G7 DESIGN RATIONALE

SIMPACT. EFFICIENCY. PERFORMANCE.

The G7 Acetabular System unites the latest technological developments in bearing design with a simple, elegant and highly flexible instrumentation system designed to optimize the operating room experience. The system’s wide range of acetabular shell, fixation and bearing options provides the power to personalize implant selection for each within a single platform that delivers:

› Modern shell design features for maximized performance
› Multiple clinically proven bearing and fixation options
› Personalized instrumentation system for increased operating room efficiency
› Patent pending color-coded implant and instrumentation system for streamlined surgical flow

SURGEON DEVELOPERS

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› Professor Nobuhiko Sugano
  Osaka University
  Osaka, Japan
SYSTEM OVERVIEW
Efficiency doesn’t demand the elimination of options. The G7 System allows surgeons and hospitals to provide the optimal implants for each patient while benefiting from the efficiency of a streamlined delivery system.
**DESIGNED FOR PERFORMANCE**

**Polyethylene and Hard Bearing Locking Mechanism**
accommodates multiple polyethylene configuration options and hard bearing surfaces where available.

**The G7 dome loading design**
provides maximum liner support to minimize locking mechanism fatigue.

**Pre-Plugged Screw Holes**
provide the operative flexibility to choose between a solid shell construct or adding screws for additional stability.

**HEMISPHERICAL DESIGN**
The hemispherical design of the G7 acetabular shell closely matches the shape of the natural acetabulum, allowing for minimal removal of bone while maximizing contact area between the implant and bone.

50 mm 180°
ADVANCED FIXATION OPTIONS

PPS POROUS PLASMA SPRAY:
PPS Porous Plasma Spray has over 25 years of clinical history providing primary implant fixation for the Biomet cementless portfolio. Using biocompatible titanium alloy powder and proven plasma spray processing, PPS offers:

› High fatigue strength achieved by never heating the substrate\(^1\)
› Short- and long-term fixation gained from variable pore size distribution\(^2\)
› Roughened scratch fit due to irregularly shaped particles\(^2,3\)

BONEMASTER:
BoneMaster is an advanced coating technology designed to improve the performance of cementless implants by mimicking natural bone physiology. With the biological benefits of hydroxyapatite (HA) and an enhanced nano-structure based on apatite crystals found in bone,\(^4\) BoneMaster offers:

› Enhanced implant stability by creating a favorable environment for osteoblast adhesion
› Roughness of PPS Porous Plasma Spray with 1/10th the thickness of traditional HA
› Reduced fibrous ingrowth due to unique nano-structure which mimics apatite found in bone, promoting osteoconductivity and faster bone integration\(^5-7\)
› Significantly greater bone density postoperatively compared to identical plasma-sprayed HA stems\(^8,9\)

SHELL CONFIGURATION
G7 shells are available in a limited hole design with three holes clustered near the apex of the shell to allow for placement of screws in the strongest part of the pelvic bone. Screw holes are pre-plugged to limit the migration of polyethylene debris that could potentially result in osteolysis and provide an uninterrupted support structure to reduce the possibility creep of the polyethylene into open screw holes. The plugs can be removed if supplemental fixation is desired.

\(^1\) Primary identification should be made using size and letter designations.
BEARING OPTIONS

POLYETHYLENE MATERIALS
Meeting the modern demands of bearing surfaces means achieving the optimal balance of maximized strength, wear resistance and oxidation resistance. Biomet’s polyethylene bearings achieve this by pairing the latest technological advancements with the strong heritage of clinically proven ArCom polyethylene. The G7 system offers two polyethylene materials for use with Biolox® delta ceramic or CoCr femoral heads.

E1 Antioxidant Infused Technology
E1 is the only antioxidant infused bearing technology to use a proprietary diffusion process to maximize strength, wear resistance and oxidative resistance via the oxidative protection of vitamin E. Vitamin E actively protects the bearing surface from the damaging effects of oxidation over time. In addition, E1 acetabular liners offer wear rates similar to hard-on-hard bearings when paired with a ceramic head.

