United®
Orthopedic Corporation

UTF™ Stem
reduced

Surgical Protocol

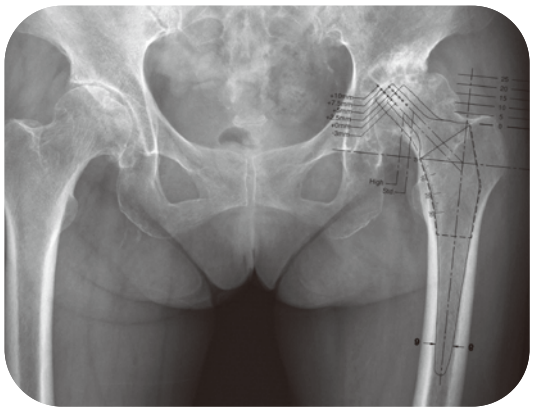
Table of Contents

Device Description

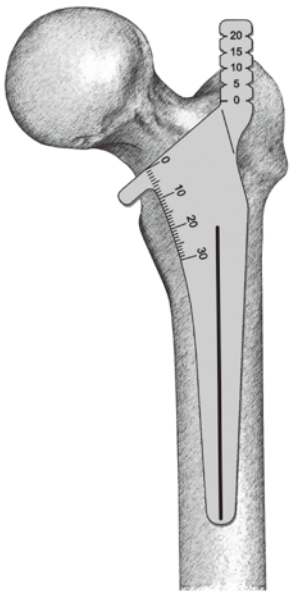
Procedure number of total hip arthroplasty (THA) is increasing annually. Recently, younger in the age of patient underwent THA is raised as well. The UOC introduces a specifically designed UTF reduced stem for whole populations, which has the advantages of metaphyseal fitting, bone preservation and simple surgical technique. UTF reduced stem characterizes refined proximal M/L width to maximize metaphyseal fitting. Also, a slim body and broach-only technique benefits minimal bone removal. Furthermore, the reduced distal M/L width accommodates all kinds of femora even the proximal/distal mismatched canal. The resected lateral shoulder and distal tip facilitates stem insertion. Standard and high offsets are supplied for reconstruction of joint biomechanics as well. In addition, offering unique instrumentations benefits easy-to-use, time-saving and many surgical approaches. UTF reduced stem design and corresponded surgical devices bring the surgeons predictable clinical outcomes and simple operations.

Preoperative Planning and Templating

Preoperative planning is essential for determining the optimized stem size, neck resected level and the appropriate neck length. Making an accurate femoral component selection begins with thorough radiographic evaluation of the involved femur: a full anteroposterior (A/P) view and lateral view. The A/P radiographic image should include bilateral hip joints to help the evaluation of the affected side. These radiographies provide the estimation of leg length inequality, femoral offset, and center of rotation to reconstruct hip biomechanics.



UTF templates with 15% magnification are offered in accordance with the common enlargement of x-ray image. UTF reduced stem is designed to obtain immediate geometrical stability depended on medial and lateral cortex contact. Templating the prosthesis size which best fits the metaphyseal canal is recommended. Standard and high offset options are available for all stem sizes. High offset provides femoral lateralization, increasing stem offset while maintains leg length. Also, multiple head offsets are offered for the adjustment of neck length. The final determination of implant options should be taken into account the acetabular cup position, cup size and center of rotation of the acetabulum.

