why iUni®?

CLINICAL RATIONALE FOR A PATIENT-SPECIFIC UNICOMPARTMENTAL KNEE REPLACEMENT SYSTEM

CONFORMIS

Key elements needed for a successful UKA:

The right patient, a highly reproducible procedure, and the right implant.

UKA can have favorable results vs. off-the-shelf TKA

Better function and ROM

UKA patients have better range of motion and function.[1]

PKR tibial axial rotation is comparable to native knees, while TKR knees show a significant difference.[2]

PKR patients have fewer problems bending their knee.[3]

Patients prefer their PKR

In a study of 23 bilateral patients, >50% prefer their PKR implant to their TKR; none preferred their TKR.[4]

In another study of 23 bilateral cases, patients reported PKR implants provide better early flexion, higher ROM and a more natural feel.[5]

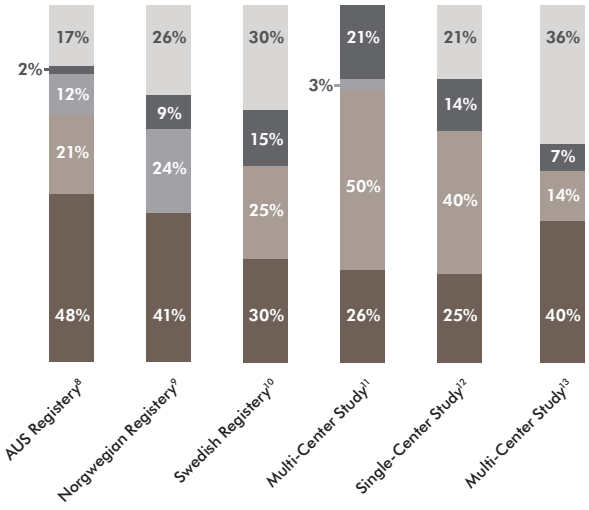
Survivorship can be comparable

PKR patients have better early function and maintain those advantages at 15 years vs. TKR, with no disadvantage on durability.[6]

In a prospective study of 62 consecutive fixed bearing PKR procedures, survivorship was at 98% after 10 years.[7]

UKA can require revision

Recent results from national registries and other multi-center studies reporting on causes of revision from over 6,500 primary fixed bearing UKA.



Disease Progression	**14-50% (Range)**
Implant loosening	**25-48%**
Pain	**NS-24%**
Poly wear	**2-21%**

- Other
- Poly wear
- Pain
- Disease Progression
- Loosening

The right UKA implant system must maximize the chance of procedural success and must minimize the chance of failure.

Key drivers of a successful UKA procedure

Preventing failure from implant loosening and subsidence

Preventing malpositioned components and malaligned (varus/valgus) tibial resections

24% of loosening is attributed to femoral and tibial component malposition or malaligned tibial resections.[14]

Maximizing tibial coverage

Poor tibial coverage, i.e. underhang, has been attributed to increased risk of tibial component loosening and subsidence.[15]

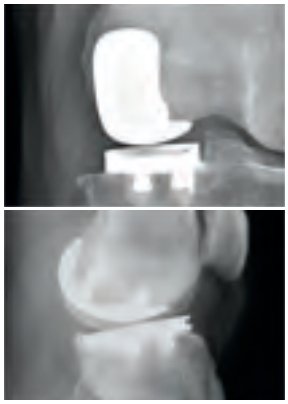
Preventing residual pain

Minimizing tibial overhang

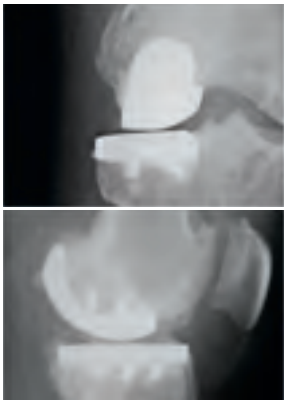
≥3mm of tibial overhang significantly increases risk for residual pain. In addition, overhang can result in putting increased stress on the MCL.[16]

Preventing patella track impingement

Studies have reported 28% of patients have patella impingement and increased pain while on stairs and rising from chairs.[17]



Off-the-shelf UKA system



ConforMIS iUni G2

Minimizing disease progression and poly wear

Achieving proper mechanical axis alignment

Studies have reported that 'slightly under-corrected' UKAs result in less long-term progression of disease and poly wear.[18]

