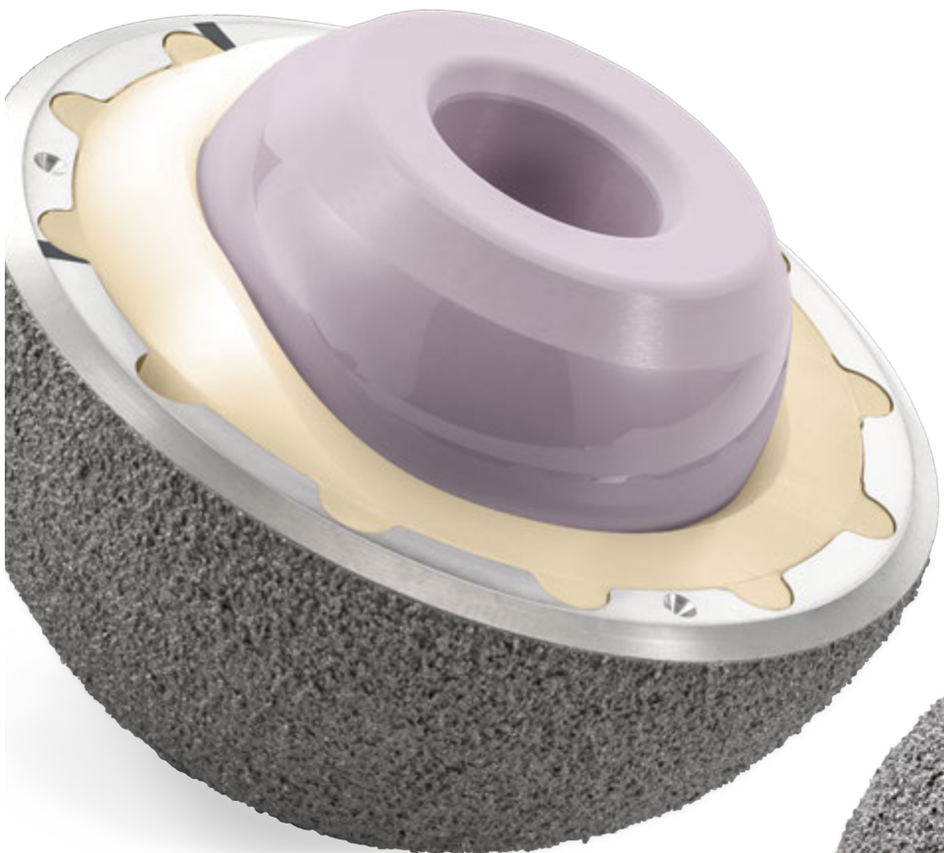
United®
Orthopedic Corporation



U-Motion II+™

Surgical Protocol

Table of Contents

Device Description

Total Hip Arthroplasty (THA) has become one of the most successful treatments in orthopedics; having both good patient satisfaction and long-term survivorship. However, challenging problems still exist-especially for physically active individuals-ranging from postoperative dislocation, bearing wear, and insufficient range of motion. The U-Motion II+ Acetabular System uses improved implant materials, BIOLOX® delta ceramic heads, highly cross-linked polyethylene (XPE) and Vitamin E stabilized highly cross-linked polyethylene (E-XPE) liners. With this unique material technology, the U-Motion II+ Acetabular System offers larger femoral head sizes to improve hip flexion and to reduce the risk of joint dislocation. The U-Motion II+ acetabular liner accommodates both ceramic and metal heads. Bearing options with 28 mm, 32 mm, 36 mm and 40 mm articulation diameters are available in the U-Motion II+ Acetabular System. Full range of acetabular cup size from 44 mm to 70 mm (in 2 mm increments) supports the variety of acetabular anatomy. TPS Plus™ surface coating increases the roughness of the implant and provides initial stability of acetabular component. The enhanced grip of the interface allows immediate bone and implant interlocking further contributing to bone ingrowth. The advanced acetabular system grants orthopedic surgeons flexibility during surgery for addressing clinical problems they might meet.

Preoperative Planning and Templating

The reconstruction of hip anatomy and restoration of joint biomechanics are the main goals of total hip replacement. A comprehensive analysis of the affected hip is needed. Anteroposterior (AP) and lateral roentgenographic images are crucial to help the determination of hip rotational center and correct component size. Also, an AP roentgenographic image of the pelvis may be necessary to verify preoperative decisions with comparison to the contralateral side.

Magnifications of 118 percentage of templates are provided to meet the roentgenographic images. Templating the outline of the component which best fit the acetabulum is recommended, thus an optimal implant position and a correct sizing can be achieved (Fig. 1).

The template of acetabular cup should be positioned toward the medial aspect of the acetabulum as possible, simultaneously, keeping in mind that a inherent 2 mm offset of the center of rotation in the U-Motion II+ acetabular system. Care should be taken to avoid overlap between the component and the teardrop, any uncovering of the component and more than 45 degree of inclination. However, the final determination should be made depending on the actual condition during surgery.

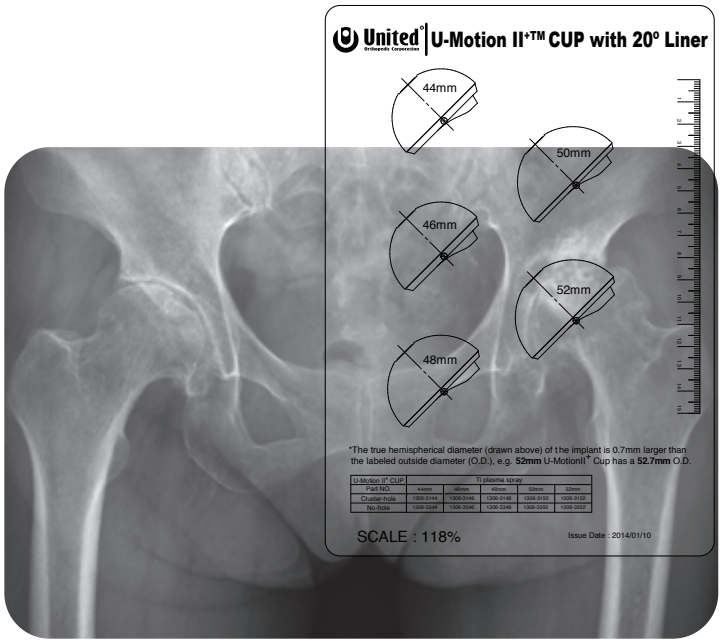


Fig. 1

Acetabular Preparation

1. Cup Reamer Handle, EZ Clean
9206 - 1101

2. Cup Reamer
C/N varies by sizes

Acetabular reaming

Appropriate reaming of the acetabulum is important for the cup to be fully seated within. All articular cartilage, osteophytes, and any soft tissues should be removed throughout the reaming process. It is important to understand the labeled size on the U-Motion II+ acetabular instrument (Reamer and Cup Trial) is an absolute dimension, however the implant has 0.35 mm surface coating thickness in each side. For example, a 58 mm U-Motion II+ cup measures 58.7 mm at the rim (Fig. 2), thus under-reaming of the cavity by 1 mm or line-to-line reaming should depend on bone quality.

