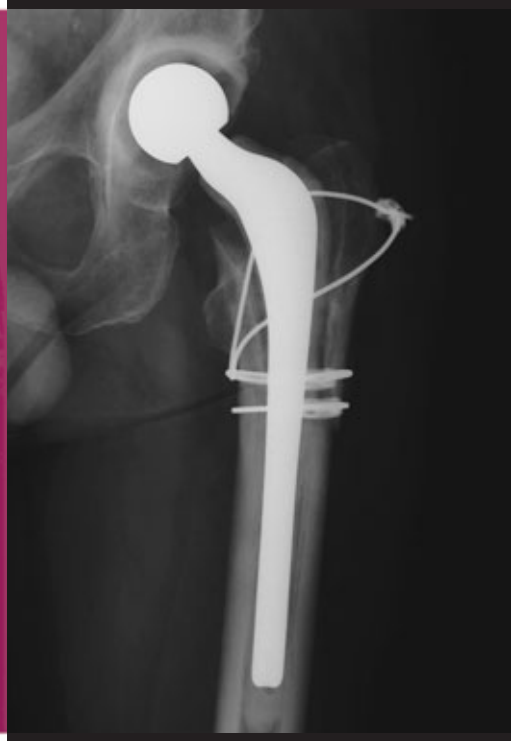
SURGICAL TECHNIQUE

Prostalac® Hip System



- TWO-STAGE TEMPORARY PROSTHESIS
- EFFECTIVE INFECTION TREATMENT
- MAINTAINS HIP MOBILITY

DePuy
a Johnson & Johnson company

250,000 REASONS
FOR THE PROSTALAC HIP SYSTEM

INTRODUCTION

In the United States, over 250,000 joint replacements are performed every year, with infection rates estimated at 1-2 percent for primary joint replacements and 3-4 percent for revision cases.[1,2]

Revisions of infected total hip arthroplasty have had variable success and can be performed in single or double-stage procedures using antibiotics to treat the infections.

APPROACHES

Overall results of single-stage procedures are generally poor, with an infection rate of up to 30 percent.[1] A double or two-stage approach has been shown to have a higher success rate, but lack of a prosthetic as a spacer to maintain the normal anatomy can create problems during the first stage. Problems can include severely limited mobility leading to muscle atrophy. Contractures (80-100 percent) can also develop bone loss, potentially distorting the normal anatomy, which can create difficulties in placing the new prosthesis in the second stage.[1]

PROSTALAC APPROACH

To prevent the complications in the two-stage approach, the **Prosthesis of Antibiotic-Loaded Acrylic Cement**, or the **Prostalac**® *(prost-allik)* Hip Temporary Prosthesis System, was developed to function temporarily as a total hip replacement (THR). It was also designed as a carrier device for local delivery of antibiotic drugs within the periprosthetic space following surgery for the explantation of an infected total hip prosthesis. This implant system acts as an articulating spacer with a structure and function similar to the traditional total hip arthroplasty components and has a proven high success rate (90-95 percent) for eradicating infection.[2] The Prostalac hip provides a means for limited mobility of the patient following excision arthroplasty surgery, eliminating the need for traction and reducing the chances of muscle atrophy, stiffness or bone loss.

The Prostalac hip is designed to remain in situ for approximately three months after which a second surgery is performed for implantation of a permanent THR prosthesis. The design of this device requires that it be protected from the stresses associated with full weight bearing throughout the three-month implantation period.

THE PROSTALAC HIP PROVIDES:

Effective treatment of sepsis; reduces patient morbidity and rehabilitation from prolonged immobility; and permits a less complicated approach to placement of the final arthroplasty components.

PROSTALAC HIP SYSTEM

The Prostalac hip is comprised of a cobalt chrome alloy core femoral component, a cobalt chrome alloy modular femoral head, a one-piece polyethylene acetabular component, a PMMA stem centering device and antibiotic-loaded bone cement.

