



MATHYS 
a company of enovis™

**15 YEARS
CLINICAL
EXPERIENCE**

Affinis Inverse

Results you can rely on

CLINICAL RESULTS

PROVEN

for more than 15 years



No compromises – solid primary stability

No compromise in terms of stability with the **2-peg** glenoid baseplate compared to a conventional 1-peg design. The solid primary stability is reflected in clinical practice by the absence of relevant radiolucent lines beneath the baseplate.¹



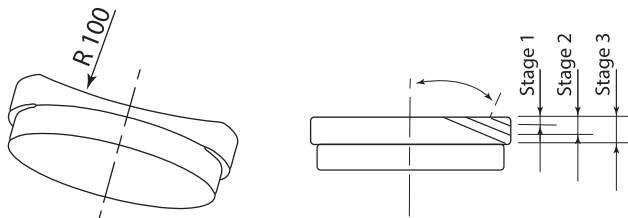
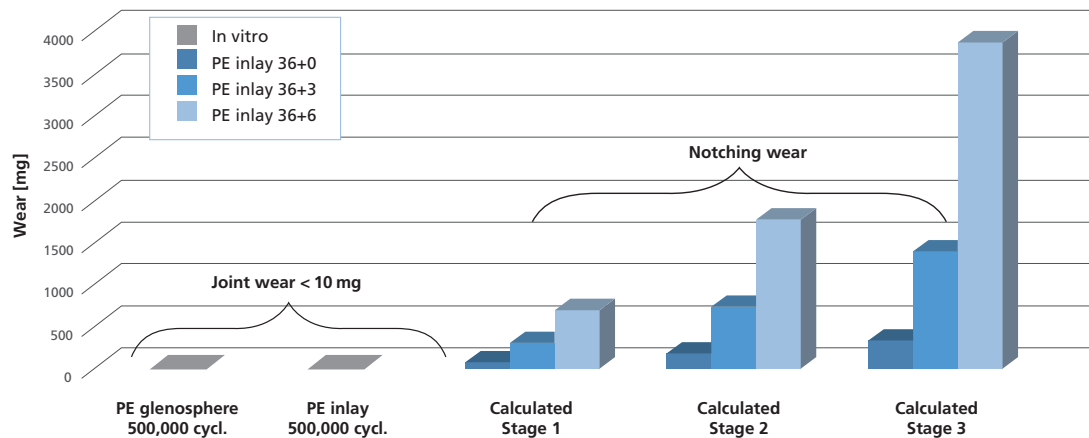
PIONEERING

in design and material



Elimination of PE abrasion

Abrasion of polyethylene (PE) inlays due to mechanical notching results in enormous wear and thus huge amounts of PE debris, which may in turn induce an active process of bone resorption.² Thanks to the inverted-bearing implant design, reduction of wear particles numbers by a factor of 462. Inverted bearings completely eliminate PE debris generation by notching.

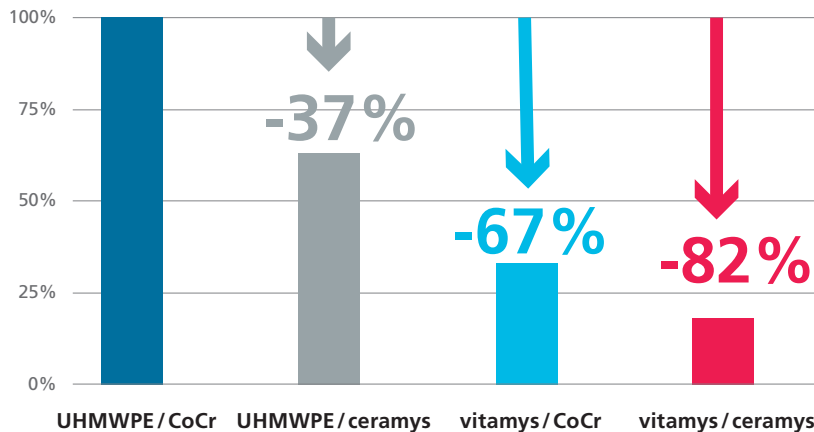


Mass loss due to wear from the articulation bearing (joint wear) and calculated notching wear.
Adapted from Kohut et al. 2012.²

Significant wear reduction

Wear from the articulation bearings is significantly reduced, by **82 %**, with modern bearing materials such as ceramys, a nano-crystalline dispersion ceramic, and vitamys, a highly cross-linked polyethylene enriched with vitamin E. ³

