SURGICAL TECHNIQUE GUIDE

#5-6
Systems 5 & 6 of 25

SHUKLA HIP

Universal Hip Implant Extraction System

and

MOD SHUKLA HIP

Universal Hip Implant Extraction System

SHUKLA MEDICAL®
Universal Orthopedic Extraction Technologies
THE EXTRACTION EXPERTS

CONTENTS

1

SHUKLA HIP

Universal Hip Implant Extraction System

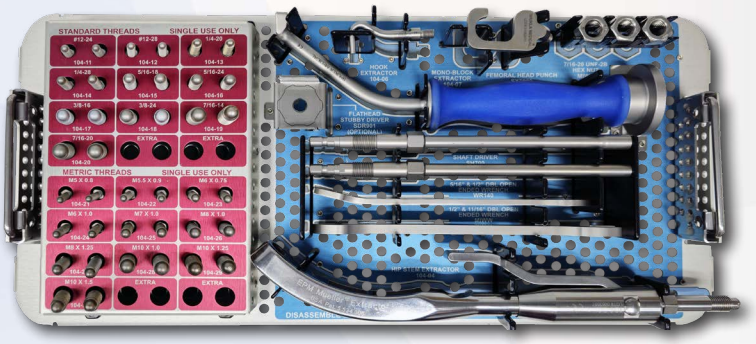
1.1 System Name: SHUKLA Hip

Part Number: S9HIP

Version: 1

1.2 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.



1.3 System History

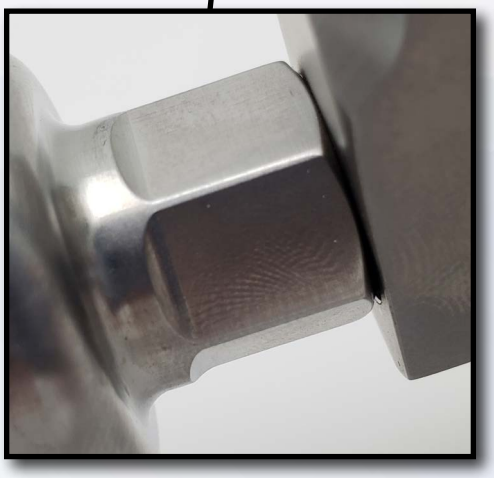
The SHUKLA Hip system was born from the hard work of our engineers and Doctors Barsoum and Krebs from the Cleveland Clinic. The need and desire for a system to universally remove hip stems from patients arose due to the medical industry rapidly moving away from Cemented Hip Stems to Porous Coated Stems.

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 as running changes.

As the lead up to the true fully fledged upgrade in Hip v2, the engineers made more running changes. This half step brings the SHUKLA Hip’s Strike Plate Frame and Mallet up to date with those found in other, more modern Shukla Medical systems. After the success of the SHUKLA Anterior Hip system the old Femoral Head Extractor was replaced with our new Femoral Head Punch as well.

2.1 HIP STEM EXTRACTOR

The Hip Stem Extractor Assembly attaches to hip stems in-line 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.

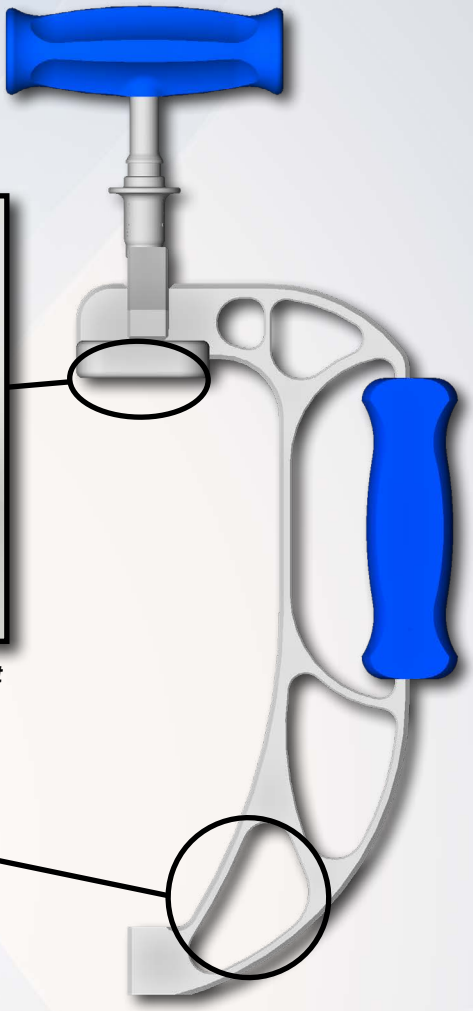
Teeth on the inside clamp down on the trunnion when the camlock is engaged.

