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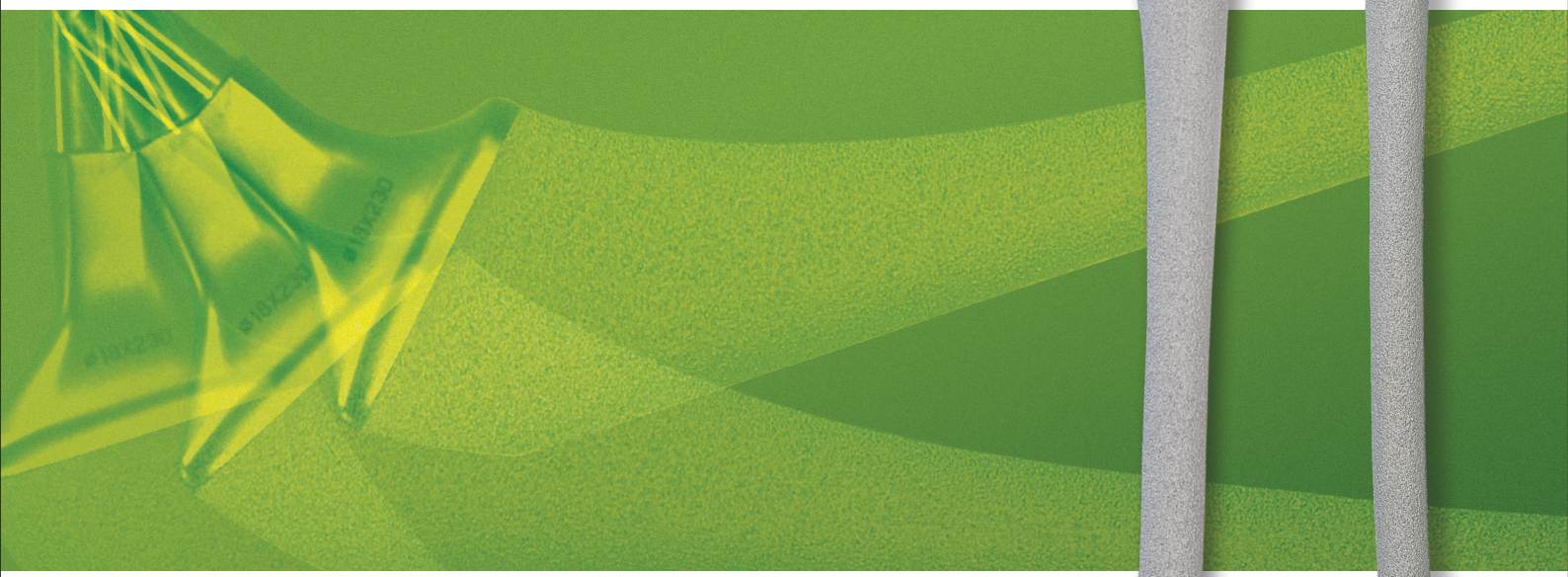
U2 Revision
Hip System



