

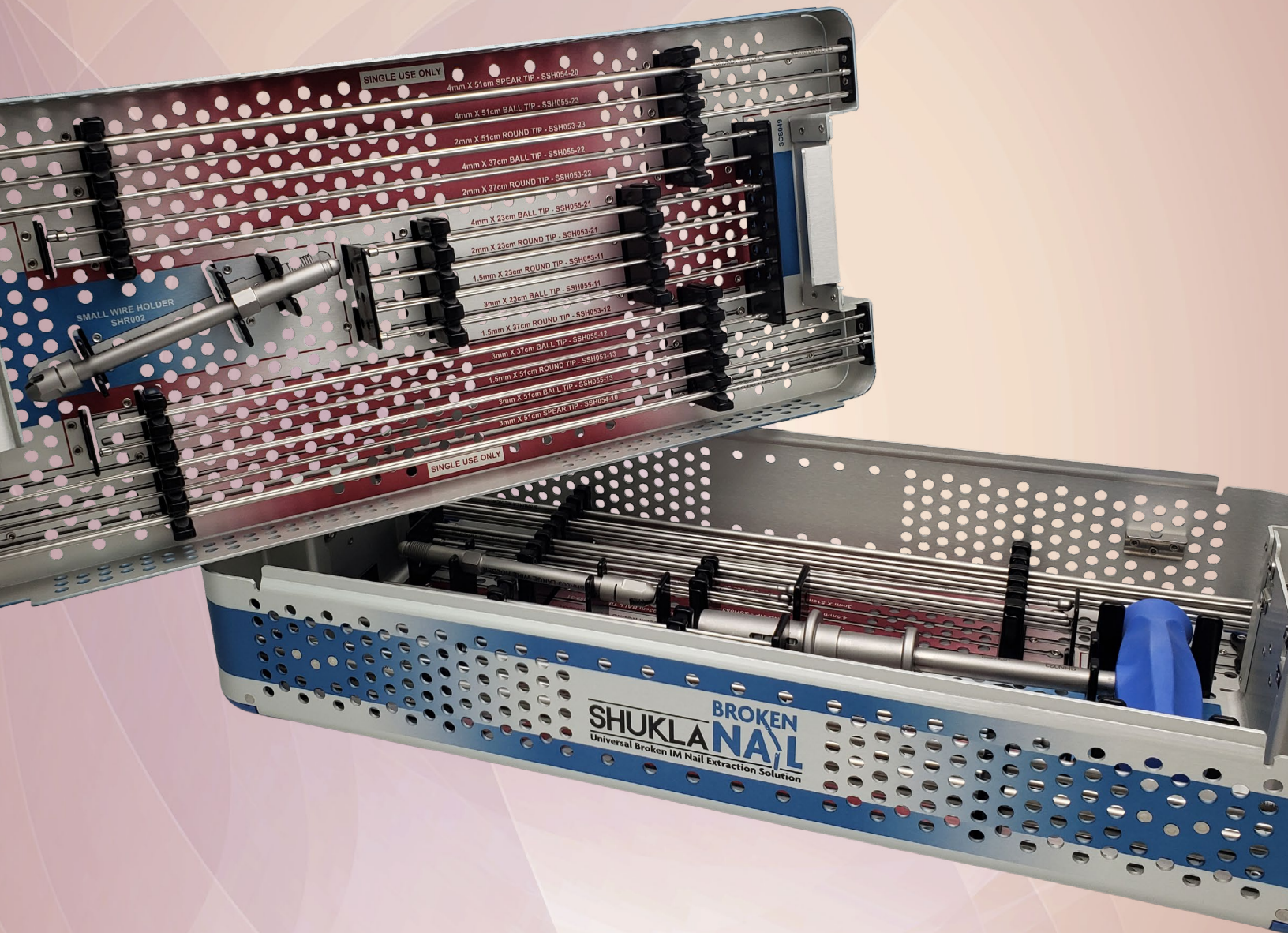
PRODUCT GUIDE

BROKEN

SHUKLA NAIL

Universal Broken IM Nail Extraction System

#9
System 9 of 15



SHUKLA MEDICAL[®]

Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

SHUKLA **BROKEN NAIL**

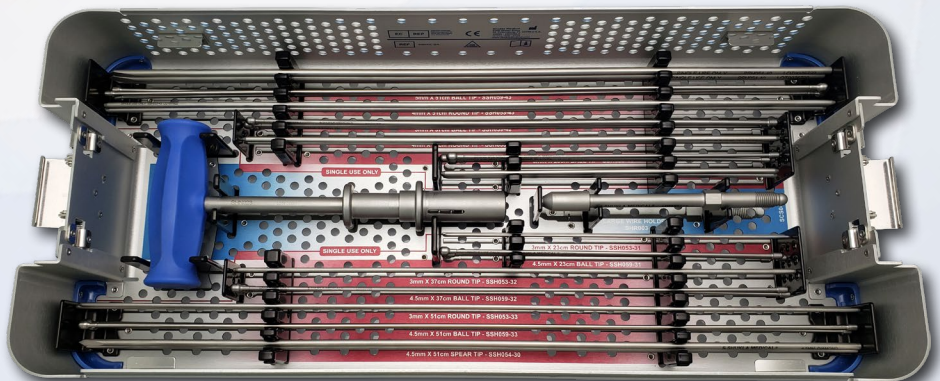
Universal Broken IM Nail Extraction System

System Name: SHUKLA Broken Nail v1

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 Spear Tip, Bal Tip, and Round 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.



This system is intended for use in conjunction with other intramedullary nail solutions from Shukla Medical. For the complete IM Nail extraction solution, use the SHUKLA Broken Nail in conjunction with the SHUKLA Nail (S9NAIL) and SHUKLA Lag Screw (S9LAG) systems.

System History

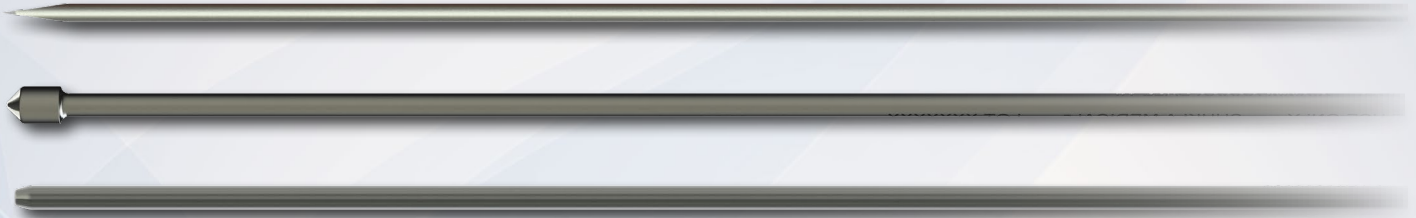
Due to the popularity and success of the SHUKLA Nail IM Nail extraction system, potential customers would inquire about how to remove distally broken IM Nails. This would frequently happen during trade shows after our IM Nail demonstrations. We initially created a set of instruments to tackle that very 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.

2020: Version 1 Introduced

Key Benefits

- Ability to remove a wide range of distally broken IM Nails, regardless of make or model.
- Three different types of wires for extracting broken IM Nails: Spear Tip, Ball Tip, and Round Tip.



- Universal variety of wires for extraction - Twelve types each of Ball Tip and Round Tip wires (Four different diameters each with three different lengths), and four types of Spear Tip wires with varying diameters.
- Quick-Connect Extractor T-Handle attaches to the wire holders and allows for the broken IM nail tip to be removed.
- Compatible with the Strike Plate Frame from the SHUKLA Nail (S9NAIL) IM Nail Extraction System when additional extraction force is needed.
- Wire Holders couple the Ball Tip wires to the preferred extraction method, either the Quick-Connect Extractor T-Handle or the Strike Plate Frame (not included in S9NAIL-BR).



