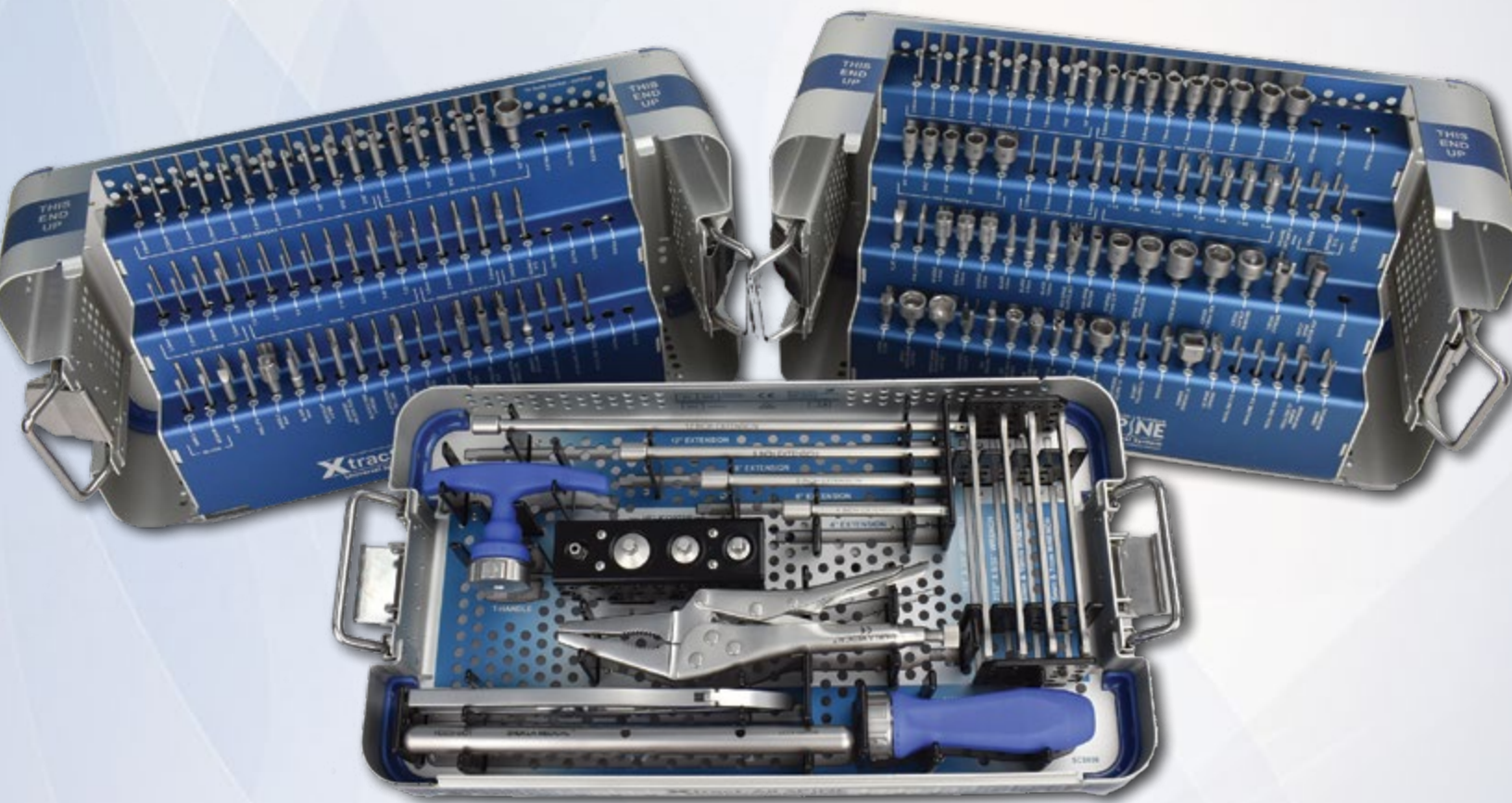


SURGICAL TECHNIQUE GUIDE

#11-14
Systems 11 - 14 of 15

SHUKLA SPINE

Universal Spinal Screw Removal Solution



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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SHUKLA SPINE

