

TriFit ™

The evidence base

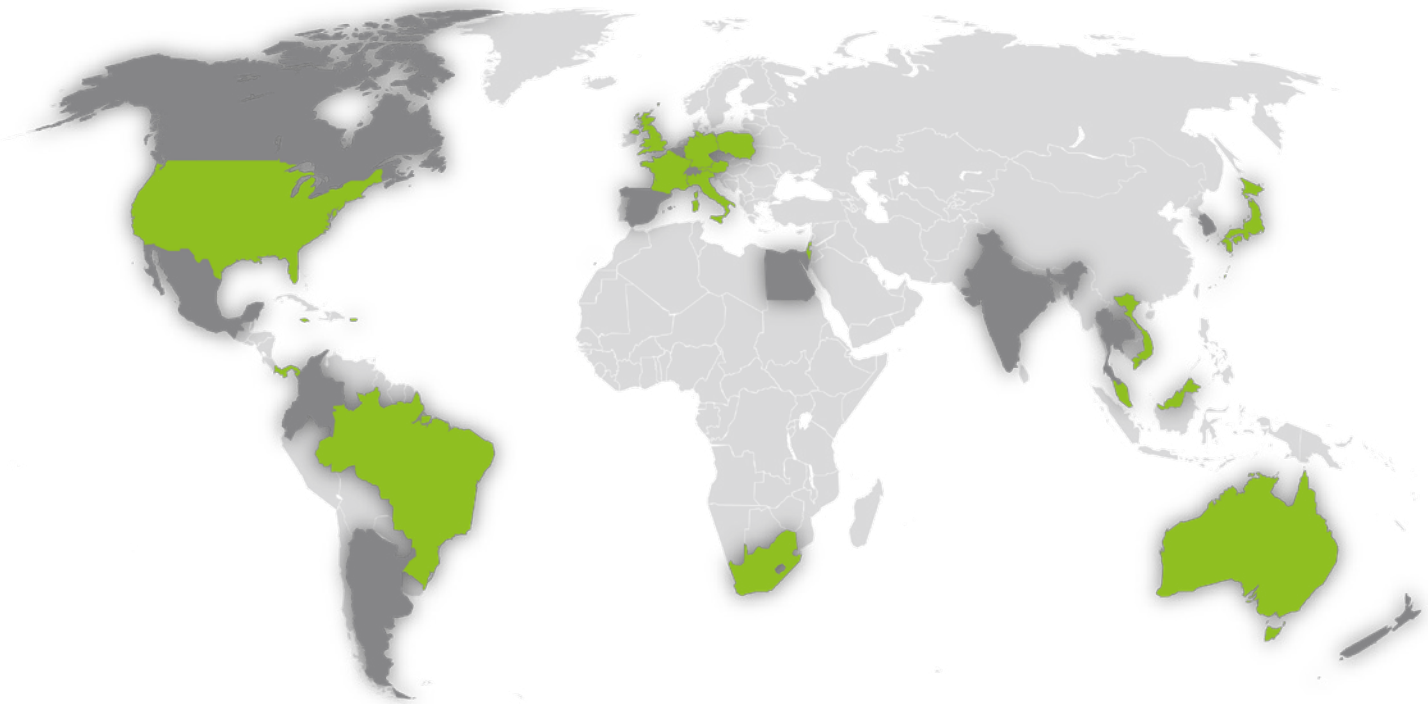


**Corin**

Connected Orthopaedic Insight

## A truly global stem

- Supplied to 17 countries worldwide<sup>1</sup>
- Over 33,000 units sold worldwide<sup>1</sup>



## Strong evidence rated by independent review

TriFit TS™ is awarded a 5A rating by the Orthopaedic Data Evaluation Panel (ODEP)<sup>2</sup> in the UK.

TriFit TS has five years of follow-up in ODEP with an “A” grade, which stands for strong evidence (generally higher numbers of patients -giving greater confidence in the results presented-, with all patients being subject to follow-up with their outcomes recorded).



Latest ODEP ratings can be found at [www.ODEP.org.uk](http://www.ODEP.org.uk)

An independent panel of experts in the UK, known as the Beyond Compliance Advisory Group, works with manufacturers to assess the relative risk of any new product, and the rate at which it should be introduced to the market. This surveillance programme collects data not only about patients who receive new implants but also about their recovery following surgery<sup>3</sup>.