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 fatigue
- Better grip/reduces slippage

Comprehensive Design

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

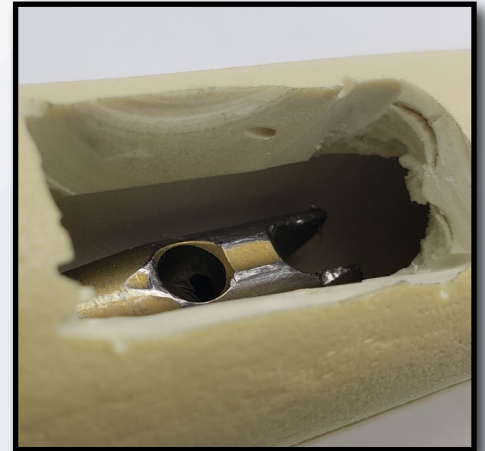
Alternative Method Comparison

There are two alternate methods surgeons rely on when there is not a SHUKLA Broken Nail in the O.R. The first method is known as “Stuffing the Nail”. Surgeons push a bent K-Wire down the length of the broken nail, and then “stuff” it with other K-Wires. Then, grabbing onto the bent K-Wire with pliers, they pull to hopefully extract the nail piece. The problem with this method is that not only does it waste a lot of time in the O.R, it also does not allow for much extraction force to be exerted, reducing the chance of a successful case.

The other tactic surgeons attempt to use is to create a bone window. By cutting out a large portion of bone, they can pluck out the broken piece of IM Nail. The major issue with this method is the severe loss of bone this causes the patient. Not only that, this method also creates a higher cost for the surgery because expensive biologics are then needed to close up the exposed bone window. The SHUKLA Broken Nail system avoids both of those scenarios allowing broken IM Nails to be extracted without requiring large amounts of time or large amounts of bone loss.



Option 1: K-Wires have been stuffed inside an IM Nail in an attempt to pull a bent K-Wire to extract the broken portion.



Option 2: A bone window is created in order to remove the broken piece of IM Nail.

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 $60 \times \$36$ per minute = \$2,160. The SHUKLA Broken Nail v1 sells for \$14,800, meaning that even at the lowest cost per minute in the O.R. it would only take seven uses for it to pay for itself. That doesn't even factor in the amount of time and money saved by not needing to resort to osteotomies and expensive biologics.

When You Don't Have It

A broken IM Nail is one of the least ideal scenarios a surgeon can encounter during revision surgery. Not having a reliable way to quickly and efficiently remove the broken piece of IM Nail not only means a delay in the completion of the case but also a high risk of bone loss due to potential osteotomies. A SHUKLA Broken Nail system allows surgeons to extract the broken IM Nail without resorting to cutting apart the bone.

Our system allows both the use of an Extractor T-Handle and our patented Strike Plate Frame and Mallet. This means that with Shukla in the O.R, surgeons know when it comes time to extract the broken piece, it will come out. No more wasting time fiddling with K-Wires and hoping a pair of pliers is sufficient to remove the nail properly. No more wasting money on biologics to try and recover from bone loss. Because when it comes to revision surgery, less time, less cost, and less bone loss are always the goal.

How We Compare

Most orthopedic 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.

While other systems exist that offer broken IM Nail extraction capabilities, none offer the universal range of the SHUKLA Broken Nail system. Some competitor's systems rely on hooks which will become stuck if they are unable to extract the broken piece. Others instrumentation cannot be impacted, which might prevent extraction of well fixed broken pieces. Only the SHUKLA Broken IM Nail system offers a universal range of instrumentation, methods to utilize stronger force during extraction, and the ability to preserve the maximum amount of bone during the revision.

The SHUKLA Broken Nail v1 system was created from the hard work of our engineering team.