Surgical Protocol

United® Orthopedic Corporation

U2 Revision Hip System

Table of Contents

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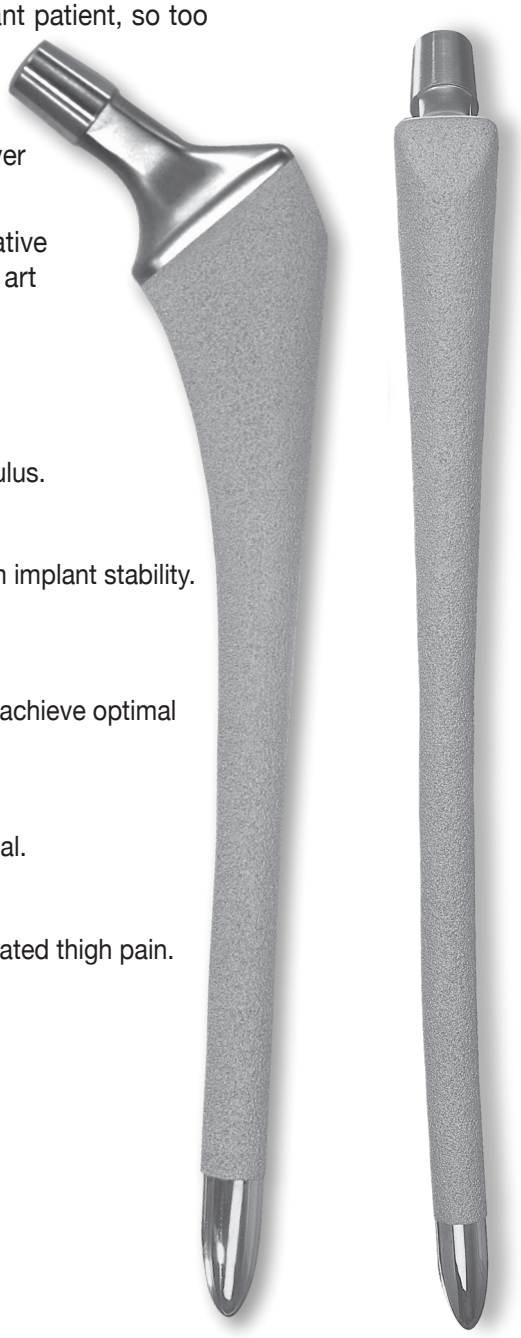
Introduction

In todays society, Total Hip Arthroplasty is considered to be among the most significant orthopedic procedures, improving the quality of living for millions of patients.

As THR has resulted in vast improvements to the quality of life for the implant patient, so too has the demands placed upon the contemporary implant materials employed. These demands are further compounded as the patient's average life expectancy has also increased. Therefore, the limits of the procedure have become far better understood, and revision THR procedures have become ever more common.



In an effort to provide both surgeons and patients with an excellent postoperative result, the U2 Revision Hip System has been designed utilizing state of the art materials, instrumentation and design concepts.

Among the key design elements of the **U2 Revision Hip System** are:

- **Forged Titanium Alloy**
  Offering high fatigue strength, proven biocompatibility, and a low elastic modulus.
- **Titanium Plasma Spray**
  Providing secure immediate fixation and excellent bone ingrowth for long term implant stability.
- **180 mm Straight and 230 mm Bowed Stem Options**
  Offered in Collarless geometries with 11, 12, 13, 14, 15, 16.5 and 18mm distal diameters available, provides excellent intra-operative fitting options to achieve optimal femoral implant fit.
- **Proximal Tri-Wedge Taper Design**
  Provides excellent rotational stability and reduced implant subsidence potential.
- **Cylindrical Distal Stem with Polished Tip**
  To optimize loading characteristics and decrease the potential for distal tip related thigh pain.

Preoperative Planning

Careful pre-operative planning is essential to help ensure a successful revision THR surgery. To optimize the surgical result, it is important to employ all clinically accepted methods of pre-operative planning, which may include, but are not limited to; a radiographic review to access important boney structure, radiographic templating to estimate ideal implant positioning goals, consideration of the surgical incision approach and patient positioning, along with a thorough review of the patient history and physical patient examination.

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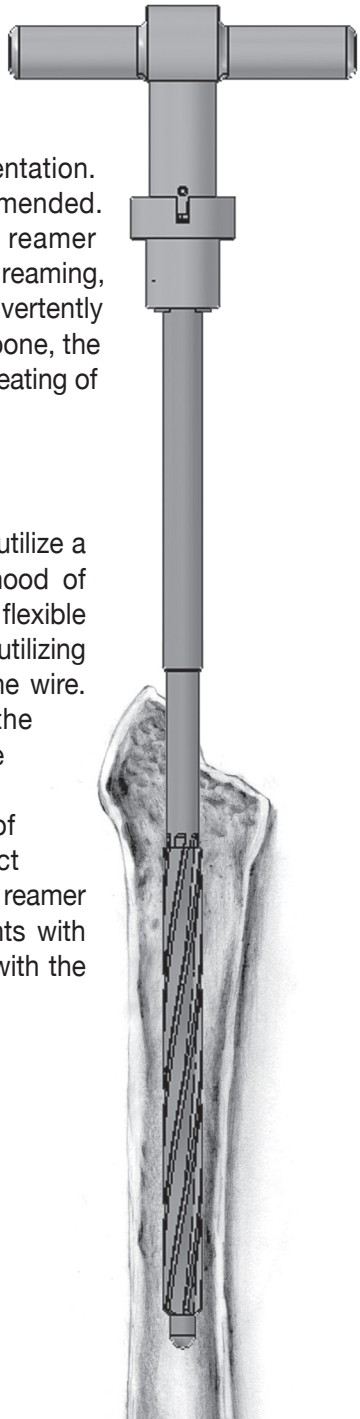
Femoral Preparation

