

TRIBOFIT™

ACETABULAR BUFFER

DESIGN RATIONALE | TRAINING MANUAL



THE CLEAR ADVANTAGE OVER POLYETHYLENE
RESTORING MORE NATURAL FUNCTION WITH A CARTILAGE-LIKE MATERIAL

DESIGN RATIONALE

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ACETABULAR BUFFER



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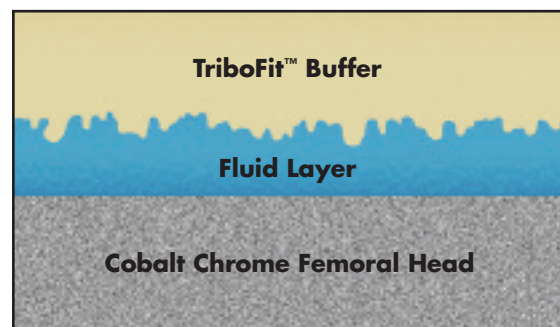
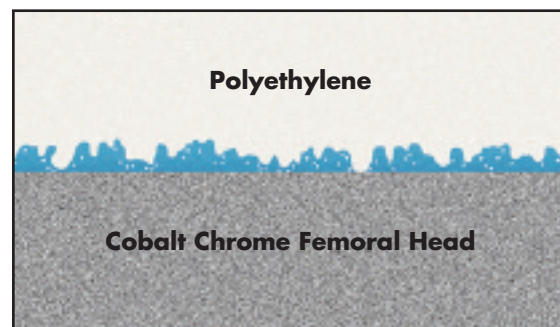


THE FIRST TRUE HIP REPLACEMENT

Tribology – the Importance of Design, Friction, Wear and Lubrication

Webster defines tribology as the scientific study or evaluation of “design, friction, wear and lubrication of interfacing surfaces in relative motion.”¹ Friction develops from the interaction of moving surfaces, or bodies in contact – one surface is called the solid body and the second surface is called the counterbody. Friction may lead to a loss of material, which is known as wear. Friction can be reduced by lubrication, wherein a material – usually a fluid film layer – interposes the two moving bodies. *Microelasto-hydrodynamic lubrication* occurs when the pressure in the fluid film layer is sufficiently high to ensure that total separation of the two moving bodies is maintained. By ensuring that microelasto-hydrodynamic lubrication is maintained, friction can be nearly eliminated, thus decreasing the potential for wear.

The natural hip is a synovial joint comprised of the synovial fluid and the cartilage on the femoral head and the acetabulum, and has excellent tribological characteristics of low friction, high load carrying capabilities, high shock absorption and long endurance. Optimizing tribology in the hip should be a goal of hip replacement.²



Microelasto-hydrodynamic Lubrication

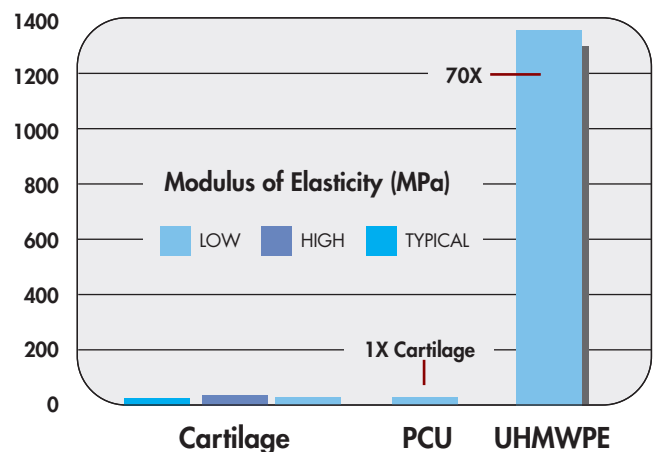
¹ Merriam-Webster's Collegiate Dictionary. Pleasantville, NY: The Reader's Digest Association; 1998: 1972.

² Wimmer MA and Fischer A: Tribology. *The Adult Hip*, Second Edition. Philadelphia: Lippincott Williams & Wilkins; 2007: 215–226.

A Natural Buffer for the Significant Loads in the Hip

The loads in a natural hip are significant and varied throughout an individual's gait cycle and during activities of daily living. Kinematic analyses have estimated the peak loads on hips as approximately 2.4 times body weight during normal gait, and the joint contact forces of 2.5 and 2.6 times body weight for ascending and descending stairs. Jogging can produce peak forces of as much as 5.5 times body weight, and inadvertent stumbling can produce forces as high as 8 times body weight.^{3,4} Thus, the joint must carry significant loads and moments. Articular cartilage, along with the synovial fluid layer, provides a natural buffer to the bone and surrounding soft tissues in the hip, so that there is reasonable stress transmission at the joint due to the shock absorbing characteristics of the cartilage and fluid layer.

Previous implant systems provided poor shock absorption, due, in part, to the significant difference in mechanical properties of the materials used – specifically, the modulus of elasticity of the implant materials – compared to the modulus of elasticity of human cartilage. *All prior systems eliminated nature's buffer.*



PCU is Polycarbonate Urethane
UHMWPE is Ultrahigh Molecular Weight Polyethylene

Pinchuk LS, Nikolaev VI, Tsvetkova, EA and Goldade VA: Tribology and Biophysics of Artificial Joints. *Tribology and Interface Engineering Series*, No. 50, B.J. Briscoe Editor, Elsevier, 2006, 176.

Dowson D, Fisher J, Jin ZM, Auger DD, and Jobbins B: Design Considerations for Cushion Form Bearings in Artificial Hip Joints. *Proc. Instn. Mech Engrs*, 1991, 205:59–68.

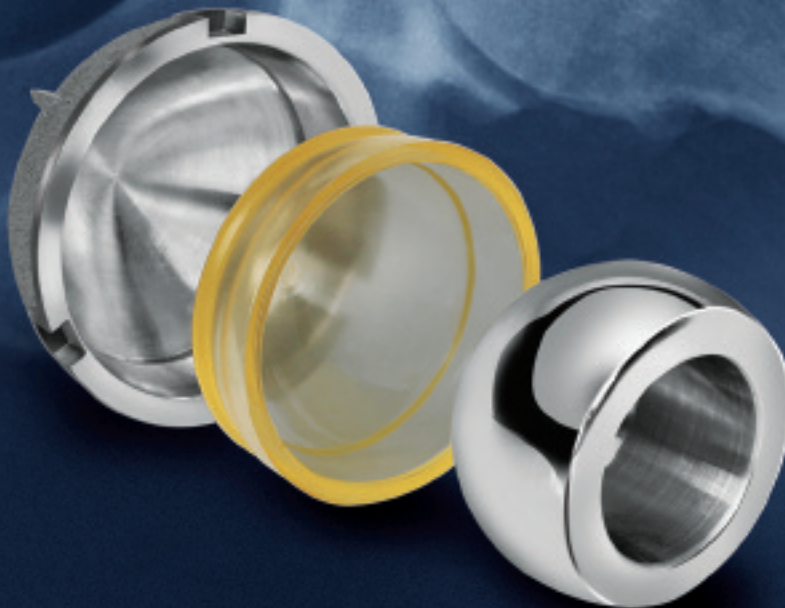
³ Wimmer MA and Fischer A: Tribology. *The Adult Hip*, Second Edition. Philadelphia: Lippincott Williams & Wilkins; 2007: 215–226.

