

Trilogy[®] IT Acetabular System



Note: Devices in this document are not available in the United States.



The essential design focuses on the power to choose from among component options that help optimize two key aspects of total hip arthroplasty: fixation and bearings.

For orthopedic surgeons treating a wide range of patients, the *Trilogy®* IT Acetabular System provides a clinically proven¹⁻⁵ Fiber Metal Material and the power to choose advanced bearing options that best meet individual patient needs.

Clinically Proven Fiber Metal Material

Over twenty-five years of clinical history¹⁻⁵

Power to choose advanced bearing technologies to match patient demands

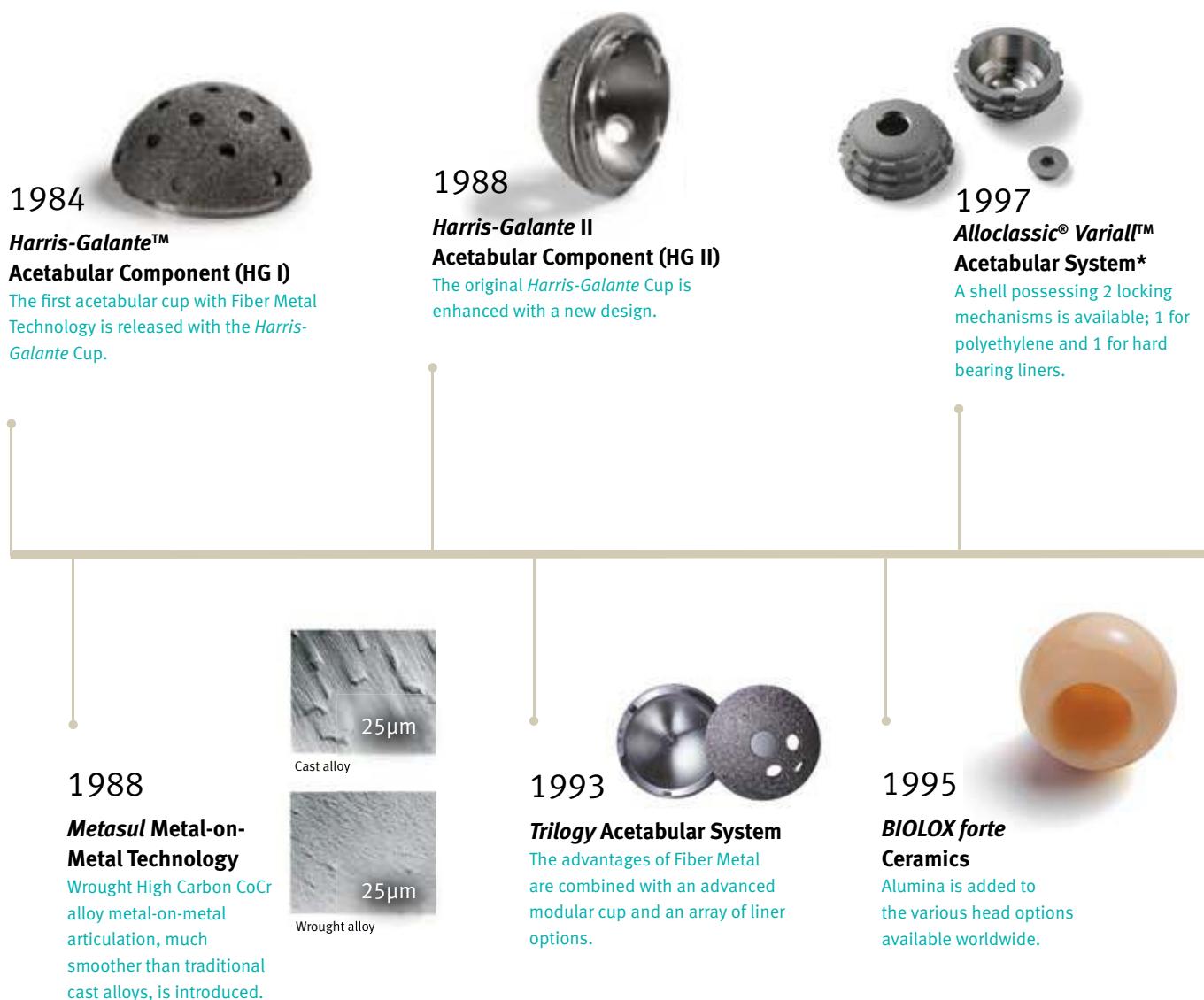
Longevity® Highly Crosslinked Polyethylene is highly resistant to wear and aging, with over ten years of proven clinical history.⁵⁻¹⁵