Cobalt chrome alloy was selected for the Prostalac hip femoral component because its greater rigidity transmits stress more evenly throughout the cement mantle. The antibiotic bone cement is made of Smart Set® MV Bone Cement. Tobramycin sulfate (3.6g per 40g of cement) and vancomycin hydrochloride (1.0g per 40g of cement) are the recommended antibiotics.

The core femoral components are available in four stem lengths. The short stem is in a neutral configuration and is available in standard and high offset options. The three long stems are in 150, 200 and 240 mm lengths and come in standard offset left and right configurations. The 32 mm femoral head is available in five offset options providing surgeons with options for the proper tensioning of soft tissues for improved muscle function, implant stability and the ability to adjust leg length for improved mobility and patient comfort.

The one-piece polyethylene acetabular component is available in one size with a 32 mm inner diameter and a 42 mm outer diameter. The component has a snap-fit design that captures the modular femoral head to resist distraction forces occurring between the femoral and acetabular prosthesis.

PREOPERATIVE PLANNING AND ASSESSMENT

Preoperative planning enables the surgeon to prepare for the case and anticipate situations that may arise during surgery. A thorough preoperative plan includes the patient's history, physical examination and radiographical analysis.

PREOPERATIVE PLANNING GOALS

- **Determine the type of infection to be treated**
- **Identify the location of all foreign material and any bone stock deficiency**
- **Choose an appropriate exposure to clearly access the acetabulum and femur, and easily remove all foreign material without devascularizing available bone stock**
- **Choose the Prostalac Hip Temporary Prosthesis femoral component that will be of appropriate size to achieve stability of the stem in the femur as well as stability of the joint itself**
- **Reconstitute a reasonable hip center and achieve satisfactory limb length and femoral offset**

ORGANISM AND ANTIBIOTIC SENSITIVITY

The organism(s) responsible for the infection should be identified before surgery as well as the antibiotic sensitivity profile. This is best accomplished by needle aspiration of the joint under aseptic conditions, with at least three specimens sent for aerobic and anaerobic culture and sensitivity.

RADIOGRAPHS

For accurate templating, obtain high-quality radiographs using a standardized protocol with known magnification. Use magnification markers attached to the patient's leg at the level of the greater trochanter to verify magnification.

The Prostalac hip templates incorporate 20 percent magnification.

Obtain an anterior/posterior (A/P) view of the pelvis with both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. Obtain a direct lateral radiograph for use in determining adequate fill of the femoral intramedullary canal.

ACETABULAR CUP POSITION

Most positioning determinations are made using the A/P radiograph of the hip. The Prostalac hip includes a single cup size and shape. It is placed at the appropriate hip center level using whatever volume of cement is required to achieve this aim. Up to two 40g packets of cement may be required in severe bone deficiency. The recommended position of the acetabular cup is 45 degrees of abduction and 20 degrees of anteversion.

FEMORAL COMPONENT SELECTION

Select the appropriate Prostalac femoral template to determine the likely size of the stem-cement composite and the depth it will need to enter the femur so as to maintain leg length and place the center of the femoral head at a desirable level. Femoral offset should be considered at this point for proper femoral head offset selection.

PROSTALAC HIP REPLACEMENT
STEP-BY-STEP SURGICAL TECHNIQUE

STEP 1—PATIENT POSITIONING

Place the patient in the lateral decubitus position with the affected hip up. Obtain sufficient patient stability prior to draping and surgical preparation. It is imperative that the pelvis remains stable but the affected leg may be mobile. The patient must be in the true lateral position with orientation of the pelvis perpendicular to the table.

STEP 2—INITIAL INCISION

A lateral incision is made, curved from the femoral shaft and middle of the greater trochanter with slight posterior curve above the greater trochanter. The distal extent will depend on the distal extent of foreign material within the femur and surgical approach.

STEP 3—EXPOSING TISSUE

Divide the subcutaneous tissue down to the fascia, split the fascia in line with its fibers curving posteriorly above the greater trochanter into the gluteus maximus. Position a Charnley retractor to hold the deep fascia open exposing the underlying tissues. Divide the trochanteric bursa. At this point, based on preoperative findings, surgeon preference and previous experience, an anterior lateral, posterior lateral, transtrochanteric or extended trochanteric osteotomy approach may be chosen. Whatever the choice, every effort must be made to leave soft tissue attached to the bone so that it will not be devascularized. This is particularly so in the case of an extended trochanteric approach, in which case care should be taken to leave the abductors and vasti attached to the trochanteric and lateral cortex of the femur.