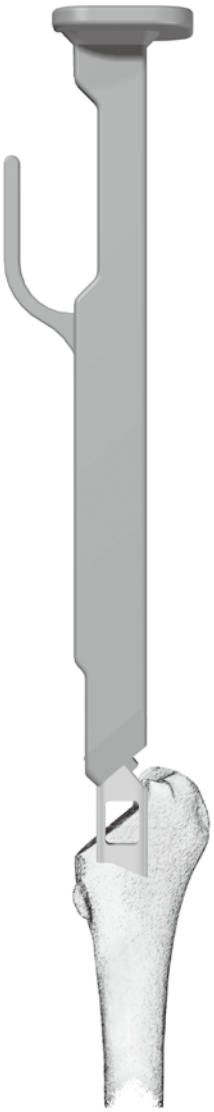


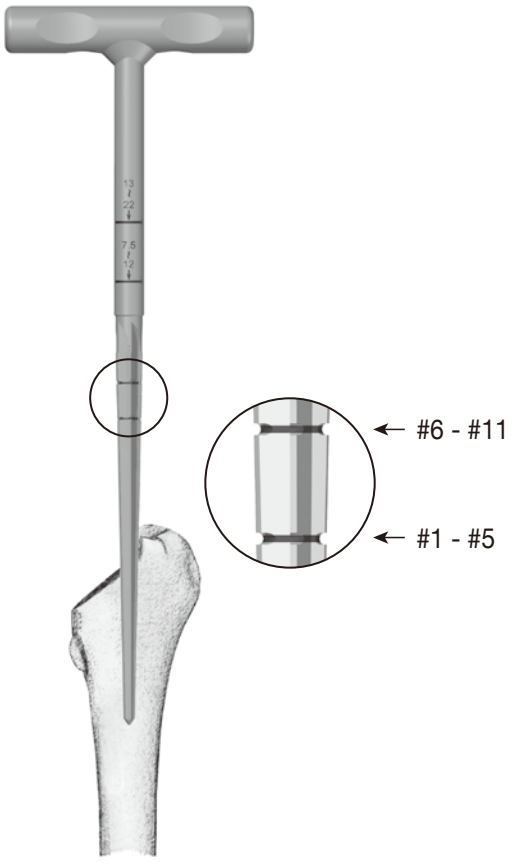
Femoral Osteotomy

Place the **Neck Resection Guide** aligned with the long axis of the femoral canal. Determine the neck resection level by measuring preoperatively determined distance above the lesser trochanter or by measuring the distance from the tip of the greater trochanter to the shoulder of the stem. The cutting line can be marked by using the electrocautery, then complete the femoral neck resection with a power saw.

Femoral Canal Accessing

Utilize the modular **Femoral Cutting Chisel** for adequate lateral/ posterior initial entry into femoral canal. Lateralization of the canal entry is important to prevent varus alignment of prosthetic stem during insertion.



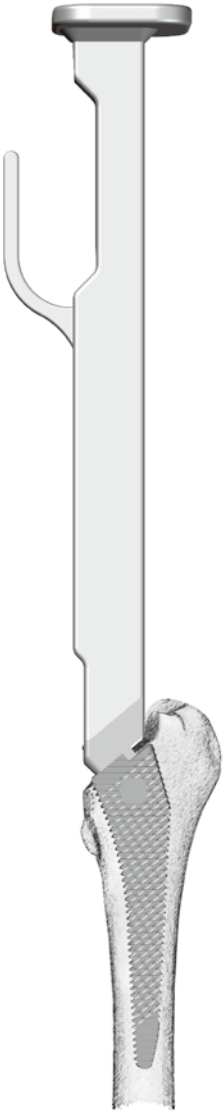


Canal Reaming

Utilize the **Start Reamer** to initiate the opening of medullary canal. For the stem size 1 to size 5, the inferior groove provides a proper guideline of reaming depth, whereas the superior groove designates another reference for stem sizes larger than size 5. Ensure the correct reamer alignment within the femoral shaft axis.

Canal Broaching

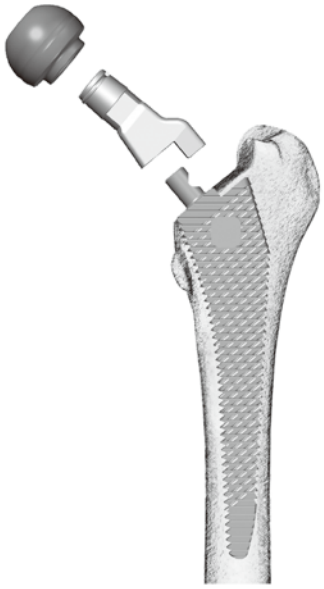
After the opening of femoral canal, proceed broach sequence for canal preparation. The UOC provides several broach handles that fulfill different hip replacement surgical approaches. A **Start Broach** can be a guideline for the direction of subsequent femoral broaching. Attach the smallest UTF Broach to the proper broach handle. Start broaching procedure along the axis of the femur and maintain the appropriate orientation of the broach. Gradually enlarge the broach size until the broach contacts the medial and lateral cortices or template size is achieved. Be sure the axial and rotational stability of the final broach such that a press-fit fixation of the implant will be predicted.



