Enhanced Stability Constrained Liners

Design Rationale - Surgical Technique

Surgical Technique Allows for Ease of Insertion

Note: Trials are available and should be used prior to implantation.

Important

The Pinnacle System is designed to provide the surgeon with the best options available to enhance range of motion. When the forces of the body exceed the capabilities of the acetabular component, a constrained liner is recommended. The constraint system is designed to improve post-operative stability and aid in the fixation of the implant (e.g., diabetes mellitus, steroid therapies, metabolic disorders or systemic pharmacological treatments).

Precautions

The use of constrained liners should be limited to cases of instability, altered anatomy, or metal wear debris or loose cement particles.

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Failure or disassociation of the locking ring may lead to dislocation or impingement. Do not reinsert the device.

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Discard any device removed after the locking mechanism has been engaged; do not reinsert the device.

Discard or return to the manufacturer any constrained insert if the retaining mechanisms appear damaged or fractured.

Prior to impaction may result in damage to the locking ring or improper seating. Only one attempt to assemble the constraining/reinforcing ring on the constrained acetabular liners should be made. If the device is not made aware that treatment of device dislocation would require the use of constrained acetabular liners without the constraint system.

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Surgical Technique Allows for Ease of Insertion

**Note:** Trials are available and should be used prior to implanting.

1. Insert the Pinnacle™ acetabular cup. A confirmation cut is made in the allograft to allow for accurate position.

2. Utilize predrilled and/or a bone tamp to align the allograft. The allograft should not be grasped with a forceps or reamers and the allograft should not be rotated or translated.

3. Assemble the Pinnacle locking ring over the neck of the implant. The collar should be facing the chamfered edge of the constraining ring. The ring over the neck of the implant should be in the correct orientation. The ring is designed to engage the locking ring.

4. Utilize peripheral and/or dome screws as needed to secure the locking ring.

5. Place the unthreaded constraining ring over the neck of the allograft. The allograft should be seated in the cup to ensure appropriate component placement.

6. With the forceps held against the base of the allograft, acquire the shell. Ensure the shell is a snug fit into the acetabulum. The shell should not be rotated or translated. The shell should not be forced onto the construct.

7. Excessively strong pressure or torque on the locking ring may lead to disorientation of the locking ring. Use caution when inserting screws as needed to secure the locking ring. The use of a torque wrench is recommended to prevent over-tightening.

**Essential Product Information**

- **Indications:**
  - The Pinnacle Constrained Acetabular Liner is indicated for use as a constrained acetabular liner without the use of the constrained acetabular liner.

- **Contraindications:**
  - The Pinnacle Constrained Acetabular Liner is contraindicated for use in patients with a constrained acetabular liner.

- **Precautions:**
  - Do not use the constrained acetabular liner in patients with a constrained acetabular liner.

**Step 1:** The versatility of the Pinnacle System is predicated on a hierarchy of system requirements. They include immediate and long-term fusion, advanced modularity for increased bonding choices, options to address instability, and wear reduction capability. Through the use of Marathon™ (GVF polyethylene) and Ultamet™ inserts.

**Step 2:** The comprehensive offering of the Pinnacle system is intended to help patients and clinicians align the elements above, contributing to a successful clinical outcome.

**Step 3:** While all of the elements which contribute to a successful outcome are outlined, the Pinnacle System will be considered based on the surgeon’s requirements.

**Step 4:** The Pinnacle® Acetabular Cup System was designed to maximize the number of options available to the surgeon, and to provide those options without compromise. The long-term success of any acetabular component is predicated on a harmony of system requirements. They include immediate and long-term fusion, advanced modularity, increased bonding choices, options to address instability, and wear reduction capability. Through the use of Marathon™ (GVF polyethylene) and Ultamet™ inserts.

**Step 5:** The comprehensive offering of the Pinnacle system is intended to help patients and clinicians align the elements above, contributing to a successful clinical outcome.

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**Step 8:** The comprehensive offering of the Pinnacle system is intended to help patients and clinicians align the elements above, contributing to a successful clinical outcome.

**Step 9:** While all of the elements which contribute to a successful outcome are outlined, the Pinnacle System will be considered based on the surgeon’s requirements.

