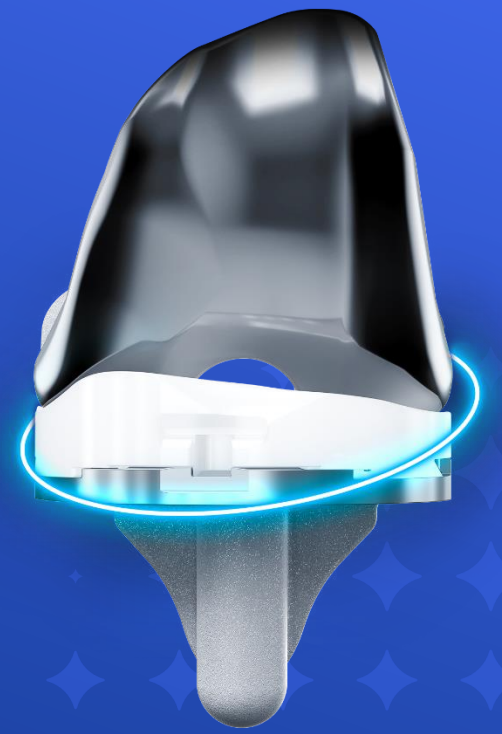
Evolution®

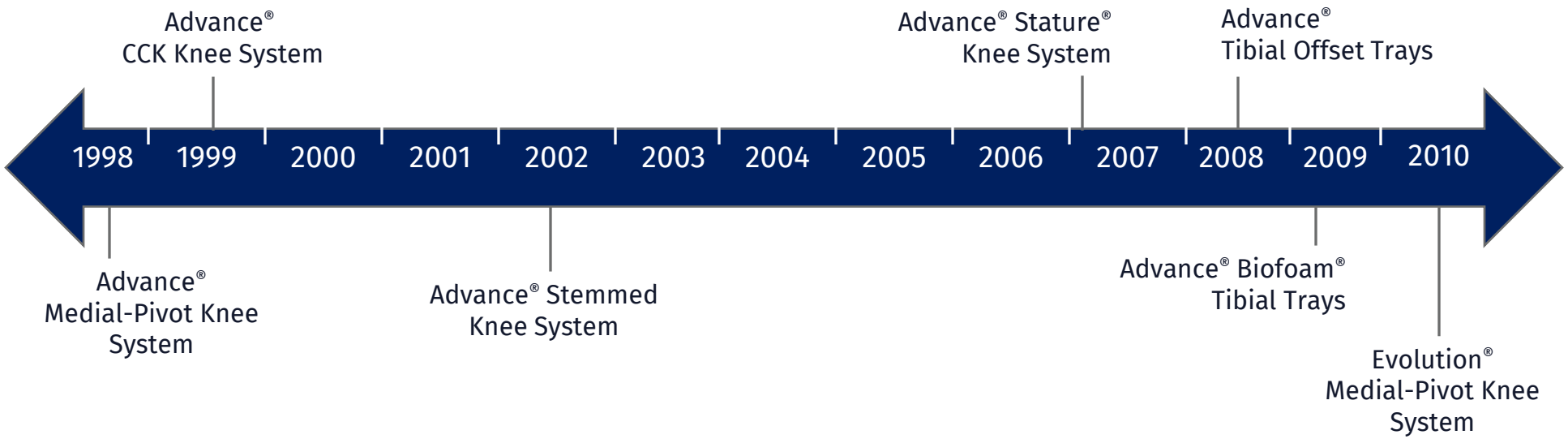
Technical Information

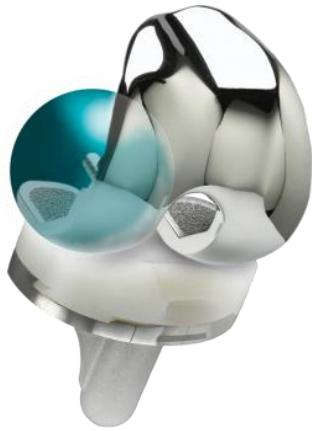


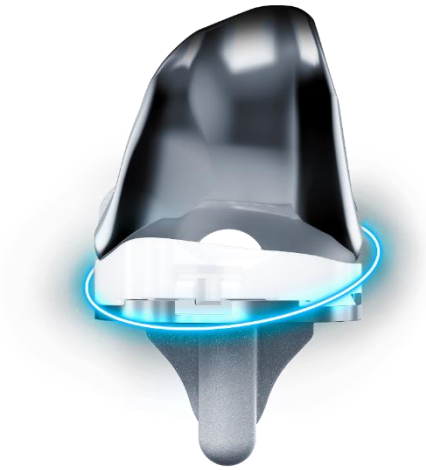
MicroPort

013822B Oct’ 21

Second Generation Medial-Pivot



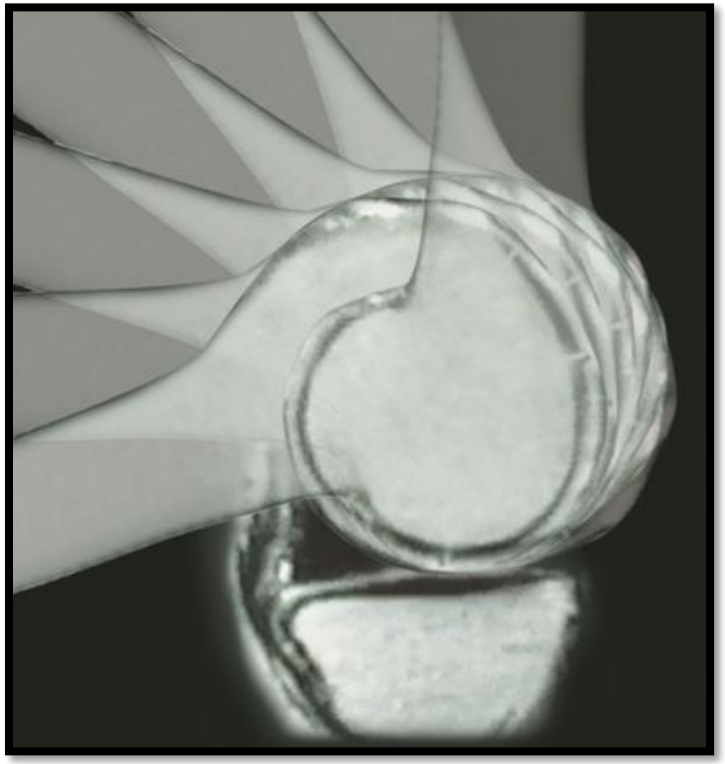




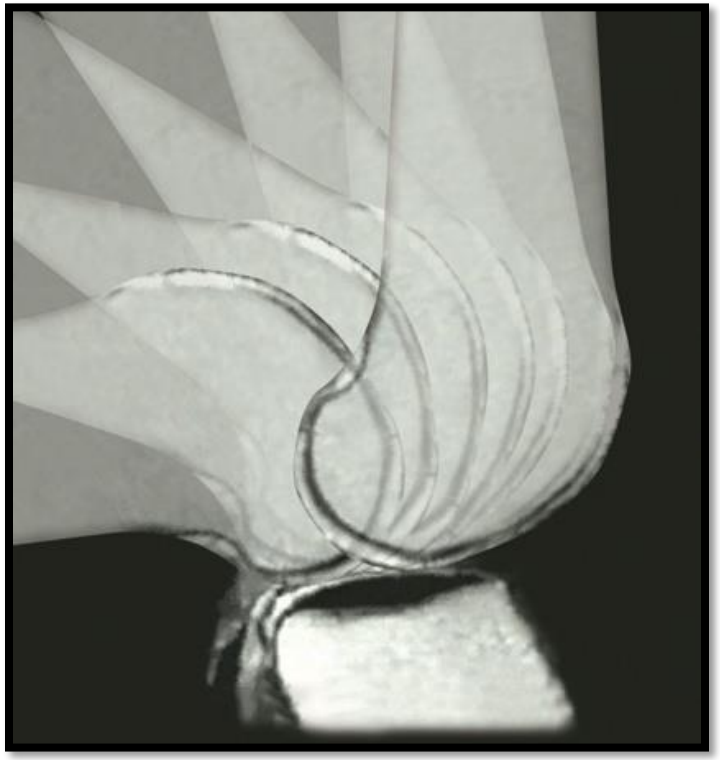
Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Medial-Pivot Kinematics



Medial Compartment[1]



Lateral Compartment[1]

Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution®

FEMUR

MicroPort

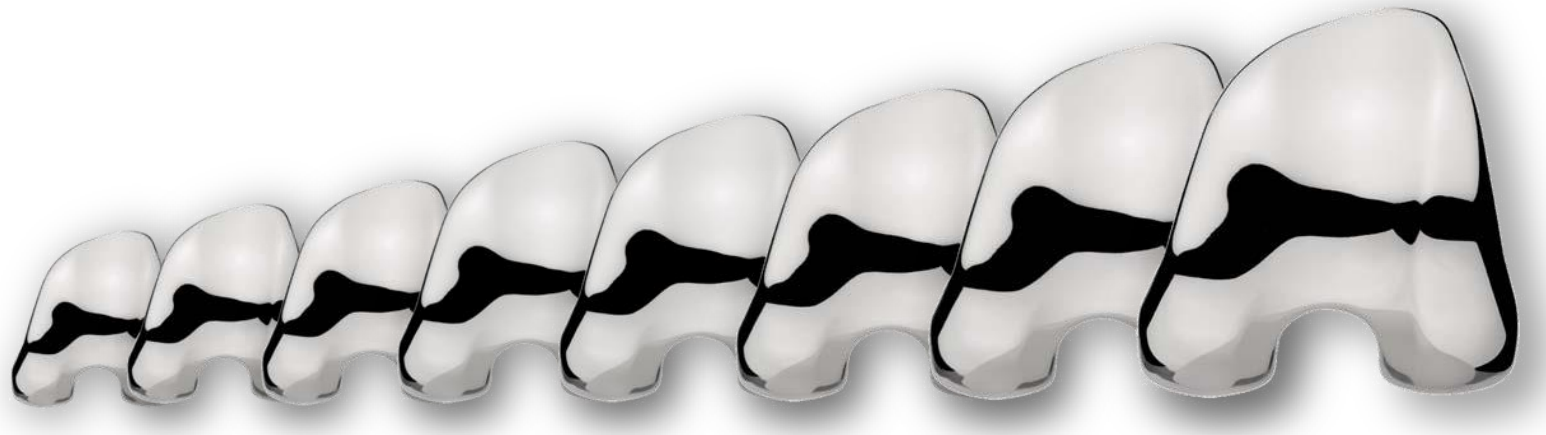
FEMUR Evaluation

- Over 100 CT scans from TKA patients from Japan, South Korea and the US were processed to allow virtual anthropometric measures
  - Verify AP and ML profile dimensions and aspect ratio

- CT scans were collected from January to September, 2007
  - 66 patients, 107 data points
  - Data

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Global Sizing



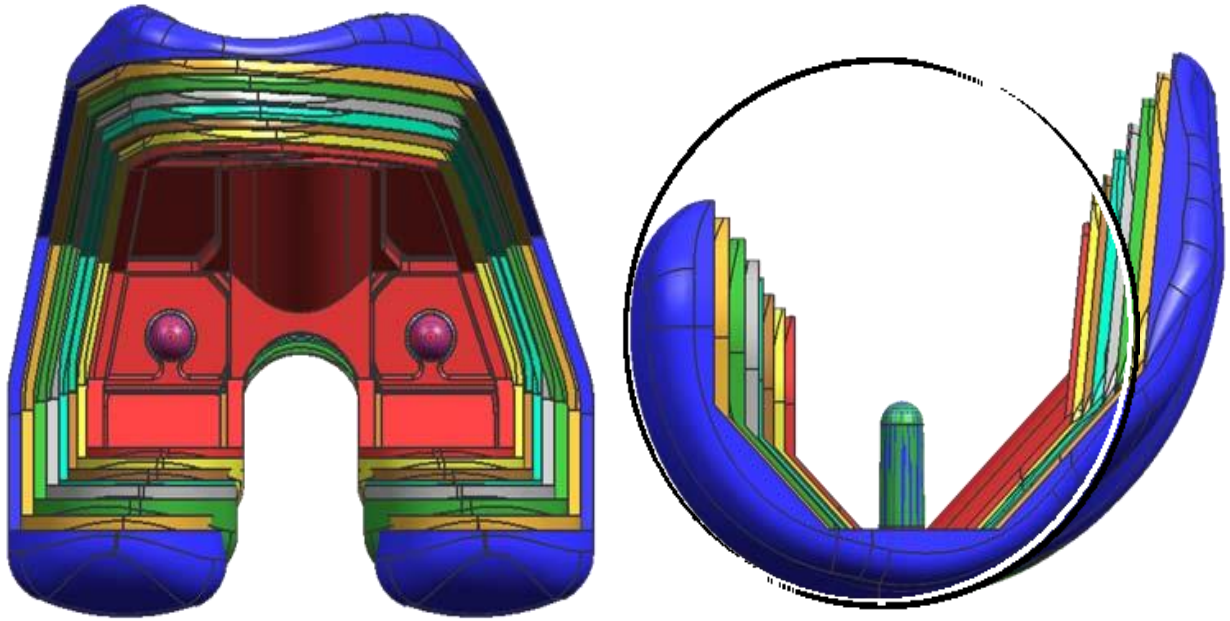
300 CT Scans

8 Sizes

CT Based Femoral Sizing

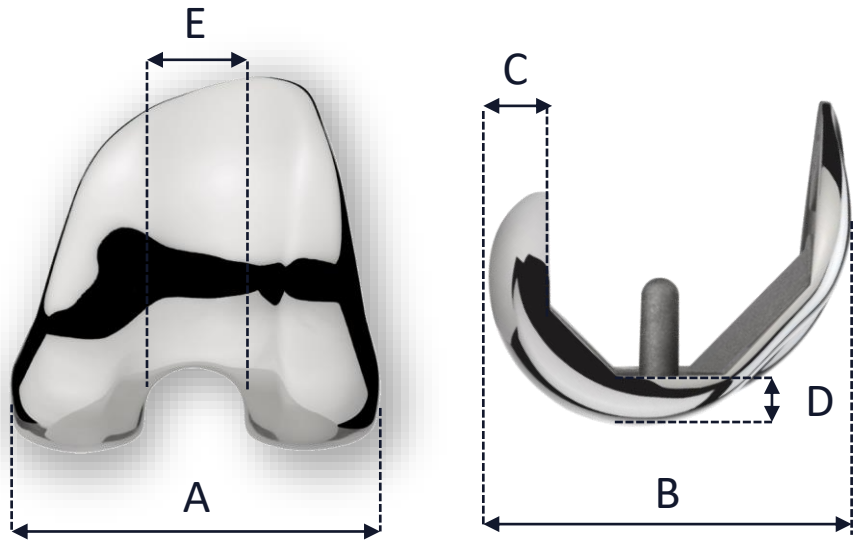
Pegs stay consistent throughout the size range
3mm to 4mm between sizes

Only removing 1mm to 2mm from Anterior or Posterior (sawblade thickness)



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Femoral Component Sizing



Size	A [mm] = M/L	B [mm] = A/P	C [mm]	D [mm]	E [mm]
1	59	51	10	9	16
2	61	54	10	9	16
3	64	57	10	9	18
4	66	60	10	9	18
5	70	64	11	9	18
6	73	68	11	9	18
7	77	72	11	9	20
8	80	76	11	9	20

- 8 sizes (Left and Right)
- **Material** CoCrMo alloy
- Cemented and cementless options
- **Inner surface** gritblasted or beads porous coated
- **M/L** 2 to 4mm increment between sizes
- **A/P** 3 to 4mm increment between sizes

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

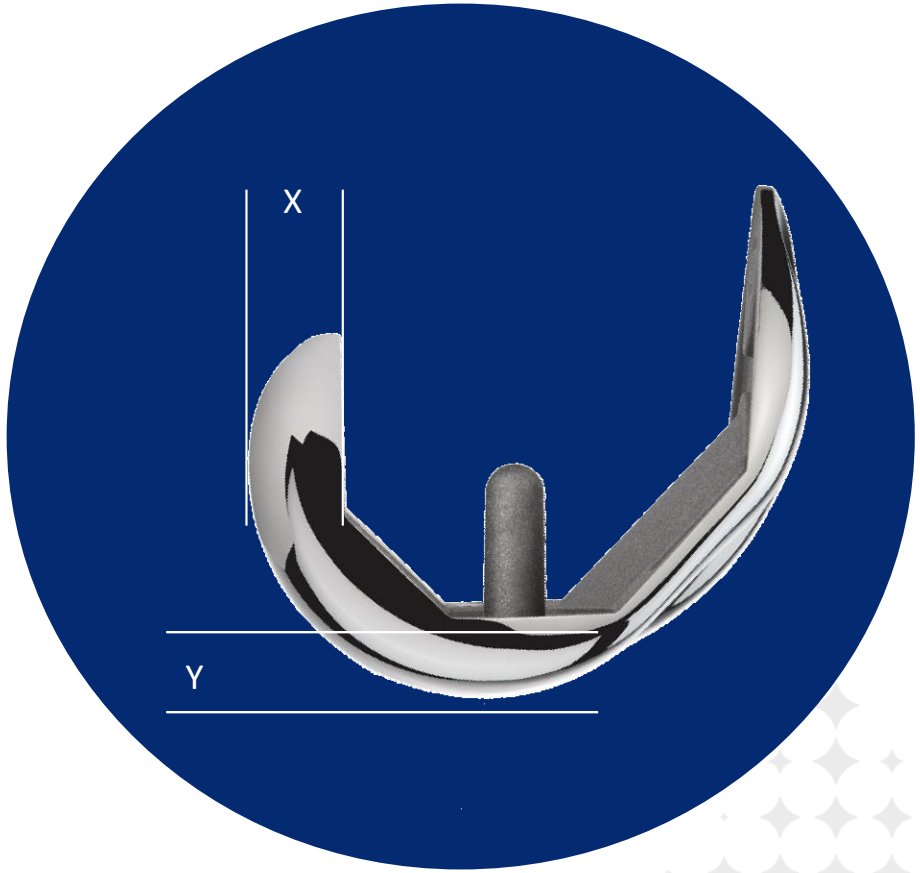
MicroPort

Posterior Condylar Thickness

Sizes 1-4: 10mm
Sizes 4-8: 11mm

Why?

