Poly-Dial®
CONSTRAINED LINER

A COMPREHENSIVE ACETABULAR REVISION SYSTEM
**Introduction**

Dislocation is the most common postoperative complication in total hip reconstruction. In revision hip surgery, dislocation rates have been reported as high as 25 percent.\(^1\) The Poly-Dial\(^\text{®}\) Constrained Liner is indicated for use in total hip cases where dislocation represents a significant postoperative concern.

The use of the Poly-Dial Constrained Liner has been reported to help reduce the incidence of dislocation in at-risk total hip patients.\(^1\) The constrained liner is used where more conservative soft tissue tensioning alternatives, such as femoral neck lengthening, component positioning and lateralized acetabular components, may not be effective.

**Features and Benefits**

- Easily retrofits into the comprehensive line of S-ROM\(^\text{®}\) acetabular components, including the Arthopor\(^\text{™}\), ZTT\(^\text{™}\) and Oblong implants
- Available in 28mm head configurations from 48-66mm and 32mm head configurations from 54-75mm
- Minimum polyethylene thickness of 5mm in all sizes
- Titanium alloy locking ring strengthens the complete construct by locking around the liner face and securing the head through stable axial capture

**Surgical Technique**

**Step 1**

- After reaming, place the appropriate trial cup in the acetabulum at the desired anteversion and inclination. Select a nonconstrained standard trial liner insert and complete trial reduction. If necessary, adjust the trial cup to establish the most favorable socket orientation, joint stability and functional range of motion. Implant the appropriate acetabular cup in a position that accurately reproduces the trial cup position.

**Step 2**

- Secure the implanted cup with screw fixation. Use a minimum of four fixation devices to secure the acetabular cup. This minimum number of screw fixation points includes two peripheral screws required to stabilize the Poly-Dial Constrained Liner. An additional trial reduction with a nonconstrained standard trial liner insert and trial head may be performed to confirm cup position.
Step 3

- Following cup fixation, select the appropriate Poly-Dial Constrained Liner and place it in the acetabular cup component. Align the lugs of the insert with the bayonet spaces of the cup and push inward without turning. Once inserted, rotate the Poly-Dial Constrained Liner in either direction to achieve the desired orientation. Once the constrained liner is in place, do not perform a trial reduction. The trial head will be very difficult to remove from the Poly-Dial Constrained Liner.

Step 4

- To secure the Poly-Dial Constrained Liner into the acetabular cup, use a minimum of two peripheral screws. Locking pins should not be used.

Step 5

- Place the constrained liner reinforcement ring over the head and neck of the femoral prosthesis with the beveled edge facing proximal. When the fixed head components are in position, the constrained liner reinforcement ring will fit over the appropriate head. Avoid using skirted heads with constrained liners.

Step 6

- When relocating the reconstructed joint, significant force is required to ensure that the head is seated in the constrained acetabular component. Relocating the femoral head requires at least 65 lbs. of pressure and will be less difficult if the neck of the femoral component is perpendicular to the face of the liner. Visually, the head must be fully seated in the constrained liner. Ensure that the inside of the reinforcement ring is clean and that the mating shoulder of the constrained acetabular insert is free of debris. Using finger and thumb pressure, secure the constrained liner reinforcement ring around the shoulder of the liner.
Poly-Dial Constrained Liners, UHMWPE

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<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>87-3435</td>
<td>M Series Constrained 0 Degree, 28mm</td>
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<tr>
<td>87-3436</td>
<td>M Series Constrained 10 Degree, 28mm</td>
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<td>87-3556</td>
<td>L Series Constrained 0 Degree, 28mm</td>
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<tr>
<td>87-5987</td>
<td>XL Series Constrained 10 Degree, 32mm</td>
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**Indications**
The Poly-Dial Constrained Acetabular Liners are indicated for use as components 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.

**Contraindications**
Any infection in or about the hip joint.
Bone or musculature compromised by disease, infections or prior implantation, which cannot provide adequate support of 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 will require additional surgery.

Use of components of other manufacturers with this implant may lead to premature wear or failure of the device.
The metal cup and constrained acetabular liner require anatomical cup alignment to prevent impingement of the liner and the femoral neck. Careful trial testing for both position and range of motion should be performed during surgery to prevent impingement of the constrained liner with the femoral head from the polyethylene liner.

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.
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.
Do not use locking pins with the Poly-Dial Liner because they may prevent correct assembly of reinforcing ring. Use only S-ROM Peripheral Bone Screws (a minimum of two) to lock the position of the Poly-Dial Constrained Acetabular Liner.

Do not place a peripheral bone screw at the low point of a Poly-Dial 10 degree face angle liner because it may prevent proper seating of the reinforcing ring.
Do not use steam autoclaving for resterilization of the UHMWPE liner, as it may result in serious deformation and material deterioration.

**Precautions**
The implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.
Inspect implants for nicks, scratches or other defects that may cause failure of the implant.

To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.

An implant should never be reused. Any implant once assembled and disassembled should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

Ensure that the size of the liner corresponds to the size of the acetabular cup.
The inner diameter of the acetabular components and the femoral head size must correspond.

**Adverse Events**
Two published case series describe the use of the Poly-Dial Constrained Acetabular Liner. The adverse events reported include bone screw breakage, dislocation due to component malfunctioning and neurologic/other problems, deep sepsis and peroneal nerve palsies. Refer to the instructions for use for additional potential adverse events in any hip replacement surgery.

**REFERENCES**

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.
Consult the package insert for complete product information.
US Patent 4,676,798; 4,678,472 and 4,801,301.

For more information about Poly-Dial Constrained Liners, visit our web site at www.jnjgateway.com/revisionhip.