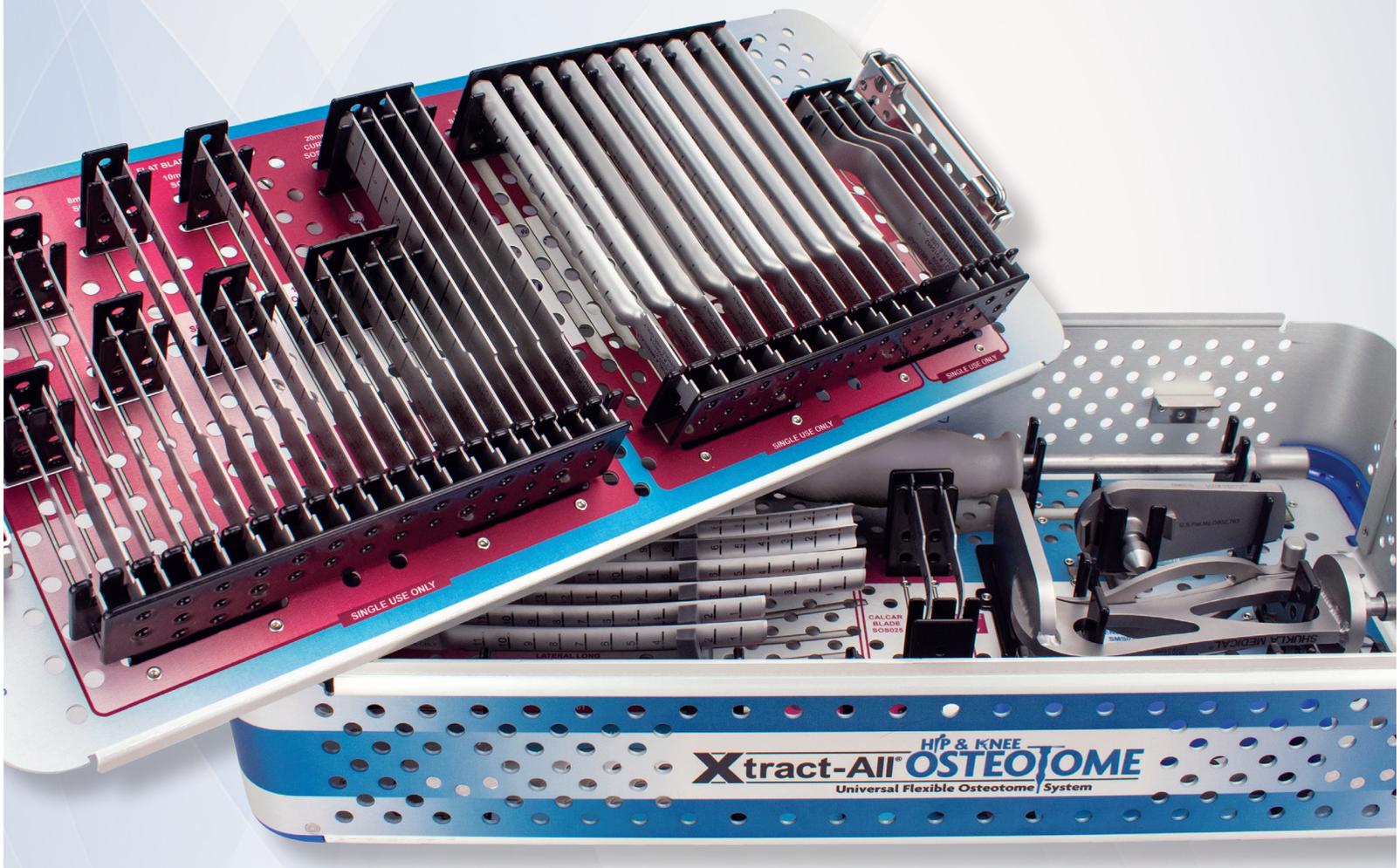
SURGICAL TECHNIQUE GUIDE

#4
System 4 of 17

SHUKLA BLADE

Universal Flexible Osteotome Solution



SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

CONTENTS

Osteotome with handle & extended strike plate

Intended Use

The SHUKLA Blade (S9BLADE, prev. S9FLEX) Universal Flexible Osteotome Solution is intended for use during revision procedures for the loosening of implant-to-bone interface or implant-to-bone cement interface to facilitate implant extraction during revision surgery.

