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Exactech®

NOVATION

Ceramic Articulation Hip System

DESCRIPTION

The Exactech® NOVATION™ Ceramic Articulation Hip System (AHS) is a ceramic-on-ceramic hip prosthesis system composed of the following components:

- Exactech® 12/14 Alumina Femoral Head (BIOLOX®*forte*)
  The alumina ceramic femoral heads have 12/14 tapers and are offered with outside diameters of 28mm, 32mm and 36mm in three neck lengths (–3.5 mm, +0 mm, +3.5 mm). Exactech® 12/14 Alumina Femoral Heads are compatible only with the Exactech femoral prostheses identified below.

- NOVATION™ Ceramic AHS Alumina Acetabular Liner (BIOLOX®*forte*)
  The alumina ceramic acetabular liners are offered in seven sizes with internal diameters of 28mm, 32mm and 36mm. The seven sizes are designated as #140-28-11 (28/37G); #140-32-12 (32/41G); #140-32-13 (32/44G); #140-32-14 (32/48G); #140-36-13 (36/44G); #140-36-14 (36/48G); and #140-36-15 (36/52G). The 28mm ID liner fits shell sizes of 48-50mm OD. The 32mm ID liners fit shell sizes 52-62mm OD. The 36mm ID liners fit shell sizes 54-68mm OD. A male taper-fit connection allows assembly into the mating metal acetabular shell components. The NOVATION™ Ceramic AHS Liners are only compatible with NOVATION™ Ceramic AHS Shells and Exactech® 12/14 Alumina Femoral Heads.

- NOVATION™ Ceramic AHS Plasma-Coated Acetabular Shell
  The metal shells feature a 3-hole cluster design, are hemispherical and are offered in 11 sizes with outside diameters ranging from 48 to 68mm in 2mm increments. The titanium alloy metal shells are plasma sprayed with a commercially pure titanium coating and are also available with and without a hydroxylapatite coating. **The acetabular shells are designed for cementless, press-fit fixation.**

- Exactech® 6.5 mm Bone Screws or Exactech® MBA 6.5mm Bone Screws (optional)

- Exactech® 12/14 Femoral Stems
  The Novation™ Ceramic AHS uses the following commercially available and compatible Exactech® cobalt chromium alloy and titanium alloy 12/14 femoral stems:

  ◊ AcuMatch™ 12/14 P-Series Press-Fit Plasma Femoral Stem
  ◊ AcuMatch™ 12/14 L-Series Press-Fit Femoral Stem
  ◊ AcuMatch™ 12/14 C-Series Cemented Femoral Stem
  ◊ AcuMatch™ 12/14 L-Series Cemented Femoral Stem
  ◊ NOVATION™ 12/14 Tapered Press-Fit Plasma Femoral Stem
  ◊ NOVATION™ 12/14 Tapered Press-Fit Plasma/HA Femoral Stem

- ◊ NOVATION™ 12/14 Splined Press-Fit Plasma Femoral Stem
- ◊ NOVATION™ 12/14 Splined Press-Fit Plasma/HA Femoral Stem
- ◊ NOVATION™ 12/14 Cemented Femoral Stem

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Component	Material	Component Sizes
Exactech® 12/14 Alumina Femoral Heads	BIOLOX®*forte* Alumina Ceramic (Al_2O_3) ASTM F603 and ISO 6474	Outside Diameters: 28 mm, 32 mm, 36 mm Head Lengths: Short (-3.5 mm) Medium (+0 mm) Long (+3.5 mm)
NOVATION™ Ceramic AHS Alumina Liner	BIOLOX®*forte* Alumina Ceramic (Al_2O_3) ASTM F603 and ISO 6474	Inside Diameters: 28 mm, 32 mm, 36 mm
Exactech® NOVATION™ Ceramic AHS Plasma-Coated Acetabular Shell	Titanium Alloy (Ti6Al4V) ASTM F1472 Plasma Spray Coating Commercially Pure Titanium ASTM F1580 HA Coating (optional) Hydroxylapatite- raw material ASTM F1185	Outside Diameters: 48 – 68 mm (2 mm increments) Press-fit coating adds 1mm to nominal diameter. Shells are available with and without the HA coating.
Exactech® 6.5 mm Bone Screw Exactech® MBA 6.5mm Bone Screw (optional)	Titanium Alloy (Ti6Al4V) ASTM F136 Titanium Alloy (Ti6Al4V) ASTM F136	Diameter: 6.5 mm Lengths: 15 – 80 mm Diameter: 6.5mm Lengths: 15-80 mm Use if supplemental fixation of the acetabular shell is required.