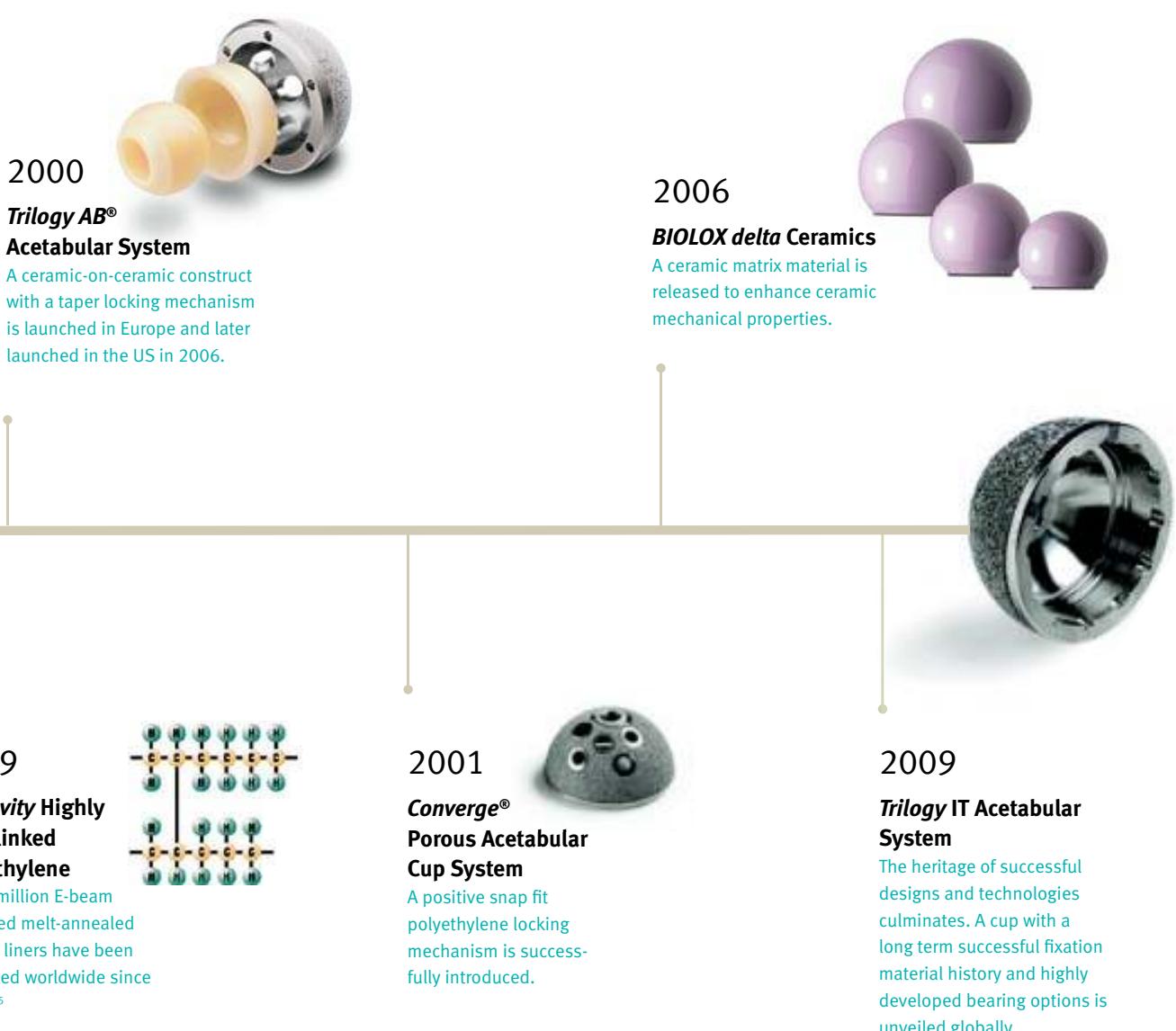
Metasul® Technology has a very low wear rate with over twenty years of clinical history.^{5,16}

BIOLOX® delta Ceramic[†] affords a very low wear rate in a material with improved mechanical properties compared to traditional ceramics.²²

Zimmer's Acetabular History

The *Trilogy IT Shell* design combines the best attributes of Zimmer's time-tested acetabular implant systems and bearing options. There has been a long clinical history of key design features that have been incorporated into the *Trilogy IT Acetabular System*.





