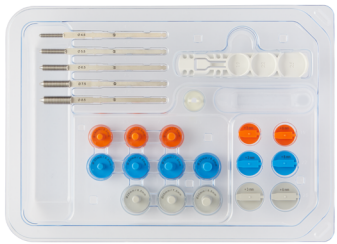


Sterile Single-Use Instrument Kits

Complete, Compact, Efficient

- Aim to improve **efficiency**, **reduce costs**, and **minimize delays**¹⁵⁻¹⁹
- May translate to **less time** spent pre-operatively searching for equipment¹⁸



Ordering Information

PART #	DESCRIPTION
03.405.000S	Radial Head Replacement Instrument Kit, Sterile
09.405.950S	Radial Head w/ Ø19mm Head, Ø5.5mm Stem, 9(+0)mm Head Height, Sterile
09.405.953S	Radial Head w/ Ø19mm Head, Ø5.5mm Stem, 9(+3)mm Head Height, Sterile
09.405.956S	Radial Head w/ Ø19mm Head, Ø5.5mm Stem, 9(+6)mm Head Height, Sterile
09.405.960S	Radial Head w/ Ø19mm Head, Ø6.5mm Stem, 9(+0)mm Head Height, Sterile
09.405.963S	Radial Head w/ Ø19mm Head, Ø6.5mm Stem, 9(+3)mm Head Height, Sterile
09.405.966S	Radial Head w/ Ø19mm Head, Ø6.5mm Stem, 9(+6)mm Head Height, Sterile
09.405.970S	Radial Head w/ Ø19mm Head, Ø7.5mm Stem, 9(+0)mm Head Height, Sterile
09.405.973S	Radial Head w/ Ø19mm Head, Ø7.5mm Stem, 9(+3)mm Head Height, Sterile
09.405.976S	Radial Head w/ Ø19mm Head, Ø7.5mm Stem, 9(+6)mm Head Height, Sterile
09.405.250S	Radial Head w/ Ø22mm Head, Ø5.5mm Stem, 10(+0)mm Head Height, Sterile
09.405.253S	Radial Head w/ Ø22mm Head, Ø5.5mm Stem, 10(+3)mm Head Height, Sterile
09.405.256S	Radial Head w/ Ø22mm Head, Ø5.5mm Stem, 10(+6)mm Head Height, Sterile
09.405.260S	Radial Head w/ Ø22mm Head, Ø6.5mm Stem, 10(+0)mm Head Height, Sterile
09.405.263S	Radial Head w/ Ø22mm Head, Ø6.5mm Stem, 10(+3)mm Head Height, Sterile
09.405.266S	Radial Head w/ Ø22mm Head, Ø6.5mm Stem, 10(+6)mm Head Height, Sterile
09.405.270S	Radial Head w/ Ø22mm Head, Ø7.5mm Stem, 10(+0)mm Head Height, Sterile
09.405.273S	Radial Head w/ Ø22mm Head, Ø7.5mm Stem, 10(+3)mm Head Height, Sterile
09.405.276S	Radial Head w/ Ø22mm Head, Ø7.5mm Stem, 10(+6)mm Head Height, Sterile
09.405.280S	Radial Head w/ Ø22mm Head, Ø8.5mm Stem, 10(+0)mm Head Height, Sterile
09.405.283S	Radial Head w/ Ø22mm Head, Ø8.5mm Stem, 10(+3)mm Head Height, Sterile
09.405.286S	Radial Head w/ Ø22mm Head, Ø8.5mm Stem, 10(+6)mm Head Height, Sterile
09.405.560S	Radial Head w/ Ø25mm Head, Ø6.5mm Stem, 11(+0)mm Head Height, Sterile
09.405.563S	Radial Head w/ Ø25mm Head, Ø6.5mm Stem, 11(+3)mm Head Height, Sterile
09.405.566S	Radial Head w/ Ø25mm Head, Ø6.5mm Stem, 11(+6)mm Head Height, Sterile
09.405.570S	Radial Head w/ Ø25mm Head, Ø7.5mm Stem, 11(+0)mm Head Height, Sterile
09.405.573S	Radial Head w/ Ø25mm Head, Ø7.5mm Stem, 11(+3)mm Head Height, Sterile
09.405.576S	Radial Head w/ Ø25mm Head, Ø7.5mm Stem, 11(+6)mm Head Height, Sterile
09.405.580S	Radial Head w/ Ø25mm Head, Ø8.5mm Stem, 11(+0)mm Head Height, Sterile
09.405.583S	Radial Head w/ Ø25mm Head, Ø8.5mm Stem, 11(+3)mm Head Height, Sterile
09.405.586S	Radial Head w/ Ø25mm Head, Ø8.5mm Stem, 11(+6)mm Head Height, Sterile

