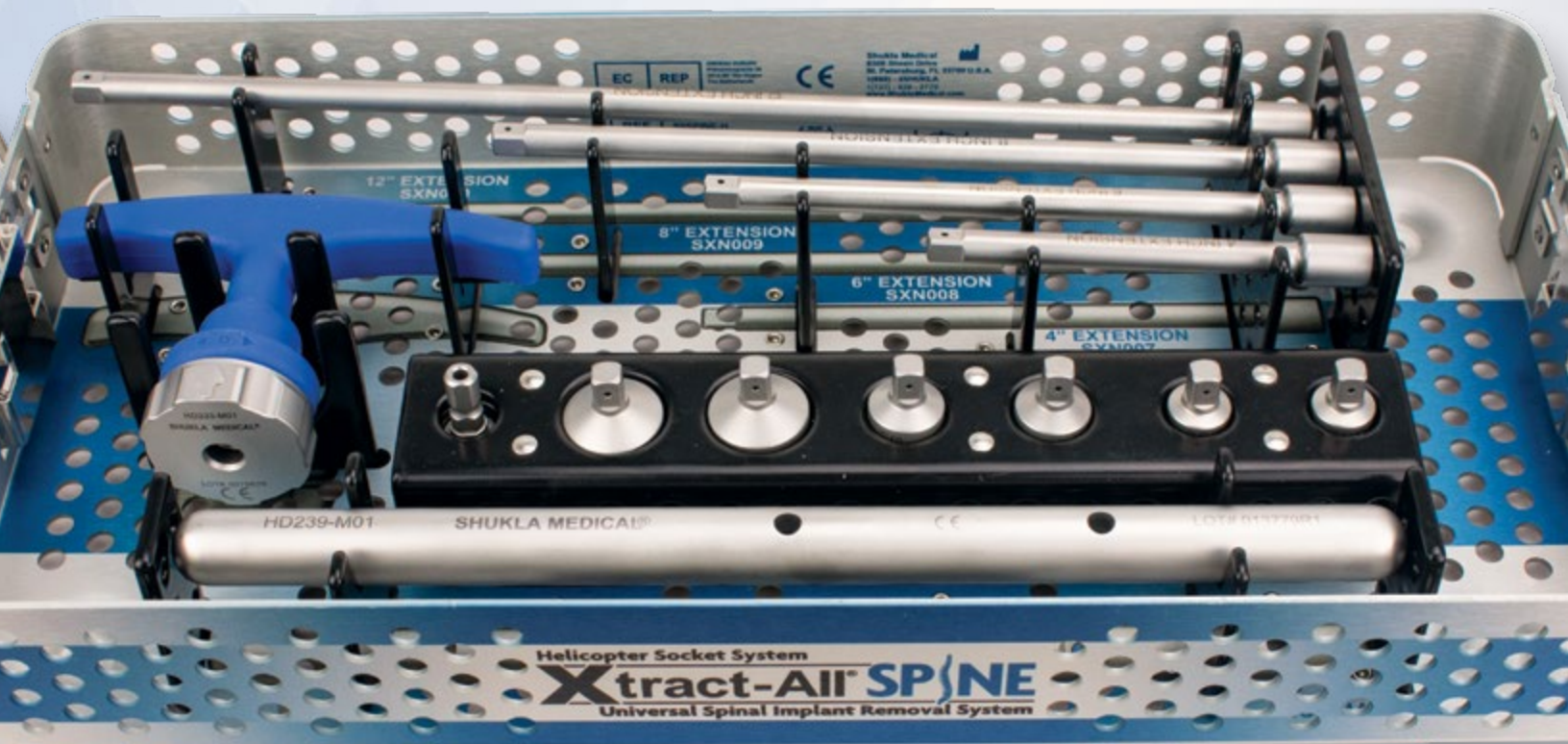


SURGICAL TECHNIQUE GUIDE

#15
System 15 of 15

SHUKLA COPTER

Universal Pedicle Screw Construct Removal Solution



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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SHUKLA COPTER

Universal Pedicle Screw Construct Removal Solution

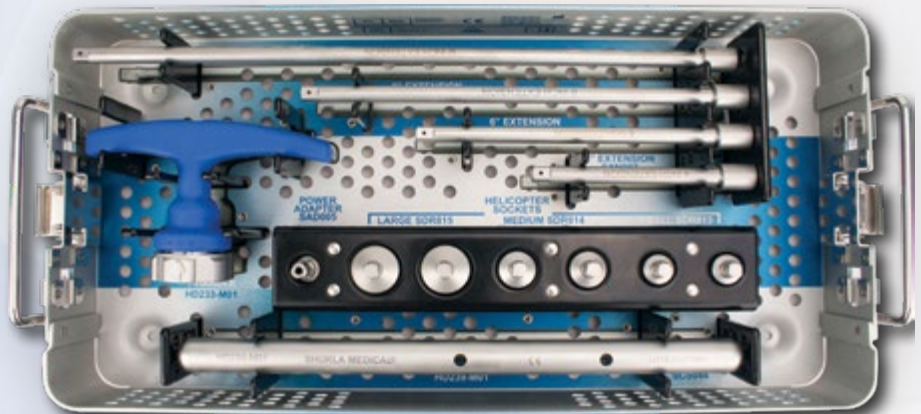
1.1 System Name: SHUKLA Copter

Part Number: S9COPTER

Version: 1

1.2 Primary Use

The SHUKLA Copter system is designed to quickly remove entire pedicle screw constructs from the spine, provided the surgeon is able to cut the spinal rod on either side. It is notably useful for all challenging screw constructs where any component (such as a locking cap, set screw, or bone screw) is fixed or the correct driver is not available.



