ZIMMER BIOMET

# PERSONA® OSSEOTI® KEEL TIBIA
# PERSONA CEMENTED KEEL TIBIA
# PERSONA PPS® FEMUR

## DESIGN RATIONALE

# Total knee replacement has long ranked among the most successful procedures in modern medicine.[1]

While excellent implant survivorship has been reported with many of today's knee replacement systems, studies suggest that one in five patients aren't fully satisfied with their new knee.[2-4] Moreover, patients are becoming more demanding and informed, wanting to return to full life with a knee replacement that provides a natural feel and normal function.[5]

To create a natural feel and normal function for patients post-operatively[6], we believe a system needs to include implants that fit precisely and instruments designed for ease of use.

**Persona The Personalized Knee® is our solution featuring personalized implants, precise instrumentation, and proven technology.[5]**

While designing the Persona Knee, we used a combination of advanced research tools like the Virtual Biomechanics Knee, ZiBRA™ database, 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 matter.[7-8] The Persona Knee was designed with all these elements in mind, because we believe the 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[5]


# REDEFINING PERSONALIZATION

## PERSONALIZED IMPLANTS DESIGNED FOR OPTIMAL FIT AND FUNCTION

Implant shape and fit matter in achieving post-operative patient satisfaction.[7-8] 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[6] feeling knee and potentially improve patient satisfaction.

**A more anatomically accurate**[7] 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?[9] Could we be more bone conserving?

Combine these enhancements with a full continuum of bearing options, and you'll see how the Persona Knee System is redefining personalization.

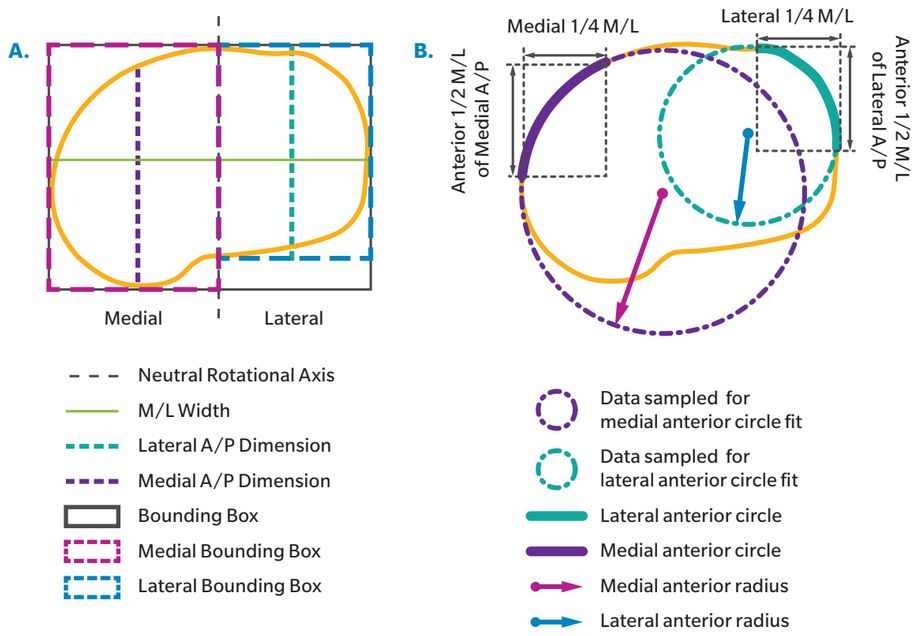
# UNDERSTANDING THE PROXIMAL TIBIA

## ANATOMIC TIBIAL IMPLANTS

In TKA, we see a high variability in the success of setting I/E tibial rotation. The shape of some tibias impose a choice between proper rotation and bone coverage, which can lead to variability in rotational alignment.[10] This is important, because several studies have shown a correlation between mal-rotation and anterior knee pain.[9-13] 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.[8,10]

The Persona tibia was designed so you don't need to make this compromise. The anatomic shape is designed to help you achieve both proper rotation and optimal bone coverage.[7,10] We believe this will help lead to improved knee function and patient satisfaction.