ArComXL Highly Crosslinked Polyethylene
ArComXL acetabular liners utilize a solid state deformation process to obtain optimal wear resistance without sacrificing mechanical strength or increasing oxidation levels. ArComXL shows a 47% decrease in volumetric wear rate when compared to a moderately crosslinked polyethylene.

POLYETHYLENE WEAR
5 million cycles on a hip simulator

Volumetric Wear (mm³/million Cycles)

*Gamma Sterilized Polyethylene 53.3 mm³

<table>
<thead>
<tr>
<th>Material</th>
<th>Volumetric Wear (mm³/million Cycles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoCr on ArComXL</td>
<td>12.89</td>
</tr>
<tr>
<td>Biolox® delta on ArComXL</td>
<td>10.04</td>
</tr>
<tr>
<td>CoCr on E1</td>
<td>3.36</td>
</tr>
<tr>
<td>Biolox® delta on E1</td>
<td>2.82</td>
</tr>
</tbody>
</table>

*Gamma Sterilized polyethylene test performed with 28 mm bearings. April, 2007
All other tests were performed with 62 mm acetabular shells and 44 mm bearings. Sept., 2012
Designed to increase range of motion, while decreasing the possibility of impingement, by means of an optimized chamfer around the inner diameter of the liner.

Offers 5mm material build up (typically positioned in the posterior superior quadrant) for additional stability.

Used to restore the center of rotation and achieve more joint stability when acetabular components have been vertically placed.

Designed to actively counter the distractive forces that can lead to recurrent hip dislocation. Utilizes a cobalt chrome head with circumferential flats for easier head reduction and a constraining ring to supplement the liner’s stability by increasing resistance to lever-out forces.

<table>
<thead>
<tr>
<th>Shell Size</th>
<th>Head Size</th>
<th>28</th>
<th>32</th>
<th>36</th>
<th>40</th>
<th>44</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 - A</td>
<td></td>
<td>4.3</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>44 - A</td>
<td></td>
<td>4.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>46 - B</td>
<td></td>
<td>6.3</td>
<td>4.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48 - C</td>
<td></td>
<td>7.3</td>
<td>5.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 - D</td>
<td></td>
<td>8.3</td>
<td>6.3</td>
<td>4.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>52 - E</td>
<td></td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54 - F</td>
<td></td>
<td>10.3</td>
<td>8.3</td>
<td>6.3</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>56 - F</td>
<td></td>
<td>10.3</td>
<td>8.3</td>
<td>6.3</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>58 - G</td>
<td></td>
<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>60 - G</td>
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<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>62 - H</td>
<td></td>
<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>64 - H</td>
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<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>66 - I</td>
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<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>68 - I</td>
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<td>11.3</td>
<td>9.3</td>
<td>7.3</td>
<td>5.3</td>
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</tr>
<tr>
<td>*70 - J</td>
<td></td>
<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
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<td></td>
</tr>
<tr>
<td>*72 - E</td>
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<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*74 - J</td>
<td></td>
<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*76 - J</td>
<td></td>
<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*78 - J</td>
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<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*80 - J</td>
<td></td>
<td>14.3</td>
<td>12.3</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Not available in limited hole configuration
The G7 Acetabular System offers Biolox® delta ceramic heads for ceramic on polyethylene articulations in 28, 32, 36, and 40 mm diameters. Biolox® delta ceramic is a highly biocompatible mixed oxide ceramic with high fracture resistance and ultra low wear. Constructed of 82% alumina, 17% zirconia and other trace elements, this third generation ceramic is an alumina matrix composite that provides increased fracture toughness and strength when compared to traditional alumina ceramic. With over 1.6 million implanted worldwide, Biolox® delta ball heads offer a clinically successful high performance option. 1.6 million implanted worldwide.
LOCKING MECHANISM STRENGTH

STRENGTH TESTING:
Acetabular systems must be strong enough to withstand the loading conditions commonly seen in the hip, maximizing strength and minimizing micromotion. Liner push out, lever out, torque out and rim impingement are industry accepted testing methods which measure the strength of both the locking mechanism and the liner. G7 polyethylene and ceramic liners were subjected to push out, lever out and torque out testing under worst case conditions.

