Vanguard® Complete Knee System

Design Rationale
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one 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 custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
Vanguard® Complete Knee System

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Vanguard® Cruciate Retaining (CR) Knee Design Features
Introduction
The proven clinical heritage of AGC®, Maxim®, and Ascent™ Total Knee Systems¹-³ and combined state-of-the-art design features have allowed Biomet to produce the most comprehensive total knee replacement system on the market. The Vanguard® Knee System offers the flexibility to change from cruciate retaining (CR) to posterior stabilized (PS) within a single system. The transition between each constraint level can be made with ease, allowing the physician to evaluate soft tissue and bone deficiencies intraoperatively without making a preoperative commitment to the level of constraint. The Vanguard® Knee is supported by five instrumentation platforms: Microplasty®, Premier™ Microplasty® Elite, Vanguard® Tensor and Premier™ Anterior Referencing Systems, accommodating a number of workflows and techniques.

Advanced Technology
The Vanguard® Complete Knee System continues to advance total knee arthroplasty with innovative technologies to provide personalized patient care. These technologies include:

- E1® Antioxidant Infused Bearing Technology
- Regenerex® Porous Titanium Construct
- Signature™ Personalized Patient Care

E1® Antioxidant Infused Bearing Technology
E1® Antioxidant Infused Tibial Bearing Technology defines a new class of bearings and overcomes the limitations of remelted and annealed polyethylenes by uniting true oxidative stability, high mechanical strength and ultra low wear⁴,⁵ (Figure 1).

See page 7 for more information regarding E1® Tibial Bearings.

Regenerex® Porous Titanium Construct
Regenerex® Porous Titanium Construct unites the proven clinical history of titanium alloy⁶ with an enhanced interconnecting pore structure, resulting in a revolutionary material that provides for biologic fixation¹⁷ (Figure 2).

See pages 8–9 for more information regarding Regenerex® material.

Signature™ Personalized Patient Care
Signature™ Personalized Patient Care utilizes MRI and CT based patient specific femoral and tibial positioning guides to offer an individualized approach to total knee replacement. The Signature™ System, which fits the femoral and tibial components independently, when used with the Vanguard® Complete Knee System, offers a comprehensive solution for personalized patient care (Figure 3).

See pages 12–13 for more information regarding The Signature™ System.
Femoral Design Features

When designing the Vanguard® Complete Knee System, every aspect of the femur, tibia and patella was reviewed for potential performance enhancements in all patient populations. Many clinically successful features found in earlier Biomet® total knee systems can be found in the Vanguard® Complete Knee System. However, many unique features were added.

The Vanguard® femoral component has four main design features:

• Rounded sagittal profile
• Deeper, swept-back trochlear groove
• Wider proximal trochlear groove
• Sizing

Rounded Sagittal Profile

Two distinct femoral designs have evolved over time (Figure 4).

• Anatomic (box-like) femoral profile
• Swept-back (rounder) femoral profile

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.9

The Vanguard® trochlear groove has been designed to sweep back posteriorly for better patellar performance10 (Figure 5).

Wider Proximal Trochlear Groove

Patellar capture during flexion must be balanced with the need for less patellar constraint in extension. The trochlear floor of the Vanguard® Knee has been widened to reduce the constraining forces in extension. The patella track provides a 6.5 degree valgus angulation and a 2 mm lateralized trochlear groove. “Valgus angulation has been shown to reduce the patellar shear stresses.”8

The wider proximal trochlear groove offers excellent patellar tracking (within 0–15 degrees of valgus) regardless of the patient’s Q-angle4 (Figure 6).

Rounded Sagittal Profile

A round sagittal profile, as found in the Vanguard® Knee, allows for greater range of motion than anatomic femoral components and may be more forgiving to the retinaculum by not over tensioning the soft tissues.5

Figure 4: Anatomic (Green) vs. Vanguard® Swept-back Sagittal Profile (Gray)

Figure 5: Standard Trochlear Groove (Green) vs. Vanguard® Deeper/Swept-back Trochlear Groove

Figure 6: Q-Angle Variability (within 0–15 degrees) Permitted by Vanguard® Trochlear Groove
Vanguard® CR Knee Design Features

Sizing
The Vanguard® Complete Knee System offers ten femoral sizes specifically designed for optimal bone coverage of all patient populations.

- Femoral sizes increase A/P by an average of 2.4 mm and M/L by 2.6 mm across all ten sizes (Figure 7)
- Narrow anterior flange maintains a small profile to reduce the likelihood of femoral overhang
- Rounded anterior flange corners to further address femoral overhang
- Posterior condyles grow proportionally in size to reduce overstuffing of the flexion gap in smaller femurs and the potential for 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 to dissipate forces on the bearing more effectively.11

Removable Femoral Lugs/Augments
The Vanguard® CR femoral lugs are removable and can be used in conjunction with distal augments (Figures 8 and 9). This feature allows for posterior and distal augmentation in a primary total knee arthroplasty or the use of a primary component in the revision of a unicompartmental knee arthroplasty.

Figure 7: Ten Femoral Sizes

Figure 8: Removable CR Lugs

Figure 9: Augment Attached to CR Knee
Articulation Features
The Vanguard® Complete Knee System features optimized tibiofemoral articulation based on the enhanced design of the following elements:

- Coronal Geometry
- Sagittal Geometry
- Curved Articulation

Coronal Geometry
The Vanguard® Complete Knee System provides a fully congruent (coronally), moderately dished articulation to reduce polyethylene stresses, while still allowing physiological motion. The 1:1 condylar geometry provides surgical flexibility by allowing complete tibial-femoral interchangeability* (Figure 10).

