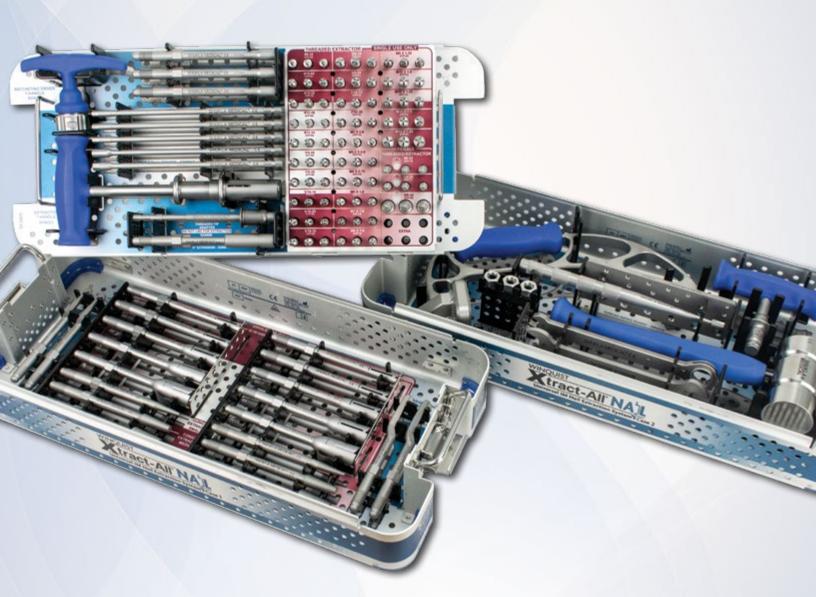
SURGICAL TECHNIQUE GUIDE

#8 System 8 of 15

SHUKLANA L Universal IM Nail Extraction Solution





Revolutionizing the Art of Revision Surgery

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SHUKLA NA L Universal IM Nail Extraction Solution

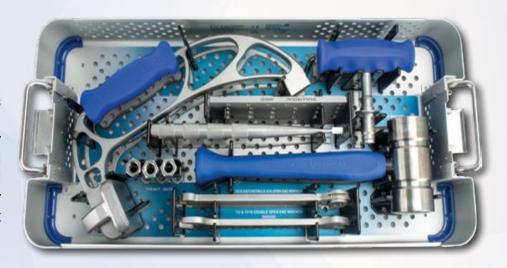
1.1 System Name: SHUKLA Nail

Part Number: S9NAIL

Version: 4

1.2 Primary Use

The SHUKLA Nail Universal IM Nail Removal System is designed to remove any IM Nail on the market today. Every part of this system is designed with surgeon efficiency in mind to give them the tools they need to get any IM nail implant out in a safe, timely manner.



