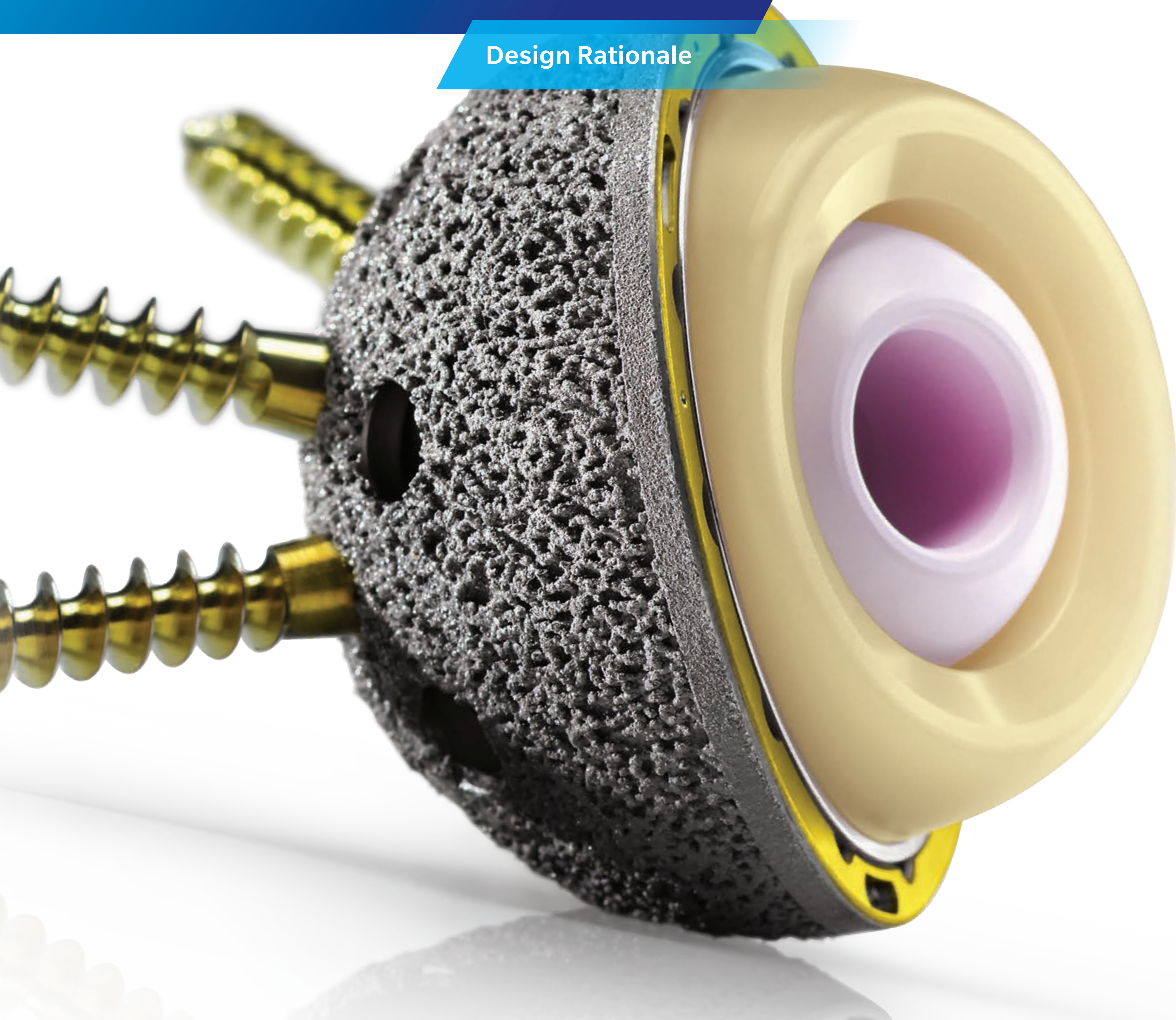
G7® Dual Mobility Construct

Design Rationale

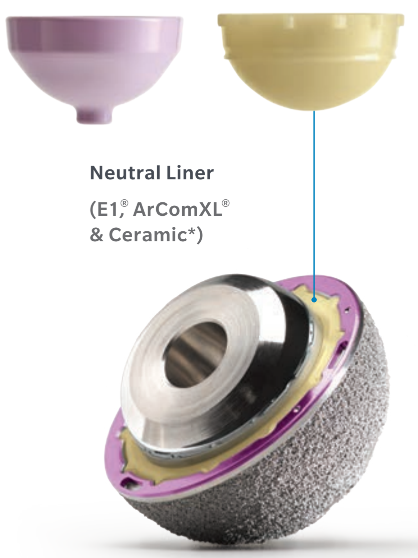


ZIMMER BIOMET
Your progress. Our promise.™

G7 Acetabular System

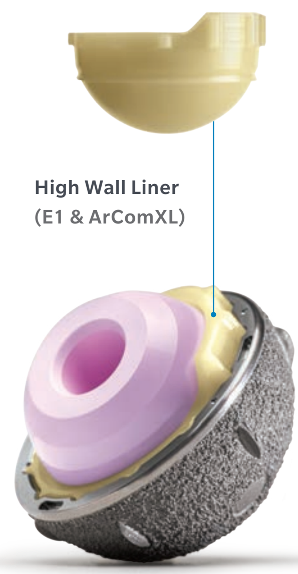
Simplicity. Efficiency. Performance.

From simple primary to complex revision arthroplasty, the G7 System offers a comprehensive portfolio of shell, fixation and bearing options designed to establish a stable joint in THA. Each is designed to address the distinct needs of individual patients, giving surgeons and hospitals the power to personalize implant selection combined with a streamlined instrumentation and delivery platform.



Neutral Liner
(E1,® ArComXL® & Ceramic*)

Designed to provide maximum range of motion, while decreasing the possibility of impingement, due to the liner seating flush with the rim of the acetabular shell.



High Wall Liner
(E1 & ArComXL)

Offers a 5 mm raised lip (typically positioned in the posterior superior quadrant) for additional stability.