The coronal geometry features softened intercondylar M/L edges. This radius enhancement provides increased contact area when the patella articulates on the condyles in flexion. A Finite Element Analysis has demonstrated a 25 percent reduction in patella contact pressure compared to the Maxim® Total Knee* (Figure 11).

Sagittal Geometry
The Vanguard® Knee has been designed to allow up to 145 degrees of flexion without additional posterior condyle resections (Figure 12), with early results showing post-op mean range of motion of 125 degrees at three year follow-up.*

Curved Articulation
To increase contact area with axial rotation, the Vanguard® Knee features a rotated articulation bearing surface (Figure 14). As compared to a linear articulation, a rotated articulation increases the contact area by 13 percent.*

*with the exception of the Vanguard® Anterior Stabilized (AS) bearing
CR Bearing Options

Vanguard® CR tibial bearings are available in both, ArCom® Direct Compression Molded polyethylene and E1® Antioxidant Infused Technology. Three bearing design options are available for use with the CR knee (Figure 15).

- Standard CR
- CR Lipped
- Anterior Stabilized (AS)

These options provide intraoperative flexibility to meet patient needs and surgeon preference.

Bearing Technologies

Biomet’s proven polyethylene clinical heritage and commitment to improving bearing technologies to address the effects of oxidation, has produced some of the industry’s most advanced bearing technologies. These technologies include:

- ArCom® Polyethylene
- E1® Antioxidant Infused Technology

ArCom® Polyethylene

Oxidation negatively impacts the mechanical properties of polyethylene by causing pitting and delamination in knee bearing surfaces. Following Biomet’s traditional engineering approach, it was the first company to use inert gas (argon) to replace oxygen during the sterilization and packaging process. The use of argon reduces the degradative effects of oxygen in polyethylene bearings. Furthermore, gamma sterilization in an argon atmosphere has been shown to decrease wear over EtO sterilized polyethylene by 44 percent (Figure 16).

Figure 15: CR Bearing Options

Figure 16: Wear Testing
Biomet has continued the commitment to Direct Compression Molded (DCM) tibial bearings within the Vanguard® Complete Knee System to minimize the potential for oxidative breakdown of the polyethylene. Biomet's ability to provide a clinically proven polyethylene along with a clinically proven method of consolidation for the Vanguard® Complete Knee System punctuates Biomet’s commitment to long term clinical success with its bearing technologies. DCM polyethylene has been clinically proven to be resistant to wear, delamination and oxidation with 97.8 percent survivorship reported at 20 years, with no implants being revised for polyethylene wear.1

**E1® Antioxidant Infused Technology**

E1® Antioxidant Infused Tibial Bearing Technology defines a new class of bearings and overcomes the limitations of remelted and annealed polyethylenes by uniting true oxidative stability, high mechanical strength and ultra low wear.4,5 The foundation of this advancement in bearing technologies is ArCom® polyethylene.

E1® Antioxidant Infused Bearings are neither annealed nor remelted. Instead, oxidative stability is achieved by the infusion of vitamin E. Environmental Stress Crack Testing (ESC) mimics cyclic loading in vivo which is a major reason or mode for bearing breakdown. ESC testing has shown E1® material to be more oxidatively stable than sequentially crosslinked and annealed polyethylene4 (Figure 17). This manufacturing process allows E1® material to achieve oxidative stability without remelting the bearing material, which ultimately allows the bearing to retain its mechanical strength4,5 (Figure 18).

An internal Biomet study demonstrated that CR E1® tibial bearings had an 86 percent reduction in wear over CR DCM tibial bearings4 (Figure 19).

**Figure 17: Oxidation Profile**

**Figure 18: Ultimate Tensile and Yield Strengths**

**Figure 19: CR E1® Wear Rate**

**E1® Antioxidant Infused Technology FDA Cleared Claims:**4

- Prevents oxidative degradation of polyethylene
- Protects polyethylene from oxidation and cracking during environmental stress crack testing
- Maintains the mechanical strength of conventional UHMWPE under small punch testing
- Maintains mechanical strength after accelerated aging
**Vanguard® CR Knee Design Features**

**Polyethylene Thickness**
Meding, et al. demonstrated excellent long-term results with 4.4 mm minimum thickness DCM tibial bearings. The Vanguard Complete Knee System provides a minimum of 6 mm of polyethylene thickness in all components (Figure 20).

<table>
<thead>
<tr>
<th>Size Thickness (mm)</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>

![Figure 20: Polyethylene Size/Thickness](image)

**Component Fixation**
The Vanguard Complete Knee System incorporates three types of fixation:
- **Interlok® Finish**
- **PPS® Porous Plasma Spray Coating**
- **Regenerex® Porous Titanium Construct**

**Interlok® Finish**
The Interlok® finish allows for proper cement interdigitation into the surface for a more secure bond in cemented applications (Figure 21).

![Figure 21: Interlok® Finish](image)

**PPS® Porous Plasma Spray Coating**
Since its introduction in 1981, Biomet’s PPS® coating has been used by surgeons throughout the world to achieve better fixation on a multitude of products including the AGC®, Maxim® and Ascent™ Knee Systems. Long-term follow-up studies show that surgeons are observing extremely low rates of osteolysis and 97 percent survivorship at 20 years with PPS® coated prostheses (Figure 22).

![Figure 22: PPS® Coating](image)

In addition, PPS® coating has been proven to:
- Provide for more biologic fixation than CoCr material and has proven superior with regard to biocompatibility and component fit over titanium fiber mesh
- Maintain the implant’s inherent fatigue strength
- Provide early stage fixation, helping to prevent micromotion
- Provide late stage fixation, helping to offload stresses between implant and bone

**Regenerex® Porous Titanium Construct**
Regenerex® Porous Titanium Construct unites the proven clinical history of titanium alloy with an enhanced interconnecting pore structure, resulting in a revolutionary material that provides for biologic fixation (Figure 23).

