

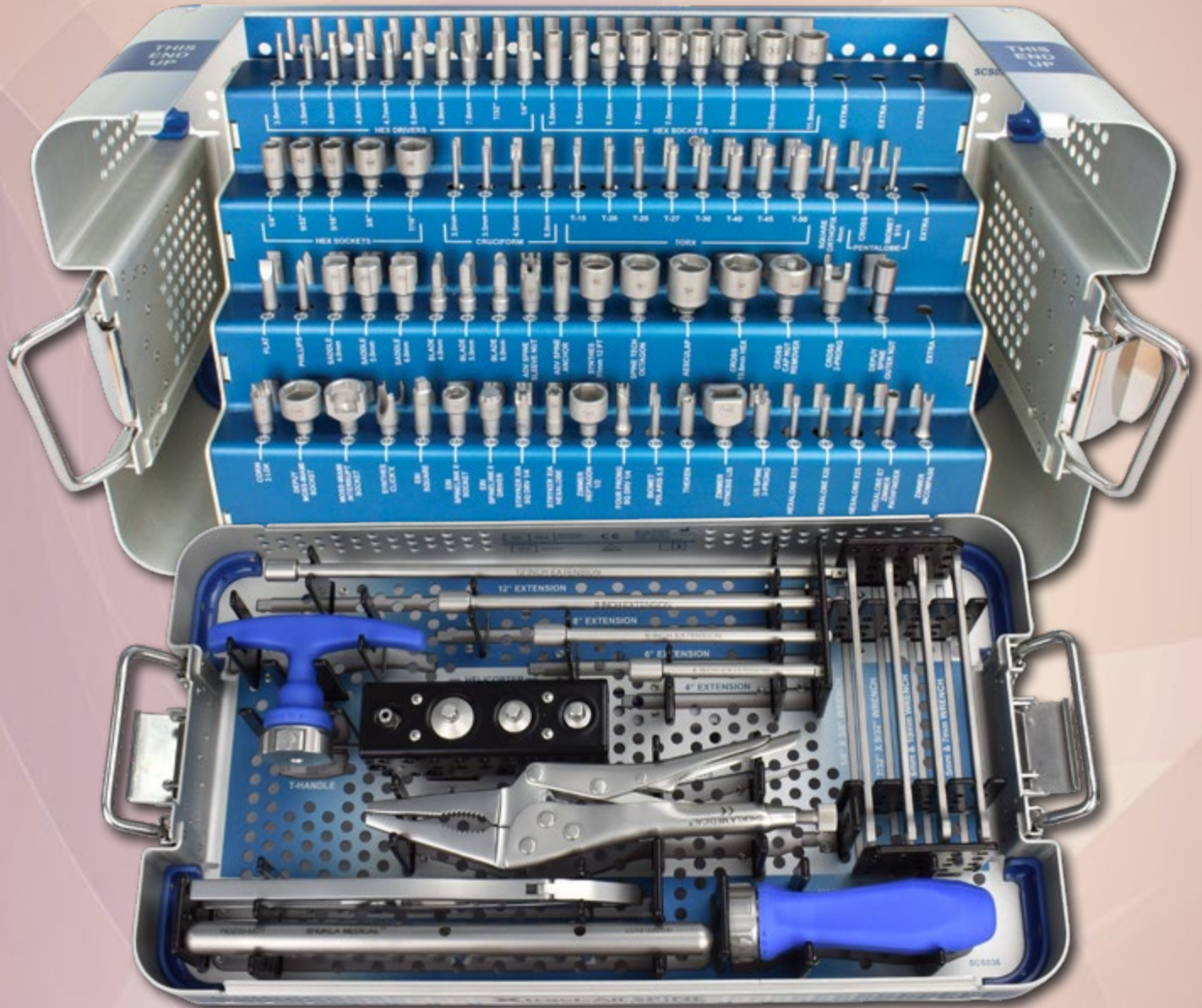
PRODUCT GUIDE

THORACIC & LUMBAR

SHUKLA SPINE

Universal Spinal Screw Removal Solution

#12
System 11 of 15



SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

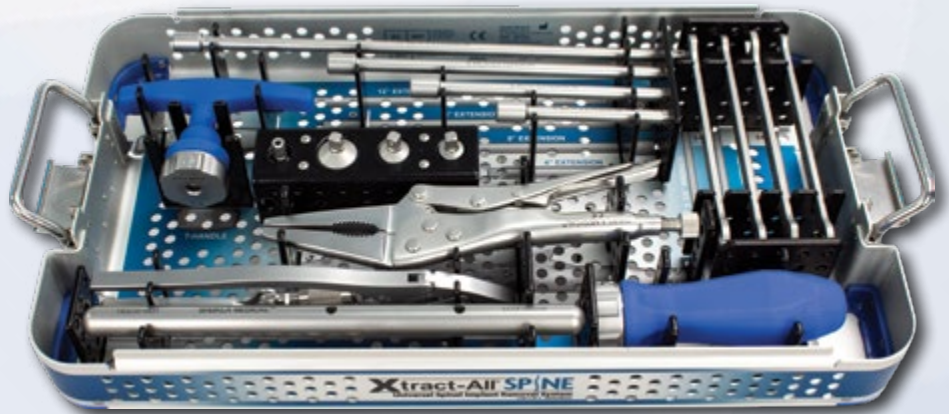
SHUKLA THORACIC & LUMBAR SPINE

Universal Spinal Screw Removal Solution

System Name: SHUKLA Spine-TL v4

Primary Use

The SHUKLA Spine-Thoracolumbar (Spine-TL) system is designed to remove thoracolumbar spinal screws, locking caps, rods, and plates from any implant system. It contains more than 75 drivers compatible with standard configurations in addition to more than 25 proprietary implant systems.



System History

The Spine-TL was the first spine set that Shukla Medical created when it decided to enter the spinal revision surgery world. While it wouldn't be until the release of the Spine-C that the total capabilities of Shukla's Spine family became truly universal, the Spine-TL is a very robust system on its own. When it comes to revisions of the thoracic and lumbar regions, there is no equal.

Thoracic and Lumbar spinal screws and constructs are so impossibly varied, trying to make a universal set seemed like a pipe dream. At Shukla, we embraced that challenge.

2000: Version 1 Introduced

2005: Version 2 Introduced

- More Drivers
- More Proprietary Implant Drivers

2009: Version 3 Introduced

- Case Redesign
- More Drivers
- More Proprietary Implant Drivers

2018: Version 4 Introduced

- Helicopter Sockets
- Case Redesign
- More Drivers
- More Proprietary Implant Drivers

Key Benefits

- More than 75 drivers specifically designed for thoracolumbar implants and screw removal.
