## PRODUCT GUIDE

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SHUKLA SCR EW



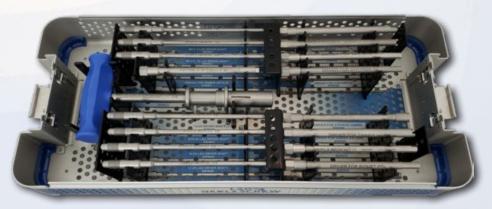
Revolutionizing the Art of Revision Surgery



System Name: SHUKLA Lag Screw v1

## **Primary Use**

The SHUKLA Lag Screw is a universally compatible extraction system for femoral lag screws. It contains a universal set of drivers that engage with exterior lag screw geometry. Interchangeable inner shafts engage with any thread dimension. Driver and shaft assemblies connect efficiently using a quick-connect T-Handle.



This system is intended for use in conjunction with our other intramedullary nail solutions from Shukla Medical. For the complete IM Nail extraction solution, use this system in conjunction with SHUKLA Nail (S9NAIL) and SHUKLA Broken IM Nail (S9NAIL-BR).

## **System History**

The SHUKLA Lag Screw system was derived after reviewing feedback from our sales representatives in the field all over the country. A common issue that would crop up during pre-operative planning was that our reps did not always know what instruments were needed in order to take out lag screws.

At the time, Shukla Medical would offer larger broken screw extractors via specialty order. It was clear at that point we needed to come up with a universal solution to the problem. After a few years in research and development, our engineers created a system designed to be compatible with a universal range of lag screws.

2020: Version 1 Introduced

## **Key Benefits**

- Ability to remove a wide range of femoral head lag screws, from a number of prominent manufacturers.
- Nine different types of Lag Drivers engineered for compatiblity with a wide range of commonly encountered, complicated Lag Screws.



 Seven different types of Threaded Inner Shafts available to lock the Lag Driver to the lag screw.



- Quick-Connect Extractor T-Handle rotates the outer shaft in order to quickly remove the lag screw.
- Compatible with the Strike Plate Frame from the SHUKLA Nail (S9NAIL) IM Nail Extraction system for certain lag screws that need to be taken straight out instead of rotated out.

#### **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 fatique
- · Better grip/reduces slippage

#### Comprehensive Design

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

## **Alternative Method Comparison**

The main alternative method to extract a femoral lag screw without a SHUKLA Lag Screw system is to contact a manufacturer representative for the lag screw and obtain the proper driver. This method works if you know exactly what kind of lag screw is being removed beforehand. However, many times surgeons either don't know that information, or when they open up the patient, they find out that it's not what they thought it would be. This leads to wasted time waiting on other reps to show up or an unsuccessful closing of the case.

A different tactic was attempting to use our SHUKLA Screw system's large broken and stripped extractors to remove the lag screw. The issue surgeons would run into using this method is that the SHUKLA Screw's extractors were not designed specifically for lag screws and thus could not guarantee removal. Another issue was some lag screws must be rotated clockwise or taken straight out. Our stripped screw extractors do not have that capability.





A SHUKLA Screw (S9SCREW) Stripped Screw Extractor attempting to engage with an embedded lag screw.

## **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! Taking just the lowest estimate of time savings, the savings per surgery can be estimated at 60 minutes. At 60 minutes per surgery, the savings would be 60 x \$36 per minute = \$2,160. The SHUKLA Lag Screw v1 sells for \$8,800, meaning that even at the lowest cost per minute in the O.R. it would only take four uses for it to pay for itself.

## When You Don't Have It

The lag screws are one of the critical areas of an IM Nail extraction case that can cause trouble for a surgeon. Not having the proper driver on hand to quickly and efficiently remove the lag screws means a delay in the eventual extraction of the IM nail itself. Being unable to remove the lag screws can even mean closing up a patient and delaying the surgery overall before the IM nail has even been worked on.

A lag screw can have many types of configurations rendering it difficult and tedious to secure the proper driver during surgery. The universal nature of the SHUKLA Lag Screw eliminates that potential road block to surgical success. No matter what manufacturer made the lag screw a surgeon is presented with, our system can help remove it with minimal bone loss.

## **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.

To date, there are no other tool sets available on the market to remove lag screws. Only the SHUKLA Lag Screw system offers dedicated, universal lag screw removal. Shukla truly stands alone.

#### **PATENT**

Quick-Connect Extractor T-Handle

The SHUKLA Lag Screw v1 system was created from the hard work of our engineering team.

#### **Extractor T-Handle**

Quick-connects to any of our Lag Driver Assemblies and allows them to be connected and disconnected rapidly.

