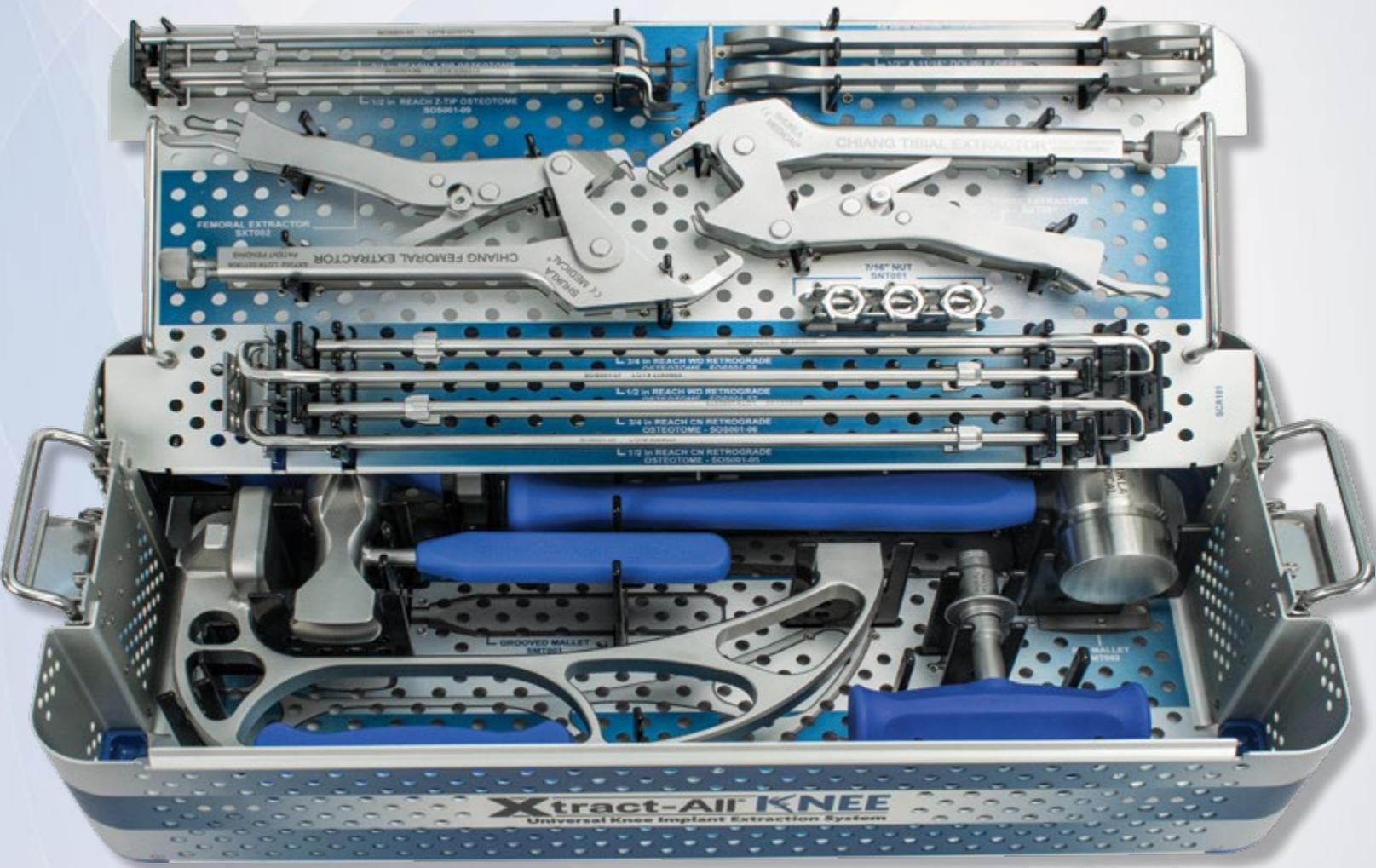


SURGICAL TECHNIQUE GUIDE

#7
System 7 of 15

SHUKLA NEE

Universal Knee Implant Extraction Solution



SHUKLA MEDICAL[®]

Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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1 SHUKLA KNEE

Universal Knee Implant Extraction Solution

1.1 System Name: SHUKLA Knee

Part Number: S9KNEE

Version: 1

1.2 Primary Use

The SHUKLA Knee Universal Implant Extraction System is designed to efficiently remove any knee implant hardware with minimal bone loss to the patient and in a more efficient manner than other methods. The critical benefit of the SHUKLA Knee is minimizing bone loss during a surgery.