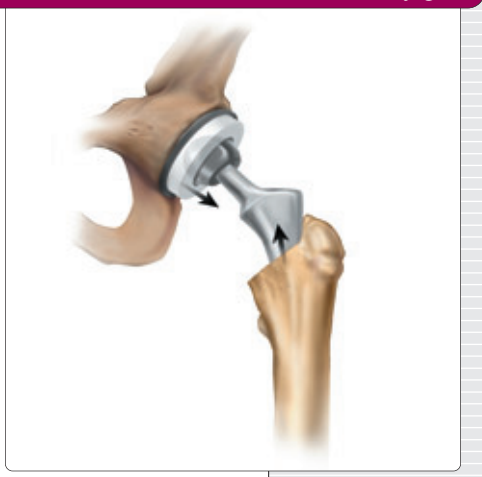
At this point a wide subtotal capsulectomy is next carried out to permit easy dislocation of the hip along with adequate exposure of the acetabular rim and proximal cortex of the femur. A minimum of three synovial soft tissue biopsies should be sent for bacteriologic study. A frozen section, white blood cell count and STAT gram stain may be considered at this point as well.

STEP 4—COMPONENT REMOVAL

Before any of the Prostalac components are prepared or used, remove all existing implanted components, cement and any other foreign material (e.g., trochanteric fixation hardware, etc.) and thoroughly debride the infected hip. This step is essential if a high success rate is to be expected (**Figure 1**).

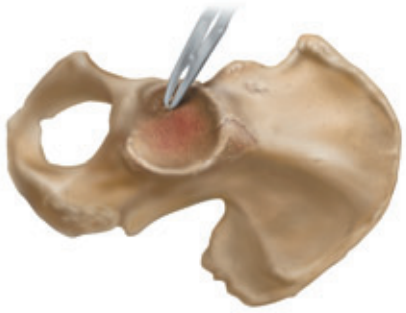
If there is doubt as to the adequacy of cement removal, an intraoperative radiograph can be helpful at this point.

fig. 1



STEP 5—ACETABULAR PREPARATION

fig. 2



Reaming of the acetabulum is not recommended in most cases. It may potentially remove valuable bone and irregularities that are useful for interference fixation of the cement mantle used later in the case.

Using manual tools, remove all foreign material and soft tissue down to bleeding bone and take care to identify and remove any hidden pieces of bone cement (**Figure 2**).

STEP 6—CEMENT MIXING-ACETABULAR COMPONENT

fig. 3

The antibiotic bone cement is prepared using Smart Set MV Bone Cement, tobramycin sulfate and vancomycin hydrochloride, all in powder form.

Proper mixing of the antibiotics and bone cement is critical to the success of this device. The safety and potential benefit of the Prostalac hip has only been demonstrated when used with tobramycin sulfate and vancomycin hydrochloride at the indicated doses.

Recommended Doses	
Antibiotic	**Bone Cement**
Tobramycin sulfate 3.6g powder and vancomycin hydrochloride 1.0g powder	Per Smart Set MV 40g packet

Smart Set MV Bone Cement Requirements	
Implant	**Bone Cement**
120 mm Std/High, 150, 200, 240 mm	1- 40g package of bone cement
Acetabular Cup	1-2 packages (depending on individual patient anatomy)

fig. 4

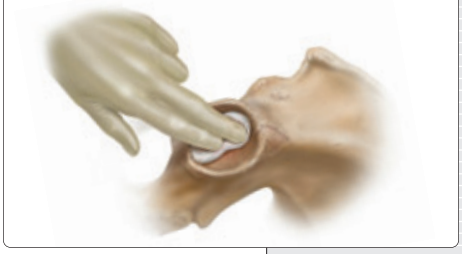
Thoroughly mix one or two 40g bags of Smart Set MV bone cement and the recommended dosage of tobramycin sulfate and vancomycin hydrochloride powders (see chart) ensuring equal distribution of each in an open bowl (**Figure 3**). Mixing is facilitated by adding the powdered cement and powdered antibiotics to a plastic container and shaking it vigorously.