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 Blade (S9BLADE, prev. S9FLEX) Universal Flexible Osteotome Solution is indicated for use during any revision procedure in which the implant to bone or bone cement interface must be loosened prior to implant extraction.

Additional Recommendations

During hip revision procedures, the SHUKLA Blade System is recommended for use in conjunction with the SHUKLA Hip (Universal Hip Implant Extraction System).

During knee revision procedures, the SHUKLA Blade System is recommended for use in conjunction with the SHUKLA Knee (Universal Knee Implant Extraction System).

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; ≤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.

CLEANING & STERILIZATION

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.

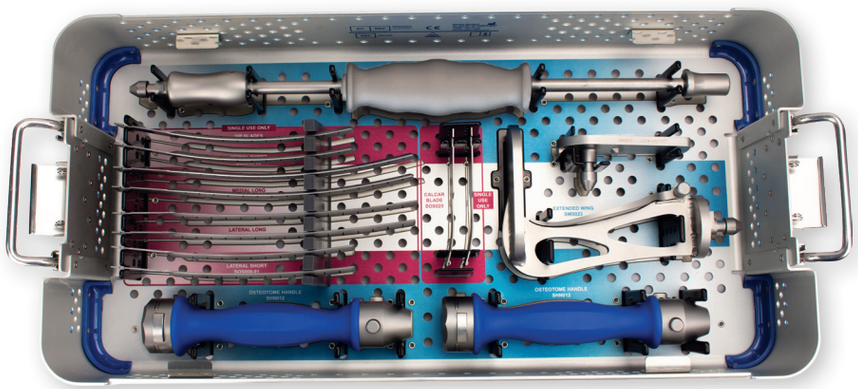
For detailed cleaning and sterilization instructions, please visit www.ShuklaMedical.com/Sterilization

EC REP	**Emergo Europe** Prinsessegracht 20 2514 AP The Hague The Netherlands	REF S9FLEX S9BLADE	**Shukla Medical** 8300 Sheen Drive St. Petersburg, FL 33709 USA	CONSULT INSTRUCTIONS FOR USE	NON STERILE NON-STERILE PRODUCT

CE

LIST OF COMPONENTS

S9BLADE (prev. S9FLEX) Universal Flexible Osteotome Solution					
Part #	Description	Qty	Part #	Description	Qty
SCS009	Case, Blade System	1	SOS006-08	Blade, Flat, 20 mm x 11 cm, Single Use	2
SCS010	Tray, Blade System	1	SOS007-01	Blade, Cupped, 10 mm x 11 cm, Single Use	2
SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems	1	SOS007-02	Blade, Cupped, 12 mm x 11 cm, Single Use	2
SHN012	Handle Assy, Osteotome, Push-to-Connect	1	SOS007-03	Blade, Cupped, 14 mm x 11 cm, Single Use	2
SHN012	Handle Assy, Osteotome, Push-to-Connect	1	SOS007-04	Blade, Cupped, 16 mm x 11 cm, Single Use	2
SIN005	Hammer Assy, Slide	1	SOS007-05	Blade, Cupped, 20 mm x 11 cm, Single Use	2
SMS019	Strike Plate	1	SOS008-01	Blade, Curved, for Lateral Hip, 12 mm x 11 cm, Single Use	2
SMS023	Strike Plate, Assy, Extended	1	SOS008-02	Blade, Curved, for Lateral Hip, 12 mm x 16 cm, Single Use	2
SOS006-01	Blade, Flat, 8 mm x 5 cm, Single Use	2	SOS008-03	Blade, Curved, for Medial Hip, 12 mm x 11 cm, Single Use	2
SOS006-02	Blade, Flat, 8 mm x 11 cm, Single Use	2	SOS008-04	Blade, Curved, for Medial Hip, 12 mm x 16 cm, Single Use	2
SOS006-03	Blade, Flat, 10 mm x 5 cm, Single Use	2	SOS009	Blade, ESSE, Flat Tip, 16 mm x 2 cm, Single Use	2
SOS006-04	Blade, Flat, 10 mm x 11 cm, Single Use	2	SOS016-01	Blade, Flat, 6 mm x 3 cm, Single Use	2
SOS006-05	Blade, Flat, 12 mm x 5 cm, Single Use	2	SOS016-02	Blade, Flat, 6 mm x 9 cm, Single Use	2
SOS006-06	Blade, Flat, Round Tip, 12 mm x 5 cm, Single Use	2	SOS025	Blade, for Calcar, 8 mm x 3 cm, Single Use	2
SOS006-07	Blade, Flat, Round Tip, 20 mm x 11 cm, Single Use	2	SOS026	Blade, ESSE, Round Tip, 16 mm x 2 cm, Single Use	2