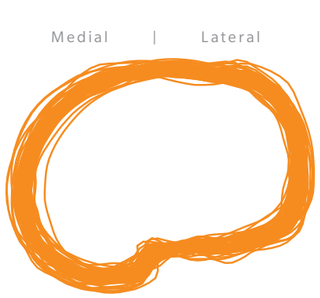
To produce an anatomic tibial tray, understanding the proximal tibia is essential. This includes measurement of the medial and lateral A/P dimensions (**A**) and reproduction of the anteriomedial and anteriolateral curves (**B**). This is a key distinction in the Persona anatomic tibia compared to symmetric and asymmetric tibia trays.[7]



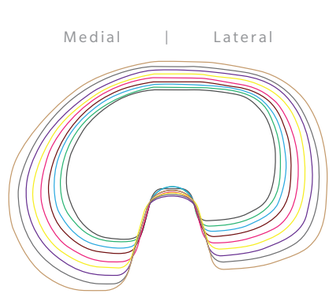




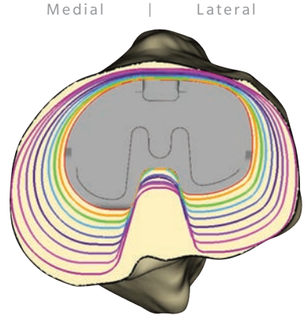

In addition, the Persona tibia was designed by studying the morphology of native tibias of various ethnicities, genders, and sizes. Hundreds of virtual tibial resections were performed and analyzed with varying surgical parameters. This thorough research helped us better understand that variation of 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.




**Native Tibial Profiles**




**Persona Tibial Profiles**




**Implanted Persona Tibial Profiles**

***In vitro*, the Persona anatomic tibia has demonstrated*:**

- 92 percent bone coverage with proper rotation[7]
- Less compromise of coverage (0.5 percent anatomic vs 5 percent non-anatomic)[7]
- Six percent average improvement in coverage compared to non-anatomic designs[7]
- More cortical support[7]
- Lower incidence of downsizing (3 percent anatomic vs 50 percent non-anatomic)[7]
- Persona anatomic tibial tray provides greater stability - less micromotion - than a symmetric tray[17-18]

***In vivo*, the Persona tibia demonstrated:**

- A statistically significant decrease in postoperative anterior knee pain and an increase in range of motion.[19]
- A statistically significant improvement in medial plateau fit for Asian populations.[20]
- Ideal rotational alignment in 81.4 percent of patients.[21]

*Laboratory results are not necessarily indicative of clinical performance

### 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
- 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 Ti-6Al-4V ELI Alloy
- Model for demonstration represents an E sized implant.

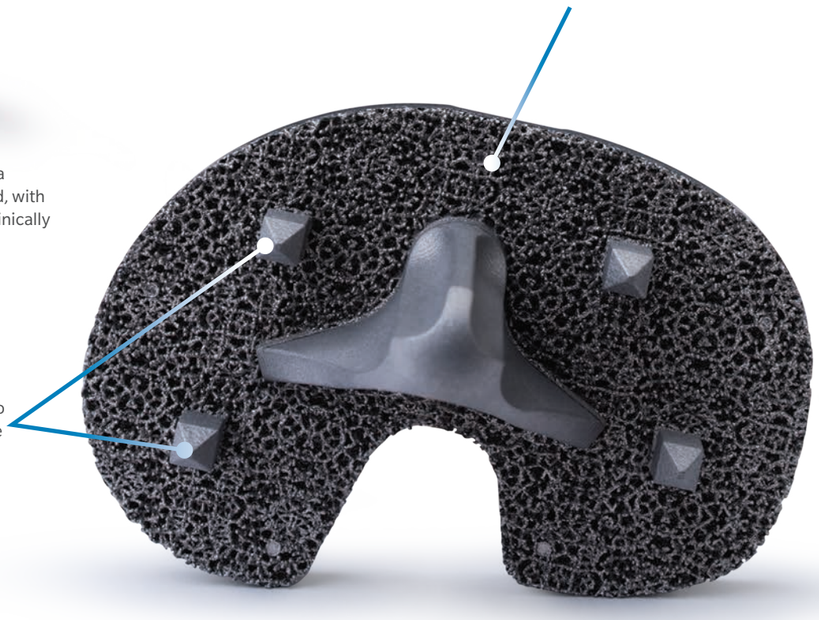
# PERSONA OSSEOTI KEEL TIBIA: STABLE. VERSATILE. ANATOMIC.

