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Orthopedic Corporation

U2™ Revision

Hip Stem

Surgical Protocol

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U2 Revision Hip Stem

Table of Contents

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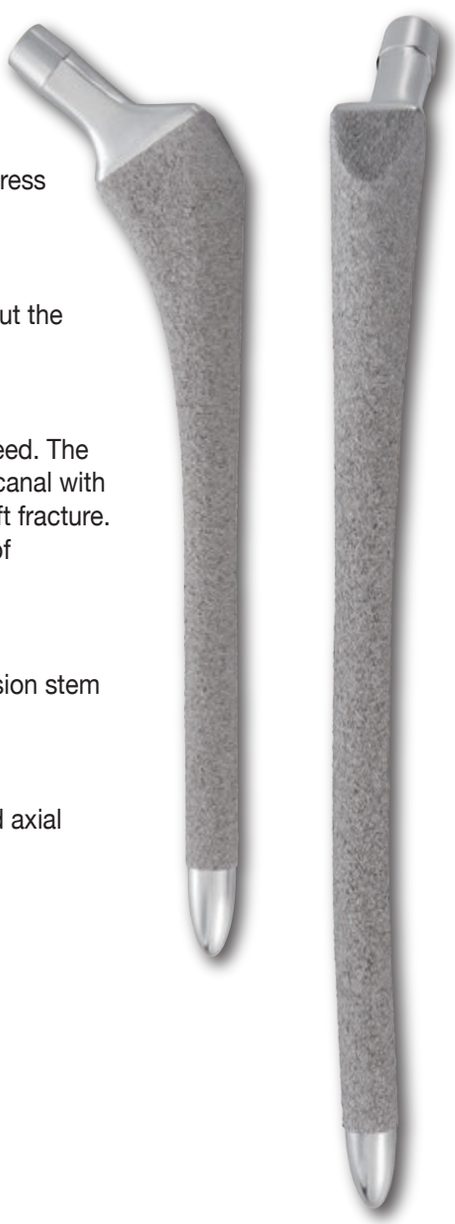
Introduction

Since 1997, the U2 Revision Hip Stem was developed to address metaphyseal bone defect during revision surgery. The versatile size options enable the orthopaedic surgeon to select a proper implant for each patient based on pre- and intraoperative assessment.

The U2 Revision Hip Stem design features as following:



- **Titanium Alloy**
  The elastic modulus of titanium alloy is close to cortical bone, thus decreasing stress shielding effect, bone resorption, and thigh pain.

- **Titanium Plasma Spray**
  Extensively coated stem increases the possibility of osteointegradation throughout the stem, which provides long-term stability of implant.

- **180 mm Straight and 230 mm Curve Stem Options**
  The standard 180 mm length enables diaphyseal fixation to meet most patient need. The curved 230 mm stem addresses more bony deficiency and anatomically fits the canal with an anterior bowed shape to prevent cortical impingement and intraoperative shaft fracture. Distal diameters offered in 11, 12, 13, 14, 15, 16.5, and 18 mm adapts a variety of anatomies.

- **Shortened Stem Offset**
  Due to soft tissue scarring or contracture induced by previous surgeries, U2 revision stem is designed with a short offset than primary implant to facilitate joint reduction.

- **Proximal Tri-Wedge Geometry**
  The three-dimensional tapered profile of U2 revision stem provides rotational and axial stability and benefits load distribution.

- **Polished and teardrop tip**
  The teardrop tip avoids distal cortical impingement and related thigh pain.