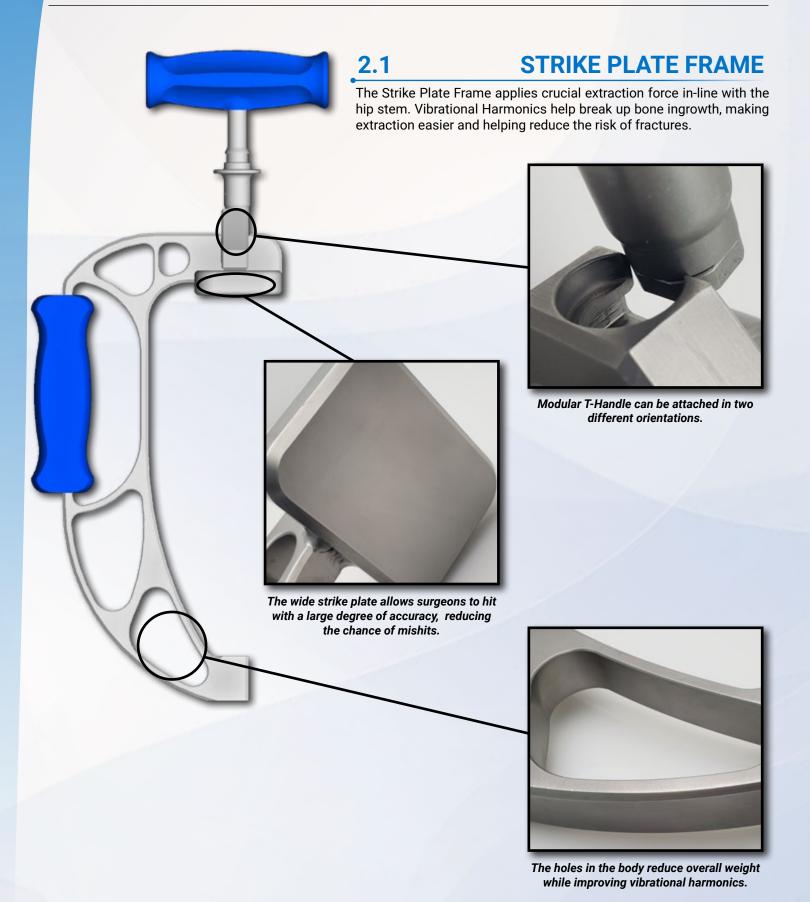
1.3 System History

The SHUKLA Nail system, formerly known as the Winquist, was named after Dr. Robert Winquist, who had an idea to create a truly universal IM nail extraction system. He worked tirelessly encouraging large orthopedic companies to work together to share their information about their own IM nail products with a non-competitive entity.

In 2005, the Shukla Medical president's first project with the company was the development and launch of the Winquist II with input and help from Dr. Winquist himself. One of the biggest changes was the shift from a single case to two - one for extractors and one for instrumentation. This was in part because of the much wider variety of tools packed into the case.

In 2010, the Winquist III was released, adding some substantial changes. All extractors were changed to singleuse disposable items to fix the problem of extractor tip integrity. Joining the existing extractors were the new solid nail extractors, along with a variety of new extractor types and sizes.

The Winquist IV, now renamed the SHUKLA Nail, debuted in 2019 thanks to sales force and surgeon field feedback. The v4 added more additions than any before it, making it the most comprehensive system on the market.



Parts not shown to scale

2.2 **CONICAL EXTRACTOR** Tapered extractors that cut into and grab onto an IM nail to create SHUKLA MEDICAL® threads to secure the nail for extraction. 2.3 **SOLID IM NAIL EXTRACTOR** Internally threaded extractors that can cut threads into the outside of an IM nail and secure it for extraction. The trephine teeth help clear away bone to provide engagement. SXT044 SOLID NAIL EXT Chip-Clearing Flutes move debris out of the area while the cutting threads bite into the nail.

3.1 Preoperative

- Appropriate x-rays and surgical notes may be used to identify manufacturer, brand, location, & condition of implanted hardware. Use the X-Ray Search Engine™ for the most up-todate compatibility information.
- 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 extracting 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.

3.4 Intended Use

The SHUKLA Nail (S9NAIL) Universal IM Nail Extraction System is intended for use during revision procedures for the removal of intramedullary (IM) nail implant hardware 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 SHUKLA Nail (S9NAIL) Universal IM Nail Extraction System is indicated for use during any revision procedure in which an IM nail must be removed.

This system may be used to remove broken IM nails provided the broken portion of the nail is accessible using the included instrumentation.

3.6 Additional Recommendations

The SHUKLA Nail (S9NAIL) Universal IM Nail Extraction System is recommended for use in conjunction with the SHUKLA Maxi (S9MAXI) Large Bone Screw Removal System for large bone screws, the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System for broken and stripped screws in the IM Nail, and the SHUKLA Blade (S9BLADE) Universal Flexible Osteotome System to break up bone ingrowth around the IM Nail.

The SHUKLA Nail (S9NAIL) Universal IM Nail Extraction System is further recommended for use in conjunction with the SHUKLA Broken Nail (S9NAIL-BR) for broken IM Nail extraction and the SHUKLA Lag Screw (S9LAG) for lag screw removal.



Determine if there are cross-locking screws present on the IM nail. If found, proceed to **Step 2**. If cross locking screws are not found, skip to **Step 3**.



STEP 2

Remove cross-locking screws (Image 1) and verify that they are all fully removed. Once all are removed, proceed to **Step 3**.

Tip: Use the included drivers or the S9MAXI Universal Large Screw Extraction System to remove the screws.



STEP 3

Determine if there is bone ingrowth around the exposed end of the IM nail. If bone ingrowth is found, proceed to **Step 4**. If no bone ingrowth is found, skip to **Step 5**.



Remove the excess bone around the exposed end of the IM nail with the chisel (SOS027) (Image 2). Once complete, proceed to **Step 5**.





Determine if there a locking cap present on the IM nail. If found, proceed to **Step 6**. If a locking cap is not found, skip to **Step 7**.



STEP 6

Remove the locking cap and verify that it is fully removed. Once removed, proceed to **Step 7**.