Clinically Proven Fiber Metal Mesh

The *Trilogy* IT Acetabular System incorporates a proven porous material possessing 25 years of history, with advanced bearing surfaces. Millions of acetabular shells with Fiber Metal have been implanted worldwide since its initial clinical launch in 1984.⁵

The history of Fiber Metal began with the introduction of the *Harris-Galante* Acetabular Cup. The *Trilogy* Acetabular System was then launched in 1993 with the same Fiber Metal Material. Due to Fiber Metal's performance, it is still one of the most popular porous materials on the market over 25 years later.

A recent clinical publication reports that the *Trilogy* Acetabular Component had 100% survival at a mean follow-up of 9.5 years.¹ Another publication that evaluated 262 hips with the *Trilogy* Acetabular System demonstrated that 99% of the cups (259) had radiographic evidence of well-fixed bone ingrowth at a mean of 7 years.² A third study, with a 14.9 year average follow up, reported evidence of bony ingrowth in all patients (80) with the *Harris-Galante* Acetabular Cup.³ Finally, a recent publication reported the performance of the *Harris-Galante* Acetabular System used in revision total hip arthroplasty. This study of 132 patients, at a follow-up of 20 to 24 years, demonstrated a 95% survivorship with revision of the shell for aseptic loosening or radiographic evidence of loosening as the end point.⁴

Advanced Bearing Options to Match Patient Demands

The *Trilogy* IT System was designed for optimum surgeon flexibility. It provides the power to choose advanced bearing surfaces that match patient demands and minimize wear. There has been considerable progress in material processing that separates conventional articular surfaces from the advanced alternative bearing surfaces.

Laboratory testing has shown that, due to these advancements, wear rates have been significantly reduced compared to first-generation polyethylene bearing surfaces.¹⁸ Zimmer's highly acclaimed research and development has led to the availability of three advanced alternative bearing options for use with the *Trilogy* IT Acetabular System:

Longevity Highly Crosslinked Polyethylene

Metasul Metal-on-Metal Articulation

BIOLOX delta Ceramic

The wear performance of a bearing surface *in vivo* is affected by many factors, including implant material, implant design, processing, sterilization, and packaging. In creating implants with these advanced bearing surfaces, Zimmer has considered all of these factors to optimize the wear performance of acetabular liners.

By offering a selection of advanced alternative bearing materials with very low wear rates, Zimmer provides surgeons with exceptional intraoperative bearing material options.[‡] The surgeon can then select the bearing component based on important factors such as patient needs.



Trilogy IT Acetabular System Overview

The system consists of a hemispherical Fiber Metal Shell, optional screws, optional hole plugs, and a selection of bearing choices, including *Longevity* Highly Crosslinked Polyethylene, *Metasul* Metal-on-Metal Articulation, and *BIOLOX delta* Ceramic.

The *Trilogy IT* design combines the best attributes of Zimmer's time-tested acetabular implant systems and bearing options. There has been a long clinical history of key design features that have been incorporated into the *Trilogy IT* System.



Trilogy IT Shell

Hemispherical Shell Options

The *Trilogy* IT Acetabular Shell has a full-hemisphere design, which creates a secure press fit and maximizes the contact area between the shell and bone. This enhances the interfacial strength and initial stability. The substrate of the hemispherical shell is made from *Tivanium* Ti-6Al-4V Alloy. The fixation surface consists of Fiber Metal Mesh Material, made from commercially pure Titanium, which is bonded to the substrate.

Two shell designs are available:

- Cluster-holed
- Multi-holed

The cluster- and multi-holed designs are for use with *Trilogy* Acetabular Screws (*Tivanium* Alloy) to facilitate secure fixation, particularly in patients who may have deficient acetabular bone stock or quality. The screw holes are positioned to allow anatomic placement of screws in the thickest and strongest part of the pelvis for secure unicortical screw fixation.

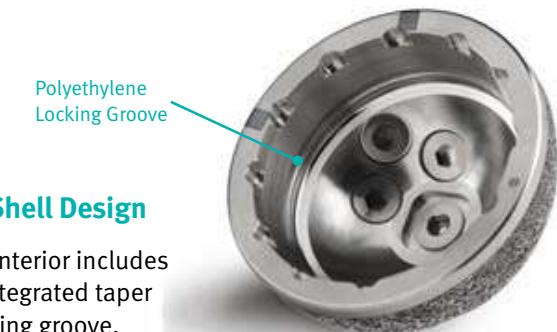
The angulation of the screw holes provides additional flexibility in the direction of screw placement. All screw holes possess the same dimensions and allow for the same angulations.