Achieving optimal function

Optimizing joint function and knee kinematics

It has been proposed that preservation of the joint line and the sagittal J-curve provide opportunity to preserve normal joint function, with potential to result in more normal knee kinematics.[19]

Importance of tibial fit

Impact of Tibial Overhang

Overhang of ≥3mm has been shown to be clinically significant

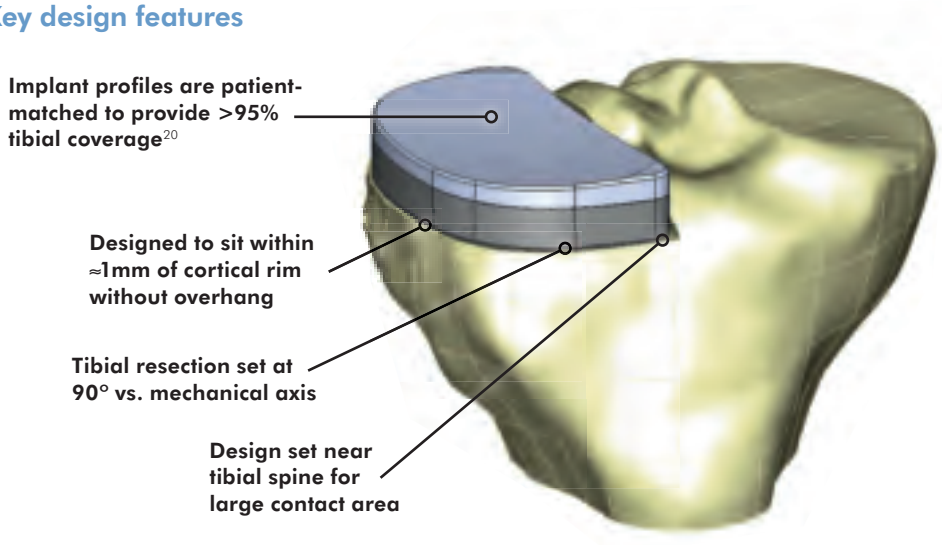
- A study of 160 Oxford UKR patients demonstrated at 5 years post-surgery that 9% of patients have major overhang (≥3mm) and significantly worse Oxford knee scores and pain scores.[15]
- In a study with six cadavers, researchers identified that tibial trays with ≥3mm of anterior overhang result in significantly higher loads on the MCL.[16]

9%
of patients have ≥3mm overhang

with significantly worse knee and pain scores[15]

iUni G2 solution: Unparalleled tibial fit

Key design features



Impact of Tibial Underhang

Multiple publications have associated underhang with tibial loosening and subsidence

- Chau, et al., stated in UKA that "…concern with an under-hanging tray is that the load is transmitted primarily through the relatively weak cancellous rather than the stronger cortical bone. This may increase the risk of tibial component subsidence and loosening."[15]
- Swienckowski, et al., stated that in UKA "…cortical support is essential for the tibial components to avoid subsidence."[21]
- Fitzpatrick, et al., in a comparison of UKA designs, stated that "Unicompartmental components [have] less cortical bone available to the implant, increasing the risk of subsidence and overhang."[22]

Off-the-shelf UKA offers limited options

Off-the-shelf UKA system

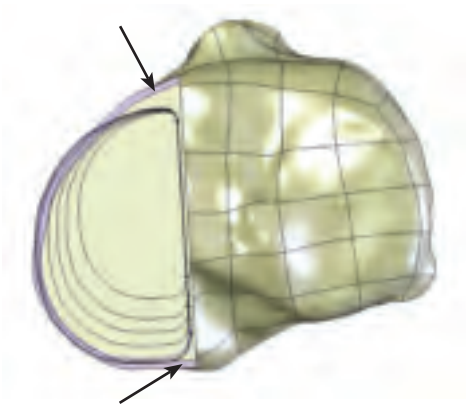
Typical configurations

- Offered in a single shape
- Come in a set range of sizes
- Surgeon may need to prioritize either A/P or M/L fit

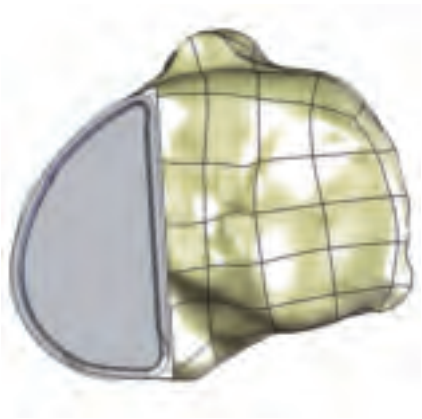
iUni G2 solution: Optimal coverage

Key design features

- Each tibial tray and poly is created specifically for each patient
- Designed for optimal fit



