

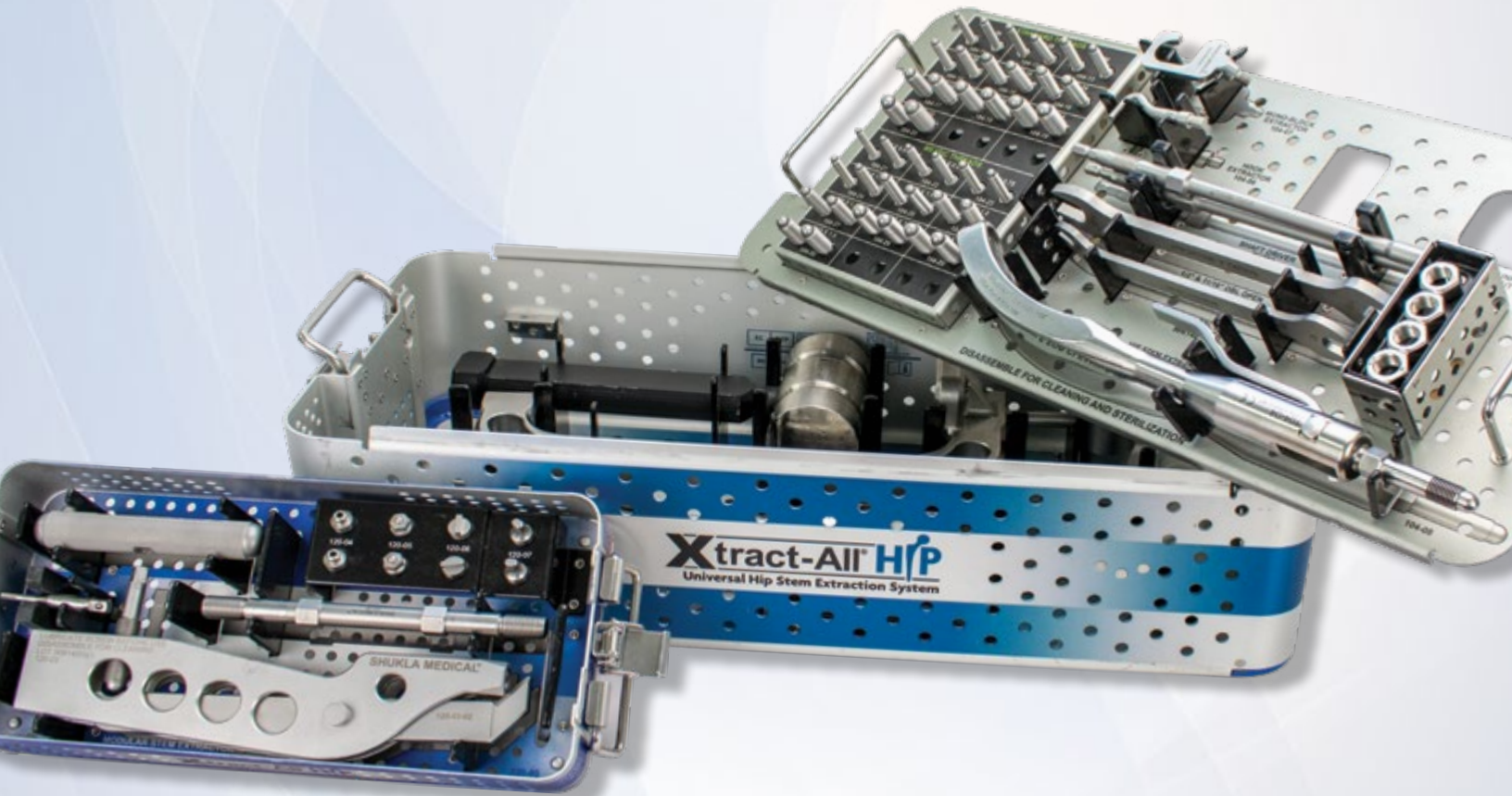
SHUKLA HIP

Universal Hip Implant Extraction Solution

and

MOD SHUKLA HIP

Universal Hip Implant Extraction Solution



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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SHUKLA HIP

Universal Hip Implant Extraction Solution

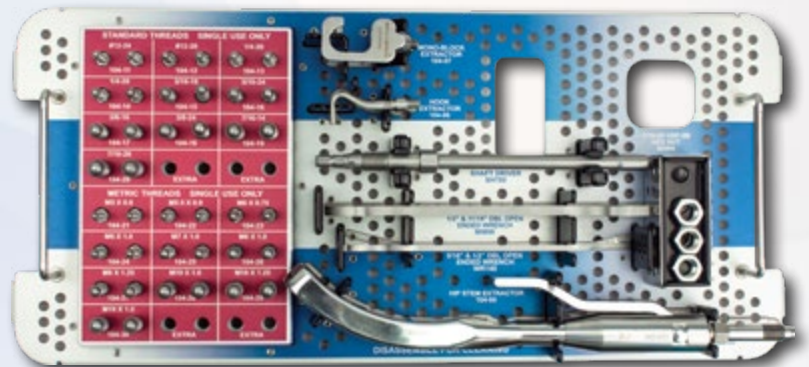
System Name: SHUKLA Hip

Part Number: S9HIP

Version: 2

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.