⁴ Johnston JD, Noble PC, Hurwitz DE, and Andriacchi TP: Biomechanics of the Hip. *The Adult Hip*, Second Edition. Philadelphia: Lippincott Williams & Wilkins; 2007: 81–90.

THE FIRST TRUE HIP REPLACEMENT

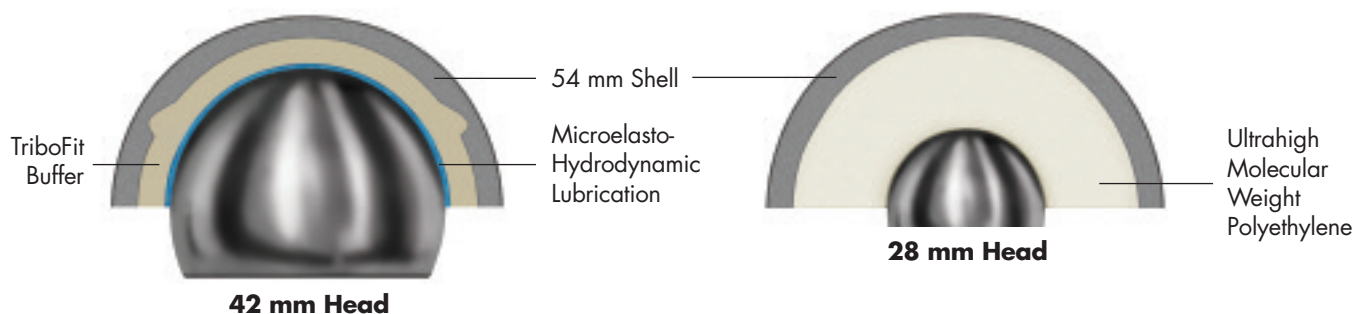
A healthy hip joint features a cartilage-covered femoral head which articulates with a cartilage-covered acetabulum separated by a synovial fluid interface. Prior total hip replacement systems provided only a two-part system: an acetabular cup combined with a femoral head. The TriboFit™ Hip System provides a hip replacement that for the first time is designed to mimic the third important component – *the fluid interface* – nature's buffer. Normal hips do not have cartilage-to-cartilage contact, but rather have a thin barrier (e.g., <1 micron) of clearance to create a cartilage-fluid-cartilage interface.

The joint space in a normal hip comprised of cartilage and a fluid interface



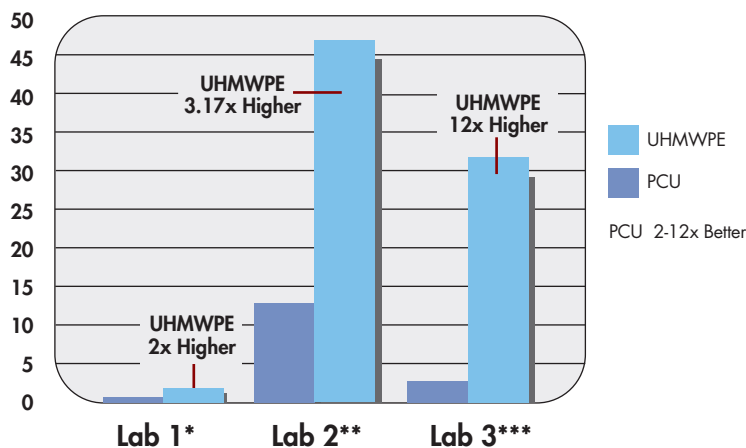
DESIGN RATIONALE

The TriboFit™ Acetabular Buffer is manufactured from a hydrophilic material which attracts fluids. This property helps to establish the full-fluid film layer between the Buffer and the femoral head in order to provide microelasto-hydrodynamic lubrication. A more understandable analogy is hydroplaning in a car. Just like a car can lose contact with the surface of the road, the femoral head loses physical contact with the acetabulum. Whenever there is no physical contact between surfaces, essentially no wear occurs. It is this fluid barrier phenomenon that the TriboFit Buffer was designed to mimic.



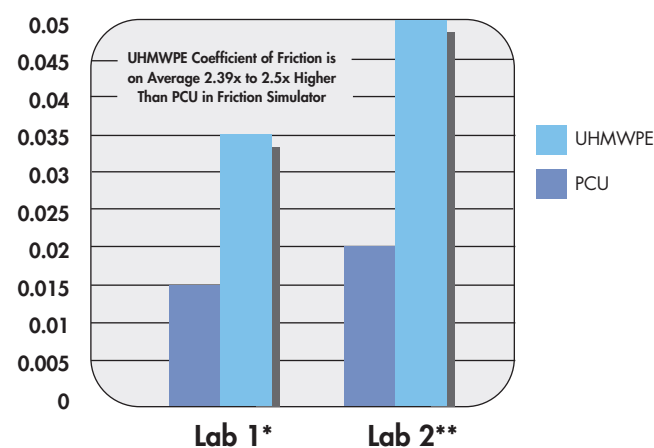
Scientific studies have demonstrated the advantages of the full-fluid film layer of lubrication in terms of enhanced wear performance, with wear performance two to twelve times better than ultrahigh molecular weight polyethylene.^{5,6}

Bovine Serum Lubricated Wear Test (mm³/year)



* Schwartz & Bahadur Wear 2006 (Flat on Flat, Low Load)
 ** Smith et al J Biomed Mat Res 2000 (Cup and Head)
 *** Jennings & Fisher J Mech E 2002

Lubricated Testing of Coefficient of Friction (μ)



* Smith SL, Ash HE, Unsworth A: A Tribological Study of UHMWPE Acetabular Cups and Polyurethane Compliant Layer Acetabular Cups. J. Biomed Mater Res. 2000; 53(66):710-716.
 ** Caravia L, Dowson D, Fisher J: Start Up and Steady State Friction of Thin Polyurethane Layers. Wear 1993; 160:191-197.

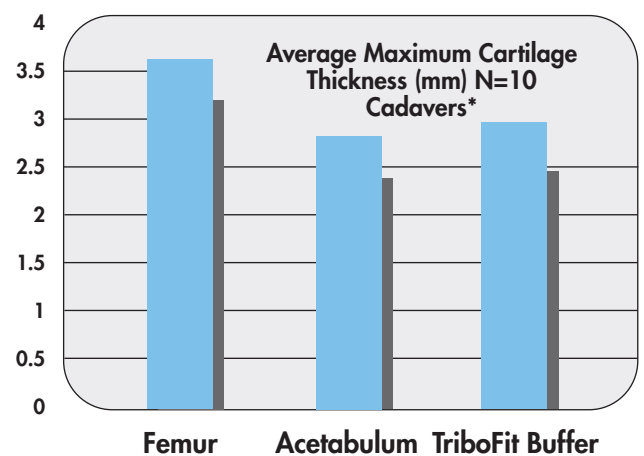
⁵ Scholes S, Unsworth A, Jones E: Polyurethane Unicondylar Knee Prostheses: Simulator Wear Tests and Lubrication Studies. *Physics in Medicine and Biology*, 2007; (52) 197-212.

⁶ Fisher J, Jennings L: Investigation of a Novel Compliant All-Polyurethane Acetabular Resurfacing System, presented at the International Conference Engineers and Surgeons – Joined at the Hip, June 2002.