1.3 System History

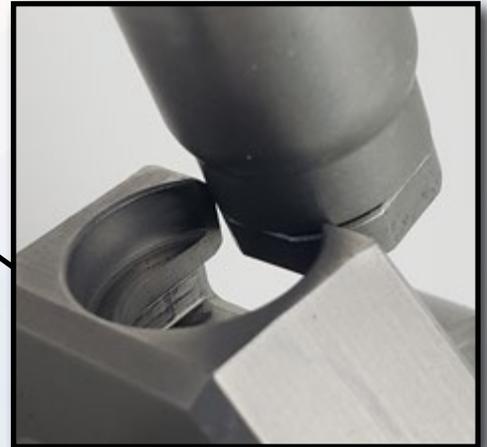
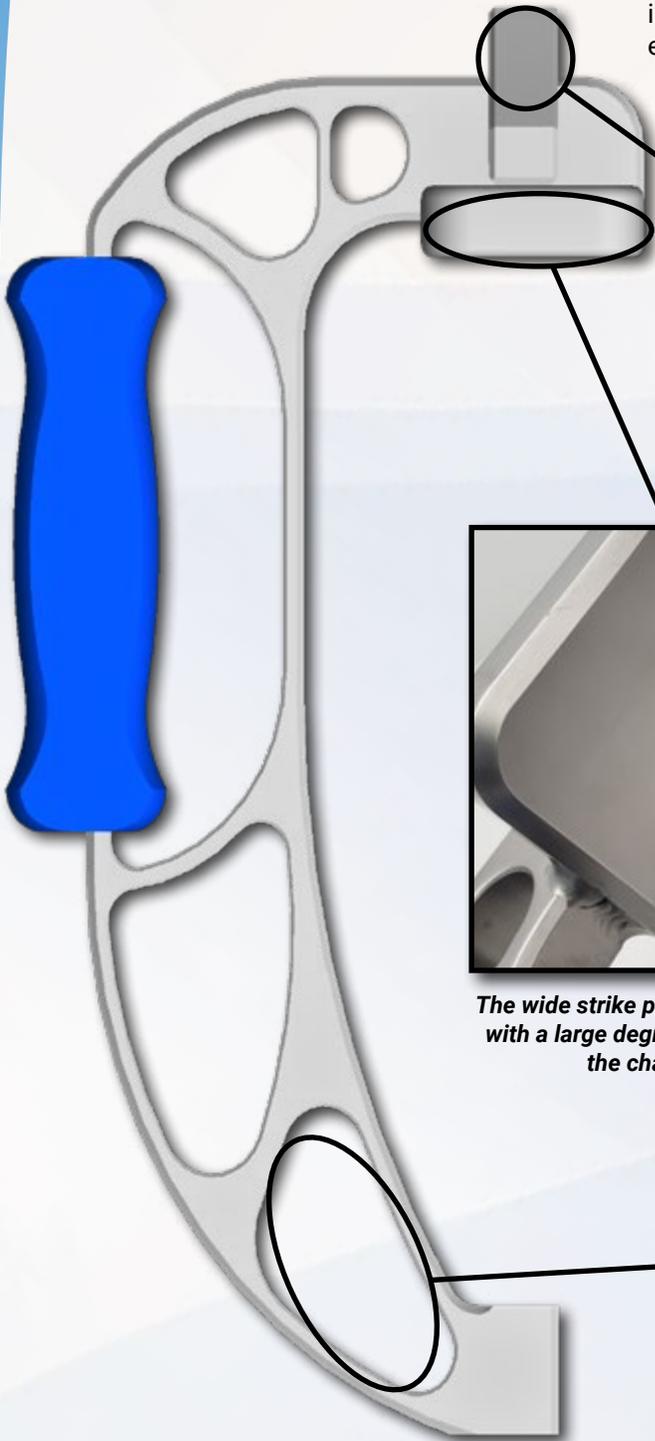
The release of the SHUKLA Hip system led Shukla Medical to meet surgeon Dr. Peter Chiang from Colorado's SCL Good Samaritan in 2011. He had purchased several of our Hip systems, and provided valuable information regarding the system's multipurpose potential for knee revisions. He was demonstrating creative solutions by combining together parts from our other sets. He pioneered using our Hook Extractors from our Winquist/SHUKLA Nail systems for knee revision. At the time, we didn't have a Knee system in development, but after witnessing Dr. Chiang's work, we became inspired.