Then add liquid monomer and carefully mix all ingredients by hand with a spatula, pressing the bone cement around the sides of the bowl until all ingredients are blended together (**Figure 4**). The antibiotic-loaded bone cement consistency will be slightly different than bone cement without antibiotics. This is normal and will not affect the setting and performance of the bone cement.

The antibiotic-loaded bone cement will be ready for use when the cement turns into a firm, doughy state, usually about 4-5 minutes after adding the monomer. The cement is ready when it no longer sticks to the surgical gloves.

STEP 7—ACETABULAR CUP INSERTION

fig. 5



Place the antibiotic-loaded bone cement into the acetabulum in the doughy state and shape around the acetabulum. Do not pressurize the cement, as deep intrusion is undesirable. This bone cement procedure is intended to achieve stable, but not rigid fixation by interdigitation and interference fit with the irregularities of the surrounding bone. It also allows easy removal during the second stage, without bone attached (**Figure 5**).

fig. 6

Insert the Prostalac cup into the cement mantle at an appropriate location and at an orientation of 45 degrees of abduction and 20 degrees of anteversion. Use a cup impactor with a 28 mm head impactor to position the cup and apply pressure until the cement has hardened (**Figure 6**).

STEP 8—FEMORAL PREPARATION

fig. 7

Utilize the Endurance broaches to prepare the femoral envelope for optimal fit of the Prostalac hip (**Figure 7**).

To confirm stem size selection, stem trials should be used to determine if a short or long stem is to be used. The long stems have an anterior bow to match the bow in the femur.

120 mm Standard/High Offset Short Stem
Attach the size 1 broach to the Endurance handle and broach down the medullary canal. Continue broaching using progressively larger broaches until reaching the broach size that corresponds to the templated implant size.

150, 200, 240 mm Long Left/Right Stems
If the long stems are to be used, then broach up to the size 3 broach. The long stem mold is based on the size 3 broach.

STEP 9—TRIAL REDUCTION

Trial neck segments and trial modular heads are available to use with the broach, to assess joint stability and range of motion. Perform a trial reduction with a +5 Prostalac head trial to allow for two up or one down adjustment in neck length without using a skirted femoral head. During trial reduction, thoroughly examine range of motion and stability. Refer to the chart at the back of this surgical technique for detailed base offset, neck length and leg length adjustment information.

Trial Neck Selection		
Stem Size	**Broach Size**	**Trial Neck**
120 mm Std	1 to 5	Size 1 Standard
120 mm High	1 to 5	Size 1 High
150, 200, 240 mm Std	3	Size 3 Revision

Note: The Prostalac trial head is slightly smaller in diameter than the final head to allow easy reduction and dislocation since the acetabular component is a snap-fit design.

STEP 10—FEMORAL MOLD PREPARATION

fig. 8

A. Mold selection (Figure 8)

120 mm Standard/High Offset Short Stems
Choose the short mold that matches the last broach size used.

150, 200, 240 mm Long Stems
Choose the left or right size 3 long mold to match the infected side of the hip.

B. Mold Preparation (Figure 9)

Before using the Prostalac molds, apply a thin layer of sterile mineral oil inside the mold to allow easy removal of the implant after the cement has hardened around the implant.

C. Mold Assembly

Do not assemble the molds at this time. The mold will be assembled in Step 12.

fig. 9

STEP 11—CEMENT MIXING-FEMORAL COMPONENT

fig. 10

Using a cement mix bowl, thoroughly mix one 40g bag of Smart Set MV bone cement and 3.6g of tobramycin sulfate and 1.0g of vancomycin hydrochloride powders ensuring equal distribution of each (**Figure 10**).Mixing is facilitated by adding the powdered cement and powdered antibiotics to a plastic container and shaking it vigorously.

