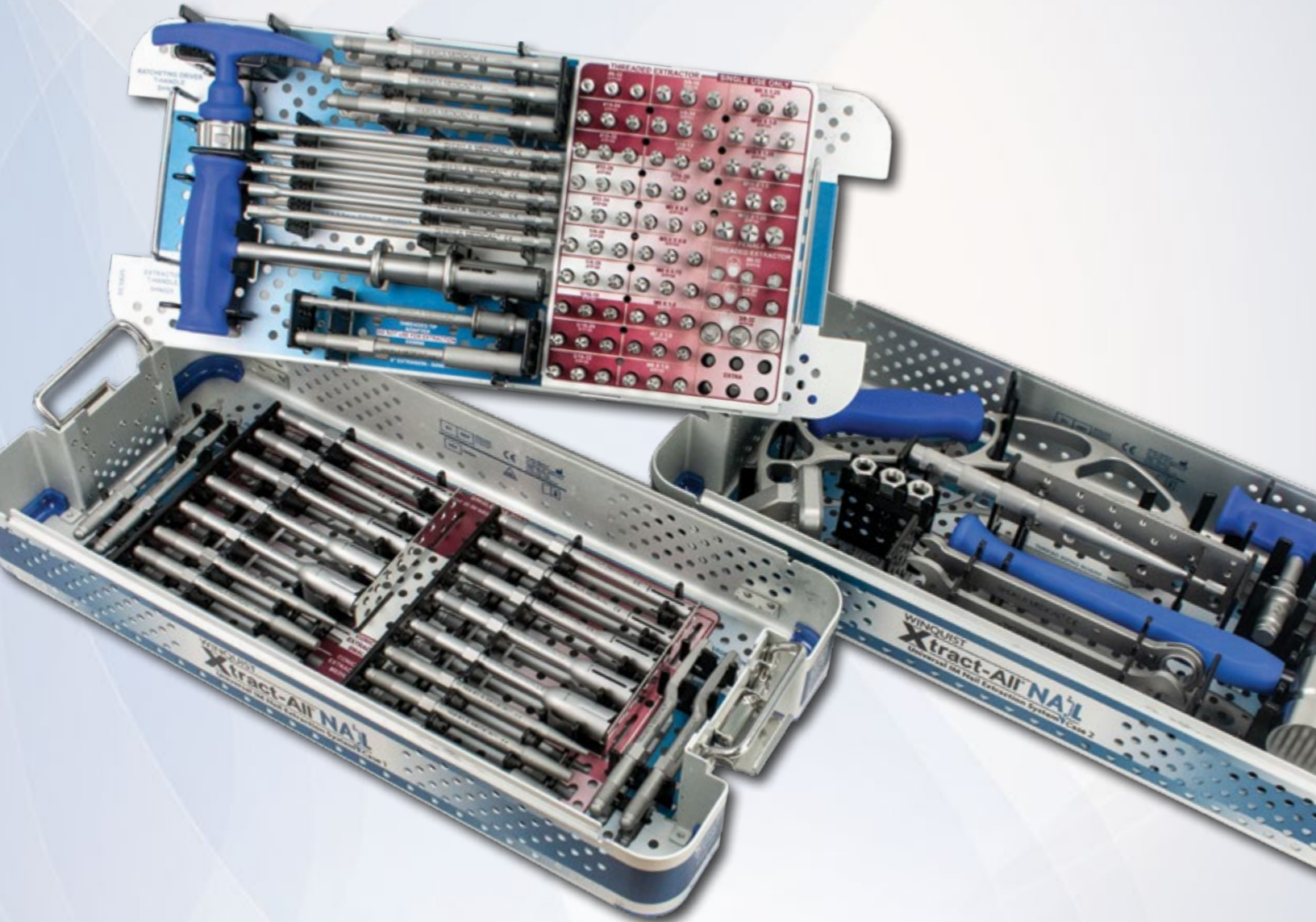


SURGICAL TECHNIQUE GUIDE

#8
System 8 of 15

SHUKLA NAIL

Universal IM Nail Extraction Solution



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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SHUKLA NAIL

