



**Shalby**  
Advanced  
Technologies, Inc.  
*Restoring Mobility, Improving Lives.*

# Technical Monograph

## Consensus<sup>®</sup> Knee System

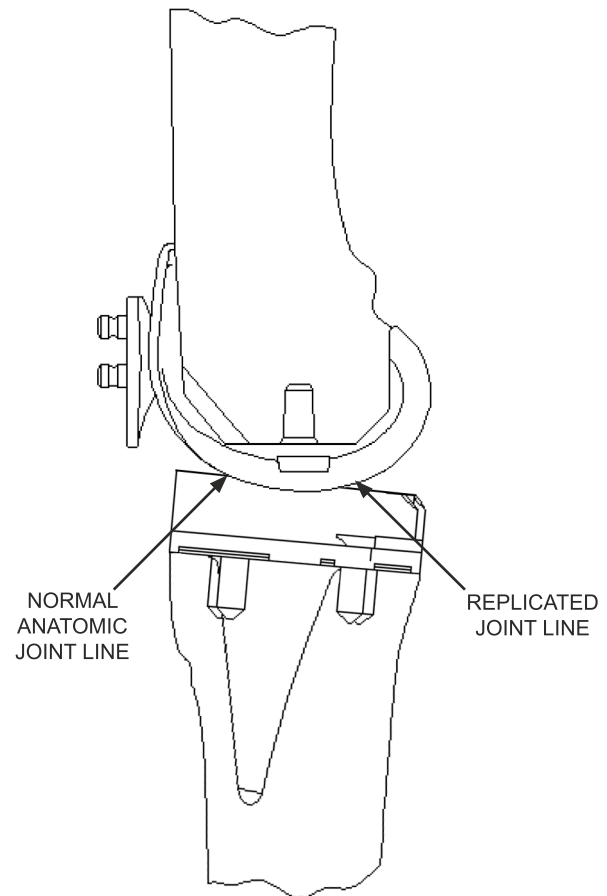
# Contents

<b>Design Rationale.....</b>	<b>1</b>
Introduction .....	1
Restoring the Knee Joint .....	2
The Tibia .....	2
The Femur .....	2
The Patella.....	2
Instrumentation.....	2
<b>Product Descriptions .....</b>	<b>3</b>
Femoral Component.....	3
Anatomic Component Sizing .....	3
Femoral Condylar Geometry – Balancing Performance and Durability.....	3
Coronal Plane.....	3
Sagittal Plane.....	3
Trochlear Groove Geometry .....	4
Femoral Box Geometry and Trochlear Step.....	4
Femoral Component Materials.....	6
Tibial Component.....	6
Anatomic Profile & Sizing .....	6
Tibial Insert Locking Mechanism .....	8
Tibial Baseplate Fixation .....	8
Tibial Stem .....	8
Tibial Baseplate Materials.....	9
Tibial Insert Geometry .....	9
PCL Substituting Inserts.....	10
Tibial Insert Materials .....	11
Consensus VitalitE .....	11
Coventional Poly.....	12
Consensus UHMWPE Wear Studies.....	12
Patellar Component .....	12
Anatomic Component Sizing .....	12
Patellar Geometry.....	13
Oval Patellar Component.....	13
Round Patellar Component .....	14
Patellar Component Materials.....	15
Bone Screws .....	15
Cancellous Bone Screw.....	15
<b>Performance Testing .....</b>	<b>16</b>
Tibial - Femoral Stability .....	16
Patello - Femoral Stability.....	18
Contact Area Testing .....	19
Tibia-Femoral Contact Area .....	19
Patello-Femoral Contact Area.....	20
<b>Component Structural Integrity Testing .....</b>	<b>21</b>
<b>By Special Request Only .....</b>	<b>22</b>
Porous .....	22
Femoral Component Materials.....	22
Titanium on CoCr Surface .....	22
Resurfacing .....	23
Resurfacing Tibial Baseplate.....	23
Patella .....	24
Metal Back Patellar Component .....	24
<b>References.....</b>	<b>25</b>

# Design Rationale

## Introduction

The evolution of total knee replacement (TKR) has yielded significant improvements in both surgical technique and implant design. Results from a wide range of total knee systems lead to a recurrent set of design features requested by physicians. The design rationale for the Consensus® Knee System arises from the consensus among mainstream orthopedic surgeons on the features required to meet the demands of today's TKR patients. Specific design features of the Consensus® Knee System were established from historical product performance over the last 30 years. Several factors, often competing, were balanced to achieve a system truly reflecting the consensus among mainstream orthopedic surgeons. In the cases where no prevailing consensus exists, variations in the product features are offered. The human knee joint is perhaps the most complicated of all bearing interfaces known. Unlike cylindrical or spherical journal surfaces where a single rotational axis or pole is varied, the knee is comprised of many interdependent rotating and translating motions in six degrees of freedom.<sup>1</sup> The primary motions are flexion and extension; however, anterior-posterior displacement, rotation, and varus and valgus motions are also important to its overall function.<sup>2</sup>



*Figure 1. Optimal kinematic function and normal gait patterns are more closely replicated by a TKR design that achieves stability by combining normal ligamentous structures and a restored joint line*

Restoration of the joint function through surgical reconstruction is dependent on load sharing between the implant and surrounding soft tissue structures. Removal or pathological weakening of these structures will result in increased dependency upon the implant system for stability.

**The Consensus RLP Femoral components were developed to provide an enhanced anterior medial-lateral fit for a more precise “patient-matching” component.**

The Consensus® Knee System has been developed to preserve and utilize healthy ligamentous structures to allow for more normal kinematics. For cases where the PCL is not functional, the PCL Substituting Tibial Inserts or the Posterior Stabilized System are available for increased stability.

## ***Restoring the Knee Joint***

The knee joint is restored by referencing the intact anatomy of the proximal tibia, distal femur, and apex of the patella. The objectives are to:

- *Restore the joint line through accurate replacement of the surface thicknesses of the tibia and femur*
- *Align and position the knee along the mechanical axis of the lower extremity*
- *Reproduce the posterior slope of the tibia*
- *Restore the function and stability of the Patello-Femoral joint*

### **The Tibia**

The proximal tibial cut is made to match the posterior slope of the anatomic tibia, with the exception of P/S, where the resection should not exceed 3°-4° posterior slope.

Tibial varus-valgus alignment may be set by referencing either external landmarks or the intramedullary canal of the tibia.

### **The Femur**

The femoral varus-valgus and flexion-extension alignment is set by referencing the femoral intramedullary canal. The alignment can also be checked with respect to extramedullary references. The femoral component is positioned by referencing the posterior condyles of the knee. However, the system allows adjustment to reduce the potential for anterior notching without “oversizing” the implant. The depth of the patellar groove is increased to allow for normal tracking of the patella. The RLP Femoral component offers improved “patient-matching” sizing in the anterior medial-lateral dimensions. The RLP Femoral component has an improved rounded design in the posterior runs and a reduced lateral anterior flange.

### **The Patella**

The thickness and angle of the patellar resection should be accurately controlled to restore proper height and alignment. An oval patella component provides maximum bone coverage for improved fixation and optimal stress transfer. The dome of the patella is medialized to reproduce anatomic tracking. A round “button” style patella is also available in 25, 28, 32 and 35mm diameters.

## ***Instrumentation***

Accurate instrumentation, which enables the surgeon to produce predictable outcomes, is essential to successful TKR. The instrumentation for the Consensus® Knee System has been designed to provide:

- Simple and easy standard alignment
- Quick and easy means to check alignment and depth at every step of the procedure
- Reliable guides to enable accurate, precise and controlled cuts
- Intuitive and easy alternative instruments to adjust alignment and depth before and after resection

Together with the Consensus® Knee implants, the Instrument System enables the surgeon to obtain consistent predictable results for a wide variety of patient indications.

## Product Descriptions

### ***Femoral Component***

#### **Anatomic Component Sizing**

The femoral component is provided in left and right side versions to replicate natural kinematic motion between the femur, tibia and patella.

Component sizing was developed based on knee morphology studies,<sup>3,4</sup> ligament mechanical structures,<sup>5</sup> and independent validation by intraoperative and cadaver size studies.<sup>6</sup> As shown in Figure 2, six sizes with medial-lateral widths ranging from 62mm to 82mm in 4mm increments were developed to cover the full spectrum of femoral anatomy. The anterior-posterior sizing is directly correlated to the medial-lateral width including allowance of a raised lateral condyle.

The RLP Femoral components offer improved “patient-matching” sizing in the anterior medial-lateral dimension. Intraoperative measurements of patients having total knee replacements were measured by a Consensus Knee surgeon. These studies found that many patients needed a more narrow component in the medial-lateral plane on the anterior portion of the femoral component. These measurements guided the RLP Femoral components design to provide improved patient-matching sizing and reduce component overhang in some patients.

#### **Femoral Condylar Geometry – Balancing Performance and Durability**

In the normal knee, the shape of the joint surfaces determines the kinematics of the joint in conjunction with the soft tissues. Natural cartilage is highly compliant and allows continuous variations in the shape of the femoral-tibial interface. In a mechanical knee, the geometry of the component surfaces also determines the kinematics of the reconstructed joint. However, the interfaces must be designed to accommodate the performance characteristics of the implant materials. With ultra-high-molecular-weight-polyethylene (UHMWPE) and VitalitE the surfaces must be designed to minimize contact stresses by providing greater contact areas during motion. This must be balanced with the kinematic performance of the knee which, generally, becomes more constrained as contact area is increased.

#### **Coronal Plane**

The Consensus<sup>®</sup> femoral component is designed to provide uniform contact zones in the coronal plane throughout the range of motion when the knee is properly aligned.

#### **Sagittal Plane**

The femoral component is also designed with a large distal radius to optimize contact areas and reduce contact stress. The full condylar posterior curve in the sagittal plane coupled with the congruent insert allows from -10° hyperextension to 120°+ of flexion in a well-balanced knee.

## Trochlear Groove Geometry

The trochlear groove in the femur is designed to allow the load from the patella to be evenly distributed on the femur with adequate lateral constraint. It is considered desirable in TKR to have a deepened patella track<sup>6</sup> to avoid functional shortening of the extensor mechanism improving the range of motion. The deep groove also minimizes the potential of patellar subluxation or dislocation. In order to maintain normal patellar tracking, the patella track diverges from parallel to the sagittal plane and gently transitions to a 6° trochlear groove angle to match the quadriceps.<sup>7</sup> The anterior face of the femoral component also transitions to a raised lateral condyle that will provide resistance to lateral subluxation of the patella

The RLP Femoral components have a reduced lateral profile on the anterior flange, as shown in Figure 3.

## Femoral Box Geometry and Trochlear Step

The Consensus<sup>®</sup> femoral components are accurately fitted on the posterior, anterior, and distal faces to maximize initial fixation using precision cutting saw guides. The saw guides are fitted with both captured and uncaptured open resection blocks to allow close inspection of resections. The deepened patella track on the articulating face is accommodated by a trochlear step in the box geometry (4.5mm). The step provides additional medial-lateral initial fixation. Grit blast cement retention pockets are provided on the non-porous femoral component to provide for optimal cement adhesion.