The Persona OsseoTi Keel Tibia is the latest offering within the Persona tibia continuum, representing our next iteration of cementless knee arthroplasty. This tibial implant combines OsseoTi, an additively manufactured porous substrate for biological fixation, with a traditional keel design to provide a unique new offering for our anatomic tibia.

The Persona OsseoTi Keel Tibia blends the history of our legacy knee systems by incorporating a spiked keel design. This design philosophy is aimed to provide **stable initial mechanical fixation**[15] through the progressive press-fit of the keel and pegs across a progressive keel dimension and depth by size. In doing so, we aim to build upon the legacy of our Natural Knee® spikes, innovate upon the clinical heritage of our Vanguard® Knee System's keel design, and couple it with our Persona anatomic tibia to provide better coverage and rotation with less micromotion than symmetric trays.[18]*


The OsseoTi tibia's keel is tapered, providing a progressive press-fit as the implant is inserted, with the overall volume of press-fit based off the clinically successful[22-23] Natural-Knee tibia implants.

OsseoTi Porous Metal Technology uses human CT data in combination with 3D printing technology to build a structure designed to mimic the architecture of human cancellous bone



- The press-fit of the pegs is based on a 3.2mm (1/8") drill prep for the 4.24mm sq pegs. The peg position is designed to avoid cortical interference via use of the ZiBRA database.
- The peg lengths:
  - 8 mm for A/B/C/D
  - 10 mm for E/F/G/H/J

*Laboratory studies are not necessarily indicative of clinical results



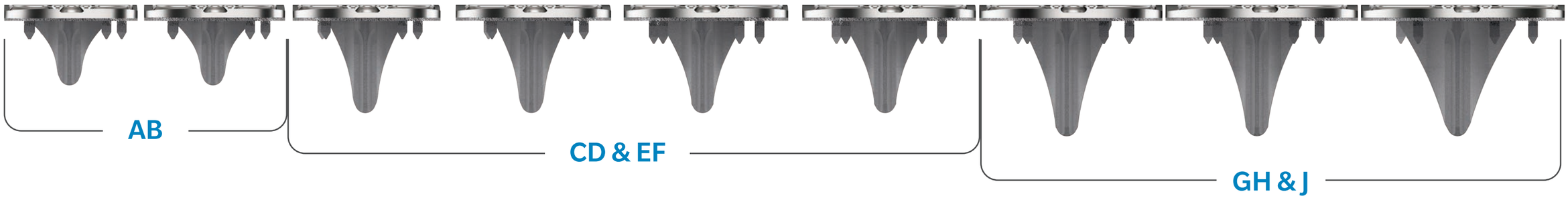


## SHOWCASE OF PROGRESSIVE PRESS-FIT


With the OsseoTi keel tibia, the press-fit of the keel increases as it gets closer to the distal surface of the tray, **allowing for up to twice as much press fit as Natural Knee II® based on volume of bone displaced.**[18] This precision tapered keel design is made possible via advanced 3D printing technology, and provides stable initial mechanical fixation to give **confidence** in cementless procedures.[18]

