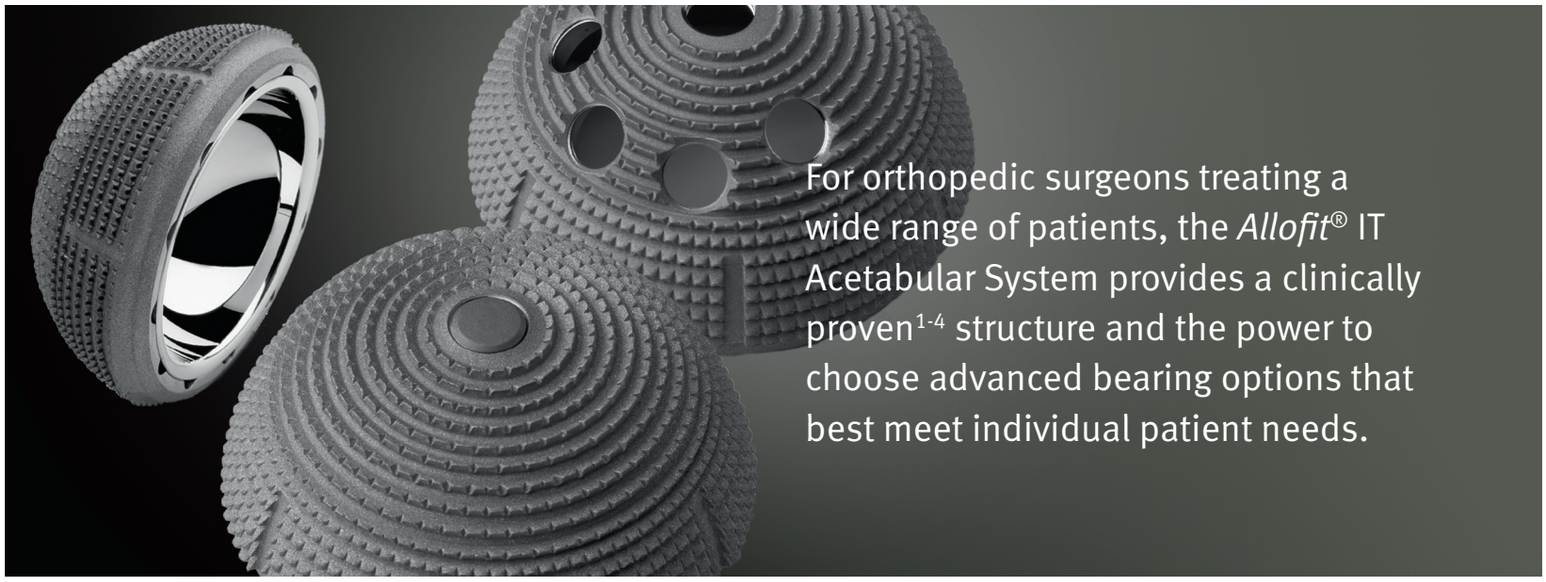


This System focuses on the *Allofit Alloclassic*® Shell design history combined with the power to choose from among component options that help optimize two key aspects of total hip arthroplasty: fixation and bearings.

Clinically proven structure of the *Allofit* Acetabular System

- Over fifteen years of clinical history [1-4]

Power to choose advanced bearing technologies to match patient demands

- *Longevity*® Highly Crosslinked Polyethylene that is highly resistant to wear and aging, with over ten years of proven clinical history.[5-14]
- *Metasul*® Technology has a very low wear rate with over twenty years of clinical history.[15,16]
- *BIOLOX*® *delta* Ceramic,† affords a very low wear rate in a material with improved mechanical properties compared to traditional ceramics.[17]

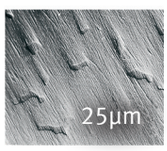
Zimmer's Time-tested Acetabular History

The *Allofit IT* Acetabular System combines attributes of Zimmer's time-tested acetabular implant systems and bearing options.

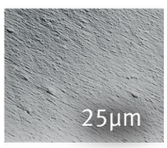
1988

***Metasul* Metal-on-Metal Technology**

Wrought High-Carbon CoCr alloy Metal-on-Metal articulation, much smoother than traditional Cast alloys, is introduced.



Cast alloy



Wrought alloy

1994

***Allofit* Acetabular System**

The first Acetabular cup with a characteristic macro and microtextured surface is launched.