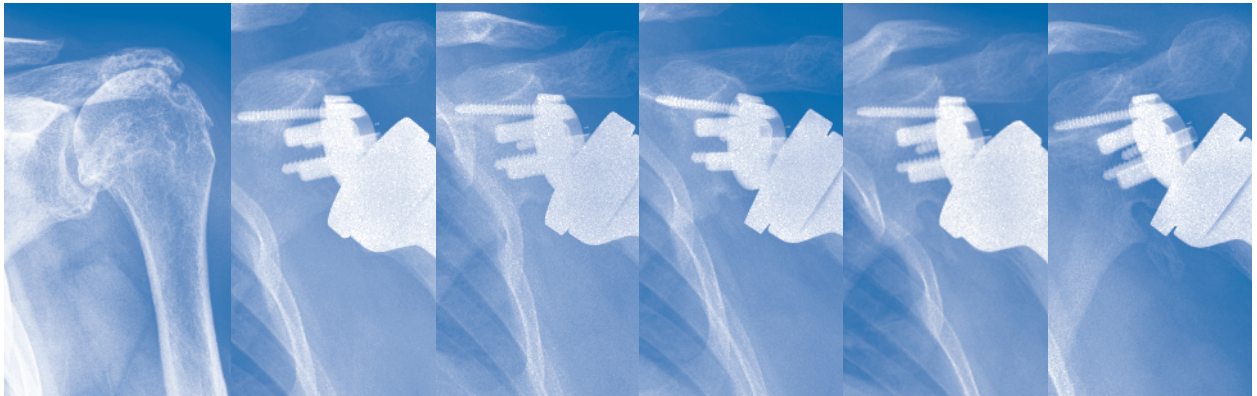
Wear reduction in % with the Affinis Inverse articulation bearing



A distinct type of notching that does not compromise results

Inverted-bearing reverse total shoulder arthroplasty (IB-RTSA) leads to a distinct type of notching resulting from the mechanical impact of the humeral component onto the scapular neck without signs of PE-induced osteolysis. ^{4,5}

X-ray



These radiographies of a patient taken 6 months and 1, 2, 4 and 7 years after surgery highlight the distinct type of notching after IB-RTSA where a sclerotic line develops over time without any indication of osteolysis.

From the **patients' perspective**,
the Affinis Inverse shoulder system
offers **high satisfaction** and
leads to **clinically relevant pain
reduction.** ^{4,6}

Visual analogue scale (VAS) for **satisfaction**⁴



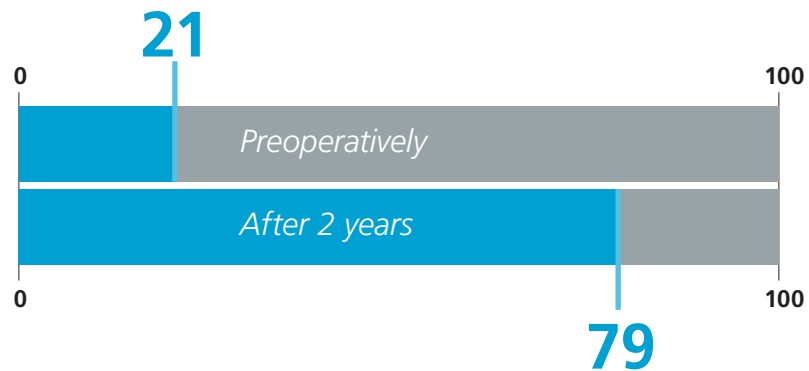
Visual analogue scale (VAS) for **pain**⁴



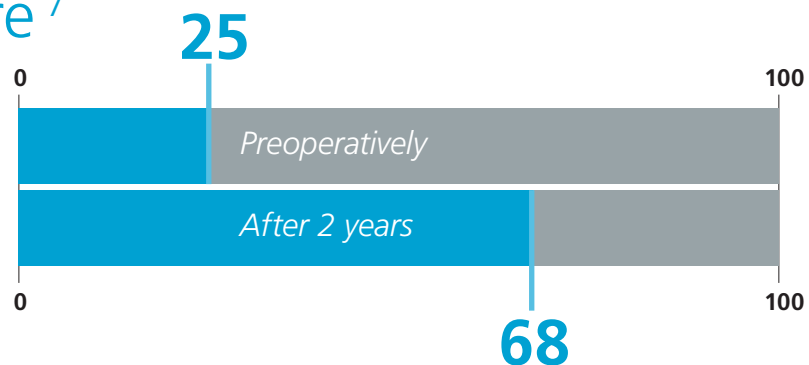
Rapid recovery benefits the patient

High clinical success for the majority of the patients is seen as early as six months after surgery.⁷⁻⁹ Every patient did benefit from the implantation of the Affinis Inverse prosthesis – men and women to the same degree.⁷ The results of the study demonstrate that the majority of the patients benefit significantly in the short-term and for at least up to five years after surgery.⁷

ASES⁷



Constant Score⁷



Patients can expect **similarly good shoulder function, implant survival and low complication rates** with the Affinis Inverse, whether **with or without scapular notching**. Scapular notching does not affect midterm clinical outcomes. ⁵

Reliable registry results

Australian Joint Replacement Registry (AOANJRR)¹¹

In the Australian Joint Replacement Registry, the mid-term safety of Affinis Inverse is clinically confirmed with its 7-year results. With a revision rate of 5.0 % after 7 years, the Affinis Inverse achieves a revision rate within the benchmark of all documented primary total reverse shoulder replacement. The average revision rate of the benchmark cohort is 4.7 % after 7 years.