THE FIRST TRUE HIP REPLACEMENT

More Natural Function with a Cartilage-Like Material

The TriboFit™ Acetabular Buffer features a pliable bearing surface – specifically formulated, biocompatible polycarbonate urethane (PCU) – a material with an extensive Master File documenting its biocompatibility and biodurability. This family of materials has been used successfully in medical devices for more than a decade. In addition, the Buffer material has a modulus of elasticity and thickness similar to that of healthy acetabular cartilage, and thus serves to help mimic the cushioning and stress distribution that occurs in a healthy human hip joint.⁷ Adding this soft, pliable material to a prosthetic replacement system should help re-establish the normal stress distribution of the hip as well as help provide shock absorption, or “buffering” in a manner similar to a healthy natural hip. Replacing and reproducing nature’s natural buffer with a prosthetic Buffer with mechanical properties similar to healthy cartilage should be advantageous to the surrounding bone and tissue. In addition, this novel material also allows minimal bone resection helping to establish a more normal physiological load transfer.



- Femoral Cartilage 25% Thicker Than Acetabulum
- AIC Buffer Matches Normal Acetabular Cartilage Thickness

⁷ Kurrat H and Oberlander W: The Thickness of Cartilage in the Hip Joint. *J Anat*, 1978, 126: 145–155.

Eliminating Known Sources of Prosthesis Problems

Avoiding the unsolved problems of total hip replacement – polyethylene, ceramic and metal-on-metal – via an alternative material.

“A survey was conducted of the entire membership of the American Association of Hip and Knee Surgeons to determine their experience with total hip arthroplasty (THA) device-related failures. The aggregate 5-year volume encompassed experience with more than 60,000 hip arthroplasties. On the basis of this survey, Polyethylene is the weakest link in THA prosthetic design. Manufacturers’ efforts should continue to address factors leading to polyethylene failure that result in premature prosthetic hip failures.”

— David Heck, MD

Quote from David A Heck, MD, et al. “Prosthetic Component Failures in Hip Arthroplasty Surgery,” *Journal of Arthroplasty*. Vol 10: No. 5, 1995.

The significant potential wear benefits of polycarbonate urethane, coupled with its biocompatibility as demonstrated in extensive studies, provides a new alternative to the conventional systems used today. The problems of alternative materials – osteolytic changes in bone due to ultrahigh molecular weight polyethylene (UHMWPE) and its debris products, ceramic and the possibility of brittle fracture and metal ion levels associated with metal-on-metal articulations – are eliminated.

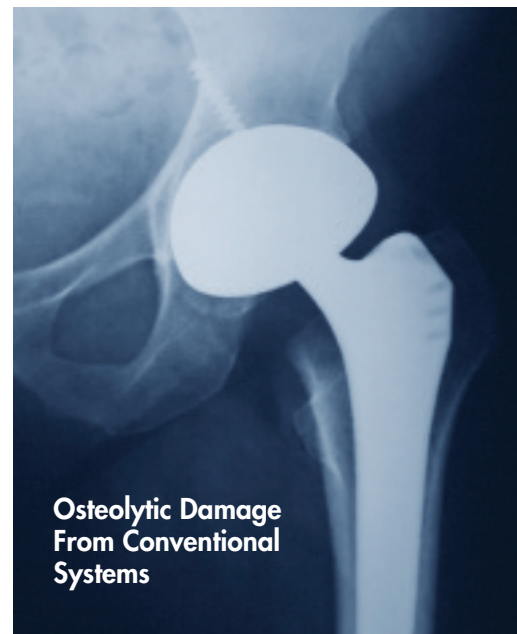


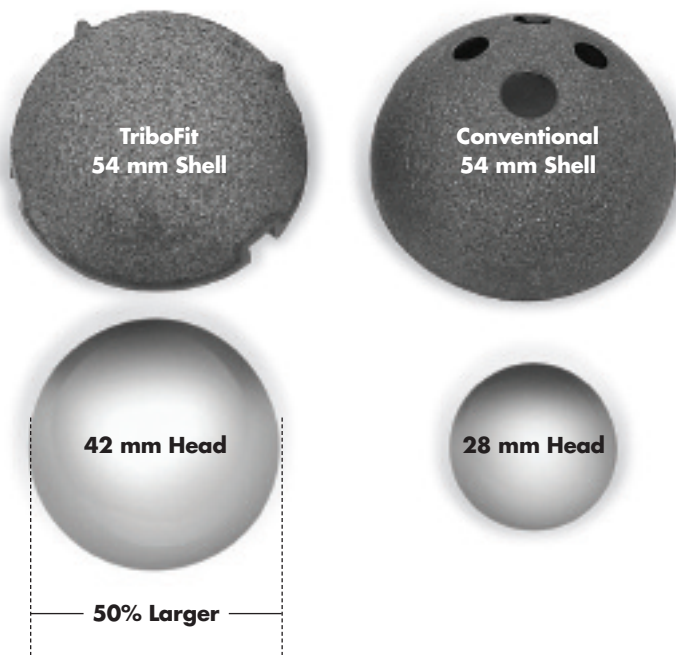
Image courtesy of Kevin Lester, M.D.

THE FIRST TRUE HIP REPLACEMENT

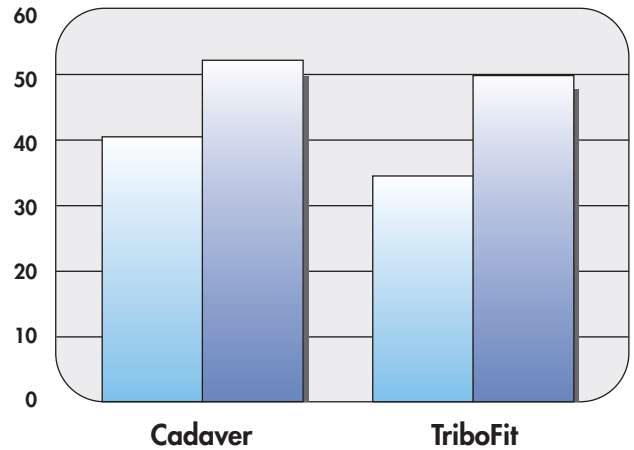
Stability and More Natural Function Through Design and Materials

The TriboFit™ Acetabular Buffer allows selection of the femoral head to optimize function and match the patient's anatomy with decreased fear of dislocation. Heads are available from 34 mm to 50 mm, in 2 mm increments to more nearly match the patient's femoral head size.

These larger femoral heads provide a greater head-to-neck ratio, allowing greater range of motion before impingement, minimizing the risk for dislocation and allowing a more active lifestyle for patients.



Min/Max Range In Femoral Head Sizes In 10 Specimens (mm)*



- 5 cadavers age 34-86, 4 males, 1 female, normal hip joints
- AIC TriboFit femoral heads match or exceed the normal range of unreamed femoral head

*Kurrat HJ, Oberlander W. The Thickness of Cartilage in the Hip Joint. *J Anat*, 1978, 126: 145 - 155.

