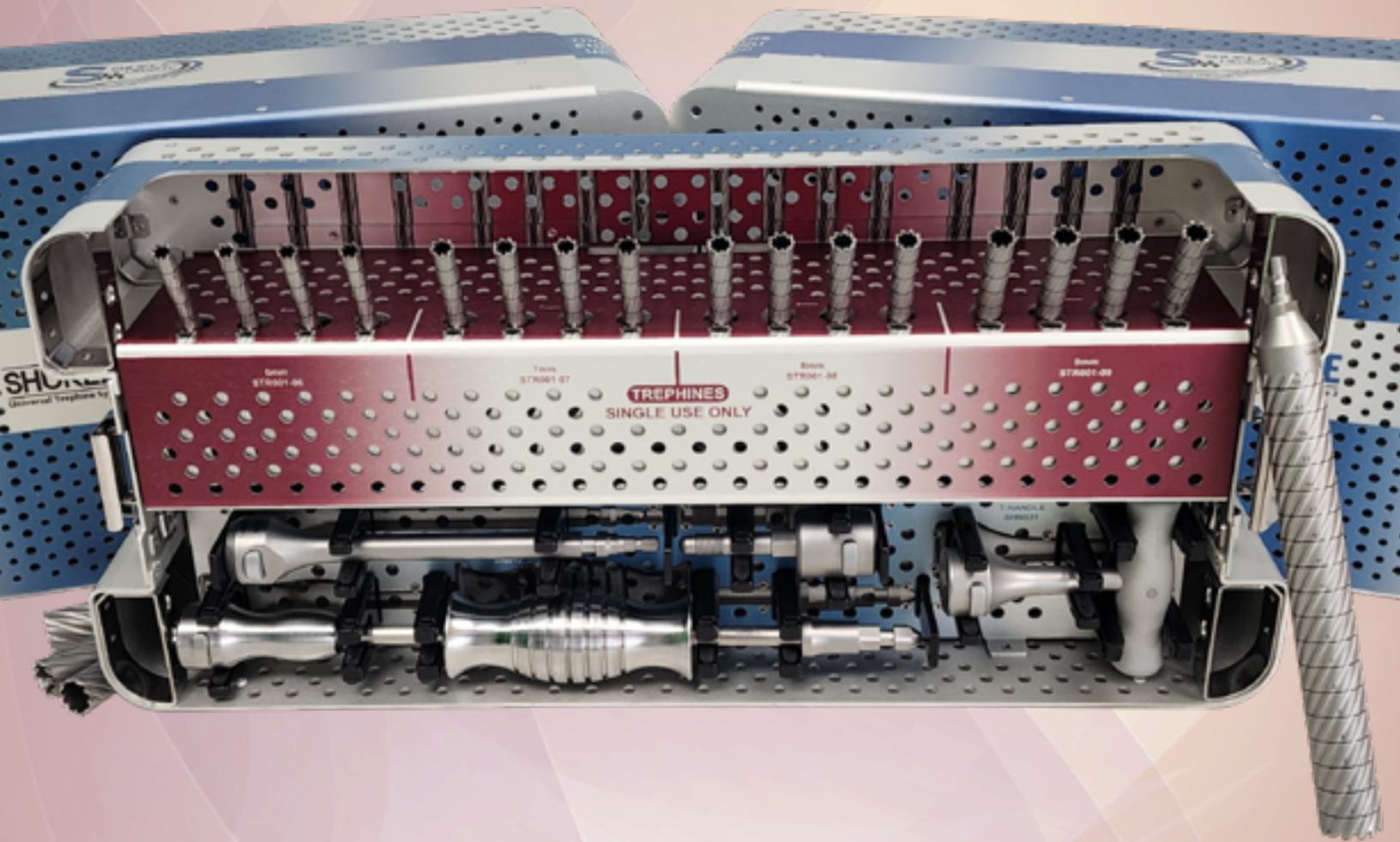


PRODUCT GUIDE

#21
System 21 of 25

SHUKLA **TREPHINE**

Universal Trephine System



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies
THE EXTRACTION EXPERTS

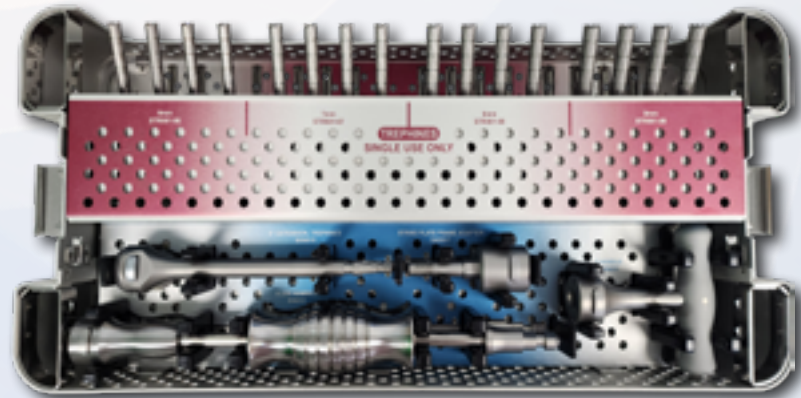
SHUKLA TREPHINE

Universal Trephine System

System Name: SHUKLA Trephine v1

Primary Use

The SHUKLA Universal Trephine system is designed for the coring over of IM Nails to break up the bone-implant interface. While primarily engineered for IM Nail revision surgeries, the trephines are also capable of coring over pins and screws as needed. The trephines can be used either by hand or under power.



System History

Engineering first began on the SHUKLA Trephine system in 2019. For years, surgeons had asked Shukla Medical if they intended on releasing a trephine set, and eventually enough demand was shown for the product that the company made the move to make it a reality. Our engineers ended up trying over twenty different trephine designs in