10 Degree Face Changing Liner
(E1 & ArComXL)

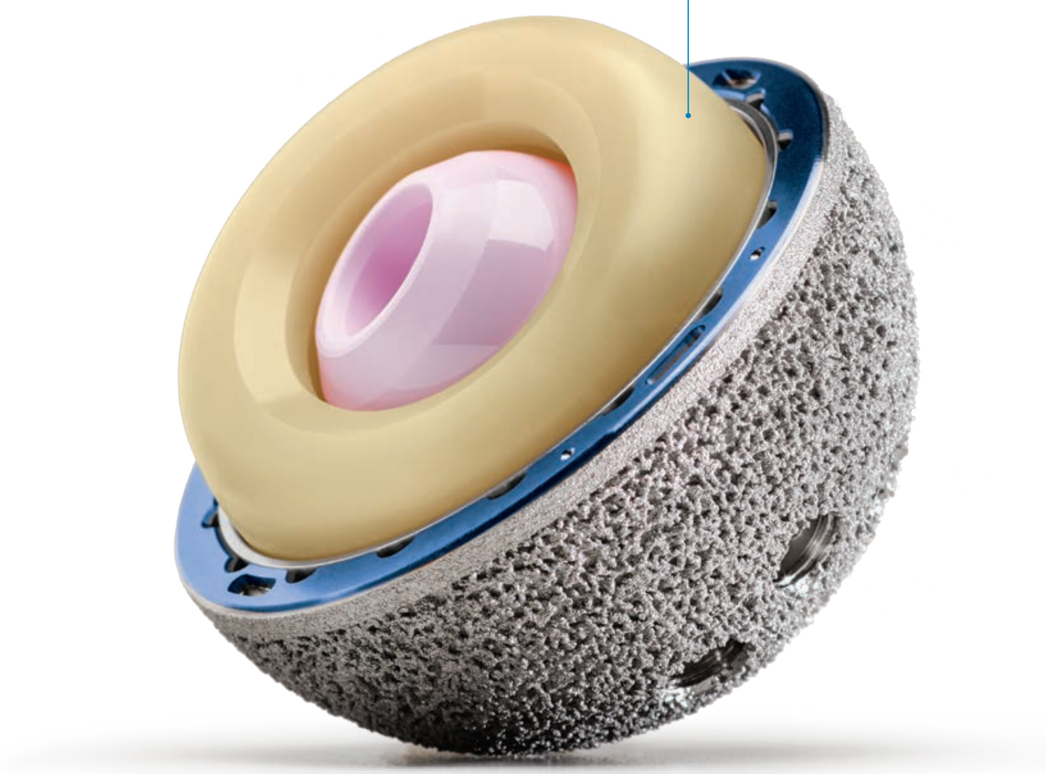
Used to restore the center of rotation and achieve more joint stability when acetabular components have been vertically placed.

*Not available for sale in the U.S.

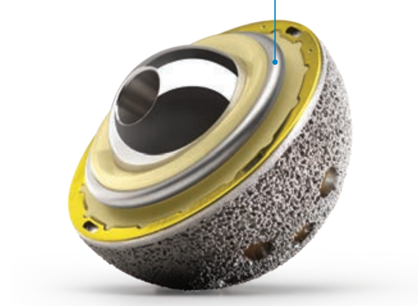
Dual Mobility Bearing

(E1 & ArComXL)

The G7 Dual Mobility construct offers dislocation resistance without the need to constrain the femoral head, providing stability and high range of motion for a variety of patient indications.[1,2]



Freedom® Constrained Liner (E1 Only)

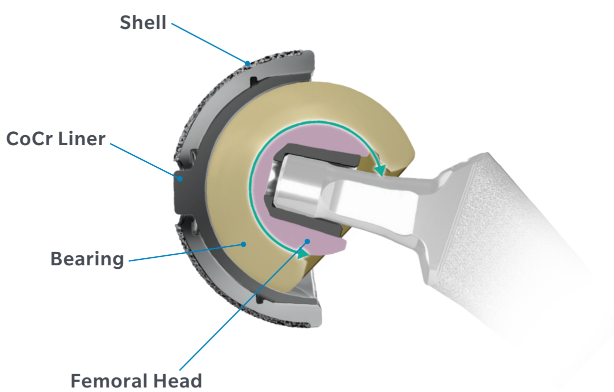


Designed to actively counter the distractive forces that can lead to recurrent hip dislocation. Utilizes a cobalt chrome head with circumferential flats for simple head reduction and a constraining ring to supplement the liner's stability by increasing resistance to lever-out forces.

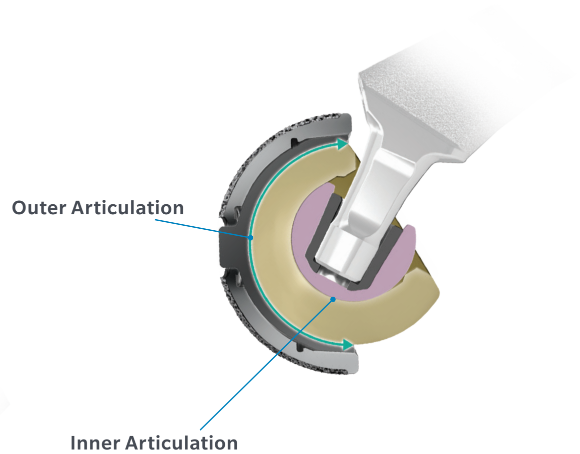
Increased Stability for More Patients

Dual Mobility Design Concept

Dual mobility constructs are designed to provide maximum range of motion while minimizing the risk of dislocation.[3] The first motion occurs between the 22 or 28 mm femoral head and the concave surface of the polyethylene bearing until the neck of the femoral stem comes into contact with the bearing (Figure 1). Secondary motion occurs between the polyethylene bearing and the metal liner when a larger range of motion is required (Figure 2).



First Motion
Figure 1



Second Motion
Figure 2

Dislocation Resistance

Studies show femoral heads larger than 32 mm significantly decrease the risk of dislocation due to the increased distance required for the femoral neck to travel before impinging on the rim of the acetabular shell.[4,5] In a dual mobility construct, the polyethylene bearing acts as a large diameter femoral head designed for the same purpose.

