INTRODUCTION

Beginning with the AGC® and continuing with the Maxim® and Ascent™, Biomet’s total knee systems have a long and rich clinical heritage. With the introduction of the Vanguard™ Complete Knee System, Biomet has taken this proven clinical heritage and combined it with state-of-the-art design features to produce the most comprehensive total knee system available. With the introduction of Microplasty® and Premier™ instrumentation platforms and advancements such as our patented Slidex® Technology, the Vanguard™ Complete Knee System is the surgeon’s ally in exceeding the demands of today’s active joint replacement patient.

ADVANCING TECHNOLOGY

When designing the Vanguard™ Complete Knee System, every feature in the femur, patella and tibia was reviewed for potential performance enhancement in all patient populations. Many clinically successful features found in earlier Biomet® total knee systems remain the same in the Vanguard™ Complete Knee System. However, many more features were added.

Patella/Femoral Joint

The Vanguard™ femoral component has four main design features incorporated into the sagittal profile:

- Rounded sagittal profile
- Deeper, swept-back trochlear groove
- Longer trochlear groove
- Wide proximal trochlear groove

Each of these variables improves lateral release rates, extensor moment arm, patella alignment and patella tracking, while reducing the potential for patellar tendon irritation.

Rounded Sagittal Profile

Two distinct femoral designs have evolved over time: an anatomic (box-like) femoral profile and a more swept-back (rounder) sagittal profile.
A round sagittal profile as found in the Vanguard™ knee may be more forgiving to the retinaculum by not over tensioning the soft tissues.

**Deeper/Swept-back Trochlear Groove**

The trochlear groove is a critical design feature for patella performance. Translation of the trochlear groove posteriorly in the femur has shown to resist patella crepitus and clunk.1 The Vanguard™ trochlear groove has been designed to sweep back posteriorly for better patellar performance.

**Longer Trochlear Groove**

The trochlear groove has also been lengthened to further support the patella in deep flexion. This longer trochlear groove also better supports the quadriceps tendon. In deep flexion, a shorter trochlear groove, as in the Maxim® knee, will articulate on the quadriceps tendon at the junction of the trochlear groove and posterior stabilized (PS) box at 75 to 80 degrees of flexion. In the Vanguard™ knee, the junction does not articulate with the quadriceps tendon until 105 to 120 degrees of flexion.

**Wider Proximal Trochlear Groove**

Patellar capture during flexion must be balanced with the need for less patellar constraint in extension. The Vanguard™ knee provides for this balance through a widened trochlear floor to reduce constraining forces in extension and a 6.5 degree valgus angulation of the patella track. “Valgus angulation has been shown to reduce the patellar shear stresses.”2

In addition to a wider proximal trochlear groove, the Vanguard™ knee offers a comprehensive approach to patellofemoral mechanics that includes femoral retinacular relief, a lateralized trochlea and a clinically proven dome patellar component. The aggregate of these features produces a component that provides for excellent patellar tracking (within 0–15 degrees of valgus) regardless of the patient’s Q-angle.3 Retinacular relief minimizes soft tissue tension, reducing the potential need for a lateral release.

The narrow anterior flange maintains a small profile to reduce the likelihood of femoral overhang. To further address overhang, the Vanguard™ knee features rounded corners on the anterior flange. Proper femoral fit with respect to overhang is a primary concern for patients with smaller anatomies, most commonly found in the female population. The Vanguard™ knee addresses this by offering a femoral component that grows medial/lateral in 2.4mm increments between its smallest six sizes, which have shown to be the most commonly utilized sizes for female patients.

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1. Valgus angulation has been shown to reduce the patellar shear stresses.
2. Patellar capture during flexion must be balanced with the need for less patellar constraint in extension.
3. Retinacular relief minimizes soft tissue tension, reducing the potential need for a lateral release.
Articulation Features

**Coronal Geometry Features**

The Vanguard™ knee system provides a fully congruent (coronally), moderately dished articulation, which reduces polyethylene stresses while still allowing physiological motion. The patented 1:1 condylar geometry provides surgical flexibility by allowing tibial-femoral interchangeability.

The Vanguard™ cruciate retaining (CR) and posterior stabilized (PS) femurs have complete size interchangeability with their respective primary bearings.*

To increase contact area with axial rotation, the Vanguard™ knee features a rotated bearing surface articulation. As compared to a linear articulation, a rotated articulation increases the contact area by 13 percent.³

*With the exception of the Vanguard™ Anterior Stabilized (AS) Bearing.

**Increased Range of Motion**

The Vanguard™ knee has been designed to accommodate patients who require an above average range of motion. The femoral posterior condyle geometry will allow for 145 degrees of flexion. The Vanguard™ knee is able to achieve this high range of motion without the need to resect an additional 2mm of posterior condyles. The Vanguard™ tibial bearings have a deeper anterior relief to minimize the potential for patella impingement during high flexion.