order to maximize the cutting power and chip removal of the final product compared to the current products on the market. Development on the Strike Plate Frame Adapter utilized within the SHUKLA Trephine also began over the course of the system's development.

Version History

- 2023: Version 1 Introduced

Key Benefits

- A universal spectrum of trephine sizes for IM Nails, screws, and pins ranging from 6mm all the way to 26mm, each with 8 inches of cutting length.
- Each size of trephine comes with four trephines each, resulting in a total of 88 trephines.



Depth markings are not calibrated, and are intended for visual reference only.

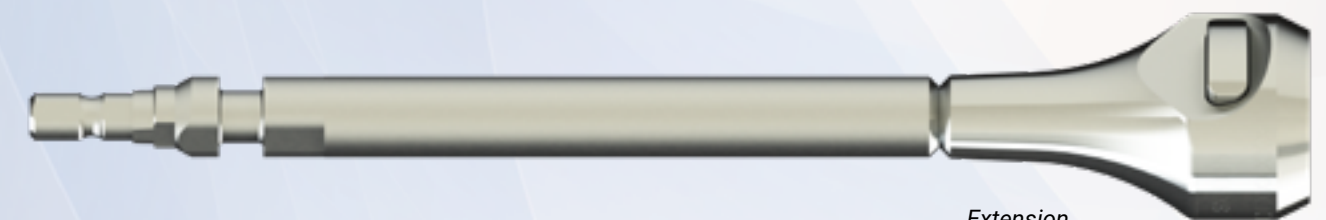
Trephine Example

- If a trephine becomes stuck, the Strike Plate Frame Adapter allows the Shukla Medical Strike Plate Frame to be connected to the end of any size of Trephine.



Strike Plate Frame Adapter

- Trephine Extension allows trephines better access through soft tissue when the situation requires it.



