

The Bodycad Unicompartmental Knee System

# NEXT GENERATION PERSONALIZED RESTORATION TECHNOLOGY: THE BODYCAD UNICOMPARTMENTAL KNEE SYSTEM

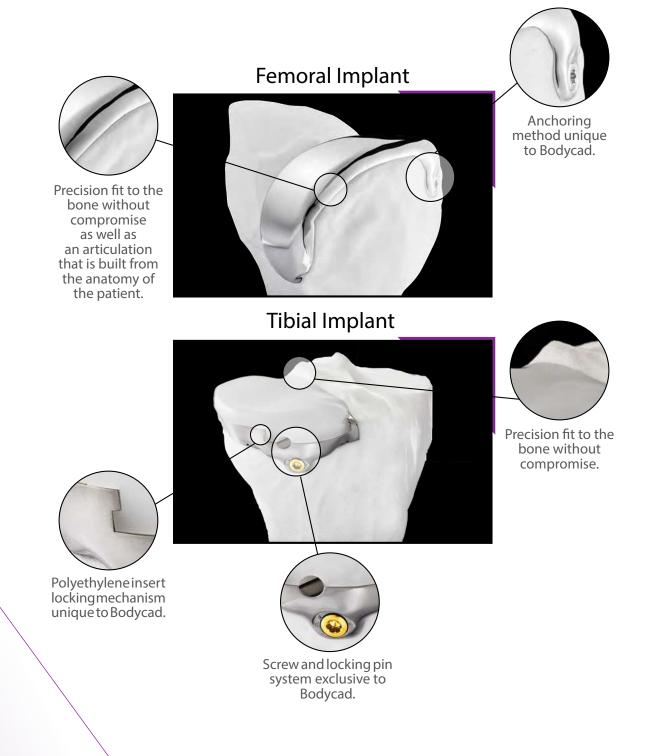
#### The First Truly Patient-Specific Implant Design

Introducing Bodycad's revolutionary Unicompartmental Knee System, designed to optimize personalized restorations of the patient's unique anatomical features and kinematics. The BUKS is based on proprietary 3D rendering of medical images of the patient's anatomy. Recent studies of Unicompartmental Knee Arthroplasty (UKA) have demonstrated favorable outcomes, shorter hospital stays versus total knee arthroplasty, and lower 30-day readmissions.<sup>5,6</sup> In addition, there is clinical evidence that modest improvements in implant survivorship for younger patients will increase the cost-effectiveness of the treatment.<sup>7</sup> The BUKS is designed to advance and improve upon this body of clinical evidence.



#### The BUKS Optimization

- Designed to preserve bone and soft tissue
- Minimizes bone loss
- Includes Instrumentation that is patient specific, intuitive and accurate
- Provides an unconstrained design for a full range of motion
- Engineered to fit the patient's anatomy and kinematics
- Has the potential for improved clinical results and patient satisfaction
- Procedure in a box provides potentially greater efficiency and quality improvements to all stakeholders
- Offers a unique and accurate resection solution which reduces issues related to saw blades



# THERE'S NOTHING STANDARD ABOUT IT

#### It Starts with Imaging

Imaging technology is evolving and innovating all the time. MRI and CT access and utility is becoming more abundant across the globe. Bodycad believes that we need to be adaptable to the latest imaging modalities for the restoration. Bodycad's proprietary imaging algorithms allow us to rapidly and automatically produce a 3D anatomic model. We have the capability to adapt and incorporate CT, MRI and Long Standing AP Radiograph data into our PREP. Our preferred imaging modality are MRI and a Long Standing AP Radiograph but we do have the capability to utilize CT and MRI interchangeably. To assist surgeons and imaging centers with providing Bodycad with the best quality images

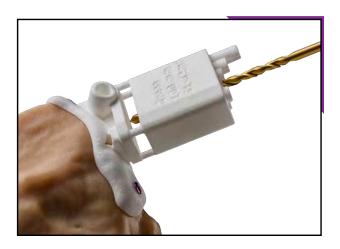
Bone model imaging		MRI			СТ		
Alignment imaging		None	Long Standing AP Radiograph	Full leg CT	None	Long Standing AP Radiograph	Full leg CT
Mechanical axis angle Hip knee ankle angle			•	•		•	•
MAD Mechanical axis deviation			•	•		•	•
Varus / valgus	Relative	-	•	•		•	٠
	Absolute			•			٠
Posterior slope	Relative		•	•		•	٠
	Absolute		•	•		•	•

we have the Bodycad Unicompartmental Knee System Imaging Guide as a reference.

## Better Precision and Accuracy

The BUKS is designed with precision in mind. Evaluation of the precision and accuracy of implanting the BUKS tibial and femoral components in cadaver knees showed it to be the most precise of any current or traditional method. The Bodycad study reviewed 10 cadaver cases performed by three surgeons of varying levels of experience with UKA. Reported implant positioning accuracy results show that using conventional, robotic and navigated methods is not as accurate as Bodycad's method on cadaveric models.<sup>11,12, 13, 14, 15</sup>

	Freehand Technique (Cobb et al.2006)	Robotic Assistance (Cobb et al.2006)	Robotic Assistance (N.J.Dunbar et al.2012)	Bodycad Cadaveric Accuracy study
Translation error (mm)	2.2	1.1	1.3	0.9
Rotation error (deg)	5.5	2.4	2.4	2.2



Our proprietary, novel method of bone resection uses a patient-specific drill guide that provides for surgeon control of depth and accuracy. This reduces adverse issues associated with saw blade deflection, positional errors, and heat generation.<sup>16,17,18,19,20</sup> One important factor in achieving precise placement of the BUKS is the provision for adjunctive fixation for both the tibial and femoral components. The final step in implanting the BUKS is securing the bone screws, which increases bone cement compression and insures complete and accurate seating in accordance with the surgical plan.