RLP & P/S Sizing							Wide Sizing						
Size	1	2	3	4	5	6	Size	1	2	3	4	5	6
M/L	59	63	67	72	76	80	M/L	62	66	70	74	78	82
A/P	52	56	60	64	68	72	A/P	52	56	60	64	68	72

### RLP – Wide – PS Femoral Components

Base Material	Cast and HIPed CoCrMo per ASTM-F75
Anatomic Sizes	6 sizes left and right
Distal Resection Thickness	10 mm
Posterior Resection Thickness	9 mm
Varus/Valgus Angle Relative to Femur	6°
Patella Track Q Angle	6°
Non-Porous Component	1mm deep textured pockets
Flexion Range	-10° hyperextension to 120° full flexion
Rotation Range	±7°

Figure 2. Femoral Component Dimensions and Features

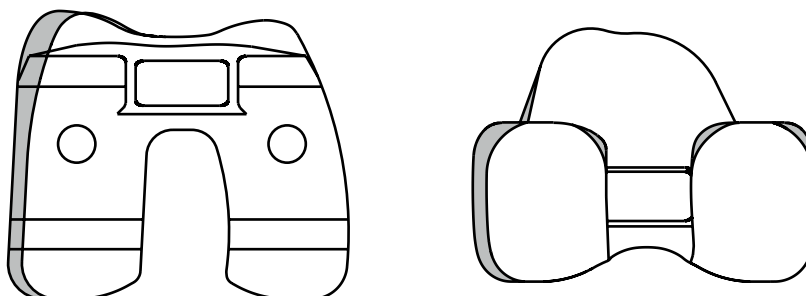
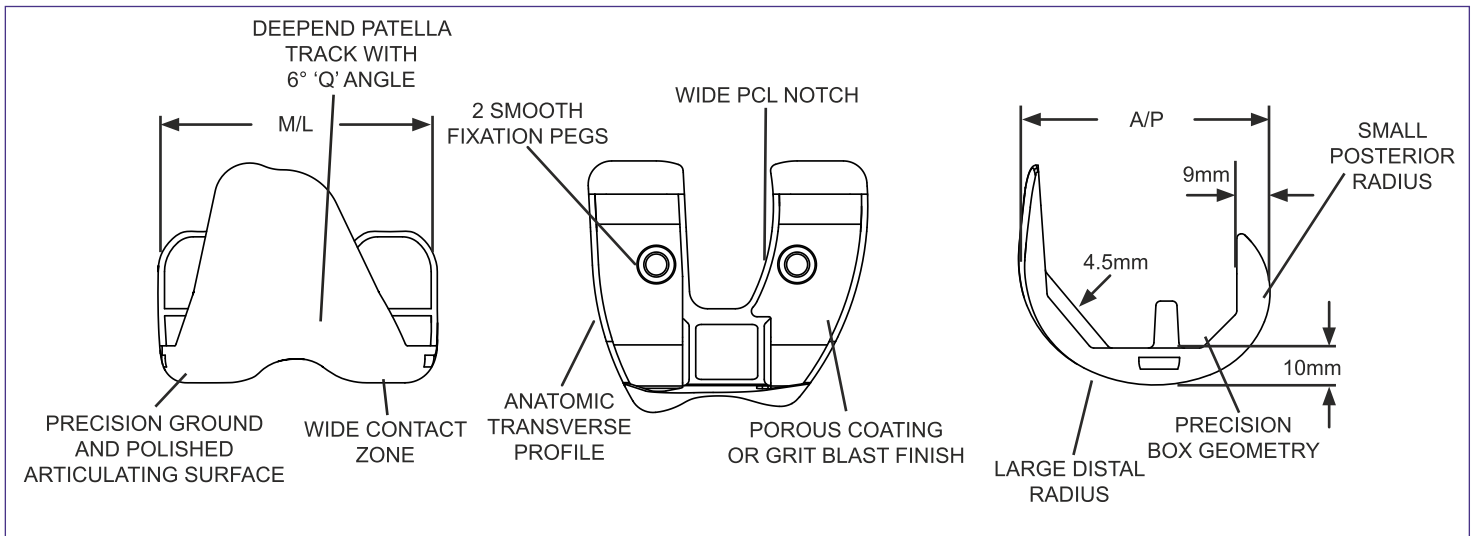
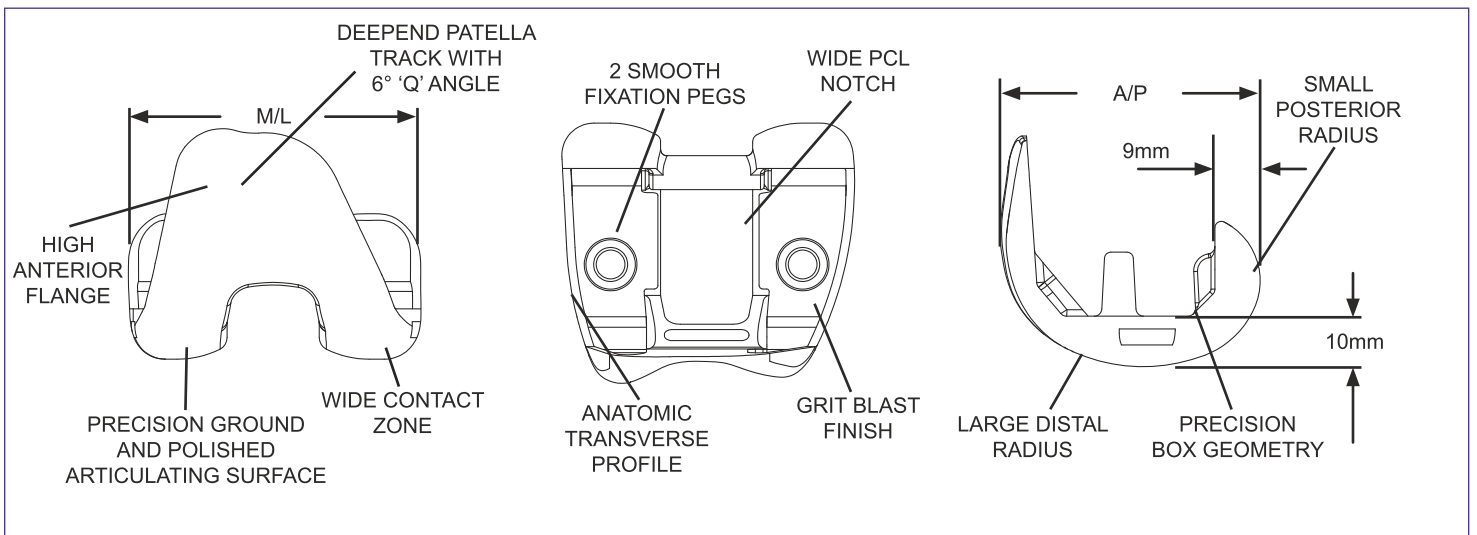


Figure 3. RLP (light) vs Wide femoral component (dark)

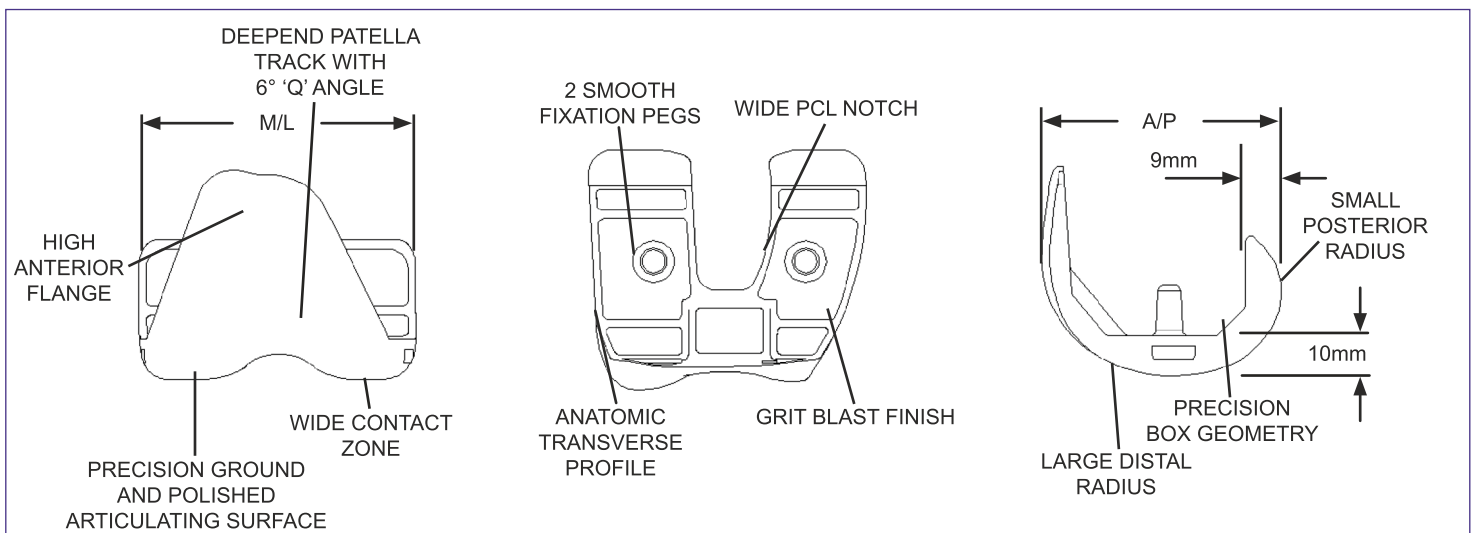
## RLP



## P/S – RLP



## Wide Femoral Component



## Femoral Component Materials

The first criteria for material selection is to address the factors driving component wear. The use of titanium for any type of wear surface has been met with complications and is considered inferior to CoCr for articular surfaces.<sup>8,9</sup> The cobalt chrome used in the Consensus® femoral components is precision investment cast, annealed and high pressure isostatically pressed (HIP) cobalt-chrome-molybdenum manufactured to ASTM F-75 with additional requirements for enhanced material performance.

## Tibial Component

### Anatomic Profile & Sizing

The shape and sizing of the tibial component, as with the femur, is based on knee morphology studies<sup>3,4</sup> and independent cadaver validation studies.<sup>6</sup> The clinical effectiveness in mitigating tibial component subsidence with an anatomic baseplate<sup>10</sup> is widely accepted. The anatomic design minimizes soft tissue impingement while providing optimal peripheral fit on the resected tibia. Figure 4 shows the peripheral fit in a superior view of the tibial component. As shown in Figure 5, seven sizes with medial-lateral widths ranging from 62mm to 86mm in 4mm increments were developed to cover the full spectrum of resected tibial anatomy. The anterior-posterior sizing is correlated to the medial-lateral width. A deep PCL notch is provided with a slightly medial shift to provide optimal clearance.<sup>11</sup>

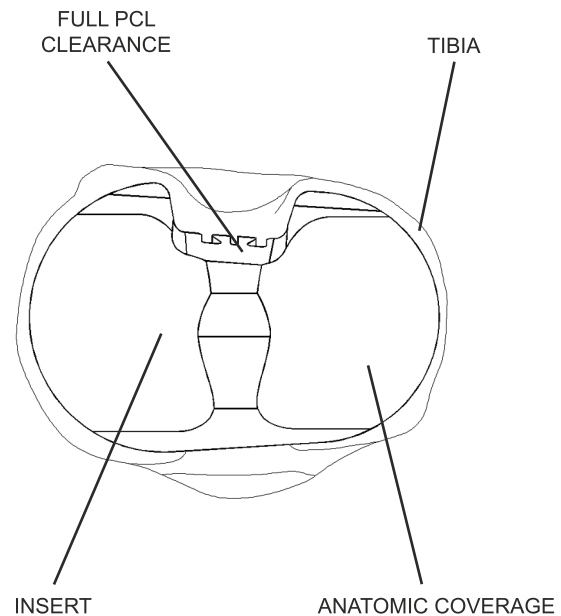


Figure 4. Anatomic sizing and shape provides optimal tibial peripheral fit, fixation, and stability

Tibial Component Dimensions

Size	0	1	2	2.5*	3	3.5*	4	5	6
M/L	62	66	70	72	74	76	78	82	86
A/P	40	43	46	47	48	49	50	53	56
K/L	32	38	38	38	44	44	44	50	50