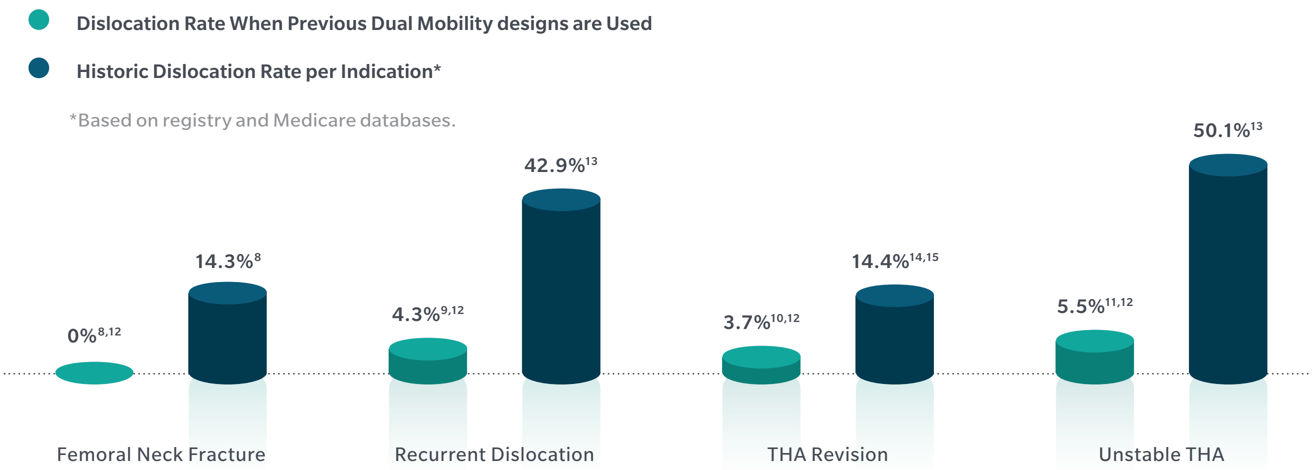
The G7 Dual Mobility construct maximizes shell to bearing ratio, providing a 32 mm or larger bearing for all shell sizes to offer joint stability, high range of motion (up to 212°)[6] and dislocation resistance to a greater number of patients.

G7 Dual Mobility Shell to Bearing Ratio

Shell Size	Bearing Size
42 - A 44 - A	32
46 - B	36
48 - C	38
50 - D	40
52 - E	42
54 - F 56 - F	44
58 - G 60 - G	46
62 - H 64 - H	50
66 - I 68 - I 70 - I 72 - I	54
74 - J 76 - J 78 - J 80 - J	60

Historical Dislocation Rates of Traditional and Dual Mobility Construct Designs

Dual mobility constructs have been used for over 30 years in a variety of patient types.[7–12]
The chart below highlights the clinical success of previous dual mobility designs compared to traditional constructs for patients with an increased risk of dislocation for reasons such as femoral neck fracture,[8] recurrent dislocation,[9] revision hip arthroplasty[10] and instability.[11]

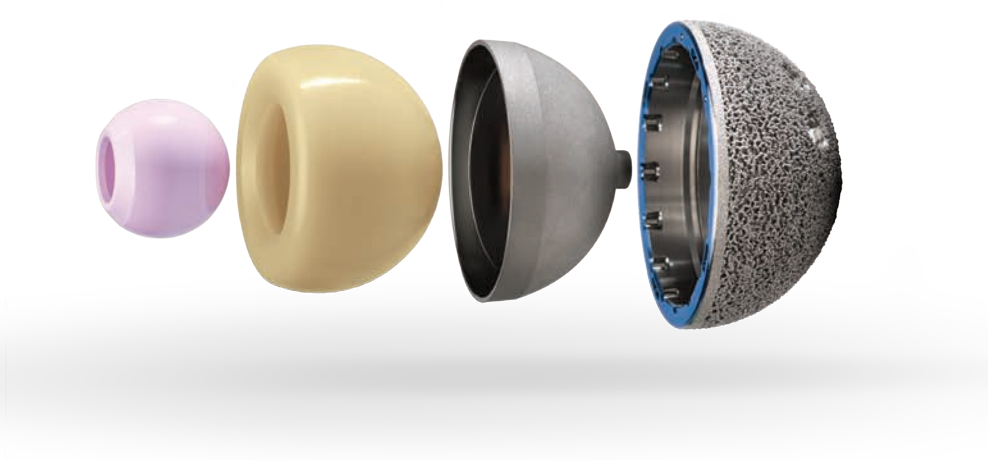


Clinically Proven Heritage

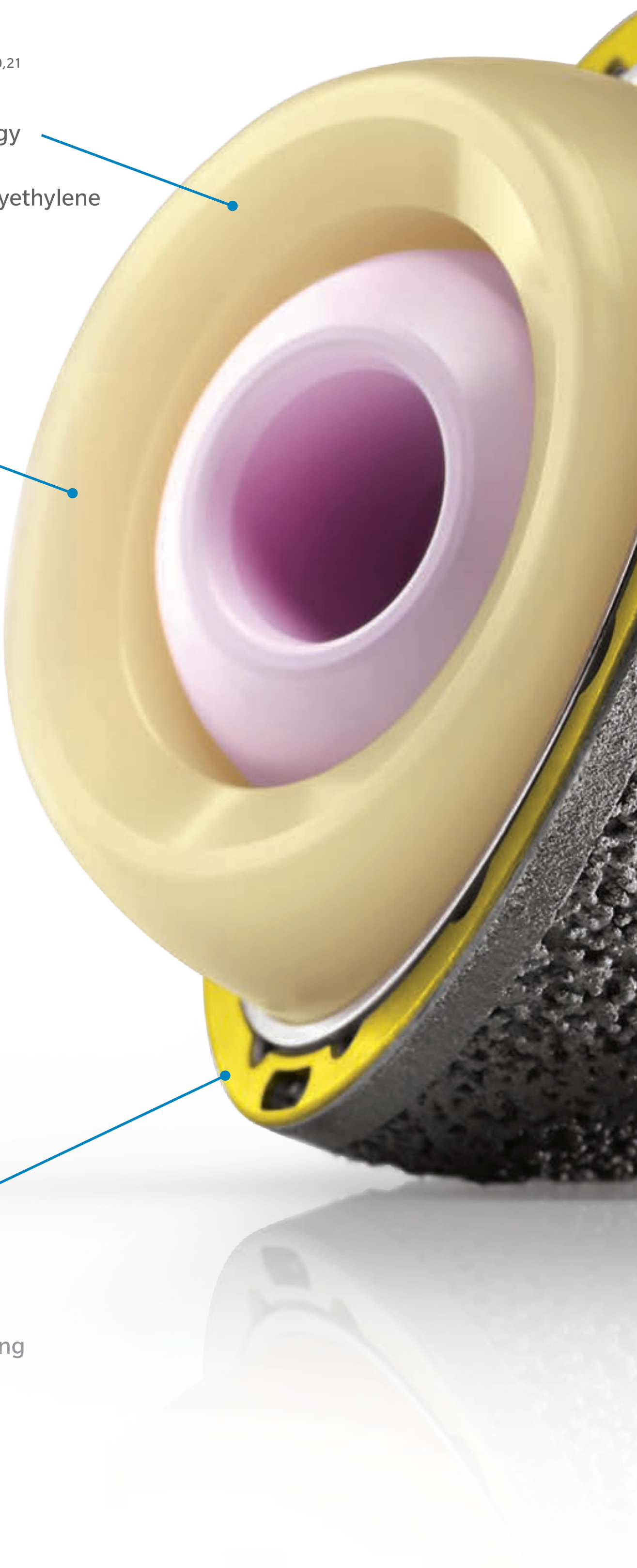
Zimmer Biomet continues to expand upon its rich history of clinically[16-19] successful acetabular products. The clinical experience with the Avantage®* acetabular system, E1 Antioxidant Infused Technology and ArComXL polyethylene has provided the foundation for the development of the G7 Dual Mobility construct.