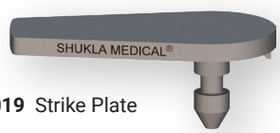


S9BLADE • Bottom Level

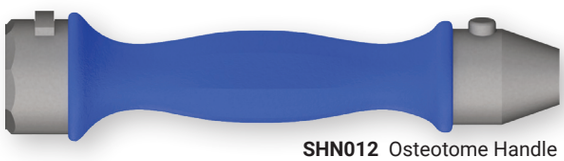
Hand Tools

Parts not shown to scale

SMS023 Extended Strike Plate



SMS019 Strike Plate



SHN012 Osteotome Handle

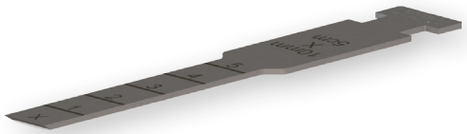
SIN005 Slide Hammer

Single-Use Osteotome Blades

Parts not shown to scale

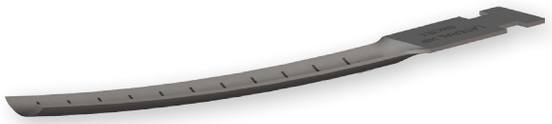
Flat Blades

SOS016-01	Blade, Flat, 6 mm x 3 cm, Single Use
SOS016-02	Blade, Flat, 6 mm x 9 cm, Single Use
SOS006-01	Blade, Flat, 8 mm x 5 cm, Single Use
SOS006-02	Blade, Flat, 8 mm x 11 cm, Single Use
SOS006-03	Blade, Flat, 10 mm x 5 cm, Single Use
SOS006-04	Blade, Flat, 10 mm x 11 cm, Single Use
SOS006-05	Blade, Flat, Round Tip, 12 mm x 5 cm, Single Use
SOS006-06	Blade, Flat, Round Tip, 12 mm x 5 cm, Single Use
SOS006-07	Blade, Flat, Round Tip, 20 mm x 11 cm, Single Use
SOS006-08	Blade, Flat, 20 mm x 11 cm, Single Use



Curved Lateral Hip Blades

SOS008-01	Blade, Curved, for Lateral Hip, 12 mm x 11 cm, Single Use
SOS008-02	Blade, Curved, for Lateral Hip, 12 mm x 16 cm, Single Use

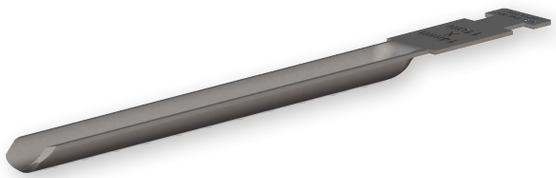


Curved Medial Hip Blades

SOS008-03	Blade, Curved, for Medial Hip, 12 mm x 11 cm, Single Use
SOS008-04	Blade, Curved, for Medial Hip, 12 mm x 16 cm, Single Use

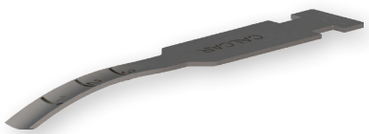
Cupped Blades (Gouges)

SOS007-01	Blade, Cupped, 10 mm x 11 cm, Single Use
SOS007-02	Blade, Cupped, 12 mm x 11 cm, Single Use
SOS007-03	Blade, Cupped, 12 mm x 11 cm, Single Use
SOS007-04	Blade, Cupped, 16 mm x 11 cm, Single Use
SOS007-05	Blade, Cupped, 20 mm x 11 cm, Single Use