\*Future Development

Pegs Lengths & Diameters

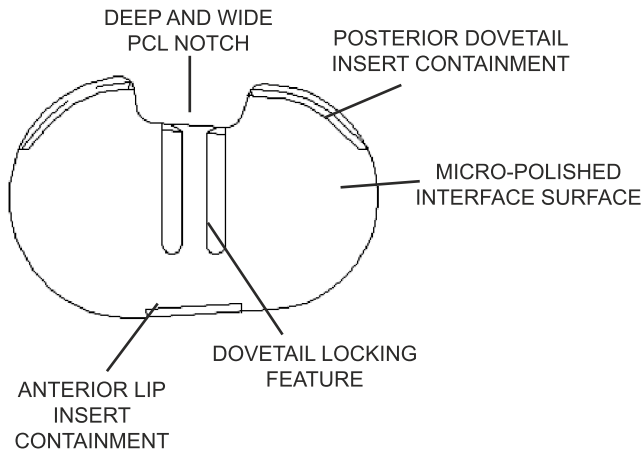
Size	0	1	2	3	4	5	6
Anterior	9	9	10	11	11	11	11
Posterior	8	8	9	10	11	11	11

Base Material	Cast CoCr per ASTM F75
Anatomic Sizes	7 sizes left and right
Baseplate Thickness	4 mm
Stem Anatomic Position in Transverse Plan	2.5 mm medial of knee center
Stem Anatomic Position in Sagittal Plane	4.9 mm anterior of knee center
Tibial Stem Pegs	Range of 8 mm - 11 mm long, 4 locations
Non-Porous Component	1.2 mm deep textured pockets
Platform Finish	12µin RMS
Screw Hole Angulation	22° included angle

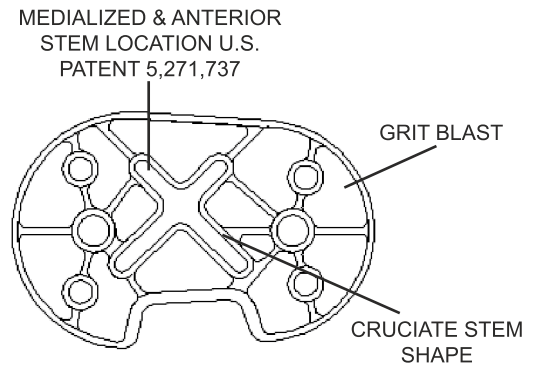
Figure 5. Tibial Component Dimensions and Features



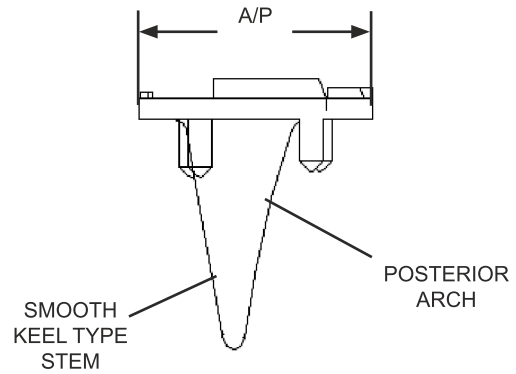
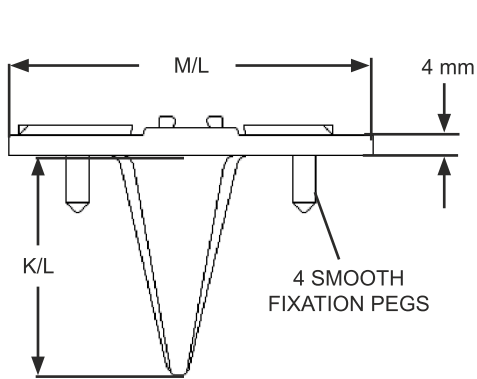
## Top – Superior



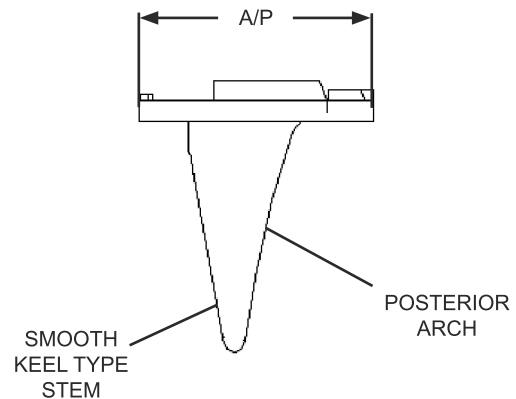
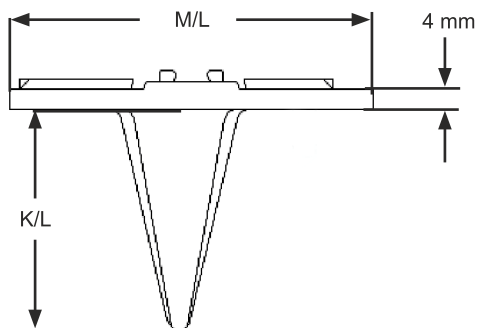
## Bottom – Inferior



## Pegged



## Pegless



## Tibial Insert Locking Mechanism

The 4mm thick tibial baseplate of the Consensus® system accepts modular tibial inserts of thickness ranging from 6mm to 18mm.<sup>12</sup> The insert is secured to the tibial baseplate with a four point locking system. A centrally located Active Dovetail holds the insert down on the baseplate with an elastic preload. The insert is securely held in A/P and M/L directions by two posterior peripheral dovetails and an anterior lip. Additionally, the sides of the central dovetail feature provide extra M/L support. Intraoperative assembly is performed easily by manually sliding the insert onto the implanted tibial baseplate until a solid snap is heard. The periphery of the assembly can then be easily inspected for full seating. To minimize the chance of insert wear<sup>13</sup>, all surfaces of the baseplate in contact with the insert are polished to a smooth finish.

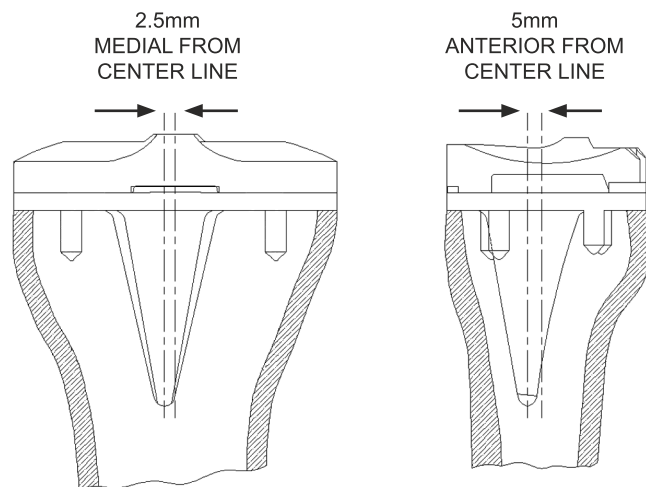
## Tibial Baseplate Fixation

The nonporous coated tibial component may be implanted using cemented fixation. Cemented fixation of the component is enhanced by the use of four pegs and optional screws in conjunction with an anatomically located cruciate stem. The nonporous stemmed tibial component is provided with a fully grit blasted stem and inferior baseplate side for maximal cement adhesion.

## Tibial Stem

The anatomy of the proximal tibia is well adapted to support the functional loads transferred to the lower leg. These loads are typically 60% greater on the medial side of the plateau.

The Tibial Shaft is located anterior and medial to the center of the tibial plateau. In this position, the tibial shaft is ideally positioned to support this off-center load. To provide the greatest stability, the tibial component has been designed to accommodate the off-center load by positioning the stem medial and anterior to the center of the baseplate (U.S. pat. no. 5,271,737).



*Figure 6. Anatomically positioned tibial stem reduces the incidence of interference with the cortical wall*

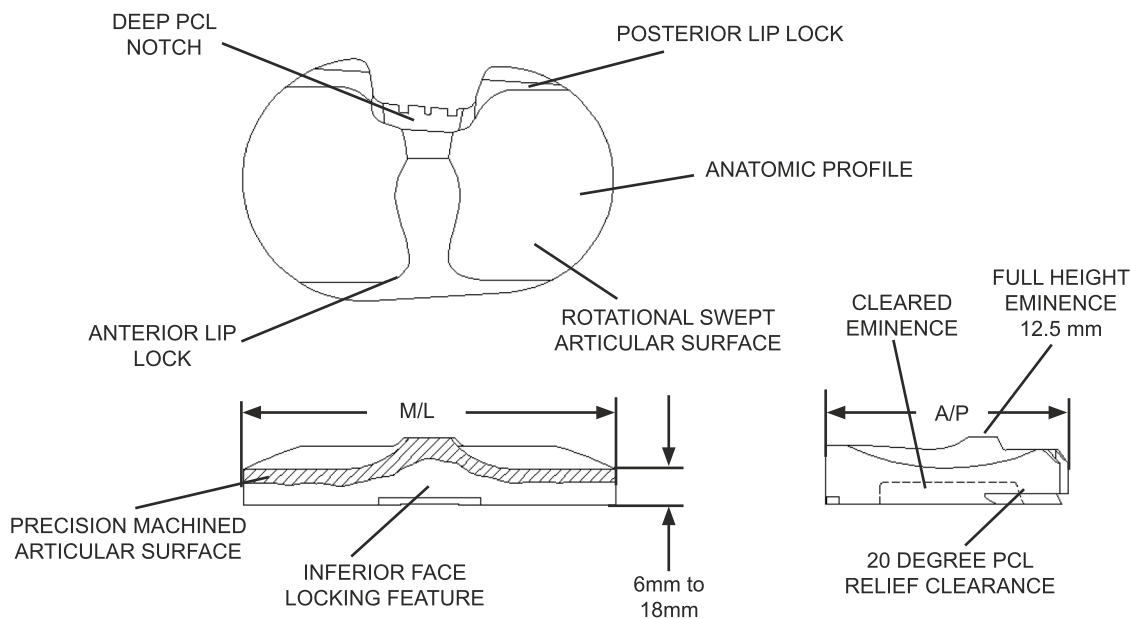
This stem position, as shown in Figure 6, also reduces the potential of the stem impinging on the posterior and lateral cortical walls of the proximal tibia. Tibial components with centrally located stems may compromise peripheral fit of the plateau. The deep cruciate stem conserves bone stock while providing for improved stability and component stiffness.

## Tibial Baseplate Materials

Tibial Baseplates are made from cast CoCr alloy (ASTM F-75), HIPed, annealed and then finally precision machined. This material provides the strength required as well as surface qualities, which minimize any backside wear of the tibial insert.

## Tibial Insert Geometry

To optimize intraoperative flexibility, three insert sizes are designed to work with 6 tibial baseplates. The inserts are provided in left and right configurations with 6mm to 18mm thickness<sup>20</sup> as shown in Figure 7. In combination with the 4mm metal baseplate, this provides for 10mm to 18mm of bone replacement. The inserts are designed with a robust combination of locking features to ensure a strong, secure couple between the insert and baseplate. A central dovetail retains the insert in a preloaded condition against the baseplate surface. Full edge posterior dovetails and an anterior lip retain the insert in anterior and posterior motion. Medial-lateral fixation is enhanced by the side walls of the central dovetail mechanism.



Size	0-1-2	3-4	5-6
M/L	66	74	82
A/P	43	48	54

Base Material	Ram molded UHMWPE per ASTM F-648 and Vitalite
Anatomic Sizes	3 sizes left and right (1 insert for 2 bases)
Thickness	10 mm to 22 mm in 2 mm increments
Eminence Height	12.5 mm all sizes

Figure 7. Congruent Tibial Insert Dimensions and Features

Anterior-Posterior constraint of the knee is accomplished by dishing of the insert in the lateral sagittal plane to mate with congruent geometric surfaces on the femoral component. The degree of constraint is modeled after studies<sup>17</sup> indicating a minimum 5mm anterior-posterior laxity is needed to avoid a reduction in range of motion. The degree of constraint must closely approximate the normal articular surfaces to avoid excessive stresses on the retained ligaments.<sup>2</sup> The tibial insert is designed to allow up to one femur size larger or smaller to be used interchangeably for maximum intraoperative flexibility.

Medial-lateral constraint of the femoral component is achieved by a raised tibial eminence. The centerline distance between the ramps to the eminence and the corresponding condylar surfaces on the femur are closely controlled to ensure even load distribution and minimal lateral shifting of components.