97% survivorship at 9 years[16] – **Avantage** Dual Mobility Acetabular System*
98% survivorship at 5 years[17,18] – **E1** Antioxidant Infused Technology
99% survivorship at 5 years[18] – **ArComXL** Polyethylene
100% survivorship at 2 years[19] – **G7** PPS® Shell

*Not available for sale in the US.



Designed for Stability and Simplicity Without Sacrifice



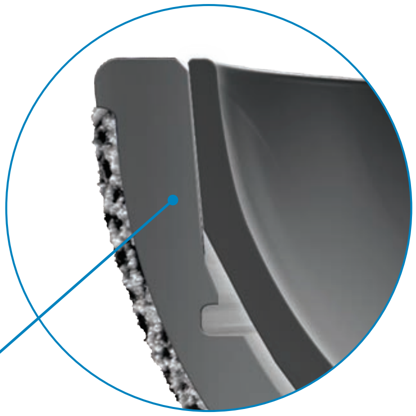
Bearing Options

Deliver high mechanical strength, low wear and oxidative resistance[20,21]

- E1 Antioxidant Infused Technology
- ArComXL Highly Crosslinked Polyethylene

Optimized Bearing to Shell Ratio

Facilitates the use of a 40 mm polyethylene bearing in a 50 mm shell



Locking Mechanism

Accommodates CoCr liner with a 10 degree taper angle for optimal engagement strength

Proprietary Color-Coded Shell

Corresponds with instrumentation and package labels to create an efficient and accurate OR environment*

*Primary identification should be made using size and letter designations.

Multiple Fixation Options

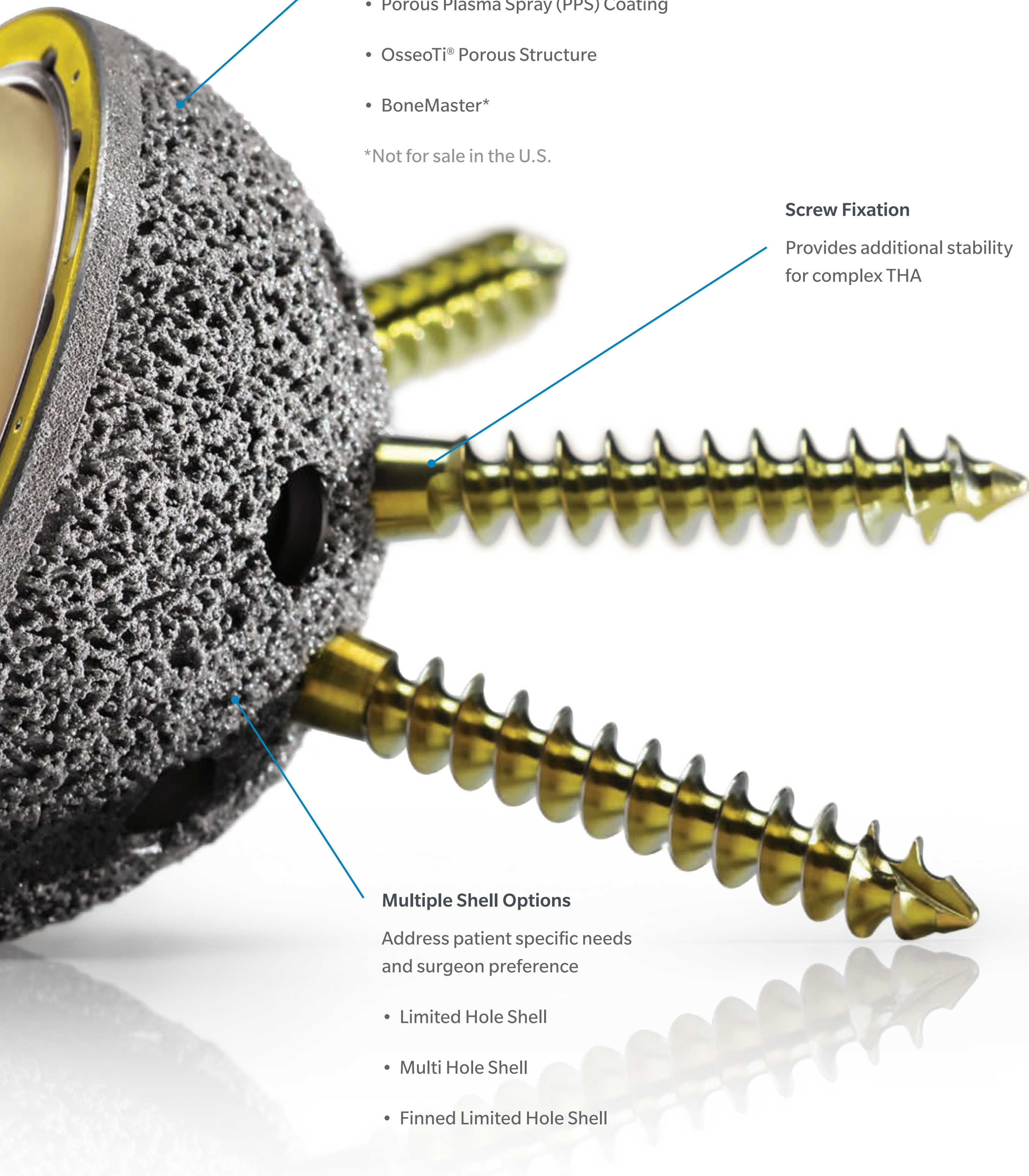
Designed to promote biological fixation[22,23]

- Porous Plasma Spray (PPS) Coating
- OsseoTi® Porous Structure
- BoneMaster*

*Not for sale in the U.S.

