Surgical Technique

smith&nephew

R3°

Acetabular System

Poly and Ceramic

Design surgeon list

Smith & Nephew thanks the following surgeons for their participation as part of the R3° system design team:

Robert Barrack, MD
St. Louis, Missouri

Robert Bourne, MD
London Health Sciences Center
London, Ontario, Canada

Jonathan Garino, MD
University of Pennsylvania
School of Medicine
Philadelphia, Pennsylvania

Wayne M. Goldstein, MD
Clinical Professor of Orthopaedics
University of Illinois at Chicago
Illinois Bone and Joint Institute

Richard Kyle, MD
Minneapolis, Minnesota

Stephen J. McMahon MB, BS, FRACS(Orth), FA(Orth)A
Senior Lecturer Monash University
Malabar Orthopaedic Clinic
Melbourne, Australia

John L. Masonis, MD
OrthoCarolina
Hip & Knee Center
Charlotte, North Carolina

Henrik Malchau, MD
Associate Professor Harvard Medical School
Co-director The Harris Orthopaedic Biomechanics
and Biomaterials Laboratory
Massachusetts General Hospital
Boston, Massachusetts

Michael Ries, MD
University of California
San Francisco, California

Cecil Rorabeck, MD
Professor of Orthopaedic Surgery
University of Western Ontario
London, Ontario, Canada

Brief System Overview

R3◇ Ceramic-on-Ceramic

Ceramic-on-Ceramic bearing surfaces have been used worldwide in total hip replacement for more than 30 years. Renewed interest in ceramics as an alternate bearing surface has been driven by the following:

- New technology
- Manufacturing processes and standards
- New designs

This translates into improvements in the following:

- Mechanical and physical properties
- Wear characteristics
- Optimized biocompatibility
- Reliability expected by today's more active patients

The R3 system's ceramic design is an assembled combination of:

- A ceramic component made from orthopaedic industry standard materials.

  Biolox® Forte
- A precision-machined support ring made of a Titanium alloy that is commonly used in orthopaedic implants.

The design of R3 ceramic acetabular components:

- Reduces the effects of impingement
- Enhances wear and durability by utilizing liners that sit flush with the shell face

Nota Bene:

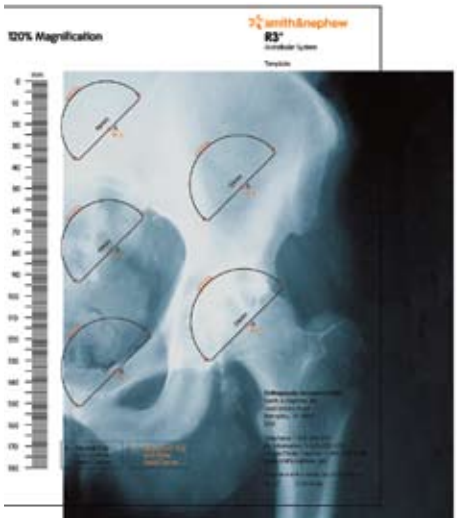
The technique description herein is made available to the healthcare professional to illustrate the manufacturer's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

Be advised of the Warnings and Precautions when using this system particularly of the intraoperative and post-operative considerations noted in the Package Insert and also at the end of this manual.

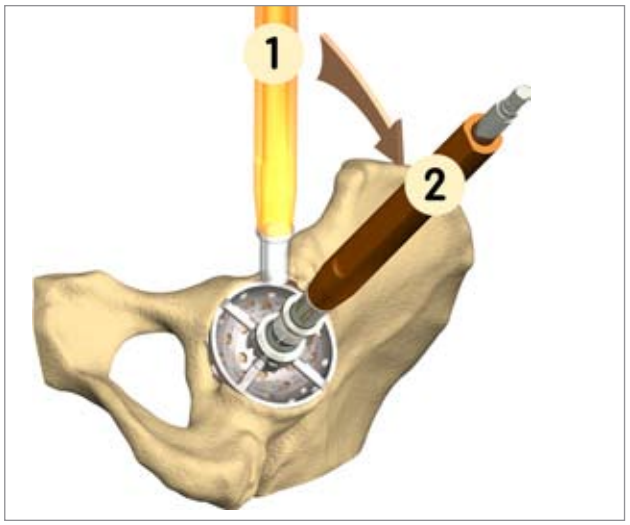
The following is an abbreviated technique description for the R3° Poly and Ceramic Acetabular System. The purpose of this technique is to provide the user with important information and tips about the implants and instruments in this system. It is expected that the user is familiar with and understands the demands of total hip surgery. However, for appropriate training on the R3 Poly and Ceramic Acetabular System, please read this surgical technique manual and the accompanying package insert. Consult your Smith & Nephew Sales Representative for a review of the system implants and instrumentation.

Of particular importance, once the ceramic liner has been impacted into its mating shell, it should not be reassembled to the shell as early failure may occur; however, the R3 locking mechanism allows the user to assemble a new R3 ceramic liner to a previously assembled R3 acetabular shell intraoperatively, or a new R3 poly liner to a previously assembled R3 acetabular shell either intraoperatively or during a revision surgery.

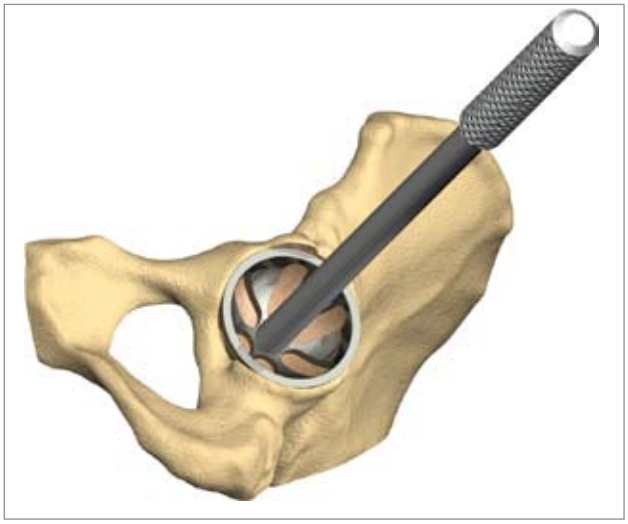
Short technique



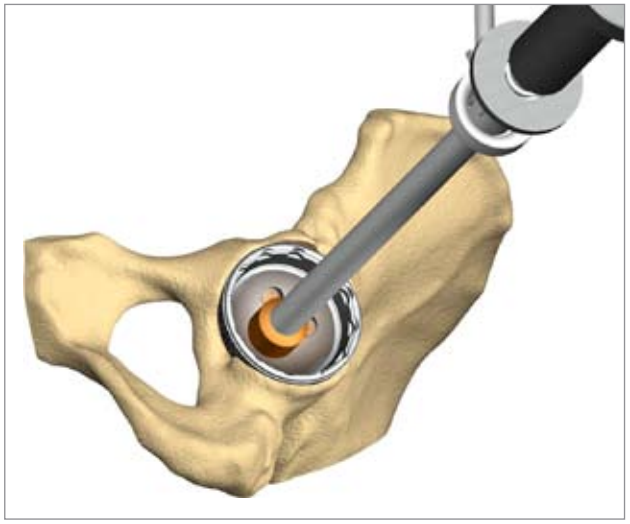
Preoperative Planning



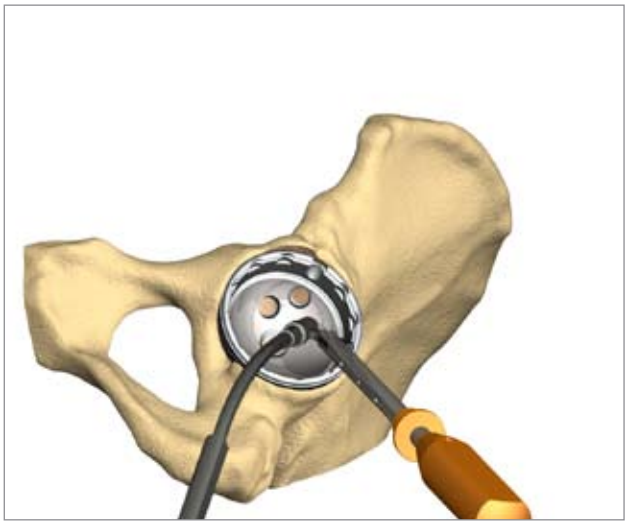
Acetabular Reaming



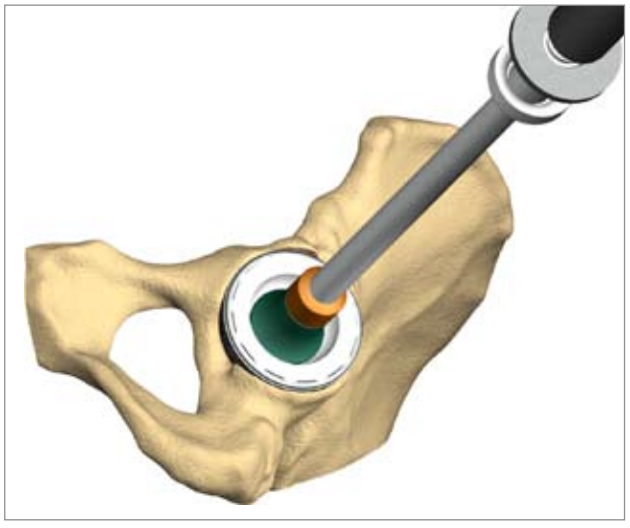
Acetabular Trialing



Acetabular Shell Insertion

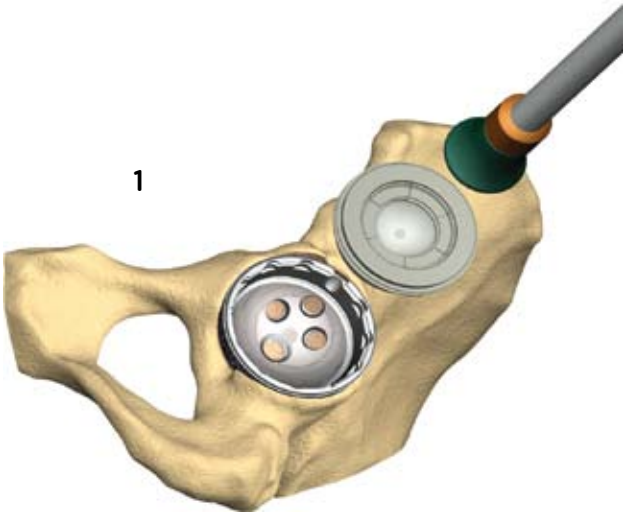


Acetabular Screw Insertion

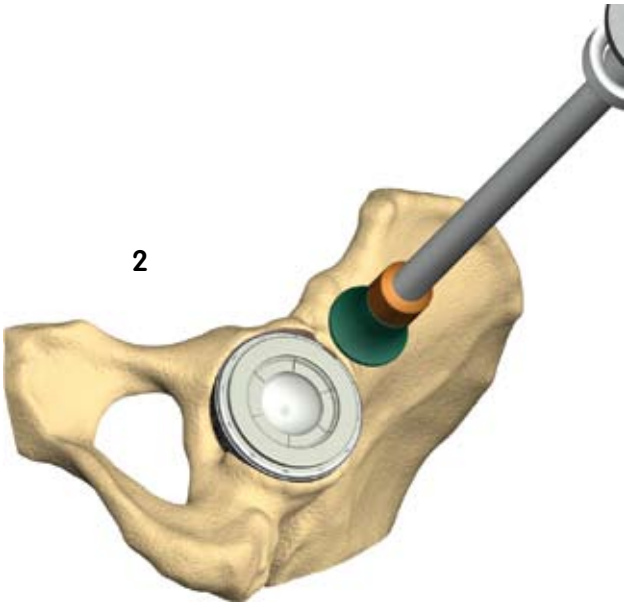


Acetabular Poly Liner Insertion

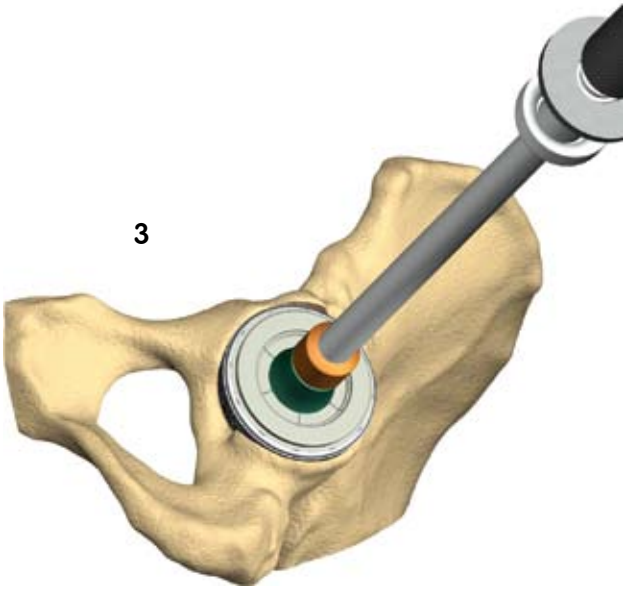
Ceramic liner insertion



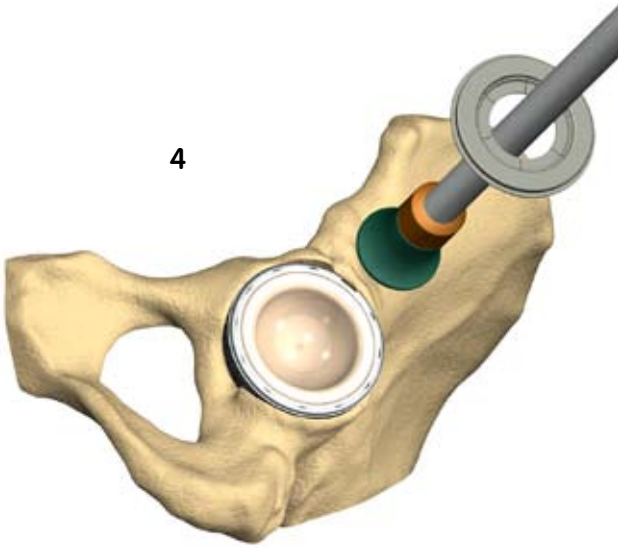
After the shell is implanted into the acetabulum, the surgeon inserts the liner with the attached alignment guide into the shell.