Then add liquid monomer and carefully mix all ingredients by hand with a spatula, pressing the bone cement around the sides of the bowl until all ingredients are blended together (**Figure 11**). The antibiotic-loaded bone cement consistency will be slightly different than bone cement without antibiotics. This is normal and will not affect the setting and performance of the bone cement.

The antibiotic-loaded bone cement will be ready for use when the cement turns into a firm, doughy state, usually about 4-5 minutes after adding the monomer. The cement is ready when it no longer sticks to the surgical gloves.

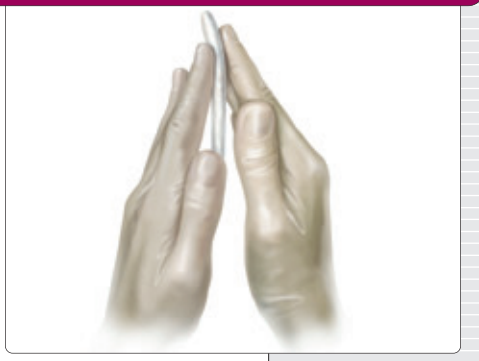
fig. 11

STEP 12—FEMORAL MOLD CEMENT PROCESS

Cement insertion into short/long mold:

When the antibiotic-loaded bone cement becomes doughy, roll the cement into the shape of a tube (**Figure 12**).

fig. 12



Lay the doughy antibiotic-loaded cement into one side of the open mold, ensuring the mold is filled from the bottom to the top (**Figure 13**).

The long mold is used for the 150, 200 and 240 mm stem. Before insertion of the antibiotic bone cement into the long mold, place an appropiate sized cement spacer insert in the bottom of the mold in order to fit the appropriate stem.

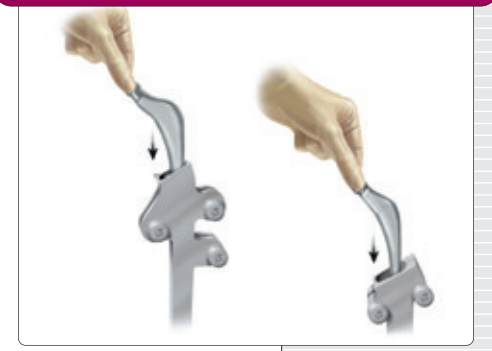
- **150 mm stem—Long insert**
- **200 mm stem—Short insert**
- **240 mm stem—No insert**

fig. 13

Assemble the other side of the mold to the mold that contains the bone cement and lock it down with the mold nuts. Place the closed mold into a vertical position and lock into the instrument base. Continue to push down the center of the mold and hand-pressurize any remaining cement.

Stem insertion into short/long mold:

fig. 14



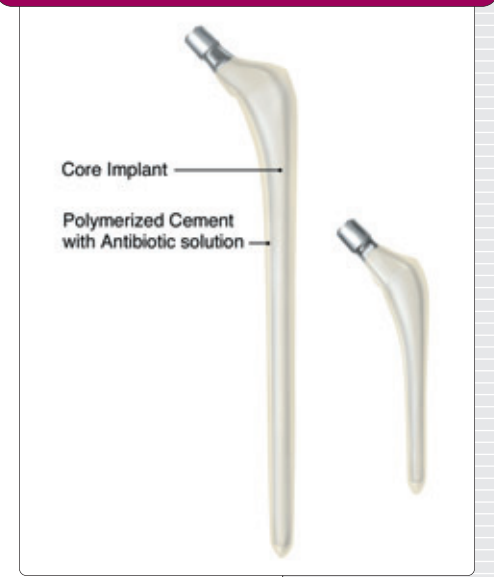
Immediately insert the appropriate short or long stem implant into the opening at the top of the mold and push down until the neck region of the stem reaches the top of the mold (**Figure 14**).

Excess cement may be used to place a thin covering around the neck of the implant, thereby minimizing the area of exposed foreign material. Ensure excess cement is not built up too much around the neck or too close to the taper, as it may interfere with proper seating of the femoral head.

Hold the stem in place to ensure it remains centered in the mold.

