

Draft Package Insert

0902-00-801

INSTRUCTIONS FOR USE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Duraloc[®] Option Ceramic Hip System consists of a modular ceramic insert that secures to a Duraloc[®] Option acetabular shell via a taper locking mechanism and a ceramic femoral head that is attached to a femoral stem to complete the total hip prosthesis. Both the insert and the femoral head are manufactured from BioloX[®] forte.

The Duraloc[®] Option ceramic acetabular insert is available in 28mm and 32mm inner diameters. Liners with a 28mm inner diameter are offered in outer diameters of 46mm, 48/50mm, 52mm, 54/56mm, 58/60mm, and 62/64/66mm. Liners with a 32mm inner diameter are offered in outer diameters of 52mm, 54/56mm, 58/60mm, and 62/64/66mm. The insert is manufactured by CeramTec from high purity, dense aluminum oxide (99.7%) conforming to ISO 6474.

The insert is secured into a Porocoat[®] porous-coated titanium alloy Ti-6Al-4V (ASTM F-620) Duraloc[®] Option acetabular shell by means of an 18° included angle taper which locks into a corresponding taper in the acetabular shell. The shells are for cementless use only. The coating consists of multiple layers of commercially pure titanium beads, which are sintered to the exterior portion of the shell.

The acetabular shells have two or three bone fixation screw holes, dependent upon shell size, and an apical threaded hole. The shells are offered in 11 sizes, from 46mm to 66mm, in 2mm increments. If required, 6.5mm cancellous bone screws, in lengths from 15mm to 70mm, and an apex hole eliminator may be used in conjunction with the shell.

The ceramic femoral heads have diameters of 28mm and 32mm, 12/14 or 11/13 tapers, and offsets of +0 to +9mm. The heads are manufactured by CeramTec of the same material as the inserts: high purity, dense aluminum oxide (99.7%) conforming to ISO 6474. The heads are assembled to Ti-6Al-4V femoral stems, with 12/14 or 11/13 tapers.

The S-ROM[®] and Summit[™] femoral stems are manufactured from titanium alloy Ti-6AL-4V (ASTM F-620) and are designed to assemble to the ceramic femoral head components described above. The femoral components also feature porous coatings of commercially pure titanium beads. The femoral stem components are for cementless use only.

The Duraloc[®] Option Ceramic Hip System is for cementless use only.

INTENDED USE/INDICATIONS

The Duraloc[®] Option Hip System is indicated for non-cemented use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease (NIDJD) such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and post-traumatic arthritis.

THE DURALOC[®] OPTION ACETABULAR LINERS ARE INTENDED FOR USE ONLY WITH DEPUY BIOLOX[®] FORTE ALUMINA CERAMIC HEADS.

CONTRAINDICATIONS

- overt or latent infection in or around the hip joint;
- skeletally immature patients;
- loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; and
- poor bone quality, such as osteoporosis, where in the surgeon's opinion, there is inadequate bone to support the implant(s).

WARNINGS and PRECAUTIONS

WARNINGS:

- Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning to decrease the chance for dislocation.
- Incorrect alignment may result in suboptimal contact between the femoral head and the acetabular prosthesis articulating surfaces, resulting in the potential for increased wear, chipping, and/or damage.
- Failure to use the optimum size implant, failure to adequately seat the component adjacent to adequate bone and/or failure to ensure that the component is stable may result in loosening, dislocation, subsidence or fracture of the prosthesis.
- Do not disassemble and reassemble the liner component to the acetabular shell because the locking joint and taper joint might become damaged.
- 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. Once the acetabular shell taper has been deformed through assembly to its mating ceramic insert, it should not be reassembled to another ceramic insert.
- Do not scratch or damage the surface or tapers of the components. Damage or scratching of the taper may prevent proper locking between the liner and the shell.
- Do not use other manufacturer's components with any of the Duraloc Option components to prevent mismatch of the tapers and other articulating surfaces. Use only compatible DePuy hip stems, femoral heads, acetabular liners and acetabular shells with the Duraloc Option components. Do not use a metal or zirconia head with

the Duraloc Option Ceramic Hip System because this may accelerate bearing wear and lead to early failure of the device.

