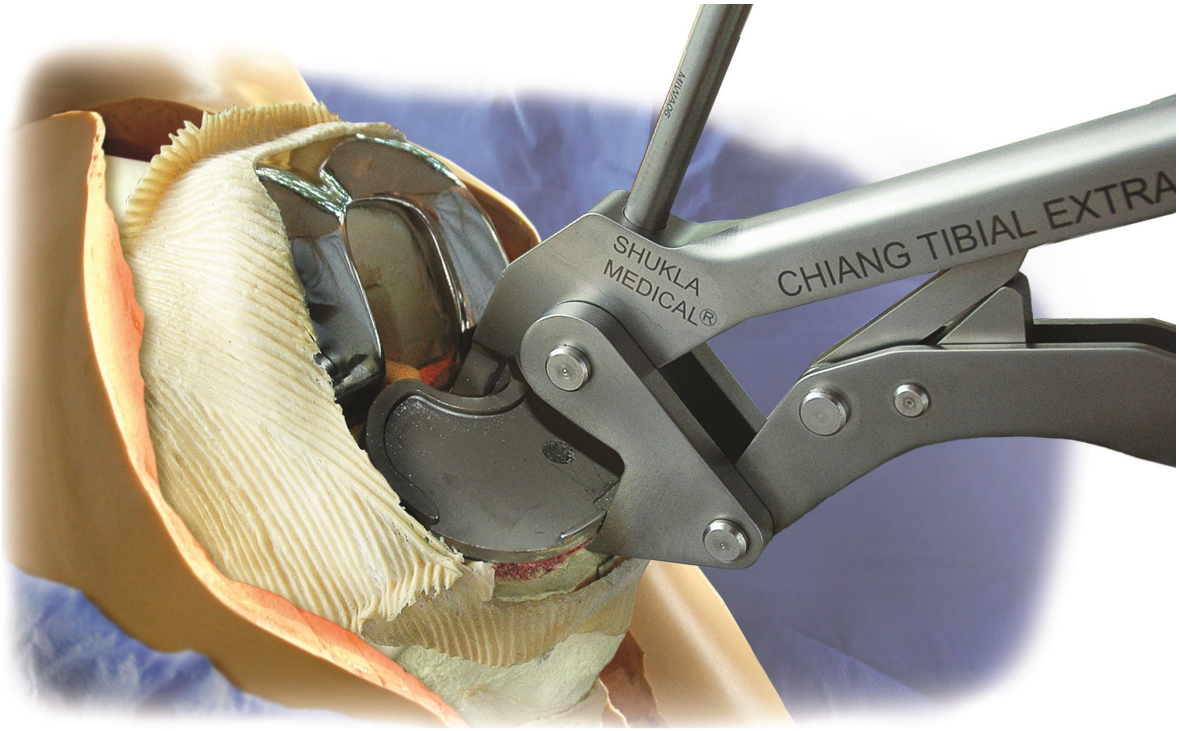
Xtract-All® KNEE

Universal Knee Implant Extraction System

Surgical Technique Guide



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SHUKLA MEDICAL®
Universal Orthopedic Extraction Technologies

Introduction

The Xtract-All® Knee System is a universal extraction system intended to remove knee implant hardware manufactured by a wide range of orthopedic companies. The Xtract-All® Knee System was designed to achieve minimum bone loss while removing the femoral component and tibial component, typically required during knee revision surgery.

The system consists of:

- a set of osteotomes, designed specifically to help break up both the anterior and posterior bone-tibial component interface
- two locking grip style extractors for clamping on to the femoral and tibial components
- a C-Frame assembly with mallet which reduces fatigue and applies impaction force in line with the components being removed

This technique guide describes surgical instruments developed by:

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Warning and Precautions

Preoperative

The surgeon should be familiar with general principles of revision surgery and techniques for removal of orthopedic implants.

The instruments should be inspected for visible damage prior to use. Do NOT use the product if damage is suspected or visible.

Only validated cleaning and sterilization procedures should be used.

Operative

Proper handling and storage of the instrumentation is mandatory. Damage to the instrumentation may produce stresses and cause defects, which could become a focal point for failure.