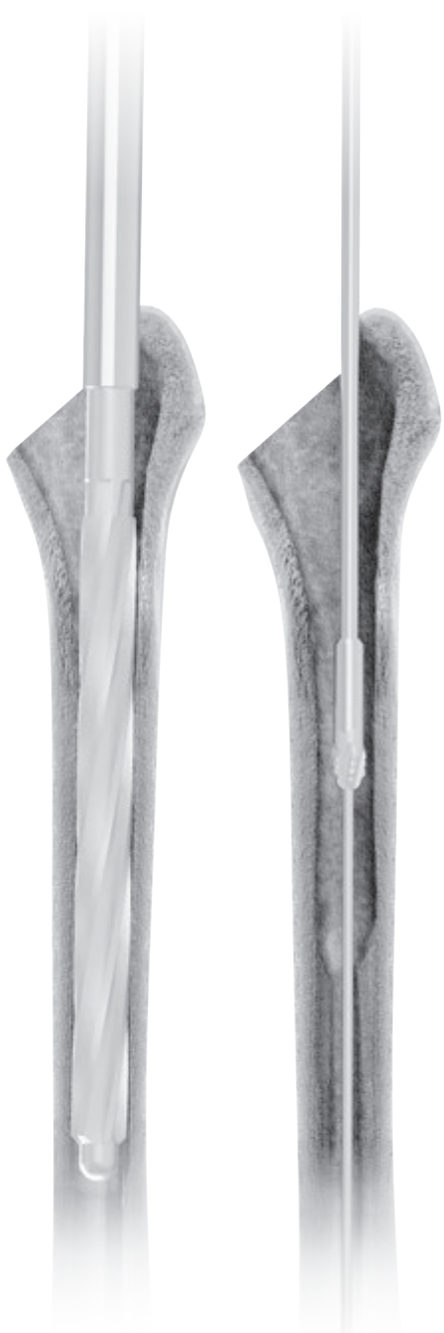
Preoperative Planning

The objectives of preoperative planning are to assess the amount of bone loss, to select an appropriate implant size, and to determine leg length and femoral offset. Special needs such as allograft, wire, and plate fixation can be determined through a radiographic review If necessary. In addition, during radiographic assessment, any acetabular reconstruction may have to be considered. U2 Revision Hip Stem offers 15 percent magnification templates to meet the enlargement from radiography. Although templating helps accomplish preliminary estimation of the proper stem size, the final determination should still be made according to operation conditions.

Femoral Preparation

Canal Reaming for a Straight Stem:

Obtaining a clear access to the femoral canal is essential to ensure proper alignment of revision stem. After careful removal of the previous stem, cement, and debris, the femoral canal is gradually reamed by attaching the **T-handle** or power device to the **Straight Reamer**. Based on the stem size determined preoperatively, start reaming with the smallest size or at least 2 mm smaller than predicted stem size until appropriate depth is obtained. Offered reamer size increment is 0.5 mm in diameter. It is recommended that at least 0.5 mm press-fit for normal bone quality. Occasionally, a line-to-line reaming may be required to treat a hard bone.