Femoral Canal Reaming with Cylindrical Reamers:

After gaining adequate surgical exposure and successful removal of the required implant(s), begin the femoral preparation by advancing the straight cylindrical reamer to an adequate distance within the canal, utilizing 0.5mm increments until adequate cortical contact is achieved. The reamers may either be inserted by hand, or by powered instrumentation. As a goal when possible, 5cm of linear diaphyseal contact is recommended. Additionally, it is generally recommended that the size of the final reamer utilized corresponds with the intended size of the final implant. During reaming, proper care should be taken to reduce the potential of the reamer inadvertently extruding from the femoral canal. (Note: In some patients with dense bone, the surgeon may elect to over-ream the canal, to assist with the complete seating of the final implant.)



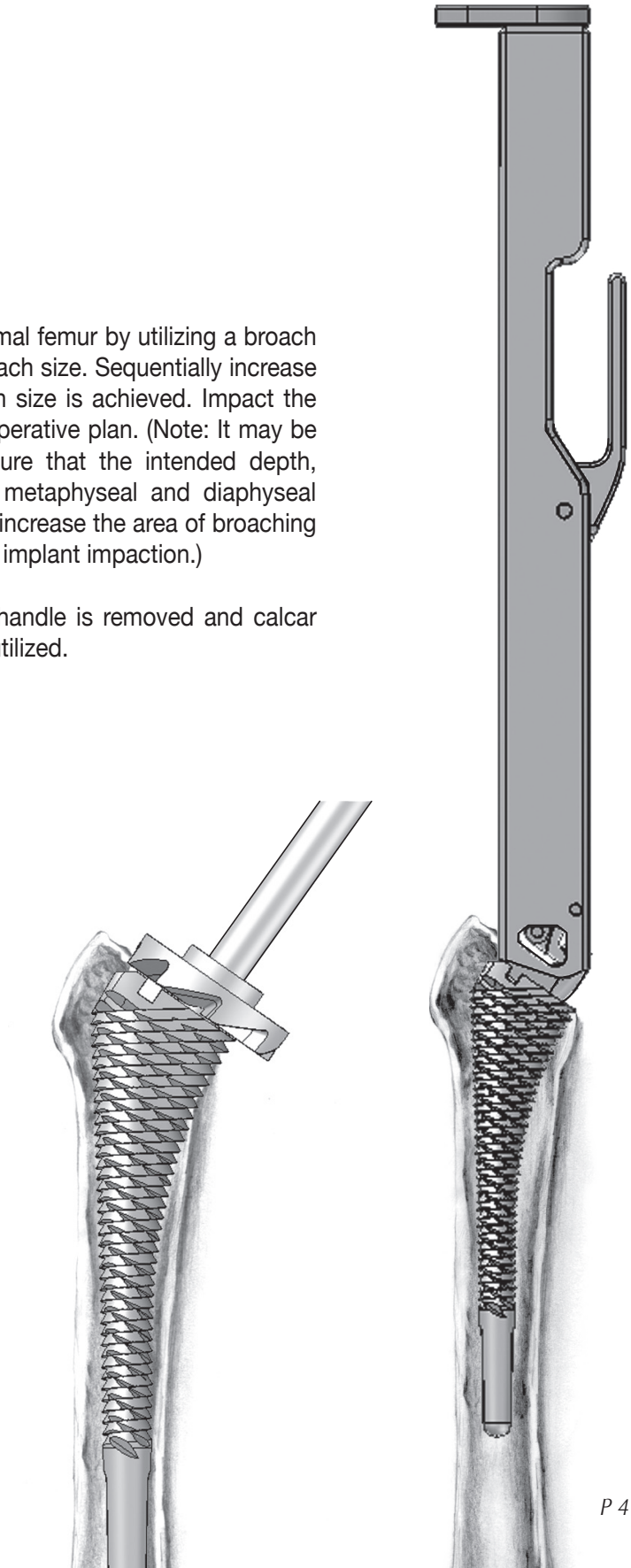
Femoral Canal Reaming with Flexible Reamers:

When electing to use the 230 mm curved stem, it is recommended to utilize a guide wire and flexible reaming system to accommodate the likelihood of curvature in the femoral canal. Initiate the reaming by placing the flexible reamer guide wire into the canal, and evaluate the position of the wire utilizing an intra-operative radiograph to help ensure the proper position of the wire. Once adequate positioning of the guide wire is accessed, advance the appropriate diameter flexible reamer over the guide wire to an adequate depth within the canal. Again, it is generally recommended that the size of the final reamer utilized should correspond with the intended size of the final implant . As a goal when possible, 5cm of diaphyseal contact is recommended. Care should be taken to reduce the potential of the reamer inadvertently extruding from the femoral canal. (Note: In some patients with dense bone, the surgeon may elect to over-ream the canal, to assist with the complete seating of the final implant.)

Femoral Broaching:

Once the reaming is completed, begin broaching the proximal femur by utilizing a broach size 2 to 3 implant sizes smaller than the final intended broach size. Sequentially increase the size of the broach used until the final intended broach size is achieved. Impact the final broach to the intended depth established in the pre-operative plan. (Note: It may be desirable to obtain an intra-operative radiograph to ensure that the intended depth, proper anatomical orientation, and AP/ML filling of the metaphyseal and diaphyseal regions are considered. Additionally, it may be desirable to increase the area of broaching in the superior-lateral region of the femur to assist with final implant impaction.)

Once the final broach is properly positioned, the broach handle is removed and calcar reaming may be performed if a collared type stem is to be utilized.



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Trial Reduction

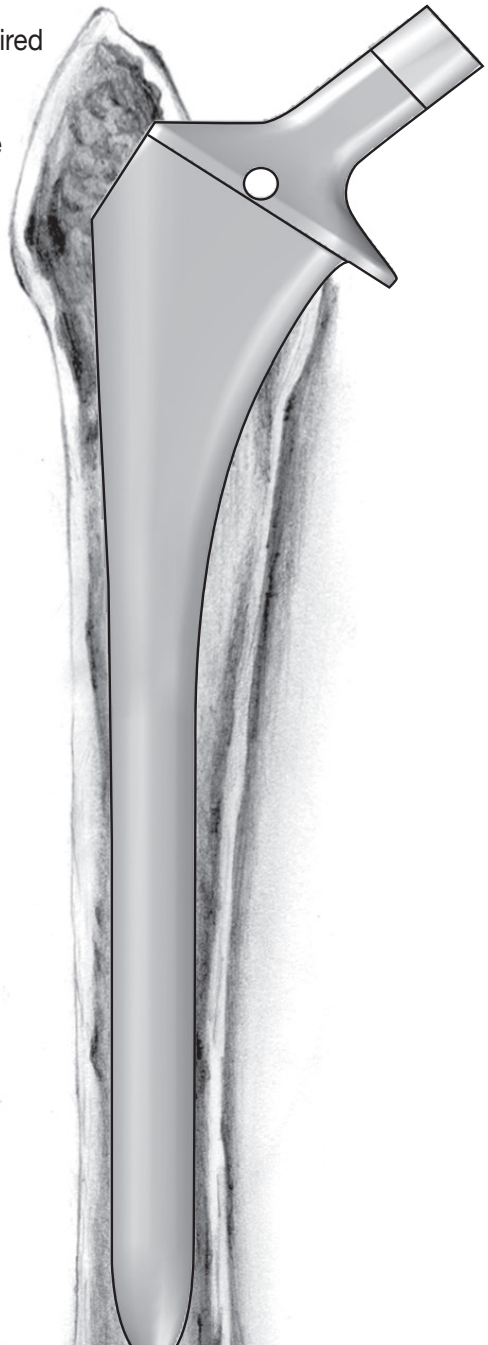
Begin by extracting the broach and inserting the corresponding size stem trail with inserter.
If resistance is encountered when attempting to seat the trial stem, additional reaming / overeaming may be considered to assure complete seating of the trial.

