Smith+Nephew

CATALYSTEM◊

Primary Hip System

Design Rationale

CATALYSTEM Primary Hip System

Achieving better patient outcomes is what drives us

Based on the heritage of Smith+Nephew's clinically successful stem designs,[1,2] CATALYSTEM is designed for use in all approaches, (especially muscle-sparing approaches[3]) to deliver precision fit for a global population,[4,5] confident surgery with proven reproducible results,[6,7] and an efficient surgical workflow with approach-specific instrumentation, based on surgeon preference.[8]

OXINIUM◊ Technology, the Smith+Nephew award winning bearing technology,[9] brings unrivalled material properties to a stem leveraging best-in-class implant design.[1,2,10-14]

OXINIUM Technology has shown strong clinical and health economic outcomes, delivering value to patients, payers and providers;[15-18] equipping you to advance today's standard of care in total hip arthroplasty.

The following Design Rationale is intended for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques, according to their own clinical judgment, for each of their patients.

Precise

Designed to address the global patient population,[4,5] CATALYSTEM provides uniform proximal loading and reduced distal stem geometry,[19,20] thereby mitigating the risk of under sizing and distal potting.

Confident

Building on POLARSTEM◊ Hip System heritage,[1,21] CATALYSTEM enables reproducible implant seating using proprietary, patent pending ACCUBROACH◊ Technology, minimising the risk of calcar fracture.[6,22]

Efficient

A single modular tray tailored by surgical approach, providing efficiencies in facilitating more shelf space and reducing sterilisation costs.[8]

Best-in-class just got better

Standard 12/14 taper

Standard and high neck offsets

Uniform growth size-to-size. Optimized neck length verified from surgeon feedback and 3D fit study.[4,23]

Collared and collarless variants

The presence of a collar increases the primary stability of the stem (demonstrated in mechanical testing) and may help minimize risk of subsidence.[24,25]

Decreased distal geometry

Compared to competitors to mitigate the risk of distal potting, and to allow for better proximal fill.[4,20]

Designed to fit a wide variety of femurs including Dorr Type A.[4]

Shorter lengths

Allow for ease of implantation in anterior approaches and is easier to insert compared to a standard-length stem.[3]

Proximally filling triple tapered stem design

AP/ ML fill verified through surgeon feedback and 3D fit study.[4,7]

The CATALYSTEM offers initial stability demonstrated in mechanical testing.[7,25]

Groove geometry

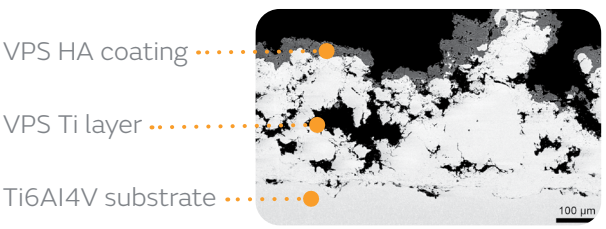
Based on POLARSTEM®, provides increased surface area intended for bony on growth and stability. The presence of grooves increases the primary stability of the stem.[1]

CATALYSTEM coating

Built on twenty years of clinical heritage and manufacturing knowledge used on POLARSTEM.[21]

Designed to provide rapid osseointegration and contribute to primary stability with an advanced surface roughness of 325µm open porous Titanium plasma spray proximally, with an additional 50µm layer of HA (Hydroxyapatite).[21]

Cross-sectional image of coating



Precise

The CATALYSTEM Primary Femoral Stem is a triple taper, proximally filling press-fit stem designed for all approaches, especially more muscle-sparing approaches.[3] This stem is designed to maximize stability while preserving bone.[2]

Designed utilizing global anthropometric data[4,5]

Utilising a 3D fit CT analysis CATALYSTEM was designed to:

- Fit a wide variety of femur types including Dorr A type femurs with the potential to reduce the risk of distal potting[4]
- Support a diverse patient population with enhanced implant fit for multiple femoral morphologies including small stature femurs[4,5]
- Demonstrate preferential proximal bony contact designed to optimize long-term fixation.[4]
- The CATALYSTEM collar grows by size to ensure optimal fit/length across the range, reducing risk of overhang.[4] An optimized collar size and incremental growth has been shown to minimize the risk of illiopsoas impingement.[4,26]

3D fit CT analysis Cloud mapping in Dorr A Type Femur

Precise *continued*

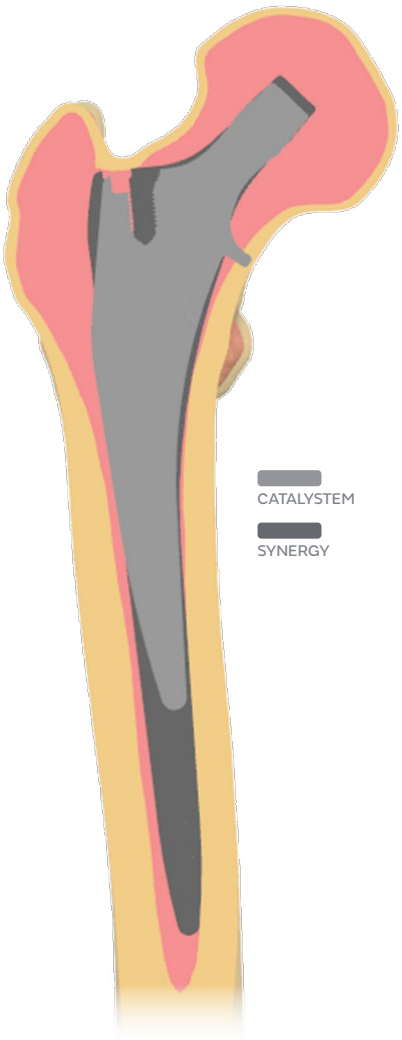
Optimized geometry – Preserve bone and maximize stability