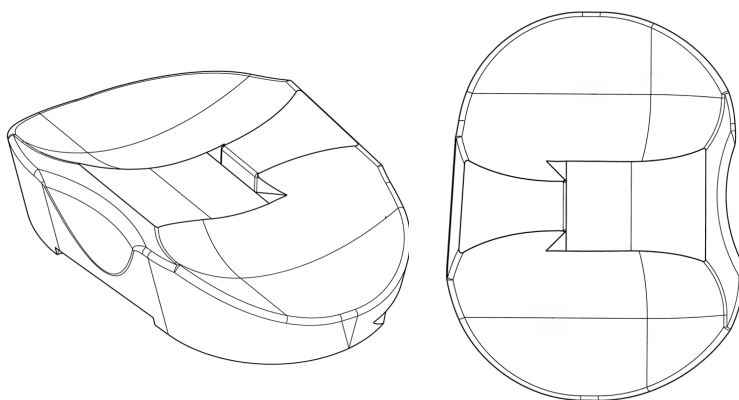
Internal and external rotary motion is limited as some degree of compensating constraint is required when the ACL has been sacrificed<sup>5</sup> or other ligaments weakened. The articular surface on the insert rotationally tracks toward the centerline of the knee in the anterior direction to allow for rotary motion with constraint. The average rotation encountered during walking has been clinically determined to be 8.7° included angle.<sup>2</sup> Additionally, the medial side of the tibial insert is dished slightly larger than the lateral side in the sagittal plane to produce less medial constraint during flexion. This difference in dishing will allow rotational movement that more closely approximates that of the normal knee.<sup>2</sup>

Flexion and extension range of motion is determined by a combination of femoral component thickness, resection thickness, posterior condylar radii, distal condylar radii, and dishing of the tibial insert as well as normal ligamentous constraints. Range of motion in excess of 120° may be attained in a well-balanced knee using the Consensus® Knee System. In addition, a relief cut is located in the raised eminence of the tibial insert to allow the femur to go into 10° of hyperextension while maintaining the full height of the eminence for medial-lateral constraint.

Varus and valgus motions of the normal knee occur when the adduction moment exceeds the intact collateral ligament tensions.<sup>2</sup> When slight tilting of the components occurs, the tibial eminence must be high enough to prevent medial or lateral dislocation. The one piece insert provides an extended height of the tibial eminence to prevent dislocation and promote alignment and stability after a varus-valgus motion.

### **PCL Substituting Inserts**

The Consensus Total Knee system offers a PCL Substituting Insert, shown in Figure 8, for posterior stabilization for patients without posterior cruciate ligaments or needing antero-posterior stabilization due to insufficient ligament support. This proven design provides stability without additional bone loss and uses a standard femoral component. The enhanced congruency provides stability and improved femoral roll-back for higher flexion.



*Figure 8. PCL Substituting Insert*

A comparison of the congruent, PCL substituting, and P/S tibial inserts are shown in Figure 9.



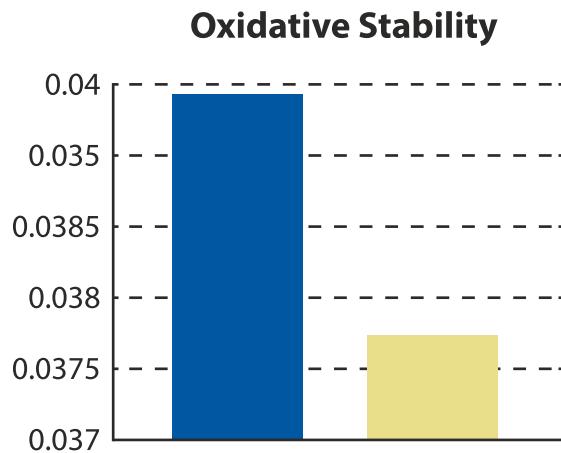
Figure 9. Comparison of Congruent, PCL Substituting, & P/S Tibial Inserts.

## Tibial Insert Materials

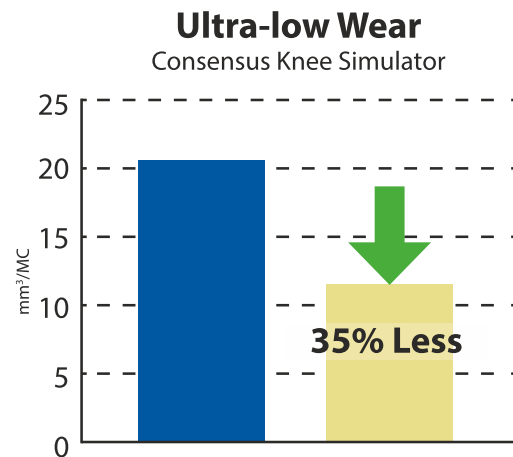
### Consensus VitalitE

Through a blended process, VitalitE cross-linked inserts demonstrate a technologically advanced material ensuring all of the desired polyethylene characteristics are maximized, with no compromises.

The VitalitE knee material contains a vitamin E concentration of 0.1% by weight and receives an irradiation dose of 75 kGy (kilograys) to achieve optimal crosslinking. The VitalitE knee material is validated for long-term implantation, meeting ISO 10993-1 biocompatibility requirements.



VitalitE inserts are more resistant to oxidation than conventional cross-linked UHMWPE<sup>14</sup>



VitalitE cross-linked inserts demonstrated a 35% reduction in wear when compared with conventional UHMWPE<sup>14</sup>



## Conventional Poly

The polyethylene tibial components used in the Consensus<sup>®</sup> system are continuous-compression-molding-sintered (ram compression extruded) from Hoechst Celanese, GUR 1050. GUR 1050 is the low calcium stearate grade and is the purest, highest molecular weight polyethylene used in the orthopedic industry today.<sup>18</sup> The final ram compression molded form of polyethylene used exceeds<sup>19,20</sup> the standards set in ASTM F648 including the limitations on fusion defects.<sup>21</sup> This is done through strict statistical process controls (SPC) and supplemental quality control methods.

## Consensus Conventional UHMWPE Wear Studies

The success of the Consensus Total Knee System can be attributed partially from its design that provides very-low wear rates when compared to competitive systems. Wear studies done by an outside testing lab provided data demonstrating superior wear rates. These results are shown in Figure 10. Patellar Component

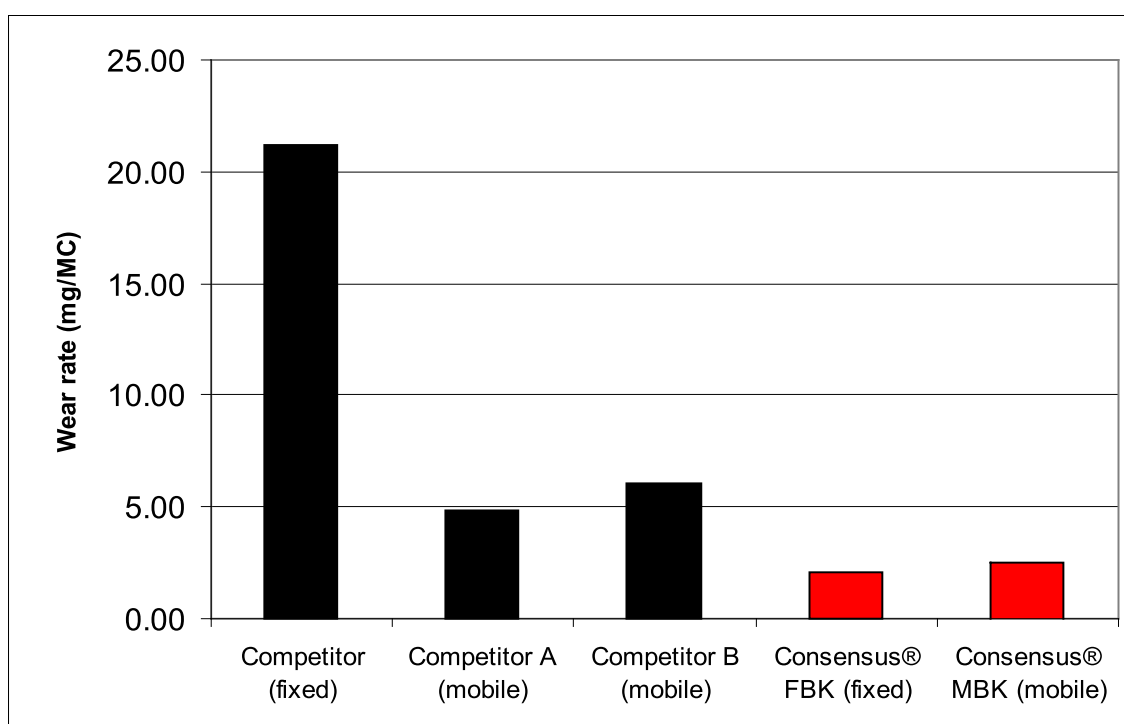


Figure 10. Wear rate of Consensus Fixed and Mobile Bearing Knee in comparison with competitive products.

## Anatomic Component Sizing

Developments in recent years have indicated that the patella can be considered a primary, integral part of TKR.<sup>22</sup> Consensus<sup>®</sup> patellar component sizing, as with the tibial and femoral components, is based on knee morphology studies<sup>3</sup> and independent dimensional studies.<sup>6</sup> The normal shape of a resected patella is elliptical or oblong. Some patellar arthroplasties only provide a contact button and neglect the far medial and lateral edges. A common mode of patellar implant failure is wear and deformation of the medial and lateral facet areas.<sup>23</sup> To address these problems, the Consensus patellar components are extended to fully cover the bony patella as shown in Figure 11. This design provides an enlarged stress distribution area between the condyles when in flexion. Four sizes of patellae are provided, ranging from 25mm to 35mm distal/proximal and 36mm to 45mm medial-lateral width.

## Patellar Geometry

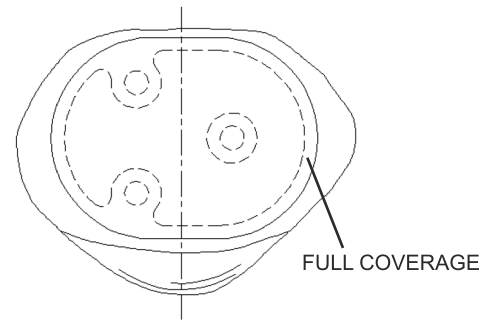
The Consensus® patella replacement, like the tibial and femoral components, is designed to restore the original joint line between femur and patella. Restoring the original height of the patella in combination with a deepened patellar track on the femoral component will more accurately reproduce normal kinematics of the patello-femoral joint.<sup>24,25</sup>

To achieve an optimal combination of stability, kinematics and low contact stresses, a conforming design that is rotationally unconstrained was selected. Patellar components with conforming saddle interfaces have improved performance characteristics over simple convex dome prostheses.<sup>23</sup> The fully extended lateral facet and slightly wider medial edge provide support for the patellar component throughout the range of high flexion to minimize the incidence of patellar clunk.