The cup impactor with impactor head is placed through the center of the alignment guide.



The surgeon then impacts the liner into the shell.



The alignment guide will disengage onto the shaft of the shell impactor, and the liner will be perfectly seated inside the shell. The alignment guide can now be removed from the impactor for disposal.

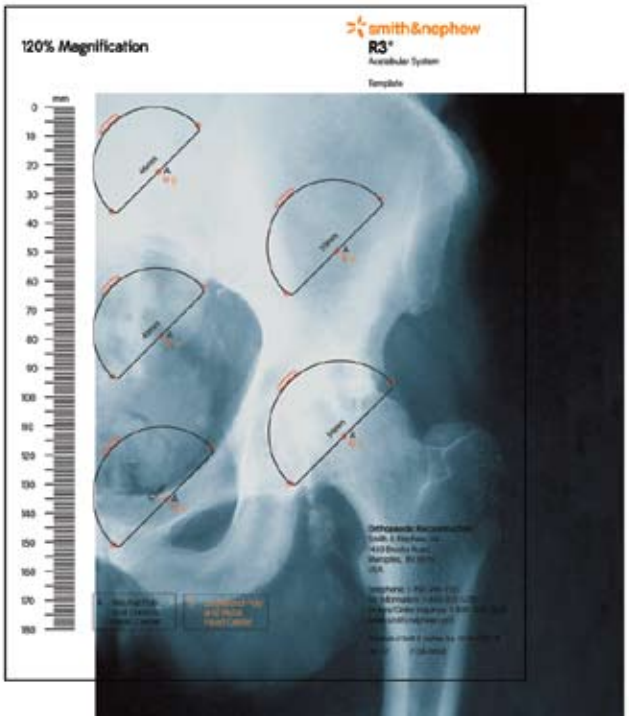
Preoperative planning

Preoperative X-Rays should include an AP of the pelvis centered over the symphysis and an AP and lateral of the affected hip.

Templating can be done on the affected side, but it is important that the contralateral hip also be templated to verify the size.

To ensure a congruent fit, the acetabular component should be medialized to the medial aspect of the acetabulum, as indicated by the teardrop.

The center of rotation also should be marked for subsequent reference.



Acetabular exposure

Complete exposure of the acetabulum is required, regardless of the type of approach. Use the approach with which you are most familiar and achieve the best surgical results.

First, resect the acetabular labrum and place a blunt retractor anteriorly.

After identifying the transverse acetabular ligament, place a blunt retractor around the inferior margin of the acetabulum.

Depending on the exposure, a third retractor can be placed posteriorly following the excision of the labrum.

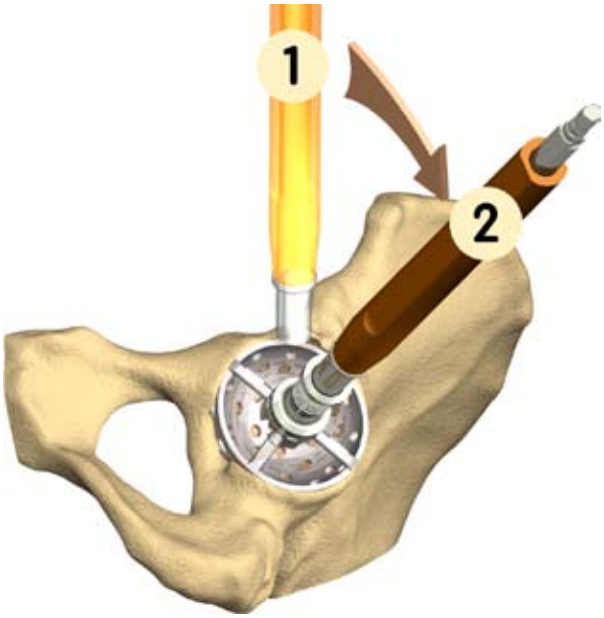
Remove all overhanging soft tissue and osteophytes in order to visualize the entire acetabular socket.

The acetabulum should be medialized to restore the normal center of hip rotation.

Surgical tips:

- To minimize the need of assistance, each of the acetabular retractors can be tied directly to a Charnley retractor.
- Dividing the transverse acetabular ligament will allow reaming to begin inferiorly, preventing the tendency of the reamer to migrate superiorly.
- Removal of soft tissue and overhanging osteophytes from the foveal notch aids visualization of the quadralateral plate and the depth that the acetabulum should be reamed.

Acetabular reaming



Select an acetabular reamer that is considerably smaller than the templated size of the cup. Generally, reaming 6–8mm lower than the templated size is suitable.

Position the initial reamer in a vertical direction (1) to ensure the reamer is taken down to the medial wall.

Direct the second reamer and all subsequent reamers in approximately 45° of abduction and 20° of anteversion for final position of the acetabular component. (2)

Preserve subchondral bone to provide good support for the prosthesis. This might mean the reamer will not be medialized all the way to the inner wall. One might suggest leaving some remaining subchondral bone and removing the medial bone that is osteophyte and is covering fatty tissue.

Frequently palpate the posterior and anterior walls of the acetabulum during the reaming process as these walls will determine the largest acetabular size that can be accommodated. Avoid allowing the reamer to drift posteriorly where the bone might be less dense and the path of least resistance for the reamer.

To press-fit the three hole and no hole cups, the acetabulum should be underreamed by 1–2mm depending on bone quality, acetabular size and the surgeon's experience. The cups are available in even sizes so the last reamer used should either be an odd size for 1mm or an even size for 2mm underreaming.

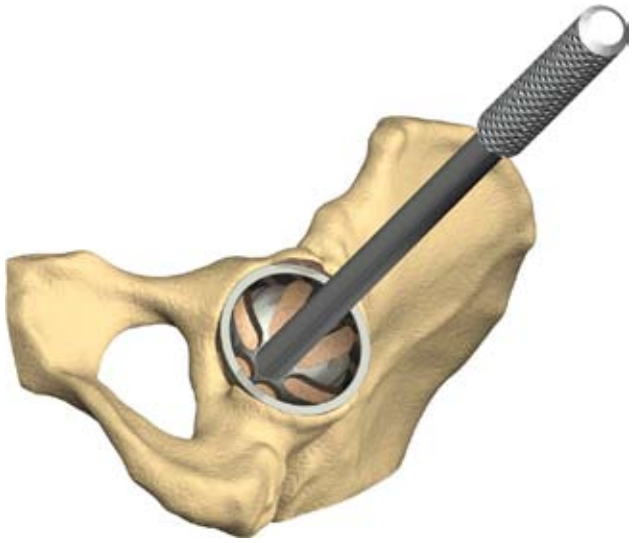
Surgical tips:

- Each successive reamer must be fully seated within the acetabulum. Failure to do so will result in lateralization of the trial and exposure of the porous coating. If lateralization occurs, go back to a smaller reamer and begin again, checking each size to ensure that the reamers are fully seated.
- Increasing the reamer size by 2mm is recommended, although in smaller patients 1mm increments may be preferred.
- Mark the medial wall with an electric cautery prior to using the last reamer. If the last reamer does not remove the mark, repeat reaming, dropping back a size if necessary.

Instrument tips:

- The acetabular reamer has an open back, which helps visualize reaming and allows easy access to bone chips. This style of reamer is hemispherical and when fully seated it should be covered by the rim of the acetabulum.
- Gently rock reamer handle back and forth approximately 5° for last size used only to ensure rim is accurate for the desired press-fit.

Acetabular trialing



After the preparation of the acetabulum, the trial shell should be inserted to verify size and position of the cup. Use a trial acetabular shell that is the same diameter as the last reamer used. The surgeon should note the appropriate orientation of the acetabular trial to position the cup correctly. The trial should be congruent with the reamed acetabular cavity and bottom out without significant force required to seat it.

A trial liner insert cannot be inserted into a trial shell for trial reduction.

If trial reduction using a trial insert is desired at this time, then the preparation of the femur should occur up until the trial reduction stage. The surgeon then has the option of inserting a trial acetabular liner (preferred) in the acetabular implant for subsequent leg length, offset and stability assessments or the real acetabular insert.

Select appropriate type and size component based on anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions.

Generally the largest cross-section component that will allow adequate bone support to be maintained is preferred. Muscle looseness and/or malpositioning of the components may result in loosening, subluxation, dislocation, fracture of components and/or bone. Firmly seat all components and check for component looseness during surgery.

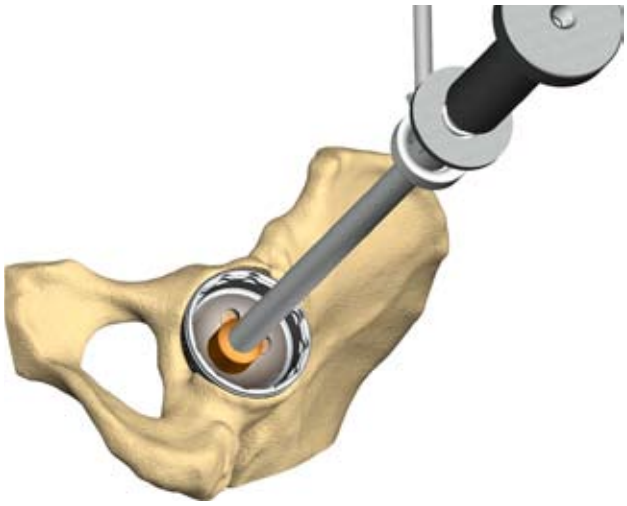
Surgical tip:

- The bone at the edge of the trial shell can be marked with an electric cautery to help in final component positioning.

Instrument tip:

- The trial shells are the exact size specified. They can be used to assess the accuracy of reaming or can be press-fit into the acetabulum if using a larger size than the final reamer.

Acetabular shell insertion



Select the appropriate acetabular implant, attach the shell to the cup positioner/impactor and insert it into the acetabulum.

Rotate the X-bar shaft so that it is in line with the liner removal slot. For the three hole cup this positions the three holes in the superior direction.

Position the X-bar so that the vertical bar is perpendicular to the long axis of the body and the appropriate crossbar (left or right) aligns with the long axis of the body.

Firmly tap the inserter with a mallet until the cup is fully seated.

Gently toggle the impactor handle to assess the stability and contact of the shell.

Remove the X-bar, then disengage the impactor handle and look through the impactor hole to judge the distance between the medial wall and the shell.

If the cup is firmly seated, there should be no gap between the shell and the medial wall and no apparent movement in the component.

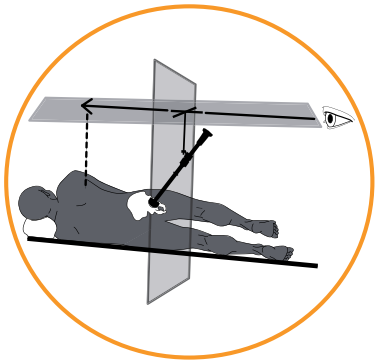
Specific to shells for R3° acetabular ceramic liners: The position of the acetabular shell is critical to provide the maximum longevity of the implant. The surgeon should use the suggested position values as a guideline while making every effort possible to avoid rim contact between the shell and stem. Proper range of motion is critical for implant longevity. If any repositioning of the shell is required, it should only be performed using the

Surgical tips:

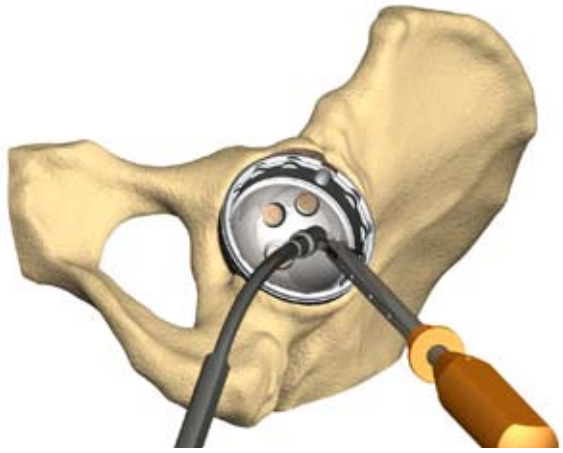
- The change in pitch that occurs as the shell is seated against the medial wall is often audible. A depth gauge can be inserted through the screw holes and apex hole to determine the adequacy of shell seating.
- The use of the slap hammer may be helpful in extracting the shell for repositioning.

Instrument tips:

- The plastic tip on the cup impactor is removable for cleaning.
- The X-bar is to be used as a guide. For poly it is suggested to reference 45° of abduction and 20° of anterversion. For ceramic it is suggested to reference 45° of abduction and 15° of anterversion



shell positioner. Any use of a punch, osteotome or other instrument on the shell's rim could result in damage to the taper section and compromise the integrity of the shell and ceramic liner mating and lead to liner fracture. It is important to protect the shell's rim and inner taper from any damage during implantation.



Screw fixation is simple, fast and the most common method of assuring additional fixation. Acetabular screws work in compression, which allows the shell to fully seat in the acetabular cavity.

For screw fixation, each screw hole must be predrilled. Using the variable angle drill guide, adjust the angle of the tip to align with the selected screw hole and press firmly in the shell. After drilling the hole, use the depth gauge to verify appropriate screw length(s).

Use the screw forceps to hold the screw. Attach the ball-joint or flexible screwdriver shaft to the end of the screw. Then introduce the screw into the hole and screw it into place using the ratcheting screwdriver handle. Make sure the screw is fully seated within the screw hole so that it will not impinge on the acetabular shell/liner.