- Optimize AP/ML fill, offering initial stability*[4,25]
- The lateral relief and anterior/posterior chamfers of CATALYSTEM◊ facilitates bone preservation in the greater trochanteric region compared to SYNERGY◊. This combination alleviates the need for bone removal in the metaphysis and assists insertion, whilst enhancing initial axial and rotational stability.[2]

*As demonstrated in mechanical testing

CATALYSTEM vs SYNERGY

Reduction in distal stem geometry

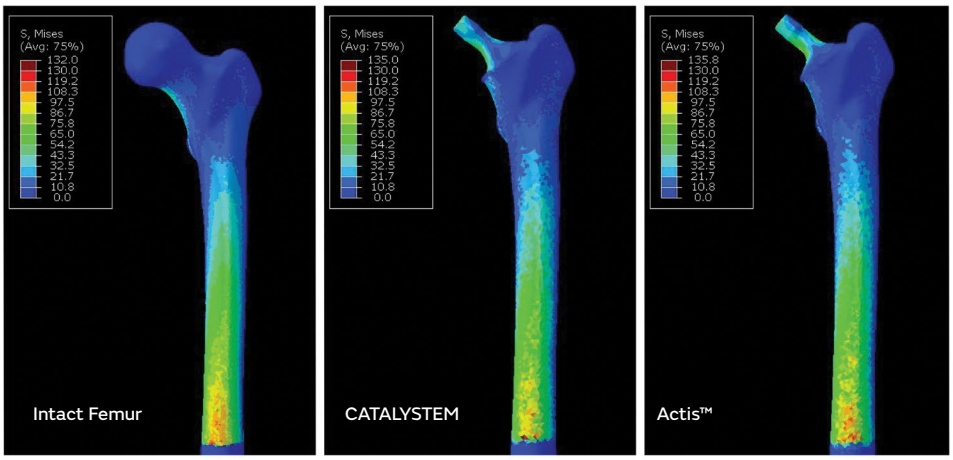


Profile in the greater trochanteric region

Uniform proximal loading

A finite element analysis was performed to compare physiological relevant loading of CATALYSTEM against a commercially available alternative and an intact femur. The analysis demonstrates that:

- The CATALYSTEM uniformly loads the proximal bone[19]
- The CATALYSTEM loads bone similarly to a commercially available shorter triple taper stem[19]



Surface Stress (Von Mises)

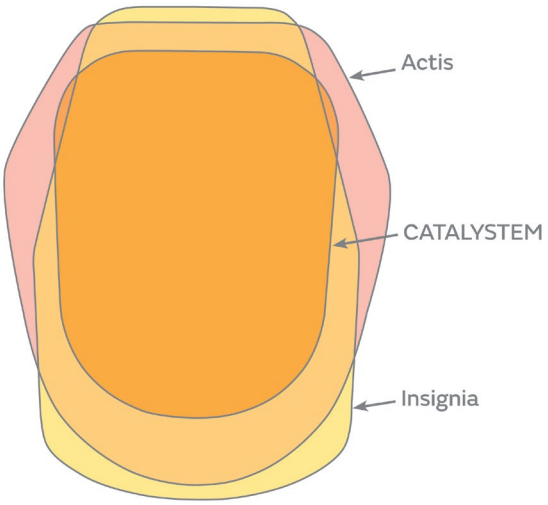
Decreased distal geometry

The decreased distal geometry of CATALYSTEM is designed to mitigate the risk of distal potting and allows for better proximal fill.[20]

Distal stem potting can cause a mismatch in proximal and distal fill which can be associated with stem subsidence, leg pain, and implant failure.

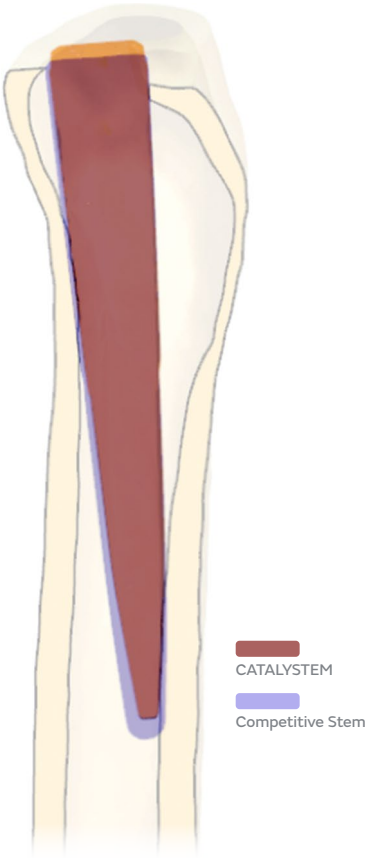
CATALYSTEM is smaller in A/P distal tip width for all sizes compared to commercially available offerings. M/L width remains smaller than both alternatives from Sizes 1 – 12.[20]