- More than 25 proprietary implant removal drivers make the removal of specific company's proprietary screws faster and simpler.



Small sample of how diverse spinal drivers can be.

- A Breaker Bar is included for applying extra torque when needed.
- Four Extensions are provided, ranging from four to twelve inches in length. These are perfect for both anterior and lateral procedures.
- Ratcheting inline handle speeds up screw removal as well as reduces surgeon hand fatigue.



- Saddle and Blade drivers allow for Monoaxial Screw compatibility.
- Helicopter sockets for when a spinal screw or cap strips out or cannot be removed. By cutting the rod on either side of the implant tulip, the entire construct can be removed.
- Specially engineered vertical case with a tiered design for easy to recognize placement of the drivers no matter the row. Easy-to-read identification for each driver available on the case itself as well.

Universal Shukla System Benefits for Better Patient Outcomes

Less Time Spent in O.R.

- Reduces risk of infection to patient
- Reduces time spent under anesthesia
- Reduces cost to the hospital

Universal Designs

- Less prep time for surgeons
- Less space taken up in the O.R.
- Reduces need for other systems or tools

Ergonomic Design

- Reduces surgeon stress
- Reduces surgeon fatigue
- Better grip/reduces slippage

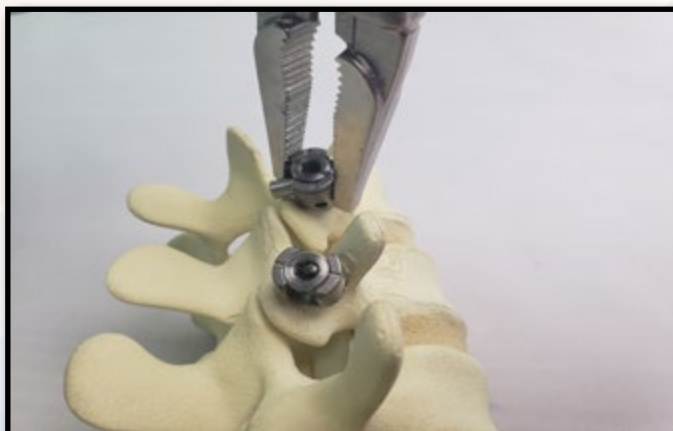
Comprehensive Design

- Addresses all known challenges
- Tools ensure surgery is a success
- Provides backup solutions during surgery

Alternative Method Comparison

While other spinal screw removal systems exist, the SHUKLA Spine-TL outshines the competition. The sheer number of driver configurations offered by the Spine-TL is unparalleled.