Straight

Offset

Dual-offset , Left & Righ



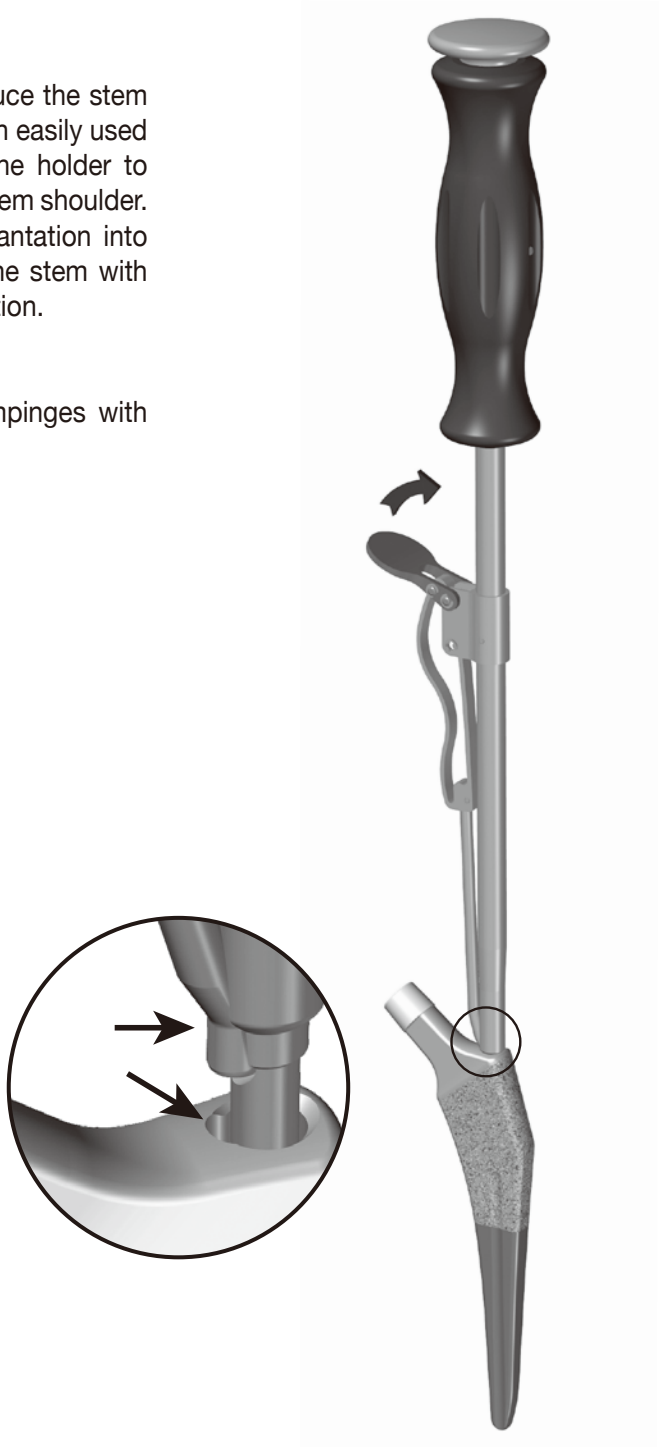
Trial Reduction

Once confirming a firmly seated broach, assemble the appropriate sized standard or high offset **Neck Trial** onto the broach. Perform the trial reduction using the femoral head trial with desired diameter and neck length. Three sets of neck trial are offered mating with different sized broach, the size 1-4, the size 5-8 and the size 9-11. Any correction of selected implant size can be made during the reassessment of leg length and joint biomechanics if required.

