Advancing Innovation with the ATTUNE S+™ Technology

Attune® Knee System

The ATTUNE S+™ Technology is yet another way that DePuy Synthes is driving evidence-based innovation intended to make continuous enhancements with the goal of positively affecting patient outcomes and satisfaction.

The ATTUNE® Knee System has demonstrated significant improvements in both clinical and value-based healthcare measures[1,2,3]

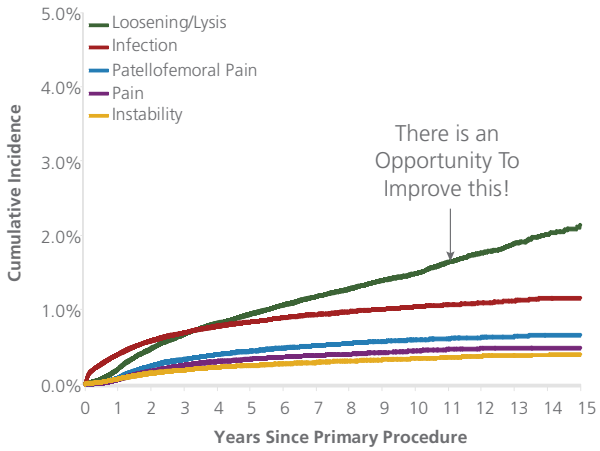
- **Improved patient reported outcome measures** compared to other leading knee systems that were tested.[1]
- **Survivorship estimate is 98.7% at four years** in the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man Implant Summary Report[2]
- **39% lower odds of patient discharge to a skilled nursing facility** for ATTUNE Knee patients vs patients who received TKA with a Triathlon™ Knee, according to the results of a large U.S. hospital administrative database review.[3]

Polyethylene (PE) wear was historically the leading cause for knee revision, today aseptic loosening is the leading cause.

Now that PE wear has been markedly reduced, the most prevalent causes of revision are infection and aseptic loosening, with evidence indicating aseptic tibial loosening being the most common cause overall for revisions after two years.[2,4,5]

Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement[7]

AOANJRR Class Data (All TKA)
Figure KT8 Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacemment.



Lipids and Motion: DePuy Synthes sought to develop a stronger understanding of the causes of aseptic loosening.

DePuy Synthes leveraged several studies including the 2014 study by Billi & Schmalzried et al.[6] This study found that lipids/marrow are major factors that can reduce the fixation strength of the cement-tibial bone interface.

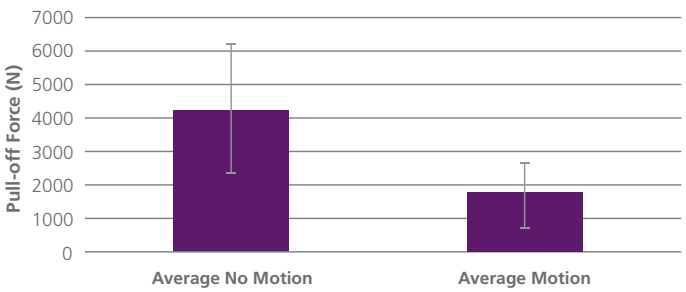
"Fat contamination of the metal-cement interface reduced the interface strength to practically zero (-99% (p=0.003), Simplex®, and -94% (p=0.030) Palacos)."[6]

DePuy Synthes subsequently conducted extensive cadaveric research, concluding that fluid/lipids infiltration is more influential during the surgical procedure than previously represented in the literature.[8,9,10]

A significant reduction of implant/cement bond strength was due to the combined effect of lipid/marrow and intra-operative motion.[7]

On average, there was a 2490 N reduction of pull-out strength when motion was introduced during the cement curing process, when averaged across 4 different designs.[8]

Effect of Simulated Intra-Op Motion – Cadaver (Cement on Bone Only)[9]