The shell dome hole is identical for both designs and is threaded for attachment of the shell positioning instrument and engagement of the hole plug.



Exterior Shell Design

The shell is a full hemisphere. The labeled size of the shell is equivalent to the actual outer diameter of the shell at the equator. The provisionals are also a full hemisphere, as are typical reamers. During preparation, any desired press fit must be considered. In other words, if press fit is desired the reamer preparation dictates the amount of press fit gained.



Interior Shell Design

The shell interior includes both an integrated taper and a locking groove, allowing flexibility to choose between polyethylene and hard bearing liner options. The integrated taper is designed to mate and lock with hard-bearing liners, while the locking groove is designed to mate and lock with polyethylene liners.

The inside rim of the shell has 12 equally spaced antirotation scallops which mate with corresponding tabs on the polyethylene liners to enable variable liner orientation.

Polyethylene Locking Mechanism

The polyethylene locking mechanism consists of a circumferential protrusion on the liner and a corresponding 360° groove on the shell, providing a secure fit, and minimizing potential for back-side wear.

Hard Bearing Locking Mechanism

The integrated taper utilizes a circumferential 18° locking taper. This taper has been used on Zimmer hard bearing acetabular products since 1997, and is designed to maximize the stability of the liner while allowing for ease of insertion into the shell.



Dome Hole and Screw Hole Plugs

Dome hole plugs mate with the threads in the dome hole of the shell. Screw hole plugs are not threaded, but have an elliptical shape that creates an interference fit with the screw holes in the shell. They are locked in place with a simple short turn. Both plugs, made from *Titanium Alloy*, can help limit potential debris migration into the acetabulum, which can lead to osteolysis induced bone resorption and loss of fixation. Both plugs are considered optional.

Dome Hole Plug



Screw Hole Plug



Shell Options

Trilogy IT shells are available in multiple sizes to fit a wide range of patient anatomies. They are available in cluster- and multi-holed styles.

Liner Exchange

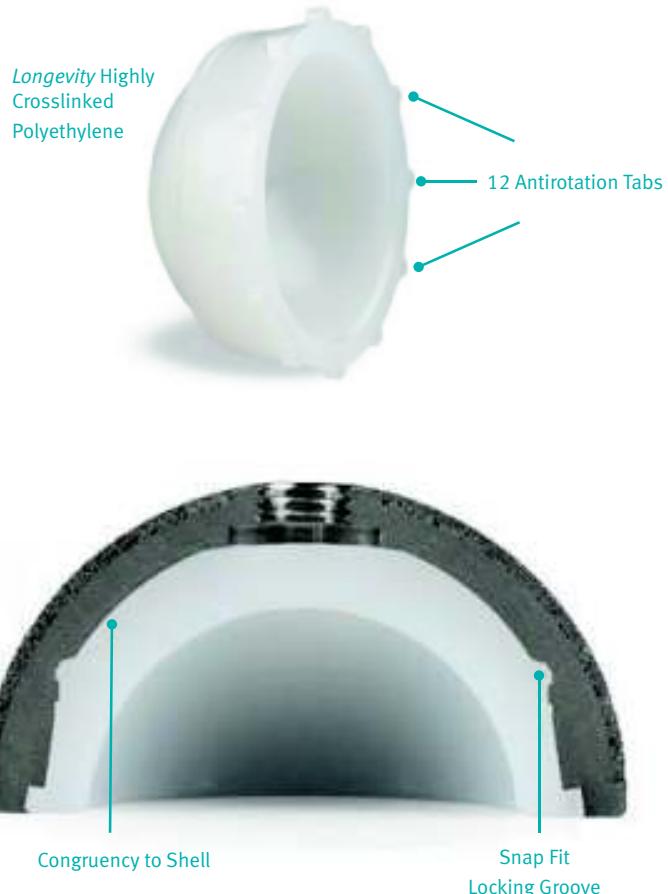
Liners can be exchanged. Special instrumentation is available to simplify hard bearing liner removal. Instructions are provided in the Surgical Technique.