Cross section at 10mm from CATALYSTEM SZ 6 distal tip



Precise *continued*

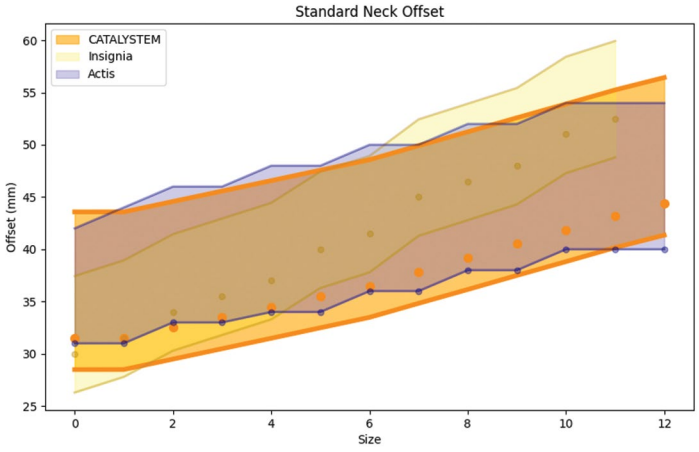
CATALYSTEM also offers an additional taper on the AP distal tip unlike commercially available alternatives from other manufacturers.[20] This taper allows for increased proximal fill prior to the stem contacting the distal cortex.[7] The shorter lengths of CATALYSTEM and distal, lateral relief allow for easy insertion, especially in anterior approaches, as well as accommodating multiple femoral morphologies.[3,4,20]

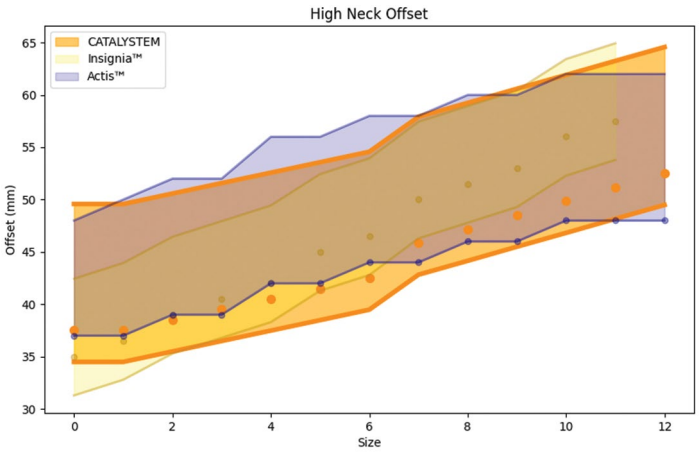


Restore biomechanics

CATALYSTEM can recreate natural head centre in multiple femoral morphologies.[4] A constant neck angle of 131° provides direct lateralization thus allowing the surgeon to recreate offset without affecting leg length. For sizes 0-6, offset increases by 6mm when moving from standard to high offset and 8mm for sizes 7-12. The linear growth of the neck allows for predictable anatomical reconstruction.[4]

CATALYSTEM has more neck length and offset options compared to commercially available alternatives with uniform growth.[23]





Leveraging our clinical heritage

CATALYSTEM builds on a best-in-class product, POLARSTEM®, which demonstrates some of the highest survivorship across multiple registries worldwide.[27,28]

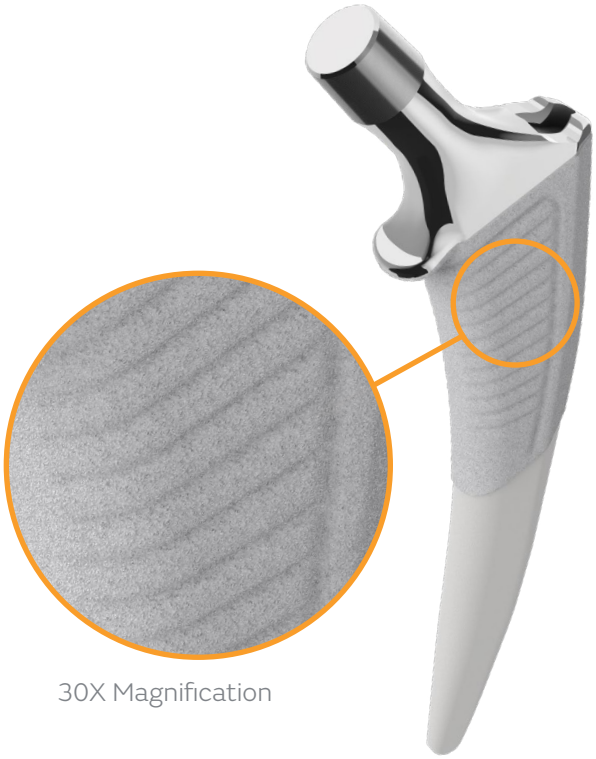
The CATALYSTEM hip system was designed to leverage features from the clinically successful POLARSTEM.[1] The circular neck, proximal groove dimensions, coating and fit in the frontal plane are all features that were leveraged to improve the range of motion and stability of the femoral stem.

