SHUKLACOP ER Universal Pedicle Screw Construct Removal Solution

#15 System 15 of 15



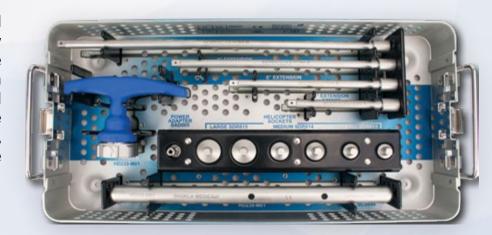




System Name: SHUKLA Copter v1

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.



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.

Version History

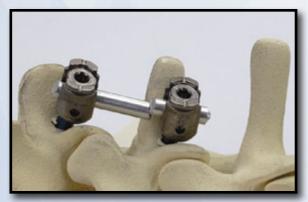
2019: Version 1 Introduced

Key Benefits

- Three different sizes of copter sockets allow for the explant of challenging screw & rod constructs, even without removing the locking cap.
- Breaker Bar allows for increased torque when removing the construct.



- Can back out the entire pedicle screw construct
 - Screw
 - Tulip
 - Rod Segment
 - Locking Cap





- Allows for successful removal when all other conventional means fail.
- Four different sizes of extensions allow for easy access to any screw construct.
- Removes the doubt of not possessing the proper drivers available for a case and eliminates the costly wasted O.R. time when the proper driver is not on hand.
- · Power Adapter allows for the copter socket to be used with an orthopedic drill.

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

Before the advent of the helicopter socket method, if a pedicle screw construct could not be removed due to a locking cap or improper drivers, most cases were closed up. In some cases, surgeons would cut the rod and grab onto the screw with a vise grip to try to rotate it out. It was an inelegant and oftentimes ineffective strategy. Thankfully, with our SHUKLA Copter system, that no longer needs to be the case.



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.! Taking just the lowest estimate of time savings, the savings per surgery can be estimated at 30 minutes x \$36 per minute = \$1,080. A SHUKLA Copter set at the current (2019) price sells at \$7,800. At this price, when you use the system a mere seven times, the full purchase price is recovered. As a rule of thumb, it can be stated that every time a SHUKLA system is used in surgery, the hospital saves a minimum of \$1,000. In many cases, SHUKLA can save hours instead of just minutes, and the savings accrue rapidly.

When You Don't Have It

No surgeon wants to be forced to stop a case because they don't have the right tools on hand. Imagine - you have begun surgery on your patient, and the pedicle screws in their spine just do not want to come out. Often the locking cap cannot be removed. Sure, you could cut the rod and try to pry it off with a vise grip. But when it comes to a patient's spine, why not use a well engineered helicopter socket that fits over the entire construct and whirly-birds it out of the spine in record time.

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.

While there are a few pedicle screw removal sets on the market, none can directly compare to the SHUKLA Copter. Our helicopter method is more advanced and simpler to execute than legacy techniques. With a SHUKLA Copter, there is no need to remove the locking cap beforehand and fewer steps are needed to safely remove the screw construct. Our patented helicopter sockets have a superior rod slot making them more stable on the spinal rod.

PATENT

Helicopter Socket

The engineers at Shukla are the best at what they do. They've worked hard to create several ingenious patented items just for the SHUKLA Copter system.

The tools and instruments they come up with are wonderful and always help make every step of the process easier.







HELICOPTER SOCKETS

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

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



Small



Medium



Large

Attention to Detail

The patented helicopter sockets possess a beveled edge on their socket openings. This small design choice improves access for the spine rod. It also requires less tissue removal under the rod.

Two of each size of helicopter socket are provided in the case. That way, if one drops or gets damaged during a revision, the surgeon can continue on unabated.



The Power Adapter works for either a Jacobs or Hudson chuck, ensuring that you can quick-connect to any drill the surgeon may have on hand.

The 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 pedicle screws.



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.

Extensions come in four sizes, allowing for the helicopter sockets to reach any pedicle screw construct encountered.



Components List

S9COPTER	Helicopter Socket System	
Part Number	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.