SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device generic name:	Prosthesis, Hip, Semi-constrained, metal/ceramic/ceramic/metal, cemented or uncemented
Device trade names:	Howmedica Osteonics® ABC System and Trident™ System
Applicant's name and address:	Howmedica Osteonics Corporation 359 Veterans Boulevard Rutherford, New Jersey 07070-2584
PMA number:	P000013
Date of Panel recommendation:	July 20, 2000
Date of Notice of Approval to the Applicant:	February 3, 2003

II. INDICATIONS FOR USE

The Howmedica Osteonics® ABC System and Trident™ System are indicated for patients requiring primary total hip arthroplasty due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, femoral fracture, failed fracture fixation or diastrophic variant).

III. DEVICE DESCRIPTIONS

The Howmedica Osteonics® ABC and Trident™ Systems are two ceramic-on-ceramic hip systems.

A. The **Howmedica Osteonics® ABC System** features a ceramic-on-ceramic acetabular bearing couple. The bearing couple consists of a Howmedica Osteonics® Alumina C-Taper Head (ceramic femoral head) and a Howmedica Osteonics® Alumina Insert (ceramic acetabular insert). Both components are manufactured out of alumina oxide ceramic manufactured by CeramTec of Germany.

1. The ceramic femoral heads (28mm and 32mm) of the ABC System are intended to be used in conjunction with the commercially available press-fit titanium alloy Howmedica Osteonics® Omnifit –HA Hip Stems.

2. The ceramic acetabular inserts of the ABC System are intended to be used in conjunction with either of the commercially available Howmedica Osteonics® PSL® MicroStructured® ABC Shells or the Howmedica Osteonics® Secur-Fit™-HA PSL®

ABC Shells (sizes 44mm to 66mm in 2mm increments) in cementless applications. Additional fixation may be achieved with commercially available cancellous bone screws. Both shells are manufactured from commercially pure titanium. The PSL® MicroStructured® ABC Shell has a beaded porous coating whereas the Secur-Fit™-HA PSL® ABC Shell features a non-porous hydroxyapatite coating. The ceramic inserts are assembled intraoperatively to the mating metal acetabular shell components via a taper locking mechanism.

B. The **Trident™ System** features the same ceramic-on-ceramic acetabular bearing couple as the Howmedica Osteonics® ABC System. However, the Trident™ Alumina Insert (ceramic acetabular insert) features a pre-assembled titanium alloy sleeve on the back of the insert which mates with the metal acetabular shell component via a taper locking mechanism. The insert is used in conjunction with the commercially available Trident™ AD with Pure-Fix™ HA Acetabular Shell in cementless applications. The Trident™ AD with Pure-Fix™ HA Acetabular Shell has the same non-porous hydroxyapatite coating as the Secur-Fit™-HA PSL® ABC Shell. The bearing couple in the Trident™ System consists of the same ceramic femoral heads as in the ABC System, as well as an additional 36mm head. The Trident System is also used in conjunction with the same press-fit Howmedica Osteonics® Omnifit –HA Hip Stems as the ABC System.

IV. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

A. Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation, which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity

B. Warnings

- Replace both the ceramic insert and the metal acetabular shell if the insert is chipped, cracked, or otherwise damaged during the implant procedure or postoperative timeframe. This is because the acetabular shell taper, once it has been deformed through assembly to its mating ceramic insert, cannot be reassembled to another ceramic insert.
- Always ensure proper alignment and seating of the insert before final impaction to prevent chipping or damage. Improper seating of the insert may cause it to bind in the wrong position, chip or be damaged.
- Do not reassemble a ceramic head and metal femoral stem or a ceramic insert and metal acetabular shell once they have been assembled due to the deformation incurred by the taper locking mechanisms during the initial assembly.
- Do not allow polished bearing areas and machined taper surfaces to come in contact with hard or abrasive surfaces, as scratching or in any way damaging these surfaces can significantly affect the structural integrity.

- Do not substitute another manufacture's device for any of the Howmedica Osteonics® ABC System because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.
- Do not implant in obese patients because additional loading may lead to loss of fixation or device failure.
- Do not implant in patients undergoing revision of previously unsuccessful femoral head replacement, cup arthroplasty, or other procedure because the safety and effectiveness of these devices for indications other than non-inflammatory degenerative joint disease have not been established.
- Discard all damaged or mishandled implants. Never reuse an implant. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.
- **Do not resterilize.** Return all packages with flaws in the sterile barrier to the supplier.

C. Precautions

- Clean bearing surfaces of debris prior to assembly as foreign particles may cause accelerated bearing wear, which may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry machine taper surfaces to ensure proper seating and assembly.
- Do not handle the hydroxylapatite treated regions as it may compromise the sterility or integrity of the coating/implant interface.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not use a metal or zirconia head with the Howmedica Osteonics® Alumina Insert or the Trident™ Alumina Insert as this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Avoid excessive verticalization of the shell which may accelerate bearing wear.

V. ALTERNATE PRACTICES AND PROCEDURES

Currently, the most commonly used implant materials for total hip arthroplasty include metallic prostheses using articulating bearing surfaces made of a combination of metallic and ultra-high molecular weight polyethylene. Other alternatives use ceramic/polyethylene, metal/metal and ceramic/ceramic bearing articulations. Total hip prostheses are implanted by either cemented or cementless techniques.

Depending on individual circumstances, alternate procedures include conservative, non-surgical treatment, hip joint fusion, or no treatment at all.

VI. MARKETING HISTORY

The Howmedica Osteonics® ABC System has been marketed internationally since February 1997. These devices were distributed in the European Union countries, Australia, Canada, China, Korea and Japan. The Trident™ System has been marketed internationally since September 1999. These devices were distributed in the European Union countries, Australia and Canada.

No country has withdrawn the Howmedica Osteonics® ABC Alumina Insert or the Trident™ Alumina Insert from the market for any safety or effectiveness related reason. These components were restricted to investigational use in the United States for clinical study.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Serious complications may be associated with any total hip joint replacement surgery. These complications include, but are not limited to: infection; genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction; temporary or permanent neuropathies; fractures of the femur; migration of the prosthesis; subluxation; dislocation; decreased range of motion; shortening or lengthening of the extremity; ectopic ossification; aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, or muscular deficiencies; metal sensitivity; possible detachment of the porous/HA coating which could lead to increased debris particles; excessive wear from damage to mating wear surfaces or debris particles; foreign body reaction; pain due to aseptic loosening; amputation; or death. While the expected life of total hip replacement components is difficult to estimate, it is finite. Component wear, breakage of the femoral head or acetabular insert, and component dissociation, are potential adverse effects related to ceramic/ceramic hip prostheses.

VIII. SUMMARY OF PRECLINICAL STUDIES

The following nonclinical laboratory studies were performed in support of the Howmedica Osteonics® ABC and Trident™ Systems: microbiological, materials, mechanical, and shelf life.