1995

***BIOLOX forte* Ceramics**

Alumina Ceramic is added to the various head options available worldwide.

1997

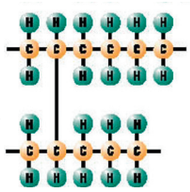
***Alloclassic Variall*™ Acetabular System**

A shell possessing 2 locking mechanisms; 1 for polyethylene and 1 for hard bearing liners is available.

1999

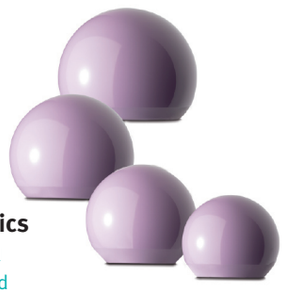
***Longevity* Highly Crosslinked Polyethylene**

Over 1 million E-beam irradiated melt-annealed Zimmer liners have been implanted worldwide since launch.[4]



2000

***Trilogy* AB®**
Acetabular System
A ceramic-on-ceramic construct with a taper locking mechanism is launched in Europe.



2006

***BIOLOX delta* Ceramics**
A ceramic matrix material is released with enhanced mechanical properties

2001

***Converge*®**
Porous Acetabular Cup System
A positive snap fit polyethylene locking mechanism is successfully introduced.

2009

***Allofit* IT Acetabular System**
The heritage of successful designs and technologies culminate. A cup with a proven fixation surface and highly developed bearing options is unveiled globally.

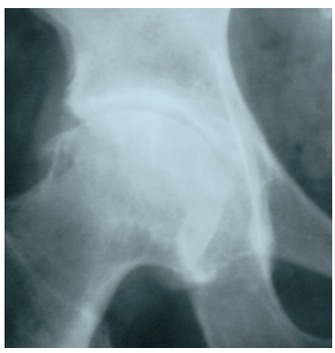
Clinically Proven Shell Structure

The *Allofit* IT Acetabular System incorporates a proven exterior shell structure possessing 15 years of history, with advanced bearing surfaces. Over 300,000 *Allofit* Acetabular Shells have been implanted since its initial clinical launch in 1994.[4]

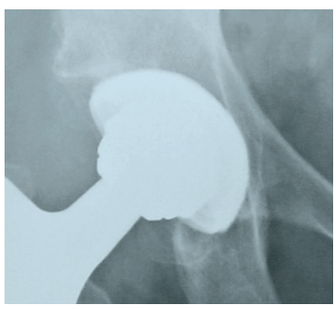
A recent clinical publication reports 10 years of follow up on the *Allofit* Cup.[1] Out of 100 hips implanted 81 were available for follow up. Of the remaining, 6 patients died, 11 did not show for follow up and 1 had a revision for deep infection. Radiographic evaluation after 10 years showed no lucencies in 78 of 81 hips. Three had a lucent line of 1mm in zone III. The authors detected no signs of osteolysis, loosening or migration. No reoperations for any reason, except the two septic cases, were performed. The authors reported the clinical and radiographic results to be "very satisfying."

An additional recent study compared usage of the *Allofit* Cup with 2 different liner types.[3] The prospective randomized study assessed the results using two different polyethylenes in the same cup. The authors compared 45 *Allofit* Acetabular components with a *Sulene*® Polyethylene Liner and 45 with a *Durasul*® Polyethylene Liner. All were matched with an *Alloclassic* Stem and a 28 mm modular femoral head. The mean follow-up was 66.3 months (approximately 5.5 years). While there was a difference in polyethylene penetration rate measured, there was no loosening of any shell component. Also, importantly, there were no radiolucent lines or osteolysis.

Overall, performance of the *Allofit* Shell has demonstrated success of this design. The exterior shell design of the *Allofit IT* Acetabular System is identical to the *Allofit* exterior shell design.