AcuMatch ™ 12/14 P-Series Press-Fit Plasma Femoral Stem	Titanium Alloy (Ti6Al4V) ASTM F1472 Plasma Spray Coating Commercially Pure Titanium ASTM F1580	Tapered stem with two neck offsets (Sizes 0-7)
AcuMatch ™ 12/14 L-Series Press-Fit Femoral Stem	Titanium Alloy (Ti6Al4V) ASTM F1472	Tapered stem with one neck offset (Sizes 0-6)
AcuMatch ™ 12/14 C-Series Cemented Femoral Stem	Cobalt-Chromium (Co28Cr6Mo) ASTM F799	Tapered stem with two neck offsets (Sizes 1-6)
AcuMatch ™ 12/14 L-Series Cemented Femoral Stem	Cobalt-Chromium (Co28Cr6Mo) ASTM F799	Tapered stem with one neck offset (Sizes 1-5)
NOVATION ™ 12/14 Tapered Press-Fit Plasma Femoral Stem	Titanium Alloy (Ti6Al4V) ASTM F1472 Plasma Spray Coating Commercially Pure Titanium ASTM F1580 HA Coating (optional) Hydroxylapatite- raw material ASTM F1185	Tapered stem with two neck offsets (Sizes 9-18) Plasma stems are available with and without the HA coating.
NOVATION ™ 12/14 Splined Press-Fit Plasma Femoral Stem	Titanium Alloy (Ti6Al4V) ASTM F1472 Plasma Spray Coating Commercially Pure Titanium ASTM F1580 HA Coating (optional) Hydroxylapatite- raw material ASTM F1185	Splined stem with two neck offsets (Sizes 9-18) Plasma stems are available with and without the HA coating.
NOVATION ™ 12/14 Cemented Femoral Stem	Cobalt-Chromium (Co28Cr6Mo) ASTM F799	Tapered stem with two neck offsets (Sizes 9,11,13,15,17)

Exactech® implants are supplied sterile and are intended for single use only.

A complete instrumentation and trial system is available to assist in the implantation of each component. For a more detailed description of the implants, instruments and their utilization, please refer to the surgical technique, or contact your Exactech® sales representative.

INDICATIONS FOR USE

The NOVATION ™ Ceramic AHS is indicated for use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

CONTRAINDICATIONS

Use of the Exactech® NOVATION ™ Ceramic AHS is contraindicated in the following situations:

- Active or latent infection in or around the hip joint;
- Acute or chronic systemic infections;
- Skeletally immature patients;
- Neurological or muscular conditions (e.g., prior paralysis, fusion and/or inadequate abductor strength) that could result in instability or overloading of the hip joint;
- Poor skin coverage around hip joint;
- Patients with inadequate bone stock to allow proper insertion and fixation of the prosthesis;
- Metabolic bone disease and osteoporosis;
- Use in patients with known allergies to the implant materials; and
- Obese patients where obesity is defined as a Body Mass Index (BMI) greater than 35.

WARNINGS AND PRECAUTIONS

Certain insertion techniques may be different from those known for conventional hip systems. The Warnings and Precautions below are recommended and were designed to reduce the potential incidence of chipping, malpositioning, breakage and improper fixation associated with ceramic-on-ceramic acetabular systems. Only qualified surgeons knowledgeable in the anatomy, biomechanics, and reconstructive surgery should utilize these devices. The surgeon should be fully knowledgeable of the implants, implant compatibility, instruments and surgical procedure prior to performing surgery. The surgeon should review all aspects of the Exactech® NOVATION ™ Ceramic AHS surgical technique and other training materials supplied by Exactech prior to use. The surgeon should be trained according to the proper use of the system instrumentation. For more information, contact your Exactech® sales representative.

Warnings

- Do not allow damage to the polished bearing surfaces or taper locking surfaces. Any alteration, damage, contour or bend to these surfaces will reduce the fatigue strength of the prostheses and may result in failure under load. Any prostheses so damaged must not be used.

- Seat the acetabular shell at 45° inclination with 20° anteversion to ensure proper positioning and to decrease the potential for dislocation and impingement.

- Always ensure proper alignment and seating of provisional implants prior to implantation of the definitive prosthesis. Improperly positioned components may not be immediately obvious and may result in device 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.

- Do not disassemble and reassemble the ceramic liner to the acetabular shell as the taper joint may become deformed during this process. Damage to the shell taper may affect the locking mechanism between the liner and shell and increase the risk of ceramic liner fracture.

- Replace both the ceramic liner and the metal acetabular shell if the ceramic liner is chipped, cracked, or otherwise damaged during shell/liner assembly. Once the acetabular shell taper has been assembled to a ceramic liner, it should not be reassembled to another ceramic liner. A deformed metal taper could significantly affect the locking mechanism between the new liner and shell and increase the risk of ceramic liner fracture.

- Do not scratch or dent the rim or internal taper of the acetabular shells. If the rim or taper joint is damaged during implantation, the acetabular shell should be replaced, as the deformation of the shell taper may affect the locking mechanism between the liner and shell and increase the risk of ceramic liner fracture.

