Xtract-All® SPINE V.2

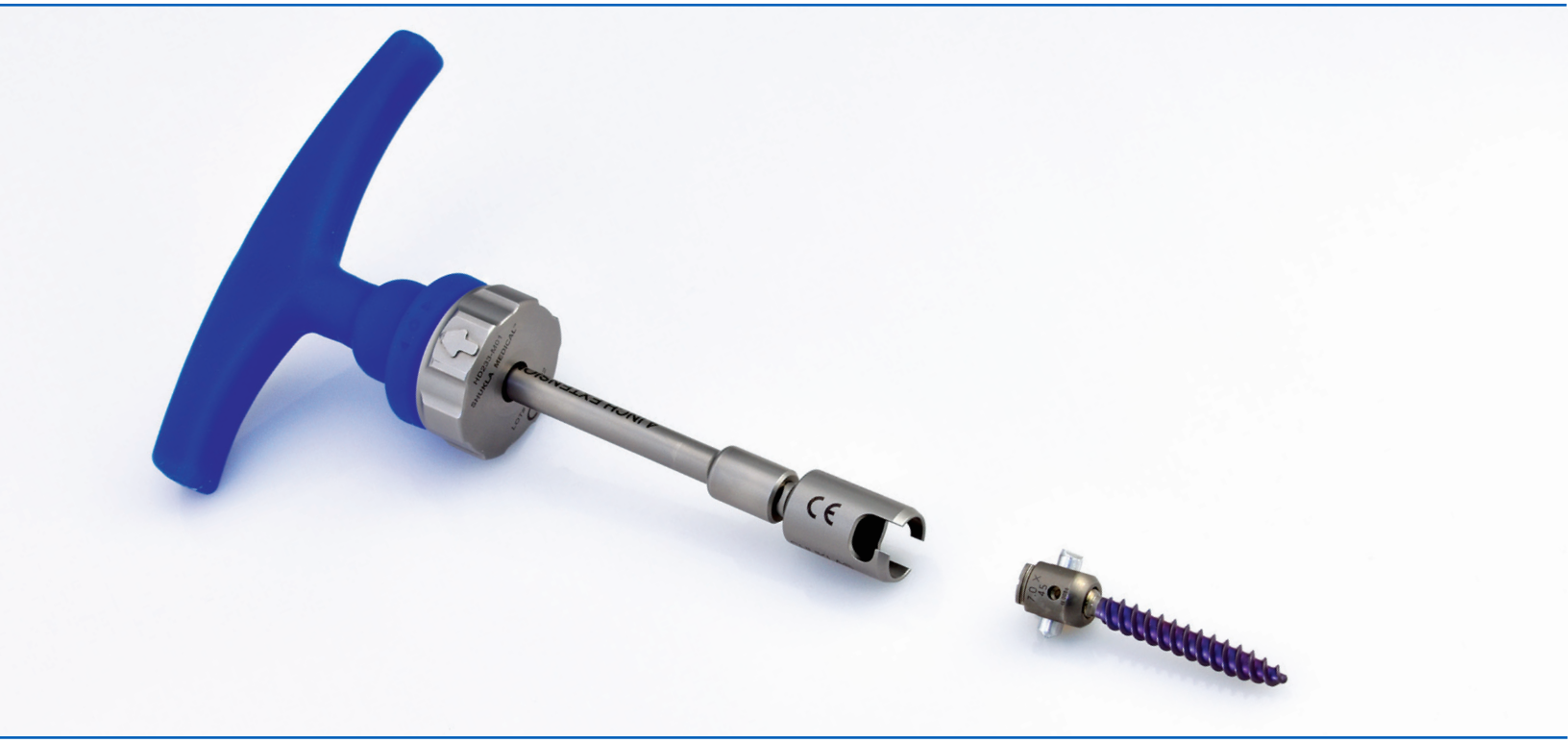
Universal Spinal Implant Removal System

...Because Every Minute Counts®

Surgical Technique Guide

SHUKLA MEDICAL®
Universal Orthopedic Extraction Technologies

Contents



Helicopter Socket with Screw Construct; page 12

Introduction

Intended Use

The Xtract-All® Universal Spinal Implant Removal System (S9SPINE) is designed to simplify spinal revisions.