Stem Insertion

After trial reduction, remove the broach and introduce the stem implant by using the stem holder. The UOC offers an easily used **Quick Connect Holder** for stem insertion. Use the holder to firmly attach the stem via 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 once the stem holder impinges with greater trochanter.



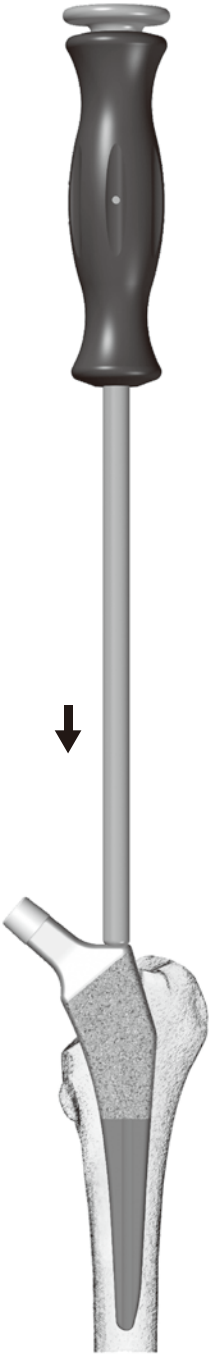
Stem Impaction

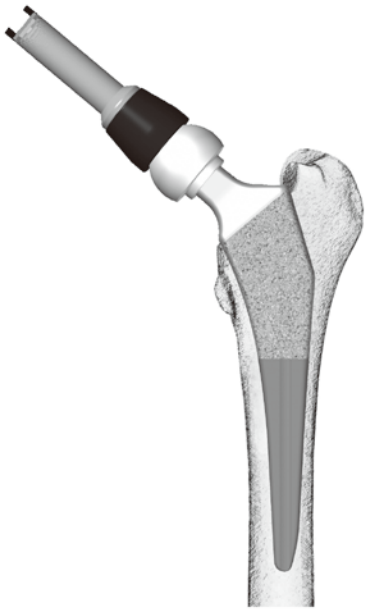
Use a mallet and stem impactor to further advance the stem into endosteal canal. Offered **Straight** and **Curved Stem Impactors** enable different surgical approaches. The prosthesis should be seated until most proximal portion of the coating surface is in line with the neck resection face.

Note:
If the stem impactor impinges with greater trochanter, any impaction may lead to bone fracture.

Straight Stem Impactor

Curved Stem Impactor





Femoral Head Impaction

A final trial reduction may be performed if desired to re-evaluate stability and leg length by using the femoral head trials. After the appropriate femoral head size has been determined, place it onto the cleaned and dried taper with manual twist. Using the head impactor, engage the head with several gentle taps until it is firmly set.