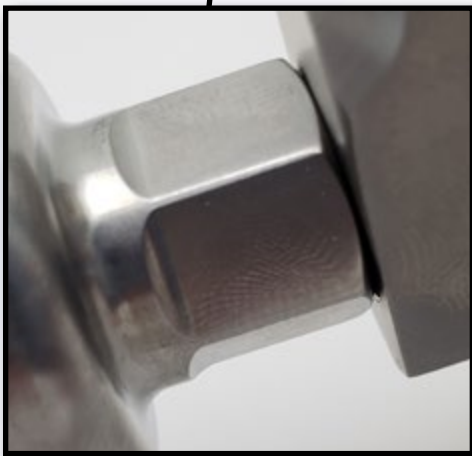
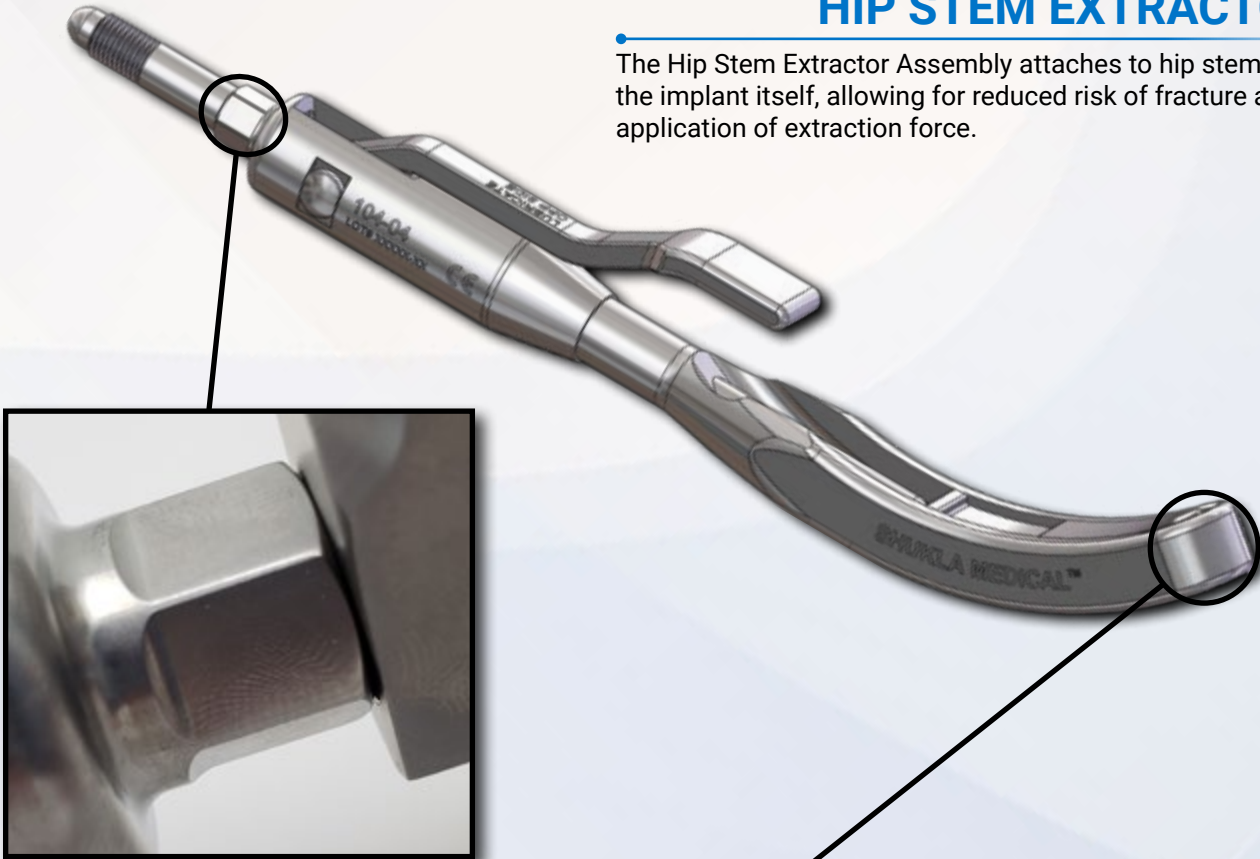
System History

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, but suffered from difficulty of the stem extractor properly gripping the hip stem. The collet had four “teeth” that would thread down and grab the trunnion, but the grip had difficulty staying. So Shukla engineers decided to add in an upgraded Universal Hip Stem Extractor and threaded tip configurations into the mix.