Surgical tip:

- Screws have been shown to be a reliable method of assuring fixation; however, it is important to avoid neurovascular complications by proper screw placement, avoiding the anterior/superior or anterior/inferior quadrants.

Acetabular Liner insertion

A trial reduction should be performed with the final shell and broach in place to appropriately assess head length, stem offset, liner style and position. With XLPE liners, use of 'skirted' modular heads should be avoided when possible to maximize range of motion.

Before inserting the R3° acetabular liner, lavage any unused holes and insert the hole covers. Using the angled hole cover inserter, place screw hole covers over any remaining screw holes and then impact with the peg impactor. Cover the apex hole with the threaded hole cover. Using the straight screwdriver, screw in the hole cover until it stops and is flush with the inner diameter of the shell.

For XLPE liner insertion, screw the appropriate sized liner impactor head on the end of the cup impactor handle and ensure that the tabs on the liner are aligned with the indentions in the shell. Impact firmly with the mallet until the liner is fully seated.

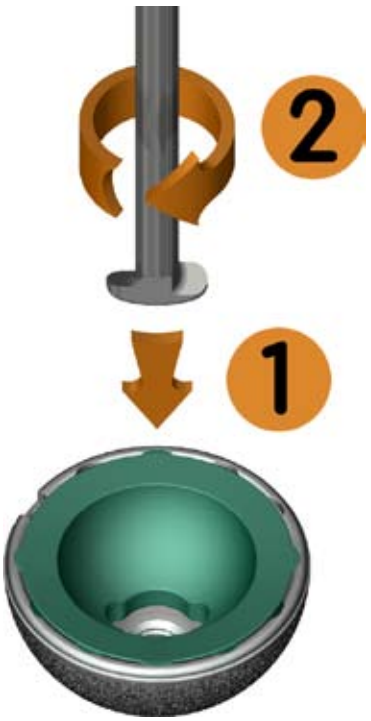
Inspect the liner/shell interface for proper seating. The liner should sit flush with the face of the shell. Insert hard bearings only after ensuring the inner taper of the shell is clean and dry.

Surgical tips:

- Running a finger around the circumference of the shell and a visual check will help determine if the liner is flush with the shell face.
- The XLPE liner requires an impaction force between 60 and 120 pounds, increasing with the diameter of the shell.
- The XLPE liners can be removed and repositioned once without compromising the locking mechanism of the liner. To remove R3 liners, insert the liner removal tool fully into the removal slot and pry or impact the liner loose.

Instrument tips:

- The liner trials are designed with flexible locking tabs around the periphery that is a quick-snap design. The trial liners are removed with the trial liner removal tool via the removal slot at the apex of the trial liner and a clockwise twist of the removal tool.



R3° Ceramic Insertion
R3 ceramic liners come pre-assembled with a disposable single-use hard bearing alignment guide. The liner/alignment guide assembly is then introduced by hand and sits flush on the face of the shell. The liner must be checked for proper orientation. Verification of proper liner seating in the shell should be confirmed by both a visual check to see that the insertion ring is sitting on the shell face and a manual check with the fingers to feel that the ring does not rock on the face of the shell. **Do not impact the liner if it is not oriented properly, as this can damage the ceramic liner.**

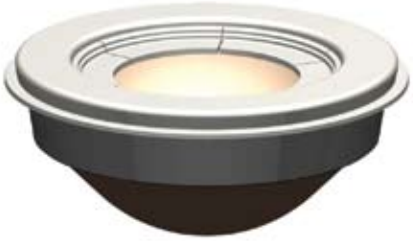
In the event that the preassembled hard bearing alignment guide is disengaged from the liner, the alignment guide should be reassembled to the liner before implantation. This is accomplished by taking the disposable alignment guide and placing it upside down on the back table. The liner can then be placed upside down on the alignment guide such that the peripheral rim is sitting on the alignment guide. Simply push the liner onto the guide until the insertion ring locks snugly on the liner. The assembly is ready for placement in the shell.

Once orientation has been confirmed, impact the liner into place using the appropriate sized liner impactor head placed on the shell positioner/impactor. Once impacted, the alignment guide will disengage onto the shell positioner/impactor and should be removed at that time.*

*** Cautionary statement**
Be sure to remove the disposable hard bearing alignment guide after liner insertion. It is not intended for implantation and should not be re-used or re-sterilized.

Surgical tip:

- It may prove helpful to rotate the liner/alignment guide slightly to ensure soft tissues and osteophytes are clear.



Surgical tips:

- Should an adjustment of an R3 ceramic liner be necessary after initial impaction, a new R3 ceramic insert must be used.
- The ceramic liner can be removed by placing the liner removal tool in the removal slot and prying or impacting if necessary the liner loose.

Acetabular Liner insertion *(continued)*

Use extreme care in handling and storage of ceramic implant components. Damage to components may induce internal stresses that are not obvious to the observer, and it may lead to premature failure of the component. Before use of ceramic implants, carefully examine each component for indications 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.

The ceramic liner and ceramic head should not be implanted if the liner or head is damaged (if damaged as a result of the shipping process, if dropped on the floor or if scratched by an instrument) or if the stem taper is damaged, as this can significantly affect the structural integrity of the components. Replace the ceramic liner if the liner is chipped, cracked or otherwise damaged during the implant procedure or postoperative timeframe.

Position the Smith & Nephew femoral head on the taper and initially seat by hand. Then place the head impactor on the head and tap with a mallet to seat the head on the taper. Only Smith & Nephew ceramic femoral heads can be used with the R3® ceramic acetabular liners. Use 32mm heads only with 32mm liners, and 36mm heads only with 36mm liners. A sizing mismatch may result in premature implant failure. Do not mix the ceramic liner or ceramic head with any other manufacturer's acetabular shell or stem, respectively. Ceramic femoral head use is limited to the 12/14 taper of the Smith & Nephew commercially available SYNERGY®, SPECTRON® EF or ANTHOLOGY® stems all available in standard and high offset versions.

Once the ceramic liner has been impacted into its mating shell, it should not be reassembled to the shell; however, the R3 locking mechanism allows the user to assemble a new R3 ceramic liner or new R3 poly liner to a previously assembled R3 acetabular shell intraoperatively, or to assemble an R3 poly liner to an existing R3 acetabular shell during a revision surgery.

Do not reassemble and disassemble the ceramic head and metal femoral stem because the locking mechanism may become damaged. Once the head is impacted, the ridges machined into the metal stem taper deform. If, for any reason, the ceramic femoral head is removed, the metal stem taper cannot be reused with a ceramic component.

In this case the revision should be made with either a CoCr or OXINIUM® head and a corresponding polyethylene liner placed in an R3® acetabular shell.

Physician should make appropriate postoperative directions and warnings to patients regarding their care. Weight-bearing status should be individualized with the non- or partial weight bearing period determined.

Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip such as sitting in low chairs, crossing legs, low bending at waist, sharp twisting hip motion, etc.

Adequate support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, clothing, or similar activities, precautions should be taken to avoid placing excessive load on the operative leg.

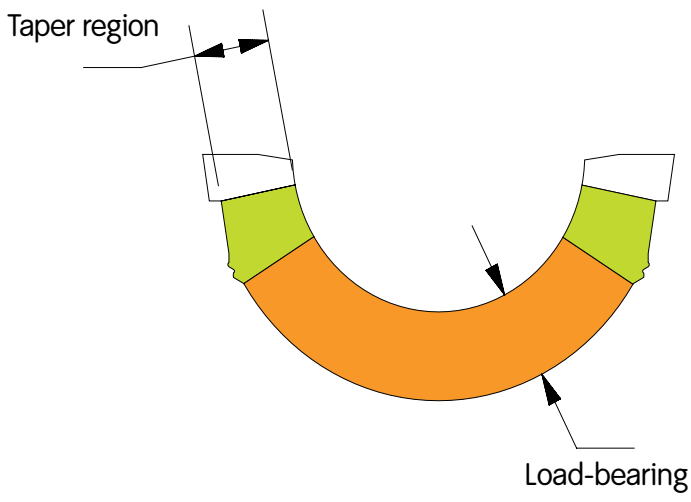
Periodic X-Rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. Patient reports of squeaking or clicking should be carefully evaluated as they may indicate position changes in the components compromising the durability of the implants.

Shell and liner offerings

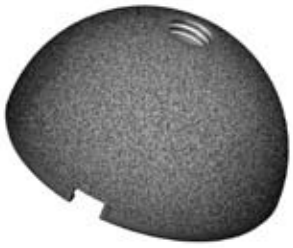
	XLPE				Ceramic	
cups	22	28	32	36	32	36
40	●					
42	●					
44	●					
46		●				
48		●	●		●	
50		●	●		●	
52		●	●	●		●
54		●	●	●		●
56		●	●	●		●
58		●	●	●		●
60		●	●	●		●
62			●	●		●
64				●		●
66/68				●		●

Poly thickness chart

Shell OD	Poly OD	Poly Thickness Taper Region mm	Poly Thickness Load Bearing Region mm
40	22	5.5	6.1
42	22	6.5	7.1
44	22	7.5	8.1
46	28	5.4	6.1
48	28	6.4	7.1
48	32	4.3	5.1
50	28	7.3	8.1
50	32	5.3	6.1
52	28	8.3	9.1
52	32	6.3	7.1
52	36	4.3	5.1
54	28	9.3	10.1
54	32	7.3	8.1
54	36	5.3	6.1
56	28	10.3	11.1
56	32	8.3	9.1
56	36	6.3	7.1
58	28	11.3	12.1
58	32	9.3	10.1
58	36	7.3	8.1
60	28	12.3	13.1
60	32	10.3	11.1
60	36	8.3	9.1
62	32	11.3	12.1
62	36	9.3	10.1
64	36	10.3	11.1
66–68	36	11.3	12.1



R3° NO HOLE Acetabular Shells



Standard size shells

Cat. no.	ODmm
7133-1846	46
7133-1848	48
7133-1850	50
7133-1852	52
7133-1854	54
7133-1856	56
7133-1858	58
7133-1860	60
7133-1862	62
7133-1864	64

Small size shells

Cat. no.	ODmm
7133-1840	40
7133-1842	42
7133-1844	44

Large shell sizes

Cat. No.	ODmm
7133-1866	66
7133-1868	68

R3 THREE HOLE Acetabular Shells

Standard size shells

Cat. no.	ODmm
7133-5546	46
7133-5548	48
7133-5550	50
7133-5552	52
7133-5554	54
7133-5556	56
7133-5558	58
7133-5560	60
7133-5562	62
7133-5564	64

Small size shells

Cat. no.	ODmm
7133-5540	40
7133-5542	42
7133-5544	44

Large shell sizes

Cat. No.	ODmm
7133-5566	66
7133-5568	68

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° XLPE Acetabular Liners

ID	OD	0° XLPE Liner Cat. no.	20° XLPE Liner Cat. no.	0° +4 XLPE Liner Cat. no.	20°+4 XLPE Liner Cat. no.
22	40	7133-4840	7133-4940	7133-5840	7133-7140
22	42	7133-4842	7133-4942	7133-5842	7133-7142
22	44	7133-4844	7133-4944	7133-5844	7133-7144
28	46	7133-7546	7133-4946	7133-5946	7133-7746
28	48	7133-7548	7133-4948	7133-5948	7133-7748
28	50	7133-7550	7133-4950	7133-5950	7133-7750
28	52	7133-7552	7133-4952	7133-5952	7133-7752
28	54	7133-7554	7133-4954	7133-5954	7133-7754
28	56	7133-7556	7133-4956	7133-5956	7133-7756
28	58	7133-7558	7133-4958	7133-5958	7133-7758
28	60	7133-7560	7133-4960	7133-5960	7133-7760
32	48	7133-9548	7133-7648	7133-6648	7133-7948
32	50	7133-9550	7133-7650	7133-6650	7133-7950
32	52	7133-9552	7133-7652	7133-6652	7133-7952
32	54	7133-9554	7133-7654	7133-6654	7133-7954
32	56	7133-9556	7133-7656	7133-6656	7133-7956
32	58	7133-9558	7133-7658	7133-6658	7133-7958
32	60	7133-9560	7133-7660	7133-6660	7133-7960
32	62	7133-9562	7133-7662	7133-6662	7133-7962
36	52	7133-2752	7133-5752	7133-6952	7133-8552
36	54	7133-2754	7133-5754	7133-6954	7133-8554
36	56	7133-2756	7133-5756	7133-6956	7133-8556
36	58	7133-2758	7133-5758	7133-6958	7133-8558
36	60	7133-2760	7133-5760	7133-6960	7133-8560
36	62	7133-2762	7133-5762	7133-6962	7133-8562
36	64	7133-2764	7133-5764	7133-6964	7133-8564
36	66/68	7133-2766	7133-5766	7133-6966	7133-8566

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° US Biolox® Forte Ceramic Liners*

ID	OD	Ceramic liner cat. no.
32	48	7133-8948
32	50	7133-8950
36	52	7133-8952
36	54	7133-8954
36	56	7133-8956
36	58	7133-8958
36	60	7133-8960
36	62	7133-8962
36	64	7133-8964
36	66/68	7133-8966

*For use with Alumina Ceramic Heads Only

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° Trial Shells

Standard size trial shells

Cat. no.	ODmm
7136-0745	45
7136-0746	46
7136-0747	47
7136-0748	48
7136-0749	49
7136-0750	50
7136-0751	51
7136-0752	52
7136-0753	53
7136-0754	54
7136-0755	55
7136-0756	56
7136-0757	57
7136-0758	58
7136-0759	59
7136-0760	60
7136-0761	61
7136-0762	62
7136-0763	63
7136-0764	64

Small size trial shells

Cat. no.	ODmm
7136-0739	39
7136-0740	40
7136-0741	41
7136-0742	42
7136-0743	43
7136-0744	44