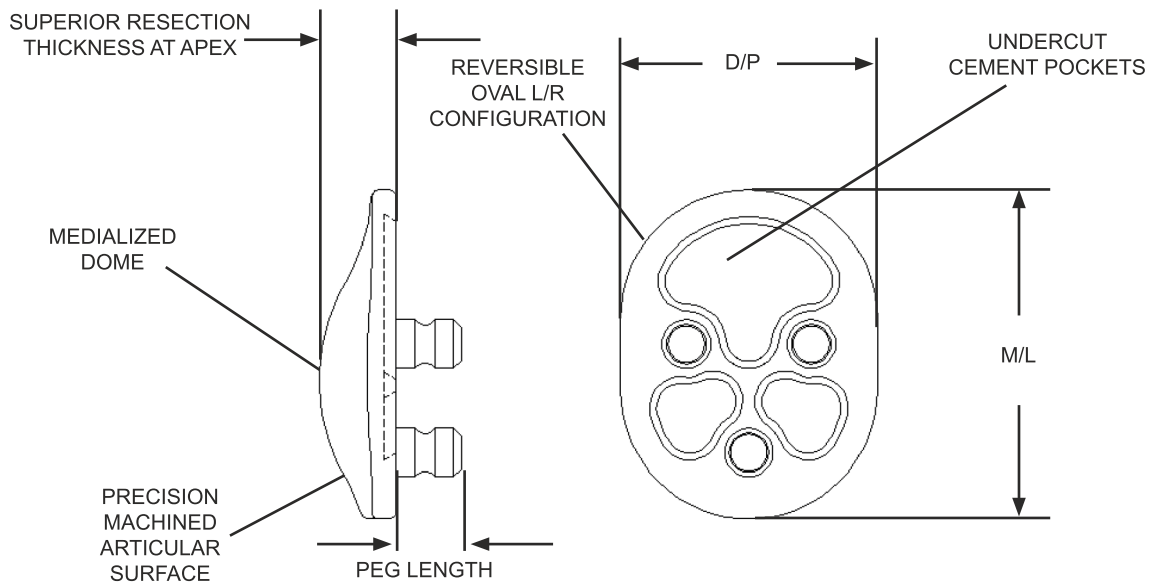
Kinematics of the patella in the trochlear groove can be improved by slight medialization of the high point on the patellar implant.<sup>26,27</sup> However, if the implant is symmetrically round, the lateral area of the bony facet will not be covered. The Consensus® system addresses this by providing patellar components with a 2.5mm medialization of the patellar dome and an extended lateral facet.

## Oval Patellar Component

The patellar component, as shown in Figure 12, provides full patellar coverage and medialized patellar dome prosthesis. The design allows for a 10mm and 7.5mm thick osteotomy to replicate the original joint line. The patellar component provides secure cemented fixation with peripheral cement dovetail retention lips on the inferior surface. Three pegs provide additional rotational stability and fixation. The patellar component is made with Conventional Polyethylene and VitalitE.



*Figure 11. Anatomically designed oval patellar implants provide dome medialization and optimal bony coverage.*



Size	0	1	2	3
M/L	32	36	41	45
D/P	25	28	32	35

Pegs (for all sizing)

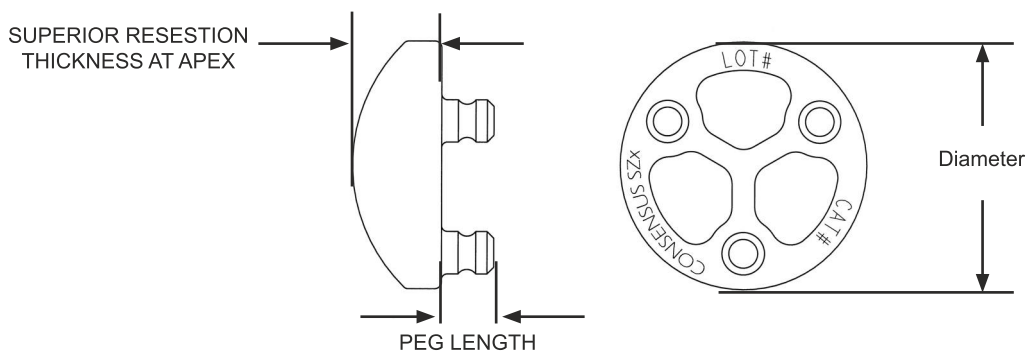
Long	6 mm
Diameter	5 mm

Base Material	Ram molded UHMWPE per ASTM F-648 and VitalitE
Anatomic Sizes	4 sizes (reversible L/R)
Superior resection thickness at apex	10mm & 7.5mm

Figure 12. Oval Patellar Implant Design and Features

## Round Patellar Component

A round, button-type patella, as shown in Figure 13, is offered in the same thicknesses, 10mm and 7.5mm, and in 25, 28, 32 and 35mm diameters.



Size	0	1	2	3
Diameter	25	28	32	35

Pegs (for all sizing)

Long	6 mm
Diameter	5 mm

Base Material	Ram molded UHMWPE per ASTM F-648 and VitalitE
Anatomic Sizes	4 sizes (reversible L/R)
Superior resection thickness at apex	10mm & 7.5mm

Figure 13. Round Patellar Implant Design and Features



## Patellar Component Materials

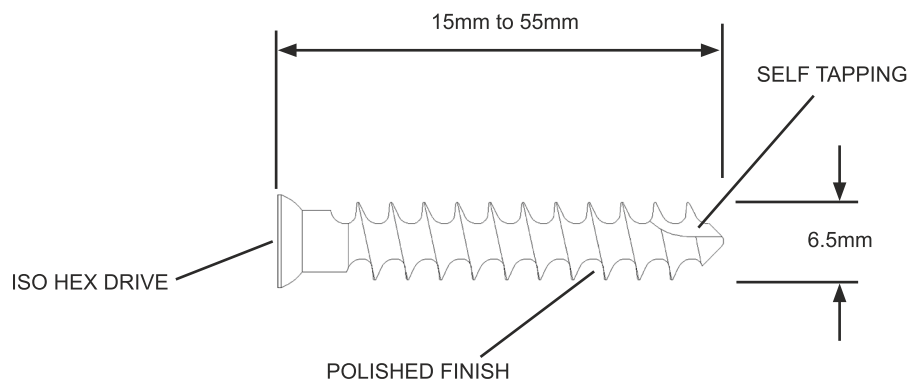
The polyethylene patellar components used in the Consensus<sup>®</sup> system are continuous-compression-molding-sintered (ram compression extruded) from Hoechst Celanese, GUR 1050 and Hostalen<sup>®</sup> GUR 415 resin. GUR 1050 is the low calcium stearate grade and is the purest, highest molecular weight polyethylene used in the orthopedic industry today.<sup>30</sup> The final ram compression molded form of polyethylene used exceeds the standards set in ASTM F648-84 including fusion defects. This is done through strict statistical process controls (SPC) and supplemental quality control methods.

The VitalitE knee material contains a vitamin E concentration of 0.1% by weight and receives an irradiation dose of 75 kGy (kilograys) to achieve optimal crosslinking. The VitalitE knee material is validated for long-term implantation, meeting ISO 10993-1 biocompatibility requirements.

## Bone Screws

### Cancellous Bone Screw

Cancellous bone screws, as shown in Figure 14, are provided in the Consensus<sup>®</sup> system to optimize initial fixation of the tibial baseplate.



Type	Cancellous
Diameter	6.5 mm diameter
Lengths	15 mm to 55 mm in 5 mm increments
Material	Wrought Ti 6AL-4V per ASTM F-136
Drive hex	3.5 mm per ISO 5835

Figure 14. Cancellous Bone Screw Design Features

# Performance Testing

## Tibial - Femoral Stability

The degree of resistance to directional loading in the anterior-posterior, medial-lateral, and rotational directions under loading defines the stability of a knee implant system. Knee arthroplasty provides a net stability resulting from the combination of remaining ligamentous structures, pathologies and implant system mechanical stability. Assessment of the implant systems stability is done using conventional, independent laboratory tests\* to replicate normal and shear loads found in the functional knee. The resultant test values may then be compared with the loads occurring in the pathologies of the normal knee as well as other commercially available devices tested under similar conditions.

Tibial-Femoral stability testing is accomplished by normal loading of the joint line in set points of flexion while applying shear and torsional resistant loads up to dislocation or test limits. The compressive normal loads and flexion angles were chosen to represent typical conditions in the gait cycle during normal walking. The testing was performed under loading conditions as follows:

Stability Test	Interface Load	Flexion Angle
Anterior	375 lbf	0°
Posterior	600 lbf	0°
Medial	600 lbf	30°
Lateral	600 lbf	0°
Rotational	430 lbf	15°

The resultant values<sup>31</sup> shown in Figure 15, Figure 16, and Figure 17 are compared to the minimal shear and maximum torsional resistance forces found to be clinically significant.<sup>32,33</sup>

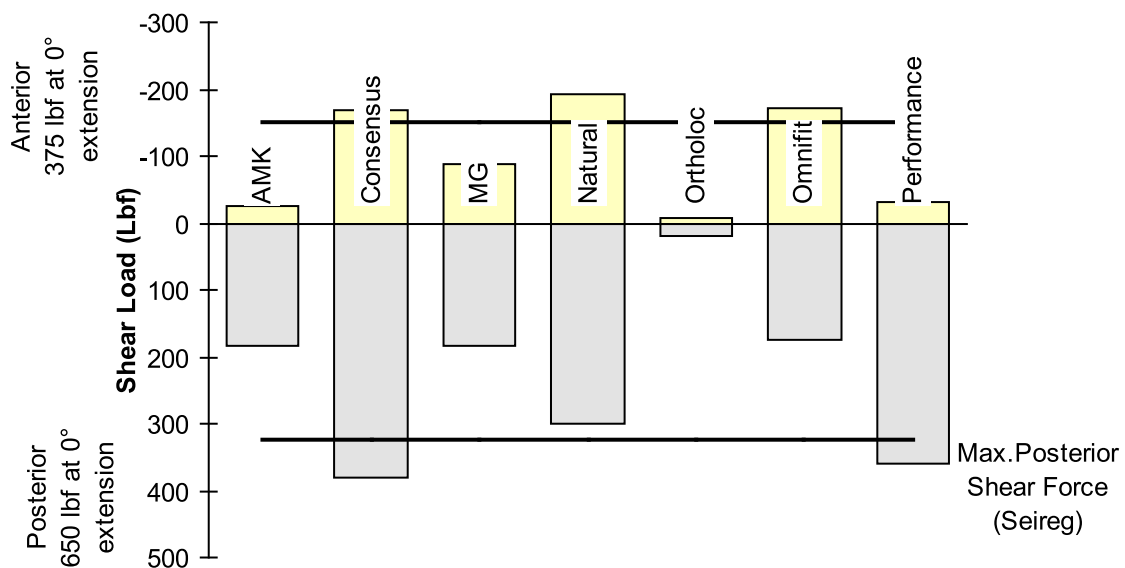


Figure 15. Anterior and Posterior Stability of the Consensus Knee in Comparison with Competitive Products.<sup>31,34</sup>

\* The Orthopaedic Research Laboratories, The Mt. Sinai Medical Center, Cleveland, Ohio

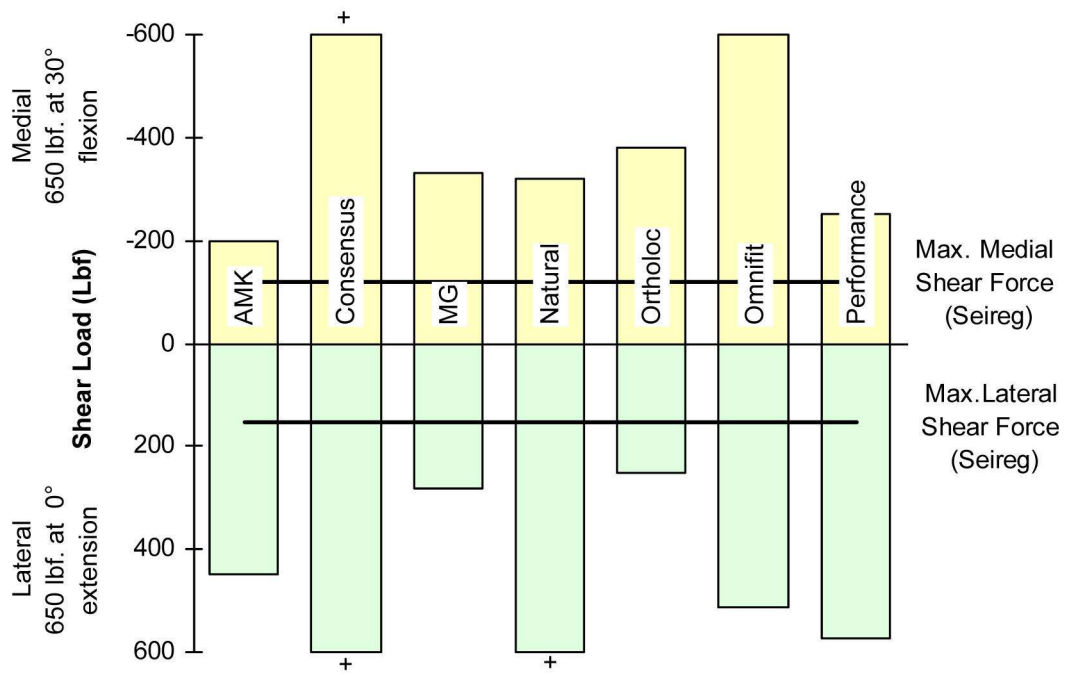


Figure 16. Medial and Lateral Stability of the Consensus Knee in Comparison with Competitive Products.<sup>31,34</sup>