A. Microbiological Testing

1. Bioburden and Sterility Testing
   Bioburden testing performed on Howmedica Osteonics® Alumina C-Taper femoral heads, ABC Alumina Inserts and Trident™ Alumina Inserts provided results within stated process specifications. Sterilization validation according to AAMI 11137, Method 3, was performed on the Howmedica Osteonics® Alumina C-Taper femoral heads (worst case) to demonstrate that a minimum gamma radiation sterilization dose of 25 kGy provides a sterility assurance level (SAL) of 10^{-6}. Bioburden data for the ABC Alumina Insert and Trident™ Alumina Insert were adequate to add these devices to the validated sterilization cycle.

2. LAL and Cytotoxicity testing
   LAL and endotoxin testing was performed on Howmedica Osteonics® Alumina C-taper femoral heads. Testing showed the product is not cytotoxic in an extract assay. Testing revealed an endotoxin level of less than 0.125 eu/ml of endotoxin, which is an acceptable

level. LAL and endotoxin testing for the Trident™ Alumina Inserts revealed an endotoxin level of less than 0.01eu/ml. Further biological testing was not performed on the ABC Alumina Inserts since this product is produced from the same material as the alumina C-taper femoral heads and Trident™ Alumina Inserts and has a similar geometry to the Trident™ Inserts.

B. Toxicological/Immunological/Biocompatibility

1. Alumina Ceramics
   Additional animal or clinical testing was not performed to confirm the material's relative biocompatibility. This material has a long history as an orthopedic implant material.

2. Titanium Alloy
   Biocompatibility testing was performed on the titanium alloy (ASTM F-136) used to fabricate the titanium alloy sleeve for the Trident™ Alumina Insert. The following extraction and implantation tests were performed:
   - In vitro cytotoxicity (MEM elution) in L-929 mouse fibroblast cell line
   - In vitro hemolysis – extracted in sodium chloride
   - USP systemic toxicity in mice – extracted in sodium chloride and cottonseed oil
   - USP intracutaneous toxicity in rabbits – extracted in sodium chloride and cottonseed oil
   - USP pyrogen study in rabbits
   - AMES mutagenicity study of a saline extract
   - Delayed contact sensitization study in the guinea pig – extracted in saline

   In all tests performed, toxicity to the test articles was not observed.

   In addition, titanium alloy discs were implanted intramuscularly in rabbits. Macroscopic and microscopic tissue evaluations were performed at 7 and 90 days. Results were considered to be within normal limits.

C. Mechanical/Wear Testing

A battery of tests was completed to qualify the mechanical performance of the components of the Howmedica Osteonics® ABC and Trident™ Systems. A summary of the tests performed and the results are given below.

1. The following tests were performed on the ABC Alumina Inserts (and their mating alumina femoral heads and metal acetabular shells):

   (a) Compressive Burst Testing of ABC Alumina Inserts (liner)
   Inserts were loaded to failure under axial compression using zirconia bearings as load application fixtures. The smallest of each inner diameter size (i.e., 28mm I.D./37mm O.D. and 32mm I.D./41mm O.D.) were chosen for testing as these represented the most severe cases of loading. The acetabular inserts exhibited average compressive burst loads greater than the specified 46.0 kN average minimum load requirement, and no insert fractured below the 20 kN minimum load specified for individual

components. These loads are approximately 63 and 27 times body weight (bw = 165 lbs), respectively.

(b) *Axial Fatigue and Residual Burst Strength Testing of ABC Alumina Inserts*
Five of the smallest sized inserts (i.e., 28mm I.D./37mm O.D. and 32mm I.D./41mm O.D.) were axially fatigue loaded under 14.0 kN (3150 lbs), R=0.1. Inserts were loaded with alumina heads and endured 10 million cycles. After fatigue testing each insert was subject to compressive burst testing to determine residual burst strength. No specimen fractured below the 20 kN minimum load. The average residual burst load for the 28 mm I.D x 37 mm O.D inserts was 63.6 kN, and the average for the 32 mm I.D x 41 mm O.D inserts was 66.5 kN. The alumina heads used for loading, which represented worst case head sizes, also successfully completed 10 million cycles and exhibited residual burst loads in excess of 20 kN.

(c) *Axial Distraction of ABC Alumina Acetabular Inserts*
Five of the smallest inserts were tested as this represented the worst case (ie., least contact area). The average axial distraction force of the 28 mm I.D / 37 mm O.D alumina insert was 2.752 kN. This compares favorably with published values for commercially available acetabular insert/shell assemblies ranging from approximately 0.224 kN to 2.937 kN.

(d) *Torsional Distraction of Alumina Inserts*
Five of the smallest inserts were assembled with three mallet blows into CP Titanium taper models with interior taper surface/geometry specific to the devices under study. The average torsional distraction torque of the insert itself could not be accurately measured because failure occurred first at the torsion fixture interface. The average torsional distraction torque was not less than 448 in-lb., which represented the failure load of the torsional fixtures. The torque generated by friction at the bearing/insert interface has been shown to be on the order of 18 in-lb. The minimum torque demonstrated by the inserts substantially exceeded these published values.

(e) *Three-Point Fixation Fatigue with Alumina Bearings (Heads and ABC Inserts)*
The smallest diameter bearings of longer neck extensions were tested as this represented the most severe case. Five test articles were placed in fixtures and loaded under 4.89 kN (1100 lbs) max., compressive fatigue load, R=0.1. All insert/head/hip stem constructs endured 10^7 cycles without failure. After completion of the fatigue testing, the inserts were removed and examined for signs of wear, or fretting, at the insert/shell interface. Light circumferential CP Ti material transfer about the major diameter of the ceramic insert taper was seen. This is similar to that produced upon simple assembly/disassembly. Slight material transfer located about the minor diameter was believed attributable to a combination of off-axis loading and cyclic loading.

2. Similarly, testing for the Trident™ Alumina Inserts included the following:

(a) *Static Burst Test for Trident® Alumina Insert with Ti-alloy Sleeve*
Static burst testing was performed on the 28mm and 32mm Trident™ Alumina Inserts. The average burst load for the 28mm Trident™ insert was 68.7 kN and the average burst load for the 32mm Trident™ insert was 70.2 kN. These values are above the specified minimum average axial burst load of 46 kN (with no single

failure below 20 kN) . These failure loads are equivalent to approximately 95 times body weight.

(b) *Post Axial Fatigue Burst Test for Trident® Alumina Insert with Ti-alloy Sleeve*
A similar static burst test was also performed on five 32mm Trident™ Alumina Inserts after 10 million cycles of fatigue loading. All samples tested in fatigue reached 10 million cycles run-out, at loads of up to 20 body weights (sinusoidal load of 315 to 3150 lbf [14kN] at 25 Hz) with no observable defects. The mean post-fatigue burst load for the 32mm Trident™ Alumina Insert was 70.1 kN.

(c) *Fatigue Testing of the Trident® Acetabular Cup System*
Additional fatigue testing of the Trident™ Alumina Insert assembled to the Trident™ Acetabular Shell was performed. Testing simulated relevant physiological loading. Loads applied were based on gait studies in the literature, where expected loads ranged from 672 lbs during normal activities to maximum loads of 1148 lbs. A cyclic axial compressive force was applied at a rate of 10 Hz. No failures occurred at load levels up to 1500 lbs. One specimen tested at 1600 lbs completed 10 million cycles but post-fatigue testing revealed failure in the ceramic liner. This result exceeds the expected physiological load levels as observed in the literature.