Universal IM Nail Extraction Solution

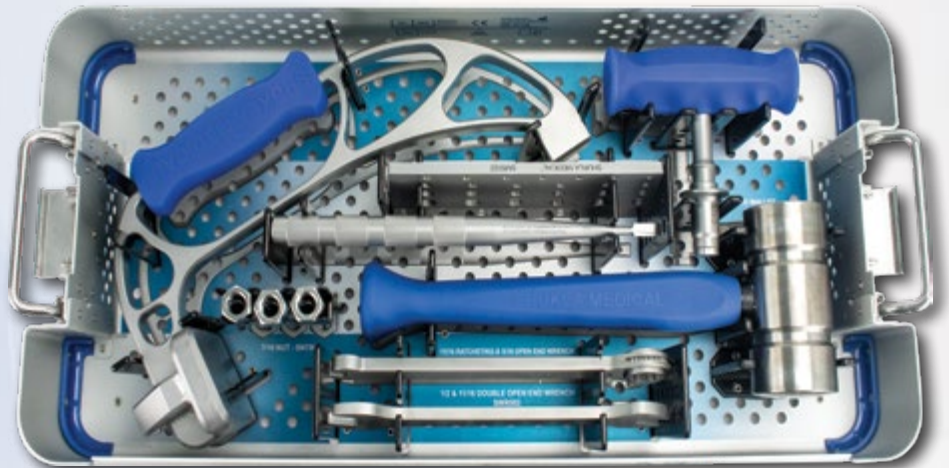
System Name: SHUKLA Nail

Part Number: S9NAIL

Version: 4

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.



System History

The SHUKLA Nail system, formerly known as the Winqvist, was named after Dr. Robert Winqvist, 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.

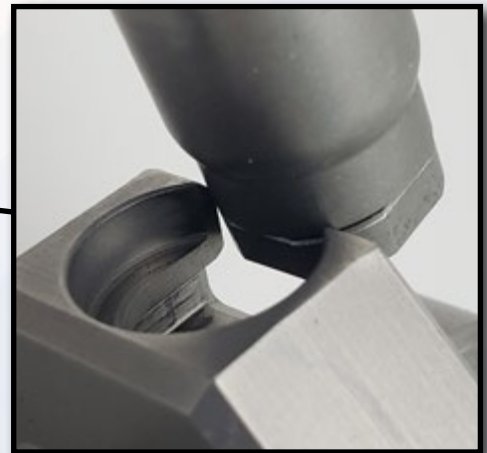
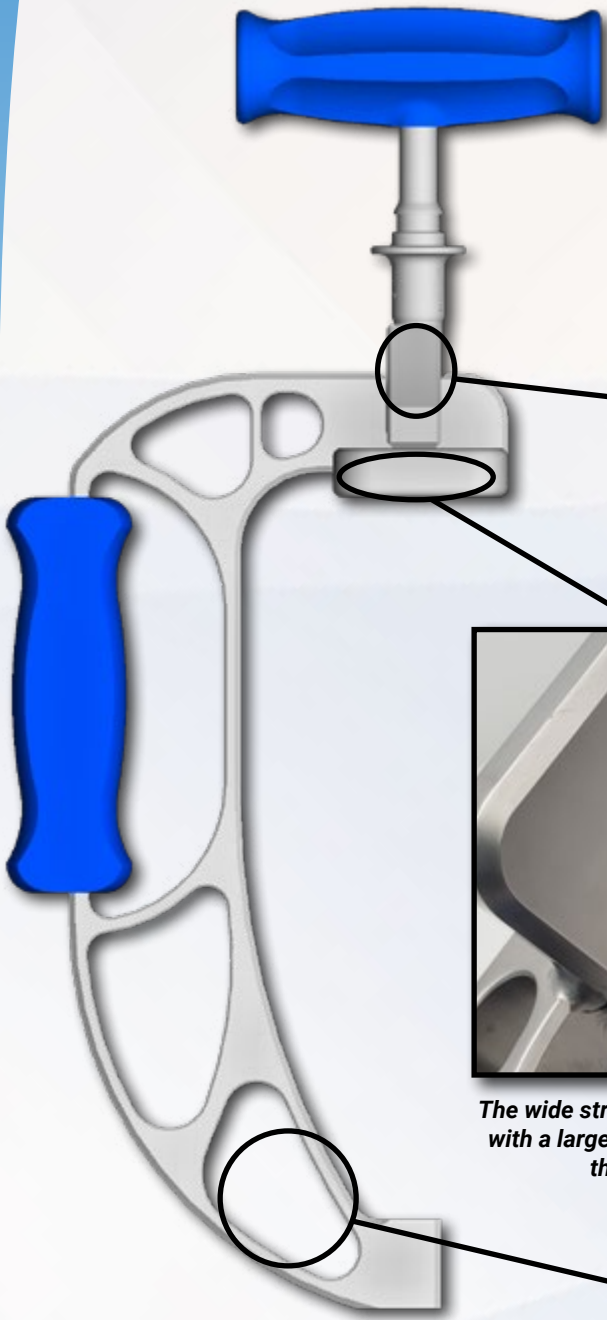
In 2005, Shukla Medical president's first project with the company was the development and launch of the Winqvist II with input and help from Dr. Winqvist himself. One of the biggest changes was the shift from a single case to two - one for extractors and one for instrumentation. This was in part because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

