MATHYS
European Orthopaedics

**20 YEARS
CLINICAL
EXPERIENCE**

balanSys BICONDYLAR
Results you can rely on

PROVEN

Proven prosthesis

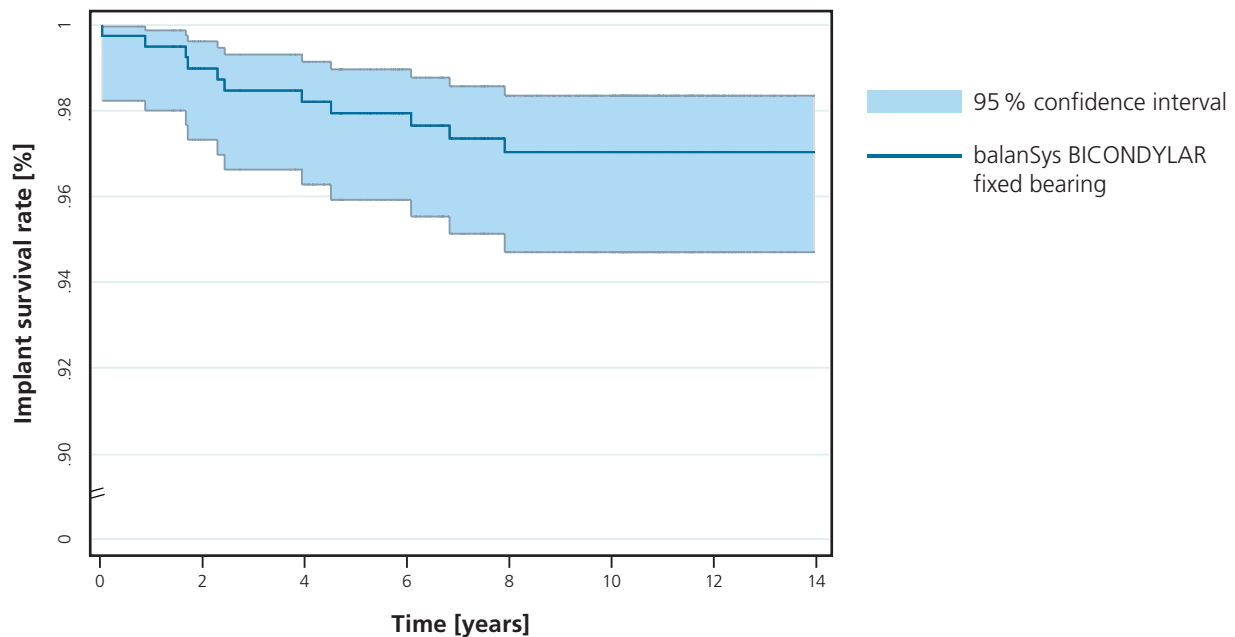In a multicentric study conducted in 2017 on 433 patients available for implant survival analysis, the cruciate-ligament-retaining (CR) version of balanSys BICONDYLAR Knee System achieved a cumulative implant survival rate of 97 % after 12.4 years*. This result shows that the system is safe to use and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

Implant survival rate for the cruciate-ligament-retaining fixed bearing version of the balanSys BICONDYLAR knee system after 12.4 years. Diagram adapted from Heesterbeek, P. et al. 2017. [1]

* 36.9 % of the patients were not available for follow-up (including death and lost-to-follow-up)

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

balanSys BICONDYLAR

Patient satisfaction with balanSys BICONDYLAR

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

8.6

0   10

Dissatisfied   *Very satisfied*

Pain in patients with balanSys BICONDYLAR

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

1.7

0   10

No pain   *Worst pain*
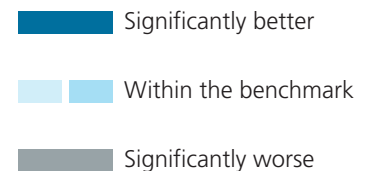
Superior results

Swiss Implant Registry (SIRIS) [2]

With the balanSys BICONDYLAR implant philosophies, results within the relevant benchmark or significantly better are achieved in the Swiss registry. In general, with a cumulative revision rate of 4.4 % after 7 years, balanSys BICONDYLAR achieves results within the benchmark.