Tip: Use the S9MAXI Universal Large Screw Extraction System to remove the locking cap.

Tip: Save the locking cap so that it can be used on the Thread Sizing Board.

SURGICAL TECHNIQUE

SHUKLA Nail | Determine Extractor Type

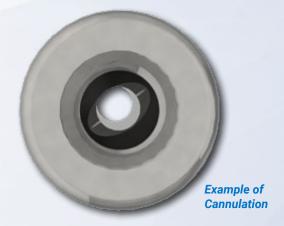


Determine if the IM nail is threaded. If the IM nail is threaded, skip to **Step 13**. If the IM nail is not threaded, proceed to **Step 8**.





Determine if the IM nail is cannulated. If the IM nail is cannulated, proceed to **Step 9**. If the IM nail is not cannulated, skip to **Step 10**.

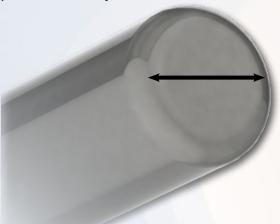




Determine if the cannulation within the IM nail is between 4 and 16mm in diameter. If it is, skip to **Step 15**. If it is not, proceed to **Step 10**.



Determine if the IM nail's outside diameter is between 6 and 18mm. If it is, skip to **Step 16**. If it is not, proceed to **Step 11**.





Determine if the IM nail possesses grabbable geometry such as a hole or a slot. If grabbable geometry exists, skip to **Step 17**. If grabbable geometry does not exist, proceed to **Step 12**.



STEP 12

Using a burr, a drill, or another technique, create grabbable geometry in the IM nail. Once grabbable geometry has been created, proceed to **Step 17**.



Determine if the threads within the IM nail are intact. If they are, proceed to **Step 14**. If they are not, skip to **Step 15**.



Using the Thread Sizing Board (SMS022) (Image 3), the Sizing Chart on the S9NAIL Lid (SCS028), or visual identification, choose the proper size of **Threaded Tip Extractor**. Once chosen, skip to **Step 18**. If an appropriate tip extractor cannot be found, proceed to **Step 15**.



Image 3 Use the Thread Sizing Board to determine the thread size of the IM nail cap. Use the size measurement to select the appropriate threaded extractor tip



Determine the correct size of Conical Extractor to use. Once chosen, skip to Step 20.



STEP 16

Determine the correct size of **Solid IM Nail Extractor** to use. Once chosen, skip to **Step 21**.

SXT044 SOLID NAIL EXT

STEP 17

Determine the correct size of **Hook Extractor** to use. Once chosen, skip to **Step 22**.



SURGICAL TECHNIQUE

SHUKLA Nail | Implant Extraction

STEP 18

Assemble the **Threaded Tip Extractor** onto the Extractor Body (SXT019) using the 5/16" & 1/2" wrenches (SWR007 & SWR002) (Image 4). Proceed to **Step 19**.



STEP 19

Attach the Extractor Body to the Extractor T-Handle (SHN023) and thread the tip into the IM nail tightly. Once complete, skip to **Step 23**.



Note: The extractor tips feature flutes that clear bone as the tip is screwed into the nail. If excessive bone ingrowth is encountered, connect the extractor tip to the Threaded Tip Adapter (SXN006) and insert the tip adapter into the Ratcheting T-Handle (SHN022) (Image 5). Twist the extractor tip back and forth to clear bone and properly seat the extractor tip. Then disconnect the tip adapter from the tip.

Do not extract the nail with the Threaded Tip Adapter & Ratcheting Driver Handle, as this can damage the instrumentation.

Threaded Extractor Tips are single-use only and must be discarded after nail removal. Used extractors may have damaged threads and will not connect securely in subsequent procedures.



Use the Extractor T-Handle (SHN023) to drive the **Conical Extractor** clockwise into the IM nail, using downward force and inserting as far as possible. (Image 6) The extractor will cross-thread the IM nail shaft threads, ensuring secure attachment.

Once complete, skip to Step 23.



Note: Once you use the conical extractor, threaded extractor tips may no longer be effective due to thread deformation inside of the IM nail.

Conical Extractors are single-use only and must be discarded after nail removal. Used extractors may have damaged threads and will not connect securely in subsequent procedures.



Use the Extractor T-Handle (SHN023) to drive the **Solid IM Nail Extractor** as far as possible onto IM nail, applying downward force in a clockwise direction. (Image 7) The threads inside of the extractor will bite into the nail shaft to create a secure attachment.