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

Parts not shown to scale

2.2 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.

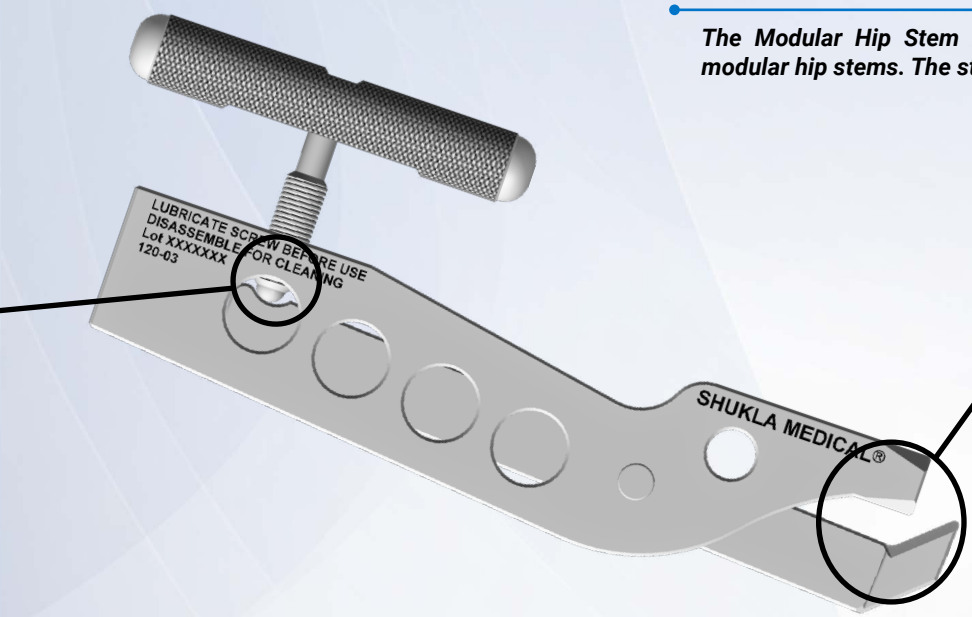


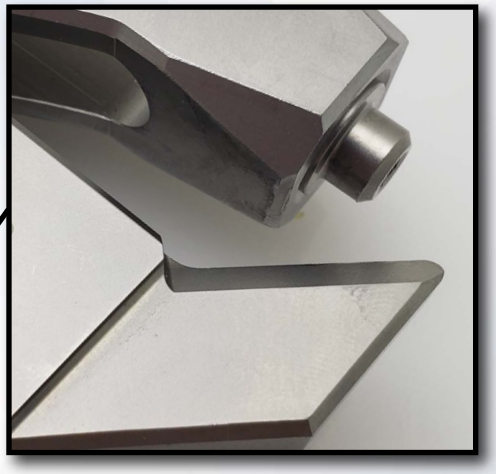
The wide strike plate allows surgeons to hit with a large degree of accuracy, reducing the chance of mishits.

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

2.3 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.

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 *Instructions for Use Cleaning & Sterilization & Preoperative Instrumentation Inspection Guide, LIT-1063*). 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 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; ≤75ºF/24ºC.
- 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.

3.4 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.

3.5 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.

3.6 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.

3.7 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.