- **Only use NOVATION ™ BIOLOX®*forte* Ceramic AHS Acetabular Liners with Exactech® 12/14 BIOLOX®*forte* Alumina Femoral Heads. Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner. Use of other components (e.g. metal femoral heads, zirconia ceramic femoral heads, another manufacturer's alumina heads) may accelerate bearing wear and lead to early failure of the system.**

- **Only use NOVATION ™ Ceramic AHS Acetabular Shells with NOVATION ™ BIOLOX®*forte* Ceramic AHS Acetabular Liners. Use of other manufacturer**

acetabular shell components may result in disassembly and/or fracture of the liner and lead to early failure of the system.

- **Only use the compatible Exactech® 12/14 Femoral Stem components identified in the Description section with the NOVATION ™ Ceramic AHS femoral head, liner and acetabular components. Use of other femoral stem components (e.g. Exactech® femoral stems that do not have a 12/14 taper, another manufacturer's femoral stems) may result in fracture or damage to the femoral head and/or liner components and lead to early failure of the system.**

- Do not implant in pregnant patients as the extra weight and exposure to radiation may be harmful to the implant and fetus.

- Do not implant in obese patients because overloading the component may lead to fracture or loss of fixation

- Implants are for single use only. Do not reuse an implant. Any implant, once used, should be discarded even though it may appear undamaged.

- Do not re-sterilize implants. In particular, heat sterilization of ceramic components followed by sudden cooling may cause undetectable damage and lead to device failure. Failure to follow these recommendations will result in increased probability of poor function, loosening, wear, fracture or premature failure.

- 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 primary non-inflammatory degenerative joint, disease have not been established.

Precautions

Pre-operative

- The patient should be informed of all potential risks and adverse effects contained in this insert. The patient should be warned that the implants can break or become damaged as a result of strenuous activity or trauma, including extreme activity or heavy labor for occupation.

- Ensure that no biological, biomechanical, biomaterial or other factors exist which might adversely affect the surgery and/or postoperative period. Bone quality should be considered to ensure that the prosthesis does not subside, tilt, or migrate; fracture of host bone should also be considered. Such events could result in adverse outcome. The expected useful life of the device may be compromised in very large or overweight individuals and in individuals who have a physically active lifestyle. The

largest size components that will achieve the desired anatomic and functional characteristics for the patient are recommended. Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and subsequent early failure/fracture of the components and /or host bone.

- Carefully examine each component and its packaging for any signs of damage that may have occurred during shipping or handling (e.g. if dropped on the floor or if scratched by an instrument). Do not implant components if the packaging is damaged or if the implant shows signs of damage. Use of damaged components may lead to premature failure of the device. Due to the brittle nature of the material, ceramic components are particularly susceptible to premature failure when scratched, cracked or otherwise damaged.

- Examine instruments and confirm functionality prior to use. Instruments that have been subjected to overuse or misuse conditions are susceptible to failure or may damage implants and should not used.

Intra-operative

- The entire prosthesis size range should be available at the time of the surgery; selecting the correct type of prosthesis with the correct size for each specific application is essential to the success of the procedure.

- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.

- Clean and dry surfaces that lock to ensure proper seating and assembly. Ensure that prior to liner insertion, soft tissue does not interfere with the shell/liner interface. Modular components should be assembled securely to prevent disassociation. When using cement for fixation of the mating femoral components, the surgeon should ensure complete cement support on all parts of the prosthesis embedded in bone cement.

- When assembling the acetabular components, first place the ceramic liner into the metal shell by hand. Prior to impacting, confirm that proper seating of the ceramic liner has occurred by palpating the shell/liner assembly. It is critical that the ceramic liner is stable within the shell prior to impacting with the ceramic liner driver instrument. Impaction should not occur and the ceramic liner should be removed if it becomes mal-aligned within the shell. **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.** 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.

- After the liner has been inserted, the liner should be examined in-situ for evidence of chipping (visible evidence of ceramic fracture). If chipped, scratched, or otherwise damaged during the implant procedure, replace both the ceramic liner and the acetabular shell.

- Once the femoral stem taper has been assembled to a ceramic head, it should not be reassembled to another ceramic head. If the ceramic head is chipped, cracked, or otherwise damaged during head /stem assembly, replace both the ceramic head and the femoral stem.

- Do not use a metal or zirconia head with the Novation™ Ceramic Articulation Hip System because this may accelerate bearing wear and lead to early failure of the device.

- In order to prevent sepsis, the physician is advised to comply with the following recommendations:
  - Consistent use of prophylactic antibiotics;
  - Utilize a laminar flow clean air system;
  - Assure that all operating room personnel, including observers, are properly attired;
  - Protect instruments from airborne contamination;
  - Use impermeable draping.