Longevity Highly Crosslinked Polyethylene Liners

Longevity Polyethylene Acetabular Liners are machined from compression molded material. They can be used with a variety of metal and ceramic heads.[‡]

Secure Locking Mechanism

Longevity Liners are secured by engaging a protruding rim on the liner with a corresponding locking groove in the shell. In addition, antirotation tabs surrounding the rim of the liner mate with the corresponding scallops on the shell to help minimize micromotion and wear, while allowing variable liner orientation to optimize femoral head coverage. Congruency between the shell and polyethylene liner has been designed to maximize liner support. This helps reduce polyethylene debris generation and increases the component's resistance to load and stress.



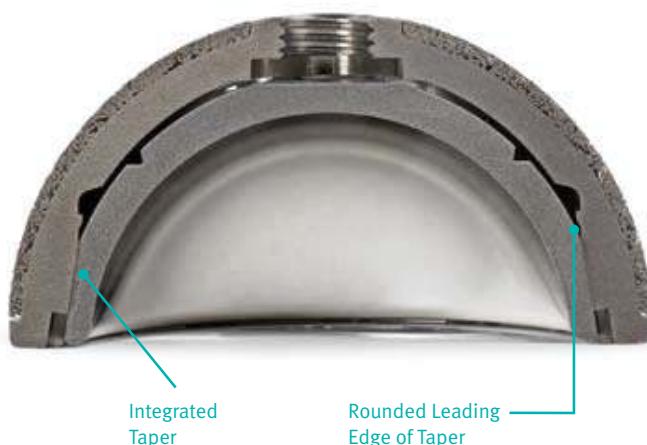
Metasul Metal-on-Metal Articulation

The *Metasul* Liner is designed for use only with the specifically designed *Metasul* Femoral Head to allow for optimum tribological function.



Secure Locking Mechanism

Metasul Liners are secured by a taper locking system, consisting of a circumferential 18° taper around the outside rim of the liner. This taper corresponds with an opposing 18° integrated taper in the shell. The leading edge of the taper is rounded to help facilitate insertion and avoid liner canting. When the liner is placed into the shell, an impaction force is used to securely lock the corresponding tapers. For disassembly, a specific hard bearing liner removal instrument is used to release the liner from the shell.



BIOLOX delta Ceramic Material

BIOLOX delta Ceramic was chosen for this system since it offers an extremely low wear rate with improved mechanical properties compared to Alumina, allowing ceramic to be considered for use in younger, more active patients.

BIOLOX delta Head

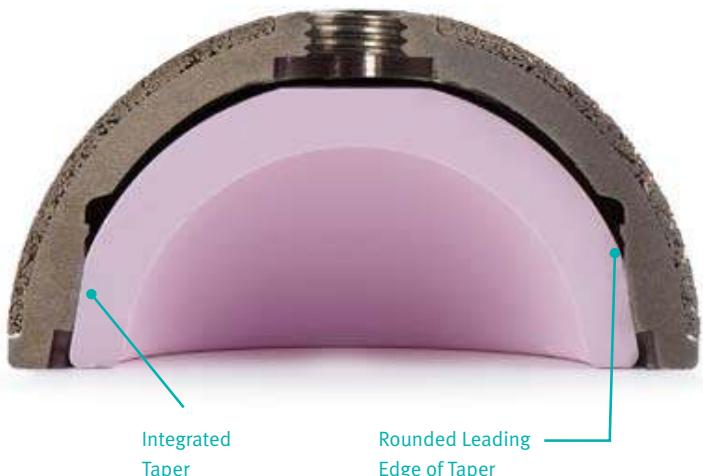


BIOLOX OPTION Head with Revision Adapter



Secure Locking Mechanism

The ceramic liner utilizes the same locking mechanism as the metal bearing liner, an 18° taper. Thus, the same secure taper connection is obtained.



Revision & Liner Exchange

BIOLOX delta OPTION Heads have a metal adapter sleeve that affords the potential to place a ceramic femoral head on a previously implanted stem. If a head has been removed from a stem taper and a new replacement ceramic head is desired, the *BIOLOX delta OPTION* Head may provide a solution. Refer to the Instructions for Use for additional information.

BIOLOX delta Liners can exchanged. Special instrumentation is available for liner removal. Instructions are provided in the Surgical Technique.