(d) *Axial Push In/Out and Fretting Test for Trident® Alumina Insert with Ti-alloy Sleeve*
The static locking strength of the shell-insert/sleeve construct was tested through an axial push-out test. The axial push-out load for the Trident™ Alumina Insert (with Ti-alloy sleeve), with an average 2 kN (450 lbf) impaction force, was 1.1 kN (248 lbf.). This compares favorably with published data.

The taper surfaces of the titanium alloy sleeve and shell were inspected qualitatively for the severity of fretting wear due to fatigue loading of the shell-insert/sleeve construct. All shells, inserts, sleeves, and femoral heads successfully endured 10 million cycles of fatigue loading without structural compromise. The degree of fretting was milder than that seen with the current ABC acetabular shell and alumina insert design.

(e) *Mechanical Evaluation of 36mm Trident Ceramic/Ceramic Liners*
Both axial distraction (or push-out) and ultimate axial compression load (burst) testing were performed. Five samples were evaluated for each test. Average distraction force was 653 ± 57 N (147 lbf). The acetabular inserts exhibited an average compressive burst load of 55.0 ± 9.2 kN (12360 lbf) and no insert failed below 46.4 kN (10427 lbf). The loads are approximately 75 and 63 times body weight, respectively. The values reported here are within the range of values reported for other similar devices. Burst testing on the 36 mm alumina femoral heads demonstrated average failure loads of 91.8 kN for the +3.5 heads and greater than 71.3 kN for the +5 heads. It should be noted that a single 36 mm alumina ceramic head was used in the burst testing for all the ceramic acetabular inserts. In every case the inserts fractured first, indicating that the 36 mm femoral heads are appropriate for use with the ceramic inserts.

3. Joint simulation wear performance testing of the Biolox® Forte alumina-alumina bearing couple has been characterized throughout a range of severe conditions, including steep

cup inclination angles, head-insert micro-separation, increased swing phase loading, and alternative lubricating media. The following wear tests have been performed:

(a) *In-vitro Wear Performance of the Biolox® Forte Alumina/Alumina Bearing Couple Under Hip Joint Simulation – Gravimetric Results*

This joint simulation study investigated the Biolox® Forte couple in an anatomic (superior) cup insert orientation and demonstrated a 400X decrease in mass and 2000X decrease in volumetric wear compared to UHMWPE inserts at 5 million cycles. The level of wear reduction and the wear surface features were consistent with those reported and observed clinically from device retrievals. Although the cup was positioned above the femoral bearing, the level of inclination was 0 degrees; hence, this model is not considered to be overly severe.

(b) *Wear of HIP'd (hot isostatic pressed) and Non-HIP'd Alumina/Alumina Hip Joints under Standard and Harsh Simulator Conditions*

Previous generation non-HIP'd alumina and the contemporary HIP'd material grade alumina were compared under standard and "harsh" testing conditions. The severe conditions were created by elevating the swing phase load (intended to deplete the lubricating film at the articulating interface) and by varying the lipid and protein concentration of the lubricating media. None of these test conditions were able to induce accelerated wear of the HIP'd alumina components (Biolox Forte). Inserts were mounted at a relatively severe 60 degrees of inclination.

(c) *Micro-Separation of the Centers of Alumina/Alumina Hip Joints During Simulator Testing that Produces Clinically Relevant Wear Rates and Patterns*

Upon incorporating a cyclic micro-separation of the head from the insert during joint simulation a 15-fold increase in the early wear rate of the alumina/alumina bearing couples was reported, as compared to results in the same simulator under standard testing conditions for a similar period. These results appear to be consistent with wear rates of retrieved alumina/alumina bearings, as reported in the literature. Inserts were oriented at 60 degrees of inclination. Micro-separation that occurs during the swing phase of normal walking may be considered a severe condition since it serves as an indicator of joint laxity.

(d) *Influence of Acetabular Cup Angle on the Wear of Biolox Forte Alumina/Alumina Hip Joints in a Physiological Simulator*

This study increased the inclination angle of alumina inserts from 45 to 60 degrees after 2 million cycles of hip joint simulation. There was no increase in wear rate associated with the greater inclination throughout an additional 2 million cycles. The increase in cup inclination may simulate the onset of cup migration/loss of fixation leading to a more vertical shell. These are scenarios that also represent non-ideal clinical conditions.

(e) *The Effect of Inclination Angle on In-Vitro Wear of Alumina/Alumina Acetabular Inserts*

Alumina insert/bearing pairs were tested at 50, 55, 60, and 65 degrees of inclination under standard hip joint simulation parameters. The inserts were positioned anatomically with respect to the bearings (i.e., cup on top). Components tested at 50, 55, and 60 degrees exhibited nearly identical wear rates, while specimens inclined at 65 degrees exhibited a 4X increase in wear rate with respect to the lower inclination angles evaluated.

D. Fretting Fatigue and Corrosion Testing of the Trident™ Acetabular Cup System

High cycle fatigue testing of the Trident™ Acetabular System with the alumina insert has been performed. Testing consisted of high cycle/short term testing (10 million cycles / 10 Hz (12 days)) at loads of approximately 3 times body weight to evaluate fretting, and high cycle/long term testing (10 million cycles / 1 Hz (120 days)) to evaluate corrosion at the metal/metal taper junction due to physiologically relevant load conditions. Acetabular shells were oriented at 45 degrees inclination. Both macro and microscopic inspection of the acetabular components showed minimal damage due to fretting and no evidence of corrosion at the metal/metal interface. Fretting testing was also performed on two femoral components so that comparisons could be made to modular connections that have been used in the clinical setting. Qualitatively, slightly more damage was seen on the femoral stem tapers than the taper lock between the acetabular shell and liner of the Trident™ components. These results indicate a stable interface exists between the liner and shell for up to ten million cycles.

E. Surface Characterization of the Alumina-Alumina Bearing Couple

The Alumina C-Taper Heads and Alumina Inserts were evaluated using 3-D laser inteferometery. Contour maps and photomicrographs under SEM at 1000X magnification were produced. The overall average roughness, R_A, of the alumina femoral bearing surface was 1.85×10^{-3}um. The level of finish produced on the polished acetabular insert surface averaged 4.32×10^{-3}um.

F. Finite Element Modeling

Finite Element Modeling was performed to evaluate stress at the metallic shell/bone interface in order to determine the differences in bone stresses when comparing the ABC and Trident™ designs. The Trident™ shell design is slightly thinner than the ABC design. The maximum observed difference in bone stress between the two shell geometries was 5%, with Trident™ producing slightly less stress at the bone interface than the ABC, approximately 1720 psi to 1810 psi, respectively.

G. Shelf Life Testing

Shelf life testing was performed to verify sterile packaging integrity equivalent to five years. This testing was performed on acetabular cups, inserts and femoral stems. Qualification of the blister package assembly for the Alumina Inserts was also performed.

IX. SUMMARY OF CLINICAL STUDIES

There were three groups evaluated in the IDE. The first group consisted of a prospective, randomized, multi-centered, concurrently controlled study of the Howmedica Osteonics® ABC

System. The second group consisted of the Continued Access cases receiving the ABC System, which was a prospective, non-randomized, non-controlled, multi-centered study. The third group consisted of those cases receiving the Trident™ System, which was a prospective, non-randomized, historically controlled, multi-centered study.