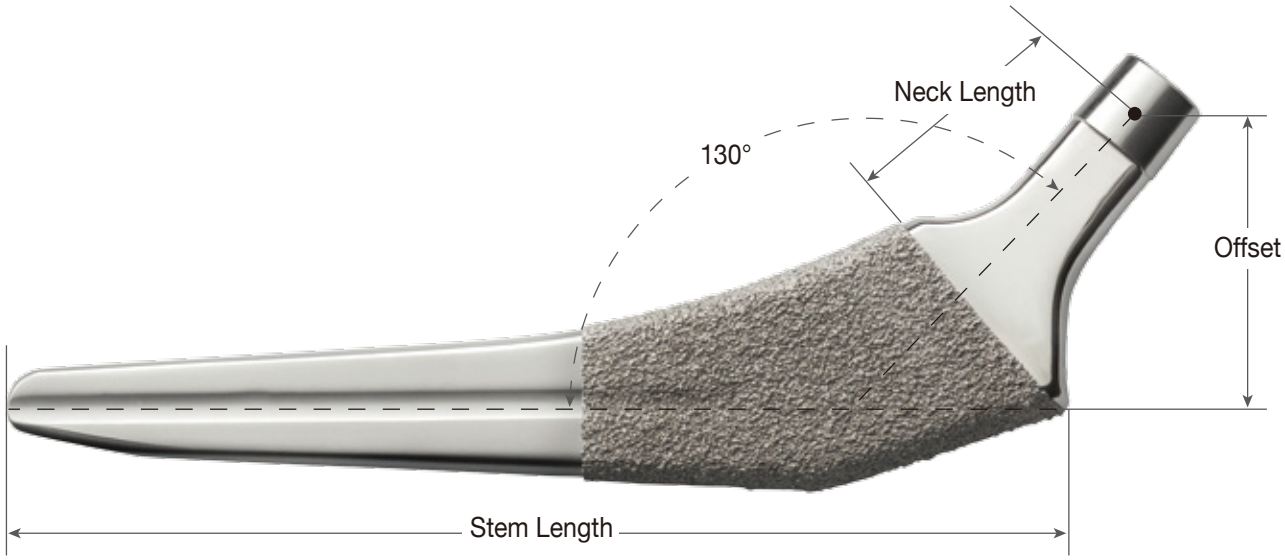
Taper Fit Stem, Reduced

Standard Offset

Catalog Number	Description
1106-3001	# 1
1106-3002	# 2
1106-3003	# 3
1106-3004	# 4
1106-3005	# 5
1106-3006	# 6
1106-3007	# 7
1106-3008	# 8
1106-3009	# 9
1106-3010	# 10
1106-3011	# 11

High Offset

Catalog Number	Description
1106-3201	# 1
1106-3202	# 2
1106-3203	# 3
1106-3204	# 4
1106-3205	# 5
1106-3206	# 6
1106-3207	# 7
1106-3208	# 8
1106-3209	# 9
1106-3210	# 10
1106-3211	# 11

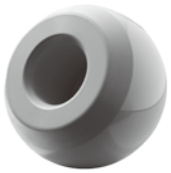


Metal Head		28 mm 32 mm 36 mm											
		-3 mm		+0 mm		+2.5 mm		+5 mm		+7.5 mm		+10 mm	
Size	Stem Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length
Standard Offset, #1	125	30	25	32	28	34	30.5	36	33	38	35.5	40	38
Standard Offset, #2	128	31	26	33	29	35	31.5	37	34	39	36.5	41	39
Standard Offset, #3	131	32	27	34	30	36	32.5	38	35	40	37.5	42	40
Standard Offset, #4	134	33	28	35	31	37	33.5	39	36	41	38.5	43	41
Standard Offset, #5	137	34	29	36	32	38	34.5	40	37	42	39.5	44	42
Standard Offset, #6	140	35	30	37	33	39	35.5	41	38	43	40.5	45	43
Standard Offset, #7	142	36	31	38	34	40	36.5	42	39	44	41.5	46	44
Standard Offset, #8	144	37	32	39	35	41	37.5	43	40	45	42.5	47	45
Standard Offset, #9	146	37	32	39	35	41	37.5	43	40	45	42.5	47	45
Standard Offset, #10	149	39	34	41	37	43	39.5	45	42	47	44.5	49	47
Standard Offset, #11	152	40	35	42	38	44	40.5	46	43	48	45.5	50	48
High Offset, #1	125	36	29	38	32	40	34.5	42	37	44	39.5	46	42
High Offset, #2	128	37	30	39	33	41	35.5	43	38	45	40.5	47	43
High Offset, #3	131	38	31	40	34	42	36.5	44	39	46	41.5	48	44
High Offset, #4	134	39	32	41	35	43	37.5	45	40	47	42.5	49	45
High Offset, #5	137	41	34	43	37	45	39.5	47	42	49	44.5	51	47
High Offset, #6	140	42	35	44	38	46	40.5	48	43	50	45.5	52	48
High Offset, #7	142	43	36	45	39	47	41.5	49	44	51	46.5	53	49
High Offset, #8	144	44	37	46	40	48	42.5	50	45	52	47.5	54	50
High Offset, #9	146	45	37	47	40	49	42.5	51	45	53	47.5	55	50
High Offset, #10	149	47	39	49	42	51	44.5	53	47	55	49.5	57	52
High Offset, #11	152	48	40	50	43	52	45.5	54	48	56	50.5	58	53

