

1 Introduction and literature review:

2 Orthopaedic implant removal is a common procedure with 10-15% of upper extremity
3 fractures repaired requiring implant removal following plate osteosynthesis.¹⁻⁵ Frequent
4 reasons for implant removal include pain, tendon irritation or rupture, infection, nonunion, and
5 hardware prominence.^{2,5} While patients who undergo implant removal often have
6 improvement in their symptoms,^{3,6-7} the ease of specific implant removal can vary considerably.
7 In fact, 85% of surgeons report that implant removal poses a significant burden on hospital
8 resources.⁸

9 The perceived burden of implant removal is not without cause, as it represents a
10 considerable cost to both the patient and healthcare system.⁹ Implant removal surgeries are
11 associated with a high frequency of complications, ranging from 12 to 41%¹⁰⁻¹³, and can be
12 associated with longer operative times and higher amounts of blood loss than initial
13 procedures.¹³ Potential complications including general operative risks such as infection,
14 bleeding, and injury to important structures are compounded by risks specific to removal of the
15 implant itself, such as broken and/or retained hardware, stripped screws, and re-fracture
16 during, or after implant removal.^{14,15} Pre-operative knowledge of the instruments needed to
17 remove a given implant is critical to minimize potential risk to the patient. Ideally, the initial
18 treating orthopaedic surgeon would also remove the implants, as is frequently the case.
19 However, patients change providers, leave prior areas of care, or present to other institutions
20 with peri-prosthetic fractures, infections, or other implant complications requiring urgent
21 removal. It is therefore critical for the treating surgeon to know the compatibility of the screw
22 removal system with the previously implanted hardware. Furthermore, despite acquisition of a

23 detailed prior operative report, there may still be ambiguity with respect to driver size and
24 configuration as this may not be specifically enumerated in the operative report.

25 To assist surgeons removing unfamiliar instrumentation, several major orthopaedic
26 implant companies have begun compiling universal extraction sets that take advantage of
27 implant and driver compatibility amongst companies and simplify the extraction process.^{16,17}
28 While helpful, these removal sets do not include a compatibility reference and require direct
29 visualization of the screw head to guide driver selection. These constraints make implant
30 removal difficult, and necessitate intraoperative determination of implant and removal-set
31 compatibility without the ability to plan instrument needs pre-operatively.

32 The purpose of this study is to facilitate removal of upper extremity specific orthopaedic
33 implants by compiling a reference detailing the compatibility of screws produced by the most
34 commonly used upper extremity orthopaedic implant companies¹⁸ with regard to two
35 commonly used implant removal sets and generally available driver configurations.

36 Material and Methods:

37 This study did not require Institutional Review Board (IRB) approval given criteria met
38 for exempt status and no involvement of human or animal subjects. Orthopaedic implant
39 manufacturer inclusion was determined by market share based upon industry-monitoring
40 financial firms.¹⁷ Publicly available surgical technique guides, typically in portable document
41 format (PDF), were retrieved for each manufacturer of plate osteosynthesis implants for the
42 phalanges, metacarpals, scaphoid, distal radius, forearm, olecranon, and humerus.
43 Intramedullary or arthroplasty implant sets were excluded. Each technique guide was
44 thoroughly reviewed for implant and screwdriver information and, in some cases, surgical

45 representatives were contacted to clarify the screw size and screw drive configuration, along
46 with known removal set compatibility options. Screw and screwdriver compatibility were
47 assessed and compared to two commonly utilized universal screw-removal sets as determined
48 by the two highest grossing orthopaedic implant companies, Johnson & Johnson
49 (J&J)/Depuy/Synthes (Raynham, MA) and Stryker (Kalamazoo, MI).¹⁹ The data was compiled in
50 table format with non-cannulated, locking, and cannulated screw offerings for each included
51 company. Guide-wire size compatibility for cannulated offerings were also assessed and
52 documented.

53 Results:

54 The top nine highest grossing upper extremity implant companies in 2017 according to
55 market share were J&J/Depuy/Synthes with 31.5% of the market share, Zimmer/Biomet 23%,
56 Wright Medical 10.5%, Stryker 8.4%, Smith & Nephew 4.2%, Exactech 4%, DJO 3.6%, Integra
57 0.8%, and Arthrex 0.2%.¹⁸ DJO medical does not produce osteosynthesis implants and
58 accordingly was excluded from this analysis. In total, eight upper extremity implant companies
59 with commonly implanted upper extremity screws were included in this review.

