

F R E E D O M[®]



K N E E



Freedom Total Knee[®] System System Overview



Pursue Life[™]

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Introduction to the Freedom Total Knee® Family

MODERN DESIGN PARADIGM

The Freedom Total Knee® System was developed using advanced design engineering technologies and extensive clinical experience to address the anatomical, physiological and lifestyle needs of today's patients. The system's significant design advances allow patients to achieve optimal high-flexion motion regardless of whether the all-poly or metal-backed tibial component is chosen. This approach provides surgeons with unique component options that deliver successful, predictable and reproducible results.

THINK GLOBALLY, DESIGN LOCALLY

Total joint replacement design has largely been an iterative process over the past 30 years. Each new design built of the successes and failures of the previous generation, making incremental changes to address the widest possible patient population. Furthermore, design has been driven by US and European companies with only passing consideration given to small but growing eastern markets. Many eastern markets (e.g. Japan and Korea) developed their own implant systems to address their unique needs, without regard to western demands.

Today, designing a total knee replacement system requires a holistic approach. We designed the Freedom® Knee by evaluating different markets for five key attributes: sizing requirements, shape differences, bone conservation needs, flexion range requirements, and the clinical environment

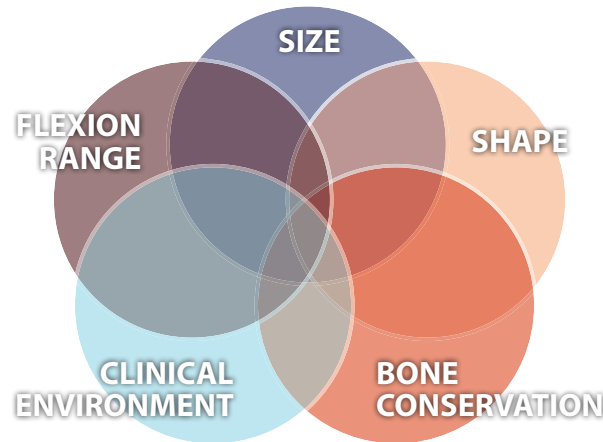


Figure 1. Critical Market Attributes

(including economic). To design a truly global product line, we not only had to appreciate these market differences, but ultimately bridge the gaps.

ANATOMIC VARIATION

Geneticists agree that humankind's mitochondrial DNA can be traced back to an ancestral female "Eve" who lived in eastern Africa 150,000 years ago. As people migrated from Africa, genetic adaptations and mutations took hold. These acquired and expressed mutations, combined with environmental and cultural influences, have produced lasting effects on global anthropometry.

SIZE

The most obvious expression of regional anthropometric differences is in the size: in general, Asian patients tend to require smaller implants than Caucasian patients. In designing the Freedom Knee, Maxx used the extensive literature describing

the anthropometric differences between the distal femoral and proximal tibial structures of eastern and western patient populations to optimize its component sizing to accommodate a global patient population. Not surprisingly, the smallest end of the sizing spectrum is Asian-dominant, while the larger sizes are predominantly implanted in Caucasian patients. We created an intermediate “D” size – only 2mm in AP and ML dimensions from the “C” and “E” sizes on either side – to provide a transitional component to bridge the two markets. The figure below shows the percentage of component sizes used in the two broad markets and illustrates the “C-to-D” transition.

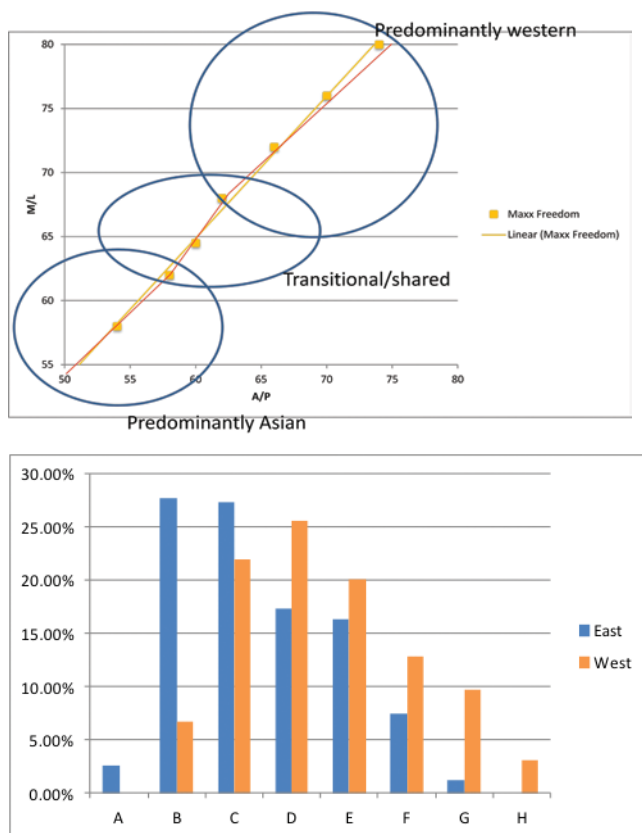


Figure 2. Femoral component dimensions and use by market

SHAPE

Perhaps less obvious but potentially more important than size, is the shape of the femoral and tibial structures. Literature published over the past decade has identified clear differences between eastern (separate studies on Indian, Chinese, Japanese, and Korean patient populations) and western anthropometry, collectively suggesting the need for consideration of these dissimilarities in Arthroplasty design.^{1,2,3,4}