POLYETHYLENE LOCKING STRENGTH
The G7 polyethylene locking feature maximizes strength and minimizes micromotion by means of a tightly toleranced tongue and groove fit between the shell and the liner. While offering high locking strength, the unique geometry of the locking barb also requires minimal impaction force to engage the liner into the shell, reducing risk of shell malalignment.

PUSH OUT STRENGTH

<table>
<thead>
<tr>
<th>Force (N)</th>
<th>Biomet G7 E1 (10 Mrad)</th>
<th>DePuy Synthes Pinnacle</th>
<th>Zimmer Continuum Longevity (10 Mrad)</th>
<th>Stryker Trident X3 (10 Mrad)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2245</td>
<td>2061 (8% Lower)</td>
<td>847 (62% Lower)</td>
<td>1420 (36% Lower)</td>
<td></td>
</tr>
</tbody>
</table>

Hard bearing locking strength

HARD BEARING LOCKING STRENGTH
The hard bearing locking feature utilizes a 10 degree conical taper as well as a roughened finish to achieve maximum surface contact with the liner, resulting in a secure taper fit. An apical button on the liner aids in alignment upon insertion but is not a part of the locking mechanism.

LEVER OUT STRENGTH

<table>
<thead>
<tr>
<th>Force (Nm)</th>
<th>Biomet G7 E1 (10 Mrad)</th>
<th>DePuy Synthes Pinnacle AltrX (7.5 Mrad)</th>
<th>Zimmer Continuum Longevity (10 Mrad)</th>
<th>Stryker Trident X3 (10 Mrad)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>51 (Statistically Equivalent)</td>
<td>23 (53% Lower)</td>
<td>28 (43% Lower)</td>
<td></td>
</tr>
</tbody>
</table>

Lever Out: Disassembly force required to dislodge a polyethylene liner from an acetabular shell.
All tests were performed with 54 mm acetabular shells and 32 mm acetabular liners.
Polyethylene Results:
The average push out force of a G7 polyethylene acetabular liner is 2245 N.\textsuperscript{11}

Liner Push Out:
Push out testing measures the axial force required to dislodge a polyethylene liner from an acetabular shell. Conducted per ASTM F1820-97, an assembled shell and liner was attached to a push-out fixture that supported the cup without distortion. An axial load of 2 inches per minute was applied to the liner through the apical hole of the shell.\textsuperscript{11}

Similar to the G7 polyethylene testing regimen, G7 ceramic liners were subjected to push out, lever out and torque out testing. Additional tests were also conducted, specific to the ceramic liner.

Hard Bearing Results: The average push out force of a G7 acetabular ceramic liner is 11,590 N,\textsuperscript{1} almost 60 times the minimum acceptance criteria of 200 N, set by Ceramtec, the manufacturer of Biolox® delta ceramic.\textsuperscript{1,12}

Almost 60 Times the Minimum Acceptance Criteria\textsuperscript{11}
LINER LEVER OUT TESTING:
Measures the disassembly force required to dislodge a polyethylene liner from an acetabular shell. Conducted per a published testing method, a metal lever arm was inserted into a slot cut into the liner (polyethylene) or a metal lever arm was inserted into a washer epoxied into the liner (hard bearing) and loaded at 2 inches per minute until liner separation.

50 Nm

DISASSEMBLY FORCE REQUIRED TO DISLODGE A POLYETHYLENE LINER FROM AN ACETABULAR SHELL

Polyethylene Results:
The average lever out force of a G7 polyethylene acetabular liner is 50 Nm.¹¹

Hard Bearing Results:
The average lever out force of a G7 ceramic acetabular liner is 32 Nm.⁵
LINER TORQUE OUT:
Measures the disassembly force required to torque-out a liner from an acetabular shell. Conducted per documented test methods\textsuperscript{13,15} the shell and liner were inserted into a test fixture which applies torsional force to the shell and liner. Torsion was applied at a rate of 1 degree per second until the liner rotated 45 degrees as noted by lines marked on the face of the shell and liner.