60 The following tables are divided into company-specific, noncannulated, cannulated, and
61 locking screws; they are further organized by screw diameter, screw type, guidewire diameter
62 (if cannulated), driver type, the driver's catalog number, and the universal removal set where
63 the required driver can be found. If the manufacturer of the implant is known, the surgeon can
64 use **Table 1** to find the relevant removal information grouped by manufacturer. If the
65 manufacturer is unknown, the surgeon can use a calibrated radiograph to identify and measure
66 the screws and refer to **Table 2** (noncannulated, nonlocking screws), **Table 3** (cannulated

67 screws), or **Table 4** (locking screws). These tables are arranged by screw diameter and contain
68 all associated extraction information for easy reference.

69 With proper preoperative planning, a surgeon can use these tables to determine which
70 of the commonly available implant removal sets contains the necessary driver for a successful
71 implant removal. While almost all the screws described in the tables can be removed by either
72 the Synthes and/or the Stryker implant removal kits, there are a few screws that have non-
73 traditional drive types. If the table indicates the necessary driver is not available in either
74 removal set, then the catalog number of the driver produced by the manufacturer is provided.
75 These catalog numbers are provided for all screws listed in the chart to allow surgeons to opt
76 for a single driver if that option is available at their institution.

77 Discussion:

78 The proliferation of orthopaedic implant designs has allowed fixation to be tailored to
79 specific injury patterns and greater options for orthopaedic surgeons. However, this diversity of
80 implants is also problematic when implanted hardware requires removal especially when the
81 operating surgeon did not perform the index procedure. Complications following implant
82 removal for upper extremity fractures can be as high as 40%.¹⁵ Selection of the appropriate
83 driver is paramount to the success and expediency of an implant removal surgery. Indeed, it
84 has been shown that a single slippage event can halve the maximal torque tolerated by a screw
85 and hamper screw removal.²⁰

86 The data reported in this study was prepared in an effort to facilitate appropriate driver
87 selection for removal of upper extremity orthopaedic implants. One potential benefit of this
88 data is reduced hospital cost. Operating room (OR) cost ranges from \$22 to \$133 per

89 minute,^{21,22} not including surgeon and anesthesiologist time. Improved OR efficiency through
90 appropriate driver selection pre-operatively and expeditious surgery can represent a significant
91 time and cost savings. More accurate instrument selection and avoided instrument tray
92 reprocessing could yield further savings, ranging from \$75 to \$330 per instrument set not
93 used.²³

94 Limitations of this study include the lack of inclusion of all upper extremity orthopaedic
95 companies in the overall analysis. Though data from industry monitoring financial firms was
96 used to compile a list representing 82% of the market share for upper extremity orthopaedic
97 implants, companies with a smaller market share were omitted due to logistical
98 necessity.¹⁸ Additionally, although care was taken to ensure the accuracy of information
99 collected for the reference, sample equipment was not available to perform physical
100 verification with the implants themselves. Accordingly, the information presented in this
101 manuscript is to serve as a guide and by no means a comprehensive or definitive source.

102 Future areas of study include the goal of identifying how readily this guide may be used
103 to facilitate specific screw identification based upon a radiograph with magnification markers
104 according to the proposed characteristics. It would further be beneficial to determine the
105 distinct cost savings incurred through use of this guide with regard to both operative time and
106 reprocessing costs.

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111 References:

- 112 1. Snoddy MC, An TJ, Hooe BS, Kay HF, Lee DH, Pappas ND. Incidence and reasons for hardware
113 removal following operative fixation of distal radius fractures. *J Hand Surg Am.* 2015;40(3):505-
114 507.
- 115 2. Margaliot Z, Haase SC, Kotsis SV, Kim HM, Chung KC. A meta-analysis of outcomes of external
116 fixation versus plate osteosynthesis for unstable distal radius fractures. *J Hand Surg Am.*
117 2005;30(6):1185-1199.
- 118 3. Reith G, Schmitz-Greven V, Hensel KO, et al. Metal implant removal: Benefits and drawbacks-
119 -a patient survey. *BMC Surg.* 2015;15:96-015-0081-6.
- 120 4. Lutsky KF, Beredjiklian PK, Hioe S, Bilello J, Kim N, Matzon JL. Incidence of hardware removal
121 following volar plate fixation of distal radius fracture. *J Hand Surg Am.* 2015;40(12):2410-2415.
- 122 5. Rutkow IM. Orthopaedic operations in the united states, 1979 through 1983. *J Bone Joint*
123 *Surg Am.* 1986;68(5):716-719.
- 124 6. Gajdos R, Bozik M, Stranak P. Is an implant removal after dorsal plating of distal radius
125 fracture always needed? *Bratisl Lek Listy.* 2015;116(6):357-362.
- 126 7. De Giacomo AF, Tornetta P,3rd, Sinicrope BJ, et al. Outcomes after plating of olecranon
127 fractures: A multicenter evaluation. *Injury.* 2016;47(7):1466-1471.
- 128 8. Hanson B, van der Werken C, Stengel D. Surgeons' beliefs and perceptions about removal of
129 orthopaedic implants. *BMC Musculoskelet Disord.* 2008;9:73-2474-9-73.