HIP STEM EXTRACTOR

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



The Hip Stem Extractor securely connects to the Strike Plate Frame allowing for inline extraction.



Teeth on the inside clamp down on the trunnion when the camlock is engaged.



The Modular Hip Stem Extractor's T-Handle tightens the jaw onto the modular hip stem, securing it into place.

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.



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

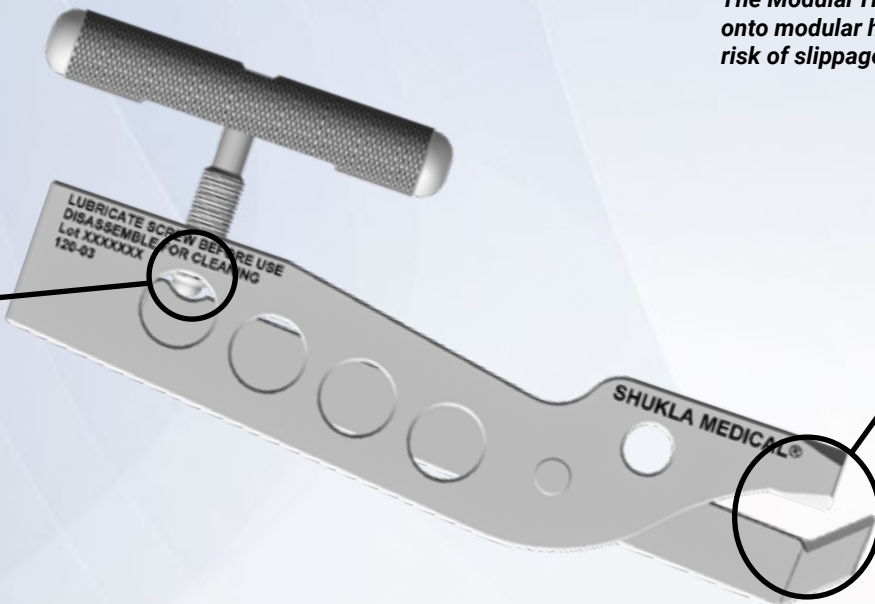


The wide strike plate allows surgeons to hit with a large degree of accuracy, reducing the chance of mishits.



MODULAR HIP STEM EXTRACTOR

The Modular Hip Stem Extractor is designed to aggressively attach onto modular hip stems. The strong grip helps with eliminating the risk of slippage.



The jaw clamps down onto the modular hip stem, securing it in place for extraction.

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.

Operative

- The surgeon should be cautious with limb position change and/or excessive force exertion while 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; $\leq 75^{\circ}\text{F}/24^{\circ}\text{C}$.
- Proper handling and storage of the instrumentation is mandatory. Long-term use of this system may produce stresses and cause weakness, which could become a focal point for failure.

Intended Use

The SHUKLA Hip (S9HIP, prev. 104-00) Universal Hip Implant Extraction Solution is designed for the removal of femoral hip components, especially hip stems, during revision procedures.

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 Hip (S9HIP, prev. 104-00) Universal Hip Implant Extraction Solution is indicated for use during any revision procedure in which femoral hip components must be extracted, including but not limited to tapered neck, monoblock, threaded, & modular stems.

Contraindications

The SHUKLA Hip System includes multiple attachment methods specific to a variety of hip stem implant styles. All attachment configurations ultimately connect to the Strike Plate Frame and require repeated strikes with a mallet to extract the implant. Therefore, when there is insufficient quality or quantity of bone, or any other condition that may result in fracture of the femur during extraction, the provided instrumentation should not be used.

Listed below are possible (not inclusive) scenarios in which the SHUKLA Hip System should not be used:

- **Fully porous-coated straight and bowed stems:** Due to the excessive bone ingrowth on fully porous-coated straight and bowed stems, it is not recommended to use this system for removal of such implants.
- **Foreign body sensitivity:** Where material sensitivity is suspected, appropriate tests should be performed to rule out sensitivity prior to use.

Additional Recommendations

If extracting a modular hip stem, or if there is any possibility that a hip component could be modular, it is recommended to use the SHUKLA Mod Hip (S9HIP-MOD, prev. 120-00) Universal Modular Hip Stem Extraction Solution in conjunction with the SHUKLA Hip.

For complete revision solutions, it is also recommended to use the SHUKLA Hip system in conjunction with the SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Extraction Solution, the SHUKLA Maxi (S9MAXI) Universal Large Bone Screw Extraction Solution, and the SHUKLA Blade (S9BLADE) Universal Flexible Osteotomes Solution.