Groove geometry

Provides an increased surface area intended for bony on growth and stability. The presence of grooves may increase the primary stability of the stem.[1]

Macro grooves in the proximal region may enhance long-term stability by increasing the surface area in contact with bone.

CATALYSTEM builds upon this concept by wrapping the grooves around the medial corners to help maximize stability whilst mimicking the groove depth, length, angle, and spacing.



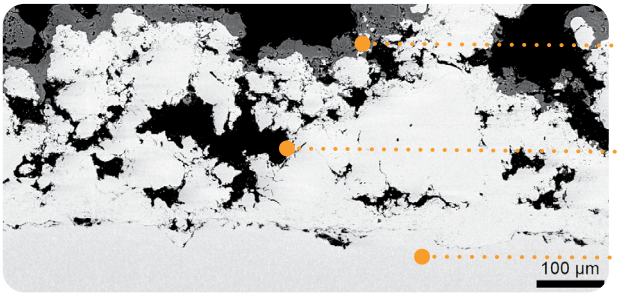
30X Magnification

CATALYSTEM coating

Built on twenty years of clinical heritage and manufacturing knowledge used on POLARSTEM.[21]

Designed to provide rapid osseointegration and contribute to primary stability with an advanced surface roughness of 325µm open porous Titanium plasma spray proximally, with an additional 50µm layer of HA (Hydroxyapatite).[21]

Cross-sectional image of coating



VPS HA coating

VPS Ti layer

Ti6Al4V substrate

Confident

The CATALYSTEM System utilizes proprietary, patent-pending, ACCUBROACH◊ Technology **providing proven reproducibility between broach and implant and predictable and reproducible stem seating.**[6,7]

ACCUBROACH◊ Technology

The ACCUBROACH design features three types of teeth to **help optimize cutting efficiency** and provide **rotational and axial stability.**[7]

Annular compaction

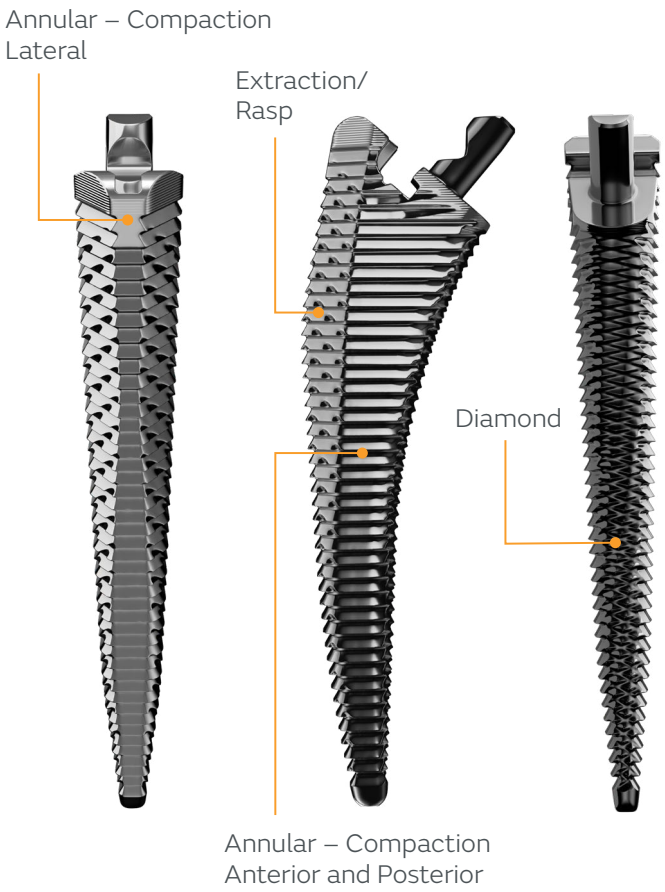
Present on the anterior, posterior and lateral faces of the broach. Compact cancellous bone in the AP direction (similar to POLARSTEM) enhancing the stability and fit of the implant.[22]

Extraction

Present on the lateral chamfers, with a more aggressive cutting profile, the extraction teeth are designed to remove compact or thin bone spurs on the anterior/ posterior lateral region.[3] This tooth design helps minimize periprosthetic fracture risks due to low bone compressing forces during the implantation of the femoral stem.[22]

Diamond

Present along the medial face of the broach. The diamond teeth cut the bone medially and play a crucial role in providing rotational stability.[22]

