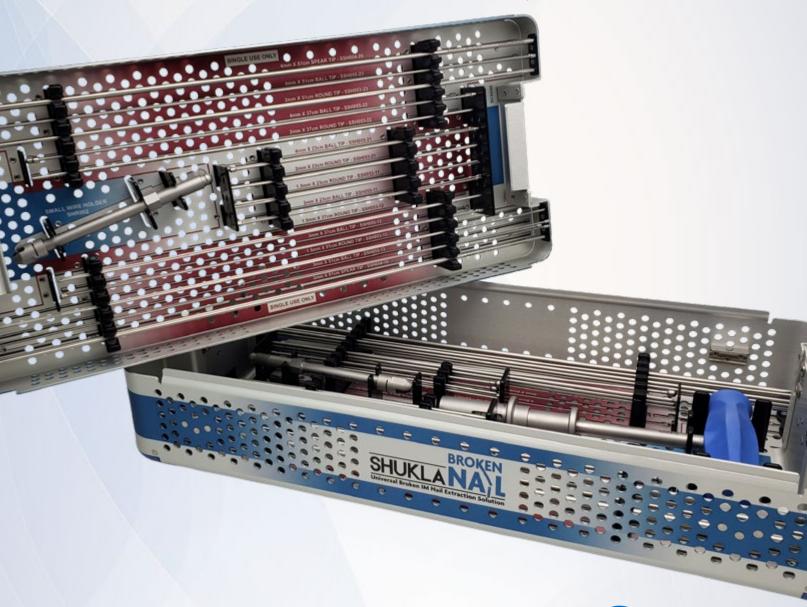
SURGICAL TECHNIQUE GUIDE

BROKEN SHUKLA A Universal Broken IM Nail Extraction System





Revolutionizing the Art of Revision Surgery

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BROKEN SHUKLANA NA L

Universal Broken IM Nail Extraction System

1.1 System Name: SHUKLA Broken Nail

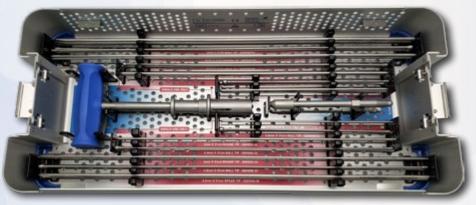
Part Number: S9NAIL-BR

Version: 1

1.2 Primary Use

The SHUKLA Broken Nail system is a universally compatible extraction system for broken cannulated intramedullary nails.

The comprehensive system contains a wide range of ball tip, round tip, and spear tip wires of varying lengths, giving surgeons



full control over the attachment method. All wires work with a quick-connect T-Handle for maximum efficiency.

1.3 System History

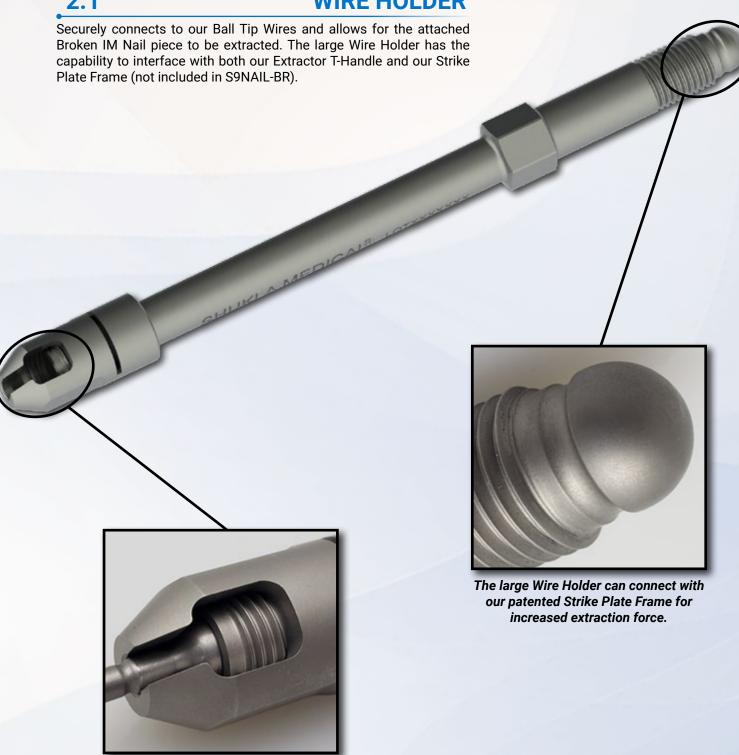
Due to the popularity and success of the SHUKLA Nail IM Nail extraction system, potential customers would inquire about how to remove distally broken IM Nails. This would frequently happen during trade shows after our IM Nail demonstrations. We initially created a set of instruments to tackle that very task. For years we would rent out the single Broken IM Nail set to customers, but only by specific request from a surgeon.