1.3 System History

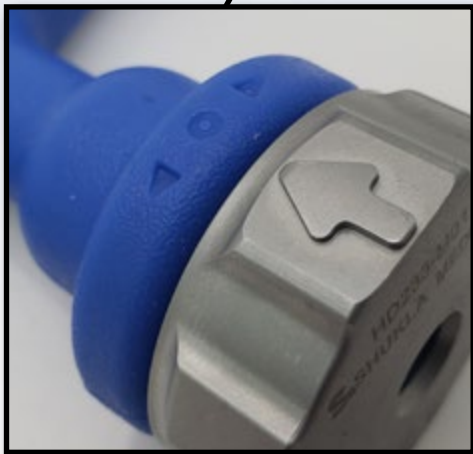
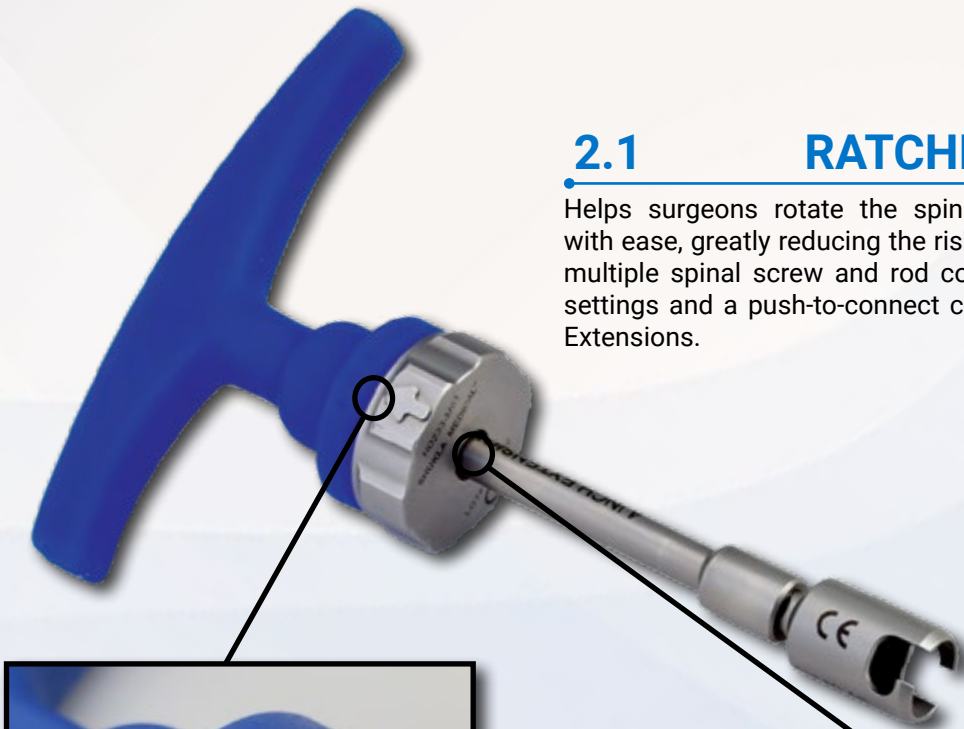
The SHUKLA Copter System launched to the national market in September of 2019. It combines all of the instrumentation necessary for the Helicopter Method into a one-stop system. It is a subset of components that are included in the complete SHUKLA Spine System.

The SHUKLA Copter was launched to provide access to the helicopter socket components for customers who A) already own the legacy spine system (MKS1031) or B) want the helicopter socket capability without committing to a full SHUKLA Spine purchase.

2 PRODUCT DESCRIPTION

2.1 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.



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



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

2.2 EXTENSIONS

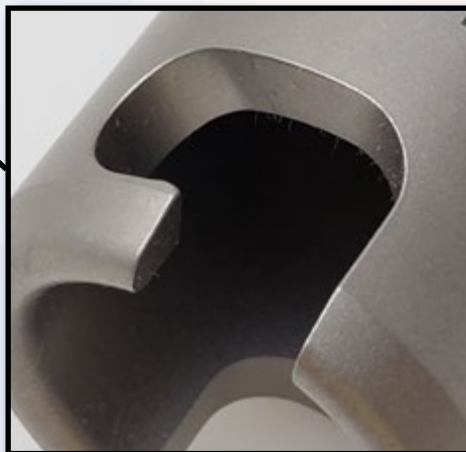
Extensions come in four different sizes (4", 6", 8", and 12") allowing for the Helicopter Sockets to reach any spinal screw and rod constructs encountered.