TriFit TS was part of Beyond Compliance from May 2015 until March 2020. By including TriFit TS in this programme during its first years in the market we have gone the extra mile to promote medical device innovation and ensure patient safety through clinically proven implants.



Latest products participating in Beyond Compliance can be found at <https://www.beyondcompliance.org.uk/>

## Superior clinical performance

Data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)<sup>4</sup>

### 1.3% cumulative percent revision (CPR) at 1yr

TriFit TS™-Trinity™ combine for a 27.7% lower revision rate than the average of the cumulative revision rate for all uncemented hips at the equivalent time period<sup>4</sup>.

### 2.1% cumulative percent revision (CPR) at 3yrs

TriFit TS-Trinity combine for a 22.2% lower revision rate than the average of the revision rate for all uncemented hips at the equivalent time period<sup>4</sup>.

### 2.3% cumulative percent revision (CPR) at 5yrs

TriFit TS-Trinity combine for a 28.1% lower revision rate than the average revision rate for all uncemented hips at the equivalent time period<sup>4</sup>.

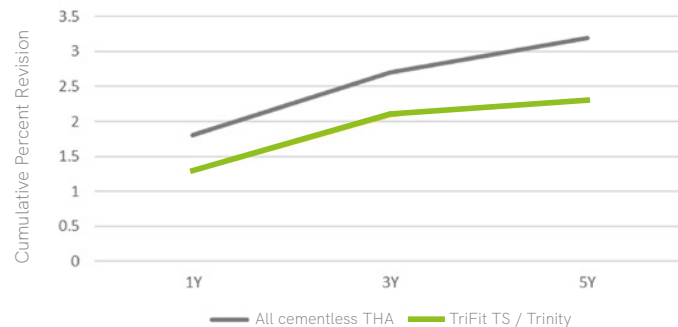


Fig. 1. Comparison of Cumulative Percent Revision of Primary Total Conventional Hip Replacement redrawn from Tables HT12 and HT21 AOANJRR Annual Report 2020.

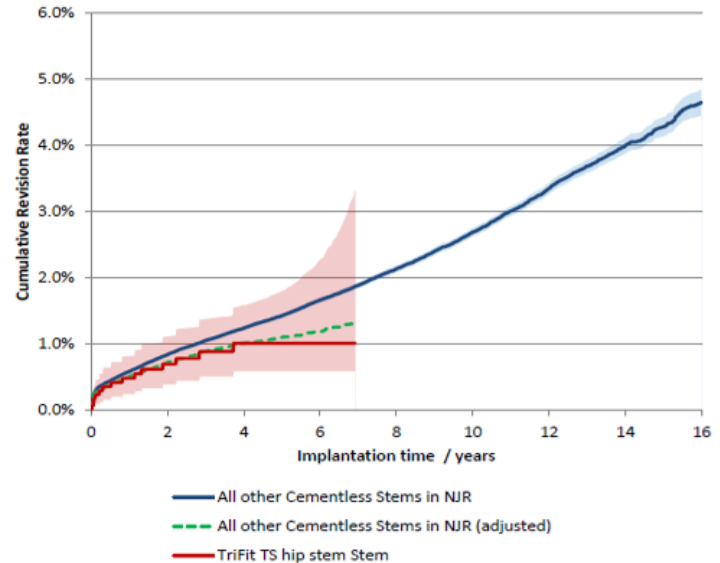
## Superior clinical performance

Data from TriFit TS™ Implant Summary Report of the UK National Joint Registry (NJR)<sup>5\*</sup>

**Lower cumulative femoral revision rate than all other cementless stems in NJR at 5 years<sup>5</sup>.**

TriFit TS has reported a cumulative femoral revision rate of 1% at 5 years compared to the 1.4% of cumulative revision rate reported for the mean of all other cementless stems reviewed by the NJR (Fig. 2)<sup>5</sup>.

Fig. 2. Cumulative femoral revision rate. All bearing types. Cox Proportional Hazards model for femoral revision risk ratio of TriFit TS hip stem/all other cementless stems in NJR, with endpoint as any revision. According to the recorded usage in NJR comprising all primary hips implanted up to the 4th March 2021 and extracted with permission from the NJR TriFit TS implant summary report dated 31st March 2021.