Higher contact area in deep flexion
Allows longer constant radius
Permits a “gentler” deep flexion closing radius



Distal Condylar Thickness

All sizes: 9mm (8.6mm)

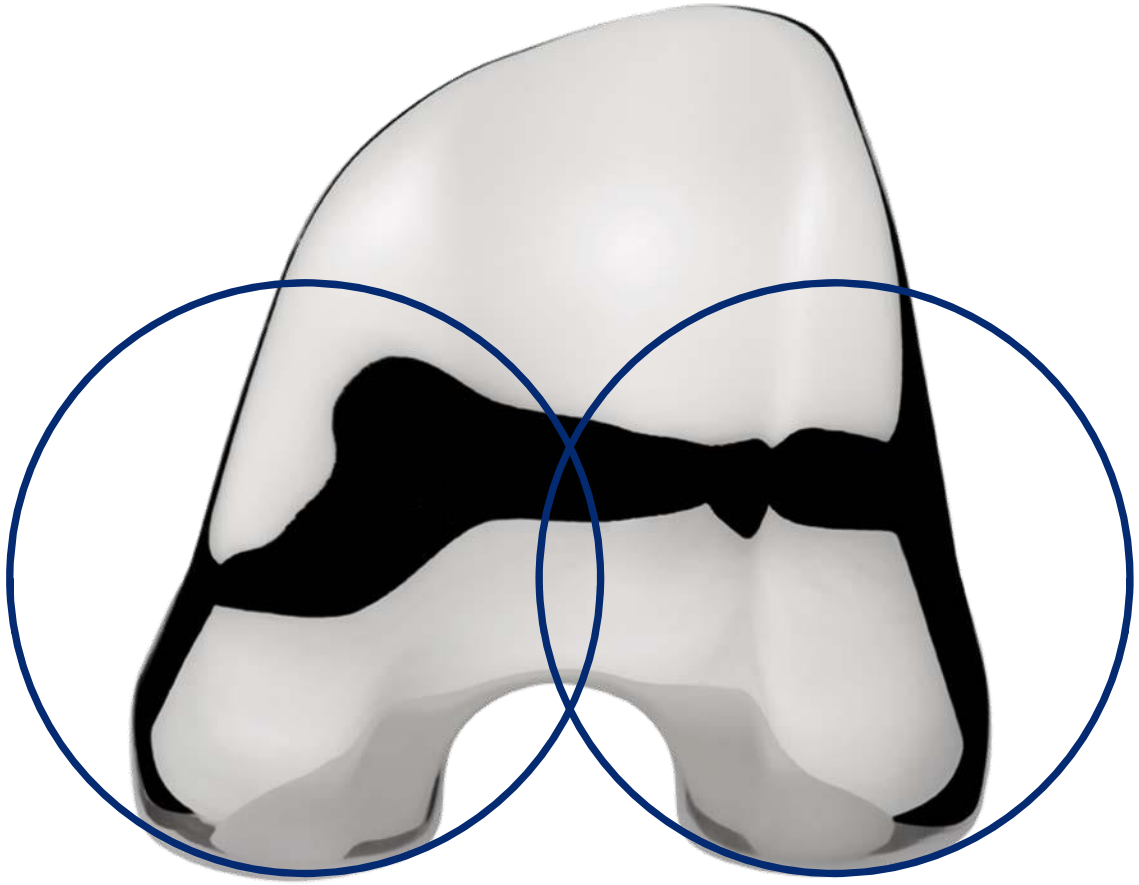
Why?

Material properties of femur
Increased strength of the femur for extension relief

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Spherical Femoral Component

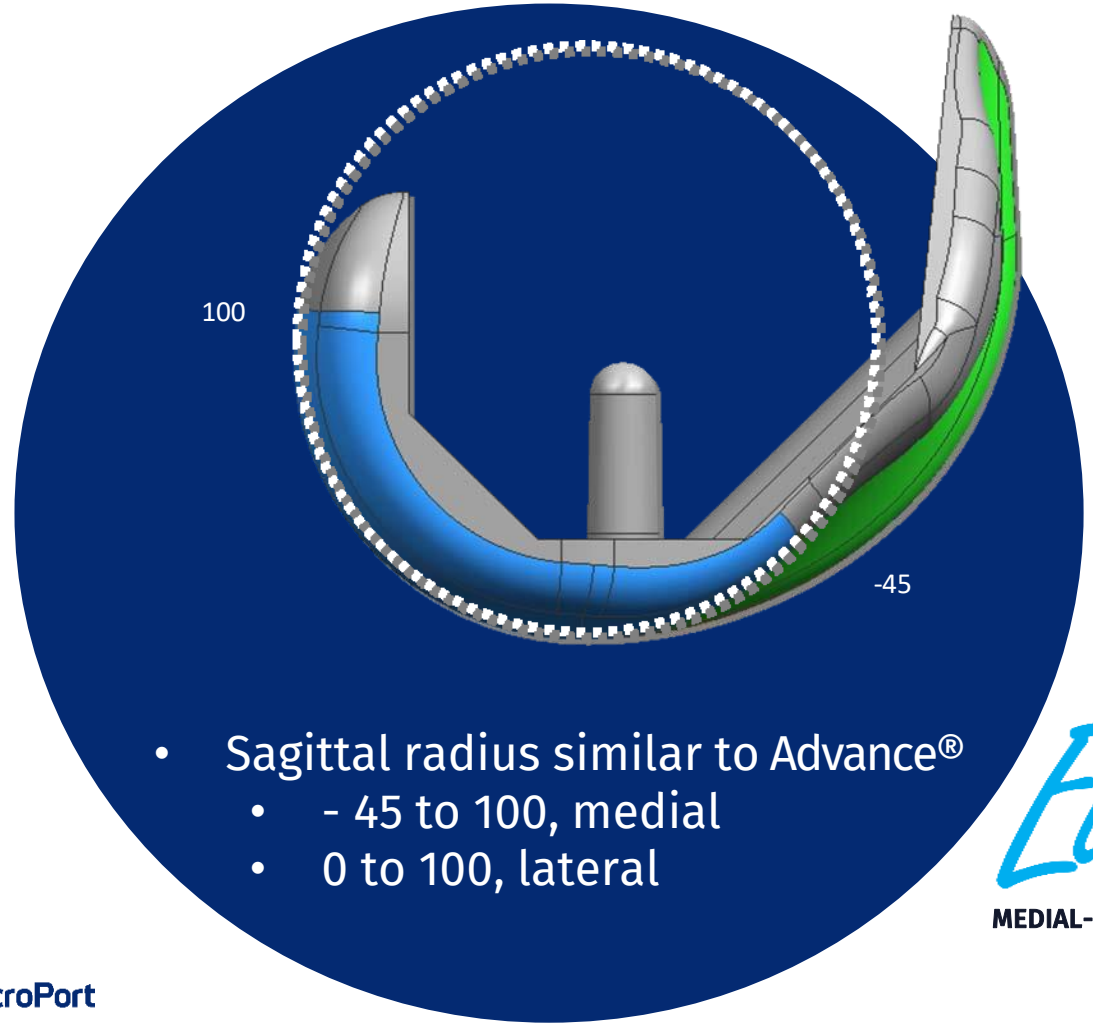
Sagittal and coronal radii are identical circles
We are the **only** company with this spherical geometry



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Constant Radius

Sagittal and coronal radii are identical circles
We are the **only** company with this spherical geometry



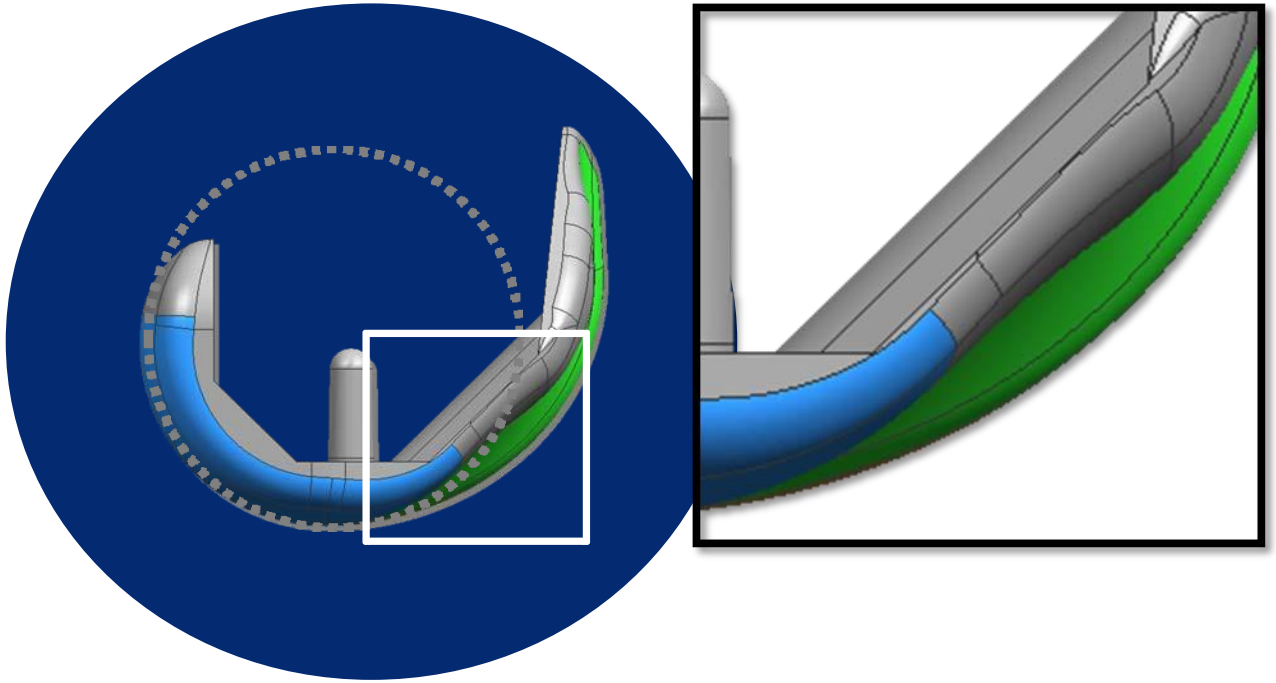
- Sagittal radius similar to Advance®
  - - 45 to 100, medial
  - 0 to 100, lateral

Advance®
Sagittal Plane
- Constant Radius 0º – 90º

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Extension Relief, “Door Ding”



Medial
-45 to 100

Lateral
0 to 100

Necessary for full extension, 8 degrees of hyper extension, due to high anterior lip
Accommodates increased posterior slope

Not needed on Lateral Side due to opened conformity

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Anterior Flange Angle

Anterior flange profile is similar to Advance®
6° flange angle

Designed to reduce incidence of anterior notching

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Femur – Box Cuts

Anterior flange thickness (x)
Evolution®: 6.1mm to 10mm

Anterior chamfer thickness (y)
Evolution®: 7.6mm to 8.4mm

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

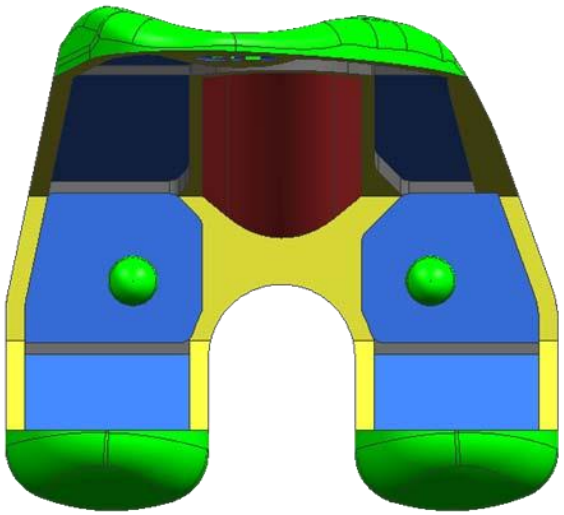
Sulcus

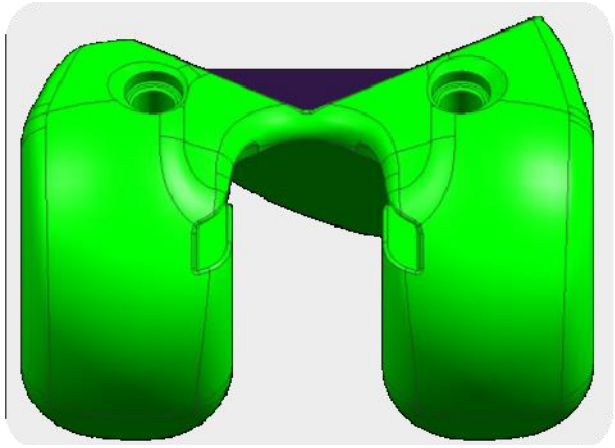
Rounded

Reduce stress risers

Bone Conserving

Reduction in resected bone volume (*no box cut for post & cam mechanism*)





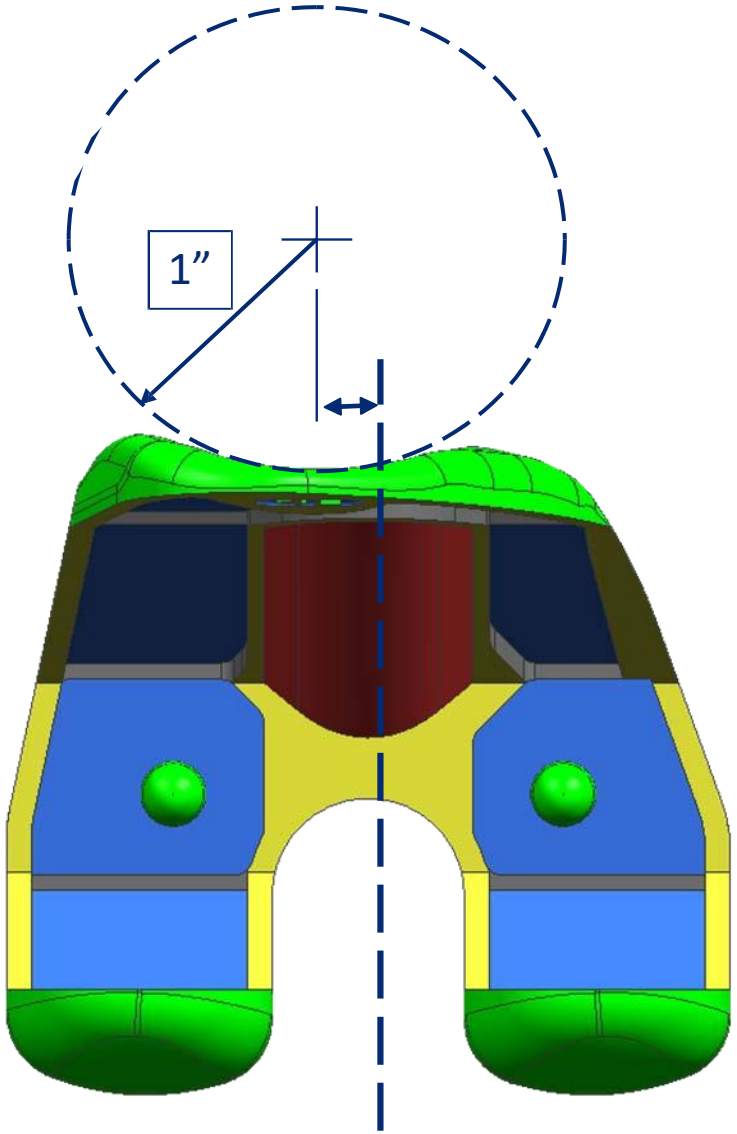
Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Femur – Patella Groove

Lateral Offset (Q-angle)

- 3.6° laterally-angled groove is same as Advance®
- 1” radius is same as Advance®
- Uses Advance® patellar implants



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Femoral Component Patella Track

Components aligned to anterior flange.

Posterior extension of trochlear groove to provide full contact area with the patella during deep flexion.