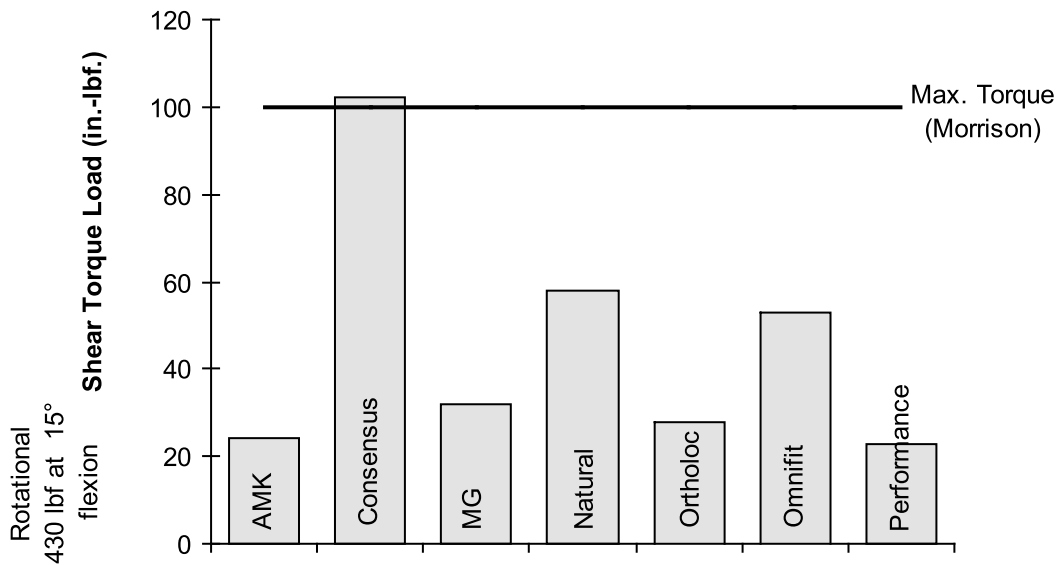


Figure 17. Rotational Stability of the Consensus Knee in Comparison with Competitive Products.<sup>31,34</sup>

## Patello - Femoral Stability

The patellar component is evaluated to ensure adequate lateral stability articular surfaces. Assessment of the lateral patellar stability is done using conventional, independent laboratory tests\* to replicate normal and shear loads found in the functional knee. The resultant test values may then be compared with the loads occurring in the pathologies of the normal knee as well as other commercially available devices tested under similar conditions.

Patello-femoral stability testing is performed by normal loading of the joint line in set points of flexion while applying lateral shear resistant loads up to dislocation. The compressive normal loads and flexion angles were chosen to represent typical conditions in the gait cycle during normal walking, stair ascent and rising from a chair. The testing was performed under loading conditions as follows:

Flexion Angle	Interface Load
15°	95 lbf
45°	395 lbf
90°	478 lbf

These shear limit resultant values<sup>35</sup> shown in Figure 18 are compared to the normal kinematic knee forces.

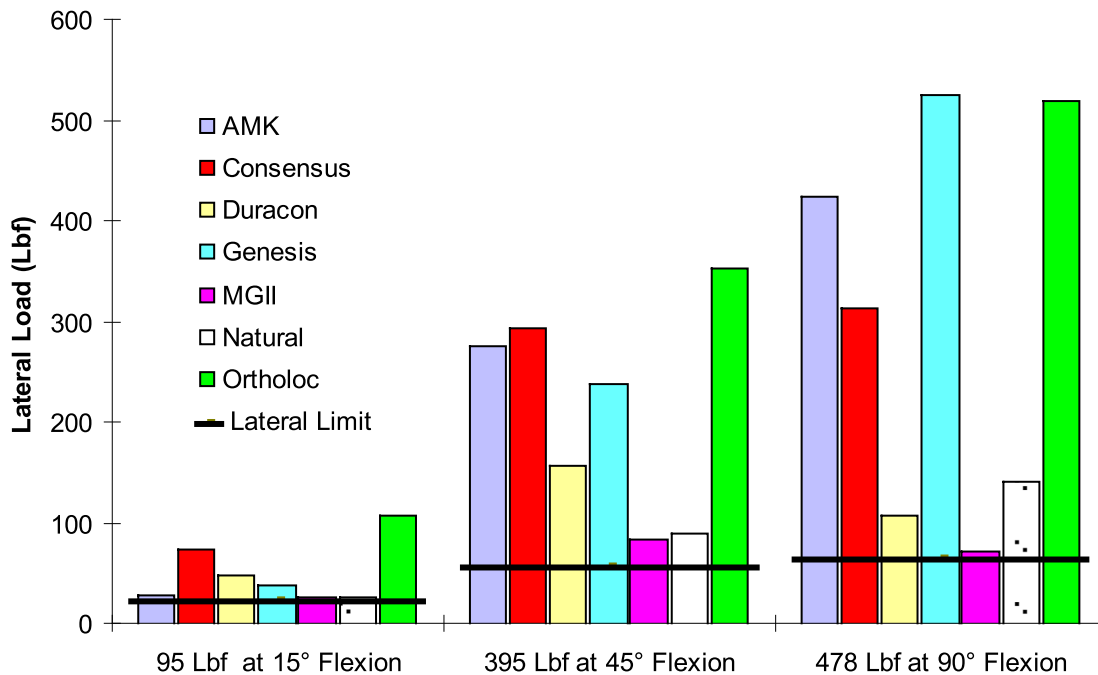


Figure 18. Lateral Patellar Subluxation Forces of the Consensus Knee in Comparison with Competitive Products.<sup>35,36,37</sup>

\* The Orthopaedic Research Laboratories, The Mt. Sinai Medical Center, Cleveland, Ohio

# Contact Area Testing

The dependable life of articular bearing surfaces is directly linked to the nature of the interface geometry, surface conditions and environment. The articular surface finishes and bearing material properties have been optimized to the best available commercial manufacturing practices and only diminishing improvements are to be expected. Studies of retrieved implants have linked point contact loading to pitting and delamination of the polyethylene component.<sup>12</sup> Optimization of contact stress, contact area and resulting cyclic fatigue characteristics may be partially accomplished in part by static load studies. Assessment of the contact characteristics is done using conventionalized, independent laboratory tests\* to indicate contact stress zones and relative concentrations. After determination of contact characteristics, comparisons may be made with other implant systems or related design.

## Tibia-Femoral Contact Area

Tibial-Femoral contact area testing is accomplished by normal loading of the joint line in set points of flexion while recording the interface contact zones for stress concentrations. The compressive normal loads and flexion angles were chosen to represent typical conditions in the gait cycle during normal walking, stair ascent, and stair descent. The testing was performed under loading conditions as follows:

Flexion Angle	Interface Load
0°	296 kgf
60°	370 kgf
90°	333 kgf

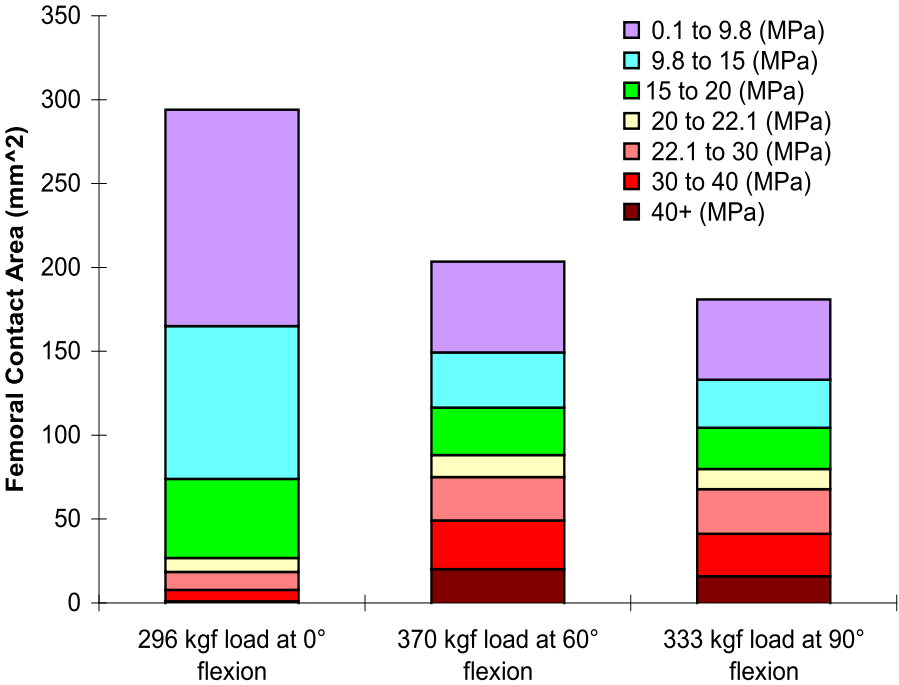


Figure 19. Tibial-Femoral Contact Area and Surface Stress of the Consensus Knee.<sup>38</sup>

\* The Orthopaedic Research Laboratories, The Mt. Sinai Medical Center, Cleveland, Ohio

The tibial-femoral surface stress distribution and contact area results<sup>38</sup> shown in Figure 19 indicate that the highest contact area and corresponding lower compressive stresses occur at 0° of flexion where cyclic motion is greatest. Results of tests at 60° and 90° of flexion indicate less contact area with the majority of compressive stress area below the 22.1 MPa tensile yield point of the polyethylene.

### Patello-Femoral Contact Area

The patello-femoral surface stress distribution and contact area results<sup>35</sup> shown in Figure 20 indicate conformity in the 45° power range and the 90° high load range of flexion. Areas of contact at 15° of flexion correspond to the patella riding on the flared anterior face of the femur. All ranges of flexion tested revealed the majority of stress contact area below the 22.1 MPa tensile yield point of the polyethylene. Load conditions were as follows:

Flexion Angle	Interface Load
15°	423 N
45°	1758 N
90°	2127 N

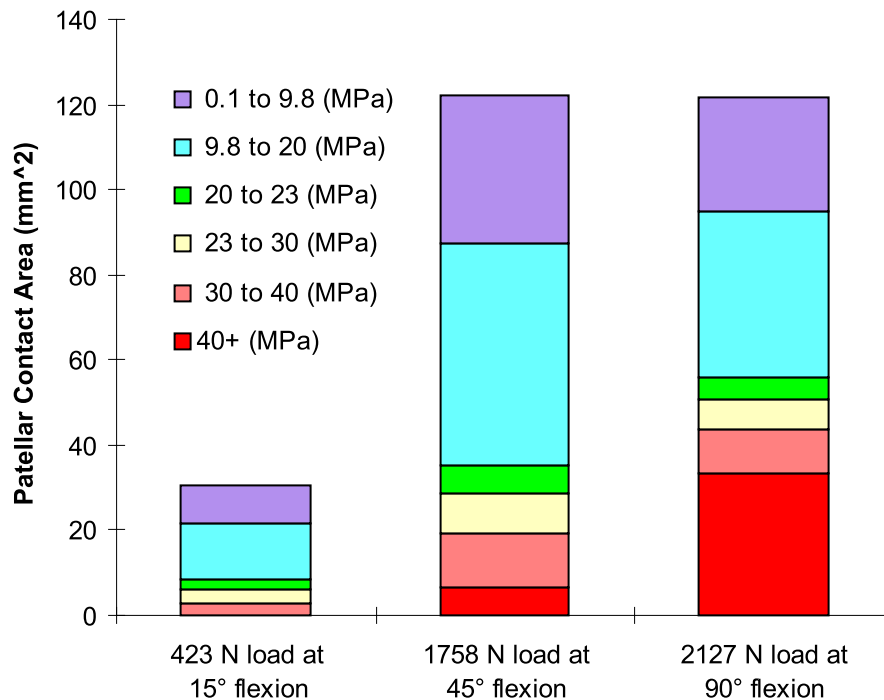


Figure 20. Patellar Contact Area and Surface Stress of the Consensus Knee.<sup>35</sup>

## Component Structural Integrity Testing

In the evolution of orthopedic implants, the need for intraoperative flexibility balanced by economic (inventory limit) constraints has led to the widespread use of intraoperative modular components. These modular components have had widespread clinical use and are not expected to decline in use in the foreseeable future.

