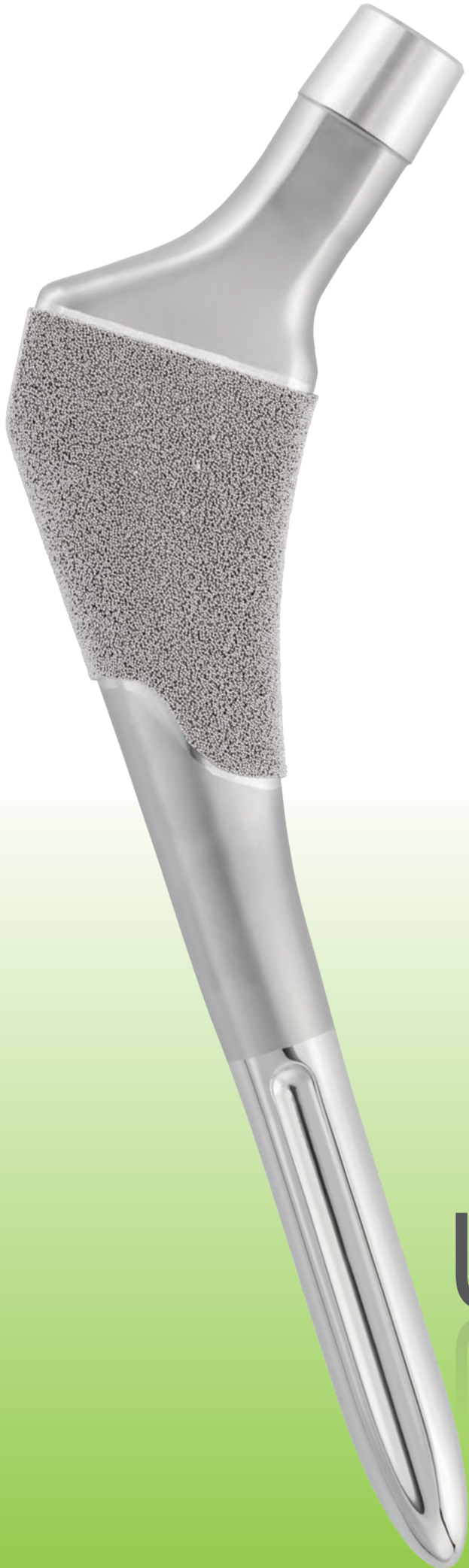
United®
Orthopedic Corporation



U2 MATRIX

Porous Stem

Surgical Protocol

United® Orthopedic Corporation

U2 MATRIX Porous Stem

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Products Review

United U2 Matrix Porous Stem is indicated for primary total hip arthroplasty, which is the newest member of the multiple stem options from the United U2 Hip system. The design adaption aimed to enhance stability through the proximal porous coating , and to reduce stress shielding via polished teardrop distal end.

Normal, stovepipe, and champagne-flute are three femoral canal types that characterized by the canal flare index. The risk of mismatching in the shape of the bone and the implant should be minimized to prevent excessive micromotion and loosening. Therefore, a close geometric fit and fill between proximal and distal is essential as designing cementless total hip implants.

United Matrix Porous Stem features 13 sizes to cope with different canal shapes. By applying the matrix concept, one distal diameter of stem shares up to three proximal sizes; while one proximal stem size shares up to three distal sizes.