Extension

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

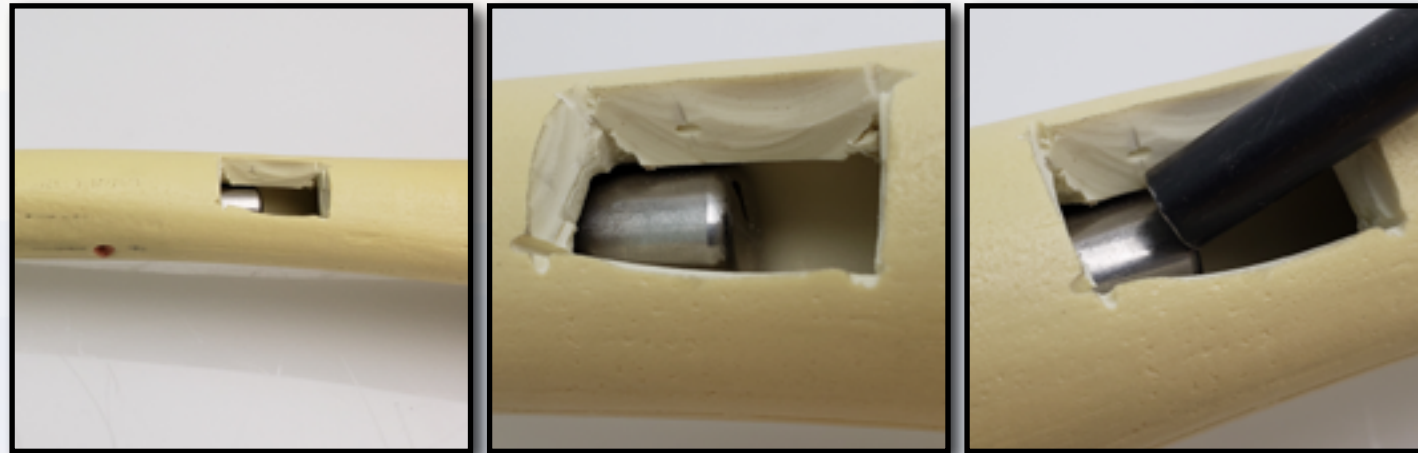
Comprehensive Design

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

Alternative Method Comparison

The main alternative method to extract an IM nail when the bone-implant interface cannot be severed is to use a variety of osteotomes to work around the implant. However most osteotomes are not designed to work around the full length of an IM nail, or to work around the shape of one. This leads to wasted time or an unsuccessful closing of the case.

Another alternative would be performing a small osteotomy on the distal end of where the IM nail is, and using a punch to force the nail out. But why waste all of that time, effort, and patient bone? A SHUKLA Trepine trephine can core around the IM nail, interrupting the bone-implant interface and saving the patient from the bone loss of an osteotomy while also saving the surgeon the time and stress they would have otherwise endured.



A window is cut in the bone on the end of the IM nail to allow a hammer and a punch to tap the IM nail out the opposite direction in which it was implanted.

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 to 90 minutes. At 75 minutes per surgery, the savings would be 75 x \$36 per minute = \$2,700. The SHUKLA Trepine v1 sells for \$35,000, meaning that even at the lowest cost per minute in the O.R. it would only take 13 uses for it to pay for itself.

When You Don't Have It

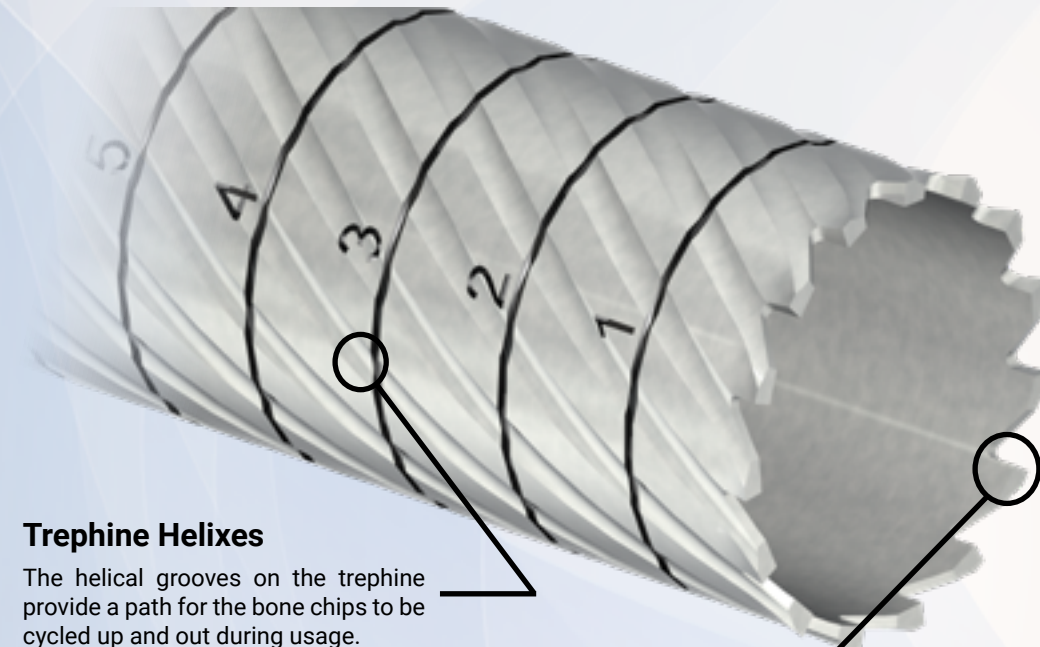
Having the SHUKLA Trepine system in the O.R. during IM nail orthopedic revision surgeries helps drastically improve the prep work required to successfully extract the implant. Instead of crossing your fingers, hoping that the bone ingrowth hasn't gotten too severe, you can have a trephine that fits perfectly to the implant. Why waste surgeon time and patient bone getting the IM nail prepped another way? The patented design of the trephines allows for the expulsion of bone chips as well as the ability to rapidly dislodge the trephine, should it ever become stuck. Our trephines help you avoid needing to have to resort to an osteotomy while at the same time reducing how long a patient needs to remain under anesthesia. This allows the hospital to rotate the operating room more often while also reducing how much fatigue the surgeon has to endure.