**Step 10:** The versatility of the Pinnacle System is predicated on a hierarchy of system requirements. They include immediate and long-term fusion, advanced modularity, increased bonding choices, options to address instability, and wear reduction capability. Through the use of Marathon™ (GVF polyethylene) and Ultamet™ inserts.
MANAGING INSTABILITY

FIXATION FIRST
Immediate and long-term fixation of the acetabular shell is a foundation for success of THA. Pinnacle cups with MacPore® porous coating have demonstrated Push Out strength across all bearing materials.

ADVANCED MODULARITY
The Pinnacle Acetabular Cup System now provides a variety of modular options to address hip dysfunction. A variety of modular options to address soft tissue laxity.

WEAR REDUCTION
The Pinnacle Acetabular Cup System’s advanced polyethylene liner allows for wear reduction. Marathon polyethylene liners, this taper provides exceptional push out strength across all bearing materials.

MANAGING INSTABILITY
Hip instability and dislocation are some serious complications with THA. A bearing system that provides multiple options is critical in helping surgeons address and minimize instability.

THE CONTINUUM OF STABILITY
The Pinnacle portfolio offers a continuum of products to address hip instability. This product set includes:

- Low wear 32 mm Ultamet metal inserts
- Modular, reconfigurable polyethylene for solutions of low wear and high wear strength
- Modular polyethylene liner for varying hip ranges of motion
- Modular ceramic liner for varying hip ranges of motion
- Modular titanium liner for varying hip ranges of motion

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Managing hip instability can be challenging, as there may be multiple sources of the instability playing either independently or in concert. These sources may include but are not limited to: super pelvic edge:

- Soft tissue or capsular augmentation
- Mechanical restoration of the polyethylene component

By understanding the causes of the instability and the options available to address them within the Pinnacle system, the goal of a more stable construct can be addressed in several ways. It is important to understand the trade-offs associated with the options available to address them within the Pinnacle system, the goal of a more stable construct can be addressed in several ways.

Potential RoM

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ORDERING INFORMATION
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Joint specifications vary by implant item number.

In the clinical situation where normal soft tissue restraint for dislocation has been compromised, the Pinnacle cups series now offers the ES™ product system that provides optimal ligament pullout strength across all bearing materials.

It is important to understand the trade-offs associated with the options available to address them within the Pinnacle system, the goal of a more stable construct can be addressed in several ways.
was achieved.

Component placement of motion to ensure appropriate the construct, and review range of motion.

The acetabular shell.

chamfered edge of the constraining ring over the neck of the implant in the correct orientation. The Place the chamfered constraining ring over the neck of the implant locked onto the head, and lock the con...

Pinnacle shell.

flush with the polished face of the Pinnacle shell.

locking ring is designed to tabs. The pre-assembled Pinnacle revision shell per the ES.

for additional femoral neck length. 1) a femoral head with a +12 neck length extension; 2) a 28mm femoral head when the femoral neck or skirt diameter exceeds 15mm; 3) a constrained acetabular insert. Passive range of motion is restricted to less than 90.

Early or late infection.

Wear or fracture of the polyethylene component

Fatigue fracture of the femoral stem

Early or late loosening of the prosthetic components

Change in position of the prosthetic components

Disabilities of other joints (i.e., knees and ankles).

Tissue reactions to implant corrosion or implant wear debris.

hip replacement.

Congenital dysplasia of the hip that may reduce the bone stock.

Allergic reactions to implant materials

Tumors of the supporting bone structures.

Positioning of the implant.

Metabolic disorders or systemic pharmacological treatments

Marked osteoporosis or poor bone stock.

CAUTION:

The following conditions tend to place patients at an increased risk for the failure of an acetabular component to function properly:

• Severe osteoporosis

• Extreme obesity or marked muscular atrophy

• Active sports participation

• Manual labor

• High level occupation that includes a significant portion of time spent in a seated or standing position

• At-risk population (i.e., patients who have had previous hip surgery, who are already using a hip prosthesis, or who have a history of dislocation or instability). The Pinnacle Constrained Acetabular Liner is indicated for...
MANAGING INSTABILITY

**FIXATION FIRST**
Immediate and long-term fixation of the acetabular shell in flat liner for the foundation of a successful clinical outcome. Pinnacle shells with Pinnacle® porous coating have exceptional 90% to 95% bone-implant survival at 5 years.

**ADVANCED MODULARITY**
The Pinnacle Acetabular Cup System incorporates a patented modular interlocking design for a secure liner locking system in a single stage design. In addition to increasing micromotion of polyethylene liners, this design provides the radiologist with an additional range of motion to assist in seating the liner.

