THE PERSONALIZED KNEE STORY
Total knee replacement has long ranked among the most successful procedures in modern medicine. While you can expect excellent implant survivorship with many of today’s knee replacement systems, recent studies suggest that one in four patients aren’t fully satisfied with their new knee. Moreover, patients are becoming more demanding and informed, expecting to return to full life with a knee replacement that provides a natural feel and normal function.

To create a more natural feel and normal function for patients postoperatively, we believe a system needs to include implants that fit better and instruments designed for ease of use, without the compromises inherent with many systems today.

Persona The Personalized Knee is our solution featuring personalized implants, precise instrumentation, and proven technology.

While designing the Persona Knee, we used a combination of advanced research tools like the Virtual Biomechanics Knee and the KUKA Robot to study hundreds of knees, creating a global bone atlas. This furthered our understanding of native anatomic shape and function which allowed us to better match our implant shapes and sizes to patients of different ethnicity, gender, and stature.

In a market focused on matching the bone to the implant shape and size, we found that the opposite needed to happen... we need to match the implant to the resected bone shape and size.

In doing so, we confirmed that implant shape really matters. Fit really matters. Instrumentation and technology really matters. The Persona Knee was designed with all these elements in mind, because we believe a way to predictably improve patient satisfaction is to more closely reproduce the original. Join us as we explore this personalized approach to restoring the unique identity of every knee.

- **Personalized Implants** designed for optimal fit and function

- **Precise Instrumentation** with personalized control

- **Proven Technology** built on a legacy of clinical performance
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PERSONALIZED IMPLANTS
DESIGNED FOR OPTIMAL FIT AND FUNCTION

Implant shape and fit matter in achieving postoperative patient satisfaction. In designing the Persona Knee, we identified several unmet needs that existed in previous implant designs that we believed, if improved, would help restore a more natural feeling knee and potentially improve patient satisfaction.

A more anatomically accurate implant was identified as one of those needs. While symmetric and asymmetric tibial designs had long since served a purpose, we wanted an implant that fit as close to the native tibia as possible. With that, the Persona Anatomic Tibia was created.

We also believed that the femoral shape should reflect certain characteristics. What was the ethnicity and gender of the patient? Would finer sizing increments help you more closely replace the resected bone? Could we be more bone conserving?

Combine these enhancements with a full continuum of bearing constraints, and you’ll see how the Persona Knee System is redefining personalization.
INTERNAL MAL-ROTATION OF IMPLANTS MAY LEAD TO OVER 50 PERCENT OF PAINFUL TKA CASES.\textsuperscript{7,9}
Tibial Implants

In TKA, we see a high variability in the success of setting I/E tibial rotation. The shape of other tibias impose a choice between proper rotation and bone coverage, which can lead to variability in rotational alignment. This is important, because several studies have shown a correlation between mal-rotation and anterior knee pain.\textsuperscript{8-12} Studies by Martin, et al. and Nicoll, et al. indicate that internal mal-rotation of implants may lead to over 50 percent of painful TKA cases.\textsuperscript{7,9}

The Persona Tibia was designed so you no longer need to decide which sacrifice to make because it’s anatomic shape should help you achieve both proper rotation and optimal bone coverage. We believe this will help lead to improved knee function and patient satisfaction.

To produce an anatomic tibial tray, understanding the proximal tibia is essential. This includes measurement of the medial and lateral A/P dimensions (A) and reproduction of the anteromedial and anterolateral curves (B). This is a key distinction from anatomic, to symmetric and asymmetric tibia trays.\textsuperscript{5}
In addition, the Persona Tibia was designed by studying the morphology of native tibias of various ethnicities, genders, and sizes. Hundreds of virtual tibial resections were performed and analyzed with varying surgical parameters. This thorough research helped us better understand that variation of the tibial shape was only subtle between ethnicities and gender. Ultimately, we determined that the optimal size and shape of the tibial implant should be anatomic.

In vitro, the Persona Anatomic Tibia has demonstrated:

• 92 percent bone coverage with proper rotation\(^5\)

• Less compromise of coverage (0.5 percent anatomic vs 5 percent non-anatomic)\(^5\)

• Six percent average improvement in coverage compared to non-anatomic designs\(^5\)

• More cortical support\(^5\)

• Lower incidence of downsizing (3 percent anatomic vs 50 percent non-anatomic)\(^5\)

In vivo, the Persona Tibia demonstrated:

• A statistically significant decrease in postoperative anterior knee pain and an increase in range of motion.\(^{13}\)

• A statistically significant improvement in medial plateau fit for Asian populations.\(^{14}\)

