



Evolution[®]
MEDIAL-PIVOT KNEE SYSTEM

Evolution[®] BioFoam[®] Tibial System
For Cementless Tibial Fixation

FIXATION WITH BITE[™]



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INTRODUCTION

Total knee arthroplasty has long been accepted as a means of relieving pain and providing patients with a long-term solution for osteoarthritis of the knee. However, with the advent of newer technologies in the orthopedic industry, TKA has subsequently become more readily demanded by a younger and more active patient population.¹ Knee systems must be able not only meet the short-term functional demands of this patient demographic, but must also provide an established and reliable cementless alternative with immediate stability and fixation.

The eMP™ Knee System with BioFoam® Cancellous Titanium is the next generation in cementless fixation. Alongside the Medial-Pivot Knee System's clinically demonstrated¹ design, built on the latest kinematic evidence of the natural stability and motion of the knee, BioFoam® Cancellous Titanium is uniquely suited to meet the challenges of today's patient population.² By offering surgeons excellent¹⁶ biologic fixation, this coating provides a true trabecular structure with enhanced rigid fixation^{17,18} to allow immediate apposition and an osteoconductive matrix.

RISING DEMANDS FOR CEMENTLESS FIXATION

Kurtz et al. reviewed the US National Inpatient Sample in 2006 and reported that approximately 70,000 TKA's were performed for patients under the age of 55 years. Extrapolating trends in the ever-growing demand of TKA, Kurtz et al. projected that **by 2030 there could be up to one million TKA's performed in the US for patients under 55 years.**¹ **Figure 1**

In 2014 Meehan et al. conducted a study from the California Patient Discharge Database of over 120,000 TKA's determining there is a **4.7 times greater risk of revision due to aseptic loosening in patients under 50 years of age.**³

Duffy et al. reported implant survivorship in **cemented TKA as low as 85% at 15 years in patients younger than 50 years.**⁴

As the number of younger and more active patients continue to rise, so has the demand for reliable cementless fixation.⁵ **Figure 2**

Figure 1

United States projections for primary and revision TKA¹

- Primary TKA
- Revision TKA

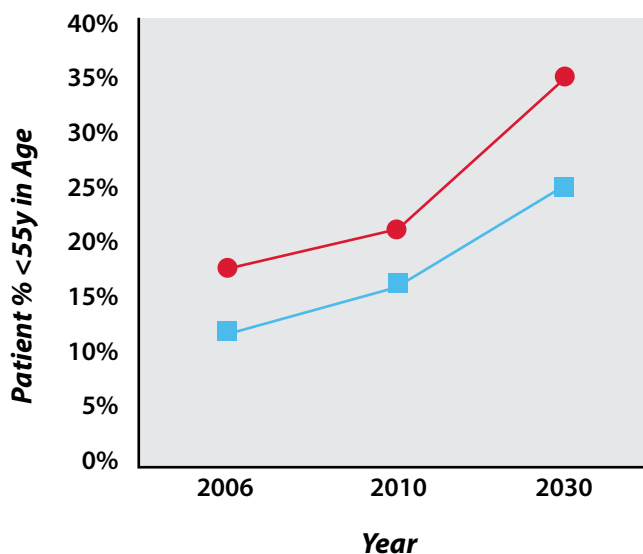
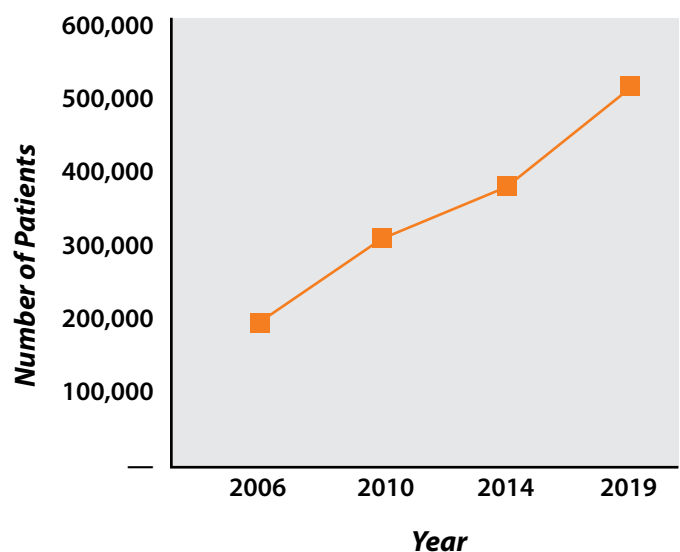