Please also refer to the package insert(s) or other labeling associated with the devices identified in this brochure for additional information.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this brochure may not have been licensed in accordance with Canadian law and may not be for sale in Canada.

Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



Radial Head Replacement System allows for direct and radiographic visualization of the radio-capitellar, proximal radio-ulnar, and ulno-humeral joints during trialing.^{1,20}

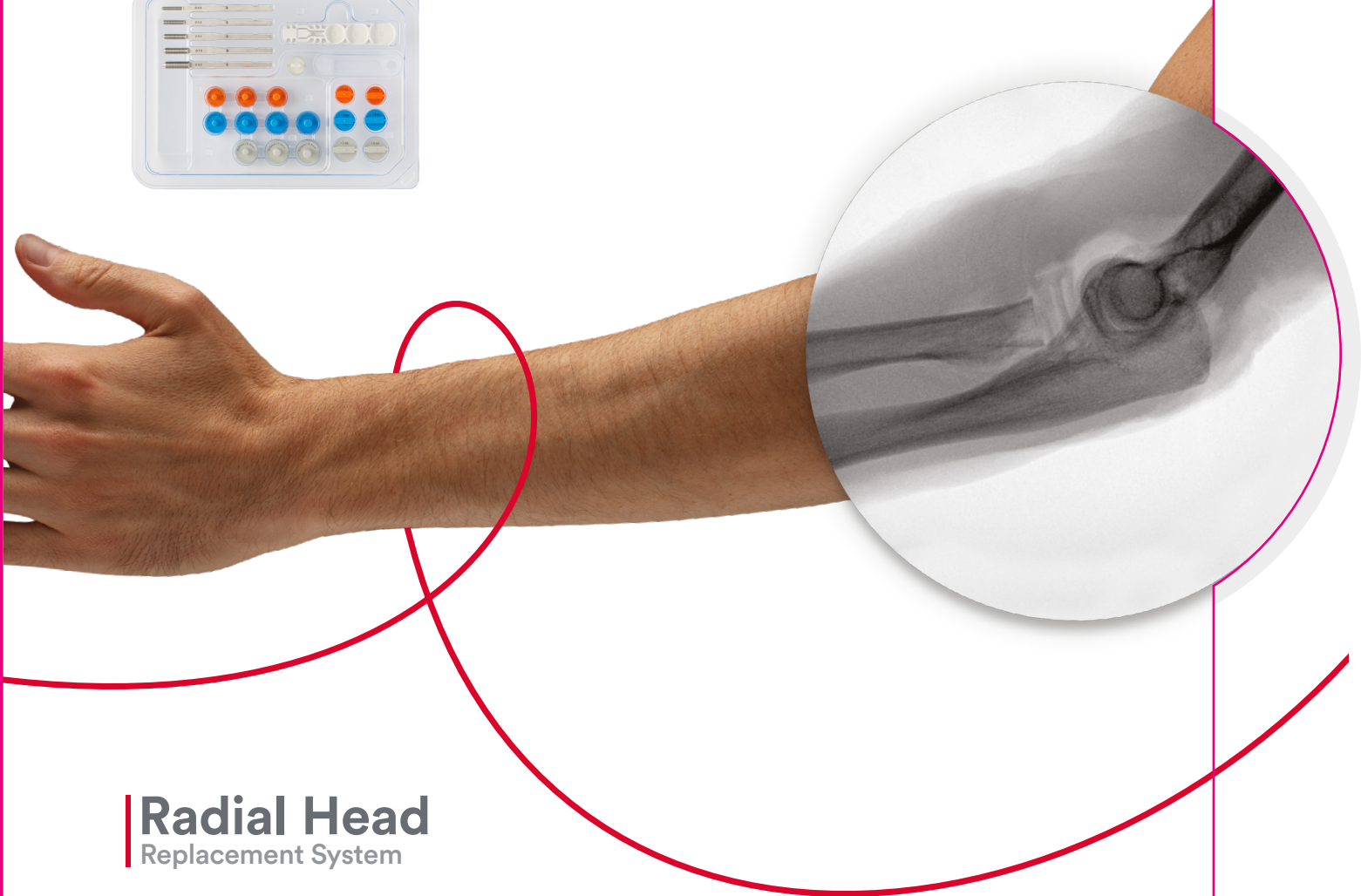
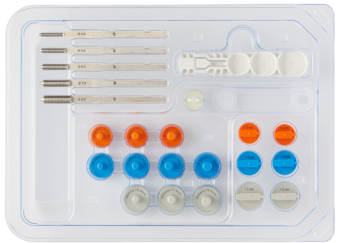
Clear visualization with Radiolucent Trials ensures that the chosen implant allows for a **degree of play** within the radial neck, helping the implant remain **centered** during elbow motion.² In addition, **efficiency** and **cost savings** can be realized with single-use instrumentation.^{1,16,20,21}

