# *TRILOGY AB*™ ACETABULAR SYSTEM

## (Ceramic-on-Ceramic)

CE 0473
Acetabular Shells
Manufactured by:
Zimmer U.K. Ltd.
South Marston Park
Swindon, SN3 4FP
UK

CE 0123
Alumina Ceramic
Inserts
Manufactured by:
Zimmer, Inc.
1800 West Center
Warsaw, IN 46580
USA

Authorized Representative:
Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP
UK

**Carefully read all instructions and be familiar with the surgical technique prior to use.**

### IMPORTANT NOTE

- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.

- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the compatibility of these devices with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.).

### DESCRIPTION

The *Trilogy AB* Acetabular System is a modular, alternate bearing acetabular cup system consisting of a shell, insert, and optional screws.

The shells are made from *Tivanium*™ Ti-6Al-4V Alloy with a full hemisphere of commercially pure titanium fiber metal. The fiber metal shells may also be provided with *Calcicoat*™ Ceramic Coating (HA/TCP). The acetabular shells are offered in 12 sizes ranging from 48-70mm in 2mm increments.

The shells have screw holes to permit the use of *Tivanium* screws for additional fixation, particularly in those cases where acetabular bone stock is deficient. Only 6250-45-xx and 6250-65-xx series screws should be used with the *Trilogy AB* shell.

The *Trilogy AB* shell is packaged separately and requires a compatible *Trilogy AB* insert to complete the acetabular component. The *Trilogy AB* insert is made from aluminum oxide ($Al_2O_3$) ceramic and should be used only with the *Trilogy AB* shell.

Once the metal shell has been seated in the acetabulum, a locking taper secures the ceramic insert into the shell.

Commercially available alumina ceramic ($Al_2O_3$) femoral heads are offered for use with the *Trilogy AB* components. The heads are offered in 28 and 32mm diameters and three neck lengths each.

The *Trilogy AB* ceramic-on-ceramic articulation system will be implanted with the following commercially available Zimmer femoral stems.

> *VerSys*™ Hip System Fiber Metal MidCoat Stems are manufactured from *Tivanium* Ti-6Al-4V Alloy, feature a proximal porous surface of commercially pure titanium fiber metal, and are indicated for cementless use. The offering includes collared and collarless stems with standard and large metaphysis body styles, as well as standard, extended and extra extended offsets. The stems are also available with *Calcicoat* Ceramic Coating (HA/TCP) applied to the porous surface.
>
> *VerSys Heritage*™ Femoral Stems are manufactured from *Zimaloy*™ Cobalt-Chromium-Molybdenum Alloy and are indicated for cemented use. The offering includes CDH, standard and extended offset stems.

Both stem families have a 12/14 neck taper to mate with the corresponding alumina ceramic femoral heads of the *Trilogy AB* System.

**INDICATIONS**

The *Trilogy AB* Acetabular System components are indicated for either cemented or noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

**CONTRAINDICATIONS**

- Skeletal immaturity
- Infection
- Any nerve or muscle disease that may have a negative effect on gait or weight bearing
- Loss of abductor musculature in the affected limb
- Poor bone stock

- Poor skin coverage around the hip joint
- Rapid disease progression as obvious by joint destruction or bone absorption seen on x-ray

**WARNINGS**

- Seat the acetabular shell at a 45° inclination with 20° anteversion for proper positioning to decrease the chance for dislocation.
- Always ensure proper alignment and seating of the acetabular liner before impacting to prevent chipping or damage.
- Do not disassemble or reassemble the liner component to the acetabular shell because the locking joint and taper joint might become damaged.
- Do not scratch modular shells and tapers to prevent damage to the locking joint.
- Do not use another manufacturer's components with any of the *Trilogy AB* components.
- Replace any component that has been chipped, scratched, or otherwise damaged. Do not replace the ceramic insert unless the metal acetabular shell is also being revised.
- Do not implant this device in obese patients because loading on the ceramic components may lead to fracture or loss of fixation.
- Implants are for single use only. Do not reuse.
- Do not resterilize ceramic components and return all packages with flaws.
- Bone necrosis induced by radiation can occur as the result of therapeutic exposure to >35 Gy for the treatment of cancer. Osteoradionecrosis of the acetabulum is a relative contraindication to total hip joint replacement because of the likelihood of failure of the acetabular implant due to poor bone stock. Where hip arthroplasty is necessary and pelvic radiotherapy has previously occurred, use of protrusio rings, bone graft harvested from outside the zones of irradiation, and bone cement may be required to minimize the risk of subsequent failure of the acetabular implant.
- Where there is loss of or insufficient acetabular bone stock, bone grafting or other adjunctive reinforcement procedures to provide socket support and cup containment are recommended.
- Screws provided with this system are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Do not use this product for other than labeled indications (off-label use).
- Improper selection, placement, and positioning of the implant components may result in unusual stress conditions and subsequent reduction in the service life of the prosthetic implants.