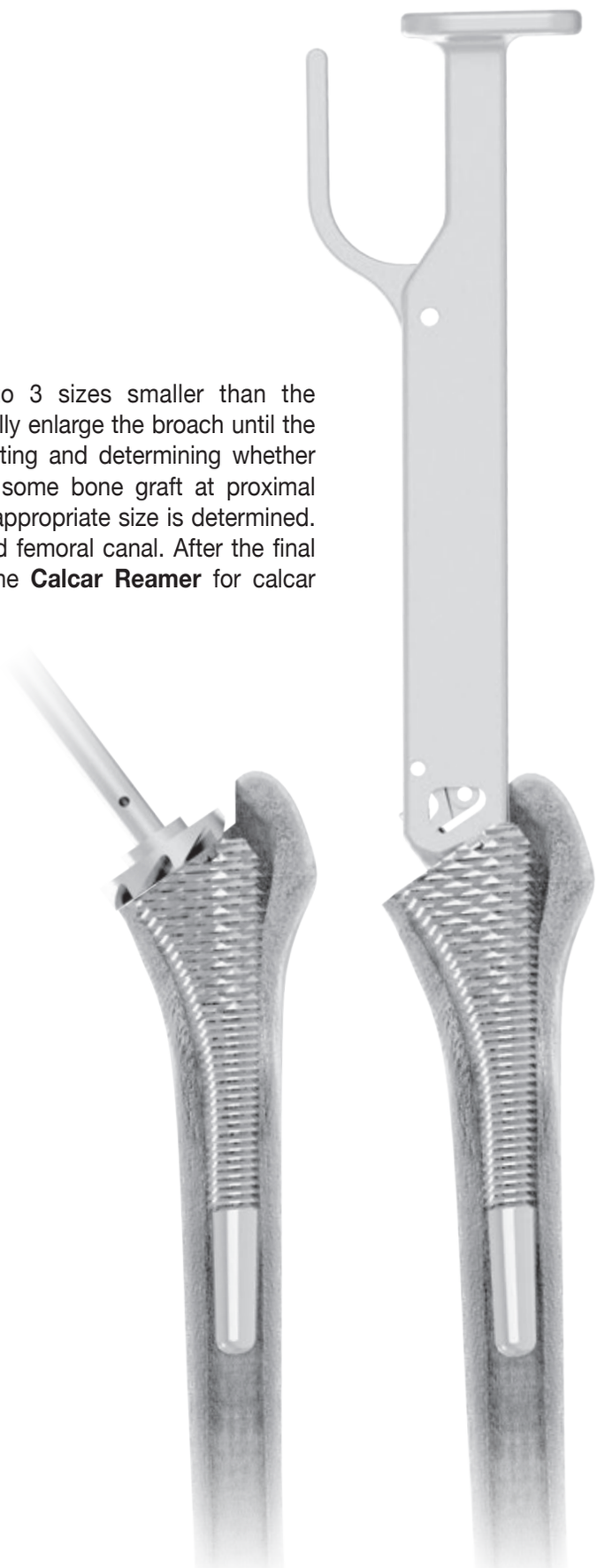


Canal Reaming for a Curved Stem:

When preparing the femoral canal for a 230 mm curved stem, utilize the flexible reaming assembly (**Guide Wire, Flexible Reamer Shaft** and **Flexible Reamer Head**) to follow the nature bow of the femur. Advance the flexible reamer into the canal, making sure it passes through diaphysis. Fluoroscopy may be used to ensure the appropriate depth and direction during reaming process. Sequentially reaming by 0.5 mm increment until the anticipated diameter and depth is achieved.

Canal Broaching:

After complete reaming, use the **Broach** that is 2 to 3 sizes smaller than the pre-determined implant size to shape the canal. Sequentially enlarge the broach until the last size is matched with the real implant. Assess the fitting and determining whether broaching and reaming should be continued, or having some bone graft at proximal femur. Continue the reaming and broaching process until appropriate size is determined. It is important that the final broach should fill the prepared femoral canal. After the final broach is properly seated in the femoral canal, utilize the **Calcar Reamer** for calcar preparation if desired.



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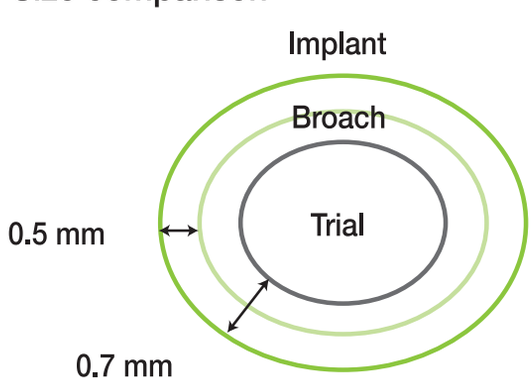
Trial Reduction

Based on the final reamer and broach size, select an appropriate **Stem Trial** for the preparation of femoral canal. If any resistance is felt as stem trial insertion, there may be a need for additional reaming or broaching to remove obstructing bone until the stem trial can be fully seated. Perform the trial reduction by using the femoral head trial with desired diameter and neck length.
Any correct of selected implant size can be made during the assessment of leg length and joint biomechanics.
Optionally, if a straight stem is selected, the surgeon may leave the final broach for trial reduction.

Note: To prevent destruction of the press-fit mechanism, the dimension of stem trial is reduced by 0.2 mm in diameter when compared with the size matched broach. As shown below, the U2 revision hip instrumentation design provides a 0.5 mm interference between the real implant and the broach to obtain a stable initial fixation.