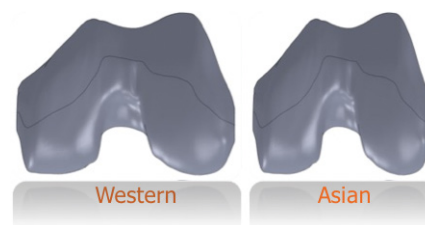


Figure 3. Distal femur comparison

As illustrated in Figure 3, for the same given AP dimension, the Western distal femur is wider in the ML dimension than its Asian counterpart. We have found that these discrepancies are most pronounced in the smallest patients and are more nuanced in larger patients.

That is, the sizing curves between western and eastern patients converge at the larger sizes. This realization allowed us to develop a global set of femoral components, which are appropriate for both patient populations within the size ranges each demands.

DESIGN WITHOUT COMPROMISE

Just as previous designs have compromised size and shape to meet the demands of one market to the detriment of another, so has gone the design philosophy around high flex components. The compromise has always been: high flexion at the expense of bone conservation.

ENABLING HIGH FLEX

High flex ($>120^\circ$) activities vary by geography and culture. Whether recreational, religious, or routine in nature, patients want to comfortably continue (or in some cases, return to) high flex activities after a TKA. Most if not all high flex systems on the market were designed first as standard flex and then altered for the new high flex standard. Usually they achieve additional flexion by increasing posterior condylar thickness, requiring additional bone resection. In designing the Freedom Knee from the ground up to be both high flex and bone conserving, we did not need to sacrifice one to achieve the other.

THE IMPORTANCE OF BONE CONSERVATION

By using a novel, multi-radius design, we were able to achieve high flex (as defined by the FDA) without sacrificing the additional posterior condylar bone. For smaller patients, every cubic millimeter of retained bone means a safer, stronger interface between the bone and implant. While this feature is especially important in Asia, it is increasingly critical in the West. The average age for TKA patients in the US is now approaching 62, which means many more patients will outlive their primary implants and require a revision TKA. By conserving bone in the primary, we leave more bone stock for the revision, hopefully increasing the overall lifespan of the combined implants. (See Technical Brief, "Femoral Design: High Flex" for more detail.)



Figure 4. All-poly and metal-backed components

NEW CLINICAL ENVIRONMENT

Just like the rest of the economy, the global healthcare economy is becoming increasingly flat, both in distribution of services from high cost to low cost markets (e.g. medical tourism) and in weakening economic disparities between markets. Reimbursements are falling in the high-cost US and mid-cost European markets, while demand and the ability to afford the best available orthopedic devices is increasing in India, China, and elsewhere in Asia. While prices are falling, performance expectations are rising, so that western companies can no longer dump their older, lower performing products on lower cost markets.

We designed the Freedom knee to be truly global and sell exactly the same products in the west and east with no prejudice. In addition, we designed an all-poly tibial option that while costing less retains all the performance characteristics of its metal-backed counterpart. In fact, ours is the first all-poly tibial cleared by the FDA for high flexion.

More important, this design attributed provides the intraoperative flexibility to select an all-poly or metal tibia without compromising performance.

REFERENCES

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The Freedom Total Knee® System

The Freedom Total Knee® System was developed using advanced design engineering technologies and clinical experience to address the anatomical, physiological and lifestyle needs of today's patients. The system's significant design advances allow patients to achieve optimal high-flexion motion regardless of whether the all-poly or metal-backed tibial component is chosen. This approach provides surgeons with unique component options that deliver successful, predictable and reproducible results.

FEMORAL COMPONENTS TECHNOLOGY

- Choice of cruciate retaining (CR) or posterior stabilized (PS) components using the same instrumentation.
- Preserves bone while promoting high flexion.
- Thin anterior flange for bone preservation.
- Six-degree angle of patellar groove assures smooth patellar tracking.
- Optimal tibio-femoral conformity in extension, with proper rotational freedom in flexion.
- Left/right components each available in eight sizes that match with several tibial sizes to accommodate patient needs.
- Cobalt chromium molybdenum alloy material.