Universal Spinal Screw Removal Solution

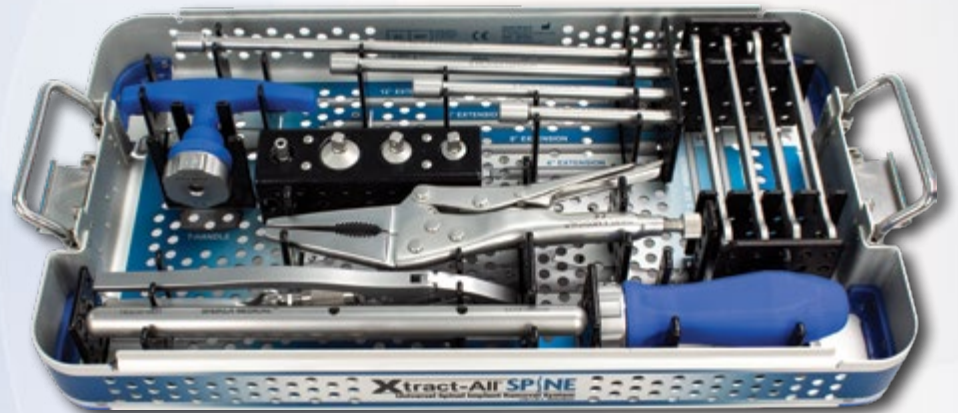
System Name: SHUKLA Spine-C, Spine-TL, Spine-CTL, Spine Plus

Part Number: S9SPINE-C, S9SPINE-TL, S9SPINE, S9SPINE-PLUS

Version: SPINE-C (v3), SPINE-TL (v4), SPINE-CTL (v3)

Primary Use

The SHUKLA Spine family of systems (Cervical, Thoracic, and Lumbar, and Total) are designed to remove spinal screws, locking caps, rods, and plates from any cervical, thoracic, or lumbar implant system. Across dedicated cervical & thoracolumbar driver systems, they contain more than 130 drivers compatible with standard configurations, as well as more than 40 proprietary implant systems.



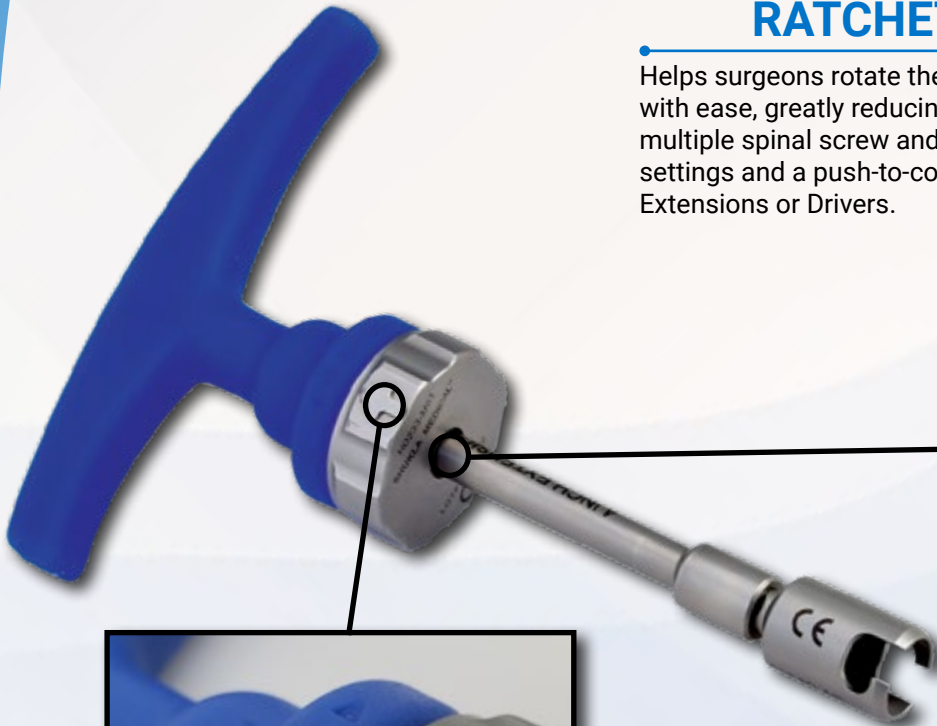
System History

The first SHUKLA Thoracic and Lumbar Spine set debuted back in 2000 and the first SHUKLA Cervical set came out in 2005. Thanks to the efforts of both the Shukla Medical Product Development Manager as well as invaluable input from surgeons, the Shukla family of spine systems became the most comprehensive ones on the market. The release of the Spine-Cervical (Spine-C) in addition to the existing Spine-Thoracolumbar (Spine-TL) made the total capabilities of Shukla's Spine family truly universal.