Allow the cement to thoroughly harden, disassemble the mold and remove the Prostalac implant (**Figure 15**).

fig. 15



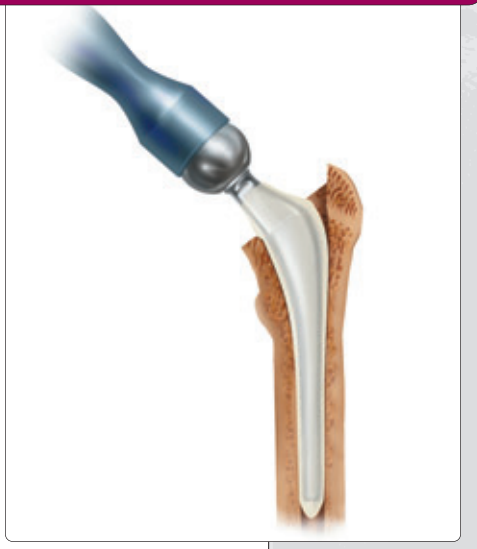
After removing the implant from the mold, remove any excess cement that may have formed around the medial and lateral sides of the stem with a Rongeur.

Note: Prior to insertion of the implant, a PMMA stem-centering device may be used to facilitate the formation of a uniform thickness cement mantle by keeping the core implant centered with the mold instrument during the cement curing process.

Alternatively, the two halves of the mold can be packed with cement and the stem embedded in the cement and the mold assembled around the implant. This can be particularly helpful with the 240 mm stem, as it requires considerable force to insert it into the cement-filled mold. Pliers can then be used to facilitate compression and closure of the mold.

Step 13—FEMORAL INSERTION AND HEAD ATTACHMENT

fig. 16



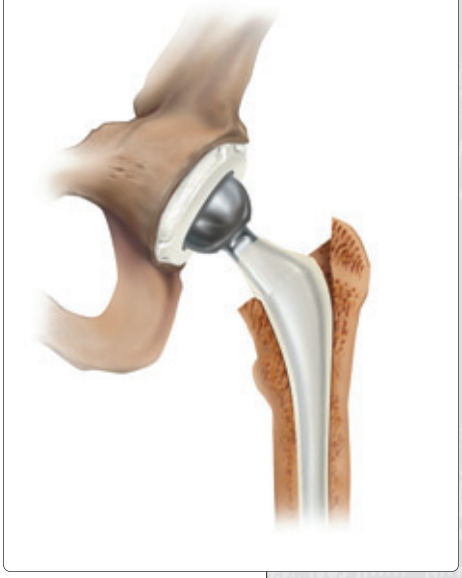
Introduce the Prostalac antibiotic-loaded prosthesis into the canal by hand. Place a femoral trial head on the stem and gently tap with a head impactor to seat the stem in the femoral canal.

Clean and dry the Articul/eze® taper. Manually introduce the appropriate 32 mm head by firmly pushing and twisting the femoral head onto the taper. Engage the head with two to three light mallet taps with the head impactor (**Figure 16**).

The long-stemmed mold can be used to reconstruct severe proximal femoral deficiencies. In this case the stem is implanted into the remnant of the femur and a bolus of cement is packed around the prosthesis bone interface proximally. Limb length is determined by first inserting the stem in the canal and the femoral head in the acetabular cup, restoring limb lengths by longitudinal traction on the limb and marking the stem at the appropriate level. The hip is then dislocated and the implant is fixed with an extra mix of cement packed around the bone prosthesis interface, such that a collar of cement provides for longitudinal stability.

STEP 14—CUP ATTACHMENT

fig. 17



Ensure the bone cement has cured around the all-poly acetabular cup. Insert the femoral head into the cup and snap into place (**Figure 17**).

Prior to reduction, ensure that the inner surface of the acetabular cup is clean and dry. Blood and other fluids will act as a hydraulic block to the snap-fit configuration. Position the femoral head on the mouth of the acetabular cup and apply gentle abduction pressure to engage the snap-fit configuration. Once engaged, it is very difficult to disengage this articulation.

