

MATHYS 
European Orthopaedics

**15 YEARS
CLINICAL
EXPERIENCE**

balanSys UNI
Results you can rely on

balanSys UNI



**15 YEARS
CLINICAL
EXPERIENCE**

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

balanSys UNI

Significantly better function

In a multicentric study conducted in 2021, 116 patients who had received a unicondylar balanSys UNI were compared with 116 patients with total knee arthroplasty (TKA) 12 months after surgery. The balanSys UNI patients achieved a significantly better Knee Society Function Score, namely an excellent 95 out of a maximum of 100 points, than the TKA patients did (80 points, $p < 0.001$).²

Knee Society Function Score²

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



High satisfaction

In the study by Tille et al., the balanSys UNI patients reported a satisfaction of 9 (median) out of a maximum of 10 points on the visual analogue scale (VAS).²

Patient satisfaction with balanSys UNI²

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



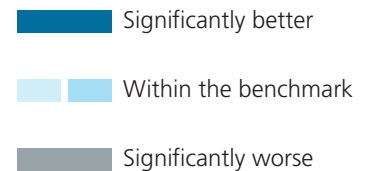
Proven

Swiss Implant Registry (SIRIS)³

In the Swiss implant registry SIRIS, the balanSys UNI knee system has proven its worth. The safety of balanSys UNI is confirmed with a cumulative revision rate of 7.1 % after 7 years. The benchmark of all other unicondylar knee systems documented in SIRIS amounts to 9.0 %.

Kaplan-Meier estimate for the probability of a revision by the respective time after implantation of the balanSys UNI knee system³

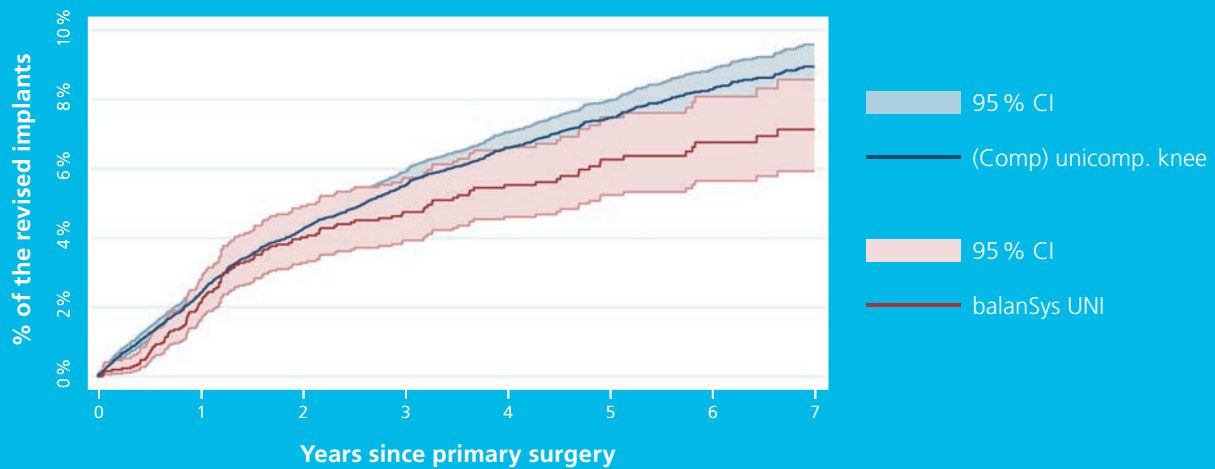
Estimated cumulative revision rates	1 year	2 years	5 years	7 years
Benchmark	2.4 (2.2–2.6)	4.2 (3.9–4.6)	7.5 (7.0–8.0)	9.0 (8.4–9.6)
balanSys UNI	2.1 (1.6–2.8)	4.0 (3.3–4.9)	6.3 (5.2–7.5)	7.1 (5.9–8.6)
<i>balanSys UNI PE</i>	2.0 (1.4–2.8)	3.9 (3.1–4.9)	6.2 (5.1–7.5)	7.1 (5.8–8.6)
<i>balanSys UNI vitamys</i>	2.5 (1.5–4.2)	3.9 (2.6–6.0)	–	–



Proven

Swiss Implant Registry (SIRIS)³

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 UNI knee system³

Reliable

Endoprosthesis Registry Germany (EPRD)⁴

In the German endoprosthesis registry, the balanSys UNI convinces with a cumulative revision rate of 7.4 % after 5 years and is thus within the benchmark of 7.4 %.