- Use only Exactech® 6.5 mm Bone Screws or Exactech® MBA 6.5 mm Bone Screws if adjunctive fixation of the acetabular shell is desired. Pre-drill screw holes using either a 4.5mm or 3.2mm drill bit to facilitate screw installation. Ensure proper selection of the bone screw length and proper screw placement to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall with screws that are too long can result in internal bleeding and possible damage to vital organs. Do not place a screw in the center apical hole of the acetabular shell. Completely seat bone screws to allow proper assembly of the ceramic liner to the metal shell.

- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, extraneous bone cement (if used), ectopic bone, etc. Foreign particles may cause excessive wear. Foreign particles may also migrate to other parts of the body. Range of motion should be used to verify stability of the joint, check for impingement and corrected as appropriate.

Post-operative

- Post-operative counseling and care is important. It is recommended that regular, long term postoperative follow-up be undertaken to detect early signs of component wear & loosening, and to consider the course of action to be taken if such events occur. A suitable rehabilitation program should be designed and implemented.

- Extreme care in patient handling (e.g., 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. Excessive activity and trauma affecting joint replacements have been associated with premature failure.

- A continuing periodic follow-up is recommended. Periodic x-rays should be taken to detect evidence of positional changes, loosening, bone loss and /or device fracture. In such cases, patients should be closely monitored and the benefits of revision surgery should be considered in order to avoid further deterioration.

- All patients should be instructed on the limitations of the prosthesis and the possibility of subsequent surgery. The patient should be cautioned to monitor activities and protect the replaced joint from unreasonable stresses, and follow the written instructions of the physician with respect to follow-up care and treatment. The patient should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip. Patients should be informed that their weight and activity level may affect the longevity of the implant. Patients should be advised to report any pain, decrease in range of motion, swelling, fever, or unusual sounds (e.g. clicking or squeaking) as this may indicate positional changes in the implant that could lead to premature failure.

ADVERSE EFFECTS

The following adverse effects may be associated with the use of this device. Although some effects are not directly attributable to the device itself, the surgeon should be aware of these potential complications and be ready to treat the patient accordingly. Failure of the prostheses due to any cause may result in the need for additional surgery.

List of Potential Adverse Events Associated with Any Total Hip Arthroplasty

- Excessive wear of the implant components secondary to impingement of components or damage of articular surfaces.
- Osteolysis
- 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.
- Possible detachment of the coating(s) on the femoral stem or acetabular shell components, potentially leading to increased debris particles.
- Unintended bone fractures, including femoral or acetabular perforation while seating the device.
- Metal sensitivity reactions or other allergic/histological reactions to implant materials.
- Superficial or deep infection.

- Delayed wound healing.
- Vascular damage resulting in blood loss and/or hematoma, potentially requiring transfusion.
- Neurologic injury or neuropathy resulting in transient or permanent weakness, pain, and/or numbness.
- Undesirable leg lengthening or shortening.
- Periarticular calcification or ossification, with or without impediment to joint mobility.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Gastrointestinal complications.
- Genitourinary complications.
- Aggravation of other joint or back conditions due to positioning during surgery or neurological injury.
- Traumatic arthrosis of the hip from intraoperative positioning of the extremity
- Decreased range of motion.
- Intractable pain.
- Death.

List of Potential Complications Associated with the NOVATION™ Ceramic AHS
In addition to the adverse effects identified above, additional adverse effects may be associated with the NOVATION™ Ceramic AHS as follows:

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

See Table 3 for a detailed listing of all adverse events reported in the clinical study of another hip system (FDA Premarket Approval Application (PMA) P010001) that utilizes the same ceramic bearings in terms of material and articulating geometry as the Exactech® NOVATION™ Ceramic AHS.

CLINICAL TRIAL INFORMATION ON NOVATION™ CERAMIC ARTICULATION HIP SYSTEM

The ceramic components of the NOVATION™ Ceramic AHS are identical in material composition to those in the Ceramic TRANSCEND Hip Articulation System. The clinical data on the TRANSCEND System (reported in FDA Premarket Approval Application P010001) are relevant to the NOVATION™ System because the two

systems have identical articulating surfaces and yielded similar results in bench top testing.

Clinical Study Design
The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from the Whiteside Total Hip System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the P010001 Clinical Trial device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol was 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

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

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

The patient accounting and baseline demographics are summarized in Tables 1 and 2. Note that there were seven deaths, none of which were related to the study or to the device.

Table 1: Patient Accounting						
Evaluation Interval	**Original Clinical Patient Population (n=329)**			**Continued Access Population (n=630)**		
	TFU	**EFU**	**AFU (%)**	**TFU**	**EFU**	**AFU (%)**
Pre-Op	329	329	100% (n=329)	630	630	100% (n=630)
6 months	329	323	93% (n=300)	602	602	71% (n=430)
12 months	329	321	91% (n=293)	443	442	53% (n=233)
24 months	329	321	94% (n=302)	151	150	0% (n=0)

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

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

Safety Results

The adverse events related to total hip replacement surgery reported in the P010001 clinical study of 959 procedures are listed in Table 3.