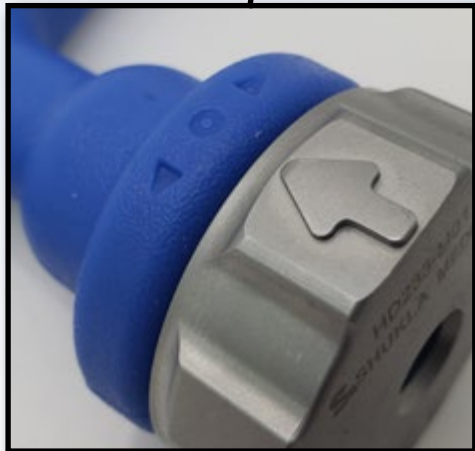
In 2018, the latest version of our Spine systems released, making an already amazing set even better and more comprehensive with additional drivers, proprietary drivers, helicopter sockets, and more.

RATCHETING T-HANDLE

Helps surgeons rotate the spinal construct out counterclockwise with ease, greatly reducing the risk of hand fatigue during a case with multiple spinal screw and rod constructs. Features three ratcheting settings and a push-to-connect chuck allowing for rapid insertion of Extensions or Drivers.



Push-to-Connect chuck allows any of the Extensions or Drivers to connect with ease.



Toggle Cap allows the T-Handle to switch between Forward Ratchet, Fixed, and Reverse Ratchet settings.

HELICOPTER SOCKETS

Engineered to fit the spine rod. Once inserted, the rod will not slip or pull off. The helicopter sockets work with all spine rods up to 6.35mm in diameter and are available in three different sizes.



The Spinal Rod Slot secures the spine rod during removal.