Through the personalization and precision of the Persona System, coupled with the familiar keel design based on the successful heritage of previous systems, the Persona OsseoTi Keel Tibia is designed to facilitate surgeon satisfaction. With the additional benefits of cementless procedures, including efficiency, preservation of bone stock, and biologic fixation, this offering facilitates further flexibility and efficiency to your O.R.[24]

OSSEOTI KEEL TIBIA




## Persona OsseoTi Keel and Cemented Keel Tibia

| Tibia Size | AB | CD | EF | GH & J |
|---|---|---|---|---|
| **Keel Length** | 28 mm | 40 mm | 40 mm | 50 mm |
| **Peg Length** | 8 mm | 8 mm | 10 mm | 10 mm |

*Cemented Keel Tibia does not have pegs*

The progressive fin and keel design is based on the clinically successful Natural Knee tibia implants, which have a keel that grows proportionally by size.

## Persona Keeled Tibial Baseplate Dimensions

| Size | Medial A/P (mm) | Lateral A/P (mm) | Overall M/L (mm) |
|---|---|---|---|
| A | 40.2 | 35.1 | 57.7 |
| B | 42.5 | 37.2 | 60.8 |
| C | 44.9 | 39.5 | 63.8 |
| D | 47.2 | 41.8 | 67.0 |
| E | 50.2 | 44.6 | 71.0 |
| F | 53.3 | 47.4 | 75.1 |
| G | 56.5 | 50.2 | 79.0 |
| H | 59.8 | 53.3 | 83.0 |
| J | 63.5 | 56.7 | 88.1 |

## OsseoTi Porous Material

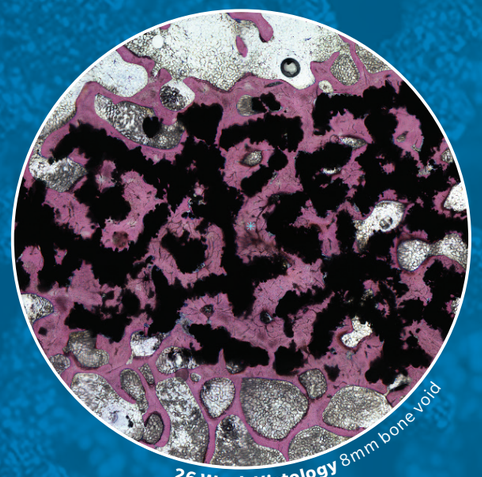
OsseoTi Porous Metal is a material created through the use of a proprietary additive manufacturing process - allowing us to remove the shackles of process limitations to provide a consistent material with a high degree of design flexibility, while being comprised of a highly biocompatible alloy material with excellent corrosion resistance and a strong history of clinical success.[25-26] This process generates a porous material from a titanium substance with a structure that is designed to mimic the architecture of human cancellous bone to facilitate biological fixation and implant stability.

- Unique porous architecture has demonstrated **excellent integration with host bone as early as 4 weeks in an animal study**[27*]
- **Porosity** of approximately **70%** directly mimics the structure of **human cancellous bone** [27-28]
- **Average pore size of 475 microns** facilitates cell migration, vascularization, and biological fixation[27-28*]
- Material strength between that of cancellous and cortical bone **facilitates biological fixation** and loading of surrounding bone[27*]

**4 Weeks** early integration with host bone

**12 Weeks** bone fusion across an 8mm thick sample

**26 Weeks** extensive biological fixation fills the entire volume of porous sample



**26 Week Histology** 8mm bone void

**Black:** OsseoTi Structure **Red:** New bone growth **White:** Void

***Animal studies are not necessarily indicative of clinical performance.**

CEMENTED KEEL TIBIA

INTRA-OPERATIVE VERSATILITY

# THE BEST OF BOTH WORLDS AT YOUR FINGER TIPS


## Persona Cemented Keel Tibia

Zimmer Biomet is proud to offer an even broader portfolio to support cemented procedures. With an ongoing commitment to being a trusted partner in healthcare, we aim to cover the full continuum of treatment options by providing an implant offering featuring the new keel based design while retaining the standard cemented procedure. This option is the Persona Cemented Keel Tibia, a design that also draws heavily from the Vanguard system's roots, providing a similar feel down to the cement mantle surrounding the fins and enhanced by a tight fit which compresses the implant into the bone to allow for the fixation of cement.