Preoperative, Female, 67 years old



Postoperative, 10-year follow-up
Allofit Cup

Advanced Bearing Options to Match Patient Demands

The *Allofit* 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 *Allofit* IT Acetabular System:

Longevity **Highly Crosslinked Polyethylene**

Metasul **Metal-on-Metal Articulation**

BIOLOX delta **Ceramic**

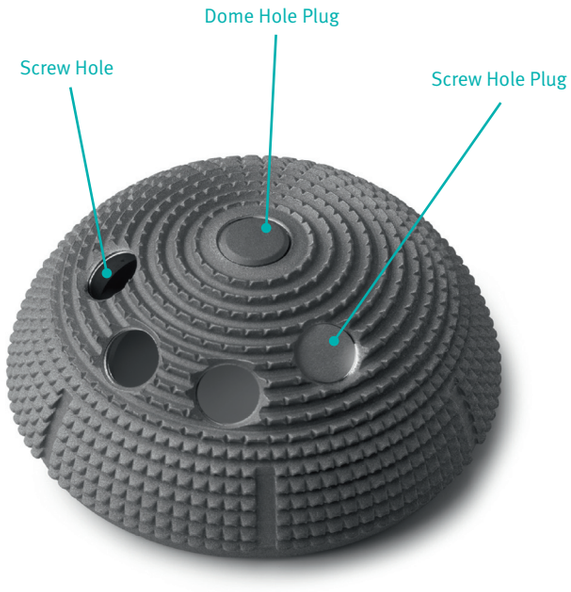
The wear performance of a bearing surface *in vivo* is affected by many factors, including implant material, implant design, processing, sterilization, and packaging. In creating implants with these advanced bearing surfaces, Zimmer has considered all of these factors to optimize the wear performance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

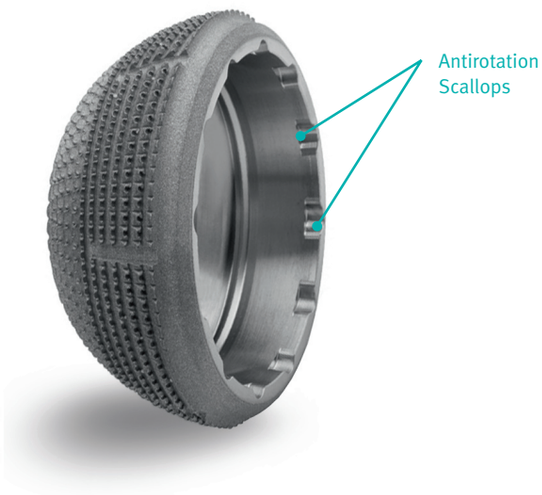
By offering a selection of advanced alternative bearing materials with very low wear rates, Zimmer provides surgeons with exceptional intraoperative bearing material options. The surgeon can then select the bearing component based on patient needs.

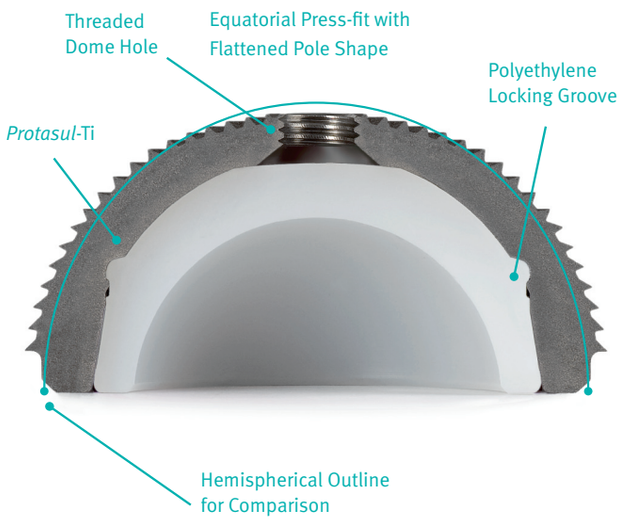
Allofit IT Acetabular System Overview

The system includes a press-fit shell featuring an oversized equatorial region and flattened polar region, with a commercially pure Titanium (*Protasul*®-Ti) macrostructured fixation surface, 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-on-Ceramic Bearing.

The *Allofit* IT Shell design combines key attributes of Zimmer's proven acetabular implant systems and bearing options. There has been a long clinical history of key design features of these components that have been incorporated into the *Allofit* IT System.