Off-the-shelf size options[23]
Size 5 in bold



ConforMIS iUni G2[23]

Highlighted area in pink represents 1.5mm cortical rim thickness[22]

Importance of femoral fit

Impact of Femoral Fit on Patient Pain

Malaligned femoral components can cause loosening

A study of 47 UKA failures during the period of 2000-2008, identified that 16% were attributed to femoral malposition or sizing issues.[14]

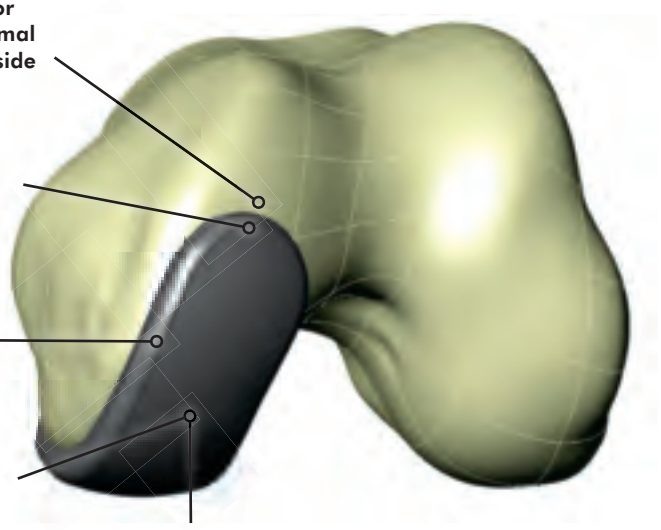
Patella impingement can cause increased pain

A study of 99 UKA knees at mean 14 year follow-up identified that 28% had patella impingement and increased pain, typically when on stairs and rising from chairs.[17]

16%
of failures attributed to
femoral malposition or sizing issues[14]

iUni G2 solution: Unparalleled femoral fit

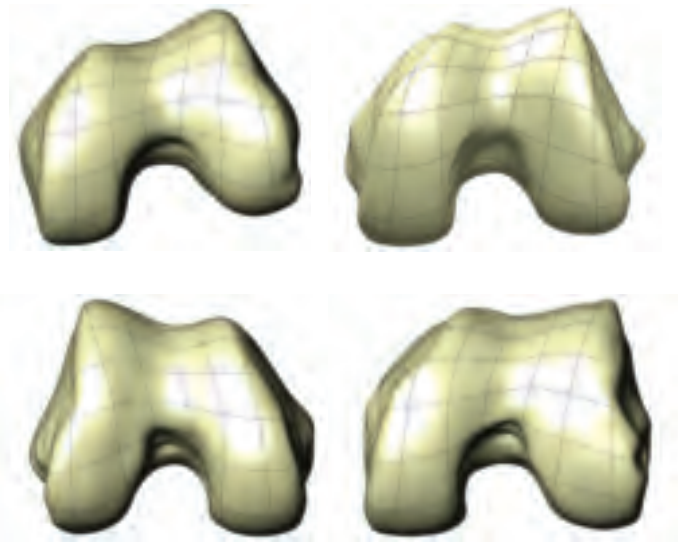
Key design features



Impact of Femoral Fit on Function

Anatomy of the femur varies

Femoral condyles have an asymmetrical shape and vary from patient to patient.[24]