Large size trial shells

Cat. no.	ODmm
7136-0765	65
7136-0766	66
7136-0767	67
7136-0768	68

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° Poly Trial Liners

ID	OD	0° XLPE Trial Liner Cat. no.	20° XLPE Trial Liner Cat. no.	0° +4 XLPE Trial Liner Cat. no.	20°+4 XLPE Trial Liner Cat. no.
22	40	7136-0540	7136-5340	7136-6140	7136-8640
22	42	7136-0542	7136-5342	7136-6142	7136-8642
22	44	7136-0544	7136-5344	7136-6144	7136-8644
28*	46	7136-9779	7136-9805	7136-9831	7136-9859
28*	48	7136-9781	7136-9806	7136-9832	7136-9861
28*	50	7136-9782	7136-9807	7136-9833	7136-9862
28*	52	7136-9783	7136-9808	7136-9834	7136-9863
28*	54	7136-9784	7136-9809	7136-9835	7136-9864
28*	56	7136-9785	7136-9811	7136-9836	7136-9865
28*	58	7136-9786	7136-9812	7136-9837	7136-9866
28*	60	7136-9787	7136-9813	7136-9838	7136-9867
32*	48	7136-9788	7136-9814	7136-9839	7136-9868
32*	50	7136-9789	7136-9814	7136-9841	7136-9869
32*	52	7136-9791	7136-9816	7136-9842	7136-9871
32*	54	7136-9792	7136-9817	7136-9843	7136-9872
32*	56	7136-9793	7136-9818	7136-9844	7136-9873
32*	58	7136-9794	7136-9819	7136-9845	7136-9874
32*	60	7136-9795	7136-9821	7136-9847	7136-9875
32*	62	7136-9796	7136-9822	7136-9848	7136-9876
36*	52	7136-9797	7136-9823	7136-9851	7136-9877
36*	54	7136-9798	7136-9824	7136-9852	7136-9878
36*	56	7136-9799	7136-9825	7136-9853	7136-9879
36*	58	7136-9801	7136-9826	7136-9855	7136-9881
36*	60	7136-9802	7136-9827	7136-9856	7136-9882
36*	62	7136-9803	7136-9828	7136-9857	7136-9883
36*	64	7136-9804	7136-9829	7136-9858	7136-9884
36	66/68	7136-5266	7136-7966	7136-8566	7136-9166

*Sterile disposable single-use only trials

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° Ceramic Trial Liners*

ID	OD	Ceramic Trial Liner Cat. No.
32*	48	7136-9769
32*	50	7136-9771
36*	52	7136-9772
36*	54	7136-9773
36*	56	7136-9774
36*	58	7136-9775
36*	60	7136-9776
36*	62	7136-9777
36*	64	7136-9778
36	66/68	7136-9766

*Sterile disposable single-use only trials

R3 Liner Impactor Heads

Cat. no.	Size mm
7136-8122	22
7136-8128	28
7136-8132	32
7136-8136	36
7136-3842	38-42
7136-4448	44-48
7136-4449	50-54

R3 MIS Instruments

Cat. no.	Decsription
7136-8569	Offset Shell Impactor
7136-6052	Offset X-Bar
7136-3077	Offset Impactor Tip
7136-4073	Offset Reamer Handle

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

Catalog *(continued)*

R3° Straight Shell Impactor
Cat. no. 7136-4450

R3 Impactor Replacement Tip
Cat. no. 7136-8570

R3 Depth Gauge
Cat. no. 7136-4451

X-Bar
Cat. no. MT-2201

Screw Forceps
Cat. no. 7136-2298

Ball Joint Screwdriver
Cat. no. 7136-2295

R3 Variable Angle Drill Guide
Cat. no. 7136-4477

Reamer Handle
Cat. no. 7136-2279

Flexible Screw Drills

Cat. no.	**Length mm**
7136-2915	15
7136-2925	25
7136-2935	35
7136-2950	50

Captured Flexible Screwdriver Shaft
Cat. no. 7136-2291

Captured U-Joint Screwdriver Shaft
Cat. no. 7136-2292

R3 Surgical Templates
(not shown)
Cat. no. 7138-0666

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° Trial Liner Removal Tool
Cat. no. 7136-4455

R3 Liner Removal Tool
Cat. no. 7136-6021

Hole Cover Impactor
Cat. no. 73-2117

Trial Shell Handle
Cat. no. 7136-2297

Flexible Screwdriver
Cat. no. 7136-2290

Ratchet Handle
Cat. no. 7136-2294

Small Slap Hammer
Cat. no. 7136-7541

REFLECTION° Mallet
Cat. no. 7136-2106

Hole Cover Inserter
Cat. no. 73-2133

Straight Screwdriver Shaft
Cat. no. 7136-2293

Power Adaptors (not shown)
Cat. no. 7136-2781
7136-2782
7136-2783

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

Reamer Domes

Standard size

Cat. no.	Size mm
7136-2742	42
7136-2743	43
7136-2744	44
7136-2745	45
7136-2746	46
7136-2747	47
7136-2748	48
7136-2749	49
7136-2750	50
7136-2751	51
7136-2752	52
7136-2753	53
7136-2754	54
7136-2755	55
7136-2756	56
7136-2757	57
7136-2758	58
7136-2759	59
7136-2760	60
7136-2761	61
7136-2762	62
7136-2763	63
7136-2764	64

Small size

Cat. no.	Size mm
7136-2738	38
7136-2739	39
7136-2740	40
7136-2741	41

Large size

Cat. no.	Size mm
7136-2765	65
7136-2766	66
7136-2767	67
7136-2768	68
7136-2769	69
7136-2770	70
7136-2771	71
7136-2772	72
7136-2773	73
7136-2774	74
7136-2775	75
7136-2776	76

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3°/REFLECTION° Threaded Hole Cover **Cat. no.** 7133-6500	
Spherical Head Screws **Cat. no.** / **Length mm** 7133-2515 / 15 7133-2520 / 20 7133-2525 / 25 7133-2530 / 30 7133-2535 / 35 7133-2540 / 40 7133-2545 / 45 7133-2550 / 50 7133-2555 / 55 7133-2560 / 60 7133-2565 / 65 7133-2570 / 70	
R3° Screw Hole Cover **Cat. no.** 7136-9894	
Small Outer Case **Cat. no.** 7112-9401	
Lid for Outer Case **Cat. no.** 7112-9402	
R3 Trial Shell Tray **Cat. no.** 7136-2213	
R3 Jumbo Trial Liner Tray **Cat. no.** 7136-1076	
R3 Main Instrument Tray **Cat. no.** 7136-2211	
R3 MIS Instrument Tray **Cat. no.** 7136-2219	
R3 Primary Reamer Dome Tray **Cat. no.** 7136-2212	
R3 CDH Trial Tray **Cat. no.** 7136-1077	
R3 Disposable Trial Tote **Cat. no.** 7136-0656	

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

R3° US Biolox® Forte 12/14 Femoral Heads

Cat. no.	Size mm
7133-0320	32 +0
7133-0324	32 +4
7133-0328	32 +8
7133-2084	36 +0
7133-2085	36 +4
7133-2086	36 +8

All implants are provided sterile and are for single use only. Unless otherwise noted, all instruments are provided non-sterile and are intended for re-use and resterilization. Refer to the instructions for cleaning and sterilizing reusable surgical instruments that are provided with Smith & Nephew Instrument sets.

Important Medical Information
Warnings and Precautions

Sterility Status

Component Description	Sterility Status
REFLECTION/R3 Acetabular Shells/Cups	Sterile
REFLECTION/R3 Ceramic Acetabular Liners/Inserts	Sterile
REFLECTION/R3 Ceramic Femoral Heads	Sterile
REFLECTION/R3 Ancillary Implant Components (i.e., Screws, Hole Covers, etc.)	Sterile
R3 Disposable Trial Liners	Sterile
REFLECTION/R3 Manual Instrumentation	Non-Sterile

DEVICE DESCRIPTION
The REFLECTION/R3 Ceramic Acetabular System is a ceramic-on-ceramic hip prosthesis composed of modular components that include a REFLECTION or R3 porous coated acetabular shell, alumina ceramic acetabular shell liner, and an alumina ceramic femoral head. All implantable devices are for single use.

REFLECTION Acetabular Shell/Cup
REFLECTION acetabular shells are manufactured from Ti-6Al-4V (ASTM F 1472 and ISO 5832/3). There are eleven sizes of acetabular shells available, ranging from 46 mm through 66 mm outer diameter in 2 mm increments. Each shell features an apex hole to accept the cup positioner / impactor instrument. Shells have five additional holes arranged about the apex hole. These holes are for optional, adjunctive screw fixation to the superior acetabulum. Universal cancellous screws in a 6.5 mm diameter are available in lengths of 15 to 50 mm in 5 mm increments. Screws are self-tapping, but the screw holes in the acetabulum need to be pre-drilled to the minor diameter of the screw. Hole covers are available to cover the shell holes if desired. Screws and hole covers are manufactured from Ti-6Al-4V ELI (ASTM F 136). The shell's internal geometry is a Morse taper that locks the ceramic liner when inserted. The outer shell geometry is hemispherical and ROUGHCOAT® porous coated with commercially pure titanium (ASTM F 67 and ISO 5832/2). The porous coating encompasses the entire outer surface of the shell except for a small one millimeter strip around the edge of the rim. The shell has a flat rim with no build-up or recessed features until the rim meets the inner taper. At that location, the rim features an approximately 1 mm bevel around the circumference. The rim surface has six small depressions equally spaced around the circumference. These shallow depressions allow the liner extraction tool prongs to be used for ceramic liner removal when necessary.

R3 Acetabular Shell/Cup
The R3 acetabular shells are only compatible with R3 acetabular liners. The R3 acetabular shells are manufactured from Ti-6Al-4V (ASTM F 1472 and ISO 5832/3). There are eleven sizes of acetabular shells available, ranging from 48 mm through 68 mm outer diameter in 2 mm increments. Each shell features an apex hole to accept the cup positioner / impactor instrument. Shells have either no screw holes or three screw holes arranged about the apex hole. These holes are for optional, adjunctive screw fixation to the superior acetabulum with Spherical Head Screws, which are available in lengths of 15, 20, 25, 30, 35, 40, 45, 50, 60, and 70mm. Screws are self-tapping, but the screw holes in the acetabulum need to be pre-drilled to the minor diameter of the screw. Hole covers are available to cover the shell holes if desired. Screws and hole covers are manufactured from Ti-6Al-4V ELI (ASTM F 136). The shell's internal geometry is a Morse taper that locks the ceramic liner when inserted. The outer shell geometry is hemispherical and STIKTITE® porous coated with commercially pure titanium (ASTM F 67 and ISO 5832/2).

REFLECTION Acetabular Liner/Insert
The alumina ceramic acetabular liners are manufactured from BIOLOX®forte Aluminum Oxide (ASTM F 603 and ISO 6474) and are available in five sizes. The shell's outer diameter size and the corresponding femoral head diameter limit the choice of acetabular liner used with an acetabular shell. Three, 28 mm internal diameter liners are available for use with the acetabular shells. One size liner(28/37G)fits 46-48 mm O.D. shells, one size (28/41G) liner fits 50-54 mm O.D. shells, and one size (28/44G) liner fits 56-66 mm O.D. shells. Two, 32 mm internal diameter liners are available for use with the acetabular shells. One size liner (32/41G) fits 50-54 mm O.D. shells, and one size (32/44G) liner fits the 56-66 mm O.D. shells.

R3 Acetabular Liner/Insert
The alumina ceramic acetabular liners are manufactured from BIOLOX® forte Aluminum Oxide (ASTM F 603 and ISO 6474), and feature a titanium band (ASTM F1472 and ISO 5832/3). They are available in ten sizes. The following table shows which R3 Ceramic Liner mates with which R3 acetabular shell and alumina ceramic head size.

R3 Ceramic Liners Compatibility		
Liner Catalog #	**OD/shell size**	**Head size**
71338948	48mm	32mm
71338950	50mm	32mm
71338952	52mm	36mm
71338954	54mm	36mm
71338956	56mm	36mm
71338958	58mm	36mm
71338960	60mm	36mm
71338962	62mm	36mm
71338964	64mm	36mm
71338966	66/68mm	36mm

Femoral Head
The alumina ceramic ball heads are manufactured from BIOLOX forte Aluminum Oxide (ASTM F 603 and ISO 6474). The alumina ceramic ball heads are available in nine sizes: three heads with an outer diameter of 28 mm, three heads with an outer diameter of 32 mm, and three heads with an outer diameter of 36mm. Each diameter head size has three different neck lengths, short (+0), medium (+4), and long (+8) for proper anatomic and musculature fit. Externally, all ball heads are highly polished. All ball heads have an internal bore taper angle of 5° 46' for high conformity with the 12/14 cone taper of the femoral stems. The alumina ceramic heads lock onto the machined taper and do not rotate on the stem. The 28mm and 32mm ball heads are used with REFLECTION Ceramic Acetabular Liners. The 32mm and 36mm ball heads are used with the R3 Ceramic Acetabular Liners.

The REFLECTION/R3 Ceramic Acetabular System is suitable for use with the 12/14 taper of Smith & Nephew's legally marketed titanium alloy cementless SYNERGY® femoral stems, cobalt chromium alloy cemented SPECTRON® EF stems, or titanium alloy cementless ANTHOLOGY® femoral stems, all available in standard and High Offset versions.

INDICATIONS FOR USE
The REFLECTION/R3 Ceramic Acetabular System is indicated for use in patients requiring primary total hip arthroplasty due to non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, avascular necrosis, or traumatic arthritis.

CONTRAINDICATIONS
The REFLECTION/R3 Ceramic Acetabular System is contraindicated in individuals exhibiting any of the following:
- Insufficient quantity or quality of bone support; metabolic bone disease; osteoporosis
- Neurological or muscular conditions that would place extreme load or instability upon the hip joint
- Active joint infections or chronic systemic infection
- Obese patients where obesity is defined as three times normal body weight
- Skeletal immaturity

WARNINGS and PRECAUTIONS
Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent early failure/fracture of the components. The surgeon should be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery. Certain insertion techniques may be different than those known for conventional hip systems, and are specifically designed to avoid potential implant failures.