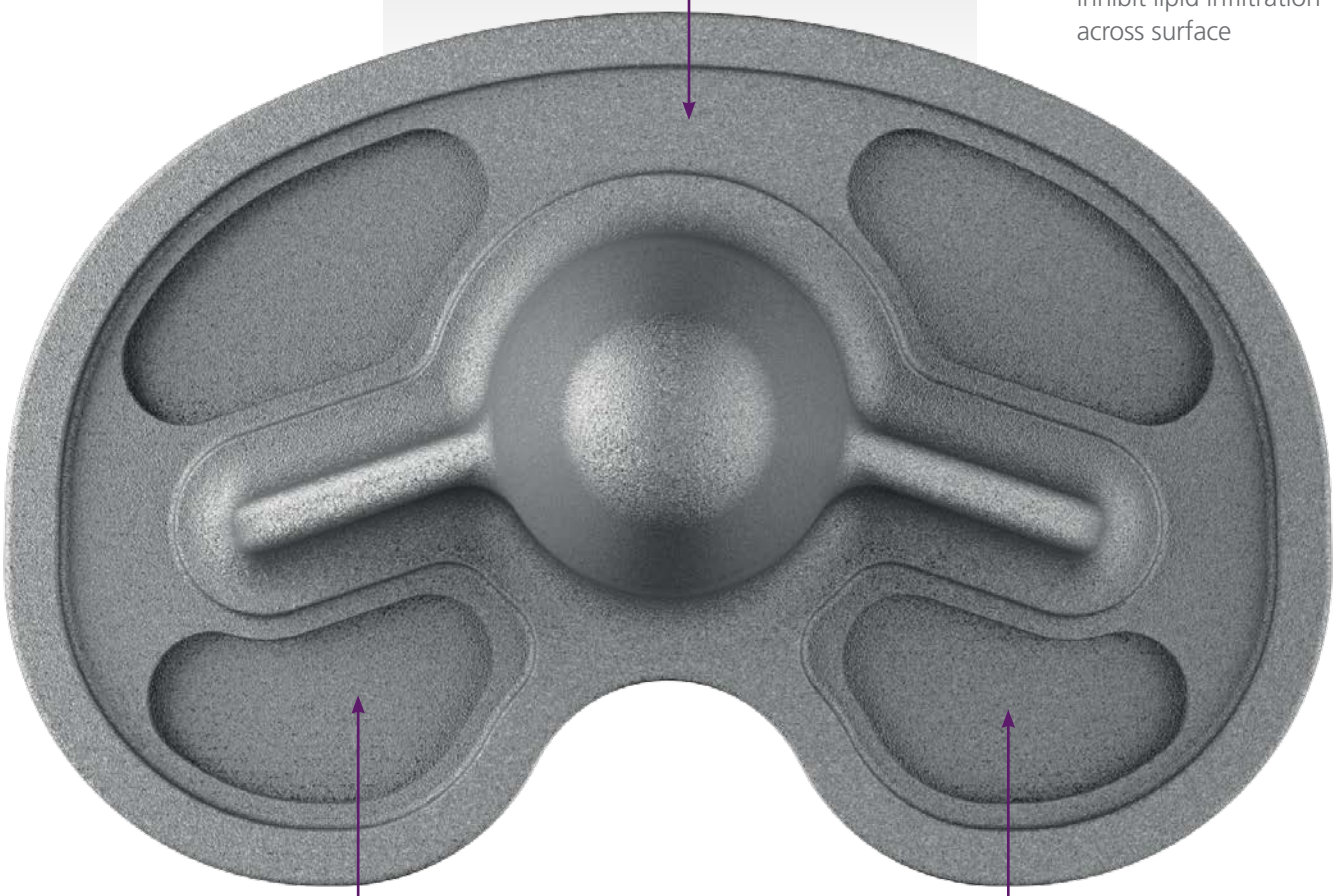


Introducing the ATTUNE S+ Technology

The tibial base with ATTUNE S+ Technology includes added features designed to provide greater residual pull off strength under a range of simulated intra-operative conditions and the presence of lipid infiltration and motion.

The ATTUNE S+ Technology is designed to enhance tibial fixation with its innovative combination of macrolock features and a microblast surface finish on the tibial base.