![Figure 23: Regenerex® Porous Titanium Technology](image)
Regenerex® material provides for:

- Average porosity of 67 percent
- Average pore size of 300 microns
- High strength and flexibility
- Fixation in as early as two weeks was reported in canine studies

The large potential surface area for biologic fixation makes this tray an optimal option for patients with good bone quality.

**Tibial Tray Design Features**

Concerns have been raised about modularity and bearing micromotion as a contributor to osteolysis and early failure. Feng, et al. have found that the most severe polyethylene wear occurs at the periphery, where the tibial component had a raised metal edge. These concerns have been addressed with the Biomet® modular tibial tray design.

The modular design of the Vanguard® tibial tray is based on clinically successful features of earlier Biomet® total knee systems, including:

- Locking Mechanism
- Sizing
- Tibial Baseplate Options
- Stem Options

**Locking Mechanism**

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 competitive components provide adequate thickness at the center, but compromise thickness around the edges due to the design of the locking mechanism.

Features of the locking mechanism design include (Figure 24):

- Peripheral polyethylene thickness is maintained by locating the locking mechanism anteriorly and within the intercondylar area
- Biomet’s locking mechanism compresses the polyethylene bearing against the tray by utilizing an oversized titanium locking bar that forces the bearing against a 10 degree posterior boss

- The Coventry Award-winning study by Parks and Engh, and a study published by Sosa, have shown the Biomet® locking mechanism to be “the most stable overall.”

**Sizing**

Many knee systems offer a variety of tibial tray sizes. However, few systems offer consistent sizing. Based on the work of Mensch and Amstutz, the Vanguard® Knee System offers 9 symmetrical tibial baseplates that change in consistent 4 mm M/L intervals (Figure 25).

<table>
<thead>
<tr>
<th>M/L</th>
<th>Micro</th>
<th>63</th>
<th>67</th>
<th>71</th>
<th>75</th>
<th>83</th>
<th>Macro</th>
<th>87</th>
<th>Macro</th>
<th>91</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/P</td>
<td>38</td>
<td>41</td>
<td>43</td>
<td>46</td>
<td>48</td>
<td>51</td>
<td>53</td>
<td>56</td>
<td>58</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 24: Anterior Compressive Locking Mechanism**

**Figure 25: Biomet® Tibial Baseplate Sizing**

Incavo, et al. examined eight tibial tray designs, consisting of six symmetrical and two asymmetrical baseplates. The study demonstrated that the sizing rationale for the AGC® Total Knee System, which is closely paralleled by the Vanguard® Knee System, offers optimal coverage as compared to competitive asymmetrical designs (Figure 26).

**Figure 26: Vanguard® Symmetrical Tibial Tray Design**
Vanguard® CR Knee Design Features

Of all the tibial trays tested in one study, the modular tray design of the AGC® Knee was ranked as the best in total tibial plateau coverage, covering 81 percent of the tibial surface.£2

Tibial Baseplate Options
Primary tibial trays are made from both titanium and cobalt chrome alloys. Modular titanium primary baseplates are available with an Interlok® finish for cemented applications, or PPS® coating and Regenerex® Porous Titanium Construct to enhance bone fixation in cementless applications.

PPS® coated baseplates accept up to four 6.5 mm cancellous bone screws (Figure 27), while Regenerex® baseplates feature four solid titanium pegs that exhibit a rough texture (Figure 28) for enhanced fixation when a cementless tibial component is utilized.

The Regenerex® Tibial Tray is compatible with four primary articulations within the Vanguard® Complete Knee System:
- CR
- CR Lipped
- AS
- PS

The Vanguard® Complete Knee System is compatible with the following cobalt chrome baseplate options: I-beam, cruciate finned, or Microplasty® tray with an Interlok® finish (Figure 29).

I-beam and cruciate finned baseplates feature a 40 mm stem design while the 20 mm cruciate stem design of the Microplasty® tibial tray allows for a less invasive procedure and arcs posteriorly to increase resistance against pull-out.

Interlok® offset tibial baseplate, Interlok® stemmed baseplate, and the PPS® baseplate can be used with block or wedge augments. All augments are fixed to the baseplates by bolts, allowing a mechanical lock between the tray and augments.
Stem Options

The modular titanium primary baseplate allows for intraoperative stem selection to match specific patient needs. An I-beam primary stem is available in 40 mm length, while cruciate fin and splined primary stems are available in 40 mm and 80 mm lengths. In addition to the 40 mm and 80 mm splined, and cruciate fin stems, a taper cap is available for the Regenerex® Primary Tibial Tray (Figure 30).

Figure 30: Modular Tibial Tray Stems

The combination of a Morse-type taper and screw fixation helps maintain a solid connection between the stem and baseplate. When more fixation is desired, the stemmed or offset tray will accept a 40, 80, 120, 160, or 200 mm stem extension (Figure 31). Stem extensions are available in splined, smooth and grit-blasted finishes. Bowed, splined, smooth and grit-blasted stem extensions are offered in 160 and 180mm lengths.

Figure 31: Stem Extensions

Patellar Articulation

The Vanguard® Complete Knee System offers multiple patella options:

- Series A
  - Single Peg
  - Three Peg
- Regenerex® Construct
  - Three Peg

Series A Patella

Ritter, Lombardi, Insall, Ranawat, et al. have shown excellent long-term results with domed patellar designs.9,11,33,34 The domed patella is more forgiving in placement than other designs and can reliably provide congruent contact10 (Figure 32).

