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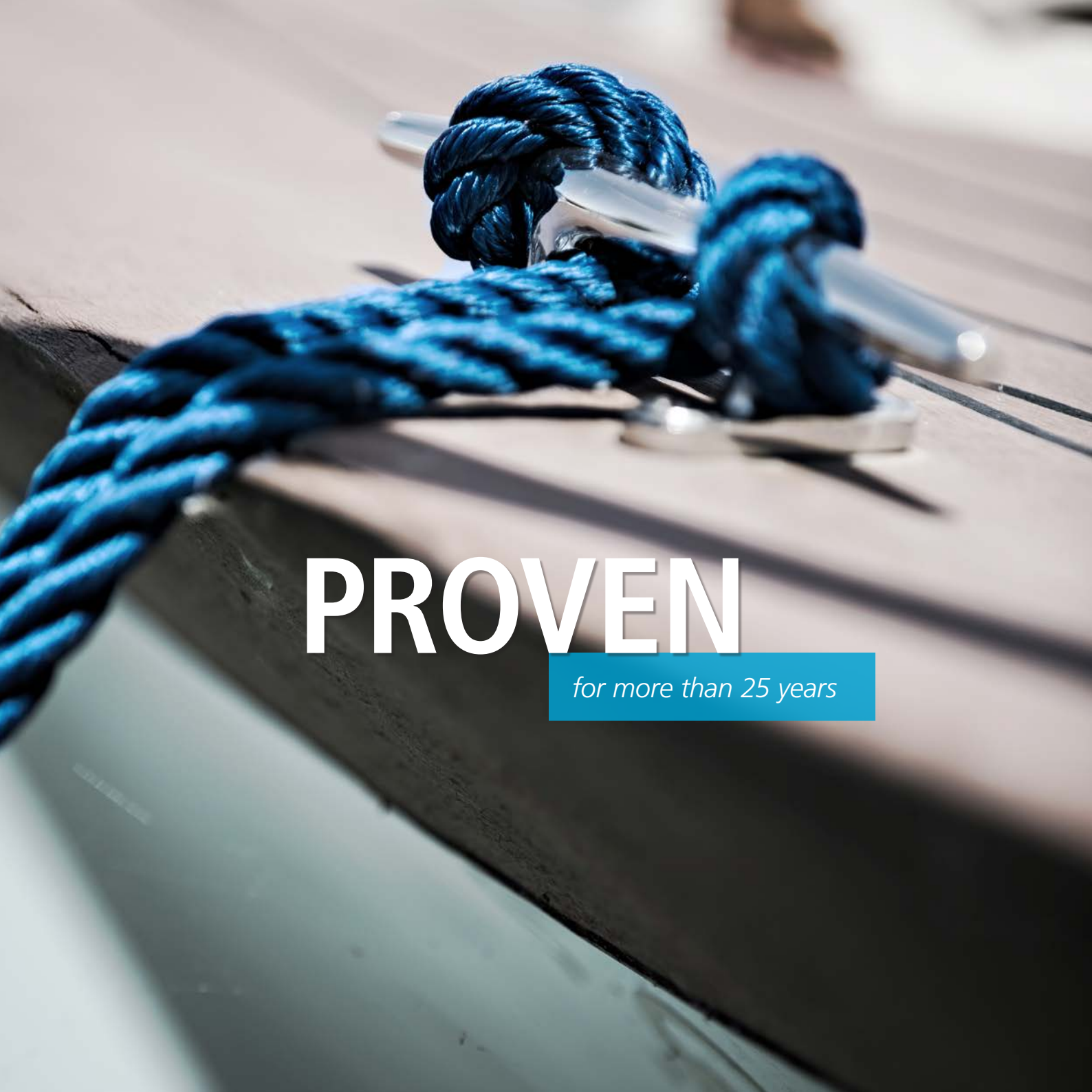
X-Ray by courtesy of Dr. D. Ganzer