Significantly less patellofemoral complications compared to PS designs[2]

Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Patella-Fem Contact Area

EVOLUTION™
Medial-Pivot Knee System

Evolution® Patellar groove designed to optimize contact area Size 1 Advance® and Evolution®

WORST CASE SCENARIO

Results:

Contact area of Evolution® knee was equal or higher than the Advance® at all flexion angles except 45°

Conclusion:

Evolution® represents a safety factor of over 50 times

High Contact area can lead to less pain

Can build off track-record of aMP™

·93

THE PATELLO-FEMORAL CONTACT AREA AND STABILITY OF THE EVOLUTION™ MP TOTAL KNEE REPLACEMENT

John Green, BEng
Wright Medical Technology, Inc
Arlington, TN

James Brownhill, PhD
Wright Medical Technology, Inc
Arlington, TN

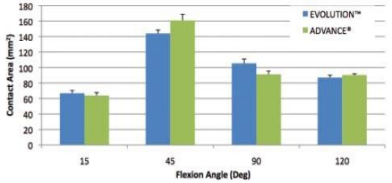


Figure 2 | Worst-case contact area results for EVOLUTION™ and ADVANCE® patello-femoral components[1]

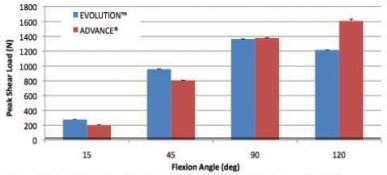


Figure 3 | Peak shear load to disassociation of the patello-femoral joint for EVOLUTION™ and ADVANCE®[1]

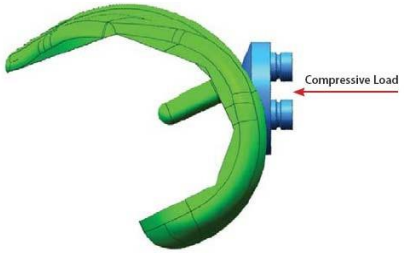


Figure 1 | Setup configuration for 120° of flexion with applied compressive load

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

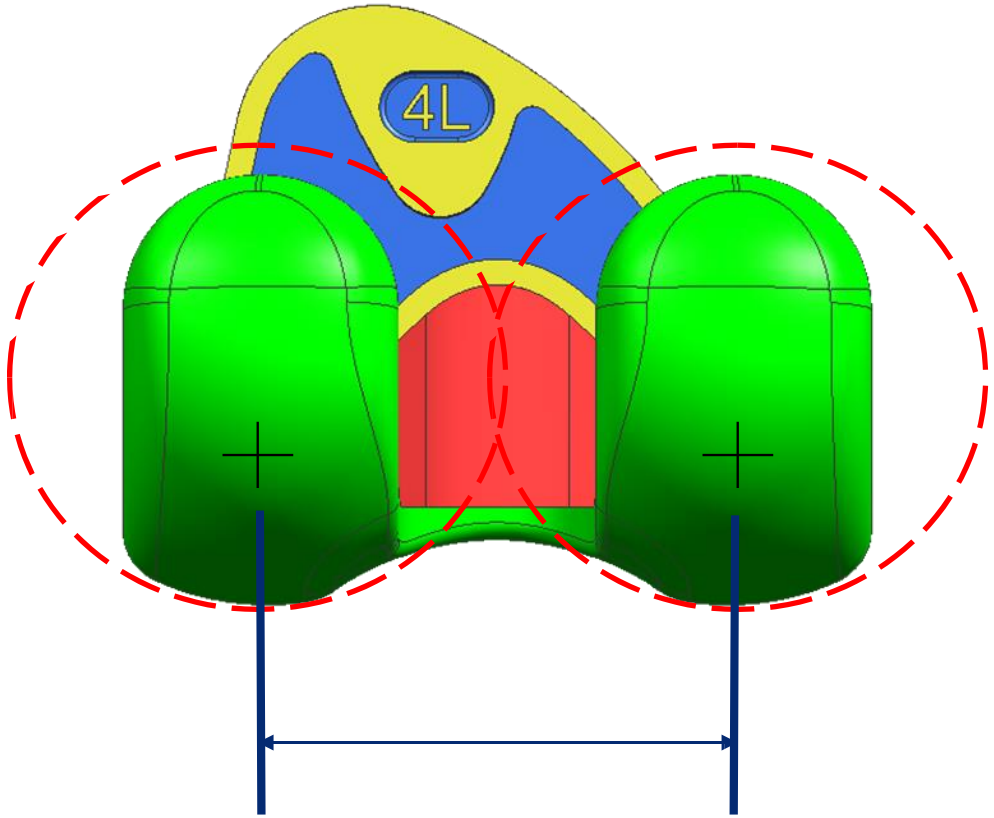
MicroPort

Femur Grouped Bearing Spacing

Bearing spacing for Evolution® varies in groups

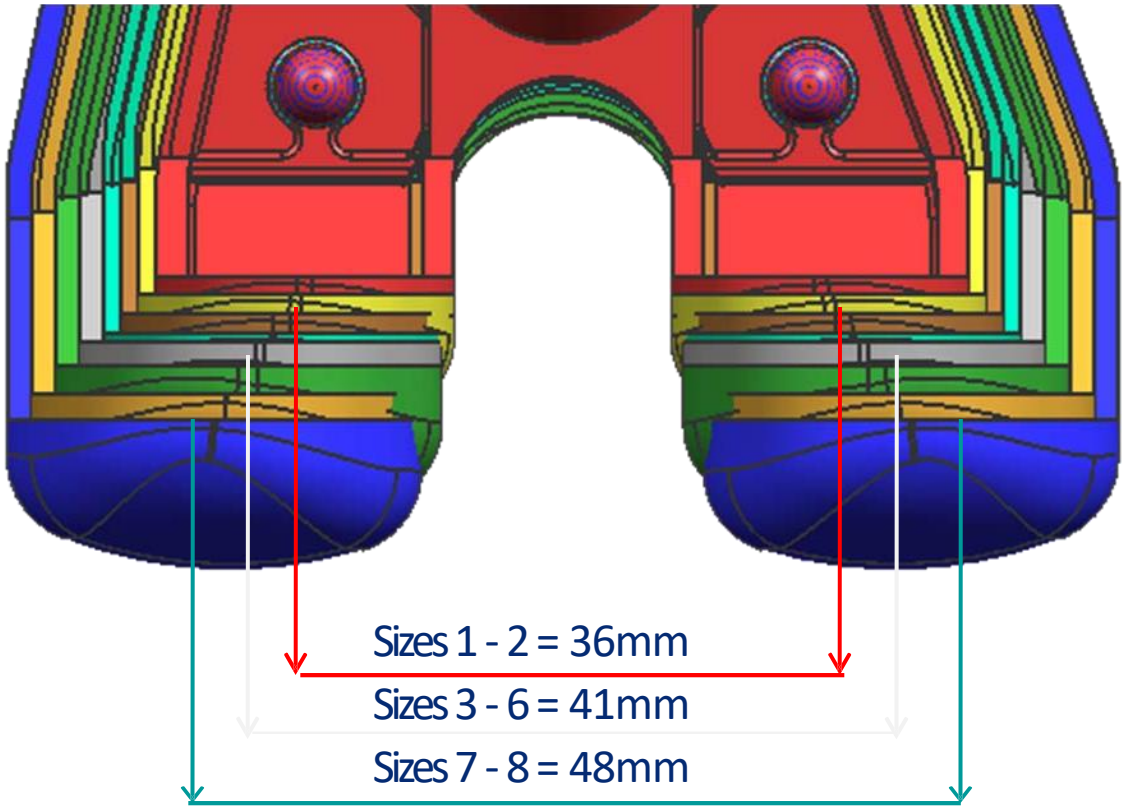
Sizes 1 & 2 = 36mm
Sizes 3 – 6 = 41mm
Sizes 7 & 8 = 48mm

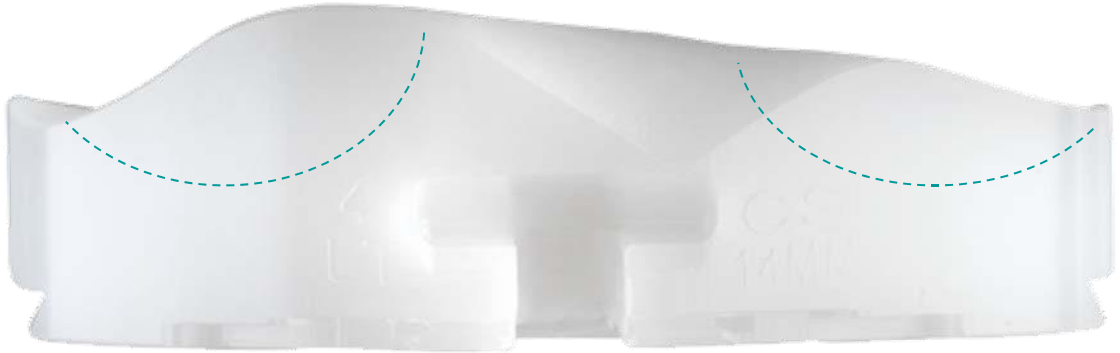
Critical for interchangeability groups, such as the need for plus bases and plus inserts



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Femur – Grouped Bearing Spacing

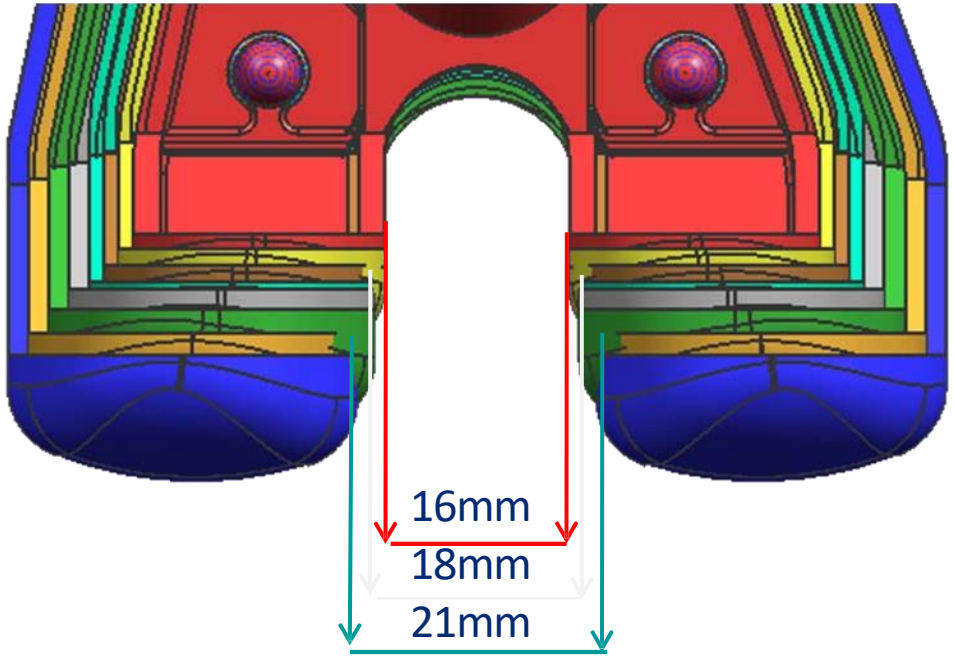




Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Femur – Intercondylar Notch



Intercondylar notch for Evolution® varies for groups

- Sizes 1 & 2 = 16mm
- Sizes 3 – 6 = 18mm
- Sizes 7 & 8 = 21mm

Allows femoral nailing for supracondylar fractures

Advance®

Advance® = 18mm for all sizes

Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution® Cementless Femoral Component

Porous sintered beads for cementless surface

- Sulcus: single bead layer
- Anterior, Posterior, Anterior Chamfer & Posterior Chamfer: Multiple Bead Layers

8 Sizes L & R

Compatible with

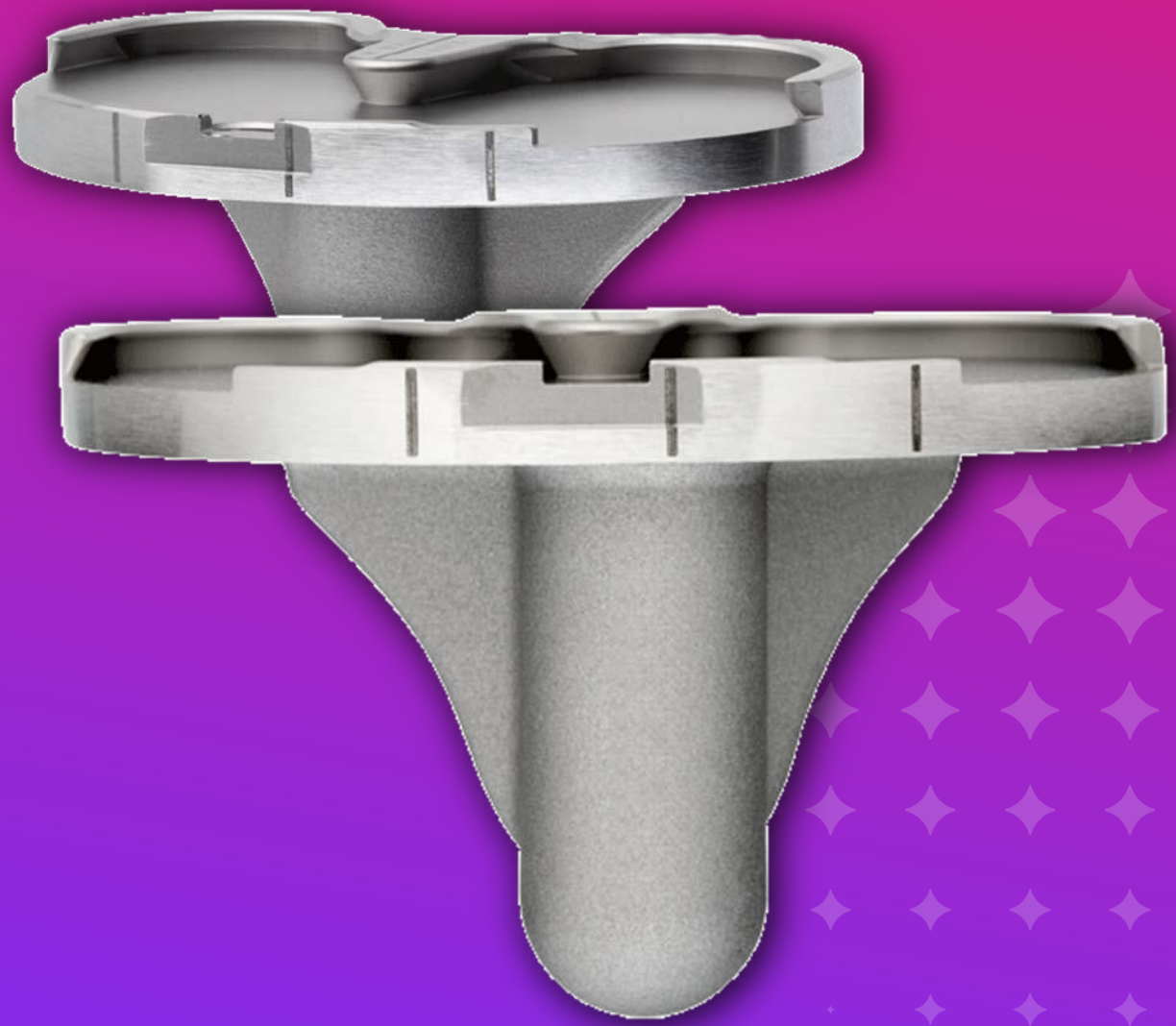
- Cemented Evolution® tibia base
- Cemented Evolution® Biofoam® tibia base
- Cemented instrument platform

Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution®

Tibia



MicroPort

Tibial Base Evaluation

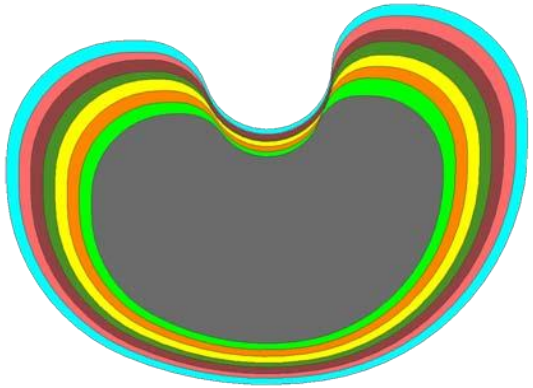
- Over 300 surgical and cadaveric assessments were performed from 2005 to 2009 in multiple countries on multiple iterations of asymmetric tibial profiles where 20 different surgeons assessed coverage on proximal tibial resections and how they related to the corresponding femoral implant size
- 8 lollipop template options were available for assessment
- 267 data points were recorded

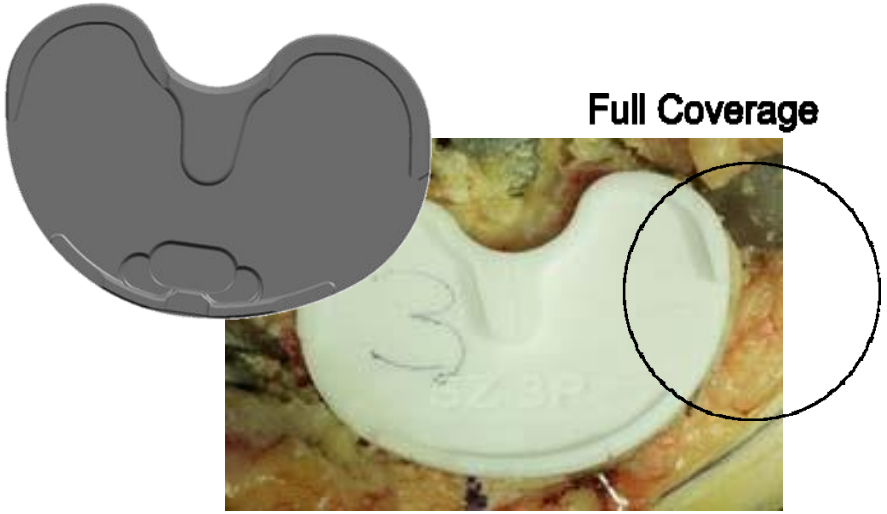
Evolution®
MEDIAL-PIVOT KNEE SYSTEM

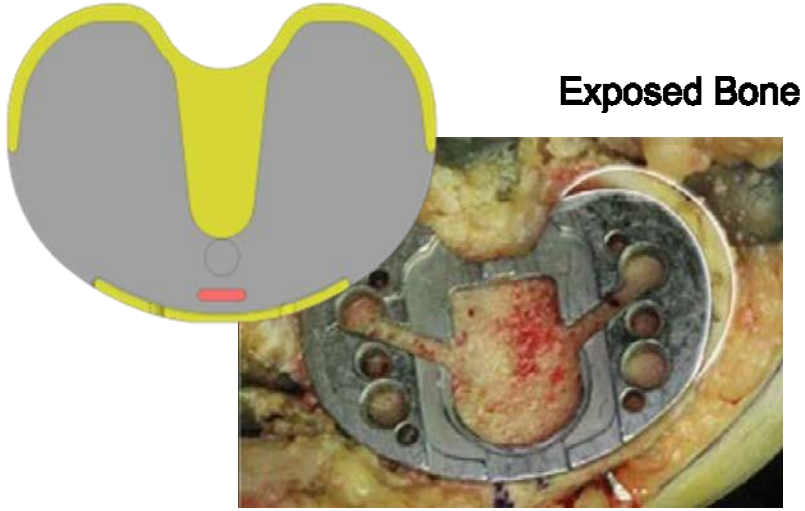
Anatomic Geometry

CT data was confirmed through intraoperative templating with approximately 300 patients;

Incredible complements in PMT.