Clinical data had been collected on a total of 820 cases at the time of database closure. Of these cases, 515 belonged to the first group. That is, 350 cases received the ABC System (173 ABC System I and 177 ABC System II) and 165 received the control (Control System). ABC System I devices consisted of the Howmedica Osteonics® Alumina C-Taper Heads, Howmedica Osteonics® Omnifit –HA Hip Stems, Howmedica Osteonics® Alumina Inserts, and the Howmedica Osteonics® PSL MicroStructured ABC Shells. The ABC System II devices consisted of the identical components except for the use of a different acetabular shell, the Howmedica Osteonics® Secur-Fit –HA PSL ABC Shell. The Control System devices consisted of the commercially available Howmedica Osteonics® Omnifit Series II Polyethylene Cup Inserts and Howmedica Osteonics® C-Taper CoCr Heads used in combination with the Howmedica Osteonics® Omnifit PSL MicroStructured Acetabular Shell and the Howmedica Osteonics® Omnifit –HA Hip Stems. Group two consisted of 116 cases receiving the ABC System (3 ABC System I, 113 ABC System II) via continued access. The remaining 189 cases (group three) were implanted with the Trident™ System. The Trident™ System features the same ceramic-on-ceramic acetabular bearing couple as the Howmedica Osteonics® ABC System. The Trident™ Alumina Insert features a pre-assembled titanium alloy sleeve. The insert is used with a Trident™ AD with Pure-Fix™ HA Acetabular Shell in cementless applications. The bearing couple in the Trident™ System consists of the same Howmedica Osteonics® Alumina C-Taper Heads as in the Howmedica Osteonics® ABC System, as well as an additional 36mm head. The Trident System can also be used with the same press-fit Howmedica Osteonics® Omnifit –HA Hip Stems as the ABC System.

All components in all three groups were implanted without cement. The –HA designated components contain an hydroxyapatite coating. Please refer to Table 1 for a time-course patient accountability of all three groups.

Four hundred and thirteen randomized cases from the first group had at least 2 year follow-up data (i.e., 140 ABC I, 140 ABC II, 133 Control). That data was used in the statistical analysis for the Howmedica Osteonics® ABC System, and is presented in section A, below. The data from the remaining 102 randomized cases with less than 2 years of follow-up, and the 116 Continued Access cases was used to provide additional safety information for the Howmedica Osteonics® ABC System. Section B, below, provides information from the Continued Access Study group. Section C provides data from the Trident™ Study group.

A. The Howmedica Osteonics® ABC System

1. Study Design

   The Howmedica Osteonics® ABC System study was a prospective, controlled, randomized, multi-center clinical trial. The total study group consisted of 514 cases diagnosed with non-inflammatory degenerative joint disease (NIDJD) requiring a primary total hip replacement. One additional non-randomized case with a diagnosis of inflammatory arthritis was implanted with Howmedica Osteonics® ABC System I as a

compassionate use approved deviation from protocol and is analyzed separately for safety in the data analysis. Each subject was randomized to receive one of three possible shell/bearing combinations: either the Howmedica Osteonics® ABC System I, the Howmedica Osteonics® ABC System II (the Investigational Systems), or the Control System in a cementless application. Two year results for 280 Investigational cases (140 ABC I and 140 ABC II) and 133 Control cases were included in the data and will be presented in this section.

2. Patient Assessments
   Preoperative functional (Harris Hip Score), demographic and Patient Satisfaction (HSQ-12; Hip Society) data as well as AP and ML radiographs were obtained. A Surgical Details case report form was completed to record relevant surgical information. Postoperatively, patients were evaluated at 7 weeks, 6 months, 12 months and 24 months. Subjects will be evaluated annually thereafter until the last patient entered into the study has completed a minimum of two years follow-up. AP and ML radiographs were reviewed by an independent reviewer (orthopedic surgeon). A patient satisfaction questionnaire was given at all follow-up intervals except the 7 week interval.

3. Patient Success/Failure Criteria
   All of the following criteria needed to be met for a patient to be considered a success in the Howmedica Osteonics® ABC study:
   - Absence of surgical revision/removal of any of the total hip system components;
   - Harris Hip Score of 70 or greater;
   - Progressive radiolucent lines less than 2mm in thickness around the acetabular component;
   - Migration of the acetabular component of less than 3mm;
   - Progressive radiolucent lines of less than 2 mm in thickness surrounding the femoral component; and,
   - Progressive subsidence of the femoral component of less than 5mm.

   A patient was defined as a failure if they did not meet all of the above success criteria.

4. Study Success/Failure Criteria
   Study success required meeting both of the following criteria:
   - Not detecting as statistically significant an increase $\geq 7.5\%$ in the 2 year patient failure rate for the treatment group compared to the 2 year failure rate for the control group; and,
   - Complication rates that are statistically no worse than the control.

5. Subject Selection
   Subjects were recruited through medical institutions of the participating investigators and have been diagnosed with non-inflammatory degenerative joint disease (NIDJD). Both male and female subjects between the ages of 21 and 75 years inclusive, were selected to participate.

6. Demographic Data
   a. Investigational Group demographics: There were more males (186 cases; 66.4%) than females (94 cases; 33.6%); the mean age of study cases was 53.4 years with the mean age of female cases reported as 53.3 years (range 21 to 75 years) and the mean

age of male cases reported as 53.4 years (range 23 to 73 years). The primary diagnosis for these cases included 225 cases (80.4%) with osteoarthritis, 10 cases (3.6%) with traumatic arthritis, 41 cases (14.6%) with avascular necrosis, 3 cases (1.1%) with diastrophic variant, and 1 case (0.4%) with slipped capital epiphysis.

b. Control Group demographics: There were more males (83 cases; 62.4%) than females (50 cases; 37.6%); the mean age of study cases was 54.5 years with the mean age of female cases reported as 56.1 years (range 28 to 74 years) and the mean age of male cases reported as 53.6 years (range 25 to 75 years).

The Investigational and Control groups had comparable demographics in terms of gender, age, height, weight, and primary diagnoses.

7. Data Analysis and Results

Two hundred eighty investigational cases (140 ABC System I, 140 ABC System II) and 133 Control cases were included in the data analysis. This population reports a study follow-up rate of 92.7%, with the Investigational and Control groups having similar follow-up rates.

a. Study Efficacy Results

The effectiveness of the Howmedica Osteonics® ABC System I and ABC System II was determined through the analysis of the Harris Hip Scores and radiographic measurements. Table 2 compares the Mean Total Harris Hip Scores and the Harris Hip Rating Scale, as well as the radiographic success rates for the Investigational and Control groups, at two years postoperatively. The mean total HHS and the HHS Good/Excellent Rating were similar for the Investigational and Control groups for all parameters that were evaluated.

