

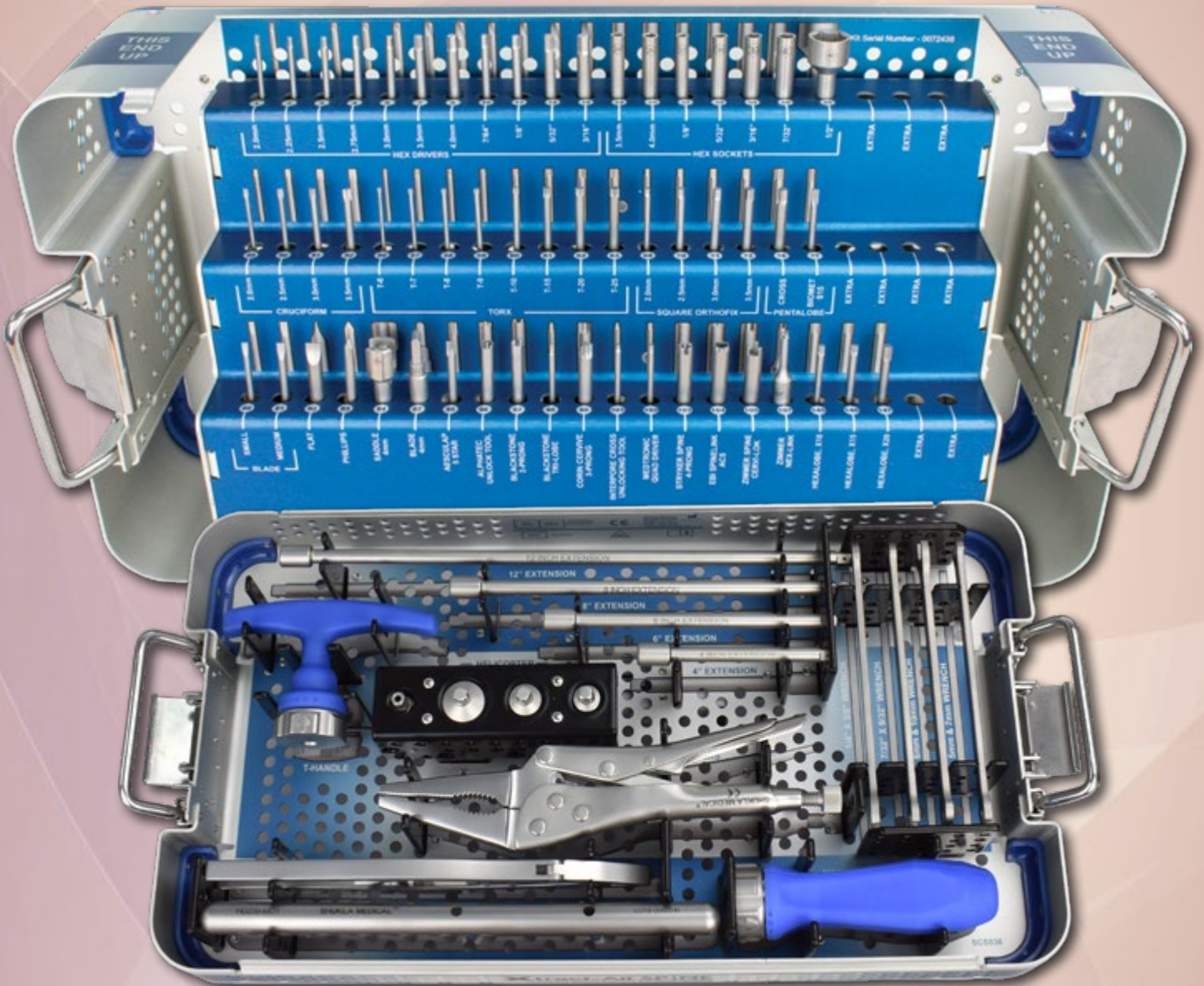
# PRODUCT GUIDE

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# SHUKLA SPINE

CERVICAL

## Universal Spinal Screw Removal Solution



**SHUKLA MEDICAL®**

Universal Orthopedic Extraction Technologies

*Revolutionizing the Art of Revision Surgery*

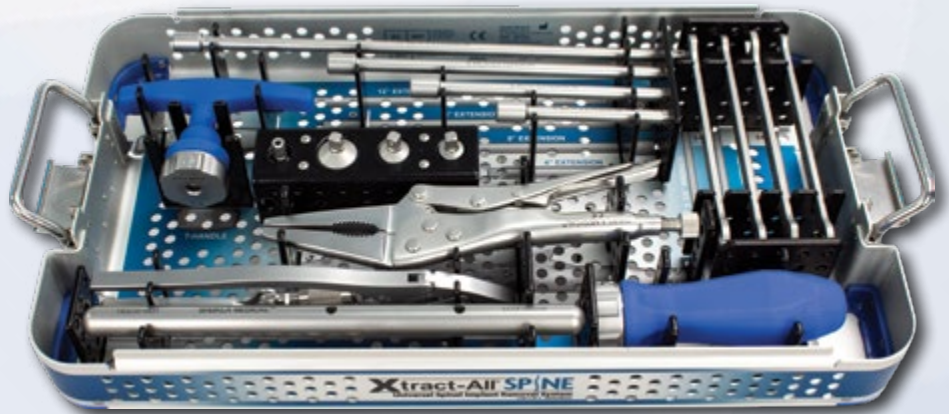
# SHUKLA SPINE CERVICAL

## Universal Spinal Screw Removal Solution

**System Name: SHUKLA Spine-C v3**

### Primary Use

The SHUKLA Spine - Cervical (Spine-C) is a system designed to remove cervical spinal screws, locking caps, rods, and plates from any implant system. It contains over 50 drivers compatible with standard configurations in addition to more than 15 proprietary implant systems.



### System History

The very first SHUKLA Spine set debuted back in 2000, but it did not contain an option for cervical implant or screw removal. This was added in as an option during a later version. The first Spine-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 release of the Spine-C made Shukla's systems for Spine family truly universal.

Cervical spinal screws come in a wild assortment of unusual shapes and sizes, making the task of removing them a daunting one. Luckily, the SHUKLA Spine-C system has solutions for all the daunting tasks.

#### 2005: Version 1 Introduced

#### 2009: Version 2 Introduced

- Case Redesign
- More Drivers
- More Proprietary Implant Drivers

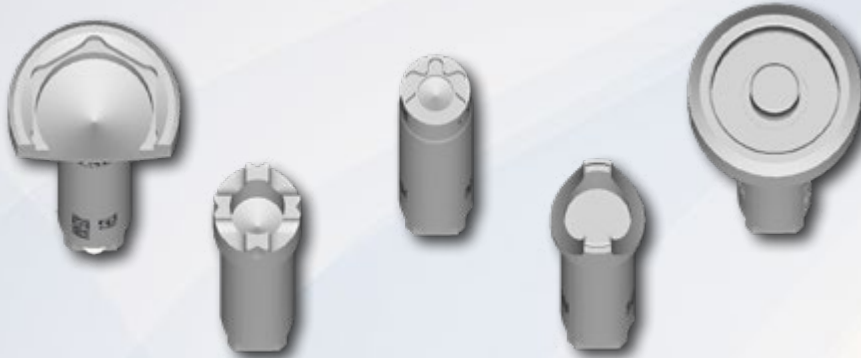
#### 2018: Version 3 Introduced

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



## Key Benefits

- More than 50 drivers specifically designed for cervical implants and screw removal.
- More than 15 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 number of driver configurations offered by them don't even come close to the SHUKLA Spine-C system. The gap between us and them is wide, and our engineers are always working towards increasing that distance.

The SHUKLA Spine-C ensures success by virtue of the huge range of driver configurations and the inclusion of cutting-edge helicopter socket instrumentation. Since competing systems do not have as many driver configurations available and do not include solutions for challenging screw constructs, the surgeon is much more likely to hit a dreaded stop-point in their procedure such as having to use pliers or a vise grip to try and manually turn out a screw on someone's very delicate spine.



*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.

However, if the O.R. is prepped with a SHUKLA Spine-C set, the surgeon avoids any chance of delay by having the right tool on hand, no matter what. A SHUKLA Spine-C system sells for \$20,000, meaning that even at the lowest possible cost per minute in the O.R. it would only take 8 uses to fully pay for itself.

## When You Don't Have It

If you don't have a SHUKLA Spine-C set for cervical spine revision surgery, you run the very real risk of longer procedure times due to searching for the right driver, waiting for the right driver to be sterilized, or not having a damaged screw extraction system that can get the job done.

The right tools in your hands can make even the most challenging cases go smoothly.