• Ideal rotational alignment in 81.4 percent of patients.\(^{15}\)

Tibial Implant Specs

• Nine anatomic sizes (A-J)

• Anatomic disproportional M/L growth

• Left and right implant options

• Medialized tibial keel designed to place the keel central to the native diaphysis

• Compatible with 14 mm x +30 mm stem extension

• Enhanced surface finish designed to aid bearing insertion and minimize backside wear

• Triple wedge design locking mechanism

• No lock-down screws

• No through holes

• Made of Tivanium® Alloy
Bearing Implants

Soft tissue balancing matters to the success of total knee arthroplasty. The number of bearing options available matters and may affect your ability to achieve both balance and stability of the joint. Furthermore, a limited bearing portfolio might not adequately promote the different movement patterns found in the medial and lateral compartments of the native knee.\textsuperscript{16-19}

The Persona Knee System includes a comprehensive range of bearing constraints and the finest sizing increments designed to allow you to personalize the balance and fit for each patient.

Bearing Implant Specs

- Cruciate retaining and sacrificing options
- 1 mm increments\textsuperscript{**}
- Conventional and Vitamin-E polyethylene options
- Minimal constraint to full constraint
- Left and right tibiofemoral designs help facilitate natural anatomic kinematics, while allowing you to make a certain philosophical approach \textsuperscript{19}

\textsuperscript{**CPS in 2 mm | CR, MC, UC, PS 1 mm 10-14 mm}
The Benefit of 1 mm Increments

Practical example: if your baseline bearing size is 12 mm, but the knee feels too tight, you might have to move down to a 10 mm bearing with some systems, which could potentially make the knee too loose. However, with the Persona Knee, you are able to decrease by only 1 mm and use an 11 mm bearing instead. This graph illustrates this point. By decreasing the bearing thickness by 2 mm, the knee laxity increases by over 4 degrees. When you are able to decrease the bearing thickness by a 1 mm increment, the knee laxity only increases by over 2 degrees.8, 20-23

The Persona Bearing 1 mm increments provide a 50% better chance of achieving stability.8, 20-23
Femoral Implants

Femoral component overhang greater than 3 mm nearly doubles the odds of clinically relevant knee pain at two years postop.²⁴ Many of today’s knee designs provide insufficient options for obtaining ideal femoral fit and therefore jeopardize postoperative function and patient outcomes (PROMs).⁶

- Instability often develops in early postop when the A/P femoral dimension is undersized.²⁵
- Instability is a cause of knee failure and why 10 to 22 percent of knees are revised.²⁶
- Symptomatic flexion instability is a common reason for revision within five years.²⁷
- Oversized femurs result in early revisions and painful knees at 1.5 years postop.²⁸

Femoral Implant Specs

The Persona Femur comes in 21 distinct profiles, with 2 mm* increments available in standard and narrow, providing the most comprehensive femoral sizing scheme on the market.²⁹ These fine increments help you achieve a personalized femoral fit.

- Restore soft tissue balance with 12 A/P sizes available in 2 mm* increments that allow for replication of the native A/P dimension.
- Improved femoral fit with a full offering of standard and narrow implants⁶ helps address the problem of femoral overhang and associated pain that’s observed in 56 percent of TKA patients.²⁴
- Enhanced high-flex design safely accommodates up to 155 degrees** of flexion³⁰ while preserving 30 percent more native bone.³¹
- Anatomic profile and articulation of the Persona Femur supports physiologic internal rotation.

*Size 11 to 12 is a 4 mm increment
**Ultracongruent is indicated for up to 145 degrees of flexion. CPS is indicated for up to 135 degrees of flexion.
The Persona Femur is able to match each patient’s native A/P dimension 97 percent of the time.\textsuperscript{32}
Patient outcomes can be driven by the precision and accuracy of each step within the surgical procedure. You should expect your instruments to be accurate, but we didn’t want to stop with just being precise. We wanted you to have instruments that feel good in your hand after repetitive use. So we studied the shapes and sizes of the hand to create ergonomic instrumentation. We wanted to reduce intraoperative glare from the instruments and make them easier to assemble, so we created a matte finish.

We continued asking ourselves, what issues and decisions do you face intraoperatively. Did you have to sacrifice stability for fit? Why? In what steps would you like better information before proceeding?

By asking these kinds of questions, we were able to design instruments and techniques that allow you to make more informed decisions with each step and provide options for you to personalize each procedure. These options found within the Persona Knee System’s instrumentation were designed to help you consistently achieve optimal outcomes.
Comprehensive Instrument Platform

Persona Instrumentation was designed to be versatile in its capabilities and philosophies, precise in its measurements, comprehensive, and comfortable with repetitive use. These options allow for more personalized control, a smooth surgical flow, and reproducible outcomes.