## Cemented or Cementless Intra-operative Versatility

Importantly, one of the key features this system will provide is the ability to switch between either a cementless or cemented procedure ***intra-operatively*** with a single tray, continuing our commitment to providing surgeons with versatility in their O.R.

This decision to proceed with either a ***cementless or cemented*** procedure can be made up ***until the moment of final implantation***, as both procedures utilize the exact ***same bone prep*** with no need for new instrument preparation to continue forward.

POROUS PLASMA SPRAY FEMUR

# Persona PPS Femur

The latest offering for the Persona family's femoral implants is the Porous Plasma Spray Femur. The clinically proven[29-36] PPS coating allows for initial scratch fit stability and biologic fixation through bone ongrowth.

PPS has already shown its capabilities in performance with **95% survivorship at 10 years**.[23] Across multiple applications, the clinical legacy of the PPS material has proven its survivorship for aseptic loosening and has demonstrated increased resistance to micromotion as shown in hip studies.[37-38]

As a new element to our femoral offering, the rails on the implant have been eliminated, allowing for the ability to increase the nominal surface area of porous material on the implants by a minimum of 18% (varying by size) compared to equivalent size of Persona TM femurs.

The PPS femoral implant will still retain the Persona family's 2 mm** increments in standard and narrow design, providing one of the **most comprehensive femoral sizing options in a single system on the market and allowing you to achieve a personalized femoral fit**. Additionally, this new line of PPS femurs will utilize the existing bone preparation instruments, allowing current Persona users to continue to use their existing resection instrumentation and provisionals.



## Femoral Implant Specs

- 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 implants[40] is designed to help address the problem of femoral overhang and associated pain that's observed in 56 percent of TKA patients.[9]
- Enhanced high-flex design safely accommodates high flexion[39] while preserving 30 percent more native bone.[38]
- Anatomic profile and articulation of the Persona Femur supports physiologic internal rotation.

***Size 11 to 12 is a 4 mm increment**

****compared to our previous designs**

# MEDIAL CONGRUENT® BEARING - STABLIZED MOTION

## Stabilized Motion

### Restores Confidence

The key to achieving a more natural feeling knee is developing implant geometries that function harmoniously with their native kinematics and more closely reproduce the motion[41] and stability they had prior to knee arthritis. When striving to achieve such a goal with an implant design, one of the most difficult obstacles to overcome is achieving maximum stability throughout the full range of motion, and maintaining it while in full extension.

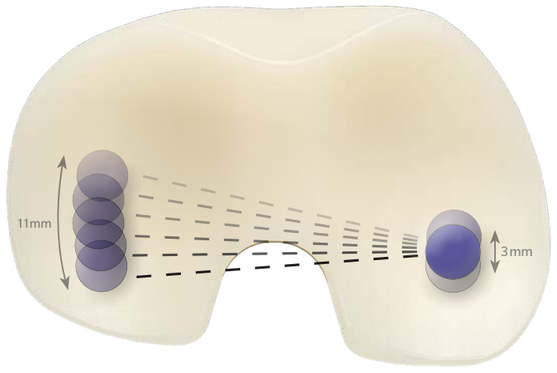
**The Medial Congruent**

**Bearing design prioritizes stability and motion through the concept of stabilized motion.** The system's medial conformity and anterior constraint stabilize the knee from full extension through deep flexion. In contrast, the lateral condyle is designed to move freely along an arcuate path to recreate the motion of a healthy knee.

