

Vanguard[®] Complete Knee System

Design Rationale



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Vanguard® Knee Design Features

Introduction

The clinical heritage of AGC®, Maxim®, and Ascent™ Total Knee Systems¹⁻³ and combined design features have allowed Zimmer Biomet to produce the Vanguard Complete Knee System. 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 accommodates numerous 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:

- Vivacit-E® HXLPE Technology
- Signature™ Personalized Patient Care

Vivacit-E HXLPE Technology

Vivacit-E HXLPE is specifically designed to maximize performance through a proprietary process providing exceptional oxidative stability, ultra-low wear, and improved mechanical strength, from a manufacturer with a trusted clinical heritage^{4,5,6; 21-26} (Figure 1).

See page 11 for more information regarding Vivacit-E HXLPE Tibial Bearings.

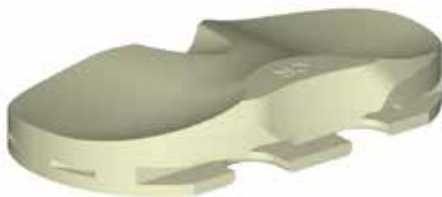


Figure 1
Vivacit-E HXLPE Tibial Bearing

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 2).

See page 18 for more information regarding the Signature System.



Figure 2
Signature™ Personalized Patient Care

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 Zimmer 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 3):

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



Figure 3
Anatomic (Green) vs.
Vanguard Swept-back Sagittal Profile (Gray)

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.⁷

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.⁸

The Vanguard trochlear groove has been designed to sweep back posteriorly (Figure 4).



Figure 4
Standard Trochlear Groove (Green) vs. Vanguard Deeper/
Swept-back Trochlear Groove

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 within 0 to 15 degrees of valgus (Figure 5). "Valgus angulation has been shown to reduce the patellar shear stresses."⁷

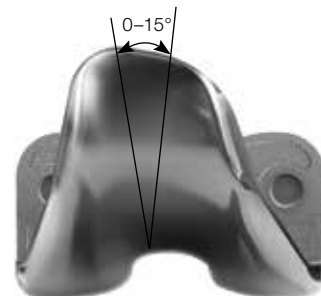


Figure 5
Q-Angle Variability (within 0–15 degrees) Permitted
by Vanguard Trochlear Groove

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 6)
- 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.⁹



Figure 6
Ten Femoral Sizes

Removable Femoral Lugs/Augments

The Vanguard CR Femoral Lugs are removable and can be used in conjunction with distal augments (Figures 7 and 8). 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
Removable CR Lugs



Figure 8
Augment Attached to CR Knee

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 9). 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.

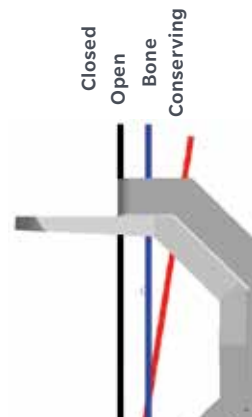


Figure 9
PS Box Resections

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

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).

Gait analysis demonstrates that the weight bearing phase occurs from 0–45 degrees.¹¹ 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.⁸



Figure 11
45 Degrees Cam and Post Engagement

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.

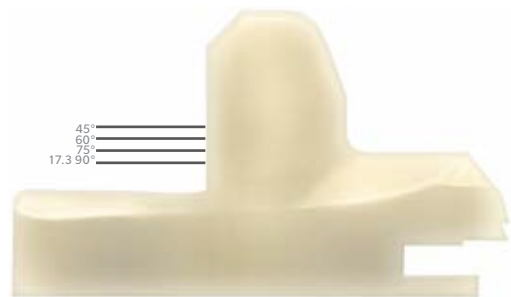


Figure 12
Cam and Post Contact Points

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 13). If needed, IM nails can be utilized in the intercondylar notch with the open box femoral component.

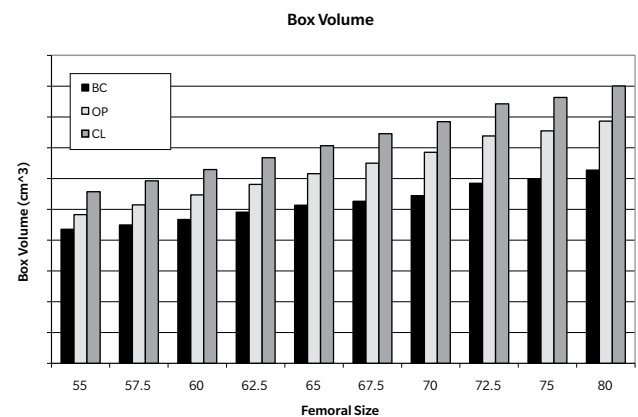


Figure 13
Maximum Box Volume for Vanguard PS Knee

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 14).



