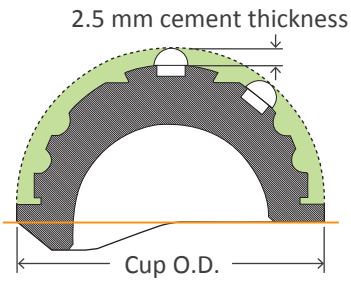
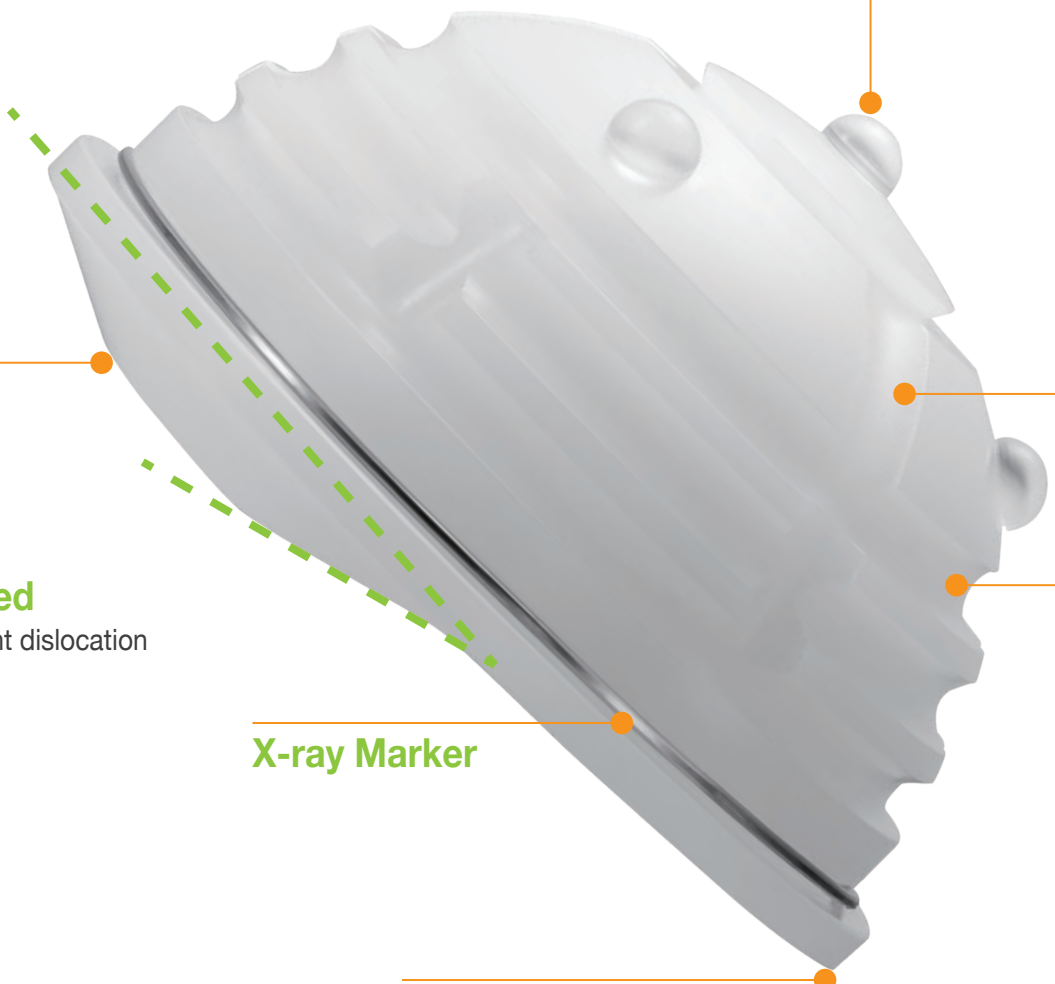
United®
Orthopedic Corporation

Full XPE™ Cup



PMMA Spacer

Uniform 2.5 mm cement thickness; the cement mantle is built within the outer dimension of acetabular cup.



20° lipped

Prevent joint dislocation

X-ray Marker

Pressurizing Flange

Prevent cement leakage during pressurization

Horizontal & Vertical Groove

Facilitate cement-implant fixation

References

1. The National Joint Registry of England and Wales. 2012. www.njrcentre.org.uk
2. Howie et al. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. J Bone Joint Surg Am. 2012 Jun 20;94(12):1095-102.
3. Amstutz et al. Prevention and treatment of dislocation after total hip replacement using large diameter balls. Clin Orthop Relat Res. 2004 Dec;(429):108-16.
4. Exeter Contemporary flange cup surgical technique, Stryker.