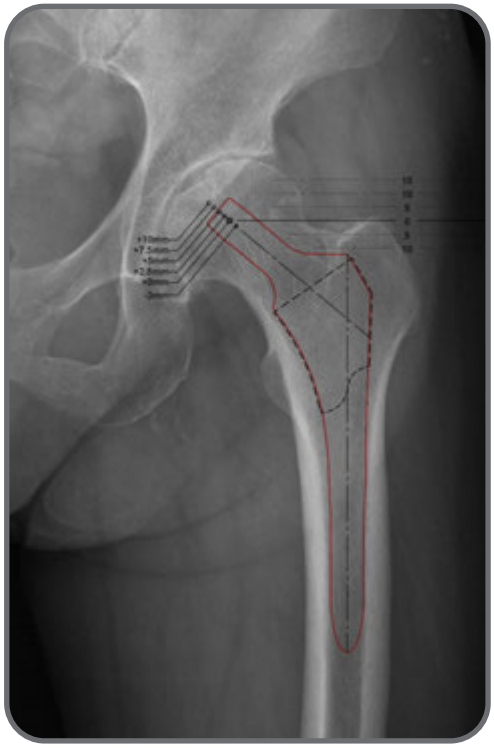
U2 Hip System
Sizing Matrix Concept

Proximal Sizes	Φ9	Φ10	Φ11	Φ12	Φ13	Φ14	Φ15
#7							#7
#6					#6	#6	
#5				#5	#5		
#4			#4	#4			
#3		#3	#3	#3			
#2		#2	#2				
#1	#1						

Distal Diameter (mm)

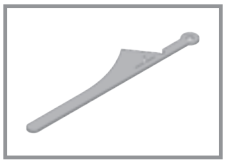
0. Preoperative Planning

Preoperative planning is essential for achieving the optimal total hip arthroplasty. Choosing the appropriate sizes and position of the femoral component would be ultimately necessary. Making an accurate femoral component selection begins with the thorough radiographic views of the involved femur: an A/P view and M/L view. For the A/P view, have the pelvis centered at the pubic symphysis. In addition, both views require at least 20 cm of the proximal femur. These radiographies should be analyzed by using the templates to determine the correct leg length, femoral offset, center of rotation of the hip joint and the implant size. The U2 Hip standard 115 % magnification templates is provided.



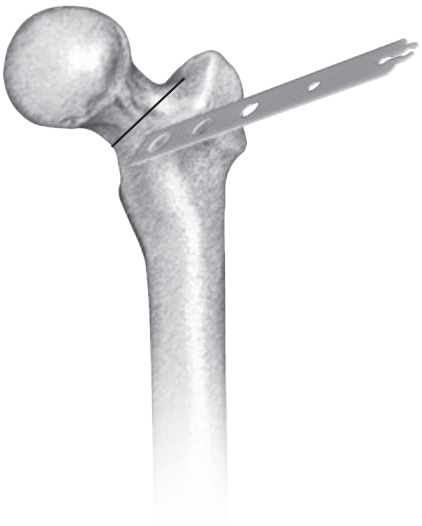
1. Osteotomy of the Femoral Neck

1. Osteotomy Guide
9104 - 2011, #1
9104 - 2012, #2-7



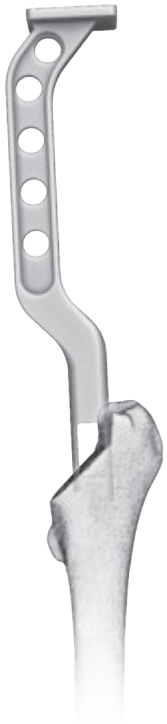
Once the joint has been dislocated, align the **Osteotomy Guide** [1] with the central line of the femur shaft. Vary the level of the reference hole on the top of the **Osteotomy Guide** [1] until it is at the same with the femoral head center, or use the pit, which below the reference hole match the piriformis fossa to determine the cut. To inscribe the femoral neck resection line with electrocautery if necessary.

Completing the femoral neck resection with the power saw.
Mark the cutting line with electrocautery and resect the femoral neck with the power saw.

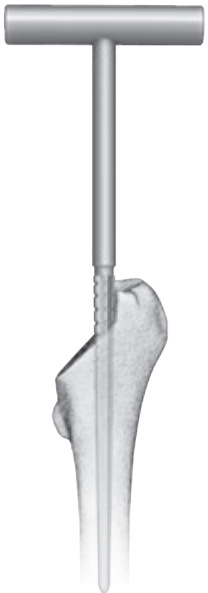


2. Femoral Preparation

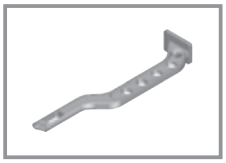
Position the **Femoral Cutting Chisel** [2] laterally toward the greater trochanter to remove a piece of the medial portion. The opening will provide an adequate entry point complementing the patient's anatomy for the reamer and broach.