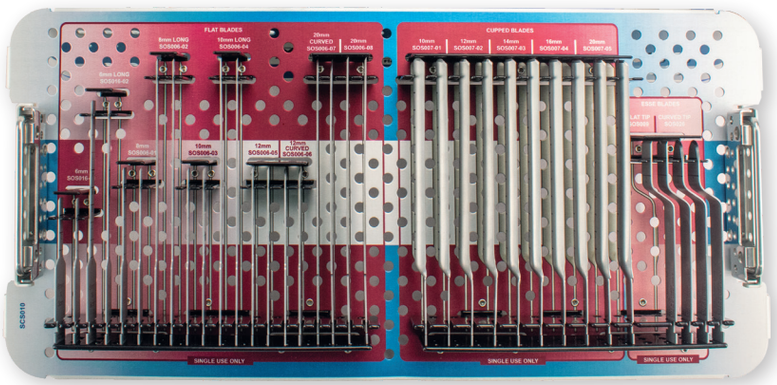
Calcar Blade

SOS025	Blade, for Calcar, 8 mm x 3 cm, Single Use



ESSE Blades

SOS009	Blade, ESSE, Flat Tip, 16 mm x 2 cm, Single Use
SOS026	Blade, ESSE, Round Tip, 16 mm x 2 cm, Single Use



S9BLADE • Tray

Single-use Only: Always use new blades in every procedure. Discard any used blades at the conclusion of the case.

Osteotome Blades

Razor sharp blade edges make cleaner cuts, minimizing unintended bone loss and allowing the blade to penetrate efficiently, lessening user fatigue & procedure time.

- Avoid driving blades into non-organic objects (i.e. the metal of an implant). Damage to the tip can occur, resulting in burrs or chips on the blade edge.
- **Single-use Only: Always use new blades in every procedure. Discard any used blades at the conclusion of the case.**

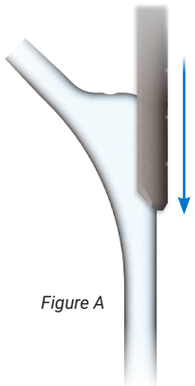


Figure A

Blade Direction

Blade edges are beveled, with one side longer than the other. Use blades with the longer side against the implant (Fig A, B). This creates a force that helps to keep the blade against the implant as the surgeon drives it forward.

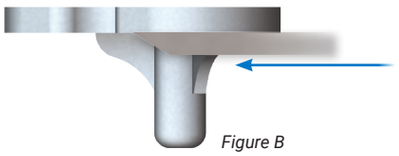


Figure B

Depth Markings

Use depth markings on osteotome blades for visual reference throughout the procedure.

- **Check that the blade is advancing appropriately** with each mallet strike by referencing visible markings.
- **Determine the maximum depth of penetration** before reaching an obstruction (i.e. a screw attaching an implant component to a stem, or a screw that extends into the bone beneath the implant).
    1. Lay the blade across the surface of the implant (Fig C1) with the blade tip flush against the anticipated obstruction (such as a screw head or the keel of a tibial plate).
    2. Note the marking near the edge of the implant (Fig C2); this shows how deep the blade can penetrate before reaching an obstruction.

Depth markings are not calibrated, and are intended for visual reference only.

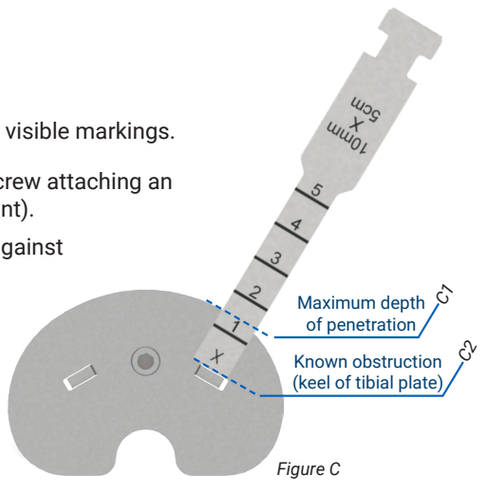


Figure C

Flat Blade Styles

Flat blades are available with various diameters, lengths, & tip styles to satisfy any surgical need (Fig D).