Over time, we saw that our one set of instruments began to get damaged from wear and tear over the years. It was then we decided to engineer a better, updated version with the goal of helping orthopaedic surgeons preserve bone and lessen recovery time by reducing osteotomies during the extraction of broken distal IM Nails.

Parts not shown to scale

2.1

WIRE HOLDER



The Wire Holder Sheath securely engages with our Ball Tip wire, locking it into place with a simple twist.

Parts not shown to scale



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 Broken Nail system (S9NAIL-BR) Universal Broken IM Nail Extraction system is intended for use for broken cannulated IM Nail extraction during revision procedures for IM Nails 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 Broken Nail system (S9NAIL-BR) is indicated for use during any revision procedure in which broken cannulated IM Nail pieces must be extracted.

3.6 Additional Recommendations

The Broken IM Nail System (S9NAIL-BR) 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 Lag Screw (S9LAG) Universal Lag Screw Removal System, and the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System.



Remove the intact portion of the IM Nail using the SHUKLA Nail (S9NAIL) Universal IM Nail Extraction system and its corresponding Surgical Technique.

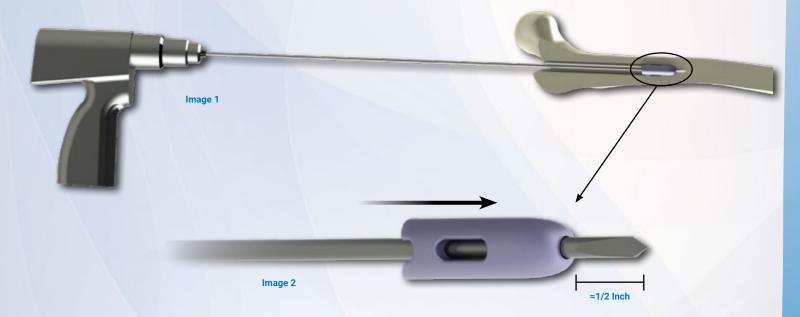


Spear Tip Wire

Select the largest Spear Tip wire (SSH054-10 - SSH054-40) that will fit through the cannulation of the IM Nail.



Use a power drill to drill down the cannulation of the IM Nail (Image 1), continiuing past approximately 1/2 inch (12-13mm) of the tip of the broken IM nail piece. (Image 2)





Ball Tip Wire

Select the appropriate length Ball Tip wire (SSH055-11 through SSH055-23 or SSH059-31 through SSH059-43) with the largest possible diameter that will fit through the broken IM Nail piece's cannulation.



Note: The wire must be long enough to reach approximately 1/2 inch (12-13mm) beyond the tip of the IM Nail piece.

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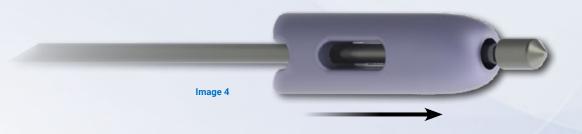


Assemble the Ball Tip wire onto the appropriate Wire Holder (SHR002 or SHR003). Make sure to fully tighten the Wire Holder using the two wrenches (SWR002)* provided in the SHUKLA Nail system (S9NAIL)* until the Wire Holder has a complete, firm grip on the wire. (Image 3)



STEP 6

Pass the Ball Tip wire through the piece of broken IM Nail until it extends past the tip. (Image 4)



STEP 7

Round Tip Wire

Select the same length Round Tip wire (SSH053-11 through SSH053-43) with the largest possible diameter that will fit through the broken IM Nail portion's cannulation.



Pass the Round Tip wire through the IM Nail until it extends past the tip of the Ball Tip wire. Pull back on the Ball Tip Wire. This will lock the Ball Tip wire into place in the IM Nail piece. (Image 5). If Small Wire Holder is being used, proceed to **Step 9.** If Large Wire Holder is being used, proceed to **Step 10**.



* Not included in the SHUKLA Broken Nail (S9NAIL-BR) System. Component can be found in the SHUKLA Nail (S9NAIL) System.





Small Diameter Wire Extraction

For smaller diameter wires (SSH055-XX) that connect to the Small Wire Holder (SHR002), attach the Extractor T-Handle (SHN023) and pull back in-line with the implant to extract the broken piece of IM Nail. (Image 6)



Large Diameter Wire Extraction

For larger diameter wires (SSH059-XX) that connect to the Large Wire Holder (SHR003), attach the S9NAIL's Strike Plate Frame (SBD008)* to the Wire Holder using the nut (SNT001)*.

Tighten the nut using the S9NAIL's two wrenches (SWR002)*. Use the Two-Handed Mallet (SMT002)* to deliver controlled extraction force in-line with the broken piece of the IM Nail to extract it. (Image 7).