Macrolock + Microblast
Designed to Enhance Fixation



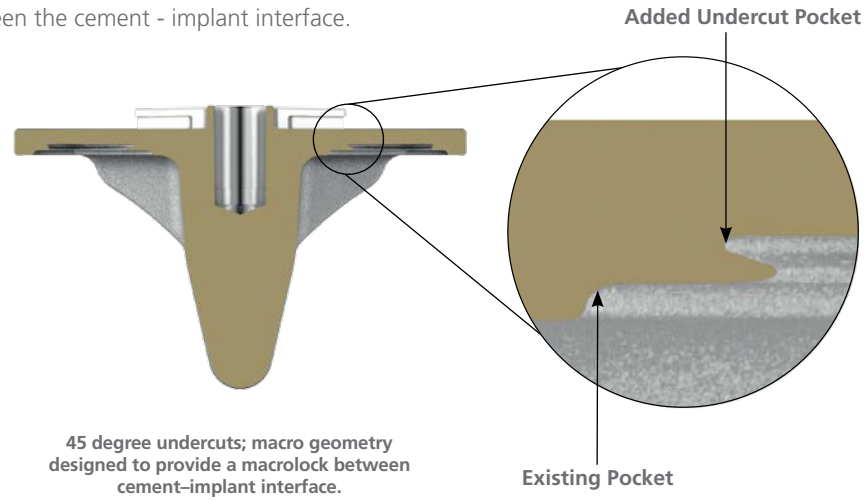
MICROBLAST
Optimized microblast to inhibit lipid infiltration across surface

MACROLOCK
- Four additional pockets (45° Undercuts)
- Provides a macrolock between cement-implant interface

The Macrolock

These additional features provide a macrolock between the cement - implant interface.

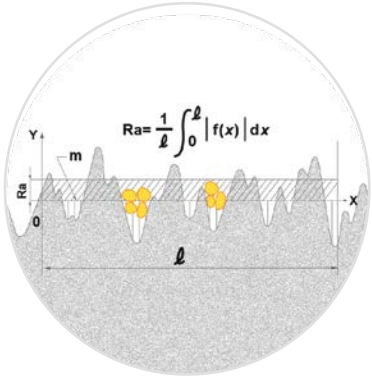
Four cement pockets; designed to provide additional macro mechanical fixation with cured cement.



45 degree undercuts; macro geometry designed to provide a macrolock between cement–implant interface.

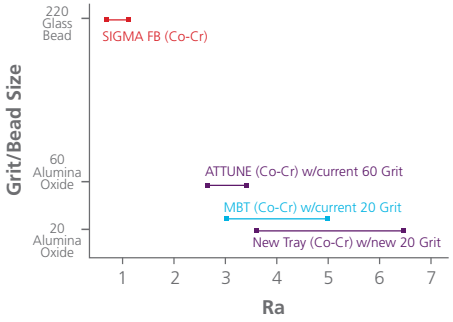
The Microblast

The microblast feature is focused on the surface finish on the underside, or distal aspect, of the implant. Increasing surface roughness of a metal implant has the potential to increase cement-implant interdigitation AND reduce infiltration of fluids into the cement-implant interface.



Surface Roughness (Ra): The quantification of how rough (high Ra) or smooth (low Ra) a surface is. Calculated as a mean of the micro peak and trough heights.

Relative Roughness Ranges



The ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested.[10]

The ATTUNE S+ Technology surface finish is designed to limit lipid infiltration and increase pull-off strength under common simulated intra-operative surgery conditions.