**WEAR REDUCTION**
The Pinnacle Acetabular Cup System’s advanced liner stability for linear wear reduction includes a patented polyethylene liners and enhanced radiographic results.

**MANAGING INSTABILITY**
Hip instability and dislocation are an enormousжаллажүү байланыштуу болушу менен. 1. Механикалык спондилозу функционалык системасын даярдоо. 2. Биостимуляция системасын даярдоо. 3. Повышение стабильности картины. 4. Медикаментозная терапия системасын даярдоо.

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**ES® PRODUCT SPECIFICATIONS**

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MANAGING INSTABILITY

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Fixation First
Intramedullary bed fixation of the available stock head to standard is the foundation of a successful clinical outcome. Pinnacle® porous coating has demonstrated infection survivorship at 4 years.

Advanced Modularity
The Pinnacle® Acetabular Cup System incorporates a polycarbonate femoral interface (PF) type to standard radial bearing options on a single shell design. In addition to decreasing micromotion of polyethylene liners, this feature provides maximum pull-out strength and surface bearing integrity.

Reduction
The Pinnacle® Acetabular Cup System’s advanced instability option for熊 retroversion includes retroversion constrained polyethylene liners and lateralized tabs.

Managing Hip Stability
Hip instability and dedication are an enormous challenge faced with THA. A bearing system that provides multiple options is critical to helping surgeons address and minimize instability. The Pinnacle® Acetabular Cup System offers lateralized femoral head changing, option for polyethylene liners and constrained options, giving surgeons the power to choose a solution that meets each of their intraoperative needs.

Constrained Liners
The Pinnacle® Acetabular Cup System is ideal for addressing and minimizing instability. The various options available to address them within the Pinnacle® System are available in 28-44 mm inner diameters.

• High strength head capture
• Optimum clearance for low wear
• +4 Neutral and +4 10° options
• May be used with uni-polar or bi-polar heads
• Lateralized 2 mm neck difference available

The Pinnacle® Acetabular Cup System incorporates advanced modularity to accept multiple bearing options in a single shell.

• Cross-linked polyethylene liners and Ultamet® metal inserts.
• Marathon® metal-on-metal bearing options for wear reduction include Marathon® metal inserts.
• Bicruciate retaining and posterior stabilized knee designs.

• Porous coating has demonstrated 99.9% fixation survivorship at 4 years.
• High-strength head capture provides up to 151° range of motion.
• Lateralized 2 mm neck difference available

Pinnacle shells with Porocoat®® porous coating have demonstrated 99.9% fixation survivorship at 4 years.

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Macro porous coating to host bone is the foundation of a successful clinical outcome. Pinnacle® porous coating has demonstrated infection survivorship at 4 years.

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MANAGING INSTABILITY

FIXATION FIRST
Irreversible and biomechanical fixation of the acetabular shell is foundational to the foundation of a successful clinical outcome. Pinnacle shell with Mackessy™ porous coating has demonstrated clinically superior performance at 4 years.

ADVANCED MODULARITY
The Pinnacle Acetabular Cup System incorporates a patented Magliner Interface (MI) taper to ascend multiple bearing options on a single shell design. In addition to decreasing micromotion of polyethylene liners, this taper provides improved push-out strength across all bearing materials.

WEAR REDUCTION
The Pinnacle Acetabular Cup System’s advanced linings system for wear reduction includes Marathon cross-linked polyethylene liners and Ultamet metal inserts.

MANAGING INSTABILITY
Hip instability and dislocations are an increasing challenge faced with THA. A bearing system that prevents multiple options is critical to helping surgeons address and minimize instability. The Pinnacle Acetabular Cup System offers lateralization from changing, lipped, large inner diameter and ARD (Anti-Rotational Device) tabs for rotational stability.

Table 1: All-Expanded Orthopaedics

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ES™ PRODUCT SPECIFICATIONS

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Fixation First
Immediate and lifelong fixation of the acetabular shell is foundational to the foundation of a successful clinical outcome. Pinnacle shell with Mackessy™ porous coating has demonstrated clinically superior performance at 4 years.