The integrity of an intraoperatively assembled tibial insert is defined by the resistance of the insert to disassociation after implantation and subsequent loading. The Consensus<sup>®</sup> tibial assemblies were evaluated to determine worst case shear loads for disassociation of the polyethylene insert from the metal base. This was done without axial (normal) interface preloading. The criteria for minimum load to force the congruent insert from the tibial baseplate is equal to the Consensus<sup>®</sup> system test result for anterior subluxation (223 lbf) multiplied by an appropriate factor of safety. The force to remove the insert resulted in an average value of 483 lbf. where the failure mode was shearing of the polyethylene at the anterior locking lip.<sup>39</sup> This indicates that the safety factor with respect to anterior insert disassociation is approximately a factor of two.

The stemmed baseplates were subjected to bending fatigue testing. The implanted stemmed baseplate undergoes a physiological cyclic load as a result of the normal walking gait cycle. Under normal circumstances the baseplate is fully supported by the resected bone of the proximal tibia, thus minimizing the effect of the cyclic load by elimination of component deflection. However, in some circumstances bone resorption may occur, leaving some areas of the baseplate unsupported and subject to cyclic fatigue and potential failure.<sup>23</sup> Under a worst case condition, this unsupported area would occur beneath the medial side of the tibia which realizes the highest loads. This condition is modeled by supporting the tibia on the lateral side near the centerline of the component and then cyclically loading the component on the medial side for 10 million cycles at a load higher than physiologically possible to ensure a factor of safety. The results of these tests showed that the stemmed baseplate can withstand 10 million cycles at 750 lbf (applied by a 600 in-lb moment).<sup>41,42</sup> The high value for the stemmed baseplate can be attributed to the strengthening effect of the cruciate stem as a projected structural rib.

## By Special Request Only

### Porous

#### Femoral Component Materials

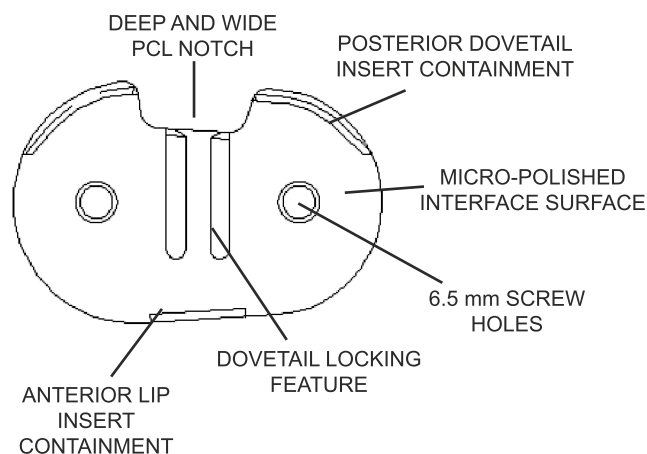
The porous coated femoral component is sintered with cobalt-chrome beads per ASTM F 75 to maximize porous tensile strength and preclude the chance of porous bead release. Optimal pore size is achieved by the use of sintered beads in the -25/+35 mesh size range. This bead size yields an average porosity volume of 36% corresponding to a mean pore size of 243 $\mu$ m. In all Consensus<sup>®</sup> porous components, the porous material is contained within recessed pockets for maximum strength to inhibit the incidence of bead release.

#### Titanium on CoCr Surface

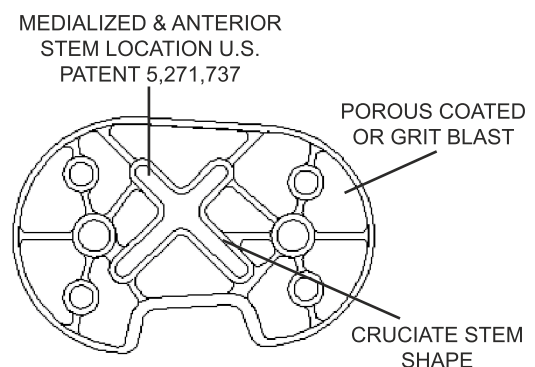
One version of the Porous Femoral Components features a proprietary Consensus Orthopedics technology. After porous coating, the entire superior surface of the porous femoral component is encapsulated in a layer of titanium. A patented process lays down a 10 $\mu$ m layer of titanium without altering the porosity or strength of the substrate material or the sintered beads.

### Tibial Baseplate

#### Top – Superior



#### Bottom – Inferior



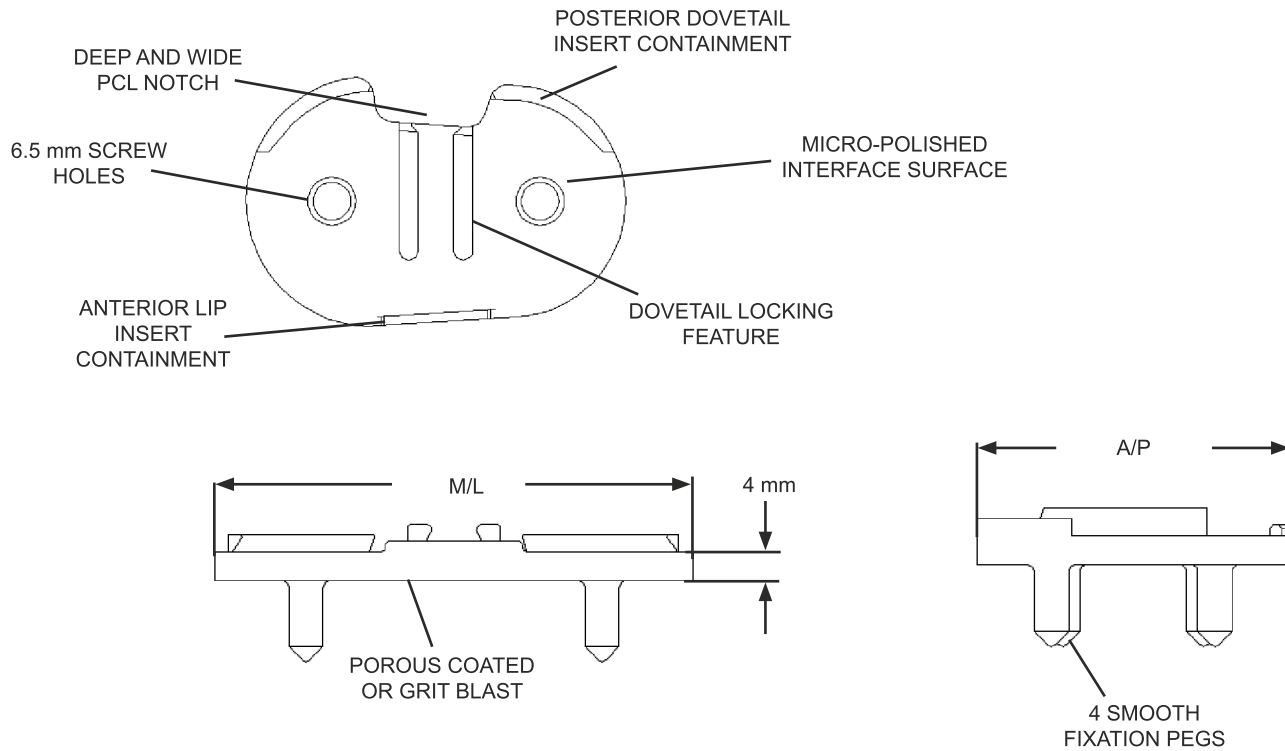


# Resurfacing

## Resurfacing Tibial Baseplate

A resurfacing baseplate, as shown in Figure 21, is provided for those patients with exceptional bone stock, previous high tibial osteotomy, or previous fracture of the proximal metaphysis<sup>15</sup> where dense bone has formed below the tibial plateau. The resurfacing component provides the same anatomic baseplate design, bone screw holes, and stabilization peg options as the cruciate stem component. The resurfacing tibial baseplate is offered in a porous coated version only.

Note: The Consensus<sup>®</sup> knee implants are marketed for cemented use only.



Size	1	2	3	4	5	6
M/L	66	70	74	78	82	86
A/P	43	46	48	51	54	56

Base Material	Cast and HIPed CoCrMo per ASTM-F75 (Forged Titanium per ASTM F-620, Special Order)
Anatomic Sizes	6 sizes left and right
Baseplate Thickness	4 mm
Tibial Stem Pegs	11 mm long 4 places
Non-Porous Component	1.2 mm deep textured pockets
Porous Coated Component	243µm pores (cp Titanium +35/-25 mesh)
Platform Finish	12µin RMS
Screw Fixation	Recessed 6.5mm bone screw 2 places
Screw Hole Angulation	22° included angle

Figure 21. Resurfacing Baseplate Dimensions and Features

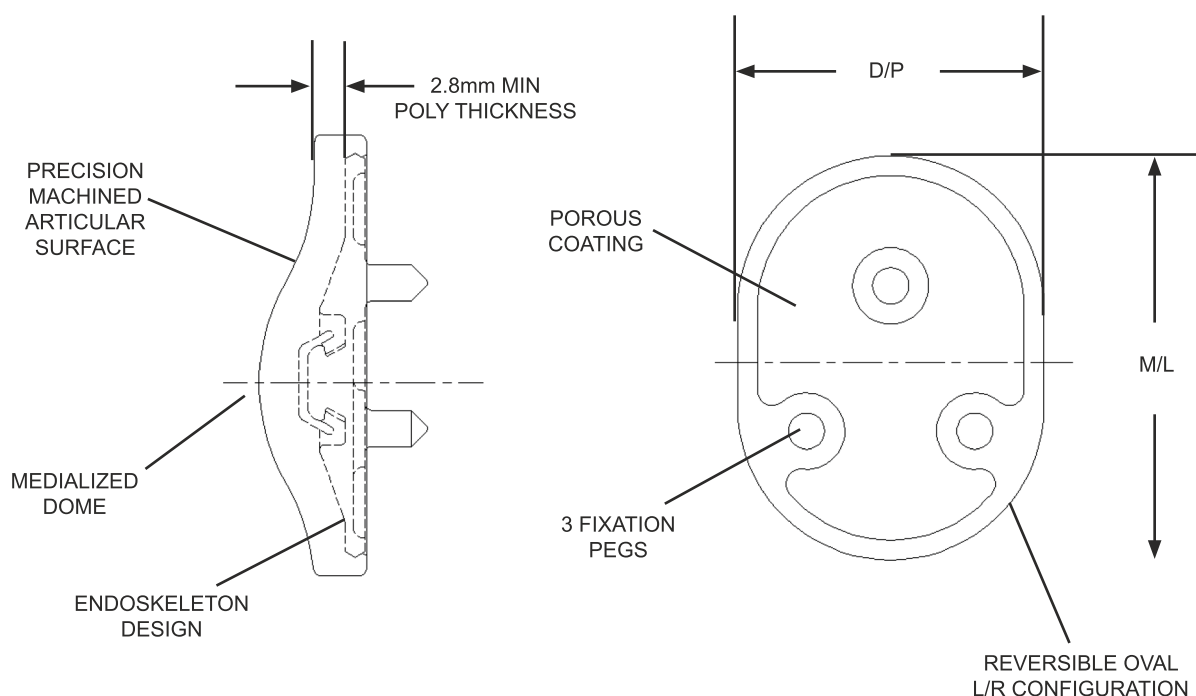
# Patella

## Metal Back Patellar Component

The Consensus<sup>®</sup> metal back patellar component, as shown in Figure 22, is designed with a highly congruent, preloaded supporting endoskeleton. The polyethylene is retained by full circumferential and central locking mechanisms to eliminate motion with the metal back. The polyethylene fully encompasses the metal back with a minimum poly thickness of 2.8mm. Three pegs are incorporated for rotational and shear stability.