**PRECAUTIONS**

- Do not use metal or zirconia ceramic femoral heads with *Trilogy AB* components. Only *Zimmer* Alumina Ceramic Heads (6428 series) are to be used with the *Trilogy AB* components.
- Clean surgical debris from the mating surfaces to help ensure proper seating and assembly and to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.

- Use caution in handling ceramic components during assembly because of the brittle nature of ceramic material.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall with screws that are too long can result in internal bleeding and possible damage to vital organs.
- Avoid detachment of porous or HA/TCP coating which could lead to increased debris particles.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.
- Do not use implant components (femoral head, acetabular insert) to perform trial reduction. Provisional components are available for this purpose. During the trial range of motion, ensure that the femoral stem does not contact the acetabular insert.
- Safety and effectiveness have not been established in patients with the following conditions:
    - Revision hip arthroplasty
    - Inflammatory hip joint disease
    - Neuropathic hip joint disease

**CLINICAL STUDY RESULTS**

The following clinical data supporting the approval decision for the Zimmer *Trilogy AB* Acetabular System is the same clinical data contained in P010001 for the Ceramic TRANSCEND Articulation System owned by CeramTec AG and approved by CDRH on February 3, 2003. The following ceramic heads and liners implanted in this clinical study have identical articulating surfaces to those used in the Zimmer *Trilogy AB* Acetabular System. The stems and shells implanted in this study are similar, but not identical to the stems and shells approved for use with the Zimmer *Trilogy AB* Acetabular System.

The study was a prospective, multi-center, non-masked clinical trial of 959 procedures in 848 patients, comparing the referenced ceramic hip system to a historical control group.

**Adverse Events**

Adverse events related to total hip replacement surgery reported in the clinical study of 959 patients are listed in Table 1.

**Table 1: Reported Adverse Events**

| Event | Clinical Study (n=959) | | Whiteside Clinical Study (n=211) | |
|---|---|---|---|---|
| **Systemic** | **Freq.** | **% of Pop.** | **Freq.** | **% of Pop.** |
| Deaths | 9 | 0.9% | 0 | 0% |
| Pulmonary Embolism | 2 | 0.2% | 2 | 0.9% |
| Deep Vein Thrombosis | 4 | 0.4% | 0 | 0% |
| **Local** | **Freq.** | **% of Pop.** | **Freq.** | **% of Pop.** |
| Revisions/Removals[1] | 11 | 1.1% | 8 | 3.8 |
| Breakage/Fracture of Component[2] | 5 | 0.5% | 2 | 0.9% |
| Dislocation (single) of Component[3] | 8 | 0.8% | 3 | 1.4% |
| Dislocation (recurrent) of Component[4] | 2 | 0.2% | 0 | 0% |
| Femoral Fracture | 18 | 1.9% | 9 | 4.3% |
| Hematoma | 2 | 0.2% | 0 | 0% |
| Heterotopic Ossification | 1 | 0.1% | 1 | 0.5% |
| Infection: Deep, Early <l year | 2 | 0.2% | 0 | 0% |
| Infection: Deep, Late > 1 year | 1 | 0.1% | 0 | 0% |
| Infection: Superficial | 7 | 0.7% | 0 | 0% |
| Loosening of Component | 3 | 0.3% | 2 | 0.9% |
| Migration of Component | 2 | 0.2% | 0 | 0% |
| Persistent Foot Drop | 2 | 0.2% | 0 | 0% |
| Pain | 10 | 1.0% | 0 | 0% |
| Perforation of Femur During Reaming | 2 | 0.2% | 0 | 0% |
| Wear of Component | 1 | 0.1% | 0 | 0% |
| Subsidence of Component | 3 | 0.3% | 2 | 0.9% |
| Soft Tissue Trauma | 0 | 0% | 0 | 0% |
| Wound Problems | 2 | 0.2% | 0 | 0% |
| Other Local Complication[5] | 10 | 1.0% | 0 | 0% |
| **Local-Hip** | **Freq.** | **% of Pop.** | **Freq.** | **% of Pop.** |
| Trochanteric Bursitis | 16 | 1.7% | 1 | 0.5% |
| Trochanteric Non-union | 0 | 0% | 0 | 0% |
| Trochanteric Avulsion | 4 | 0.4% | 0 | 0% |