## High-Flexion Design: Renews Life

The ability to achieve deep flexion is essential for performing daily activities in many cultures throughout the world. **The dwell points of the Persona Medial Congruent Bearing have been moved posterior to allow surgeons to restore a patient's full range of flexion.**

### Persona MC




**Posterior Dwell Point**

A more posterior dwell point accommodates deeper flexion before posterior, femoral bone contacts the posterior lip of a tibial insert.





**Medial Congruent Polyethylene Offers Satisfactory Early Outcomes and Patient Satisfaction in Total Knee Arthroplasty** [42]

*(Authors: Frye, B., Patton, C., Kinney, J., Murphy, T., Klein, A. and Dietz, M., 2021.)*

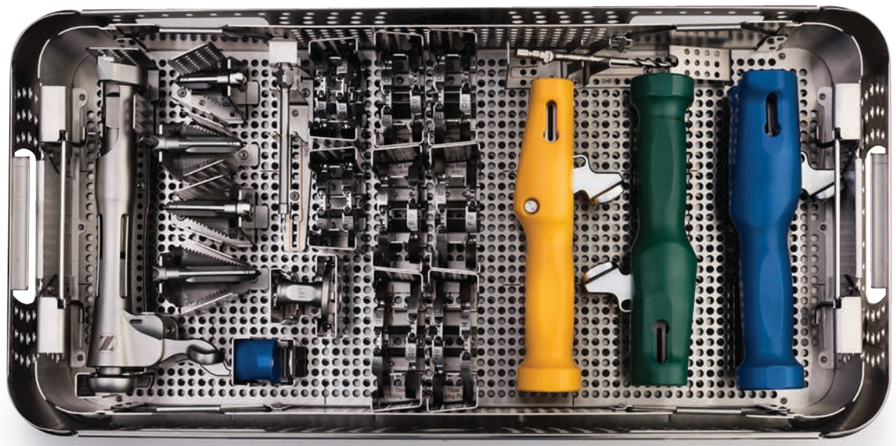
- Patients with an MC bearing reported significantly higher forgotten joint scores than patients with a CR bearing. This is important because a patient's ability to forget their joint replacement during everyday activities is an important expectation and goal of the surgery, as it reflects patient satisfaction.
- More patients with an MC bearing were "very satisfied" and fewer were "not at all satisfied" compared to patients with a CR bearing
- 92.6% of patients with an MC bearing were "very satisfied" compared to just 81.5% of patients with a CR bearing

| Score | Persona MC | Persona CR | Persona PS |
|---|---|---|---|
| FJS at 1 year (95% CI) | 71.62 (65.44-77.81) | 58.68 (51.9-65.46) | 68.71 (64.07- 73.34) |
| KOOS pain at 1 year (SD) | 80.67 (18.29) | 76.56 (22.56) | 0.047 (22.40) |
| KOOS ADL at 1 year (SD) | 82.01 (17.68) | 76.56 (20.02) | 86.69 (21.03) |
| KOOS QoL at 1 year (SD) | 60.66 (26.49) | 58.62 (22.79) | 67.99 (28.29) |
| KOOS sport at 1 year (SD) | 58.53 (33.46) | 57.52 (28.95) | 65.57 (32.96) |
| KOOS symptom at 1 year (SD) | 80.55 (18.47) | 76.05 (18.96) | 82.58 (19.87) |
| PROMIS-10P 1 year (SD) | 52.12 (8.75) | 51.28 (7.45) | 51.08 (8.84) |
| PROMIS-10M 1 year (SD) | 52.12 (7.35) | 51.28 (6.37) | 51.08 (9.72) |

**According to the authors, these results indicate that the MC bearing provided similar or improved early pain, ROM, KOOS, PROMIS-10, FJS-12, and patient satisfaction as compared with standard bearings in TKA. Additionally, the MC bearing scored higher in patient satisfaction as compared to CR.**

