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FOR THE PERSONAL
ATTENTION OF THE SURGEON

PROSTALAC® (Prosthesis of Antibiotic-Loaded Acrylic Cement) HIP TEMPORARY PROSTHESIS

Humanitarian Device: Authorized by Federal Law U.S. for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin and tobramycin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s). The effectiveness of this device for this use has not been demonstrated.

Caution: Federal Law U.S. restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

PRODUCT DESCRIPTION

The Prosthesis of Antibiotic-Loaded Acrylic Cement, also known as the PROSTALAC Hip Temporary Prosthesis system, is comprised of a core femoral implant, a modular femoral ball head, a one-piece, ultrahigh molecular weight polyethylene (UHMWPe) acetabular component, a polymethylmethacrylate (PMMA) stem centering device, and Endurance® Medium Viscosity Bone Cement (PMMA) mixed with tobramycin sulfate and vancomycin hydrochloride antibiotics.

Please refer to the Surgical Technique Manual for detailed instructions on the intraoperative construction of the PROSTALAC Hip Temporary Prosthesis device.

INDICATIONS FOR USE

The PROSTALAC™ Hip Temporary Prosthesis is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin and tobramycin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s).

CONTRAINDICATIONS

The following conditions are contraindications for the use of the PROSTALAC Hip Temporary Prosthesis implant system:

1. Patient is immunocompromised, nutritionally deficient and/or is otherwise systemically compromised to the degree that a two-stage excision arthroplasty is contraindicated;
2. destruction of the proximal femur that precludes support of the PROSTALAC temporary femoral prosthesis;
3. destruction of acetabulum that precludes support of the temporary acetabulum component;
4. loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified;
5. poor bone quality, such as osteoporosis, where, in the physician's opinion, there could be considerable migration of the prosthesis and/or a considerable chance of fracturing the femoral shaft;
6. insufficient bone stock to allow for a sound biomechanical reconstruction for a permanent total hip replacement prosthesis, i.e., resection arthroplasty or Girdlestone's procedure is required;
7. infection cannot be confirmed;
8. unable to remove all infected THR device components;
9. pathogens are resistant to antibiotics to be locally administered to treat the infection;
10. patient sensitivity to antibiotics to be locally administered to treat the infection;
11. systemic infection or a secondary remote infection is either confirmed or suspected; and/or
12. patient does not have a total hip replacement prosthesis, e.g., hip infection is secondary to septic arthritis, trauma, ORIF, osteotomy, arthrodesis, etc.

WARNINGS

The patient's wound drainage fluids should not be re-infused during or following the PROSTALAC Hip Temporary Prosthesis surgery. Wound drainage following PROSTALAC Hip Temporary Prosthesis surgery contains high levels of antibiotics eluted from the device and re-infusion of this fluid has the potential for the introduction of large quantities of antibiotics into the systemic circulation.

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Peak and trough serum concentrations of tobramycin sulfate and vancomycin hydrochloride should be monitored periodically during intravenous administration of these antibiotics in the presence of the PROSTALAC Hip system to avoid potentially toxic levels. Tobramycin sulfate and/or vancomycin hydrochloride administered by the intravenous route have the potential for causing ototoxicity and nephrotoxicity. The PROSTALAC Hip system should be used with caution in patients who may be predisposed to tobramycin sulfate and vancomycin hydrochloride toxicity, since combined PROSTALAC and systemic administration of these antibiotics may result in higher than expected serum levels. Patients with the risk factors of advanced age, preexisting renal dysfunction, dehydration, receipt of large cumulative antibiotic doses, or concurrent or sequential use of other nephrotoxic and/or neurotoxic antibiotics are at increased risk of toxicity. Please consult the product labels for tobramycin sulfate and vancomycin hydrochloride for a complete list of adverse events, as well as for information regarding systemic administration.

The PROSTALAC Hip Temporary Prosthesis should not be re-implanted. Even though the implant may appear undamaged, it may be fatigued from previous stresses and may have developed microscopic imperfections, which may lead to implant failure.

PRECAUTIONS

Consult the product labels for Endurance® Medium Viscosity Bone Cement for specific Contraindications, Warnings, Precautions, and Instructions for Use for this component of the PROSTALAC Hip Temporary Prosthesis.