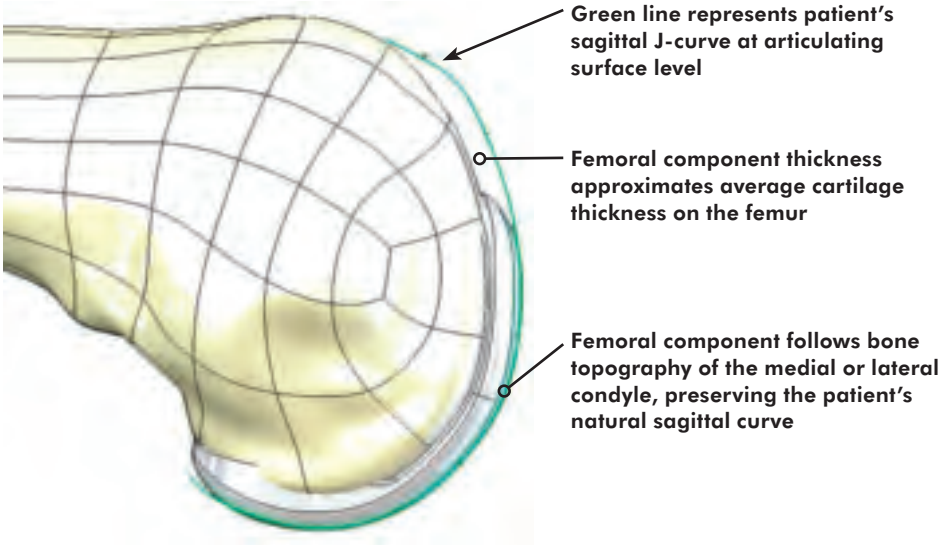
Off-the-shelf systems offer limited options

A typical UKA system has the following femoral component configuration.

- A single shape
- A set range of sizes

iUni G2—an opportunity to maintain patients' anatomy

Key design features



Impact of implant design on long-term

Mechanical Axis Alignment Can Impact Disease Progression and Polyethylene Wear

Slight 'undercorrection' can provide optimal results

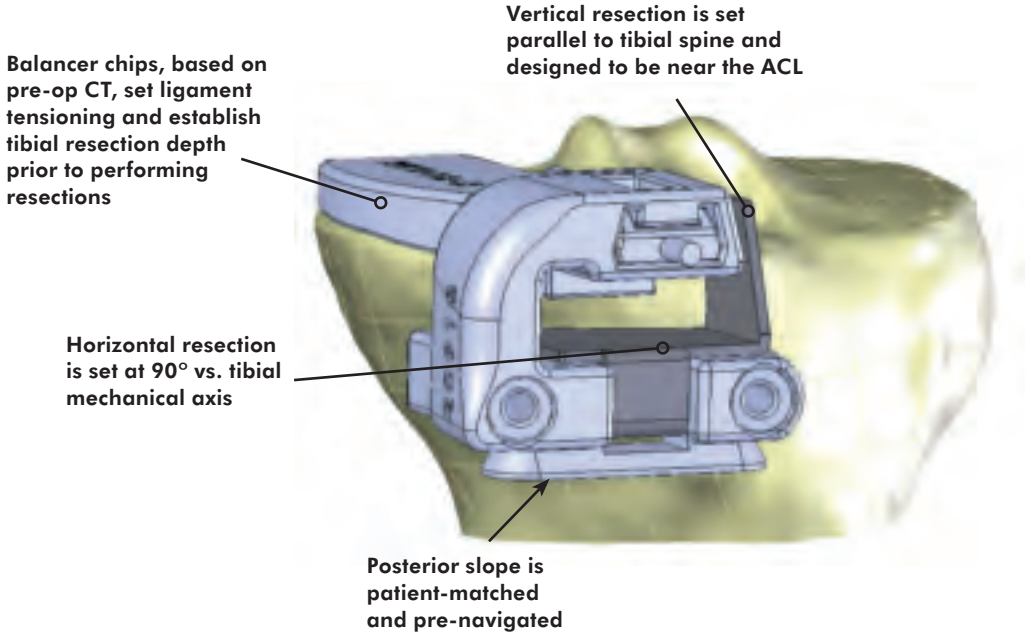
- Studies have shown 'slight undercorrection' (e.g. between 171° to 179° post-operative varus angle in a medial UKA) can provide optimal results.[25]
- A follow-up study of 58 medial uni knees with mean 15 year follow-up, reported that 'overcorrected' knees (e.g. post-operative valgus angle in a medial UKA) had 92% more cartilage loss in the opposite condyle.[25]
- In the same study, 'significantly undercorrected' knees (e.g. ≤170° post-operative varus angle in a medial UKA) had 50% more poly wear vs. 'slight undercorrection.'[25]

Slight under-correction

provides optimal axis alignment

iUni G2 solution: Intra-operative soft-tissue balancing

Key design features



survivorship

Other Factors Impacting Polyethylene Wear

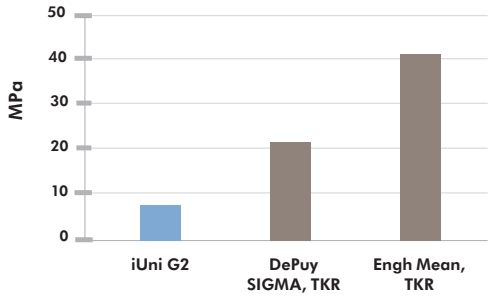
Contact stress can impact topside wear

Reducing contact stress has been shown to reduce wear on the articulating surface of the poly insert.[26]