Allofit IT Shell

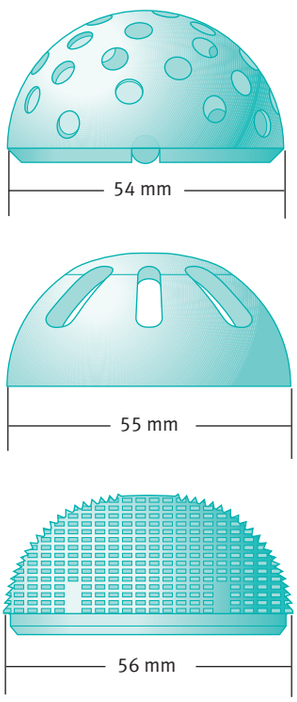
Press-fit Shell Design

The *Allofit* IT Shell is made from commercially pure Titanium (Protasul-Ti). The outer surface is grit-blasted. Equatorial oversizing and flattening in the dome are essential design characteristics of this type of acetabular shell. The design is characterized by a macrostructure consisting of numerous small, barb-like shaped teeth, oriented in different directions.

The *Allofit* IT Cup imitates the natural shape of the acetabulum, and is therefore bone-conserving. As a result, it is possible to preserve and use the subchondral bone as support for the implant.

The flattened polar zone, in combination with the oversize in the equator of the shell, enhances the press-fit effect because the area of bone contact and load transfer is concentrated on the equatorial portions of the implant. This improves primary and secondary stability, which closely correlates to the physiological load transfer in a natural hip joint.[19]

The labeled size of the shell provides 2mm of press fit at the equator. The provisionals are oversized by 1mm compared to a typical reamer, which is a full hemisphere.

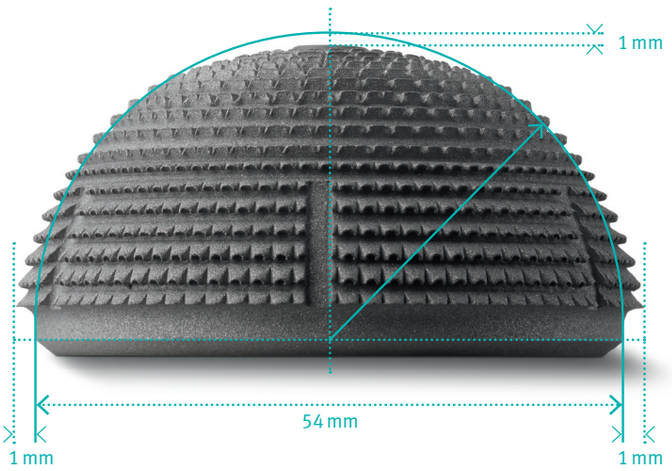


Acetabular Reamer
Labeled 54 mm
Measures 54 mm

Provisional Shell
Labeled 54 mm
Measures 55 mm

Implant Shell
Labeled 54 mm
Measures 56 mm

Allofit Shell shape relative to provisionals and reamers.



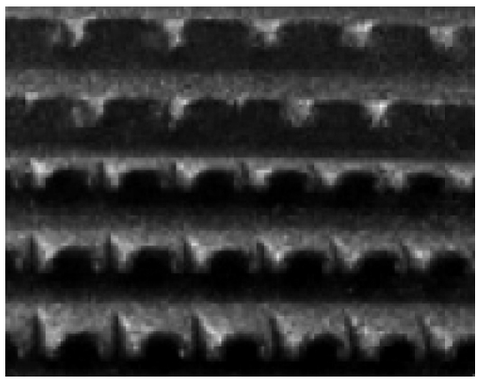
Equatorial oversizing and polar zone flattening are essential design characteristics.

Macrostructure

A large number of small teeth, one millimeter in height, form the macrostructure on the surface of the *Allofit* IT Cup.

The surface area is significantly increased as a result of the macrostructure. This combined with the grit-blasted surface of the biocompatible pure Titanium provides good conditions for rapid, firm secondary stability which is a pre-condition for durable long-term fixation.

The exterior surface of the shell has two differently structured zones.



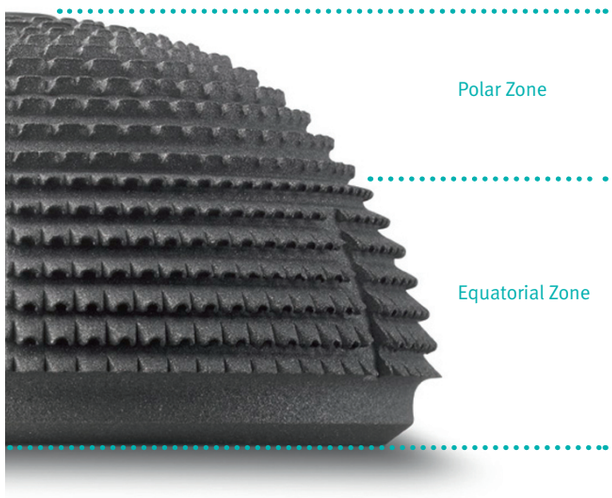
More than 1,000 teeth help ensure primary stability.