The surgeon should be cautious with limb position change and/or excessive force exertion while extracting implants using the instrumentation provided in this system.

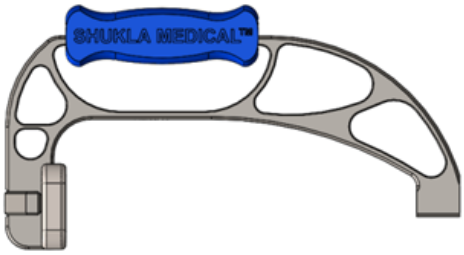
List of Components

1. **Chiang Tibial Extractor** (PN: SXT001)

2. **Chiang Femoral Extractor** (PN: SXT002)

3. **Grooved Mallet** (PN: SMT001)

4. **Big Mallet** (PN: SMT002)



5. **C-Frame** (PN: SBD008)

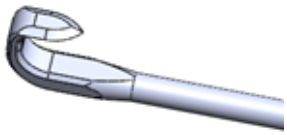
6. **7/16 Nut** (PN: SNT001)

7. **½ & $^{11}/_{16}$ in. Open end Wrench** (PN: SWR002)

8. **Twist Lock Osteotome Handle** (PN: SIN001)

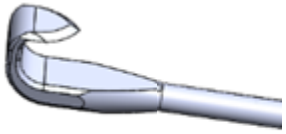
List of Components *(Continued)*

9. **C-Frame Connecting Rod** (PN: SSH007)

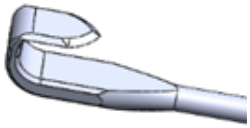


10. **½ in Reach CN Retrograde Osteotome** (PN: SOS001-05)

11. **¾ in Reach CN Retrograde Osteotome** (PN: SOS001-06)

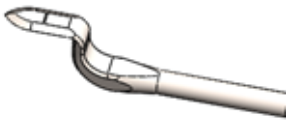


12. **½ in Reach WD Retrograde Osteotome** (PN: SOS001-07)



13. **¾ in Reach WD Retrograde Osteotome** (PN: SOS001-08)

14. **½ in Reach Z-Tip Osteotome** (PN: SOS001-09)



15. **¾ in Reach Z-Tip Osteotome** (PN: SOS001-10)

16. **Case** (PN: SCA101)

Step 1

Once the surgical site has been exposed and both the tibial and femoral components are ready for extraction, the surgeon must remove the plastic bearing between these components.

Step 2

Typically the surgeon will want to remove the femoral component first. This is usually the easier of the two components to remove and although it may be cemented into place, this interface can be broken with minimal bone loss.

The femoral component is removed by threading a C-Frame Connecting Rod (SSH007) into the Chiang Femoral Extractor (SXT002). Next, tighten the rod into the Extractor with one of the Open end Wrenches (SWR002).

Use the adjustment screw on the Extractor to adjust the size of the jaws appropriately to the size of the implant.

Then, connect the Chiang Femoral Extractor to the femoral component from either the medial to lateral side or from the lateral to medial side. *See Figure 1.*

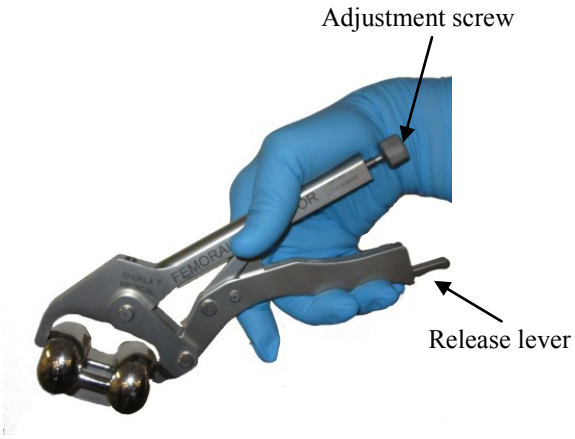


Figure 1: Chiang Femoral Extractor connected to femoral component

If the Extractor needs to be repositioned or tightened, the jaws can be released using the release lever.