Screw Fixation

Provides additional stability for complex THA



Multiple Shell Options

Address patient specific needs and surgeon preference

- Limited Hole Shell
- Multi Hole Shell
- Finned Limited Hole Shell

Advanced Technology

OsseoTi Porous Metal

OsseoTi Porous Metal is created through the use of a proprietary additive manufacturing (3D printing) process. Human CT data is first digitized to recreate the natural human architecture of cancellous bone. Using clinically proven[24,32,33] titanium (Ti6Al4V) material, acetabular constructs are then printed layer by layer to build a fully integrated part with solid and porous regions. This process maintains consistent porosity and strength in order to facilitate tissue ingrowth and implant stability.[24*] When applied to the G7 system, this enables surgeons to realize the benefits of highly porous technology without compromising head to shell ratio.

› Unique porous architecture has demonstrated excellent integration with host bone as early as **4 weeks** in an animal study[21, 24*]

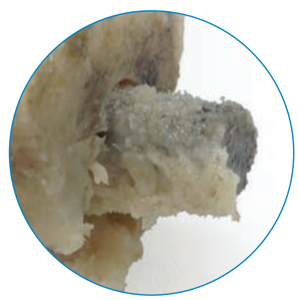
› Porosity of approximately **70%** directly mimics the structure of human cancellous bone

› Average **pore size of 475** microns facilitates cell migration, vascularization and bone ingrowth[21*]

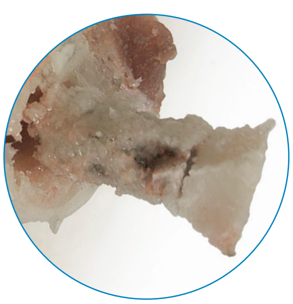
› Material strength between that of cancellous and cortical bone facilitates biological fixation and loading of surrounding bone[21, 24*]

* Animal studies are not necessarily indicative of clinical performance.

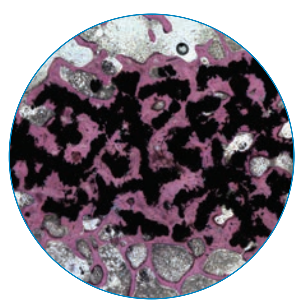
4 Weeks
Early Integration with Host Bone



12 Weeks
Bone Fusion Across an 8 mm Thick Sample



26 Weeks
Extensive Biological Fixation Fills the Entire Volume of Porous Sample



26 Week Histology
8 mm Bone Void

Black: OsseoTi structure
Red: New bone growth
White: Void

Polyethylene Materials

Meeting the modern demands placed upon bearing surfaces means achieving the optimal balance of maximized strength, wear resistance and oxidation resistance. The dual mobility polyethylene bearings achieve this by pairing the latest technological advancements with the strong heritage of clinically proven[34-36] ArCom® polyethylene. The G7 Dual Mobility CoCr liner accommodates two polyethylene bearing materials for use with BIOLOX® *delta* ceramic or CoCr femoral heads.

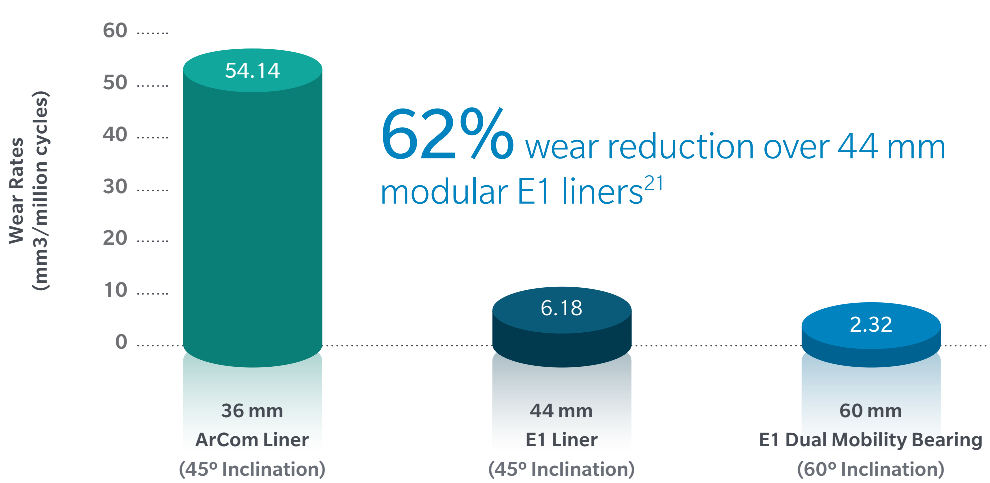
E1 Antioxidant Infused Technology

E1 technology is the only antioxidant infused bearing technology to use a proprietary diffusion process that provides oxidative stability via Vitamin E while maintaining strength and wear resistance. E1 antioxidant infused technology prevents oxidative degradation of the polyethylene.[25]

ArComXL Highly Crosslinked Polyethylene

ArComXL acetabular bearings utilize a solid state deformation process to obtain optimal wear resistance without sacrificing mechanical strength or increasing oxidation levels. ArComXL bearings have shown a 47% decrease in volumetric wear rate when compared to gamma sterilized polyethylene.[21]

Wear Rates for Acetabular Constructs[21]

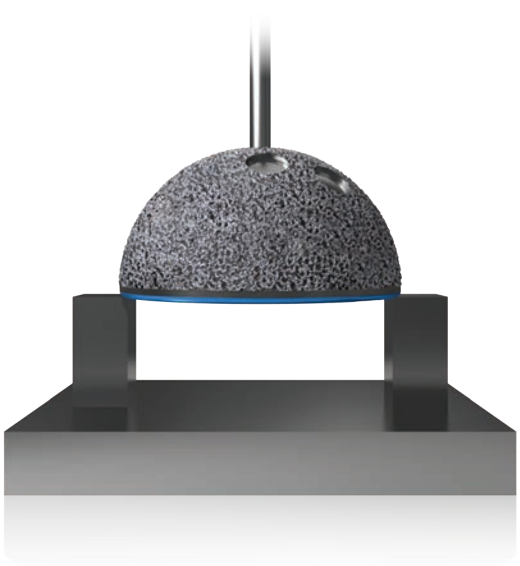


Strength Testing

Testing Methods

Acetabular systems must be strong enough to withstand the loading conditions commonly seen in the hip, maximizing strength and minimizing micromotion. Push out, lever out and fatigue tests are industry accepted testing methods which measure the strength of both the locking mechanism and the liner. In a dual mobility construct, it is also important to perform lever out testing to measure the strength of the polyethylene bearing. G7 metal liners and bearings were subjected to these testing methods under worst case conditions.[21]