In 2010, the Winqvist III was released, adding some substantial changes. All extractors were changed to single-use 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.

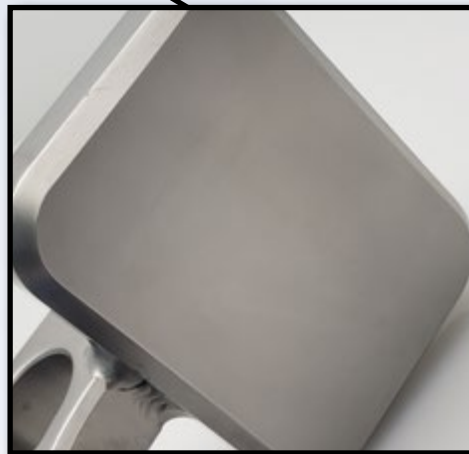
The Winqvist IV, now renamed the Shukla NAIL, debuted in 2019 thanks to sales force and surgeon field feedback. The v4 added more additions than any before it, making it the most comprehensive system on the market.

STRIKE PLATE FRAME

The Strike Plate Frame applies crucial extraction force in-line with the hip stem. Vibrational Harmonics help break up bone ingrowth, making extraction easier and helping reduce the risk of fractures.



Modular T-Handle can be attached in two different orientations.



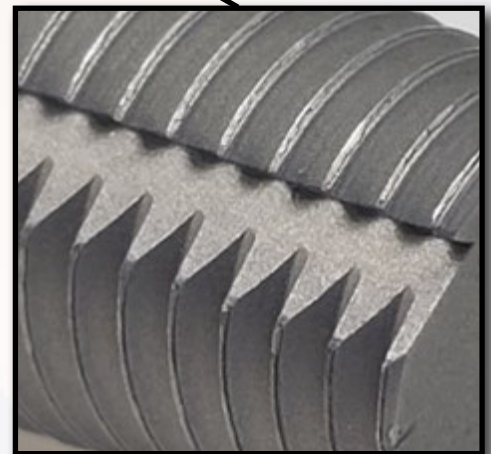
The wide strike plate allows surgeons to hit with a large degree of accuracy, reducing the chance of mishits.



The holes in the body reduce overall weight while increasing the vibrations of the resonant frequencies.

CONICAL EXTRACTOR

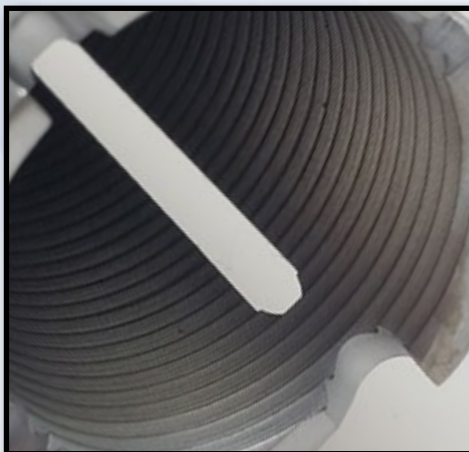
Tapered extractors that cut into and grab onto an IM nail to create threads to secure the nail for extraction.