Secure Fixation for Secure Results

The TriboFit™ Acetabular Shell combines the advantages of both cobalt chromium and titanium. The shell is produced in cobalt chromium alloy and coated with titanium plasma spray to ensure secure fixation for the implant by providing clinically proven⁸ enhanced bony attachment to the acetabulum. The metal shell and Buffer assembly can be press-fit into the acetabulum and will be rotationally stable due to the superior anti-rotation fins. The pliable structured Buffer features a circumferential ridge for immediate and secure fixation at time of surgery. In addition, the elimination of screw holes reduces the opportunity for wear debris transfers to the backside of the acetabular component.

At the surgeon's option where the anatomy and age of the patient would allow it, the Buffer may be implanted directly into bone without the use of the TriboFit Metal Shell (see training manual), replacing the patient's acetabulum cartilage bed with a compliant layer.

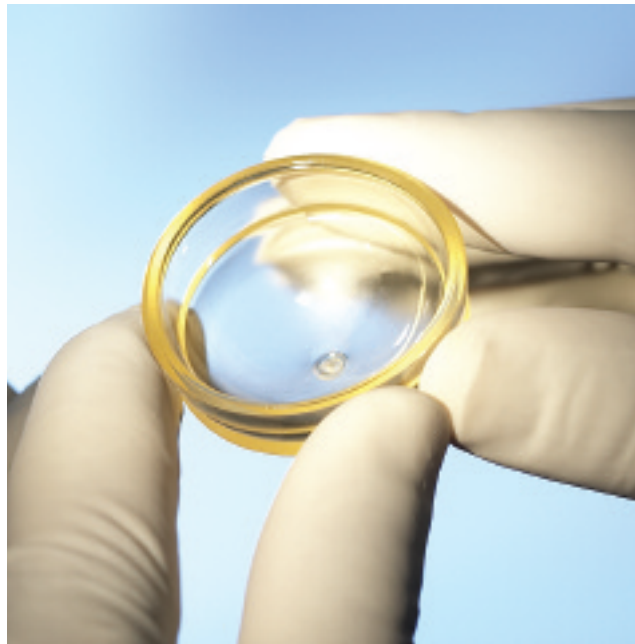


⁸ Neginhall V, et al.; Hemispherical Titanium Plasma Spray Coated Acetabular Components: 5 to 9 Year Follow-Up Study, Poster #20; AAHKS Annual Meeting; Nov. 2001; Dallas TX.

TRAINING MANUAL

TRIBOFIT™

ACETABULAR BUFFER



RESTORING MORE NATURAL FUNCTION
WITH A CARTILAGE-LIKE MATERIAL



NOTA BENE: The following is a suggested surgical technique as reviewed by Prof. Dr. med. Werner Siebert, Dr. med. Sabine Mai, Prof. Dr. med. Antonio Moroni and Prof. Dr. med. Burkhard W. Wippermann. The actual technique used in surgery will be determined by the surgeon based upon the patient's anatomy and medical condition.



IMPLANTATION OF TRIBOFIT ACETABULAR

1.

Preoperative Planning and Templating

Preoperative planning and templating are essential steps to perform to help assure a successful outcome. While templating the radiographs should be performed on the affected/implanted side, an important consideration should be given to the contralateral side. It is recommended that preoperative radiographs include an A/P of the pelvis and hip, and a lateral view of the affected hip. Preoperative use of a template on the radiographs helps identify the appropriate size implants to have ready during surgery.

2.

Acetabular Exposure

While the surgical approach and resection of the femoral head are left to the surgeon's preference, it is suggested that complete exposure of the acetabulum is necessary for a successful outcome (*Figure 1*). Complete circumferential resection of the labrum is advised so as to determine with complete accuracy the landmarks of the acetabulum. Removal of soft tissue and osteophytes from the fovea are important in visualization of the medial wall and inferior floor. Attention should be directed to protecting the surrounding soft tissues by careful placement of the retractors prior to the reaming process.

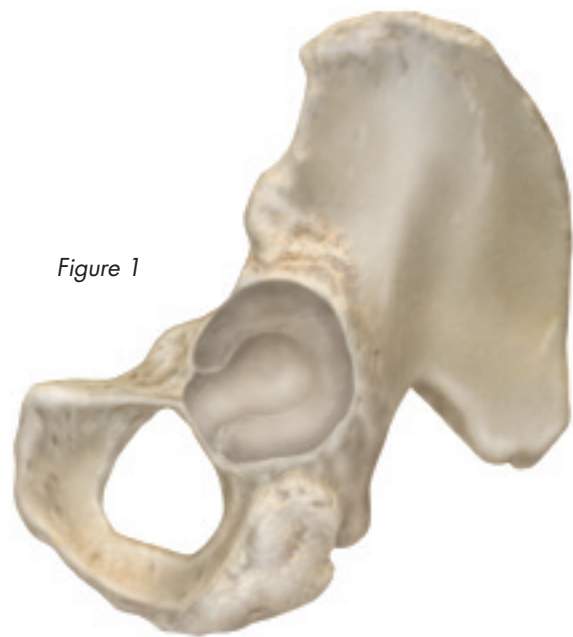


Figure 1

3.

Initial Acetabular Reaming

Please note that unlike other systems, the selection and use of the instruments to prepare the acetabulum is critical with the TriboFit™ Hip System. Because of this importance, only TriboFit Acetabular Reamers should be used to implant the TriboFit acetabular components. To allow reaming based on the anatomic center of the acetabulum, it is suggested that reaming of the acetabulum begin with a reamer size that fits easily into the completely exposed acetabulum (*Figure 2*). The initial reaming should take place only after identifying the medial wall. Reaming should continue along the same axis as the desired final implant location. The final acetabular component is usually located at approximately 45° of abduction and 15° to 20° of forward flexion. Care must be taken not to violate the medial wall. At this point the surgeon may choose to either implant the Buffer alone or use it with the metal shell.

Note: Surgical techniques for preparing the acetabulum for each option are as follows.

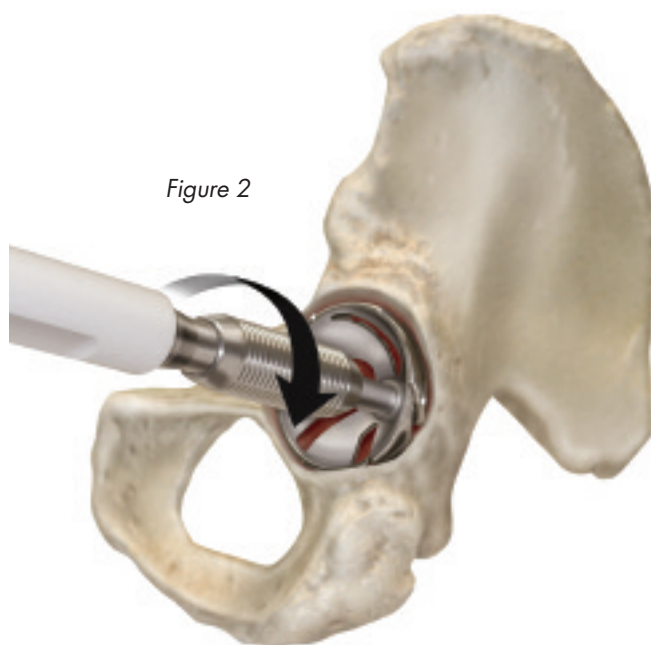


Figure 2



TriboFit™ Acetabular Reamer



4.