- Do not use any component that has been chipped, scratched, or otherwise damaged during the implant procedure. Do not use ceramic femoral heads or any other components if they have been dropped or have impacted a hard surface. Damage to the component may not be visible, but could cause early failure of the prosthesis.
- Do not implant in obese patients because excessive loading on the ceramic femoral heads may lead to fracture or loss of fixation.
- Implants are for single use only. Do not reuse an implant in order to ensure there has been no damage to the implants.
- Do not implant in pregnant patients as the extra weight and exposure to radiation may be harmful to the implant and baby.
- Do not re-sterilize components.
- Do not implant this hip system in patients undergoing revision of previously unsuccessful femoral head replacement, cup arthroplasty, or other indications (e.g., inflammatory hip joint disease) because the safety and effectiveness of these devices for indications other than non-inflammatory degenerative joint disease have not been established.

PRECAUTIONS:

Preoperative

- The surgeon should be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery. The surgeon should review the surgical technique manual and other training materials supplied by DePuy.
- The surgeon should discuss all physical and mental limitations particular to the patient and all aspects of the surgery and the prostheses with the patient before surgery. The discussion should include the limitations and possible consequences of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight.
- Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Carefully examine each ceramic component for any signs of damage that may have occurred during shipping or prior in-hospital handling. All surfaces should be smooth

without pitting, scratches, or other surface irregularities. Do not implant any damaged components.

- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures.
- Avoid detachment of porous coatings which could lead to increased debris particles.
- Clean and dry surfaces which lock to ensure proper seating and assembly.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.

Intraoperative

- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, etc., as the corresponding components to be permanently implanted.
- It is recommended that components at least one size larger and one size smaller than were preoperatively determined be available at surgery to accommodate intraoperative selection of the appropriate size(s). Protective covers should be left on until the components are ready to be implanted.
- Ensure that prior to liner insertion, soft tissue does not interfere with the shell/liner interface. Modular components must be assembled securely to prevent disassociation.
- Before implanting a ceramic femoral head, the male taper on the femoral stem should be wiped clean of any blood, bone chips or other foreign materials. Foreign material between the ceramic head and the femoral stem taper may impede proper seating of the head on the stem. This could affect the performance of the femoral head or the locking mechanism between the femoral head and the femoral stem.
- Do not alter or modify implants in any way.
- In order to prevent sepsis, the physician is advised to follow the following recommendations:
 - Consistent use of prophylactic antibiotics.
 - Utilizing a laminar flow clean air system.
 - Having all operating room personnel, including observers, properly attired.
 - Protecting instruments from airborne contamination.
 - Impermeable draping.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, extraneous bone cement (if used), ectopic bone, etc. Foreign particles may cause

excessive wear. Range of motion should be thoroughly checked for improper mating, instability, or impingement and corrected as appropriate.

Postoperative

- Strict adherence by the patient to the surgeon's instructions and warnings is extremely important. Accepted practices should be followed in postoperative care.
- The patient should be released from the hospital with complete written instructions and warnings regarding exercises and therapies and any limitations on their activities.
- The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant fixation failure.
- A continuing periodic patient follow-up is recommended. Because of the unknown functional lifetime of the implant, particularly with respect to the maintenance of implant fixation, A-P radiographs of the pelvis should be taken at each follow-up and compared with previous radiographs and correlated with the clinical assessment of the patient. If any radiographic changes are observed, such as the occurrence of radiolucencies, bone resorption, or any changes in the position of an implant, these changes should be closely monitored to determine whether they are static or progressive and the patient should be treated appropriately.
- The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement:
 - Obesity or excessive patient weight.
 - Manual labor.
 - Active sports participation.
 - High levels of patient activity.
 - Likelihood of falls.
 - Alcohol or drug addiction.
 - Other disabilities, as applicable.
- The following conditions singularly or concurrently, tend to adversely affect the fixation of hip replacement implants:
 - Marked osteoporosis or poor bone stock.
 - Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).
 - History of general or local infections.
 - Severe deformities leading to impaired fixation or improper positioning of the implant.
 - Tumors of the supporting bone structures.

- Allergic reactions to implant materials (e.g., bone cement, metal, polyethylene).
- Tissue reactions to implant corrosion or implant wear debris.
- Disabilities of other joints (i.e., knees and ankles).