**Notes:**

1 See details in the following Table 4 for n=959.

2 Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision. Whiteside Clinical Study: Broken metal peg of acetabular cup.

3 2 were revised for this reason.

4 1 was revised for this reason.

5 Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off.

## Potential Adverse Effects Associated with any Total Hip Arthroplasty

- Excessive wear of the ceramic components secondary to damage of mating wear surfaces or debris particles;
- Although rare, metal sensitivity reactions in patients following joint replacement have been reported;
- Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts;
- Possible detachment of the porous coating, which could lead to increased debris particles;

- Pain;
- Femoral or acetabular perforation, or bone fracture while seating the device;
- Damage to blood vessels resulting in hematoma;
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- Undesirable shortening or lengthening of the limb;
- Traumatic arthrosis of the hip from intraoperative positioning of the extremity;
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- Temporary or permanent neuropathies;
- Delayed wound healing;
- Infection;
- Migration, loosening, subluxation, or dislocation of the prosthesis;
- Periarticular calcification or ossification, with or without impediment to joint mobility;
- Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification; and
- Death.

**Potential Adverse Effects Associated with the *Trilogy AB* Acetabular System**

- Wear of the ceramic acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
- While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
- Component dissociation.
- Breakage or chipping of the femoral head or acetabular insert.

**Pivotal Clinical Study**

The study was a prospective, multi-center, non-masked clinical trial of 959 procedures in 848 patients, comparing the Ceramic TRANSCEND Hip Articulation System to the historical control group of the Whiteside Total Hip System, which was approved in 1990.

Although the primary efficacy endpoint in the clinical study was the survivorship of the Ceramic TRANSCEND Hip Articulation System as assessed at the two year postoperative interval, for the purpose of the clinical study, the primary efficacy endpoints included Harris Hip Score (HHS) and radiographic assessments at 2 years, as well. In addition, patient satisfaction was assessed by the SF-12 at two years.

Complication rates were the primary safety endpoint.

**Study Design**
The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hips System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the Ceramic TRANSCEND device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

**Clinical Patient Assessment**
Each patient was evaluated at the immediate and 6, 12, and 24-month post-operative intervals, unless otherwise indicated by complications. At each follow-up visit, a Harris Hip Score and SF-12 was administered as well as obtaining AP and lateral radiographs. Radiographs were reviewed by the implanting surgeon. There were no pre-specified success/failure criteria in the pivotal clinical study.

**Demographics**
For the study population, there were a total of 965 procedures performed in 854 patients at 12 sites by 19 surgeons. Six of these patients did not meet study inclusion criteria (one procedure enrolled as a replacement for a previously implanted THR and five procedures performed in patients with rheumatoid arthritis). These six procedures are excluded from this analysis. Therefore, the primary analysis sample included 959 procedures for first hip replacements performed in 848 patients.

The patient accounting and Baseline Demographics are summarized in Tables 2 and 3. Note that there were 9 deaths, none of which were related to the study or to the device.