Kaplan-Meier estimate for the probability of a revision by the respective time after implantation of the balanSys BICONDYLAR knee system (without secondary retropatellar replacement) [2]

Estimated cumulative revision rates	1 year	2 years	5 years	7 years
Benchmark	1.3 (1.2–1.3)	2.5 (2.4–2.6)	4.2 (4.0–4.3)	4.8 (4.6–5.0)
balanSys BICONDYLAR	0.9 (0.7–1.1)	1.9 (1.7–2.2)	3.6 (3.2–4.0)	4.4 (4.0–4.9)
balanSys BICONDLYAR **UC** PE	0.8 (0.5–1.2)	2.0 (1.6–2.6)	3.6 (2.9–4.4)	4.8 (3.9–6.0)
balanSys BICONDLYAR **PS** PE	0.9 (0.5–1.4)	1.7 (1.2–2.4)	3.6 (2.7–4.7)	4.8 (3.4–6.7)
balanSys BICONDLYAR **CR** PE	0.6 (0.2–1.4)	0.9 (0.5–1.9)	1.5 (0.8–2.7)	1.8 (1.0–3.3)
balanSys BICONDLYAR **RP** PE	1.0 (0.7–1.3)	2.0 (1.6–2.4)	3.7 (3.2–4.4)	4.3 (3.7–5.1)

- Significantly better
- Within the benchmark
- Significantly worse

Superior results

Swiss Implant Registry (SIRIS) [2]

Kaplan-Meier estimator for the probability of a revision
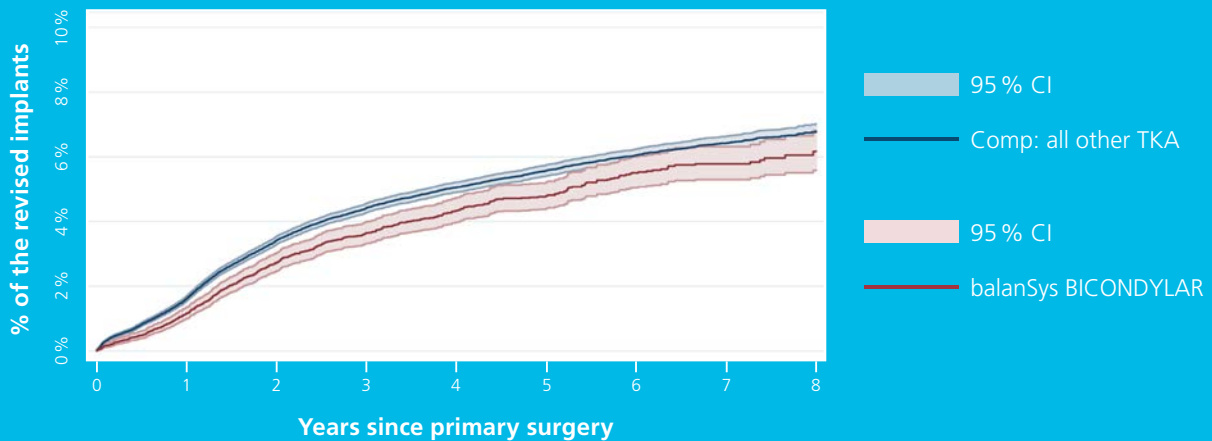
Kaplan-Meier estimate for the probability of a revision by the respective time after implantation of the balanSys BICONDYLAR knee system (without secondary retropatellar replacement) [2]
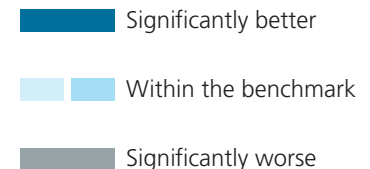
Reliable

Endoprosthesis Registry Germany (EPRD)[3]

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

Kaplan-Meier estimate for the probability of a revision by the respective time after implantation of the balanSys BICONDYLAR knee system[3]

Total knee endoprostheses (TKE)	1 year	2 years	5 years
Benchmark **CR**	**1.5** (1.4–1.6)	**2.3** (2.2–2.4)	**3.4** (3.2–3.5)
balanSys BICONDYLAR **CR** PE	**1.9** (1.3–2.8)	**2.5** (1.8–3.5)	**4.4** (2.7–7.3)
Benchmark **PS**	**1.9** (1.8–2.1)	**3.0** (2.8–3.2)	**4.0** (3.7–4.3)
balanSys BICONDYLAR **PS** PE	**2.4** (1.6–3.7)	**4.4** (3.2–6.1)	**5.9** (4.2–8.2)
Benchmark **RP**	**2.0** (1.8–2.1)	**3.1** (2.9–3.3)	**4.2** (3.9–4.5)
balanSys BICONDYLAR **RP** PE	**1.7** (1.1–2.7)	**3.1** (2.2–4.3)	**3.6** (2.6–5.1)
Benchmark **UC**	**1.8** (1.7–1.9)	**2.8** (2.6–3.0)	**4.3** (4.0–4.6)
balanSys BICONDYLAR **UC** PE	**2.5** (1.8–3.3)	**3.8** (2.9–4.8)	**6.0** (4.6–7.8)

Significantly better

Within the benchmark

Significantly worse

15 years of clinical evidence

Australian Registry (AOANJRR) [4]

In the Australian registry, the long-term safety of balanSys BICONDYLAR is clinically demonstrated with 15-year results. The cumulative revision rate of balanSys BICONDYLAR of 6.8 % after 15 years is within the benchmark for primary total knee replacements.