When the surgeon determines that the hip replacement is the best medical option available and decides to use this prosthesis in a patient who has any of the above conditions or who is simply young and active, it is imperative that the patient be instructed about the strength limitations of the materials used in the device and for implant fixation, and the resultant need to substantially reduce or eliminate any of the above conditions.

Safety and Effectiveness have not been established in patients with the following conditions:

- **revision hip arthroplasty**
- **inflammatory hip joint disease**
- **neuropathic hip joint disease**

ADVERSE EVENTS

The Duraloc® Option Ceramic Hip System is similar to a previously approved ceramic hip system (P010001). DePuy references the clinical data from P010001, under a licensing agreement, as clinical support for the safety and effectiveness of the Duraloc® System. The clinical data are relevant because the ceramic acetabular inserts of the Duraloc® system are identical to the ceramic acetabular inserts of the previously approved system (P010001) and the ceramic femoral heads of the Duraloc® System are nearly identical to the ceramic femoral heads of the previously approved system (same articulating surface). The Duraloc® System and the referenced hip system yielded similar results on the bench.

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.

The adverse events related to total hip replacement surgery reported in the clinical study are listed in Table 1.

Table 1: Reported Adverse Events

<u>Event</u>	<u>Clinical Study</u> (n=959)		<u>Historical Control Group</u> (n=211)	
	<u>Freq.</u>	<u>% of Pop.</u>	<u>Freq.</u>	<u>% of Pop.</u>
<u>Systemic</u>				
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
<u>Local</u>	<u>Freq.</u>	<u>% of Pop.</u>	<u>Freq.</u>	<u>% of Pop.</u>
Breakage/Fracture of Component ¹	5	0.5%	2	0.9%
Dislocation (single) of Component ²	8	0.8%	3	1.4%
Dislocation (recurrent) of Component ³	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 < 1 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 ⁴	10	1.0%	0	0%
<u>Local – Hip</u>	<u>Freq.</u>	<u>% of Pop.</u>	<u>Freq.</u>	<u>% of Pop.</u>
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

¹ Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision.

Whiteside Clinical Study: Broken metal peg of acetabular cup

² 2 were revised for this reason

³ 1 was revised for this reason.

⁴ 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. None of these complications were related to the study hip or the procedure.

Potential Complications Associated with Any Total Hip Arthroplasty

1. Excessive wear of the ceramic components secondary to damage of mating wear surfaces or debris particles;
2. Although rare, metal sensitivity reactions in patients following joint replacement have been reported;
3. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts;
4. Possible detachment of the porous coating, which could lead to increased debris particles;
5. Pain;
6. Femoral or acetabular perforation, or bone fracture while seating the device;

7. Damage to blood vessels resulting in hematoma;
8. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
9. Undesirable shortening or lengthening of the limb;
10. Traumatic arthrosis of the hip from intraoperative positioning of the extremity;
11. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
12. Temporary or permanent neuropathies;
13. Delayed wound healing;
14. Infection;
15. Migration, loosening, subluxation, or dislocation of the prosthesis;
16. Periarticular calcification or ossification, with or without impediment to joint mobility;
17. Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification; and
18. Death.

Potential Complications Associated with the Duraloc® Option Ceramic Hip System

1. 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.
2. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
3. Component dissociation.
4. 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 referenced ceramic hip system to a historical control group.

Although the primary efficacy endpoint in the clinical study was the survivorship of the referenced ceramic hip system (as assessed at the two year postoperative interval), for the purpose of the clinical study, the primary efficacy endpoints included Harris Hip Score 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 of patients implanted with a metal on polyethylene hip 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 referenced ceramic hip system in the original clinical population (Original Clinical Population). An additional 630 procedures 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 control group.

Pivotal 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 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 total hip replacement (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 7 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)	Historical Control Group (n=211)
Mean Age in years	51.4 years (range 20-80)	62.7 years (range 22-87)
Gender	595 (62%) Males 364 (38%) Females	112 (53%) Males 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:		
Osteoarthritis	692 (72.2%)	180 (85.3%)
Avascular Necrosis	189 (19.7%)	31 (14.7%)
Traumatic Arthritis	36 (3.8%)	0
Congenital Hip Dysplasia	42 (4.4%)	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 ^o (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 procedures 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 days	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	Historical Control Group (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:

¹Original clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacement 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 24 months or later was available (n=4)

²The *Continued Access* sample (N=630) includes procedures performed after the original clinical 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)	Historical Control Group (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% pf the acetabular cups. In the Historical Control Group 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 referenced ceramic hip system. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the referenced ceramic hip system and the historical control group 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: Referenced Ceramic Hip System 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	0.9308	0.0562

Table 8: Historical Control Group 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
24 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	Historical Control Group (n=211)
Absence of Revision (%)	96.7% (n=318)	98.1% (n=207)
Total HHS \geq 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, values after Month 24 were used. Original clinical study 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 24 months or later was available (n=4)

² Absence of complete radiolucency was 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.