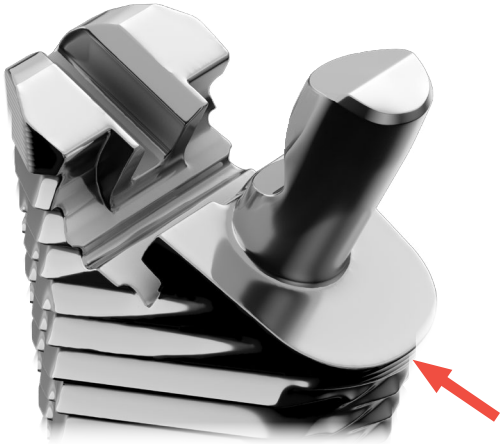


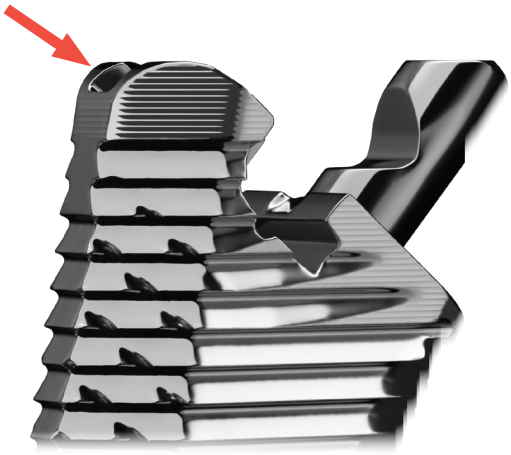
Soft tissue and bone conserving

CATALYSTEM and ACCUBROACH◊ technology are designed to be bone-conserving and soft tissue-sparing and are easy to insert through anterior approaches, providing tactile feedback (pitch change and feel) when at the correct size.[3,22]

The ACCUBROACH design includes a smoothed region on the medial aspect of the broach, spanning the entirety of the medial arc. The smoothing of the proximal cutting teeth is designed to reduce the risk of calcar fracture whilst preparing the femur.[22]

Additionally, the lateral shoulder of the ACCUBROACH is smoothed to protect soft tissues in the greater trochanteric region, proportionately increasing with broach size.[21]



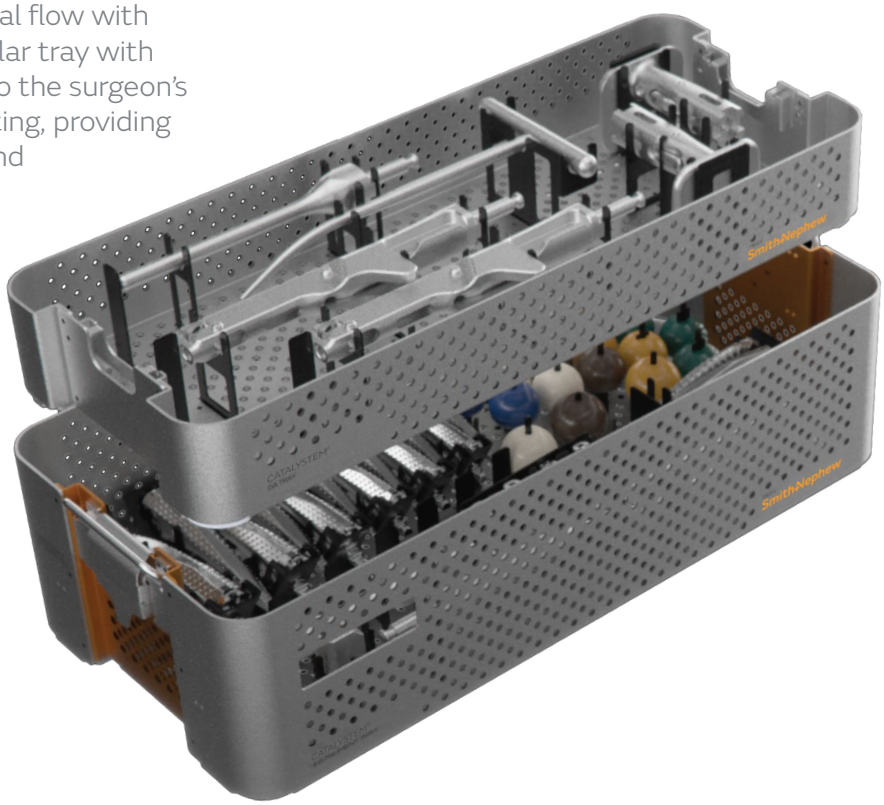


Efficient

An ergonomic and efficient solution for you

A single modular tray

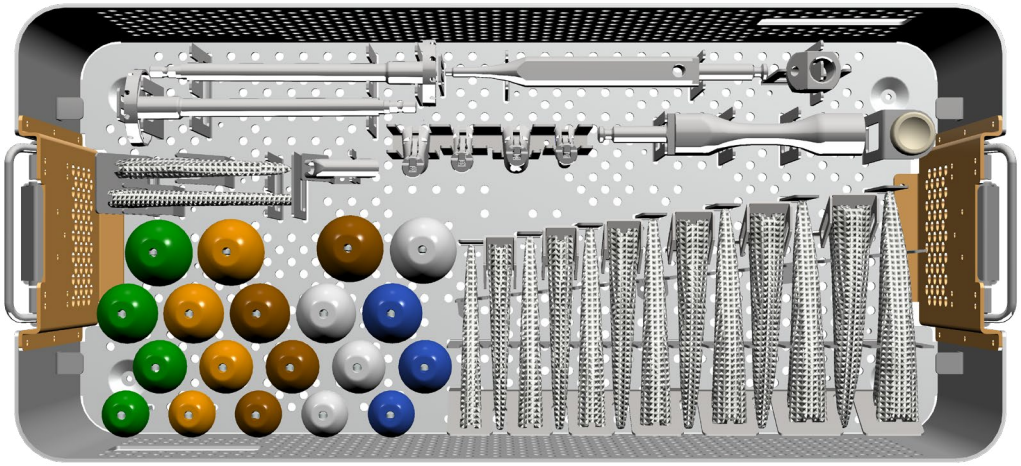
CATALYSTEM is designed for seamless surgical flow with instrumentation configured in a single, modular tray with approach-specific instrumentation tailored to the surgeon's preference.[8] It is ideally suited to an ASC setting, providing efficiencies in facilitating more shelf space and reduced sterilization cost.[8]