Figure 14
Tibiofemoral Contact

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 (Figure 15).

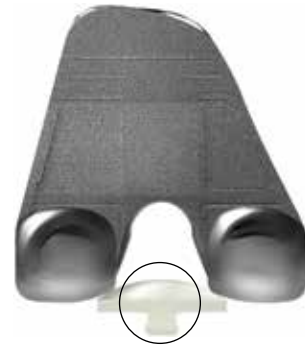


Figure 15

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

Sagittal Geometry

The Vanguard Knee has been designed to allow up to 145 degrees of flexion without additional posterior condyle resections (Figure 16).



Figure 16

145 Degrees Range of Motion with Primary Bone Cuts

*with the exception of the Vanguard Anterior Stabilized (AS) Bearing

The Vanguard Tibial Bearings have a deep anterior relief to accommodate the patella tendon during high flexion (Figure 17).

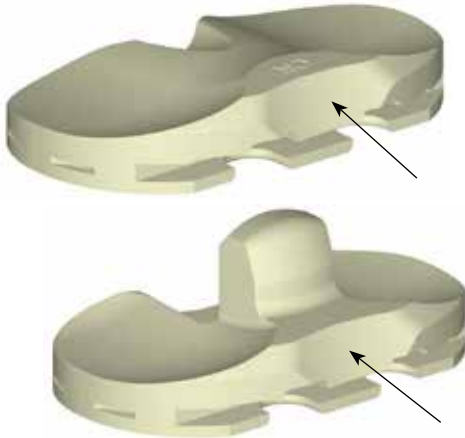


Figure 17

High Flexion Patellar Tendon Relief

Curved Articulation

To increase contact area with axial rotation, the Vanguard Knee features a rotated articulation bearing surface (Figure 18). As compared to a linear articulation, a curved articulation can prevent the increase in contact stresses and improve durability against wear.¹²



Figure 18

Rotated Articulation Bearing Surface

Patellar Articulation

The Vanguard Complete Knee System offers multiple patella options:

- Series A™
 - Single Peg (1-Peg)
 - Three Peg (3-Peg)

Series A Patella

Ritter, Lombardi, Insall, Ranawat, *et al.* have shown excellent long-term results with domed patellar designs.^{13,14} The domed patella can reliably provide congruent contact¹⁵ (Figure 19).



Figure 19

Domed Patella

Series A patellas are available in one and three peg options (Figure 20), 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 20

Series A Standard One and Three Peg Patellas

CR Bearing Options

Vanguard CR Tibial Bearings are available in both, ArCom® Direct Compression Molded Polyethylene and Vivacit-E HXLPE Technology. Three bearing design options are available for use with the CR knee (Figure 21).

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

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



Standard CR:

- 3 degrees posterior slope
- 15 degrees internal/external rotation
- No varus/valgus constraint



CR Lipped:

- Enhanced posterior lip
- 15 degrees internal/external rotation
- No varus/valgus constraint



AS Bearing:

- Ultracongruent deep dish design
- 6 degrees internal/external rotation
- No varus/valgus constraint

Figure 21
CR Bearing Options

PS Bearing Options

Vanguard PS Tibial Bearings are available in both ArCom Direct Compression Molded Polyethylene and Vivacit-E HXLPE 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 22).

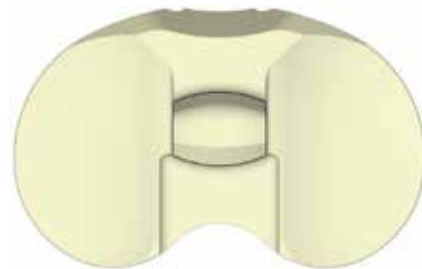


Figure 22
Vanguard Rounded PS Post

PS Plus Bearing Design

The prominent anterior lip of the PS Plus bearing helps resist paradoxical anterior femoral slide during gait (Figure 23). 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.

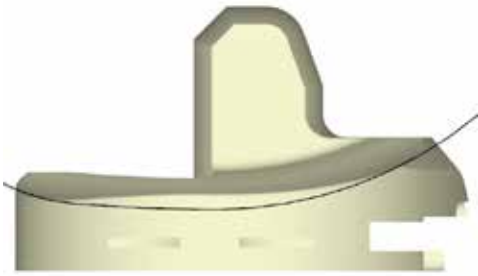


Figure 23
Prominent Anterior Lip

The PS Plus bearing is more constrained than the standard PS bearing (Figure 24). The PS Plus bearing is developed 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.

