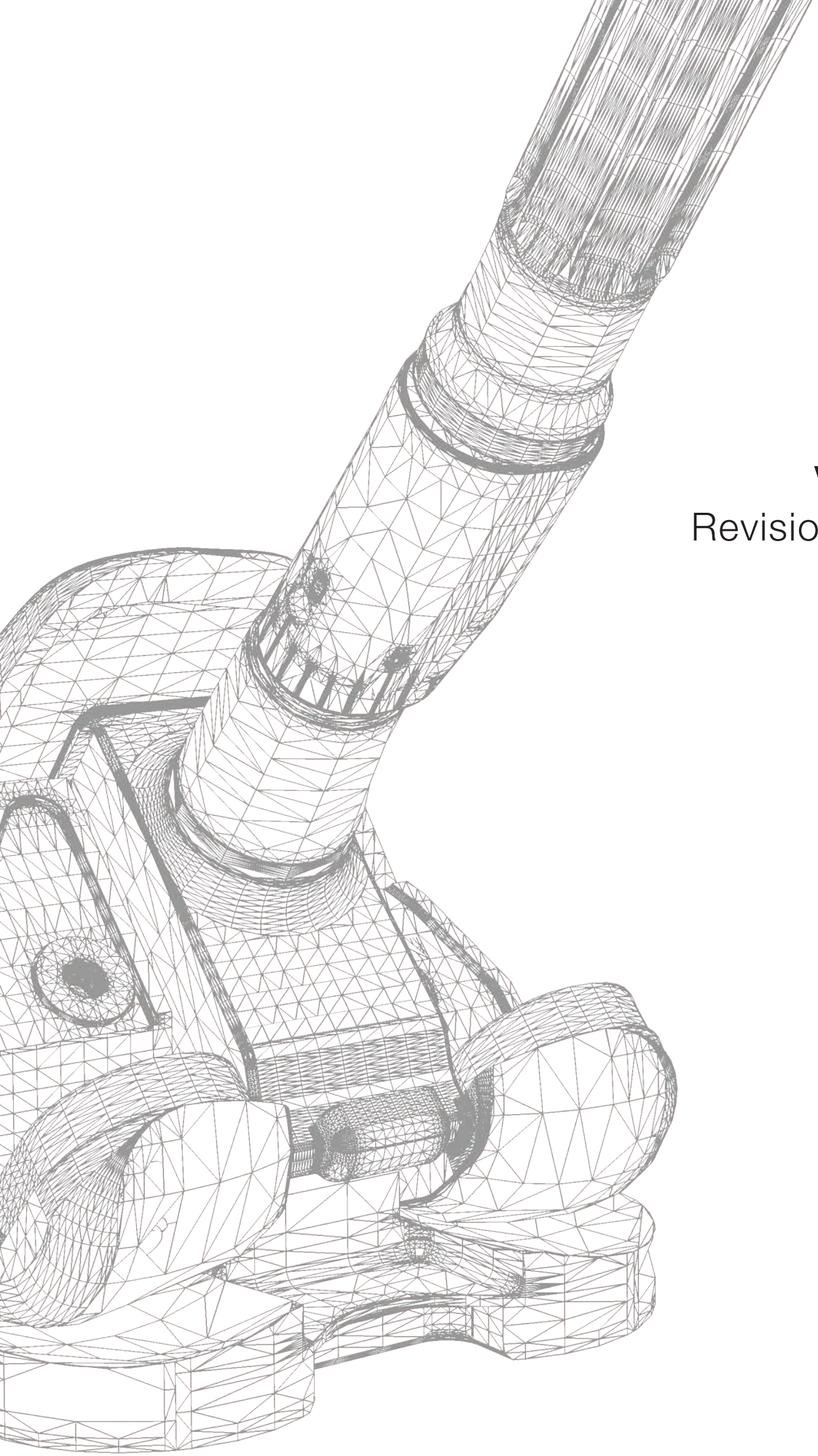


Vanguard® 360
Revision Knee System

Design Rationale

BIOMET®

One Surgeon. One Patient.®

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 patient-matched implant.