## Versatile stem applications

Data from TriFit TS™ Implant Summary report of the UK National Joint Registry (NJR)<sup>5\*</sup>

**The use of TriFit TS in young patients is higher than for all other cementless stems in NJR<sup>5\*</sup>.**

It is noticeable how the UK surgeons have used TriFit TS to treat a higher percentage (22%) of young patients compared to all other cementless stems in the NJR (8.4%) (Fig. 3)<sup>5</sup>.

**TriFit TS has been used more frequently to treat patients suffering from AVN and CDH/DDH compared to the all other cementless stems in NJR<sup>5\*</sup>.**

Cementless stems have been proven as an adequate option for patients suffering from Avascular Necrosis (AVN)<sup>6</sup>, Congenital (CDH)<sup>7</sup> and Developmental Dysplasia (DDH)<sup>8</sup>.

Between them, tapered stems have shown favourable long-term results in patients suffering from DDH, also in the case of young patients<sup>7</sup>.

Existing evidence shows that TriFit TS has been used more frequently in patients suffering from avascular necrosis (3.6%) and CDH/DDH (9.49%) compared to all other cementless stems in the NJR (2.57% and 2.07%, respectively) (Fig. 3)<sup>6</sup>.

Indications	TriFit TS hip stem	All other cementless stems in NJR	All NJR hip replacement
Osteoarthritis	85.36%	93.03%	91.29%
Rheumatoid Arthritis	1.54%	1.22%	1.32%
Avascular Necrosis	3.60%	2.57%	2.53%
Fractured neck of femur	0.46%	1.89%	3.65%
CDH/DDH	9.49%	2.07%	1.58%
Other	3.60%	1.78%	2.12%
Mean age	56.2	65.3	68.6
<50	22.20%	8.40%	5.90%
50-59	39.40%	19.20%	13.80%
60-69	29.00%	34.80%	28.90%
70-79	8.50%	28.40%	34.70%
>-80	0.90%	9.10%	16.60%

Fig. 3. Percentage of use by indication and mean age according to Recorded Usage in NJR comprising primary hips implanted up to 4th March 2021 and extracted from the NJR TriFit TS implant summary report dated 31st March 2021.

## Initial stability proven through radiostereometric analysis (RSA)<sup>9</sup>

**Title** Primary stability of a proximally coated and tapered stem.  
**Authors** Alsousou J, Oragui E, Martin A, Strickland L, Newman S, Kendrick B, Taylor A, Glyn-Jones S.  
**Publication** Bone Joint Journal. 2021 April;103-B(4):644-649.

**Methods** 19 patients undergoing primary THA for osteoarthritis of the hip were recruited and followed up for two years. All patients received a TriFit TS™ and Trinity™ cup with a vitamin E-infused HXLPE liner. Radiographs for RSA were taken postoperatively and then at 3, 12, and 24 months. Oxford Hip Score (OHS), EuroQol five-dimension questionnaire (EQ-5D), and adverse events were reported.

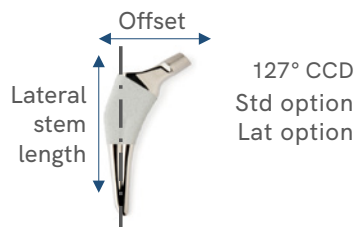
**Results** At 24 months, the mean subsidence of the head and tip for the TriFit TS stem was 0.38mm (SD 0.32) and 0.52mm (SD 0.36), respectively. The total migration of the head and tip was 0.55mm (SD 0.32) and 0.71mm (SD 0.38), respectively. There were no statistically significant differences between the 3 to 12 months' migration ( $p = 0.105$ ) and 12 to 24 months' migration ( $p = 0.694$ ). The OHS and EQ-5D showed significant improvements at 24 months.

**Conclusions** Radiostereometric analysis (RSA) remains the gold-standard method for measuring early stem migration to host bone, which in turn predicts loosening and implant failure. The maximum acceptable limit of migration for cementless stems is unclear, however migration of less than 1mm at two years has been associated with good long-term functional and clinical outcomes<sup>10</sup>. The results of this RSA study of TriFit TS at 24 months confirm a total migration of less than 0.63mm. The migration reported in the study compares favourably with other cementless stem designs. The negligible anteroposterior migration (0.12mm) indicates that the device is able to resist torsional forces across the implant in axial plain. This proven short-term stability suggests that the TriFit TS implant is likely to be stable in the long term.