Hold the **Cup Reamer Handle**[1] at abduction of 40°- 45° and anteversion of 15°- 20° (Fig. 3). Utilize the smallest **Cup Reamer**[2] to begin acetabular reaming, then gradually proceed with enlarged reamers in 1 mm increments until the anticipated size is achieved.

Acetabular Reamer
58 mm Reamer has a 58 mm O.D.

Cup Trial
58 mm Trial has a 58 mm O.D.

Acetabular Cup
58 mm Cup has a 58.7 mm O.D.

Fig. 2

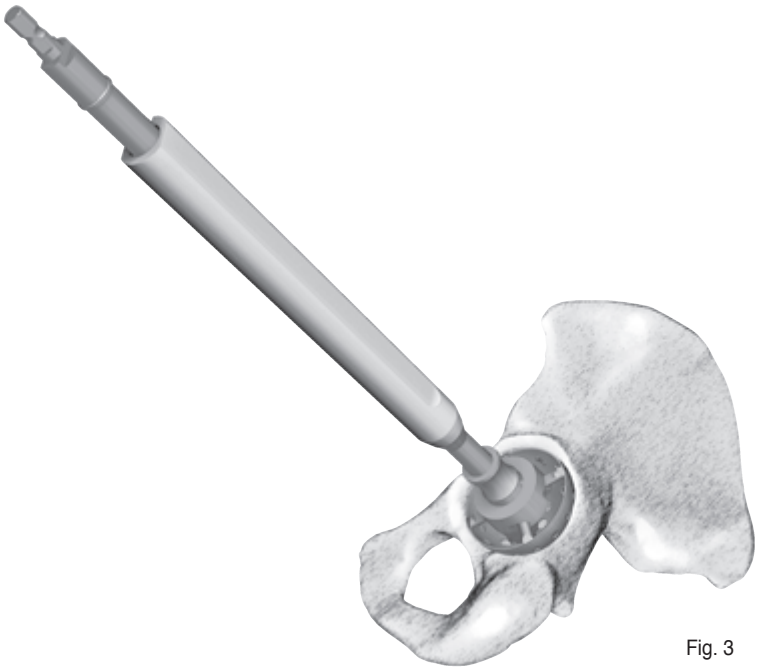


Fig. 3

Acetabular Preparation

Cup trialing

Once a proper acetabular cavity is established, place an **Acetabular Cup Trial**[3] to : (1) confirm the bone-implant congruency via the peephole on the trial; (2) verify the prepared acetabulum is truly hemispherical; and (3) check the stability of the trial cup before final implant insertion.

Thread the appropriate trial cup onto the **U-M II Cup Impactor**[4] The same diameter trial of the last reamer is recommended to avoid destruction of press-fit mechanism. The profile of the trial cup is characterized as true hemisphere corresponded to the marked diameter.

Before trialing, clean acetabular cavity and excise any protruded tissues. Control the trial cup to be inserted with 40°-45° abduction and 15°-20° anteversion, impact it into the cavity with a mallet (Fig. 4). Palpate the peripheral edge of the trial cup to ensure it is fully seated at an appropriate orientation.

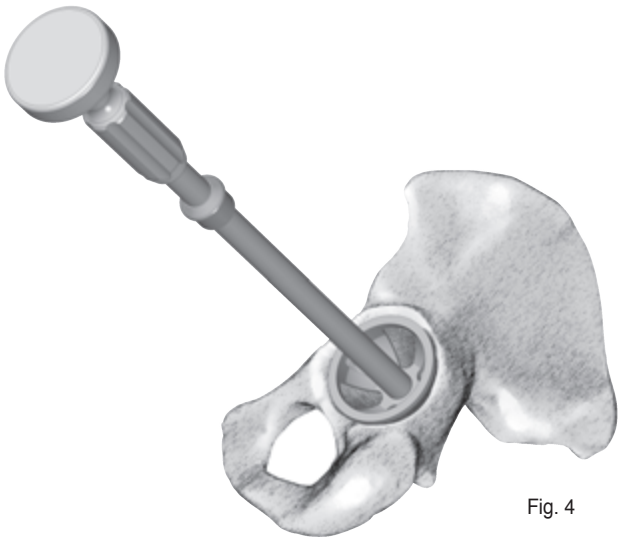
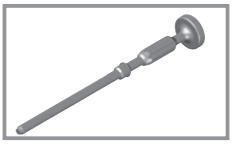


Fig. 4

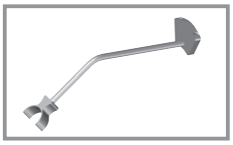
3. Acetabular Cup Trial
C/N varies by sizes

4. U-M II Cup Impactor
9206 - 1103

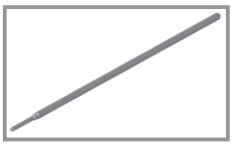


Cup Insertion

5. U-M II Alignment Tower, lateral
9206 - 5102



6. Alignment Rod
9206 - 5104



Cup orientation

Proper implant orientation can be guided by the external alignment system. The U-Motion II+ alignment system assists in directing a satisfactory level of acetabular cup abduction and anteversion.

Attach the quick connect **U-M II Alignment Tower**[5] to the cup impactor and thread the **Alignment Rod**[6] into left/right screw hole of the tower. Firmly secure the acetabular cup onto the tip of the cup impactor.

As the patient in lateral side position, make the vertical bar perpendicular to the operating table with the alignment rod parallel to the floor (Fig. 5). The cup impactor subsequently be rotated until the alignment rod is in line with the longitudinal axis of the patient body (Fig. 6). Then, an anatomic positioning of 45° abduction and 20° anteversion is built up.

Before implant insertion, attention should be taken as employing a cluster-holed cup where the screw holes must be placed superoposteriorly and/or inferoposteriorly (Fig. 7) for a correct orientation. The laser marks on outer face of the cup helps indicate the position of screw holes.