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

Vanguard® 360 Revision Knee System

Introduction

The proven clinical heritage of AGC®, Maxim® and Ascent™ Total Knee Systems 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® Complete Knee System. As part of the Vanguard® Complete Knee System, the Vanguard® 360 Revision Knee System maintains the key design fundamentals and sizing options to allow surgeons the flexibility to choose the appropriate implant combination for the patient. The Vanguard® 360 Revision Knee System delivers customizable implant combinations due to independent fit of each component and comprehensive instrumentation to aid surgeons in addressing diverse, often challenging procedures while choosing a personalized patient approach to revision knee surgery.

Surgeon Developers

The design team for the Vanguard® 360 Revision Knee System includes surgeons with vast experience in addressing complex knee revisions. Their experience and individual philosophies were combined to ensure that various implant and surgical technique preferences were incorporated into the platform.

The design team includes the following:

- **Keith R. Berend, M.D.**, Joint Implant Surgeons, New Albany, OH, USA
- **Michael E. Berend, M.D.**, Center for Hip and Knee Surgery, Mooresville, IN, USA
- **Thomas K. Donaldson, M.D.**, Empire Orthopedic Center, Colton, CA, USA
- **Adolph V. Lombardi, M.D.**, Joint Implant Surgeons, New Albany, OH, USA
- **Christopher Peters, M.D.**, University of Utah, Salt Lake City, UT, USA
- **James W. Scott, M.D.**, Georgia Sports Medicine and Ortho, Tifton, GA, USA

Vanguard® Femoral Design Heritage

While designing the Vanguard® 360 Revision Knee System, aspects of the femur, patella and tibia were reviewed for potential performance enhancements in all patient populations. Many clinically successful features of standard Biomet® Total Knee Systems can be found in the Vanguard® 360 Revision Knee System.

The Vanguard® 360 Revision Knee femoral component is made of a cobalt chrome alloy and incorporates the five main design features from the Vanguard® Primary Knee System:

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

Rounded Sagittal Profile

Two distinct femoral designs have evolved over time (Figure 1).

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

Figure 1: Anatomic (Green) vs. Swept-back (Gray) 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.[1]

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 minimize patella crepitus and clunk.[2]

The Vanguard® trochlear groove has been designed to sweep back posteriorly for better patellar performance (Figure 2).[3]

Figure 2: Standard Trochlear Groove (Green), Deeper and Longer Trochlear Groove (Gray)

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 2). 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 sheer stresses."[1]

The wider proximal trochlear groove offers excellent patellar tracking (within 0–15 degrees of valgus) regardless of the patient's Q-angle[4] (Figure 3).

Figure 3: Wider Proximal Trochlear Groove

Sizing

The Vanguard® 360 Revision Knee System offers ten femoral sizes specifically designed for optimal bone coverage.

- Femoral sizes increase A/P by an average of 2.4 mm and M/L by 2.6 mm across all ten sizes
- 9 mm distal and posterior implant thicknesses (Figure 4)

Figure 4: Implant Thicknesses

- Narrow anterior flange maintains a small profile to reduce the likelihood of femoral overhang
- Rounded anterior flange corners minimize soft tissue irritation
- Relative to the stem, on average, posterior condyles change 2 mm while the anterior flange changes 0.4 mm between sizes. Increasing femoral size can aid in tightening the flexion gap (Figure 5)

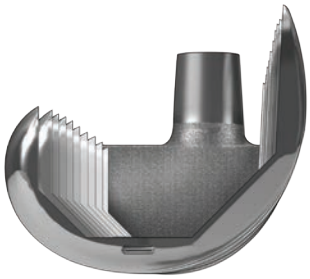


Figure 5: Ten Femoral Sizes

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.[5]

Vanguard® 360 Revision Femoral Design Features

While the Vanguard® 360 femoral component integrates all the primary femoral component design features, there are a few differentiating design features specific to the Vanguard® 360 revision femoral component (Figure 6).

Figure 6: 360 Femoral Component

Stem Boss Angle

The Vanguard® 360 femur has a five-degree stem valgus angle which accepts offset stem adapters and/or multiple stem lengths in straight and bowed versions to match the patient's anatomy (Figure 7).