Since other competing systems cannot match our level of driver configurations, nor do they possess our patented helicopter socket capabilities, surgeons are much more likely to hit the point of a surgery where they have to declare it unsuccessful. Their only common recourse beyond that is to use a vise grip or pliers to hack away at the screw, and manually try to turn it out.



The Vise Grip method, an attempt to emulate what a helicopter socket does easier and more effectively.

Return On Investment Justification

According to a study published in *JAMA Surgery*, the cost of one minute in an O.R. can vary anywhere from \$36 per minute to \$100 per minute, with the average cost of a minute in the O.R. at a staggering \$66! It is estimated that you would save 60 to 90 minutes per surgery by using SHUKLA system. Taking just the lowest estimate of time savings, the savings per surgery can be estimated at 75 minutes x \$36 per minute = \$2,700.

With an average cost per minute of O.R. time that high, the delays that occur when waiting on proper instrumentation gets costly. Waiting on it to be found, to be sterilized, to be brought in, it all adds up. You *could* go through that each time, or you could have a Spine-TL prepped and ready to tackle any thoracic and/or lumbar spinal constructs that come your way. A SHUKLA Spine-TL sells for \$24,500, so the absolute highest end amount of cases it would take to fully justify its cost is just over 9 uses.

When You Don't Have It

If you don't have a SHUKLA Spine-TL set when it comes to thoracic and lumbar spine revision surgery, you run into a lot of potential roadblocks. As a spine surgeon, imagine going into a case and your patient is in need of a revision. The patient received their primary surgery in a different country and you do not have the proper tools to get out all of his screws and constructs. You have two options: grab some pliers and hope for the best or close up the patient and hope the proper tools arrive next time.

Luckily, there is a third option, one that gives a simpler solution, the SHUKLA Spine-TL system.

Not having a Spine-TL system is a lot like not having health insurance. You might not need it every day, but you sure are glad you have it when the time comes to use it.

How We Compare

Most orthopaedic implant manufacturers provide revision/extraction tools suited *only* for their own implants. Even suppliers that claim to offer extraction sets basically have an assortment of tools thrown together as an afterthought. For Shukla Medical, **extraction is what we do**. Our engineers design truly universal tools to help remove any implant/hardware out there, making our competition essentially nonexistent. Our patented designs are revolutionizing the art of revision surgery; we proudly stand alone. We have still tried to provide a comparison to other systems on the market.

There are several other spinal screw removal systems on the market and even though they occasionally loan their sets out free of charge, surgeries have to be adjusted based on their availability. Not only is that more inconvenient but they only offer drivers and sockets compatible with their own implants.

Hospitals worldwide are upgrading to the SHUKLA Spine for many obvious reasons. With over 100 available drivers, the SHUKLA system is truly universal; every driver and socket combination we can think of is included. We also include many proprietary drivers designed for specific screws or implants. No other manufacturer that supplies screw removal options includes such proprietary drivers. Other systems not only cost significantly more than ours but are no match to the SHUKLA Spine.

PATENT

- Helicopter Socket

The SHUKLA Spine systems all share our patented Helicopter Sockets. Our engineering team worked tirelessly to provide surgeons with an intelligent, effective system.

HELICOPTER SOCKETS

Available in three different sizes, engineered to fit any type of pedicle screw construct you could possibly come across.



Small



Medium



Large

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 6.35 mm in diameter.

Made with medical grade stainless steel, the helicopter sockets also have a ball detent that allows for quick-attach capability with our range of Extensions.

For spinal systems that use a PEEK Rod, our helicopter sockets are still compatible. However, since torque must be limited in that situation, only the Ratcheting T-Handle should be used, **not** the breaker bar.