The patient must be informed as to the necessity of adherence to the physician's instructions regarding protected weight bearing throughout the implantation period and the need for additional surgery to explant the PROSTALAC Hip Temporary Prosthesis. The PROSTALAC Hip Temporary Prosthesis has been designed to withstand approximately three months of protected weight bearing for a person being treated for infection of his/her total hip joint replacement prosthesis and is not intended as a permanent hip prosthesis implant. The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the PROSTALAC Hip Temporary Prosthesis:

1. Obesity
2. Heavy labor
3. Active sports participation
4. Likelihood of falls
5. Alcohol or drug addiction
6. Unprotected weight bearing

Keep prosthesis in the supplied protectors during sterilization cycle and until implantation. Do not allow contact of prosthesis with hard objects.

ADVERSE EVENTS

ADVERSE EVENTS FROM THE RETROSPECTIVE CLINICAL STUDY

Adverse effects of the PROSTALAC Hip Temporary Prosthesis were determined from a single center, retrospective study of 135 PROSTALAC Hip cases. The frequencies of the complications reported for the intraoperative, interoperative and postoperative time intervals are provided in the following tables:

PROSTALAC Hip Surgery Intraoperative Complications
(135 Cases)

Type	Frequency	
Femoral Component Removal	16	(11.9%)
Femoral Fracture	8	(5.9%)
Difficult Bone Cement Removal	7	(5.2%)
Acetabular Component Removal	4	(3.0%)
Vascular Damage	4	(3.0%)
Deficient Femoral/Acetabular Bone	3	(2.2%)
Acetabular Defect	2	(1.5%)
Femur Perforated	2	(1.5%)
Sinus Excision	2	(1.5%)

Other PROSTALAC Hip Surgery interoperative adverse events included: bone cement retained; nerve damage; acetabulum perforated; difficult insertion of acetabular component; cardiac arrest; fat embolism; difficult removal of antibiotic beads; trochanter avulsed; draining abscess; difficult dislocation of hip; tight cable grip; difficult screw removal (broke); cerclage wire removal; extended osteotomy of femur; fracture (type not specified); femoral prosthesis reinserted; allograft required; and antibiotic beads required.

Second Stage Surgery Intraoperative Complications
(118 Cases)

Type	Frequency	
Femoral/Acetabulum Bone Grafts	7	(5.9%)
PROSTALAC Removal Difficult	5	(4.2%)
Femoral Fracture	3	(2.5%)
Acetabulum Fracture	2	(1.7%)
Acetabular Defect	2	(1.7%)
Heterotopic Bone	2	(1.7%)

Other Second Stage Surgery Intraoperative adverse events included: femoral defect; femoral component retained; instability; and poor bone stock.

***Interoperative Operative Site Complications**
(118 Cases)

Type	Frequency	
Recurrent or Persistent Infection	17	(14.4%)
PROSTALAC Reimplanted	8	(6.8%)
Dislocation/Subluxation	6	(5.1%)
Fracture	5	(4.2%)
†Wound Problem	5	(4.2%)
Pain	2	(1.7%)
Bone Cement Fracture	2	(1.7%)

Other *Interoperative Operative Site adverse events included: heterotopic ossification; acetabulum loosening; femoral loosening; skin reaction; nerve damage; patient fell; and wire removal.
*Defined as Time Interval Between PROSTALAC Hip and Second Stage Surgeries
†Categorized as Dehiscence, Necrosis and Superficial Infection.

***Interoperative Systemic Complications**
(118 Cases)

Type	Frequency	
Cardiovascular	11	(9.3%)
Gastrointestinal	8	(6.8%)
Genitourinary	6	(5.1%)
Hematological	3	(2.5%)
Central Nervous System	3	(2.5%)
Thrombosis/Thrombophlebitis	2	(1.7%)
Death	2	(1.7%)

Other *Interoperative Systemic adverse events included: endocrine/metabolic; swelling of leg; vasovagal episode; contralateral hip revision; optic neuropathy; psychosis; orbital fracture from fall; depression; knee infection; contralateral thigh abscess; skin rash; oral thrush; and respiratory.
*Defined as Time Interval Between PROSTALAC Hip and Second Stage Surgeries

**Postoperative Operative Site Complications
(112 Cases)

Type	Frequency
Dislocation/Subluxation	15 (13.4%)
Pain	11 (9.8%)
Persistent or Recurrent Infection	13 (11.6%)
†Wound Problem	9 (8.0%)
Partial or Complete Removal/Revision of Prosthesis	8 (7.1%)
Painful/Broken Cerclage Wires	5 (4.5%)
Fracture	4 (3.6%)
Patient Falls	4 (3.6%)
Trochanter Nonunion	4 (3.6%)
Hematoma	2 (1.8%)
Heterotopic Ossification	2 (1.8%)
Femoral Component Loosening	2 (1.8%)
Bone Cement Fractured	2 (1.8%)

Other **Postoperative Operative Site adverse events included: needle biopsy; bone cement extruded; bone screw failure; instability; and pain.
**Defined as Time Interval Following the Second Stage Surgeries
†Categorized as Dehiscence, Necrosis and Superficial Infection.