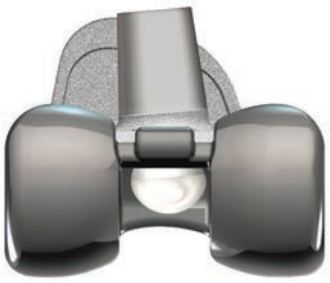


Figure 7: Stem Boss Angle

Offset Stem Adapters

Modular Offset Stem Adapters are available in 2.5, 5.0 and 7.5 mm magnitudes and can be positioned in any direction to allow precise femoral component placement. Adapters accept multiple stem options and can be used with both the femur and tibia (Figure 8).

Figure 8: Offset Stem Adapters

Stem Options

The combination of a Morse-type taper and screw fixation maintains a solid connection between the stem and femur. To provide the appropriate level of fixation, the femur will accept a 40, 80, 120, 160 or 200 mm stem extension. Stem extensions are made from a titanium alloy and are available in splined, smooth and grit-blasted finishes (Figure 9). Splined, smooth and grit-blasted stem extensions are offered either bowed or straight in 160 and 200 mm lengths.

Figure 9: Stem Extensions

Regenerex® Sleeve Augmentation

Designed to address bone deficiencies, Regenerex® Sleeve Augments provide for biologic fixation (Figure 10). Sleeve Augments are available in two heights 25 mm and 40 mm and four widths 36, 48, 56 and 64 mm. They also have a 24 mm hole diameter which accepts a 22 mm cemented stem or various offset stem adapters. (See page 9 for more information about Regenerex® technology.)

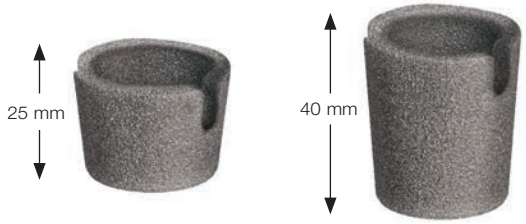


Figure 10: Regenerex Sleeve Augments

Femoral Block Augmentation

Individual distal (5, 10 and 15 mm thicknesses) and posterior (5 and 10 mm thicknesses) augment blocks are available for patients with inadequate bone stock (Figure 11). Femoral Augments are made from a titanium alloy and attached to the femoral component with titanium screws. Posterior blocks are universal and can be used on either the medial or lateral side of the femur.

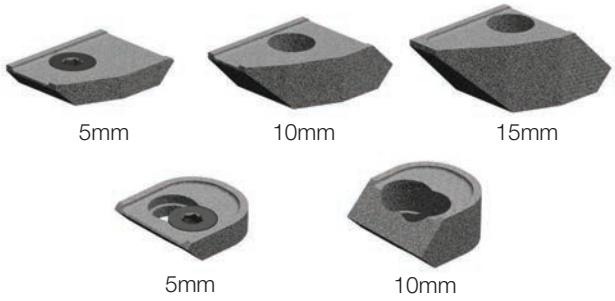


Figure 11: Femoral Block Augments

Cam and Post Design

The Vanguard® 360 femoral component has been specifically designed to enhance performance. It includes the Extended Trochlear Cam and the Cam and Post Engagement Design from the Vanguard® Primary Knee and also features an increased dislocation height to address revision needs.

Bearing Options

The Vanguard® 360 revision system offers two bearing options: the 360 PS tibial bearing and the 360 PS constrained (PSC) tibial bearing (Figure 12). These options provide the surgeon with intraoperative flexibility allowing them to select the appropriate level of constraint based on the patient's need.

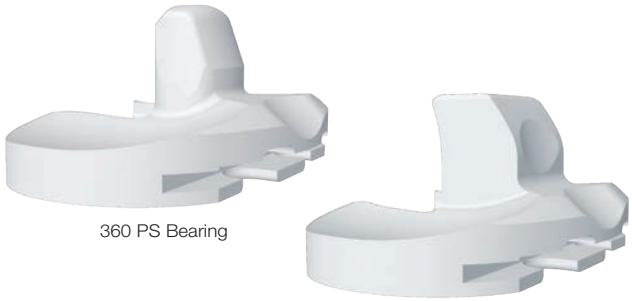


Figure 12: 360 PS Bearing and 360 Constrained Bearing

The 360 PS bearing is designed to allow 15 degrees internal/external rotation and no varus/valgus constraint.

The 360 PS constrained (PSC) bearing is designed to allow for 0.5 degrees of internal/external rotation and 1 degree of varus/valgus lift off.

