Balanced Knee™ System

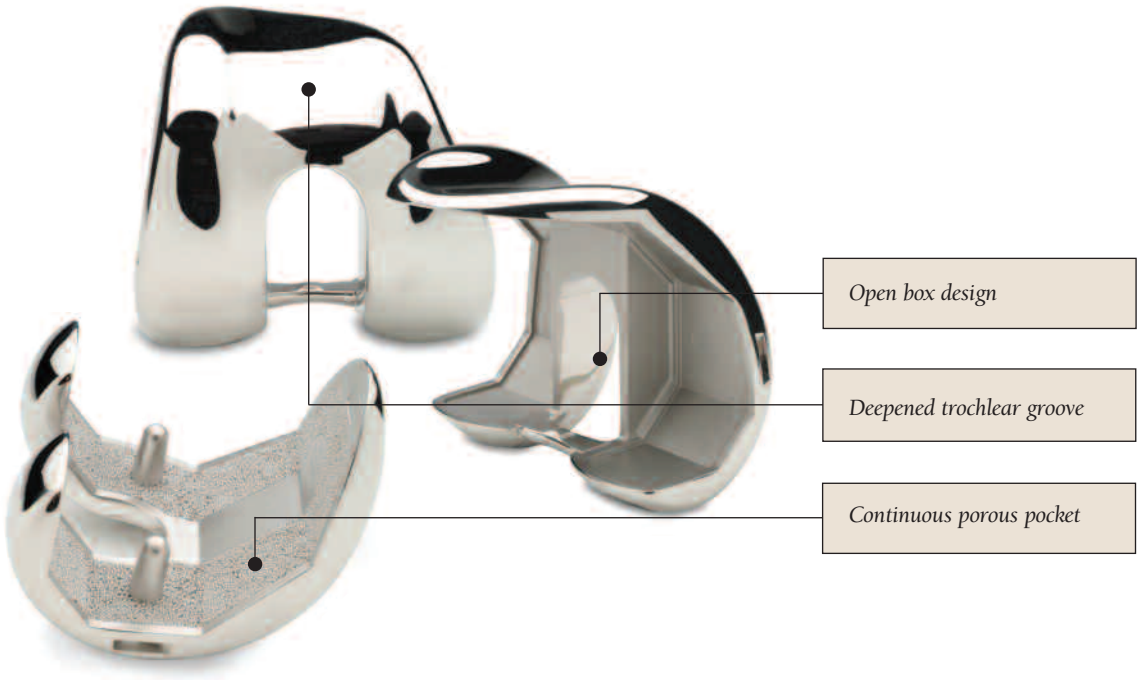
PRODUCT / SURGICAL SUMMARY

Balanced Knee™ System

The Balanced Knee™ System is designed to restore balance both in flexion/extension and varus/valgus. The instruments are designed for ease-of-use and repeatability in the hands of every surgeon. The implants allow for balancing refinement to the nearest millimeter with a patented* tibial insert locking mechanism that is simple to engage and virtually eliminates micromotion.