**Postoperative Systemic Complications
(112 Cases)

Type	Frequency
Cardiovascular	9 (8.0%)
Genitourinary	8 (7.1%)
Pain (Shoulder, Knee, Contralateral hip)	6 (5.4)%
Death	4 (3.6%)
Revision/Removal of Contralateral Hip	4 (3.6%)
Musculoskeletal	3 (2.7%)
Respiratory	3 (2.7%)
Central Nervous System	2 (1.8%)
Tibia Fractured	2 (1.8%)
Femur Fractured (Contralateral)	2 (1.8%)
Contralateral Hip Replaced	2 (1.8%)
Gastrointestinal	2 (1.8%)

Other **Postoperative Systemic adverse events included: endocrine/metabolic; hematological; contralateral knee replaced; hardware removal of contralateral hip; prostate removed; unexplained fever; edema; delirium; cataracts; knee aspirated; cancer; trochanteric bursitis of contralateral hip; and infection from IV.
**Defined as Time Interval Following the Second Stage Surgeries

POTENTIAL ADVERSE EVENTS

Many of the known or potential adverse effects or complications associated with single-stage exchange arthroplasty and two-stage excision arthroplasty for the treatment of infected THR prostheses are also associated with the PROSTALAC Hip temporary prosthesis implant system.

General Surgical Risks

Cardiovascular disorders including: venous thrombosis, pulmonary embolism, transitory hypotension, arrhythmias and myocardial infarction, and/or anesthesia-related adverse effects.

Device Risks

Local or systemic toxicity from the eluted antibiotics delivered to treat the infection; incomplete removal of necrotic and/or avascularized bone and other tissues, bone cement, previously implanted prosthetic components, fixation and/or reinforcement devices, e.g., cerclage wires, cement restrictor devices, etc., thereby increasing the likelihood for a recurrent or persistent hip infection; inability to eradicate the pathogen(s) due to resistance to, or ineffectiveness of, the vancomycin hydrochloride and tobramycin sulfate eluted from the PMMA; and/or the inability to regulate the dose or treatment duration of the locally administered antibiotics; and decreased mechanical strength of the PMMA due to the quantities of antibiotics contained within the PMMA.

Hip Joint Surgery Risks

Risks known or potentially associated with THR prosthesis surgery are also applicable to surgery with the PROSTALAC device. Adverse effects and complications that may result from this surgery include: Femoral and/or acetabular perforation; fractures of the femur or bones of the pelvis necessitating internal fixation; breakage of the prosthetic device components; damage to blood vessels; temporary or permanent nerve damage resulting in weakness, pain or numbness of the affected extremity; difficulty with insertion of the permanent hip prosthetic device components and/or difficulty with removal of the PROSTALAC Hip at the second stage surgery; subluxation and/or dislocation of the hip joint implant components; arthrofibrosis; limb-length discrepancy; phlebitis and thrombophlebitis; hematoma; delayed wound healing; wound problems (dehiscence, necrosis and superficial infection); and extensive blood loss.

CLINICAL STUDIES

A retrospective study was conducted on a series of patients implanted with the PROSTALAC Hip Device at the University of British Columbia (UBC), Vancouver, British Columbia, Canada, between November 1989 and September 1998. The study consisted of 135 hips in 125 patients with confirmed or suspected infections of their hip replacements.

There were 66 PROSTALAC Hip cases in men and 69 cases in women. The mean age was 65.8 years (range: 27.2 – 87.7 years). All patients had confirmed infections either from cultures obtained from aspiration prior to surgery and/or from cultures obtained during the PROSTALAC Hip surgery. There were 37 cases that grew out more than one pathogen species. Staphylococcus was the pathogen confirmed prior to surgery in 76/122 cases, 62.3%.

A variety of antibiotics were used in the construction of the PROSTALAC Hip Temporary Prosthesis device, including vancomycin, tobramycin, gentamicin, streptomycin, penicillin, ampicillin, cefuroxime, ceftizoxine, and cefamandol. Vancomycin or tobramycin was used in 110/135, or 81.5%, of the cases, and the vancomycin and tobramycin combination was used in 89/135, or 65.9%, of the cases. The average time between the PROSTALAC Hip implantation procedure and the second-stage surgical procedure was 4.6 months (range = 0.1 - 41.6 months). The 7 cases that retained the PROSTALAC Hip implants or died prior to the second stage were not included in these figures. The mean postoperative follow-up was 13.1 months.