In 2012, Dr. Chiang contacted the president of Shukla Medical for help which got the ball rolling. In 2013, Shukla Medical's Product Design Engineer Manager joined up with Dr. Chiang to tag team the challenge of creating a universal Knee system. Before our system released into the market, there had been no truly universal set available that surgeons could rely on.

2.1

STRIKE PLATE FRAME

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



A Modular T-Handle (SHN019) can be attached in two different orientations. (Not included in the SHUKLA Knee system)



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.

2.2 TIBIAL EXTRACTOR

Vise grip style extractor that can universally adjust to a wide range of styles and sizes of knee implants. It applies impaction force inline with the implant stem to minimize bone loss.



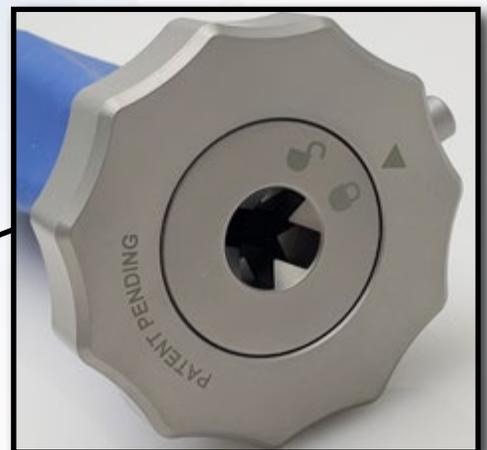
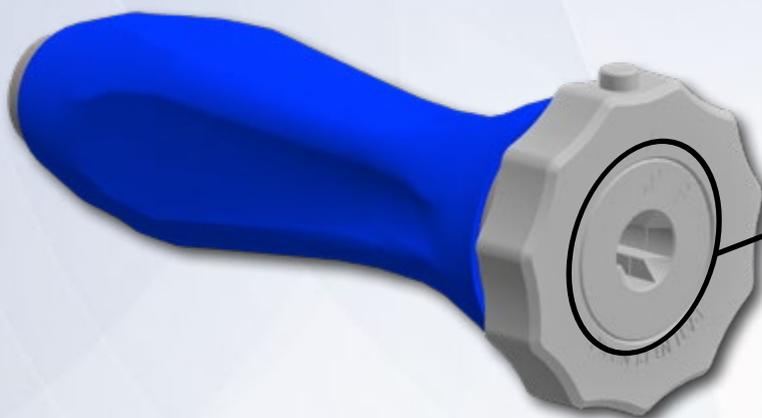
Locking button prevents accidental disengagement during use from Strike Plate Frame impacts.



Modular Jaw allows for quick replacement upon accidental damage or overuse.

2.3 TWIST-LOCK OSTEOTOME HANDLE

Possesses strike plates on both the front and the back of the handle, allowing for osteotome blades to be tapped in or out.



Locking button prevents osteotomes from dislodging during a procedure.

3.1 Preoperative

- Appropriate x-rays and surgical notes may be used to identify manufacturer, brand, location, & 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 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 Knee (S9KNEE) Universal Knee Implant Extraction System is intended for use during revision procedures for the removal of femoral & tibial knee components 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 Knee (S9KNEE) Universal Knee Implant Extraction System is indicated for use during any revision procedure in which the femoral component and/or tibial component of a knee implant must be removed.

3.6 Additional Recommendations

The SHUKLA Knee (S9KNEE) Universal Knee Implant Extraction System is recommended for use in conjunction with the SHUKLA Maxi (S9MAXI) Large Bone Screw Removal System, the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction System, and the SHUKLA Blade (S9BLADE) Universal Flexible Osteotome System.

This technique guide describes surgical instruments developed in conjunction with:

Peter P. Chiang, M.D.
Orthopedic Surgeon
Lafayette, CO

Jonathan P. Garino, M.D.
Orthopedic Surgeon
King of Prussia, PA

Retrograde & Z-Tip Osteotomes

SOS001-05 through SOS001-10

Break up bone growth & cement in the prosthesis interface by using osteotomes around all sides of the implant to minimize bone loss during extraction. Retrograde & Z-tip osteotomes in 1/2" & 3/4" sizes easily access the space beneath tibial & femoral components.