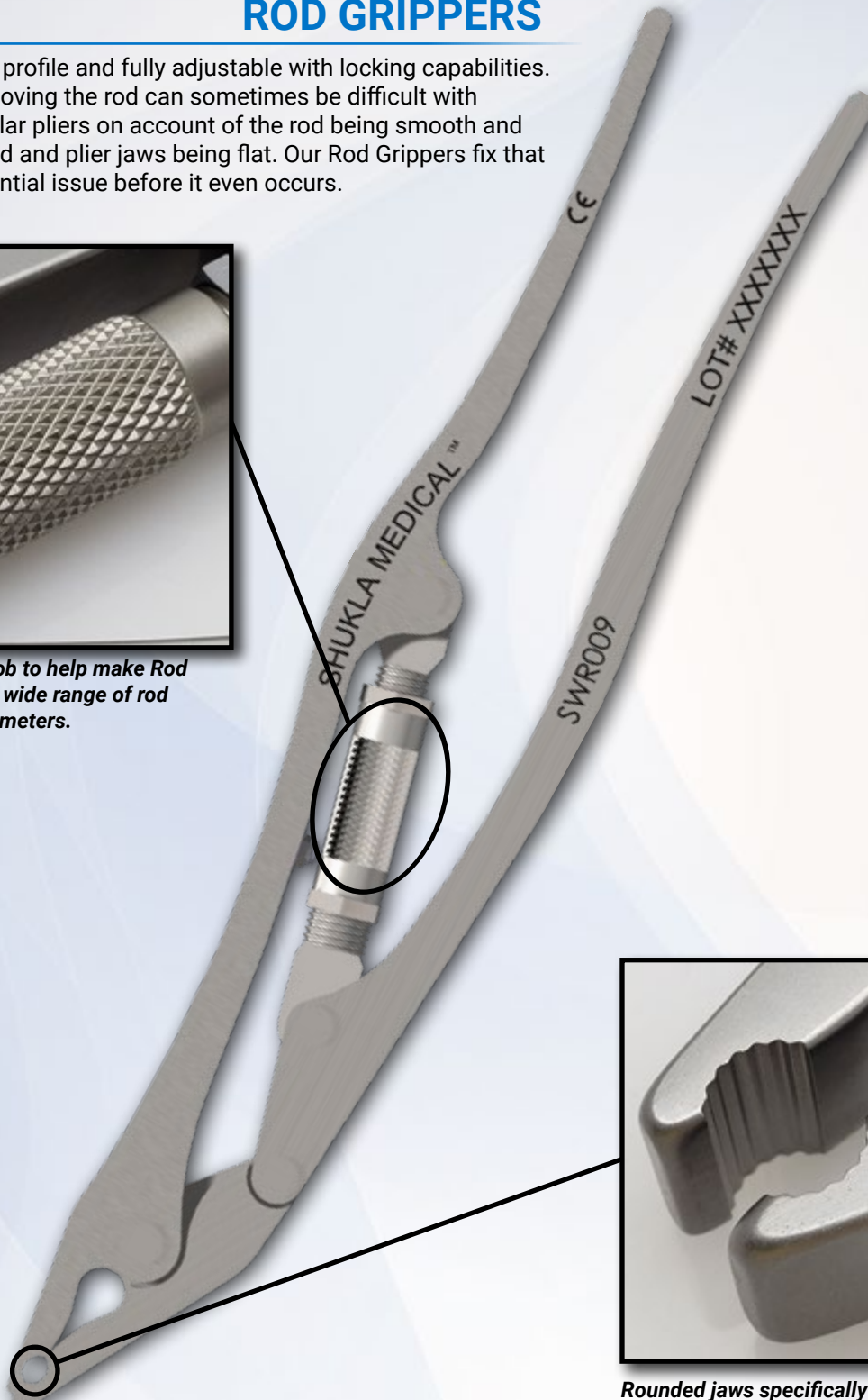


ROD GRIPPERS

Low profile and fully adjustable with locking capabilities. Removing the rod can sometimes be difficult with regular pliers on account of the rod being smooth and round and plier jaws being flat. Our Rod Grippers fix that potential issue before it even occurs.



Adjustment knob to help make Rod Grippers fit a wide range of rod diameters.



Rounded jaws specifically designed to grasp smooth curvature of spinal rods.

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 SHUKLA Screw Universal Broken & Stripped Screw Extraction System (S9SCREW) in the event that instrumentation fails.

Storage

- It is recommended to store all Shukla Medical instrumentation in a clean, dry environment. Under 50% relative humidity; $\leq 75^{\circ}\text{F}/24^{\circ}\text{C}$.

Intended Use

The SHUKLA Spine Universal Spinal Screw Removal System (S9SPINE) is designed to simplify spinal revisions.

Instrumentation from Shukla Medical is recommended for use only within the intended design, and only by licensed healthcare professionals. Any uses other than those indicated may cause adverse results to the instrumentation or to the patient.

Indications for Use

The SHUKLA 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 SHUKLA 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 SHUKLA Screw Universal Broken & Stripped Screw Extraction System (S9SCREW).

Additional Recommendations

The SHUKLA Spine (S9SPINE) Universal Spinal Screw Removal System is recommended for use in conjunction with the SHUKLA Mini (S9MINI) Universal Small Screw Removal System, the SHUKLA Maxi (S9MAXI) Large Bone Screw Removal System, and the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System.

1 Identification & Selection

Identify the spinal implant system from the surgical notes and X-rays. Select the appropriate SHUKLA Spine drivers.



- 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 SHUKLA Screw (S9SCREW) 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 or MRHS0311). Rotate handle to change between ratcheting mode.

- Forward:** Insert screws
- Fixed:** Ratcheting disabled
- Reverse:** Remove screws



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

Ratcheting In-Line Handle

MRHS0311

Suitable for most implant removals. Ratcheting mode switches between forward, reverse, or fixed.



Ratcheting T-Handle

HD233

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



Breaker Bar

HD239

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) and/or Long Nose Locking Pliers (SWR008) (Fig. A, panels 3 & 4).