Once complete, skip to **Step 23**.



Solid IM Nail Extractors are single-use only and must be discarded after nail removal. Used extractors may have damaged threads and may not connect securely in subsequent procedures.



Ensure that the **Hook Extractor** can fully access and engage with the IM nail grabbable geometry. (Image 8) Once confirmed, skip to **Step 24**.



Image 8

Note: Connect the Strike Plate Frame (SBD008; see **Step 24**) *prior to* engaging the **Hook Extractor** with the IM nail.



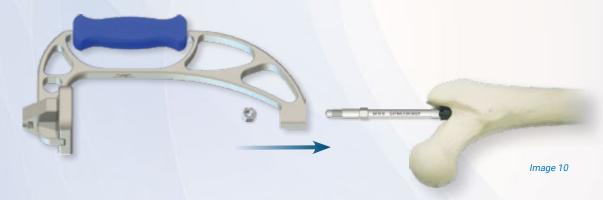
Once the chosen extractor is securely attached to the IM nail, remove the T-Handle (Image 9). Proceed to **Step 24**.



STEP 24

Connect the Strike Plate Frame (SBD008) to the chosen extractor using a Hex Nut (SNT001). (Image 10) Tighten the nut fully with the 11/16" Wrench (SWR007), applying counter-torque with the 1/2" Wrench (SWR002).

If the **Threaded Tip Extractor**, **Conical Extractor**, or **Hook Extractor** is not long enough to attach to the Strike Plate Frame while engaged with the IM nail, proceed to **Step 25**. If this is not an issue, skip to **Step 26**.



STEP 25

Attach the 6" Extension (SXN011) to the chosen extractor, then connect to the Strike Plate Frame using a Hex Nut (SNT001). (Image 11) Tighten the nut fully with the 11/16" Wrench (SWR007), applying counter-torque with the 1/2" Wrench (SWR002).

Once connected, proceed to Step 26.





Extract the implant using repeated strikes of the Big Mallet (SMT002) on the Strike Plate Frame's strike plate. (Image 12)

If implant is successfully extracted, continue on with any remaining procedures required at surgeon's discretion. (Outside SHUKLA Nail scope).

If implant does not successfully extract, proceed to Step 24.

Tip: If additional grip is needed, attach the Modular T-Handle (SHN019) to the Strike Plate Frame.

Note: If the implant resists removal after several strikes, use the Bone Chisel (SOS027) or osteotomes from the SHUKLA Blade (S9BLADE) system to loosen bone around implant before continuing.



If a **Threaded Tip Extractor** was chosen and failed to extract the implant, return to **Step 8**.

If a **Conical Extractor** was chosen and failed to extract the implant, return to **Step 10**.

If a **Solid IM Nail Extractor** was chosen and failed to extract the implant, return to **Step 11**.

If a **Hook Extractor** was chosen and failed to extract the implant, and all other extractor options could not be chosen or failed to extract the implant, move to alternate methods at surgeon's discretion. (Outside SHUKLA Nail scope)



If an extractor tip breaks, (Image 13) use the Threaded Tip Adapter (SXN006) or the Ratcheting Combo Wrench (SWR007) to remove the broken tip from the IM nail. Replace with a new tip and make another attempt.



Image 12



5 TIPS & TRICKS

SHUKLA Nail

- When removing tibial nails, clear bone at both the proximal end and posterior to the bend in the nail before using the
 extraction tools in this system.
- This system is equipped to remove broken nails provided the broken portion of the nail is accessible using the included instrumentation.
- If the nail is fixed by bone ingrowth through screw openings, bone must be cleared prior to removal. Use a drill bit to clear the bone from screw openings, rocking the drill to ensure the nail is freed from bone.