Femoral Components

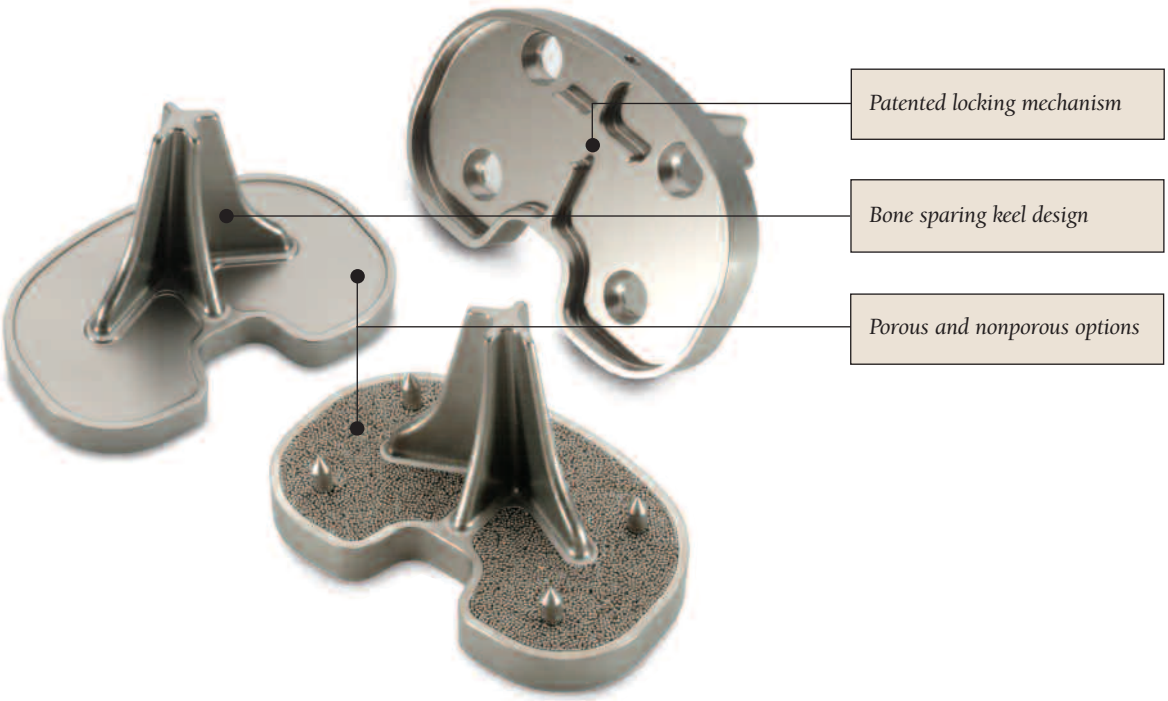
The Balanced Knee™ System femoral components are available in five options to allow for surgeon preference. The PS and PS-C femoral components are designed with an open box to minimize intercondylar bone removal and allow access to the I/M canal for potential retrograde fracture nail implantation. The trochlear groove is deepened without the need for additional bony resection in all five options.



- Posterior Stabilized (PS), Posterior Stabilized Non-pegged (PS-C) and Cruciate Retaining (CR) options
  - *Surgeon preference for PCL retention or sacrificing are supported to allow for intra-operative selection*
  - *PS spine/cam mechanism minimizes intercondylar bone removal and maximizes dislocation resistance in deep flexion*
  - *Instrumentation assures proper femoral rotation*
  - *The anterolateral margin is contoured to reduce lateral retinacular release rates*
  - *Trochlear groove is deepened to reduce the liklihood of patellofemoral complications*
- Porous and nonporous options
  - *Porous components feature multi-layered cobalt chrome beads*
  - *Continuous porous pocket*
- Non-pegged PS-C option to preserve distal femoral bone

Tibial Tray

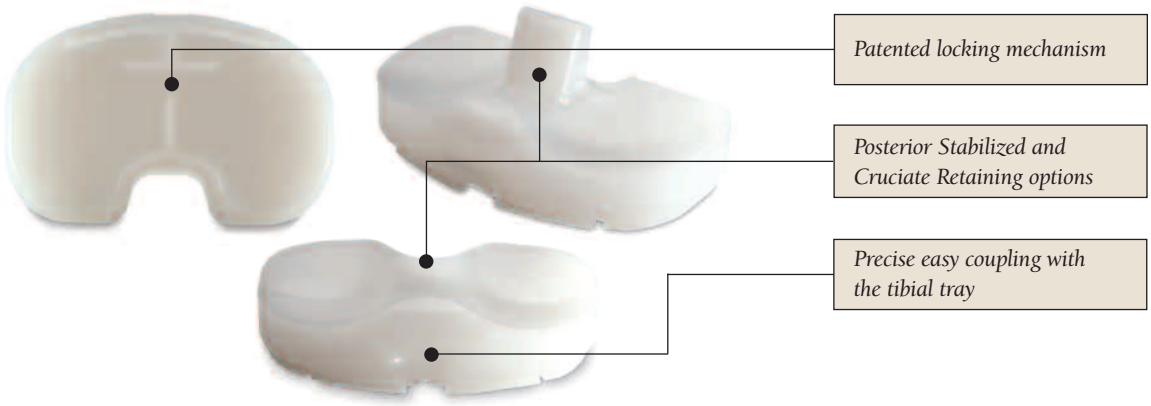
The one-piece tibial tray design is available in three options, all of which incorporate a streamlined keel to minimize bone removal without sacrificing stability. The patented locking mechanism, with its continuous peripheral rail, fully captures the tibial insert to reduce micromotion. Testing shows 94% less micromotion than the industry standard and 88% less than that of the nearest competitor.** The front loading tibial inserts are easily coupled to the tray and do not require locking clips, pins or screws.