## High offset stems are protective of dislocation in high-risk total hip arthroplasty<sup>11</sup>

**Title** High Offset Stems Are Protective of Dislocation in High-Risk Total Hip Arthroplasty.  
**Authors** Vigdorichik J, Sharma A, Elbuluk A, Carroll K, Mayman D, Lieberman J.  
**Publication** Journal Arthroplasty. 2021 Jan;36(1):210-216.

**Methods** 12,365 patients undergoing THA from 2016-2018 were retrospectively reviewed to determine dislocation rates and utilisation of standard versus high offset stems. For 50 consecutive patients with spinal stiffness, a CT-based bony or prosthetic impingement model was performed. The model was run 5 times for each patient with varying offsets. Range of motion was simulated in each scenario to determine the degree at which impingement occurred.



**Results** There were 51 dislocations for a 0.41% dislocation rate. Total utilisation of high offset in the entire cohort was 49%. Of those patients who sustained a dislocation, 49 (96%) utilised a standard offset stem. The impingement modelling demonstrated 5 degrees of added range of motion until impingement for every 1mm offset increase.

**Conclusions** In the impingement model, high offset stems facilitated greater RoM before bony impingement and resulted in lower dislocation rates. In the setting of high-risk THA due to spinal stiffness, surgeons should consider the use of high-offset stems and pay attention to offset restoration.



## Powerful insights

TriFit TS™ is compatible with Corin OPS™\*\* technology, providing insights into the patient's joint biomechanics which can reduce the risk of certain failure modes.

The OPS technology uses a radiodensity mapping tool (Fig. 4), which can help to optimise component selection and orientation to avoid problems related to subsidence and malalignment<sup>12</sup>. It has been shown to be a good predictor of stem selection and sizing, potentially increasing efficiencies in the OR and avoiding unexpected situations.

TriFit TS also uses a "one-tray philosophy" (except rasps) shared with TriFit CF™\*\*, our fit-and-fill stem. This system can help to reduce inventory in the hospital and speed-up surgery. OPS is fully compatible with both implants, which can help the surgeon to select the best component for different patients.

In addition, TriFit TS and OPS are fully compatible with the Trinity™ system, which offers a wide array of options for different patient needs.

### OPS (Optimized Positioning System)

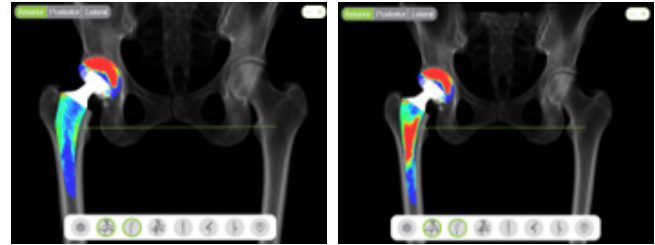
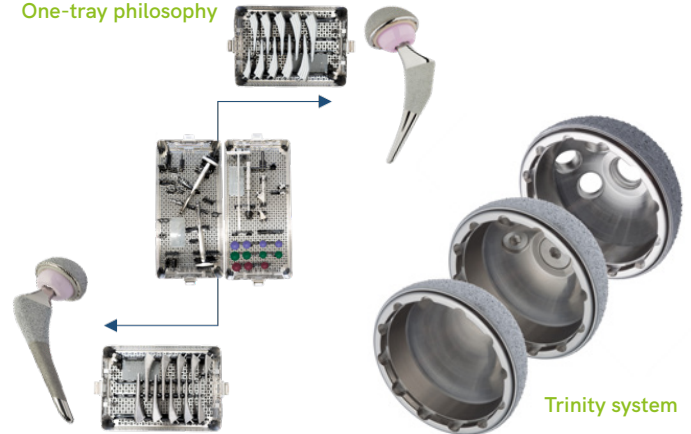


Fig. 4. Left: Case example, Patient A - Anterior view of a TriFit TS stem in OPSInsight™ applying the radiodensity tool.

Fig. 4. Right: Anterior view of a TriFit CF stem in OPSInsight™ applying the radiodensity tool.

### One-tray philosophy



## Cementless stem anteversion is not dictated by the native femoral anteversion<sup>13</sup>

**Title** Native femoral version does not dictate stem version with a cementless implant.  
**Authors** Pierrepont J, Miller A, Bruce W, Baré J, McMahon S, Shimmin A.  
**Publication** Orthopaedic Proceedings. Vol. 100-B, No. Supp. 5.