STEP 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). If the stem is modular, skip to **Step 7.**

- If the stem is Threaded, skip to **Step 6**.
- If the Femoral Head is Removable, proceed to **Step 2**.
- If the stem is Tapered, skip to **Step 3**.
- If the Femoral Head is not Removable, skip to **Step 4**.
- If there is proximal grabbable geometry on the hip stem, such as a slot or a hole, skip to **Step 5**.

Modular Stems

Tapered Neck Stem

Monoblock Stem

Proximally Threaded Stem

STEP 2

Femoral Head Removal

1. Position the Femoral Head Punch (SXT080) against the femoral head of the implant (Image 1).
2. Slide the instrument onto the hip implant neck, with the femoral head inside the wedge of the punch.
3. Use the Mallet (SMT002) to strike the impact cap of the Femoral Head Punch to dislodge the Femoral Head from the implant.
4. Proceed to **Step 3** to extract the remaining hip stem.

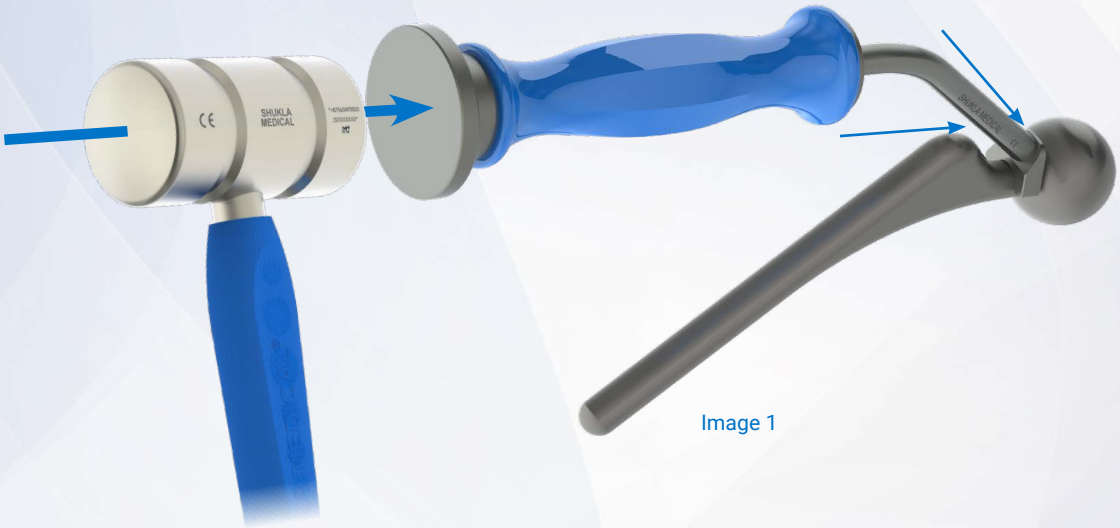


Image 1

STEP 3

Tapered Neck Stem Extraction

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 (Image 3).

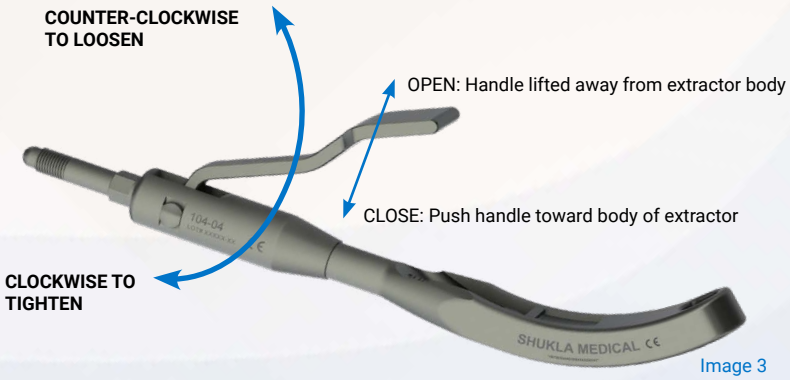


Image 3

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 (Image 4).