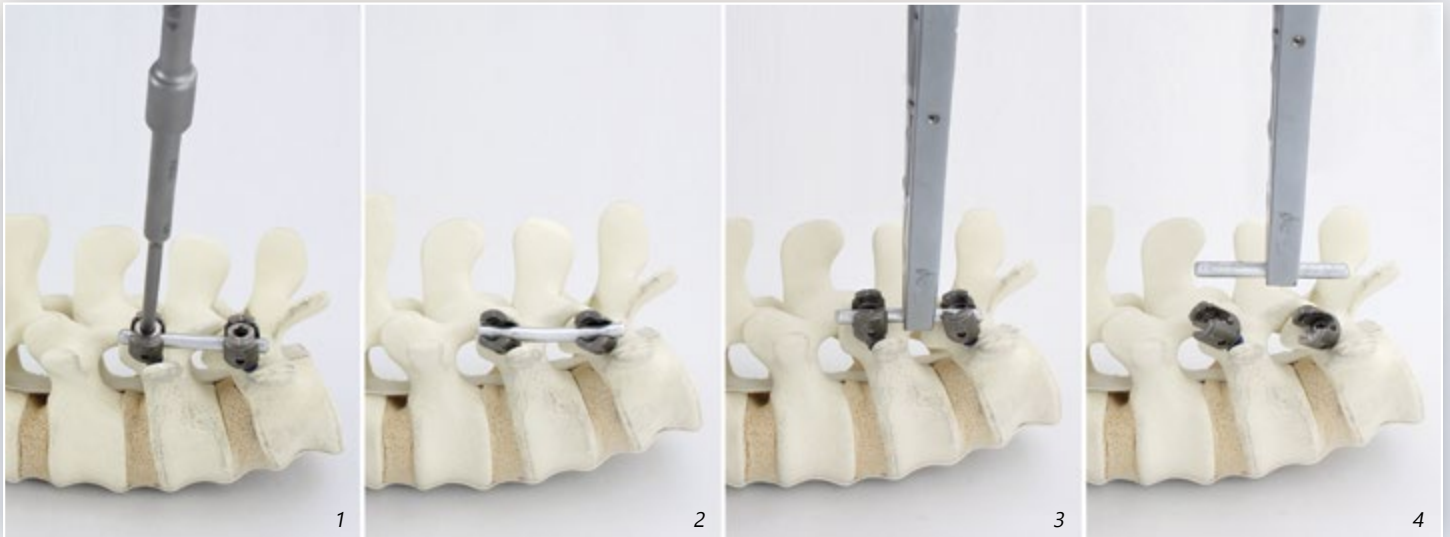


Figure A

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 9).

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

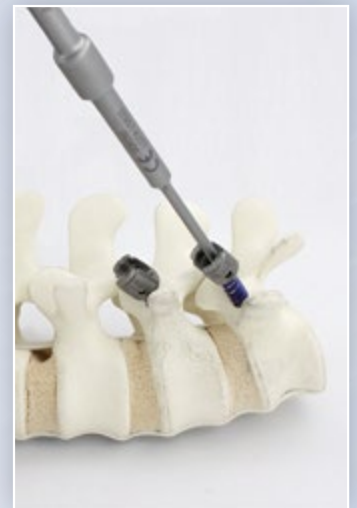


Figure B

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).

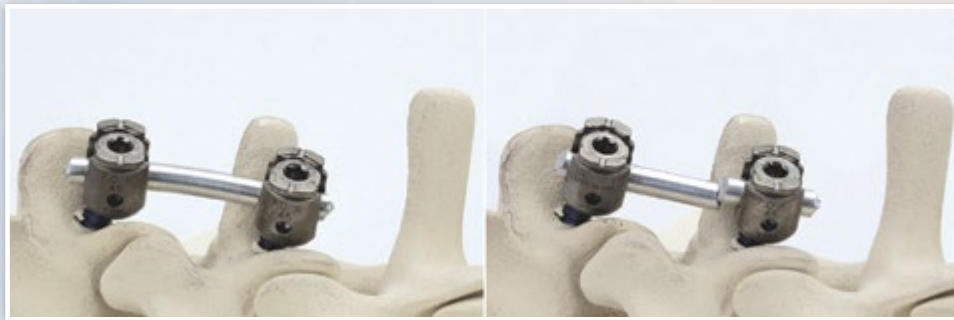
The screw construct consists of the screw, rod, & locking cap.

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

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.
 - Instrumentation to cut the spinal rod is not included in the SHUKLA Spine systems



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).
 - Ratcheting mode must be fixed 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) to extension and turn counterclockwise.



Cervical System

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



Thoracolumbar System

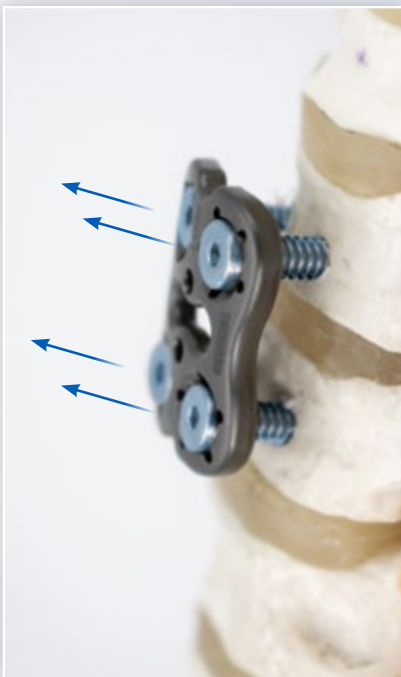
The TL Case includes 76 drivers covering standard and proprietary configurations.