HOW SUPPLIED

Femoral stem, femoral head, acetabular liner, and acetabular cup components are individually packaged and supplied STERILE. All metal and ceramic components are sterilized using radiation.

Remove from the package using accepted aseptic technique only after the correct size has been determined.

For metal components only: if the packaging appears to be damaged or the sterile implant is determined to be aseptically compromised but still acceptable for intended use based on physician determination, the implant must be rinsed and sterilized prior to implantation according to the following instructions.

RINSING/CLEANING

Use sterile room temperature water or physiological saline to soak the implant. Soak the implant for a minimum of 5 minutes. Immediately dry the product. Inspect the implant prior to sterilization.

STERILIZATION (metal components only)

If sterilization of metal component is necessary, the following parameters are recommended as they have been validated for a Sterility Assurance Level (SAL) of 10^{-6} .

<u>Method</u>	<u>Cycle</u>	<u>Temperature</u>	<u>Exposure Time</u>
Steam	Pre-vacuum	270°F (132°C)	10 minutes

NOTE: The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

CAUTION: Ceramic heads, liners, prostheses with ceramic coatings and components manufactured from or containing UHMWPE CANNOT be re-sterilized. Do not use these components if the sterile packaging appears damaged.

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DRAFT PATIENT LABELING

What is the device?

Your new hip is called the “Duraloc® Option Ceramic Hip System.” The type of ceramic is “alumina.” Its trade name is “Bilox® forte.”

The system consists of

- A Duraloc Option metal cup that fits into your hip bone,
- A ceramic liner (this locks into the metal cup),
- A ceramic femoral head (this replaces the top of your thigh bone)
- A metal femoral stem, either Summit® or S-ROM®, (the head fits onto this stem and the stem fits into your thigh bone).

What is the purpose of the device?

The Duraloc® Option Ceramic Hip System is meant for use in total hip joint replacement for pain relief or reduction and/or improved hip function in skeletally mature patients with no swelling, redness or pain in the joint tissues due to diseases. These conditions are defined as follows:

OSTEOARTHRITIS: when the tissue that cushions your hip (“cartilage”) breaks down, usually over time, and causes your hipbones to rub together and cause pain.

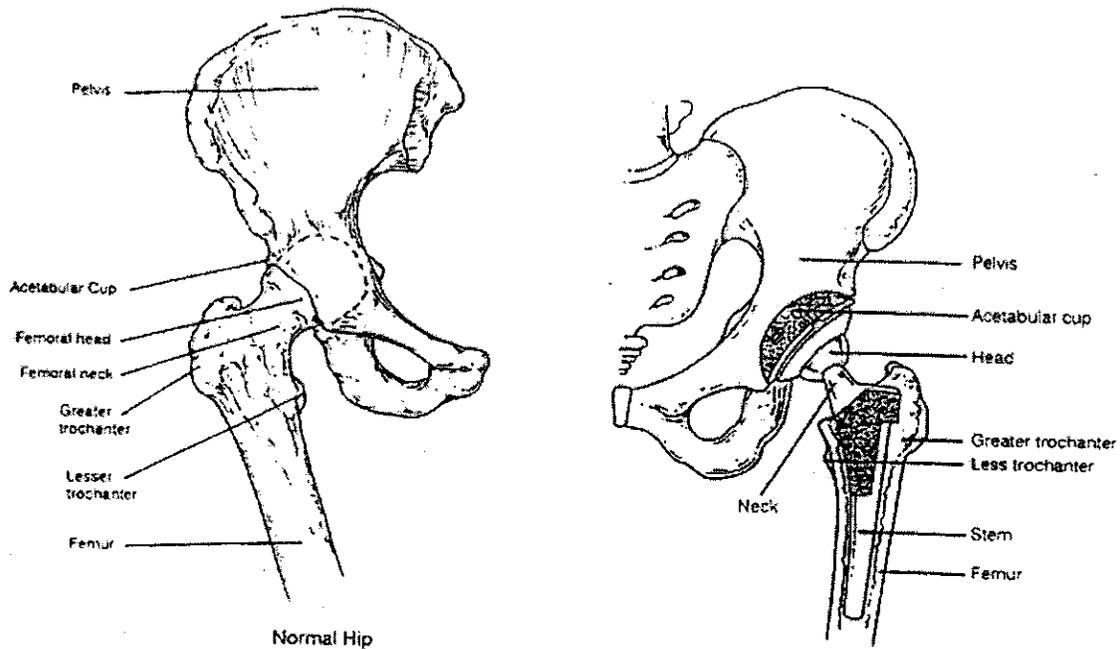
AVASCULAR NECROSIS: a loss of blood supply to the hipbones, changing the shape of the bones and increasing the thickness of the bones or a flattening of the joint surface.