#### Clinical Outcomes for Personalized Arthroplasty

A personalized restoration has the potential for improved clinical results versus off-the-shelf products. A recent multi-center study of 120 custom UKA knees found improved range of motion, higher functional outcome scores, and lower pain scores. Patient satisfaction was high, with 99% of patients saying they were satisfied – 89% were very or extremely satisfied with the results of the procedure and 89% said the movement of the knee felt natural. Two years after surgery, only 2 patients had undergone revision for tibial loosening.<sup>1</sup> In a quote from an orthopaedic surgeon's in-press publication for The Journal of Arthroplasty, the following statement was made : "Patients really feel more stable with their custom knee replacements especially when they do activities like bending or walking down stairs which some patients with off-the-shelf knee replacements have difficulty with due to mid-flexion instability."<sup>2</sup>

#### Potential Quality and Economic Improvements for Personalized Arthroplasty

The potential for quality and economic improvements for personalized restorations versus off-the-shelf solutions has started to emerge in the clinical body of evidence. Reduced blood loss and swelling, decreased length of stay, and discharge optimization may lead to a better economic case for patient-specific solutions. One study concluded that the, "differences in blood loss and swelling may be explained by the lack of femoral canal preparation and the ability to completely cover all cut bone surfaces in the customized TKR group." <sup>3</sup> Another study documented a decrease of 1.1 days Length of Stay (LOS), a 36% increase in the 24hr discharge rate, and a higher percentage of patients discharged directly to home versus off-the-shelf solutions.<sup>4</sup> These quality improvements should translate to considerable upgrades in episode of care efficiencies and cost effectiveness.

#### Anatomical Fit and Bone Preservation

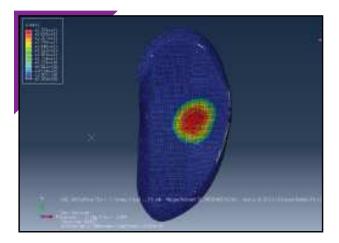
The titanium tibial baseplate of the BUKS fits and covers the bone resection. It has recently been documented that a custom UKA provides significantly greater cortical rim surface area coverage compared to off-the-shelf implants: 77% versus 43% medially and 60% versus 37% laterally. In addition, significantly less cortical rim overhang and under coverage were measured.<sup>8</sup> This increased coverage of resected bone may lead to decreased blood loss. The matching of the tibial baseplate to resected bone is inherent to the Bodycad design and manufacturing process, which translates into optimal coverage all of the time. The femoral component is also designed to match closely the anatomy of the patient's femur. The femur is prepared by denuding the surface of cartilage and osteophytes, keeping bone removal to a minimum. This is important because studies have shown that a femoral component overhang of more than 3mm nearly doubles the odds of clinically important knee pain two years after total knee arthroplasty.<sup>9</sup>





## Natural Kinematics

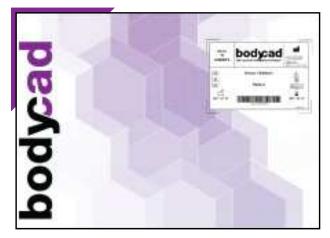
Bodycad's solution is to re-establish the normal kinematics of the patient's articulation by using a proprietary algorithm to best match the patient's movement and anatomy. The Bodycad PREP Tech uses this information to develop an articulation specific to each patient. The results of one study postulate that knees with patient-specific implants generate kinematics more closely resembling normal knee kinematics than standard knee designs.<sup>10</sup> Each and every Bodycad kinematic solution undergoes finite element analysis (FEA) to validate the design kinematics and contact stresses on the surface of the polyethylene insert. The polyethylene insert is available in 6mm to 10mm thicknesses in 1mm increments giving the surgeon flexibility for proper balancing of the knee.





#### Efficient Surgical Work Flow and Lower Asset Intensity

A personalized arthroplasty greatly reduces inventory of instruments, eliminates implant inventory, and reduces costs of reprocessing instruments and unused implants because the delivery comes in a self-contained kit, a procedure in a box. This procedure in a box provides for all the patient-specific instruments and implants. Traditional off-the-shelf products require a significant amount of asset intensity and human resources to ensure all components and instruments arrive on time into the operating room theatre, and instruments are cleaned and prepared for the next surgery. The reduction of asset intensity has the potential to increase the efficiency of the work flow in the hospital and operating theatre. These reductions may lead to improved cost benefits for all stakeholders. The BUKS kit is better suited for procedures performed in an out-patient surgery center, as well as for the bundled care approach, as it drives overall efficiency for the episode of care.



Procedure in a Box



Traditional Orthopaedics

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