Delta-Ceramic Head		28 mm 32 mm 36 mm						32 mm		36 mm 40 mm	
		-3 mm		+1 mm		+5 mm		+8 mm		+9 mm	
Size	Stem Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Neck Length
Standard Offset, #1	125	30	25	33	29	36	33	38	36	39	37
Standard Offset, #2	128	31	26	34	30	37	34	39	37	40	38
Standard Offset, #3	131	32	27	35	31	38	35	40	38	41	39
Standard Offset, #4	134	33	28	36	32	39	36	41	39	42	40
Standard Offset, #5	137	34	29	37	33	40	37	42	40	43	41
Standard Offset, #6	140	35	30	38	34	41	38	43	41	44	42
Standard Offset, #7	142	36	31	39	35	42	39	44	42	45	43
Standard Offset, #8	144	37	32	40	36	43	40	45	43	46	44
Standard Offset, #9	146	37	32	40	36	43	40	45	43	46	44
Standard Offset, #10	149	39	34	42	38	45	42	47	45	48	46
Standard Offset, #11	152	40	35	43	39	46	43	48	46	49	47
High Offset, #1	125	36	29	39	33	42	37	44	40	45	41
High Offset, #2	128	37	30	40	34	43	38	45	41	46	42
High Offset, #3	131	38	31	41	35	44	39	46	42	47	43
High Offset, #4	134	39	32	42	36	45	40	47	43	48	44
High Offset, #5	137	41	34	44	38	47	42	49	45	50	46
High Offset, #6	140	42	35	45	39	48	43	50	46	51	47
High Offset, #7	142	43	36	46	40	49	44	51	47	52	48
High Offset, #8	144	44	37	47	41	50	45	52	48	53	49
High Offset, #9	146	45	37	48	41	51	45	53	48	54	49
High Offset, #10	149	47	39	50	43	53	47	55	50	56	51
High Offset, #11	152	48	40	51	44	54	48	56	51	57	52

Femoral Head

Metal Head	Catalog Number	Description	
	1201 - 1028	ø 28 mm	- 3
	1201 - 1128	ø 28 mm	+ 0
	1201 - 1228	ø 28 mm	+ 2.5
	1201 - 1428	ø 28 mm	+ 5
	1201 - 1628	ø 28 mm	+ 7.5
	1201 - 1828	ø 28 mm	+ 10
	1201 - 1032	ø 32 mm	- 3
	1201 - 1132	ø 32 mm	+ 0
	1201 - 1232	ø 32 mm	+ 2.5
	1201 - 1432	ø 32 mm	+ 5
	1201 - 1632	ø 32 mm	+ 7.5
	1201 - 1832	ø 32 mm	+ 10
	1201 - 1036	ø 36 mm	- 3
	1201 - 1136	ø 36 mm	+ 0
	1201 - 1236	ø 36mm	+ 2.5
	1201 - 1436	ø 36 mm	+ 5
	1201 - 1636	ø 36mm	+ 7.5
	1201 - 1836	ø 36 mm	+ 10

Delta Ceramic Head	Catalog Number	Description		
	1203 - 5028	ø 28 mm	- 2.5	S
	1203 - 5228	ø 28 mm	+ 1	M
	1203 - 5428	ø 28 mm	+ 4	L
	1203 - 5032	ø 32 mm	- 3	S
	1203 - 5232	ø 32 mm	+ 1	M
	1203 - 5432	ø 32 mm	+ 5	L
	1203 - 5632	ø 32 mm	+ 8	XL
	1203 - 5036	ø 36 mm	- 3	S
	1203 - 5236	ø 36 mm	+ 1	M
	1203 - 5436	ø 36 mm	+ 5	L
	1203 - 5636	ø 36 mm	+ 9	XL
	1203 - 5040	ø 40 mm	- 3	S
	1203 - 5240	ø 40 mm	+ 1	M
	1203 - 5440	ø 40 mm	+ 5	L
	1203 - 5640	ø 40 mm	+ 9	XL