Attention to Detail

The Spine-TL system boasts a large amount of attention to the small details. A lot of thought went into the newly designed cases that the Spine-TL sports. The case is now vertical, so that the drivers are displayed upright and are labeled clearly on the case, as well as on each driver *itself* for simple identification. The tiered driver displays take up minimal space on the operating table, keeping O.R. surfaces organized. Each driver is marked with a number that identifies its slot placement. Corresponding numbers are displayed clearly on the case itself, making it easy to find what you need and easy to put it back.



The Spine-TL set not only has long low profile drivers to help you reach anything that needs to be reached, but it also comes with four different sizes of driver extensions. With sizes ranging from four to twelve inches in length, there won't be a screw or construct around that you won't be able to reach.



Components List

Component List			
Std Qty	ID #	Part Number	Description
1		HD233	THandle, Ratcheting, Square, 1/4"
1		HD239	Handle, Breaker Bar
1		MHRS0311	Handle Assy, In-Line, Ratcheting, Square, 1/4"
1		SAD005	Adapter, 1/4" Square to Hudson
1		SCS036	Case, Spine System, Instruments
1		SCS039	Lid, Spine System, Instruments
1		SDR813	Driver Assy, Socket, Helicopter, Small
1		SDR814	Driver Assy, Socket, Helicopter, Medium
1		SDR815	Driver Assy, Socket, Helicopter, Large
1		SWR003	Wrench, Double Open End, 7/32" & 9/32"
1		SWR004	Wrench, Double Open End, 1/4" & 3/8"
1		SWR005	Wrench, Double Open End, 5 mm & 7 mm
1		SWR006	Wrench, Double Open End, 6 mm & 10 mm
1		SWR008	Pliers, Long Nose, Locking, 9"
1		SWR009	Pliers, Rod Gripper
1		SXN007	Extension Assy, 4"
1		SXN008	Extension Assy, 6"
1		SXN009	Extension Assy, 8"
1		SXN010	Extension Assy, 12"
1		SCS035	Case, Thoracic & Lumbar Spine System, Drivers
1		SCS038	Lid, Thoracic & Lumbar Spine System, Drivers
1	5	SDR705	Driver Assy, Male, Hex, 3 mm
1	7	SDR707	Driver Assy, Male, Hex, 3.5 mm
1	8	SDR708	Driver Assy, Male, Hex, 4 mm
1	9	SDR709	Driver Assy, Male, Hex, 4.5 mm
1	10	SDR710	Driver Assy, Male, Hex, 4.7 mm
1	11	SDR711	Driver Assy, Male, Hex, 5 mm
1	12	SDR712	Driver Assy, Male, Hex, 6 mm
1	13	SDR713	Driver Assy, Male, Hex, 7 mm
1	20	SDR720	Driver Assy, Male, Hex, 7/32"
1	21	SDR721	Driver Assy, Male, Hex, 1/4"
1	26	SDR726	Driver Assy, Female, Hex, 5 mm
1	27	SDR727	Driver Assy, Female, Hex, 5.5 mm
1	28	SDR728	Driver Assy, Female, Hex, 6 mm
1	29	SDR729	Driver Assy, Female, Hex, 7 mm
1	30	SDR730	Driver Assy, Female, Hex, 7.5 mm
1	31	SDR731	Driver Assy, Female, Hex, 8 mm
1	32	SDR732	Driver Assy, Female, Hex, 9 mm
1	33	SDR733	Driver Assy, Female, Hex, 10 mm
1	34	SDR734	Driver Assy, Female, Hex, 11 mm
1	41	SDR741	Driver Assy, Female, Hex, 1/4"
1	42	SDR742	Driver Assy, Female, Hex, 9/32"
1	43	SDR743	Driver Assy, Female, Hex, 5/16"
1	44	SDR744	Driver Assy, Female, Hex, 3/8"
1	45	SDR745	Driver Assy, Female, Hex, 7/16"
1	51	SDR751	Driver Assy, Male, Cruciform, 3 mm
1	52	SDR752	Driver Assy, Male, Cruciform, 3.5 mm
1	53	SDR753	Driver Assy, Male, Cruciform, 4.5 mm
1	54	SDR754	Driver Assy, Male, Cruciform, 6 mm