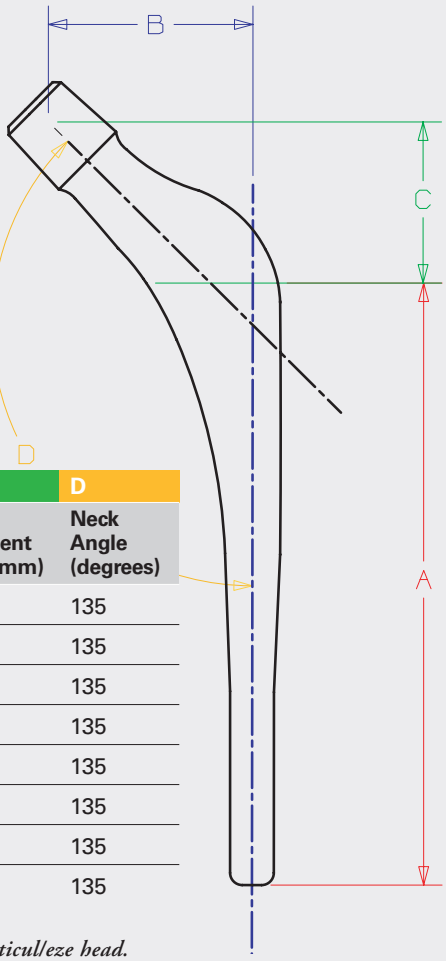
Second-stage Reimplantation

At the time of the second stage reimplantation, the hip can be managed as if it were a failed total hip arthroplasty secondary to aseptic loosening. The surgical exposure and reconstructive implant selection is per surgeon preference. Antibiotic-impregnated cement is not a necessary component of the second-stage reimplantation and cementless implants can be utilized. As the Prostalac stem is often incarcerated in the femur following an extended trochanteric osteotomy, a repeat osteotomy is suggested to facilitate component removal. If not, care should be taken to remove the cement from the shoulder of the prosthesis.

Dislocation of the Snap-fit Acetabular Cup

The snap-fit configuration is robust and must be destroyed to allow for ease of dislocation. This is accomplished by removing a thin strip of polyethylene from the lip of the acetabular cup. Approximately one-third the circumference of the acetabular cup rim should be removed, allowing for dislocation of the hip. The polyethylene is easily separated from the mantle of cement in the acetabulum, and the acetabular cement is then split into pie-shaped pieces to facilitate extraction.

PROSTALAC HIPS
PIECE-BY-PIECE



	A	B	C	D
Size (mm)	Stem Length (mm)	Base Offset (mm)	Leg Adjustment Length (mm)	Neck Angle (degrees)
120 Std	120	35	26	135
120 High	120	41	26	135
150 Std Left	150	44	30	135
150 Std Right	150	44	30	135
200 Std Left	200	44	30	135
200 Std Right	200	44	30	135
240 Std Left	240	44	30	135
240 Std Right	240	44	30	135

Note: All measurements are based on a 32 mm +5.0 Articul/eze head.

Stem Offset	32 mm Head Size				
Size (mm)	+1	+5	+9	+13	+17
120 Std	32	35	38	41	43
120 High	38	41	44	47	49
150 Std Left	41	44	47	50	52
150 Std Right	41	44	47	50	52
200 Std Left	41	44	47	50	52
200 Std Right	41	44	47	50	52
240 Std Left	41	44	47	50	52
240 Std Right	41	44	47	50	52

Cementralizer Information		
Cat. No.	Stem Size	Minimum Recommended Cementralizer (mm)
1376-38-000	120 mm-Size 1 Mold	10.5
1376-38-000	120 mm-Size 2 Mold	10.5
1376-20-000	120 mm-Size 3 Mold	11.0
1376-21-000	120 mm-Size 4 Mold	12.0
1376-22-000	120 mm-Size 5 Mold	13.0
1376-20-000	150, 200, 240 mm-Size 3 Mold	11.0