PATENTS

- Wire Holder
- Quick-Connect Extractor T-Handle

Wire Holder

Attaches to our Ball Tip wires and allows for the secured Broken IM Nail piece to be extracted.

Hub

Connects to our extraction devices - the small Wire Holder utilizes the Extractor T-Handle while the large Wire Holder can connect with either the Extractor T-Handle or our Strike Plate Frame.

Sheath

Spins to secure the ball tip wire to prepare it for extraction.

Extractor T-Handle

Quick-connects to either of our Wire Holders and allows them to be connected and disconnected rapidly.

Silicone Handle

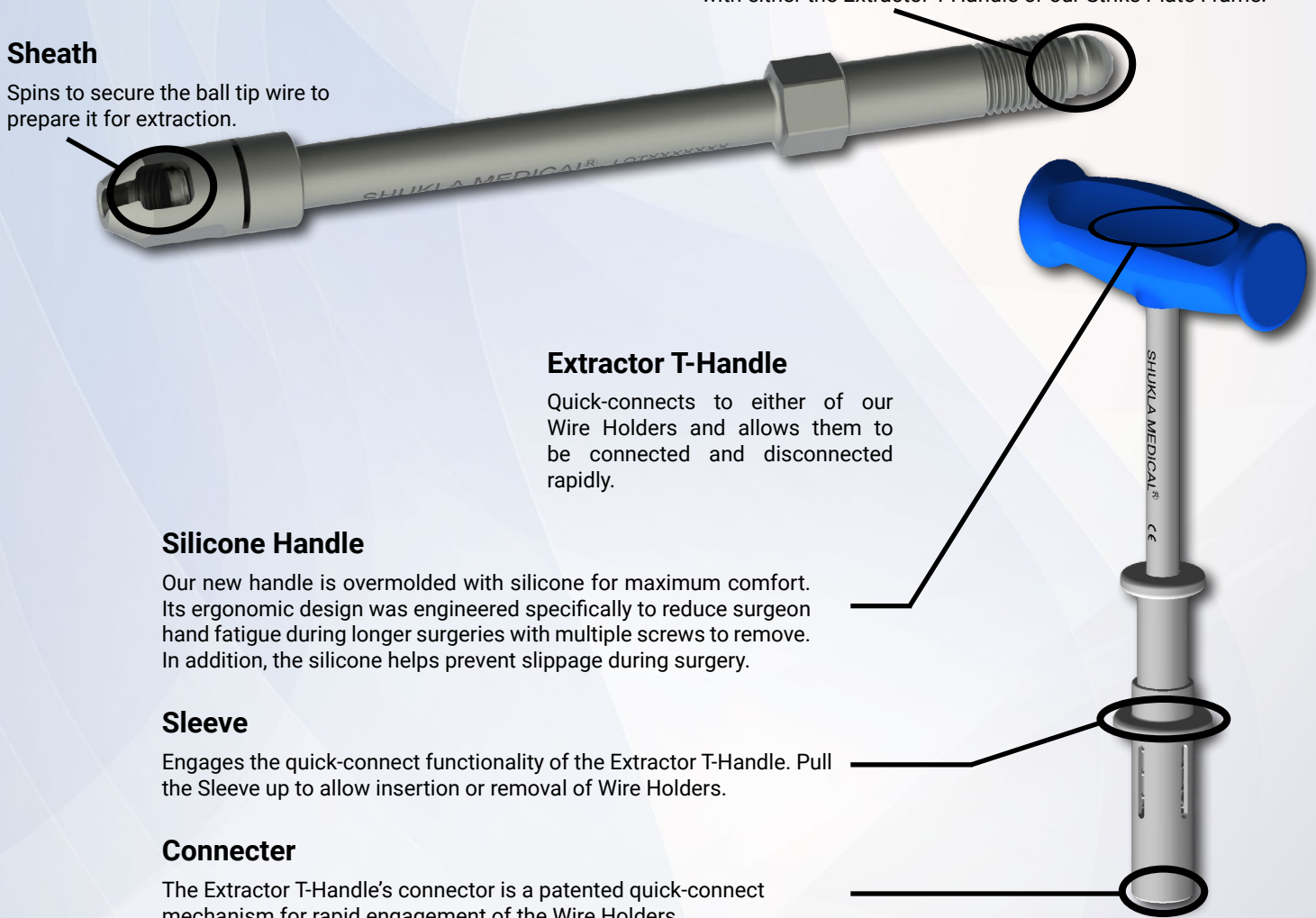
Our new handle is overmolded with silicone for maximum comfort. Its ergonomic design was engineered specifically to reduce surgeon hand fatigue during longer surgeries with multiple screws to remove. In addition, the silicone helps prevent slippage during surgery.