References: 1. DePuy Synthes Report: See Better Size Better Memo. 10/2/2019. Windchill Document #0000290188. 2. Acevedo DC, Paxton ES, Kukelyansky I, Abboud J, Ramsey M. Radial head arthroplasty: state of the art. J Am Acad Orthop Surg. 2014;22(10):633-642. 3. Szmít J, King GJ, Johnson JA, Langohr DG. The effect of stem fit on the radiocapitellar contact mechanics of a metallic axisymmetric radial head hemiarthroplasty: is loose fit better than rigidly fixed? J Shoulder Elbow Surg. 2019;28:2394-2399. 4. Flínkkilä T, Kaisto T, Sirniö K, Hyvönen P, Leppilähti J. Short- to mid-term results of metallic press-fit radial head arthroplasty in unstable injuries of the elbow. J Bone Joint Surg Br. 2012;94(6):805-810. 5. Allavena C, Delclaux S, Bonneville N, Rongières M, Bonneville P, Mansat P. Outcomes of bipolar radial head prosthesis to treat complex radial head fractures in 22 patients with a mean follow-up of 50 months. Orthop Traumatol Surg Res. 2014;100(7):703-709. 6. Nestorson J, Josefsson PO, Adolfsson L. A radial head prosthesis appears to be unnecessary in Mason-IV fracture dislocation. Acta Orthop. 2017;88(3):315-319. 7. Rodriguez-Quintana D, Comulada DB, Rodriguez-Quintana N, Lopez-Gonzalez F. Radial head ingrowth anatomic implant versus smooth stem monoblock implant in acute terrible triad injury: a prospective comparative study. J Orthop Trauma. 2017;31(9):503-509. 8. Grewal R, MacDermid JC, Faber KJ, Drosdowech DS, King GJ. Comminuted radial head fractures treated with a modular metallic radial head arthroplasty. Study of outcomes. J Bone Joint Surg Am. 2006;88(10):2192-2200. 9. Duckworth AD, Wickramasinghe NR, Clement ND, Court-Brown CM, McQueen MM. Radial head replacement for acute complex fractures: what are the rate and risks factors for revision or removal? Clin Orthop Relat Res. 2014;472(7):2136-2143. 10. Moghaddam A, Raven TF, Dremel E, Studier-Fischer S, Grutzner PA, Biglari B. Outcome of radial head arthroplasty in comminuted radial head fractures: short and midterm results. Trauma Mon. 2016;21(1):e20201. 11. Doornberg JN, Parisien R, van Duijn PJ, Ring D. Radial head arthroplasty with a modular metal spacer to treat acute traumatic elbow instability. J Bone Joint Surg Am. 2007;89(5):1075-1080. 12. Pappas N, Bernstein J. Fractures in brief: radial head fractures. Clin Orthop Relat Res. 2010;468(3):914-916. 13. Pike JM, Athwal GS, Faber KJ, King GJ. Radial head fractures: an update. J Hand Surg Am. 2009;34(3):557-565. 14. Van Glabbeek F, Van Riet RP, Baumfeld JA, et al. Detrimental effects of overstuffing or understuffing with a radial head replacement in the medial collateral-ligament deficient elbow. J Bone Joint Surg Am. 2004;86(12):2629-2635. 15. Shippert RD. A study of time-dependent operating room fees and how to save \$100,000 by using time-saving products. Am J Cosmetic Surg. 2005;22(1):25-34. 16. Traverso LW, Hargrave K. A prospective cost analysis of laparoscopic cholecystectomy. Am J Surg. 1995;169(5):503-506. 17. Anwar F, Shoaib RF. Critical incident identification in common orthopaedic injury. J Pak Med Assoc. 2009;59(2):71-74. 18. McCormack J. Satisfy surgeons by improving instrument turnaround time. Mater Manag Health Care. 1995;4(8):18,20. 19. Harden JL, Hiscox JA. Cost savings and quality improvement—single-use suture instruments? Scott Med J. 2006;51(3):30-33. 20. Ford S. Nurses waste 'an hour a shift' finding equipment. Nurs Times. 2009;105(5):1. 21. Wong J, Khu KJ, Kaderali Z, Bernstein M. Delays in the operating room: signs of an imperfect system. Can J Surg. 2010;53(3):189-195.

