Enhanced Stability Constrained Liners

Design Rationale

Surgical Technique

DePuy
a Johnson & Johnson company

The Pinnacle® Acetabular Cup System was designed to maximize the number of options available to the surgeon, and provide those options without compromise. The long-term success of any acetabular component is predicated on a hierarchy of system requirements. They include immediate and long-term fixation, advanced modularity for increased bearing choices, options to address hip instability, and wear reduction capability, through the use of Marathon® or GVF polyethylene and Ultamet® metal inserts. 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 ESC™ constrained liners will be focused on here.

"The versatility of the Pinnacle System provides a variety of options to manage the unstable Total Hip Arthroplasty. The use of constrained liners should be limited."

Tom Fehring
Ortho - Carolina
Charlotte, NC

THE CONTINUUM OF STABILITY

The DePuy portfolio offers a continuum of products to address hip instability. This product portfolio includes:

- Low wear 36 mm Ultamet metal inserts
- Marathon cross-linked polyethylene for a balance of low wear and mechanical strength
- Marathon polyethylene liner IDs ranging from 28 – 48 mm
- Neutral, +4 Neutral, +4 10 degree face changing, Lipped (15°) and constrained liner options (only available in GVF polyethylene)

Neutral
- 28, 32, 36 IDS
- Minimum 6 mm thickness in dome loaded region

Ultamet Metal Insert
- Lateralized 2 mm
- Available in 36 mm ID to achieve ROM up to 151°
- Optimum clearance for low wear

+4 Neutral
- Lateralizes head center 4 mm to address soft tissue laxity

+4 10 Degree Face Changing
- Lateralizes head center
- Redirects available range of motion

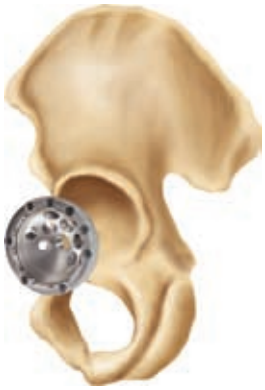
Lipped
- 4 mm vertical wall for increased head coverage
- Redirects available range of motion
- Available in 28 & 32 IDs
- 15°

ES^{3}™ Enhanced Stability Liners
- 2–4 mm Charnley bore provides increased sublaxation jump distance
- Provides up to 140° ROM
- Utilizes uni-polar or bi-polar
- 36, 40, 44, 48 mm IDs

ES^{c} Enhanced Stability Constrained Liners
- High strength head capture
- May be used with uni-polar or bi-polar heads
- +4 Neutral and +4 10° options
- Up to 113° range of motion
- GVF polyethylene for enhanced mechanical integrity
- 28, 32, 36, 40, 44 mm IDs

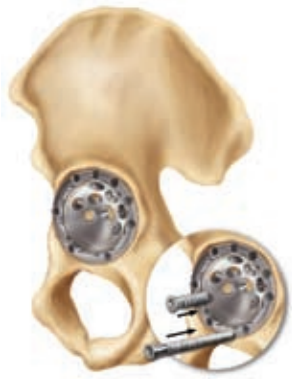
SURGICAL TECHNIQUE ALLOWS FOR EASE OF INSERTION

NOTE: TRIALS ARE AVAILABLE AND SHOULD BE USED PRIOR TO IMPLANTING.



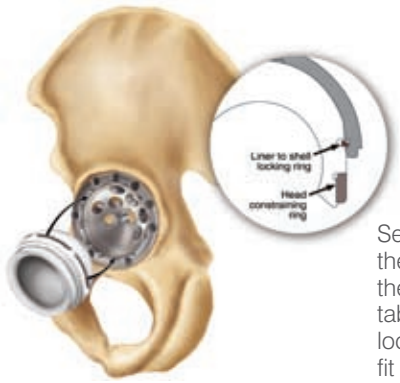
STEP 1

Insert the Pinnacle primary or Pinnacle revision shell per the shell surgical technique.



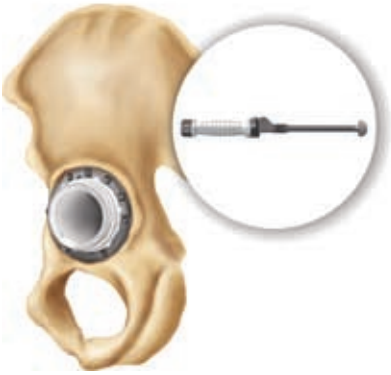
STEP 2

Utilize peripheral and/or dome screws as needed to securely fix shell in place. Irrigate and clean inside of shell to ensure it is free of debris.