- 130 9. Nearly 68% of patients improve after hardware removal, but surgery is costly. . Healio
131 Orthopedic Today Web site.
132 [http://www.healio.com/orthopedics/trauma/news/online/%7B1f854283-164c-4fda-b169-
d53ee35e324c%7D/nearly-68-of-patients-improve-after-hardware-removal-but-surgery-is-
costly](http://www.healio.com/orthopedics/trauma/news/online/%7B1f854283-164c-4fda-b169-
133 d53ee35e324c%7D/nearly-68-of-patients-improve-after-hardware-removal-but-surgery-is-
134 costly). Accessed 05/30, 2017.
- 135 10. Tyllianakis ME, Panagopoulos AM, Saridis A. Long-term results of dorsally displaced distal
136 radius fractures treated with the pi-plate: Is hardware removal necessary? *Orthopedics*.
137 2011;34(7):e282-6.
- 138 11. Gaspar MP, Lou J, Kane PM, Jacoby SM, Osterman AL, Culp RW. Complications following
139 partial and total wrist arthroplasty: A single-center retrospective review. *J Hand Surg Am*.
140 2016;41(1):47-53.e4.
- 141 12. Langkamer VG, Ackroyd CE. Removal of forearm plates. A review of the complications. *J*
142 *Bone Joint Surg Br*. 1990;72(4):601-604.
- 143 13. Brown OL, Dirschl DR, Obrebsky WT. Incidence of hardware-related pain and its effect on
144 functional outcomes after open reduction and internal fixation of ankle fractures. *J Orthop*
145 *Trauma*. 2001;15(4):271-274.
- 146 14. Jacobsen S, Honnens de Lichtenberg M, Jensen CM, Torholm C. Removal of internal fixation-
147 -the effect on patients' complaints: A study of 66 cases of removal of internal fixation after
148 malleolar fractures. *Foot Ankle Int*. 1994;15(4):170-171.
- 149 15. Yao CK, Lin KC, Tarng YW, Chang WN, Renn JH. Removal of forearm plate leads to a high risk
150 of refracture: Decision regarding implant removal after fixation of the forearm and analysis of
151 risk factors of refracture. *Arch Orthop Trauma Surg*. 2014;134(12):1691-1697.

- 152 16. Screw Removal Set – Instruments for removing syntheses screws. West Chester, PA: Synthes
153 (USA), Inc; 2009.
- 154 17. *Implant Extraction Set*. Schonkirchen, Germany: Stryker, LLC; 2014.
- 155 18. *SmartTrak financial dashboard - 2017 WW upper extremities market*. Irvine, CA:
156 BioMedGPS, LLC; 2017.
- 157 19. World preview 2016, outlook to 2022. Evaluate MedTech Web site.
158 <http://www.evaluategroup.com/public/reports/EvaluateMedTech-World-Preview-2016.aspx>.
159 Accessed 05/30, 2017.
- 160 20. Behring JK, Gjerdet NR, Molster A. Slippage between screwdriver and bone screw. *Clin*
161 *Orthop Relat Res*. 2002;(404)(404):368-372.
- 162 21. Macario A. What does one minute of operating room time cost? *J Clin Anesth*.
163 2010;22(4):233-236.
- 164 22. Shippert R. A study of time-dependent operating room fees and how to save \$100 000 by
165 using time-saving products. *Am J Cosmet Surg*. 2005;22:25–34.
- 166 23. Mont MA, Pivec R, Johnson AJ, Issa K. Single-use cutting blocks and trials lower costs in
167 primary total knee arthroplasty. *Surg Technol Int*. 2012;22:331-335.