Size comparison

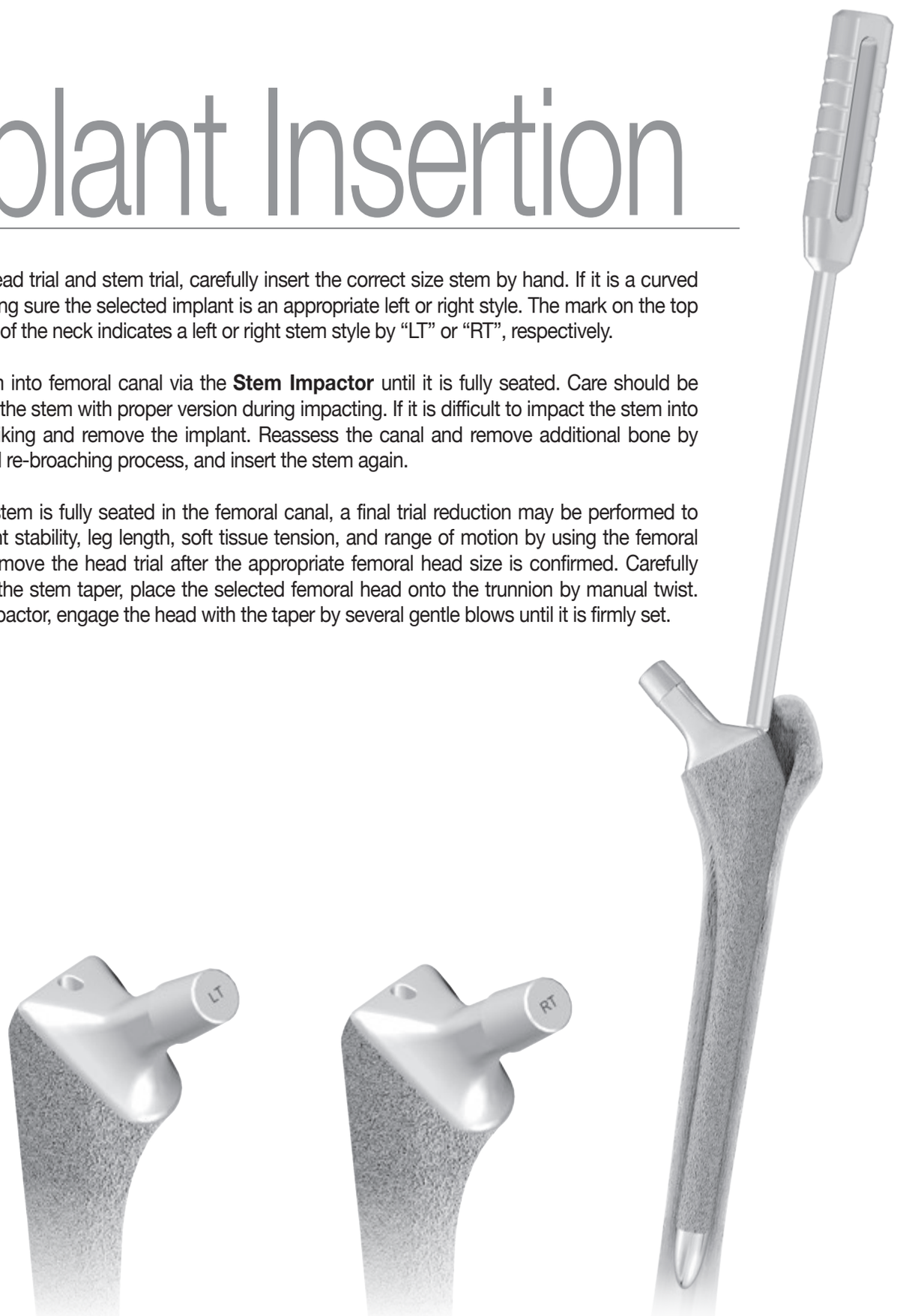


Implant Insertion

Remove the head trial and stem trial, carefully insert the correct size stem by hand. If it is a curved hip stem, making sure the selected implant is an appropriate left or right style. The mark on the top of the trunnion of the neck indicates a left or right stem style by “LT” or “RT”, respectively.