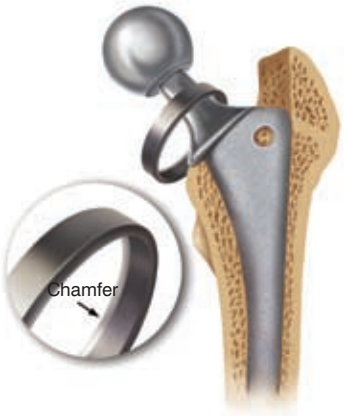
STEP 3

Seat ES^{C} constrained liner into the Pinnacle shell and align the ARD (anti-rotation device) tabs. The pre-assembled locking ring is designed to fit into the groove around the inner circumference of the Pinnacle shell.



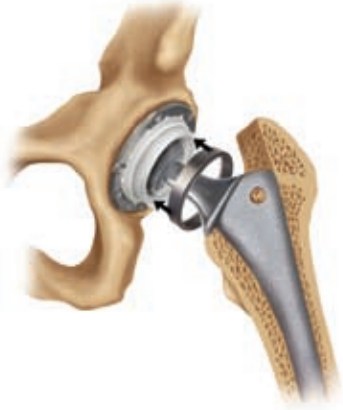
STEP 4

Utilizing an impactor tip one size smaller than the ID of the liner to be impacted, seat the constrained liner into the shell. The top of the ARDs should be flush with the polished face of the Pinnacle shell.



STEP 5

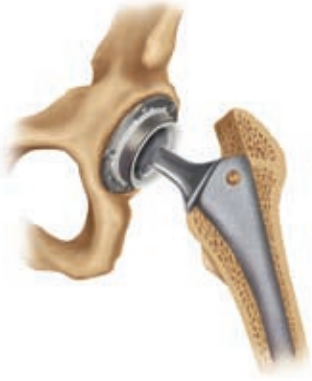
Place the chamfered constraining ring over the neck of the implant in the correct orientation. The chamfered edge of the constraining ring should be facing the acetabular shell.



STEP 6

With the femoral head implant locked onto the stem, reduce the femoral head, and lock the constraining ring onto the face of the constrained liner.

Note: Do not insert a trial femoral head into the constrained liner, as it will be difficult to remove.



STEP 7

Verify complete assembly of the construct, and review range of motion to ensure appropriate component placement was achieved.

"Constraint should almost never be needed - only in cases of soft tissue insufficiency."

Andy Engh, M.D.
Anderson Orthopaedic Clinic
Alexandria, VA

MANAGING INSTABILITY

FIXATION FIRST

Immediate and long-term fixation of the acetabular shell to host bone is the foundation of a successful clinical outcome. Pinnacle shells with Porocoat® porous coating have demonstrated 99.9% fixation survivorship at 4 years.[1]

ADVANCED MODULARITY

The Pinnacle Acetabular Cup System incorporates a patented Variable Interface Prosthesis (VIP) taper to accept multiple bearing options in a single shell design. In addition to decreasing micromotion of polyethylene liners, this taper provides exceptional push out strength across all bearing materials.