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 or Screw Removal

Well-fixed locking nuts or screws

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



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



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



S9SPINE
S9SPINE-C
S9SPINE-TL
S9SPINE



SHUKLA Medical
8300 Sheen Drive
St. Petersburg, FL 33709
USA



CONSULT
INSTRUCTIONS
FOR USE



NON-STERILE
PRODUCT

COMPONENTS LIST

Component List			
Std Qty	Part Number	Description	\$/ea
1	HD233	THandle, Ratcheting, Square, 1/4"	\$975
1	HD239	Handle, Breaker Bar	\$450
1	MHRS0311	Handle Assy, In-Line, Ratcheting, Square, 1/4"	\$975
1	SAD005	Adapter, 1/4" Square to Hudson	\$400
1	SCS044	Case, Helicopter Socket System	\$990
1	SCS045	Lid, Helicopter Socket System	\$288
1	SCS036	Case, Spine System, Instruments	\$900
1	SCS039	Lid, Spine System, Instruments	\$300
1	SDR813	Driver Assy, Socket, Helicopter, Small	\$800
1	SDR814	Driver Assy, Socket, Helicopter, Medium	\$800
1	SDR815	Driver Assy, Socket, Helicopter, Large	\$800
1	SWR003	Wrench, Double Open End, 7/32" & 9/32"	\$275
1	SWR004	Wrench, Double Open End, 1/4" & 3/8"	\$275
1	SWR005	Wrench, Double Open End, 5 mm & 7 mm	\$275
1	SWR006	Wrench, Double Open End, 6 mm & 10 mm	\$275
1	SWR008	Pliers, Long Nose, Locking, 9"	\$990
1	SWR009	Pliers, Rod Gripper	\$990
1	SXN007	Extension Assy, 4"	\$525
1	SXN008	Extension Assy, 6"	\$525
1	SXN009	Extension Assy, 8"	\$550
1	SXN010	Extension Assy, 12"	\$550
1	SCS035	Case, Thoracic & Lumbar Spine System, Drivers	\$1,300
1	SCS038	Lid, Thoracic & Lumbar Spine System, Drivers	\$550
1	SDR705	Driver Assy, Male, Hex, 3 mm	\$275
1	SDR707	Driver Assy, Male, Hex, 3.5 mm	\$250
1	SDR708	Driver Assy, Male, Hex, 4 mm	\$250
1	SDR709	Driver Assy, Male, Hex, 4.5 mm	\$250
1	SDR710	Driver Assy, Male, Hex, 4.7 mm	\$250
1	SDR711	Driver Assy, Male, Hex, 5 mm	\$250
1	SDR712	Driver Assy, Male, Hex, 6 mm	\$275
1	SDR713	Driver Assy, Male, Hex, 7 mm	\$250
1	SDR720	Driver Assy, Male, Hex, 7/32"	\$250
1	SDR721	Driver Assy, Male, Hex, 1/4"	\$250
1	SDR726	Driver Assy, Female, Hex, 5 mm	\$250
1	SDR727	Driver Assy, Female, Hex, 5.5 mm	\$250
1	SDR728	Driver Assy, Female, Hex, 6 mm	\$250
1	SDR729	Driver Assy, Female, Hex, 7 mm	\$250
1	SDR730	Driver Assy, Female, Hex, 7.5 mm	\$250
1	SDR731	Driver Assy, Female, Hex, 8 mm	\$250
1	SDR732	Driver Assy, Female, Hex, 9 mm	\$250
1	SDR733	Driver Assy, Female, Hex, 10 mm	\$250

Instrumentation

Thoracic & Lumbar

Component List			
Std Qty	Part Number	Description	\$/ea
1	SDR734	Driver Assy, Female, Hex, 11 mm	\$250
1	SDR741	Driver Assy, Female, Hex, 1/4"	\$250
1	SDR742	Driver Assy, Female, Hex, 9/32"	\$250
1	SDR743	Driver Assy, Female, Hex, 5/16"	\$250
1	SDR744	Driver Assy, Female, Hex, 3/8"	\$250
1	SDR745	Driver Assy, Female, Hex, 7/16"	\$250
1	SDR751	Driver Assy, Male, Cruciform, 3 mm	\$250
1	SDR752	Driver Assy, Male, Cruciform, 3.5 mm	\$250
1	SDR753	Driver Assy, Male, Cruciform, 4.5 mm	\$250
1	SDR754	Driver Assy, Male, Cruciform, 6 mm	\$250
1	SDR759	Driver Assy, Male, Torx, T15	\$250
1	SDR760	Driver Assy, Male, Torx, T20	\$250
1	SDR761	Driver Assy, Male, Torx, T25	\$250
1	SDR762	Driver Assy, Male, Torx, T27	\$250
1	SDR763	Driver Assy, Male, Torx, T30	\$250
1	SDR764	Driver Assy, Male, Torx, T40	\$250
1	SDR765	Driver Assy, Male, Torx, T45	\$250
1	SDR766	Driver Assy, Male, Torx, T50	\$250
1	SDR773	Driver Assy, Male, Square, 4 mm for Orthofix	\$275
1	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross	\$275
1	SDR777	Driver Assy, Male, Pentalobe, S15	\$250
1	SDR782	Driver Assy, Male, Flat Head, .250" Wide	\$250
1	SDR783	Driver Assy, Male, Phillips	\$250
1	SDR784	Driver Assy, Saddle, 4 mm	\$250
1	SDR785	Driver Assy, Saddle, 5 mm	\$250
1	SDR786	Driver Assy, Saddle, 6 mm	\$250
1	SDR787	Driver Assy, Blade, 4 mm	\$250
1	SDR788	Driver Assy, Blade, 5 mm	\$250
1	SDR789	Driver Assy, Blade, 6 mm	\$250
1	SDR805	Driver Assy, Female, Dodecagon, for Outer Nut by Depuy Spine	\$275
1	SDR811	Driver Assy, Male, 2-Prong, for Incompass by Zimmer	\$325
1	SDR850	Driver Assy, Sleeve Nut, For Adv Spine	\$275
1	SDR851	Driver Assy, Anchor, For Adv Spine	\$325
1	SDR852	Driver Assy, Double Hex, 11 mm, For Synthes	\$325
1	SDR853	Driver Assy, Octagon, For Spine Tech	\$325
1	SDR854	Driver Assy, 4 prong, For Aesculap	\$325
1	SDR855	Driver Assy, Female, Hex, 13.8mm, For Interpore Cross	\$275
1	SDR856	Driver Assy, Female, Hex, Cap Nut Remover for Interpore Cross	\$275
1	SDR857	Driver Assy, 2 Prong, For Interpore Cross	\$275
1	SDR858	Driver Assy, Trilobe, Male, For 3-lok by Corin	\$325
1	SDR859	Driver Assy, Female, For Moss-Miami by DePuy	\$325
1	SDR860	Driver Assy, Female, Horse Shoe, For Moss-Miami by DePuy	\$325