Instrument Design

Highly sophisticated engineering transforms the shape and motion of the hand into the instruments.

- Anatomic contouring of the instruments designed to maximize comfort over repetitive use.
- Weight balanced design helps minimize strain and allow for improved reproducibility and accuracy.
- Proprietary surface finish reduces intraoperative glare and provides an enhanced grip in the surgical environment.
Instrument Kitting

The Persona Instrument System was designed with modular kitting, patient specific, and other instrument options that provide a greatly reduced instrument footprint without compromising the surgical technique, functionality, or procedural outcome. Persona Instrumentation is designed to offer an efficient, personalized approach to modern TKA.

- Reduced surgical steps
- Reduced instrument trays
- Increased instrument versatility
- Increased ease of assembly
- Seamless intraoperative transitions
Comprehensive Instrument Platform (cont.)

Zimmer FuZion® Instruments

Advanced balancing options found in the Zimmer FuZion Instruments combine bony landmarks and soft tissue inputs to help optimally size and position the implant, harmonizing measured resection and gap balancing philosophies.

The ABC’s of Zimmer FuZion

Assess: Dynamic scales designed to facilitate effortless assessment of leg alignment and extension gap measurement.

Balance: Simple distraction methods for simultaneously establishing flexion gap and femoral rotation.

Confirm: Intuitive quick-connect accessories to confirm femoral size and rotation prior to bony resections.
TASP

The Tibial Articular Surface Provisional (TASP) adds sophistication to your trialing system.

- Seamless soft tissue balancing with no need to remove the provisional.
- Effortlessly make 1 mm adjustments designed to find the optimal bearing thickness every time.
- Eliminate 68 percent of the bearing provisionals while maintaining a full range of size options.34
Personalized Solutions
Patient Specific Guides

The demand for primary total knees is projected to grow by 673 percent from 2005 to 2030 to about 3.5 million. The future, therefore, must include technologies that continue to offer efficient procedures that allow you to tailor the implant position to the specific needs of each patient.

Virtual Planning Meets Clinical Results

Zimmer Biomet’s Personalized Guide Systems provide interactive, 3D preoperative planning software and intraoperative guides that assist surgeons in the precise positioning of knee implants.

- Patient imaging is used to generate a 3D virtual model for an unobstructed view of critical anatomic landmarks.
- Interactive, 3D virtual surgeon planning enhances visualization of patient anatomy and implant position.
- Virtual planning attributes are embodied in patient specific, 3D printed guides.
- The use of interactive planning and patient specific guides help to streamline the surgical workflow.
- Technology is a significant driver for patients to undergo total joint replacement surgery.
STUDIES HAVE DEMONSTRATED BETTER ACCURACY AND CLINICAL OUTCOMES THROUGH THE USE OF PATIENT SPECIFIC GUIDES\textsuperscript{37-41}
Personalized Solutions (cont.)

iASSIST® Knee Alignment Instrument

In the OR today, we need precise, intraoperative feedback to ensure the best outcomes for patients. Guidance technologies enhance precision, giving intraoperative feedback just when you need it - without expensive capital equipment, preoperative steps, and logistical headaches.

The iASSIST Knee Alignment Instrument provides a compact, electronic guidance system designed to help surgeons align and validate bony resections in real-time within the surgical field.

- Works with traditional instruments for minimal workflow disruption.
- Intraoperative validation of resections in the surgical field without the use of additional imaging equipment.
- Guidance technologies have shown a 25% lower revision rate due to loosening or lysis at 8 years.42
- Radiological outcomes have shown that the iASSIST Knee Alignment Instrument’s validation feature increases precision and accuracy compared to conventional instruments.43
- iASSIST Knee Alignment Instrument provides 88% good or excellent patient satisfaction.44
eLIBRA® Dynamic Knee Balancing System

The eLIBRA Dynamic Knee Balancing System provides patient specific soft tissue balancing designed to help establish the optimal position of the femoral implant in harmony with the patient’s ligament characteristics.

Objectively Balanced

- The eLIBRA Dynamic Knee Balancing System electronically measures soft tissue force and provides objective, real-time feedback for personalized femoral component rotation.

- Quantifiable evaluation of flexion gap balance with the patella is reduced prior to committing to femoral component rotation.45

- Dynamic instruments with objective feedback eliminate the subjectivity of gap balancing with traditional instruments.46-47
PROVEN TECHNOLOGY BUILT ON A LEGACY OF CLINICAL PERFORMANCE

The Persona Knee System gives you the ability to address the unique needs of each patient with our proven technology. It incorporates an innovative approach designed to improve intraoperative efficiency, patient satisfaction, and long-term survivorship.