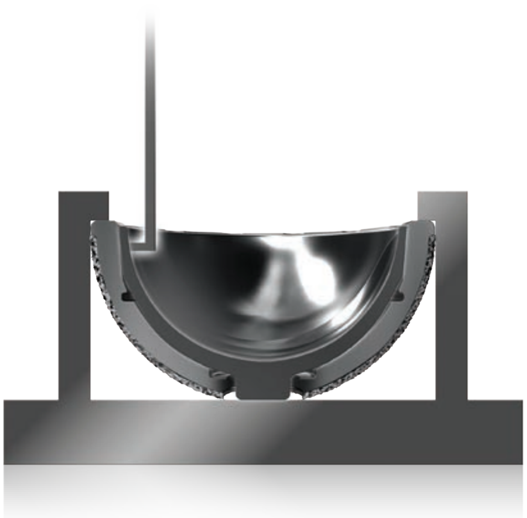
1879 lbf (8358 N) is the average push out force of a G7 Dual Mobility CoCr acetabular liner

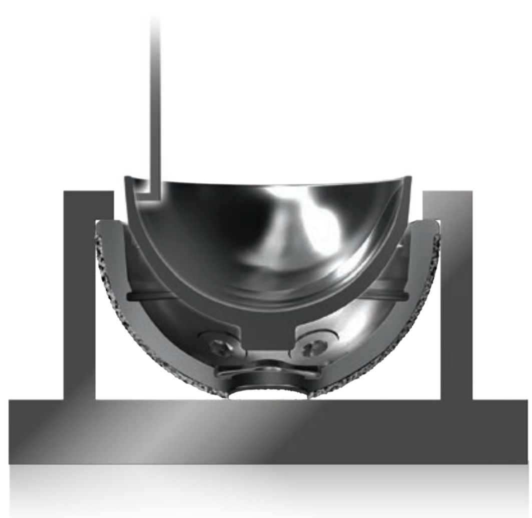


Metal Liner Push Out Testing

Push out testing measures the axial force required to dislodge a metal liner from an acetabular shell. Conducted per ASTM F1820-13, an assembled shell and liner was attached to a push out fixture that supported the cup without distortion. An axial load of 2 inches (50.8 millimeters) per minute was applied to the liner through the apical hole of the shell.[26]

206 in-lbf (916 N) is the average lever out torque of a G7 Dual Mobility CoCr acetabular liner



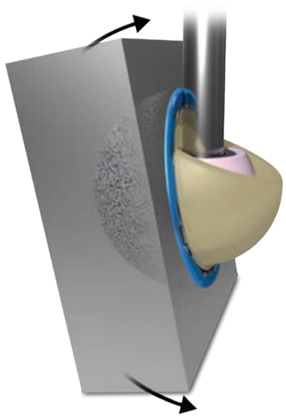


Metal Liner Lever Out Testing

Lever out testing measures the strength required to dislodge a fully seated liner from an acetabular shell. Conducted per ASTM F1820-13, a metal washer was epoxied to the articulating surface of the metal liner and a lever arm was inserted into the hole of the washer. The lever arm was then loaded at a constant tensile feed rate of 1.33 radians per minute until either washer or liner separation.[27]

Rim Impingement

The ability for the acetabular liner to withstand possible rim impingement, or impaction of the rim on the liner by the stem trunnion, is also key to the long term success of the implant. Rim impingement loading can occur in-vivo as a result of malalignment or patient movements that require a large range of motion. Conducted per ASTM F2582-08, the trunnion of a stem was allowed to contact the rim of the CoCr liner at a joint reactive force of 1000 N and torque of 1.50 Nm for one million cycles, simulating rim impingement loading conditions. Following the test, the liners were visually inspected for signs of damage.[28]



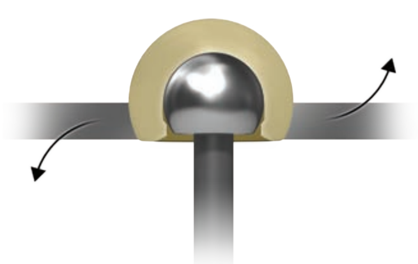
Metal Liner Results

Visual inspection of the CoCr liners showed no fracture, gross deformation or dislocation of any modular components.[28]

Femoral Head Lever Out Testing

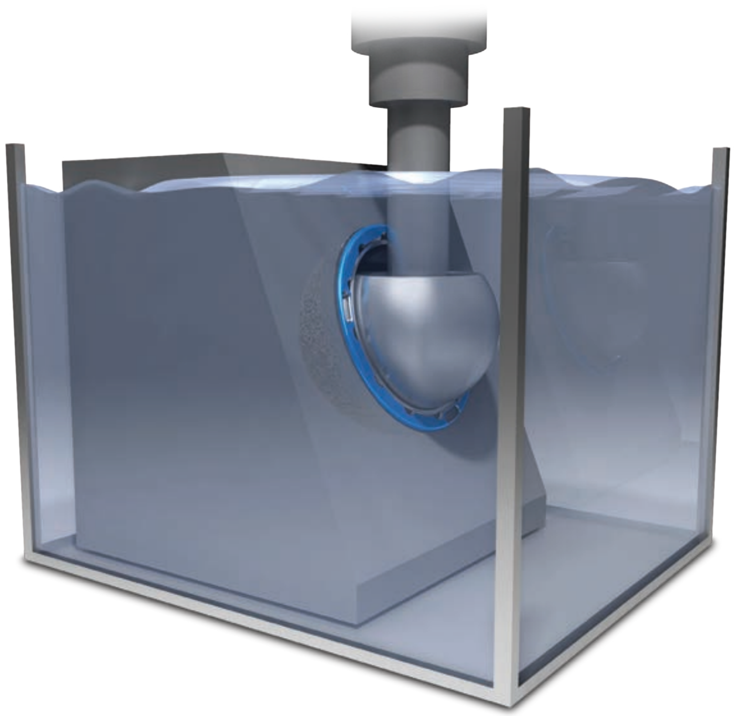
Femoral head lever out testing measures the force required to dislodge the femoral head from the dual mobility polyethylene bearing. Conducted per ASTM F1820-13, load was applied to the femoral head with a lever arm attached at the rate of 2 inches (50.8 millimeters) per minute until the head dislodged from the polyethylene bearing or liner dislodged from the shell.[31]