Indications for Use

The Xtract-All® Spine (S9SPINE) is appropriate for any spinal revision case. For use by, or as directed by, a surgeon during spinal revision surgeries. The system includes over 130 implant drivers in a wide range of configurations and sizes, covering both standard and proprietary implant configurations. They can be used to remove hardware from virtually any spinal implant system.

Contraindications

The Xtract-All® Spine system is designed to be used when removing spinal hardware with intact screw heads. The system cannot be used with broken or stripped screws. For broken and stripped screw removal, please contact Shukla Medical Customer Service for information about the Xtract-All® Screw Universal Broken & Stripped Screw Extraction System (S9SCRW).

Warning and Precautions

Preoperative

- Clear x-rays and surgical notes may be used to identify manufacturer, brand, location, & condition of implanted hardware.
- The surgeon should be familiar with general principles of revision surgery and techniques for removal of implants.
- The instruments should be inspected for visible damage prior to use. Do not use the product if damage is suspected.
- Only validated cleaning and sterilization procedures should be used

Operative

- Proper handling and storage of the instrumentation is mandatory. Damage to the instrumentation may produce stresses and cause defects, which could become a focal point for failure.
- The surgeon should be cautious with spinal position change and/or excessive force exertion while removing implants using the instrumentation provided in the tray.
- All instrumentation has physical limits. Excessive force may result in instrument failure. It is recommended to maintain access to the Xtract-All® Screw Universal Broken & Stripped Screw Extraction System (S9SCRW) in the event that instrumentation fails.

Cleaning and Sterilization

For detailed sterilization instructions, please refer to industry standards ANSI/AAMI ST79:2012 & A1:2012 and ANSI/AAMI ST8:2001.

NOTE: All Shukla Medical surgical instruments require manual cleaning with a neutral pH cleanser. Open and disassemble all instruments, making sure to remove all contamination during cleaning. Instruments must be reassembled prior to sterilization. Machine washing is not recommended. Maintenance and care using an autoclaveable lubricant on movable parts is required to preserve the life of the instrument. For more cleaning, inspection, maintenance, and care tips, contact Shukla Medical directly.

For detailed cleaning and sterilization instructions, please visit www.ShuklaMedical.com/Sterilization.

EC REP **Emergo Europe** Prinsessegracht 20 2514 AP The Hague The Netherlands	REF S9SPINE	**Shukla Medical** 8300 Sheen Drive St. Petersburg, FL 33709 USA	CONSULT INSTRUCTIONS FOR USE	NON STERILE NON-STERILE PRODUCT

CE

List of Components

Standard Drivers for Cervical Spine

Cervical Spine System

SCS034	Case 1: Cervical Spine System
SCS037	Lid: Cervical Spine System

Key

Case Location ID	Part #	Part Description

Hex

1	SDR701	Hex 2.0mm
2	SDR702	Hex 2.25mm
3	SDR703	Hex 2.5mm
4	SDR704	Hex 2.75mm
5	SDR705	Hex 3.0mm
7	SDR707	Hex 3.5mm
8	SDR708	Hex 4.0mm
16	SDR716	Hex 7/64"
17	SDR717	Hex 1/8"
18	SDR718	Hex 5/32"
19	SDR719	Hex 3/16"

Hex Sockets

24	SDR724	Hex Socket 3.5mm
25	SDR725	Hex Socket 4.0mm
37	SDR737	Hex Socket 1/8"
38	SDR738	Hex Socket 5/32"
39	SDR739	Hex Socket 3/16"
40	SDR740	Hex Socket 7/32"
46	SDR746	Hex Socket 1/2"

Cruciform

49	SDR749	Cruciform 2.0mm
50	SDR750	Cruciform 2.5mm
51	SDR751	Cruciform 3.0mm
52	SDR752	Cruciform 3.5mm

Torx

56	SDR756	Torx T6
57	SDR767	Torx T7
58	SDR757	Torx T8
59	SDR768	Torx T9
60	SDR758	Torx T10
61	SDR759	Torx T15
62	SDR760	Torx T20
63	SDR761	Torx T25