Thoracic & Lumbar

COMPONENTS LIST

Component List			
Std Qty	Part Number	Description	\$/ea
1	SDR861	Driver Assy, 2 prong, For Click'X by Synthes	\$325
1	SDR862	Driver Assy, Male, Square, For EBI	\$325
1	SDR863	Driver Assy, Female, Flower Shaped, for Spinelink II by EBI	\$325
1	SDR864	Driver Assy, Male, Flower Shaped, for Spinelink II by EBI	\$325
1	SDR865	Driver Assy, Male, 4 prong, for Xia by Stryker Spine	\$325
1	SDR866	Driver Assy, Female, Hexalobe, for Xia III by Stryker Spine	\$325
1	SDR867	Driver Assy, Female, Heptagon, 1/2", for Silhouette by Zimmer	\$325
1	SDR868	Driver Assy, 4 prong, for Radius by Stryker Spine	\$325
1	SDR869	Driver Assy, Male, Pentalobe, for Polaris 5.5 by Biomet	\$325
1	SDR872	Driver Assy, Male, 2-Prong, for Theken	\$325
1	SDR873	Driver Assy, Female, for Dynesys LIS by Zimmer	\$325
1	SDR874	Driver Assy, Male, 3-Prong, for US Spine	\$325
1	SDR876	Driver Assy, Male, Hexalobe, X15	\$250
1	SDR877	Driver Assy, Male, Hexalobe, X20	\$250
1	SDR878	Driver Assy, Male, Hexalobe, X25	\$250
1	SDR879	Driver Assy, Female, Hexalobe, E7, for Pathfinder by Zimmer	\$275
1	SCS034	Case, Cervical Spine System, Drivers	\$1,300
1	SCS037	Lid, Cervical Spine System, Drivers	\$550
1	SDR701	Driver Assy, Male, Hex, 2 mm	\$250
1	SDR702	Driver Assy, Male, Hex, 2.25 mm	\$275
1	SDR703	Driver Assy, Male, Hex, 2.5 mm	\$250
1	SDR704	Driver Assy, Male, Hex, 2.75 mm	\$275
1	SDR705	Driver Assy, Male, Hex, 3 mm	\$275
1	SDR707	Driver Assy, Male, Hex, 3.5 mm	\$250
1	SDR708	Driver Assy, Male, Hex, 4 mm	\$250
1	SDR716	Driver Assy, Male, Hex, 7/64"	\$250
1	SDR717	Driver Assy, Male, Hex, 1/8"	\$250
1	SDR718	Driver Assy, Male, Hex, 5/32"	\$250
1	SDR719	Driver Assy, Male, Hex, 3/16"	\$250
1	SDR724	Driver Assy, Female, Hex, 3.5 mm	\$250
1	SDR725	Driver Assy, Female, Hex, 4 mm	\$250
1	SDR737	Driver Assy, Female, Hex, 1/8"	\$250
1	SDR738	Driver Assy, Female, Hex, 5/32"	\$250
1	SDR739	Driver Assy, Female, Hex, 3/16"	\$250
1	SDR740	Driver Assy, Female, Hex, 7/32"	\$250
1	SDR746	Driver Assy, Female, Hex, 1/2"	\$250
1	SDR749	Driver Assy, Male, Cruciform, 2 mm	\$250
1	SDR750	Driver Assy, Male, Cruciform, 2.5 mm	\$250
1	SDR751	Driver Assy, Male, Cruciform, 3 mm	\$250