Trial Head

Metal Head Trial	Catalog Number	Description	
	1201 - 2028 - RB	ø 28 mm	- 3
	1201 - 2128 - RB	ø 28 mm	+ 0
	1201 - 2228 - RB	ø 28 mm	+ 2.5
	1201 - 2428 - RB	ø 28 mm	+ 5
	1201 - 2628 - RB	ø 28 mm	+ 7.5
	1201 - 2828 - RB	ø 28 mm	+ 10
	1201 - 2032 - RB	ø 32 mm	- 3
	1201 - 2132 - RB	ø 32 mm	+ 0
	1201 - 2232 - RB	ø 32 mm	+ 2.5
	1201 - 2432 - RB	ø 32 mm	+ 5
	1201 - 2632 - RB	ø 32 mm	+ 7.5
	1201 - 2832 - RB	ø 32 mm	+ 10
	1201 - 2036 - RB	ø 36 mm	- 3
	1201 - 2136 - RB	ø 36 mm	+ 0
	1201 - 2236 - RB	ø 36 mm	+ 2.5
	1201 - 2436 - RB	ø 36 mm	+ 5
	1201 - 2636 - RB	ø 36 mm	+ 7.5
	1201 - 2836 - RB	ø 36 mm	+ 10

Delta Ceramic Head Trial	Catalog Number	Description		
	1203 - 6028 - RB	ø 28 mm	- 2.5	S
	1203 - 6228 - RB	ø 28 mm	+ 1	M
	1203 - 6428 - RB	ø 28 mm	+ 4	L
	1203 - 6032 - RB	ø 32 mm	- 3	S
	1203 - 6232 - RB	ø 32 mm	+ 1	M
	1203 - 6432 - RB	ø 32 mm	+ 5	L
	1203 - 6632 - RB	ø 32 mm	+ 8	XL
	1203 - 6036 - RB	ø 36 mm	- 3	S
	1203 - 6236 - RB	ø 36 mm	+ 1	M
	1203 - 6436 - RB	ø 36 mm	+ 5	L
	1203 - 6636 - RB	ø 36 mm	+ 9	XL
	1203 - 6040 - RB	ø 40 mm	- 3	S
	1203 - 6240 - RB	ø 40 mm	+ 1	M
	1203 - 6440 - RB	ø 40 mm	+ 5	L
	1203 - 6640 - RB	ø 40 mm	+ 9	XL

Instruments

Catalog Number	Description
9101 - 1302	Femoral Head Extractor

Catalog Number	Description
9104 - 9001	Femoral Head Remover

Catalog Number	Description
9106 - 1005	Anteversion Handle

Catalog Number	Description
9106 - 1106 - RB	Straight Stem Impactor

Catalog Number	Description
9106 - 1107 - RB	Curved Stem Impactor

Instruments

Catalog Number	Description
9106 - 1101	Straight Broach Handle

Catalog Number	Description
9106 - 1301	Offset Broach Handle

Catalog Number	Description
9106 - 1501	Dual-offset Broach Handle, Left
9106 - 1502	Dual-offset Broach Handle, Right

Catalog Number	Description
9106 - 1311	UTF Stem, Reduced, Quick Connect Holder

Catalog Number	Description
9106 - 2002	Neck Resection Guide

Instruments

Catalog Number	Description
9106 - 3301	Start Reamer, Reduced

Catalog Number	Description
9106 - 4001	Femoral Cutting Chisel

Catalog Number	Description
9106 - 5001	Hammer

Catalog Number	Description
9106 - 5003	Stem Extractor Wrench

Catalog Number	Description
9106 - 5101	Slide Hammer Rod

Instruments

Catalog Number	Description
9106 - 5302	UTF Stem, Reduced, Extractor, M6

Catalog Number	Description
9106 - 5311	Standard, # 1~# 4
9106 - 5312	Standard, # 5~# 8
9106 - 5313	Standard, # 9~# 11

Catalog Number	Description
9106 - 5321	High Offset, # 1~# 4
9106 - 5322	High Offset, # 5~# 8
9106 - 5323	High Offset, # 9~# 11