With our universal trephines, it does not matter what type, make, or model the IM nail implant is. Our trephines will make sure you are able to core over the implant and disrupt the bone-implant interface while also minimizing the bone loss and bone chip debris usually associated with trephine usage.

PATENTS

- Trepine Helixes
- Trepine Teeth
- Connection Hub

The SHUKLA Trepine v1 system utilizes several patents to showcase why our trephines are so powerful and capable.

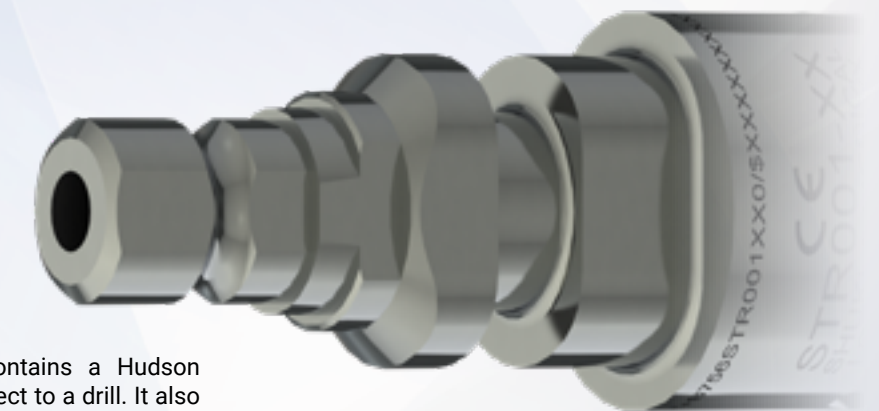


Trepine Helixes

The helical grooves on the trephine provide a path for the bone chips to be cycled up and out during usage.

Trepine Teeth

Our trephine teeth are flared outwards and combine with the helixes to send the bone chips out of the patient. This increases the cutting speed and reduces the heat generated. The teeth are specifically designed for cutting into both bone and bone cement.



Connection Hub

The backend hub of the trephine contains a Hudson connection that allow it to directly connect to a drill. It also features a Quick-Connect attachment for both our slide-hammer and t-handle instrumentation.

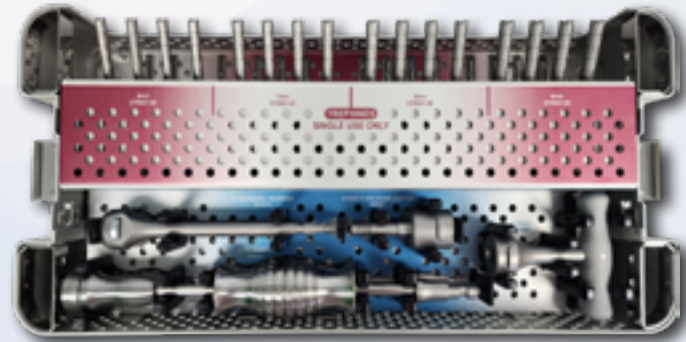
How We Compare

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.