Revision rate after primary total reverse shoulder replacement

Table ST6: Cumulative relative revision rate of primary total shoulder replacement; revision rate in % incl. 95% confidence interval in parentheses.

| Shoulder Class | N Revised | N total | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs |
|-----------------------|-------------|--------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Total Stemmed Reverse | 1728 | 47251 | 2.4 (2.2–2.5) | 3.5 (3.4–3.7) | 4.1 (3.9–4.4) | 4.7 (4.4–4.9) |

Revision rate of Affinis Inverse

Table ST56: Cumulative relative revision rate of primary total stemmed reverse shoulder replacement by prosthesis combination; revision rate in % incl. 95% confidence interval in parentheses.

| Humeral Stem | Glenoid Component | N Revised | N total | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs |
|--------------|-------------------|-----------|-------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Affinis | Affinis | 62 | 1868 | 1.8 (1.3–2.5) | 3.5 (2.7–4.6) | 4.0 (3.1–5.2) | 5.0 (3.2–7.6) |

National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and Guernsey (NJR)⁹

In the NJR, the revisions rates of both the humerus and the glenoid demonstrate values within the benchmark for any fixation method. With a 9-year revision rate of 3.2 % of the stem and 1.3 % of the glenoid components, the cementless Affinis Inverse system achieves results within the expected range and is comparable to the benchmark of all other primary total shoulder replacements documented in the NJR.

Revision rate at the respective time after implantation of the Affinis Inverse cementless; revision rate in % incl. 95 % confidence interval in parentheses. Only time points with at least 40 cases under observation are listed.

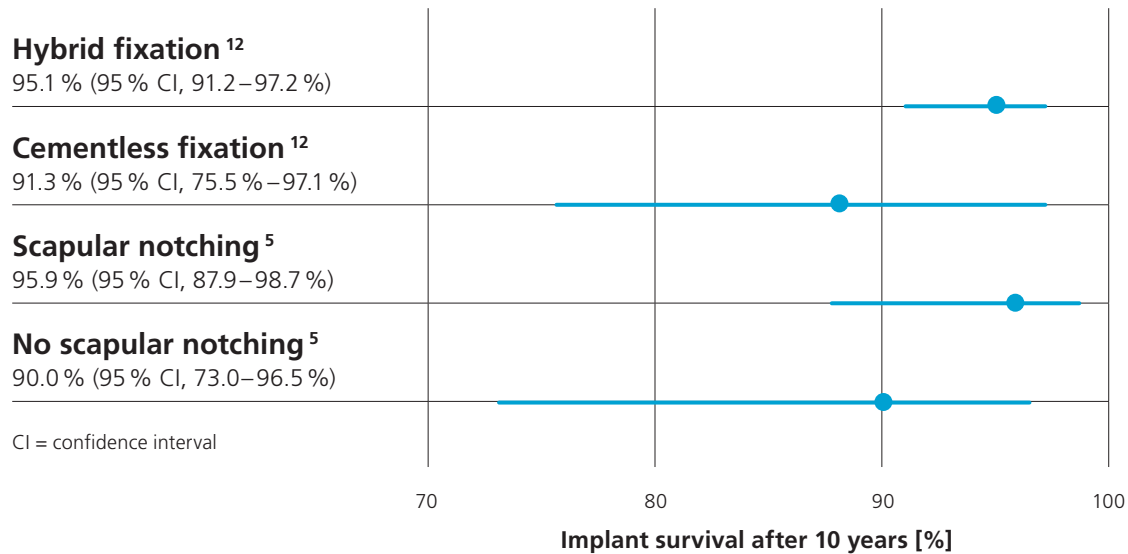
| Endpoint | Shoulder system | 5 years | 7 years | 9 years |
|------------------|-----------------|-------------------------|-------------------------|-------------------------|
| Humeral revision | Benchmark | 3.0 (2.8–3.1) | 3.7 (3.5–3.9) | 4.5 (4.3–4.8) |
| | Affinis Inverse | 2.7 (1.7–4.2) | 3.2 (1.9–5.0) | 3.2 (1.9–6.7) |
| Glenoid revision | Benchmark | 1.0 (0.9–1.1) | 1.3 (1.2–1.4) | 1.7 (1.6–1.9) |
| | Affinis Inverse | 1.3 (0.7–2.4) | 1.3 (0.7–3.0) | 1.3 (0.7–4.5) |

Significantly better

Within the benchmark

Above benchmark

Excellent 10-year survival



Strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP)¹³

The ODEP lists the Affinis Inverse uncemented with 7 years of strong evidence and the Affinis Inverse cemented with 5 years of good evidence.