See Better

Size Better

The first **Radial Head Replacement System** with **color-coded Radiolucent Trials** that allow in-situ height determination and visualization of proximal ulna and joint¹



Radial Head Replacement System



The Market Leader Worldwide for Trauma



Manufactured or Distributed by: Synthes USA, LLC,
1101 Synthes Avenue, Monument, CO 80132
Synthes gmbH Luzernstrasse 21, 4528 Zuchwil, Switzerland
jnjmedicaldevices.com

©DePuy Synthes 2020, 2022. All rights reserved. 129822-220114 DSUS/EMEA

Radial Head Replacement System

Smooth Stem Design Placement, Positioning, and Optimal Mechanics

- May enhance the implant's ability to **self-align** and “**dial in**” when the elbow goes through a range of motion and may articulate with the capitellum throughout the entire arc of motion^{2,3}
- Associated with **less removal due to implant loosening** than press-fit implants⁴⁻¹¹



The need for Accurate Sizing of Radial Head replacements

Radial head fractures present a common problem

- 33% of all elbow injuries^{12,13}
- Reduce the quality of life for patients^{12,13}

Inaccurate sizing can lead to common complications after surgery

- Decreased range of motion¹⁴
- Elbow stiffness¹⁴
- Capitellum erosion¹⁴
- Elbow and/or wrist pain both post-operatively and long term¹⁴

Common problems with under or overstuffing

- Undersizing a radial head implant may fail to stabilize the elbow properly¹⁴
- Lengthening of 2.5 mm or more alters joint kinematics and leads to excessive radiocapitellar load¹⁴

Overstuffing rates up to **23%**¹⁴

The See Better Size Better System

Radiolucent Color-coded Plastic Trials See More Than Metal

- Designed for **better visualization** of proximal ulna and joint¹
- Allow for **in-situ height determination** without repeated removal of trial stems¹
- Facilitate **increased visibility**¹



Indications

For replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with joint destruction and/or subluxation visible on x-ray and/or resistance to conservative treatment; for primary replacement after fracture of the radial head or symptomatic sequelae after radial head resection.



 **DePuy Synthes**
THE ORTHOPAEDICS COMPANY OF 