PREOPERATIVE
- The patient should be warned of the brittle nature of the ceramic components and the possibility of failure of the device leading to additional surgery in the future. The patient should be warned that the implant can break or become damaged as a result of strenuous activity or trauma including extreme activity or heavy labor for occupation or recreation.
- Do not implant in pregnant patients as the extra weight and exposure to radiation may be harmful to the implant and baby, respectively.
- Do not substitute another manufacturer's device for any of the REFLECTION/R3 Ceramic Acetabular System components because design, material, or tolerance differences may lead to premature device and/or functional failure. Components have been specifically designed to work together. (see product literature for list of appropriate components).
- Use extreme caution in storage and handling of ceramic components during assembly because of the brittle nature of ceramic material. Cutting, bending, or scratching the surface or taper area of components can alter the mechanical characteristics of the implant system leading to failure. Do not allow the porous coating surfaces to encounter cloth or fiber-releasing material as cloth fibers may interfere with implant stability leading to early failure of the implants.
- 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.
- Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Examine instruments for wear or damage prior to surgery. Instruments that have experienced extensive use or excessive force are susceptible to fracture and must not be used.

- Do not resterilize REFLECTION/R3 Ceramic Acetabular System Implants (i.e. alumina ceramic heads, liners or porous coated metal implants) as they require special cleaning instructions and are to be returned to the manufacturer (see Sterilization section below).
- 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.

INTRAOPERATIVE

- Implants are for single use only. Never reuse an implant component as internal stresses that are not visible may lead to early failure of these components. If broken ceramic material is encountered intraoperatively or postoperatively, remove all loose identifiable fragments, and thoroughly irrigate and suction the operative site.
- For REFLECTION Ceramic Acetabular Cups: **Replace both the ceramic insert and the metal acetabular shell (refer to specific procedure in Surgical Technique manual) 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. Return the broken fragment(s) to Smith & Nephew for evaluation.
- For R3 Ceramic Acetabular Cups: **Replace the ceramic insert (refer to specific procedure in Surgical Technique manual) if the insert is chipped, cracked, or otherwise damaged during the implant procedure or postoperative timeframe.** Once the ceramic insert has been impacted into its mating shell, it should not be reassembled to the shell as early failure may occur; however, the R3 locking mechanism allows the user to assemble a new R3 Ceramic Liner to a previously assembled R3 acetabular shell intraoperatively, or to assemble a new R3 Poly Liner to a previously assembled R3 Acetabular Shell either intraoperatively or during a revision surgery. Return the broken fragment(s) to Smith & Nephew for evaluation.
- The ceramic liner and ceramic head should not be implanted if the liner or head is damaged (e.g., if damaged as a result of the shipping process, if dropped on the floor, or if scratched by an instrument) or if cone of the stem is damaged as this can significantly affect the structural integrity of the components.
- Do not reassemble and disassemble the ceramic head and metal femoral stem because the locking joint and taper joint may become damaged. Once the head is impacted, the ridges machined into the metal stem taper deform. If, for any reason, the ceramic femoral head is removed, the metal stem taper cannot be reused with a ceramic component.
- Ensure appropriate type and size components selected correspond with anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery. Generally, the largest cross-section component that will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, subluxation, dislocation, bending or fracture of the component and/or bone.
- Universal Cancellous Bone Screws are compatible with the REFLECTION acetabular shells. Spherical Head Screws are compatible with the R3 acetabular shells. Ensure appropriate selection of the length and location of bone screws if adjunctive fixation of the acetabular shell is to be used. Do not place a screw in the center (apex) hole of the acetabular shell. Bone screws and hole covers must be completely seated in the shell holes to allow proper locking of the ceramic liner. Do not use pegs in the shell holes.
- Do not cut, bend or scratch the surface or taper area of components as this can significantly alter the mechanical characteristics of the implant system causing failure under load.
- Do not use a metal or zirconia head with the REFLECTION/R3 Ceramic Acetabular System because this may accelerate bearing wear and lead to early failure of the device.
- Clean surgical debris (including bone cement) and dry all shell taper and stem taper surfaces prior to seating and impacting the ceramic components. Do not allow the porous surfaces to encounter cloth or fiber-releasing material. Debris may inhibit the component locking mechanism leading to early failure of the implants.
- 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.
- Always ensure proper alignment and seating of the trial insert before seating the actual insert. Subtle mal-alignment may not be immediately obvious and can result in liner failures (chipping/cracking/splitting) during impacting. Range of motion should be thoroughly checked for impingement or instability with the trial insert. If ROM is unsatisfactory, component repositioning should be performed unless attributable to obvious causes that can be corrected (e.g., presence of osteophytes, bony protrusions, or other movement limiting features).
- Seat the insert gently by hand into the shell before impacting (with plastic impactor head placed on the shell positioner/impactor) to prevent chipping or damage. **Repeated impaction of the liner in the shell when the initial attempt at seating the liner is unsuccessful is not recommended and may lead to early failure.**
- Ensure correct selection of the head neck length, cup and stem. Increased neck length and varus positioning will increase stresses that must be borne by the stem. Suggested seating of acetabular shell is a 45° inclination with 15° anteversion for proper positioning to decrease the chance for dislocation.
- For REFLECTION Ceramic Acetabular Cups: **If the ceramic liner and shell are not fully seated or are aligned incorrectly after final impaction, it will be necessary to revise the shell and liner with new components.**
- For R3 Ceramic Acetabular Cups: **If the ceramic liner and shell are not fully seated or are aligned incorrectly after final impaction, it will be necessary to revise the liner with a new component; however, the R3 acetabular shell can be reassembled to a new R3 Ceramic Liner or R3 Poly Liner.**

POSTOPERATIVE

- Strict adherence to the postoperative weight bearing and activity protocol is needed to protect the implant from failure until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated with premature failure.
- Extreme care in patient handling (moving patient, placing on bedpans, changing clothes, etc.) immediately after surgery is necessary. Adequate support should be provided to the operative leg when moving the patient to avoid placing excessive load on the operative leg.
- The patient should be advised to report any pain, decrease in range of motion, swelling, fever, squeaking or clicking noises and unusual incidences. Patient reports of squeaking or clicking should be carefully evaluated as they may indicate position changes in the components compromising the durability of the implants.
- The patient should be cautioned to monitor activities and protect the replaced joint from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment. In particular, the patient should be warned against unassisted activity, particular use of toilet facilities and other activities requiring excessive motion of the hip.
- Periodic x-rays are recommended to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. Should there be evidence of loosening, bending and/or cracking of components or bone loss; patients are to be closely observed with the possibilities of further deterioration evaluated, and the benefits of early revision considered. If the ceramic head must be revised for any reason and the hip stem is firmly fixed, the revision should be made with a CoCr head and corresponding polyethylene liner and metal shell.
- REFLECTION Acetabular Cups: If the REFLECTION Ceramic Liner requires revision, both the Ceramic Liner and the Reflection Acetabular Shell must be replaced. The existing REFLECTION Acetabular Shell cannot be reassembled to any liner.
- R3 Acetabular Cups: If the R3 Ceramic Liner requires revision, and the R3 Acetabular Shell is well fixed, a new R3 Poly Liner may be assembled to the existing R3 Acetabular Shell.

SPECIFIC PRODUCT WARNINGS/PRECAUTIONS

The REFLECTION Ceramic Acetabular System clinical study investigated the following cohorts: non-inflammatory arthritis (RNIA); inflammatory arthritis (RIA); revision of failed implant (RR). Subsequent to completion of enrollment in the RNIA cohort, additional non-inflammatory arthritis patients were followed in the Continued Access (CAC) cohort. The investigational REFLECTION® Ceramic Acetabular System (C/C) is compared to the REFLECTION® alumina ceramic-on-polyethylene (C/P) control. Please refer to the "SUMMARY OF CLINICAL TESTING" for more clinical study details. The information below is provided for the REFLECTION interim 5+ Year time point.

Heterotopic Ossification at Interim 5+ Year Time Point

At the interim 5+ year data time point, the RNIA investigational (C/C) cohort yielded a higher incidence of heterotopic ossification (HO) than the C/P control cohort. This occurred for all grades of heterotopic ossification.

Incidence of Hips with HO – RNIA Cohort at 5+ Years		
HO[1]	**C/C (174 hips)**	**C/P (142 hips)[2]**
Grade I	53 (30.5%)	36 (25.3%)
Grade II	14 (8.0%)	9 (6.3%)
Grade III	10 (5.7%)	6 (4.2%)
Grade IV	2 (1.1%)	0 (0%)
Total	79 (45.4%)	51 (35.9%)

1 Brooker Classification
2 One previously enrolled RNIA C/P patient had the contralateral hip implanted; therefore, the total number of RNIA C/P hips at the interim 5+ year time point was 142.

Dislocations at Interim 5+ Year Time Point

At the interim 5+ year data time point, for all investigational C/C cohorts studied, the patients receiving the 28mm femoral head hip constructs had a higher rate of dislocation incidence (5.9%) than the patients receiving the 32mm femoral head hip constructs (1.2%) suggesting that a smaller femoral head diameter may be associated with a higher risk of dislocation.

Incidence of Dislocation by Device - All Hips at 5+ Years		
Head Size	**C/C**	**C/P**
28mm	7/118 (5.9%)	8/150 (5.3%)
32mm	3/254 (1.2%)	1/13 (7.7%)
Total	10/372 (2.7%)	9/163 (5.5%)

Note: Cohort's dislocation postoperative was RNIA (8 C/C, 8 C/P); RIA (0); RR (1 C/P); CAC (2 C/C).
Only post-operative hips were included, as they represent an event that occurred during postoperative patient use of device dislocations that occurred after a revision is excluded. Not all dislocations resulted in revisions.

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential Complications Associated with Any Total Hip Arthroplasty surgery

- excessive wear of the implant components secondary to impingement of components or damage of articular surfaces
- fracture, migration, loosening, subluxation, or dislocation of the prosthesis or any of its components; any of which may require a second surgical intervention or revision;
- intractable pain
- unintended bone fractures
- metal sensitivity reactions or other allergic/histological reactions to implant material
- vascular damage resulting in significant blood loss, or
- neurologic injury resulting in transient or permanent functional and/or sensory deficits
- leg length change/discrepancy
- deep venous thrombosis
- pulmonary or vascular embolism
- superficial or deep infection, delayed wound healing
- periarticular calcification
- myocardial infarction
- Gastrointestinal complications
- Genitourinary complications
- Decreased range of motion
- Aggravation of other joint or back conditions (due to positioning during surgery, postoperative leg length discrepancy, muscular deficiencies, etc.)
- death

Potential Complications Associated with Ceramic on Ceramic Hip Systems

Due to the materials of the device, these may include, but are not limited to, femoral head breakage, acetabular insert (liner) fracture, component dissociation dislocation and component wear debris. Other adverse events, common to other hip systems may also occur but at different frequencies.

SUMMARY OF CLINICAL TESTING

A multicenter, prospective, open-label concurrently controlled clinical trial comparing outcomes for patients randomized to either REFLECTION Ceramic Acetabular System (C/C) or the REFLECTION alumina ceramic-on-polyethylene system (C/P) as a control was conducted at 10 investigational centers by 14 investigating surgeons. The study was designed as non-inferiority trial with a 10% non-inferiority margin to evaluate the safety and effectiveness of the REFLECTION Ceramic Acetabular System (i.e., the success rate in the REFLECTION Ceramic Acetabular System group is not worse than the success rate in the active control group by more than 10%.)

Three diagnostic indications were eligible for randomized enrollment: 1) non-inflammatory arthritis (RNIA) 2) inflammatory arthritis (RIA) or 3) revision of failed implant (RR). Subsequent to completion of enrollment limit in the non-inflammatory arthritis diagnostic indication, additional subjects were enrolled in a non-randomized manner under 'Continued Access' at the same investigational centers (CAC). Device effectiveness was assessed by comparison of preoperative and postoperative changes in hip pain, function, and range of motion as measured by Harris Hip Score (HHS) tool. Pain appraisal involved the patient's current assessment of the affected hip discomfort level. Functional parameters include gait assessment of limp, support required to walk, and distance able to walk, activity assessments of ability to use stairs, put on shoes and socks, sitting, and access transportation. Range of motion measurements included flexion, abduction, adduction, and internal and external rotation movements. Device safety was assessed by analysis of all adverse events experienced by patients in each treatment group. Pre-defined criteria were compared to determine overall success between groups.

A. Study Design

Pre-defined inclusion/exclusion criteria were identified in the investigational plan. Patient randomization occurred prior to surgery, using a 1:1 randomization scheme whereby a patient (hip) was to receive either a ceramic-ceramic articulation (C/C) construct or a ceramic-polyethylene articulation (C/P) construct. Bilateral hip arthroplasty patients were randomized only once with the contralateral hip receiving the same treatment as the first hip was randomized to receive, except in one case. For each diagnostic indication group, randomization was stratified by investigational center with a fixed block size of 2. Sequentially numbered envelopes containing the randomized treatment assignment were prepared and distributed to each center. The patients and investigators were not masked to the hip system received. All x-ray films were reviewed by an independent radiologist who was not specifically advised as to treatment group prior to, or during the review. Each hip was assessed separately and followed up according to its own evaluation schedule. Patients were evaluated preoperatively to establish demographics and baseline effectiveness measurements; then intraoperatively, at discharge from the hospital, and at 3, 6, 12, and 24 months postoperatively using surrogate endpoints of pain, function, quality of life, radiographic parameters and the occurrence of adverse events to demonstrate safety and effectiveness. Patients were evaluated biennially thereafter until all patients had reached their 24 months evaluation.