Better Range of Motion, Better Satisfaction

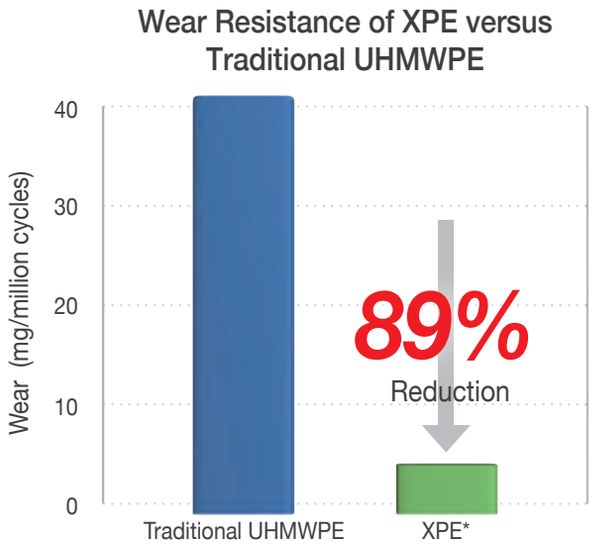
The use of larger size of femoral head is a growing trend[1]. Benefits are known to reduce dislocation rate[2] and improve range of motion[3].

Cup Size (mm)	UOC	Stryker
	Full XPE Cup	Exeter Contemporary[4]
 42	 **26 mm**	*N.A.
 44	 **28 mm**	 26 mm
 48	 **32 mm**	 28 mm
 52	 **36 mm**	 32 mm

*N.A. : Size not available

Improved Longevity with the Use of XPE Material

United high cross-linked PE (XPE) shows **89%** wear reduction comparing to traditional UHMWPE.

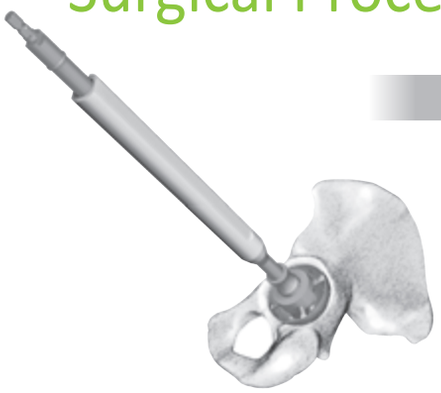


* Report Number: UOC-RD-TR-10012

Experience the Ease of Handling

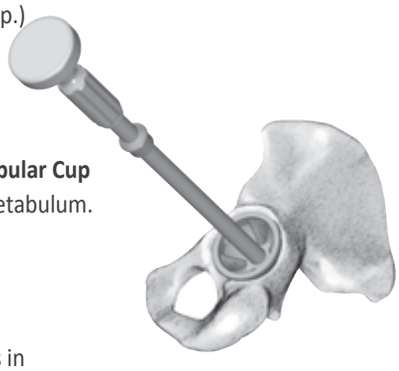
With the featured locking mechanism, the innovated cup positioner secures all sizes of implants easily.

Surgical Procedures



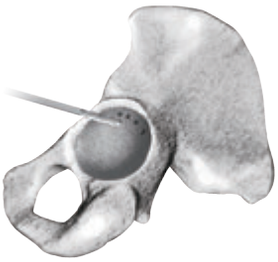
1. Acetabular Reaming

Hold the **Cup Reamer Handle** at abduction of 40°- 45° and anteversion of 15°- 20°. Utilize the smallest **Cup Reamer** to start acetabular reaming, then subsequently proceed with enlarged reamer in 2 mm increment until exposure of cancellous bone.
The final implant size should match with the last reamer used. (e.g., if the last reamer size is 52 mm, select 52 mm implant; 2.5 mm cement thickness is built within the outer dimension of acetabular cup.)



2. Cup Trialing

Once a proper acetabular cavity is established, place a **Acetabular Cup Trial** to check the fit, contact and congruency of prepared acetabulum.

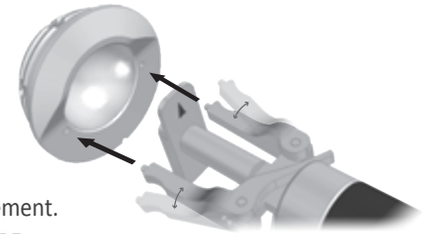


3. Preparation of Anchoring Hole

Use **Straight Drill** to introduce multiple small anchoring holes in acetabular wall for the enhancement of cement fixation is a recommended procedure, care must be taken not to penetrate into the pelvis.

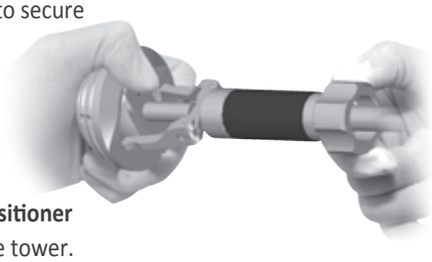
4. Cement Introduction

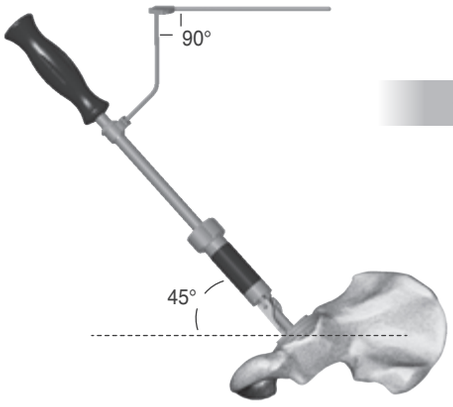
Proper cleaning, lavage and dry the prepared acetabulum is recommended before introduce bone cement.