NOTE:

- Care should be taken to ensure that the Connecting Rod is aligned with the desired direction of extraction.
- If the surgeon cannot get the jaws of the Chiang Femoral Extractor between the implant and the bone interface, the Osteotome and Small Mallet should be used to open a small gap between the bone and implant.
- It is extremely important to ensure that the jaw tips of the Extractor are under the implant prior to extraction. *See Figure 2.* If the jaw tips are compressed into the sides of the implant, instead of under the implant, damage to the jaws may occur.

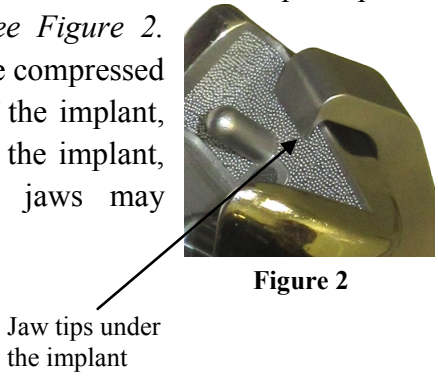


Figure 2

Step 3

Once the Chiang Femoral Extractor has been securely affixed to the implant, slide the locking pin on the Extractor by pushing on the side of the pin with an image of a lock on it. *See Figure 3*. This will ensure that the Extractor remains in place during the extraction.

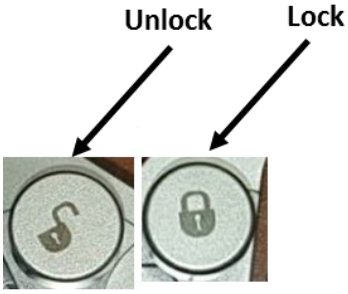


Figure 3

Next, attach the C-Frame (SBD008) to the Extractor by inserting the end of the Connecting Rod through the hole in the end of the C-Frame and securing it with one of the Nuts (SNT001). *See Figure 4.*

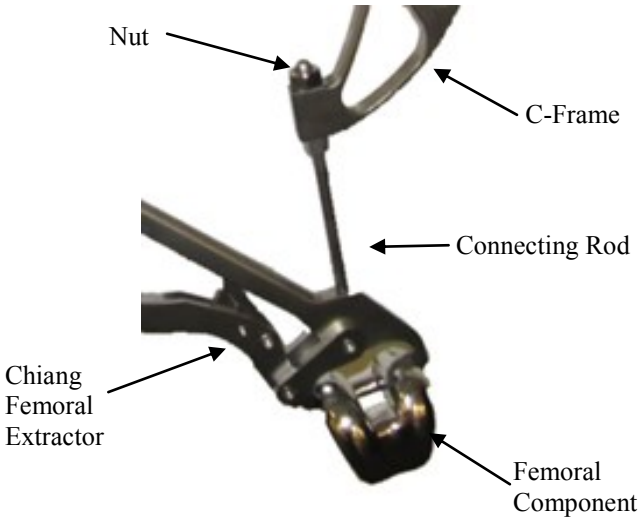


Figure 4

NOTE:

- It is important to tighten the nut using the two wrenches (SWR002) to keep the C-Frame securely attached to the Chiang Femoral Extractor during the extraction.

Step 4

Remove the implant by using the Big Mallet (SMT002) to strike the impaction component of the C-Frame until the implant separates from the bone. *See Figure 5.*

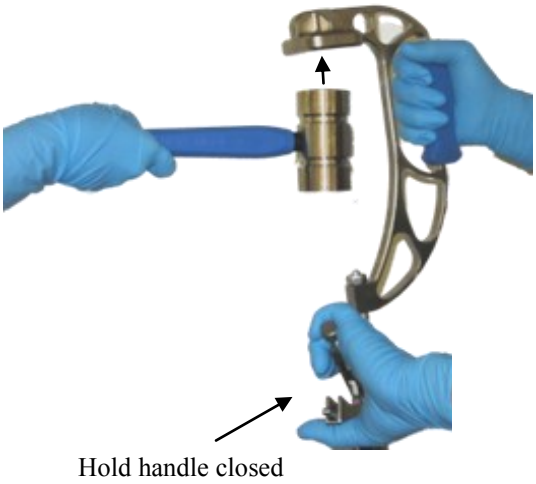


Figure 5

NOTE:

- Avoid using excessive force with the Mallet or damage to the bone may occur.
- Hold the Chiang Femoral Extractor handles closed while striking the C-Frame.
- Care should be taken to strike the C-Frame in-line with the extractor, to prevent damage to the Connecting Rod.