Table 3. Reported Adverse Events

Event	P010001 Clinical Study (n=959)		Whiteside Clinical Study (Control) (n=211)	
Systemic	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
Local	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Revisions/Removals[1]	11	1.1%	8	3.8%
Breakage/Fracture of Component[2]	5	0.5%	2	0.9%
Dislocation (single) of Component[3]	8	0.8%	3	1.4%
Dislocation (recurrent) of Component[4]	2	0.2%	0	0%
Femoral Fracture	18	1.9%	9	4.3%
Hematoma	2	0.2%	0	0%
Heterotopic Ossification	1	0.1%	1	0.5%
Infection: Deep, Early < 1year	2	0.2%	0	0%
Infection: Deep, Late >1 year	1	0.1%	0	0%
Infection: Superficial	7	0.7%	0	0%
Loosening of Component	3	0.3%	2	0.9%
Migration of Component	2	0.2%	0	0%
Persistent Foot Drop	2	0.2%	0	0%
Pain	10	1.0%	0	0%
Perforation of Femur During Reaming	2	0.2%	0	0%
Wear of Component	1	0.1%	0	0%
Subsidence of Component	3	0.3%	2	0.9%
Soft Tissue Trauma	0	0%	0	0%
Wound Problems	2	0.2%	0	0%
Other Local Complication[5]	10	1.0%	0	0%
Local - Hip	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

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

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

[3] 2 were revised for this reason.

[4] 1 was revised for this reason.

[5] Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off. None of these complications were related to the study hip or the procedure.

Revisions and Removals

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

Table 4. Summary of Revisions and Removals

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

Efficacy Results

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

Table 5. Efficacy Results – HHS

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

Notes:
[1] Original clinical study population includes the first 329 procedures enrolled in the pivotal clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)
[2] The *Continued Access* sample (N=630) includes procedures performed after the original clinical population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation Carried Forward (LOCF) and represent the latest clinical results available for that procedure.

Any Radiographic Lucency

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

Table 6. Any Radiolucency

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

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

Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the P010001 Clinical Trial. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the P010001 Clinical Trial and the Whiteside hip over time.

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

Table 7. P01001 Clinical Trial Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	528	69	8	0.9909	0.0041
24 months	279	78	1	0.9876	0.0066
36 months	1	0	0	0.9308	0.0562

Table 8. Whiteside Clinical Study Implant Survivorship

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

Patient Success Criteria

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

Table 9. Patient Success Criteria at Two Years

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

Notes:

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

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

UTILIZATION AND IMPLANTATION

Component selection depends upon the judgment of the surgeon with relationship to the requirements of the patient. The surgeon shall become thoroughly familiar with the surgical technique of these prostheses by: 1) appropriate reading of the literature, 2) specific training in the operative skills and techniques required for the implant system, & 3) reviewing any other relevant information regarding the use of instrumentation designed for device implantation.

Use During Pregnancy:

Surgery should be avoided during pregnancy.

Use in Children:

There are no tests that demonstrate the device is safe for use in children. The device should only be used in skeletally mature individuals.

HOW IMPLANTS ARE SUPPLIED

Implants are supplied sterile (gamma radiation) to a sterility assurance level (SAL) of 10^{-6} and are intended for single use only. Never resterilize an implant. Resterilization may adversely affect implant materials and result in premature failure.

HOW SURGICAL INSTRUMENTS ARE SUPPLIED

Surgical instruments are supplied non-sterile and are re-useable. Surgical instruments are intended to be cleaned and steam sterilized by the health care facility prior to use. Please refer to the recommended and validated procedures described in "Exactech Reprocessing Instruction for Reusable Surgical Instruments."

STORAGE AND HANDLING

Implants should be stored in their original, sealed packaging in clean, dry conditions. This packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility and component integrity, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for seal integrity. If the device has been opened, damaged or adulterated in any way, it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

DEVICE RETRIEVAL EFFORTS

Should it become necessary to remove any or all of the Exactech® Ceramic AHS components, please call Exactech® at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

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

INFORMATION
For further product information, please contact Customer Service, Exactech®, Inc., Gainesville, Florida 32653, USA (352) 377-1140, (800) 392-2832 or
FAX (352) 378-2617.

Authorized European Representative
MediMark® Europe
11, rue Emile Zola B.P. 2332
38033 Grenoble Cedex 2
France

Some components may not be currently available. Please contact your Exactech® representative for additional information.

Patient Labeling

Exactech® NOVATION™ Ceramic Articulation Hip System (AHS)

TABLE OF CONTENTS

Patient Labeling

Exactech® NOVATION™ Ceramic Articulation Hip System (AHS)

GLOSSARY

Acetabulum- cup-shaped socket in the hip bone.

Artificial- man-made.

Avascular Necrosis – a loss of blood supply to the hip bones, which progresses to joint problems, characterized by changed shape and increased thickness and hardness of the bone ends, a flattening of the joint surface and cartilage failure leading to a painful joint.