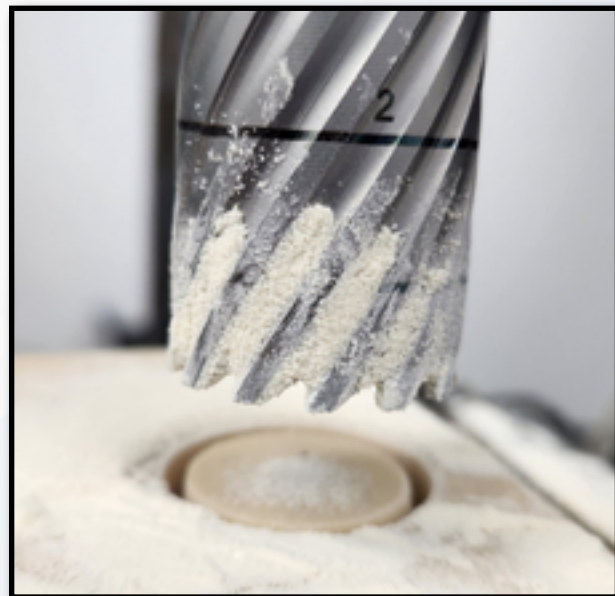
The SHUKLA Trepine is the market's most comprehensive and universally sized set of trephines currently available. It is also the only trephine set that can utilize Shukla Medical's patented and powerful Strike Plate Frame and Mallet combination. No other set out there can help guarantee you have the right trephine at the right time like the SHUKLA Trepine system.

Attention to Detail

The SHUKLA Trepine cases were designed to be as efficient and as convenient as possible for an O.R. setting. The vertically tiered design takes up minimal space on the O.R. table. This allows for the rapid identification of the proper trephines and instrumentation to use without waste.



The backend of each trephine has a combination connection end. This allows all of the SHUKLA Trepine system's trephines to connect to either an orthopedic drill natively via the Hudson adapter or the system's included slide-hammer and/or T-handle. Surgeons will be able to both impact or twist a stuck trephine rapidly without needing to swap out instrumentation. Each trephine boasts an extended length to allow it to reach the distal end of most IM nail implants and is also cannulated for alignment over the implant. The provided Extension further allows the trephine to reach through soft tissue if needed.



Our engineers designed our trephines with flared cutting teeth as well as helical paths to allow the bone chips to be pushed up and out during coring. This reduces the heat generated from cutting and therefore minimizes the risk of heat damage to the bone. It also increases the cutting speed, minimizing the bone loss incurred during the coring process.

Components List

Component List			
Std Qty	Part Number	Description	
1	SCS077	Case 1 with Lid, Universal Trephines	CASE #1
1	SIN012	Slide Hammer, Female Chuck, Adapter Cap	
1	SAD017	Adapter, Strike Plate Frame	
1	SHN031	T-Handle, Female Chuck	
1	SXN015	Extension, 6", Trephines	
4	STR001-06	Trepine, 06mm, <i>Single Use</i>	
4	STR001-07	Trepine, 07mm, <i>Single Use</i>	CASE #2
4	STR001-08	Trepine, 08mm, <i>Single Use</i>	
4	STR001-09	Trepine, 09mm, <i>Single Use</i>	
1	SCS078	Case 2 with Lid, Universal Trephines	
4	STR001-10	Trepine, 10mm, <i>Single Use</i>	
4	STR001-11	Trepine, 11mm, <i>Single Use</i>	
4	STR001-12	Trepine, 12mm, <i>Single Use</i>	
4	STR001-13	Trepine, 13mm, <i>Single Use</i>	
4	STR001-14	Trepine, 14mm, <i>Single Use</i>	
4	STR001-15	Trepine, 15mm, <i>Single Use</i>	
4	STR001-16	Trepine, 16mm, <i>Single Use</i>	CASE #3
4	STR001-17	Trepine, 17mm, <i>Single Use</i>	
4	STR001-18	Trepine, 18mm, <i>Single Use</i>	
4	STR001-19	Trepine, 19mm, <i>Single Use</i>	
1	SCS080	Case 3 with Lid, Universal Trephines	
4	STR001-20	Trepine, 20mm, <i>Single Use</i>	
4	STR001-21	Trepine, 21mm, <i>Single Use</i>	
4	STR001-22	Trepine, 22mm, <i>Single Use</i>	
4	STR001-23	Trepine, 23mm, <i>Single Use</i>	
4	STR001-24	Trepine, 24mm, <i>Single Use</i>	
4	STR001-25	Trepine, 25mm, <i>Single Use</i>	
4	STR001-26	Trepine, 26mm, <i>Single Use</i>	

Single-use Only: Always use new trephines in every procedure. Discard any used single-use parts at the conclusion of the case.



THE EXTRACTION EXPERTS

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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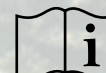
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S9TREPINE



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USA



CONSULT
INSTRUCTIONS
FOR USE



NON-STERILE
PRODUCT



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.