Acetabular Reaming for the TriboFit™ Metal Shell

The acetabulum is reamed cautiously so as to remove only the existing cartilage. The reamer is rotated slowly and deliberately using copious irrigation so that bone removal is avoided or minimized and that an exact hemispheric shape is obtained. Protruding osteophytes at the rim of the acetabulum must be removed so as not to restrict the seating or motion of the implant.

If the patient's bone stock and absence of deformity will allow it, the surgeon may, at this point, elect to implant the Buffer directly into the acetabulum, without a metal shell. If this technique is desired, refer to Steps 4A – 7A beginning on page 20.

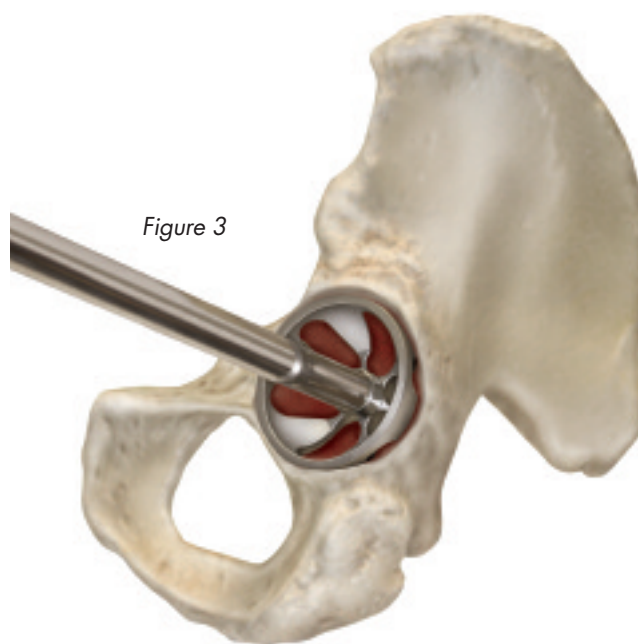
The TriboFit Reamers should be placed along the same axis as the final position of the acetabular shell, usually approximately 45° of abduction and 15° to 20° of forward flexion. Reaming should medialize the prepared socket taking care not to violate the medial wall. It is important to preserve subchondral bone so as to provide support for the implant. Any remaining cartilage or soft tissue should be removed and the reaming continued until uniform subchondral bleeding is observed. The last reamer used determines the size of the trial.

5.

Acetabular Trialing and Sizing of the TriboFit™ Metal Shell

Following the preparation of the acetabulum, a shell trial which is the same size as the last reamer used, is inserted into the prepared acetabulum to confirm the size and position of the final implant (*Figure 3*). The trial permits visualization of the floor of the acetabulum. If the trial is flush with the floor of the acetabulum, the appropriate size has been obtained. The TriboFit Metal Shell features a bi-radial design. The superior surface diameter corresponds to the size reamed. The shell then flares at the edge, and the equatorial diameter of the shell is larger than the superior diameter. This difference assures that a slight interference press-fit will help provide instantaneous stability.

Note: Care should be taken not to under ream, as is sometimes required by other systems.





6.

TriboFit™ Acetabular Buffer/Shell Insertion

After confirming the metal shell size using the trial, the surgeon should select the final implant shell and corresponding Buffer. (Note: The Buffer is 6 mm smaller than the shell size selected.) Care must be taken to keep both the metal shell and Buffer completely dry during this assembly process. The shell has a 2 mm interior groove that corresponds to the 2 mm peripheral ridge on the Buffer (*Figure 4*). The inner surface of the shell has no screw holes and a finished surface. It is recommended that prior to the Buffer/Shell assembly, the surgeon change his gloves in order to ensure a completely dry assembly. On the back table, carefully place the sterile metal shell implant on a sterile surgical towel in order to protect the plasma spray coating. The Buffer should be placed in the metal shell and pressed in place with finger pressure (*Figure 5*). To assure proper locking of the Buffer, care should be taken to make sure it is completely seated within the shell and unable to move or toggle. In most cases the surgeon will feel and hear a snap that ensures proper assembly.



Figure 4

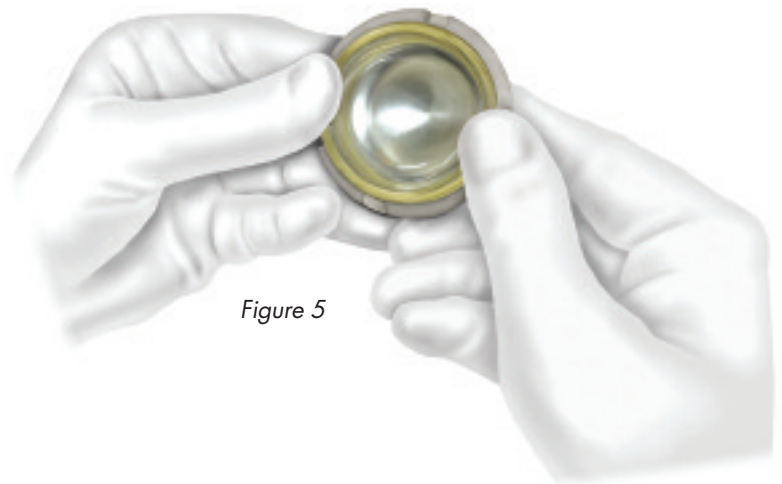


Figure 5

Nota bene: The TriboFit Acetabular Shell is designed for cementless use. In the event that the patient's bone is of poor quality, or in the case of revision, the shell may also be cemented into position. In those cases, ream the acetabulum to a larger size allowing for the desired cement mantle.

7.

TriboFit™ Acetabular Buffer/Shell Insertion

The mated Buffer/Shell assembly is then attached to the appropriate color-coded coupled impactor. The Buffer/Shell assembly is fitted onto the inserter by aligning the three prongs on the impactor with the three corresponding peripheral indentations on the shell and advancing the sleeve on the impactor. Once the impactor is seated in the Buffer/Shell assembly, the instrument is locked by turning the sleeve clockwise or counterclockwise one half turn (*Figure 6*). Prior to final placement of the Buffer/Shell assembly, copious irrigation should be performed to remove any soft tissue and bone from the inner surface of the finally prepared acetabulum. The metal shell has two fins to help provide initial and rotational stability. These two fins should be positioned caudally on both sides of the fovea. The bi-radial geometry of the shell helps provide equatorial press-fit fixation. Firmly tap the impactor with a mallet until the metal shell with Buffer assembly is fully seated (*Figure 7*). Assess the stability and line-to-line contact of the shell by gently toggling the impactor. Upon implantation, no gaps between the shell and medial wall should exist and no movement of the shell should be detected. To remove the impactor, turn the sleeve one half turn either way. Protect the Buffer by placing the color-coded protector into the Buffer before preparing the femur.