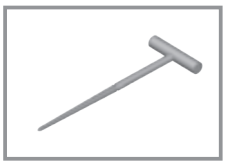
It is recommended to employ the "Ream-Broach-Ream" technique. Once a piece of cancellous bone is removed, use the **T-Handle Stem Reamer** [3] manually to enlarge the medullar canal. As inserting the stem reamer, be sure that the grip handle is perpendicular to the canal.



2. Femoral Cutting Chisel
9101 - 1301

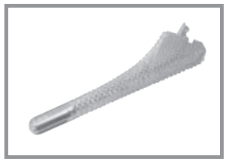


3. T-Handle Stem Reamer
9101 - 3008

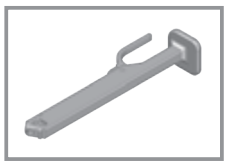


2. Femoral Preparation

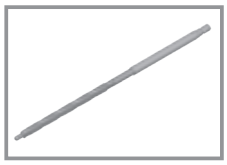
4. U2 Broach
9104 - 6010-RC
9104 - 6020-RC
9104 - 6030-RC
9104 - 6040-RC
9104 - 6050-RC
9104 - 6060-RC
9104 - 6070-RC



5. Broach Handle
9104 - 6103-RA



6. U2 Stem Reamer
9104 - 3009
9104 - 3010
9104 - 3011
9104 - 3012
9104 - 3013
9104 - 3014
9104 - 3015



After proper distal diameter is obtained by using the **T-Handle Stem Reamer** [3] , attach the smallest **U2 Broach** [4] to the **Broach Handle** [5] and gradually enlarge the broach until it reaches to the optimal proximal press-fit size. Slightly enlarge the canal by using the **U2 Stem Reamer** [6] if there is any inference while broaching.

U2 Broach

Size	Distal Diameter
#1	Ø9
#2	Ø10
#3	Ø10
#4	Ø11
#5	Ø12
#6	Ø13
#7	Ø15

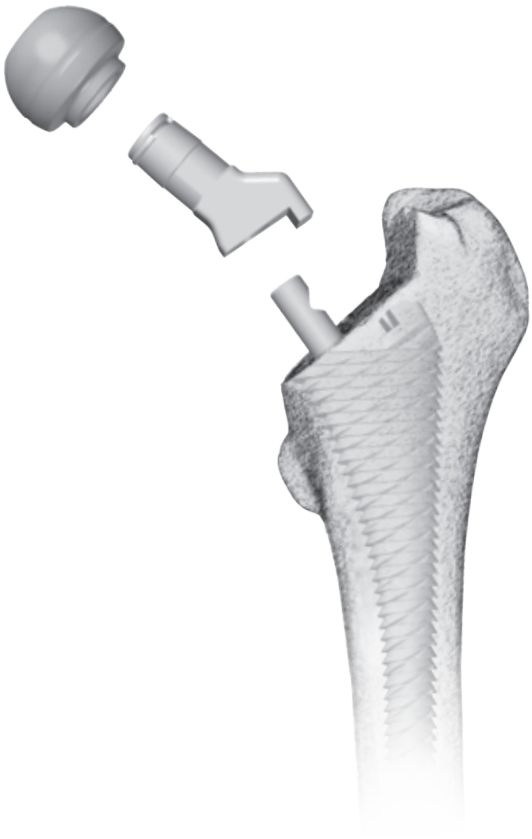
Once the proximal size is determined, employ **U2 Stem Reamer** [6] and ream the canal to the most advantageous diameter that corresponds with the decided proximal size. Reaming range should not be in excess of the cortical bone contact.

U2 Matrix Porous Stem

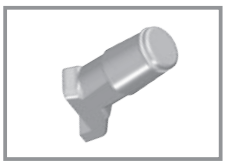
Proximal Size	Available Distal Diameter
#1	Ø9
#2	Ø10, Ø11
#3	Ø10, Ø11, Ø12
#4	Ø11, Ø12
#5	Ø12, Ø13
#6	Ø13, Ø14
#7	Ø15

3. Trial Reduction

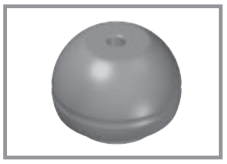
Once confirming a firmly seated broach, assemble the final broach with corresponded **Neck Trial** [7] . Perform the trial reduction using the **Femoral Head Trial** [8] with desired diameter and desired neck length.