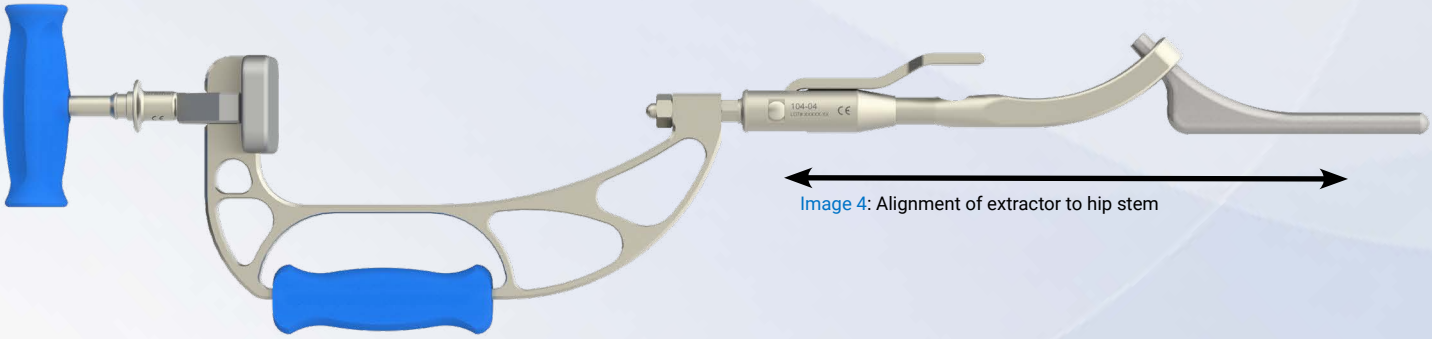


Image 4: Alignment of extractor to hip stem

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 (SBD008) 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. Attach Modular T-Handle (SHN019) (Optional) to the Strike Plate Frame (SBD008) for additional grip and handling if needed.

6. Extract implant with repeated strikes of the Mallet (SMT002) on extraction Strike Plate Frame (Image 5). If implant resists removal after several strikes, loosen bone around implant prior to continuing.

7. After implant is pulled free from the femur, open extractor & remove implant from extraction assembly.

Image 5

STEP 4 Monoblock Stem Extraction

1. Thread Monoblock Stem Extractor (104-07) onto Shaft Driver (SH700).
2. Slide the Strike Plate Frame (SBD008) 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 (Image 6).
4. **Keeping impaction force in-line with the axis of the implant,** use repeated strikes of the Mallet (SMT002) on the strike plate to extract stem. If implant resists removal after several strikes, loosen bone around implant prior to continuing.

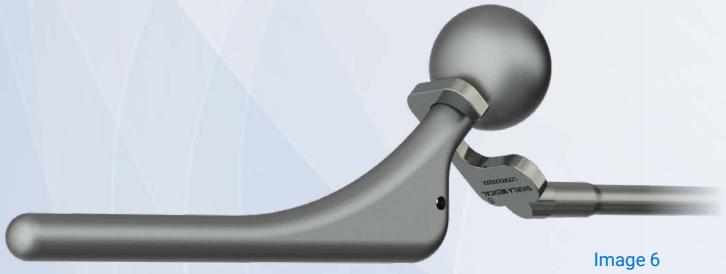


Image 6

STEP 5 Slotted or Cross Hole Stem Extraction

1. Thread Hook Extractor (104-06) onto Shaft Driver (SH700).
2. Slide the Strike Plate Frame (SBD008) 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 (Image 7).
4. **Keeping impaction force in-line with the axis of the implant,** use repeated strikes of the Mallet (SMT002) on the strike plate to extract stem. If implant resists removal after several strikes, loosen bone around implant prior to continuing.

Image 7

STEP 6 Threaded Stem Extraction

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 (Image 8).
4. Remove T-Handle from Shaft Driver. Slide the Strike Plate Frame (SBD008) 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. Attach Modular T-Handle (SHN019) (Optional) to the Strike Plate Frame (SBD008) for additional grip and handling if needed.
6. Extract implant with repeated strikes of the Mallet (SMT002) on the strike plate (Image 9). If implant resists removal after several strikes, loosen bone around implant prior to continuing.
7. After extraction, use wrenches to remove Extractor Tip from assembly and discard.