5. Cup Mounting

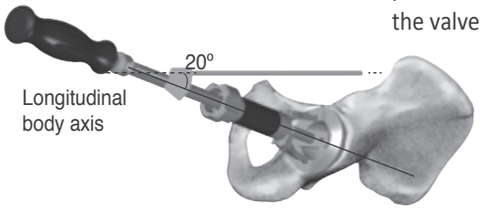
Select the cup size based on the last reamer used.
XPE cup is loaded with **XPE Cup Positioner** by pin-hole engagement.
Laser mark on the plate should align with 20° lipped part of XPE cup.
Hold the cup with thumb on the plate while locking the valve to secure the cup and positioner.





6. Cup Insertion

Attach the quick connect **Alignment Tower** to the **XPE Cup Positioner** and thread the **Alignment Rod** into left/right screw hole of the tower.
As the patient in lateral side position, make the vertical bar perpendicular to the operating table with the **Alignment Rod** parallel to the floor. Rotate the positioner until the alignment rod is in line with the longitudinal axis of the patient body. Then, an anatomic positioning of 45° abduction and 20° anteversion is built up.
Place the 20° lipped part in the ideal region of acetabulum and pressurize the cup into cement until cement is polymerized. Unlock the valve to disengage the **XPE Cup Positioner** from the cup.



Order Information

★ *Special Order Items*

XPE Cemented Cup

Catalog No.	Size (Outer Diameter)	Inner Diameter
★1302-3042	42 mm	26 mm
1302-3844	44 mm	28 mm
1302-3846	46 mm	28 mm
1302-3248	48 mm	32 mm
1302-3250	50 mm	32 mm
1302-3652	52 mm	36 mm
1302-3654	54 mm	36 mm
1302-3656	56 mm	36 mm
1302-3658	58 mm	36 mm
1302-3660	60 mm	36 mm
1302-3662	62 mm	36 mm

Trials & Instruments

Cup Trial

Catalog No.	Description
★1306-2042	Φ 42 mm
1306-2044	Φ 44 mm
1306-2046	Φ 46 mm
1306-2048	Φ 48 mm
1306-2050	Φ 50 mm
1306-2052	Φ 52 mm
1306-2054	Φ 54 mm
1306-2056	Φ 56 mm
1306-2058	Φ 58 mm
1306-2060	Φ 60 mm
1306-2062	Φ 62 mm

Cup Reamer

Catalog No.	Description
9203-4042	Φ 42 mm
9203-4044	Φ 44 mm
9203-4046	Φ 46 mm
9203-4048	Φ 48 mm
9203-4050	Φ 50 mm
9203-4052	Φ 52 mm
9203-4054	Φ 54 mm
9203-4056	Φ 56 mm
9203-4058	Φ 58 mm
9203-4060	Φ 60 mm
9203-4062	Φ 62 mm

Catalog No.	Description
9201-4201	Straight Drill

Catalog No.	Description
9206-1103	Cup Impactor

Catalog No.	Description
9203-1201-RA	Cup Reamer Handle

Catalog No.	Description
9206-5102	Alignment Tower, lateral

Catalog No.	Description
9203-1328	XPE Cup Positioner

Catalog No.	Description
9206-5104	Alignment Rod

Safety Statement of United Full XPE Cup

Important
This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information

INDICATIONS
Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, and painful hip dysplasia; Inflammatory degenerative joint disease such as rheumatoid arthritis; Correction of function deformity; Revision procedures where other treatments or devices have failed; Treatment of nonunion and femoral neck fractures of the proximal femur with head involvement that is unmanageable using other techniques. This device is a single use implant and intended for cemented use only.

CONTRAINDICATIONS
Any active or suspected latent infection in or about the hip joint. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis. Skeletal immaturity. 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.

POSSIBLE ADVERSE EFFECT
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. Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
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. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
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.
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. Intraoperative fissure, fracture, or perforation of the acetabulum can occur due to impaction of the component into the prepared acetabulum. Postoperative acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock. Metal sensitivity reactions have been reported following joint replacement. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb. 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
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. 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. This device is designed for single use only. Never use prosthetic components which have been used before. 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. 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. 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. 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 cups which are too steep, surface pressure on the acetabular edge increases. This can lead to increased wear. The cup position is oriented in accordance with the safety zone described by Lewinnek. The joint may luxate with strenuous exercise, or subluxate through the impingement of implant components or soft tissues. The inclination of the cups should not significantly exceed or fall below a value of 40-45°. The anteversion of the cups 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 cup. Bearing areas must always be clean and free of debris prior to assembly. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize. 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. Any such use will negate the responsibility of UOC for the performance of the resulting mixed component implant.

United® Orthopedic Corporation

Each Step **We Care**

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