Poly/tray micro-motion and undersurface can impact backside wear

Studies have shown micro-motion can cause wear. In addition, examinations of explanted inserts have identified the poly undersurface as a second source of wear.[27, 28]

Micro-motion Index Comparison
Standard[29,30] vs. ConforMIS G2 implants[31]

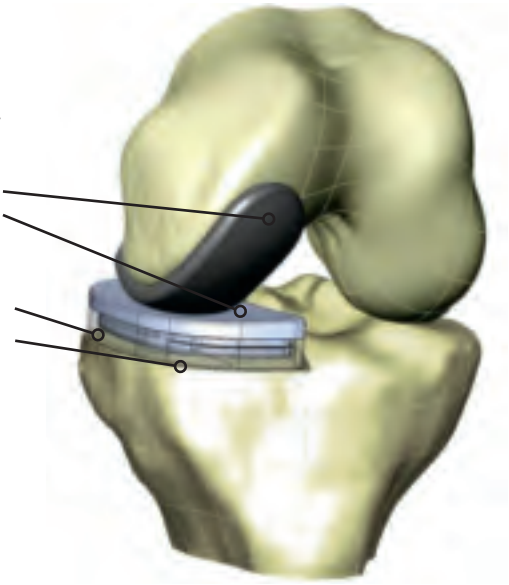


iUni G2 solution: Engineered femoral and tibial components

Key design features

Femoral component and poly surface has a matched 1-to-5 ratio of increased contact area and less contact stress[26]

Interference fit of tibial insert minimizes micro-motion and, combined with the highly finished inside pocket, potential for backside wear[31]



So, why iUni?

FIT

- Individualized fit that virtually eliminates overhang and sizing compromises
- Designed to follow the contour of each patient's anatomy
- Tibial tray designed for maximized cortical rim coverage and proper rotational alignment

SHAPE

- Individualized medial or lateral femoral J-curves
- Wear optimized by matching femur and tibial inserts for maximized surface contact area

SIMPLE SURGICAL TECHNIQUE

- Reduced number of intra-operative decisions such as implant sizing and rotation
- Mechanical and rotational alignment are pre-determined in the individualized iJig instrumentation
- iView surgical planning images for proper iJig placement and detailed resection values

OR EFFICIENCIES

- Simplified set-up and tear down
- Minimal instrumentation required
- Disposable system delivered in a single pre-sterilized box
- Reduced sterilization and inventory costs