Cartilage- rubbery type of tissue that pads the joints.

Ceramic- In this device, a very hard material made from aluminum and oxygen known as alumina (Al_2O_3).

Congenital Dysplasia of the Hip (CDH) – dislocation of the hip at the time of birth due to abnormal development of one or all of the components of the hip joint: the acetabulum; the femoral head; and the surrounding joint tissue.

Femoral Head- the ball portion at the top end of the thighbone.

Hip Dislocation- separation of the ceramic ball and acetabular cup (liner/shell) in an artificial hip replacement device.

Hip Fractures – traumatic or spontaneous fracture of the bones of the hip, which, because of the severity of the injury, might require replacement of the ball and socket portions of the hip joint.

Inflammation- swelling, redness and pain in tissues caused by injury or damage.

Osteoarthritis – the breakdown of cartilage in your joints, which causes your hip bones to rub painfully together.

Range of Motion- all the movements of the leg in multiple directions due to the movement of the ceramic ball and socket joint.

Revision Surgery- surgery to replace a failed implant with a new implant.

Traumatic Arthritis – inflammation of a joint resulting from an injury and characterized by breakdown of the bone and cartilage, bleeding in the joint space, and increased thickness of the bone, a flattening of the joint surface, separation of joint cartilage from the underlying bone and/or erosion of the bone.

Exactech® NOVATION™ Ceramic Articulation Hip System (AHS)

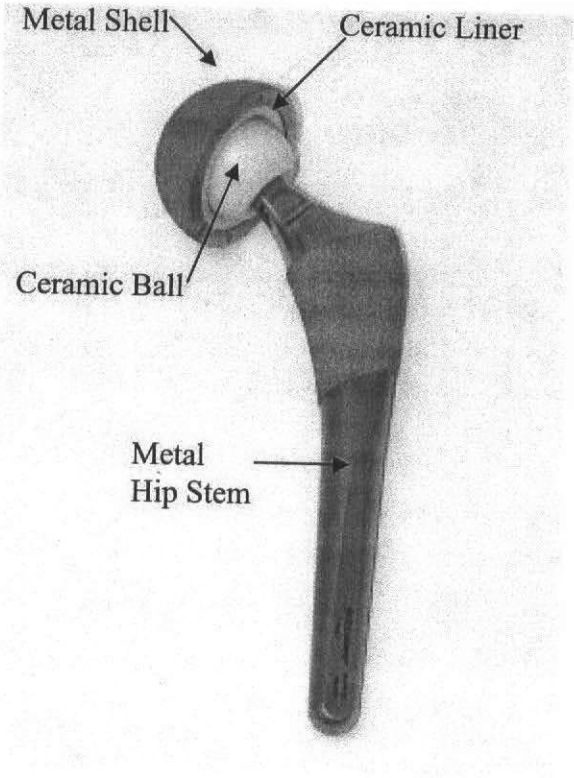
DEVICE DESCRIPTION & CONTRAINDICATIONS

What is the purpose of the device?

The Novation™ Ceramic Articulation Hip System is for use in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, traumatic arthritis, and hip fractures. These diagnoses are defined in the glossary.

What is the device?

Your overall ceramic hip replacement includes a ceramic socket and a ceramic ball head affixed to a metal hip stem. The ceramic socket is a two-piece component that consists of an outer metal casing (or "shell") with a ceramic inside layer (or "liner"). When implanted, the ceramic ball moves within the ceramic socket.



NOVATION™ Ceramic AHS

When should the device not be used (Contraindications)?
This device should not be used if you have any of the following contraindications:

- infection;
- allergies to material the implant is made of (e.g., known allergic reactions to metals or ceramics);
- rapid disease progression as obvious by joint destruction or bone resorption (loss of bone) seen on x-ray radiographs;
- patients whose bones have not stopped growing;
- cases where muscles may be too weak to work satisfactorily (e.g., prior paralysis [loss of function] and fusion [joining together], poor bone stock [weak bones], and poor skin coverage around hip joint);
- inflammatory degenerative joint disease (like rheumatoid arthritis);
- joints with nerve disorders;
- obesity; or
- nerve or muscle disease that may have a negative effect on walking or weight bearing.

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

RISKS & COMPLICATIONS

What are the risks and benefits?
While there can be no guarantee of success, benefits can include the potential relief of pain and potential return of normal use of the hip. There is also the possibility for this type of ceramic/ceramic implant to outlast metal/plastic implants currently being used.

Although ceramic style components have been reported to last the life of the patient, there are also reports of failure of the ball or socket portion in a small fraction of those patients who receive them.

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

- Particles of hip implant materials, cement, and bone may be generated by contact between the hip implant parts and bone. Particles may be caused in different ways including "surface bonding" (adhesive wear), "surface scraping" (abrasive wear), and/or component breakage. These particles may cause local responses such as bone breakdown, or migrate to other parts of the joint and cause painful tissue irritation.