7. Neck Trial
9104 - 5002-RB
9104 - 5003-RB
9104 - 5004-RB
9104 - 5005-RB



8. Femoral Head Trial
C/N varies by size



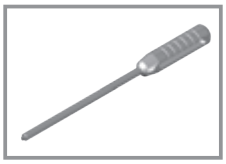
Metal

delta Ceramic

4. Stem Insertion

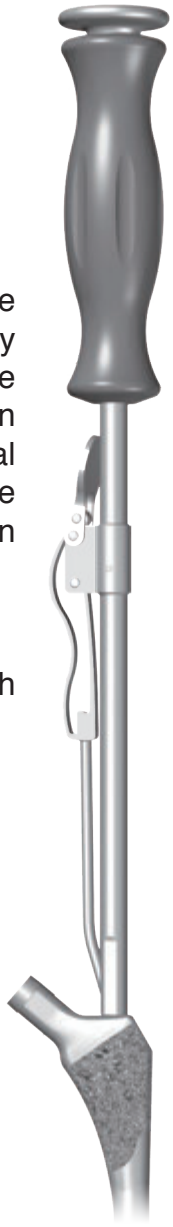
9. U2 Stem Quick Connect Holder 9104 - 1214

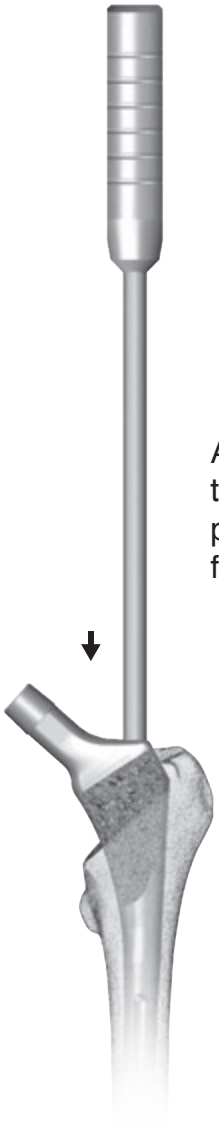
10. Stem Impactor, Long 9104 - 1213-RA



After trial reduction, remove the broach and introduce the stem implant by using the stem holder. UOC offers an handy **U2 Stem Quick Connect Holder** [9] for stem insertion. Use the holder to firmly attach the stem to the inserting hole on the stem shoulder. Gently tap the holder to achieve initial stem implantation into medullary canal. Care should be taken to orient the stem with proper alignment and version during implant impaction.

Note:
Stop tapping the holder if the stem holder impinges with greater trochanter.