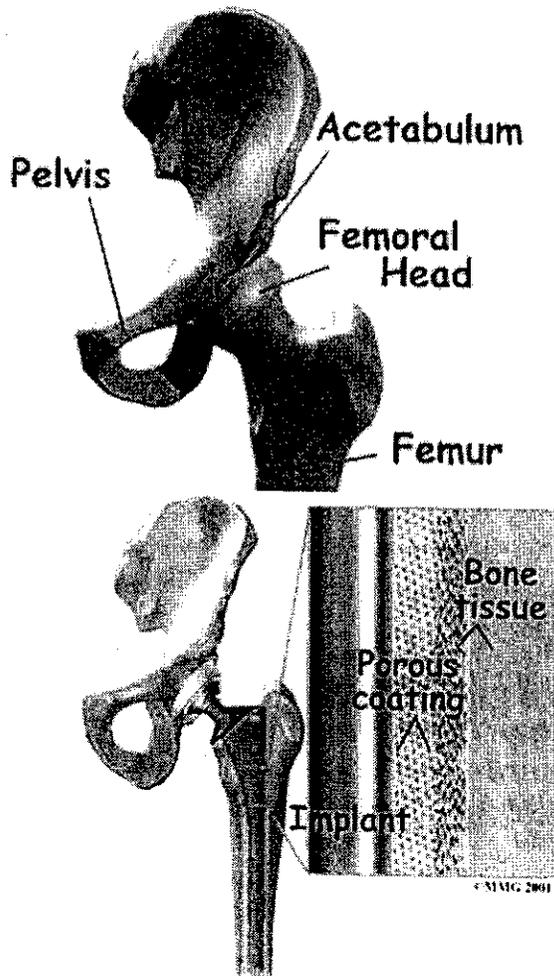
CONGENITAL HIP DYSPLASIA: dislocation of your hip at the time of birth due to abnormal growth of the hip joint. The affected parts could be the bones (either the socket part of your hip bone or your thigh bone) or the nearby joint capsule and soft tissues.

TRAUMATIC ARTHRITIS: the swelling, redness, or pain of a joint from an injury or damage, resulting in a 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 wearing away of the bone.

What happens during the implant procedure?

The surgery for a total hip system involves removing your diseased hipbone and replacing it with a ball on a stem. The stem is inserted into your thighbone. After a special tool makes the right size and shape socket, the shell is screwed into place in the socket. The liner is then inserted into the shell. Finally, the ball is placed into the new socket.





When should the device not be used (also called “CONTRAINDICATIONS”)?

CONTRAINDICATIONS include:

1. Obvious infection,
2. Distant centers of infections (which can spread through the bloodstream or through circulation to the site of the implant),
3. Rapid spreading of the disease, seen on x-rays as joint damage or loss of bone,
4. Patients whose bones have not stopped growing (not “skeletally mature”),
5. Cases where the muscles may be too weak to work properly – for example, in cases of prior loss of function or joining together, weak bones or poor bone stock, or poor skin coverage around the hip joint,

6. Swelling, redness and pain in tissues due to injury or damage
7. Joints with nerve disorders,
8. Patients who are very overweight (obese), or
9. Nerve or muscle disease that may negatively have an effect on walking or weight bearing.