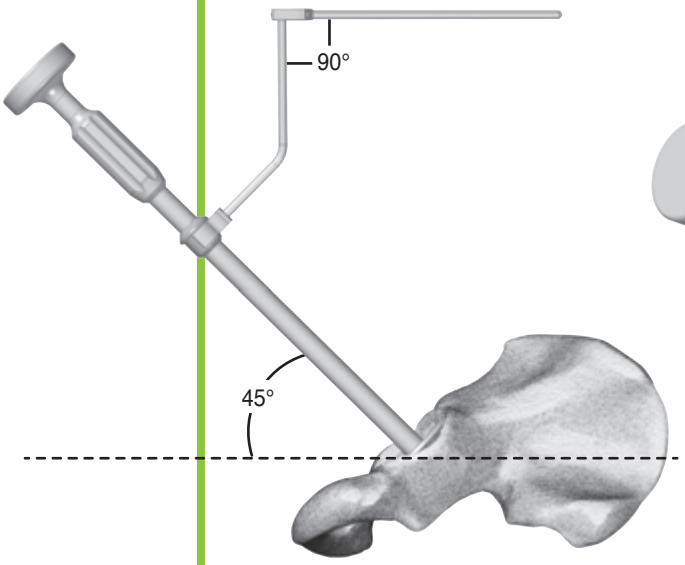


Fig. 5

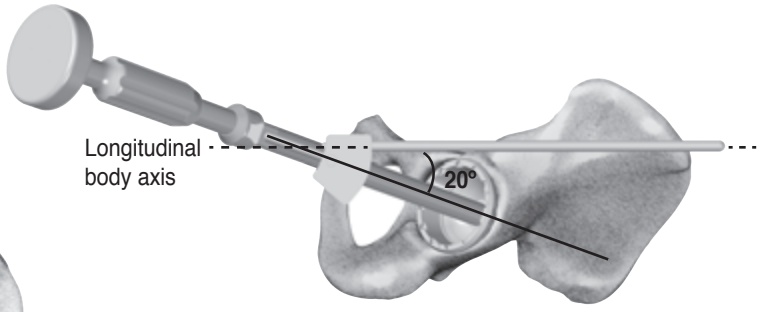


Fig. 6

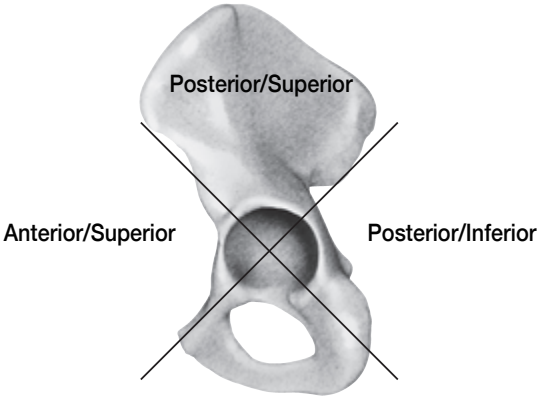


Fig. 7

Cup Insertion

Dome hole plugging

Each U-Motion II+ acetabular cup style is implanted with the same surgical technique. While handling the cup prosthesis at proper position and alignment, strike the cup impactor with a mallet until the cup is fully seated. By sighting through the apical hole or screw holes if present, confirm whether a congruent contact between bone-implant interface.

An apical hole cover among the **Screw-Hole Cover**[7] set is then plugged with a hex head **Straight Screwdriver**[8] by the **Ratchet Handle**[9] following cup seating (Fig. 8). Supplementary threaded covers is supplied for residual screw holes as well.

Surgical tip:
Run finger around the edge of dome holes to verify the covers are below the inner face of the cup.

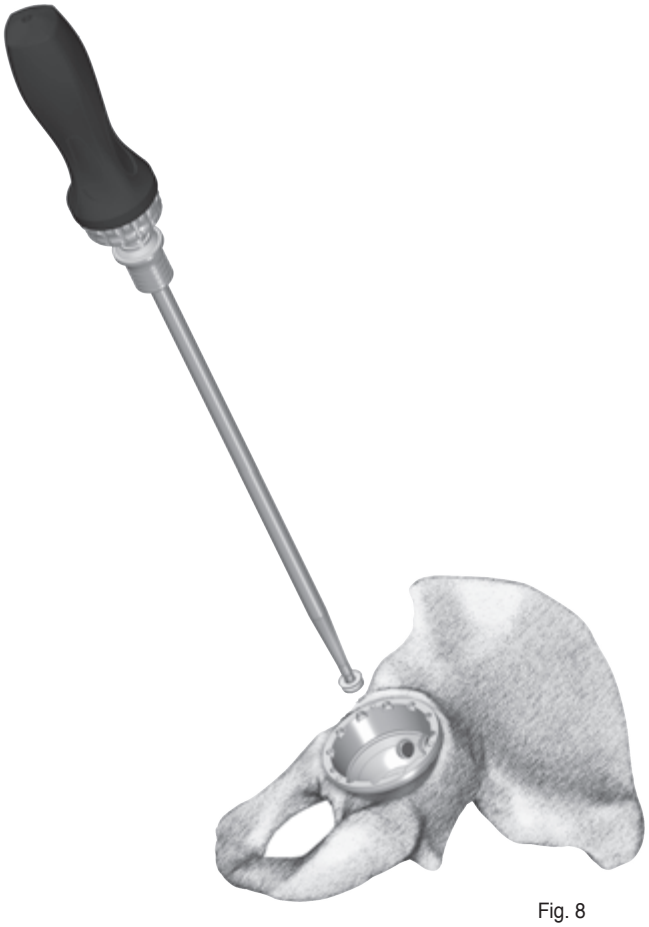
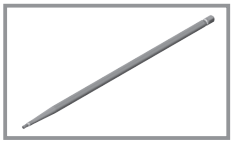


Fig. 8

7. Screw-Hole Cover
1306 - 1001

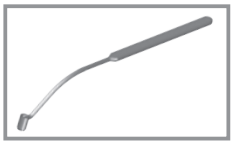
8. Straight Screwdriver
9206 - 1113



9. Ratchet Handle
9721 - 1041

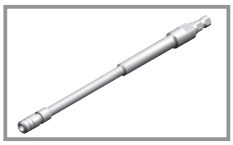
Cup Insertion

10. U-M II Drill Guide
9206 - 2101

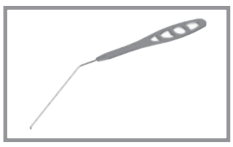


11. Drill Bit
9206 - 3115, 15mm
9206 - 3125, 25mm
9206 - 3135, 35mm
9206 - 3150, 50mm

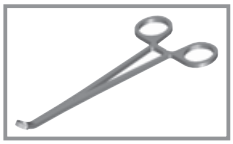
12. Modular Flex Shaft
9206 - 1107



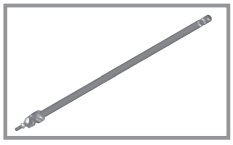
13. Depth Gauge
9206 - 7101



14. U-M II Screw Forceps
9206 - 5106



15. Universal Screwdriver
9206 - 1114



Screw insertion

The U-Motion II+ Acetabular System offers cluster-hole and no-hole cups. For primary cases with good bone stock, no-hole cup may be a preferred choice. However, additional screw fixation is necessary whenever a deficient acetabulum or poor bone quality is met.

The cluster-hole cup contains three screw holes. The screw placement should be inserted in the posterior superior quadrant of the acetabulum (Fig. 7) on a thick part of the ilium where there is a lower risk area of neurovascular damage.

Use the **U-M II Drill Guide**[10], **Drill Bit**[11] and **Modular Flex Shaft**[12] for drilled hole preparation (Fig. 9). The effective lengths of four drill bits are 15, 25, 35 and 50 mm. Carefully drill into acetabulum within selected holes, utilize the **Depth Gauge**[13] to determine an appropriate screw length (Fig. 10).

Grasp the screw with the **U-M II Screw Forceps**[14]. Attach the flexible **Universal Screwdriver**[15] to the screw head, then insert the screw using the ratchet handle (Fig. 11). Allowed screw angulation varies by as much as 32° (Fig. 12). Care should also be taken to confirm the screw is fully seated within the screw hole without damaging the liner.

Surgical tip:
Run finger around the edge of dome holes to verify inserted screws are below the inner face of the cup.