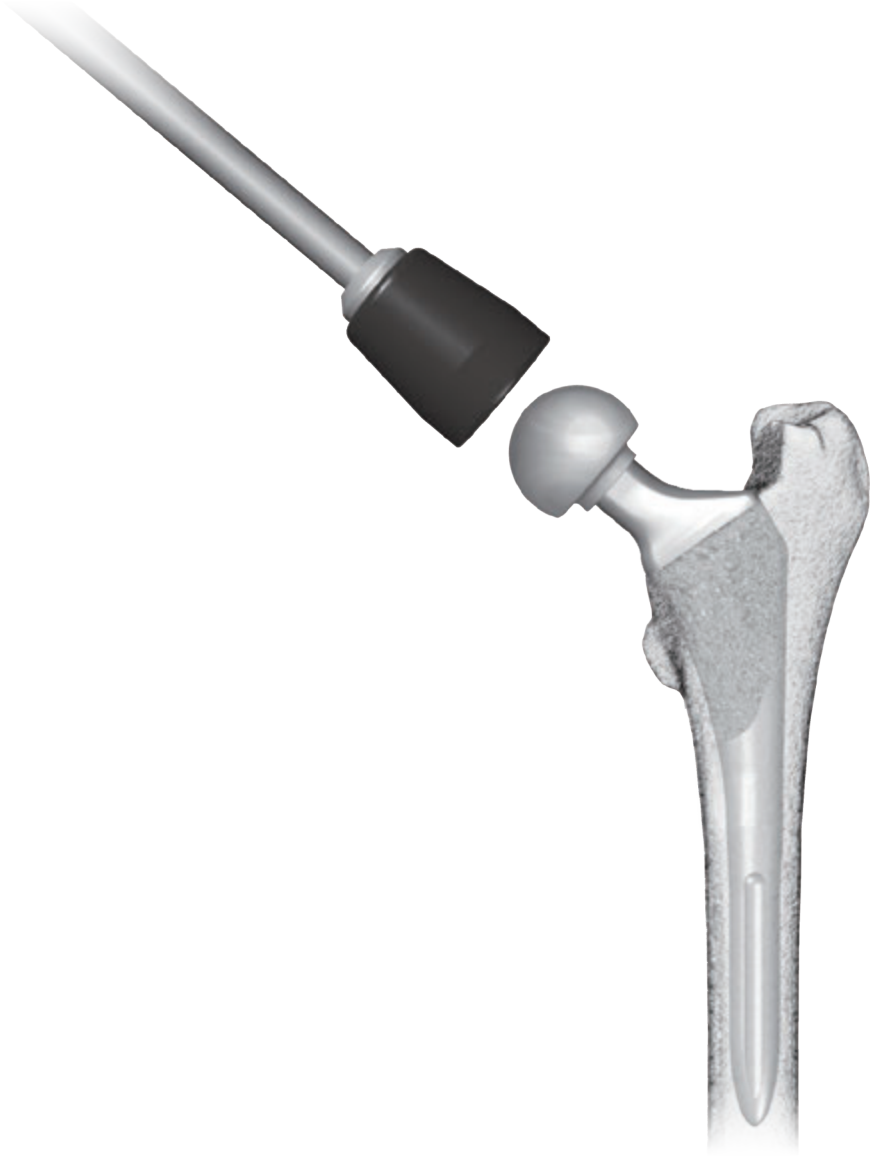




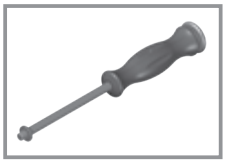
Apply the **Stem Impactor** [10] to the implant and begin to tap the handle with a mallet until the implant is properly positioned. Ensure the impacting is in the central axis of the femur.

5. Femoral Head Assembly

Following the stem insertion, clean and dry the taper of the femoral stem. Place the selected femoral head onto the taper and lightly tap using the **Universal Handle** [11] which attached with the appropriate **Femoral Head Impactor** [12].