Figure 2

Global Projections for Cementless TKA,⁵ 2012

- Primary Cementless TKA



MICROPORT ORTHOPEDIC'S LEGACY IN CEMENTLESS TKA

Since the early 1980's with the launch of Dr. Leo Whiteside's cementless Ortholoc® I Knee System, MicroPort Orthopedics (formerly Wright Medical) has been a pioneer in the field of cementless TKA*.

The addition of BioFoam® Cancellous Titanium to the eMP™ Medial-Pivot Knee System is the next generation in cementless TKA designs.

1980

Ortholoc® I

- ▶ Used smooth pegs and a stem for early fixation.
- ▶ Porous tibial base undersurface for secondary fixation.

Ortholoc® II

- ▶ Tibial component fixation enhanced with four peripheral screws.⁶

1990

Advantim®

- ▶ Addition of pegs, screwholes, and cylindrical stem. Fins angled posterior for rotational stability.

Lacey

- ▶ Design features to allow bone apposition.
- ▶ No porous coating but approved for press fit use.

* Ortholoc®, Advantim® and Lacey are not to be considered predicates for the Biofoam® system

Advance® Medial-Pivot with BioFoam® Tibial System

- ▶ Highly porous cancellous titanium on modular tibial component.

Evolution® Medial-Pivot with BioFoam®

- ▶ Clinical success of Advance® BioFoam® continued into Evolution® tibial component.¹⁹
- ▶ Modular system offering customizable fixation.
- ▶ Screw and screwhole® bases available.

2000

2010



Evolution® Medial-Pivot
with BioFoam®

* Not available in EU.

INITIAL CLINICAL SUCCESS OF BIOFOAM® FIXATION

Initial and short-term fixation of cementless tibial implant is critical to early patient satisfaction and long-term biologic apposition. A recent 2015 study by Waddell et al demonstrated strong evidence early radiographic and functional outcomes.⁷

Early radiographic and functional outcomes of a cancellous titanium-coated tibial component for total knee arthroplasty

D. D. Waddell¹ • K. Sedacki² • Y. Yang² • D. A. Fitch²

STUDY HIGHLIGHTS

- 104 TKA's performed in 85 subjects by four surgeons;
- Subjects were evaluated preoperatively, and at 6, 12, and 24 months postoperatively;
- **KSS scores and maximum flexion were significantly improved at 12 and 24 months;**
- **No progressive radiolucencies;**
- Only 1 patient presented with a radiolucency around the tibial component.