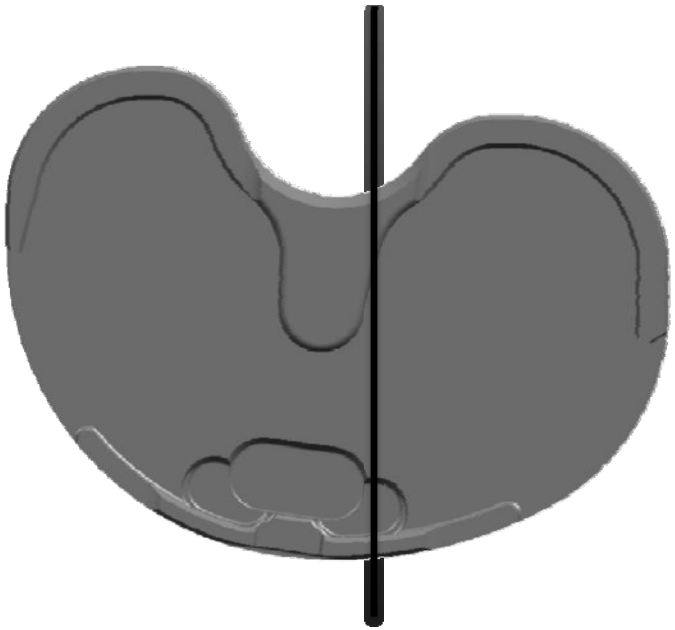




Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Orientation

8° anterior-medial angled lock detail



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

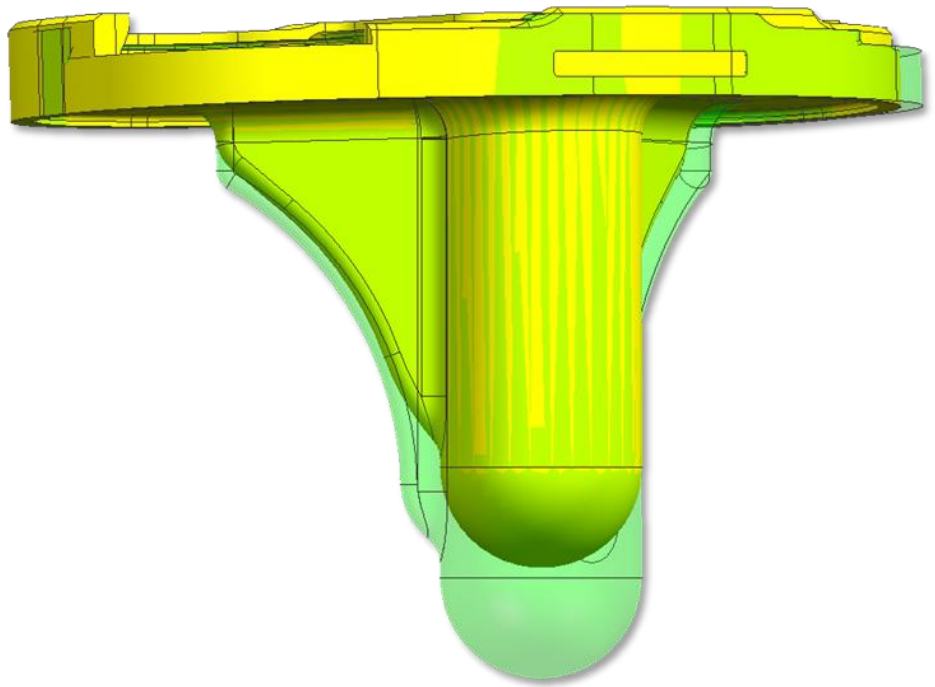
Keel

Stem diameter:

- Size 3-8: 15mm - equal to Advance®
- Size 1-2: 12mm

Stem length shorter than Advance® for less invasive insertion (tibia is not subluxed as far anteriorly)

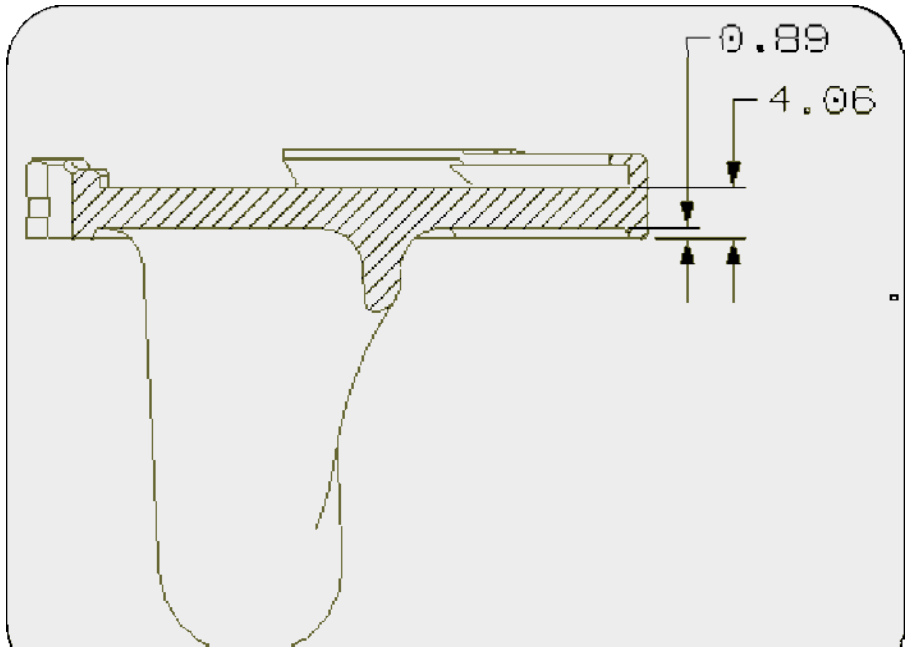
- Evolution® : 31mm to 41mm
- Advance® : 35mm to 50mm



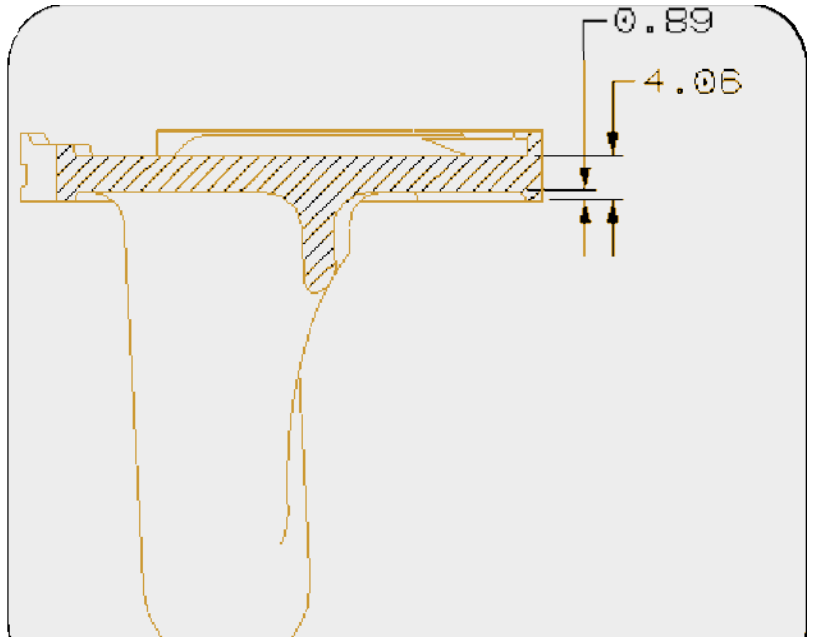
Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Baseplate Thickness

Evolution®



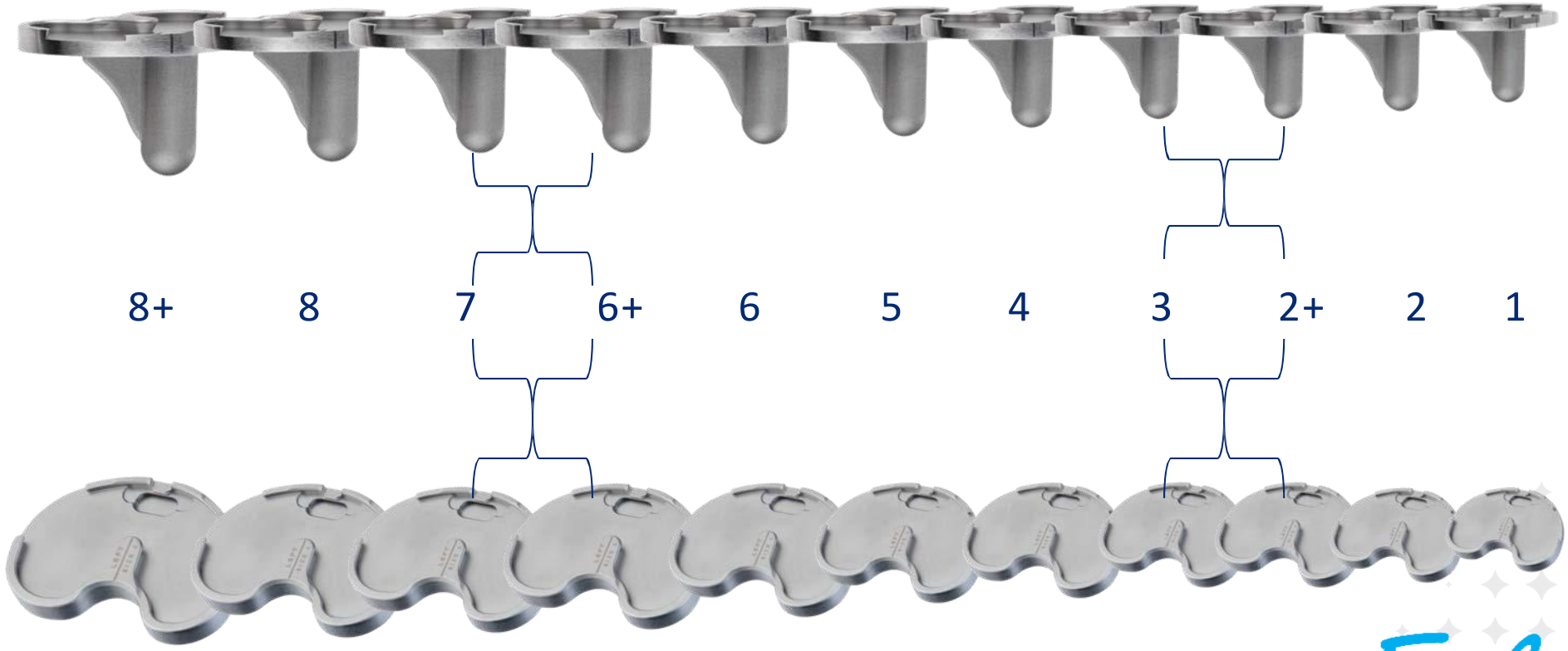
Advance®



Tibial Baseplate thickness of 4mm

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Sizing



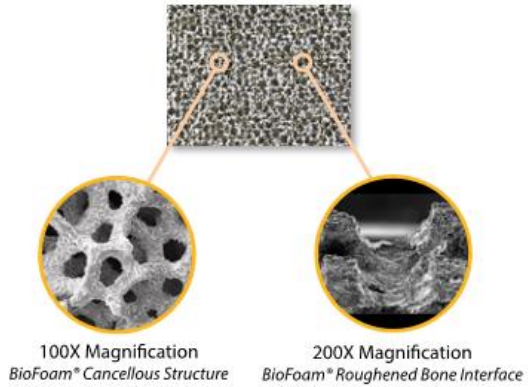
Evolution®

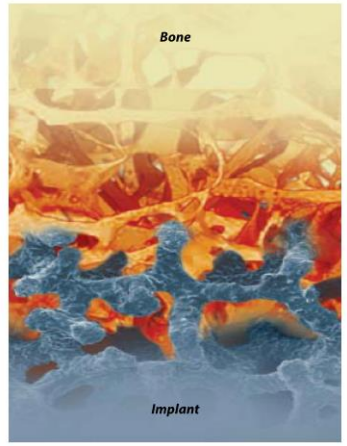
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Biofoam ® Tibia Cementless

The structure of Biofoam® Cancellous Titanium acts as a biological scaffold designed to allow fast, fluid bone apposition.

- 60-70% Porous
- Full Interconnecting Porosity
- Manufactured from Commercially Pure (CP) Titanium Metal
- Osteoconductive Matrix





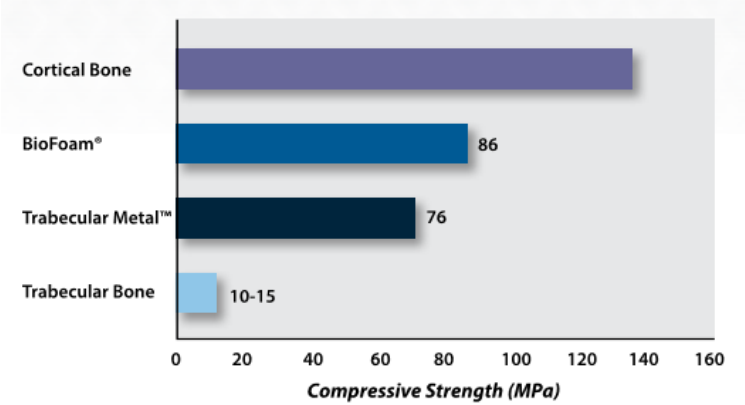
Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution® Biofoam® Tibia Cementless Fixation

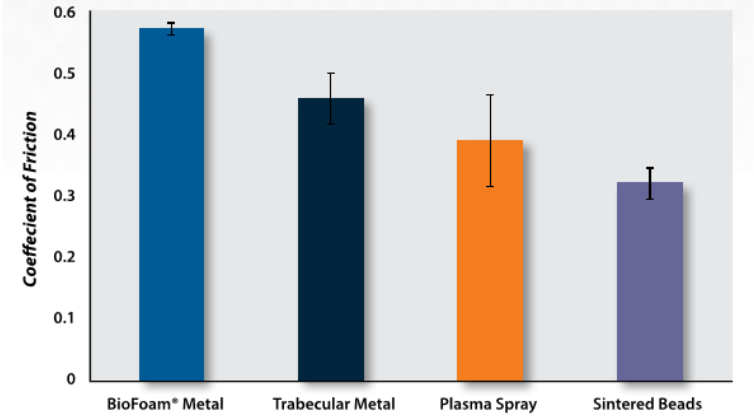
- Anti-rotation spikes
- 3 press-fit keels
  size 2+ 3/4
  size 5/6
  size 6+ 7/8

High compressive strength[1,2]



*Data not statistically significant due to small sample size.

