Scratching of femoral heads and proximal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component **must** be clean and dry before assembly. Do not resterilize femoral prostheses with femoral heads seated on the stem.

Stems with the Wright Direct 12/14 SLT Taper should only be used in combination with femoral heads with the Wright Direct 12/14 SLT Taper. Cobalt chrome femoral heads with the Wright Direct 12/14 SLT Taper are designed for use with cobalt-chromium-molybdenum and titanium alloy femoral components with the Wright Direct 12/14 SLT Taper

HIP BEARING SYSTEM

H. INDICATIONS

Intended Use
Wright Direct total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use
1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.
Shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

Bipolar Hip System is indicated for the following conditions:
1) Pathological fractures of the femoral neck;
2) Non-union of femoral neck fractures;
3) Aseptic necrosis of the femoral head and neck; and,
4) Primary pathology in the young involving the femoral head but with a non deformed acetabulum.

I. CONTRAINDICATIONS

Patients should be warned of these contraindications.
Contraindications include:
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 absorption apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion

and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

J. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

NEVER combine modular components made by different manufacturers.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Acetabular Fixation Screws. Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner.

- Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.
- **Note:** There is currently no clinical evidence supporting the long term use of large diameter femoral heads with cross-linked polyethylene liners.

In order to prevent mismatch of tapers:

- Modular liners from Wright Direct must be used only with shell components of the same system from Wright Direct.

Cobalt chrome femoral heads with the Wright Direct 12/14 SLT Taper are designed to articulate with UHMWPE liners only.

Bipolar cups should **not** be used with skirted femoral heads. Once a removal key has been used to disassociate a head from a **bipolar cup**, the head must be replaced with a new implant to avoid potential scratch damage.