STEP 1

Choose an osteotome configuration that will access the desired area of interface between the implant and bone or bone-cement. (Image 1).

Retrograde osteotomes (Image 1A) are ideal for accessing the posterior notch of a tibial plate.

Z-tip osteotomes (Image 1B) are ideal for accessing soft tissue around the femoral component and the posterior-lateral corner of tibial components.



STEP 2

Push the osteotome into the Twist-Lock Osteotome Handle (SIN001), twisting the handle collar to lock the blade with an audible click (Image 2).



STEP 3

Use the Grooved Mallet (SMT001) to strike against the handle, breaking up the interface around all sides of the implant (Image 3).

Slide the mallet along the length of the osteotome to strike against the handle collar for retrograde force (Image 3), or strike the impact cap for antegrade force (Image 4).



Windshield Wiper Method

1. Loosen the interface beneath the posterior notch of the tibial plate using a retrograde osteotome.
2. Move the blade in a side to side pattern, like the blades of a windshield wiper (Image 5).

This applies pressure to the interface with a high mechanical advantage, allowing the curved and pointed tip to penetrate more easily.



If the osteotome cannot be advanced beneath the implant without difficulty, use a standard punch to create a groove in the posterior space to anchor the retrograde osteotome blade before advancing into the implant/bone interface with the mallet.

Tibial & Femoral Extractors

SXT001 & SXT002

Extract the tibial component using the Tibial Extractor, and the femoral component using the Femoral Extractor.

STEP 4

Screw the Connecting Rod (SSH007) into the Extractor (SXT001 or SXT002) (Image 6A). Tighten the rod using the 1/2" wrench (SWR002).

STEP 5

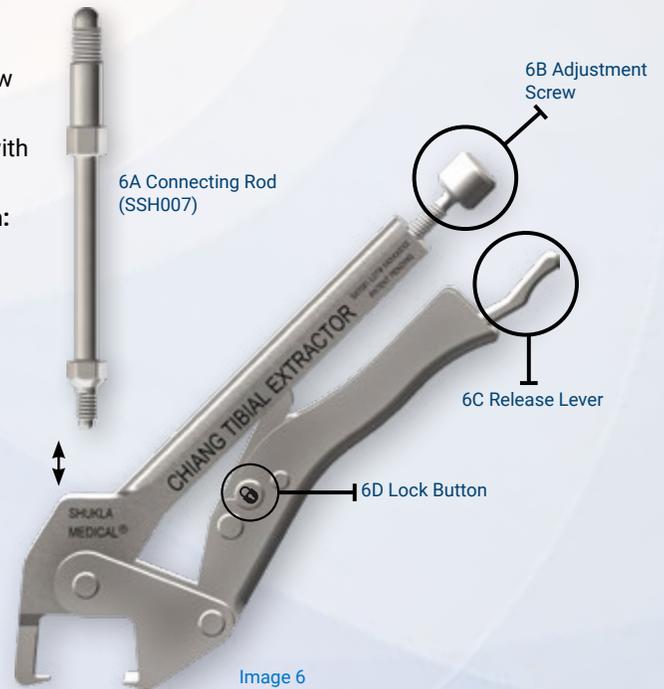
1. Adjust the jaws to fit the implant using the adjustment screw (Image 6B)
2. Position the jaws around the femoral or tibial component, with the tips beneath the implant.

A) Begin with jaws fully expanded, too large to grip down: position jaws with tips below the implant and tighten the adjustment screw until you feel resistance. Tighten another half turn and clamp down.

or

B) Begin with jaws too small for the grip to close: position the jaws with tips below the implant, hold the grip closed, & back out the adjustment screw while applying pressure until the jaw releases enough to clamp down with a click.

3. Lock the jaws onto the implant by pressing the lock button on the side (Image 6D).
4. If issues with the tibial extractor jaw occur, skip to **Step 8**.



Femoral Component

Position the jaws across the component laterally (Image 7) and adjust to clamp down securely.