Cumulative revision rate for primary total knee replacement

Table KT10: Cumulative relative revision rate of primary total knee replacement (primary diagnosis: osteoarthritis) [4]

Knee Class	N Revised	N Total	5 Yrs	10 Yrs	15 Yrs
Total Knee	27 580	699 283	**3.5** (3.5 – 3.6)	**5.2** (5.2 – 5.3)	**7.3** (7.2 – 7.4)

Cumulative revision rate for balanSys BICONDYLAR

Table FY2: Cumulative relative revision rate of primary total knee replacement combinations with 15-year results (primary diagnosis: osteoarthritis) [4]

Femoral Component	Tibial Component	N Revised	N Total	5 Yrs	10 Yrs	15 Yrs
balanSys	balanSys	77	3722	**2.3** (1.8 – 3.0)	**4.5** (3.3. – 6.1)	**6.8** (4.3 – 10.7)

■ Significantly better	■ Within the benchmark	■ Significantly worse

Strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP) [5]
The Orthopaedic Data Evaluation Panel (ODEP) lists the balanSys BICONDYLAR systems ultracongruent (UC) with 3 years of very strong evidence, posterior stabilised (PS) with 5 years of strong evidence, rotating platform (RP) with 5 years of very strong evidence, and the cruciate-ligament-retaining (CR) balanSys BICONDYLAR system even with 7 years of strong evidence.

ODEP 3A* [5]	ODEP 5A [5]	ODEP 5A* [5]	ODEP 7A [5]
balanSys BICONDYLAR UC **Ultracongruent**	balanSys BICONDYLAR PS **Posterior stabilised**	balanSys BICONDYLAR RP **Rotating platform**	balanSys BICONDYLAR CR **Cruciate-ligament-retaining**

balanSys BICONDYLAR

Glossary

Implant survival rate
The percentage of patients in whom the implant is still in the body (in situ) after a certain time.

Observed component years («Ocy»)
The observed component years describe the total of the years that all registered prostheses have spent in the body.

Revisions per 100 component years
The number of revisions per 100 component years is the number of prostheses revised divided by the observed component years and multiplied by 100.

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. There is a probability of 95 % that the true value lies within this range. The minimum and maximum of the confidence interval are called the lower and upper confidence interval.

Kaplan-Meier
A Kaplan-Meier curve presents clinical outcomes by expressing the number of revisions as a percentage of the number of surgeries at a given time. Due to the lower number of patients for whom long-term values are available, the uncertainty of the estimate increases, which is shown by a wider confidence interval.

References

[1] Heesterbeek P, Van Houten A H, 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 Implant Registry (SIRIS), balanSys BICONDYLAR SIRIS Implant Report (Extended), December 2020.

[3] EPRD Endoprothesenregister Deutschland. Herstellerauswertung 2020. Mathys Orthopädie GmbH.

[4] Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2020 Annual Report. Adelaide: AOA, 2020, Tables FY2 and KT10.

[5] http://www.odep.org.uk/products.aspx, last access 23.07.2021.

Table FY2   Cumulative Percent Revision of Primary Total Knee Replacement Prosthesis Combinations with 15 Year Data (Primary Diagnosis OA) [4]

Femoral Component	Tibial Component	N Revised	N Total	Type of Revision				5 Yrs	10 Yrs	15 Yrs
				TKR	Femoral	Tibial	Other			
BalanSys	BalanSys	77	3722	21	3	7	46	2.3 (1.8, 3.0)	4.5 (3.3, 6.1)	6.8 (4.3, 10.7)

Table KT10   Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA) [4]

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	19 Yrs
Total Knee	27580	699283	1.0 (1.0, 1.0)	2.7 (2.6, 2.7)	3.5 (3.5, 3.6)	5.2 (5.2, 5.3)	7.3 (7.2, 7.4)	9.0 (8.7, 9.3)
TOTAL	**27580**	**699283**						