**Methods** 116 patients had 3D templating using OPSInsight™. 96 patients received a TriFit TS™ stem and 18 patients received a MetaFix™ stem. All patients received a postoperative CT scan which was superimposed onto the preop. CT scan. The difference between native and achieved stem anteversion was then measured.

**Results** The mean deviation between native and stem anteversion of the blade stems was  $-3.5^\circ$  ( $-34.8^\circ$  to  $13.8^\circ$ ). The mean deviations of the three surgeons using the blade stem were  $-7.9^\circ$ ,  $-3.1^\circ$  and  $2.7^\circ$ . These were statistically significant, and represented a difference in philosophy around target anteversion amongst surgeons.



Fig. 5. Case example applying the OPSInsight radiodensity tool to a patient with a TriFit TS stem implanted. Left: Anterior view. Right: Lateral view.

**Conclusions** Correct prosthetic alignment is a fundamental factor for maintaining adequate stability and performance after a THA. This study shows that the anteversion of TriFit TS is not dictated by the femoral anteversion, which stresses the importance of planning an achieving the right prosthetic alignment for each patient. The version for TriFit TS can be adjusted using OPST™ according to the patient's unique anatomy, biomechanics, and radiodensity pattern (Fig. 5).

## Optimising intraoperative delivery through accurate sizing and stem selection<sup>14</sup>

**Title** Sizing accuracy of the trinity 3D planning software for total hip replacement conclusions.  
**Authors** Pierrepont J, Miles B, Walter L, Marel E, McMahon S, Solomon M, Baré JV, Shimmin AJ.  
**Publication** International Congress for Joint Reconstruction (ICJR); April 16-18, 2015; Paris, France.

**Methods** A consecutive series of 49 patients, from three surgeons at a single institution, were sent for OPS™ preoperative planning and received a Trinity™ acetabular component and a TriFit TS™ through the posterior approach. Of the 49 patients, 16 received a standard offset stem and 33 had lateralised stems. The size of the implants used was compared to the planned sizes in the OPS reports.

**Results** 92% of TriFit TS femoral stems implanted with OPS were within one size of that predicted<sup>8</sup>. 18 stems were one size above and four stems were within two sizes (Fig. 6). The use of standard or high-offset stems was predicted correctly in 80% of cases.

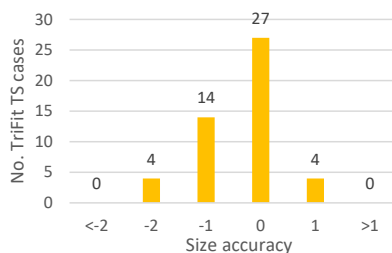


Fig. 6. TriFit TS implant sizing accuracy of using Corin OPS technology<sup>8</sup>.

**Conclusions** Implant size accuracy when using a cementless taper-wedge stems is essential to avoid the risk of subsidence and aseptic loosening<sup>15</sup>. The OPS technology can be used as a support tool to predict accurate sizing of TriFit TS with the intention of minimising the risk of under-sizing.

## Surgeon testimonials

“The TriFit TS™ stem sits at the same height as the final rasp. The neck length of the this system is the same for all sizes and shorter than the products of other manufacturers, for this reason it is very easy to use in Japanese patients (who typically have a smaller anatomy), especially female patients.”

**Dr M Morita. Fujita Health University, Aichi (Japan).**

“Great stem stability requires reliable immediate fixation in order to allow for long-term biologic fixation. TriFit TS has the design and the CaP coating to achieve this in a trustworthy, reproducible manner for my patients.”

**Dr Roehrig. Orthopaedic Institute of Central Jersey (USA).**

“I have performed around a hundred surgeries with TriFit TS using the anterior approach and I am satisfied with the results. I did not notice any subsidence, which can happen with other short stems. The primary press-fit is excellent. My advice is to go one size up with this stem. I typically use it in patients under 65 years old with good bone density. The instrumentation is ergonomic and very pleasant.”

**Dr Guillaume Autissier. Clinique du Cambrésis (France).**



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## Disclaimers

\* The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the Healthcare Quality Improvement Partnership ("HQIP"). HQIP, the NJR and/or its contractor, Northgate Public Services (UK) Limited ("NPS") take no responsibility (except as prohibited by law) for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to the maximum extent permitted by legislation including any duty of care to third party readers of the data analysis.

\*\*Please note that specific product features and availability vary based on location.

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