1. Inclusion and Exclusion Criteria

Inclusion Criteria

Patients meeting all of the following inclusion criteria were enrolled in the study:

- Primary diagnosis of osteoarthritis, rheumatoid, or revision
- Males or females, 21-80 years old
- Able to follow-up for 2 years
- HHS ≤ 60
- Preoperative medical clearance; free or treated for cardiac, pulmonary, hematological conditions that pose excessive operative risk
- Meets no exclusion criteria

Exclusion Criteria

Patients who met one of the exclusion criteria were not eligible for enrollment in the study:

- Morbid Obesity ≥ 100 pounds over desirable body weight
- Insufficient bone from cancer, femoral osteotomy, Girdlestone, osteoporosis, metabolic disorders
- Charcot joint, muscle deficiencies, multiple joint disabilities
- Active localized or systemic infection
- Skeletal immaturity
- Psychological illness, mental illness, mental retardation, or drug, alcohol abuse
- Pregnancy
- Immunosuppressive disorder: corticosteroid use*, cytotoxic drugs, antilymphocytic serum, irradiation, AIDS, immunosuppressive therapy, auto immune diseases (except rheumatoid arthritis). * Patients using 0.1 to 80 mg/day were not excluded in this study.
- Subject participating in any other pharmaceutical, biologic, or medical device clinical investigation
- Known sensitivity to the materials in the device

2. Clinical Assessment

Clinical patient evaluations were performed preoperatively, intraoperatively, and at discharge. Evaluations were also performed postoperative at 3 months, 6 months, 12 months, and 24 months and biennially thereafter for any applicable patients. Preoperatively, patient demographics and basic medical history was collected. Patient outcomes were evaluated for the involved hip using a modified Harris Hip Score Scale* a rating scale that incorporates subsections relating to hip pain; functional gait and activities of daily living; deformity and range of motion. The Harris Hip Score scale scoring ranges from 0 (worst) to 100 (best). A modified Harris Hip Score was used, which allowed simpler calculation of range of motion results. A patient self-assessment (SF-12) general health survey was administered to collect quality of life outcome information also. Intraoperatively, information was collected that consisted of the surgical technique performed, any intraoperative or perioperative complications/adverse events which may have occurred and any other relevant implant-related information needed to characterize the performance of the device. At discharge, patients were assessed for ambulatory status and incidence of adverse events since surgery. Discharge x-rays served as the baseline radiographic assessment for later comparisons. A/P and Lateral radiographs were assessed for implant position and evidence of radiolucencies. Clinical evaluations were standard at each postoperative interval. Each postoperative visit consisted of a Harris Hip Score evaluation, radiographic assessment and SF-12 Health Survey. Any adverse event occurring since the previous visit evaluation interval was recorded. At some early intervals (3 months), collection of radiographs and SF-12 surveys were optional. Site investigators were responsible for assessing patients at all intervals. For the 24 month interval, radiographs were also independently evaluated by a radiologist.

3. Success Criteria

The primary endpoint of the clinical trial was an overall patient success outcome determination at 24 months, which included a composite of implant survivorship, Harris Hip Score, and radiographic evaluation. A successful patient at 24 months met all of the following required criteria:

- no revision of any device system component through the two years evaluation;
- a total Harris Hip Score greater than or equal to 80 (excellent to good score); and
- no evidence of unacceptable radiolucencies or position change along the cup and stem (radiographic failure) as defined by exhibiting radiolucencies of:
  a. greater than 50% of the total bone prosthesis interface; and/or
  b. greater than or equal to 2 millimeters in two or more zones; or
  c. if the patient has subsidence of the femoral stem or migration of the acetabular prosthesis of greater than 5 millimeters with associated clinical findings.

The success criteria were used to assess the overall treatment success for the study device versus control device populations. Patients (hips) were categorized as a success or non-success, and the comparison between the two treatment groups is indicative of the devices performance in the study populations.

4. Statistical Analysis

The randomized non-inflammatory arthritis cohort (RNIA) represented over 80% of the total hip replacements performed in the study; therefore, any statistical testing between device groups were only performed for this cohort at the 2-year visit. For the other two diagnostic groups, only descriptive statistics were generally provided.

The safety and effectiveness of the REFLECTION Ceramic Acetabular System was assessed by analyzing the Patient Success Criteria, which include revision status, functional/clinical evaluation, and radiographic assessments. A non-inferiority hypothesis was used to test the difference in the probability of patient's success with a 10% margin. The null hypothesis was the success outcome rate at 2 years in the control group is greater than the success rate in the study device group by at least 10%, and the alternative hypothesis is that the difference in success rates between the two groups is less than 10%. The null hypothesis will be rejected if the upper bound of the two-sided 90% confidence interval (CI) for the difference in success rates is less than 10% and conclude that the study device is non-inferior to the control. A logistic regression

* Canale, T., editor. Campbell's Operative Orthopaedics. St. Louis:Mosby, Inc.; 2003.

model and GEE model for the success outcome at 2 years were also performed to evaluate the effect of device group, body mass index, age, gender, type of hip replacement (unilateral vs bilateral), femoral stem cement use (yes vs no) and investigational site.

Additionally, the risk of ceramic-ceramic articulation was assessed by analyzing the revision rate by two years, applicable operative and postoperative adverse events (device related or otherwise); Survivorship analysis was assessed using Kaplan-Meier methodology.

Results on hip pain, function, and range of motion were also compared between the study and control groups using Wilcoxon rank sum test. The incidence of radiographic failures were compared between the two groups using Fisher's Exact Test. Fisher's Exact Test was also used to compare the percentage of patients reporting each type of adverse event between the two device groups. Multiple occurrences of the same event reported by the same patients were counted as only once. Results from SF-12 health survey at 2 years were compared using a two-sample t-test.

B. Study Population/Demographics

In total, 399 patients were implanted with 460 devices in the investigational study under the study protocol at 10 investigational sites by 14 investigating surgeons. One patient was counted twice as the patient had one of each device implanted in each of his hips. In the randomized non-inflammatory arthritis (RNIA) study cohort, there were 146 patients who received the investigational device and 130 patients who received the control device at 10 investigational sites. In the inflammatory arthritis cohort, there were 14 patients at 7 investigational sites who received the investigational device. In the revision cohort, 5 patients received the investigational device at 4 sites. All patient cohorts were evaluated in the safety analysis. Effectiveness was based on only the RNIA cohort.

For all RNIA subjects enrolled, males accounted for 114/174 (65.5%) and 84/141 (59.2%) in the study and control groups, respectively; and the mean body mass index was 28.9 and 28.1 kg/m2 in the study and control groups, respectively. The mean age at surgery as determined from a patient analysis was 50 years and 54.3 years in the study and control groups, respectively; and difference in average age between the two groups is significantly different (p-value 0.0121, Wilcoxon rank sum test). The two treatment groups were very similar demographically, and there were no statistically significant ($p< 0.05$) differences for any of the other variables. Ethnic demographic data was not collected. There was a predominance of male patients; younger patients and more bilateral patients were enrolled in the investigational group. The demographics of the randomized non-inflammatory arthritis cohort as determined from an all Hip analysis is detailed in Table 1.

Table 1, Demographics – All Hips

Description of the Study Populations							
	Non-Inflammatory RNIA		Inflammatory RIA		Revision RR		Continued Access CAC
	C-C	C-P	C-C	C-P	C-C	C-P	C-C
Number of hips/ (patients)*	**174 (146)**	**141 (130)**	**17 (14)**	**13 (10)**	**5(5)**	**7(7)**	**103 (88)**
Bilateral hips (%)	57 (33%)	23 (16%)	6 (35%)	6 (46%)	0	0	30 (29%)
Men / Women	114/60	84/57	10/7	4/9	3/2	4/3	60/43
Age, year (mean)	50	53.9	47.6	44.3	50	62.7	46.2
Age < 40	23.5%	11.5%					
40 ≤ Age ≤ 69	70.3%	74.6%					
Age > 69	6.2%	13.9%					
Height (cm)	173.9	172.7	166.1	169	174.8	170	173.1
Weight (Kg)	87.6	84.3	77.8	78.3	89.2	77.4	86.3
BMI (kg/m²)	28.8	28.1	28.5	27.4	29.4	26.9	28.7
Previous surgery on affected hip							
YES	33	23	2	0	5	7	21
NO	141	118	15	13	0	0	82
Other joint involvement:							
YES	107	83	14	10	3	4	47
NO	67	58	3	3	2	3	56
Physical activity:							
None	12	4	0	0	2	1	7
Light	107	94	13	12	3	5	66
Moderate	50	37	4	1	0	0	27
Intense	5	6	0	0	0	0	3

*one patient was counted twice because the patient had one of each device implanted in each of his hips

C. Hip/Patient Accountability

Accountability of numbers of hip and patients analyzed is shown in Table 2 below for the RNIA cohort as this is the primary study group. Note that eighteen ceramic-ceramic hips and twenty-five ceramic-poly hips were identified as either minor or major protocol deviations, and these hips are excluded from the efficacy analysis. This resulted in 156 ceramic-ceramic hips and 116 ceramic-poly hips analyzed for effectiveness in the RNIA cohort at 2 years.

Discontinued Patients

At the 2 years evaluation interval there were 86 hips, that were discontinued during the course of the study (70 hips in the RNIA, 9 hips in the RIA, 7 hips RR). Discontinued refers to hips that did not have clinical follow-up at two years due to any reason, i.e. lost to follow-up, dead, revised, not yet due for follow-up at 2 years, etc.

Table 2, Hip Procedure Follow-up Accountability – Per Protocol RNIA Cohort

Category	Preop		3-months		6-months		1-year		2-years		2+ years	
	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P
Theoretically Due[1]	156	116	156	116	155	116	154	116	150	116	150	116
Deaths *	0	0	1	0	1	0	1	0	0	1	1	0
Revisions	0	0	2	1	1	0	0	0	1	0	2	0
Expected[2]	156	116	153	115	151	115	150	115	145	114	145	114
Evaluated[3]	156	116	142	104	137	99	128	94	126	85	128	85
Actual % Follow-Up	100%	100%	92.8%	90.4%	90.7%	86.1%	85.3%	81.7%	86.9%	74.6%	88.3%	74.6%

C/C = ceramic-ceramic; C/P = ceramic-polyethylene

Note: Modified per protocol analysis excludes all major and minor deviations from the investigational plan

(C/C: 174-18 protocol deviations = 156, C/P: 141-25 protocol deviations = 116)

1 Theoretically due is the number due at each interval based on the date of surgery and date of database closure.

2 Expected is the number theoretically due minus cumulative deaths and revisions.

3 Evaluated is actual Total Harris Hip Score or Function Score obtained but the number excludes evaluations on previously revised hips.

* Deaths post-revision are not subtracted from Theoretically Due to achieve Expected. 2 patients (hips) died after revision. In C/C group, there are 7 cumulative deaths and revisions through 2 years, and thus only 5 hips are subtracted from Theoretically Due at 2 years.

At the completion of the study there had been four deaths in the RNIA investigational group and one in the control group. No other deaths occurred in any of the other cohorts or in the Continued Access cohort. Revision surgery was performed in 6/156 (3.9%) RNIA hips in the investigational and 2/116 (1.7 %) hips in the control group. One revised RNIA C/P hip was a protocol deviation that is not reflected in the per protocol accounting of Table 2. Revisions occurred in 1/17(5.9%) of hips in the RIA cohort, 0/5 (0%) of the hips in the Revision cohort, and 5/103 (4.8%) of the hips by one year in the CAC cohort. There were no revisions in the control groups of the RIA or Revision cohorts. At 24 months, 126 hips were evaluated in the RNIA investigational group and 85 hips were evaluated in the control group. Since the overall success criteria was based on a three part composite of revision status, clinical function, and radiographic results at two years, some hips may be evaluated at two years but still be missing one or more components of the three components. However, at two years, there were 122 hips in the ceramic-ceramic group and 81 hips in the ceramic-poly group with all three components necessary to evaluate success. At the time of data base closure no patients in the continued access cohort had reached the 24 month evaluation interval.

D. Study Period

The first patient was implanted in November of 1998. All patients in the randomized non-inflammatory arthritis cohort had reached their 24 month postoperative period as of the data base closure on February 24, 2003. However, the second hip replacement in 7 investigational device patients was not yet due at 2 years follow-up. With 2 year follow-up required on all patients, the total duration of this study was 4.25 years. A change to the device was made on April 17, 2001, which redesigned the accepting shell/cup to have a chamfered edge in an attempt to reduce the potential cracking, chipping, fracture or other damage to the ceramic liner upon insertion. This design change would not have significant impact on the results of the clinical trial.

E. Safety and Effectiveness Data

1. Safety Data

Safety was determined through the comparison of adverse event rates both device related and unrelated, implant survival, and radiographic analyses for all patients, randomized or non-randomized, receiving the device. In the total enrolled population, there were 4 intraoperative revisions due to liner chipping upon insertion, and 12 postoperative revisions in 299 hips implanted (for any indication and including the Continued Access hips – see Table 1) with the ceramic on ceramic hip system. One intraoperative revision due to instability and 2 postoperative revisions in 161 hips occurred with the control device.

The rate of specific adverse events, particularly, revisions, HO, dislocation, and proximal linear femur fractures were higher in the investigational group for all hips in the RNIA cohort.

Revisions

In the RNIA cohort, six postoperative revisions in 174 hips (3.4%) occurred in the C/C group. Two hips revised at three months due to dislocation in one hip and infection in the other case. One hip was revised at six months due to recurrent dislocations. At two years or greater, revisions were required for one hip with a fractured ceramic femoral head, one hip with a fractured ceramic acetabular liner, and one hip with a loose femoral component. Two postoperative revisions in 141 hips (1.4%) occurred in the C/P RNIA group. Revision was required in the discharge period for one hip due to instability, and one hip at three months due to an infection (Table 3). The estimate of the proportion of hips without revision at two years, in the RNIA cohort was 98% (95% CI: 95%-100%) for the C/C group and 99% (97%-100%) for the C/P group. The revision free-survival was not statistically significantly different between the two groups (Log- rank test, p=0.3438).