2.3 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.

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



The Spinal Rod Slot secures the spine rod during removal.



Three different sizes of Helicopter Sockets available for use.

3.1 Preoperative

- Appropriate x-rays and surgical notes may be used to identify manufacturer, brand, location, and condition of implanted hardware.
- The surgeon should be familiar with general principles of revision surgery and techniques for removal of implants.
- The instrumentation should be inspected for visible wear prior to use (see *Reusable Instrument Inspection Manual*, FCD-17089). Do not use the product if damage is suspected.
- Recommended cleaning and sterilization guidelines should be used.

3.2 Operative

- The surgeon should be cautious with spinal position change and/or excessive force exertion while removing implants using the instrumentation provided in the tray.

3.3 Storage

- It is recommended to store all Shukla Medical instrumentation in a clean, dry environment. Under 50% relative humidity; $\leq 75^{\circ}\text{F}/24^{\circ}\text{C}$.
- Proper handling and storage of the instrumentation is mandatory. Always inspect instrumentation for visible wear prior to use.

3.4 Intended Use

The Helicopter Socket System (S9COPTER) for SHUKLA Spine is intended for use during spinal revision procedures for the removal of spinal screw and rod constructs manufactured by a wide range of orthopedic companies.

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.

3.5 Indications for Use

The Helicopter Socket System (S9COPTER) for SHUKLA Spine is indicated for use during any revision procedure in which spinal screw and rod constructs must be removed and the surgeon is able to safely cut the rod on either side of the screw construct, especially:

- 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 or otherwise cannot be removed with a screwdriver

3.6 Additional Recommendations

The Helicopter Socket System (S9COPTER) for SHUKLA Spine is recommended for use in conjunction with the SHUKLA Spine (S9SPINE) Universal Spinal Implant Extraction System, the SHUKLA Maxi (S9MAXI) Large Bone Screw Removal System, and the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System.

The Helicopter Method facilitates total screw construct removal by rotating the spinal screw and rod constructs while still attached to the rod using a Helicopter Socket (SDR813-SDR815). The screw construct consists of the screw, rod, and locking cap.

The screw construct must be fully assembled in order for the *Helicopter Method* to be effective.

STEP 1

Cut rod on either side of tulip

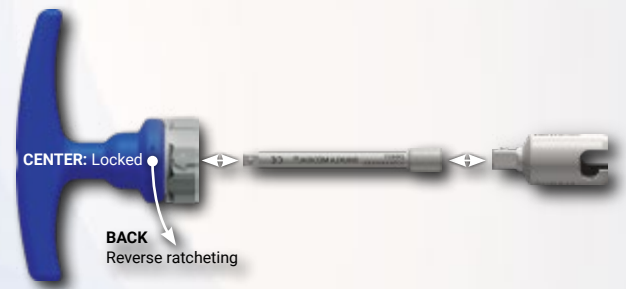
- Use method of choice (not included) to cut the rod.
- Approximately 5 mm of rod should remain extending from sides of tulip head.
- Rod cut length must be long enough to engage with helicopter socket, but short enough to minimize damage to surrounding live tissue as screw construct rotates.



STEP 2

Assemble driver with Helicopter Socket

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



STEP 3

Use Helicopter Socket to remove screw construct

- Place the Helicopter Socket over the tulip and rod so that the rod is engaged in the grooves of the helicopter socket.
- Turn counterclockwise until the screw construct backs out.
 - If additional torque is needed, attach the Breaker Bar (HD239) to the helicopter socket assembly.



- If extra torque is required to helicopter out a spinal construct, use the provided Breaker Bar as opposed to the Ratcheting T-Handle.
- 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.
- Two of each size of Helicopter Socket are provided in the case; that way, if one drops or gets damaged during a revision, surgery can continue unimpeded.
- The Helicopter Method allows the removal of the entire spinal screw and rod constructs - the screw, tulip, rod segment, and locking cap.
- The Helicopter Sockets possess a beveled edge on their socket openings. This improves access for the spine rod, as well as requiring less tissue removal under the rod.

6 CLEANING & STERILIZATION

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	S9COPTER	 Shukla Medical 8300 Sheen Drive St. Petersburg, FL 33709 USA	 CONSULT INSTRUCTIONS FOR USE	 NON-STERILE NON-STERILE PRODUCT
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7 COMPONENTS LIST

S9SPINE-HELI		Helicopter Socket System
Part #	Description	QTY
SCS044	Case	1
SCS045	Lid	1
HD233	Ratcheting T-Handle	1
SXN007	Extension Shaft 4"	1
SXN008	Extension Shaft 6"	1
SXN009	Extension Shaft 8"	1
SXN010	Extension Shaft 12"	1
SDR813	Helicopter Socket Small	2
SDR814	Helicopter Socket Medium	2
SDR815	Helicopter Socket Large	2
SAD005	Power Adapter	1
HD239	Breaker Bar	1

Use in conjunction with SHUKLA Spine (S9SPINE) for complete spinal screw removal capabilities





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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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.