**Table 2: Patient Accounting**

| Evaluation Interval | Original Clinical Patient Population (n=329) | | | Continued Access Population (n=630) | | |
|---|---|---|---|---|---|---|
| | TFU | EFU | AFU(%) | TFU | EFU | AFU(%) |
| Pre-Op | 329 | 329 | 100% (n=329) | 630 | 630 | 100% (n=630) |
| 6 months | 329 | 323 | 93% (n=300) | 602 | 602 | 71% (n=430) |
| 12 months | 329 | 321 | 91% (n=293) | 443 | 442 | 53% (n=233) |
| 24 months | 329 | 321 | 94% (n=302) | 151 | 150 | 0% (n=0) |

TFU = Theoretical Follow-Up; EFU = Expected Follow-Up (Theoretical Follow-Up minus deaths and removals without replacement); AFU = Actual Follow-up

**Table 3: Baseline and Demographics**

| Values | Total Study Procedures (n=959) | Whiteside Clinical Study (n=211) |
|---|---|---|
| Mean Age in Years | 51.4 Years (range 20-80) | 62.7 years (range 22-87) |
| Gender | 595 (62%) Males<br>364 (38%) Females | 112 (53%) Males<br>99 (47%) Females |
| Mean Body Mass Index ($kg/m^2$) | 28.8 (range 17.7-65.8) | 27.1 (range 22.8-40.9) |
| Diagnosis<br>Osteoarthritis<br>Avascular Necrosis<br>Traumatic Arthritis<br>Congenital Hip Dysplasia | <br>692 (72.2%)<br>189 (19.7%)<br>36 (3.8%)<br>42 (4.4%) | <br>180 (85.3%)<br>31 (14.7%)<br>0<br>0 |
| Mean Baseline Total HHS (range 1-100) | 45.1 (range 8.3-95.9) | 42.7 (range 11-79) |
| Mean Baseline Pain HHS (range 0-44) | 12.9 (range 0-44) | 13.2 (range 0-30) |
| Mean Baseline Harris ROM°(range 0-5) | 3.8 (range -3.1-4.88) | 4.1 (range not available) |

## Safety and Effectiveness Data

### Safety Results

The adverse events related to total hip replacement surgery reported in the pivotal clinical study of 959 procedures in 848 patients are listed in Table 1.

### Revisions and Removals

Eleven devices out of the 959 primary patients enrolled in the trial have been revised or removed. Table 4 summarizes the clinical information pertaining to these cases.

**Table 4: Summary of Revisions and Removals**

| Procedures | Age/ Gender | Diagnosis | Duration of Implantation | Reason for Revision/Removal |
|---|---|---|---|---|
| Revision of acetabular component with bone graft and cage implantation | 50/F | AVN | 84 days | Migration of acetabular component |
| Revision of femoral head with a longer neck | 29/F | Congenital Hip Dysplasia | 1 day | Dislocation |
| Replaced acetabular component to larger size (32mm) and replaced femoral head to 35mm | 43/M | Severe Osteoarthritis with mild hip dysplasia | 1 day | Dislocation |
| Replacement of acetabular component, liner, and femoral head. Repair of abductor mechanism. | 62/M | Osteoarthritis | 38 days | Persistent dislocation following closed reduction, trochanteric fracture with avulsion of abductors. |
| Revision followed by removal and girdlestone procedure | 51/M | Traumatic arthritis | 210 days | Deep infection and stitch abscess |
| Replacement of acetabular liner | 36/F | Congenital hip dysplasia | 3 days | Acetabular liner disassociated from shell |
| Replacement of acetabular liner and femoral head | 41/M | Osteoarthritis | 14 days | Increasing pain, suspected infection |
| Replacement of acetabular liner and femoral head | 58/M | Avascular Necrosis | 953 days | Excessive wear due to impingement on acetabular cup rim |
| Replacement of femoral head from 32mm to 28mm | 50/M | Osteoarthritis | 1 day | Liner/head size mismatch noted on postoperative film |
| Replacement of (uncemented) femoral stem to cemented stem | 56/M | Osteoarthritis | 657 days | Pain and progressive subsidence due to undersized (uncemented) femoral stem |
| Replacement of femoral stem and head | 56/F | Osteoarthritis | 786 | Femoral component loosening |

**Efficacy Results**

Table 5, below, shows the mean and range of Harris Hip Scores for each study cohort preoperatively and two years postoperatively.