references

1. Rougraff B, et al.; "A comparison of tricompartmental and unicompartmental arthroplasty for the treatment of gonarthrosis"; Clin Orthop Relat Res; Dec 1991; Vol. 273: pp. 157–164
2. Patil S, et al.; "Can normal knee kinematics be restored with unicompartmental knee replacement?"; J Bone Joint Surg AM; Feb 2005; Vol. 87(2): pp. 332-338
3. Lastad-Lygre S., Pain and function in patients after primary unicompartmental and total knee arthroplasty; J Bone Joint Surg Am; Dec 2010; Vol. 92(18): pp. 2890-2897
4. Dalury D., et al.; "Unicompartmental knee arthroplasty compares favorably to total knee arthroplasty in the same patient"; Orthopedics; Apr 2009; Vol. 32(4): pp. 253
5. Laurencin C; Unicompartmental versus total knee arthroplasty in the same patient: A comparative study; Clin Orthop Relat Res; Dec 1991; Vol. 273: pp. 151-156
6. Newman JH, et al.; Unicompartmental or total knee replacement? 15 year results of a prospective, randomized controlled trial; J Bone Joint Surg Br; Jan 2009; Vol. 91-B(1): pp. 52-57
7. Berger RA, et al.; "Results of Unicompartmental Knee Arthroplasty at a Minimum of Ten Years of Follow-up"; J Bone Joint Surg Am; May 2005; Vol. 87(5): pp. 999-1006
8. Davidson, D., et al.;" Hip and Knee Arthroplasty Annual Report; National Joint Replacement Registry; Australian Orthopaedic Association; 2011; P112
9. Furnes, O., et al.; "Failure Mechanisms After Unicompartmental and Tricompartmental Primary Knee Replacement with Cement"; JBJS; Mar 2007; V89-A:N3;PP519-525; doi:10.2106/JBJS.F.00210
10. Sundberg, M, et al.; "Annual Report 2011 The Swedish Knee Arthroplasty Register; Dept. of Orthopedics, Skåne University Hospital, Lund; 2011; Part II, P23
11. Gioe, T., Et. Al.; "Analysis of Unicompartmental Knee Arthroplasty in a Community-Based Implant Registry"; CORR; Nov 2003; Number 416, pp. 111–119; DOI: 10.1097/01.blo.0000093004.90435.d1
12. Citak, M., et. al.; "Failed Unicompartmental Arthroplasty : Analysis of 471 Cases"; AAHKS Annual Meeting; Nov 2012; Poster #58
13. Epinette, J., et al.; "UKA knee arthroplasty modes of failure: Wear is not the main reason for failure: multicentre study of 418 failed knees"; Orth& Traum: Surgery & Research (2012) 98S, S124—S130
14. Fehring, TK, et al.; "Early Failures in Unicondylar Arthroplasty"; Orthopedics; Jan 2010; V33: Issue 1:pp.1124-10
15. Chau, R., et al.; "Tibial component overhang following unicompartmental knee replacement - does it matter?"; The Knee; 2009; V16:pp. 310-313
16. Gudena, et al., "A Safe Overhang Limit for Unicompartmental Knee Arthroplasties Based on Medial Collateral Ligament Strains: An In Vitro Study"; JOA; 2012
17. Hernigou, P, et al.; "Patellar impingement following unicompartmental arthroplasty"; JBJS(Am); July 2002; V84-A(7); pp. 1132-1137
18. Hernigou, Ph., et al; "Alignment Influences Wear in the Knee after Medial Unicompartmental Arthroplasty"; CORR; Jun 2004; V423:pp.161–165
19. Fitz, W.; "Unicompartmental Knee Arthroplasty with Use of Novel Patient-Specific Resurfacing Implants and Personalized Jigs"; J Bone Joint Surg Am; 2009; V91-1:P69-76
20. ConforMIS data on file
21. Swienckowski, J, et al.; "Unicompartmental Knee Arthroplasty in Patients Sixty Years of Age or Younger"; JBJS;2004
22. Fitzpatrick, et al.; "Statistical design of unicompartmental tibial implants and comparison with current devices"; The Knee; 2007; V14:pp. 138–144
23. ConforMIS data on file
24. Mensch, et al.; "Knee morphology as a guide to knee replacement"; Clin Orthop Relat Res; Oct 1975; V112 pp. 231:241
25. Hernigou, Ph., et al; "Alignment Influences Wear in the Knee after Medial Unicompartmental Arthroplasty"; CORR; Jun 2004; V423:pp.161–165
26. Steklov N, Slamin J, Srivastav S, D'Lima D. Unicompartmental Knee Resurfacing: Enlarged Tibio-Femoral Contact Area and Reduced Contact Stress Using Novel Patient-Derived Geometrics. The Open Biomedical Engineering Journal. February 2010, 4, 85-92
27. Parks,, NL., et al.; "Modular Tibial Insert Micro-motion"; CORR; Nov 1998; V356: pp.10–15
28. Wasielewski, RC, et al: "Tibial insert undersurface as a contributing source of polyethylene wear debris"; CORR; Nov 2002; V345: pp. 53-59
29. J. Slamin. A new cobalt chrome tibial tray and moderately cross-linked tibial insert is added to the PFC Sigma modular knee system, Slamin, DePuy Orthopaedics, Inc.; Technical Paper, 2005
30. G. Engh, Tibial baseplate wear; a major source of debris with contemporary modular knee implants, AAOS, 67th Annual Meeting—Scientific Exhibit, Orlando, Florida.
31. Steklov N, Chao N, Srivastav S. Patient-Specific Unicompartmental Knee Resurfacing Arthroplasty: Use of Novel Interference Lock to Reduce Tibial Insert Micro-motion and Backside Wear. The Open Biomedical Engineering Journal. July 2010, 4, 151-156

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CAUTION: USA federal law restricts this device to sale by or on the order of a physician. The ConforMIS partial knee resurfacing system (iUni G2) is intended for use only by medically trained physicians. Prior to use of a ConforMIS device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use

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