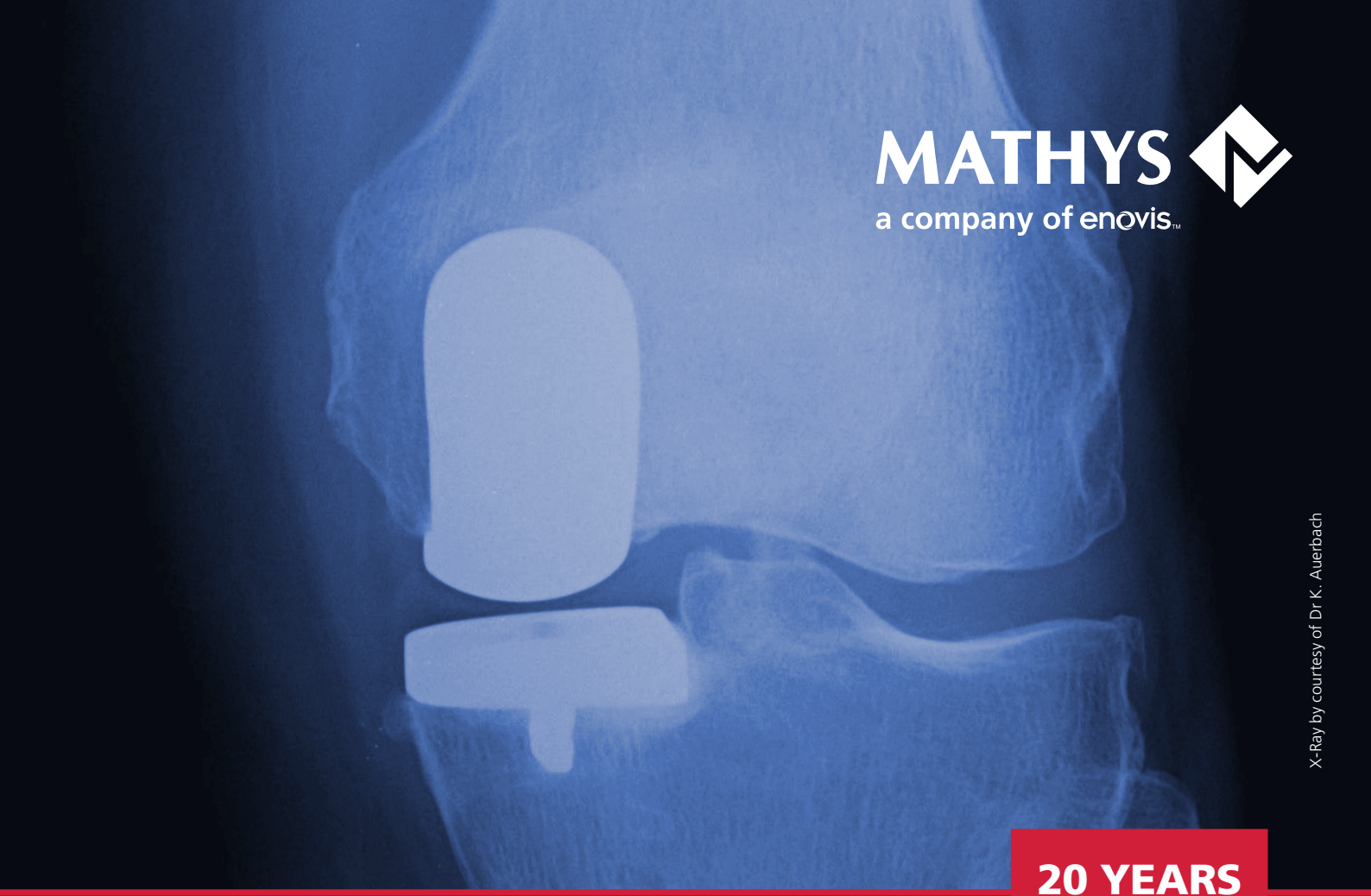

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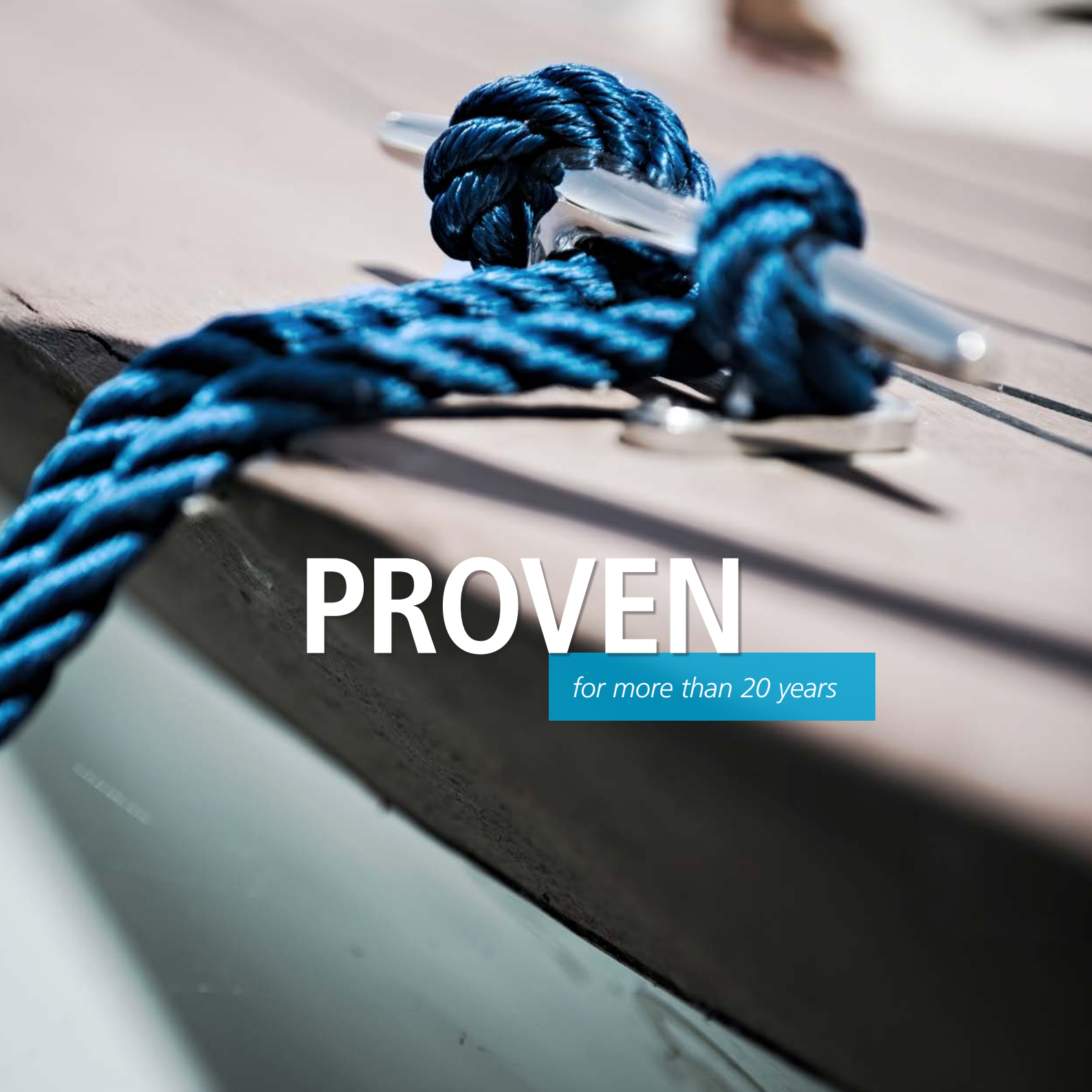
X-Ray by courtesy of Dr K. Auerbach

20 YEARS CLINICAL EXPERIENCE

balanSys UNI

Results you can rely on

CLINICAL RESULTS


PROVEN
for more than 20 years

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

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 a different knee endoprosthesis (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 Score (VAS) for **function** [2]

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]

Visual analogue scale (VAS) for **satisfaction** [2]