Instrumentation

Thoracic & Lumbar Drivers

Component List			
Std Qty	ID #	Part Number	Description
1	61	SDR759	Driver Assy, Male, Torx, T15
1	62	SDR760	Driver Assy, Male, Torx, T20
1	63	SDR761	Driver Assy, Male, Torx, T25
1	64	SDR762	Driver Assy, Male, Torx, T27
1	65	SDR763	Driver Assy, Male, Torx, T30
1	66	SDR764	Driver Assy, Male, Torx, T40
1	67	SDR765	Driver Assy, Male, Torx, T45
1	68	SDR766	Driver Assy, Male, Torx, T50
1	73	SDR773	Driver Assy, Male, Square, 4 mm for Orthofix
1	76	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross
1	77	SDR777	Driver Assy, Male, Pentalobe, S15
1	82	SDR782	Driver Assy, Male, Flat Head, .250" Wide
1	83	SDR783	Driver Assy, Male, Phillips
1	84	SDR784	Driver Assy, Saddle, 4 mm
1	85	SDR785	Driver Assy, Saddle, 5 mm
1	86	SDR786	Driver Assy, Saddle, 6 mm
1	87	SDR787	Driver Assy, Blade, 4 mm
1	88	SDR788	Driver Assy, Blade, 5 mm
1	89	SDR789	Driver Assy, Blade, 6 mm
1	100	SDR805	Driver Assy, Female, Dodecagon, for Outer Nut by Depuy Spine
1	106	SDR811	Driver Assy, Male, 2-Prong, for Incompass by Zimmer
1	120	SDR850	Driver Assy, Sleeve Nut, For Adv Spine
1	121	SDR851	Driver Assy, Anchor, For Adv Spine
1	122	SDR852	Driver Assy, Double Hex, 11 mm, For Synthes
1	123	SDR853	Driver Assy, Octagon, For Spine Tech
1	124	SDR854	Driver Assy, 4 prong, For Aesculap
1	125	SDR855	Driver Assy, Female, Hex, 13.8mm, For Interpore Cross
1	126	SDR856	Driver Assy, Female, Hex, Cap Nut Remover for Interpore Cross
1	127	SDR857	Driver Assy, 2 Prong, For Interpore Cross
1	128	SDR858	Driver Assy, Trilobe, Male, For 3-lok by Corin
1	129	SDR859	Driver Assy, Female, For Moss-Miami by DePuy
1	130	SDR860	Driver Assy, Female, Horse Shoe, For Moss-Miami by DePuy
1	131	SDR861	Driver Assy, 2 prong, For Click'X by Synthes
1	132	SDR862	Driver Assy, Male, Square, For EBI
1	133	SDR863	Driver Assy, Female, Flower Shaped, for Spinelink II by EBI
1	134	SDR864	Driver Assy, Male, Flower Shaped, for Spinelink II by EBI
1	135	SDR865	Driver Assy, Male, 4 prong, for Xia by Stryker Spine
1	136	SDR866	Driver Assy, Female, Hexalobe, for Xia III by Stryker Spine
1	137	SDR867	Driver Assy, Female, Heptagon, 1/2", for Silhouette by Zimmer
1	138	SDR868	Driver Assy, 4 prong, for Radius by Stryker Spine
1	139	SDR869	Driver Assy, Male, Pentalobe, for Polaris 5.5 by Biomet
1	142	SDR872	Driver Assy, Male, 2-Prong, for Theken
1	143	SDR873	Driver Assy, Female, for Dynesys LIS by Zimmer
1	144	SDR874	Driver Assy, Male, 3-Prong, for US Spine
1	146	SDR876	Driver Assy, Male, Hexalobe, X15
1	147	SDR877	Driver Assy, Male, Hexalobe, X20
1	148	SDR878	Driver Assy, Male, Hexalobe, X25
1	149	SDR879	Driver Assy, Female, Hexalobe, E7, for Pathfinder by Zimmer

Thoracic & Lumbar Drivers



Revolutionizing the Art of Revision Surgery

Shukla Medical designs and manufactures instrumentation for orthopedic implant extraction at our headquarters in St. Petersburg, Florida, USA. We are proud to be an *ISO 13485:2016* Certified company.

In 1998, aerospace component manufacturer S.S. White Technologies, Inc. acquired the Medical Products Division of Snap-On. 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

Shukla Medical
8300 Sheen Drive
St. Petersburg, FL 33709
www.ShuklaMedical.com

T: 888-4-SHUKLA
T: 888-474-8552
F: 727-626-2770
CS@ShuklaMedical.com



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.