**Table 5: Efficacy Results--HHS**

| Primary Efficacy Assessment | Original Patient Population (n=329)[1] | Continued Access Population (n=630)[2] | Whiteside Clinical Study (n=211) |
|---|---|---|---|
| Preoperative mean HHS (range) | 44.8 (13-89) | 45.2 (8-96) | 42.7 (11-79) |
| 2 year postop mean HHS (range) | 94.8 (34-100) | 88.1 (17-100) | 92.7 (39-100) |
| % Excellent/Good Results (HHS 80-100 points) at 2 years postop | 92.2% | 76.9% | 88.2% |

**Notes:**

[1] Original clinical study population includes the first 329 procedures enrolled in the pivotal clinical study. This includes replacements and removals prior to 24 months (n=9), death prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4).

[2] The *Continued Access* sample (N=630) includes procedures performed after the original population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation carried Forward (LOCF) and represent the latest clinical results available for that procedure.

Any Radiographic Lucency

Radiolucencies were recorded at each follow-up visit based on if they involved the entire Gruen zone (7 AP femoral zones, 7 lateral femoral zones, 3 AP acetabular zones, and 3 lateral acetabular zones). Table 6 summarizes these results.

**Table 6: Any Radiolucency**

| Lucency | Original Study Population (n=329) | Whiteside Clinical Study (n=211) |
|---|---|---|
| Femoral | 18 (5.5%) | 66 (31.3%) |
| Acetabular | 9 (2.8%) | 56 (26.5%) |
| Overall | 22 (6.8%) | 77 (36.5%) |

In addition, any subsidence was reported for the original study population for 0.9% of the femoral stems and 0.3% of the acetabular cups. In the Whiteside Clinical Study there were two instances of femoral stem subsidence (1.0%).

## Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the Ceramic TRANSCEND hip. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the Ceramic TRANSCEND and the Whiteside hips over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in Tables 7 and 8 based on the longest duration of follow-up available in each study cohort.

**Table 7: Ceramic TRANSCEND Implant Survivorship**

| Interval | Number Entering Interval | Number Withdrawn | Number Revised in Interval | Cumulative Survival | Standard Error |
|---|---|---|---|---|---|
| 12 months | 528 | 69 | 8 | 0.9909 | 0.0041 |
| 24 months | 279 | 78 | 1 | 0.9876 | 0.0066 |
| 36 months | 1 | 0 | 0 | 0.9876 | 0.0562 |

**Table 8: Whiteside Clinical Study Implant Survivorship**

| Interval | Number Entering Interval | Number Withdrawn | Number Revised in Interval | Cumulative Survival | Standard Error |
|---|---|---|---|---|---|
| 12 months | 234 | 8 | 3 | 0.9870 | 0.0074 |
| 34 months | 223 | 70 | 1 | 0.9817 | 0.0090 |
| 36 months | 152 | 103 | 1 | 0.9719 | 0.0131 |
| 48 months | 48 | 34 | 3 | 0.8779 | 0.0481 |
| 60 months | 11 | 11 | 0 | 0.8779 | 0.0481 |

## Patient Success Criteria

Table 9 describes the proportion of patients meeting individual clinical success criteria at 2 years postoperatively.

**Table 9: Patient Success Criteria at 2 Years**

| Patient Success Criteria | Original Patient Population (n=329)[1] | Whiteside Clinical Study (n=211) |
|---|---|---|
| Absence of Revision (5) | 96.7% (n=318) | 98.1% (n=207) |
| Total HHS > 70 | 96.8% (n=318) | 95.3% (n=201) |
| No Complete Radiolucencies[2] | 99.7% (n=328) | 88.5% (n=184) |

**Notes:**

[1] The *Original Patient Population* sample includes procedures in the *Complete Endpoint* (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N =7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study.' *For Complete Follow-up* procedures (N=329), the Month 24+ endpoint was defined as the Month 24 value and if not available, value after Month 24 were used. Original pivotal clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7) and cases in which only a partial Harris Hip score at 34 months or later was available (n=4).

[2] Absence of complete radiolucency were determined by radiographic evaluation for four views: acetabular AP view (3 regions), acetabular lateral view (3 regions) femoral stem AP view (7 regions), and femoral stem lateral view (7 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. Absence of complete radiolucency was defined to be present if none of these four views had complete radiolucency.

## ASSEMBLY/DISASSEMBLY INFORMATION

The following assembly instructions assume that the *Trilogy AB* shell is securely implanted in the acetabulum.

