SURGICAL TECHNIQUE GUIDE LAG SHUKLA SCREW Universal Femoral Lag Screw Extraction Solution





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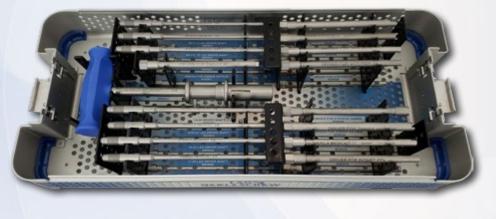
1.1 System Name: SHUKLA Lag Screw

Part Number: S9LAG

Version: 1

1.2 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).

1.3 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.



2 PRODUCT DESCRIPTION

Parts not shown to scale

2.1 SHUKLA MEDICAL®

EXTRACTOR T-HANDLE

Quick-connects to any of our Lag Driver Assemblies and allows them to be connected and disconnected rapidly. The Extractor T-Handle is made from medical grade stainless steel.



Silicone handle with an ergonomic design to reduce hand fatigue and help prevent slippage.



Quick-Connect mechanism for rapid engagement of Lag Driver Assemblies.



3 PREOPERATIVE & INTENDED USE

SHUKLA Lag Screw

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.
- Only recommended cleaning and sterilization guidelines should be used.

3.2 Operative

• The surgeon should be cautious with limb 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; ≤75°F/24°C.
- Proper handling and storage of the instrumentation is mandatory. Always inspect instrumentation for visible wear prior to use.

3.4 Intended Use

The Lag Screw System (S9SLAG) is intended for use for femoral lag screw removal during revision procedures for lag screws 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 Lag Screw System (S9LAG) is indicated for use during any revision procedure in which femoral lag screws must be removed.

3.6 Additional Recommendations

The Lag Screw System (S9LAG) is recommended for use in conjunction with the SHUKLA Nail (S9NAIL) Universal IM Nail Extraction System, the SHUKLA Maxi (S9MAXI) Large Bone Screw Removal System, the SHUKLA Broken IM Nail (S9NAIL-BR) Universal Broken IM Nail Extractiom System, and the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System.



Nine Lag Drivers (SDR003 - SDR018) and seven Threaded Inner Shafts (SSH041 - SSH046, SSH056) are included in the SHUKLA Lag Screw system. The combined Lag Driver Assembly consists of a paired Lag Driver and Threaded Inner Shaft.



Identification and Selection

SURGICAL TECHNIQUE

- Pre-operative x-rays should be examined closely to identify the type of lag screw to be removed and whether or not it is threaded.
- Once lag screw has been identified, select the appropriate Lag Driver (SDR003 through SDR018).



Pre-op Planning: For assistance identifying implants and determining compatible drivers, please contact Shukla Medical Customer Service and let our team of experts help you.



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Preperation

- Ensure the locking screw has been removed from the proximal end of the IM nail. In some cases, this locking screw may be different from the IM nail cap.
- Assemble the corresponding Threaded Inner Shaft (SSH041 through SSH056) into the Lag Driver (Image 1) and tighten to the lag screw using the 1/2" and 5/16" wrenches. (SWR002, SWR007)* (Image 2)

Image 2



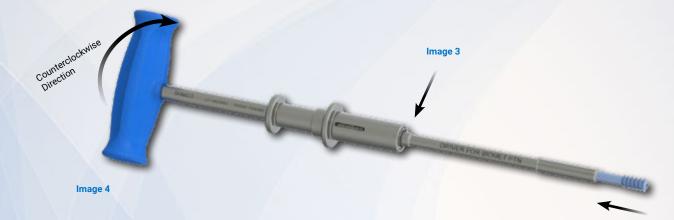


Image 1



Removing Threaded Lag Screws

- Attach the Extractor T-Handle (SHN023) to the Lag Driver Assembly using the quickconnect mechanism. (Image 3)
- Unthread the lag screw by turning the Extractor T-Handle counterclockwise. (Image 4)





Removing Non-Threaded Lag Screws

- Non-threaded lag screws such as the Synthes TFN Helical Blade must be rotated clockwise while providing a steady pulling force with the Extractor T-Handle.
- Alternatively, attach the Strike Plate Frame (SBD008)* to the Lag Driver Assembly and thread the nut (SNT001)* on loosely. Gently impact the lag screw and it will freely rotate itself clockwise as it is extracted. (Image 5)
- For Zickel (or similar) lag screws, the Strike Plate Frame (SBD008)* is required, due to the lag screw's three straight blades. These lag screws cannot be rotated in either direction. To remove, attach the Strike Plate Frame to the Lag Driver Assembly and gently impact for extraction. (Image 6)





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5 TIPS and TRICKS

- In the case of limited exposure of the lag screw, the lag driver can be advanced over a K-wire due to the outer shafts being cannulated. The K-wire can then be removed so that the Threaded Inner Shaft can be locked in place.
- A Threaded Inner Shaft is not strictly required to remove a femoral lag screw. If the Lag Driver is able to engage with the lag screw by itself, no further steps are needed.
- If the proximal locking screw of the IM nail is still present and is prohibiting the removal of the femoral lag screw, the SHUKLA Maxi (S9MAXI) system can be used to remove it.
- The SHUKLA Lag Screw system is designed to be used in conjunction primarily with the SHUKLA Nail system. All
 instruments referenced in this technique guide that are not included in the SHUKLA Lag Screw system can be found in
 the SHUKLA Nail system.



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





7 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	













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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.