With trial stem properly positioned, select the femoral head trial to determine desired neck length and associated offset.

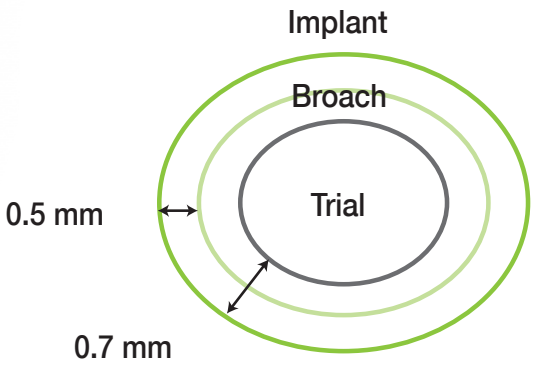
If straight stem implant is planed, the broach may leave in the canal and place the appropriate size of neck trial onto it. Perform the trial reduction using the femoral head trial of desired diameter and neck length.

Note: To help preserve the secure fit of the final intended femoral implant, the dimensions of both the trial stem and the femoral broach have been somewhat reduced as compared to the actual femoral implant. The dimensional reduction of the broach and trial are as follows:

Femoral Broach Dia. vs. Femoral Implant Dia. = 0.50 mm per side
Femoral Trial Dia. vs. Femoral Implant Dia. = 0.70 mm per side



Size comparison



Implant Insertion

Final Stem Insertion

Care should be utilized when introducing the final implant stem. When initially inserting the stem by hand, it is recommended to carefully assess the initial directional axis along with the rotational orientation to help assure complete seating of the final implant. Once established in an appropriate position, begin with gentle impaction of the stem with the femoral impactor. The proper alignment should be reassessed as the implant is gradually impacted.

In the event that the implant will not fully seat, it may be advantageous to consider removal of the stem, and re-ream and re-broach the femoral canal to provide additional clearance for the implant.

Once fully seated, the femoral bone may be inspected for peri-prosthetic fractures occasionally encountered with some patients. If observed, various methods of repair should be utilized to optimize implant stability.

Final Femoral Head Trialing:

Once the final implant is seated, an additional trial reduction with a trial femoral head may be performed. Assessment of appropriate soft tissue tension and function along with the overall ROM stability is evaluated in a standard manner.

Final Femoral Head Impaction:

Once the final head diameter and neck length have been selected, the femoral head implant is chosen. Impaction of the head is performed with the head impactor in a standard manner.

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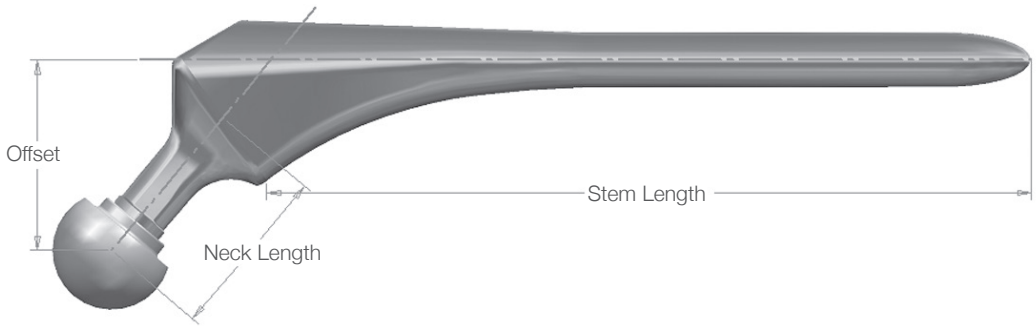
Ordering Information