Catalog Number	Description
9106 - 6000	Start Broach

Catalog Number	Description
9106 - 6301	UTF Broach, Reduce, # 1
9106 - 6302	UTF Broach, Reduce, # 2
9106 - 6303	UTF Broach, Reduce, # 3
9106 - 6304	UTF Broach, Reduce, # 4
9106 - 6305	UTF Broach, Reduce, # 5
9106 - 6306	UTF Broach, Reduce, # 6
9106 - 6307	UTF Broach, Reduce, # 7
9106 - 6308	UTF Broach, Reduce, # 8
9106 - 6309	UTF Broach, Reduce, # 9
9106 - 6310	UTF Broach, Reduce, # 10
9106 - 6311	UTF Broach, Reduce, # 11

Instruments

Catalog Number	Description
9106 - 8030	UTF Stem, Case #3, Dual Offset Broach Handle

Catalog Number	Description
9106 - 8310	UTF Stem, Reduced, Case # 1
9106 - 8320	UTF Stem, Reduced, Case # 2

Catalog Number	Description
9204 - 1228 - RA	Femoral Head Impactor, 28 mm

Catalog Number	Description
9206 - 1110	Universal Handle

Catalog Number	Description
9401 - 7012	Caliper

United®
Orthopedic Corporation

Devotion *to Orthopedics*

Safety Statement - UTF Stem System

DESCRIPTION

UNITED Hip System - UTF Stem is a modular, wedge-shaped stem with 12/14 neck taper, which is indicated for use in primary or revision hip arthroplasty. The stem substrate is made of a Ti-6Al-4V and is proximally coated with titanium plasma spray which provides biological fixation.

For total hip replacement, UTF Stem can be used in conjunction with UNITED Femoral Head, U2 Acetabular Cup Liner, XPE Cup Liner, U2 HA/Ti Plasma Spray Cup, U2 Ti Plasma Spray Cup and U2 Ti Porous Coated Cup. As using with the U2 Acetabular Cup Liner, UTF Stem can be used with 26 mm and 28 mm Femoral Head and 28 mm Ceramic Femoral Head. As using with XPE Cup Liner, UTF Stem can be used with 28 mm, 32 mm and 36 mm metal Femoral Head, and 28 mm and 32 mm ceramic Femoral Head. Only U2 Ti Porous Coated Cup and XPE Cup Liner can be used in conjunction with the 32 mm and 36 mm Femoral Head. For bipolar hip replacement, UTF Stem also can be used in conjunction with 26 mm, 28 mm, 32mm and 36mm Femoral Head and Bipolar implants.

MATERIALS

ASTM F-620 Ti alloy	Femoral stem
ASTM F-1580 Unalloyed Titanium	Metallic powder for Ti plasma spray

INDICATIONS

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatments or devices have failed.
   This device is designed for cementless use.

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 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 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.
9. Acetabular pain may occur after bipolar/hemi-hip arthroplasty due to localized pressure associated with incongruities of fit or tissue inflammation.
10. Metal sensitivity reactions have been reported following joint replacement.
11. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.

12. 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.
3. Polished neck 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 may result in a discrepancy in neck length, component disassociation and/or dislocation.
7. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
8. Intra-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. 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.

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. Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, mal-alignment, trauma,non-union, or excessive weight.
4. 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 returned to the supplier. A suitable handling will be done.

SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT

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

United®
Orthopedic Corporation

Devotion *to Orthopedics*

United®
Orthopedic Corporation

Office

- **Taiwan**
  12F, No. 80, Sec. 1, Chenggong Rd, Yonghe Dist.,
  New Taipei City 23452, Taiwan
  Tel: +886 2 2929-4567 Fax: +886 2 2922-4567

- **USA**
  UOC USA Inc.
  20 Fairbanks, Suite 173
  Irvine, CA 92618
  Tel: +1 949-328-3366 Fax: +1 949-328-3367

- **China**
  United Medical Instrument Co. Ltd.
  7F, No.1405, GongheXin Road, Shanghai, China
  Tel: +86 21 3661-8055 Fax: +86 21 6628-3031

- **EU Representative**
  mdi Europa GmbH
  Langenhagener Strasse 71, 30855 Langenhagen, Germany
  Tel: +49-511-3908 9530 Fax: +49-511-3908 9539

www.uoc.com.tw

01PS-S-14-01