**Proportional Posterior Condyles**

The posterior condyles grow proportionally in size. This provides better bone coverage and reduces overstuffed the flexion gap in smaller femurs or undersizing the posterior condyles in larger femurs. Better coverage of the posterior condyles aids in achieving high flexion and restoring femoral offset.

The posterior condyle geometry has also been optimized to provide larger contact areas in deep flexion. Larger contact areas will dissipate forces more effectively.⁴

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²Finite Element Analysis Demonstrates a Gradual Dispersion of Forces Along the Patella

¹145 Degrees Range of Motion with Primary Bone Cuts

¹:¹ Tibial-Femoral Contact

Rotated Tibial Articulating Surface

High Flexion Patellar Tendon Relief

Finite Element Analysis Demonstrates a Gradual Dispersion of Forces Along the Patella

¹:¹ Tibial-Femoral Contact

Rotated Tibial Articulating Surface

High Flexion Patellar Tendon Relief

Finite Element Analysis Demonstrates a Gradual Dispersion of Forces Along the Patella
Intermediate Femoral Sizes
The Vanguard™ knee has introduced four additional intermediate sized primary femoral components to enhance the traditional femoral offering.

Ten Vanguard™ femoral component sizes, combined with nine Vanguard™ tibial component sizes, while maintaining complete interchangeability among all sizes, provide intraoperative flexibility to fit varying patient anatomies of both the femur and the tibia independently. The end result is a complete knee system that is the most flexible on the market, allowing a custom fit for the entire population, regardless of race, gender or stature.

Specific Posterior Stabilized Design Features
A multitude of design features affect the performance of a cam and spine type of posterior stabilized knee. The following design features are key elements in the Vanguard™ PS system:

Cam and Post Engagement
The cam on the PS femoral component is designed to engage the spine on the tibial component at 45 degrees of flexion. Gait analysis demonstrates that weight bearing phase occurs from 0 to 45 degrees. After stance phase (weight bearing), the cam engages the spine to provide stability and increase quadriceps efficiency, specifically during activities such as ascending and descending stairs.

Mid-flexion cam engagement avoids cam/post contact during high cycle activities but ensures stability during high moment activities.

Enhanced Anterior Lip
To help resist paradoxical anterior femoral slide during gait, the anterior lip of the tibial bearing is more prominent. This is achieved by moving the anterior radius posteriorly. The anterior lip provides resistance for the femoral condyles, preventing anterior slide. This cradling effect controls the femoral component on the articulating surface without sacrificing freedom of rotation. The combination of 45 degrees cam engagement with (anterior lip) stability optimizes cam/post engagement, limiting premature wear of the tibial post.

Low Cam Engagement/High Dislocation Height
The cam engages relatively low on the tibial post and remains low throughout full range of motion. This decreases the forces at the tibial-bone interface and at the locking mechanism while maintaining a high dislocation height. The dislocation height of the Vanguard™ PS is never less than 17.3mm at 90 degrees of flexion or greater. The Vanguard™ PS component allows for 10 degrees of hyperextension before anterior post impingement.
**Post Geometry Designed for Stability, Reduced Wear**

The PS post geometry is rounded to minimize forces on the post due to rotation of the femur and resultant rotation of the PS box. According to mechanical wear test simulation, the Vanguard™ PS bearing had a 71 percent reduction in gravimetric wear at 5.5 million cycles as compared to a standard square post design geometry.³

![Rounded PS Post](image)

**PS Plus—An Additional Constraint Option**

The Vanguard™ PS femoral component will accept the standard PS bearing as well as the PS plus, a more constrained bearing. The PS plus bearing is indicated for use in a primary situation when more stability is desired to resist rotation and varus/valgus lift-off.

The standard PS post does not constrain the femur in rotation or varus/valgus lift-off.

**Note:** The PS plus bearing does not articulate with the Vanguard™ SSK femoral component and is not indicated for use as a revision bearing.

![PS Bearing](image)

**PS Box Resection Options**

The Vanguard™ knee offers several options for PS box resection. The choices of standard bone conserving or closed box cuts are available for the open box femoral component. The standard cut allows for a parallel cut to be made relative to the distal resection, whereas the bone conserving cut produces an angled cut, conserving bone near the anterior chamfer area.

The Premier™ instrumentation also provides the option of milling the PS box resection. The mill conserves bone at the corners of the box, resulting in a five percent reduction in box volume as well as reducing the stress risers created by square corners.

![Premier™ PS Femoral Mill Box Resection](image)

**Finite Element Analysis Demonstrating Lower Concentration of Stress at Corner of Box**

![Square Corner](image)

![Round Corner](image)
Specific Cruciate Retaining Design Features

The Vanguard™ CR femoral component incorporates all design and articulation features of the posterior stabilized design as well as key features specific to the CR femoral component.