25 YEARS CLINICAL EXPERIENCE

balanSys BICONDYLAR

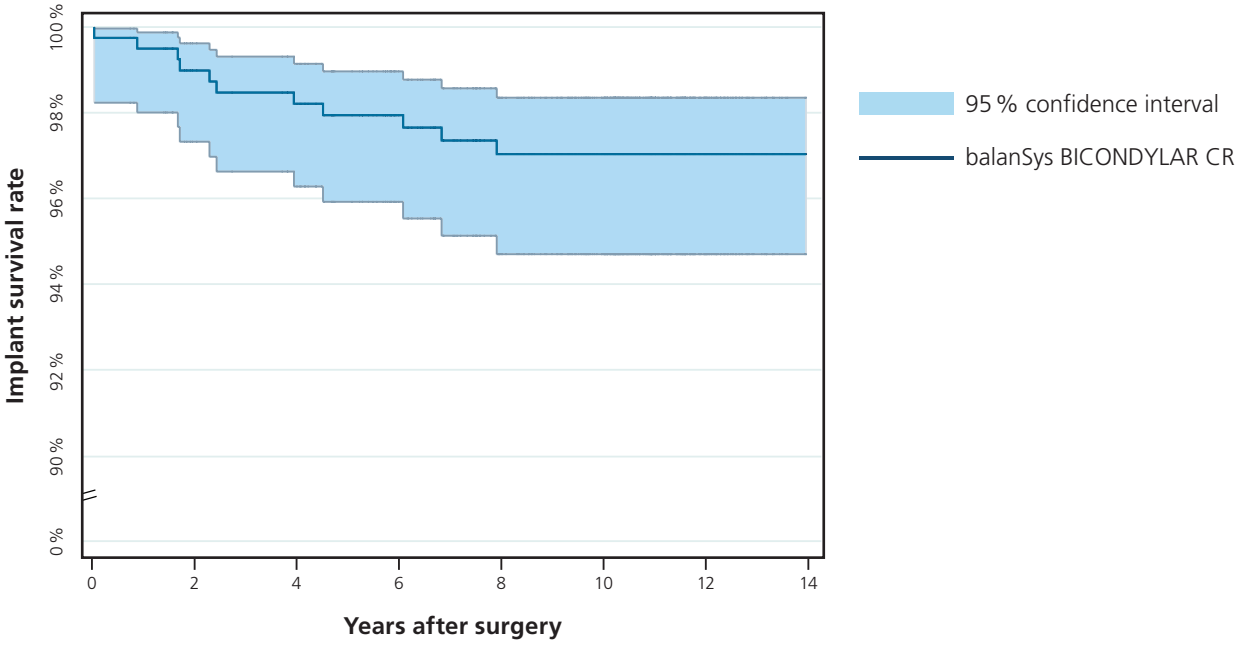
Results you can rely on

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 and PS achieved significantly better revision rates after 9 years, namely 3.8 % for CR and 5.6 % for PS, than the benchmark did.

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 parentheses.[2]

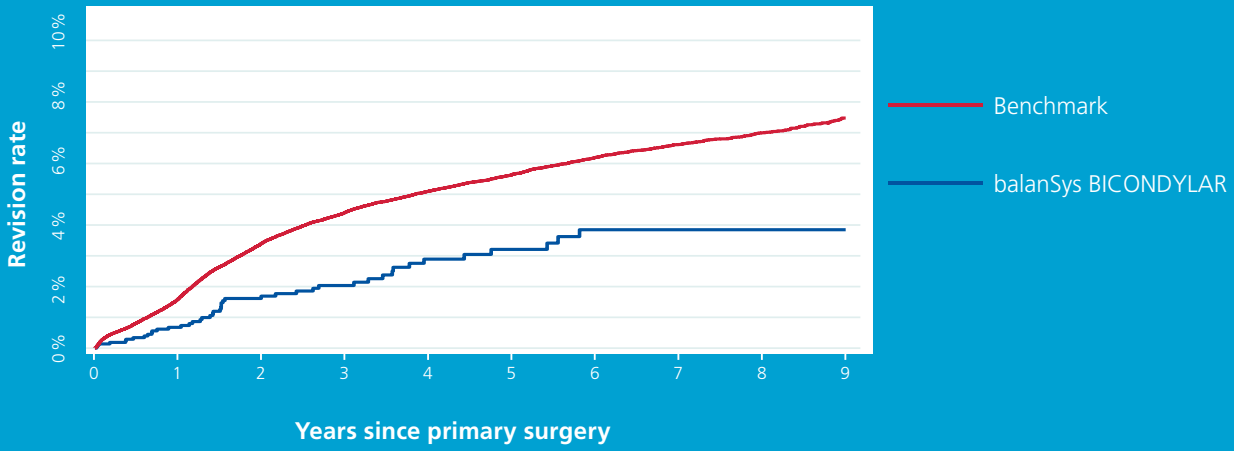
Knee system	1 year	3 years	5 years	9 years
Benchmark	**1.6** (1.5–1.7)	**4.3** (4.2–4.4)	**5.5** (5.4–5.7)	**7.3** (7.1–7.6)
balansys BICONDYLAR **CR**	**0.7** (0.4–1.2)	**2.0** (1.4–2.9)	**3.2** (2.3–4.4)	**3.8** (2.8–5.3)
balansys BICONDYLAR **UC**	**1.0** (0.8–1.4)	**4.0** (3.4–4.7)	**5.1** (4.4–5.9)	**6.8** (5.8–7.9)
balansys BICONDYLAR **RP**	**1.3** (1.0–1.6)	**4.0** (3.6–4.6)	**5.4** (4.8–6.0)	**7.6** (6.6–8.7)
balansys BICONDYLAR **PS**	**1.2** (0.9–1.7)	**3.2** (2.6–3.9)	**4.5** (3.8–5.4)	**5.6** (4.6–6.8)