Radiographic parameters of femoral radiolucency, femoral component subsidence, acetabular radiolucency, acetabular component migration, and excessive wear as demonstrated by migration of the femoral head in the insert were used to assess the stability of the study components. Only one of the 245 Investigational cases (0.4%)with two year radiographic data was determined to be a radiographic failure. This patient received the ABC System II and displayed a progressive subsidence of the femoral component greater than 5mm, which was considered a radiographic failure as defined by the study protocol. The radiographic results for the Investigational and Control groups were very similar for all parameters evaluated.

b. Study Safety Results

The primary safety variables used to measure the success of the Howmedica Osteonics® ABC System are intraoperative and postoperative complications/adverse events and component removal events. Complications, whether device-related or not, were recorded and reported for both the Investigational and Control groups. Table 3 provides a time course distribution for all reported operative site related adverse events. Table 4 provides a time course distribution for all reported systemic adverse events. Included within these tables are the adverse events reported for those cases

who have not yet reached two year postoperative follow-up. Safety data from the Continued Access patient group are also included in these tables.

The three revisions reported in the Investigational device group were due to postoperative femoral fracture (ABC System I), recurrent anterior dislocation (ABC System II), and deep joint infection (ABC System II). The femoral fracture required the removal and revision of the femoral head and stem components. The dislocation case required removal and revision of the acetabular shell and insert, as well as the femoral head. The deep joint infection required the removal and revision of all four components (acetabular shell and insert, femoral head and stem). The five revisions identified in the control group were due to a femoral fracture related to a traumatic event, painful leg length discrepancy, deep joint infection, recurrent dislocation, and dislocation that could not be reduced by closed reduction. There was no evidence of any differences in adverse event rates between the various study groups. Adverse event rates were similar for both Investigational groups and the Control group.

c. Study Success

Table 5 summarizes the 2 year patient success rates as they relate to the success/failure criteria of the Howmedica Osteonics® ABC Study. For the purposes of the study, a patient who failed to meet all seven of the success criteria outlined in the table was considered a failure. Success for the ABC System Study was defined, in part, by demonstrating patient success rates for ABC System I and ABC System II that were no more than 7.5 percentage points worse than the Control System patient success rate. In addition, success was based on achieving complication rates that were statistically no worse than the Control System.

Both ABC System I and ABC System II demonstrated slightly higher patient success rates than the Control System at two years postoperatively. As previously discussed, adverse event rates were found to be similar for both ABC and Control Systems. The results of the study demonstrate that the use of the ABC System I and System II devices can, at least two years after implantation, produce clinical results comparable to the Control System.

B. Continued Access Cases

The Continued Access portion of the Howmedica Osteonics® ABC System study allowed surgeons to continue use and study the ABC System I and System II investigational devices in a non-randomized manner. Each of these systems was used in combination with the commercially available Howmedica Osteonics® Omnifit –HA Hip stem. A maximum of 336 cases were allowed to be enrolled in the Continued Access study arm. No statistical analysis was performed for this study group. Data from this study arm was used for safety and effectiveness comparison purposes only. The clinical protocol for this arm of the investigation was identical to the protocol for the original cohort with the following exceptions:

- Study is non-randomized
- Surgeons involved in this arm were allowed to choose either ABC System I or System II components

- The Twelve Item Health Questionaires (HSQ-12) were not collected
- Postoperatively, data were collected at 7 week and 1 year follow-up intervals and biannually thereafter until all patients in the original cohort reach two year follow-up. Functional evaluation and x-rays were taken at these time periods. The clinical protocol for the original cohort also included a follow-up at six months.

Subjects in this prospective, non-randomized study arm received either the Howmedica Osteonics® ABC System I or System II at the discretion of the operating surgeon. To date, 116 cases have been enrolled. Three cases received System I; 113 cases received System II. The data was pooled for data analysis. Two cases were removed from the analysis, as one compassionate use patient did not meet the inclusion criteria and in one case the decision was made intraoperatively not to use the investigational alumina insert.

Data on 114 cases was presented for this device group. There were more males (80 cases; 70%) than females (34 cases; 30%). The mean age of study cases was 48.2 years with the mean age of females reported as 47.7 years (range 24 to 66 years) and the mean age of male cases reported as 48.4 years (range 24 to 73 years). The primary diagnosis for these cases included 83 cases (73.0 %) with osteoarthritis, 8 cases (7.0%) with traumatic arthritis, 18 cases (15.8%) with avascular necrosis, 2 cases (1.8%) with slipped capital epiphysis, and one case (0.9 %) with congenital hip dysplasia. Seven patients were reported to be bilaterally implanted.

The average length of follow-up for these cases is 260.9 days (range 27 – 420 days). One hundred thirteen of one hundred fourteen expected cases (99.1%) had seven week evaluation data reported and 77 of 86 expected cases (89.5%) had one year evaluation data reported. At 7 weeks postoperatively the mean Harris Hip Score was 80.9 points (range 42.7 to 100). At one year postoperatively the mean Harris Hip Score was 96.8 points (range 54.9 to 100). No radiographic review was available for this group at the time of data base closure.

There were no deaths or revisions reported for this study population. There were six reports of intraoperative chipping of the ceramic acetabular inserts in this group. These cases were reported to have no untoward results due to the intraoperative chipping. There was one reported case of intraoperative femoral fracture and three reported cases with intraoperative femoral cracks. One case of dislocation was reported. Time course distributions of adverse events (operative site related and systemic) were provided for this study group and are included in Tables 3 and 4, respectively.

C. Trident™ Study Arm

This study design is a prospective, non-randomized historically controlled, multicenter clinical trial. The total study group will consist of 213 cases diagnosed with NIDJD. The Trident™ System data were compared to the ABC I, ABC II, and control group data collected in the ABC System study. Patient enrollment began on 9/20/99. To date, 189 cases have been enrolled, 4 of which did not meet the study inclusion criteria and are not included in the study analysis.

The Trident™ study protocol is identical to the original ABC protocol, with the exception of using the historical control (ABC control device) instead of incorporating a randomized control. There were more males (125 cases; 67.6%) than females (60 cases; 32.4%); the mean age of study cases was 51.8 years with the mean age of female cases reported as 52.0

years (range 31 to 74 years) and the mean age of male cases reported as 51.8 years (range 31 to 74 years). The primary diagnosis for these cases included 150 cases (81.1%) with osteoarthritis, 7 cases (3.8%) with traumatic arthritis, 20 cases (10.8%) with avascular necrosis, 7 cases (3.8%) with slipped capital epiphysis, and 1 case (0.5%) with a femoral fracture. Preoperatively, the Trident™ data were comparable with the ABC I, ABC II, and Control systems of the ABC study.

The average length of follow-up for these cases is 120.2 days (range 29 – 262 days). One hundred seventy-eight of the 182 cases expected (97.8%) had a seven week evaluation and 97 of the 103 cases expected (94.2%) had a 6 month evaluation. There have been no reports of intraoperative chipping of the Trident™ Alumina Insert and there has been one femoral component revision reported due to a femoral fracture. No deaths have been reported. There are two cases with Harris Hip Scores < 70 reported at 6 months. No radiographic review was available for this group at time of data base closure.

No statistical differences were found in the comparisons of the preoperative, 7 week and 6 month mean Harris Hip Scores between the Trident™ cohort and the other cohorts. A time course distribution that compares the early effectiveness data (Harris Hip Scores) of the Trident™ System to the ABC System I, ABC System II, and Control System is provided in Table 6.