In the Continued Access population of 103 hips, five hips (4.9%) were revised by 1 year. One hip was revised at 3 months for prolonged dislocation. Two hips were revised at 6 months (one hip for dislocation and one hip for loose stem). At one year or more, two hips were revised due to one infected hip and one case of osteolysis. One ceramic-ceramic hip in the RIA cohort was revised at 6 months due to stem subsidence. There were four hips revised intraoperatively due to liner chipping during insertion that required immediate cup/liner exchange.

The revision rate for this study to date is 16/299 (5.4%) hips (see Table 1) with revisions in the C/C group at all evaluation intervals for all cohorts. The rate for the RNIA Cohort C/C group is 8/134 = 6% (174 – 40 hip exclusions) and is 8/174 = 4.6% without hip exclusions. The rate for the RNIA Cohort for the C/P control group is 3/102 =3% (141 – 39 hip exclusions) and is 3/141=2.1% without hip exclusions. The rate for the non-inflammatory Continued Access cohort is 7/103 =6.8% at 1.5 years, with incomplete follow-up at 2 years (1 hip with a revision at 2 year window included).

Table 3, Revised Hips – RNIA Cohort

Treatment	Interval	Reason for Revision	Components Revised
C/C	Intraop	Chipped liner	cup, liner
C/C	Intraop	Chipped liner	cup, liner
C/C	3 month	Dislocation	liner, head
C/C	3 month	Infection	All components
C/C	6 month	recurrent anterior dislocations	cup, liner, head
C/C	2 year	Ceramic head fracture	liner, head
C/C	Post 2 year	Ceramic liner fracture	cup, liner, head
C/C	Post 2 year	loose femoral component	head, stem
C/P	Intraop	Instability	Liner
C/P	Discharge	Instability	liner, head
C/P	3 months	Infection	All components

C/C=ceramic-ceramic; C/P=ceramic/polyethylene

Heterotopic Ossification

The overall incidence of heterotopic ossification was found as follows in Table 4 for the RNIA Cohort.

Table 4, Incidence of Hips with HO- RNIA Cohort

HO *	C/C (N=174)	C/P (N=141)
Grade I	36 (20.7%)	31 (22%)
Grade II	7 (4%)	3 (2.1%)
Grade III	7 (4%)	2 (1.4%)
Grade IV	1 (0.6%)	0 (0%)

*Brooker Classification

Dislocations

There were 25 dislocations reported for this study for all cohorts at all intervals. Of these, 11 events (4 intraoperative and 7 postoperative) occurred in 7 hips in those patients randomized to the ceramic-poly group. In the ceramic-ceramic group, there were 14 postoperative dislocation events in 9 hips. A majority of the dislocations (7 hips /10 events) in the ceramic-ceramic hips occurred in the first 3 months.

Proximal linear femur fractures

These events occurred intraoperatively in 7 ceramic-ceramic hips, 4 in the control group and 3 in the continued access group. All fractures occurred during preparation of the femoral canal or during actual stem insertion.

Adverse Events by time of occurrence

Within the RNIA cohort, there were a total of 34 intraoperative Operative Site adverse events that were seen in 17/174 hips (9.8%) that received the REFLECTION Ceramic Acetabular device and 8/141 hips (5.7%) in the control group. The intraoperative, Operative Site adverse events that occurred most frequently in the ceramic-ceramic group were proximal medial linear split (bone) fracture in 7/174 hips (4.0%), blood loss greater than 1500 ml in 6/174 hips (3.4%) and difficulty implanting the alumina ceramic acetabular liner in 2/174 hips (1.1%). Other events reported once (1/174=0.6%) were insufficient bone stock, nerve injury, and trochanteric fracture. The rate of events was comparable to the control group with the exception of difficulty implanting a ceramic liner.

In the RNIA cohort, 117 postoperative Operative Site Adverse Events were reported in 62 hips in the C/C study group, as compared to 72 events in 45 hips in the C/P group. The postoperative complications involving HO Grades I, II, and/or III, dislocation, incisional drainage, trochanteric bursitis, hematoma, DVT/PE, deep infection ≤ 6 weeks, superficial infection, and revisions (partial or complete) were the most frequently reported adverse events in the ceramic-ceramic group. The rates of these adverse events, when directly compared to the rate in the control group, did not demonstrate a statistically significant difference.

In the RNIA cohort, 54 C/C patients had a total of 95 postoperative systemic adverse events during the discharge interval through the post 2 year interval. 52 control patients had a total of 83 postoperative systemic adverse events. The most common systemic adverse events observed in both groups were related to the skeletal system. Nineteen of 146 (13%) patients reported 26 events and 22/130 (17%) patients reported 25 events related to the skeletal system in the C/C and C/P groups, respectively.

In the RNIA cohort, the other most frequently reported postoperative systemic adverse events in C/C patients were related to circulatory, digestive, integumentary, nervous, cardiac, muscular, or urinary systems. Rates of these and falls, anemia, deaths, DVT, PE, and surgery of the involved hip (but not affecting the implant) occurred with a frequency of between 1.4% (2/146 patients) and 6.2% (9/146 patients). DVT, PE occurred with greater frequency in the investigational group (2 patients) but none were reported in the control group. Intraoperatively, one incidence of hypoxia occurred in a bilaterally implanted C/C patient, and one incidence of hypotension occurred in a C/P patient.

In the RNIA cohort, the systemic postoperative adverse events in the C/C patients included allergic reaction, motor vehicle accident, pneumonia, electrolyte, hepatobiliary, renal, or respiratory abnormalities which occurred at a rate of 0.7% (each event reported once in 146 patients).

In the RNIA cohort, the operative site postoperative adverse events in the C/C hips included audible squeak in the hip, pelvic fracture, delayed wound healing, heterotopic ossification grade IV, I&D local, femoral head fracture, acetabular liner fracture, loosened stem, insufficient bone stock, head migration, and head subluxation which occurred at a rate of 0.6% (each event reported once in 174 hips). The majority of these appear to be device- or procedure-related.

Deaths

There were 6 deaths during the course of this study; 5 in the C/C group and one in the C/P group. All were in the RNIA cohort. One patient who died was a protocol deviation that is not reflected in Table 2 - Hip Accounting. Three of these patients in the C/C group died at, or prior to, the 1 year follow-up: one within the 18 days post operatively, and one 4 months post operatively, one at one year postoperatively. Two patients, died at the time of the 2 year or greater follow-up. In the C/P group, the patient died at the 2 year postoperative time point. Three patients' deaths (house fire death, 2 deaths due to lung cancer) in the C/C group and the one C/P group patient (heart disease) are clearly not related to the procedure or the device. The remaining 2 deaths occurred close to the surgical procedures associated with confirmed or suspected sepsis after revision or dislocation events.

Operative Site and systemic adverse events as well as revisions occurring in RNIA population are provided in time course adverse event distribution Tables 9-13 provided at the end of this document.

Summary of Safety
Patients in the REFLECTION ceramic group experienced more adverse events associated with the implant or procedure than the control group did, however this difference was not statistically significant.

There are different adverse events associated with the ceramic couple specifically liner fractures. The reasons for revision are similar with that anticipated of any total hip prosthesis (dislocation, infection, bone loss, component loosening/migration) except for intraoperative chipping of the ceramic liner that required cup/liner exchange and postoperative ceramic component fractures requiring revision. In this study, a higher incidence of heterotopic ossification was observed.

Treatment Results
For the RNIA cohort, mean operative time and blood loss were similar. The majority of bilateral procedures in both groups were staged procedures although more patients in the investigational group had same day bilateral surgeries (24) than in the control group (8). A posterior lateral approach was the most common surgical approach to the hip. In the investigational group the left hip and in the control group the right hip was implanted more frequently. The SYNERGY hip stem was used in 120 investigational hips and 94 hips in the control group. The SPECTRON EF stem was used as part of the construct in 53 investigational hips and 46 control hips. Bone graft was not used in the majority of patients in either group. When bone graft was used, the acetabulum was the site grafted most in both treatment groups. In the majority of procedures no cement was used to fix the components. When cement was used, the femur was cemented in 54 and 47 procedures in the investigational and control groups respectively.

2. Effectiveness Results
Success outcome is based on a three part composite at the two years interval, whereby the hip had not undergone revision, had Total Harris Hip Score greater than or equal to 80, and no radiographic failure due to unacceptable radiolucencies or component subsidence/migration. Radiographs were evaluated by an independent radiologist at 24 months only.

RNIA Cohort preoperative baseline effectiveness evaluations on the HHS, ROM, and SF-12 were similar between the two groups (Table 5).

Table 5, Baseline Evaluations - RNIA Cohort

Baseline Evaluations		
	RNIA C/C	**RNIA C/P**
Harris Hip Score (100 pts)	44.6	43.8
HHS Pain score (44 pts)	13.5	13.6
HHS Function score (47 pts)	24.3	23.3
ROM Flexion (degrees)	86.3	84.2
SF-12 PCS	29.5	28.7
SF-12 MCS	52.2	51.6

Table 6 provides a summary of Success Outcome for the two study groups (per protocol analysis).

Table 6, Effectiveness Results and Success Criteria at Two Years Per Protocol[1]

	2-year results						1-year results
	RNIA		RIA		RR		CAC
Category	**C/C**	**C/P**	**C/C**	**C/P**	**C/C**	**C/P**	**C/C**
Enrolled *	174	141	17	13	5	7	103
Evaluated [A]	126	85	12	6	2	1	53
Mean Harris Hip Score (Total 100)	96.0 (n=126)	92.6 (n=85)	92.8 (n=12)	88.3 (n=6)	98.5 (n=2)	71.0 (n=1)	95.3 (n=53)
Revision Success (hip not revised)	122/126 (96.8%)	84/85 (98.8%)	11/12 (91.7%)	6/6 (100%)	2/2 (100%)	1/1 (100%)	49/53 (92.4%)
Harris Hip Success (≥ 80)	121/126 (96.0%)	76/85 (89.4%)	11/12 (91.7%)	5/6 (83.3%)	2/2 (100%)	0/1 (0%)	49/53 (92.5%)
Radiographic Success [B]	118/118 (100%)	77/78 (98.7%)	12/12 (100%)	6/6 (100%)	2/2 (100%)	1/1 (100%)	50/50 (100%)
Overall Success [C]	113/122 (92.6%)	70/81 (86.4%)	11/13 (84.6%)	5/6 (83.3%)	2/2 (100%)	0/1 (0%)	46/54 (85.2%)

1 Per protocol patients evaluated at 24 months
* Enrolled is the number of hips implanted in the study by cohort.
A The number of evaluated, non-revised hips with an actual Total Harris Hip Score obtained at the 2 years follow-up. Partial evaluations not included in table.
B Denominator is the number of actual independent-read radiographs and not the number with any evaluations.
C Denominator is number of failures plus the number of hips with independent-read radiographs that were judged a success in the per-protocol population at 24 months.

The study device group (C/C) was demonstrated to be at least as good as the control (C/P) with respect to the success rate among all hips with complete data regardless of whether or not there was a protocol deviation at 2 years (C/P: 85/102=83.3% (141 – 39 hip exclusions) vs. C/C: 123/134=91.8% (174 – 40 hip exclusions) and the upper bound of one-sided 95% CI for the difference was less than 10%). Sensitivity analyses (e.g., last observation carry forward) including all the randomized hips showed that the missing data at 2 years did not change the conclusion that the REFLECTION Ceramic device (C/C) was not inferior to the control.

Results of multivariate regression analyses (logistic regression model and GEE model) justified the pooling across centers, hip replacement (bilateral/unilateral) and femoral stem cement use (yes/no). There was no statistically significant effect of age, gender or body mass index on the success outcome at 2 years. The adjusted odds ratio of success for C/C compared to C/P based on the logistic regression model (hips with missing data at 2 years were excluded) was 1.8 (95% CI: 0.8-4.3).

The overall success outcome reported in Table 6 incorporates elements of effectiveness. Other clinical measurements of clinical effectiveness are summarized in Table 7 for the RNIA cohort.

Table 7, Time Course Effectiveness and SF-12 Health Survey Physical Scale - all Hips (RNIA)

	Preop		3 Months		6 Months		12 Months		24 Months	
	C/C	**C/P**	**C/C**	**C/P**	**C/C**	**C/P**	**C/C**	**C/P**	**C/C**	**C/P**
N	174	141	157	127	151	120	144	115	139	106
Total Harris Hip Score Mean[1] (SD)	44.6 (10.7)	43.8 (9.7)	84.2 (14.4)	86.2 (13.6)	90.8 (13.1)	92.1 (10.6)	93.9 (9.0)	92.9 (10.8)	95.6 (7.5)	92.1 (10.5)
Total Harris Hip Pain Subscore Mean[2] (SD)	13.5 (4.9)	13.6 (5.0)	37.7 (8.3)	38.8 (7.9	39.8 (7.5)	40.9 (6.2)	41.0 (5.8)	41.1 (6.2)	42.2 (4.6)	
Total Harris Hip Function SubScore Mean[3] (SD)	24.3 (7.6)	23.3 (7.4	38.1 (7.9)	38.9 (7.3)	42.4 (6.5)	42.4 (6.4)	44.1 (5.0)	43.1 (5.7)	44.6 (4.5)	42.8 (6.1)
Flexion (degrees) Range of MotionMean (SD)	86.3 (18.4)	84.2 (22.3)	102.2 (14.5)	104.7 (13.5)	109.0 (15.5)	110.6 (15.8)	109.9 (16.7)	110.3 (16.2)	111.8 (15.6)	112.1 (16.6)
SF-12 Health Survey Physical Scale Score Mean[4] (SD)	29.5 (7.5)	28.7 (7.3)	41.9 (9.9)	41.9 (9.4)	48.2 (9.4)	47.9 (8.9)	49.2 (9.0)	48.3 (9.3)	49.5 (8.6)	47.1 (10.3)

C/C=Ceramic-Ceramic group, C/P = Ceramic-Poly group
1 Total Harris Hip Score scale from 0 (worst) to 100 (best)
2 Harris Hip Pain Sub-Score scale from 0 (worst) to 44 (best)
3 Harris Hip Function Sub-Score scale from 0 (worst) to 47 (best)
4 The mean of the Physical Component Summary scale in the general U.S. population is 50±10

Clinical results in the RNIA cohort shows improvement in overall and subscore Harris hip scores indicating improvement in pain and function over the course of the study, with approximately 90% of the patients in the evaluated group with good to excellent results, with few radiographic failures, acceptable implant survival at 2 years comparable with the control and that in the conventional hip implant literature, and improved physical quality of life scores on the SF-12 health survey. Range of motion improved in both groups as compared to preoperative measurements, but were not statistically significant.
Overall success rates are no worse than the control.