Step 5

Remove the tibial component by using the Osteotome first, to break up the cement-prosthesis interface.

NOTE:

- It is important to break this interface all the way around the implant to minimize the loss of excessive bone during the extraction.

Select the appropriate Osteotome from the tray. Insert it fully into the handle, then twist the collar on the handle until it clicks to lock the blade. *See Figure 6*

Figure 6

NOTE:

- The Osteotome should be used with the Grooved Mallet (SMT001) and used in either retrograde or antegrade directions, depending on the Osteotome tip style and the location of the bone being separated from the implant. *See Figure 7 and 8.*

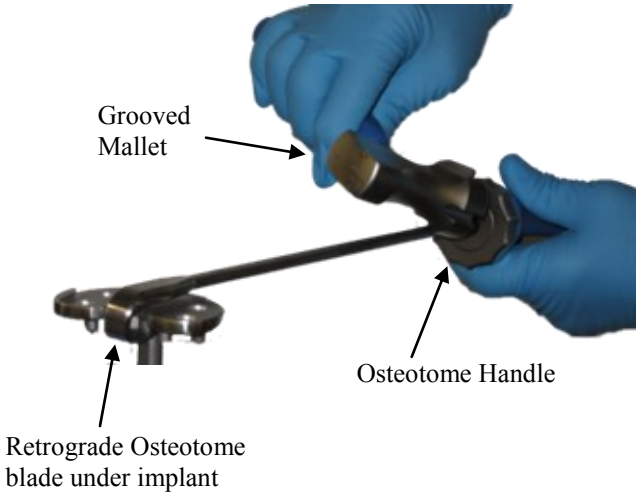


Figure 7

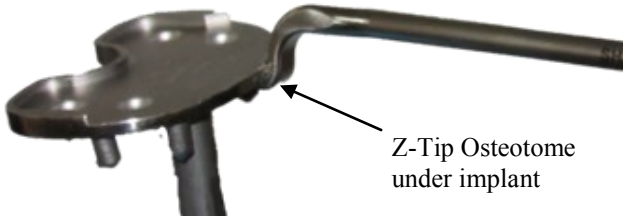


Figure 8

NOTE:

- The Retrograde Osteotomes are ideal for separating the posterior parts of the implant from the underlying bone. *See Figure 9.*

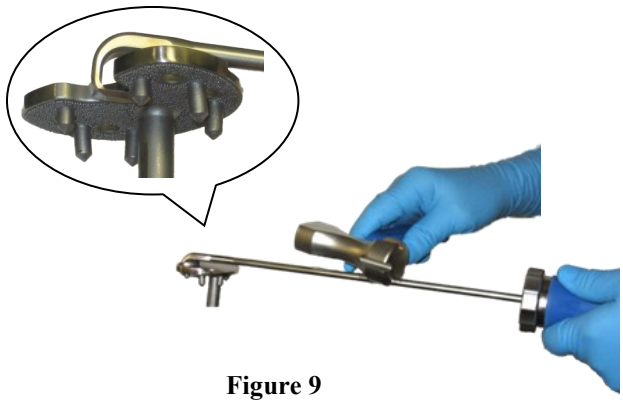


Figure 9

Step 6

After the cement interface has been broken, extraction can begin. Thread the second Connecting Rod (SSH007) into the Chiang Tibial Extractor (SXT001). Tighten the rod into the Chiang Tibial Extractor, with one of the Wrenches (SWR002).
Use the adjustment screw on the Chiang Tibial Extractor to adjust the size of the jaws appropriate to the implant.