INVERSE SHOULDER

Affinis Inverse
uncemented



INVERSE SHOULDER

Affinis Inverse
cemented



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 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 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>

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- ¹ Irlenbusch U and Kohut G. Evaluation of a new baseplate in reverse total shoulder arthroplasty – comparison of biomechanical testing of stability with roentgenological follow up criteria. *Orthop Traumatol Surg Res.* 2015;101(2):185-90.
- ² Kohut G, Dallmann F, Irlenbusch U. Wear-induced loss of mass in reversed total shoulder arthroplasty with conventional and inverted bearing materials. *J Biomech.* 2012;45(3):469-73.
- ³ Lerf R, Wuttke V, Reimelt I, Dallmann F, Delfosse D. Tribological Behaviour of the «Reverse» Inverse Shoulder Prosthesis. 7th International UHMWPE Meeting; Philadelphia 2015.
- ⁴ Irlenbusch U, Kaab M, Kohut G, Proust J, Reuther F, Joudet T. Reversed shoulder arthroplasty with inversed bearing materials: 2-year clinical and radiographic results in 101 patients. *Arch Orthop Trauma Surg.* 2015;135(2):161-9.
- ⁵ Kohut G, Reuther F, Joudet T, Kääh MJ, Irlenbusch U. Inverted-bearing reverse total shoulder arthroplasty: scapular notching does not affect clinical outcomes and complications at up to 7 years of follow-up. *J Shoulder Elbow Surg.* 2021;31(4):868-74.
- ⁶ Kääh M, Kohut G, Irlenbusch U, Joudet T, Reuther F. Reverse total shoulder arthroplasty in massive rotator cuff tears: does the Hamada classification predict clinical outcomes? *Arch Orthop Trauma Surg.* 2021;142(7):1405-11.
- ⁷ Huber J, Irlenbusch U, Kääh MJ, Reuther F, Kohut G, Judge A. Treatment effects of reverse total shoulder arthroplasty – a simple method to measure outcomes at 6, 12, 24 and 60 months for each patient. *BMC Musculoskelet Disord.* 2020;21(1):397.
- ⁸ National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and Guernsey (NJR). Summary Report SP Humeral Affinis Inverse. 17.05.2023. Data valid to 12 May 2025.
- ⁹ NJR. National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and Guernsey (NJR). Summary Report SP Humeral Affinis Inverse Cementless. 17.05.2023. Data valid to 12 May 2025.
- ¹⁰ Hamada K, Fukuda H, Mikasa M, Kobayashi Y. Roentgenographic findings in massive rotator cuff tears. A long-term observation. *Clin Orthop Relat Res.* 1990(254):92-6.
- ¹¹ 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 ST6 and ST56
- ¹² Joudet T and Egger M. L'Inversion du couple frottement. In: L. Favard and P. Mansat, editors. *Prothèse totale d'épaule inversée.* Elsevier (SOFECOT): Elsevier; 2020.
- ¹³ <https://www.odep.org.uk/odep-products>, last access 16.08.2023.

AOANJRR tables¹¹

Table ST6 Cumulative Percent Revision of Primary Total Shoulder Replacement by Class (All Diagnoses)

| Shoulder Class | N Revised | N Total | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs | 10 Yrs | 14 Yrs |
|-----------------------|-----------|---------|----------------|----------------|----------------|----------------|----------------|----------------|
| Total Stemmed Reverse | 1728 | 47251 | 2.4 (2.2, 2.5) | 3.5 (3.4, 3.7) | 4.1 (3.9, 4.4) | 4.7 (4.4, 4.9) | 5.7 (5.3, 6.1) | 7.3 (6.4, 8.3) |

Note: Restricted to modern prostheses

Table ST56 Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement by Prosthesis Combination

| Humeral Stem | Glenoid Component | N Revised | N Total | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs | 10 Yrs | 14 Yrs |
|--------------|-------------------|-----------|---------|----------------|----------------|----------------|----------------|--------|--------|
| Affinis | Affinis | 62 | 1868 | 1.8 (1.3, 2.5) | 3.5 (2.7, 4.6) | 4.0 (3.1, 5.2) | 5.0 (3.2, 7.6) | | |

Note: Restricted to modern prostheses

Only prostheses with >50 procedures have been listed

Preservation in motion

