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X-Ray by courtesy of Dr. D. Ganzer

**25 YEARS
CLINICAL
EXPERIENCE**

balanSys BICONDYLAR

Results you can rely on

CLINICAL RESULTS

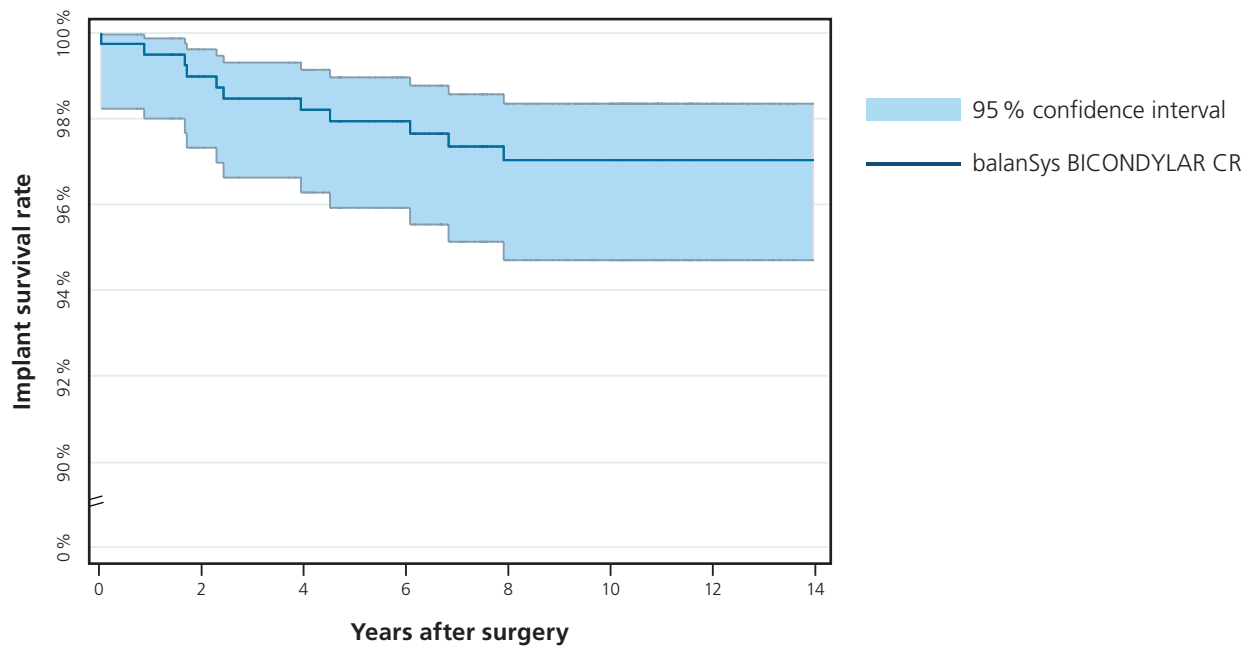


PROVEN

for more than 25 years

Proven prosthesis

In a multicentric study conducted in 2017 on 433 patients available for implant survival analysis, the cruciate-ligament-retaining (CR) version of balanSys BICONDYLAR Knee System achieved a cumulative implant survival rate of 97 % after 12.4 years. This result shows that the system is safe to use and provides reliable clinical results over long periods of time. ¹



Implant survival rate for the cruciate-ligament-retaining version of the balanSys BICONDYLAR knee system. Diagram adapted from Heesterbeek, P. et al. 2017. ¹

From the **patients' perspective**, the balanSys BICONDYLAR knee system offers **high satisfaction** and leads to **clinically relevant pain reduction**.¹

Visual analogue scale (VAS) for **satisfaction** ¹



Visual analogue scale (VAS) for **pain** ¹



Superior results

Swiss Implant Registry (SIRIS)²

With the balanSys BICONDYLAR implant philosophies, results within the relevant benchmark (all other total knee endoprostheses) or significantly better are achieved in the Swiss registry. balanSys BICONDYLAR CR achieved significantly better revision rates than the benchmark did after 5, 7 and 10 years, namely 5.2 % compared to 7.6 % after 10 years.

Revision rate up to the relevant time after implantation of the balanSys BICONDYLAR knee system (without secondary retropatellar replacement); revision rate in % incl. 95 % confidence interval in brackets.²

Knee system	1 year	5 years	7 years	10 years
Benchmark	1.6 (1.5–1.6)	5.5 (5.4–5.6)	6.5 (6.3–6.6)	7.6 (7.4–7.8)
balansys BICONDYLAR CR	1.1 (0.8–1.6)	4.0 (3.2–5.2)	4.8 (3.8–6.2)	5.2 (4.0–6.8)
balansys BICONDYLAR UC	1.1 (0.8–1.5)	5.2 (4.5–6.0)	6.7 (5.9–7.7)	7.2 (6.3–8.3)
balansys BICONDYLAR RP	1.4 (1.1–1.7)	5.5 (4.9–6.1)	6.9 (6.2–7.6)	8.1 (7.2–9.2)
balansys BICONDYLAR PS	1.3 (1.0–1.7)	4.7 (4.0–5.5)	5.7 (4.8–6.8)	6.4 (5.3–7.8)