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





Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands





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





7 COMPONENTS LIST

Component List					Component List			
Std Qty	Part Number	Description		Std Qty	Part Number	Description		
1	SBD008	Strike Plate, Assy, Frame	CASE #1	3	STP111	Tip, Male, 3/8-24 UNF-2A, Single Use		
1	SCS027	Case, Instruments, IM Nail removal System		2	CTD112	The Male 7/14 14 INIO 24 Constaller	1	
1	SCS028	Lid, Instruments, IM Nail removal System		3	STP112	Tip, Male, 7/16-14 UNC-2A, Single Use	-	
1	SHN019	T-Handle, Assy, for Strike Plate Frame		3	STP113	Tip, Male, 7/16-20 UNF-2A, Single Use		
1	SMS022	Gauge, Thread Identifier		3	STP114	Tip, Male, M5 X 0.8 - 6g, Single Use		
1	SMT002	Mallet Assy, Big		3	STP115	Tip, Male, M5.5 X 0.9 - 6g, Single Use	1	
3	SNT001	Nut, Hex, 7/16-20 UNF-2B		3	STP116	Tip, Male, M6 X 0.75 - 6g, Single Use	1	
1	SOS027	Chisel, Bone		3	STP117	Tip, Male, M6 X 1.0 - 6g, Single Use]	
2	SWR002	Wrench, Double Open End, 1/2" & 11/16"		3	STP118	Tip, Male, M7 X 1.0 - 6g, Single Use	1	
1	SWR007	Wrench, Assy Ratcheting 11/16" & Open End 5/16"		3	STP119	Tip, Male, M8 X 1.0 - 6g, Single Use]	
1	SCS024	Case, Components, IM Nail removal System		3	STP120	Tip, Male, M8 X 1.25 - 6g, Single Use	1	
1	SCS025	Tray, IM Nail removal System		1	SXN006	Adapter Assy, Hex, Female, Quick Connect, 5/16"	1	
1	SCS026	Lid, Components, IM Nail removal System		1	SXN011	Extension, Threaded, 6"	1	
1	SDR013	Driver, Hex, Male, 2 mm		3	SXT019	Connector Shaft for Strike Plate	1	
1	SDR014	Driver, Hex, Male, 2.5 mm		2	SXT033	Extractor, Nail, Hook, Small	<u>و</u>	
1	SDR015	Driver, Hex, Male, 6 mm		2	SXT034	Extractor, Nail, Hook, Large	CASE #2	
1	SDR016	Driver, Hex, Female, 6 mm		3	STP121	Tip, Male, M10 X 1.0 - 6g, Single Use	#2	
1	SDR017	Driver, Hex, Male, 8 mm		3	STP122	Tip, Male, M10 X 1.25 - 6g, Single Use	1	
1	SHN022	T-Handle Assy, Ratcheting, Hex, 1/4"		3	STP123	Tip, Male, M10 X 1.5 - 6g, Single Use		
1	SHN023	T-Handle Assy, Quick Connect, Hex, 1/2"	CASE #2	3	STP124	Tip, Male, M12 X 1.25 - 6g, Single Use	1	
3	STP100	Tip, Male, 8-32 UNC-2A, Single Use		3	STP130	Tip, Female, 8-32 UNC-2B, Single Use		
3	STP101	Tip, Male, 10-24 UNC-2A, Single Use		3	STP131	Tip, Female, 1/4-20 UNC-2B, Single Use	1	
3	STP102	Tip, Male, 10-32 UNF-2A, Single Use		3	STP132	Tip, Female, 3/8-32 UNEF-2B, Single Use	1	
3	STP103	Tip, Male, 12-28 UNF-2A, Single Use		2	SXT043	Extractor, Nail, Solid, 6 mm to 8 mm, Single Use	1	
3	STP104	Tip, Male, 12-24 UNC-2A, Single Use		2	SXT044	Extractor, Nail, Solid, 8 mm to 10 mm, Single Use		
3	STP105	Tip, Male, 1/4-20 UNC-2A, Single Use		2	SXT045	Extractor, Nail, Solid, 10 mm to 12.5 mm, Single Use	1	
3	STP106	Tip, Male, 1/4-28 UNF-2A, Single Use		2	SXT046	Extractor, Nail, Solid, 12 mm to 15 mm, Single Use	1	
3	STP107	Tip, Male, 5/16-18 UNC-2A, Single Use		2	SXT047	Extractor, Nail, Solid, 15 mm to 18 mm, Single Use	1	
3	STP108	Tip, Male, 5/16-24 UNF-2A, Single Use		2	SXT048	Extractor, Nail, Conical, 4 mm to 8 mm, Single Use	1	
3	STP109	Tip, Male, 5/16-32 UNEF-2A, Single Use		2	SXT049	Extractor, Nail, Conical, 8 mm to 12 mm, Single Use	1	
3	STP110	Tip, Male, 3/8-16 UNC-2A, Single Use		2	SXT050	Extractor, Nail, Conical, 12 mm to 16 mm, Single Use	1	

Single-use Only: Always use new extractors or threaded tips in every procedure.

Discard any used single use parts at the conclusion of the case.



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.