Figure 32: Domed Patella

Series A patellas are available in one and three peg options (Figure 33), and are available in standard thickness as well as a low profile which is on average 1.5 mm thinner than the standard patella.

Figure 33: Series A Standard One and Three Peg Patellas
Vanguard® CR Knee Design Features

Regenerex® Patella

The Regenerex® primary three peg patella incorporates Biomet’s Regenerex® Porous Titanium Construct with the Series A true dome shape and the standard poly thickness. The octagonal pegs provide for initial fixation on the resurfaced bone (Figure 34).

Figure 34: Regenerex® Three Peg Patella

Series A and Regenerex® Patella size and thickness offering listed below (Figure 35):

<table>
<thead>
<tr>
<th>Patella Sizing Chart</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25</td>
</tr>
<tr>
<td>Series A 1 Peg</td>
<td>Low Profile Standard</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
</tr>
<tr>
<td>Series A 3 Peg</td>
<td>Low Profile Standard</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
</tr>
<tr>
<td>Regenerex® 3 Peg</td>
<td>Standard</td>
</tr>
</tbody>
</table>

Figure 35: Patella Sizing Chart

Signature™ Planning Landmarks

The Signature™ system features proprietary planning algorithms to generate an initial preoperative plan incorporating traditional resection guides and allowing intraoperative position verification by the surgeon.

These landmarks include (Figure 36):

- A: Anterior/Posterior Axis
- B: Epicondylar Axis
- C: Distal Femoral Mechanical Axis
- D: Lateral Distal Femoral Condyle
- E: Medial Distal Femoral Condyle
- F: Posterior Condylar Axis
- G: Lateral Plateau
- H: Proximal Tibial Mechanical Axis Landmark
- I: Medial Plateau
- J: Medial One-third of the Tibial Tubercle

Figure 36: Signature™ Planning Landmarks

Signature™ Personalized Patient Care

Signature™ Personalized Patient Care utilizes patient specific femoral and tibial positioning guides developed from MRI and CT imaging modality to offer an individualized approach to total knee replacement. The Signature™ system fits the femoral and tibial components independently. When used with the Vanguard® Complete Knee System, it offers a comprehensive solution for personalized patient care. Features of the Signature™ system include:

- Signature™ Planning Landmarks
- Signature™ Total Knee Planning Software
- Signature™ Positioning Guides
**Signature™ Total Knee Planning Software**

Software built into the Signature™ system allows surgeons to visualize and specify an implant position for each patient plan.

- Automated planning algorithms generate preoperative plan based off mechanical axis
- User-friendly software for surgeon fine-tuning
- Positioning guides incorporate preoperative surgeon alteration

The result of the preoperative surgical planning is a more focused intervention with the instruments required for surgery as well as the operative plan.

**Signature™ Positioning Guides**

Preoperative surgeon planning is integrated into Signature™ positioning guides (Figure 37).

Tibial positioning guides register on the anteromedial tibial plateau to establish:

- Tibial resection
- Varus/valgus angle
- Tibial slope angle
- Tibial rotation

**Instrumentation Platforms**

The Vanguard® Complete Knee System is supported by five instrumentation platforms, allowing the physician to evaluate soft tissue and bone deficiencies intraoperatively without making a preoperative commitment to the level of constraint.

These instrumentation platforms include:

- Microplasty® Instrumentation
- Premier™ Instrumentation
- Microplasty® Elite Instrumentation
- Vanguard® Tensor Instrumentation
- Premier™ Anterior Referencing Instrumentation

**Microplasty® Total Knee Instrumentation**

Microplasty® Total Knee Instrumentation is designed for use with minimally invasive surgical techniques and includes Biomet’s Slidex® technology which allows for minimal disruption to soft tissues during total knee arthroplasty (Figure 38).
Premier™ Total Knee Instrumentation
Premier™ Total Knee Instrumentation is designed for conventional total knee replacement. Enhanced instrument functionality allows for reproducible and reliable results (Figure 39).

Figure 39: Premier™ Total Knee Instrumentation

Premier™ Anterior Referencing Instrumentation
Anterior Referencing Instrumentation is available for use with the Vanguard® Complete Knee System. This instrumentation allows for anterior referencing during femoral preparation to accommodate the preferred approach of individual surgeons (Figure 42).

Figure 42: Premier™ Anterior Referencing Instrumentation

Microplasty® Elite Total Knee Instrumentation
Microplasty® Elite Total Knee Instrumentation is designed for use with both traditional surgical methods as well as minimally invasive techniques. This instrumentation is designed for minimization of soft tissue trauma that occurs during total knee arthroplasty (Figure 40).

Figure 40: Microplasty® Elite Total Knee Instrumentation

Vanguard® Tensor Instrumentation
Utilizing Premier™ Total Knee Instrumentation, the Vanguard® Tensor is designed to assist in balancing soft tissues during total knee arthroplasty (Figure 41).

Figure 41: Vanguard® Tensor Instrumentation
Vanguard® Posterior Stabilized (PS) Knee Design Features
Introduction
The proven clinical heritage of AGC®, Maxim®, and Ascent™ Total Knee Systems¹⁻³ and combined state-of-the-art design features have allowed Biomet to produce the most comprehensive total knee replacement system on the market. The Vanguard® Knee System offers the flexibility to change from cruciate retaining (CR) to posterior stabilized (PS) within a single system. The transition between each constraint level can be made with ease, allowing the physician to evaluate soft tissue and bone deficiencies intraoperatively without making a preoperative commitment to the level of constraint. The Vanguard® Knee is supported by five instrumentation platforms: Microplasty®, Premier™, Microplasty® Elite, Vanguard® Tensor and Premier™ Anterior Referencing Systems, accommodating a number of workflows and techniques.