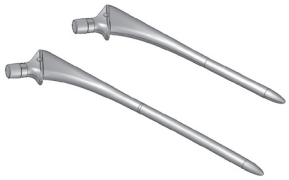
Straight Stem

Catalog No.	Stem Size	Stem Length	Offset Hd/ Nk -3 / +0 / +5 / +10	Nk Lgth Hd/ Nk -3 / +0 / +5 / +10
1104-1611	11.0	180	33/ 35/ 39/ 42	24.0/ 27.0/ 32.0/ 37.0
1104-1612	12.0	180	33/ 35/ 39/ 42	24.0/ 27.0/ 32.0/ 37.0
1104-1613	13.0	180	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1614	14.0	180	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1615	15.0	180	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1616	16.5	180	43/ 45/ 49/ 52	38.0/ 41.0/ 46.0/ 51.0
1104-1618	18.0	180	43/ 45/ 49/ 52	38.0/ 41.0/ 46.0/ 51.0

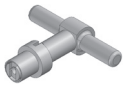
Curved Stem

Left	Right	Stem Size	Stem Length	Offset Hd/ Nk -3 / +0 / +5 / +10	Nk Lgth Hd/ Nk -3 / +0 / +5 / +10
1104-1711	1104-1811	11.0	230	33/ 35/ 39/ 42	24.0/ 27.0/ 32.0/ 37.0
1104-1712	1104-1812	12.0	230	33/ 35/ 39/ 42	24.0/ 27.0/ 32.0/ 37.0
1104-1713	1104-1813	13.0	230	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1714	1104-1814	14.0	230	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1715	1104-1815	15.0	230	38/ 40/ 44/ 47	31.5/ 34.5/ 39.5/ 44.5
1104-1716	1104-1816	16.5	230	43/ 45/ 49/ 52	38.0/ 41.0/ 46.0/ 51.0
1104-1718	1104-1818	18.0	230	43/ 45/ 49/ 52	38.0/ 41.0/ 46.0/ 51.0

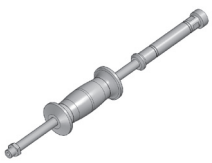
Instruments



Catalog Number	Description
1104 - 2211	Revision hip stem trial, straight, ø 11X180 mm
1104 - 2212	Revision hip stem trial, straight, ø 12X180 mm
1104 - 2213	Revision hip stem trial, straight, ø 13X180 mm
1104 - 2214	Revision hip stem trial, straight, ø 14X180 mm
1104 - 2215	Revision hip stem trial, straight, ø 15X180 mm
1104 - 2216	Revision hip stem trial, straight, ø 16.5X180 mm
1104 - 2218	Revision hip stem trial, straight, ø 18X180 mm
1104 - 2311	Revision hip stem trial, curved, left, ø 11X230 mm
1104 - 2312	Revision hip stem trial, curved, left, ø 12X230 mm
1104 - 2313	Revision hip stem trial, curved, left, ø 13X230 mm
1104 - 2314	Revision hip stem trial, curved, left, ø 14X230 mm
1104 - 2315	Revision hip stem trial, curved, left, ø 15X230 mm
1104 - 2316	Revision hip stem trial, curved, left, ø 16.5X230 mm
1104 - 2318	Revision hip stem trial, curved, left, ø 18X230 mm
1104 - 2411	Revision hip stem trial, curved, right, ø 11X230 mm
1104 - 2412	Revision hip stem trial, curved, right, ø 12X230 mm
1104 - 2413	Revision hip stem trial, curved, right, ø 13X230 mm
1104 - 2414	Revision hip stem trial, curved, right, ø 14X230 mm
1104 - 2415	Revision hip stem trial, curved, right, ø 15X230 mm
1104 - 2416	Revision hip stem trial, curved, right, ø 16.5X230 mm
1104 - 2418	Revision hip stem trial, curved, right, ø 18X230 mm