#### Silicone Handle

Our new handle is overmolded with silicone for maximum comfort. Its ergonomic design was engineered specifically to reduce surgeon hand fatigue during longer surgeries with multiple screws to remove. In addition, the silicone helps prevent slippage during surgery.

#### **Stainless Steel**

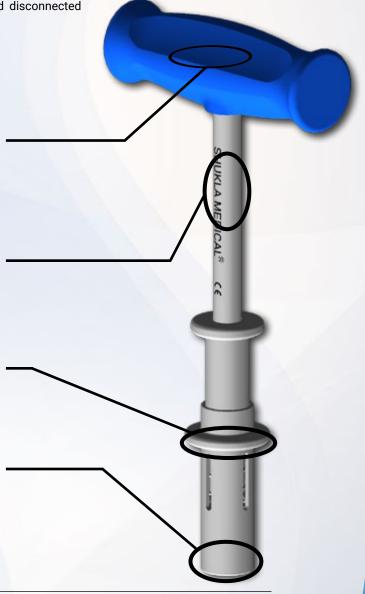
The Extractor T-Handle is made from medical grade stainless steel. This helps it to resist both rust and corrosion.

#### Sleeve

Engages the quick-connect functionality of the Extractor T-Handle. Pull the Sleeve up to allow insertion or removal of Lag Driver Assemblies.

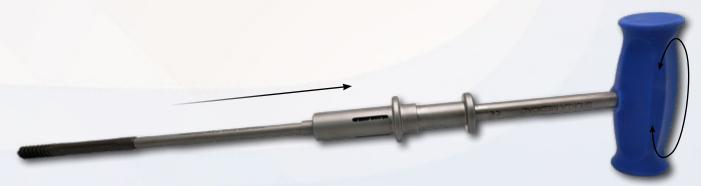
#### Connecter

The Extractor T-Handle's connector is a patented quick-connect mechanism for rapid engagement of Lag Driver Assemblies.



### **Attention to Detail**

The SHUKLA Lag Screw uses a two-part design that allows it to effectively remove lag screws from the femoral head. The Lag Driver Assembly securely attaches to the lag screw via its internal shaft. This leads to two things: 1) Surgeons only worry about rotating the Extractor T-Handle to remove the lag screw. They no longer worry about keeping the driver lined up and engaged with the lag screw itself. 2) If the lag screw is just spinning within the bone, the surgeon can exert a pulling force on the lag screw via the Extractor T-Handle while they rotate it out.



The SHUKLA Lag Screw Extractor T-Handle is capable of rotating a lag screw out or pulling it out, depending on the type of lag screw present.

The SHUKLA Lag Screw offers multiple attachment options for a full spectrum of lag screws whether they need to be rotated out or driven out. Surgeons can choose between the included Extractor T-Handle and the Strike Plate Frame and Mallet included in the SHUKLA Nail, SHUKLA Knee, or SHUKLA Hip systems.

The SHUKLA Lag Screw system is designed to work on all known and commonly encountered lag screws on the market. While most lag screws need to be rotated out like a normal screw, some lag screws, like the Zickel, must be pulled out directly using our Strike Plate Frame and Mallet (not included in the SHUKLA Lag Screw). Other unique lag screws, such as the TFN Helical, must be rotated **clockwise** while a steady pulling force is exerted.

Our system takes those more unique lag screws into account. Surgeons can confidently progress in their case without worrying about the lag screw becoming a roadblock to their success.



# **Components List**

Component List		
Std Qty	Part Number	Description
1	SCS050	Lid, Lag Screw System
1	SCS051	Case, Lag Screw System
1	SHN023	T-Handle Assy, Quick-Connect, Hex, 1/2"
1	SDR003	Driver, Lag Screw, For Synthes TFN
1	SDR004	Driver, Lag Screw, For S&N Trigen
1	SDR005	Driver, Lag Screw, For S&N IMHS
1	SDR006	Driver, Lag Screw, For Stryker T1
1	SDR007	Driver, Lag Screw, For Zimmer Affixus
1	SDR008	Driver, Lag Screw, For Stryker Gamma
1	SDR009	Driver, Lag Screw, For Zimmer Natural
1	SDR010	Driver, Lag Screw, For Zimmer ITST
1	SDR018	Driver, Lag Screw, For Biomet PTN
1	SSH041	Shaft, Threaded, M5x.5 for Lag Driver
1	SSH042	Shaft, Threaded, M4.5x.75 for Lag Driver
1	SSH043	Shaft, Threaded, M5x.8 for Lag Driver
1	SSH044	Shaft, Threaded, 1/4-28 for Lag Driver
1	SSH045	Shaft, Threaded, 5/16-24 for Lag Driver
1	SSH046	Shaft, Threaded, 10-24 for Lag Driver
1	SSH056	Shaft, Threaded, 12-28 for Lag Driver



# 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.