High friction coefficient[2]



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Evolution®

Inserts

MicroPort

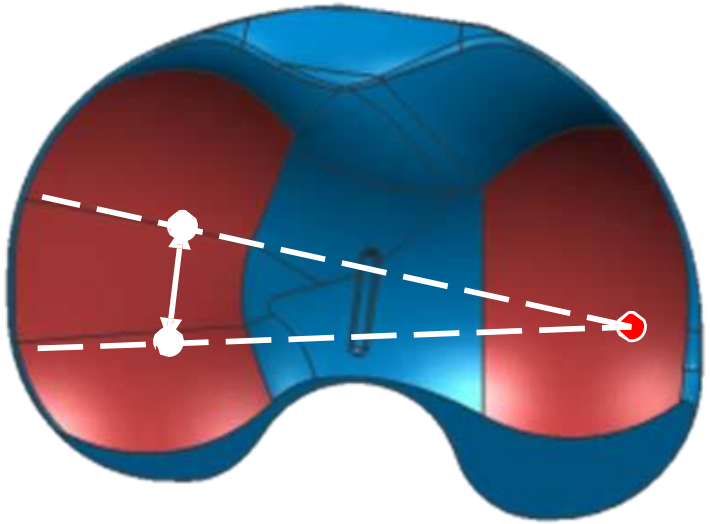
Evolution® System Insert

CS – Cruciate Substituting :

2nd generation medial-pivot knee

Medial ball-in-Socket

Differentiating feature - Bone Conserving Post-Stab



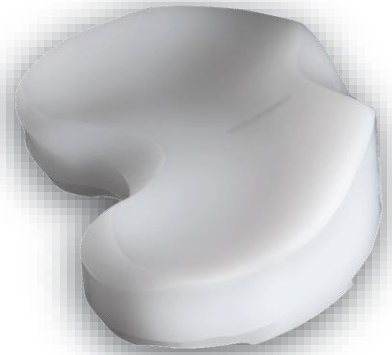
- 8 sizes (Left and Right) and “plus” inserts
- UHMWPE: DURAMER®
- Medial surface - ball in socket
- Lateral surface - allows rotation around any point on medial side

Evolution®

MEDIAL-PIVOT KNEE SYSTEM

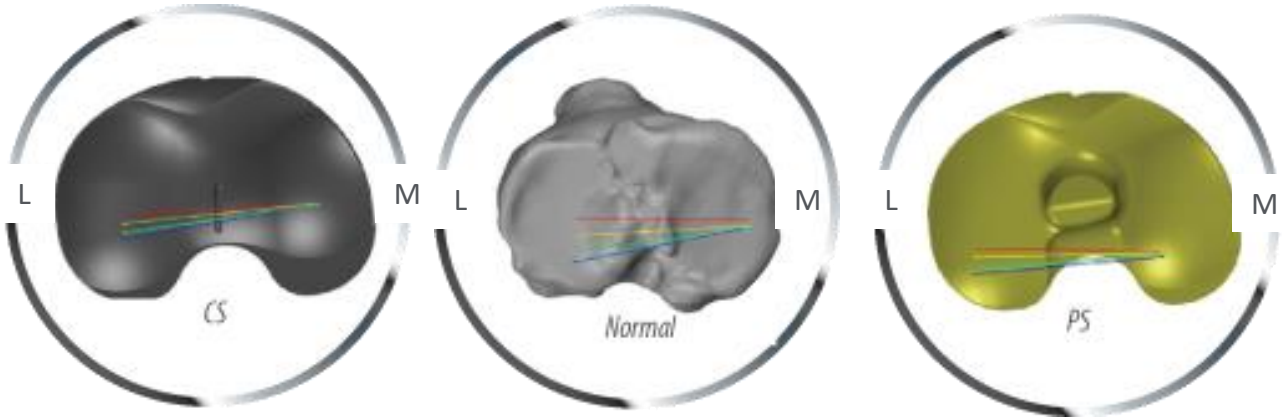
Evolution® Insert Kinematics

Ball <-----> Socket



Medial stability and Lateral mobility

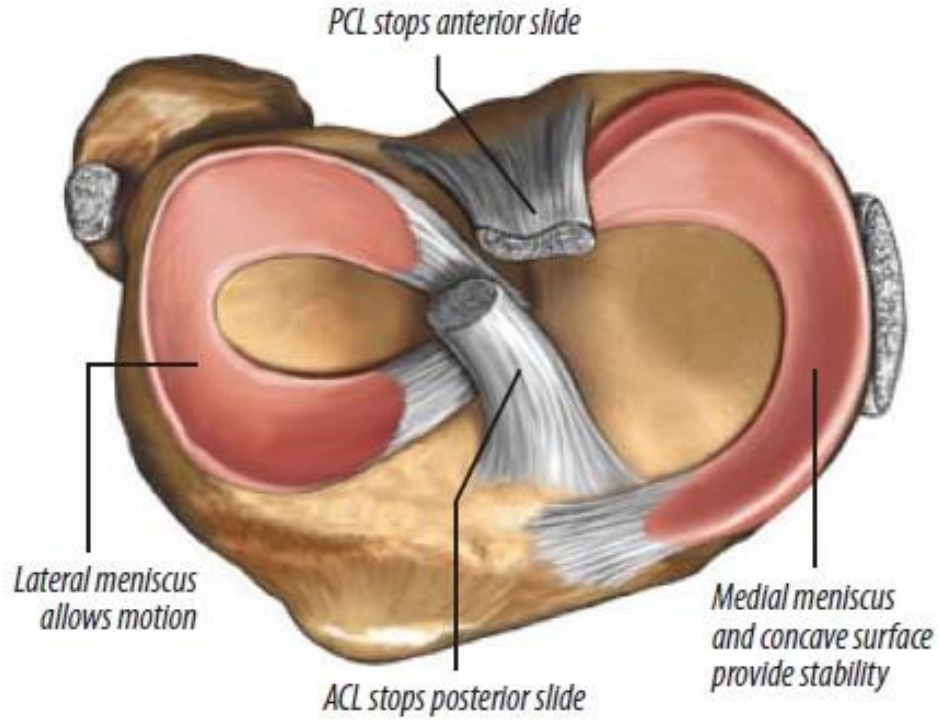
In-vitro closed chain kinematics study on cadavers



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

MicroPort

Evolution® Insert Kinematics

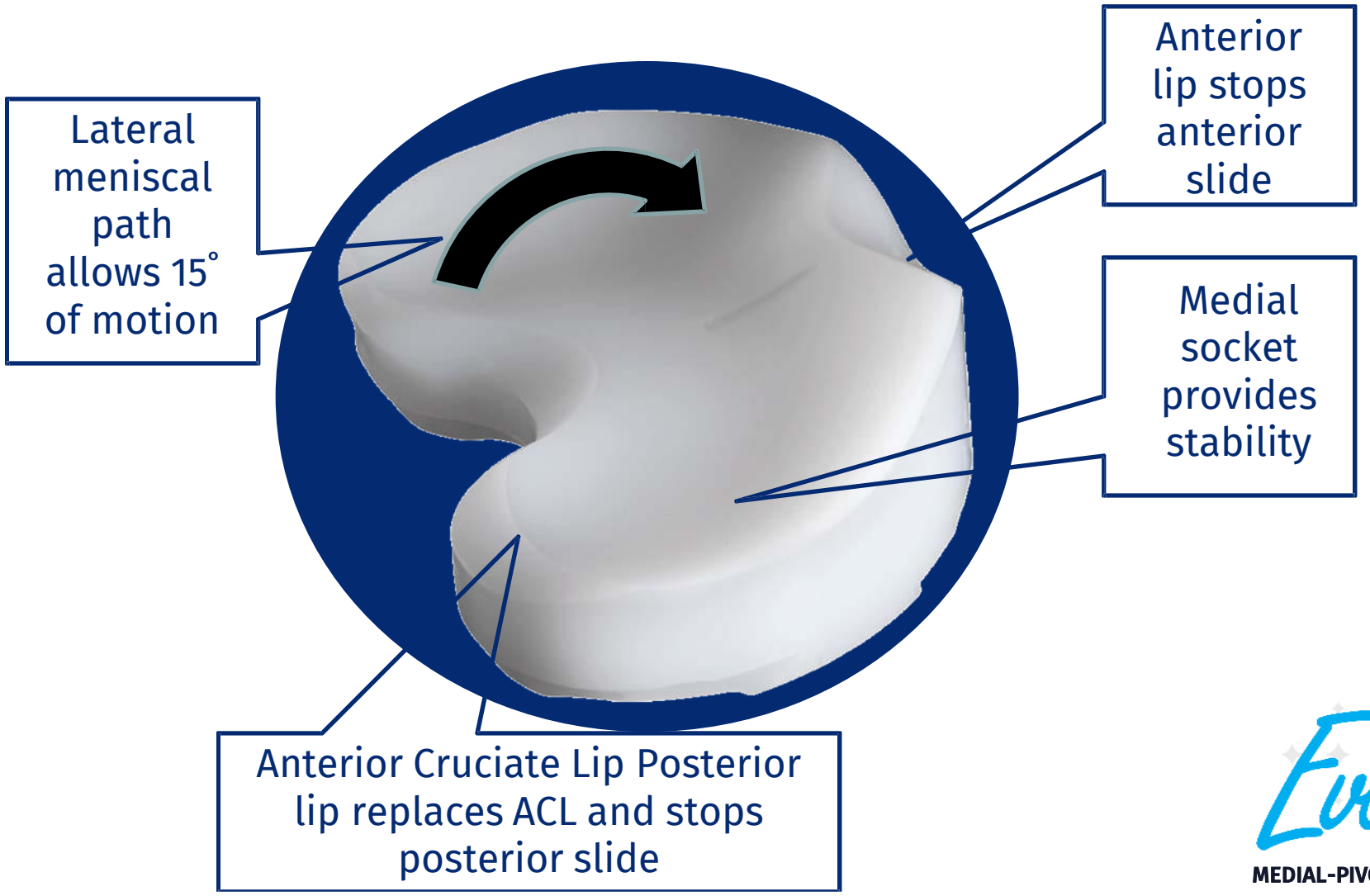


Mobile Lateral Compartment
- Lateral meniscus is mobile
- Lateral tibial plateau is convex
- LCL is rounded and narrow

Stable Medial Compartment
- Medial meniscus is firmly attached around medial tibial plateau, creating a cupped surface
- Medial tibial plateau is concave
- MCL is broad, flat and stabilize knee

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Replicates the natural structures



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

CS Anterior Posterior Flange Height Thickness Options

Anterior Flange Height

11mm, size 1-7+

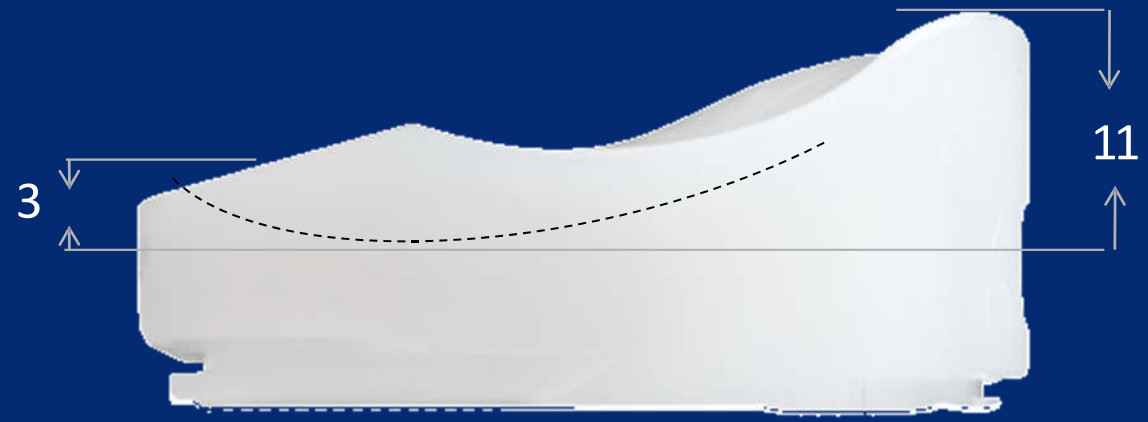
12mm, size 8

Anterior Cruciate Lip

3mm all sizes

Available in Thickness

10, 12, 14, 17, 20, 24



Evolution®

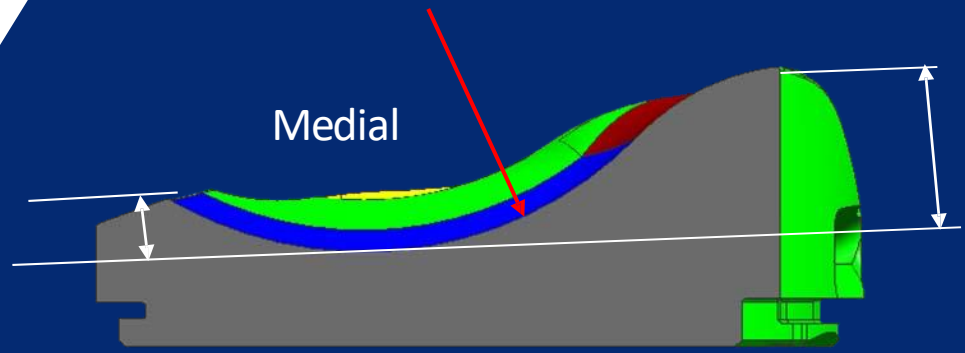
MEDIAL-PIVOT KNEE SYSTEM

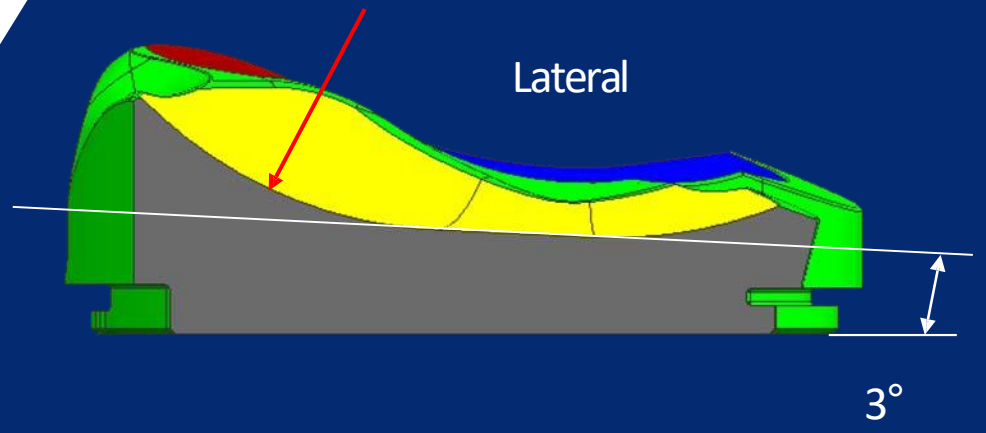
MicroPort

Evolution® CS Conformity

Medial Compartment
1.04:1 conformity, configured to same size femur (**Advance®: 1.04 to same size femur**)

Lateral Compartment
1.14:1 conformity, configured to same size femur (**Advance® : 1.15 to same size femur**)
Due to 1-up, 1-down





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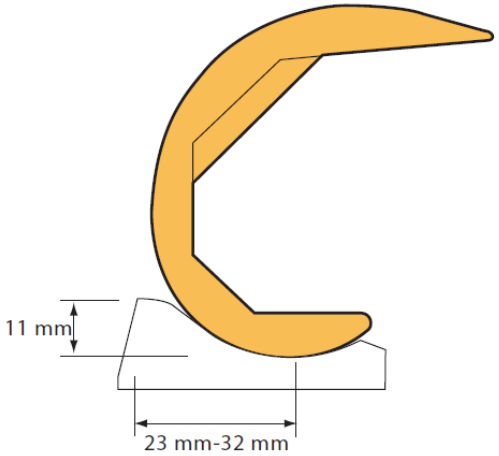
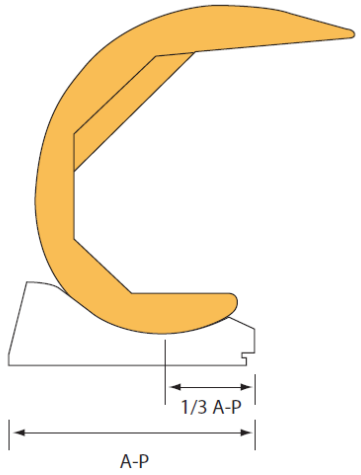
Resistance to subluxation[3]

Evolution®



Inserts feature an anterior lip

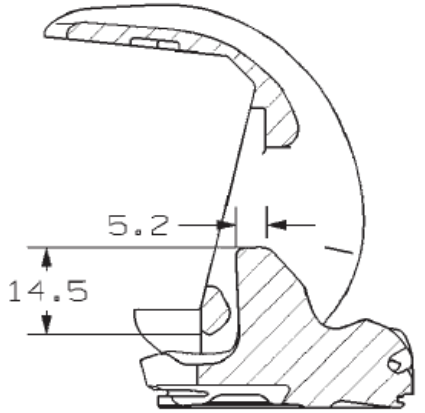
11mm vertical jumping distance
23-32mm (size depending)
horizontal jumping distance



Femoral component is maintained in the posterior third of articular surface

Longer quadriceps lever arm
Reduce anterior sliding in flexion[1]

PS Knee System



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MEDIAL-PIVOT KNEE SYSTEM

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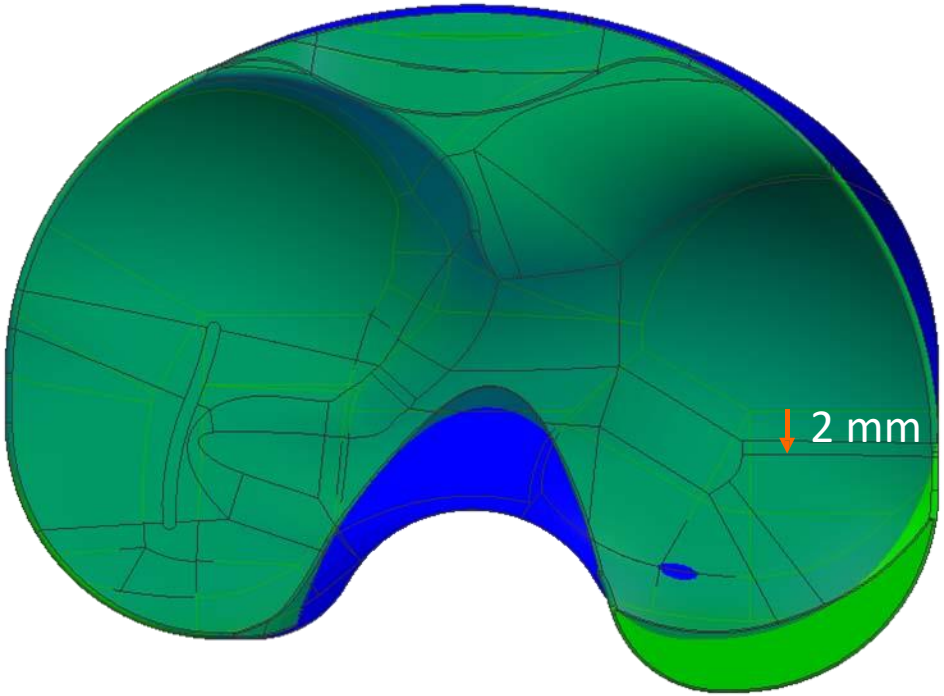
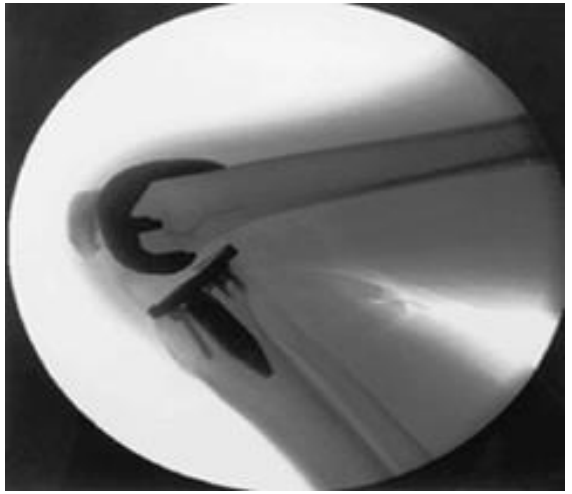
Dwell point moved posterior