Flat

80	SDR780	Flat Small
81	SDR781	Flat Medium
82	SDR782	Flat Large

Phillips

83	SDR783	Phillips

Saddle

84	SDR784	Saddle 4.0mm

87	SDR787	Blade 4.0mm

Hexalobe

145	SDR875	Hexalobe X10
146	SDR876	Hexalobe X15
147	SDR877	Hexalobe X20

Parts not shown to scale

Drivers for Proprietary Configurations

Aesculap®

95	SDR800	Aesculap® 5-Star

Alphatec Spine®

96	SDR801	Alphatec® Unlock Tool

Blackstone®

97	SDR802	Blackstone® 2-Prong

98	SDR803	Blackstone® Tri-Lobe

Biomet®

77	SDR777	Biomet® Pentalobe S15

Corin®

99	SDR804	Corin® Cervive 3-Prong

EBI®

104	SDR809	EBI® SpineLink® ACS

Interpore Cross®

76	SDR776	Interpore Cross® Pentalobe

101	SDR806	Interpore Cross® Unlocking Tool

Medtronic®

102	SDR807	Medtronic® Quad

Orthofix®

69	SDR769	Orthofix® Square 2.0mm
70	SDR770	Orthofix® Square 2.5mm
71	SDR771	Orthofix® Square 3.0mm
72	SDR772	Orthofix® Square 3.5mm

Stryker®

103	SDR808	Stryker Spine® 4-Prong

Zimmer®

105	SDR810	Zimmer Spine® Cervi-Lok®

107	SDR812	Zimmer® Nex-Link®

X-RAY
Xtract-All® Search Engine

For the most up-to-date information on supported implants, use the X-Ray Search Engine™ Implant Compatibility Database.

The X-Ray Search Engine™ makes cross-compatibility identification easy. Enter keywords for any implant, manufacturer, or brand to find a list of all compatible Xtract-All® tools and related surgical techniques, x-rays, and videos. Our database is updated frequently as we are made aware of other implant systems.

Contact customer service or your sales representative to access the X-Ray Search Engine™.

Parts not shown to scale

List of Components

TL Spine System

SCS035	Case 1: TL Spine System
SCS038	Lid: TL Spine System

Hex

5	SDR705	Hex 3.0mm
7	SDR707	Hex 3.5mm
8	SDR708	Hex 4.0mm
9	SDR709	Hex 4.5mm
10	SDR710	Hex 4.7mm
11	SDR711	Hex 5.0mm
12	SDR712	Hex 6.0mm
13	SDR713	Hex 7.0mm
20	SDR720	Hex 7/32"
21	SDR721	Hex 1/4"

Hex Sockets

26	SDR726	Hex Socket 5.0mm
27	SDR727	Hex Socket 5.5mm
28	SDR728	Hex Socket 6.0mm
29	SDR729	Hex Socket 7.0mm
30	SDR730	Hex Socket 7.5mm
31	SDR731	Hex Socket 8.0mm
32	SDR732	Hex Socket 9.0mm
33	SDR733	Hex Socket 10.0mm
34	SDR734	Hex Socket 11.0mm
41	SDR741	Hex Socket 1/4"
42	SDR742	Hex Socket 9/32"
43	SDR743	Hex Socket 5/16"
44	SDR744	Hex Socket 3/8"
45	SDR745	Hex Socket 7/16"

Standard Drivers for TL Spine

Key

Case Location ID	Part #	Part Description

Cruciform

51	SDR751	Cruciform 3.0mm
52	SDR752	Cruciform 3.5mm
53	SDR753	Cruciform 4.5mm
54	SDR754	Cruciform 6.0mm

Torx

61	SDR759	Torx T15
62	SDR760	Torx T20
63	SDR761	Torx T25
64	SDR762	Torx T27
65	SDR763	Torx T30
66	SDR764	Torx T40
67	SDR765	Torx T45
68	SDR766	Torx T50