- Particles generated in the hip joint can cause further damage if they get in between the moving parts of the implant. This damage makes more particles that can cause breakdown of the bone.
- Bone breakdown and loss may occur around the hip implant parts due to reaction to particles and can lead to future problems requiring removal or replacement of the hip implant parts.
- Wear of ceramic hip implants has been reported following surgery. Higher rates of wear may be caused by particles of cement, metal, or other debris which can cause abrasion of the joint surfaces. If your implant has excessive wear, your doctor may want to replace it with a new implant.
- The presence of any implant material can be seen as foreign and the body tissue may react to it. Although rare, metal allergy reactions in patients following hip surgery have been reported. Possible consequences include skin irritation, painful joint, implant loosening, infection and revision surgery.
- Nerve damage has been reported, and may occur as the result of having hip surgery.
- Hip parts can loosen or migrate (move) due to trauma or improper attachment.
- Dislocation and partial dislocation of hip parts can result from improper positioning or loss of position of the components. Muscle and cartilage laxity (slackness) can also contribute to these conditions.
- Infection can lead to failure of the hip joint replacement.
- Hip replacements can result in gastrointestinal (GI) or urinary complications.
- While rare, fatigue fracture (breakage) of the hip implant parts can occur as a result of high body mass index (large height and weight) resulting in large loading forces, the impact of trauma, strenuous activity, improper position, or length of time implanted in the body (service life).
- While rare, some complications of hip replacement surgery may be fatal.

What might increase the risk of failure?

- patients who are unable to follow instructions given by health care providers
- noticeable bone loss, severe decreased bone mass (osteoporosis)
- disorders that interfere with the body's ability to absorb nutrients, which may slow bone formation
- softening of the bones
- wound healing difficulties (e.g., chronic pressure ulcers, end-stage diabetes, severe protein deficiency, malnutrition [not enough food to serve the body's needs] and/or smoking)
- allergic reaction to implant material

Exactech® NOVATION™ Ceramic Articulation Hip System (AHS)

What are the possible complications during surgery or shortly after?

- pain
- thighbone (femoral) or pelvis (acetabular) perforation (hole in hip parts), or broken bones
- broken bone while seating the device
- damage to blood vessels
- temporary or permanent nerve damage resulting in pain or numbness of the affected leg
- undesirable shortening or lengthening of the leg caused by improper selection of the implant size
- intraoperative damage to bone or soft tissue in the joint area
- cardiovascular disorders including blood clots in the veins or lungs, or heart attack
- pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue"
- delayed wound healing
- infection
- problems with early healing of the tissues
- problems with the anesthesia
- while rare, some complications may be fatal

What kind of problems could happen later on?

- pain
- hip (implant) dislocation
- a small piece of the thigh bone where the muscles attach could be pulled away as a result of excess muscular tension, early weight bearing, or weakening during surgery
- the top portion of the thigh bone could break due to weak reattachment and/or early weight bearing
- problems with either leg because of differences in leg lengths or due to inadequate muscle tone
- broken bone by trauma or excessive loading (weight or force), particularly in the presence of poor bone quality
- calcium or bone deposits can form around the joint, which may limit motion of the joint
- inadequate range of motion due to improper selection or positioning of hip parts
- joint surfaces can wear excessively or the implant itself could loosen or break

What alternatives are there?

- Total Hip Replacement with another commercially available implant or implant parts made of different materials. Choices available include a metal femoral head and a plastic liner, a metal femoral head and a metal liner, a ceramic femoral head and plastic liner, or another hip replacement system consisting of a ceramic ball and a ceramic liner.
- Non-surgical treatment. Your health care provider may also recommend particular exercises, reduced activity, bracing, medicine or a combination of any of these treatments.
- Surgical treatments that do not involve the use of an implant such as hip fusion surgery. This surgery involves attaching the thigh bone to the hip (pelvis) causing the two bones to heal together. In this scenario, the hip cannot move.

SURGICAL INFORMATION

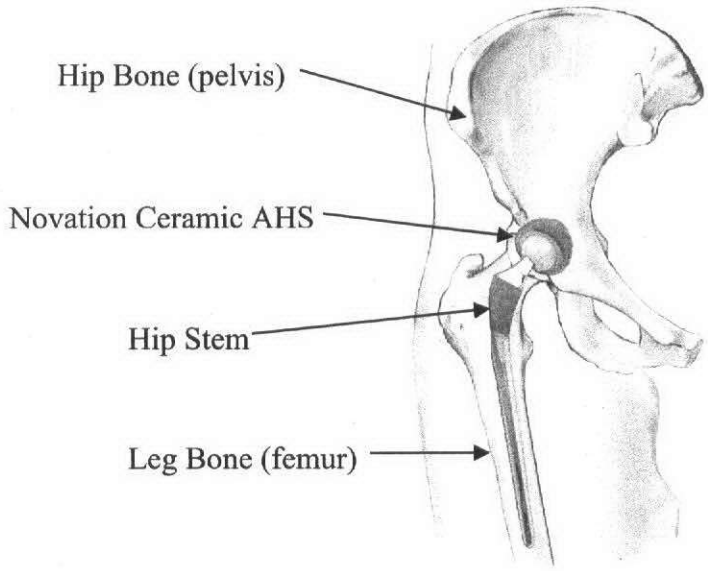
What you need to know before surgery.