PROSTALAC HIP
ORDERING INFORMATION

Prostalac Instrumentation	
Cat. No.	**Description**
2541-13-000	Femoral Trial, Size 3, Left, 150 mm
2541-23-000	Femoral Trial, Size 3, Left, 200 mm
2541-33-000	Femoral Trial, Size 3, Left, 240 mm
2541-18-000	Femoral Trial, Size 3, Right, 150 mm
2541-28-000	Femoral Trial, Size 3, Right, 200 mm
2541-38-000	Femoral Trial, Size 3, Right, 240 mm
2541-41-000	Mold Base
2541-42-000	Mold Jaw
2541-43-000	Mold Quick Release Nut
2541-44-000	Mold Handle
2541-51-000	Mold, Size 1
2541-52-000	Mold, Size 2
2541-53-000	Mold, Size 3
2541-54-000	Mold, Size 4
2541-55-000	Mold, Size 5
2541-83-000	Long Stem Mold, Size 3, Left, 240 mm
2541-88-000	Long Stem Mold, Size 3, Right, 240 mm
2541-83-165	Long Stem Mold, 165 mm Insert
2541-83-215	Long Stem Mold, 215 mm insert
2541-91-320	Trial Ball, +1 Neck, 32 mm OD
2541-92-320	Trial Ball, +5 Neck, 32 mm OD
2541-93-320	Trial Ball, +9 Neck, 32 mm OD
2541-94-320	Trial Ball, +13 Neck, 32 mm OD
2541-95-320	Trial Ball, +17 Neck, 32 mm OD
2541-96-000	Extractor Instrument
2541-99-000	X-ray Templates

32 mm Femoral Heads	
Cat. No.	**Description**
1365-21-000	+1
1365-22-000	+5
1365-23-000	+9
1365-24-000	+13
1365-25-000	+17

Smart Set MV Bone Cement	
Cat. No.	**Description**
5450-50-000	40g

Neck Segments	
Cat. No.	**Stem/Size**
2521-01-501	120 mm Std/Size 1 Std
2521-11-501	120 mm High/Size 1 High
2521-23-501	150/200/240 mm/Size 3 Revision

Endurance Instruments	
Cat. No.	**Description**
2521-01-510	Broach Size 1
2521-02-510	Broach Size 2
2521-03-510	Broach Size 3
2521-04-510	Broach Size 4
2521-05-510	Broach Size 5
2521-00-506	Broach Handle
2521-00-508	Broach Extractor

Implants	
Cat. No.	**Size**
1541-01-000	120 mm Std
1541-06-000	120 mm High
1541-13-000	150 mm Std-Left
1541-18-000	150 mm Std-Right
1541-23-000	200 mm Std-Left
1541-28-000	200 mm Std-Right
1541-33-000	240 mm Std-Left
1541-38-000	240 mm Std-Right

All-Poly Cup	
Cat. No.	**Size**
1541-42-320	42 OD x 32 ID

Antibiotics/Sterile Mineral Oil (Supplied by hospital)	
	Description
Tobramycin Sulfate	3.6g powder per 40g Smart Set MV Cement
Vancomycin Hydrochloride	1.0g powder per 40g Smart Set MV Cement
Sterile Mineral Oil	

ESSENTIAL PRODUCT INFORMATION

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

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 acetabular 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 AND PRECAUTIONS

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.

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.

Consult product labels for the bone cement used in conjunction with the PROSTALAC®.

The patient must be informed as to the necessity of adherence to the physician's instructions regarding the 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 system 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 and until implantation. Do not allow contact of prosthesis with hard objects.

ADVERSE EVENTS

Potential adverse effects of the PROSTALAC® Hip were determined from a single center, retrospective study of 135 PROSTALAC® Hip cases. The frequencies of the complications reported are available in the Instructions for Use.

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 a 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 or 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.

References:

1. Gee, R. et al. "Radiography of the Prostalac (Prosthesis with Antibiotic-Loaded Acrylic Cement) Orthopedic Implant. *AJR*. 180 2003:1701-1706.

2. Younger, ASE, C. Duncan, and B. Masri. "Treatment of Infection Associated with Segmental Bone Loss in the Proximal Part of the Femur in Two Stages with Use of an Antibiotic-Loaded Interval Prosthesis." *JBJS*. 80-A 1998: 60-69.

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