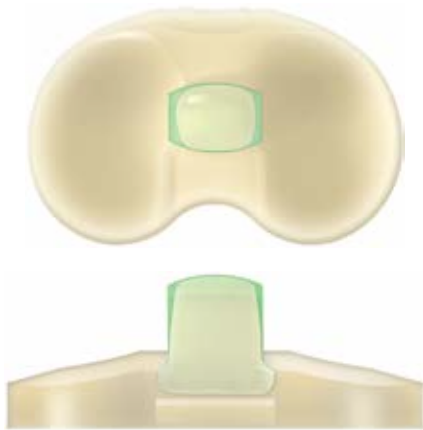


Figure 24
PS Bearing and PS Plus Bearing (Green)

NOT ALL POLYETHYLENES ARE CREATED EQUAL

The formulation of polyethylene is complex. While one step can help with one material characteristic, it can compromise another.

- Free radicals in HXLPEs can be reduced via passive stabilization by thermally processing below the melt temperature (annealing, including sequentially), which retains the initial strength of the material; however, doing so comes at the expense of oxidative stability due to the incomplete removal of free radicals.¹⁶
- Conversely, free radicals in HXLPEs can be eliminated via passive stabilization by thermally processing above the melt temperature (remelting); however, doing so comes at the expense of initial strength and toughness.¹⁶
- Actively stabilized blended antioxidant HXLPEs that are cold (gamma) irradiated solve the *in vivo* oxidation problem but sacrifice wear resistance of the material.¹⁶
- Actively stabilized blended antioxidant HXLPEs that are warm (e-beam) irradiated solve the oxidation problem with NO COMPROMISE of the material’s strength and wear resistance.¹⁶
- **Note:** Laboratory testing is not necessarily indicative of clinical performance.

Is Your Polyethylene Performing as Well as It Should?

	Cross-linking Process	Oxidative Stabilization Method	Oxidative Stability	Improved Mechanical Strength	Ultra-low Wear
HXLPE (Thermally Processed)					
X3™ Stryker	Gamma	Annealed	⊘	⚠	⚠
XLPE (S & N)	Gamma	Remelted	⊘	⊘	⚠
HXLPE (with Antioxidants)					
Vitamin E Blends ECIMA™ (Corin)	Gamma	Blended	✓	✓	⊘
AOX™ (DePuy)	Gamma	Blended	✓	✓	⊘
HXLPE (with Antioxidants and Warm E-Beam)					
Vivacit-E HXLPE	Warm E-Beam	Blended	✓	✓	✓

Bearing Technologies

Zimmer 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
- Vivacit-E HXLPE Technology

ArCom Polyethylene

Oxidation negatively impacts the mechanical properties of polyethylene by causing pitting and delamination in knee bearing surfaces. Following Zimmer 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.¹⁷

Zimmer 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. Zimmer Biomet's ability to provide a clinically proven polyethylene¹⁸⁻²⁰ along with a clinically proven method of consolidation for the Vanguard Complete Knee System punctuates Zimmer 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

Vivacit-E HXLPE Technology

Vivacit-E HXLPE is specifically designed to maximize performance through a proprietary process providing exceptional oxidative stability, ultra-low wear, and improved mechanical strength, from a manufacturer with a trusted clinical heritage.^{4,5,6; 21-26}



Figure 25

Vivacit-E HXLPE Vitamin E enriched Tibial Bearing

VIVACIT-E HXLPE: DESIGNED FOR **LONG-TERM PERFORMANCE**



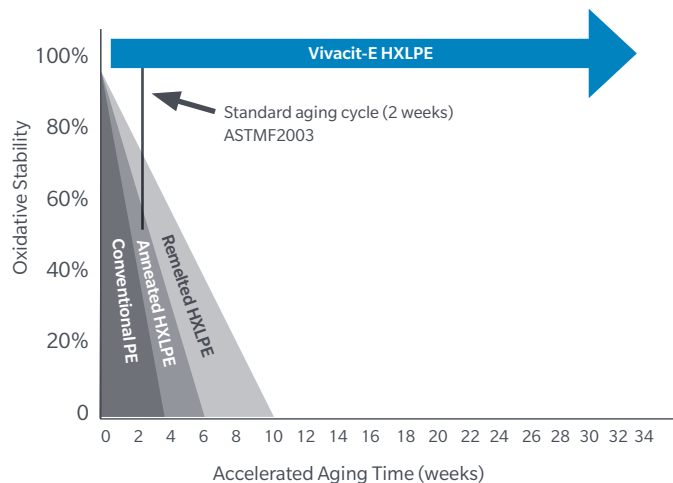
Choosing the right polyethylene for use in joint replacement could mean the difference between long-term performance and the premature need for revision surgery.