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 revision rate of 10.2 % after 9 years. The benchmark of all other cemented unicondylar knee systems documented in SIRIS amounts to 11.7 %.

Revision rate up to the relevant time after implantation of the balanSys UNI knee system; revision rate in % incl. 95 % confidence interval in parentheses[3]

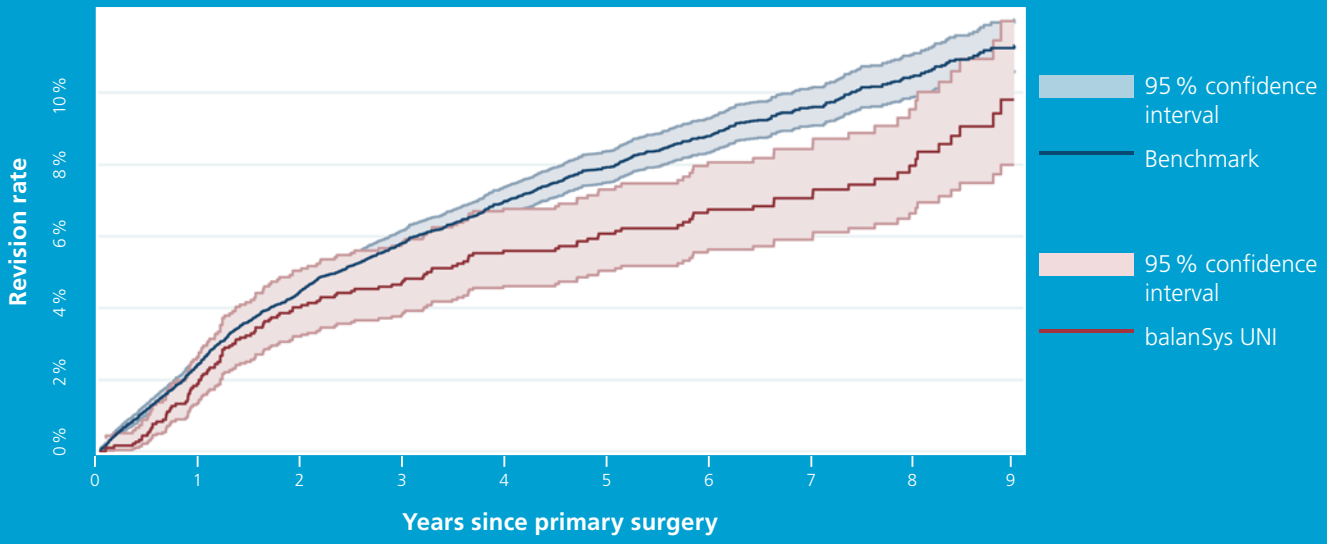
	1 year	3 years	5 years	7 years	9 years
Benchmark	**2.3** (2.1–2.5)	**5.6** (5.2–5.9)	**7.6** (7.2–8.1)	**9.4** (8.9–9.9)	**11.7** (10.9–12.6)
balanSys UNI	**2.2** (1.7–2.8)	**4.7** (4.0–5.6)	**6.1** (5.2–7.2)	**7.2** (6.1–8.5)	**10.2** (8.2–12.8)