Polar Zone

Towards the dome, the teeth are oriented towards the pole of the cup. This structure provides additional stability but does not prevent the cup from being impacted into the desired position.

Equatorial Zone

This area includes a number of concentric rows of teeth that are shaped like small barbs. In addition, in this area the cup has six vertical grooves that ensure additional rotational stability. These structures give the implant high rotational and lever-out stability and provide a firm and stable press-fit.



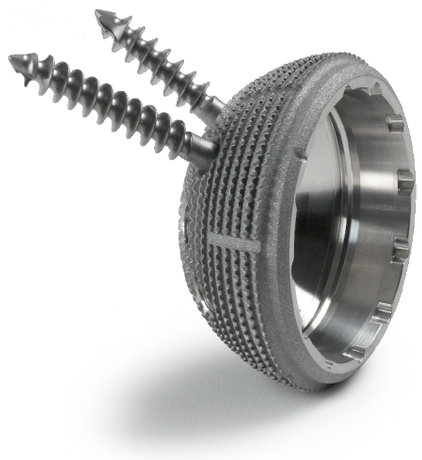
Two shell designs are available.

The Allofit IT Shell is designed for applications where no screws are desired, with a single polar dome hole to aid in shell placement and to provide visual confirmation that the shell is fully seated into the acetabulum. The *Allofit*-S IT Shell is designed for additional screw fixation. Depending on the shell size, up to seven screw holes are available. 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 shells and is threaded for attachment of the shell impactor and engagement of the dome hole plug. The screw hole plug and the dome hole plug are both made of Titanium and are considered optional.

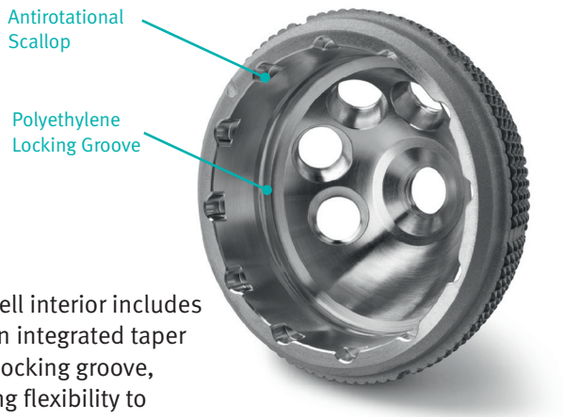
Allofit IT Shell without screw holes

Allofit-S IT Shell for additional screw fixation



Screws can be angled to achieve good bone purchase.

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 interior of the shell at the pole is offset by 1mm. It should also be noted that the liners are offset at the pole by 1mm. This shifts the center of head rotation out by 2mm.

Polyethylene Locking Mechanism

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

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.

Hard Bearing Locking Mechanism

The integrated taper utilizes a circumferential 18° locking taper. This taper has been utilized 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 also threaded and mate with the screw holes in the shell. Both plugs, made from Titanium, can help limit potential debris migration into the acetabulum, which can lead to osteolyis induced bone resorption and loss of fixation. Both plugs are considered optional.

Dome Hole Plug

Screw Hole Plug

Liner Exchange

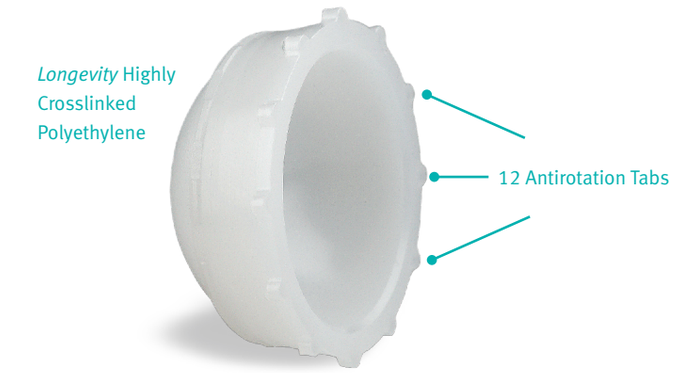
Liners can be exchanged. Special instrumentation is available to simplify hard bearing liner removal. Instructions are provided in the Surgical Technique.