Vivacit-E HXLPE is specifically designed to maximize performance through a proprietary process providing exceptional oxidative stability, ultra-low wear, and improved mechanical strength, from a manufacturer with a trusted clinical heritage.^{4,5,6; 21-26}

Exceptional Oxidative Stability⁴⁻⁶

Oxidation is a primary degradation mechanism of polyethylene that can lead to osteolysis and implant failure.²⁷⁻³⁰ The vitamin E in Vivacit-E HXLPE is a powerful antioxidant that continuously quenches harmful free radicals to prevent oxidative degradation.⁴

After accelerated aging for 33 weeks—more than 16 times longer than the industry standard—Vivacit-E HXLPE showed no sign of oxidation or significant changes in mechanical properties.⁶



Vivacit-E HXLPE retained mechanical strength and showed no oxidation after 33 weeks of accelerated aging

Note: Laboratory testing is not necessarily indicative of clinical performance.

Ultra-low Wear

Osteolysis induced by wear particles has been recognized as one of the major causes of long-term failure in total joint replacement. Vivacit-E HXLPE is irradiated to an equivalent of 10MRad with warm electron beam (e-beam) radiation, resulting in an ultra-low wear HXLPE that has been tested out to 100 million cycles (Mc) in a 40 mm hip wear simulator test.³¹

Vivacit-E HXLPE’s wear performance is maintained even after accelerated oxidation aging.⁶ Wear testing showed no statistically significant difference between both 2-week and 6-week extreme-aged Vivacit-E HXLPE groups (Figure 26).⁶

Retention of Wear Properties After Extended Aging

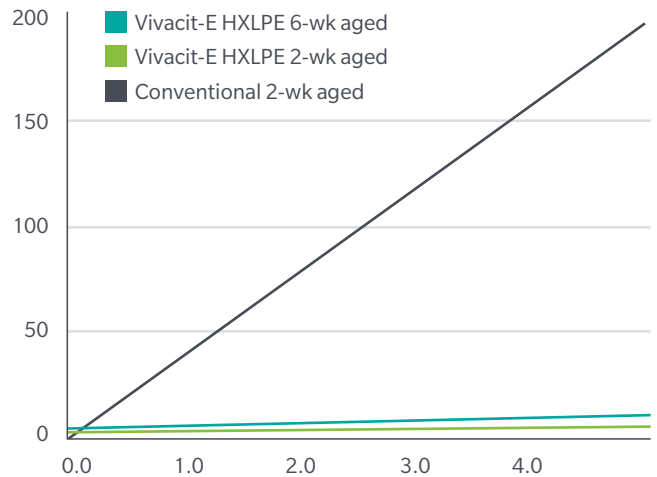


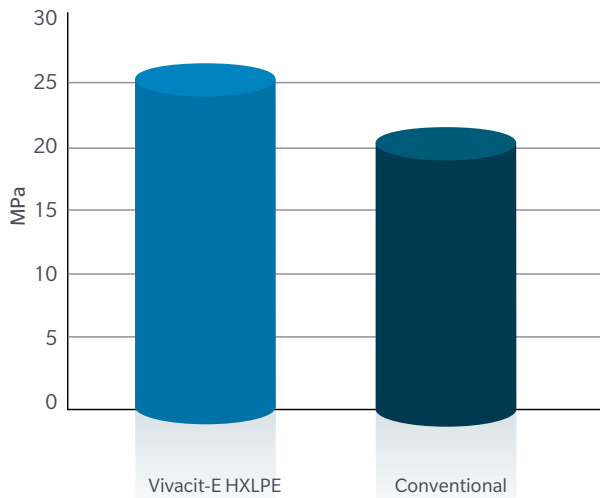
Figure 26

Improved Mechanical Strength

Conventional polyethylene has long been considered the gold standard in mechanical properties.