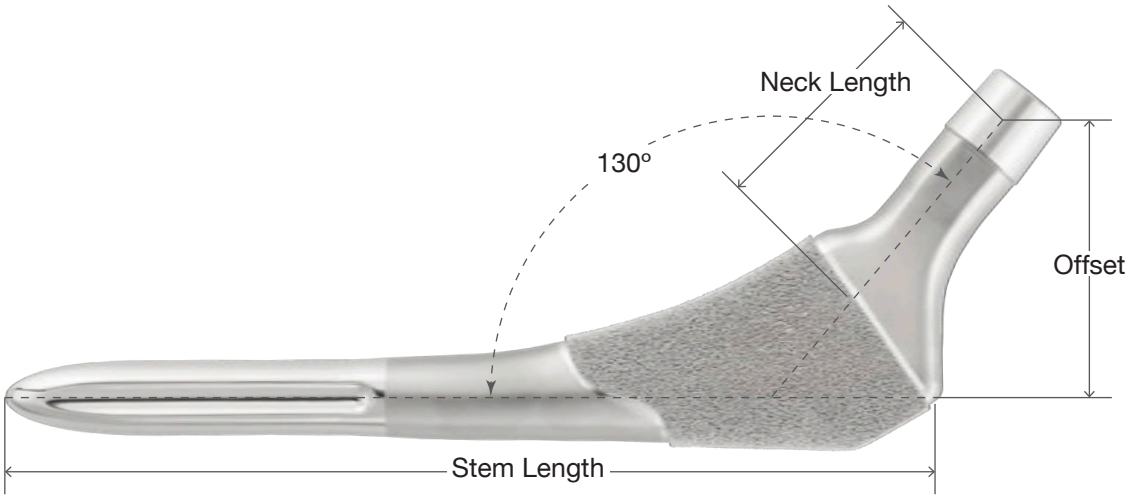
11. Universal handle
9206 - 1110



12. Femoral Head Impactor
9204 - 1226-RA

U2 Matrix Porous Stem

Catalog Number	Size	Distal Diameter
1104-3212	# 1	Φ9
1104-3223	# 2	Φ10
1104-3233	# 3	Φ10
1104-3224	# 2	Φ11
1104-3234	# 3	Φ11
1104-3244	# 4	Φ11
1104-3235	# 3	Φ12
1104-3245	# 4	Φ12
1104-3255	# 5	Φ12
1104-3256	# 5	Φ13
1104-3266	# 6	Φ13
1104-3267	# 6	Φ14
1104-3278	# 7	Φ15



*SS=Stem Size *DD=Distal Diameter *SL=Stem Length *OF=Offset *NL=Neck Length

Metal Head				26 mm								28 mm 32 mm 36 mm											
				+0 mm		+3 mm		+6 mm		+9 mm		-3 mm		+0 mm		+2.5 mm		+5 mm		+7.5 mm		+10 mm	
Cat. No.	*SS	*DD	*SL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL
1104-3212	#1	Ø9	126	35	30	37	33	39	36	41	39	32.5	26.5	34.5	29.5	36.5	32	38.5	34.5	40.5	37	42.5	39.5
1104-3223	#2	Ø10	132	36	30	38	33	40	36	42	39	34	26.5	36	29.5	38	32	40	34.5	42	37	44	39.5
1104-3233	#3	Ø10	132	39	34	41	37	43	40	45	43	37	30.5	39.5	33.5	41	36	43	38.5	45	41	47	43.5
1104-3224	#2	Ø11	138	36	30	38	33	40	36	42	39	34	26.5	36	29.5	38	32	40	34.5	42	37	44	39.5
1104-3234	#3	Ø11	138	39	34	41	37	43	40	45	43	37	30.5	39.5	33.5	41	36	43	38.5	45	41	47	43.5
1104-3244	#4	Ø11	138	39	34	41	37	43	40	45	43	37	30.5	39.5	33.5	41	36	43	38.5	45	41	47	43.5
1104-3235	#3	Ø12	145	39	34	41	37	43	40	45	43	37	30.5	39.5	33.5	41	36	43	38.5	45	41	47	43.5
1104-3245	#4	Ø12	145	39	34	41	37	43	40	45	43	37	30.5	39.5	33.5	41	36	43	38.5	45	41	47	43.5
1104-3255	#5	Ø12	145	43	38	45	41	47	44	49	47	40.5	35	42.5	38	44.5	40.5	46.5	43	48.5	45.5	50.5	48
1104-3256	#5	Ø13	152	43	38	45	41	47	44	49	47	40.5	35	42.5	38	44.5	40.5	46.5	43	48.5	45.5	50.5	48
1104-3266	#6	Ø13	152	45	41	47	44	49	47	51	50	42.5	38	45	41	47	43.5	49	46	50.5	48.5	52.5	51
1104-3267	#6	Ø14	158	45	41	47	44	49	47	51	50	42.5	38	45	41	47	43.5	49	46	50.5	48.5	52.5	51
1104-3278	#7	Ø15	166	45	41	47	44	49	47	51	50	42.5	38	45	41	47	43.5	49	46	50.5	48.5	52.5	51