Advanced Technology
The Vanguard® Complete Knee System continues to advance total knee arthroplasty with innovative technologies to provide personalized patient care. These technologies include:

- E1® Antioxidant Infused Bearing Technology
- Regenerex® Porous Titanium Construct
- Signature™ Personalized Patient Care

E1® Antioxidant Infused Bearing Technology
E1® Antioxidant Infused Tibial Bearing Technology defines a new class of bearings and overcomes the limitations of remelted and annealed polyethylenes by uniting true oxidative stability, high mechanical strength and ultra low wear⁴,⁵ (Figure 1).

Regenerex® Porous Titanium Construct
Regenerex® Porous Titanium Construct unites the proven clinical history of titanium alloy⁶ with an enhanced interconnecting pore structure, resulting in a revolutionary material that provides for biologic fixation¹⁻¹ (Figure 2).

See page 24 for more information regarding Regenerex® material.

Signature™ Personalized Patient Care
Signature™ Personalized Patient Care utilizes MRI and CT based patient specific femoral and tibial positioning guides to offer an individualized approach to total knee replacement. The Signature™ System, which fits the femoral and tibial components independently, when used with the Vanguard® Complete Knee System, offers a comprehensive solution for personalized patient care (Figure 3).

See pages 28–29 for more information regarding the Signature™ System.
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.

The Vanguard® trochlear groove has been designed to sweep back posteriorly for better patellar performance.

Extended Trochlear Groove
The trochlear groove has been lengthened to further support the patella in deep flexion and provide more support of the quadriceps tendon (Figure 5). The junction of the trochlear groove and PS box articulates with the quadriceps tendon at 105–120 degrees of flexion.

Wider Proximal Trochlear Groove
Patellar capture during flexion must be balanced with the need for less patellar constraint in extension. The trochlear floor of the Vanguard® Knee has been widened to reduce the constraining forces in extension. The patella track provides a 6.5 degree valgus angulation and a 2 mm lateralized trochlear groove. “Valgus angulation has been shown to reduce the patellar shear stresses.”

Rounded Sagittal Profile
Two distinct femoral designs have evolved over time (Figure 4).

- Anatomic (box-like) femoral profile
- Swept-back (rounder) femoral profile

A round sagittal profile, as found in the Vanguard® Knee, allows for greater range of motion than anatomic femoral components and may be more forgiving to the retinaculum by not over tensioning the soft tissues.

When designing the Vanguard® Complete Knee System, every aspect of 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 can be found in the Vanguard® Complete Knee System. However, many unique features were added.

The Vanguard® femoral component has five main design features:

- Rounded sagittal profile
- Deeper/swept-back trochlear groove
- Extended trochlear groove
- Wider proximal trochlear groove
- Sizing

Patella performance.

The Vanguard® trochlear groove has been designed to sweep back posteriorly for better patellar performance.

Extended Trochlear Groove
The trochlear groove has been lengthened to further support the patella in deep flexion and provide more support of the quadriceps tendon (Figure 5). The junction of the trochlear groove and PS box articulates with the quadriceps tendon at 105–120 degrees of flexion.

Wider Proximal Trochlear Groove
Patellar capture during flexion must be balanced with the need for less patellar constraint in extension. The trochlear floor of the Vanguard® Knee has been widened to reduce the constraining forces in extension. The patella track provides a 6.5 degree valgus angulation and a 2 mm lateralized trochlear groove. “Valgus angulation has been shown to reduce the patellar shear stresses.”
**Vanguard® PS Knee Design Features**

The wider proximal trochlear groove offers excellent patellar tracking (within 0–15 degrees of valgus) regardless of the patient’s Q-angle (Figure 6).

![Figure 6: Q-Angle](image)

**Sizing**

The Vanguard® Complete Knee System offers ten femoral sizes specifically designed for optimal bone coverage of all patient populations.

- Femoral sizes increase A/P by an average of 2.4 mm and M/L by 2.6 mm across all ten sizes (Figure 7)
- Narrow anterior flange maintains a small profile to reduce the likelihood of femoral overhang
- Rounded anterior flange corners to further address femoral overhang
- Posterior condyles grow proportionally in size to reduce overstuffing of the flexion gap in smaller femurs and the potential for 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 to dissipate forces on the bearing more effectively.11

**PS Femoral Box Design**

The Vanguard® Complete Knee System offers a closed box and open box femoral component.

Vanguard® instrumentation offers three resections that accommodate both closed and open box femoral component designs (Figure 8). The closed box (CL) resection level is utilized when implanting a closed box femoral component. The open box femoral component can be implanted utilizing either the open box (OP) or the bone conserving (BC) resection level.

The open box design allows for additional preservation of distal bone. Utilizing the bone conserving resection with the open box design will conserve bone anteriorly while additional box resection is made for closed box design (Figure 9). If needed, IM nails can be utilized in the intercondylar notch with the open box femoral component.

![Figure 8: PS Box Resections](image)

![Figure 9: Maximum Box Volume for Vanguard® PS Knee](image)
Cam and Post Design
The Vanguard® PS femoral component has been specifically designed to enhance performance. Key elements in the Vanguard® PS design include:

- Extended Cam
- Cam and Post Engagement
- Dislocation Height

Extended Cam
The Vanguard® PS features an extended cam (Figure 10) for increased resistance to dislocation in deep flexion.

![Figure 10: Extended Cam](image)

Cam and Post Engagement
The cam, of the Vanguard® PS femoral component, is designed to engage the post of the tibial bearing at 45 degrees of flexion (Figure 11).