172 in-lbf (765 N) is the average lever out torque required to dislodge the femoral head from the dual mobility bearing



Liner Fatigue Fretting Testing

Liner fatigue fretting testing evaluates the potential for fretting between the acetabular shell and metal liner. Conducted per ASTM F1875-98, an assembled G7 shell and metal liner were potted at a 60 degree inclination angle to simulate extreme cup placement. The assembly was fully submerged in phosphate buffered saline solution at a temperature of 37°C to simulate physiological conditions. The femoral head and dual mobility bearing assembly was loaded and subjected to a 10 million cycle fatigue test. Once the test was completed a sample of saline solution was collected and examined by a third party laboratory for signs of debris. In addition, the liners were visually inspected for signs of damage.[29]



Metal Liner Results

There were no signs of fretting corrosion, deformations or failure due to fatigue on the metal liner or the shell. The debris analysis of the saline solution resulted in rates lower than those clinically reported in patients three years post THA.[30]* Additionally, there were no instances of dislocation of the polyethylene bearing or separation of the metal liner from the acetabular shell.[29]

*The articulating couple in this clinical report consisted of a modular cobalt-alloy femoral head and polyethylene liner.

Organized for Efficiency

Optimized Delivery System

Streamlining total hip replacement goes beyond implant design and bearing options. Full optimization of implant and instrument delivery systems is desired for improving flow and performance from implantation through processing. The G7 platform introduces a number of instrumentation advancements coupled with Zimmer Biomet's unique color-coding system in order to:

› Reduce the need for a large number of trays and instruments in the OR

› Customize instrumentation based on surgeon preference

› Simplify implant and instrument selection during surgery

Shell Provisional

Shell Implant

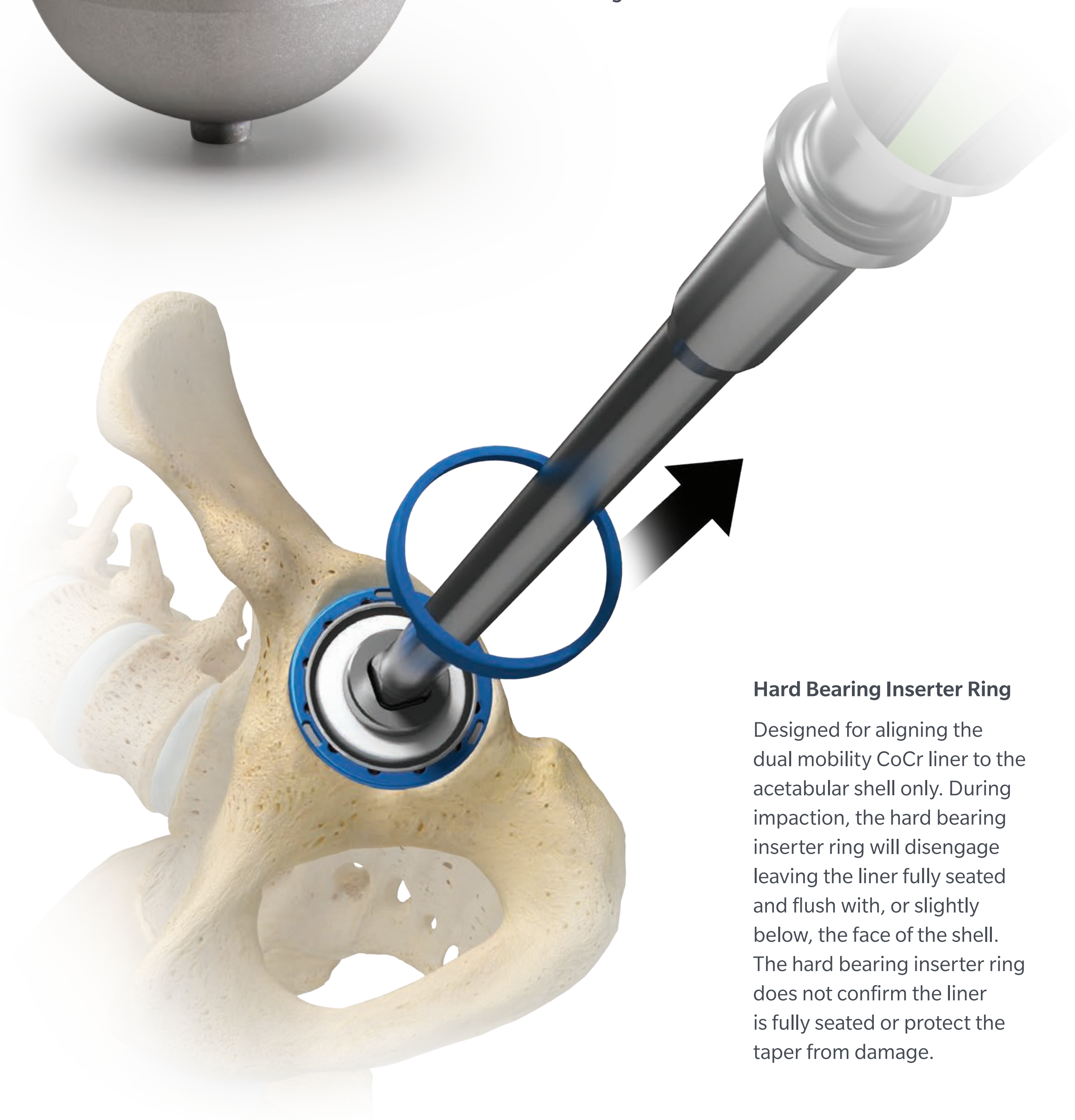
Face Plate Impactor

Liner Provisional

Bearing Provisional

Hard Bearing Inserter Ring

Dual Mobility CoCr Liner with Inserter Ring



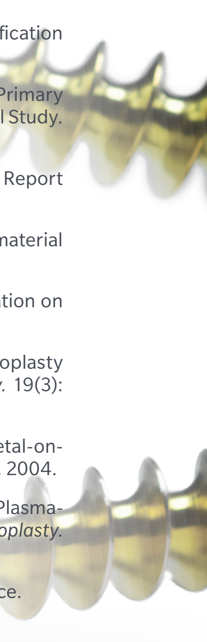
Hard Bearing Inserter Ring

Designed for aligning the dual mobility CoCr liner to the acetabular shell only. During impaction, the hard bearing inserter ring will disengage leaving the liner fully seated and flush with, or slightly below, the face of the shell. The hard bearing inserter ring does not confirm the liner is fully seated or protect the taper from damage.

