PRODUCT GUIDE



#5 System 5 of 15



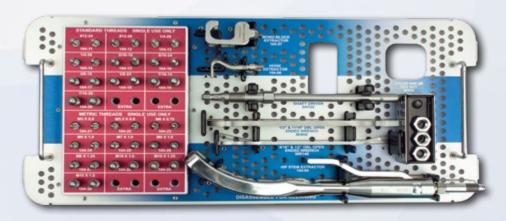




System Name: SHUKLA Hip v2

Primary Use

The SHUKLA Hip Universal Hip Stem Extraction System is designed for the removal of hip stems during revision surgeries. The system consists of a variety of instrumentation geared towards universal removal of varying designs of hip stems including Tapered Neck, Monoblock, Proximally Threaded, Slotted, and Cross Hole stems.



System History

The SHUKLA Hip system was born from the hard work of our engineers and Doctors Barsoum and Krebs from the Cleveland Clinic. The need and desire for a system to universally remove hip stems from patients arose due to the medical industry rapidly moving away from Cemented Hip Stems to Porous Coated Stems.

The Hip v1 was a solid start. The collet had four "teeth" that would thread down and grab the trunnion. We realized that we wanted to improve the grip on the trunnion, so Shukla engineers decided to add in an upgraded Universal Hip Stem Extractor and threaded tip configurations into the mix for the v2.

2010: Version 1 Introduced

2012: Version 2 Introduced

- Femoral Head Extractor
- Threaded Tip Configurations
- · Universal Hip Stem Extractor

Key Benefits

- Strike Plate Frame and Mallet combo makes extraction simple, effective, and fast.
- Extraction force remains inline with implant. This greatly reduces side-loading, reducing risk of fractures.
- Ability to remove Tapered, Monoblock, Proximally Threaded, Slotted, and Cross Hole hip stems.



 Femoral Head Extractor securely locks onto trunnion and removes the head with a pull of the lever.



- Removes the need to perform an osteotomy.
- Quick-connect Hudson T-Handle easily tightens onto threaded tips, allowing for Strike Plate Frame attachment.

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

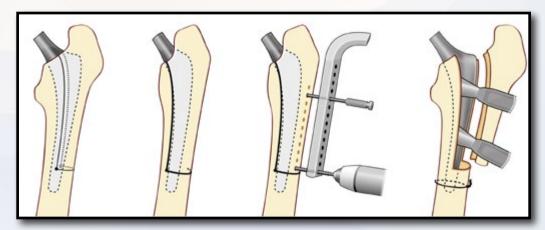
- Addresses all known challenges
- Tools ensure surgery is a success
- Provides backup solutions during surgery

Alternative Method Comparison

Without a SHUKLA Hip set, the most common alternative method in the O.R. is to perform an osteotomy. An osteotomy is a surgical operation whereby part of the bone is removed to allow easier access to the implant. Think of it as a surgery within a surgery. Some surgeons are actually trained in school to resort to an osteotomy if a procedure looks as if it will take longer than fifteen minutes - this is something Shukla strives to help correct. With a SHUKLA Hip system, you can reduce the amount of osteotomies by a staggering amount.

Benefits to Avoiding an Osteotomy

- · Reduces risk of infection
- Reduces risk of nonunion fractures
- Reduces risk of complication due to bone loss
- · Reduces need for physical therapy
- Reduces cost to hospital
- Reduces length of hospital stay for patient



Visual representation of an Extended Trochanteric Osteotomy procedure.

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 30 minutes x \$36 per minute = \$1,080. With the SHUKLA Hip system, a hip stem extraction that would normally take anywhere between one to two hours or more can be done in much less time! Between that and the time saved not having to hunt down the proper rep or extractor for the procedure, the SHUKLA Hip system is easy to justify. In fact, a SHUKLA Hip sells for \$20,500. With an average time saved in the O.R. being around an hour per use, the system recoups its cost in just nine cases!

When You Don't Have It

When using a hip stem extraction system from our competitors, you immediately run into the "Three Strikes" of extraction for hip stems.

- **STRIKE ONE** Competitor's system extractors are not inline with the hip stem itself, wasting up to 60% of the force exerted and increasing the risk of fractures.
- **STRIKE TWO** Failing to get a good "bite" on the trunnion, resulting in wasted time and effort for the surgeon.
- STRIKE THREE The inefficiency of the traditional slap hammer system. The slap hammer does not generate significant force on the implant, does not employ vibrational harmonics, and leads to both increased surgeon fatigue as well as wasted time in the O.R.

The SHUKLA Hip system directly counters all of those strikes.

- **COUNTER STRIKE ONE** Our extractors are all inline with the hip stem, leading to a quicker extraction and a greater reduction in the risk of a fracture.
- COUNTER STRIKE TWO Our methods of extraction don't slip off the trunnion once clamped down. This ensures that a surgeon will not waste time trying to get the needed "bite" in order to extract.
- COUNTER STRIKE THREE Our Strike Plate Frame and Mallet combo offer unparalleled vibrational harmonics and impact force control that facilitates the separation of the implant to bone growth interface. This leads to quicker extraction, less surgeon fatigue, and less time spent in the O.R.