F. Clinical Results in Other Diagnostic Cohorts
The results presented in previous tables are specific to patients with a primary diagnosis of non-inflammatory arthritis of the involved hip. The clinical study also permitted enrollment of patients with inflammatory arthritis or patients requiring revision surgery for other hip devices that have failed. Patients were subject to the same inclusion/exclusion criteria and the same investigational plan as the RNIA cohort.

Summary of Inflammatory, Revision and Continued Access cohorts
Data was collected for patients with a diagnosis of inflammatory arthritis cohort (17 hips) and revision of previously implanted hips (5 hips) The data from the inflammatory arthritis and revision cohorts is insufficient to make absolute statements regarding safety and effectiveness in these diagnostic indications, however patients in both cohorts tended to have similar pain relief after surgery, and the patient outcomes in these populations showed a trend toward significant clinical benefit; relief of pain and return to function as measured by the Harris Hip Score, outweighing the risks of surgery in this population. Intraoperative (liner fractures, proximal linear femoral split fracture and postoperative events were similar to those of the primary osteoarthritis cohort including subsidence, migration, heterotopic ossification and revision (1 RIA).

In the Continued Access cohort, 5 revisions were reported in 103 hips (4.8%). These included 2 fractured liners during impaction which required revision of liner and cup. Three revisions occurred within 6 months. One hip had increased blood loss of 2300cc. Postoperative revision and loosening occurred in 5 patients.

Revisions for the Continued Access cohort are detailed in Table 8.

Table 8, Hips Revised - Continued Access Cohort

Treatment	Interval	Reason for Revision	Components Revised
C/C	3 month	prolonged dislocation/soft tissue laxity	Head
C/C	6 month	recurrent posterior dislocations	Stem
C/C	6 month	subsidence/loosening of stem	head, stem
C/C	1 year	infection/loosened cup	cup, liner
C/C	2 years	Osteolysis	head, stem

C/C=ceramic-ceramic

Safety
As with the RNIA cohort, the preliminary safety data for the RIA, RR, and CAC cohorts indicate that there are certain adverse events associated with the brittle material and different implantation techniques as compared to the conventional hip systems. The data suggest there are specific patients who had less successful outcomes (less successful HHS) including those who were protocol deviations in this study, (e.g. weight above recommended BMI), and those with preoperative/intraoperative risk factors including noncemented components, male gender, prior surgery, prior ectopic bone, anterolateral surgical approach , complexity of surgery. These suggest that specific patient and intraoperative selection criteria be advised. The data related to the formation of Heterotopic ossification suggest a recommendation for prophylaxis in those conditions, even in primary hip arthroplasty.

Effectiveness
The absolute effectiveness data for the RIA cohort cannot be determined due to the small sample size; however preliminary data shows that the Reflection Ceramic Acetabular System device used in the treatment of inflammatory arthritis of the hip may improve the majority of patients' pain and function with improved physical quality of life as measured by the HHS, SF-12.

PACKAGING AND LABELING
Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION
Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization methods for system components are shown below:

Component	Sterilization Method
REFLECTION/R3 Acetabular Shells	Gamma irradiation, minimum 25 kGy
REFLECTION Ceramic Liners	Ethylene Oxide
R3 Ceramic Liners	Gamma irradiation, minimum 25 kGy
Alumina Ceramic Heads	Ethylene Oxide

All components are supplied in protective packaging and trays. Inspect packages for punctures or other damage prior to surgery.

The disposable alignment guides packaged with the R3 Ceramic Liners are sterilized by ethylene oxide to a sterility assurance level of 10^{-6}. The disposable acetabular trial liners for sizes 48mm through 64mm are sterilized by ethylene oxide to a sterility assurance level of 10^{-6}. Do not reuse or resterilize these disposable instruments.

All other instruments used to implant the device system are supplied non-sterile and must be cleaned and sterilized prior to use using one of the following validated, recommended methods:

CYCLE PARAMETERS
- Dynamic Air Removal (Prevacuum) Steam Cycle
  - Exposure temperature: 4 pulses, 132°C (270°F) or 3 pulses, 135°C (275°F)
  - Minimum exposure time: 3 minutes
  - Minimum drying time: 30 minutes
- Gravity Displacement Steam Cycle
  - Exposure temperature: 132° - 135°C (270° - 275°F)
  - Exposure time: 30 minutes
  - Vacuum drying time: 30 minutes
- Flash Steam Cycle
  - Exposure temperature: 132° - 135°C (270° - 275°F)
  - Exposure time: Gravity Displacement Cycle: 15 minutes; Dynamic Air Removal (Prevacuum) Cycle: 3 – 4 minutes

Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

RESTERILIZATION
DO NOT RESTERILIZE REFLECTION/R3 Ceramic Acetabular System implant components. Porous coated metal implants and alumina ceramic implant components require special cleaning procedures. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components.

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

INFORMATION
For further information, please contact Smith & Nephew, Inc. Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Alumina ceramic components manufactured by:
CeramTec AG
Medical Products Division
Fabrikstrasse 23-29
D-73207 Plochingen
Germany

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116 USA

81065383 Rev. 0 02/09

Table 9, Time Course Distribution of Operative Site Adverse Events for Non-Inflammatory Arthritis (RNIA) Hips

Cohort	Ceramic-Ceramic Group 174 Hips								Ceramic-Poly Group 141 Hips								Continued Access Group 103 Hips							
Interval	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**
No. of Hips Evaluated	174	174	158	151	144	139	5	174	141	141	127	120	115	106	3	141	103	103	87	82	61	1	0	103
Total No. of Events	21	12	38	18	12	23	3	127	8	13	24	10	7	12	3	77	8	1	8	3	2	0	0	22
Audible Squeak							1	1																
Blood Loss > 1500 ml	6							6	2							2	1							1
Bone Fracture: Femur														1		1								
Bone Fracture: Pelvis					1			1																
Cardiac Arrythmia																	1							1
Deep Vein Thrombosis			2					2																
Delayed Wound Healing		1						1			1					1								
Difficulty Implanting Liner	2							2									1							1
Dislocation: Head			7			2	1	10	1	4				1	2	8			3	1				4
Fracture: Liner	3							3									2							2
Hematoma			3					3			1					1			1					1
HO: Grade I		7	14	11	4	8		44		7	13	6	5	6		37			1					1
HO: Grade II			1	2		5		8			1	2	1	1		5								
HO: Grade III			3	2	3	1		9						2		2								
HO: Grade IV						1		1																
I&D Local			2					2			1					1								
I&D Non-Local											1					1								
Implant Fracture: Head						1		1																
Implant Fracture: Liner						1		1																
Implant Loosened: Cup																				1				1
Implant Loosened: Stem							1	1				1				1				1				1
Incisional Drainage		3	3					6		1	1					2			1					1
Incisional Tenderness												1				1								
Infection: Deep < 6 WKS			1			1		2			1					1			1					1
Infection: Deep > 6 WKS										1						1					1			1
Infection: Superficial		1	1					2			3					3								
Insufficient Bone Stock	1			1				2																
Migration: Head						1		1																
Nerve Injury	1							1										1						1
Osteolysis																					1			1
Proximal Femur Fracture	7							7	4							4	3							3
Pulmonary Embolism					2			2																
Reoperation (Not A Revision)			1	1				2																
Subluxed / Subside Head					1			1						1		1								
Subluxed / Subside Stem																			1					1
Trochanteric Bursitis				1	1	2		4			1		1		1	3								
Trochanteric Fracture	1							1	1							1								

IO=intraoperative; DC=discharge; 3M= 3 months; 6M= 6 months; 12M= 12 months; 24M= 24 months; 24+M= post 24 months. Excludes adverse events after the first revision of a C/C or C/P device.
Revisions are considered Operative Site events, and RNIA revisions are reported separately in Table 3 and listed in time course as Table 11.

Table 10, Time Course Distribution of Systemic Adverse Events for Non-Inflammatory Arthritis (RNIA) Subjects

Cohort	Ceramic-Ceramic Group 146 Subjects								Ceramic-Poly Group 130 Subjects								Continued Access Group 88 Subjects							
Interval	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**	**IO**	**DC**	**3M**	**6M**	**12M**	**24M**	**24+M**	**Tot**
No. of Hips Evaluated	146	146	133	125	122	119	4	146	130	130	118	114	108	98	3	130	88	88	74	69	54	1	0	88
Total No. of Events	1	24	29	10	12	14	6	96	1	19	15	6	7	23	13	84	0	9	7	2	6	2	0	26
Allergic Reaction			1					1		1						1								
Anemia		3	2					5		2						2								
Death			1			1	1	3						1		1								
Dislocation Non-Operative Hip														1		1								
Fall		1	1	2		1		5			1	1	1	4		7								
Fever		3	3					6		1	2					3			1					1
Hernia												1				1								
Hypotension									1							1								
Hypoxia	1							1																
Motor Vehicle Accident				1				1						1		1								
Pneumonia			1					1																
Surgery (unrelated To Study Hip)			1				1	2			1		1		4	6								
Systemic: Cardiac		1	2					3		5	2					7								
Systemic: Circulatory		2	4		1	1		8		1	3	1		1		6		3	1		1			5
Systemic: Digestive		7	2		1			10		5				1		6		2	1					3
Systemic: Genetic Disorder																			1					1
Systemic: Fluid and Electrolyte		1						1		1						1								
Systemic: Hepatobiliary			1					1																
Systemic: Infection (unrelated to surgical wound)																		1						1
Systemic: Integumentary		3	1		2			6		1			1		1	3		1						1
Systemic: Muscular		1	2					3						1		1		1			1			2
Systemic: Nervous		1	1	3	2	2		9						3		3								
Systemic: Renal			1					1			1				1	2			1					1
Systemic: Reproductive															1	1					1			1
Systemic: Respiratory						1		1			1			1		2			1					1
Systemic: Skeletal		1	4	4	6	7	4	26			4	2	4	9	6	25			1	2	3	2		8
Systemic: Urinary			1			1		2		2		1				3		1						1

IO=intraoperative; DC=discharge; 3M= 3 months; 6M= 6 months; 12M= 12 months; 24M= 24 months; 24+M= post 24 months. Excludes adverse events after the first revision of a C/C or C/P device.

Table 11, Time Course of Hip Revisions - RNIA Cohort

	Number of Hips by Interval															
	IO		DC		3M		6M		12M		24M		24+M		Total	
Revised	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P
No. of Revisions †	2	1		1	2	1	1				1		2		8	3
Cup	2				1	1	1						1		5	1
Liner	2	1		1	2	1	1				1		1		7	3
Head				1	2	1	1				1		2		6	2
Stem					1	1							1		2	1

Intervals: IO=Intraoperative; DC=Discharge; 3M=3 months; 6M=6 months; 12M=12 months; 24M=24 months; 24+M=post-24 months

† Number of revisions for any primary component implanted. The numbers on subsequent rows for each identified implant component denote number of primary implants revised, i.e. in the "IO" interval 2 cups and 2 liners were revised in two separate hip revisions. "Total" columns for each group summarize the number of revision events and number of components revised.

Two (2) intraoperative revisions in C/C hips were due to chipping of ceramic liners during placement that required cup and liner exchange. One (1) intraoperative revision in C/P hip was due to instability. Postoperatively, in the RNIA cohort, the reasons for revision in C/C device hips were dislocation (1 at 3M, 1 at 6M), infection (3M), head fracture (24M), liner fracture (24+M) and loose stem (24+M). In the C/P device hips, the reasons for revision were instability (1 at IO, 1 at DC) and infection (3M).

Table 12, Time Course of Hip Revisions - CAC Cohort

	Number of Hips by Interval															
	IO		DC		3M		6M		12M		24M		24+M		Total	
Revised	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P
No. of Revisions†	2				1		2		1		1				7	
Cup	2								1						3	
Liner	2								1						3	
Head					1		1				1				3	
Stem							2				1				3	

Intervals: IO=Intraoperative; DC=Discharge; 3M=3 months; 6M=6 months; 12M=12 months; 24M=24 months; 24+M=post-24 months. CAC cohort had only ceramic/ceramic implants.

† Number of revisions for any primary component implanted.

Two (2) intraoperative revisions in C/C hips were due to chipping of ceramic liners during placement that required cup and liner exchange. Postoperatively, in the CAC cohort, the reasons for revision in C/C device hips were dislocation (1 at 3M, 1 at 6M), loose stem (6M), infection/loose cup (24M), and osteolysis (24M).

Table 13, Time Course of Hip Revisions - RIA Cohort

	Number of Hips by Interval															
	IO		DC		3M		6M		12M		24M		24+M		Total	
Revised	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P	C/C	C/P
No. of Revisions †							1								1	
Cup																
Liner																
Head							1								1	
Stem							1								1	

Intervals: IO=Intraoperative; DC=Discharge; 3M=3 months; 6M=6 months; 12M=12 months; 24M=24 months; 24+M=post-24 months. CAC cohort had only ceramic/ceramic implants enrolled.

† Number of revisions for any primary component implanted.

In the RIA cohort, the reason for revision in the C/C device hip was stem subsidence at 6M.

Notes

Notes

Orthopaedic Reconstruction & Trauma
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538

7138-1479 45940103a 05/09