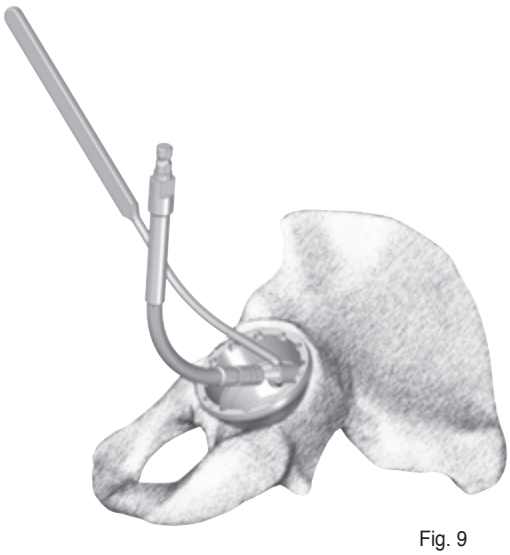


Fig. 9

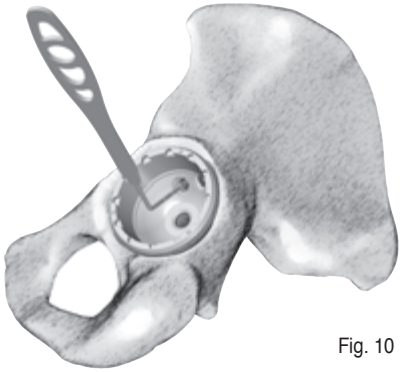


Fig. 10

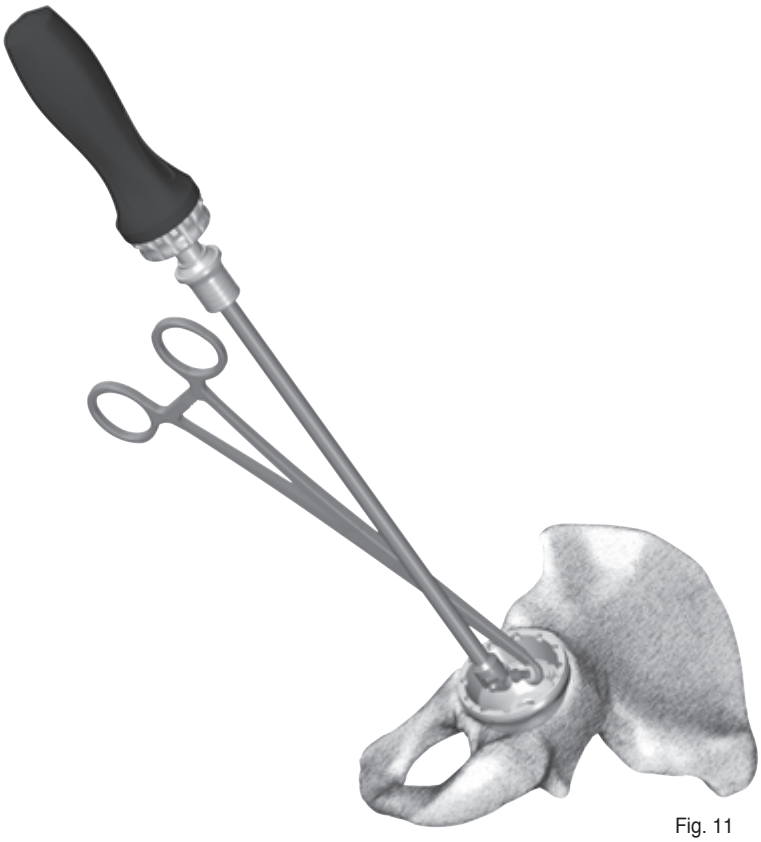


Fig. 11

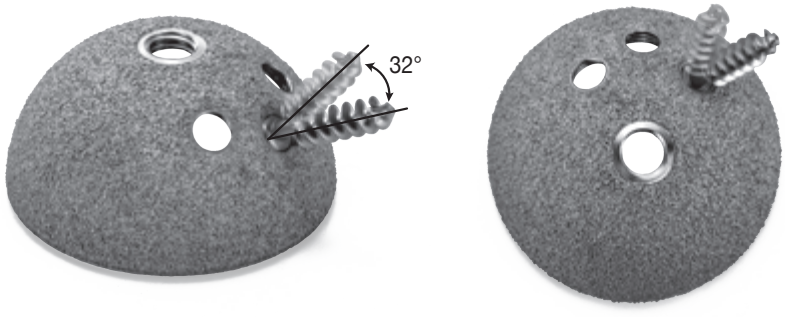
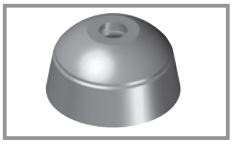


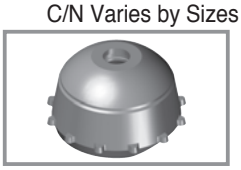
Fig. 12

Liner Trial Placement

16. Acetabular Liner Trials
C/N Varies by Sizes



17. Acetabular Liner Trials
20°
C/N Varies by Sizes



After securing the prosthetic cup into the acetabular cavity, introduce a size-matched **Acetabular Liner Trial**[16,17] for trial reduction (Fig. 13). Make sure the orientation of the liner trial if a 20º lipped liner is desired. Laser mark on the acetabular cup aids in final positioning of the lipped liner (Fig. 14). Ensure the liner trial is well-fixed within the cup before a overall evaluation of joint biomechanics.

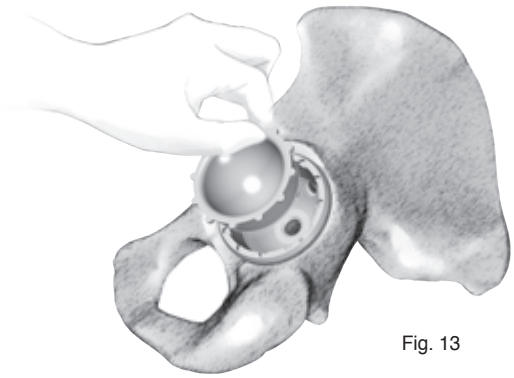


Fig. 13

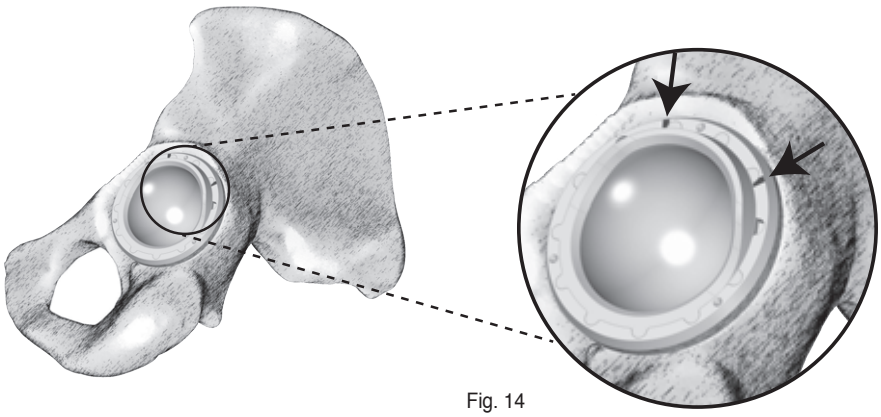


Fig. 14

Trial Reduction

Following acetabular and femoral preparation, the trial reduction can be carried out. Trial heads with 28 mm, 32 mm, 36 mm and 40 mm diameters are available options for surgeons to select an optimized size, which corresponds to the implanted acetabular cup.