A comparison of the adverse event rates for the Trident™ System, ABC System I, ABC System II, and Control System was performed for the purposes of evaluating safety. There was one statistically significant finding made involving the intraoperative operative site event rates. There was a significantly higher rate for the ABC Systems compared to the Trident™ System, but not for the Control System versus the Trident™ System. This difference was due to the intraoperative chipping of a few of the ABC inserts. Other than this one exception, the adverse event rates for the Trident™ study arm were generally not significantly different from the other study groups. Time course distributions of adverse events (operative site related and systemic) were provided for this study group and are included in Tables 7 and 8, respectively.

X. CONCLUSIONS DRAWN FROM THE STUDIES

A. Risk/Benefit Analysis

Other than the risks generally associated with total hip arthroplasty the following additional risks were identified for the Howmedica Osteonics® ABC System and Trident™ System components: breakage of the ceramic insert or femoral head, the necessity for removal of all ceramic components if one must be removed/revised (ABC System only), corrosion between the metal acetabular shell and the metal sleeve of the acetabular insert (Trident™ System only) and intraoperative chipping of the ceramic insert. Including those cases with less than 2 years follow-up and the continued access cases, there were 16 incidences of chipping for the 466 cases implanted with the ABC alumina insert (3.4%). To date there have been no untoward events reported as a result of any of the chipping cases. In all instances the chipped inserts were replaced at time of surgery with no subsequent clinical sequelae. The clinical

outcomes of those patients with chipped inserts were comparable to those patients without chipped inserts. This chipping problem has not been seen with the Trident™ Insert.

It is reasonable to conclude that the benefits of the use of the ABC System and Trident™ System for the intended target population outweigh the risk of injury when used in accordance with the directions for use.

B. Safety and Effectiveness

The effectiveness of the Howmedica Osteonics® ABC System was demonstrated through the compilation of data exhibiting the relief of pain and return to normal function which was collected during the course of this prospective, randomized, controlled clinical trial. The safety of the Howmedica Osteonics® ABC System was established through the collection of complications/adverse events and component removal events. The overall failure rates for the Howmedica Osteonics® ABC System compared favorably to the Control System.

The modification to the Howmedica Osteonics® ABC Insert, which is incorporated into the Trident™ design, involves the locking mechanism between the insert and the shell. The safety of the Trident™ Alumina Insert has been established through the evaluation of the perioperative adverse event rates. There was one statistically significant finding made in the safety analysis comparing the Trident™ and Howmedica Osteonics® ABC Systems. The intraoperative operative site event rate was significantly higher for the ABC Systems compared to the Trident™ System. This difference can be attributed to the absence of ceramic insert chipping events in the Trident™ group. The clinical data which established the efficacy of the Howmedica Osteonics® ABC System has been used in support of the Trident™ design. The results of the trial demonstrate that the ABC Systems (ABC I and ABC II) are safe and effective. The preclinical and the early safety and effectiveness comparisons of Trident to the ABC I, ABC II, and control system devices demonstrates that the Trident device is safe and effective.

XI. PANEL RECOMMENDATIONS

The PMA was presented to the Orthopedic and Rehabilitation Devices Advisory Committee (the Panel) on July 20, 2000. At that time the Panel recommended, based on a 7 – 0 vote, that the ABC System (i.e., both ABC System I and II) be found approvable with conditions. The conditions of approval suggested by the Panel included: disclosure to the surgeons in the technical manual as well as in the package insert concerning the chipping, brittleness, and revision limitations, etc., of the ceramic components; basic science education on the material properties (e.g., corrosion, fracture, etc.) of the involved materials in addition to workshops; an extensive manual; monitoring of the surgeons; in-office training available in the form of either a CD ROM or a video; postmarket surveillance out to five years, including retrieval analysis; and wear testing on the subject components under a range of conditions a surgeon might encounter.

The Panel also recommended, based on a 4 – 3 vote, that the Trident™ System be found not approvable based on a lack of 24-month follow-up data. To put the Trident™ System in approvable form the Panel recommended that the initial 2 year clinical study be completed. The Panel recommended the same approval conditions as identified above for the ABC System, with the exception of the revision limitations, as this is an advantage of the Trident™ System. In addition, the Panel recommended that corrosion testing be performed to demonstrate the potential for corrosion between the titanium insert sleeve and titanium acetabular shell.

XII. FDA DECISION

FDA agreed with the Panel's recommendation for the ABC System (approvable with conditions). The sponsor submitted an amendment to the PMA that adequately addressed the conditions of approval recommended by the Panel. Therefore, since the conditions of approval have been met, FDA finds in favor of approval of the ABC System.

FDA did not agree with the Panel's not approvable recommendation for the Trident™ System. The Panel had recommended that the 24-month clinical study be completed before consideration of approval and that corrosion testing should be performed. However, due to the similarities in the design of the ABC and Trident™ Systems FDA believes that the clinical data from the ABC System, along with the interoperative and perioperative clinical data from the Trident™ study compared to the ABC I, ABC II, and control devices, and pre-clinical testing on the Trident™ System compared to the ABC I, ABC II, and control devices is adequate to support approval of the Trident™ System. Both systems use the identical articulating surface geometries and femoral stems. The only difference between the two systems is the locking mechanism between the acetabular insert and shell. Corrosion testing results evaluating the interface between the insert sleeve and acetabular shell were provided by the sponsor to address the concerns raised by the Panel.

The Trident™ was developed to address the incidence of intraoperative chipping during insertion, and allow for revision of ceramic inserts. Although the Trident™ did not have long term (24-month) clinical data, none of the 183 Trident™ inserts implanted were chipped, compared to 16 incidences of insert chipping reported for the ABC System for a chipping rate of 3.4% (466 ABC System devices implanted overall, including continued access patients and those with less than 2 years follow-up). In addition, the adverse event rate out to six months post-operatively, is comparable to both the ABC System and Control System.

Additional long-term concerns may be addressed through the completion of a post-market study and post-market surveillance. The sponsor has agreed to complete and extend the original 24-month study out to 60 months on all 213 Trident cases and 328 ABC cases. Safety and effectiveness data will be collected as specified in the ABC/Trident IDE protocol, and reported annually until all patients have reached their 5 year post-operative follow-up. In addition, these patients will each be sent a postcard annually from six to ten years postoperatively to assess the patient's general well-being and if the study components are still in place. This will ultimately provide ten year survival data on a majority of the original study participants.

FDA issued an approval letter to the applicant on February 3, 2003.

Quality System Inspections were performed on 12/19/00 and 12/21/00 at the Stryker Howmedica Osteonics manufacturing sites in Allendale, NJ and Carrigwohil, Ireland, and on 11/22/02 at the ceramic supplier CeramTec of Plochingen, Germany, as well as on 10/16/01 and 4/25/02 at the contract sterilizers Steris Isomedix of Whippany, NJ and Morton Grove, Il, and on 11/12/01 at the contract sterilizer Gammaster Ireland of Westport, Ireland. Inspections revealed that the company was in compliance with the Quality System regulation (21 CFR Part 820).