- One-piece design for overall component strength
- Patented locking mechanism with continuous peripheral rail secures insert to virtually eliminate micromotion
- Streamlined keel design minimizes bone removal without sacrificing tray stability
- Nonporous, porous with screwholes and porous pegged options

Tibial Insert

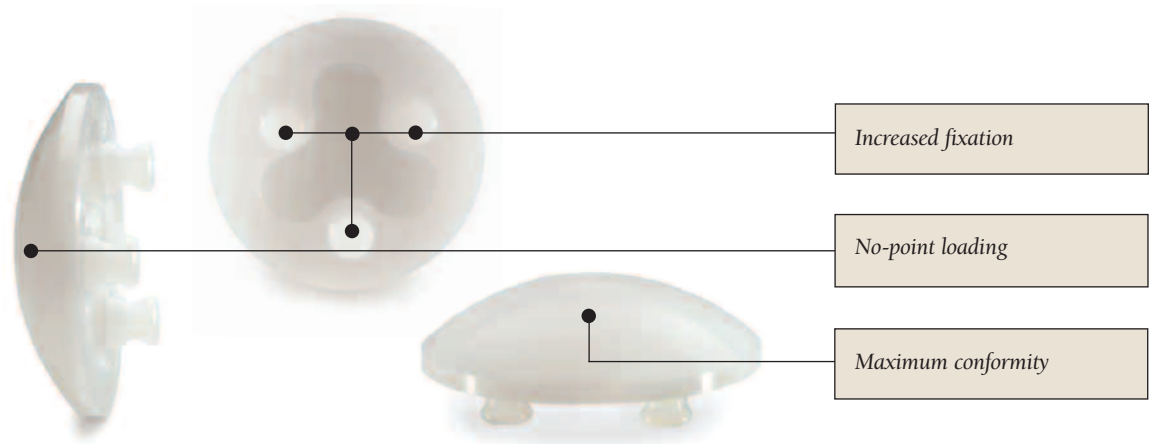
Tibial inserts are available in both Posterior Stabilized (PS) and Cruciate Retaining (CR) options. The inserts are available in 1mm increments in the most popular thicknesses to give the surgeon the ability to microtune the knee during trial reduction.



- Patented locking mechanism is designed to decrease micromotion known to cause polyethylene debris
- Inserts are available in 1mm increments
- Inserts are labeled with the true minimum polyethylene thickness
- Precise easy coupling with the tibial tray that requires no impaction

Dome Patella

The dome shape insures maximum conformity with the deepened trochlear groove in the femoral component even in deep flexion, thereby reducing the risk of point loading. The three-pegged design offers stability and an undercut cement pocket provides increased fixation.



- Maximum conformity, regardless of design
- All patellae conform to all femoral components, even in deep flexion, reducing the risk of point loading which can cause premature polyethylene wear
- Under-cut cement pocket for increased fixation

Surgical Technique Summary

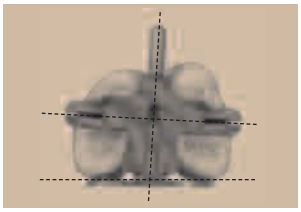
The following technique is a general guide for instrumentation of the Balanced Knee™ System. It is expected that the surgeon is already familiar with the fundamentals of total knee replacement. Each patient represents an individual case that may require modification of the technique according to the surgeon's judgment and experience.