**Assembly Instructions:**

1. Position the provisional insert in the *Trilogy AB* shell and perform the trial reduction.
2. Assess range of motion and verify that the femoral stem does not contact the provisional insert or *Trilogy AB* shell.
3. If impingement between components is detected, the *Trilogy AB* shell should be repositioned so that impingement is avoided or, in the event that impingement cannot be avoided, the *Trilogy AB* shell should be removed and replaced with a standard *Trilogy*™ Acetabular System shell and polyethylene liner.
4. Remove the provisional insert. Remove blood and debris from the locking taper of the shell to ensure that no particulate matter is present and that the taper surfaces are dry.
5. Carefully position the alumina insert so that the mating tapers are aligned, then slide the insert into the *Trilogy AB* shell.
6. Ensure that the insert is uniformly seated by palpating at the component rims.
7. Place insert assembly instrument into insert. Strike the end of the instrument with a mallet to seat the insert within the *Trilogy AB* shell. Again, ensure that the insert is uniformly seated by palpating at the component rims.
8. Perform trial reduction. Assess range of motion, verifying that the femoral stem does not contact the ceramic insert or *Trilogy AB* shell.

**Disassembly Instructions:**

Insert the tips of the disassembly instrument into the release holes on the face of the metal shell. Strike the instrument with a mallet to release the ceramic insert.

## STERILITY

The *Trilogy AB* shells and inserts are packaged separately and provided sterile by prior exposure to gamma irradiation. The devices remain sterile as long as the package integrity has not been violated. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the *Trilogy AB* shell must be used, discarded, or resterilized, if applicable.

## RESTERILIZATION INFORMATION

- If required, the *Trilogy AB* shells can be resterilized using Association for the Advancement of Medical Instrumentation (AAMI) guidelines and/or Association of Operating Room Nurses (AORN) recommended practices for sterilization.
- Do not resterilize components that have been contaminated with body fluids or debris or previously implanted.
- Do not resterilize alumina ceramic components by any method.

- Do not resterilize hydroxyapatite (HA) or hydroxyapatite/tricalcium phosphate (HA/TCP) ceramic-coated components by any method.
- Do not contaminate porous coated implants with lint and debris.
- Additional resterilization information is available upon request. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574-267-6131.

**PATIENT COUNSELING INFORMATION**

Complications and/or failure of total hip prostheses[1-4] are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically-active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the hip implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. The implant may not, and is not guaranteed to, last the rest of the patient's life, or any specified length of time. Because prosthetic joints are not as strong, reliable, or durable as a natural, healthy joint, all prosthetic hips may need to be replaced at some point. Ceramic components, such as those in the *Trilogy AB* System, are at risk to fracture.

**REFERENCES**

References to relevant literature (see superscripts) may be obtained by calling the Zimmer Regulatory Affairs Department at 1-800-613-6131. For calls outside the USA, call the local international access code +1-574-267-6131.

**℞** only

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3. Pellicci, P.M., et al.: Mechanical Failures in Total Hip Replacement Requiring Reoperation, *JBJS,* 61A(1):28-36, 1990.
4. Ranawat, C.S., et al.: Conventional Total Hip Arthroplasty for Degenerative Joint Disease in Patients Between the Ages of Forty and Sixty Years, *JBJS,* 66A(5):745-52, 1984.

**Patient Labeling**

**What is the device?**

The hip system is the *Trilogy AB*® Acetabular System and is composed of the following parts: The alumina ceramic acetabular insert, the alumina ceramic femoral head, the compatible *Trilogy AB* acetabular shell, and a commercially available, compatible hip stem. Hip replacement with ceramic parts includes a ceramic socket (that fits into the metal shell) and a ceramic ball.

