ESC™ Enhanced Stability Liners

Design Rationale & Surgical Technique

DePuy Revision Solutions

never stop moving™

DePuy Orthopaedics Inc.
a Johnson & Johnson company

Choice Without Compromise

DePuy Pinnacle® Hip Solutions are designed with a wide range of acetabular cup options, biological and mechanical fixation alternatives and advanced bearing technologies. With more options than any competitive system, these proven modular solutions provide you with the power to choose without compromise. Specifically, the Pinnacle ES^{C}™ Constrained Liner system addresses hip instability and dislocation through optimal dislocation resistance and high range of motion with simple, reproducible insertion instruments.

Bantam 38-46 mm

100 Series 44-66 mm

Sector 48-66 mm

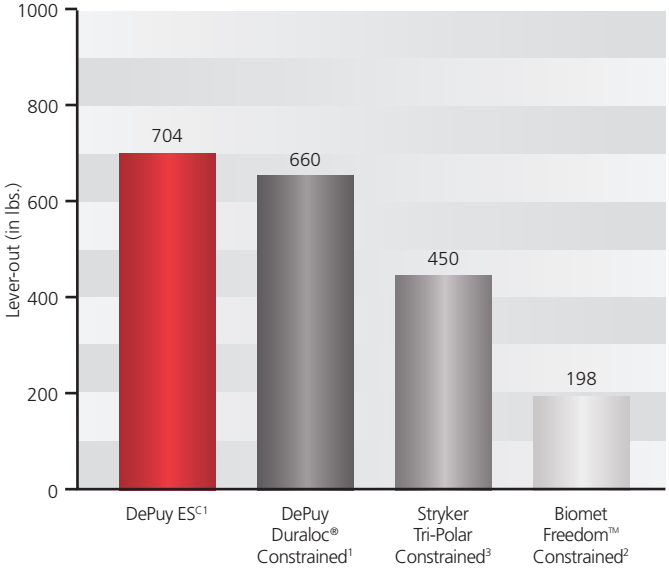
Multi-Hole 48-72 mm

Advanced Strength

Synergy in Managing Instability

Pinnacle ES^{C} liners provide up to 355 percent higher lever-out strength than conventional constrained liners.[2] Six individual slots around the liner rim reduce the force and energy needed for head reduction, allowing smooth assembly while providing optimal dislocation resistance with the addition of the titanium locking ring.

Lever-out Strength[2]