delta-Ceramic Head				28 mm						32 mm 36mm 40mm						32 mm		36 mm 40 mm	
				-2.5 mm		+1 mm		+4 mm		-3 mm		+1 mm		+5 mm		+8 mm		+9 mm	
Cat. No.	*SS	*DD	*SL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL	*OF	*NL
1104-3212	#1	Ø9	126	33	27	35.5	30.5	38	34	32.5	26.5	35.5	30.5	38.5	34.5	41	37.5	41.5	38.5
1104-3223	#2	Ø10	132	34	27	37	30.5	39.5	34	34	26.5	37	30.5	40	34.5	42.5	37.5	43	38.5
1104-3233	#3	Ø10	132	37.5	31	40	34.5	42.5	38	37	30.5	40	34.5	43	38.5	45.5	41.5	46	42.5
1104-3224	#2	Ø11	138	34	27	37	30.5	39.5	34	34	26.5	37	30.5	40	34.5	42.5	37.5	43	38.5
1104-3234	#3	Ø11	138	37.5	31	40	34.5	42.5	38	37	30.5	40	34.5	43	38.5	45.5	41.5	46	42.5
1104-3244	#4	Ø11	138	37.5	31	40	34.5	42.5	38	37	30.5	40	34.5	43	38.5	45.5	41.5	46	42.5
1104-3235	#3	Ø12	145	37.5	31	40	34.5	42.5	38	37	30.5	40	34.5	43	38.5	45.5	41.5	46	42.5
1104-3245	#4	Ø12	145	37.5	31	40	34.5	42.5	38	37	30.5	40	34.5	43	38.5	45.5	41.5	46	42.5
1104-3255	#5	Ø12	145	40.5	35.5	43.5	39	46	42.5	40.5	35	43.5	39	46.5	43	49	46	49.5	47
1104-3256	#5	Ø13	152	40.5	35.5	43.5	39	46	42.5	40.5	35	43.5	39	46.5	43	49	46	49.5	47
1104-3266	#6	Ø13	152	43	38.5	45.5	42	48.5	45.5	42.5	38	45.5	42	49	46	51	49	52	50
1104-3267	#6	Ø14	158	43	38.5	45.5	42	48.5	45.5	42.5	38	45.5	42	49	46	51	49	52	50
1104-3278	#7	Ø15	166	43	38.5	45.5	42	48.5	45.5	42.5	38	45.5	42	49	46	51	49	52	50

Femoral Head

Metal Head	Catalog No.	Description (mm)	
	1201-1126	Ø 26	0
	1201-1326	Ø 26	+3
	1201-1526	Ø 26	+6
	1201-1726	Ø 26	+9
	1201-1028	Ø 28	-3
	1201-1128	Ø 28	+0
	1201-1228	Ø 28	+2.5
	1201-1428	Ø 28	+5
	1201-1628	Ø 28	+7.5
	1201-1828	Ø 28	+10
	1201-1032	Ø 32	-3
	1201-1132	Ø 32	+0
	1201-1232	Ø 32	+2.5
	1201-1432	Ø 32	+5
	1201-1632	Ø 32	+7.5
	1201-1832	Ø 32	+10
	1201-1036	Ø 36	-3
	1201-1136	Ø 36	+0
	1201-1236	Ø 36	+2.5
	1201-1436	Ø 36	+5
	1201-1636	Ø 36	+7.5
	1201-1836	Ø 36	+10

delta **Ceramic Head**	Catalog No.	Description (mm)	
	1203-5028	Ø 28	-2.5
	1203-5228	Ø 28	+1
	1203-5428	Ø 28	+4
	1203-5032	Ø 32	-3
	1203-5232	Ø 32	+1
	1203-5432	Ø 32	+5
	1203-5632	Ø 32	+8
	1203-5036	Ø 36	-3
	1203-5236	Ø 36	+1
	1203-5436	Ø 36	+5
	1203-5636	Ø 36	+9
	1203-5040	Ø 40	-3
	1203-5240	Ø 40	+1
	1203-5440	Ø 40	+5
	1203-5640	Ø 40	+9