Sleeve

Engages the quick-connect functionality of the Extractor T-Handle. Pull the Sleeve up to allow insertion or removal of Wire Holders.

Connector

The Extractor T-Handle's connector is a patented quick-connect mechanism for rapid engagement of the Wire Holders.

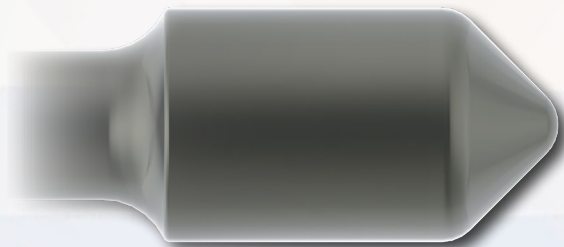


Attention to Detail

Each of the three types of wires utilized in the SHUKLA Broken Nail system have a specific purpose in the extraction of broken IM Nail pieces.



Spear Tip Wires are designed to clear tissue and bone past the broken tip of the nail. This clearing will give space for the Ball Tip and Round Tip Wires to pass and engage with the tip of the nail.

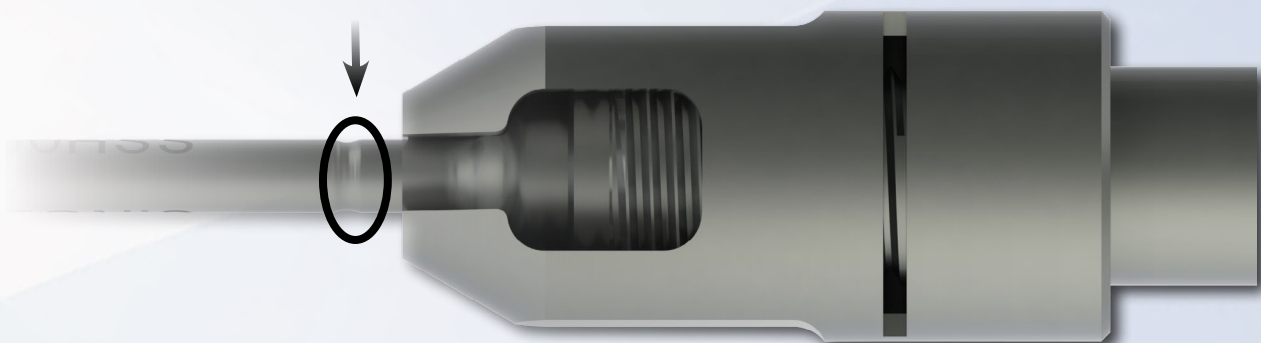


Ball Tip Wires pass through the cannulation in the broken portion of the nail. The overhang of the ball engages with the nail's wall and provides interference for extraction.



Round Tip Wires will lock the Ball Tip Wires in place by forcing the ball tip laterally within the broken portion of the nail. This will provide a solid mechanical connection in preparation for extraction.

Engineered Weak Point: The larger Ball Tip Wires are able to be impacted with the full force of our Strike Plate Frame and Mallet. Whenever these types of forces are introduced, there is a chance that the wire itself can break. That is why we have an engineered break point on the wire itself; to assure that if it does break, it breaks outside the body, allowing it to be removed and re-attempted.