Thoracic & Lumbar

Cervical

Component List			
Std Qty	Part Number	Description	\$/ea
1	SDR752	Driver Assy, Male, Cruciform, 3.5 mm	\$250
1	SDR756	Driver Assy, Male, Torx, T6	\$250
1	SDR757	Driver Assy, Male, Torx, T8	\$250
1	SDR758	Driver Assy, Male, Torx, T10	\$250
1	SDR759	Driver Assy, Male, Torx, T15	\$250
1	SDR760	Driver Assy, Male, Torx, T20	\$250
1	SDR761	Driver Assy, Male, Torx, T25	\$250
1	SDR767	Driver Assy, Male, Torx, T7	\$250
1	SDR768	Driver Assy, Male, Torx, T9	\$250
1	SDR769	Driver Assy, Male, Square, 2 mm for Orthofix	\$275
1	SDR770	Driver Assy, Male, Square, 2.5 mm for Orthofix	\$275
1	SDR771	Driver Assy, Male, Square, 3 mm for Orthofix	\$275
1	SDR772	Driver Assy, Male, Square, 3.5 mm for Orthofix	\$275
1	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross	\$275
1	SDR777	Driver Assy, Male, Pentalobe, S15	\$250
1	SDR780	Driver Assy, Male, Flat Head, .110" Wide	\$250
1	SDR781	Driver Assy, Male, Flat Head, .140" Wide	\$250
1	SDR782	Driver Assy, Male, Flat Head, .250" Wide	\$250
1	SDR783	Driver Assy, Male, Phillips	\$250
1	SDR784	Driver Assy, Saddle, 4 mm	\$250
1	SDR787	Driver Assy, Blade, 4 mm	\$250
1	SDR800	Driver Assy, Male, Star shaped, for Aesculap	\$275
1	SDR801	Driver Assy, Male, U shape, unlock tool, for Alphatec	\$275
1	SDR802	Driver Assy, Male, 2 prong, for Blackstone	\$275
1	SDR803	Driver Assy, Male, Tri-Lobe, for Blackstone	\$275
1	SDR804	Driver Assy, Male, 3 prong, for Cervive by Corin	\$275
1	SDR806	Driver Assy, Male, Square, Unlock tool, For Interpore by Cross	\$275
1	SDR807	Driver Assy, Male, Square, For Medtronic	\$275
1	SDR808	Driver Assy, Male, 4 prong, for Stryker Spine	\$275
1	SDR809	Driver Assy, Male, Flower Shaped, For Spinelink ACS by EBI	\$275
1	SDR810	Driver Assy, Male, 3 pronged, for Cervi-Lok by Zimmer	\$250
1	SDR812	Driver Assy, Male, 3-Prong, for Nex-Link by Zimmer	\$275
1	SDR875	Driver Assy, Male, Hexalobe, X10	\$250
1	SDR876	Driver Assy, Male, Hexalobe, X15	\$250
1	SDR877	Driver Assy, Male, Hexalobe, X20	\$250

Cervical



Revolutionizing the Art of Revision Surgery

Shukla Medical designs & manufactures instrumentation for orthopedic implant extraction in St. Petersburg, Florida, USA.

In 1998, aerospace component manufacturer S.S. White Technologies, Inc. acquired the Snap-On Winquist IM Nail system. S.S. White rebranded the medical division in 2007 to create Shukla Medical.

Today, Shukla Medical is the industry leader in orthopedic implant extraction tools. We are the only company to offer a comprehensive, truly universal orthopedic revision line for removing IM nails, hip and knee implants, spine hardware, and broken or stripped screws. Surgeons and industry leaders know: **If Shukla can't get it out, no one can.**

Contact us to learn more

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SHUKLA Surgical Tech Support
24 hours a day, 7 days a week
727-626-2771

When you have tried all known techniques to extract an implant or remove a screw but determine you need suggestions for alternate techniques, help is only a phone call away. We will quickly put you in touch with our Technical Experts who will suggest other solutions to use our tools.



SHUKLA Medical offers the best warranty in the industry. Every component in a SHUKLA extraction system is designed and manufactured by us. Every component in our extraction systems that is not a single-use* or a wear* component is warranted against manufacturing defects for the life* of the system. All other parts are covered for as long as the purchased version of the system is actively marketed by SHUKLA Medical.

*Please see our website for the complete explanation of these terms and full details on our warranty.