Kaplan-Meier estimate for the probability of a revision by the respective time after implantation of the balanSys UNI knee system⁴

Unicondylar knee prostheses	1 year	2 years	5 years	
Benchmark	2.9 (2.6–3.2)	5.0 (4.6–5.5)	7.6 (6.9–8.4)	 Significantly better
balanSys UNI PE	2.7 (1.4–5.4)	4.3 (2.5–7.5)	7.4 (4.2–12.9)	 Within the benchmark
				 Significantly worse

Superior results

Australian Registry (AOANJRR)⁵

In the Australian registry, the long-term safety of balanSys UNI is clinically confirmed with superior 10-year results. With a cumulative revision rate of 8.4% after 10 years, the balanSys UNI achieves a significantly lower revision rate than the average of all documented unicondylar knee replacement systems. The average cumulative revision rate for all unicondylar knee prostheses after 10 years is 14.3%.

Cumulative revision rate for primary unicondylar knee replacement

Table KP7: Cumulative relative revision rate of primary unicondylar knee replacement (primary diagnosis: osteoarthritis)⁵

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs
Unicompartmental	7 864	59 810	2.2 (2.1–2.3)	5.5 (5.3–5.6)	7.7 (7.5–8.0)	14.3 (13.9–14.6)

Cumulative revision rate of balanSys UNI

Table KP6: Cumulative relative revision rate of primary unicondylar knee replacement by prosthesis combination⁵

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs
balanSys UNI	balanSys UNI Fixed	38	747	2.6 (1.6–4.1)	3.9 (2.6–5.9)	4.7 (3.2–7.0)	8.4 (5.9–12.0)

Significantly better
 Within the benchmark
 Significantly worse

Very strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP)⁶

The Orthopaedic Data Evaluation Panel (ODEP) awards the balanSys UNI knee system the 7A* ODEP rating. The 7A* ODEP rating 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 UNI
fixed bearing

balanSys UNI

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 Campbell D, Schuster A J, Pfluger D, Hoffmann F. Unicondylar knee replacement with a new tensioner device: clinical results of a multicentre study on 168 cases. Arch Orthop Trauma Surg. 2010;130(6):727-32.
- ² Tille E, Beyer F, Auerbach K, Tinius M, Lütznert J. Better short-term function after unicompartmental compared to total knee arthroplasty. BMC Musculoskelet Disord. 2021;22(1):326.
- ³ Swiss Implant Registry (SIRIS), balanSys Unicondylar SIRIS Implant Report (Extended), November 2020.
- ⁴ EPRD Endoprothesenregister Deutschland. Herstellerbewertung 2020. Mathys Orthopädie GmbH.
- ⁵ Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2020 Annual Report. Adelaide: AOA, 2020, Tables KP6 and KP7.
- ⁶ <http://www.odep.org.uk/products.aspx>, last access 23.07.2021.

Table KP6 Cumulative Percent Revision of Primary Unicompartmental Knee Replacement by Prosthesis Combination ⁵

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	19 Yrs
BalanSys Uni	BalanSys Uni Fixed	38	747	2.6 (1.6, 4.1)	3.9 (2.6, 5.9)	4.7 (3.2, 7.0)	8.4 (5.9, 12.0)		

Table KP7 Cumulative Percent Revision of Primary Unicompartmental Knee Replacement (Primary Diagnosis OA) ⁵

Knee Type	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	19 Yrs
Unicompartmental	7864	59810	2.2 (2.1, 2.3)	5.5 (5.3, 5.6)	7.7 (7.5, 8.0)	14.3 (13.9, 14.6)	22.1 (21.6, 22.6)	29.5 (28.1, 30.9)
TOTAL	7864	59810						