Femoral Components

TIBIAL INSERTS TECHNOLOGY

- An all-poly tibial component specifically designed for high flexion and cleared by the US FDA.
- Ultra High Molecular Weight Polyethylene (UHMWPE) tibial inserts are available in CR, PS and UC (ultra congruent) options.
- Designed using advanced computer modeling technology to reproduce natural knee kinematics while accommodating anatomic femoral rollback and internal rotation.
- Features a deep anterior patellar cut-out to allow for tendon clearance during deep flexion.
- All-poly tibial component offers an excellent alternative to metal-backed tibial design.



Tibial Inserts

TIBIAL BASEPLATE TECHNOLOGY

- Cobalt chromium alloy tibial baseplate is shaped for optimal stability in deep flexion with a low profile keel.
- Locking mechanism features “5 points of peripheral locking” to ensure security and reduce potential for micro-motion.
- Universal tibial baseplate accommodates left and right sides as well as CR and PS liners.
- An optional bone conserving, low profile stemmed baseplate that also provides extremely proximal stem offset.



Tibial Baseplates

ALL-POLY PATELLA COMPONENT

- UHMWPE material with symmetric design for optimal tracking within the patellar groove of the femoral component.
- Available in a selection of diameters and thicknesses to ensure proper sizing for each patient.
- Central cement recess and three-peg design ensures best bone interface and optimal stability.



Patella Component

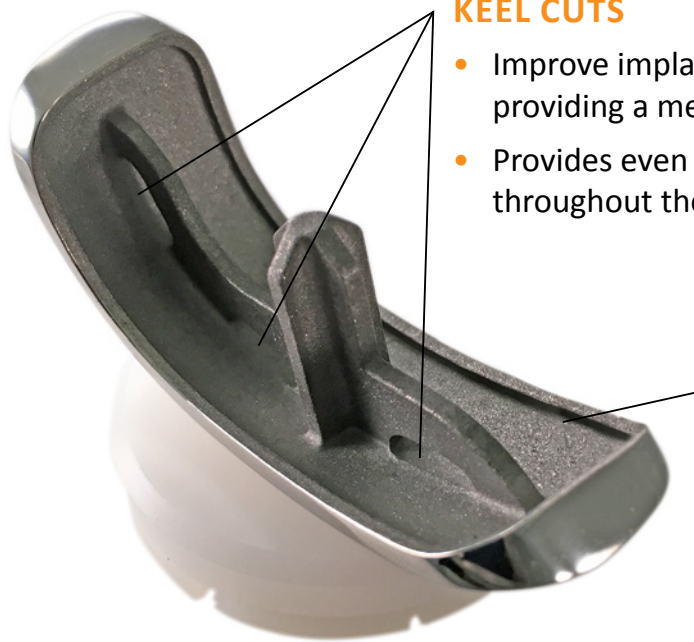
SIZING INNOVATION

The FreedomTotal Knee® System offers surgeons the freedom to customize their size options to better fit the implant to the patient’s knee, allowing for adequate flexion-extension spacing, optimal tension in the quadriceps muscle mechanism, appropriate coverage of the resected bone surface to support even stress distribution, and smooth tracking of the patella in the trochlear groove during flexion.

Key innovations include:

- Incorporates an innovative design that redefines the high-flexion arc of the femur while limiting bone resection along the posterior condyles of the femur.
- Provides a deeper patella-femoral groove for natural patella tracking with or without resurfacing the patella.
- Offers multiple size options that feature dynamically proportioned M/L and A/P femoral components in CR and PS options.

The Partial Knee



KEEL CUTS

- Improve implant strength and stability providing a mechanical lock.
- Provides even cement coverage throughout the underside of implant.