XIII. APPROVAL SPECIFICATIONS

Directions for use: See the Device Labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling

Post-approval Requirements and Restrictions: See approval order

TABLE 1: Time Course Distribution of Patient Accountability for ABC System I, ABC System II, Trident™, and Control Systems.

Evaluation Interval	ABC SYSTEM I			ABC SYSTEM II			CONTINUED ACCESS*			TRIDENT**			CONTROL		
	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)
Pre-Op	172	172	172 (100%)	177	177	177 (100%)	114	114	114 (100%)	185	185	185 (100%)	165	165	165 (100%)
7 weeks	172	172	170 (98.8%)	177	177	177 (100%)	114	114	113 (99.1%)	182	182	178 (97.8%)	165	165	163 (98.8%)
6 months	172	172	166 (96.5%)	177	177	167 (94.4%)				103	103	97 (94.2%)	165	164	157 (95.7%)
12 months	172	171	168 (98.2%)	177	176	173 (98.3%)	86	86	77 (89.5%)				165	164	155 (94.5%)
24 months	140	139	131 (94.2%)	140	139	129 (92.8%)							133	131	119 (90.8%)

TFU = Theoretical Follow-Up; EFU = Expected Follow-Up; AFU = Actual Follow-up

*Continued Access cases include 3 with the ABC System I and 111 with the ABC System II devices. No data was collected at the 6 month postop interval for continued access patients. No continued access patients had yet reached 24 months postoperatively at the time of data base closure.

**No Trident patients had yet reached 12 months postoperatively at the time of data base closure.

TABLE 2: Primary Efficacy Assessments for ABC System I and ABC System II vs. Control System. Efficacy assessment based on mean Harris Hip Score (HHS) and radiographic success reported for those cases with 2 year follow-up data.

Primary Efficacy Assessment	**ABC SYSTEM I** 140 cases enrolled	**ABC SYSTEM II** 140 cases enrolled	**CONTROL** 133 cases enrolled
Preoperative mean HHS (range)	49.6 (19.3 - 89.6) n=126	49.0 (24.7 - 75.2) n=131	49.3 (21.4 - 87.3) n=125
2 year postop mean HHS (range)	96.3 (48.0 - 100) n=122	96.9 (56.9 - 100) n=120	95.1 (58.8 - 100) n=110
% Excellent/Good Results (HHS 80-100 points) at 2 years postop	95.9% (117/122)	96.7% (116/120)	93.6% (103/110)
% Total HHS ≥ 70 at 2 years postop	98.4% (120/122)	99.2% (119/120)	98.2% (108/110)
% Radiographic Success at 2 years postop	100% (123/123)	99.2% (121/122)	100% (113/113)

n = number of cases that had evaluable data

TABLE 3: Time Course Distribution of Operative Site Adverse Event Incidences for ABC System I and ABC System II vs. Control System out to 24 Months Post-Operatively.

Operative Site Related	ABC SYSTEM I[1] (172 cases enrolled)						ABC SYSTEM II[2] (177 cases enrolled)						CONT. ACCESS* (114 enrolled)				CONTROL (165 cases enrolled)					
Visit	io	ea	6	12	24	Tot	io	ea	6	12	24	Tot	io	ea	12	Tot	io	ea	6	12	24	Tot
N = cases evaluated	172	170	166	168	131		177	177	167	173	129		114	113	77		165	163	157	155	119	
[ψ]Revision: Femoral				1		1												2				2
Acetabular								1				1									1	1
Acetabular Insert								1				1						2			2	4
Femoral Head				1		1		1				1						2			2	4
All Components										1		1										
Femoral Fracture/Crack	6	3	1			10	7	2				9	4			4	7	1	1			9
Trochanteric Frac/Crack	4					4	3					3					1					1
Acetabular Frac/Crack	2					2																
Loosening: Fem. Comp																						
Acetabular Comp																						
Both Comp																						
Superficial Infection		1				1		4				4						5				5
Deep Joint Infection										1		1						1		1		2
Hematoma		2				2								1		1		1				1
Wound Related		8				8		8				8		4		4	1	6				7
Dislocation: Single		4				4		5				5		1		1	1	3			1	5
Recurrent								1				1						1		1		2
Nerve Palsy	1					1		1				1	1			1						
Subluxation																			1			1
Excessive Hip Pain	1	1				2			1			1							2			2
Bursitis		1	1	2	1	5			4	4		8			1	1		1	1	3		5
Heterotopic bone		3	2			5		3	3			6						6	4			10
Subsidence			1			1		2				2										
Trochanteric non-union																						
Soft Tissue Trauma			2	2	1	5			1	5		6		1		1		1	1	3		5
Alumina Insert Chip	4					4	4					4	6			6						
Miscellaneous	2	5	3	2		12	4	3	1	4		12	2	2		4	3	6	2	3	2	16
TOTAL	20	28	10	8	2	**68**	18	32	10	15	0	**75**	13	9	1	**23**	13	38	12	11	8	**82**

io = intraoperatively; ea = early (7 weeks); 6 = 6 months; 12 =12 months; 24 = 24 months postoperative; Tot = total

data for ABC I, ABC II, and Control includes those cases with less than 24 month postoperative follow-up

*includes 3 cases with ABC System I and 113 cases with ABC System II out to 12 months postoperative follow-up at time of data base closure. A 6 month evaluation was not performed on these cases.

[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

[ψ] values represent the number of *components* revised, this does not correspond to the number of *patients* (*cases)* that were revised.

TABLE 4: Time Course Distribution of Systemic Adverse Event Incidences for ABC System I and ABC System II vs. Control System out to 24 Months Post-Operatively.

Systemic Medical Events	ABC SYSTEM I[1] (163 patients enrolled)						ABC SYSTEM II[2] (172 patients enrolled)						CONTINUED ACCESS* (107 patients enrolled)				CONTROL (161 patients enrolled)					
Visit	io	ea	6	12	24	Tot	io	ea	6	12	24	Tot	io	ea	12	Tot	io	ea	6	12	24	Tot
Death				1		1													1		2	3
Pulmonary Embolism								1				1		2		2			1		1	2
Thrombus		1				1		1				1		2		2		2				2
Urinary Tract Infection		1				1		1				1	1	1		2		2				2
Genitourinary (non UTI)	2	5				7	3	2	2	1		8	2			2	4	4	2			10
Carcinoma		1	1	2		4														1	1	2
Bronchiopulmonary	1		3			4		2	1			3		1		1		1	1		1	3
Cardiovascular	4	4		4	1	13	3	2	1	1		7		1		1	1	5	1	2	1	10
Gastrointestinal	1	5		1	2	9	1	2			1	4		2		2		3	1			4
Neurosensory	1	3	1	5	1	11		2	1	3	1	7		1		1	1	2	1	2	1	7
Trauma (non-op hip related)			3	3	1	7			2	3	1	6			1	1			2	6	1	9
Dermatologic				1	1	2		2		3		5					1	1	1			3
Miscellaneous	1	7	6	5	5	24	1	8	4	11	2	26		2		2		6	6	5	1	18
TOTAL	10	27	14	22	11	**84**	8	23	11	22	5	**69**	3	12	1	**16**	7	26	17	16	9	**75**

io = intraoperatively; ea = early (7 weeks); 6 = 6 months; 12 =12 months; 24 = 24 months postoperative
data for ABC I, ABC II, and Control includes those cases with less than 24 month postoperative follow-up
*includes data from 3 cases with ABC System I and 113 cases with ABC System II out to 12 months postoperative follow-up at time of data base closure
** 103 cases out to 6 months postoperative follow-up at time of data base closure
[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