*Advance® BioFoam®
Base without screwholes*

RSA DATA SUMMARY

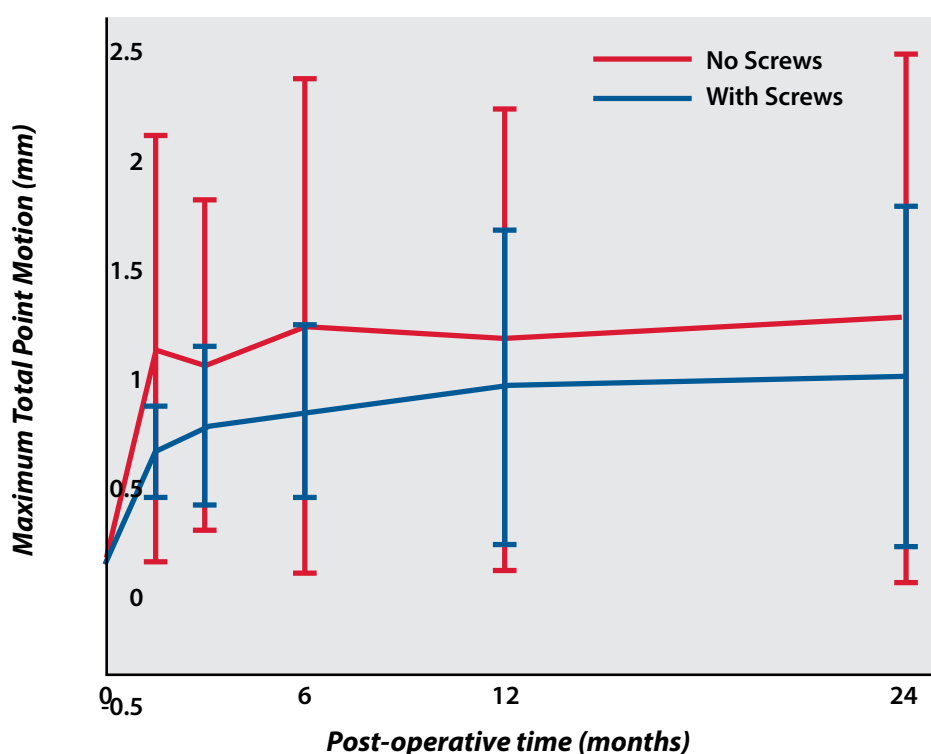
2 Year Clinical Report using RSA to Evaluate Fixation of the BioFoam® Advance® Total Knee Arthroplasty Components with and without Screw Augmentation⁸

Figure 3

REPORT HIGHLIGHTS

- 49 subjects were assessed at 6, 12, and 24 months;
- Pattern of initial fixation followed by stabilization;
- Low bone mineral density (BMD) changes over the two years;
- Migration was found to be not significantly different from the Trabecular Metal™ Tibial Component;
- Addition of screw fixation did not significantly improve fixation over the two years.

Figure 3



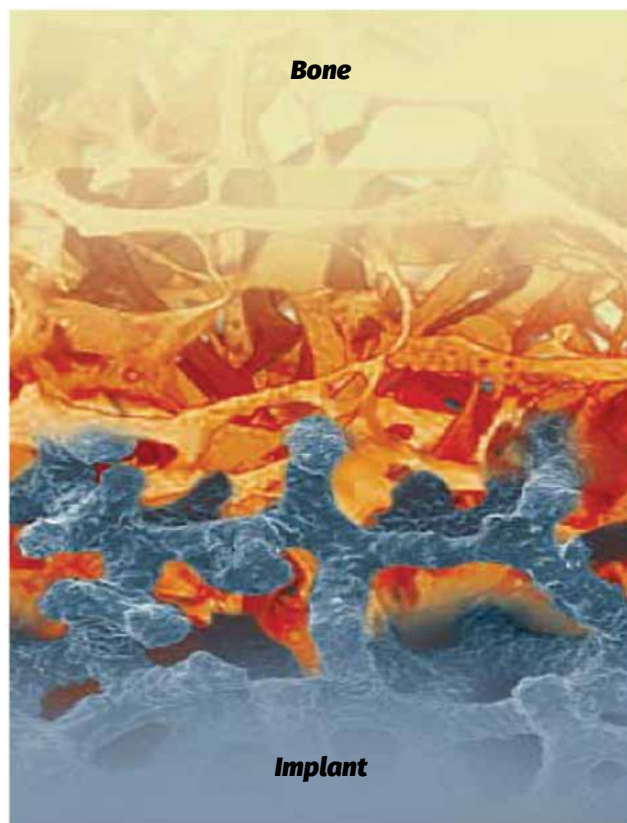
TRUE TRABECULAR ARCHITECTURE¹⁷

The structure of BioFoam® Cancellous Titanium acts as a biological scaffold designed to allow fast, fluid bone apposition¹⁶. Osteoblasts are able to cling to the course titanium struts; conducting angiogenesis through the interconnecting pores.⁹ These same biologic pathways allow the body to create a living implant/bone interface leading to implant survivorship.

LOOKS LIKE BONE, ACTS LIKE BONE¹⁷

In terms of pore/strut geometry, mechanical stiffness and bone apposition.