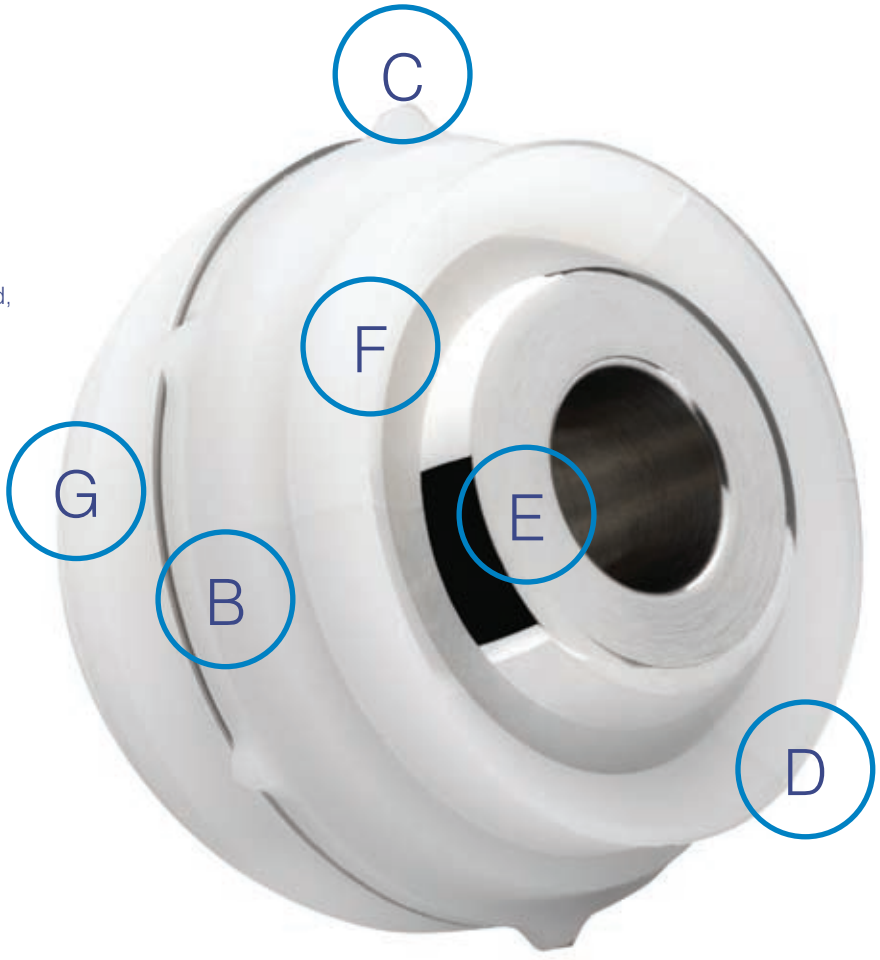
WEAR REDUCTION

The Pinnacle Acetabular Cup System's advanced bearing options for wear reduction include Marathon cross-linked polyethylene liners and Ultamet metal inserts.

MANAGING INSTABILITY

Hip instability and dislocation are uncommon yet significant issues with THA. A bearing system that provides multiple options is critical in helping surgeons address and minimize instability. The Pinnacle Acetabular Cup System offers lateralized, face changing, lipped, large inner diameter and constrained liners, giving surgeons the power to choose a solution that meets each of their intraoperative needs.

[1] Data on file at DePuy Orthopaedics



Managing hip stability can be challenging, as there may be multiple causes of the instability acting either independently or in tandem. These causes may include, but are not limited to, such things as:

- Soft tissue or bony impingement
- Mechanical impingement of the prosthetic components caused by suboptimal positioning
- Soft tissue laxity

By understanding the causes of the instability and the number of 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 various options and the appropriate indications for use.

Available in +4 neutral / +4 10°

- Lateralizes head center
- Redirects articulation of available range of motion

A Chamfered Titanium constraining ring provides ease of assembly and increased stability.

B Titanium locking ring securely holds the ES^{C} liner into the Pinnacle shell to minimize potential disassembly.

C ARD (Anti-Rotational Device) tabs for rotational stability.

D Poly slits and a flex groove for ease of head insertion.

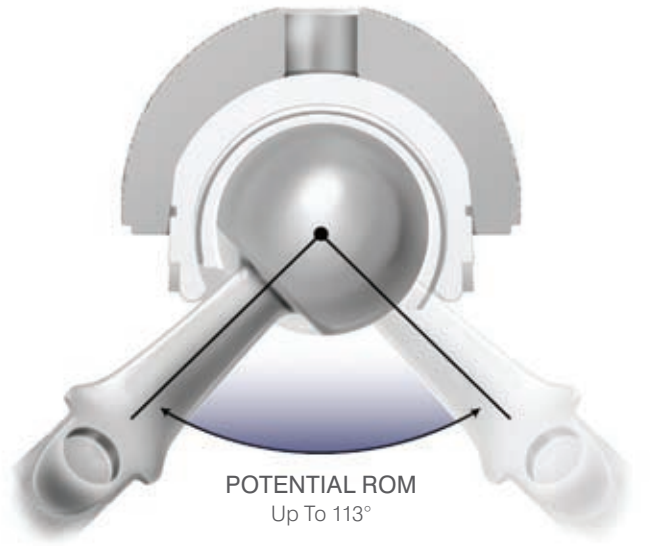
E Progressively larger ID sizes provide up to 113° range of motion.

F Ridge to aid in preventing constraining ring slippage.

G GVF polyethylene for enhanced mechanical integrity.

ES^{C} PRODUCT SPECIFICATIONS

Liner Size	ID Size	Poly Thickness (mm)		
		Dome	45°	ROM
28 x 48	28	9.6	8.2	92°
28 x 50	28	10.6	9.3	92°
32 x 52	32	9.6	8.3	96°
32 x 54	32	10.6	9.2	96°
36 x 56	36	9.7	8.3	104°
36 x 58	36	10.4	9.1	104°
36 x 60	36	11.2	9.8	104°
40 x 62	40	9.9	8.6	109°
40 x 64	40	10.6	9.3	109°
40 x 66	40	11.4	10.1	109°
40 x 68	40	12.2	10.8	109°
44 x 70	44	11.2	9.8	113°
44 x 72	44	12.1	10.8	113°
44 x 74	44	13.2	11.8	113°
44 x 76	44	14.2	12.9	113°



"In the clinical situation where normal soft tissue restraint for dislocation has been compromised, the Pinnacle cup series now offers the ES^{C} constrained liner as a viable solution to this difficult problem."