The Vanguard® 360 PS constrained (PSC) bearing offers a large swept back tibial post that is designed to provide stability and continued constraint in deep flexion. The large tibial post also maintains increased post/box contact. At 90 degrees of flexion, 17 mm of the post remains in the box (Figure 13).

Figure 13: 360 Tibial Post in Box

Extended Cam

The Vanguard® 360 features an Extended Cam for increased resistance to dislocation in deep flexion (Figure 14).

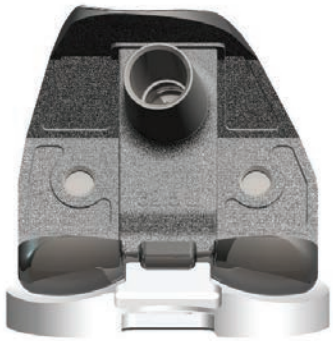


Figure 14: Extended Cam

Cam and Post Engagement

The cam of the Vanguard® 360 femoral component is designed to engage the post of the tibial bearing at 45 degrees of flexion (Figure 15).

Figure 15: 45 Degrees Cam and Post Engagement

Gait analysis demonstrates that the weight bearing phase occurs from 0–45 degrees.[17] 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.[18]

Mid-flexion cam engagement avoids cam and post contact during high 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® 360 is up to 23 mm at 90 degrees of flexion (Figure 16). The Vanguard® 360 component allows for 5 degrees of hyperextension.

Figure 16: Cam and Post Contact Points

Articulation Features

The Vanguard® 360 Revision Knee System features optimized tibiofemoral articulation based on the enhanced design of the following elements:

- Coronal Geometry
- Sagittal Geometry

Coronal Geometry

The Vanguard® 360 Revision 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 17).

Figure 17: Tibial-Femoral 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. A Finite Element Analysis has demonstrated a 25 percent reduction in patella contact pressure compared to a conventional total knee (Figure 18).[4]

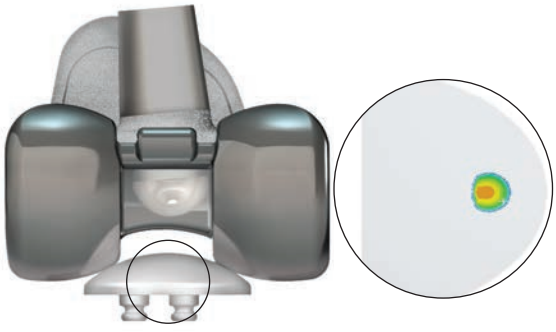


Figure 18: Finite Element Analysis Demonstrates a Gradual Dispersion of Forces Along the Patella

Sagittal Geometry

The Vanguard® Knee has been designed to allow up to 145 degrees of flexion without additional posterior condyle resections (Figure 19).

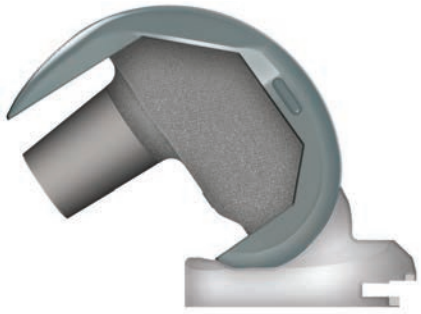


Figure 19: 145 Degrees Range of Motion with Primary Bone Cuts

The Vanguard® 360 Tibial Bearings have a deep anterior relief to accommodate the patella tendon during high flexion (Figure 20).

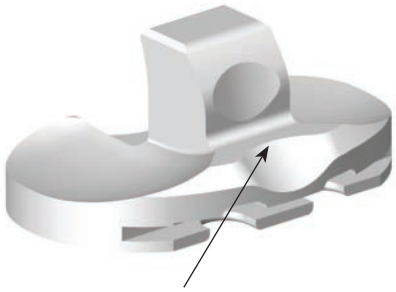


Figure 20: High Flexion Patellar Tendon Relief

Vanguard® Tibial Tray Design Heritage

Concerns have been raised about modularity and bearing micromotion as a contributor to osteolysis and early failure.[10–14] Feng, *et al.* have found that the most severe polyethylene wear occurs at the periphery, where the tibial component has a raised metal edge.[15] 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

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 edge due to the design of the locking mechanism.