- 60-70% Porous¹⁶
- Full Interconnecting Porosity
- Manufactured from Commercially Pure (CP) Titanium Metal
- Osteoconductive Matrix



COMPRESSIVE STRENGTH

Cancellous or trabecular bone is composed of a network of rod- and plate-like elements that provide porous macrostructure for blood vessels and marrow. Trabecular bone accounts for only 20% of total bone mass, but has nearly ten times the surface area of compact bone.¹⁰

The structure of BioFoam® Cancellous Titanium resembles that of trabecular bone. The pore cell size averages 530µm and the diameter of interconnecting pores averages 200µm.¹⁶ Figure 4

The porosity is between 60-70%, demonstrating equivalent compressive and flexural strength to commercially available porous tantalum products. Figure 5

Figure 4

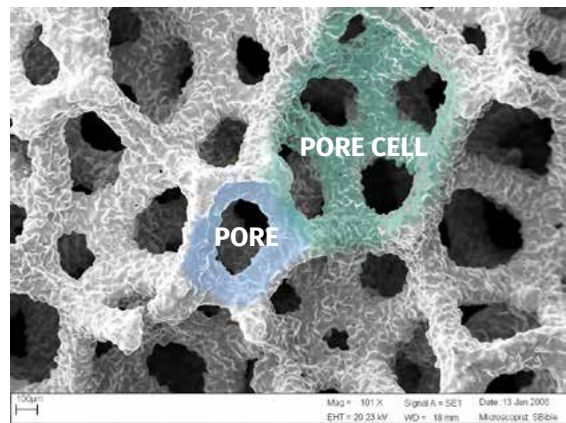
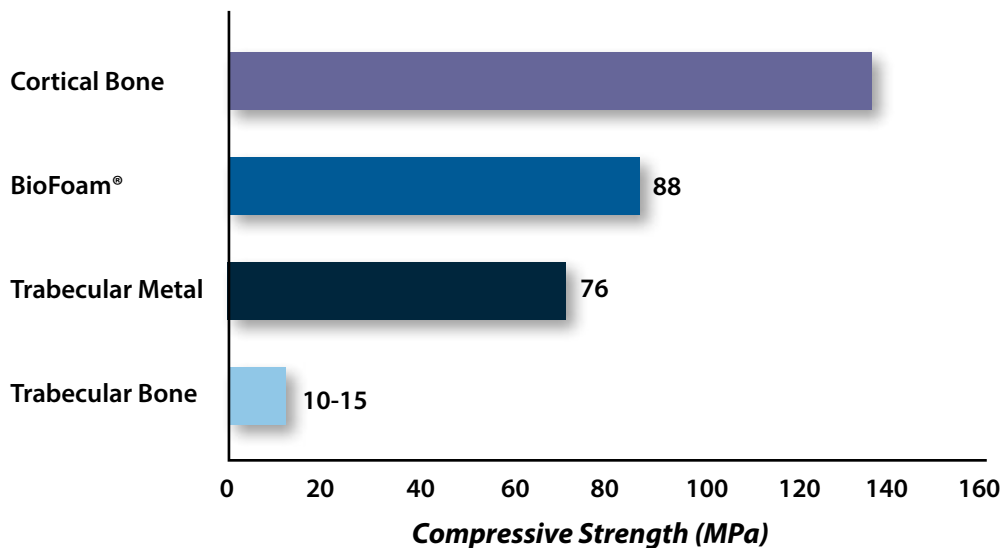


Figure 5

*Compressive Strength of BioFoam® Cancellous Titanium compared to Bone and Trabecular Metal*¹⁴⁻¹⁵*