Vivacit-E HXLPE has demonstrated superior tensile strength over conventional polyethylene due to a warm e-beam irradiation process that grafts vitamin E onto the polyethylene. This process results in Vivacit-E retaining its mechanical strength even after long-term aging and oxidation challenges.⁴⁻⁶

Tensile Yield Strength



Note: Laboratory testing is not necessarily indicative of clinical performance.

Trusted Clinical Heritage

Vivacit-E HXLPE builds on a 40-year heritage of excellence that has made Zimmer Biomet a trusted polyethylene manufacturer.

Polyethylene Thickness

Meding, *et al.* demonstrated excellent long-term results with 4.4 mm minimum thickness DCM tibial bearings.¹⁹ The Vanguard Complete Knee System provides a minimum of 6 mm of polyethylene thickness in all components (Figure 26).

Size Thickness (mm)	10	12	14	16	18	20	22	24
Polyethylene Articulating Thickness (mm)	6	8	10	12	14	16	18	20

Figure 26
Polyethylene Size/Thickness

Component Fixation

The Vanguard Complete Knee System incorporates two types of fixation:

- Interlok Finish
- PPS® Porous Plasma Spray Coating

Interlok Finish

The Interlok Finish allows for proper cement interdigitation into the surface for a more secure bond in cemented applications (Figure 27).



Figure 27
Interlok Finish

PPS Porous Plasma Spray Coating

Since its introduction in 1981, Zimmer Biomet’s PPS® Coating has been used by surgeons throughout the world to achieve 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 prostheses³² (Figure 28).



Figure 28
PPS Coating

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 mesh³³
- Maintain the implant’s inherent fatigue strength^{12; 34-36}
- Provide early stage fixation, helping to prevent micromotion³²
- Provide late stage fixation, helping to offload stresses between implant and bone³²

Tibial Tray Design Features

Concerns have been raised about modularity and bearing micromotion as a contributor to osteolysis and early failure.³⁷⁻⁴¹ Feng, *et al.* have found that the most severe polyethylene wear occurs at the periphery, where the tibial component had a raised metal edge.⁴² These concerns have been addressed with the Zimmer Biomet modular tibial tray design.

The modular design of the Vanguard Tibial Tray is based on the features of earlier Zimmer 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
- The Vanguard 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



Figure 29

Anterior Compressive Locking Mechanism

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,⁴³ the Vanguard Knee System offers nine symmetrical tibial baseplates that change in consistent 4 mm M/L intervals (Figure 30).

M/L	Micro							Macro	
	A/P	59	63	67	71	75	79	83	87

Figure 30

Zimmer 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 designs¹⁰ (Figure 31).



Figure 31

Vanguard Symmetrical Tibial Tray Design

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.¹⁰

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 for cementless applications.

PPS coated baseplates accept up to four 6.5 mm cancellous bone screws (Figure 32) when a cementless tibial component is utilized.



Figure 32

PPS[®] Baseplate

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 33).

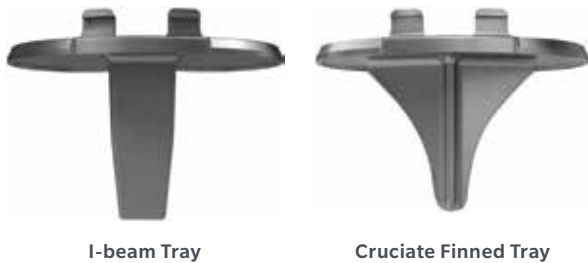


Figure 33
Cobalt Chrome Baseplate Options

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. (Figure 34).



Figure 34
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 35). Stem extensions are available in splined, smooth and grit-blasted finishes. Bowed, splined, smooth and grit-blasted stem extensions are offered in 160 and 180 mm lengths.



Figure 35
Stem Extensions

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 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

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.

Femoral positioning guides register on femoral bearing 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

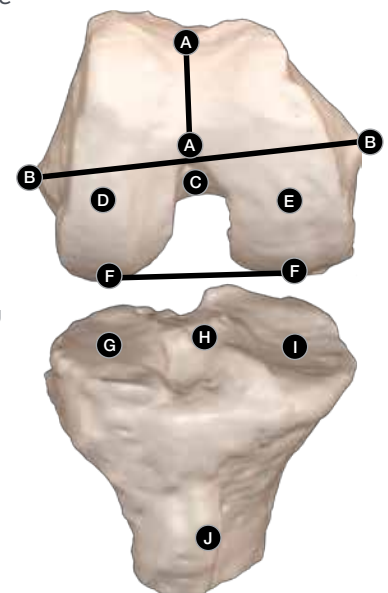


Figure 36
Signature™ Planning
Landmarks

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