1 Determine Stem Type

For the best possible surgical outcome of the SHUKLA Universal Hip Stem Extraction System (S9HIP), it is necessary to preoperatively determine if the hip stem is a standard stem or a modular stem.

Removal of a modular stem requires the SHUKLA Modular Hip Stem Extraction System (S9HIP-MOD) in addition to the standard system (S9HIP). See page 11.



Tapered Neck Stem



Monoblock Stem



Proximally Threaded Stem



Modular Stems



2 Femoral Head Removal

1. Rotate knob in center of Femoral Head Disassembly Instrument (104-05) until the inner sleeve is fully descended, such that the inner and outer sleeves are nested together at the distal end.
2. Slide the instrument onto the hip implant neck, with the femoral head inside the nested sleeves.
3. Rotate knob to adjust sleeve spacing, raising the inner sleeve until it rests against the femoral head and the outer sleeve rests against the femoral neck (Fig. 2a).
4. Press handle toward instrument body (Fig. 2b) to detach femoral head from neck.
5. The femoral head is retained inside the inner sleeve for easy disposal.



Figure 2a

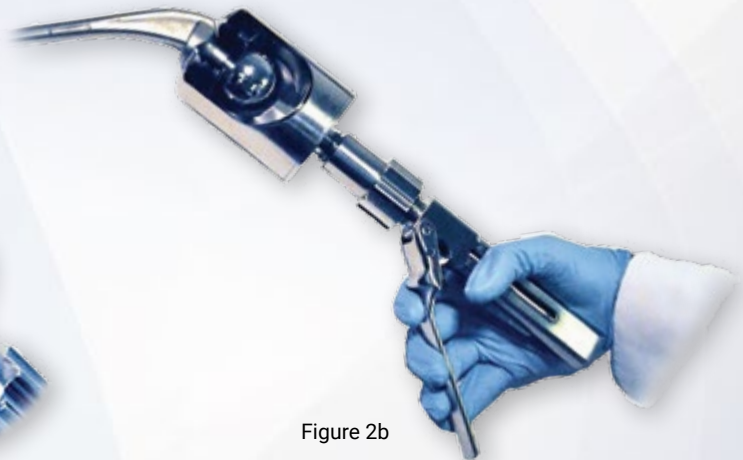


Figure 2b

3 Tapered Neck Stem Removal

1. With handle in open position, slide Hip Stem Extractor (104-04) over implant neck as far down as possible. Rotate the extractor handle counter-clockwise to loosen the jaw if necessary (Fig 3a).

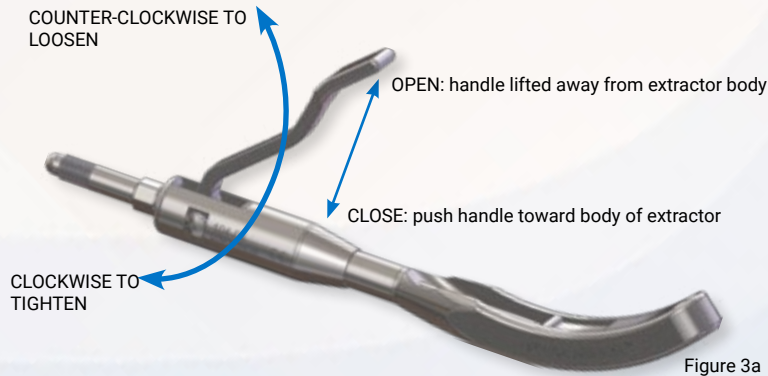


Figure 3a

2. Tighten jaw grip by rotating handle clockwise. Tighten as far as possible, then reverse 180° to close the handle. Stop when you first experience resistance - the jaw has begun to clamp onto the neck. **Check to ensure the extractor axis is in line with the hip stem before closing fully.** Make manual adjustment if not aligned properly (Fig. 3b).



Figure 3b: Alignment of extractor to hip stem

3. Press handle toward extractor body until it locks completely closed. Handle must close fully to ensure a secure grip on the implant neck. Confirm secure attachment by pulling slightly.
4. With extractor aligned and securely locked onto hip stem, slide the Strike Plate Frame (MIWE) and a Hex Nut (MIWN) onto the proximal end. Tighten nut fully with the 11/16" Wrench (MIWW) while applying counter-torque with the 1/2" Wrench (WR140).
5. Extract implant with repeated strikes of the Mallet (MMM5) on extraction Strike Plate Frame (Fig. 3c). If implant resists removal after several strikes, loosen bone around implant prior to continuing.
6. After implant is pulled free from the femur, open extractor & remove implant from extraction assembly.