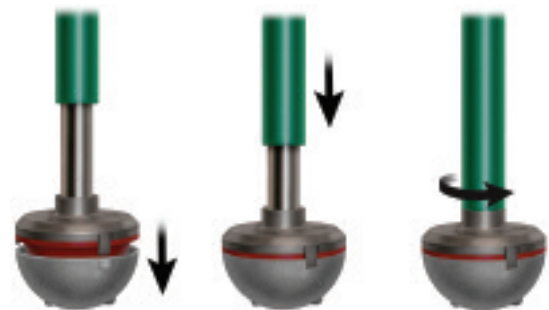


Figure 6

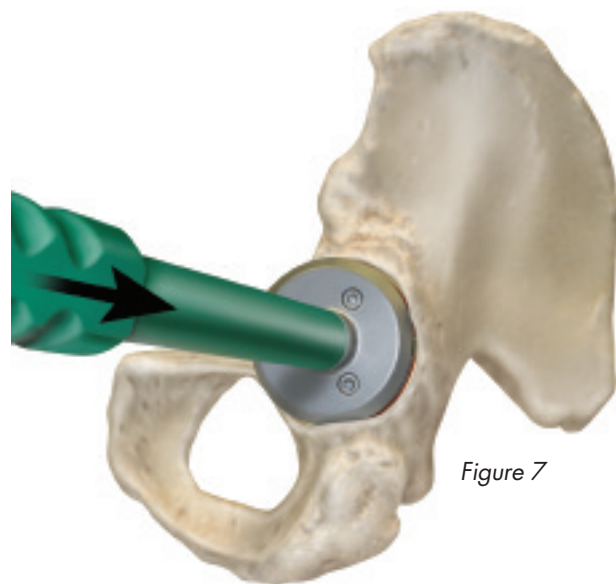


Figure 7



8.

TriboFit™ Modular Femoral Heads

TriboFit Modular Femoral Heads are packaged together with the Buffers to ensure proper sizing and tolerances. The neck length adaptors and metal shells are packaged individually. Based on the chosen trial neck length, the corresponding neck length implant is selected based on the size of the modular femoral head. The neck adaptor is placed inside the femoral head and squeezed together (*Figure 8*). The neck adaptor components are only intended for use with titanium alloy or cobalt chrome stems with 12/14 mm tapers.



Figure 8



9.

Femoral Head Assembly

After assembly, the modular femoral head is placed on the taper of the femoral stem. With the use of a plastic impactor to protect the surface of the femoral head, use multiple mallet blows to firmly fix the femoral head assembly onto the taper on the femoral stem (*Figure 9*). In cases where the head and neck adaptor needs to be removed from the femoral stem, a blunt offset punch will need to be used. Place the blunt offset punch on the base of the neck adaptor and drive the head/neck assembly off the stem with a mallet. A disassembly tool is available to separate the neck adaptor from the head. It is recommended, following this procedure, that a new neck adaptor and head be used as possible damage may have occurred to the taper which could affect the implant's performance.

Reduce the hip and check for leg length equality and stability. Close in the usual manner.

See package insert for additional medical information.

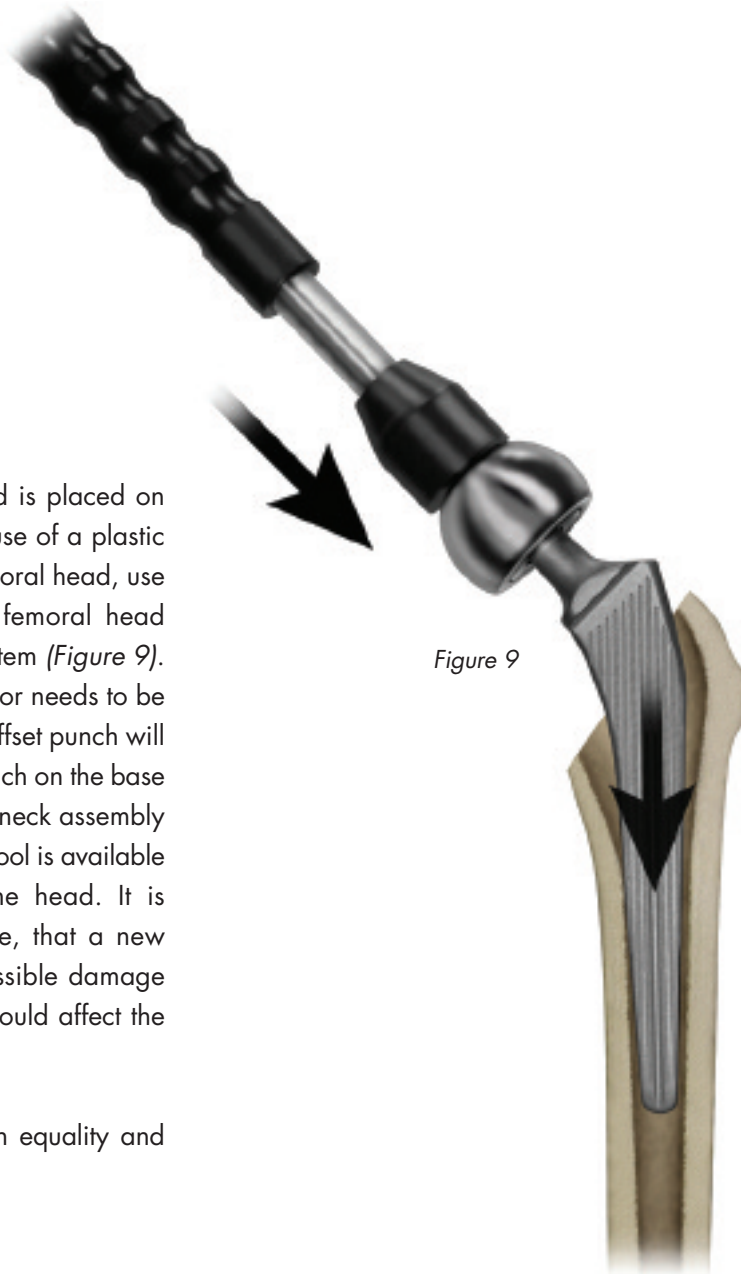
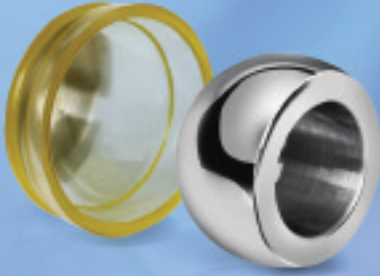


Figure 9



4A.

Acetabular Reaming and Grooving for the TriboFit™ Acetabular Buffer

The acetabulum is reamed cautiously so as to remove only the existing cartilage (*Figure 10*). The reamer is rotated slowly and deliberately with copious irrigation so that bone removal is avoided or minimized and that an exact hemispheric shape is obtained. Protruding osteophytes at the rim of the acetabulum must be removed so as not to restrict the seating or motion of the implant.

The size of the last reamer used determines the size selection of the TriboFit Groover. The groover is designed with a retractable platform with dual locking pins onto which sized groovers can be affixed. To attach the groover, the surgical assistant should depress the retractable head platform and then place the sized groover (corresponding to the last reamer used) onto the head platform. The assistant should then turn the groover one-quarter turn to seat the groover. The assistant should then release the head platform to lock the assembly.