It is important to note that only the larger sized Wire Holder can attach to the Strike Plate Frame for extraction. The smaller Wire Holder is only compatible with the Extractor T-Handle. This is because the smaller diameter wires would not be able to withstand the impact force of the Mallet.

Components List

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, <i>Single Use</i>
3	SSH055-12	Wire, Ball Tip, 37 cm length, 3 mm dia, <i>Single Use</i>
3	SSH055-13	Wire, Ball Tip, 58 cm length, 3 mm dia, <i>Single Use</i>
3	SSH055-21	Wire, Ball Tip, 23 cm length, 4 mm dia, <i>Single Use</i>
3	SSH055-22	Wire, Ball Tip, 37 cm length, 4 mm dia, <i>Single Use</i>
3	SSH055-23	Wire, Ball Tip, 58 cm length, 4 mm dia, <i>Single Use</i>
3	SSH059-31	Wire, Ball Tip, 23 cm length, 4.5 mm dia, <i>Single Use</i>
3	SSH059-32	Wire, Ball Tip, 37 cm length, 4.5 mm dia, <i>Single Use</i>
3	SSH059-33	Wire, Ball Tip, 58 cm length, 4.5 mm dia, <i>Single Use</i>
3	SSH059-41	Wire, Ball Tip, 23 cm length, 5 mm dia, <i>Single Use</i>
3	SSH059-42	Wire, Ball Tip, 37 cm length, 5 mm dia, <i>Single Use</i>
3	SSH059-43	Wire, Ball Tip, 58 cm length, 5 mm dia, <i>Single Use</i>
3	SSH053-11	Wire, Round Tip, 23 cm length, 1.5 mm dia, <i>Single Use</i>
3	SSH053-12	Wire, Round Tip, 37 cm length, 1.5 mm dia, <i>Single Use</i>
3	SSH053-13	Wire, Round Tip, 58 cm length, 1.5 mm dia, <i>Single Use</i>
3	SSH053-21	Wire, Round Tip, 23 cm length, 2 mm dia, <i>Single Use</i>
3	SSH053-22	Wire, Round Tip, 37 cm length, 2 mm dia, <i>Single Use</i>
3	SSH053-23	Wire, Round Tip, 58 cm length, 2 mm dia, <i>Single Use</i>
3	SSH053-31	Wire, Round Tip, 23 cm length, 3 mm dia, <i>Single Use</i>
3	SSH053-32	Wire, Round Tip, 37 cm length, 3 mm dia, <i>Single Use</i>
3	SSH053-33	Wire, Round Tip, 58 cm length, 3 mm dia, <i>Single Use</i>
3	SSH053-41	Wire, Round Tip, 23 cm length, 4 mm dia, <i>Single Use</i>
3	SSH053-42	Wire, Round Tip, 37 cm length, 4 mm dia, <i>Single Use</i>
3	SSH053-43	Wire, Round Tip, 58 cm length, 4 mm dia, <i>Single Use</i>
3	SSH054-10	Wire, Spear Tip, 58 cm length, 3 mm dia, <i>Single Use</i>
3	SSH054-20	Wire, Spear Tip, 58 cm length, 4 mm dia, <i>Single Use</i>
3	SSH054-30	Wire, Spear Tip, 58 cm length, 4.5 mm dia, <i>Single Use</i>
3	SSH054-40	Wire, Spear Tip, 58 cm length, 5 mm dia, <i>Single Use</i>
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.

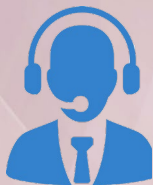
In 1998, aerospace component manufacturer S.S. White Technologies, Inc. acquired the Medical Products Division of Snap-On. S.S. White rebranded the medical division in 2007 to create Shukla Medical.

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.