 Significantly better

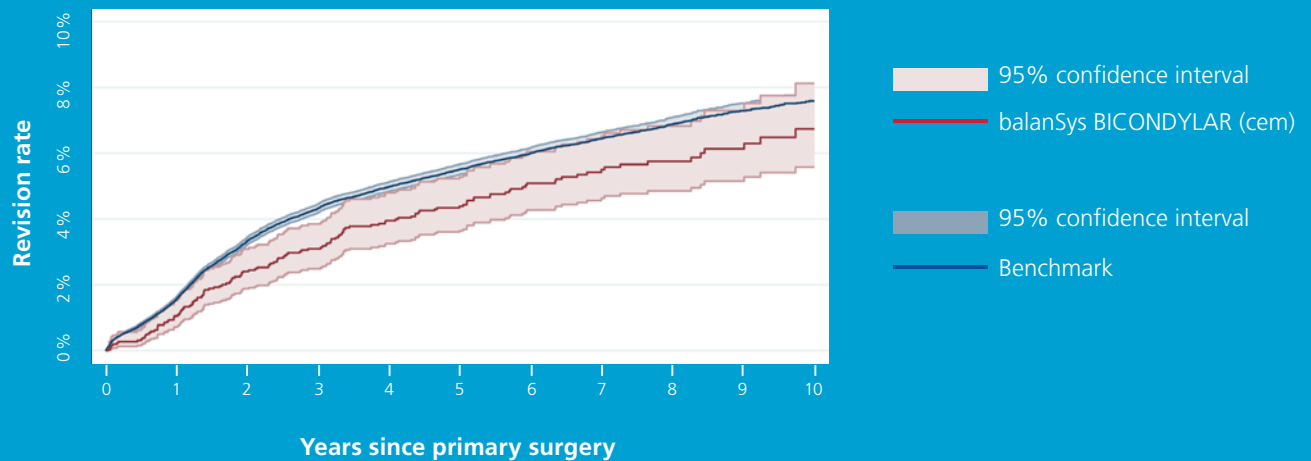
 Within the benchmark

 Above benchmark

Good survival rate

Swiss Implant Registry (SIRIS) ³

Revision rate of balanSys BICONDYLAR cemented versus the benchmark
(all other cemented total knee endoprostheses)



Reliable

Endoprosthesis Registry Germany (EPRD)⁴

Safety and reliability of the balanSys BICONDYLAR system are confirmed in the German endoprosthesis registry by results within the respective benchmarks.

Revision rate by the respective time after implantation of the balanSys BICONDYLAR knee system, revision rate in % incl. 95 % confidence interval in brackets. Only time points with at least 40 implants under surveillance are listed.⁴

Knee system	1 year	4 years	6 years	7 years
Benchmark CR	1.5 (1.4–1.5)	3.0 (2.9–3.1)	3.4 (3.3–3.5)	3.5 (3.4–3.7)
balansys BICONDYLAR CR hybrid	0.6 (0.2–2.4)	2.5 (1.0–6.5)		
balansys BICONDYLAR CR cemented	2.1 (1.6–2.7)	3.4 (2.7–4.3)	3.9 (3.0–5.0)	3.9 (3.0–5.0)
Benchmark UC	1.7 (1.6–1.8)	3.4 (3.2–3.6)	4.1 (3.9–4.4)	4.4 (4.2–4.8)
balansys BICONDYLAR UC hybrid	2.4 (1.7–3.6)	4.0 (3.0–5.5)	4.3 (3.1–5.8)	4.3 (3.1–5.8)
balansys BICONDYLAR UC cemented	2.1 (1.6–2.9)	4.1 (3.1–5.3)	4.8 (3.6–6.3)	4.8 (3.6–6.3)
Benchmark PS	2.0 (1.9–2.1)	3.9 (3.8–4.1)	4.5 (4.3–4.7)	4.9 (4.6–5.1)
balansys BICONDYLAR PS cemented	2.0 (1.4–3.0)	5.5 (4.2–7.2)	5.8 (4.5–7.6)	

 Significantly better

 Within the benchmark

 Above benchmark

15 years of clinical evidence

Australian Joint Replacement Registry (AOANJRR)⁵

In the Australian Joint Replacement Registry, the long-term safety of balanSys BICONDYLAR is clinically demonstrated with 15-year results. The cumulative revision rate of balanSys BICONDYLAR amounts to 5.6 % after 15 years and is thus within the benchmark for primary total knee replacements.