![Figure 11: 45 Degrees Cam and Post Engagement](image)

Gait analysis demonstrates that the weight bearing phase occurs from 0 – 45 degrees. After weight bearing phase occurs, the cam engages the post to provide stability and increase quadriceps efficiency, specifically during activities such as ascending and descending stairs.

Mid-flexion cam engagement avoids cam and post contact during cycle activities but provides for stability during load activities.

High Dislocation Height
The cam engages relatively low on the tibial bearing post and remains low throughout full range of motion. The forces at the tibial bone interface and locking mechanism are decreased, while maintaining a high bearing dislocation height. The dislocation height of the Vanguard® PS is never less than 17.3 mm at 90 degrees of flexion or greater (Figure 12). The Vanguard® PS component allows for 10 degrees of hyperextension before anterior post impingement.

![Figure 12: Cam and Post Contact Points](image)
Articulation Features

The Vanguard® Complete Knee System features optimized tibiofemoral articulation based on the enhanced design of the following elements:

- Coronal Geometry
- Sagittal Geometry
- Curved Articulation

Coronal Geometry

The Vanguard® Complete Knee System provides a fully congruent (coronally), moderately dished articulation to reduce polyethylene stresses, while still allowing physiological motion. The 1:1 condylar geometry provides surgical flexibility by allowing complete tibial-femoral interchangeability* (Figure 13).

![Figure 13: Tibial-Femoral Contact](image)

The coronal geometry features softened intercondylar M/L edges. This radius enhancement provides increased contact area when the patella articulates on the condyles in flexion. A Finite Element Analysis has demonstrated a 25 percent reduction in patella contact pressure compared to a conventional total knee [4] (Figure 14).

![Figure 14: Finite Element Analysis Demonstrates a Gradual Dispersion of Forces Along the Patella](image)

*Sagittal Geometry

The Vanguard® Knee has been designed to allow up to 145 degrees of flexion without additional posterior condyle resections (Figure 15), with early results showing post-op mean range of motion of 125 degrees at three year follow-up.[4]

![Figure 15: 145 Degrees Range of Motion with Primary Bone Cuts](image)

The Vanguard® Tibial Bearings have a deep anterior relief to accommodate the patella tendon during high flexion (Figure 16).

![Figure 16: High Flexion Patellar Tendon Relief](image)

Curved Articulation

To increase contact area with axial rotation, the Vanguard® Knee features a rotated articulation bearing surface (Figure 17). As compared to a linear articulation, a rotated articulation increases the contact area by 13 percent.[4]

![Figure 17: Rotated Articulation Bearing Surface](image)
PS Bearing Options

Vanguard® PS tibial bearings are available in both ArCom® Direct Compression Molded polyethylene and E1® Antioxidant Infused Technology.

Two bearing design options are available for use with the PS knee.

- PS
- PS Plus

PS Bearing Design

The Vanguard® PS post geometry is rounded to minimize forces on the post due to femoral rotation (Figure 18). According to a mechanical wear simulation test, the Vanguard® PS bearing had a 71 percent reduction in gravimetric wear at 5.5 million cycles, as compared to standard square post design geometry.4

PS Plus Bearing Design

The prominent anterior lip of the PS Plus bearing helps resist paradoxical anterior femoral slide during gait (Figure 19). This cradling effect controls the femoral component on the articulating surface without sacrificing freedom of rotation. The combination of 45 degrees cam engagement with a prominent anterior lip limits premature wear of the tibial post and provides mid-flexion stability.

Figure 19. Prominent Anterior Lip

The PS Plus bearing is more constrained than the standard PS bearing (Figure 20). The PS Plus bearing is indicated for use in a primary situation when more stability and initial constraint is desired to resist rotation and varus/valgus lift-off. The PS Plus bearing limits rotation to +/-2 degrees and varus/valgus lift-off to 2 degrees. The standard PS bearing does not constrain the femur in rotation or varus/valgus lift-off.

Figure 20: PS Bearing and PS Plus Bearing (Green)
**Bearing Technologies**

Biomet’s proven polyethylene clinical heritage and commitment to improving bearing technologies to address the effects of oxidation, has produced some of the industry’s most advanced bearing technologies. These technologies include:

- ArCom® Polyethylene
- E1® Antioxidant Infused Technology

**ArCom® Polyethylene**

Oxidation negatively impacts the mechanical properties of polyethylene by causing pitting and delamination in knee bearing surfaces. Following Biomet’s traditional engineering approach, it was the first company to use inert gas (argon) to replace oxygen during the sterilization and packaging process. The use of argon reduces the degradative effects of oxygen in polyethylene bearings. Furthermore, gamma sterilization in an argon atmosphere has been shown to decrease wear over EtO sterilized polyethylene by 44 percent\(^1\) (Figure 21).

System punctuates Biomet’s commitment to long term clinical success with its bearing technologies. ArCom® polyethylene has been clinically proven to be resistant to wear, delamination and oxidation with 97.8 percent survivorship reported at 20 years, with no implants being revised for polyethylene wear. \(^1\)

**E1® Antioxidant Infused Technology**

E1® Antioxidant Infused Tibial Bearing Technology defines a new class of bearings and overcomes the limitations of remelted and annealed polyethylenes by uniting true oxidative stability, high mechanical strength and ultra low wear.\(^4,5\) The foundation of this advancement in bearing technologies is ArCom® polyethylene.