Tibial Component

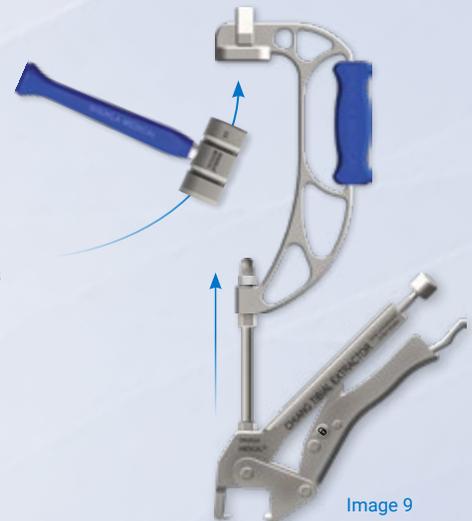
Position the jaws so that the narrow tip fits in the posterior notch of the implant, with the wider tip locking beneath the anterior face (Image 8).

STEP 6

Attach the Strike Plate Frame (SBD008) to the connecting rod. Secure with a Hex Nut (SNT001) using 1/2" and 11/16" wrenches (SWR002) to tighten.

STEP 7

Extract the implant using the Big Mallet (SMT002) to strike the Strike Plate Frame (Image 9). Ensure that the extraction assembly remains in-line with the preferred axis of extraction.



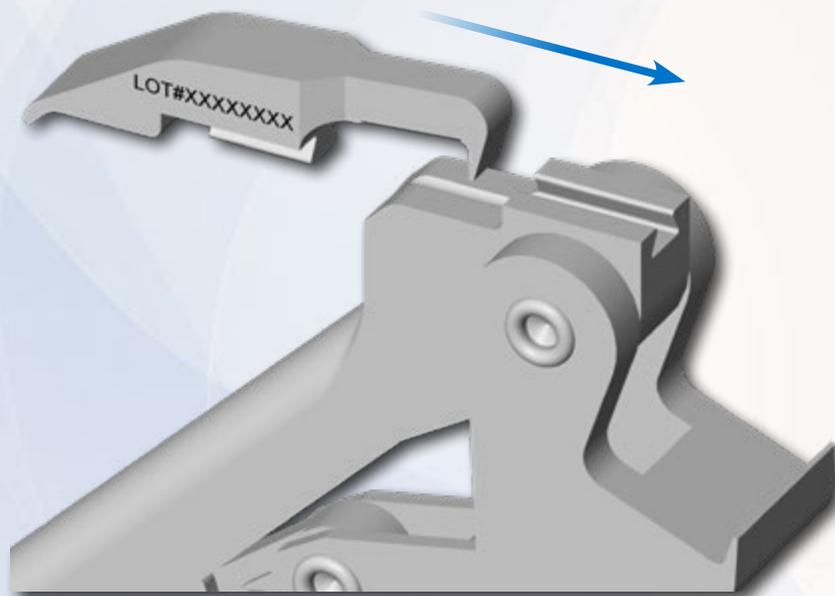
Tibial Extractor Modular Jaw

STP048

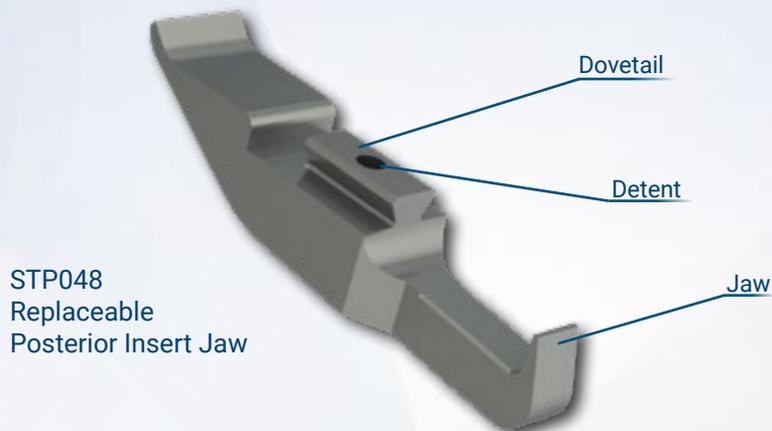
STEP
8

If the extractor is overtightened, the posterior jaw may permanently deflect. If the jaw is damaged in this way or some other way, it can be removed and replaced. To remove the jaw:

1. If the Strike Plate Frame is attached, first remove that.
2. Then, the connecting rod must be removed. The jaw cannot be removed without taking off the connecting rod because the rod provides a stop to prevent the jaw from coming out during use.
3. Once the connecting rod is removed, grab the sides of the jaw (taking care not to grab the tip of the jaw, which is sharp) and pull back. The jaw will slide off the rest of the extractor.
4. Take the new tip and line up the dovetails on the jaw and on the extractor. Slide the jaw on the extractor until you feel the detent click.
5. Reconnect the connecting rod. This will lock the jaw in place.