Flat

82	SDR782	Flat Large

Phillips

83	SDR783	Phillips

Saddle

84	SDR784	Saddle 4.0mm
85	SDR785	Saddle 5.0mm
86	SDR786	Saddle 6.0mm

87	SDR787	Blade 4.0mm
88	SDR788	Blade 5.0mm
89	SDR789	Blade 6.0mm

Pedicle Screws

138	SDR868	4-Prong Pedicle Screw

Hexalobe

146	SDR876	Hexalobe X15
147	SDR877	Hexalobe X20
148	SDR878	Hexalobe X25

Parts not shown to scale

Drivers for Proprietary Configurations

Advanced Spine®

120 SDR850 Advanced Spine® Sleeve Nut

121 SDR851 Advanced Spine® Anchor

Aesculap®

124 SDR854 Aesculap® 4-Prong

Biomet®

77 SDR777 Biomet® Pentalobe S15

139 SDR869 Biomet® Polaris® 5.5

Corin®

128 SDR858 Corin® 3-Lok

Depuy®

100 SDR805 Depuy Spine® Outer Nut

129 SDR859 Depuy® Moss-Miami® Socket

130 SDR860 Depuy® Moss-Miami® Interrupted Socket

EBI®

132 SDR862 EBI® Square

133 SDR863 EBI® SpineLink® II Socket

134 SDR864 EBI® SpineLink® II

Interpore Cross®

125 SDR855 Interpore Cross® Hex 13.8mm

126 SDR856 Interpore Cross® Cap Nut Remover

127 SDR857 Interpore Cross® 2-Prong

76 SDR776 Interpore Cross® Pentalobe

Orthofix®

73 SDR773 Orthofix® Square 4.0mm

Theken Spine®

142 SDR872 Theken Spine® Driver

Spine Tech®

123 SDR853 Spine Tech® Octagon

Stryker®

135 SDR865 Stryker® Xia® Pedicle Screw

136 SDR866 Stryker® Xia® III Hexalobe

Synthes®

122 SDR852 Synthes® 11mm 12pt Hex

131 SDR861 Synthes® Click'X®

Zimmer®

106 SDR811 Zimmer® Incompass®

137 SDR867 Zimmer® Silhouette® Heptagon 1/2"

143 SDR873 Zimmer® Dynesys® L.I.S.

149 SDR879 Zimmer® Pathfinder® Hexalobe E7

US Spine®

144 SDR874 US Spine® 3-Prong

Parts not shown to scale

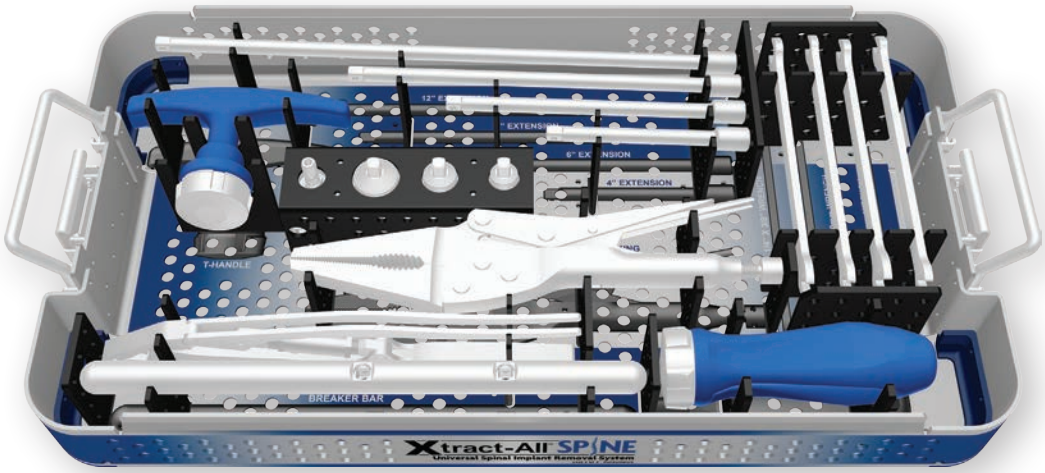
List of Components

Key

Part #	Part Description

Instrument Case

SCS036	Case 2: Spine Instrumentation
SCS039	Lid: Spine Instrumentation

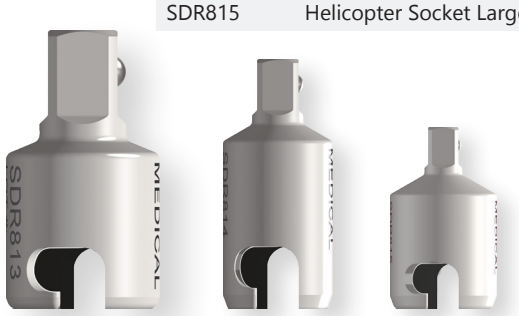


Handles

MHRS0311	Ratcheting In-Line Handle
HD233-M01	Ratcheting T-Handle

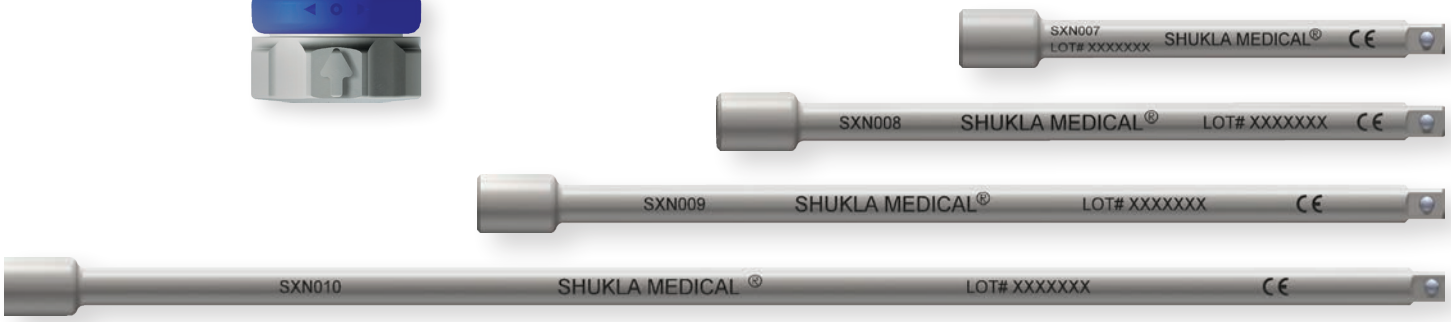
Helicopter Sockets