Worst case scenario for not having a SHUKLA Spine-C set on hand? Closing up the patient without being able to finish the surgery successfully.

## 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 75 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

A lot of thought went into our new vertical case. The drivers are displayed upright and are labeled clearly on the case and each driver itself is clearly laser marked. The tiered driver displays take up minimal space on the table, keeping surfaces clear and organized. Each driver is also 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-C set not only has long low profile drivers to help you reach anything that needs reaching, 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"

Instrumentation

1		SCS034	Case, Cervical Spine System, Drivers
1		SCS037	Lid, Cervical Spine System, Drivers
1	1	SDR701	Driver Assy, Male, Hex, 2 mm
1	2	SDR702	Driver Assy, Male, Hex, 2.25 mm
1	3	SDR703	Driver Assy, Male, Hex, 2.5 mm
1	4	SDR704	Driver Assy, Male, Hex, 2.75 mm
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	16	SDR716	Driver Assy, Male, Hex, 7/64"
1	17	SDR717	Driver Assy, Male, Hex, 1/8"
1	18	SDR718	Driver Assy, Male, Hex, 5/32"
1	19	SDR719	Driver Assy, Male, Hex, 3/16"
1	24	SDR724	Driver Assy, Female, Hex, 3.5 mm
1	25	SDR725	Driver Assy, Female, Hex, 4 mm
1	37	SDR737	Driver Assy, Female, Hex, 1/8"
1	38	SDR738	Driver Assy, Female, Hex, 5/32"
1	39	SDR739	Driver Assy, Female, Hex, 3/16"
1	40	SDR740	Driver Assy, Female, Hex, 7/32"
1	46	SDR746	Driver Assy, Female, Hex, 1/2"
1	49	SDR749	Driver Assy, Male, Cruciform, 2 mm
1	50	SDR750	Driver Assy, Male, Cruciform, 2.5 mm
1	51	SDR751	Driver Assy, Male, Cruciform, 3 mm

Cervical Drivers

Component List			
Std Qty	ID #	Part Number	Description
1	52	SDR752	Driver Assy, Male, Cruciform, 3.5 mm
1	56	SDR756	Driver Assy, Male, Torx, T6
1	58	SDR757	Driver Assy, Male, Torx, T8
1	60	SDR758	Driver Assy, Male, Torx, T10
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	57	SDR767	Driver Assy, Male, Torx, T7
1	59	SDR768	Driver Assy, Male, Torx, T9
1	69	SDR769	Driver Assy, Male, Square, 2 mm for Orthofix
1	70	SDR770	Driver Assy, Male, Square, 2.5 mm for Orthofix
1	71	SDR771	Driver Assy, Male, Square, 3 mm for Orthofix
1	72	SDR772	Driver Assy, Male, Square, 3.5 mm for Orthofix
1	76	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross
1	77	SDR777	Driver Assy, Male, Pentalobe, S15
1	80	SDR780	Driver Assy, Male, Flat Head, .110" Wide
1	81	SDR781	Driver Assy, Male, Flat Head, .140" Wide
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	87	SDR787	Driver Assy, Blade, 4 mm
1	95	SDR800	Driver Assy, Male, Star shaped, for Aesculap
1	96	SDR801	Driver Assy, Male, U shape, unlock tool, for Alphatec
1	97	SDR802	Driver Assy, Male, 2 prong, for Blackstone
1	98	SDR803	Driver Assy, Male, Tri-Lobe, for Blackstone
1	99	SDR804	Driver Assy, Male, 3 prong, for Cervive by Corin
1	101	SDR806	Driver Assy, Male, Square, Unlock tool, For Interpore by Cross
1	102	SDR807	Driver Assy, Male, Square, For Medtronic
1	103	SDR808	Driver Assy, Male, 4 prong, for Stryker Spine
1	104	SDR809	Driver Assy, Male, Flower Shaped, For Spinelink ACS by EBI
1	105	SDR810	Driver Assy, Male, 3 pronged, for Cervi-Lok by Zimmer
1	107	SDR812	Driver Assy, Male, 3-Prong, for Nex-Link by Zimmer
1	145	SDR875	Driver Assy, Male, Hexalobe, X10
1	146	SDR876	Driver Assy, Male, Hexalobe, X15
1	147	SDR877	Driver Assy, Male, Hexalobe, X20

Cervical 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

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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.