Predecessor to the Persona System, the NexGen® Knee System is the most widely used and clinically proven total knee system in the world. This, along with the Natural-Knee® II System, created the foundation for what would become the Persona Knee. We took the elements that made the NexGen Knee and Natural-Knee II Systems so successful and looked for ways to further enhance those designs. By addressing those opportunities in the Persona Knee, we believe we’ve achieved a big leap forward in total knee arthroplasty, making us very excited about the future of the Persona Knee.
Vivacit-E Vitamin-E Highly Crosslinked Polyethylene (HXPE)

Zimmer Biomet’s Vivacit-E Polyethylene is actively stabilized with Vitamin-E to help protect against oxidation and maintain wear resistance and strength throughout the life of the implant.

Vivacit-E Highly Crosslinked Polyethylene (HXPE) results in a technologically advanced material that provides superior oxidative stability, wear resistance, and mechanical strength over other polyethylenes.49-54

- Exceptional oxidative stability with delamination resistance and retention of mechanical properties 12 times longer than industry standards.49-50

- Ultra-low wear with 96 percent wear reduction compared to conventional polyethylene and 73 percent wear reduction compared to re-melted HXPE polyethylene.51

- Improved mechanical strength with a 10 percent improvement in spine fatigue strength over conventional polyethylene.52-55

*Laboratory testing not necessarily indicative of clinical performance.
ALL FIVE PERSONA BEARING CONSTRAINT OPTIONS AND PATELLA COMPONENTS ARE AVAILABLE IN VIVACIT-E VITAMIN-E HXPE.
Trabecular Metal Technology

Trabecular Metal Technology is available in femoral and patellar implants. Persona Implants are designed to maximize the surface contact area of this material, enabling you to reduce procedure time and eliminate third-body wear generation by removing cement from your operation.

- Made from Tantalum:
  - Element 73
  - Commercially pure
  - Biocompatible
  - Corrosion resistant
- Trabecular Metal Material is a highly porous biomaterial made from elemental Tantalum with structural, functional, and physiological properties similar to cancellous bone.
- Cancellous architecture up to 80 percent porous with a 100 percent open-interconnected cell structure designed to support bony ingrowth and vascularization.
- Twenty years of clinical results and boasts over 350 peer reviewed papers, posters, and abstracts documenting its effectiveness in a variety of applications.

Procedural Excellence

Modern Cementing Technique (MCT) - improved clinical outcome

Modern Cementing Technique Knee (MCT Knee) is a proven concept addressing implant loosening. The objective of MCT is to optimize cement quality and the interfaces between Implant-Cement and Cement-Bone for optimal implant fixation and long term implant stability. Modern Cementing Technique, compared to earlier techniques, has been linked to a 20% reduction of the risk for revision for aseptic loosening.

Zimmer Biomet offers solutions for standardized mixing procedures resulting in homogeneous cement with very low porosity. The mixing and collection under vacuum reduces the cement’s porosity, which can lead to substantial improvements in cement strength and fatigue life.
PERSONALIZED IMPLANTS DESIGNED FOR OPTIMAL FIT AND FUNCTION

PRECISE INSTRUMENTATION WITH PERSONALIZED CONTROL

PROVEN TECHNOLOGY BUILT ON A LEGACY OF CLINICAL PERFORMANCE
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29. Data based on knee product Design Rationales.


32. AAOS_Femur_AP_Diff_Chart Reference based on ZiBRA femoral analysis project on file at Zimmer Biomet.

33. ZIMMER BIOMET Instrumentation Industrial Design Style Guideline Revised 2015.05.02.

34. Data based on calculation of total trials in instrument trial system compared to the trials needed with the TASP system.


42. de Steiger R. The Outcome of Computer Navigation for Primary Knee Replacement. AOA. 2013.


48. Statement based on:

- 5 million implantations across 300+ Publications
- 100% Survivorship at 17 Years
- Lowest revision rate
- 10A* ODEP rating for CR and PS knees both with and without patella
- Every 90 seconds a patient receives a NexGen knee
- 1 in 5 knees implanted globally is a NexGen Knee


48g. Latest ODEP ratings can be found at http://www.odep.org.uk.

48h. 2016 Sales data available at Zimmer Biomet.

48i. EMBASE search: «NexGen» AND «Knee».

49. Zimmer ZRR_WA_2409_11.


52. Zimmer TM1140.98.


55. Zimmer ZRR_WA_2401_11.