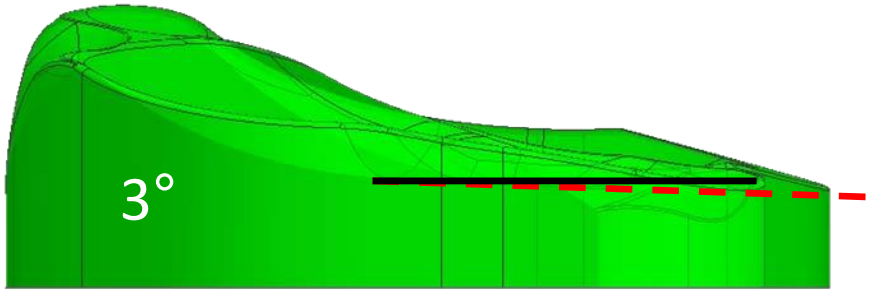


- Compared to Advance®, the dwell point of the femur has been shifted 2mm posterior
- Keeps femur in posterior 1/3rd of the tibia base
- Designed to help reduce early impingement

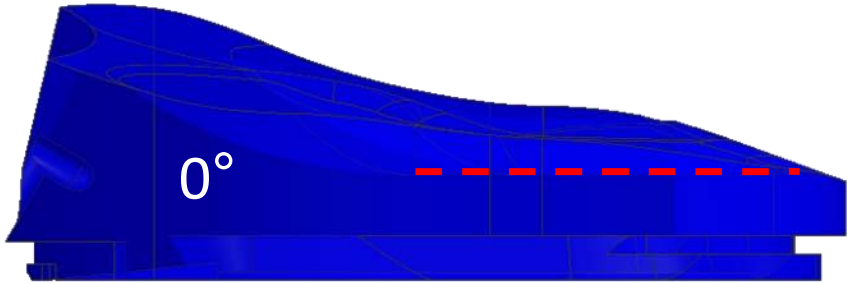
Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Built-in Posterior Slope

Evolution®



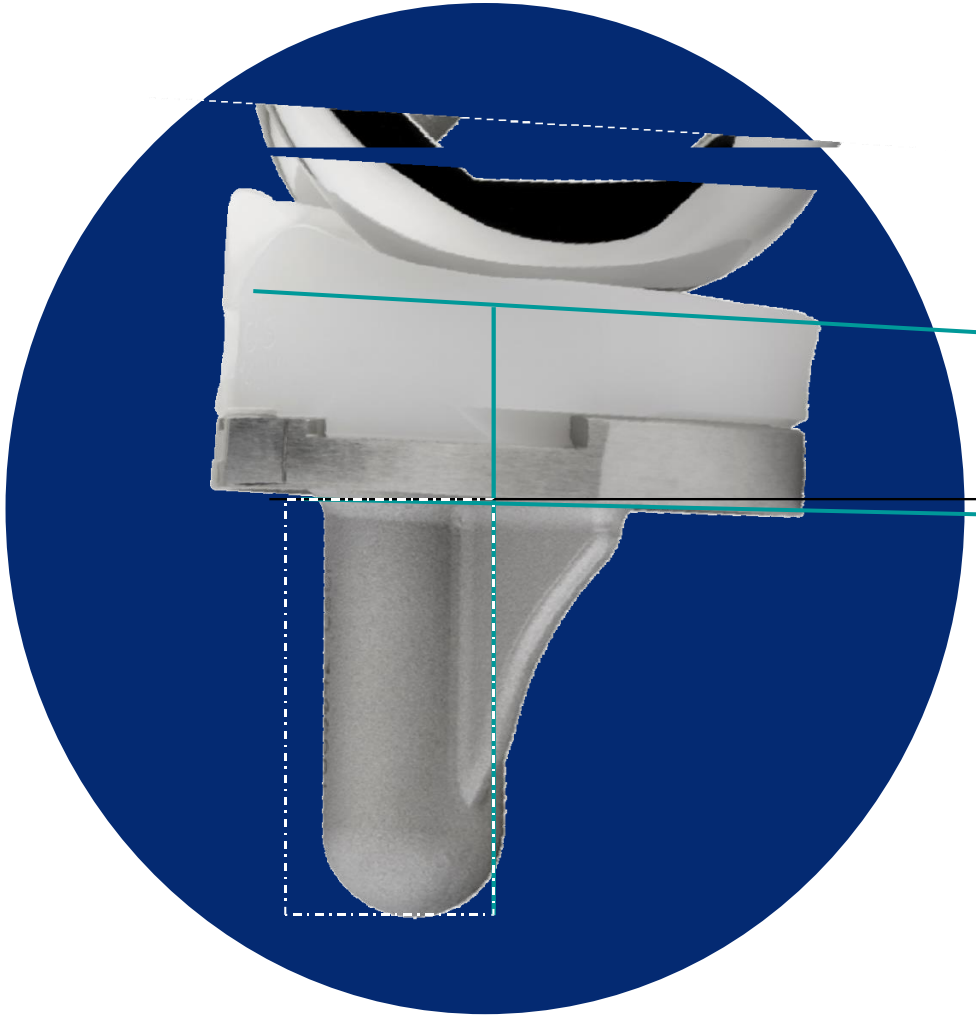
Advance®



- 3° posterior slope built into the lateral side of the Evolution® Insert
  - Ease Flexion
  - Facilitate Roll-back

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Total Posterior Slope



3° Posterior Slope Insert

3° Posterior Slope Tib Base

6° Total Posterior Slope

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MEDIAL-PIVOT KNEE SYSTEM

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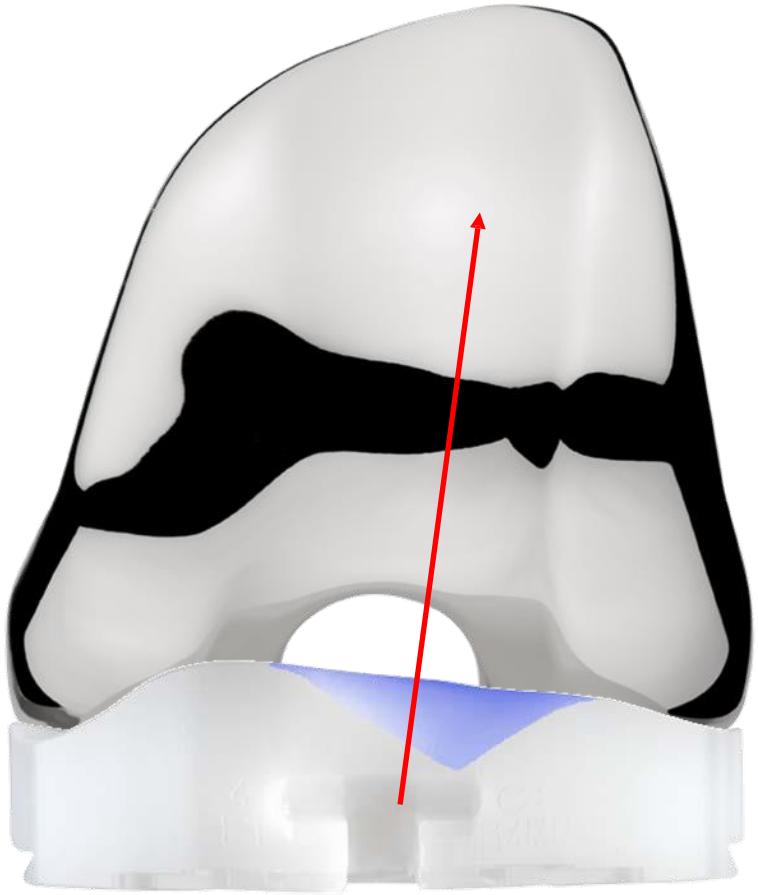
Patellar Groove

- Insert patella relief made rounder and angled in path of patellar pull
- Prevents impingement of the patella tendon in flexion
- Angled to draw toward the lateral compartment
  - Rounder than Advance®



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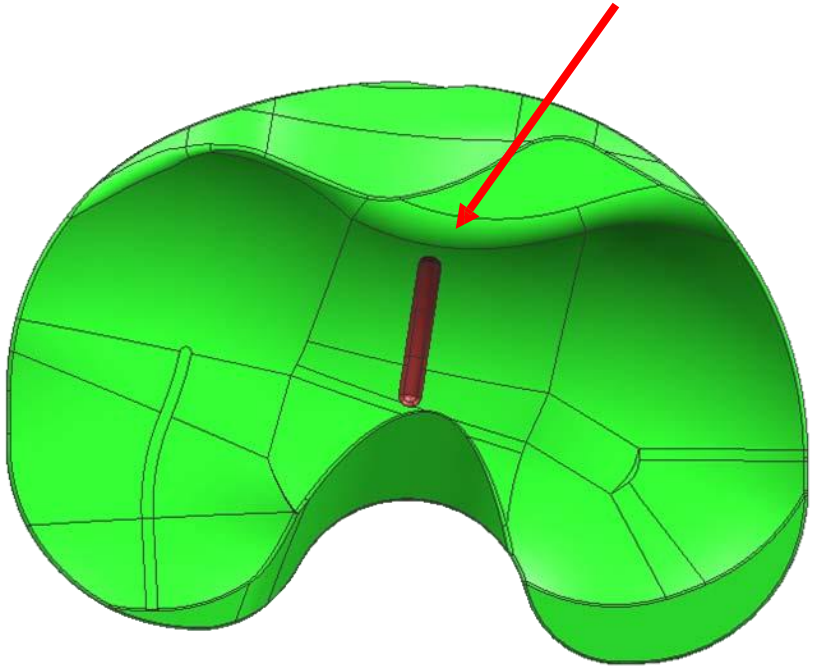
Insert Alignment and Patellar Path

- Alignment groove added to give surgeon a visual cue on assembly direction of insert to base
  - Due to angled locking mechanism.



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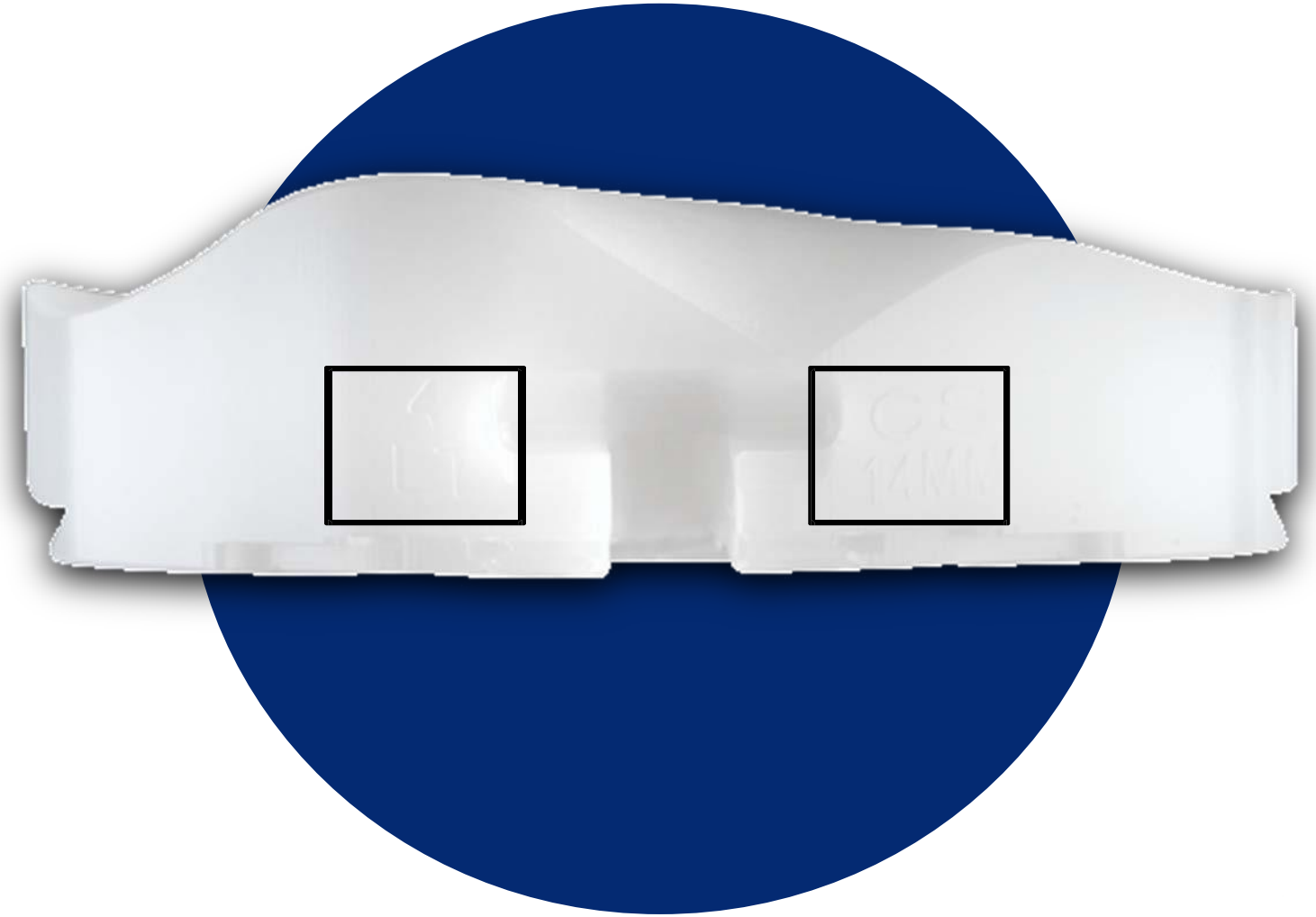
MEDIAL-PIVOT KNEE SYSTEM

Laser Markings for Size



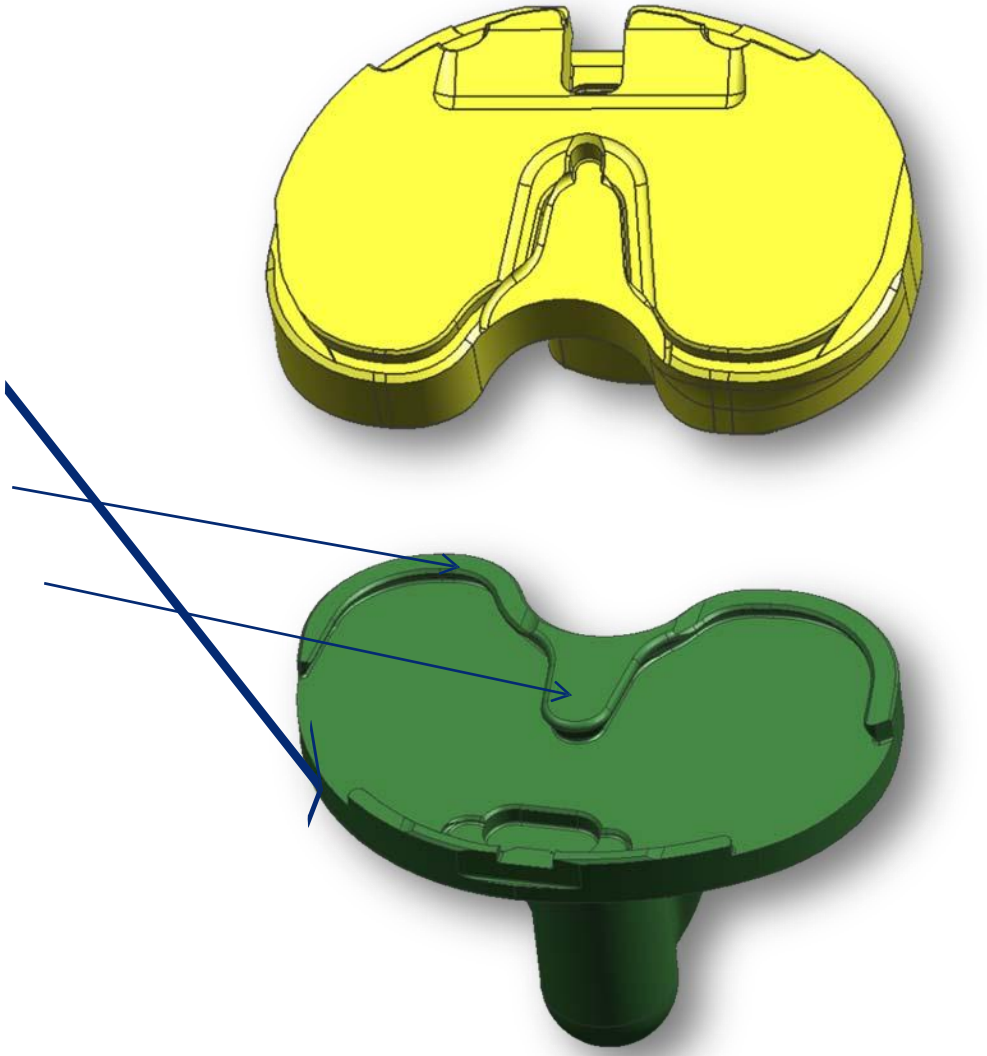
Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution® Lock Detail