Chip-Clearing Flutes move debris out of the area while the cutting threads bite into the nail.

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.



Tapered internal threading cut into the IM Nail to secure grip.

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-to-date 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.

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.

Storage

- It is recommended to store all Shukla Medical instrumentation in a clean, dry environment. Under 50% relative humidity; ≤75°F/24°C.

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.

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.

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.

1 Remove Bone Screws

1. Remove all proximal & distal screws (Fig. A).
2. Verify that all locking screws are removed.
- * SHUKLA Maxi (S9MAXI) recommended for this step.



Figure A

2 Prepare Nail for Extraction

1. Remove excess bone around proximal neck of IM nail with Bone Chisel (SOS027). (Fig. B)
2. Remove threaded cap if present.



Figure B

3 Extraction Method Selection

The SHUKLA Nail IM nail extraction system contains several options (A-D) to remove IM nail implants in the event that primary or subsequent methods are unable to be used.

Extraction methods are presented in the recommended order of execution. Some methods are destructive, causing damage to the nail threads that can make it difficult to return to preceding methods.

Option A: Threaded Extractor Tips (Single-Use)

STP100-STP132

1. Select the compatible extraction tip by matching threads on the IM nail to an extractor (Fig. C.1). If a nail cap is present, use the thread sizing board (SMS022) (Fig. C.2) to accurately identify the appropriate tip.
2. Tighten the tip into the Extractor Body (SXT019) using the 5/16" & 1/2" wrenches (SWR007 & SWR002) (Fig. D).
3. Attach the extractor body to the Extractor T-Handle (SHN023) and thread the tip into the IM nail tightly.

** 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.*



Figure C.1



Figure C.2 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

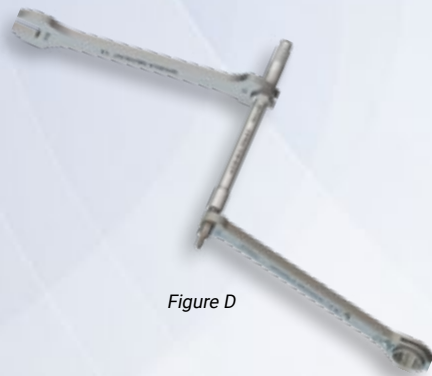


Figure D

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) (Fig. E). 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.



Figure E

Option B: Conical Extractor (Single-Use)

SXT048-SXT050

If a compatible tip cannot be identified, or nail threads are damaged, use a Conical Extractor (Fig. F).

1. Select the size that fits best into the IM nail based on the diameter of the nail threads.
2. Use the Extractor T-Handle (SHN023) to drive the extractor clockwise into IM nail, using downward force and inserting as far as possible, engaging at least 3-4 threads. The extractor will cross-thread the IM nail shaft threads, ensuring secure attachment.

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.

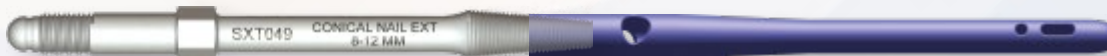


Figure F

Option C: Solid IM Nail Extractor (Single-Use)

SXT043-SXT047

If the IM nail has no opening, if the nail is broken, or if the IM nail threads are otherwise inaccessible, use a Solid IM Nail Extractor (Fig. G). Solid Extractors feature bone-clearing trephine teeth that improve access to the IM nail during attachment.

1. Choose an extractor large enough to fit completely over the exterior of the IM nail shaft. Reaming may be necessary to create space for the extractor over the IM nail.
2. Use the Extractor T-Handle (SHN023) to drive the extractor as far as possible onto IM nail, applying downward force in a clockwise direction. The threads inside of the extractor will bite into the nail shaft to create a secure attachment.

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.



Figure G

Option D: Hook Extractor

SXT033-SXT034

If the IM nail cannot be removed using Options A, B, or C, and if a slot, hole, or recess is present, a Hook Extractor may be used (Fig. H).