Femoral heads with different neck length are also supplied for surgeons to make a proper determination and to revalidate preoperative decision. After final trial reduction, assessment of joint stability, range-of-motion, leg length and component size can be accomplished.

XPE Liner Insertion

Eliminate any particles on the inner surface of acetabular cup like bone fragment prior to insert the final liner. It is important to inspect the cup/liner locking groove is free from debris.

Attach a **Liner Impactor**[18] matched with the selected liner to the tip of the **Universal Handle**[19]. Place the XPE liner into acetabular cup by hand making sure that the tabs on the liner is aligned with corresponding scallops in the acetabular cup (Fig. 15). There are 12 scallops in the cup that provides variable liner position in 30 degree increments, for a well alignment of the 0° lipped liner.

Impact the universal handle until the liner is fully seated (Fig. 16). To confirm a complete seating of the liner, palpate around the face of the cup.

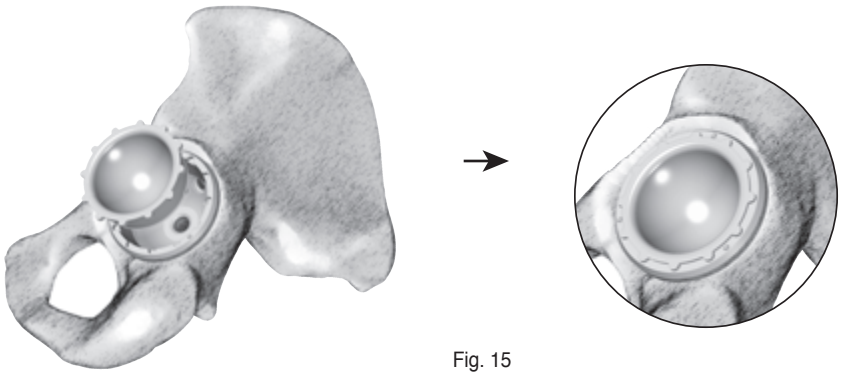


Fig. 15

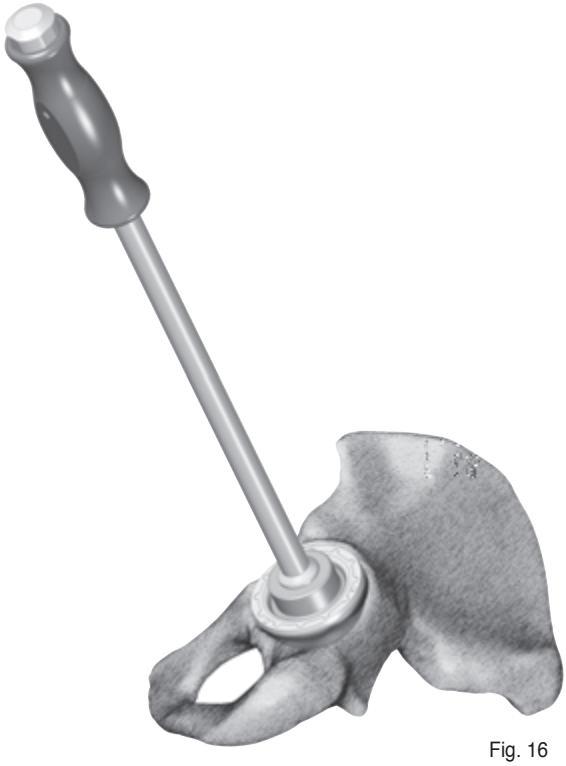
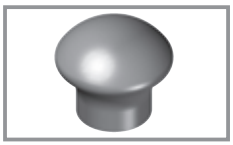


Fig. 16

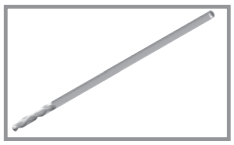
18. Liner Impactor
9206 - 5028, 28 mm
9206 - 5032, 32 mm
9206 - 5036, 36 mm
9206 - 5040, 40 mm



19. Universal Handle
9206 - 1112, 230 mm

XPE Liner Extraction

20. Straight Drill
9201 - 4201



Utilize a **Straight Drill**[20] combined with the drill guide to perform an eccentric hole in the polyethylene liner (Fig. 17). Applying a hex-driver, a cancellous screw is then be advanced into the drilled hole until dislodgement of the polyethylene liner from the acetabular cup (Fig. 18).

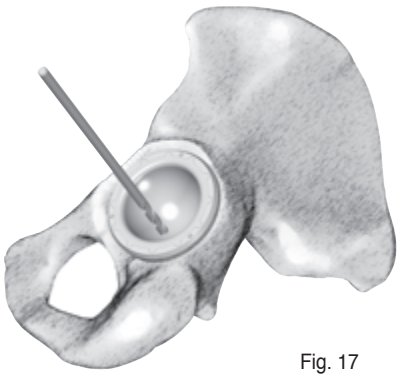


Fig. 17

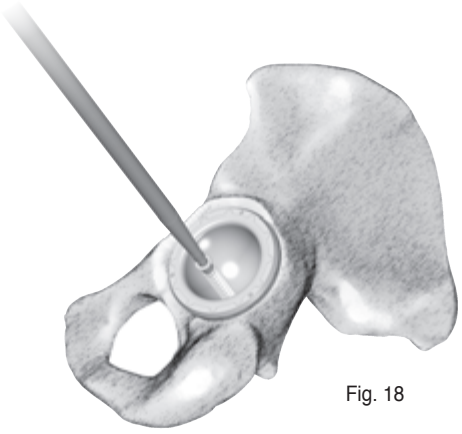


Fig. 18

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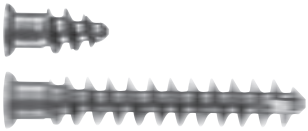
Orthopedic Corporation

Each Step
We Care

Order Information
Implants

★ *Special Order Items*



Ti Cancellous Screw, Ø 6.5 mm	
Length (mm)	Cat. No.
15	5206-1015
20	5206-1020
25	5206-1025
30	5206-1030
35	5206-1035
40	5206-1040
★45	5206-1045
★50	5206-1050

	Screw Hole Covers
Cat. No.	1306-1001

Screw hole covers are pre-assembled with multi-hole cup.