- **Dovetail Feature** allows for jaw insert to be replaced without the need of fasteners.
- **Revised Tibial Extractor** will fit in the existing SHUKLA Knee case. The Replaceable Jaw (**STP048**) will need to be removed for cleaning. The Tibial Extractor and Replaceable Jaw can be assembled for sterilization.



- Jaws must be fully seated beneath the implant to avoid damage to the tips.
- If bone growth limits the grip of the extractor, use osteotomes to clear room for the jaw tips.
- Check that the connecting rod is aligned with the preferred axis of extraction.
- To reposition or tighten the jaws, first push the unlock button and release the grip with the release lever. Adjust & re-clamp.

6 CLEANING & STERILIZATION

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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CONSULT
INSTRUCTIONS
FOR USE

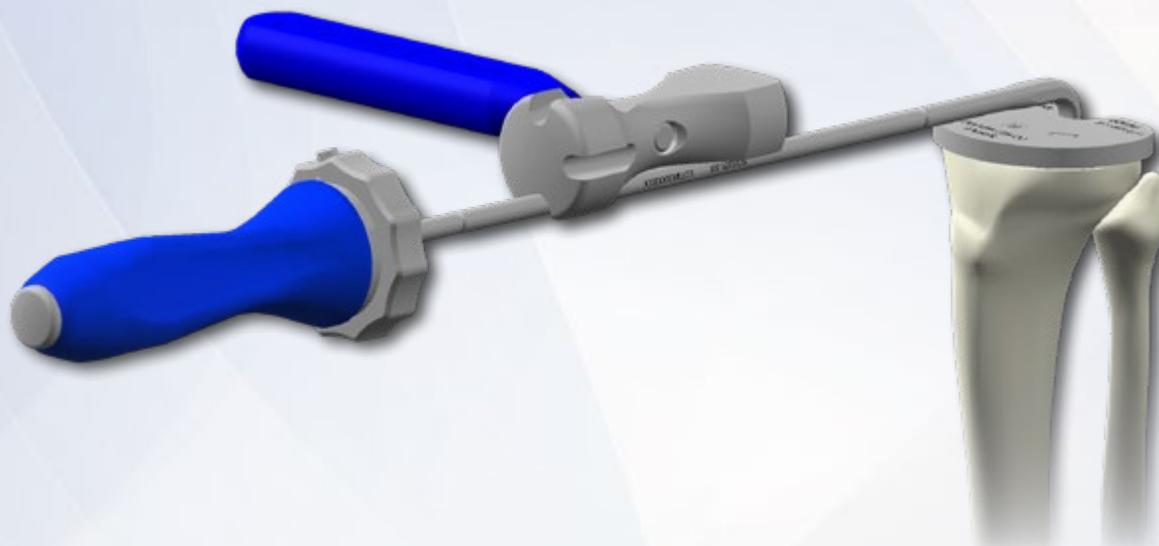


NON-STERILE
PRODUCT



7 COMPONENTS LIST

Component List		
Std Qty	Part Number	Description
1	SBD008	Strike Plate, Assy, Frame
1	SCA101	Case & Tray, Knee System
1	SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems
1	SIN001	Handle Assy, Osteotome, Twist Lock
1	SMT001	Mallet Assy, Grooved
1	SMT002	Mallet Assy, Big
3	SNT001	Nut, Hex, 7/16-20 UNF-2B
2	SOS001-05	Osteotome Assy, Retrograde, 1/2" Reach, .313" Wide
1	SOS001-06	Osteotome Assy, Retrograde, 3/4" Reach, .313" Wide
1	SOS001-07	Osteotome Assy, Retrograde, 1/2" Reach, .500" Wide
1	SOS001-08	Osteotome Assy, Retrograde, 3/4" Reach, .500" Wide
2	SOS001-09	Osteotome Assy, Z Shaped, 1/2" Reach, .313" Wide
1	SOS001-10	Osteotome Assy, Z Shaped, 3/4" Reach, .313" Wide
2	SSH007	Connector Shaft for Strike Plate
2	SWR002	Wrench, Double Open End, 1/2" & 11/16"
1	SXT001	Extractor Assy, Tibial Component
1	SXT002	Extractor Assy, Femoral Component
1	STP048	Jaw Tip, Knee Tibial Extractor, Replaceable





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

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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.