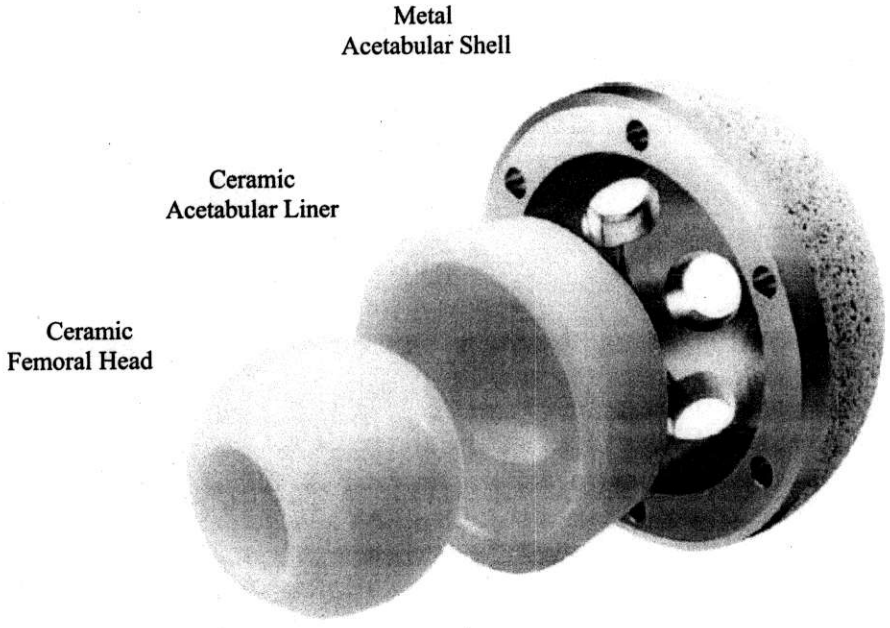


**Figure 1. Unassembled View *Trilogy AB* Components**

**What is the purpose of the device?**

The *Trilogy AB* Acetabular System is indicated for use in total hip joint replacement for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis. These diagnoses are defined below:

*Osteo/degenerative Arthritis*—the breakdown of cartilage (rubbery type of tissue that pads the joints) which causes pain when the hip bones rub together.

*Traumatic Arthritis*—inflammation (swelling, redness, and pain in tissues caused by injury or damage) of a joint resulting from an injury and characterized by breakdown of the bone and rubbery tissue, bleeding in the joint space, and increased thickness of the bone, a flattening of the joint surface, joint rubbery tissue separation from the underlying bone and erosion of the bone.

*Congenital Hip Dysplasia*—dislocation of the hip at the time of birth due to abnormal development of one or all the components of the hip joint: the acetabulum (the cup shaped socket in the hipbone; the femoral head; and the surrounding joint capsule and soft tissues.

*Avascular Necrosis*—a loss of blood supply to the hip bones characterized by changed contour (shape) and increased density (thickness) of the bone, a flattening of the joint surface.

**What happens during the implant procedure?**

The surgical procedure for a total hip involves removing the diseased hip bone and replacing it with a ball on a femoral stem. The stem is inserted into the thighbone. After a special instrument makes the right size and shape, the metal shell and ceramic insert are placed. Screws may be used in the shell for additional security. The ball is then placed into its new socket.

**When should the device not be used (Contraindications)?**

Absolute contraindications include:

- Obvious infection
- Distant centers of infections (which may spread through the blood stream or circulation to the implant site)
- Rapid disease progression as obvious by joint destruction or bone absorption (loss of bone) seen on x-rays
- Patients whose bones have not stopped growing
- Cases where muscles may be too weak to work satisfactorily (e.g., prior paralysis [loss of function] and fusion [joining together], poor bone stock (weak bones), poor skin coverage around the hip joint causing the procedure to be ill advised
- Inflammatory degenerative joint disease (like rheumatoid arthritis)
- Joints with nerve disorders
- Patients who are obese
- Nerve or muscle disease that may negatively have an effect on gait (walking) or weight bearing

This implant has not been tested to see if it is safe or effective to use as a replacement of an existing total hip replacement.

**What are the risks and benefits?**

While there can be no guarantee of success, benefits can include the potential relief of pain and return of normal use of the hip.

The risks and complications associated with this hip replacement are expected to be similar to those of other hip replacements. Each of these reactions/complications can arise during and after surgery and may require medical intervention (such as surgery) and/or implant removal. The risks and complications include:

- Advancing bone breakdown and loss may occur around the hip implant parts due to foreign body reaction to particles.
    - Particles of hip implant materials, cement, and bone are generated by contact between hip implant parts and contact between hip implant parts and bone.
    - Particles may be caused by bonding (attachment), scraping, and/or breakage.
    - Particles in between the hip implant parts or between the hip implant parts and bone may cause more particles of implant materials or bone to be formed at an increasing rate.
    - Particles may migrate to other parts of the body.