Significantly better Within the benchmark Above benchmark

Proven

Swiss Implant Registry (SIRIS) [4]

Revision rate of balanSys UNI versus the benchmark (all other unicondylar knee prostheses)



Revision rate of the balanSys UNI knee system [4]

Reliable

Endoprosthesis Registry Germany (EPRD)[5]

In the German endoprosthesis registry, the balanSys UNI convinces with a revision rate of 7.8 % after 5 years and is thus within the benchmark.

Revision rate up to the relevant time after implantation of the balanSys UNI knee system; revision rate in % incl. 95 % confidence interval in parentheses. Only time points with at least 40 implants under surveillance are listed.[5]

	1 year	3 years	5 years
Benchmark	**3.0** (2.8–3.1)	**5.8** (5.6–6.1)	**7.2** (6.9–7.6)
balanSys UNI	**3.0** (1.8–5.0)	**7.0** (4.8–10.1)	**8.0** (5.5–11.4)

Significantly better | Within the benchmark | Above benchmark

Superior results

Australian Joint Replacement Registry (AOANJRR)[6]

In the Australian Joint Replacement Registry, the long-term safety of balanSys UNI is clinically confirmed with superior 10-year results. With a revision rate of 8.1 % after 10 years, the balanSys UNI achieves a significantly lower revision rate than the average of all documented unicondylar knee replacement systems. The average revision rate for all unicondylar knee prostheses after 10 years is 12 %.

Revision rate after primary unicondylar knee replacement *

Table KP7: Cumulative relative revision rate of primary unicondylar knee replacement (primary diagnosis: osteoarthritis)[6]

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs
Unicompartmental	4449	45423	**2.0** (1.8–2.1)	**4.6** (4.4–4.8)	**6.5** (6.2–6.7)	**12.0** (11.6–12.5)	**19.5** (18.8–20.1)

Revision rate of balanSys UNI *

Table KP6: Cumulative relative revision rate of primary unicondylar knee replacement combinations with 10-year results (primary diagnosis: osteoarthritis) by prosthesis combination[6]

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs
balanSys UNI	balanSys UNI Fixed	52	1085	**1.8** (1.1–2.8)	**3.6** (2.6–5.1)	**4.4** (3.1–6.1)	**7.9** (5.7–11.0)	**13.0** (8.9–18.8)

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

Significantly better Within the benchmark Above benchmark

Very strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP)[7]
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.

ODEP 7A*[7]

balanSys UNI
fixed bearing

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

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, Lützner J. Better short-term function after unicompartmental compared to total knee arthroplasty. BMC Musculoskelet Disord. 2021;22(1):326

3 Swiss National Joint Registry (SIRIS). SIRIS Report 2012 – 2021. Annual Report 2022

4 Swiss Implant Registry (SIRIS), balanSys Unicondylar SIRIS Implant Report (Extended), August 2022

5 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

6 Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2022 Annual Report. Adelaide: AOA, 2022, Tables KP6 and KP7

7 http://www.odep.org.uk/products.aspx, last access 26.04.2023

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

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
BalanSys Uni	BalanSys Uni Fixed	52	1085	1.8 (1.1, 2.8)	3.6 (2.6, 5.1)	4.4 (3.1, 6.1)	7.9 (5.7, 11.0)	13.0 (8.9, 18.8)	

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

Knee Type	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
Unicompartmental	4449	45423	2.0 (1.8, 2.1)	4.6 (4.4, 4.8)	6.5 (6.2, 6.7)	12.0 (11.6, 12.5)	19.5 (18.8, 20.1)	28.4 (27.0, 29.8)
TOTAL	**4449**	**45423**						

Note: Restricted to modern prostheses

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