1. Ensure that the hook can fully access and engage with the IM nail slot.
2. Connect the C-Frame (SBD008; see step 4) **prior to** engaging the Hook Extractor with the IM nail.



Figure H

4 Build Extractor Assembly

1. Connect Extractor T-handle (SHN023) to the chosen extractor. Screw extractor into IM nail. (Fig. I)
2. Once the extractor is securely attached to the IM nail, remove the t-handle (Fig. J).
3. Connect the Strike Plate Frame (SBD008) to the extractor using a Hex Nut (SNT001). (Fig. K) Tighten the nut fully with the 11/16" Wrench (SWR007), applying counter-torque with the 1/2" Wrench (SWR002).



Figure I



Figure J



Figure K

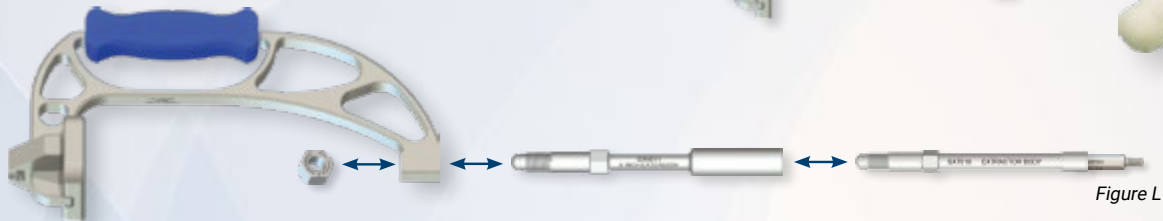


Figure L

If the threaded tip extractor, conical extractor, or hook extractor is not long enough to attach to the Strike Plate Frame when engaged with the IM nail, attach the 6" Extension (SXN011) (Fig. L)

5 Extract Implant

1. Extract the implant using repeated strikes of the Big Mallet (SMT002) on the Strike Plate Frame's strike plate. (Fig. M)
 - If additional grip is needed, attach the Modular T-Handle (SHN019) to the Strike Plate Frame.
 - 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.



Figure M

A Note on Breakage

If an extractor tip breaks, (Fig. N) 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.

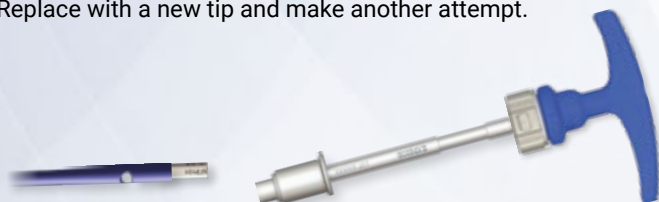


Figure N

- 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.

CLEANING & STERILIZATION

SHUKLA Nail

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



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S9NAIL



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CONSULT
INSTRUCTIONS
FOR USE



NON-STERILE
PRODUCT



COMPONENTS LIST

Component List		
Std Qty	Part Number	Description
1	SBD008	Strike Plate, Assy, Frame
1	SCS027	Case, Instruments, IM Nail removal System
1	SCS028	Lid, Instruments, IM Nail removal System
1	SHN019	T-Handle, Assy, for Strike Plate Frame
1	SMS022	Gauge, Thread Identifier
1	SMT002	Mallet Assy, Big
3	SNT001	Nut, Hex, 7/16-20 UNF-2B
1	SOS027	Chisel, Bone
2	SWR002	Wrench, Double Open End, 1/2" & 11/16"
1	SWR007	Wrench, Assy Ratcheting 11/16" & Open End 5/16"
1	SCS024	Case, Components, IM Nail removal System
1	SCS025	Tray, IM Nail removal System
1	SCS026	Lid, Components, IM Nail removal System
1	SDR013	Driver, Hex, Male, 2 mm
1	SDR014	Driver, Hex, Male, 2.5 mm
1	SDR015	Driver, Hex, Male, 6 mm
1	SDR016	Driver, Hex, Female, 6 mm
1	SDR017	Driver, Hex, Male, 8 mm
1	SHN022	T-Handle Assy, Ratcheting, Hex, 1/4"
1	SHN023	T-Handle Assy, Quick Connect, Hex, 1/2"
3	STP100	Tip, Male, 8-32 UNC-2A, <i>Single Use</i>
3	STP101	Tip, Male, 10-24 UNC-2A, <i>Single Use</i>
3	STP102	Tip, Male, 10-32 UNF-2A, <i>Single Use</i>
3	STP103	Tip, Male, 12-28 UNF-2A, <i>Single Use</i>
3	STP104	Tip, Male, 12-24 UNC-2A, <i>Single Use</i>
3	STP105	Tip, Male, 1/4-20 UNC-2A, <i>Single Use</i>
3	STP106	Tip, Male, 1/4-28 UNF-2A, <i>Single Use</i>
3	STP107	Tip, Male, 5/16-18 UNC-2A, <i>Single Use</i>
3	STP108	Tip, Male, 5/16-24 UNF-2A, <i>Single Use</i>
3	STP109	Tip, Male, 5/16-32 UNEF-2A, <i>Single Use</i>
3	STP110	Tip, Male, 3/8-16 UNC-2A, <i>Single Use</i>