* Not included in the SHUKLA Broken Nail (S9NAIL-BR) System. Component can be found in the SHUKLA Nail (S9NAIL) System.

- Use the extracted portion of the IM Nail to properly size the wires needed for the extraction of the broken piece.
- The tray level that holds the Wire Holder also contains all of the wires that that particular Wire Holder is compatible with.
- Larger diameter Ball Tip wires have an engineered weak point so in the event that it breaks during an extraction, it will break outside of the body, allowing for its removal so another attempt can be made.
- Push down on the wires to release tension buildup.
- To remove the broken IM Nail extractor, first pull out the Round Tip wire, which will then allow the Ball Tip wire to be removed.
- Do not twist the Extractor T-Handle while pulling to extract a broken IM Nail piece.

6 CLEANING & STERILIZATION

For detailed cleaning and sterilization instructions, please consult the SHUKLA Medical Instructions For Use (IFU) document or visit www.ShuklaMedical.com/Sterilization



Emergo Europe Prinsessegracht 20 2514 AP The Hague



S9NAIL-BR



Shukla Medical 8300 Sheen Drive St. Petersburg, FL 33709 USA



CONSULT INSTRUCTIONS FOR USE





Component List			
Std Qty	Part Number	Description	
1	SCS048	Case, Broken Nail System	
1	SCS049	Tray, Broken Nail System	
1	SHR002	Holder, Wire, Small	
1	SHR003	Holder, Wire, Large	
3	SSH055-11	Wire, Ball Tip, 23 cm length, 3 mm dia, Single Use	
3	SSH055-12	Wire, Ball Tip, 37 cm length, 3 mm dia, Single Use	
3	SSH055-13	Wire, Ball Tip, 58 cm length, 3 mm dia, Single Use	
3	SSH055-21	Wire, Ball Tip, 23 cm length, 4 mm dia, Single Use	
3	SSH055-22	Wire, Ball Tip, 37 cm length, 4 mm dia, Single Use	
3	SSH055-23	Wire, Ball Tip, 58 cm length, 4 mm dia, Single Use	
3	SSH059-31	Wire, Ball Tip, 23 cm length, 4.5 mm dia, Single Use	
3	SSH059-32	Wire, Ball Tip, 37 cm length, 4.5 mm dia, Single Use	
3	SSH059-33	Wire, Ball Tip, 58 cm length, 4.5 mm dia, Single Use	
3	SSH059-41	Wire, Ball Tip, 23 cm length, 5 mm dia, Single Use	
3	SSH059-42	Wire, Ball Tip, 37 cm length, 5 mm dia, Single Use	
3	SSH059-43	Wire, Ball Tip, 58 cm length, 5 mm dia, Single Use	
3	SSH053-11	Wire, Round Tip, 23 cm length, 1.5 mm dia, Single Use	
3	SSH053-12	Wire, Round Tip, 37 cm length, 1.5 mm dia, Single Use	
3	SSH053-13	Wire, Round Tip, 58 cm length, 1.5 mm dia, Single Use	
3	SSH053-21	Wire, Round Tip, 23 cm length, 2 mm dia, Single Use	
3	SSH053-22	Wire, Round Tip, 37 cm length, 2 mm dia, Single Use	
3	SSH053-23	Wire, Round Tip, 58 cm length, 2 mm dia, Single Use	
3	SSH053-31	Wire, Round Tip, 23 cm length, 3 mm dia, Single Use	
3	SSH053-32	Wire, Round Tip, 37 cm length, 3 mm dia, Single Use	
3	SSH053-33	Wire, Round Tip, 58 cm length, 3 mm dia, Single Use	
3	SSH053-41	Wire, Round Tip, 23 cm length, 4 mm dia, Single Use	
3	SSH053-42	Wire, Round Tip, 37 cm length, 4 mm dia, Single Use	
3	SSH053-43	Wire, Round Tip, 58 cm length, 4 mm dia, Single Use	
3	SSH054-10	Wire, Spear Tip, 58 cm length, 3 mm dia, Single Use	
3	SSH054-20	Wire, Spear Tip, 58 cm length, 4 mm dia, Single Use	
3	SSH054-30	Wire, Spear Tip, 58 cm length, 4.5 mm dia, Single Use	
3	SSH054-40	Wire, Spear Tip, 58 cm length, 5 mm dia, Single Use	
1	SHN023	T-Handle Assy, Quick Connect, Hex, 1/2"	



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

Shukla Medical 8300 Sheen Drive St. Petersburg, FL 33709 www.ShuklaMedical.com

T: 888-4-SHUKLA T: 888-474-8552 F: 727-626-2770 CS@ShuklaMedical.com





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.