Femoral Head Trial

Metal Head Trial	Catalog No.	Description (mm)	
	1201-2126-RB	Ø 26	+0
	1201-2326-RB	Ø 26	+3
	1201-2526-RB	Ø 26	+6
	1201-2726-RB	Ø 26	+9
	1201-2028-RB	Ø 28	-3
	1201-2128-RB	Ø 28	+0
	1201-2228-RB	Ø 28	+2.5
	1201-2428-RB	Ø 28	+5
	1201-2628-RB	Ø 28	+7.5
	1201-2828-RB	Ø 28	+10
	1201-2032-RB	Ø 32	-3
	1201-2132-RB	Ø 32	+0
	1201-2232-RB	Ø 32	+2.5
	1201-2432-RB	Ø 32	+5
	1201-2632-RB	Ø 32	+7.5
	1201-2832-RB	Ø 32	+10
	1201-2036-RB	Ø 36	-3
	1201-2136-RB	Ø 36	+0
	1201-2236-RB	Ø 36	+2.5
	1201-2436-RB	Ø 36	+5
	1201-2636-RB	Ø 36	+7.5
	1201-2836-RB	Ø 36	+10

delta **Ceramic Head Trial**	Catalog No.	Description (mm)	
	1203-6028-RB	Ø 28	-2.5
	1203-6228-RB	Ø 28	+1
	1203-6428-RB	Ø 28	+4
	1203-6032-RB	Ø 32	-3
	1203-6232-RB	Ø 32	+1
	1203-6432-RB	Ø 32	5
	1203-6632-RB	Ø 32	+8
	1203-6036-RB	Ø 36	-3
	1203-6236-RB	Ø 36	+1
	1203-6436-RB	Ø 36	+5
	1203-6636-RB	Ø 36	+9
	1203-6040-RB	Ø 40	-3
	1203-6240-RB	Ø 40	+1
	1203-6440-RB	Ø 40	+5
	1203-6640-RB	Ø 40	+9

Instruments

Catalog No.	Description
9101 - 1301	Femoral Cutting Chisel

Catalog No.	Description
9101 - 1302	Femoral Head Extractor

Catalog No.	Description
9101 - 3008	T-Handle Stem Reamer

Catalog No.	Description
9104 - 1202 - RA	Stem extractor

Catalog No.	Description
9104 - 1213 - RA	Stem Impactor

Catalog No.	Description
9104 - 1214	U2 Stem Quick Connect Holder

Catalog No.	Description
9104 - 2011	Osteotomy Guide #1
9104 - 2012	Osteotomy Guide #2~7

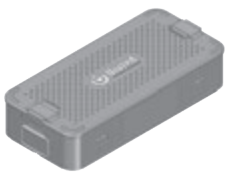
Instruments

Catalog No.	Description (mm)	
9104 - 3009	U2 Stem Reamer	Ø 9
9104 - 3010	U2 Stem Reamer	Ø 10
9104 - 3011	U2 Stem Reamer	Ø 11
9104 - 3012	U2 Stem Reamer	Ø 12
9104 - 3013	U2 Stem Reamer	Ø 13
9104 - 3014	U2 Stem Reamer	Ø 14
9104 - 3015	U2 Stem Reamer	Ø 15

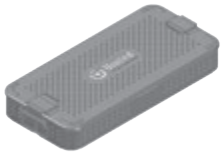
Catalog No.	Description	
9104 - 5002-RB	Neck Trial	#1 #2
9104 - 5003-RB	Neck Trial	#3 #4
9104 - 5004-RB	Neck Trial	#5
9104 - 5005-RB	Neck Trial	#6 #7

Catalog No.	Description	
9104 - 6010-RC	U2 Broach	#1
9104 - 6020-RC	U2 Broach	#2
9104 - 6030-RC	U2 Broach	#3
9104 - 6040-RC	U2 Broach	#4
9104 - 6050-RC	U2 Broach	#5
9104 - 6060-RC	U2 Broach	#6
9104 - 6070-RC	U2 Broach	#7

Catalog No.	Description
9104 - 6103 - RA	Broach Handle



Catalog No.	Description
9104 - 8110	U2 Hip Basic Case



Catalog No.	Description
9104 - 8120	U2 Hip Stem Case

Instruments

Catalog No.	Description
9104 - 9001 - RA	Femoral Head Remover

Catalog No.	Description
9106 - 5001	Hammer

Catalog No.	Description
9106 - 5101	Slide Rod

Catalog No.	Description
9204 - 1226-RA	Femoral Head Impactor

Catalog No.	Description
9206 - 1110	Universal Handle

Catalog No.	Description
9303 - 1300	T-Handle

Catalog No.	Description
9401 - 7012	Caliper

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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.

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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Each Step **We Care**

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