CASE #1

CASE #2

Component List		
Std Qty	Part Number	Description
3	STP111	Tip, Male, 3/8-24 UNF-2A, <i>Single Use</i>
3	STP112	Tip, Male, 7/16-14 UNC-2A, <i>Single Use</i>
3	STP113	Tip, Male, 7/16-20 UNF-2A, <i>Single Use</i>
3	STP114	Tip, Male, M5 X 0.8 - 6g, <i>Single Use</i>
3	STP115	Tip, Male, M5.5 X 0.9 - 6g, <i>Single Use</i>
3	STP116	Tip, Male, M6 X 0.75 - 6g, <i>Single Use</i>
3	STP117	Tip, Male, M6 X 1.0 - 6g, <i>Single Use</i>
3	STP118	Tip, Male, M7 X 1.0 - 6g, <i>Single Use</i>
3	STP119	Tip, Male, M8 X 1.0 - 6g, <i>Single Use</i>
3	STP120	Tip, Male, M8 X 1.25 - 6g, <i>Single Use</i>
1	SXN006	Adapter Assy, Hex, Female, Quick Connect, 5/16"
1	SXN011	Extension, Threaded, 6"
3	SXT019	Connector Shaft for Strike Plate
2	SXT033	Extractor, Nail, Hook, Small
2	SXT034	Extractor, Nail, Hook, Large
3	STP121	Tip, Male, M10 X 1.0 - 6g, <i>Single Use</i>
3	STP122	Tip, Male, M10 X 1.25 - 6g, <i>Single Use</i>
3	STP123	Tip, Male, M10 X 1.5 - 6g, <i>Single Use</i>
3	STP124	Tip, Male, M12 X 1.25 - 6g, <i>Single Use</i>
3	STP130	Tip, Female, 8-32 UNC-2B, <i>Single Use</i>
3	STP131	Tip, Female, 1/4-20 UNC-2B, <i>Single Use</i>
3	STP132	Tip, Female, 3/8-32 UNEF-2B, <i>Single Use</i>
2	SXT043	Extractor, Nail, Solid, 6 mm to 8 mm, <i>Single Use</i>
2	SXT044	Extractor, Nail, Solid, 8 mm to 10 mm, <i>Single Use</i>
2	SXT045	Extractor, Nail, Solid, 10 mm to 12.5 mm, <i>Single Use</i>
2	SXT046	Extractor, Nail, Solid, 12 mm to 15 mm, <i>Single Use</i>
2	SXT047	Extractor, Nail, Solid, 15 mm to 18 mm, <i>Single Use</i>
2	SXT048	Extractor, Nail, Conical, 4 mm to 8 mm, <i>Single Use</i>
2	SXT049	Extractor, Nail, Conical, 8 mm to 12 mm, <i>Single Use</i>
2	SXT050	Extractor, Nail, Conical, 12 mm to 16 mm, <i>Single Use</i>

CASE #2

**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 & manufactures instrumentation for orthopedic implant extraction in St. Petersburg, Florida, USA.

In 1998, aerospace component manufacturer S.S. White Technologies, Inc. acquired the Snap-On Winquist IM Nail system. 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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