SDR813	Helicopter Socket Small
SDR814	Helicopter Socket Medium
SDR815	Helicopter Socket Large



Extensions

SXN007	Extension Shaft 4”
SXN008	Extension Shaft 6”
SXN009	Extension Shaft 8”
SXN010	Extension Shaft 12”



Parts not shown to scale

Wrenches

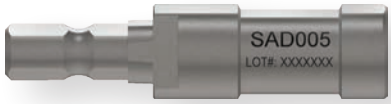
SWR003	Double Ended Wrench 7/32" x 9/32"
SWR004	Double Ended Wrench 1/4" x 3/8"
SWR005	Double Ended Wrench 5mm x 7mm
SWR006	Double Ended Wrench 6mm x 10mm

Breaker Bar

HD239-M01	Breaker Bar

Power Adapter

SAD005	Power Adapter



Locking Pliers

SWR008	Long Nose Locking Pliers 9"

Rod Grippers

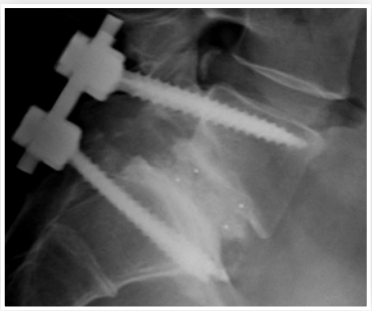
SWR009	Rod Grippers

Parts not shown to scale

Surgical Technique for Total Spine

1 Identification & Selection

Identify the spinal implant system from the surgical notes and X-rays. Select the appropriate Xtract-All® drivers. For the most up-to-date information on supported systems, contact customer service or your local rep for access to our X-Ray Search Engine™ Implant Compatibility Database.



- If a range of drivers is recommended or the spinal implant system cannot be identified, inspect the locking nuts & screws to visually select the most appropriate driver.
- If the appropriate driver cannot be identified, or a nut or screw is unable to be removed from the construct, the Helicopter Method may be used.

Note: For broken and stripped screws, please contact Shukla Medical Customer Service for information about the Xtract-All® Screw (S9SCRW) Universal Broken & Stripped Screw Extraction System.

Pre-op Planning: For assistance identifying implants and determining compatible drivers, please contact Shukla Medical Customer Service and let our team of experts help you.

2 Assemble Driver

Insert the selected driver into the appropriate Extension Shaft (SXN007-SXN010) if needed. Insert Extension Shaft into Ratcheting Screwdriver Handle (HD233-M01 or MRHS0311). Rotate handle to change between ratcheting mode.