Features of the locking mechanism design include (Figure 21):

- 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 pulished by Sosa, have shown the Biomet® locking mechanism to be "the most stable overall"[10,11,13]

Figure 21: 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,[16] the Vanguard® 360 Revision Knee System offers 9 symmetrical tibial baseplates that change in consistent 4 mm M/L intervals (Figure 22).

M/L	Micro 59	63	67	71	75	79	83	Macro 87	Macro 91
A/P	38	41	43	46	48	51	53	56	58

Figure 22: Tibial Plate Sizing

Incavo *et al*. examined eight tibial tray designs, consisting of six symmetrical and two asymmetrical baseplates. The study demonstrated that the sizing rationale fo the AGC® Total Knee System, which is closely paralleled by the Vanguard® 360 Revision Knee System, offers optimal coverage as compared to competitive asymmetrical designs (Figure 23).[17]

Figure 23: Symmetrical Tibial Tray Design of the Vanguard®

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.[17]

Vanguard® 360 Revision Tibial Tray Design Features

The tibial tray is made from a cobalt chrome alloy and features a 25 mm tapered stem boss (Figure 24). The stem boss accepts offset stem adapters, stem extensions and cruciate wing augments. The tibial tray accepts block augments from underneath eliminating through holes to prevent osteolytic pathways.

Figure 24: 360 Baseplate

Cruciate Wing Augments

Cruciate Wing Augments provide additional rotational stability and attach to the tapered stem boss. They are made from a titanium alloy and they are available in small and large sizes (Figure 25).

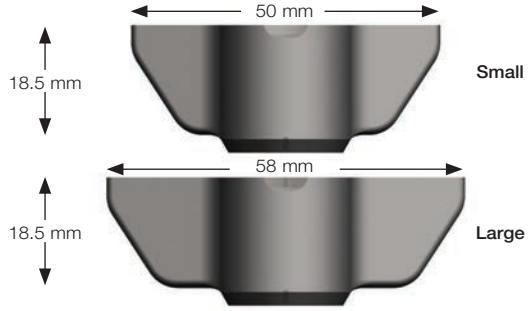


Figure 25: Cruciate Wing Augments

Offset Stem Adapters

Modular Offset Stem Adapters are available in 2.5, 5.0 and 7.5 mm magnitudes and can be positioned in any direction to allow precise tibial component placement. Adapters accept multiple stem options and can be used with both the femur and tibia (Figure 26).

Figure 26: Offset Stem Adapters

Stem Options

The combination of a Morse-type taper and screw fixation maintains a solid connection between the stem and tibial tray. When more fixation is desired, the tibial tray will accept a 40, 80, 120, 160 or 200 mm stem extension. Stem extensions are made from a titanium alloy and are available in splined, smooth and grit-blasted finishes (Figure 27). Splined, smooth and grit-blasted stem extensions are offered either bowed or straight in 160 and 200 mm lengths.

Figure 27: Stem Extensions

Regenerex® Sleeve Augmentation

Designed to address bone deficiencies, Regenerex® Sleeve Augments provide for biologic fixation (Figure 28). Sleeve Augments are available in two heights 25 mm and 40 mm and four widths 36, 48, 56 and 64 mm. They also have a 24 mm hole diameter which accepts a 22 mm cemented stem or various offset stem adapters. (See page 9 for more information about Regenerex® technology.)

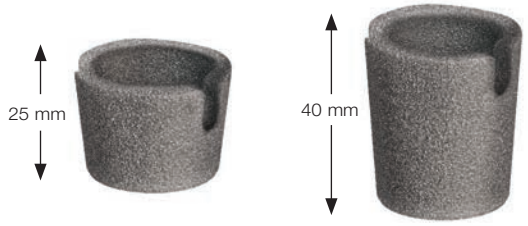


Figure 28: Regenerex Sleeve Augments

Tibial Block Augments

Tibial Block Augments are made of a titanium alloy and fill areas of bone loss underneath the tibial tray. They are available in 5, 10 and 15 mm thicknesses. 5 and 10 mm block augments are universal and can be positioned on either side of the tray. 15 mm augments have a 14 degree edge taper and are left/right specific (Figure 29).