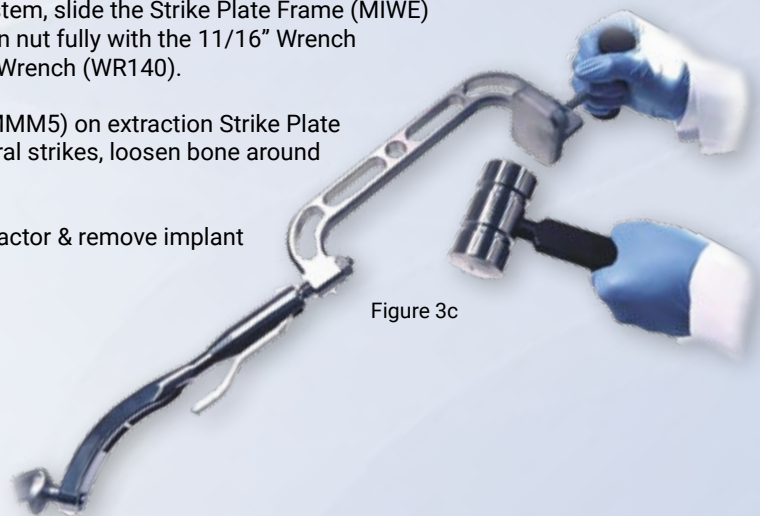


Figure 3c

4 Monoblock Stem Removal

1. Thread Monoblock Stem Extractor (104-07) onto Shaft Driver (SH700).
2. Slide the Strike Plate Frame (MIWE) and a Hex Nut (MIWN) onto the proximal end. Tighten nut fully with the 11/16" Wrench (MIWW) while applying counter-torque with the 1/2" Wrench (WR140).
3. Hook Monoblock Stem Extractor around implant neck (Fig. 4).
4. **Keeping impaction force in line with the axis of the implant**, use repeated strikes of the Mallet (MMM5) on the strike plate to extract stem. If implant resists removal after several strikes, loosen bone around implant prior to continuing.



Figure 4

5 Slotted or Cross Hole Stem Removal

1. Thread Hook Extractor (104-06) onto Shaft Driver (SH700).
2. Slide the Strike Plate Frame (MIWE) and a Hex Nut (MIWN) onto the proximal end. Tighten nut fully with the 11/16" Wrench (MIWW) while applying counter-torque with the 1/2" Wrench (WR140).
3. Hook the extractor through the cross hole shaft (Fig. 5).
4. **Keeping impaction force in line with the axis of the implant**, use repeated strikes of the Mallet (MMM5) on the strike plate to extract stem. If implant resists removal after several strikes, loosen bone around implant prior to continuing.



Figure 5

6 Threaded Stem Removal

1. Determine size of threaded implant neck and select corresponding single-use Extractor Tip (104-11 through 104-30).
2. Screw selected Extractor Tip into Shaft Driver. Then attach Shaft Driver (SH700) to Hudson T-Handle (MMI1222) by pulling handle shaft up, inserting & aligning the driver, & releasing handle to lock in place.
3. Use the T-handle to screw the Shaft Driver assembly tightly into implant neck (Fig. 6a).
4. Remove T-handle from Shaft Driver. Slide the Strike Plate Frame (MIWE) and a Hex Nut (MIWN) onto the proximal end. Tighten nut fully with the 11/16" Wrench (MIWW) while applying counter-torque with the 1/2" Wrench (WR140).
5. Extract implant with repeated strikes of the Mallet (MMM5) on the strike plate (Fig. 6b). If implant resists removal after several strikes, loosen bone around implant prior to continuing.
6. After extraction, use wrenches to remove Extractor Tip from assembly and discard.

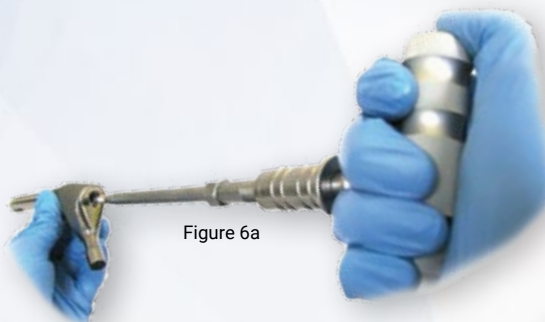


Figure 6a

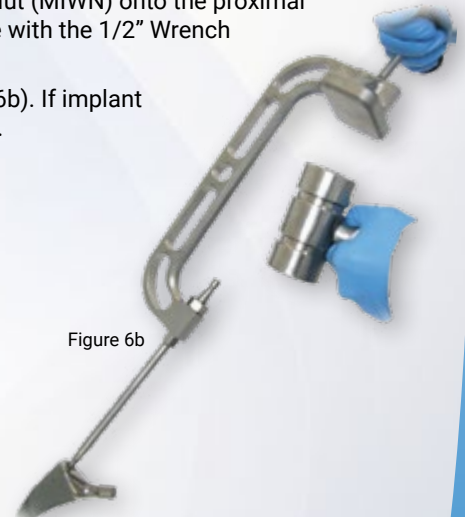


Figure 6b

MOD SHUKLA HIP

Universal Hip Implant Extraction Solution

System Name: SHUKLA Mod Hip v1

Part Number: S9HIP-MOD

Version: 2

Primary Use

SHUKLA Mod Hip is an accessory system, intended to be used with the SHUKLA Hip Mallet & Strike Plate Frame instrumentation.