  Osteolysis (dissolving of bone) can lead to future problems such as removing or replacing the hip implant parts.

- Wear of the alumina ceramic joint surfaces of hip parts has been reported following total hip replacement. Higher rates of wear may be caused by particles of cement, metal, or other debris, which can cause scraping of the joint surfaces. Higher rates of wear may shorten the useful life of the hip implants, and lead to early revision surgery to replace the worn out hip parts.

- Although rare, metal allergy reactions in patients following hip surgery have been reported. The presence of any implant material can be seen as foreign and the body tissues may react against it.

- Nerve damage, without clinical signs or symptoms, has been reported and may occur as the result of having hip surgery.

- Dislocation and subluxation (partial dislocation) of hip parts can result from improper positioning of the components. Muscle and rubbery tissue laxity (slackness) can also contribute to these conditions.

- Hip parts can loosen or migrate (move) due to trauma or improper attachment.

- Infection can lead to failure of the hip joint.

- While rare, fatigue fracture (breakage) of the hip parts can occur as a result of trauma, strenuous activity, improper positioning, or time implanted in the body (service life).

**What might increase the risk of failure?**

- Patients who are unable or unwilling to follow instructions given by medical professionals
- Noticeable bone loss, severe decreased bone mass (osteoporosis)
- Disorders that interfere with the body's ability to absorb nutrients, which may slow bone formation
- Softening of the bones (osteomalacia)
- Poor hope for good wound healing (e.g., chronic pressure ulcers, end-stage diabetes, severe protein deficiency and/or malnutrition (not enough food to serve the body's needs)
- Foreign body sensitivity; when material sensitivity is suspected, appropriate tests should be made prior to material selection or implant procedure

**What complications might occur during surgery or shortly thereafter?**

- Pain
- Femoral or acetabular perforation (hole in hip parts), or broken bones
- Broken bone while seating the device
- Damage to blood vessels
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb
- Undesirable shortening of the limb caused by improper selection of the implant size
- Traumatic arthrosis (disease of the joint) of the hip from intraoperative positioning of the extremity
- Cardiovascular disorders including blood clots in the veins or lungs, or heart attack
- Pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue"
- Delayed wound healing
- Infection

**What kind of problems could happen later on?**

- Pain
- Trochanteric avulsion (where a small piece of the thighbone is pulled away) as a result of excess muscular tension, early weight bearing, or accidental weakening during surgery
- Trochanteric non-union (broken bone that does not heal properly) due to weak reattachment and/or early weight bearing
- Problems with either leg because of differences in leg lengths or because of lack of enough muscle
- Broken bone by trauma or excessive force (weight or force), particularly in the presence of poor bone stock
- Periarticular calcification (calcium deposits around a joint) or ossification (bone formation), with or without obstacles to joint mobility (able to move)

- Inadequate range of motion due to improper selection or positioning of hip parts by femoral impingement (parts striking each other) and periarticular calcification (calcium deposits around a joint)

**What is the patient's role?**

There are limits to what you can do after you receive your new hip. You will need to protect your hip implant from full weight bearing until adequate attachment and healing have occurred. After you have adequate attachment and healing, any activity above normal (such as playing basketball or heavy physical work) or trauma to the hip can cause broken bones, loosening, wear or breakage of the hip implant or its parts. Loosening of the hip parts can result in increased production of wear particles, as well as damage to the bone, making another surgery (revision) more difficult.

Please read and comply with the follow-up care and treatment instructions given to you by your physician.

**When should the patient contact the doctor?**

You should contact your doctor if you have any of the following symptoms:

- Redness, swelling around, or drainage from the incision
- An unexplained fever (temperature over 100 degrees Fahrenheit or 38 degrees Centigrade) or chills that last more than a day
- Severe hip pain that is not relieved by pain medicine
- Any unusual shortening or rotation (turning) of the leg
- Any sudden swelling in the thigh or calf

This hip device does not replace normal healthy bone. The hip parts can break or become damaged as a result of strenuous activity, trauma, or even normal use, have a limited expected service life, and may need to be replaced at some time in the future.

**What alternatives does the patient have?**

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement parts; non-surgical treatment such as reduced activity and/or pain medication; or other surgical treatments that do not involve the use of a prosthetic implant.