### + Evidence in focus

## Smith-Nephew

### Smith+Nephew cementless total knee arthroplasty (TKA)

#### Summary

- LEGION<sup>o</sup> Cementless Total Knee System tibial options are based on PROFIX<sup>o</sup> cementless knee<sup>1</sup>
- PROFIX cementless knee has demonstrated high mid- to long-term survivorship in both clinical studies<sup>2</sup> and national joint registries<sup>3,4</sup>
- PROFIX cementless knee is associated with good functional outcomes<sup>2</sup> and early stabilisation<sup>5</sup>

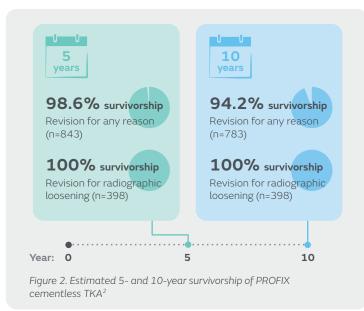
LEGION porous tibial baseplate is based on PROFIX Knee System design, which has over 25 years of clinical history.<sup>1</sup> All distal design features of the LEGION porous tibial baseplate have been based on the PROFIX Knee System.<sup>6</sup>

### **Clinical outcomes of PROFIX cementless TKA**

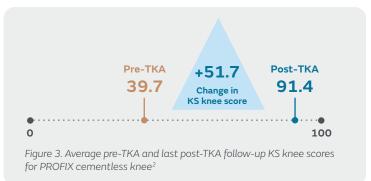
A systematic literature review published in 2012, identified eight studies reporting clinical outcomes for 987 PROFIX TKA patients (1,152 knees; Figure 1).<sup>2</sup>



Four studies (843 knees), reported mid- to long-term survivorship with cementless implants. The overall estimated survivorship with revision for any reason was 98.6% and 94.2% at 5 and 10 years, respectively (Figure 2).<sup>2</sup> When radiographic loosening was selected as the survival endpoint (two studies), the estimated survivorship was 100% at both 5 and 10 years (Figure 2).<sup>2</sup>



The Knee Society (KS) knee score assesses three areas: pain, knee stability and range of motion, with a maximum score of 100.7.<sup>6</sup> KS knee scores were reported in all eight studies identified by the systematic literature review.<sup>2</sup> Four studies reported mean pre- and last post-TKA follow-up KS knee scores for PROFIX cementless, demonstrating a mean improvement of 51.7 points from pre-TKA to last post-TKA follow-up (Figure 3).<sup>2</sup>



The authors concluded that PROFIX knee system demonstrates good mid- to long-term clinical results, stating that the survival data at 10 years seems to confirm the osseointegrative properties of the PROFIX cementless components.<sup>2</sup>

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### Radiostereometric analysis of PROFIX<sup>o</sup> cementless tibia without holes

For successful, long-term survivorship with cementless fixation, initial rigid fixation to bone is important.<sup>5</sup> A study by Nilsson KG, et al, specifically assessed the migration patterns of PROFIX cementless hydroxyapatite (HA) coated tibia without holes in patients under 65 years old.<sup>5</sup> The study consisted of 97 knees (85 patients) randomised into three groups: PROFIX cemented, PROFIX cementless HA coated with holes and PROFIX cementless HA coated with holes.

Clinical evaluations and radiostereometric analysis were carried out at 6 weeks and 3, 6, 12 and 24 months post-TKA. Migration was determined by assessing anterior-posterior rotation, varus-valgus rotation, maximum lift-off and maximum subsidence.

Overall, the results showed that the cemented knees migrated less over the first 3 months; however, there was no statistical difference in migration between PROFIX cemented and cementless knees at 24 months.<sup>5</sup> All migration, including subsidence, of the PROFIX cementless TKA knees occurred within the first 3 months and was followed by a period of stabilisation until last follow-up, whereas the PROFIX cemented TKA experienced gradual migration over the course of the study (Figure 4). There was no statistical difference in migration between PROFIX cementless HA with holes and without holes.<sup>5</sup>

Given the additional complications associated with screw use, such as osteolysis, the authors concluded that, for patients younger than 65 years, the cementless HA-coated tibial component of the PROFIX design without additional screw fixation was the design with the highest probability for long-term survival.<sup>5</sup> This potential for long-term survival of PROFIX cementless HA coated without holes tibial component is supported by national registry data.