Treatment success is defined as no growth of a microorganism on any culture obtained from the operative site during the second stage surgery. The sponsor reported that 96/116 (82.8%) cases were treatment successes. There were 19 cases that were not deemed eligible for clinical success determinations. Two did not have cultures taken at the time of the second surgical procedure, and 17 did not undergo the second surgical procedure and either retained the PROSTALAC Hip device or died prior to the second stage surgery. For the 116 eligible cases, 112 received a total hip prosthesis and 4 underwent Girdlestone resection arthroplasties.

Clinical success is defined as no growth of a microorganism on any culture obtained from the operative site during the second stage surgery and no reoperations resulting from a recurrent or persistent infection of the affected hip at a minimum of one month postoperatively. There were 89/97 (91.7%) cases that were clinical successes. There were 38 cases that did not meet the eligibility criteria to determine clinical success: 17 did not undergo a second surgery, 6 had Girdlestone resections, and 15 had insufficient follow-up for review.

The complications were reported in the ADVERSE EVENTS section above. The 66 intraoperative complications for the first-stage PROSTALAC Hip surgery included only one complication related to the PROSTALAC Hip device (difficulty inserting the acetabular component), while the remainder were complications commonly experienced in revision surgeries.

There were 25 second-stage intraoperative complications in 22 cases. In one case, the cement mantle disassociated from the core stem component. The remaining complications, e.g., acetabular and femoral fractures or additional bone graft requirements, are commonly experienced in revision hip surgery due to the presence of diminished bone stock.

The interoperative complications included 6 dislocations or subluxations of the PROSTALAC Hip. There were 5 femoral fractures. One patient had radiographic evidence of loosening of both components and was treated with observation only. One patient had a dermatological reaction to the vancomycin eluting from the PROSTALAC Hip. This was treated with oral and topic steroid medication. There were 5 patients with wound problems, such as dehiscence, necrosis, and superficial infection.

There were 17 recurrent or persistent infections in 12 cases. Three of these cases required a second PROSTALAC Hip implantation, two had the PROSTALAC Hip removed, two had aspirations, one had an incision and debridement, one had insertion of antibiotic beads, two had courses of antibiotics, and one was observed. The postoperative period, there were 4 fractures in the postoperative time period. One fracture was treated with open reduction with internal fixation (ORIF), and the others were treated with braces.

There were 15 dislocations or subluxations in 9 cases during the postoperative interval . The 20 operative site complications categorized as "other" included two cement fractures and one extruded cement. The remainder do not appear to be related to the PROSTALAC Hip device. The 20 systemic complications categorized as "other" included four cases of total hip revision, three total hip replacements, and three cases with hip pain.

There were 33 reoperations in 29 cases performed in the interoperative and postoperative intervals. There were eight reoperations for implantation of another PROSTALAC Hip. There were six cases re-implanted for recurrent or persistent infections, one for dislocation, and one for acetabular instability. One of the recurrent/persistent infections had antibiotic beads implanted prior to the re-implantation of the PROSTALAC Hip. The remaining reoperations in the interoperative interval included incision and debridement (1), cerclage band removal (1), arthrogram and biopsy (1), and hip aspiration (1).

In the postoperative interval, there were 20 reoperations. There were three acetabular revisions, one femoral revision, and four revisions of both components. Components were revised for the following: Four cases were revised for recurrent/persistent infections, two for dislocations or subluxations, one for acetabular component failure, and one was not specified.

The causes for the remaining postoperative reoperations were: Four cases for cerclage wire removal, two cases of biopsy/arthrogram, one case for ORIF, one case for hip aspiration, one case for insertion of antibiotic beads and one case for an open reduction for dislocation. One case underwent two reoperations of the ipsilateral knee joint to remove cement fragments that migrated from the PROSTALAC Hip device during the postoperative time interval.

There were six patients who died during the observation period: two during the interoperative period and four in the postoperative period. None of the deaths were device-related.

The results of the retrospective study were compared to a literature control group (see Appendix for the literature control references). The clinical success rate and treatment success rate for the PROSTALAC Hip treatment group were 92% and 83%, respectively, compared to 88% and 77% for the literature control group. There were no differences between the PROSTALAC Hip group and the control group for persistent/recurrent first or second stage infections, or combined first and second stage infections, and no differences in the death rates.

INFORMATION FROM THE LITERATURE

Additional information supporting the safety and probable benefit of the PROSTALAC Hip Temporary Prosthesis was found in the literature.

PATIENT COUNSELING INFORMATION

See the Patient Labeling document.