**Mid-flexion stability in the anteroposterior plane is achieved with a medial congruent insert in cruciate-retaining total knee arthroplasty for varus osteoarthritis** [42]

- This study has shown that the Persona MC bearing restored physiologic AP kinematics more in mid-flexion than the Persona CR bearing under PCL-retaining conditions.
- Mid-flexion AP stability was greater with the MC bearing than with the CR bearing.
- The results for the CR bearing showed that the femoral position relative to the tibia was significantly anterior at 45°, 60°, and 90° flexion compared to the preoperative condition.
- The authors acknowledged that this paradoxical motion or mid-flexion instability is more common in CR knee designs, and can be one of the causes of dissatisfaction after CR-TKA.
- By comparison the femoral position in the MC group at 45°, 60°, and 90° flexion did not differ significantly from that of the preoperative condition.



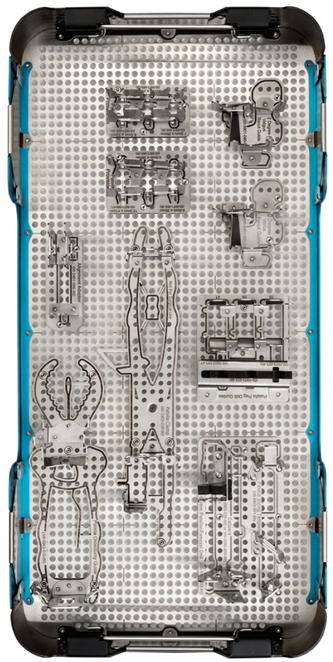
## EFFICIENT INSTRUMENTATION KIT

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 with quick connect features, eliminating need for threaded components*
- ☑ Seamless intra-operative transitions

The OsseoTi Keel Tibia and Cemented Keel Tibia features a singular new instrument tray to incorporate into the existing line of Persona family instrument trays. In this one tray, the surgeon will have the ability to ***seamlessly switch*** between either the ***cementless or cemented*** procedure up to the point of implantation, providing versatility and options within the O.R.

*compared to previous implant systems







## VIVACIT-E® VITAMIN E ADVANCED BEARING TECHNOLOGY

**Meeting the long-term performance[43] needs of patients**

The Persona System also gives you the ability to address the needs of your most demanding patients with proven, proprietary technologies. The Vivacit-E Vitamin E Advanced Bearing Technology provides:

**Benefits:**

| | | |
|---|---|---|
| Exceptional oxidative stability[44-48] | Improved strength[49-51] | Ultra-low wear[52] |

Vivacit-E Vitamin E Advanced Bearing Technology is grafted (locked) directly to the polyethylene chain to prevent elution for long-term oxidative protection.