Strike the stem into femoral canal via the **Stem Impactor** until it is fully seated. Care should be taken to orient the stem with proper version during impacting. If it is difficult to impact the stem into canal, stop striking and remove the implant. Reassess the canal and remove additional bone by re-reaming and re-broaching process, and insert the stem again.

Once the hip stem is fully seated in the femoral canal, a final trial reduction may be performed to re-evaluate joint stability, leg length, soft tissue tension, and range of motion by using the femoral head trials. Remove the head trial after the appropriate femoral head size is confirmed. Carefully clean and dry the stem taper, place the selected femoral head onto the trunnion by manual twist. Using head impactor, engage the head with the taper by several gentle blows until it is firmly set.



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Ordering Information

Metal Head

	Cat. No.		Stem Size	Stem Length (mm)	**Offset**(mm) when head/neck prosthesis is :				**Neck Length**(mm) when head/neck prosthesis is :			
					28/32/36mm Head				28/32/36mm Head			
					-3	+0	+5	+10	-3	+0	+5	+10
Straight Stem	1104-1611		11	180	33	35	39	42	24	27	32	37
	1104-1612		12	180	33	35	39	42	24	27	32	37
	1104-1613		13	180	38	40	44	47	32	35	40	45
	1104-1614		14	180	38	40	44	47	32	35	40	45
	1104-1615		15	180	38	40	44	47	32	35	40	45
	1104-1616		16.5	180	43	45	49	52	38	41	46	51
	1104-1618		18	180	43	45	49	52	38	41	46	51
	Left	Right										
Curved Stem	1104-1711	1104-1811	11	230	33	35	39	42	24	27	32	37
	1104-1712	1104-1812	12	230	33	35	39	42	24	27	32	37
	1104-1713	1104-1813	13	230	38	40	44	47	32	35	40	45
	1104-1714	1104-1814	14	230	38	40	44	47	32	35	40	45
	1104-1715	1104-1815	15	230	38	40	44	47	32	35	40	45
	1104-1716	1104-1816	16.5	230	43	45	49	52	38	41	46	51
	1104-1718	1104-1818	18	230	43	45	49	52	38	41	46	51

BIOLOX® delta Ceramic Head

	Cat. No.		**Offset**(mm) when head/neck prosthesis is :							**Neck Length**(mm) when head/neck prosthesis is :							
			28mm			32/36/40mm			32mm	36/40mm	28mm			32/36/40mm			32mm	36/40mm
			-2.5	+1	+4	-3	+1	+5	+8	+9	-2.5	+1	+4	-3	+1	+5	+8	+9
Straight Stem	1104-1611		34	36	38	33	36	39	41	42	29	32	35	28	32	36	39	40
	1104-1612		34	36	38	33	36	39	41	42	29	32	35	28	32	36	39	40
	1104-1613		39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1614		39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1615		39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1616		44	46	48	43	46	49	51	52	38	41	44	37	41	45	48	49
	1104-1618		44	46	48	43	46	49	51	52	38	41	44	37	41	45	48	49
	Left	Right																
Curved Stem	1104-1711	1104-1811	34	36	38	33	36	39	41	42	29	32	35	28	32	36	39	40
	1104-1712	1104-1812	34	36	38	33	36	39	41	42	29	32	35	28	32	36	39	40
	1104-1713	1104-1813	39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1714	1104-1814	39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1715	1104-1815	39	41	43	38	41	44	46	47	32	35	38	31	35	39	42	43
	1104-1716	1104-1816	44	46	48	43	46	49	51	52	38	41	44	37	41	45	48	49
	1104-1718	1104-1818	44	46	48	43	46	49	51	52	38	41	44	37	41	45	48	49

* BIOLOX® delta is the registry trademak of Ceramtec AG.