	Cluster-Hole Cup	No-Hole Cup
Cup Size (mm)	TPS Plus	TPS Plus
Ø 44	1306-3144	1306-3344
Ø 46	1306-3146	1306-3346
Ø 48	1306-3148	1306-3348
Ø 50	1306-3150	1306-3350
Ø 52	1306-3152	1306-3352
Ø 54	1306-3154	1306-3354
Ø 56	1306-3156	1306-3356
Ø 58	1306-3158	1306-3358
Ø 60	1306-3160	1306-3360
Ø 62	1306-3162	1306-3362
★ Ø 64	1306-3164	1306-3364
★ Ø 66	1306-3166	1306-3366
★ Ø 68	1306-3168	1306-3368
★ Ø 70	1306-3170	1306-3370

★ *Special Order Items*

	XPE Liner		E-XPE Liner		Head Size	
Cup Size (mm)	Standard	20° lipped	Standard	20° lipped	CoCrMo	*delta* Ceramic
Ø 44	1406-3844	1406-5844	1406-7144	1406-7544	28 mm	28 mm
Ø 46	1406-3846	1406-5846	1406-7146	1406-7546		
Ø 48	1406-3248	1406-5248	1406-7248	1406-7648	32 mm	32 mm
Ø 50	1406-3250	1406-5250	1406-7250	1406-7650		
Ø 52	1406-3652	1406-5652	1406-7352	1406-7752	36 mm	36 mm
Ø 54	1406-3654	1406-5654	1406-7354	1406-7754		
Ø 56	1406-3656	1406-5656	1406-7356	1406-7756	36 mm	40 mm
Ø 58	1406-3658	1406-5658	1406-7358	1406-7758		
Ø 60	1406-3660	1406-5660	1406-7360	1406-7760		
Ø 62	1406-3662	1406-5662	1406-7362	1406-7762		
★ Ø 64	1406-3664	1406-5664	1406-7364	1406-7764		
★ Ø 66	1406-3666	1406-5666	1406-7366	1406-7766		
★ Ø 68	1406-3668	1406-5668	1406-7368	1406-7768		
★ Ø 70	1406-3670	1406-5670	1406-7370	1406-7770		

	Head					
Cup Size (mm)	CoCrMo			*delta* Ceramic		
	1201-1028	-3	28 mm			
	1201-1128	+ 0	28 mm	1203-5028	-2.5	28 mm
Ø 44	1201-1228	+ 2.5	28 mm	1203-5228	+ 1	28 mm
Ø 46	1201-1428	+ 5	28 mm	1203-5428	+ 4	28 mm
	1201-1628	+ 7.5	28 mm			
	1201-1828	+ 10	28 mm			
	1201-1032	-3	32 mm			
	1201-1132	+ 0	32 mm	1203-5032	-3	32 mm
Ø 48	1201-1232	+ 2.5	32 mm	1203-5232	+ 1	32 mm
Ø 50	1201-1432	+ 5	32 mm	1203-5432	+ 5	32 mm
	1201-1632	+ 7.5	32 mm	1203-5632	+ 8	32 mm
	1201-1832	+ 10	32 mm			
				1203-5036	-3	36 mm
Ø 52				1203-5236	+ 1	36 mm
Ø 54				1203-5436	+ 5	36 mm
	1201-1036	-3	36 mm	1203-5636	+ 9	36 mm
Ø 56	1201-1136	+ 0	36 mm			
Ø 58	1201-1236	+ 2.5	36 mm			
Ø 60	1201-1436	+ 5	36 mm	1203-5040	-3	40 mm
Ø 62	1201-1636	+ 7.5	36 mm	1203-5240	+ 1	40 mm
★ Ø 64	1201-1836	+ 10	36 mm	1203-5440	+ 5	40 mm
★ Ø 66				1203-5640	+ 9	40 mm
★ Ø 68						
★ Ø 70						

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

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Instrument Catalog

Acetabular Cup Trials	Catalog Number	Description
	1306-2044	Φ44 mm
	1306-2046	Φ46 mm
	1306-2048	Φ48 mm
	1306-2050	Φ50 mm
	1306-2052	Φ52 mm
	1306-2054	Φ54 mm
	1306-2056	Φ56 mm
	1306-2058	Φ58 mm
	1306-2060	Φ60 mm
	1306-2062	Φ62 mm
	1306-2064	Φ64 mm
	1306-2066	Φ66 mm
	1306-2068	Φ68 mm
	1306-2070	Φ70 mm

Instrument Catalog

Acetabular Liner Trials	Catalog Number	Description	Head Size
	1406-4844	44 mm	28 mm
	1406-4846	46 mm	
	1406-4248	48 mm	32 mm
	1406-4250	50 mm	
	1406-4652	52 mm	36 mm
	1406-4654	54 mm	
	1406-4056	56 mm	40 mm
	1406-4058	58 mm	
	1406-4060	60 mm	
	1406-4062	62 mm	
	1406-4064	64 mm	
	1406-4066	66 mm	
	1406-4068	68 mm	
	1406-4070	70 mm	

Acetabular Liner Trials, 20°	Catalog Number	Description	Head Size
	1406-6844	44 mm	28 mm
	1406-6846	46 mm	
	1406-6248	48 mm	32 mm
	1406-6250	50 mm	
	1406-6652	52 mm	36 mm
	1406-6654	54 mm	
	1406-6056	56 mm	40 mm
	1406-6058	58 mm	
	1406-6060	60 mm	
	1406-6062	62 mm	
	1406-6064	64 mm	
	1406-6066	66 mm	
	1406-6068	68 mm	
	1406-6070	70 mm	

Instrument Catalog

Catalog Number	Description
9201-4201	Straight drill

Catalog Number	Description
9201-7101-RA	Depth gauge

Catalog Number	Description
9206-7101	Depth gauge

Catalog Number	Description
9206-1101	Cup reamer handle, EZ clean

Instrument Catalog

Catalog Number	Description
9203-4042	Φ42 mm
9203-4043	Φ43 mm
9203-4044	Φ44 mm
9203-4045	Φ45 mm
9203-4046	Φ46 mm
9203-4047	Φ47 mm
9203-4048	Φ48 mm
9203-4049	Φ49 mm
9203-4050	Φ50 mm
9203-4051	Φ51 mm
9203-4052	Φ52 mm
9203-4053	Φ53 mm
9203-4054	Φ54 mm
9203-4055	Φ55 mm
9203-4056	Φ56 mm
9203-4057	Φ57 mm
9203-4058	Φ58 mm
9203-4059	Φ59 mm
9203-4060	Φ60 mm
9203-4061	Φ61 mm
9203-4062	Φ62 mm
9203-4063	Φ63 mm
9203-4064	Φ64 mm
9203-4065	Φ65 mm
9203-4066	Φ66 mm
9203-4067	Φ67 mm
9203-4068	Φ68 mm
9203-4069	Φ69 mm
9203-4070	Φ70 mm

Instrument Catalog

Catalog Number	Description
9206-1103	U-M II Cup impactor

Catalog Number	Description
9206-1107	Modular flex shaft

Catalog Number	Description
9206-1112	Universal handle, long

Catalog Number	Description
9206-1113	Straight screw driver

Instrument Catalog

Catalog Number	Description
9206-1114	Universal screw driver

Catalog Number	Description
9206-2101	U-M II Drill guide

Catalog Number	Description
9206-3115	Drill bit, 15mm
9206-3125	Drill bit, 25mm
9206-3135	Drill bit, 35mm
9206-3150	Drill bit, 50mm