Center: Ratcheting disabled
Forward: Insert screws
Back: Remove screws

Multiple handle styles are available depending upon surgeon preference and desired level of torsion.

Ratcheting In-Line Handle
MRHS0311

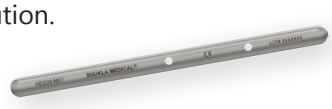
Suitable for most implant removals. Ratcheting mode switches between forward, backward, or neutral/locked.

Ratcheting T-Handle
HD233

Suitable when additional torque is required during manual implant removal. Ratcheting mode switches between forward, back, or neutral/locked. Use while locked for the Helicopter Method (facing page).

Breaker Bar
HD239-M01

A breaker bar is included in case of difficulty due to well-fixed screws. Using the breaker bar can generate significant torsional force that may not be optimal in some spinal procedures. Use with caution.



3 Rod Removal

a. Remove locking nuts with assembled screwdriver (Fig. A, panels 1 & 2).

b. Stabilize & remove spinal rods using Rod Gripper (SWR009) & Long Nose Locking Pliers (SWR008) (Fig. A, panels 3 & 4).

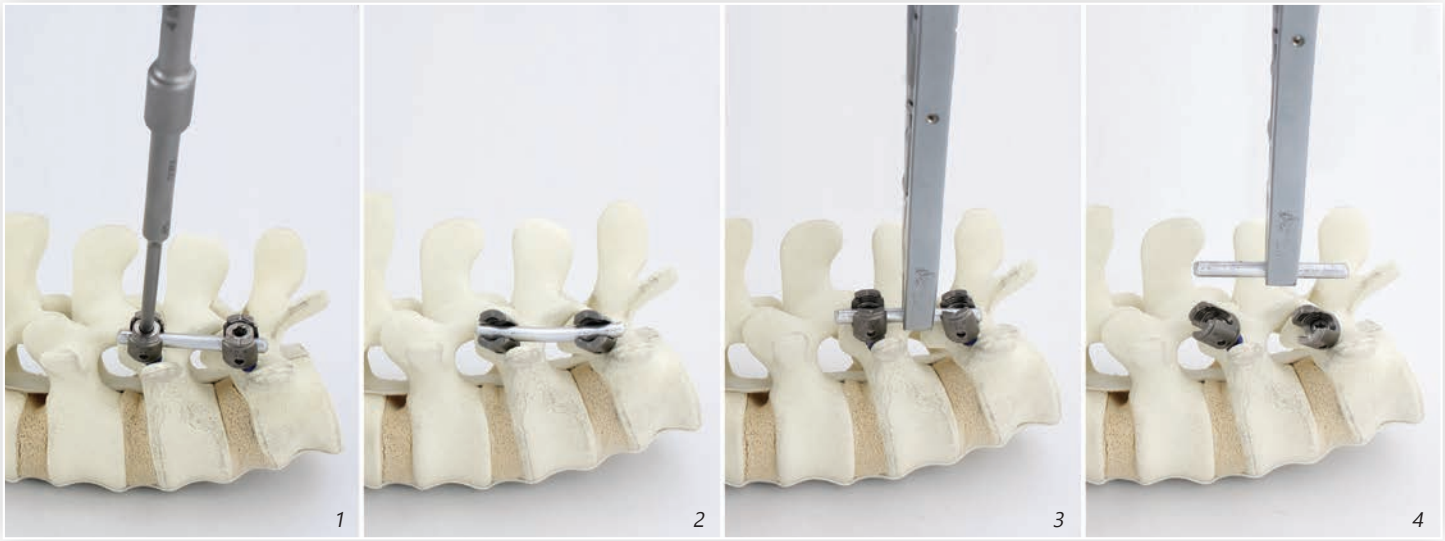


Figure A

4 Screw Removal

Select the appropriate driver. Assemble screwdriver as per Step 2.

- **Note:** For screws that do not have an internal configuration at the bottom of their uni-axial screw, use the blade or saddle drivers (SDR784-SDR815). If available drivers do not fit, reassemble the locking nut & proceed to use the *Helicopter Method (pg 12).*

Remove screw using screwdriver assembly. Locking Pliers (SWR008) may be used to aid with removal. (Fig. B)

Figure B

OPTIONAL: *The Helicopter Method*

The Helicopter Method facilitates total screw construct removal by rotating the pedicle screw while still attached to the rod using a Helicopter Socket (SDR813-SDR815).