The system includes multiple tip configurations for universal compatibility with any modular hip stem.



System History

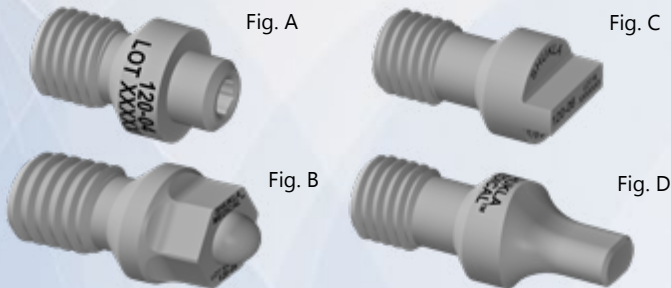
Work on the Modular Hip system began right after the main Hip system launched thanks to a surgeon from Wisconsin. Due to a nationwide recall on a modular hip stem, the call went out for revisions.

Osteotomies were being ordered for everyone affected - over 170 of them by that surgeon alone! A Shukla engineer flew out to Wisconsin to help design a modular hip extractor. This would go down as the fastest product development cycle ever for Shukla Medical.

The SHUKLA Modular Hip Stem Extraction System (S9HIP-MOD) should be used in conjunction with the SHUKLA Hip System (S9HIP) when removing any modular hip stem.

- 1 Choose Clamping Pin (120-04 through 120-07) that corresponds to implant.

- 120-04 Stryker Rejuvenate (Fig. A)
- 120-05 Smith & Nephew (Fig. B)
- 120-06 Wright Medical (Fig. C)
- 120-07 Zimmer (Fig. D)



- 2 Screw Clamping Pin into Modular Hip Stem Extractor (120-03). Loosen extractor jaw to improve access if necessary.

- 120-04 may be tightened manually or with the 3.0mm Driver Bit (MBT130) (Fig. E).
- 120-05 should be tightened manually
- 120-06 & 120-07 should be screwed in manually and will spin freely when fully engaged.



- 3 Align Clamping Pin with implant and fit extractor lever hook into vacated trunnion fitting (Fig. F, Fig. G).



- 4 Attach T-Handle (HD218-M01) to Clamping Screw (Fig. H) by pushing until you hear a click.

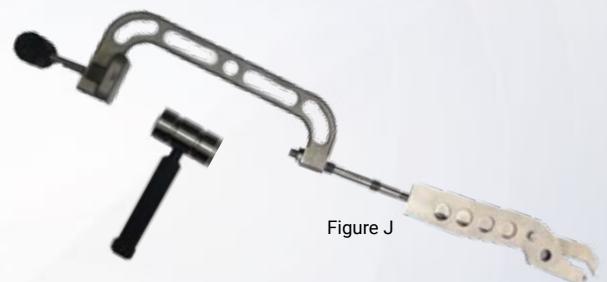


- 5 Tighten Clamping Screw with T-Handle until you begin to experience resistance. At this point, tighten the screw 1/2 to 1 full turn maximum past this point. **Do not over-tighten.** The extractor is now fully engaged (Fig. I).



- 6 Remove T-Handle from Clamping Screw. Screw Extension Adapter (120-08) into Extractor. Slide the Strike Plate Frame (MIWE) and a Hex Nut (MIWN) onto the proximal end. Tighten nut fully with the 11/16" Wrench (MIWW) while applying counter-torque with the 1/2" Wrench (WR140).

- 7 Extract implant with repeated strikes of the Mallet (MMM5) on the strike plate (Fig. J). If implant resists removal after several strikes, loosen bone around implant prior to continuing.



For detailed sterilization instructions, please refer to industry standards ANSI/AAMI ST79:2012 & A1:2012 and ANSI/AAMI ST8:2001.

NOTE: 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.