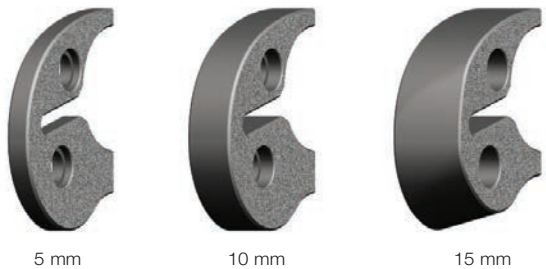


Figure 29: Tibial Block Augments

Bearing Technologies

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

- ArCom® Polyethylene

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.[6] Furthermore, gamma sterilization in an argon atmosphere has been shown to decrease wear over EtO sterilized polyethylene by 44 percent (Figure 30).[7]

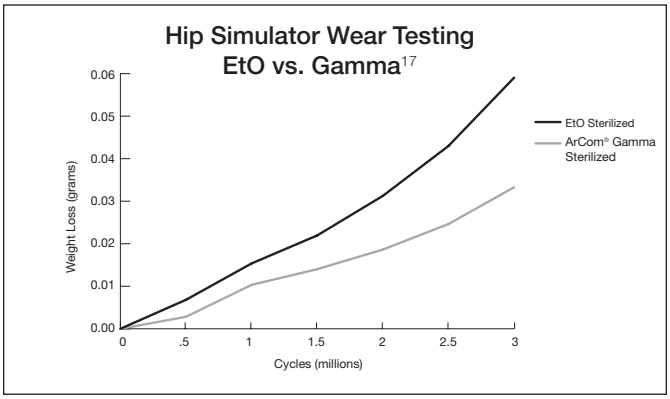


Figure 30: Wear Testing

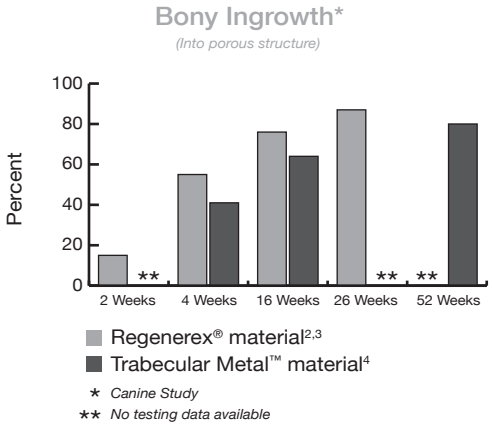
Biomet has continued the commitment to Direct Compression Molded (DCM) tibial bearings within the Vanguard® Complete Knee System to minimize the potential for oxidative breakdown of the polyethylene. Biomet's ability to provide a clinically proven method of consolidation for the Vanguard® Complete Knee System punctuated 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.[8]

Polyethylene Thickness

Meding, *et al.* demonstrated excellent long-term results with 4.4 mm minimum thickness DCM tibial bearings.[9] The Vanguard® 360 Revision Knee System provides a minimum of 6 mm of polyethylene thickness in all components (Figure 31).

Size Thickness	10	12	14	16	18	20	22	24
Polyethylene Articulating Thickness (mm)	6	8	10	12	14	16	18	20
Tray Thickness (mm)	4							

Figure 31: Polyethylene/Size Thickness



Regenerex® Porous Titanium Technology

Regenerex® Porous Titanium Construct unites the proven clinical history of titanium alloy[19] with an enhanced interconnecting pore structure, resulting in a revolutionary material that provides for biologic fixation (Figure 32).[4, 20]