Significantly better Within the benchmark Above benchmark

Superior results

Swiss Implant Registry (SIRIS) [2]

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



Revision rate of the balanSys BICONDYLAR knee system (without secondary retropatellar replacement) up to the respective time after implantation. [2]

Reliable

Endoprosthesis Registry Germany (EPRD) [3]

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. [3]

Knee system	1 year	4 years	6 years
Benchmark **CR**	**1.5** (1.4–1.6)	**3.0** (2.9–3.1)	**3.4** (3.3–3.6)
balansys BICONDYLAR **CR** hybrid	**0.7** (0.2–2.7)	**1.8** (0.7–5.0)	
balansys BICONDYLAR **CR** cemented	**1.8** (1.3–2.5)	**3.1** (2.4–4.1)	**3.5** (2.7–4.7)
Benchmark **UC**	**1.8** (1.6–1.9)	**3.5** (3.3–3.7)	**4.2** (3.9–4.5)
balansys BICONDYLAR **UC** hybrid	**2.5** (1.7–3.6)	**4.9** (3.7–6.6)	**4.9** (3.7–6.6)
balansys BICONDYLAR **UC** cemented	**2.4** (1.8–3.2)	**4.8** (3.7–6.2)	**5.6** (4.2–7.5)
Benchmark **RP**	**2.0** (1.9–2.1)	**3.9** (3.7–4.1)	**4.2** (4.0–4.4)
balansys BICONDYLAR **RP** hybrid	**1.7** (1.0–2.8)	**3.4** (2.3–5.0)	**3.4** (2.3–5.0)
balansys BICONDYLAR **RP** cemented	**1.2** (0.6–2.5)	**2.3** (1.3–4.0)	
Benchmark **PS**	**2.0** (1.9–2.1)	**4.0** (3.8–4.1)	**4.6** (4.4–4.9)
balansys BICONDYLAR **PS** cemented	**1.8** (1.3–2.5)	**5.1** (4.0–6.5)	**5.5** (4.2–7.1)

Significantly better Within the benchmark Above benchmark

15 years of clinical evidence

Australian Joint Replacement Registry (AOANJRR)[4]

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 5.1 % after 15 years and is thus within the benchmark for primary total knee replacements.

Revision rate for primary total knee replacement *

Table KT12: Revision rate of primary total knee replacement (primary diagnosis: osteoarthritis)[4]

Knee Class	N Revised	N Total	1 Yr	5 Yrs	10 Yrs	15 Yrs
Total Knee	25251	711978	**1,0** (1,0–1,0)	**3,2** (3,2–3,3)	**4,7** (4,7–4,8)	**6,4** (6,3–6,5)

Revision rate for balanSys BICONDYLAR *

Table KT9: Revision rate of primary total knee replacement combinations with 15-year results (primary diagnosis: osteoarthritis)[4]

Knee Class	N Revised	N Total	1 Yr	5 Yrs	10 Yrs	15 Yrs
balanSys	61	2141	**0,4** (0,2–0,8)	**2,1** (1,5–2,8)	**3,7** (2,8–4,9)	**5,1** (3,5–7,5)

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

Significantly better Within the benchmark Above benchmark

Strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP) [5]

The Orthopaedic Data Evaluation Panel (ODEP) lists the balanSys BICONDYLAR system ultracongruent (UC) with 5 years of very strong evidence, posterior stabilised (PS) with 7 years of strong evidence, and the cruciate-ligament-retaining (CR) balanSys BICONDYLAR system with 7 years of strong evidence.

[5]

balanSys
BICONDYLAR UC
Ultracongruent

[5]

balanSys
BICONDYLAR PS
Posterior stabilised

[5]

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 a confidence 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 interval, 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

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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 – 2021. Annual Report 2022

3 German Arthroplasty Registry (EPRD): Annual Report 2022, available from the website of the German Arthroplasty Registry https://www.eprd.de/en/, accessed on December 12, 2022

4 Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2022 Annual Report. Adelaide: AOA, 2022, Tables KT9 and KT12

5 http://www.odep.org.uk/products.aspx, last access 01.02.2023

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**						

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