Image 8

Image 9

SHUKLA MOD HIP

Universal Hip Implant Extraction System

System Name: SHUKLA Mod Hip v1

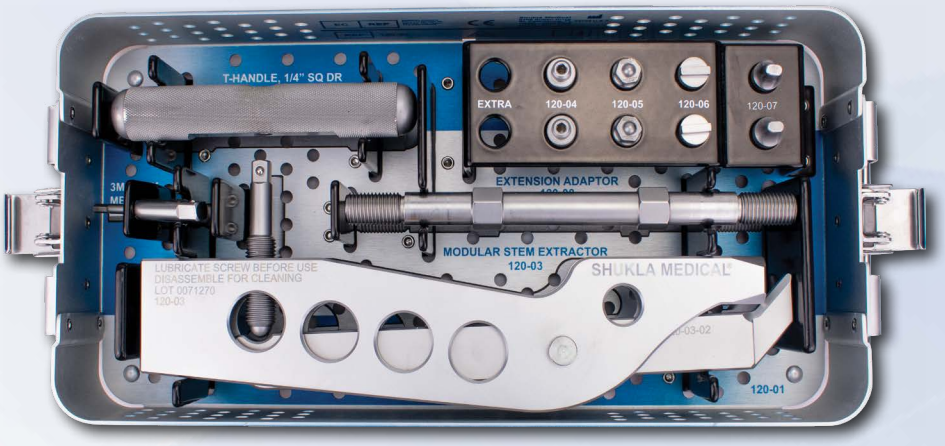
Part Number: S9HIP-MOD

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.

STEP 7

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

- **120-04** Stryker Rejuvenate (Image 10)
- **120-05** Smith & Nephew (Image 11)
- **120-06** Wright Medical (Image 12)
- **120-07** Zimmer (Image 13)

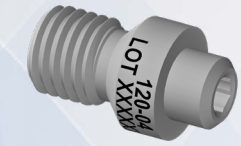


Image 10

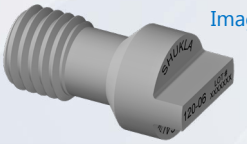


Image 12

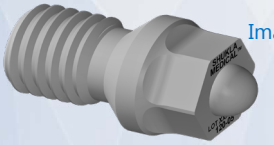


Image 11

Image 13

STEP 8

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) (Image 14).
- **120-05** should be tightened manually
- **120-06 & 120-07** should be screwed in manually and will spin freely when fully engaged.

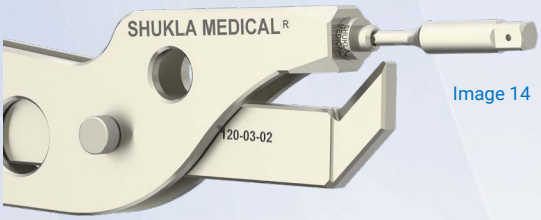


Image 14

STEP 9

Align Clamping Pin with implant and fit extractor lever hook into vacated trunnion fitting (Image 15, Image 16).

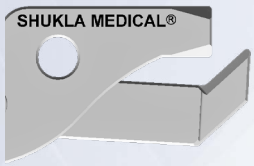


Image 15

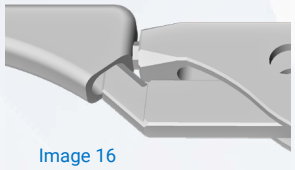


Image 16

STEP 10

Attach T-Handle (HD218-M01) to Clamping Screw (Image 17) by pushing until you hear a click.

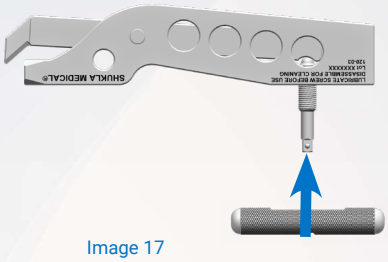


Image 17

STEP 11

Tighten Clamping Screw with T-Handle until you begin to experience resistance. At this point, tighten the screw ½ to 1 full turn maximum past this point. **Do not over-tighten.** The extractor is now fully engaged (Image 18).