To provide maximum initial fixation and minimal tilt of the metal back patellar component, this device may be recessed<sup>25</sup> 2.5mm into the patellar bone. A unique patented instrumentation system to recess the oval implant is utilized. This multi-step reaming process creates a uniform pocket in the osteotomized surface of the patella and assures the surgeon of accurate, repeatable placement of the medialized patellar dome while optimizing bony patellar coverage. Recessing the metal back patellar component allows for improved stability and resistance to shear loads.

Note: The Consensus<sup>®</sup> knee implants are marketed for cemented use only.



Size	1	2	3
M/L	36	41	45
D/P	28	32	35

Base Material	Ram molded UHMWPE per ASTM F-648
Anatomic Sizes	3 sizes (reversible L/R)
Superior resection thickness at apex	10mm
Minimum Poly Thickness	2.8 mm
Porous Coating	243µm pores (cp Titanium +35/-25 mesh)

Figure 22. Metal Back Patellar Implant Design and Features

## References

1. **A. Rosenburg, R.P. Mikosz, C.G. Mohler;** *The Knee, Ch. 4, Basic Knee Biomechanics*, W.N. Scott editor, Mosby - Year Book Inc., St. Louis, Missouri, pp.75, 1994
2. **T.P. Andriacchi, T.S. Stanwyck, J.O. Galante;** Knee biomechanics and total knee replacement, *J. of Arthroplasty*, Vol.1 No.3, pp 221-219, 1986
3. **J.S. Mensch, H.C. Amstutz;** Knee morphology as a guide to knee replacement, *Clinical Orthopedics and Related Research*, V.112, pp.231-241, 1975
4. **B.B. Seedhom, E.B. Longton, V. Wright, D. Dowson;** Dimensions of the knee, *Annals of the Rheum. Dis.*, Vol. 31, pp. 54-58, 1961
5. **F.H. Fu, C.D. Harner, D.L. Johnson, M.D. Miller, S.L.Y. Woo;** Biomechanics of knee ligaments, *J. of Bone and Joint Surgery*, Vol. 75-A, No. 11, 1993
6. Data on File at US Medical Products Inc.
7. **A. van Kampen, R. Huiskes;** The three-dimensional tracking pattern of the human patella, *J. of Orthopedic Research*, 8:372-382, 1990
8. **J.A. Davidson;** The improvement in total knee articulation performance of cobalt-chrome alloy prosthetic bearing surfaces over plain and nitrogen ion implanted Ti-6Al-4V, *Orthopedic Research Report*, OR-90-17, Feb 1990
9. **P.G. Kirk, C.H. Rorabeck, R.B. Bourne;** Clinical comparison of the Miller Galante I and AMK total knee systems, *J. of Arthroplasty*, Vol 9, No. 2, 1994
10. **A.A. Hofmann, J.R. Smith, L.E. Murdock;** Experience with an asymmetric tibial tray, *State of the Art in Total Joint Replacement*, Harrington Arthritis Research Center International Symposium, Scottsdale AZ Nov 18-21, 1990
11. **S.A. Wilson, V.J. Vigorita, W.N. Scott;** *The Knee, Ch. 2, Anatomy*, W.N. Scott editor, Mosby - Year Book Inc., St. Louis, Missouri, pp. 26-32, 1994
12. **G.A. Engh, K.A. Dwyer, C.K. Hanes;** Polyethylene wear of metal-backed tibial components in total knee and unicompartmental knee prosthesis, *J. of Bone and Joint Surgery*, Vol. 74-B, No. 1, 1992
13. **V.G. Williams, S.E. White, L.A. Whiteside;** Fixation of ultra high molecular weight polyethylene liners to metal-backed acetabular shells, *62nd Meeting of the American Academy of Orthopedic Surgeons*, Orlando FL, Feb. 16-21, 1995
14. Data on file at Consensus Orthopedics Inc.
15. **A.A. Hofmann, S. von Glinski, D. Riley, M. Brodie;** Stemmed versus resurfacing tibial component total knee arthroplasty, *59th meeting of the American Academy of Orthopedic Surgeons*, Washington DC, Feb. 20-25, 1992
16. **P.B. Messersmith, F.W. Cooke;** Stress enhancement and fatigue susceptibility of porous coated Ti-6Al-4V implants: an elastic analysis, *J. of Biomedical Materials Research*, Vol. 24, pp591-604, 1990
17. **P.J. Warren, T.K. Olanlokun, A.G. Cobb, P.S. Walker, B.F. Iverson;** Laxity and function in knee replacements, *Clinical Orthopedics and Related Research*, Number 305, pp 200-208, 1994
18. **S. Li, A.H. Burstein;** Current concept review, Ultra-high molecular weight polyethylene, *J. of Bone and Joint Surgery*, V. 76-A, pp 1080-1090, 1994
19. Issues in UHMWPE February 1994, Westlake Plastics Co., Medical Plastics Division, Lenni, PA, ©1994(Hostalen GUR is a registered trademark of Hoechst AG)
20. **J.S. Serwatka, J.J. Ploskonka;** A statistical study of ram extruded Lennite® ultra-high-molecular-weight polyethylene, *The 20th Annual Meeting of the Society for Biomaterials*, April 5-9, Boston MA, 1994
21. Issues in UHMWPE February 1995, Westlake Plastics Co., Medical Plastics Division, Lenni, PA, ©1995
22. **K.A. Krackow,** The Patella in Total Knee Replacement - Replacement, *Presented at Current Concepts in Joint Replacement*, Orlando FL, 1994

23. **H.P. Hsu, P.S. Walker;** Wear and deformation of patellar components in total knee arthroplasty; *Clinical Orthopedics and Related Research*, Number 246, pp 260-265, 1989
24. **T.M.G.J. van Eijden, E. Kouwenhoven, J. Verburg, W.A. Weijjs;** A mathematical model of the patellofemoral joint, *J. Biomechanics*, Vol. 19, No. 3, pp. 219-229, 1986
25. **J.A. Rand;** Current concept review, The patellofemoral joint in total knee arthroplasty, *J. of Bone and Joint Surgery*, V. 76-A, No. 4, pp 612-620, 1994
26. **A.A. Hoffman, K.R. Kane, T.T. Tkach, M.P. Camargo;** Patellar component medialization in total knee arthroplasty, *62nd Meeting of the American Academy of Orthopedic Surgeons*, Orlando FL, Feb. 16-21, 1995
27. **I. Yoshii, L.A. Whiteside, Y.A. Anouchi;** The effect of patellar button placement and femoral component design on patellar tracking in total knee arthroplasty; *Clinical Orthopedics and Related Research*, Number 275, pp 211-219, 1992
28. **J.M. Bert,** Design of an all polyethylene tibial component, *The Fifth Annual Conference on Techniques and Science for Successful Joint Arthroplasty*, Burlington VT, Oct 14-15, 1993
29. **M.E. Carroll, R.D. Paxson, J.M. Bert, M.A. McShane;** Does variance in the undersurface macrostructure of a cemented all-polyethylene tibial component (APT) improve fixation?, *62nd Meeting of the American Academy of Orthopedic Surgeons*, Orlando FL, Feb. 16-21, 1995
30. **S. Li, A.H. Burstein;** Current concept review, Ultra-high molecular weight polyethylene, *J. of Bone and Joint Surgery*, V. 76-A, pp 1080-1090, 1994
31. **C.S. Heim, P.D. Postak;** Stability characteristics of the Consensus total knee system, *Special Report, Orthopedic Research Laboratories, Mt. Sinai Medical Center*, Cleveland OH, Sept 20, 1993.
32. **A.A. Seireg, R.J. Arvikar;** The Prediction of the Muscular Load Sharing and Joint Forces in the Lower Extremities During Walking. *Journal of Biomechanics*, Vol 8, pp 89-102, 1975.
33. **J.B. Morrison;** The Mechanics of the Knee Joint in Relation to Normal Walking, *Journal of Biomechanics*, Vol 3 pp 51-61, 1970
34. **P.D. Postak, T.D. Blake, A.S.Greenwald;** Performance characteristics of primary modular total knee systems, Scientific Exhibit, *59nd Meeting of the AAOS*, Washington DC, Feb. 20-25, 1992
35. **C.S. Heim, P.D. Postak;** Patello-femoral resistance to lateral subluxation contact areas and surface stress distributions of the Consensus total knee system, *Special Report, Orthopedic Research Laboratories, Mt. Sinai Medical Center*, Cleveland OH, June, 1993.
36. **C.M. Steubben, P.D. Postak, A.S.Greenwald; P.D. Postak, T.D. Blake, A.S.Greenwald;** Mechanical characteristics of patello-femoral replacements, Scientific Exhibit, *59nd Meeting of the AAOS*, Washington DC, Feb. 20-25, 1992
37. **C.M. Steubben, P.D. Postak, A.S.Greenwald; P.D. Postak, T.D. Blake, A.S.Greenwald;** Mechanical characteristics of patello-femoral replacements, Scientific Exhibit, *60th Meeting of the AAOS*, Washington DC, Feb. 18-23, 1993
38. **C.S. Heim, P.D. Postak;** Tibial-femoral surface stress distributions and contact areas of the Consensus total knee system, *Special Report, Orthopedic Research Laboratories, Mt. Sinai Medical Center*, Cleveland OH, Sept 20, 1993.
39. **T.Scrimshire;** Push in, push out forces of the tibial insert on the Consensus total knee system, *Special Report RCN 642-201-12-01, Radian Corporation*, Austin TX, July 22, 1993.
40. **B.L. Bland;** Testing of patella components, *Special Report No. 943-7, Engineering Materials Laboratory*, Santa Fe Springs CA, April 19, 1994
41. **B.L. Bland;** Fatigue testing of stemmed tibial baseplates, *Special Report No. 933-3B, Engineering Materials Laboratory*, Santa Fe Springs CA, Sep. 28, 1993
42. **B.L. Bland;** Fatigue testing of resurfacing tibial baseplates, *Special Report No. 933-3A, Engineering Materials Laboratory*, Santa Fe Springs CA, Sep. 28, 1993

# NOTES

A series of 25 horizontal dashed lines for writing notes.



**Shalby**  
**Advanced**  
**Technologies, Inc.**  
*Restoring Mobility, Improving Lives.*

#### USA

**Shalby Advanced Technologies, Inc.**  
1115 Windfield Way, Suite 100,  
El Dorado Hills, CA 95762,  
Ph: +1 916 355 7100

#### Singapore

**Shalby Global Technologies Pte. Ltd.**  
Regus One Fullerton, 1 Fullerton Rd,  
#02-01, One Fullerton, Singapore- 049231  
Ph: +65 88707885 /+60 125065062

#### India

**Mars Medical Devices Ltd.**  
Mondeal Heights, B-301 & 302,  
Sarkhej - Gandhinagar Highway,  
Ahmedabad, Gujarat-380015  
Ph: +91 91671 20390