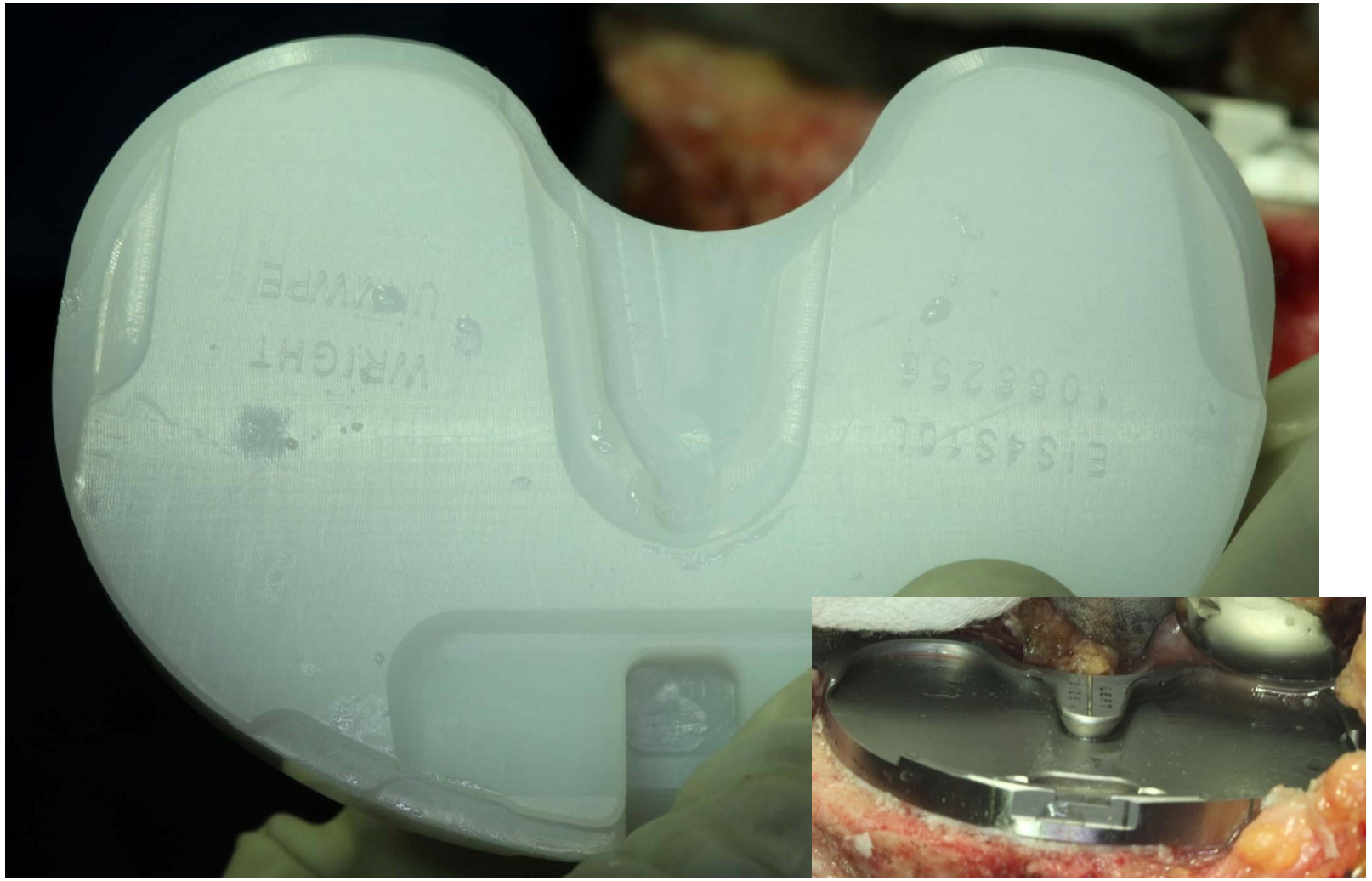
Tri-Capture Design

- Anterior Capture
- Posterior Capture
- Posterior Dovetail



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Lock Detail



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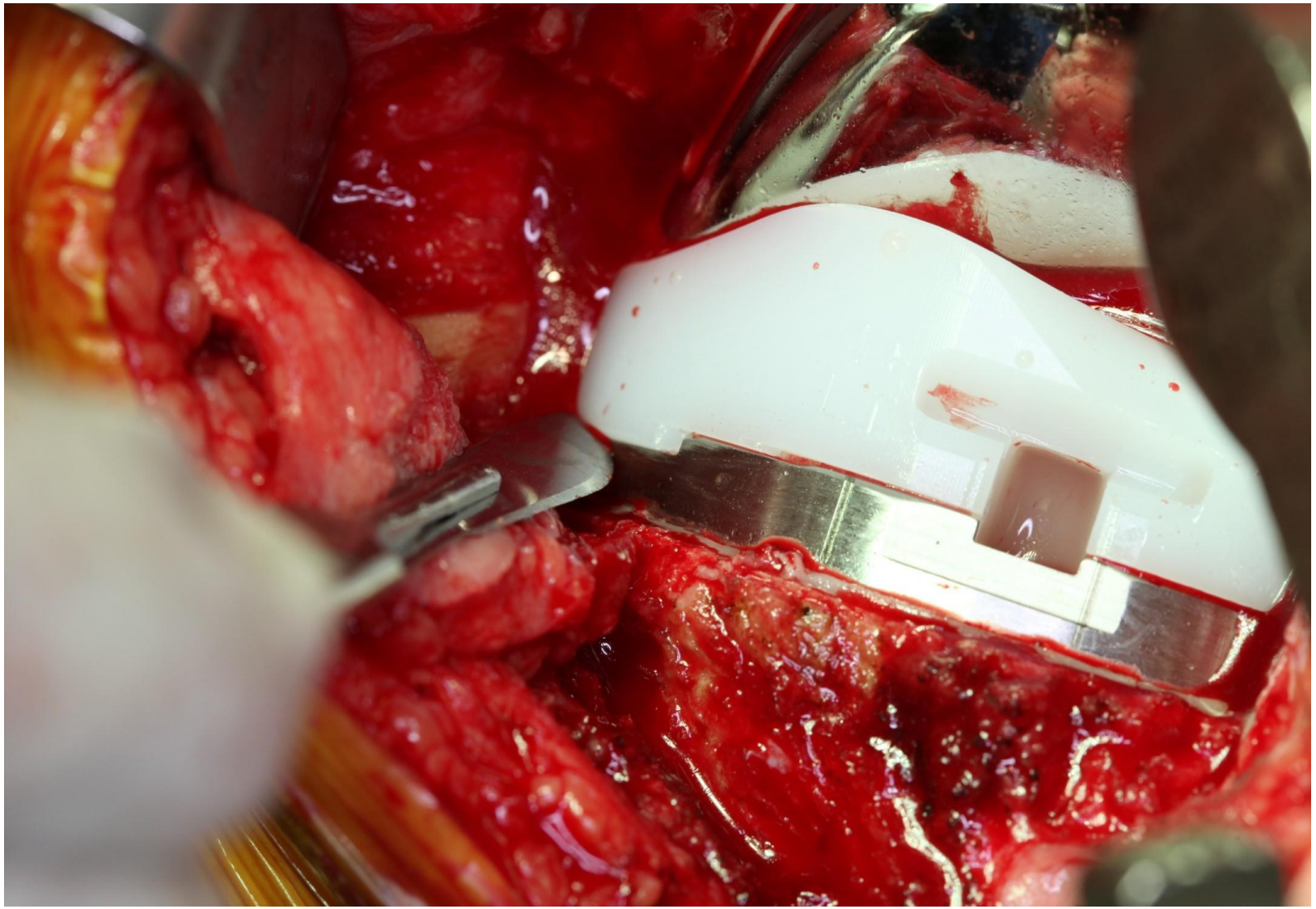
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Lock Detail

- Posterior Dovetail
  - Raised to ease engagement
  - Shortened to ease insertion
  - Angled for Medial insertion

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

Evolution® Lock Detail



Evolution®

MEDIAL-PIVOT KNEE SYSTEM

Evolution® Lock Detail Testing Micromotion

Compared to Advance® and NexGen

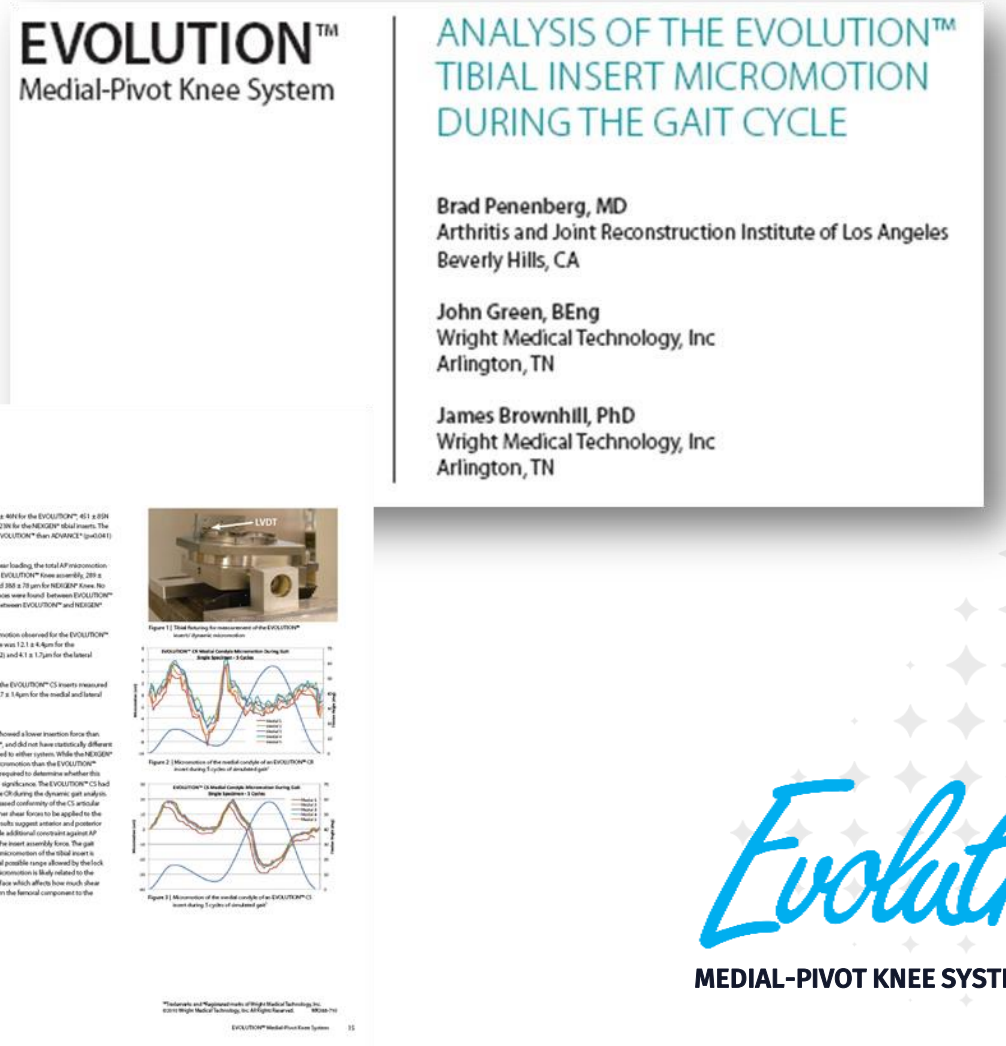
Gait Cycle

CS and CR Designs

5 consecutive Gait Cycles

Results

Evolution® has lower insertion force than both Advance® and NEXGEN and did not have statistically different AP micromotion



EVOLUTION™
Medial-Pivot Knee System

ANALYSIS OF THE EVOLUTION™ TIBIAL INSERT MICROMOTION DURING THE GAIT CYCLE

Brad Penenberg, MD
Arthritis and Joint Reconstruction Institute of Los Angeles
Beverly Hills, CA

John Green, BEng
Wright Medical Technology, Inc
Arlington, TN

James Brownhill, PhD
Wright Medical Technology, Inc
Arlington, TN

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

DURAMER® Polyethylene

ETO Sterilized
Compression Molded
Machined

No Crosslinked Polyethylene in the Evolution® Knee System

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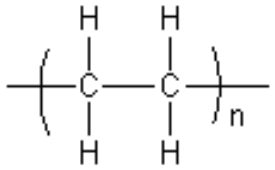
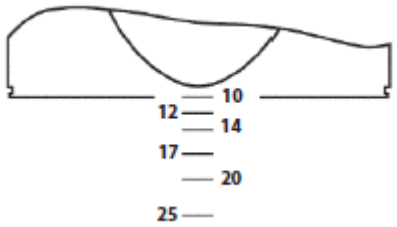
Evolution® Knee System Wear

Wear is one of the most common failure mechanism in TKA[4]

Coupling surfaces
Material



Insert thickness



Components design
Stresses/Area between tibial and femoral components

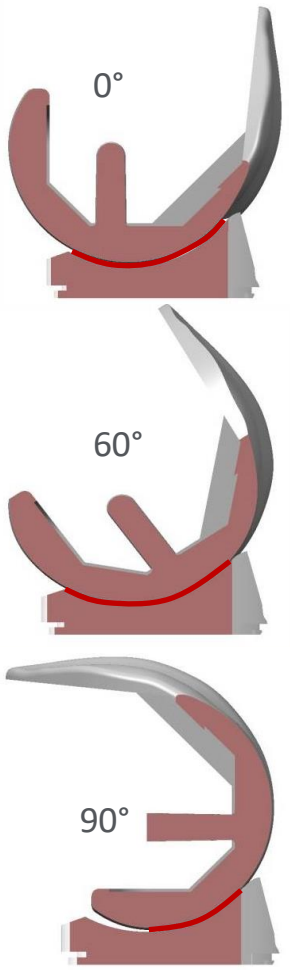
Contact Area

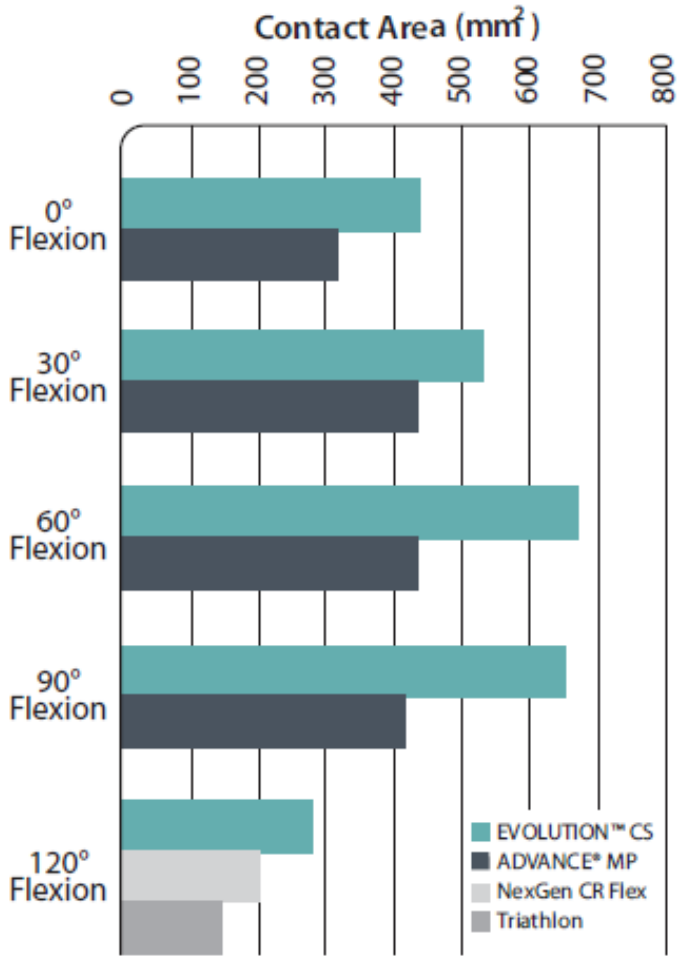
Stresses
Wear

Evolution®
MEDIAL-PIVOT KNEE SYSTEM

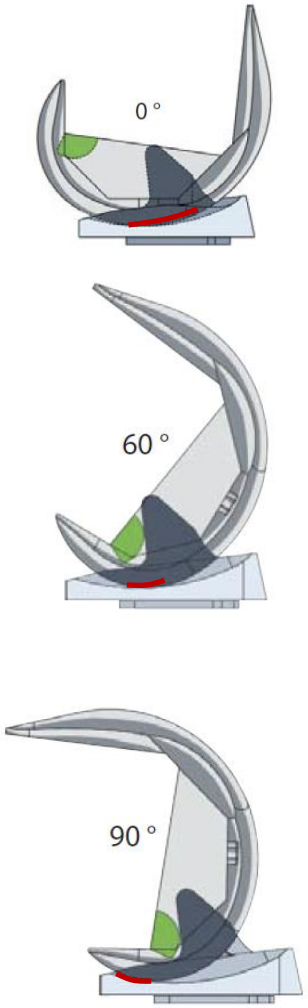
Evolution® Contact Area Comparison[4]

Evolution® CS





Competitor PS (J-Curve)



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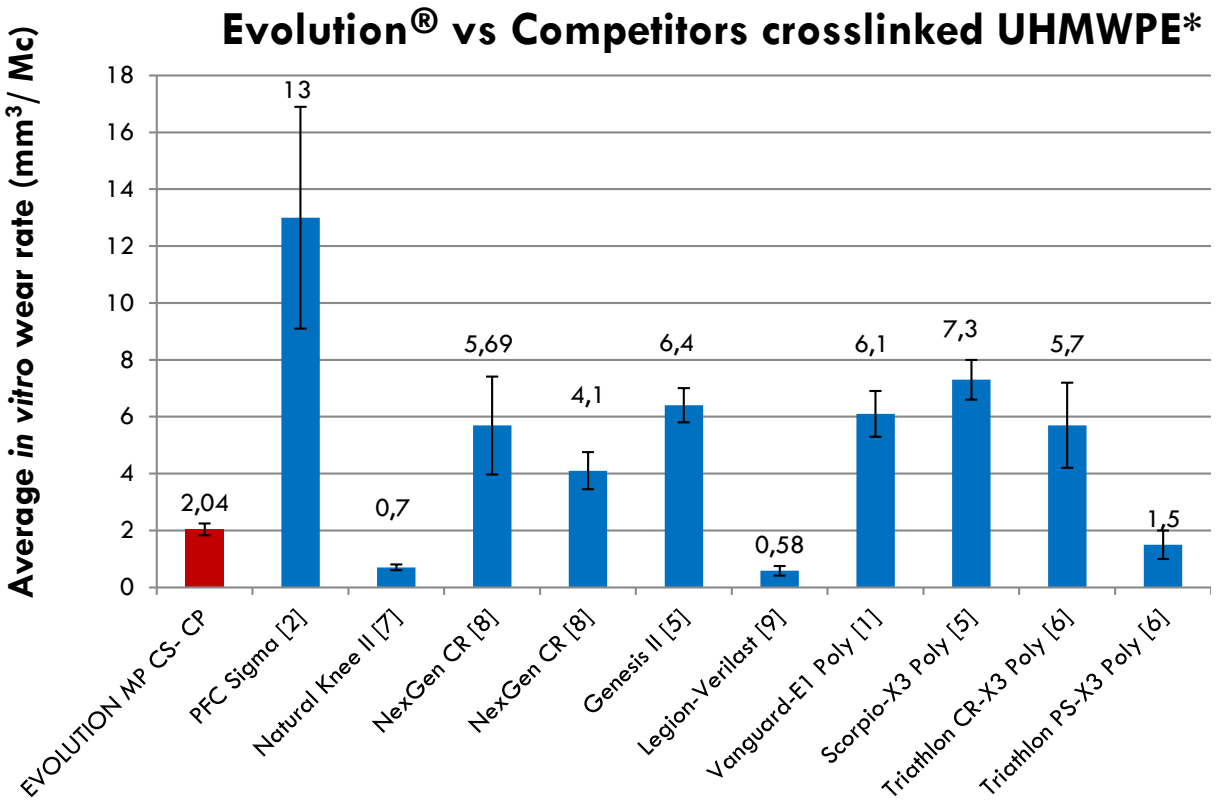
Evolution® Wear Rate



*Wear data retrieved from literature sources.
Testing was performed at different institutions and may affect results comparison.