TABLE 5: 2 Year Patient Success Rates

Patient Success Criteria	**ABC I**[1] 140 cases enrolled	**ABC II**[2] 140 cases enrolled	**CONTROL** 133 cases enrolled
Abscence of Revision (%)	139 / 140 (99.3%)	138 / 140 (98.6%)	128 / 133 (96.2%)
Total HHS ≥ 70	120 / 122 (98.4%)	119 / 121* (98.4%)	117 / 120** (97.5%)
Acetabular RLL ≤2mm	122 / 122 (100%)	120 / 120 (100%)	112 / 112 (100%)
Acetabular Migration ≤3mm	122 / 122 (100%)	120 / 120 (100%)	112 / 112 (100%)
Wear Acetabular Insert <0.5mm/yr	122 / 122 (100%)	120 / 120 (100%)	112 / 112 (100%)
Femoral RLL ≤2mm	118 / 118 (100%)	115 / 115 (100%)	110 / 110 (100%)
Progressive Femoral Component Subsidence ≤5mm	122 / 122 (100%)	119 / 120 (99.2%)	111 / 111 (100%)
Patient Success Rate	97.5% (118/121)	95.8% (115/120)	93.2% (110/118)

* One case with HHS <70 at 12 months, and no 24 month follow-up and is included
** One case, with HHS <70 at 12 months, died before 24 month follow-up and is included
[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

TABLE 6: Time Course Distribution Table that compares early effectiveness data (mean Harris Hip Score - HHS) of the Trident™ System to the ABC System I, ABC System II, and Control System data.

Summary of Effectiveness Data	**ABC SYSTEM I[1]**			**ABC SYSTEM II[2]**			**TRIDENT**			**CONTROL**		
Visit	Pre-Op	7 weeks	6 months	Pre-Op	7 weeks	6 months	Pre-Op	7 weeks	6 months	Pre-Op	7 weeks	6 months
N=evaluable cases	170	162	162	176	177	166	184	175	97	165	160	156
HHS	48.3	78.6	93.2	48.7	79.2	94.7	47.5	80.3	95.4	48.9	77.3	91.7
(Std)	(13.0)	(11.4)	(9.6)	(10.7)	(13.1)	(7.8)	(11.7)	(9.8)	(7.4)	(12.3)	(10.1)	(10.7)

[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells

TABLE 7: Time Course Distribution of Operative Site Adverse Event Incidences for the Trident™ System vs. ABC I, ABC II and Control Systems out to Six Months Post-Operatively.

Operative Site Related	ABC SYSTEM I[1] (172 cases enrolled)				ABC SYSTEM II[2] (177 cases enrolled)				TRIDENT* (185 enrolled)				CONTROL (165 enrolled)			
Visit	io	ea	6	Tot	io	ea	6	Tot	io	ea	6	Tot	io	ea	6	Tot
N = cases evaluated	172	170	166		177	177	167		185	178	97		165	163	157	
[Ψ]Revision: Femoral										1		1		2		2
Acetabular						1		1								
Acetabular Insert						1		1						2		2
Femoral Head						1		1		1		1		2		2
All Components																
Femoral Fracture/Crack	6	3	1	10	7	2		9	3	1		4	7	1	1	9
Trochanteric Frac/Crack	4			4	3			3	3			3	1			1
Acetabular Frac/Crack	2			2					2			2				
Loosening: Fem. Comp																
Acetabular Comp																
Both Comp																
Superficial Infection		1		1		4		4		4		4		5		5
Deep Joint Infection														1		1
Hematoma		2		2						3		3		1		1
Wound Related		8		8		8		8		14		14	1	6		7
Dislocation: Single		4		4		5		5		2		2	1	3		4
Recurrent						1		1						1		1
Nerve Palsy	1			1		1		1								
Subluxation															1	1
Excessive Hip Pain	1	1		2			1	1		1	1	2			2	2
Bursitis		1	1	2			4	4		3	1	4		1	1	2
Heterotopic bone		3	2	5		3	3	6		5		5		6	4	10
Subsidence			1	1		2		2								
Trochanteric non-union																
Soft Tissue Trauma			2	2			1	1		1	1	2		1	1	2
Alumina Insert Chip	4			4	4			4								
Miscellaneous	2	5	3	10	4	3	1	8	2	4	4	10	3	6	2	11
TOTAL	20	28	10	**58**	18	32	10	**60**	10	40	7	**57**	13	38	12	**63**

io = intraoperatively; ea = early (7 weeks); 6 = 6 months postoperative; Tot = total
data for ABC I, ABC II, and Control includes those cases with less than 24 month postoperative follow-up
* 103 cases out to 6 months postoperative follow-up at time of data base closure
[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells
[Ψ] values represent the number of *components* revised, this does not correspond to the number of *patients* (*cases)* that were revised.

TABLE 8: Time Course Distribution of Systemic Adverse Event Incidences for Trident™ vs. ABC System I, ABC System II, and the Control Systems at Six Months Post-Operatively.

Systemic Medical Events	ABC SYSTEM I[1] (163 patients enrolled)				ABC SYSTEM II[2] (172 patients enrolled)				TRIDENT* (173 patients enrolled)				CONTROL (161 patients enrolled)			
Visit	io	ea	6	Tot	io	ea	6	Tot	io	ea	6	Tot	io	ea	6	Tot
Death															1	1
Pulmonary Embolism						1		1							1	1
Thrombus		1		1		1		1						2		2
Urinary Tract Infection		1		1		1		1						2		2
Genitourinary (non UTI)	2	5		7	3	2	2	7		5		5	4	4	2	10
Carcinoma		1	1	2												
Bronchiopulmonary	1		3	4		2	1	3						1	1	2
Cardiovascular	4	4		8	3	2	1	6	2	7	1	10	1	5	1	7
Gastrointestinal	1	5		6	1	2		3	1	9		10		3	1	4
Neurosensory	1	3	1	5		2	1	3	1	2	1	4	1	2	1	4
Trauma (non-op hip related)			3	3			2	2		1		1			2	2
Dermatologic						2		2		3		3	1	1	1	3
Miscellaneous	1	7	6	14	1	8	4	13	3	21	2	26		6	6	12
TOTAL	10	27	14	**51**	8	23	11	**42**	7	48	4	**59**	7	26	17	**50**

io = intraoperatively; ea = early (7 weeks); 6 = 6 months postoperative; Tot = total.
This table does not include data from the 107 Continued Access patients (see Table X)
All patients enrolled in the ABC I, ABC II, and Control groups have achieved at least 12 months postoperative follow-up.

* 103 cases out to 6 months postoperative follow-up at time of data base closure.
[1]ABC System I utilized Howmedica Osteonics® PSL® MicroStructured® ABC Shells; [2]ABC System II utilized Howmedica Osteonics® Secur-Fit™-HA PSL® ABC Shells