Removable Femoral Lugs

The femoral lugs on the Vanguard™ CR are removable. This feature allows for augmentation if required in primary total knee arthroplasty or in the revision of a failed unicompartmental knee arthroplasty.

Two Fixation Options

The Vanguard™ CR and PS femoral components are available in two fixation options: Interlok® roughened finish for cement fixation or PPS® Porous Plasma Spray Coating for cementless fixation.

The Vanguard™ CR and PS porous options have been cleared by the FDA for cementless fixation.

Cruciate Retaining Bearing Options

The options for tibial bearings include standard (with three degrees posterior slope built into the articulating surface), posterior lipped and anterior stabilized.

These options provide a multitude of choices to meet patient needs and surgeon preferences.
Specific Vanguard™ SSK Revision Femoral Design Features
While the Vanguard™ SSK femoral component integrates all the primary femoral component design features, there are a few differentiating design features specific to the Vanguard™ SSK revision femoral component.

SSK Bearing Options
The Vanguard™ SSK revision system offers two bearing options: the SSK PS tibial bearing and the SSK constrained tibial bearing. This feature allows the surgeon intraoperative flexibility in the case of collateral deficiencies.

The SSK PS bearing provides only posterior stabilization with the Vanguard™ SSK revision femur.

Stability
The SSK constrained bearing offers a large swept back tibial post that provides stability and continued constraint in deep flexion. The large tibial post also maintains increased post/box contact. At 90 degrees of flexion, 17mm of the post remains in the box.

SSK Femoral Component Extended Cam
The Vanguard™ SSK femoral component adds an additional 3mm of material on the cam. This provides for a higher dislocation height, up to 23mm, prior to dislocation.

Stem Boss Angle
The Vanguard™ SSK femur has a five-degree stem valgus angle which will accept multiple stem lengths in straight and curved profiles to match the patient’s anatomy.
**Femoral Augmentation**

Individual distal (5mm, 10mm and 15mm thicknesses) and posterior (5mm and 10mm thicknesses) augmentation blocks are available for patients with inadequate bone stock.

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**CLINICAL HERITAGE**

**ArCom® Polyethylene**

Biomet has made the commitment to Direct Compression Mold all tibial bearings within the Vanguard™ system to minimize the potential for wear and oxidative breakdown. Biomet’s ability to combine clinically proven polyethylene with the Vanguard™ knee system punctuates Biomet’s engineering-driven approach. Knee wear is thought to predominately be a fatigue mechanism, which may lead to delamination and pitting of the bearing surface. Traditional machining of tibial articulations has been shown to be detrimental to the long-term performance of knee replacements. The cutting tools used in machining shear the polyethylene and pull the material apart, creating regions of residual stress. This residual stress may sensitize the material to localized breakdown and oxidation.

Oxidation may negatively impact the fatigue characteristics of the polyethylene, causing delamination.

Biomet was the first company to use an inert gas, argon, to replace oxygen during the sterilization and packaging processes. The use of argon reduces the degradative effects of oxygen present in polyethylene-bearing designs. Furthermore, gamma sterilization in an argon atmosphere has been shown to decrease wear over EtO sterilized polyethylene by 44 percent. ArCom® polyethylene has been clinically proven to be more resistant to wear, delamination and oxidation.

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**Polyethylene Thickness/Locking Mechanism Design**

Meding, et al. demonstrated excellent long-term results with 4.4mm minimum thickness Direct Compression Molded tibial bearings. The Vanguard™ knee system provides a minimum of 6mm of polyethylene thickness in its primary, posterior stabilized and revision components. Thicknesses for all polyethylene sizes are listed in the polyethylene size/thickness chart.

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**Polyethylene Size/Thickness**

<table>
<thead>
<tr>
<th>Size Thickness</th>
<th>10</th>
<th>12</th>
<th>14</th>
<th>16</th>
<th>18</th>
<th>20</th>
<th>22</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene Articulating Thickness (mm)</td>
<td>6</td>
<td>8</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>16</td>
<td>18</td>
<td>20</td>
</tr>
</tbody>
</table>

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*May not be applicable to custom products.*
Effective polyethylene thickness is determined by evaluating not only thickness at the center of the tibial condyle but also by measuring the periphery of the polyethylene insert. Many currently manufactured components provide adequate thickness at the center but compromise thickness around the edges due to the design of the locking mechanism. Feng, et al. have found that the most severe polyethylene wear occurs at the periphery, where the component had a raised metal edge. These concerns have been addressed in the Biomet modular tibial trays. The peripheral polyethylene thickness is maintained by locating the locking mechanism anteriorly and within the intercondylar area. Concerns have been raised about modularity and bearing micromotion as a contributor to osteolysis and early failure. Biomet’s locking mechanism compresses the polyethylene bearing against the tray, thereby reducing micromotion. Published literature has also shown the Biomet® locking mechanism to be the most stable overall.