Catalog Number	Description
9206-5028	Liner Impactor, 28 mm
9206-5032	Liner Impactor, 32 mm
9206-5036	Liner Impactor, 36 mm
9206-5040	Liner Impactor, 40 mm

Catalog Number	Description
9206-5102	U-M II Alignment tower, lateral

Instrument Catalog

Catalog Number	Description
9206-5104	Alignment rod

Catalog Number	Description
9206-5106	U-M II Screw forceps

Catalog Number	Description
9206-8010	U-M II Case #1
9206-8020	U-M II Case #2

Catalog Number	Description
9721-1041	Ratchet handle

Instrument Catalog (MIS Device)

Catalog Number	Description
9203-8102-RC	MIS set case

Catalog Number	Description
9206-1102-RA	Cup reamer handle, Offset

Catalog Number	Description
9206-1105	Cup impactor, offset

Catalog Number	Description
9206-1111	Universal handle, offset

Catalog Number	Description
9206-5103	Alignment tower, **supine**

UNITED U-Motion II+ ™ Acetabular Components Safety statement

DESCRIPTION

UNITED U-Motion II Acetabular components include acetabular shell, Delta ceramic and XPE cup liners, Ti cancellous screw and metallic screw-hole covers. It is used with the United U2 hip stems and the ceramic and metallic femoral heads. It is a modular type of product system with hemispherical design with HA/Ti plasma spray (HA cup, HA+ cup) or Ti plasma spray (PS cup, PS+ cup) on the metallic shell. Three types for different screw hole distributions are available：cluster-hole, no-hole, and multi-hole. Screw holes with spherical geometry are intended for variable screw fixation angle. Delta ceramic and XPE cup liners fit directly into the metallic shell by taper and snap-in locking mechanism, respectively. XPE cup liner is capable of 12 options for angle adjustment. The Delta ceramic liner is a high-purity alumina ceramic compound in accordance with ISO 6474-2.

Note: The delta ceramic liners are not for sale in the US.

MATERIALS

ASTM F-620 Ti alloy (raw materials: ASTM F-136)	Acetabular cup, HA / Ti plasma spray or Ti plasma spray
ASTM F-1580 Titanium	Metallic powder for plasma spray
ASTM F-1185 Hydroxylapatite	Hydroxylapatite powder for plasma spray
ASTM F-136 Ti alloy	Ti cancellous screw, screw-hole covers
ISO 6474-2 Highly pure aluminum matrix with zirconia reinforcement	Ceramic acetabular cup liner--delta
ISO 5834/ASTM F-648 extruded highly-cross linked UHMWPE bars	XPE cup liner

INDICATIONS

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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 previous 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.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.

The device is intended 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 that 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 that can lead to failure of the fixation of the device or to failure of the device itself.
6. The U-Motion II acetabular components are designed for uncemented application and single use only.
7. For cup positions which are not recommended, Ceramic Liner should not be used. For cup positions which inclination exceed or fall below a value of 40-45°, anteversion exceed or fall below a value of 10-20°, ceramic liner should not be used. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the femoral head from the ceramic liner. For cups in retroversion, no ceramic liners should be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the ceramic liner associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reactions, loosening of the prosthesis and in extreme cases ceramic breakage. Ensure adequate joint tension is achieved on implantation, as luxation can lead to the adverse results aforementioned listed.

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 ceramic liner had been reported although in a small percentage of cases.
5. Acetabular cup fracture may occur in the heavy, physically active individual or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
6. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
7. 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.
8. Acetabular pain may occur after acetabular replacement due to loosening of the implant or tissue inflammation.
9. 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
10. Adverse effects may necessitate re-operation, revision, arthrodesis of the involved joint, Girdle-stone and/or amputation of the limb.
11. 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 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. Also, particulate can be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

WARNINGS

1. This device should only be applied by qualified and specially trained surgeons who have the corresponding knowledge and experience in the field of hip joint replacement. The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
2. Factors outside the control of UOC are not UOC's responsibility, including any modification after delivering to the hospitals and any mishandled pre-operation, intra-operation or post-operation. The operating surgeon shall be responsible for any negative effects and complications resulting from non-compliance with the user instructions, improper treatment of the material or an incorrect assessment of indications.
3. The U-Motion II acetabular components are designed for single use only. Never use prosthetic components which have been used before.
4. Surgeon must inform the patient about the relative information of this device, including its effects and the possible risks during operation, possible post-surgical complications, as well as inspect the materials biocompatibility of the products used with this device.
5. If the product does not meet the specifications, please immediately notify the supplier, and dilate the problems that occur. If possible, please return the product to the supplier.
6. Only unused implants taken from the original packaging may be used. Never reuse an implant again, even though it may appear undamaged. Reuse of this product will cause the risk of cross infection and unpredictable health threat. Likewise, a ceramic liner with any kind of damage must not be used, but discarded instead. This also applies to a ceramic liner that has fallen to the floor, for example. With ceramic liners that have already been used, there is risk that they could have damages invisible to the naked eye. Since any kind of damage can adversely affect the ceramic's functionality and/or stability, a safe use cannot be guaranteed. For this reason, only unused and undamaged ceramic liners packaged in their original packaging may be implanted.
7. Exclusively use brand-new components for the configuration of metal shells and inserts, as an exact fit of the insert in the shell must be guaranteed.
8. On rare occasions, in vivo fracturing of the ceramic liner may occur. In order to minimize this risk, the ceramic liner was individually examined before delivery. One cause of failure can be the incorrect fixation of the ceramic liner with the cup. The use of prosthesis components which are not released by UOC for combination with a ceramic liner can also lead to the fracture of the ceramic liner. The same applies if the recommended position of the ceramic liner (inclination/anteversion) is not observed.
9. The position of the prosthesis components has a direct influence on the range of movement and thus represents a potential risk of impingement, luxation or subluxation. For cup casings which are too steep, surface pressure on the acetabular edge increases. This can lead to increased wear and tear. The cup position is oriented in accordance with the safety zone described by Lewinnek.
10. The joint may luxate with strenuous exercise, or subluxate through the impingement of implant components or soft tissues.
11. The inclination of the cup components should not significantly exceed or fall below a value of 40-45°. The anteversion of the cup components should not significantly exceed or fall below a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the head from the ceramic liner. For a cup which lies outside the above-mentioned values, a ceramic liner must not be used. For cups in retroversion, no ceramic liners should be used.
12. Bearing areas must always be clean and free of debris prior to assembly.
13. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.
14. UOC strongly advises against the use of another manufacturer's femoral component with any UOC acetabular cup component. This device may only be combined with prosthetic components released by UOC for use with this device. U-Motion II acetabular cups can only collocate with Delta ceramic liners or XPE cup liners in this system. Only ever use Delta ceramic liners with UOC ceramic femoral heads. Coupling with a different femoral head or with a ceramic ball from other manufacturers is not allowed. Any such use will negate the responsibility of UOC for the performance of the resulting mixed component implant.
15. Ceramic head replacements (See Fig. 6):-In case a ceramic component breaks, a pairing of metal (ball head) with polyethylene (liner) is contraindicated in a revision.