E1® Antioxidant Infused Bearings are neither annealed nor remelted. Instead, oxidative stability is achieved by the infusion of vitamin E. Biomet Environmental Stress Crack Testing (ESC) mimics cyclic loading in vivo which is a major reason or mode for bearing breakdown. ESC testing has shown E1® material to be more oxidatively stable than sequentially crosslinked and annealed polyethylene\(^4\) (Figure 22). This manufacturing process allows E1® material to achieve oxidative stability without remelting the bearing material, which ultimately allows the bearing to retain its mechanical strength\(^4,5\) (Figure 23).

![Figure 21: Wear Testing](image)

![Figure 22: Oxidation Profile](image)
A second, independent study conducted through the University of Nebraska, reported that PS E1® tibial bearings had an 87 percent reduction in wear over PS DCM tibial bearings (Figure 24).\(^4\)

**Polyethylene Thickness**

Meding, *et al.* demonstrated excellent long-term results with 4.4 mm minimum thickness DCM tibial bearings.\(^14\) The Vanguard® Complete Knee System provides a minimum of 6 mm of polyethylene thickness in all components (Figure 25).

### Component Fixation

The Vanguard® Knee system incorporates three types of fixation:

- **Interlok® Finish**
- **PPS® Porous Plasma Spray Coating**
- **Regenerex® Porous Titanium Construct**

#### Interlok® Finish

The Interlok® finish allows for proper cement interdigitation into the surface for a more secure bond in cemented applications (Figure 26).
PPS® Porous Plasma Spray Coating
Since its introduction in 1981, Biomet’s PPS® coating has been used by surgeons throughout the world to achieve better fixation on a multitude of products including the AGC®, Maxim® and Ascent™ Knee Systems. Long-term follow-up studies show that surgeons are observing extremely low rates of osteolysis and 97 percent survivorship at 20 years with PPS® coated prostheses9, 20 (Figure 27).

Regenerex® material provides for:
• Average porosity of 67 percent4
• Average pore size of 300 microns4
• High strength and flexibility4
• Fixation in as early as two weeks was reported in canine studies4,7

The large potential surface area for biologic fixation makes this tray an optimal option for patients with good bone quality.

Tibial Tray Design Features
Concerns have been raised about modularity and bearing micromotion as a contributor to osteolysis and early failure.25–29 Feng, et al. have found that the most severe polyethylene wear occurs at the periphery, where the tibial component had a raised metal edge.30 These concerns have been addressed with the Biomet® modular tibial tray design.

The modular design of the Vanguard® tibial tray is based on clinically successful features of earlier Biomet® total knee systems, including:
• Locking Mechanism
• Sizing
• Tibial Baseplate Options
• Stem Options

Locking Mechanism
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 competitive components provide adequate thickness at the center, but compromise thickness around the edges due to the design of the locking mechanism.
Features of the locking mechanism design include (Figure 29):

- Peripheral polyethylene thickness is maintained by locating the locking mechanism anteriorly and within the intercondylar area
- Biomet's locking mechanism compresses the polyethylene bearing against the tray by utilizing an oversized titanium locking bar that forces the bearing against a 10 degree posterior boss
- The Coventry Award-winning study by Parks and Engh, and a study published by Sosa, have shown the Biomet® locking mechanism to be “the most stable overall.”

Of all the tibial trays tested in one study the modular tray design of the AGC® Knee was ranked as the best in total tibial plateau coverage, covering 81 percent of the tibial surface.

Tibial Baseplate Options

Primary tibial trays are made from both titanium and cobalt chrome alloys. Modular titanium primary baseplates are available with an Interlok® finish for cemented applications, or PPS® coating and Regenerex® Porous Titanium Construct to enhance bone fixation in cementless applications.

PPS® coated baseplates accept up to four 6.5 mm cancellous bone screws (Figure 32), while Regenerex® baseplates feature four solid titanium pegs that exhibit a rough texture (Figure 33) for enhanced fixation when a cementless tibial component is utilized.

Incavo, et al. examined eight tibial tray designs, consisting of six symmetrical and two asymmetrical baseplates. The study demonstrated that the sizing rationale for the AGC® Total Knee System, which is closely paralleled by the Vanguard® Knee System, offers optimal coverage as compared to competitive asymmetrical designs (Figure 31).
The Regenerex® Tibial Tray is compatible with four primary articulations within the Vanguard® Complete Knee System.

- CR
- CR Lipped
- AS
- PS

The Vanguard® Complete Knee System is compatible with the following cobalt chrome baseplate options: I-beam, cruciate finned, or Microplasty® tray with an Interlok® finish (Figure 34).

I-beam and cruciate finned baseplates feature a 40 mm stem design while the 20 mm cruciate stem design of the Microplasty® tibial tray allows for a less invasive procedure and arcs posteriorly to increase resistance against pull-out.

Interlok® offset tibial baseplate, Interlok® stemmed baseplate, and the PPS® baseplate can be used with block or wedge augments. All augments are fixed to the baseplates by bolts, allowing a mechanical lock between the tray and augments.

**Stem Options**

The modular titanium primary baseplate allows for intraoperative stem selection to match specific patient needs. An I-beam primary stem is available in 40 mm length, while cruciate fin and splined primary stems are available in 40 mm and 80 mm lengths. In addition to the 40 mm and 80 mm splined and cruciate fin stems, a taper cap is available for the Regenerex® Primary Tibial Tray (Figure 35).

The combination of a Morse-type taper and screw fixation helps maintain a solid connection between the stem and baseplate. When more fixation is desired, the stemmed or offset tray will accept a 40, 80, 120, 160, or 200 mm stem extension (Figure 36). Stem extensions available in splined, smooth and grit-blasted finishes. Bowed splined, smooth and grit-blasted stem extensions are offered in 160 and 180 mm lengths.
Patellar Articulation

The Vanguard® Complete Knee System offers multiple patella options:

- Series A
  - Single Peg
  - Three Peg
- Regenerex® Construct
  - Three Peg

Series A Patella

Ritter, Lombardi, Insall, Ranawat, et al. have shown excellent long-term results with domed patellar designs. The domed patella is more forgiving in placement than other designs and can reliably provide congruent contact (Figure 37).