Tibial Tray Sizing

Many knee systems offer a variety of tibial tray sizes. However, few systems offer consistent, close sizing. The Vanguard™ knee system offers nine tibial sizes that change in consistent 4mm M/L intervals, based on the work of Mensch and Amstutz. A scientific study was conducted that examined eight tibial tray designs, six symmetrical and two asymmetrical. Incavo, et al. showed that the sizing rationale for the AGC® Total Knee System, which is closely paralleled by the Vanguard™ system, offers optimal coverage as compared to competitive asymmetrical designs. Of all the tibial trays tested, the AGC® knee was ranked as the best in total coverage, covering 80.8 percent of the tibial surface.

Achieving Optimal Bone Coverage

The Vanguard™ femoral components are based on extensive cadaver studies. Mensch and Amstutz reviewed 200 cadaver knees which served as the basis of AGC®, Maxim® and Vanguard™ femoral component sizing. Four additional sizes are offered with the Vanguard™ system, reducing the interval between sizes in the center of the usage distribution.
Patellar Articulation

Ritter, Lombardi, Insall, Ranawat and others have shown excellent long-term results with domed patellar designs.\textsuperscript{6,8,29–31} The domed patella is more forgiving in placement than other designs and can more reliably provide congruent contact.

Component Fixation

The Vanguard\textsuperscript{TM} knee system incorporates two types of fixation finishes. The Interlok\textsuperscript{®} finish allows for proper cement interdigitation into the surface for a more secure bond.

Series A Patellas

The Vanguard\textsuperscript{TM} total knee system offers multiple patella options. Patellas are available in one and three peg options in standard thicknesses and in a thinner version which is on average 1.5mm thinner than the standard patella.

Domed Patella

Since its introduction in 1981, Biomet’s PPS\textsuperscript{®} Porous Plasma Spray Coating has been used by surgeons throughout the world to achieve better fixation on a multitude of products including the AGC\textsuperscript{®} knee, Maxim\textsuperscript{®} knee, Ascent\textsuperscript{™} knee, Taperloc\textsuperscript{®} hip, and Bio-Modular\textsuperscript{®} total shoulder. At follow-up, surgeons are observing extremely low rates of osteolysis and nearly 100 percent survivorship at over 10 years with PPS\textsuperscript{®} coating prostheses.\textsuperscript{32–35}

Series A Standard One and Three Peg Patellas

Interlok\textsuperscript{®} Finish

PPS\textsuperscript{®} Coating
Additionally, it has been clinically proven that titanium porous surfaces facilitate increased ingrowth as compared to similar cobalt chrome surfaces. Biomet’s proprietary PPS® Porous Plasma Spray application is unique in comparison to competitors’ techniques in that only the titanium alloy powder is heated, not the substrate of the implant. The sintering process (used to apply beads and wire mesh coatings) compromises the substrate’s strength and results in a greatly decreased ability to withstand in-vivo stresses. Biomet’s plasma spray process maintains the implant’s inherent fatigue strength.

**Fatigue Strength**

**Tibial Baseplate Options**

Biomet’s tibial tray options are the most comprehensive on the market today. Primary tibial trays are made from both titanium and cobalt chrome alloys. Titanium baseplates come either with an Interlok® finish or a PPS® coating to enhance bone ingrowth. PPS® coated baseplates accept up to four 6.5mm cancellous bone screws for enhanced fixation when a cementless tibial component is desired. The porous, stemmed and offset tibial plates can be used with block or wedge augments. All augments are fixed to the baseplates via bolts, allowing a mechanical lock between the tray and augments. Cobalt chrome baseplate options come in either fixed I-beam or fixed cruciate fin with an Interlok® finish.

**Offset Tibial Tray**

The Biomet® offset tibia offers offset immediately from the bottom of the tibial tray and can be positioned 360 degrees for exact offset placement. The offset is available in neutral, 2.5mm and 5.0mm.
Stem Options

The modular primary tray provides for the intraoperative selection of the stem to match the specific needs of the patient. The combination of a Morse-type taper and screw fixation helps maintain a solid connection between the stem and plate. When more fixation is desired, the stemmed tray or offset tray will accept stem extensions.

Modular Tibial Tray Stems

Stem Extensions
REFERENCES


3. Data on file at Biomet.*


38. Luedemann, Biomet In-House Testing, 1987.*


40. Luedemann, Biomet In-House Testing, 1992.*


*Bench test results are not necessarily indicative of clinical performance.