**Builds on the legacy of Longevity® Highly Crosslinked Polyethylene with more than 13 years of clinical success.[43]**

Oxidation or Significant Decline in Mechanical in Vivacit-E

**0 SIGNS**

**When subjected to accelerated aging for 33 weeks[52]**

A Lifetime of Wear Resistance In Vivacit-E

**95%**

**Wear Reduction Over Conventional Polyethylene at 100 Million Cycles[53]**

INSTRUMENTATION

# **Precise** Instrumentation with **Personalized** Control

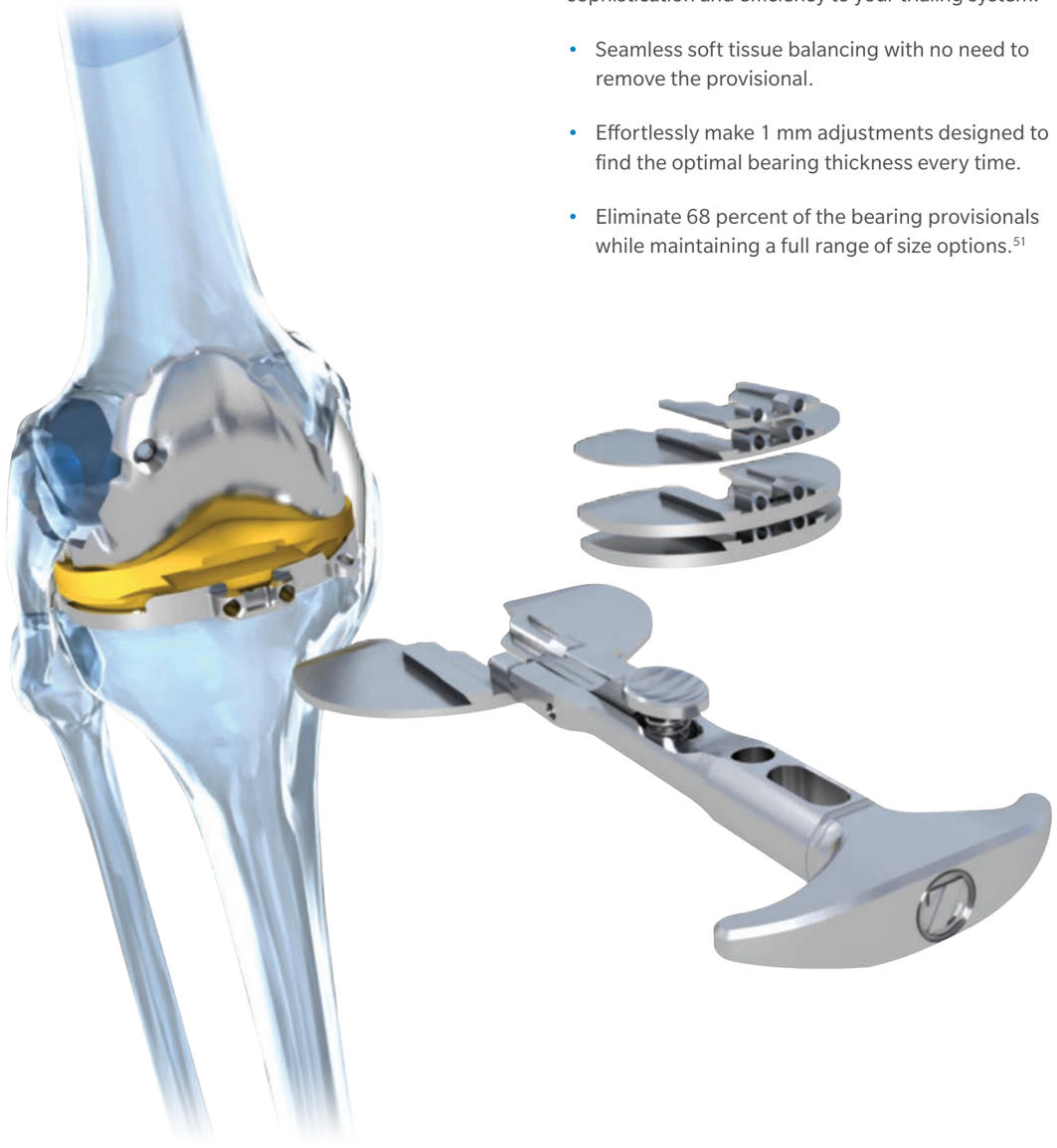
## Comprehensive Instrument Platform

Persona Instrumentation was designed to be versatile in its capabilities and philosophies, precise in its measurements, comprehensive, and comfortable with repetitive use. These options were designed to help you regularly achieve optimal outcomes.

- Intuitively designed instruments
- Designed to make knee replacement intuitive, precise, and simple.
- Intraoperative Flexibility

## Precision and reproducibility engineered to simplify the surgical procedure

The Persona tibial resection workflow provides precision for proximal tibial resection. The instrument is easy to read and adjust, and its contour design fits to the bone for stability, designed to enable highly reproducible and accurate cuts.



## TASP

The Tibial Articular Surface Provisional (TASP) adds sophistication and efficiency 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.[51]

## Notes



## Notes

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