References

1. Lachiewicz, PF, et al., Polyethylene Wear and Osteolysis with a New Modular Titanium Acetabular Component, *J Arthroplasty*. 2008; 23 (7): 971 - 976
2. Della Valle, AG, et al., Clinical and Radiographic Results Associated with a Modern, Cementless Modular Cup Design in Total Hip Arthroplasty *J Bone Joint Surg Am.* 2004; 86: 1998-2003
3. Parvizi J, et al., Fifteen-year clinical survivorship of Harris-Galente total hip arthroplasty, *J Arthroplasty*. 2004; 19 (6): 672-677
4. Park DK, et al., Revision of the Acetabular Component Without Cement, A Concise Follow up at Twenty to Twenty-four years, of a previous report, *J Bone Joint Surg Am.* 2009; 91: 350-355
5. Data on file at Zimmer
6. Medel FJ, Kurtz SM, MacDonald DW, et al., First-generation highly crosslinked polyethylene in THA: clinical and material performance. 55th Annual Meeting of the Orthopaedic Research Society, Las Vegas, 2009
7. Kärrholm J, Five to seven years experiences of highly crosslinked PE. Abstract number 19059, SICOT Hong Kong, August 2008
8. McCalden RW, MacDonald SJ, Rorabeck CH, Bourne RB, Chess DG, Charron KD, Wear Rate of Highly Crosslinked Polyethylene in Total Hip Arthroplasty. A Randomized Controlled Study. *J Bone Joint Surg Am.*, 2009; 91: 773-782
9. Bragdon CR, et al., Seven to Ten Year Follow-Up of Highly Crosslinked Polyethylene Liners in Total Hip Arthroplasty, Poster No. 2444, 55th Annual Meeting of the Orthopaedic Research Society, Las Vegas, 2009
10. Wannomae KK, et al. In vivo oxidation of retrieved crosslinked ultra-high molecular-weight polyethylene acetabular components with residual free radicals. *J Arthroplasty*. 2006; 21(7):1005-1011
11. Collier JP, et al., Comparison of crosslinked polyethylene materials for orthopaedic applications. *Clin Orthop.* September 2003; (414) :289-304
12. Bhattacharyya S et al., Severe *In Vivo* Oxidation in a Limited Series of Retrieved Highly Crosslinked UHMWPE Acetabular Components with Residual Free Radicals, 50th Annual Meeting of the Orthopaedic Research Society, Paper 0276, Las Vegas, 2004
13. Jibodh SR, et al., Minimum Five Year Outcome and Wear Analysis of Large Diameter Femoral Heads on Highly Crosslinked Polyethylene Liners, Poster No. 2445, 55th Annual Meeting of the Orthopaedic Research Society, Las Vegas, 2009
14. Bragdon CR, et al., Minimum 6-year Follow up of Highly Crosslinked Polyethylene in THA, *Clin Orthop.* December 2007; (465): 122-127
15. Digas et al., Crosslinked vs. Conventional Polyethylene in Bilateral Hybrid THR Randomised Radiostereometric Study, 50th Annual Meeting of the Orthopaedic Research Society, Poster No. 0319, Las Vegas, 2004
16. Rieker CB, Schön R, Köttig P, et al., Development and validation of a second-generation metal-on-metal bearing: laboratory study and analysis of retrievals. *J Arthroplasty*. 2004; 19 (8, suppl 3): 5-11
17. Stewart TD, et al., Long-term wear of ceramic matrix composite materials for hip prostheses under severe swing phase micro-separation, *J Biomed Mater Res B Appl Biomater.* 2003; 66: 567-573
18. Laurent MP et al., Characterization of a Highly Crosslinked Ultra High Molecular Weight Polyethylene in Clinical Use in Total Hip Arthroplasty. *J Arthroplasty*, 2008; 23 (5): 751-761

[†] BIOLOX is a registered trademark of CeramTec AG Corporation

[#] Refer to the Zimmer compatibility website at www.productcompatibility.zimmer.com for more detailed information regarding compatibility of the Trilogy IT System with other Zimmer products

*Alloclassic Variall Acetabular System is not approved for sale in the United States

Disclaimer

This document is intended exclusively for physicians and is not intended for laypersons.

Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Information contained in this document was gathered and compiled by medical experts and qualified ZIMMER personnel. The information contained herein is accurate to the best knowledge of ZIMMER and of those experts and personnel involved in its compilation. However, ZIMMER does not assume any liability for the accuracy, completeness or quality of the information in this document, and Zimmer is not liable for any losses, tangible or intangible, that may be caused by the use of this information.