Please see the package insert for intended uses/indications, device description, contraindications, precautions, warnings, and potential risks associated with the Balanced Knee™ System. US Federal Law restricts this device to sale by or on the order of a physician.

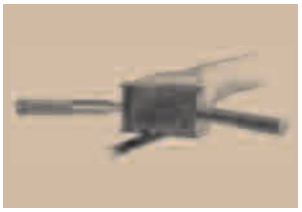
I. Entering the Medullary Canal

II. I/M Alignment

III. Distal Femoral Resection



IV. Femoral Sizing and External Rotation



V. Anterior and Posterior Resections

VI. Proximal Tibial Resection

VII. Flexion/Extension Gap Verification

VIII. Femoral Chamfer Resections

IX. Notch Cut

X. Patella Preparation

XI. Trial Reduction

XII. Femoral Peg Drilling

XIII. Tibial Keel Preparation

Nonporous and Porous Tibial Trays

Femoral Component

Patella

Tibial Insert

XIV. Implanting the Components

Appendix

BKS Implant Interchangeability

The Balanced Knee™ System tibial inserts are interchangeable with the femoral components and tibial trays (matched one to one with the tibial tray and up/down one with the femoral component) as illustrated in the chart, where the shaded areas are the tibial insert sizes:

Femoral Component Size

Tibial Tray Size	1	2	3	4	5	6	7
1	**1**	**1**					
2	**2**	**2**	**2**				
3		**3**	**3**	**3**			
4			**4**	**4**	**4**		
5				**5**	**5**	**5**	
6					**6**	**6**	**6**
7						**7**	**7**

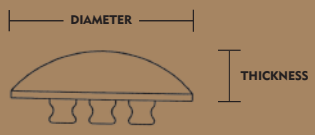
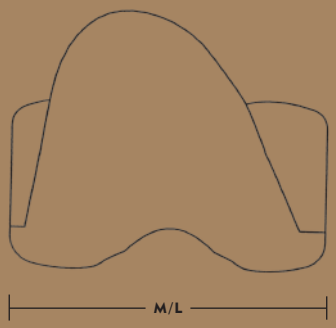


Figure A



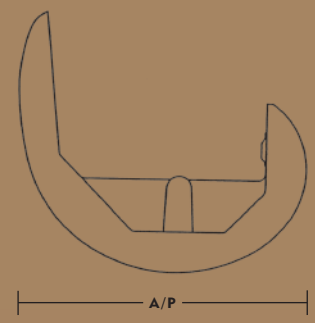


Figure B

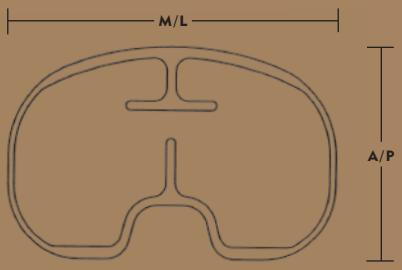


Figure C

Component Dimensions

Patella (Figure A)

SIZE (DIAMETER)	HEIGHT (THICKNESS)
29mm	7.5mm
32mm	8.0mm
35mm	9.0mm
38mm	10.0mm

Femoral Component (Figure B)

SIZE	A/P (mm)	M/L (mm)
1	50.0	56.5
2	54.0	59.5
3	57.5	62.5
4	61.5	66.5
5	65.5	70.5
6	69.5	74.5
7	74.0	79.5

Tibial Tray (Figure C)

SIZE	A/P (mm)	M/L (mm)
1	36.5	57.5
2	39.0	61.0
3	41.5	65.0
4	44.5	69.5
5	48.0	75.0
6	51.5	80.5
7	55.0	86.0

ORTHO DEVELOPMENT®
engineering simplicity™

12187 South Business Park Drive Draper, Utah 84020 Telephone: 801.553.9991 Fax: 801.553.9993 www.orthodevelopment.com