Revision hip stem trial

Catalog Number	Description			
1104 - 2211 - RB	straight,	ø11	X	180 mm
1104 - 2212 - RB	straight,	ø12	X	180 mm
1104 - 2213 - RB	straight,	ø13	X	180 mm
1104 - 2214 - RB	straight,	ø14	X	180 mm
1104 - 2215 - RB	straight,	ø15	X	180 mm
1104 - 2216 - RB	straight,	ø16.5	X	180 mm
1104 - 2218 - RB	straight,	ø18	X	180 mm
1104 - 2311 - RB	curved, left,	ø11	X	230 mm
1104 - 2312 - RB	curved, left,	ø12	X	230 mm
1104 - 2313 - RB	curved, left,	ø13	X	230 mm
1104 - 2314 - RB	curved, left,	ø14	X	230 mm
1104 - 2315 - RB	curved, left,	ø15	X	230 mm
1104 - 2316 - RB	curved, left,	ø16.5	X	230 mm
1104 - 2318 - RB	curved, left,	ø18	X	230 mm
1104 - 2411 - RB	curved, right,	ø11	X	230 mm
1104 - 2412 - RB	curved, right,	ø12	X	230 mm
1104 - 2413 - RB	curved, right,	ø13	X	230 mm
1104 - 2414 - RB	curved, right,	ø14	X	230 mm
1104 - 2415 - RB	curved, right,	ø15	X	230 mm
1104 - 2416 - RB	curved, right,	ø16.5	X	230 mm
1104 - 2418 - RB	curved, right,	ø18	X	230 mm

Catalog Number	Description
9104 - 1001	Flexible reamer shaft, ø5x470 mm

Catalog Number	Description
9104 - 1202 - RA	Stem extractor

Catalog Number	Description
9104 - 1213 -RA	Stem impactor

Catalog Number	Description
9104 - 1214	U2 Stem quick connect holder

Catalog Number	Description
9104 - 2001	Guide wire, ø3 mm, 820 mm

Catalog Number	Description
9104 - 3109	Revision hip stem straight reamer, ø9 mm
9104 - 3209	Revision hip stem straight reamer, ø9.5 mm
9104 - 3110	Revision hip stem straight reamer, ø10 mm
9104 - 3210	Revision hip stem straight reamer, ø10.5 mm
9104 - 3111	Revision hip stem straight reamer, ø11 mm
9104 - 3211	Revision hip stem straight reamer, ø11.5 mm
9104 - 3112	Revision hip stem straight reamer, ø12 mm
9104 - 3212	Revision hip stem straight reamer, ø12.5 mm
9104 - 3113	Revision hip stem straight reamer, ø13 mm
9104 - 3213	Revision hip stem straight reamer, ø13.5 mm
9104 - 3114	Revision hip stem straight reamer, ø14 mm
9104 - 3214	Revision hip stem straight reamer, ø14.5 mm
9104 - 3115	Revision hip stem straight reamer, ø15 mm
9104 - 3215	Revision hip stem straight reamer, ø15.5 mm
9104 - 3116	Revision hip stem straight reamer, ø16 mm
9104 - 3216	Revision hip stem straight reamer, ø16.5 mm
9104 - 3117	Revision hip stem straight reamer, ø17 mm
9104 - 3217	Revision hip stem straight reamer, ø17.5 mm
9104 - 3118	Revision hip stem straight reamer, ø18 mm

Instruments

★ *Special Order Items*

Catalog Number	Description
9104 - 3509	Flexible reamer head, ø9 mm
9104 - 3609	Flexible reamer head, ø9.5 mm
9104 - 3510	Flexible reamer head, ø10 mm
9104 - 3610	Flexible reamer head, ø10.5 mm
9104 - 3511	Flexible reamer head, ø11 mm
9104 - 3611	Flexible reamer head, ø11.5 mm
9104 - 3512	Flexible reamer head, ø12 mm
9104 - 3612	Flexible reamer head, ø12.5 mm
9104 - 3513	Flexible reamer head, ø13 mm
9104 - 3613	Flexible reamer head, ø13.5 mm
9104 - 3514	Flexible reamer head, ø14 mm
9104 - 3614	Flexible reamer head, ø14.5 mm
9104 - 3515	Flexible reamer head, ø15 mm
9104 - 3615	Flexible reamer head, ø15.5 mm
9104 - 3516	Flexible reamer head, ø16 mm
9104 - 3616	Flexible reamer head, ø16.5 mm
9104 - 3517	Flexible reamer head, ø17 mm
9104 - 3617	Flexible reamer head, ø17.5 mm
9104 - 3518	Flexible reamer head, ø18 mm
9104 - 3618	Flexible reamer head, ø18.5 mm
9104 - 3519	Flexible reamer head, ø19 mm
9104 - 3619	Flexible reamer head, ø19.5 mm
9104 - 3520	Flexible reamer head, ø20 mm