The instrument case must be sterilized following the parameters listed below:

Sterilizer Type: Prevacuum
Preconditioning Pulses: 4
Temperature: 132° C
Full Cycle Time: 4 minutes

Dry Time: 60 minutes
Open Door Time: 15 minutes
Cool-down Time: 30 Minutes outside of chamber on a wire rack

For detailed cleaning and sterilization instructions, please visit www.ShuklaMedical.com/Sterilization

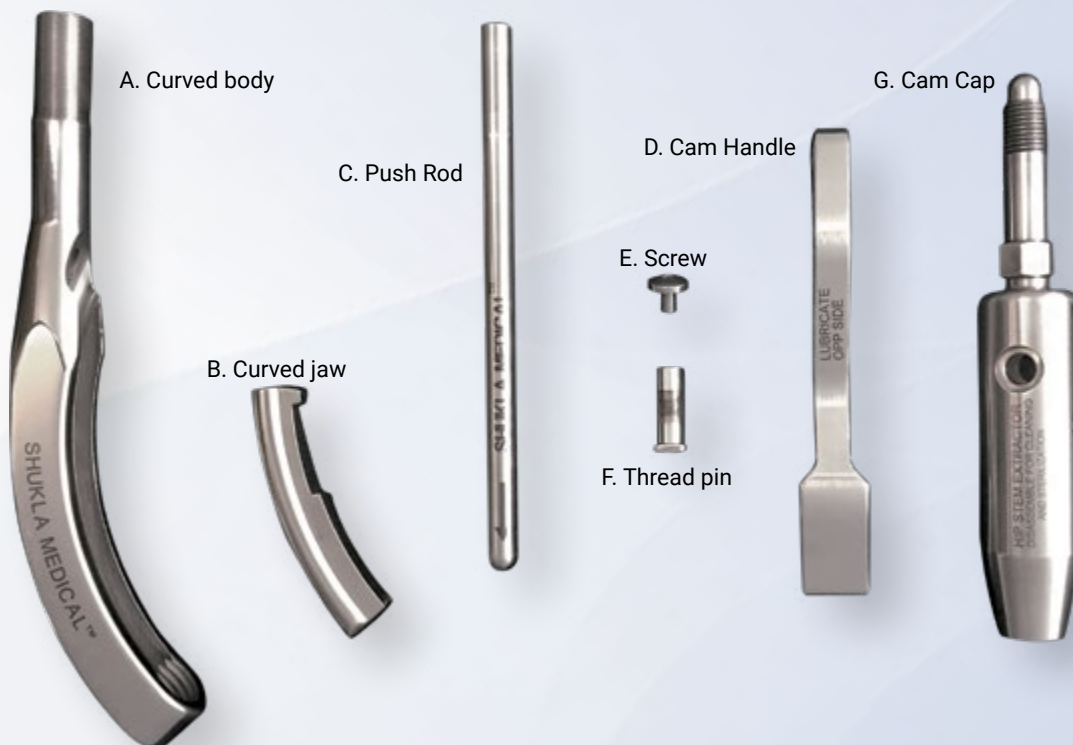
Disassembly Instructions: Hip Stem Extractor

SHUKLA Universal Hip Stem Extractor Assembly (104-04) must be disassembled completely for cleaning. All contamination must be removed at this stage. The extractor must be reassembled prior to sterilization.

1. Unscrew the cam cap by lifting the cam handle & turning counterclockwise
2. Remove the push rod from inside the assembly
3. Grasp the curved jaw and slide out from the curved body
4. Unthread the cam cap screw from the pin using 3mm hex key (not included)
5. Pull the cam handle free from the instrument

Disassembled extractor should result in a total of seven (7) pieces:

- A. Curved body (104-04-01)
- B. Curved jaw (104-04-02)
- C. Push rod (104-04-15)
- D. Cam handle (104-04-17)
- E. Screw (104-04-12)
- F. Thread pin (104-04-10)
- G. Cam Cap (104-04-07)



Reassembly Instructions: Hip Stem Extractor

Once all contamination has been removed from the disassembled extractor, the instrument must be reassembled for sterilization.



1. Insert cam handle into cam cap, lining up holes.



2. Insert threaded pin into holes.



3. Insert screw into threaded pin; tighten using 3mm hex key (not included).



4. Insert curved jaw into curved body. There is an arrow on the jaw to indicate direction.



5. Insert push rod into the curved body, resting on top of the curved jaw. Use the arrow on the jaw as a directional guide.



6. Connect the cam cap/handle assembly to the curved body/jaw assembly via the push rod.

Disassembly Instructions: Modular Hip Extractor

The Modular Hip Stem Extractor must be disassembled for cleaning.

1. Use T-handle to loosen extractor jaw and remove Clamping Screw.
2. Unscrew the knurled pivoting screw (Fig. A-1) and remove pivoting body and lever (Fig. A-2).
3. Unscrew Clamping Pin from Extractor tip.
4. Clean extractor as normal.
5. Reassemble prior to sterilization.