![Liner Torque Out Diagram](image)

Polyethylene Results: The average torque-out force of a G7 polyethylene acetabular liner is 29 Nm. The maximum frictional torque seen \textit{in-vivo} at the femoral head to liner interface is approximately 2 Nm.\textsuperscript{11,13,16}

Hard Bearing Results: The average torque-out force of a G7 ceramic acetabular liner is 63 Nm. The maximum frictional torque seen \textit{in-vivo} at the femoral head to liner interface is approximately 2.4 Nm.\textsuperscript{1,13,16}

RIM IMPINGEMENT:
The ability of the acetabular liner to withstand possible rim impingement, or impaction of the rim of the liner by the stem trunnion, is also key to the long term success of the implant. Rim impingement loading can occur \textit{in-vivo} as a result of malalignment or patient movements that require a large range of motion.

Conducted per ASTM F2582, the trunnion of a stem was allowed to contact the rim of the liner at a joint reactive force of 1000 N, simulating rim impingement loading conditions. Following the test, the liners were visually inspected for signs of damage.

![Rim Impingement Diagram](image)

Polyethylene Results: Visual inspection of ArComXL and E1 liners showed no cracking, pitting or gross damage to the inner and outer region of the rim.\textsuperscript{1}
FREEDOM CONSTRAINED LINER LEVER OUT:
Liner lever out was also measured for the Freedom Constrained acetabular liner. Conducted per a published testing method, load was applied to a femoral head with a lever arm attached at the rate of 2 inches per minute until the head or liner dislodged from the shell.

Freedom Constrained Liner Results:
Shell/liner combinations, the average lever out force of a G7 Freedom Constrained acetabular liner is 18 Nm, although none of the constrained liners actually levered out during the test. Per its designed intent, the constrained femoral head dislodged before the liner in all of the samples. This feature is designed to prevent forces that might dislodge the fixation of the acetabular shell in the case of a constrained liner.
Fracturing of a ceramic liner is the most common complication in the rare instance of ceramic failure. This fracture may be caused by intraoperative chipping that can occur when the ceramic liner is not aligned properly in an acetabular shell upon impaction or if the surgeon forcibly tries to realign a malaligned liner. For this reason, the G7 ceramic liner is designed with an apical button to help aid in alignment upon insertion. Additional testing validated this design feature.

Insertion Validation
A cadaveric validation study was conducted to simulate intraoperative insertion of a ceramic liner into an acetabular shell. This demonstrates the optimal performance of the G7 Acetabular System with regards to intraoperative liner chipping. On separate occasions, two practicing surgeons exposed the hip joint while maintaining standard incision lengths and soft tissue dissection and inserted 40 ceramic liners. In total 80 ceramic liners were included in the validation study.

Results: During the cadaveric validation study none of the ceramic liners chipped when inserted into an acetabular shell that had been impacted using a “line to line” or “2 mm under” reaming technique.
Apical Button Fatigue Burst
Evaluates any impact of a novel apical button feature on the burst strength of the ceramic liner, under extreme loading conditions in excess of any testing parameters prescribed by national or international standards. G7 acetabular shells were potted at a 60 degree inclination angle to simulate extreme cup placement. Ceramic liners were then inserted and subjected to a 10 million cycle fatigue test. Post fatigue testing, load was applied until the liner burst.1

Results: There was no significant difference between the burst strength of the liners before and after fatigue testing. Examination of the fracture patterns before and after fatigue of the liners showed that the liners failed with a spiraled crack originating from the rim of the liner. The fracture pattern of the liners does not show any interaction with the apical feature, indicating that the novel geometry is not detrimental to the strength or performance of the liner.1
Over 1 million times per year, Biomet helps a single surgeon provide personalized care to a single patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

References

10. US FDA cleared claim. See biomet.com/e1 for complete claim language.
11. Study conducted by Biomet with independent lab. Laboratory testing completed June 2013. Test results are not necessarily indicative of clinical performance.
12. Data on file at Ceramtec GmbH.
13. FDA draft guidance: Testing of acetabular prosthesis