Catalog Number	Description
9104 - 4040	Calcar reamer, ø40 mm

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

Catalog Number	Description
9104 - 6103 - RA	Broach handle

★ *Special Order Items*

Catalog Number	Description	
9104 - 6330	Revision hip stem broach,	ø11 mm
9104 - 6340	Revision hip stem broach,	ø12 mm
9104 - 6350	Revision hip stem broach,	ø13 mm
9104 - 6360	Revision hip stem broach,	ø14 mm
9104 - 6370	Revision hip stem broach,	ø15 mm
9104 - 6380	Revision hip stem broach,	ø16.5 mm
9104 - 6390	Revision hip stem broach,	ø18 mm

Catalog Number	Description
9104 - 8040 - RA	U2 Revision Hip, Case #1
9104 - 8050 - RA	U2 Revision Hip, Case #2
9104 - 8060	Flexible reamer set case
★ 9104 - 8110	U2 Hip basic case

Catalog Number	Description
★ 9104 - 9001 - RA	Femoral Head Remover

Catalog Number	Description
9106 - 5001	Hammer

Catalog Number	Description
9106 - 5101	Slide Rod

Catalog Number	Description
9303 - 1300	T-handle

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Safety Statements - U2 Hip Stem

MT50225 Rev 19

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. UNITED U2 Hip Stem consists of Cemented Stem, Press-fit Stem, Ti porous Stem, Revision Stem, and HA/Ti Plasma Stem. The femoral stems are available in five surface structure types such as bead blasted for U2 Cemented Femoral stem, grit blasted for U2 Press-fit Stem, sintered Ti bead porous coated for U2 Ti porous Stem, Ti plasma spray for U2 Revision Stem and Ti plasma spray with Hydroxylapatite surface treatment for U2 HA/Ti Plasma Stem. The UNITED U2 Cemented Stem is intended to be fixed only with the use of PMMA bone cement. The UNITED U2 Hip Stem may be used with UNITED Femoral Heads, UNITED Ceramic Femoral Heads, UNITED U2 Acetabular Cups, UNITED U2 Cup Liners and UNITED XPE Cup Liners for total hip arthroplasty. UNITED U2 Hip Stem may be used with a UNITED Femoral Heads and UNITED U1 or U2 Bipolar prosthesis as a bipolar hip replacement.

Note: The 22mm UNITED femoral head is not for sale in the US.
Note: The Cemented Stem is designed for cemented use only and can not be used with Ceramic Femoral Head.

MATERIALS

ASTM F-620 Ti alloy
Ti porous femoral stem, Revision femoral stem, HA/Ti Plasma spray femoral stem and Press-fit femoral stem
ASTM F-1185 Hydroxylapatite Metallic powder for Ti Plasma spray coating
ASTM F-1580 Ti alloy Metallic powder for Ti Porous coating
ASTM F-75 Co-Cr-Mo alloy Cemented Femoral stem (casting)
ASTM F-799 Co-Cr-Mo alloy Cemented Femoral stem (forged)
ISO D5436 PMMA Spacer & Centralizer

INDICATIONS

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 function deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.

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. Reuse of this product will cause the risk of cross infection and unpredictable health threat. Polished bearing areas and machined taper surfaces must not come in contact with hard or abrasive surfaces.
3. Bearing areas must always -be clean and free of debris prior to assembly.
4. At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
5. Improper seating of the head or Endo neck extension may result in a discrepancy in neck length, component disassociation and/or dislocation.
6. Handling of the hydroxylapatite treated regions must be avoided as it may compromise the effectiveness of the device.
7. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
8. 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
9. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
10. 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.
11. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.
12. 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, biomechanical 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.

SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT

The U2 Hip Stem has not been evaluated for safety and compatibility in the MR environment. The U2 Hip Stem has not been tested for heating or migration in the MR environment.

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