In vitro wear rate results for the Evolution® have been reported to be similar or lower than 70% of other TKR systems with crosslinked UHMWPE, suggesting that implant design may play a larger role in TKR debris generation than tibial insert materials.[5]

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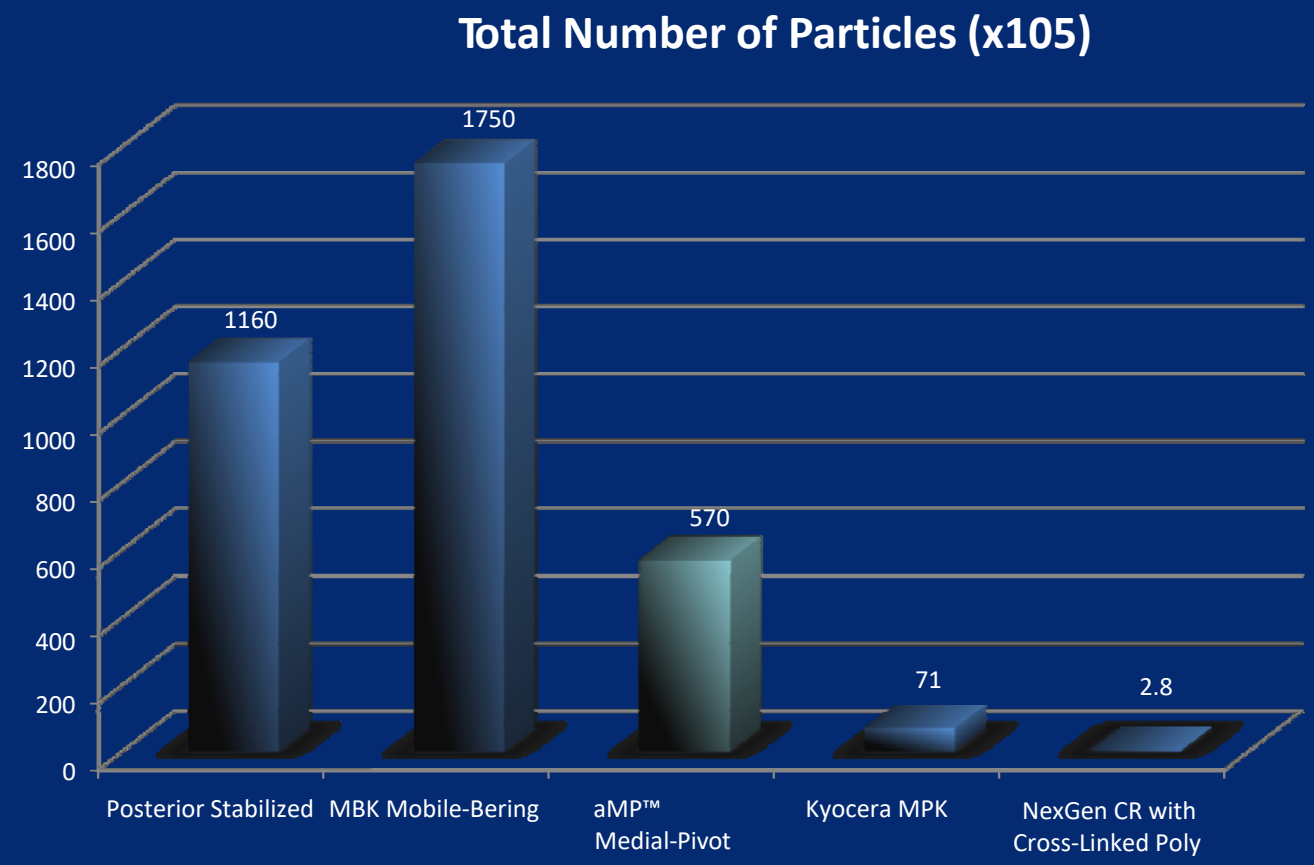
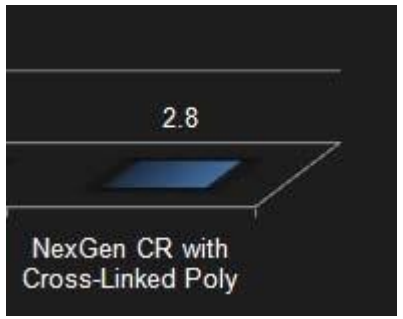
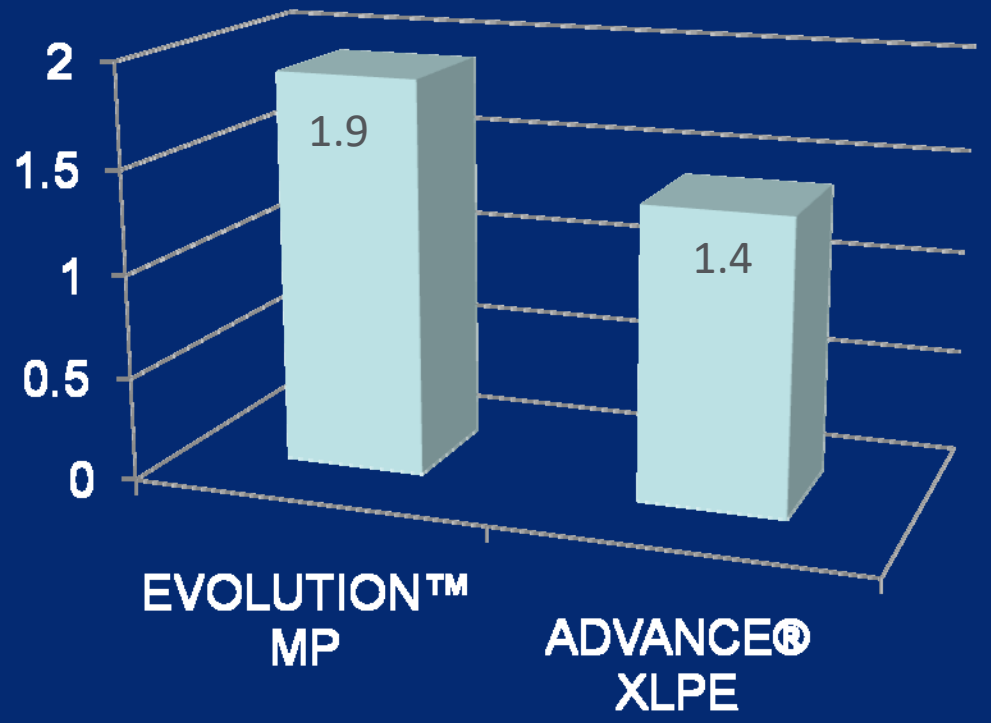
Wear Rates



Data presented in JBJS in November 2009. Shows that outside crosslink aMP™ Medial-Pivot has the lowest wear available in the US

Wear Rates

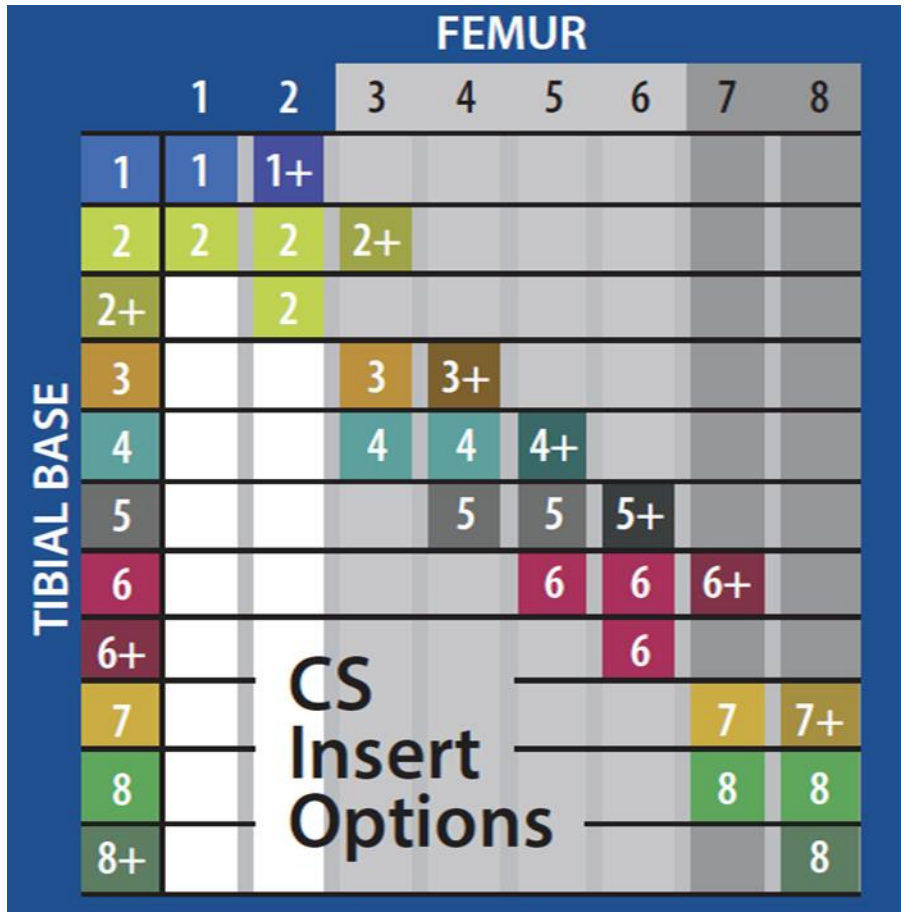


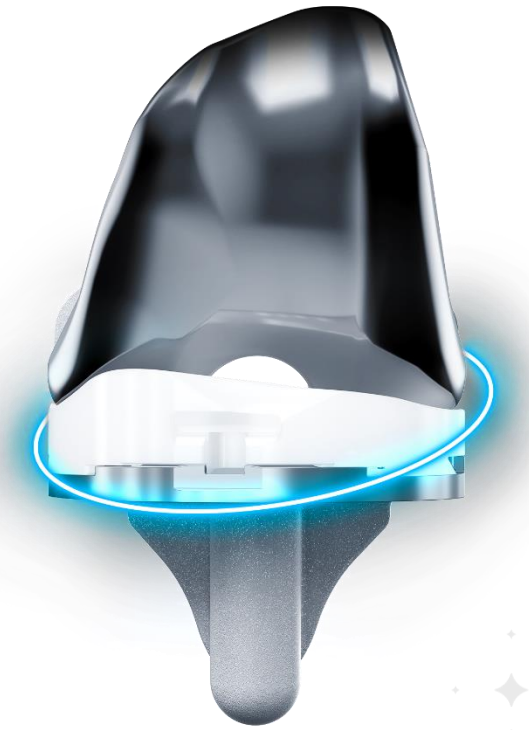


Take home message

DURAMER® non-XLPE Polyethylene has comparable wear rates to competitive XLPE designs without sacrificing mechanical properties

Evolution® Interchangeability Chart





Evolution®

MEDIAL-PIVOT KNEE SYSTEM

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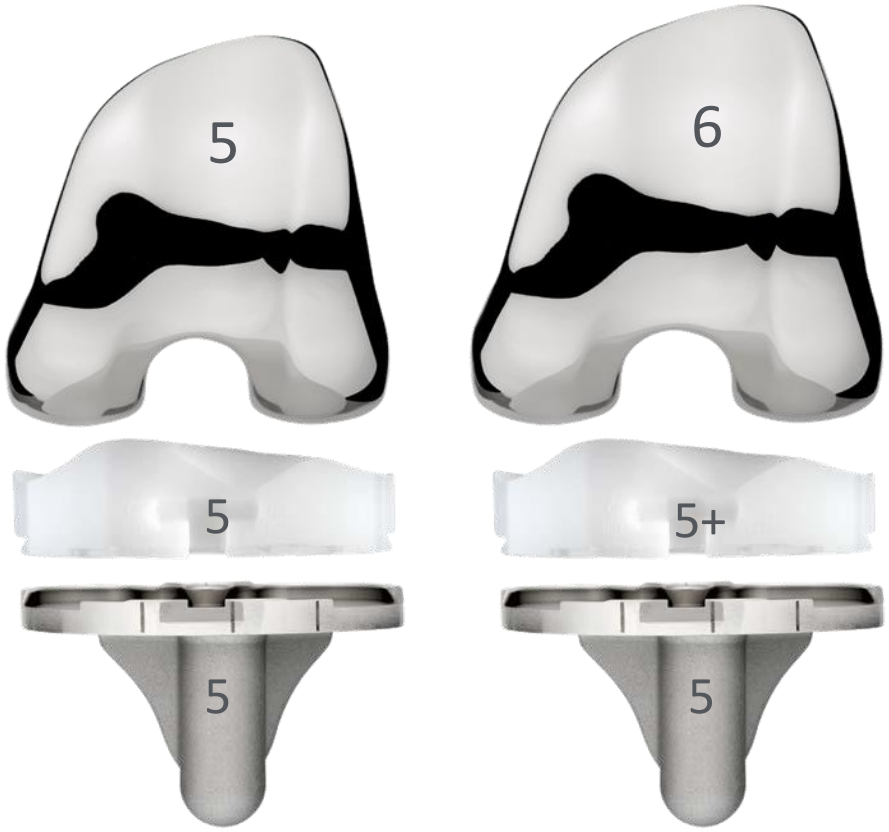
Evolution® CS Sizes

- 8 sizes
- Standard and Plus
- Plus Inserts for 1-up Femur

- 5 Std CS -> 4 or 5 Fem, 5 Tib
- 5 Plus CS -> 6 Fem, 5 Tib
  - Always can use one size smaller femur



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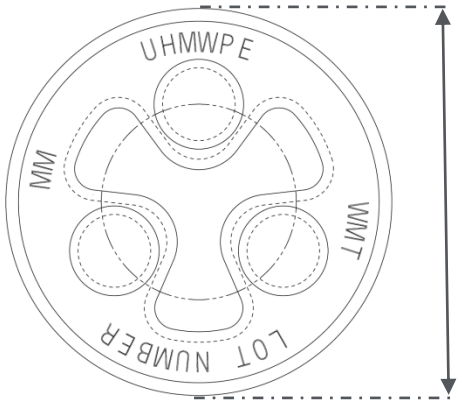
Evolution®

Patella

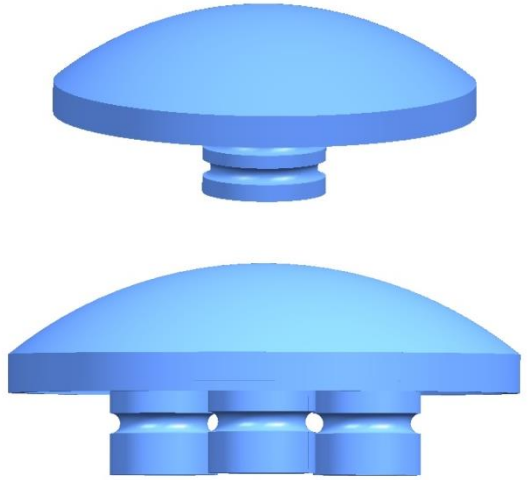
MicroPort

Evolution® Patella



- Spherical dome allows freedom of patellar tilt and rotation[4]
- Single or tri-pegs option
- Material: UHMWPE

SIZE (DIAMETER)	SINGLE PEG	TRIPEG	THICKNESS (mm)
25	-		7 or 9
26		-	8
28	-		7 or 9
29		-	8
32	-	-	8
35	-	-	8
38	-	-	10
41	-	-	11



Evolution®
MEDIAL-PIVOT KNEE SYSTEM

References

1. Benchtop data on file at MicroPort Orthopedics
2. J.D. Bobyn. JBJS [Br] 1999;81-B:907-14
3. Komisteck. CORR 410, 2003: 114-130
4. Bartel et al. “The effect of conformity, thickness and material on stresses in UHMWPE components for total joint replacement” JBJS 68A: 7, 1986
5. Parker A et al. “A medial-pivot total knee replacement system with conventional polyethylene exhibits similar or reduced wear to other designs with conventional or crosslinked polyethylene”, e-poster ISTA 2015, Wien

MicroPort

THANK YOU