How We Compare

Most orthopaedic 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.

Our competitor's extractors primarily use slap-hammers which do not provide as much extraction force. Only the SHUKLA Hip offers a Hip Stem Extractor to allow for the use of a strike plate frame and "Thor" mallet to generate much higher extraction force. In addition, it can adjust to any diameter of trunnion and offers a 360-degree grip for superior positioning.

Some competitor's extraction instruments apply the extraction force in-line with the trunnion which can fracture proximal bone. The SHUKLA Hip Stem Extractor ensures the extraction force is applied directly in-line with the hip stem which minimizes bone loss.

PATENT

Strike Plate Frame

The engineers at Shukla are the best at what they do. They've worked hard to create ingenious patented items like our Strike Plate Frame.



Strike Plate

The wide strike plate allows surgeons to hit the "sweet spot" with a much larger degree of accuracy. This reduces the chance of a mishit which could result in unwanted lateral force.

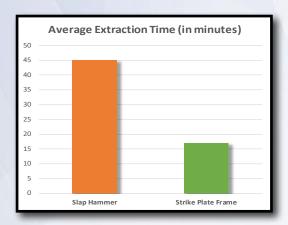


Our Strike Plate Frame features an integrated connection adaptor as well as an integrated t-handle for proper grippage. The body has been reinforced to help withstand the immense vibrational harmonics that occur with every strike.



Mallet

Stainless steel head and aluminum handle allow for precise blows to the Strike Plate for exceptional extraction force.





Comparisons between the efficiency of the Strike Plate Frame and a standard slap-hammer.

Attention to Detail

Every aspect of the SHUKLA Hip system is the result of our engineers being hyper focused on quality, ease of use, and universal compatibility. Their eye for detail serves the Hip system well, with everything from the Femoral Head Extractor to the Strike Plate Frame getting serious time put into it.



The Strike Plate Frame has more modes of frequency than a slap hammer, which vibrates the bone-implant interface with each hit. Because bone has a complex shape and its density varies throughout, varied frequencies are more important than amplitude of frequencies. This increases the likelihood of matching the bone's natural frequency and thus weakening and loosening the implant.

The SHUKLA Hip system has dedicated methods for extracting all types of hip stem configurations - from Monoblock, to Slotted, to Cross Hole, to Threaded, and more. If it is a Hip Stem, we are going to get it out.

The Universal Hip Extractor Assembly attaches to hip stems inline with the implant itself, allowing for reduced risk of fracture and maximum application of extraction force.



Components List

Component List			
Std Qty	Part Number	Description	
1	104-01	Case, Hip System	
1	104-04	Extractor Assy, Stem, Cam lock	
1	104-05	Extractor Assy, Femoral Head	
1	104-06	Extractor, Stem, Hook	
1	104-07	Extractor, Stem, Monoblock Assy	
1	104-08	Tray, Hip System	
2	104-11	Tip, Male, 12-24 UNC-2A, Single Use	
2	104-12	Tip, Male, 12-28 UNF-2A, Single Use	
2	104-13	Tip, Male, 1/4-20 UNC-2A, Single Use	
2	104-14	Tip, Male, 1/4- 28 UNF-2A, Single Use	
2	104-15	Tip, Male, 5/16- 18 UNC-2A, Single Use	
2	104-16	Tip, Male, 5/16-24 UNF-2A, Single Use	
2	104-17	Tip, Male, 3/8-16 UNC-2A, Single Use	
2	104-18	Tip, Male, 3/8-24 UNF-2A, Single Use	
2	104-19	Tip, Male, 7/16-14 UNC-2A, Single Use	
2	104-20	Tip, Male, 7/16-20 UNF-2A, Single Use	
2	104-21	Tip, Male, M5 X 0.8-6g, Single Use	

Component List			
Std Qty	Part Number	Description	
2	104-22	Tip, Male, M5.5 X 0.9-6g, Single Use	
2	104-23	Tip, Male, M6 X 0.75-6g, Single Use	
2	104-24	Tip, Male, M6 X 1.0-6g, Single Use	
2	104-25	Tip, Male, M7 X 1.0-6g, Single Use	
2	104-26	Tip, Male, M8 X 1.0-6g, Single Use	
2	104-27	Tip, Male, M8 X 1.25-6g, Single Use	
2	104-28	Tip, Male, M10 X 1.0-6g, Single Use	
2	104-29	Tip, Male, M10 X 1.25-6g, Single Use	
2	104-30	Tip, Male, M10 X 1.50-6g, Single Use	
1	MIWE	Strike Plate Frame Assy, with Handle	
3	MIWN	Nut, Hex, 7/16-20 UNF-2B	
1	MIWW	Wrench, Double Open End, 1/2" & 11/16"	
1	MMI1222	THandle, Assy, Quick Connect, Hudson	
1	МММ5	Mallet Assy	
1	SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems	
2	SH700	Connector Shaft for Strike Plate	
1	WR140	Wrench, Double Open End, 5/16" & 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.