PRECAUTIONS

PREOPERATIVE

1. Surgeon must inform the patient that an artificial joint cannot be subjected to the same demands as a natural joint, and the patient should not have unrealistic functional expectations. Surgeons should instruct patients about the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient's weight or activity, and be taught to govern their activities accordingly. Any kind of competitive sport, i.e. sport types with jolting or jerking movements, involving the artificial joint is contraindicated and leads to excessive strains. 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. An additional risk is posed by patients with high body weight, with a weak osseous system or by those who are physically very active. Brief, extreme overloading such as a trauma, an accident or excessive strain can lead to fracturing, sometimes long after the event. The patient also must be informed of possible post-surgical complications.
2. The implant must be carefully preserved and transported properly. Cut or scratch the surface of the implant will significantly reduce its static, fatigue strength or influence its friction characteristics. These may have small defects and internal stress patterns invisible to the naked eye which may lead to early failure of the device. Implants and instruments are not stored in the salt air.
3. Enough sizes of the implants should prepare for surgery, including larger and smaller size. Special size is also recommended to prepare.
4. Pay attention to special conditions of patient as the description of contraindication.
5. Preoperative screening should be considered if the materials of the device cause allergy or other reaction of patients although this condition occurs seldom.
6. Radiographic templates are available to assist in the preoperative prediction of component size and style.
7. Surgeon must read the surgical protocol carefully before operation.
8. Check the colored sterilization indicator of the packaging.
9. The labels, especially the size designation the package labels, must be checked to see that they match the labels on the devices.

INTRAOPERATIVE

1. The UOC Surgical Protocols provide additional procedural information.
2. Appropriate selection, placement and fixation of the femoral stem and/or acetabular components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics 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. If use bone screws with acetabular components, care must be taken not to damage blood vessels, nerves or abdominal tissue when drilling screw holes and inserting screws. Use drill guide before drilling screw holes and measure the depth of drilling by the depth gauge for selecting the proper length of screw. Don't use screws longer than 50 mm. Bone screws must be completely fixed into the screw hole of the acetabular shell, so that the acetabular liner can properly be embedded within the acetabular shell.
4. Before place the Delta ceramic or XPE cup liner into the cup, make sure that any foreign matter from the prosthesis components, such as tissue particles, bone or cement particles from the surface of the acetabulum cup has been removed.
5. The Delta ceramic or XPE cup liner should be placed and fitted in accordance with UOC's instructions (see the figures below).
6. At time of assembly, inner taper of the shell must be clean and dry to ensure proper seating and assembly security.

7. For ceramic liner insertion, fix the ceramic liner centrally in place in the metal shell with the greatest of care, following the diagrams below (Figs. 1~5) provided for this purpose. A perfect fit of the ceramic liner in the cup must ensue.
8. Before the final fitting of the Delta ceramic liner with a plastic impactor, the correct fit of the liner should be tested with the finger. Never bring a metal hammer into contact with the Delta ceramic liner.
9. For XPE cup liner insertion, ensure the tabs on the liner are aligned with the indentions in the shell. Impact firmly with the mallet until the liner is fully seated. The liner should sit flush with the face of the shell.
10. Care must be taken to protect the components from being marred, nicked or notched as a result of contacting with metal or abrasive objects.
11. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
12. The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.

- Before a decision is made to implant a Delta ceramic or XPE cup liner, a sample inlay made of plastic is placed into the cup and the stem components are implanted. Please take care that the plastic insert will be removed after checking.
- The joint is tested for free movement and stability using sample heads of the intended diameter. Please take care that the plastic femoral head will be removed after checking.
- The joint may not luxate with movement, or subluxate through the impingement of implant components or soft tissues.

POSTOPERATIVE

1. Postoperative care and instructions for patients are very important. Postoperative weight bearing must increase gradually and individually.
2. After postoperative, patients must be reminded, do not make large movement of hip joint individually with no help or without auxiliaries, especially when going to the toilet or performing the higher degree of activities.
3. Moving the patient carefully and paying attention to support the affected area and avoid exerting pressure on it.
4. The postoperative treatment should take care of the strength of muscles around the hip and increase activity gradually.
5. Regular X-rays shall be taken to evaluate if the implant move, loose, bend, fracture or the cement or bone loss. If these conditions occur, please pay attention to the progress of condition and consider the advantage of revision.
6. Should consider the use of antibiotics in patients to prevent bacterial infection.

PACKAGING AND LABELING

1. This device is sterile and double packaged to ensure the product is suitable for surgery at any time. The sealed package can protect the implants and keep the sterilized condition under normal storage and transport.
2. The packaging of all products should be inspected for their integrity and should only be accepted with proper packaging and labeling intactness.
3. All implants should be stored in their original packaging in a clean and dry environment.
4. If the sterile blister pack became wet or damaged, the implants should not be used and be returned to the supplier.

STERILIZATION

1. All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label
2. Ceramic and metal components are sterilized by gamma radiation at at least 25 kGy, while the plastic components are ethylene oxide sterilized. All components can be verified from the colored sterilization indicator on the packaging.
3. The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of any flaws, 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.
4. This device delivered in sterilized form and must be kept unopened in the original packaging until it is ready to be used. Check the sterilization expiry date on the sterile packing and check the protective packing for damage prior to use. If the sterilization expiry date has passed or in case of any damage to the protective packaging, the implants must not be used or re-sterilized and must be discarded or returned to the supplier.
5. Aseptic methods must be followed when removing the component from its original packaging and during the entire implantation. In the event of contamination, this product must be discarded.
6. Ceramics sterilized by gamma rays may be changed in color. This has no influence on the strength or any other characteristic of the ceramic liners.

RE-STERILIZATION

If the package is opened, but the product is not used, the component must not be resterilized (including Delta ceramic and XPE components) and must be returned to the supplier. A suitable handling will be done. HA / Ti plasma spray cup needs special clean procedures and ceramic components cool down quickly after sterilization with high temperature could affect their mechanical properties.

STORAGE AND HANDLING

1. All implants must be stored unopened in the original packaging.
2. The protective packaging must be inspected for signs of damage before the devices are removed, since this could affect the sterility. The sterility expiry date must be observed. If the protective packaging is damaged or the sterility date has passed, the implants must be returned to UOC.Protection may only be removed directly before use.
3. The implants which can no longer be used may be returned to the manufacturer for correct disposal.
4. Ceramic liners are extremely sensitive to damage. Even small scratches or impact points can cause wear, tear or fracture and lead to complications. Extremely careful handling is therefore required.

Interaction with drugs

There have been no reported interactions with drugs to date.

SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT

U-Motion II Acetabular Components have not been evaluated for safety and compatibility in the MR environment. U-Motion II Acetabular Components have not been tested for heating or migration in the MR environment.

United®
Orthopedic Corporation

20 Fairbanks, Suite 173, Irvine, CA 92618
Tel: (949) 328-3366 Fax: (949) 328-3367
www.uocusa.com

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Each Step **We Care**

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

For our valued distribution partners, you can reach our customer service associates at customerservice@uocusa.com

For assistance on general and/or product related inquiries, please email us at sales@uocusa.com

Please refer to the product-specific package inserts for important information, including indications, contraindications, warnings, precautions, and potential adverse effects.

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