Ideal for ASCs

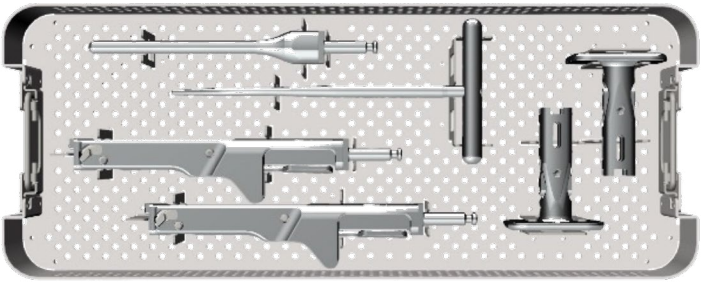
Comprised of a core base layer tray with an interchangeable approach-specific top layer insert.

Core tray

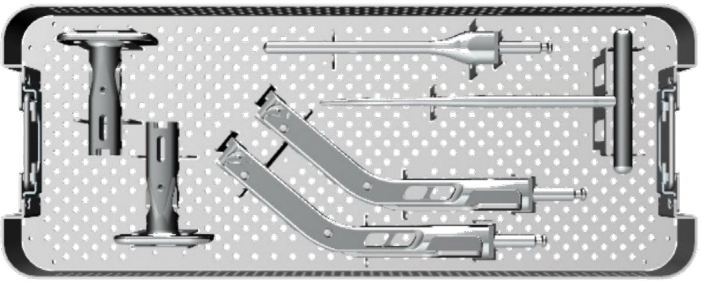


Choice of top layer insert

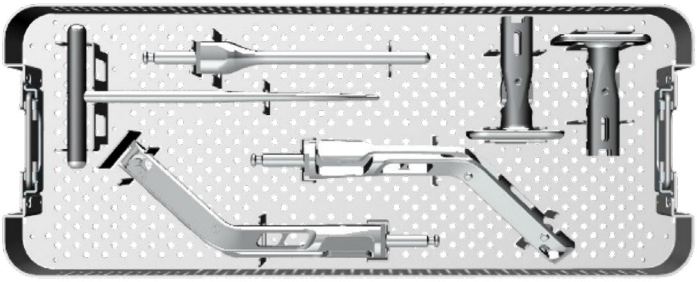
CATALYSTEM DA Broach Handle Tray



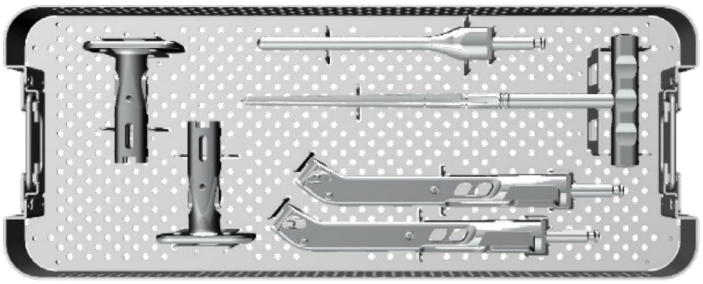
CATALYSTEM Single Offset Broach Handle Tray



CATALYSTEM Dual Offset Broach Handle Tray



CATALYSTEM Straight Broach Handle Tray



Efficient *continued*

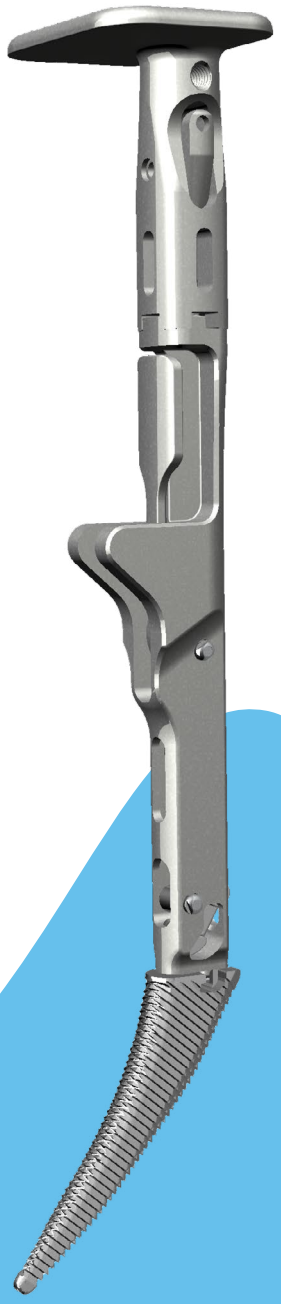
For settings where there are varied surgical approaches, we offer the flexibility to add a different broach layer insert in a separate tray (71313156).

In harmony with our ACCUBROACH◊ Technology broach design, our broach handles are engineered to facilitate muscle-sparing approaches.

The DA Broach Handle (71313142) provides a 40° insertion angle to aid broach preparation in the Direct Anterior approach and a 40° striking surface to extract at the centreline of the broach.