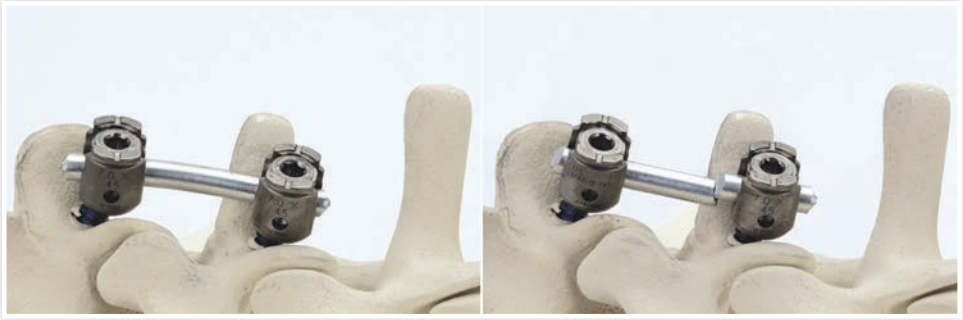
The screw construct consists of the screw, rod, & locking cap.

Indications for the *Helicopter Method*:

- If the correct driver cannot be identified
- If any cap, nut, or screw is fixed so tightly that it cannot be removed
- If the locking cap or screw is stripped

1 Cut rod on either side of tulip

- Approximately 5mm of rod should remain extending from sides of tulip head.
- Rod cut length must be long enough to engage with helicopter socket, but short enough to minimize damage to surrounding live tissue as screw construct rotates.



2 Assemble driver with Helicopter Socket

- Select Helicopter Socket (SDR813-SDR815) that best fits over tulip head.
- Connect socket to an Extension Shaft (SXN007-SXN010), then attach socket assembly to T-Handle (HD233-M01).
  - Ratcheting mode must be locked or set to reverse.

3 Use Helicopter Socket to remove screw construct

- Screw construct must be fully assembled in order for the *Helicopter Method* to be effective.
- Place Helicopter Socket over tulip and rod, so that rod is engaged in socket grooves.
- Turn counterclockwise until screw construct backs out.
  - If additional torque is needed, attach Breaker Bar (HD239-M01) to extension and turn counterclockwise.

Tips & Pearls

Cervical System

The Cervical Case includes 56 drivers covering standard and proprietary implant configurations.

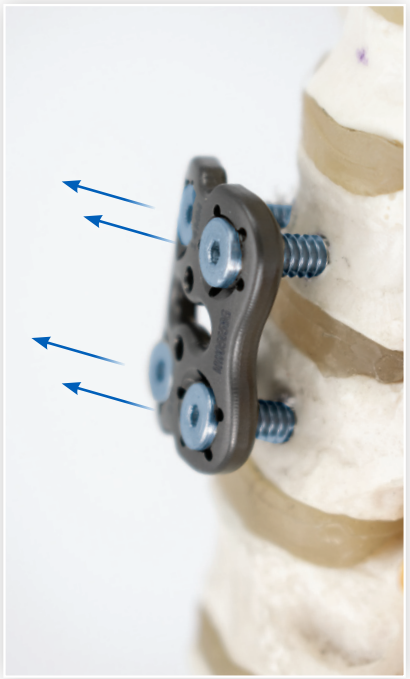
Thoracolumbar System

The TL Case includes 76 drivers covering standard and proprietary configurations.

Plate Removal via the *Levitating Plate Method*

Bone screws secured with locking o-rings

If screws holding plate are secured with locking o-rings, plate may be removed by loosening all bone screws incrementally so that they lift the plate evenly from the surface of the bone all together.



Rod Removal

Well-fixed locking nuts

If additional torque is required, use the breaker bar (HD239-M01). Using the breaker bar can generate significant torsional force that may not be optimal in some spinal procedures. Use with caution.

Notes

For more information about the
Xtract-All® Spine (S9SPINE) Universal Spinal Implant Removal System
Call us at 888-4-SHUKLA (888-474-8552) or visit
www.ShuklaMedical.com

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