Catalog Number	Description
9101 - 1100	Reamer T-handle



Catalog Number	Description
9101 - 1203	Sliding hammer

Catalog Number	Description
9104 - 1001	Nitinol shaft, ø 5 mm, 470 mm

Catalog Number	Description
9104 - 1202	Stem extractor

Catalog Number	Description
9104 - 1213	Stem impactor

Catalog Number	Description
9104 - 2001	Guide wire, ø 3 mm, 820 mm

Catalog Number	Description
9104 - 3109	Revision hip stem straight reamer, ø 9 mm
9104 - 3209	Revision hip stem straight reamer, ø 9.5 mm
9104 - 3110	Revision hip stem straight reamer, ø 10 mm
9104 - 3210	Revision hip stem straight reamer, ø 10.5 mm
9104 - 3111	Revision hip stem straight reamer, ø 11 mm
9104 - 3211	Revision hip stem straight reamer, ø 11.5 mm
9104 - 3112	Revision hip stem straight reamer, ø 12 mm
9104 - 3212	Revision hip stem straight reamer, ø 12.5 mm
9104 - 3113	Revision hip stem straight reamer, ø 13 mm
9104 - 3213	Revision hip stem straight reamer, ø 13.5 mm
9104 - 3114	Revision hip stem straight reamer, ø 14 mm
9104 - 3214	Revision hip stem straight reamer, ø 14.5 mm
9104 - 3115	Revision hip stem straight reamer, ø 15 mm
9104 - 3215	Revision hip stem straight reamer, ø 15.5 mm
9104 - 3116	Revision hip stem straight reamer, ø 16 mm
9104 - 3216	Revision hip stem straight reamer, ø 16.5 mm
9104 - 3117	Revision hip stem straight reamer, ø 17 mm
9104 - 3217	Revision hip stem straight reamer, ø 17.5 mm
9104 - 3118	Revision hip stem straight reamer, ø 18 mm

Instruments

★ *Special Optional Items*

Catalog Number	Description
9104 - 3509	Flexible reamer head, ø 9 mm
9104 - 3609	Flexible reamer head, ø 9.5 mm
9104 - 3510	Flexible reamer head, ø 10 mm
9104 - 3610	Flexible reamer head, ø 10.5 mm
9104 - 3511	Flexible reamer head, ø 11 mm
9104 - 3611	Flexible reamer head, ø 11.5 mm
9104 - 3512	Flexible reamer head, ø 12 mm
9104 - 3612	Flexible reamer head, ø 12.5 mm
9104 - 3513	Flexible reamer head, ø 13 mm
9104 - 3613	Flexible reamer head, ø 13.5 mm
9104 - 3514	Flexible reamer head, ø 14 mm
9104 - 3614	Flexible reamer head, ø 14.5 mm
9104 - 3515	Flexible reamer head, ø 15 mm
9104 - 3615	Flexible reamer head, ø 15.5 mm
9104 - 3516	Flexible reamer head, ø 16 mm
9104 - 3616	Flexible reamer head, ø 16.5 mm
9104 - 3517	Flexible reamer head, ø 17 mm
9104 - 3617	Flexible reamer head, ø 17.5 mm
9104 - 3518	Flexible reamer head, ø 18 mm
9104 - 3618	Flexible reamer head, ø 18.5 mm
9104 - 3519	Flexible reamer head, ø 19 mm
9104 - 3619	Flexible reamer head, ø 19.5 mm
9104 - 3520	Flexible reamer head, ø 20 mm

Catalog Number	Description
9104 - 4040	Calcar reamer assembly, ø 40 mm

Catalog Number	Description
★ 9104 - 5301	Neck trial #11 / 12
★ 9104 - 5302	Neck trial #13 / 14 / 15
★ 9104 - 5303	Neck trial #16.5 / 18

Catalog Number	Description
9104 - 6103	Broach handle

Catalog Number	Description
9104 - 6200	Broach handle adaptor

Catalog Number	Description
9104 - 6330	Revision hip stem broach, ø 11 mm
9104 - 6340	Revision hip stem broach, ø 12 mm
9104 - 6350	Revision hip stem broach, ø 13 mm
9104 - 6360	Revision hip stem broach, ø 14 mm
9104 - 6370	Revision hip stem broach, ø 15 mm
9104 - 6380	Revision hip stem broach, ø 16.5 mm
9104 - 6390	Revision hip stem broach, ø 18 mm

Catalog Number	Description
9104 - 8040	U2 Revision Hip, Case # 1
9104 - 8050	U2 Revision Hip, Case # 2
9104 - 8060	Flexible reamer set case

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UNITED U2 Hip Stem Safety Statements

MT50225 Rev6

DESCRIPTION

UNITED U2 Hip Stem is intended to use in primary or revision hip arthroplasty. It is available in an array of styles and matrixed sizes to accommodate various hip surgical requirements. The femoral stems are available in four surface structure styles such as grit blasted, Ti plasma spray, Ti plasma spray with Hydroxylapatite surface treatment and sintered Ti bead porous coated. The grit blasted stems are intended to be fixed only with the use of PMMA bone cement. The femoral stem prosthesis may be used in conjunction with an Head as a bipolar hip replacement oranother acetabular component for total hip arthroplasty.