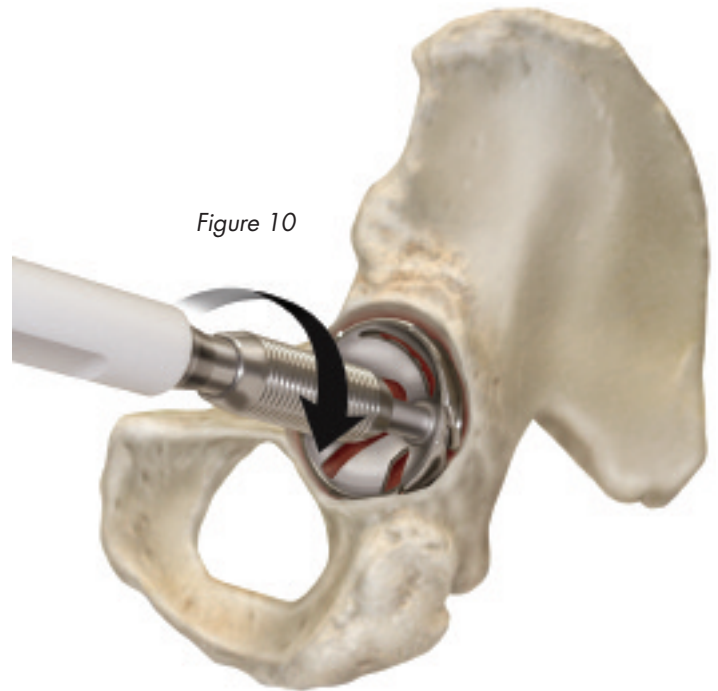


Figure 10



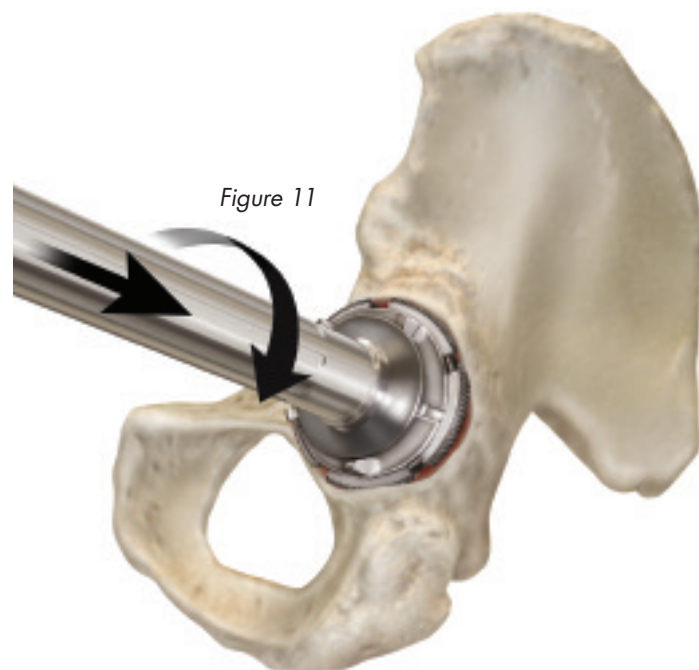
TriboFit™ Acetabular Reamer

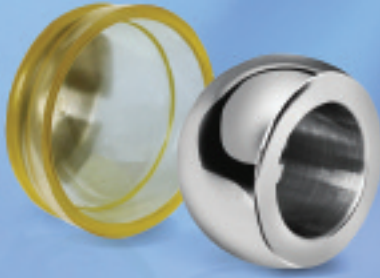
TRAINING MANUAL

ACETABULAR BUFFER WITHOUT METAL SHELL

A circumferential groove should be formed in the acetabulum by placing the groover in the same orientation as the final reamer. Prior to inserting the groover into the acetabulum, the cutting blades of the groover should be aligned with the acetabular notch. While maintaining pressure on the handle, the sleeve of the groover is gripped firmly by the surgeon and pushed down towards the acetabulum. This action spreads the retractable platform to ensure that the groover is locked in the acetabulum so that the groove cut in the acetabulum will be at the correct depth, corresponding to the depth of the peripheral ridge on the implant. With pressure on the sleeve maintained, the handle of the groover should be turned in a clockwise direction exactly one 360° turn until the cutting blades return to the original position in the acetabular notch (*Figure 11*).

After removing the groover, copious irrigation should be performed to remove any bone fragments or soft tissue from the acetabulum. The groove created is then checked to assure that it is completely formed. For successful implantation of the Buffer, the circumferential groove must be at least 270° allowing for the acetabular notch.





5A.

Implantation of the TriboFit™ Acetabular Buffer

The TriboFit Acetabular Buffer is designed with a 2 mm peripheral ridge to snap-fit into the circumferential groove prepared in the reamed acetabulum. The size of the implant corresponds with both the reamer and groover last used and is always 6 mm larger than the modular femoral head. (Please note that for surgeon convenience, the Buffer is packaged together with the corresponding modular femoral head.)

The surgeon should take the Buffer and place it in the prepared acetabulum, and align it along the axis of the reaming. With the use of finger pressure, the 2 mm peripheral ridge of the Buffer is pushed into the corresponding previously prepared circumferential groove in the acetabular bone (*Figure 12*). In most cases, the surgeon should feel and observe a “snap” upon insertion that confirms proper seating of the Buffer. When properly implanted, the Buffer should be flush with the bone. Should additional force be required to place the Buffer into the acetabulum, a TriboFit Pusher is available to assist in the final placement.

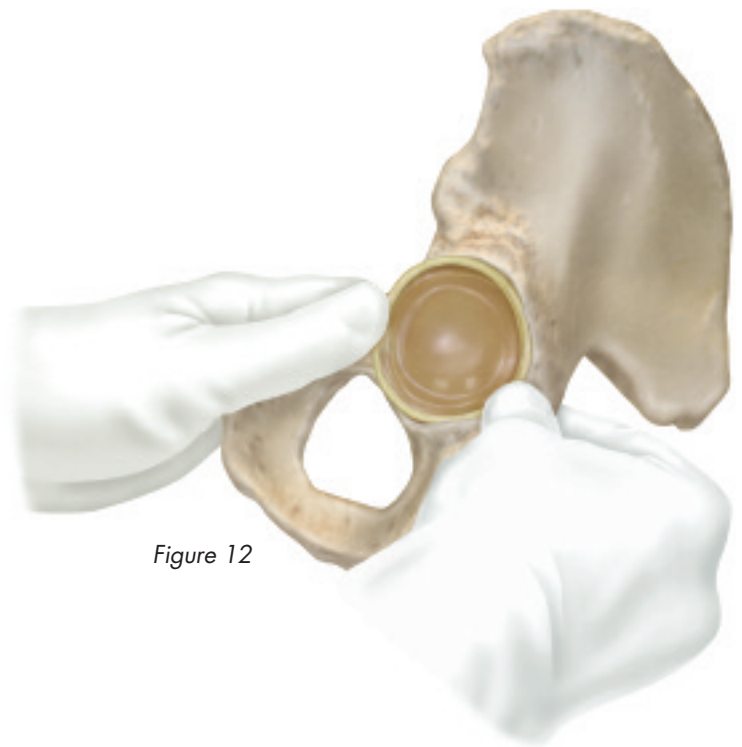


Figure 12

TRAINING MANUAL

ACETABULAR BUFFER WITHOUT METAL SHELL

Once the Buffer is fully seated, a “spin test” is required to ensure that the Buffer is completely deployed within the acetabulum. The “spin test” is accomplished by opening the appropriate TriboFit™ Modular Femoral Head implant (6 mm smaller than the Buffer). A rod is available in the instrument set to place into the head. Lubricate the inner surface of the Buffer with a drop of fluid and place the assembly into the Buffer using the rod (*Figure 13*). The femoral head should spin freely within the Buffer. In cases in which the head does not spin freely, the Buffer is not seated properly, meaning that additional reaming and grooving may be necessary to implant the next larger size Buffer.