CEMENT DAM

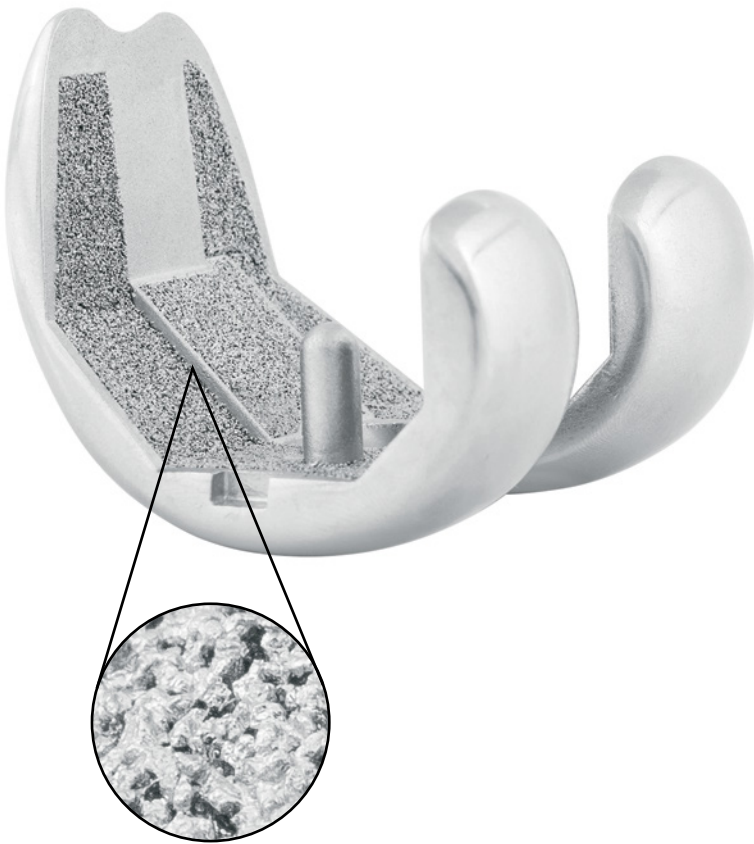
- Cement containment to minimize extrusion.

THE LATEST INNOVATION IN PARTIAL KNEE TECHNOLOGY

The Freedom® Knee Partial Knee provides the following:

- Faster Recovery Time.
- Minimized Post Operative Pain.
- Early Mobilization.
- Minimal Bone resection.
- Easy, reproducible procedure with guided resection technique. Little to no free hand technique.
- Full femoral resurfacing.

The Cementless Knee



PROVEN GEOMETRY

- Proven performance backed by years of clinical performance.
- Bone conserving design that promotes high flexion.
- Choice of cruciate retaining (CR) or posterior stabilized (PS) components.
- Same instrumentation platform as Freedom® Total Knee System.

ASYMMATRIX® POROUS COATING

- Unique structure developed through multi layers of irregular shaped CoCr beads gives **SCRATCH-FIT FEEL** for enhanced initial stability.
- Increased average pore size and greater porosity than traditional spherical beads maximizing opportunity for **BONE IN-GROWTH**.
- Interconnected pores from substrate through surface for **LONG-TERM FIXATION**.

ASYMMATRIX® is a registered trademark of Orchid Orthopedic Solutions.

The Stemmed Tibial Baseplate



In situations where a primary knee replacement surgery requires additional stability, due to poor bone stock or severe deformity, the Freedom Knee® provides surgeons the option of a stemmed tibial baseplate. The stemmed tibial baseplate employs the Freedom Knee's innovative 5-point locking mechanism, with the additional modularity of:

- 30 straight stem extensions ranging in diameter from 7.5mm to 20mm and lengths of 40mm to 150mm.
- Optional, indexed adapters that provide 4mm or 6mm of offset between the baseplate and stem extension.
- Reversible (left/right) 5mm augments, which can be stacked to create a straight or conical profile.



SYSTEM FEATURES INCLUDE:

- A bone conserving, low profile stemmed baseplate that also provides extremely proximal stem offset.
- Designed to resist baseplate lift-off due to tilting that can result from poor bone stock.
- Adapter and stem combinations provide optimal canal fill and component positioning options.
- Simple and reproducible surgical technique.
- Easy intra-operative assembly with minimal instrumentation.



The PCK Revision Knee



- Tapered cemented **FEMORAL STEM EXTENSIONS** for both the femur and tibia are offered in a variety of diameters to meet specific patient needs.
- **PATENTED** box of the Freedom PCK provides a **VARYING CONSTRAINT PROFILE** from high constraint in extension to less constraint in flexion.
- Built on clinical success of the Freedom Knee geometry to promote optimum size and shape for modern needs.
- **CONSTRAINED LINER** with pre-assembled liner securing pin to provide additional locking and stability while reducing locking tab stresses.
- Bone conserving, low profile **TIBIAL BASEPLATE** to manage poor bone stock or severe deformities.
- Reversible and stackable **AUGMENTS** allow for better match to the replaced deficient bone.
- 360° rotating femoral and tibial **OFFSET JUNCTION** allows for optimal canal filling and fixation.
- Canal filling **STEMS** with spline and flute design provide immediate rigid fixation and resistance to torsional movements. A flexible coronal slot provides a dynamic structure to address long-term endosteal bone changes.

Pursue Life™

For more information about Freedom® Knee,
please contact your local representative.

LEARN MORE ABOUT MAXX PRODUCTS
WITH OUR APP:



SEARCH: Maxx Ortho

Please see the package inserts for complete device description, product selection information, indications, contraindications, precautions, adverse effects, warnings, materials, sterilization and patient guidance associated with the Freedom Total Knee® System.

CAUTION: THESE DEVICES ARE RESTRICTED TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

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