Image 18

STEP 12

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).

STEP 13

Extract implant with repeated strikes of the Mallet (MMM5 or SMT002)) on the strike plate (Image 19). If implant resists removal after several strikes, loosen bone around implant prior to continuing.

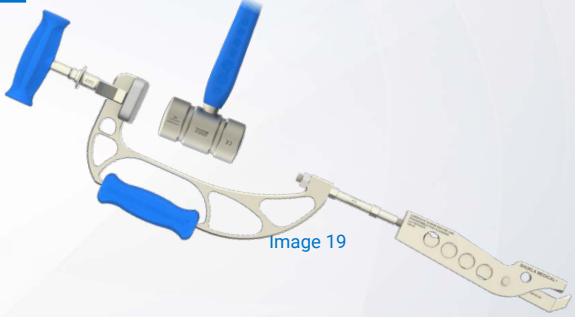


Image 19

For detailed cleaning and sterilization instructions, please consult the SHUKLA Medical Instructions For Use (IFU) document or visit www.ShuklaMedical.com/Sterilization

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

CONSULT INSTRUCTIONS FOR USE

NON STERILE NON-STERILE PRODUCT

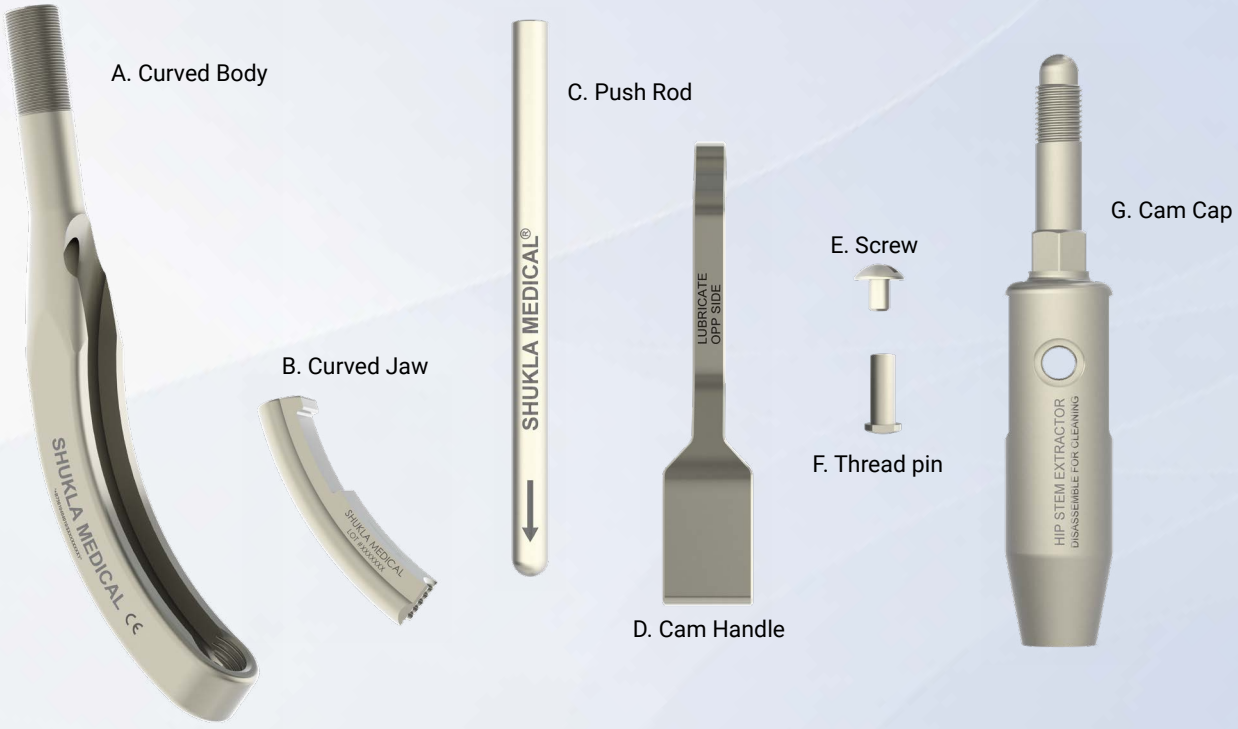
Disassembly Instructions: Hip Stem Extractor