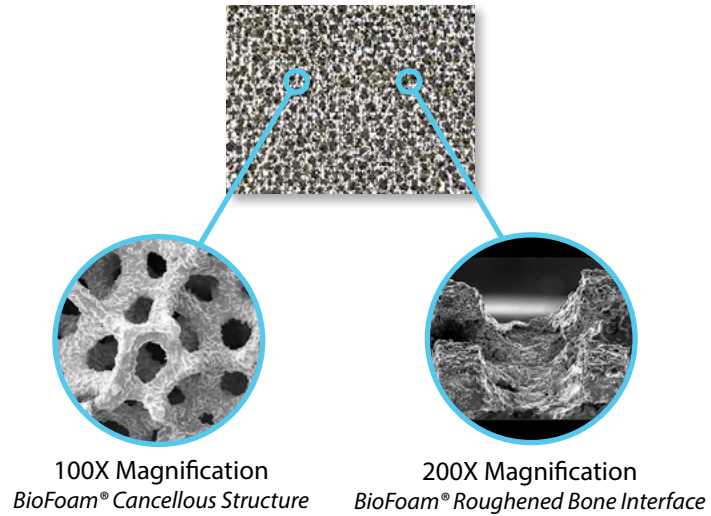


*Data not statistically significant due to small sample size.

FRICIONAL PROPERTIES

ROUGHENED TO ENHANCE IMMEDIATE FIXATION

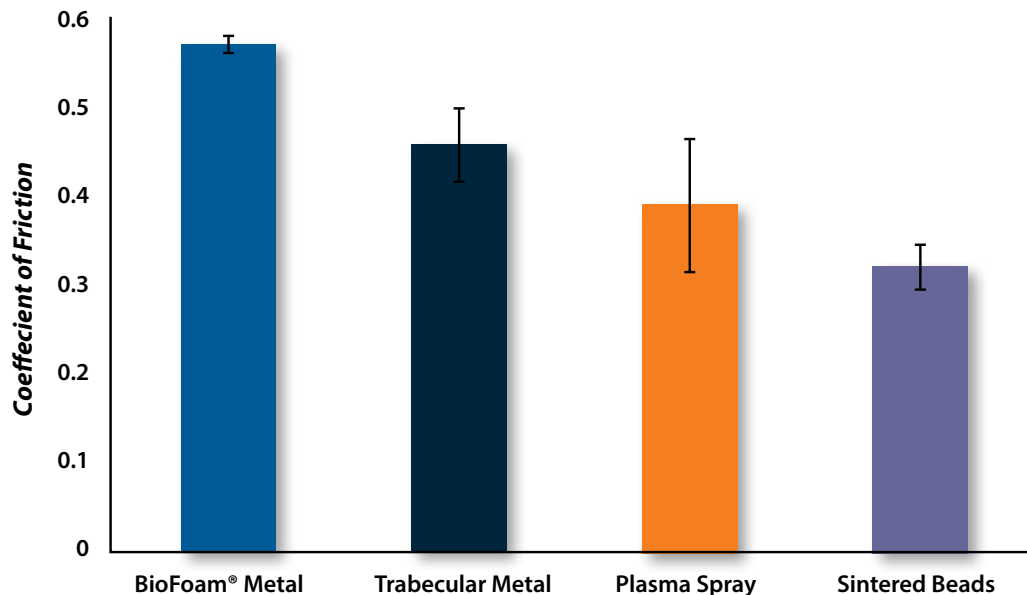
- Provides initial Scratch-fit;
- Coarse Struts “Bite” into bone.



HIGH COEFFICIENT OF FRICTION¹¹

- Coefficient of friction of BioFoam® cancellous titanium, Trabecular Metal™; (Zimmer Inc., Warsaw, IN), Titanium plasma spray, and Titanium porous sintered beads. Figure 6
- Ten artificial bones tested on a biaxial test machine;
- 65 N vertical load applied to contacting surfaces;
- Horizontal displacement was applied at a rate of 0.025 mm/sec.

Figure 6



ECONOMIC AND PROCEDURAL BENEFITS OF CEMENTLESS TKA'S

OR EFFICIENCY AND COST SAVINGS

- Kamath et al. reported an average 12 minutes less of tourniquet time with cementless fixation.¹²
- Shippert et al. reviewed time-dependent costs at 100 US hospitals and determined an average cost per minute of \$62.13

By extrapolating these examples and analyzing the savings generated by time gained, cementless TKA could save on average nearly \$750 per case.

NO CHANGE TO TECHNIQUE

- Cemented and cementless femoral and tibial preparation utilizes the same instrumentation with screwless fixation.



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MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN USA 38002
866 872 0211

www.microportortho.com

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