Series A and Regenerex® Patella size and thickness offering listed below (Figure 40).

<table>
<thead>
<tr>
<th>Patella Sizing Chart</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25</td>
</tr>
<tr>
<td>Series A 1 Peg</td>
<td>6.2</td>
</tr>
<tr>
<td>Low Profile</td>
<td>8.0</td>
</tr>
<tr>
<td>Standard</td>
<td>8.0</td>
</tr>
<tr>
<td>Series A 3 Peg</td>
<td>6.2</td>
</tr>
<tr>
<td>Low Profile</td>
<td>8.0</td>
</tr>
<tr>
<td>Standard</td>
<td>8.0</td>
</tr>
<tr>
<td>Regenerex® 3 Peg</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Figure 37: Domed Patella

Series A patellas are available in one and three peg options (Figure 38), and are available in standard thickness as well as a low profile which is on average 1.5 mm thinner than the standard patella.

Figure 38: Series A Standard One and Three Peg Patellas

Regenerex® Patella

The Regenerex® primary three peg patella incorporates Biomet’s Regenerex® Porous Titanium Construct with the Series A true dome shape and standard poly thickness. The octagonal pegs provide for initial fixation on the resurfaced bone (Figure 39).

Figure 39: Regenerex® Three Peg Patella
Signature™ Personalized Patient Care

Signature™ Personalized Patient Care utilizes patient specific femoral and tibial positioning guides developed from MRI and CT imaging modality to offer an individualized approach to total knee replacement. The Signature™ system fits the femoral and tibial components independently. When used with the Vanguard® Complete Knee System, it offers a comprehensive solution for personalized patient care. Features of the Signature™ system include:

- Signature™ Planning Landmarks
- Signature™ Total Knee Planning Software
- Signature™ Positioning Guides

Signature™ Planning Landmarks

The Signature™ System features proprietary planning algorithms to generate an initial preoperative plan incorporating traditional resection guides and allowing intraoperative position verification by the surgeon.

These landmarks include (Figure 41):

- Anterior/Posterior Axis
- Epicondylar Axis
- Distal Femoral Mechanical Axis
- Lateral Distal Femoral Condyle
- Medial Distal Femoral Condyle
- Posterior Condylar Axis
- Lateral Plateau
- Proximal Tibial Mechanical Axis Landmark
- Medial Plateau
- Medial One-third of the Tibial Tubercle

Signature™ Total Knee Planning Software

Software built into the Signature™ system allows surgeons to visualize and specify an implant position for each patient plan.

- Automated planning algorithms generate preoperative plan based off mechanical axis
- User-friendly software for surgeon fine-tuning
- Positioning guides incorporate preoperative surgeon alteration

The result of the preoperative surgical planning is a more focused intervention with the instruments required for surgery as well as the operative plan.

Figure 41: Signature™ Planning Landmarks
**Signature™ Positioning Guides**

Preoperative surgeon planning is integrated into Signature™ positioning guides (Figure 42).

![Signature™ Positioning Guides](image)

Femoral positioning guides register on femoral articular surface to establish:

- Distal femoral resection
- Distal femoral valgus angle
- Distal femoral flexion angle
- Femoral component rotation
- A/P position
- Femoral component sizing

Tibial positioning guides register on the anteromedial tibial plateau to establish:

- Tibial resection
- Varus/valgus angle
- Tibial slope angle
- Tibial rotation

**Instrumentation Platforms**

The Vanguard® Complete Knee System is supported by five instrumentation platforms, allowing the physician to evaluate soft tissue and bone deficiencies intraoperatively without making a preoperative commitment to the level of constraint. These instrumentation platforms include:

- Microplasty® Instrumentation
- Premier™ Instrumentation
- Microplasty® Elite Instrumentation
- Vanguard® Tensor Instrumentation
- Premier™ Anterior Referencing Instrumentation

**Microplasty® Total Knee Instrumentation**

Microplasty® Total Knee Instrumentation is designed for use with minimally invasive surgical techniques and includes Biomet’s Slidex® technology which is designed for minimal disruption to soft tissues during total knee arthroplasty (Figure 43).

![Microplasty® Total Knee Instrumentation](image)

**Premier™ Total Knee Instrumentation**

Premier™ Total Knee Instrumentation is designed for conventional total knee replacement. Enhanced instrument functionality allows for reproducible and reliable results (Figure 44).

![Premier™ Total Knee Instrumentation](image)
Microplasty® Elite Total Knee Instrumentation

Microplasty® Elite Total Knee Instrumentation is designed for use with both traditional surgical methods as well as minimally invasive techniques. This instrumentation is designed for minimization of soft tissue trauma that occurs during total knee arthroplasty (Figure 45).

Figure 45: Microplasty® Elite Total Knee Instrumentation

Vanguard® Tensor Instrumentation

Utilizing Premier™ Total Knee Instrumentation, the Vanguard® Tensor is designed to assist in balancing soft tissues during total knee arthroplasty (Figure 46).

Figure 46: Vanguard® Tensor Instrumentation

Premier™ Anterior Referencing Instrumentation

Anterior Referencing Instrumentation is available for use with the Vanguard® Complete Knee System. This instrumentation provides for anterior referencing during femoral preparation to accommodate the preferred approach of individual surgeons (Figure 47).

Figure 47: Premier™ Anterior Referencing Instrumentation
References

7. Testing done on animal models.
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