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 Thread Pin using 3mm flat 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)



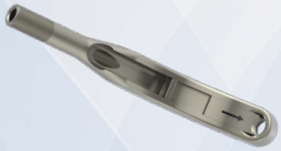
Reassembly Instructions: Hip Stem Extractor

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

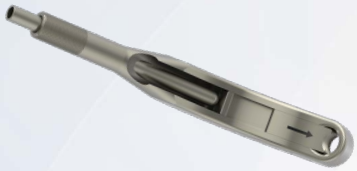
1. Insert cam handle into cam cap, lining up holes.

2. Insert threaded pin into holes.

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



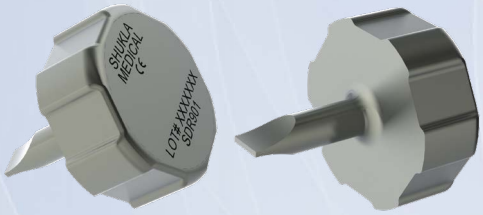
4. Insert curved jaw into curved body. There is an arrow on the jaw to indicate direction.



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.

Optional Disassembly/Reassembly Tool



If a flathead driver is not on hand, our optional Stubby Driver (SDR901) can be used during the disassembly and reassembly of the Hip Stem Extractor (104-04).

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 (Image 20-1) and remove pivoting body and lever (Image 20-2).
3. Unscrew Clamping Pin from Extractor tip.
4. Clean extractor as normal.
5. Reassemble prior to sterilization.

Image 20

6 TIPS and TRICKS

- 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 still needs to be tightened. Rotate handle in a clockwise direction and attempt again.

7 COMPONENTS LIST

Components List

Component List - HIP-MOD		
Std Qty	**Part Number**	**Description**
1	120-01	Case, Modular Hip System
1	120-02	Lid, Modular Hip System
1	120-03	Extractor Assy, Modular Stem
2	120-04	Tip, Modular Stem, Stryker
2	120-05	Tip, Modular Stem,
2	120-06	Tip, Modular Stem,
2	120-07	Tip, Modular Stem,
1	120-08	Connector Shaft, Strike Plate to Extractor, 7/16-20 UNF 2A Both Ends
1	HD218	T-Handle Assy, Square, 1/4"
1	MBT130	Tip Assy, Hex, Male, 3mm

For use in conjunction with the SHUKLA Hip (S9HIP)

Components List

Component List		
Std Qty	**Part Number**	**Description**
1	104-04	Extractor Assy, Stem, Cam Lock
1	104-06	Extractor, Stem, Hook Assy
1	104-07	Extractor, Stem, Monoblock Assy
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
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
3	MIWN	Nut, Hex, 7/16-20 UNF-2B
1	MIWW	Wrench, Double Open End, 1/2" & 11/16"
1	MMI1222	T-Handle, Assy, Quick Connect, Hudson
1	SBD008	Strike Plate, Assy, Frame
1	SCS098	Case, Hip 1.5 System
1	SCS099	Tray, Hip 1.5 System
1	SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems
2	SH700	Connector Shaft for Strike Plate
1	SMT002	Mallet Assy, Big
1	SXT080	Punch, Femoral Head
1	WR140	Wrench, Double Open End, 5/16" & 1/2"

SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

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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ISO 13485:2016 | CE | FDA REGISTERED

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REF S9HIP

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

CONSULT INSTRUCTIONS FOR USE

NON STERILE 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.

WARRANTY

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.

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