Additional broach handle options:

Double Offset Left 71365731
Double Offset Right 71365729
Straight 71365727
Single Offset 71365728



Unlock the power of Smith+Nephew

Discover Smith+Nephew's best-in-class orthopedic hip solutions portfolio, backed by a proven track record of delivering superior outcomes and allowing patients to live a life unlimited.

OXINIUM◊ DH Technology

The only primary hip stem of its kind to feature OXINIUM Technology, offering the durability of metal, the wear resistance of ceramic and corrosion resistance better than both.[29-32] Demonstrating performance over 20 years of clinical use, OXINIUM Technology has been shown to minimize taper corrosion in total joint arthroplasty.[33,34]

The unique combination of OXINIUM Oxidized Zirconium heads with a highly cross-linked polyethylene (XLPE) liner has been shown to result in the lowest revision rate of all modern bearing combinations in four national joint registries.*[15,28,35,36]

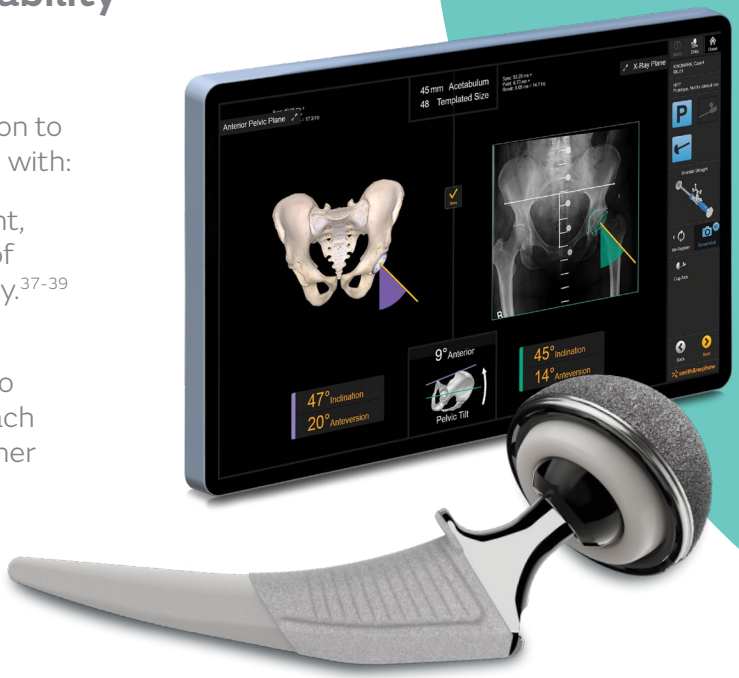
*Vs all other reported bearing combinations NJREW data from 2004-2016; RIPO data from 2000-2015; LROI data from 2007-2016; AOANJRR Annual Report

A comprehensive solution for hip instability

Harnessing the advantages of digital joint replacement technology and other portfolio implant solutions, CATALYSTEM offers a distinct and comprehensive solution to address the challenges of hip instability when combined with:

RI.HIP NAVIGATION: Personalized component alignment, accurate control of pelvic tilt and digital measurement of leg length/offset using CORI◊ Surgical System technology.[37-39]

OR3O◊ Dual Mobility and R3◊ Acetabular System: Compatible with a range of acetabular system options to allow surgeons versatility in deciding the optimal approach for their patient, including modular dual mobility, flush liner seating, biological ingrowth[40-43] and diffusion-hardened OXINIUM DH Technology.



Discover more here:

OXINIUM◊
Oxidized Zirconium

OR3O◊
Dual Mobility with
OXINIUM DH Technology

RI.HIP Navigation
Total Hip Arthroplasty

R3◊
Acetabular System with
OXINIUM Technology

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References

1. Smith+Nephew 2024. CATALYSTEM Comparison to Legacy Stem: POLARSTEM. Internal Report. 10143423 REVA. **2.** Smith+Nephew 2024. CATALYSTEM comparison to legacy stem: SYNERGY. Internal Report. 10143364 REV A. **3.** Smith+Nephew 2024. Surgeon Feedback on the CATALYSTEM Total Hip System. Internal Report. CSD.REC.24.001. **4.** Smith+Nephew 2024. Three-dimensional assessment stem fit and restoration of natural biomechanics in a globally diverse population of femoral CT scans. Internal Report. TM-24-034. **5.** Smith+Nephew 2024. CATALYSTEM summary of global evaluations. Internal Report. 10143591. **6.** Smith+Nephew 2024. Cadaveric study of the repeatability of CATALYSTEM broach and femoral stem seating level. Internal Report. 10144794. **7.** Smith+Nephew 2023. Cadaver validation of the CATALYSTEM Total Hip System. Internal Report. OR-23-106. **8.** Smith+Nephew 2024. CATALYSTEM claims tray efficiency memo. Internal Report. 10143458 REV A. **9.** 2005 ASM International Engineering Materials Achievement Award. **10.** Hunter G, Dickinson J, Herb B, et al. Creation of oxidized zirconium orthopaedic implants. Journal of ASTM International. 2005;2:1-14. **11.** Parikh A, Hill P, Pawar V, Sprague J. Long-term simulator wear performance of an advanced bearing technology for THA. Poster presented at: 2013 Annual Meeting of the Orthopaedic Research Society. Poster no. 1028. **12.** Papannagari R, Hines G, Sprague J, Morrison M. Long-term wear performance of an advanced bearing technology for TKA. Poster presented at: 2011 Annual Meeting of the Orthopaedic Research Society. Poster no. 1141. **13.** Dalal A, Pawar V, McAllister K, Weaver C, Hallab NJ. Orthopedic implant cobalt-alloy particles produce greater toxicity and inflammatory cytokines than titanium alloy and zirconium alloy-based particles in vitro, in human osteoblasts, fibroblasts, and macrophages. J Biomed Mater Res Part A. 2012;100A:2147-2158. **14.** Pawar V, Jones B, Sprague J, Salehi A, Hunter G. Acidic fretting tests of oxidized Zr-2.5Nb, CoCr and SS femoral heads. Paper presented at: Materials & Processes for Medical Devices Conference, ASMI, St. Paul, Minnesota, 2004. **15.** Davis ET, Pagkalos J, Kopjar B. Bearing surface and survival of cementless and hybrid total hip arthroplasty in the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man. Journal of Bone Joint Surgery. 2020;5(2):pe0075. **16.** Innocenti M, Matassi F, Carulli C, Nistri L, Civinini C. Oxidized zirconium femoral component for TKA: A follow-up note of a previous report at a minimum of 10 years. The Knee. 2014;21:858–861. **17.** Mayman DJ, Patel AR, Carroll KM. Hospital related clinical and economic outcomes of a bicruciate knee system in total knee arthroplasty patients. Poster presented at: ISPOR Symposium; May 19-23, 2018; Baltimore, Maryland, USA. **18.** Patrick C, Delhougne G, Patel A. Retrospective analysis of oxidized zirconium bearing surface in hip replacement 90-day episode claims. ISPOR EU Poster, 2019. **19.** Smith+Nephew 2024. Finite element analysis of the CATALYSTEM hip stem design. Internal Report. OR-24-025. **20.** Smith+Nephew 2024. CATALYSTEM distal taper and cross section comparisons of competitive stems. Internal Report. 10142796 Rev B. **21.** Smith+Nephew 2024. Morphological and mechanical properties of a dual layered porous plasma spray coating. Internal Report. 10145064. **22.** Smith+Nephew 2024. CATALYSTEM ACCUBROACH femur to bone interaction design rationale. Internal Report. 10142827. **23.** Smith+Nephew 2024. CATALYSTEM comparison to competitive neck geometries. Internal Report. 10143689. **24.** Nerys-Figueroa J, Parsa A, Curley A et al. Slightly reduced early subsidence with similar outcomes and complications rate in collared stems – a systematic review of randomized clinical trials. Journal of Orthopaedics, 2024; 50; 170-176. **25.** Smith+Nephew 2024. CATALYSTEM foam femur torsion stability. Internal Report. OR-24-082. **26.** Qiu, J. et al. Risk factors for iliopsoas impingement after total hip arthroplasty using a collared femoral prosthesis. Journal of Orthopaedic Surgery and Research (2020) 15:267. https://doi.org/10.1186/s13018-020-01787-3. **27.** National Joint Registry for England, Wales and Northern Ireland. 20th Annual Report, 2023. Available at: https://reports.njrcentre.org.uk. Accessed May 24, 2024. **28.** Australian Orthopaedic Association National Joint Replacement Registry Hip, Knee & Shoulder Arthroplasty: 2023 Annual Report. Available at: https://aoanjrr.sahmri.com/annual-reports-2023. Accessed May 24, 2024. **29.** Sheth NP, Lementowski P, Hunter G, Garino JP. Clinical applications of oxidized zirconium. J Surg Orthop Adv. 2008;17(1):17-26. **30.** Davidson JA, et al. Friction and UHMWPE wear of cobalt alloy, zirconia, titanium nitride, and amorphous diamond-like carbon implant bearing surfaces. Poster presented at: 4th World Biomaterials Con1992; Berlin, FRG. **31.** Hobbs L, et al. Int J Appl Ceram Technol. 2005. **32.** Long M, et al, Hunter G. Nano-Hardness Measurements of Oxidized Zr.2.5Nb and Various Orthopaedic Materials. 1998. **33.** Cartner J, et al. Hss j. 2017;13(1):35-41. **34.** Cartner J, et al. Journal of Orthopaedic Research. 2016;34. **35.** Peters RM, et al. Acta Orthopaedica. 2018;89(2):163-169. **36.** Atrey A, et al. Poster presented at: Canadian Orthopedic Association; June 20–23, 2018; Victoria, British Columbia, Canada. **37.** Clavé A, et al. In Orthopaedics & Traumatology, Surgery & Research. 2015;101:647-653. **38.** Renkawitz T, et al. J Arthroplasty. 2014;29(5):1021–1025. **39.** Ulivi M, et al. J Arthroplasty. 2014;29(5):1026–1029. **40.** Naudie D, et al. J Arthroplasty. 2013;28(8 Suppl):48-52. **41.** Bourne R, et al. Orthopedics. 2008;31(12 Suppl 2). **42.** Bobyn J, et al. Clin Orthop Relat Res. 1980(150):263-270. **43.** Kienapfel H, et al. J Arthroplasty. 1999;14(3):355-368.