Revision 54-80 mm

Deep Profile 54-72 mm

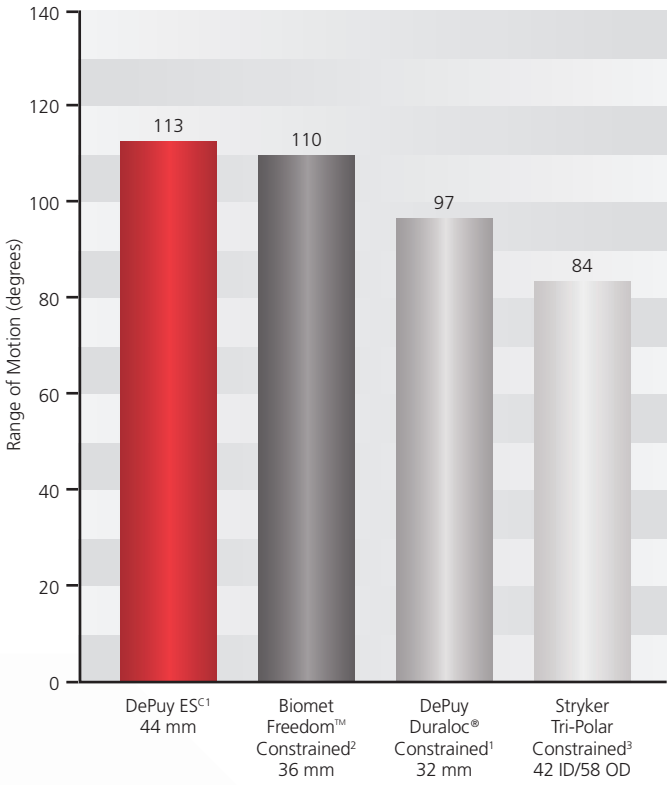
300 Tri-Spike 48-66 mm

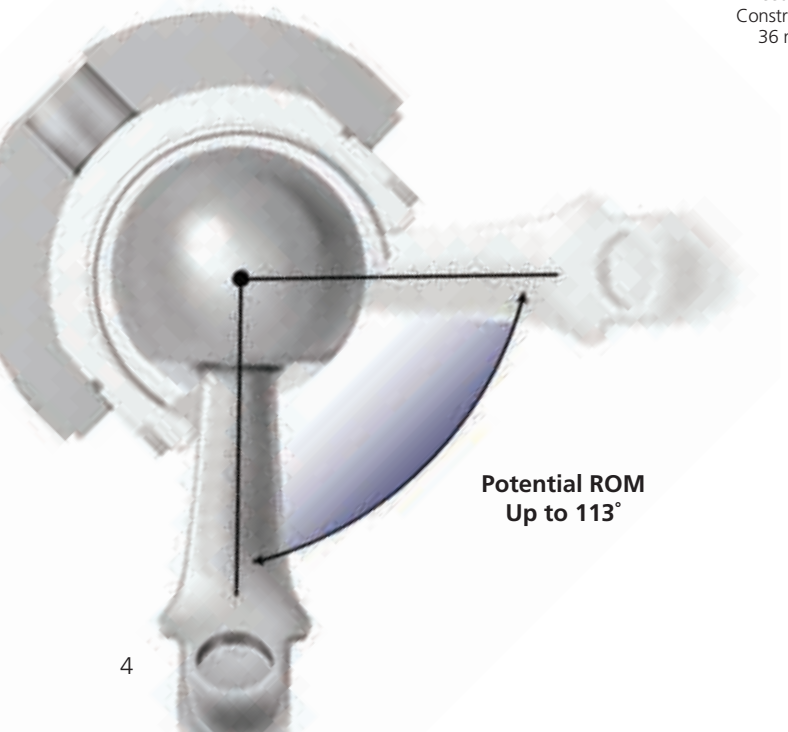
Advanced Stability

A Smooth Range of Natural Motion

Our unique approach to modularity gives you many ways to bring together all the right components and materials for optimized performance. The ES^{C}™ liner is one piece of the puzzle that allows you to achieve stability, wear reduction and surgical flexibility. With head sizes up to 44 mm, the ES^{C} liner is designed to provide an enhanced head-to-shell ratio and up to a 113-degree range of motion.[1]

Potential Range of Motion





Potential ROM Up to 113˚

Advanced Instrumentation

Designed for Ease of Use

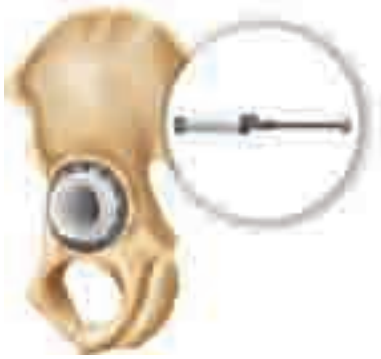
The Pinnacle® ES^{C} system provides unique instrumentation that enables simple, reproducible and intraoperative liner assembly. A locking ring inserter allows for clear visibility of liner and rim upon assembly.

If removal of the ES^{C} liner is required, a quick-release removal tip disengages the liner without damaging the shell.

ES^{C}™ Surgical Technique

Step 1

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



Step 2

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

Step 3

Place the chamfered constraining ring over the neck of the implant in the correct orientation. **The chamfered edge is contained on the inside of the ring and should be facing the acetabular shell.**

Note: *It may be useful for the surgeon or OR aide to color the chamfer with the OR marker for visible clarity.*

Step 4

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 utilizing the locking ring inserter with the size-specific ring holder.

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

Step 5

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

ES^{C} Product Specifications

Liner Size	ID Size	Poly Thickness (mm)		ROM
		Dome	45°	
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°
32 x 56	32	11.6	10.2	96°
32 x 58	32	12.3	11	96°
32 x 60	32	13	11.8	96°
32 x 62	32	13.9	12.5	96°
32 x 64	32	14.6	13.3	96°
32 x 66	32	15.3	14	96°
32 x 68	32	16.1	14.8	96°
32 x 70	32	17.1	15.8	96°
32 x 72	32	18.1	16.8	96°
32 x 74	32	19.1	17.8	96°
32 x 76	32	19.1	17.8	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°

Ordering Information

+4 Neutral	***+4 10 Neutral***		
Item Number	**Item Number**	**ID**	**OD**
1218-28-648	1218-28-748	28	48
1218-28-650	1218-28-750	28	50
1218-32-652	1218-32-752	32	52
1218-32-654	1218-32-754	32	54
1218-32-656	1218-32-756	32	56
1218-32-658	1218-32-758	32	58
1218-32-660	1218-32-760	32	60
1218-32-662	1218-32-762	32	62
1218-32-664	1218-32-764	32	64
1218-32-666	1218-32-766	32	66
1218-32-668	1218-32-768	32	68
1218-32-670	1218-32-770	32	70
1218-32-672	1218-32-772	32	72
1218-32-674	1218-32-774	32	74
1218-32-676	1218-32-776	32	76
1218-36-656	1218-36-756	36	56
1218-36-658	1218-36-758	36	58
1218-36-660	1218-36-760	36	60
1218-40-662	1218-40-762	40	62
1218-40-664	1218-40-764	40	64
1218-40-666	1218-40-766	40	66
1218-40-668	1218-40-768	40	68
1218-44-670	1218-44-770	44	70
1218-44-672	1218-44-772	44	72
1218-44-674	1218-44-774	44	74
1218-44-676	1218-44-776	44	76

For liner trials, replace the 1218 in implant item # with 2218.

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
2218-00-020	Ring Insertion Handle
2218-00-028	28 mm Ring Insertion Tip
2218-00-032	32 mm Ring Insertion Tip
2218-00-036	36 mm Ring Insertion Tip
2218-00-040	40 mm Ring Insertion Tip
2218-00-044	44 mm Ring Insertion Tip
2218-00-010	ES^{C} Extractor Tip

* Use an impactor tip one size smaller than the ID of the liner.

Pinnacle® ES^{C}™ Enhanced Stability Constrained Acetabular Liners, 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® ES^{C} 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 ES^{C} 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 liner 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 degrees. These include 1) a femoral head with a +12 neck length extension, 2) a 28 mm femoral head when the femoral neck or skirt diameter exceeds 15 mm, and 3) a 32 mm or 36 mm femoral head with a head skirt which is used for additional femoral neck length.

CAUTION: The following conditions tend to place the patient at higher risk for failure or 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}™ Enhanced Stability Constrained Liner, visit our web site at www.depuyorthopaedics.com.

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References

1. Data on file at DePuy.
2. Biomet Printed Literature;Y-BMT-815/073103/M.
3. SHO Literature # LSP 41 Rev. © Osteonics Corp. 1998.

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