CONFORMANCE TO STANDARDS

The following are voluntary standards that apply to the PROSTALAC Hip Temporary Prosthesis.

ASTM F75-98	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R300075).
ASTM F648-98	Standard Specification for Ultra-High Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F983-86	Standard Practice for Permanent Marking of Orthopaedic Implant Components
ASTM F1636-95el	Standard Specification for Bores and Cones for Modular Femoral Heads
ASTM F1814-97a	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F451-95	Standard Specification for Acrylic Bone Cement

HOW SUPPLIED

The charts below detail the sizes and dimensions of the component parts of the PROSTALAC Hip Temporary Prosthesis implants.

Femoral Core Components

Catalogue Number	Offset	Stem Length (mm)	Side
1541-01-000	Standard	120	R/L
1541-06-000	High	120	R/L
1541-13-000	Standard	150	Left
1541-18-000	Standard	150	Right
1541-23-000	Standard	200	Left
1541-28-000	Standard	200	Right
1541-33-000	Standard	240	Left
1541-38-000	Standard	240	Right

Modular Heads

Catalogue Number	Diameter (mm)	Neck Length
1365-21-000	32	+1
1365-22-000	32	+5
1365-23-000	32	+9
1365-24-000	32	+13
1365-25-000	32	+17

Acetabular Cup

Catalog Number	Inner Diameter (mm)	Outer Diameter (mm)
1541-42-320	32	42

Endurance® Medium Viscosity Bone Cement

Catalog Number	Package Size
5450-50-000	40.0 gram unit

Generic Antibiotics (powder only)

Tobramycin sulfate	3.6 grams/package of cement
Vancomycin hydrochloride	1.0 grams/package of cement

Endurance® Bone Cement Requirements (Estimated):

Standard femoral stem, 120mm	1 package of cement
Long femoral stem, 150mm	1 package of cement
Long femoral stem, 200mm	1 package of cement
Long femoral stem, 240mm	1 package of cement
Acetabulum	1-2 packages (depending on individual patient anatomy)

HANDLING INSTRUCTIONS

Keep prosthesis in the supplied protectors during sterilization cycle and until implantation. Do not allow contact of prosthesis with hard objects. Re-sterilization of an unused femoral core component is possible; however, extreme care should be taken while handling the prosthesis. The assembled PROSTALAC device, i.e., femoral core plus antibiotic bone cement, should never be re-sterilized.

A prosthesis should never be re-implanted. Even though the implant appears undamaged, it may be fatigued from previous stresses and may have developed microscopic imperfections, which could lead to implant failure.

Proper handling of any implant is mandatory. Prior to surgical use, a visual inspection of each implant for possible imperfections should be performed routinely. Damage or alterations to the implant may produce stresses and cause defects, which could become the focal point for implant failure. Femoral head protective covers, if used, should be left on until the prosthesis is ready to be used. The stem protective cover, if used, should be removed before manufacture of the PROSTALAC construct. If re-sterilization of the femoral stem component is necessary, the prosthesis should be placed carefully in a metal tray for autoclaving.

STERILITY

Femoral Core Stem and Femoral Ball

The metallic femoral component (core stem) and head (ball) are supplied sterile. If resterilization is necessary, the detachable metal femoral head should be disassembled from the femoral core stem and each component steam sterilized using the following parameters:

Method	Cycle	Temperature	Exposure Time (Min.)
Steam	Gravity	250°F (121°C)	30 minutes
Steam	Gravity	270°F (132°C)	15 minutes
Steam	Vacuum	270°F (132°C)	10 minutes

NOTE: Good Manufacturing Practices (GMP) require that the adequacy of any sterilization procedure must be suitably tested and developed by persons who have training and expertise in sterilization processes. As each type of sterilization equipment has its own operating parameters, individual performance qualifications under actual load conditions with a defined sterilizer-product combination should be performed. This qualification should substantiate the reliability and consistency of the sterilization process. It is critical that the data be generated to ensure that an effective process has been established.

Acetabular Component

The Ultra High Molecular Weight Polyethylene (UHMWPe) acetabular component is supplied sterile. Remove from package, using accepted sterile technique, only after the correct size has been determined. The UHMWPe acetabular component cannot be resterilized and must be discarded.

APPENDIX

LITERATURE REFERENCES

CONTROL GROUP FOR THE RETROSPECTIVE STUDY

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Wilson, MG, Dorr, LD: Reimplantation of infected total hip arthroplasties in the absence of antibiotic cement. J. Arthroplasty, 4: 263-269, 1989.

INFORMATION

Contact the Department of Clinical Research at DePuy Orthopaedics, Inc. or your DePuy representative for further information about this device.

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