References

1. Active Articulation Hip Bearings. IFU 01-50-1254 Rev B. April 2015.
2. Data on file at Biomet Freedom Constrained Liner vs G7 Dual mobility simulation testing. Bench testing is not necessarily indicative of clinical results.
3. De Martine, I. *et al.* Dual Mobility Cups in Total Hip Arthroplasty. *World Journal of Orthopedics.* 5(3): 180-7, 2014.
4. Burroughs, B. *et al.* Range of Motion and Stability in Total Hip Arthroplasty with 28-, 32-, 38- and 44-mm Femoral Head Sizes. *Journal of Arthroplasty.* 20(1):11- 19, 2005.
5. Beaule P. *et al.* Jumbo Femoral heads for the treatment of recurrent dislocation following total hip replacement. *Journal of Bone and Joint Surgery.* 84-A: 256-63, 2002.
6. Data on file at Biomet. G7 Dual Mobility Range on Motion Study. April 2015.
7. Vielpeau, C. *et al.* The Dual Mobility Concept: Experience with 668 Cases. *International Orthopaedics.* 35:225-30, 2011.
8. Tarasevicius, S. *et al.* Dual Mobility Cup Reduces Dislocation Rate after Arthroplasty for Femoral Neck Fracture. *BMC Musculoskeletal Disorders.* 11:175-8, 2010.
9. Hamadouche, M. *et al.* The Use of a Cemented Dual Mobility Socket to Treat Recurrent Dislocation. Clinical Orthopaedics and Related Research. Published online: June 8, 2010.
10. Philippot, R. *et al.* Prevention of Dislocation in Total Hip Revision Surgery Using a Dual Mobility Design. *Orthopaedics and Traumatolology: Surgery and Research.* 95:407-13, 2009.
11. Guyen, O. *et al.* Use of a Dual Mobility Socket to Manage Total Hip Arthroplasty Instability. *Clinical Orthopaedics and Related Research.* 467:465-72, 2009.
12. Pietrzak, W. Dual-Mobility Acetabular Components: Design Rationale for Enhanced Stability. Biomet Orthopedics Form No. BOI0480.0.
13. Khatod, M. *et al.* Revision Total Hip Arthroplasty: Factors Associated with Re-Revision Surgery. *Journal of Bone and Joint Surgery.* 97:359-66, 2015.
14. Moskal, *et al.* Improving the Accuracy of Acetabular Component Orientation: Avoiding Malpositioning. *Journal of Bone and Joint Surgery.* 95:e76 (1-10), 2013.
15. Millienium Research Group. US Markets for Large-Joint Reconstructive Implants, 2013.
16. NJR data extract, March 2014 - analyzed by Biomet.
17. Nebergall, A.K. *et al.* Five year experience of Vitamin E Stabilized, Irradiated Ultrahigh Molecular Weight Polyethylene wear and stability of Regenerex™ Acetabular Shells and Femoral Components using Radiostereometric Analysis (RSA). ORS 2014, Poster #1831.
18. Ongoing Biomet-funded study; data on file at Biomet.
19. G. Grappiolo. G7 Acetabular Cup System Two Year Clinical Follow-up. On-going clinical study; data on file at Biomet.
20. Kurtz, S. *et al.* Anisotropy and Oxidative Resistance of Highly Crosslinked UHMWPE after Deformation Processing by Solidstate Ram Extrusion. Biomaterials. 27:24-34, 2006.
21. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance. Laboratory testing.
22. Biomet 510(k) Number K140669. G7 OsseoTi Acetabular Shells. 2014.
23. Biomet 510(k) Number K121874. G7 PPS Acetabular Shells. 2012.
24. Gupta, G. OsseoTi Porous Metal For Enhanced Bone Integration: an Animal Study. Biomet Form No. BMET0718.0-GBL. Animal studies are not necessarily indicative of clinical performance.
25. FDA cleared claim. See biomet.com/e1 for complete claim language
26. Data on file at Biomet. Metal Liner Fatigue and Push-out Test. Verification Report VV143. February 2015.
27. Data on file at Biomet. Metal Liner Fatigue and Lever-out Test. Verification Report VV144. January 2015.
28. Data on file at Biomet. Metal Liner Rim Impingement Test. Verification Report 148. February 2015.
29. Data on file at Biomet. Metal Liner Fatigue Fretting Test. Verification Report VV142. January 2015.
30. Jacobs, J. *et al.* Metal Release in Patients Who Have Had a Primary Total Hip Arthroplasty: A Prospective, Controlled, Longitudinal Study. *Journal of Bone and Joint Surgery.* 80-A (10): 1447 -58, 1998.
31. Data on file at Biomet. Metal Head Lever Out Test. Verification Report VV154. February 2015.
32. Long M, RAck HJ. Titanium alloys in total joint replacement - A material science prospective. (1998) Biomaterials 19:1621-1639.
33. Woodell-May J, Kumar M. In vitro comparison of cell proliferation on Ti6Al4V and Tantalum Metal. ORS 2007, Poster #1578.
34. Berend, K,. *et al.* Cementless Double-Tapered Total Hip Arthroplasty in Patients 75 Years of Age and Older. *Journal of Arthroplasty.* 19(3): 288-95, 2004.
35. Lombardi, A., *et al.* Mid-Term Results of a Polyethylene-Free Metal-on-Metal Articulation. *Journal of Arthropalsty.* 19(7 Suppl. 2): 42-7, 2004.
36. Klassen, M.A., *et al.* Midterm Survivorship of a Press-fit, Plasma-sprayed , Tri-Spiked Acetabular Component. *Journal of Arthroplasty.* 24(3): 391-9, 2009.

* Animal studies are not necessarily indicative of clinical performance.



For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and www.zimmerbiomet.com

This material is intended for health care professionals and the Zimmer Biomet sales force. Distribution to any other recipient is prohibited.

Please check for local product clearances and reference product specific instructions for use.

Not for distribution in France.

ZIMMER BIOMET
Your progress. Our promise.™

0006.1-GLBL-en-REV1215

Legal Manufacturer
Biomet Orthopedics
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA
UK

Note: For Ceramic components contained within this Surgical Technique, Biomet UK, Ltd is the Legal Manufacturer.

EC REP **European Representative**
Biomet UK, Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA
UK

CE 0086

CE mark is not valid unless there is a CE mark on the product label.

www.zimmerbiomet.com