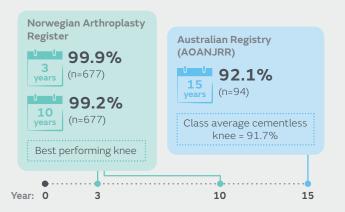


Figure 5. Survivorship of PROFIX porous HA cementless without holes as reported in Norwegian and Australian national joint registries<sup>3,4,8</sup>



Cemented Operation Cementless with holes Operation Cementless without holes

Figure 4. Mean maximum subsidence (mm) of the tibial components of PROFIX cemented and PROFIX cementless with and without holes.<sup>5</sup> Error bars represent ±95% confidence interval

# Registry analysis of PROFIX cementless tibia without holes

The Norwegian Arthroplasty Register and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) are the only national joint registries to publish annual reports that split the data into cemented and cementless TKA implants.<sup>3,8</sup>

In the 2020 Norwegian register, PROFIX CR porous cementless without holes (n=677) was reported as the best performing knee at both 3 and 10 years post-TKA (Figure 5).<sup>3</sup>

Good long-term survivorship has also been reported in the AOANJRR. A report specifically looking at the survivorship of PROFIX HA porous tibia without holes data from the AOANJRR,<sup>†</sup> has demonstrated a numerically higher survivorship at 15 years than that of the class average for cementless knees in the AOANJRR 2020 annual report (Figure 5).<sup>4,8</sup>

#### Conclusion

Hydroxyapatite coated, cementless TKA offers the potential for biological fixation and high long-term survivorship.<sup>5</sup> A systematic literature review has shown that PROFIX cementless TKA is associated with high mid- to long-term survivorship and good functional outcomes.<sup>2</sup> National joint registry data support this high survivorship for the PROFIX HA porous tibia without holes.<sup>3,4</sup> The PROFIX Knee System has been superseded by the LEGION<sup>o</sup> Cementless Total Knee System, which benefits from sharing the tibial design elements of the PROFIX cementless knee.<sup>6</sup>

#### References

1. Smith & Nephew 2012. LEGION Porous Tibia HA surgical technique 7128–1607 REVA. 2. Viganó R, Marega L, Breemans E, Miró RL. A systematic literature review of the Profix in primary total knee arthroplasty. Acta Orthop. 2012:78;55–60. 3. Helse Bergen HF. Norwegian National Advisory Unit on Arthoplasty and Hip Fractures. June 2020. Available at: http://nrlwebihelse.net/ eng/Rapporter/ Report2020\_english.pdf. 4. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Automated Industry Report System (AIRS). ID No.3550 for Smith+Nephew, PROFIX/PROFIX total knee, (Procedures from 1 September 1999 – 22 January 2021). AOA, Adelaide: 1–16. 5. Nilsson K, Henricson A, Norgren B, Dalén T. Uncemented HA-coated implant is the optimum fixation for TKA in the young patient. *Clin Orthop Relat Res.* 2006;448:129–138. 6. Smith & Nephew 2012. LEGION Porous Tibia HA surgical technique 7128–1607 REVA. 7. Odeum SM, Fehring TK. Can original knee society scores be used to estimate new 2011 Knee Society Scores? *Clin Orthop Relat Res.* 2017;475:160–167. 8. Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee and Shoulder arthroplasty. Annual report 2020. Available at: https://aoanjrr.sahmri.com/documents/10180/689619/Hip%2C+Knee+%26+Shoulder+Arthroplasty+New/6a07a3b8-8767-06cf-9069-d165dc9baca7.

<sup>+</sup>AOANJRR is confident in the accuracy of the data included in the report, at the time it was provided. However, it was generated using an automated reporting system and has not been reviewed by the AOANJRR personnel.

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