Dr. David DeBoer
Southern Joint Replacement Institute
Nashville, TN

ORDERING INFORMATION

+4 Neutral

Item Number	Description ID	OD
1218-28-648	28	48
1218-28-650	28	50
1218-32-652	32	52
1218-32-654	32	54
1218-36-656	36	56
1218-36-658	36	58
1218-36-660	36	60
1218-40-662	40	62
1218-40-664	40	64
1218-40-666	40	66
1218-40-668	40	68
1218-44-670	44	70
1218-44-672	44	72
1218-44-674	44	74
1218-44-676	44	76

+4 10 Degree

Item Number	Description ID	OD
1218-28-748	28	48
1218-28-750	28	50
1218-32-752	32	52
1218-32-754	32	54
1218-36-756	36	56
1218-36-758	36	58
1218-36-760	36	60
1218-40-762	40	62
1218-40-764	40	64
1218-40-766	40	66
1218-40-768	40	68
1218-44-770	44	70
1218-44-772	44	72
1218-44-774	44	74
1218-44-776	44	76

Instruments

Item Number	Description*
2244-08-000	Curved Impactor
2217-50-041	Straight Impactor
2217-50-005	26 mm Impactor Tip
2217-50-006	28 mm Impactor Tip
2217-50-007	32 mm Impactor Tip
2217-50-008	36 mm Impactor Tip
2217-50-060	40 mm Impactor Tip

For Liner Trials replace the 1218 in implant item # with 2218
* Use an impactor tip one size smaller than the ID of the liner

ESSENTIAL PRODUCT INFORMATION

Important
This Essential Product Information sheet 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 Pinnacle Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability. The Pinnacle Constrained Acetabular Liner is indicated for use with the Pinnacle Acetabular Cup in cementless application.

Contraindications
- Any infection in or about the hip joint.
- Bone or musculature compromised by disease, infections or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal immaturity.

Warnings
- Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation would require additional surgery.
- Only one attempt to assemble the constraining/reinforcing ring on the constrained acetabular liners should be made. If the device is not assembled correctly the first time then remove and replace with a new liner and ring.
- Improper alignment of the acetabular insert within the acetabular shell prior to impaction may result in damage to the locking ring or improper seating of the constrained acetabular insert.
- Discard or return to the manufacturer any constrained insert if the retaining mechanisms appear damaged or fractured.
- Discard any device removed after the locking mechanism has been engaged; do not reinsert the device.
- Failure or disassociation of the locking ring may lead to dislocation and require additional surgery.
- **Do not install** the constrained acetabular liner without the constraining/reinforcing ring in place. The ring constrains the polyethylene of the liner, aiding in femoral head capture.

Precautions
To avoid impingement, do not use the constrained liner with any femoral component or extended type of femoral head where the passive range of motion is restricted to less than 90°. These include 1) a femoral head with a +12 neck length extension; 2) a 28mm femoral head when the femoral neck or skirt diameter exceeds 15mm; and 3) a 32mm or 36mm femoral head with a head skirt which is used for additional femoral neck length.

Revision date 050505.

CAUTION: The following conditions tend to place the patient at higher risk for failure adversely affect the fixation of hip replacement implants:
- Obesity or excessive patient weight.
- Manual labor.
- Active sports participation.
- High levels of patient activity.
- Likelihood of falls.
- Alcohol or drug addiction.
- Other disabilities, as applicable.
- Marked osteoporosis or poor bone stock.
- Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.)
- History of general or local infections.
- Severe deformities leading to impaired fixation or improper positioning of the implant.
- Tumors of the supporting bone structures.
- Allergic reactions to implant materials (e.g., bone cement, metal polyethylene).
- Congenital dysplasia of the hip that may reduce the bone stock available to support the acetabular cup prosthesis in total hip replacement.
- Tissue reactions to implant corrosion or implant wear debris.
- Disabilities of other joints (i.e., knees and ankles).

Adverse Events and Complications
The following are generally the most frequently encountered adverse events and complications in hip arthroplasty:
- Change in position of the prosthetic components
- Early or late loosening of the prosthetic components
- Fatigue fracture of the femoral stem
- Wear or fracture of the polyethylene component
- Early or late infection.
- Peripheral neuropathies. Subclinical nerve damage may also occur as a result of surgical trauma.
- Tissue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergic reactions, or the accumulation of polyethylene or metal wear debris or loose cement particles.

For more information about the ES^{C} Constrained Liner, visit our web site at www.jnjgateway.com/Joint Reconstruction Components/Hip Acetabular Bearings

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