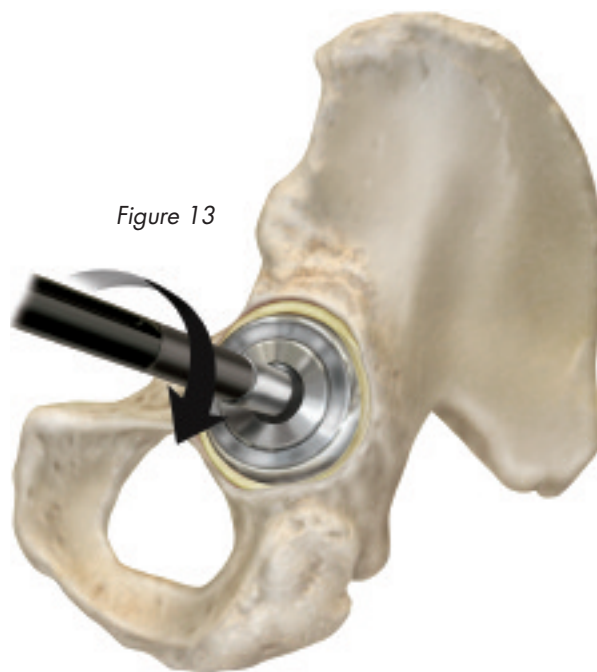
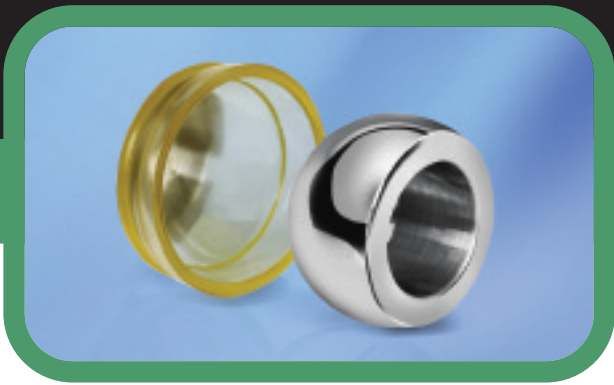


Figure 13



6A.

TriboFit™ Modular Femoral Heads

TriboFit Modular Femoral Heads are packaged together with the Buffers to ensure proper sizing and tolerances. The neck length adaptors and metal shells are packaged individually. Based on the chosen trial neck length, the corresponding neck length implant is selected based on the size of the modular femoral head. The neck adaptor is placed inside the femoral head and squeezed together (Figure 14). The neck adaptor components are only intended for use with titanium alloy or cobalt chrome stems with 12/14 mm tapers.



Figure 14



7A.

Femoral Head Assembly

After assembly, the modular femoral head is placed on the taper of the femoral stem. With the use of a plastic impactor to protect the surface of the femoral head, use multiple mallet blows to firmly fix the femoral head assembly onto the taper on the femoral stem (*Figure 15*). In cases where the head and neck adaptor needs to be removed from the femoral stem, a blunt offset punch will need to be used. Place the blunt offset punch on the base of the neck adaptor and drive the head/neck assembly off the stem with a mallet. A disassembly tool is available to separate the neck adaptor from the head. It is recommended, following this procedure, that a new neck adaptor and head be used as possible damage may have occurred to the taper which could affect the implant's performance.

Reduce the hip and check for leg length equality and stability. Close in the usual manner.

See package insert for additional medical information.

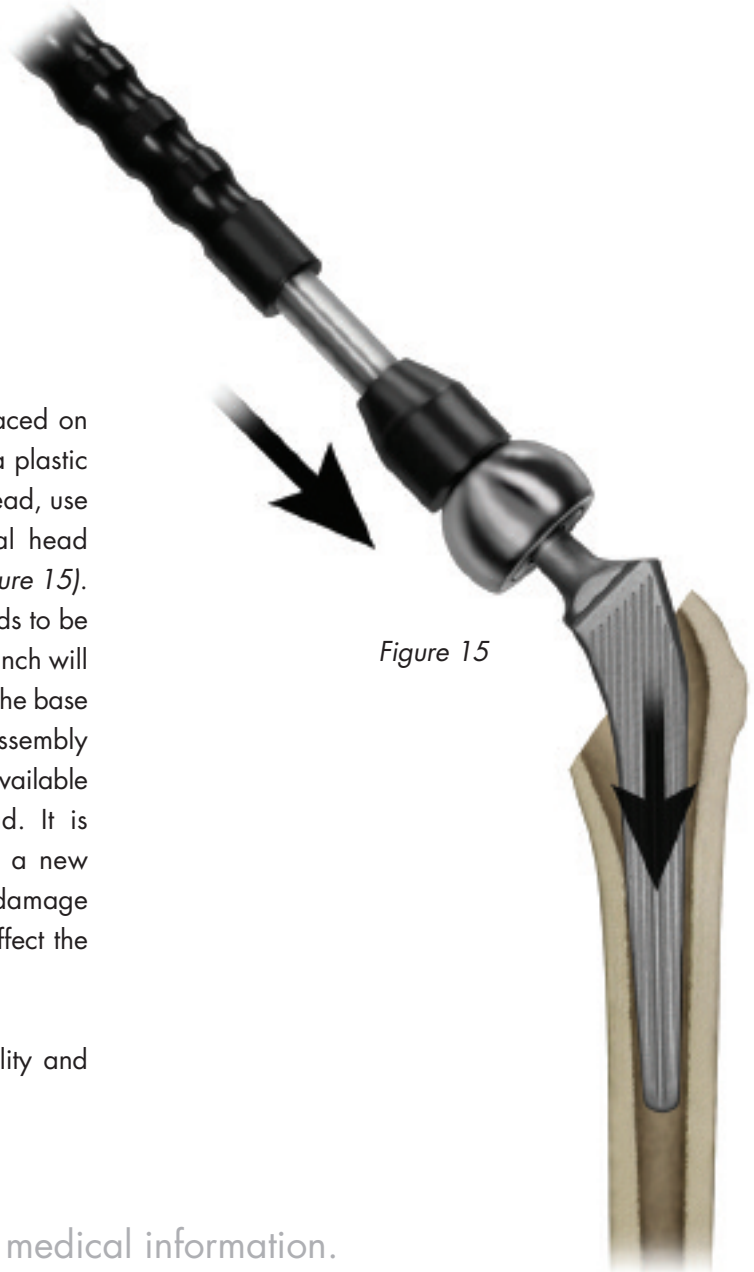


Figure 15

TRIBOFIT™

ACETABULAR BUFFER

THE CLEAR ADVANTAGE OVER POLYETHYLENE



Global Headquarters
Active Implants Corporation
5865 Ridgeway Center Parkway
Suite 218
Memphis, TN 38120
USA
+901.762.0352

Active Implants Israel
43 Hamelacha Street
Sapir Industrial Zone
Netanya, Israel 42504
Office: +972.9.865.9220
Fax: ++972.9.865.9221

www.activeimplants.com



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Other patents are pending on the TriboFit implants and instruments.

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