MATERIALS

ASTM F-620 Titanium 6Al-4V ELI alloy Femoral stem, Revision hip stem
ASTM F-67 CP Titanium Plasma spray coating
ASTM F-1185 Hydroxylapatite Plasma spray coating
ASTM F-1580 CPTi bead Porous coating
ASTM F-75 Co-Cr-Mo alloy Femoral stem (for cement)

INDICATIONS

For use as a Bipolar Hip Replacement
1. Femoral head/ neck factures or non-unions.
2. Aseptic necrosis of the femoral head.
3. Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

For use as a Total Hip Replacement
1. Painful, disabling joint disease of the Hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of pervious unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

CONTRAINDICATIONS

1. Any active or suspected latent infection in or about the hip joint
2. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
3. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/ or fixation to the prosthesis.
4. Skeletal immaturity.
5. Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.
6. For use as a Bipolar Hip Replacement, pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/ or a well-seated and supported smooth acetabular articulation of the head.

POSSIBLE ADVERSE EFFECT

1. While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials placed within the body for the potential restoration of mobility or 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 indefinitely withstand the activity level and loads of normal healthy bone.
2. Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
3. Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
4. Fatigue fracture of femoral stems and/or fracture of ceramic heads occurred in a small percentage of cases. Stem/head fracture is more likely to occur in the heavy, physically active individual or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
5. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
6. Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
7. Acetabular pain may occur after acetabular replacement due to loosening of the implant, or after bipolar Hip arthroplasty due to localized pressure associated with incongruities of fit or tissue inflammation.
8. Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock. Metal sensitivity reactions have been reported following joint replacement.
9. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.

Safety Statements

10. With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/ or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third- body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

WARNINGS

1. Discard all damaged or mishandled implants.
2. Never reuse an implant, even though it may appear undamaged.
3. Polished bearing areas and machined taper surfaces must not come in contact with hard or abrasive surfaces.
4. Bearing areas must always -be clean and free of debris prior to assembly.
5. At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
6. Improper seating of the head or Endo neck extension may result in a discrepancy in neck length, component disassociation and/ or dislocation.
7. Handling of the hydroxylapatite treated regions must be avoided as it may compromise the effectiveness of the device.
8. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
9. Infra-operative preparation and implantation of a femoral stem component can result in cracks of the proximal femur. The application of prophylactic cerclage wiring to the proximal femur may aid in the prevention of femoral cracks, crack propagation or their displacement.
10. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
11. UOC strongly advises against the use of another manufacturer's tapered head, PMMA spacer or acetabular component with any UOC femoral stem component. Any such use will negate the responsibility of UOC for the performance of the resulting mixed component implant.
12. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.
13. The shelf-life of UHMWPE made components is five years.

PRECAUTIONS

1. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
2. Appropriate selection, placement and fixation of the femoral stem and/or acetabular components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
3. Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.

UTILIZATION AND IMPLANTATION

1. The recommended trial components should be used for size determination, canal preparation evaluation, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
2. Radiographic templates are available to assist in the preoperative prediction of component size and style.
3. The UOC Surgical Protocols provide additional procedural information.

PACKAGING AND LABELING

All implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION

1. All components have been sterilized by gamma radiation.
2. The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
3. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
4. If the package is opened, but the product is not used, the component must not be resterilized and must be discarded or returned to the supplier.

IMPORTANT FOR OPENED COMPONENTS

The plastic components, if opened, are not permitted be re-sterilization by any method. The metal components, if opened, please return to United Orthopedic Corporation. A suitable handing in cleaning (if necessary), packaging and gamma radiation will be done.

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