- If an allergy or sensitivity to the implant material is suspected, appropriate tests should be made prior to material selection or implant procedure.
- Consult with your health care provider regarding continuing use of any existing medications prior to surgery.
- Transportation away from the hospital should be arranged for after the surgery, since driving immediately after a hip replacement is not possible due to medications and mobility limitations.

Exactech® NOVATION™ Ceramic Articulation Hip System (AHS)

What happens during the surgical procedure?

The surgical procedure involves an incision through the skin and access to the hip joint through the muscles overlying the hip while under anesthesia. The typical surgery time is about an hour. After the surgeon exposes the hip, your diseased hip ball (femoral head) is removed. It is replaced with an artificial ball on a stem that goes down into the hollow part of the thighbone and may be pressed into place or cemented using a special acrylic cement. The hip socket is prepared by machining it (reaming) using special instruments to make it the right size and shape and a metallic shell is pressed into place and sometimes further secured with bone screws. A cup-shaped liner is then placed in this shell forming the socket part of the ball and socket replacement. The ball and socket are then placed together to complete the implant procedure and the tissues are repaired to finish the surgery. See the figure below to visualize how the implant fits in the body:



Hip Implant in Body

What should you expect after surgery?

You can expect to stay in the hospital for 2-3 days, depending on the complexity of your surgery. Immediately after surgery, pain will spread outward from your hip joint and may worsen with motion. Pain management will be based on how much pain you feel and medication will be given according to the recommendations of your health care provider. Occasionally, a special stocking may be worn to control swelling, or drainage tubes may be connected to the incision to keep the joint from collecting excess fluid. Until your health care provider says you can walk on your own, you must have someone to help you walk to the toilet or perform other activities of daily living that may cause too much motion of the hip. Your health care provider will recommend standing and walking as soon as your post-surgical condition allows it. Post-operative visits should be scheduled with your health care provider.

GENERAL WARNINGS & PRECAUTIONS

Important information to know if you already have a hip replacement.
Avoid choosing this hip replacement if you need to have your doctor remove and replace your old hip implant. The Novation™ Ceramic Articulation Hip System has not been studied to see if it works well to replace an old hip replacement. Use of this hip to replace an old hip implant may not work for you and may harm you.

Importance of following care instructions.
You will play an important role in the overall success of your new implant. There are limits to what you can do after you receive your surgery. You will need to protect your hip implant from full weight bearing until your health care provider has directed you otherwise. Your health care providers will give you instructions to follow as you heal. Instructions will include progressing through modest levels of activity, such as walking slowly, during the healing process to protect the joint, then moving on to activities you have enjoyed before your surgery. You will be instructed when to begin unrestricted walking and other activities including swimming, biking, etc. "Impact" activities such as jogging or skiing should be avoided. Check with your health care provider to be sure of the lifestyle changes you will be required to make. It is important that you understand what you can and cannot do after surgery in order to prevent excess weight and stress on your bones and implants.

During rehabilitation and after healing the implants can break or become damaged from strenuous activity such as heavy lifting, or trauma that might result from a fall. Loosening of the hip parts can result in increased production of wear particles, as well as damage to the bone, making another surgery (revision) more difficult. Particles created during implantation of the prosthesis or by wear after the surgery may migrate to other parts of the body and cause breakdown of the bone and/or irritation of the joint tissues.

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

When should you contact the doctor?
You should contact your doctor if you experience any of the following symptoms:

- redness, swelling, or drainage from around your incision;
- an unexplained fever (temperature over 100 degrees Fahrenheit or 38 degrees Centigrade) or chills that last more than a day;
- severe hip pain that is not relieved by your pain medicine;
- any unusual shortening or rotation (turning) of your leg;
- any sudden swelling in your thigh or calf; or
- unusual sounds (like clicking or squeaking) in you hip joint during movement.

Will the hip implant set off security systems?

Your implant may set off airport security systems because some of the parts are metallic. Your health care provider can give you a card or other type of note to show to the authorities. You may wish to notify the screening authorities as you proceed through inspection.

Who do I contact for additional information?

For further product information, please contact:

Exactech, Inc. - Customer Service,
2320 N.W. 66th Court
Gainesville, Florida 32653, USA

Phone: (352) 377-1140,
Toll Free: (800) 392-2832
Fax: (352) 378-2617.