Revision rate of primary total knee replacement *

Table KT12: Revision rate of primary total knee replacement (primary diagnosis: osteoarthritis)⁵

Knee Class	N Revised	N Total	1 Yr	5 Yrs	10 Yrs	15 Yrs
Total Knee	26 004	741 847	1.0 (0.9–1.0)	3.1 (3.1–3.2)	4.6 (4.5–4.7)	6.2 (6.1–6.3)

Revision rate of balanSys BICONDYLAR *

Table KT9: Revision rate of primary total knee replacement combinations by prosthesis combination⁵

Knee Class	N Revised	N Total	1 Yr	5 Yrs	10 Yrs	15 Yrs
balanSys	68	2 258	0.4 (0.2–0.8)	2.0 (1.5–2.7)	3.7 (2.8–4.7)	5.6 (3.8–8.1)

* Revision rate in % incl. 95 % confidence interval in brackets

 Significantly better

 Within the benchmark

 Above benchmark

Strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP)⁶

The Orthopaedic Data Evaluation Panel (ODEP) lists the balanSys BICONDYLAR system ultracongruent (UC) with 7 years of acceptable evidence, posterior stabilised (PS) and rotating platform (RP) with 7 years of strong evidence, and the cruciate-ligament-retaining (CR) balanSys BICONDYLAR system with 7 years of very strong evidence. The 7A* ODEP rating for balanSys BICONDYLAR CR is the highest rating that can be achieved with 7 years of clinical results, and is based on very strong evidence of clinical performance including low revision rates.



balanSys
BICONDYLAR UC
Ultracongruent



balanSys
BICONDYLAR PS
Posterior stabilised



balanSys
BICONDYLAR RP
Rotating platform



balanSys
BICONDYLAR CR
**Cruciate-ligament-
retaining**

Glossary

Confidence interval

The confidence interval is a value range that describes the uncertainty surrounding a calculated parameter. A 95 % confidence interval is most commonly used. This means a probability of 95 % that an interval is obtained that comprises the unknown expected value. The minimum and maximum values of the confidence interval are called the lower and upper confidence limit, respectively.

Estimation of survival and revision rates

The survival and revision rates of implants in registries and scientific publications are often calculated by means of the Kaplan-Meier estimation. In the Kaplan-Meier estimation, the time to the first implant revision corresponds to the survival rate. The cumulative revision rate at a certain point in time, e. g. after 5 years, is the complement (in terms of probability) of the Kaplan-Meier survival calculation at that point in time. If a patient is deceased or the implant is in the patient at the time the database is closed (data export), the data will be censored at that time.

ODEP

ODEP is an acronym meaning «Orthopaedic Data Evaluation Panel». It is an independent panel of experts drawn mainly from British surgeons but also including some non-clinical experts with many years of industry experience.

The panel was established by the National Health Purchasing and Supply Agency (PASA, later replaced by SCCL – the Supply Chain Coordination Limited).

The numbers indicate the number of years of clinical evidence. The letter represents the clinical evidence of the data provided by the manufacturer.

Further information can be found at <http://www.odep.org.uk/ODEPExplained.aspx>

References

- ¹ Heesterbeek P, Van Houten AH, Klenk J S, Eijer H, Christen B, Wymenga A, Schuster A. Superior long-term survival for fixed bearing compared with mobile bearing in ligament-balanced total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2017
- ² Swiss National Joint Registry (SIRIS). SIRIS Report 2012 – 2022. Annual Report 2023
- ³ Swiss Implant Registry (SIRIS), SIRIS Implant Report (Extended) for balanSys cemented total knee system PS – RP – UC – CR, September 2023
- ⁴ EPRD. Endoprothesenregister Deutschland – Jahresbericht 2023, <https://www.eprd.de>.
- ⁵ Smith PN, Gill DR, McAuliffe MJ, McDougall C, Stoney JD, Vertullo CJ, Wall CJ, Corfield S, Page R, Cuthbert AR, Du P, Harries D, Holder C, Lorimer MF, Cashman K, Lewis PL. Hip, Knee and Shoulder Arthroplasty: 2023 Annual Report, Australian Orthopaedic Association National Joint Replacement Registry, AOA: Adelaide, South Australia. 2023. <https://doi.org/10.25310/YWQZ9375>; Tables KT9 and KT12
- ⁶ <http://www.odep.org.uk/products.aspx>, last access 01.02.2024

Table KT9 Cumulative Percent Revision of Cemented Primary Total Knee Replacement by Prosthesis Combination

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs
BalanSys	BalanSys	61	2141	0.4 (0.2, 0.8)	1.6 (1.1, 2.2)	2.1 (1.5, 2.8)	3.7 (2.8, 4.9)	5.1 (3.5, 7.5)

Table KT12 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
Total Knee	25251	711978	1.0 (1.0, 1.0)	2.5 (2.4, 2.5)	3.2 (3.2, 3.3)	4.7 (4.7, 4.8)	6.4 (6.3, 6.5)	8.0 (7.8, 8.3)
TOTAL	25251	711978						