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

What are the risks and benefits?

While there is no guarantee of success, benefits can include possible relief of pain and the return of normal use of the hip. This ceramic hip liner could possibly last longer than the standard replacements currently being used.

The risks and problems linked with this hip replacement are expected to be similar to those of other hip replacements. Each of these reactions or issues can happen during and after surgery and may need revision surgery and implant removal. The risks and issues include:

1. Continuing bone breakdown and loss may happen around the hip implant parts due to foreign body reaction to particles.
 - Contact between the hip implant parts, bone, or cement can form particles.
 - Attachment, scraping, and/or breakage may also cause particles.
 - Also, particles in between the hip implant parts or between the hip implant parts and bone may cause more particles to form at an increasing rate.

Dissolving of the bone can lead to having to remove or replace the hip implant parts.

2. Wear of the 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, and lead to another operation to replace the worn out hip parts.
3. It's rare, but some cases of metal allergy reactions in patients following hip surgery have been reported. The metal particles from the implant can be seen as foreign and the body tissue may react against it.
4. Nerve damage, without medical signs or symptoms, has been reported, and may occur as the result of having hip surgery.

5. Dislocation and partial dislocation of hip parts can result from improper positioning of the components. Muscle and rubbery tissue slackness can also contribute to these conditions.
6. Hip parts can loosen or move due to trauma or improper attachment.
7. Infection can lead to failure of the hip joint.
8. While rare, breakage of the hip parts can occur because of trauma, strenuous activity, improper position, or time implanted in the body (service life).

What might increase the risk of failure of the new hip?

1. Patients who are unable to follow instructions given by the nurse or doctor.
2. Noticeable bone loss, severely decreased bone mass.
3. Disorders that interfere with the body's ability to absorb nutrients, which may slow bone formation,
4. Softening of the bones,
5. Poor hope for good wound healing – for example, chronic pressure ulcers, end-stage diabetes, severe protein deficiency or there is not enough food to serve the body's needs and
6. When material sensitivity is suspected, the right tests should be made prior to choosing the implant or material for the surgery.

What are the difficulties during surgery or shortly after surgery?

1. Pain
2. Holes in the thigh bone or pelvis or broken bones
3. Broken bones while implanting the device
4. Damage to blood vessels
5. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb
6. Differences in leg lengths (shortening or lengthening) caused by choosing the wrong implant size
7. Disease of the joint of the hip from placing or moving the leg during surgery
8. Blood clots in the veins or lungs, or heart attack
9. A pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue"
10. A wound that won't heal, and
11. Infection.

What kind of problems could happen later on?

1. Pain
2. Where a small piece of the thigh bone is pulled away, from too much muscular tension, trying to walk too soon or accidental weakening during surgery

3. A broken bone that does not heal properly due to weak reattachment or early weight bearing (non-union)
4. Problems with either leg because of differences in leg lengths or because of lack of enough muscle
5. Broken bone by trauma or excessive weight or force (loading), particularly in the presence of poor bone stock
6. Calcium deposits around the joint or bone formation, with or without obstacles to being able to move and
7. Poor range of motion due to choosing or placing the wrong hip parts, by parts striking each other, and calcium deposits around the joint.

What is my role?

There are limits to what you can do after your surgery. You will need to protect your hip implant from full, unaided walking until you've had enough time to heal and your muscles have attached.

After you have enough attachment and healing, any activity above normal (such as playing basketball or heavy physical work), or damage to the hip can cause broken bones, loosening, or wear of the hip implant and its parts.

Loosening of the hip parts can result in higher rates of wear particles, as well as damage to the bone, making another surgery more difficult.

Please read and follow the follow-up care and treatment instructions your doctor gives you.

When should I contact my doctor?

- Redness, swelling or drainage from around your incision
- An unexplained fever, where your temperature is more than 100°F or 38°C, or chills that last more than a day
- Severe hip pain that won't go away with your pain medication
- Any strange shortening or turning of your leg or
- Any sudden swelling in your thigh or calf.

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

What choices are there?

Based on each person's situation, other choices may be to use other total hip replacement parts offered for sale and already approved or cleared by the FDA; non-surgical treatment such as reduced activity and/or pain medication; or other surgical treatments that do not involve the use of an implant.

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CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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