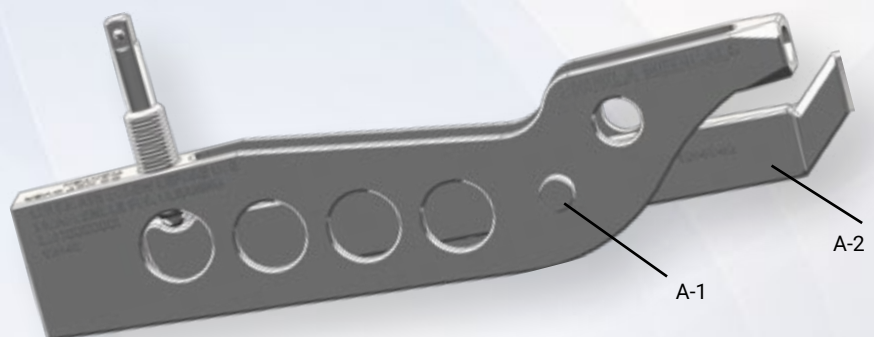


Figure A

EC REP
 Emergo Europe
 Prinsessegracht 20
 2514 AP The Hague
 The Netherlands

REF
 S9HIP
 S9HIP-MOD
 104-00
 120-00

SHUKLA Medical
 8300 Sheen Drive
 St. Petersburg, FL 33709
 USA

i CONSULT
 INSTRUCTIONS
 FOR USE

CE
 NON-STERILE
 PRODUCT

- Use universal flexible osteotomes (S9BLADE) to remove bone ingrowth from around the implant before proceeding with the extraction to reduce the risk of fractures and to minimize bone loss.
- The Strike Plate Frame can be oriented in two different positions based on either surgeon preference or surgical necessity.
- The Strike Plate Frame can be used in place of a traditional slap-hammer for increased impact strength, vibrational harmonics, and decreased time until extraction.
- If the Hip Stem Extractor's camlock is not properly clamping down onto the hip stem's trunnion, reverse the handle (counter clockwise motion) to loosen it before trying again.
- If the Hip Stem Extractor can rotate around the implant after clamping down onto the trunnion, it needs to be tightened. Rotate handle in a clockwise direction and attempt again.

Components List

Component List - HIP		
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, <i>Single Use</i>
2	104-12	Tip, Male, 12-28 UNF-2A, <i>Single Use</i>
2	104-13	Tip, Male, 1/4-20 UNC-2A, <i>Single Use</i>
2	104-14	Tip, Male, 1/4-28 UNF-2A, <i>Single Use</i>
2	104-15	Tip, Male, 5/16-18 UNC-2A, <i>Single Use</i>
2	104-16	Tip, Male, 5/16-24 UNF-2A, <i>Single Use</i>
2	104-17	Tip, Male, 3/8-16 UNC-2A, <i>Single Use</i>
2	104-18	Tip, Male, 3/8-24 UNF-2A, <i>Single Use</i>
2	104-19	Tip, Male, 7/16-14 UNC-2A, <i>Single Use</i>
2	104-20	Tip, Male, 7/16-20 UNF-2A, <i>Single Use</i>
2	104-21	Tip, Male, M5 X 0.8-6g, <i>Single Use</i>

Component List - HIP		
Std Qty	Part Number	Description
2	104-22	Tip, Male, M5.5 X 0.9-6g, <i>Single Use</i>
2	104-23	Tip, Male, M6 X 0.75-6g, <i>Single Use</i>
2	104-24	Tip, Male, M6 X 1.0-6g, <i>Single Use</i>
2	104-25	Tip, Male, M7 X 1.0-6g, <i>Single Use</i>
2	104-26	Tip, Male, M8 X 1.0-6g, <i>Single Use</i>
2	104-27	Tip, Male, M8 X 1.25-6g, <i>Single Use</i>
2	104-28	Tip, Male, M10 X 1.0-6g, <i>Single Use</i>
2	104-29	Tip, Male, M10 X 1.25-6g, <i>Single Use</i>
2	104-30	Tip, Male, M10 X 1.50-6g, <i>Single Use</i>
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	MM1222	THandle, Assy, Quick Connect, Hudson
1	MMM5	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"

Component List - HIP-MOD		
Part #	Description	Std Qty
120-01	Case, Modular Hip System	1
120-02	Lid, Modular Hip System	1
120-03	Extractor Assy, Modular Stem	1
120-04	Tip, Modular Stem, Stryker	2
120-05	Tip, Modular Stem, Smith & Nephew	2
120-06	Tip, Modular Stem, Wright Medical	2
120-07	Tip, Modular Stem, Zimmer	2
120-08	Connector Shaft, Strike Plate to Extractor, 7/16-20 UNF 2A both ends	1
HD218	THandle Assy, Square, 1/4"	1
MBT130	Tip Assy, Hex, Male, 3 mm	1

For use in conjunction with the SHUKLA Hip (S9HIP)



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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