Next, clamp the Chiang Tibial Extractor onto the tibial component with the narrow jaw into the posterior notch of the tibial tray and the wider jaw on the anterior face. *See Figure 10.*

Figure 10: Chiang Tibial Extractor connected to tibial component

Ensure that the jaw tips are firmly gripping and fully seated under the implant.

If the Chiang Tibial Extractor needs to be repositioned or tightened, release the jaws using the release lever.

Once the Extractor is properly placed, slide the locking pin on the Extractor by pushing on the side of the pin with an image of a lock on it, *See Figure 11*. This will ensure that the Extractor remains attached to the tibial component during the extraction.

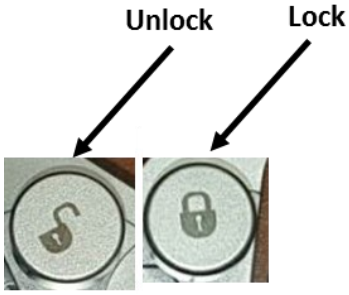


Figure 11

Attach the C-Frame to the Chiang Tibial Extractor using the Connecting Rod and tighten the Nut with the wrenches. Strike the C-Frame impaction component with the Big Mallet to generate force to extract the implant.

NOTE:

- Hold the Chiang Tibial Extractor handles closed while striking the C-Frame.
- It is extremely important to ensure that the jaw tips of the Extractor are under the implant prior to extraction. If the tips of the extractor jaw are compressed into the sides of the implant, instead of under the implant, damage to the jaws may occur.
- Avoid using excessive force with the Mallet or damage to the bone may occur.
- Care should be taken to strike the C-Frame in-line with the extractor, to prevent damage to the Connecting Rod.

S9KNE Part Number

No	Part Number	Description	Qty
1	SXT001	Chiang Tibial Extractor	1
2	SXT002	Chiang Femoral Extractor	1
3	SMT001	Grooved Mallet	1
4	SMT002	Big Mallet	1
5	SBD008	C-Frame	1
6	SNT001	7/16 Nut	3
7	SWR002	½ in & 11/16" Double Open end Wrench	2
8	SIN001	Twist Lock Osteotome Handle	1
9	SSH007	C-Frame Connecting Rod	2
10	SOS001-05	½ in Reach CN Retrograde Osteotome	2
11	SOS001-06	¾ in Reach CN Retrograde Osteotome	1
12	SOS001-07	½ in Reach WD Retrograde Osteotome	1
13	SOS001-08	¾ in Reach WD Retrograde Osteotome	1
14	SOS001-09	½ in Reach Z-Tip Osteotome	2
15	SOS001-10	¾ in Reach Z-Tip Osteotome	1
16	SCA101	Case	1

Cleaning and Sterilization

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 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.

Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270° F). When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded. Drying times will vary according to load size and should be increased for larger loads

"Flash" sterilization by exposure at 270° F (132° C), unwrapped, in a gravity displacement sterilizer should only be used as an emergency procedure

Steam sterilization is the preferred method for metal instrument sets. Instrument sets should be properly prepared and packaged in a case or tray that will allow steam to penetrate and make direct contact with all surfaces

The following charts summarize exposure times and temperatures that are customarily recommended by manufacturers of steam sterilizers for metal instruments sterilized alone or in combination with porous materials. Time and temperature relationships indicate holding time after the specific temperatures have been reached and do not include heating or drying times

Cycle Type	Minimum Temperature	[4] Pressure	[5] Minimum Exposure Time		[8] Minimum Dry Time
			[6] Wrapped	[7] Unwrapped	
[1,2] Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27psi	4 min	4 min	45 mins
[2,3] Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5psi	18 min	18 min	

1 Minimum validated steam sterilization temperature required to achieve a 10^{-6} sterility assurance level (SAL).
2 Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table
3 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing Instruments where there is concern regarding TSE/CJD contamination
4 Sea Level
5 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable
6 Rigid sterilization container that complies with ANSI/AAMI ST46
7 Flash (unwrapped) sterilization by exposure at 132°C /270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled
8 Drying times vary according to load size and should be increased for larger loads

Notes