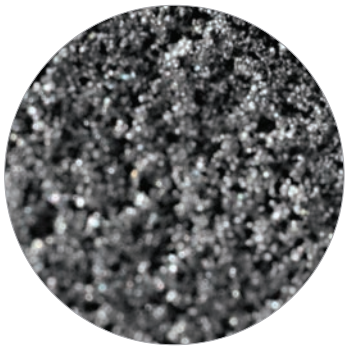
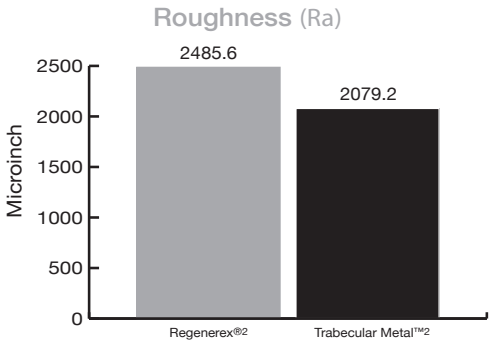
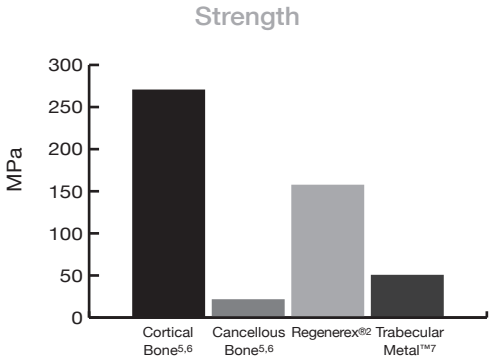


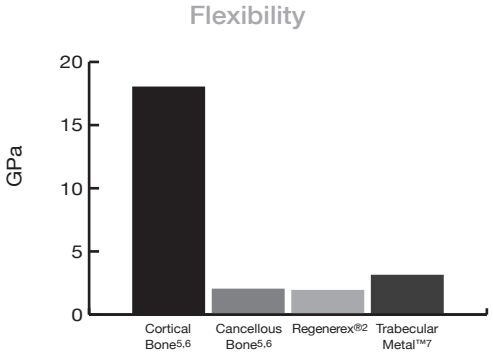
Figure 32: Regenerex® Material

Regenerex® material provides for:

- Average porosity of 67 percent[4]
- Average pore size of 300 microns[4]
- High strength and flexibility[4]
- Fixation in as early as two weeks was reported in canine studies[4, 20]







Instrumentation

The Vanguard® 360 Revision Knee System delivers a comprehensive instrumentation platform, featuring a simplified trial first approach to aid surgeons in addressing diverse, often challenging, revision knee procedures.

Cut-through Femoral Trial

- Allows the ability to prepare for an offset, cut femoral augments, box resection and trial all in one instrument
- Neutral (0 mm), 2.5, 5.0 and 7.5 mm offset modular bosses integrate with the cut-through trial to allow attachment of a trial stem to evaluate femoral position prior to making bone resections
- A modular femoral box integrates with the cut-through femoral to complete the femoral trial

Figure 33: Cut-through Femoral Trial

Offset Capable Four-in-One Cut Block

- The optional cut block can be used with either a non-offset (0 mm), a 2.5, 5.0 or 7.5 mm offset coin and trial stem to determine optimal position
- Evaluating offset position with a trial stem:
  - Allows balancing flexion/extension gaps
  - Provides accurate preparation for final implant
- The medial/lateral dimensions correspond to the femoral implant width
- The 9 mm block thickness/posterior tabs correspond to the implants distal and posterior thicknesses

Figure 34: Offset Capable Four-in-One Cut Block

Tibial Sled

- Tibial sled provides a way to size and prepare for the tibial implants
- The tibial sled can be used with a non-offset (0 mm), a 2.5, 5.0 or 7.5 mm offset coin and trial stem to determine optimal position
- Evaluating offset position with a trial stem:
  - Allows balancing flexion/extension gaps
  - Provides accurate preparation for final implant
- The medial/lateral and anterior/posterior dimensions correspond to the final implant with the 10 mm thickness representing the thinnest available bearing.

Figure 35: Tibial Sled

Notes

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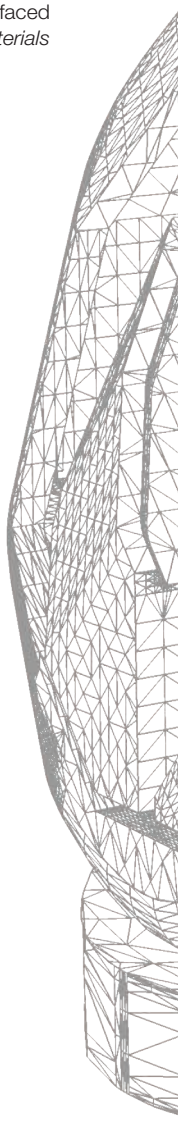

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