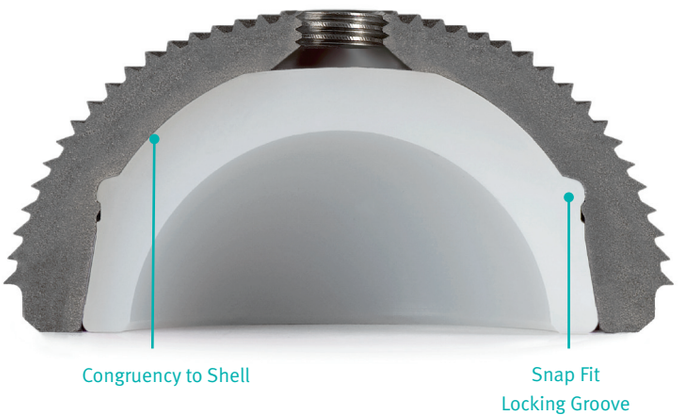
Longevity Highly Crosslinked Polyethylene Liners

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 placement. 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.



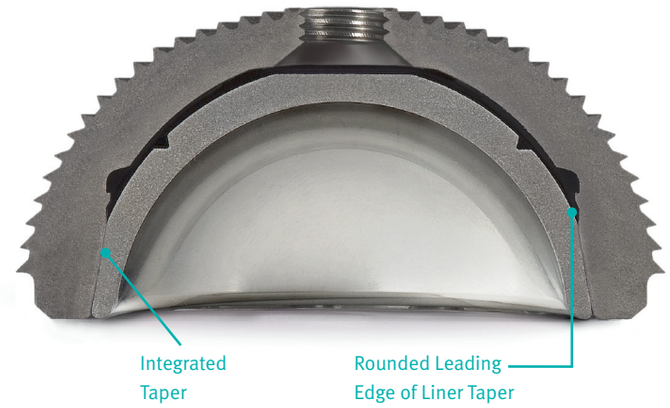


Metasul Metal-on Metal Articulation

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

Secure Locking Mechanism

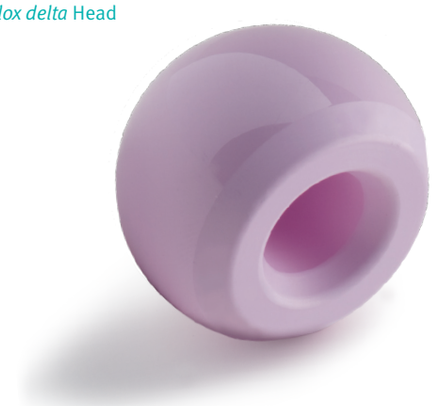
Metasul Liners are secured by a taper locking system consisting of a circumferential, 18° taper around the outside rim of the liner. This taper corresponds with an opposing, 18° integrated taper in the shell. The leading edge of the liner taper is rounded to help facilitate insertion and avoid canting. 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 Ceramic, allowing it to be considered for use in younger, more active patients than was traditionally considered.

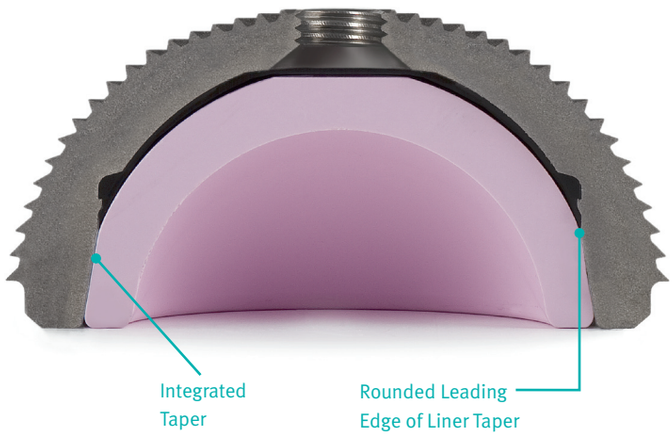
Biolox delta Head



Biolox OPTION Head with Revision Adapter

Secure Locking Mechanism

The ceramic liner utilizes the same locking mechanism as the *Metasul* Metal-on-Metal liner, an 18° taper.



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 be exchanged. Special instrumentation is available for liner removal. Instructions are provided in the Surgical Technique.

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† *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 *Allofit* IT System with other Zimmer products.

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