Neutral
Up to 113° range of motion
• Excellent polyethylene liners
• Ultamet metal inserts
• ±4 Neutral and ±4 10° options
• Optimum clearance for low wear
• 4 mm vertical wall for increased mechanical integrity
• 28, 32, 36, 40, 44 mm IDs

+4 Neutral
• 6 mm greater head coverage
• Redirects articulation of available range of motion
• Lateralizes head center 4 mm
• Provides up to 140° ROM
• 36, 40, 44, 48 mm IDs

+4 10° Neutral
• Provides up to 137° ROM
• +4 Neutral and +4 10° options
• Optimum clearance for low wear
• 4 mm vertical wall for increased mechanical integrity
• 28, 32, 36 IDS

+4 10° Lateralized
• Provides up to 137° ROM
• +4 Neutral and +4 10° options
• Optimum clearance for low wear
• 4 mm vertical wall for increased mechanical integrity
• 28, 32 IDS

Soft tissue or bony impingement
• Low wear and mechanical strength
• Marathon polyethylene liner IDs ranging of low wear and mechanical strength
• Lipped (15°) and constrained liner options

Intraoperative needs.
• Managing instability
• Redirects available range of motion
• Lateralizes head center
• 2– 4 mm Charnley bore provides increased sublaxation jump distance

To address soft tissue laxity
• High strength head capture
• Minimum 6 mm thickness in loaded region
• 28, 32, 36, 40, 44 mm IDs

Managing hip instability can be challenging, as there may be multiple sources of the instability acting either independently or in concert. These sources may include, but are not limited to, suppleness of
...
**Surgical Technique Allows for Ease of Insertion**

**Step 1**
Insert the Pinnacle® primary or revision femoral head with a shell and liner.

**Step 2**
Utilize the 14° neck extension for all options except the Pinnacle® ES cup. This is designed to ensure ease of insertion in the correct orientation. The Pinnacle® ES is designed for constrained acetabular liner insertion.

**Step 3**
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**Step 4**
Utilizing an impactor tip one size below the selected femoral head, reduce the femoral head into the shell with the polished face of the femoral head aligned flush with the polished face of the Pinnacle® shell.

**Step 5**
Place the chamfered constraining/reinforcing ring onto the face of the femoral component or extended type of femoral head where the constraining/reinforcing ring will be engaged; do not reinsert the device. Discard any device removed after the locking mechanism has been engaged.

**Step 6**
With the femoral head engaged but not yet fully seated, reduce the femoral head into the shell and lock the constrained/reinforcing ring in place. Do not insert a trial liner.

**Step 7**
Verify the placement of all components using fluoroscopy or a localizer. The components must be assembled correctly the first time then remove and replace with additional surgery.

**Essential Product Information**

**Contraindications**

1. a femoral head with a +12 neck extension; 2) a 28mm femoral component or extended type of femoral head where the femoral component or extended type of femoral head may not reduce the femoral head into the shell; 3) a 32mm or 36mm femoral head with a head skirt which is used in cases of soft tissue insufficiency. 

**Procedures**

- Failure or disassociation of the locking ring may lead to dislocation of the constrained acetabular insert.
- Improper alignment of the acetabular insert within the acetabular shell may lead to disassociation of the locking ring which is used in cases of soft tissue insufficiency.
- Any infection in or about the hip joint.

**Indications**

- This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see the Pinnacle® Acetabular Cup System Design Rationale, Surgical Technique, and Instructions for Use for complete information.

**CAUTION**

- The following conditions lead to implant failure in the acetabular component: 1) poor bone stock; 2) history of prior dislocation; 3) a history of prior dislocation, bone loss, or both; and 4) high risk of hip dislocation due to a history of prior dislocation, bone loss, or both.

**Precautions**

- Bryan-Agarwal et al. (J Bone Joint Surg Am. 2005;87-A:1199-1207) have recommended that a constrained acetabular shell be used in cases of 1) high risk of hip dislocation, 2) severe deformities leading to impaired fixation or improper component placement, and 3) low bone density. The likelihood of failure adversely affects the fixation of hip replacement implants.

**Design Rationale Surgical Technique**

The Pinnacle® Acetabular Cup System was designed to maximize the number of options available to the surgeon; accommodate those options without compromise. The long-term success of any acetabular component is predicated on a harmony of system requirements. They include an implant and long-term fixation, enhanced modularity by increased bearing choices, options to address hip instability, and wear reduction capability through the use of Marathon® or Ultamet® polyethylene and Osseous implants. The comprehensive offering of the Pinnacle system is intended to help prioritize and deliver the elements above, contributing to a successful clinical outcome.

While all of the elements which contribute to a successful acetabular system are outlined, the Pinnacle® constrained liners will be focused on here.

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