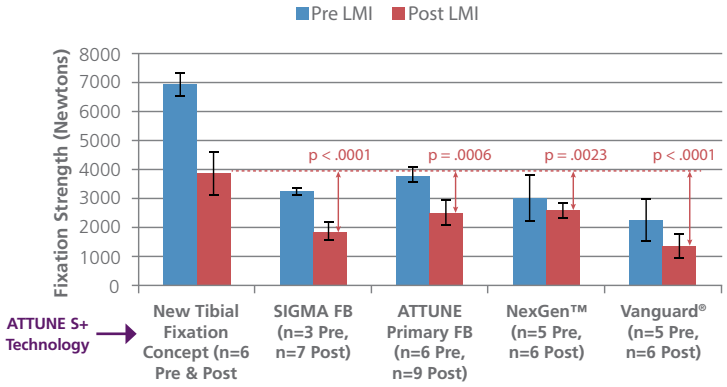
Macrolock + Microblast — Designed to Enhance Fixation

To create baseline figures for pull-out strength without motion and lipids as indicated by the blue bars, we compared the ATTUNE FB Knee to SIGMA® FB Knee and multiple predicate FB devices.[8] The ATTUNE FB Knee compared positively to the predicate devices that were tested.

Subsequently, we tested these same designs under simulated motion with lipids. As you can see with the red bars, the fixation strength of all designs was impacted.

In the bar graph to the right taken from a research study published at EFORT 2017 in Vienna, "A New Tibial Fixation Concept" referred to the Attune S+ Technology.[8] The design statistically significantly improved pull-out strength compared to other tested designs—both with and without lipid and simulated intra-operative motion.

Fixation Test Results[8]



Growing our Portfolio to Meet our Patient and Surgeon Needs

The ATTUNE Knee System continues to grow its portfolio to provide surgeons with a broad range of solutions for their patients.

PRIMARY TIBIAL BASE

CEMENTLESS
– Limited Launch –

Attune®
Knee System

ATTUNE S+™
TECHNOLOGY

REVISION:
STEMMABLE TIBIA

1. Hamilton W.G., Brenkel, I., Clatworthy, M., Dwyer, K,. Himden, S., Lesko, J., Kantor, S. Early Outcomes with a New Primary TKA System vs. Contemporary TKA: Interim Results of Two Worldwide, Multi-Center Prospective Studies. AAOS, San Diego, California, March 14-18, 2017. Tested implants include: 89% SIGMA, 3% Nex Gen®, 7% Triathlon®, 1% Other.
2. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Implant Summary Report for DePuy ATTUNE CR and ATTUNE PS. NJR Database extract April 7, 2017, pages 1-17. Licensed for use until April 19, 2018. Available at www.ATTUNEevidence.com (US) and www.provingthepromise.com (EMEA).
3. Etter K, Lerner J, deMoor C, Yoo A, Kalsekar I. Comparative Analysis of Hospital Length of Stay and Discharge Status of Two Contemporary Primary Total Knee Systems Premier Perspective™ Database analysis including 38 hospitals, representing 1,178 primary, unilateral TKAs with the ATTUNE Knee and 5,707 primary, unilateral TKAs with Triathlon™. Journal of Knee Surgery. 2017; 193: 1-33.
4. Sharkey F, et al. Why are total knee arthroplasties failing today – has anything changed after 10 years. The Journal of Arthroplasty. 2014; 29: 1774-1776.
5. Khan, M., Osman, K., Green, G., Haddad F. S. The epidemiology of failure in total knee arthroplasty. The Bone & Joint Journal. 2016. 98-B, No. 1, 105-112.
6. Billi F., PhD, Kavanaugh A., Schmalzried H., Schmalzried T., MD. Factors Influencing the Initial Strength of the Tibial Tray-PMMA Cement Bond. ORS 2014 Annual Meeting. 2014; Poster Number 1854.
7. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. (2016). Figure KT8 Retrieved from: https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty.
8. Maag C, Peckenpaugh E, Metcalf A, Haines A, Dun S, Langhorn J, Heldreth M. Influence of intra-operative lipid/marrow infiltration and intra-operative motions upon cemented tibial implant fixation. European Federation of National Associations of Orthopaedics and Traumatology (E.F.O.R.T.). 2017; Poster 1239.
9. Data on file at DePuy Synthes Companies. U. Denver Cadaveric Research – Cemented Tibial Fixation w/ & w/o Intraoperative Motion TR-000001797.
10. Data on file at DePuy Synthes Companies. TRTR-000000947, TR-000000928, TR-000001242, 103270337.

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