- **6mm flat blades** are ideal for narrow pockets of implant to bone or bone-cement interface, such as narrow chamfers of a femoral component during a knee revision.
- **Regular flat blades** are ideal for loosening tibial plates & femoral components, and for starting the cut in an area that may require a longer blade.
- **Long flat blades** are ideal for deeper pockets of implant to bone or bone-cement interface.

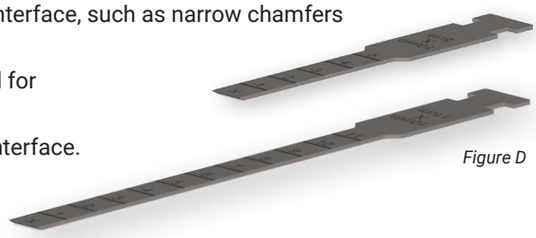


Figure D

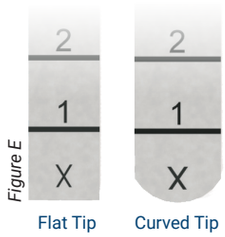


Figure E

Tip Styles: Flat vs Curved (Fig E)

- Flat tips transfer all of the impaction force evenly across the entire length of the tip edge.
- Curved tips transfer impaction force primarily via the small surface area of the front edge of the curve.
    - This means that for curved tip blades, the greatest impaction force is applied at the front of the blade without requiring additional force from the mallet. This makes curved tips easier to advance than flat tips.

Osteotome Handle

All blades and accessories attach quickly and easily with a push-to-connect chuck at either end of the handle, detaching with the push of a button to allow simple interchange of devices as needed during the case.

Quick Attachment

Insert blades or accessories into the push-to-connect (PTC) chucks at the ends of the handle (Fig F).

1. Push the device into the handle until an audible click is heard. Check for secure attachment by pulling firmly on the device while grasping the handle.
2. Depress the release button to remove blades or accessories for exchange or at the end of the procedure.

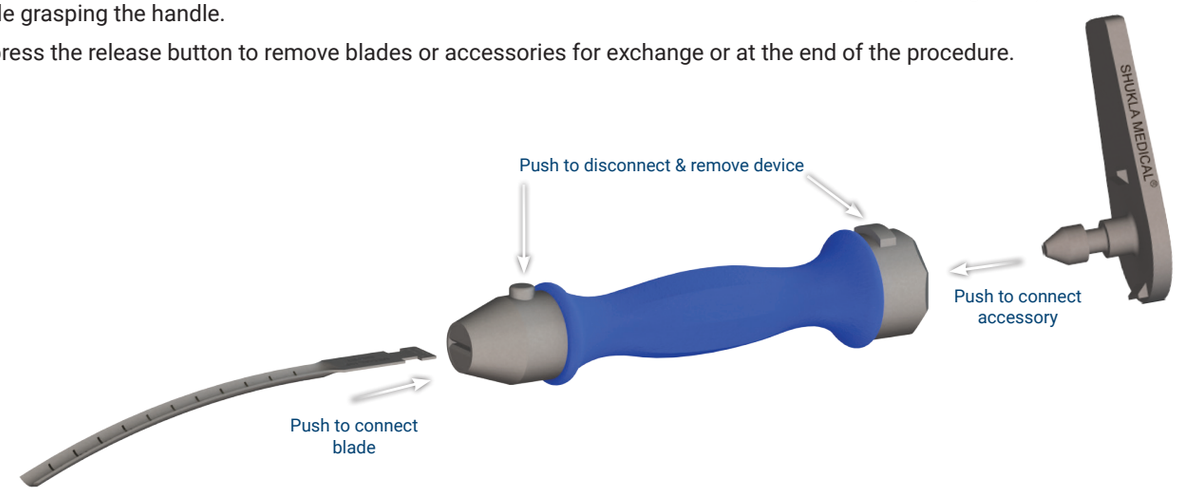


Figure F

Driving the Osteotome Blade

- Direct impact should be applied to the rear of the handle using a general surgical mallet, not included (Fig G). This is the most effective way to apply driving force to any osteotome blade.

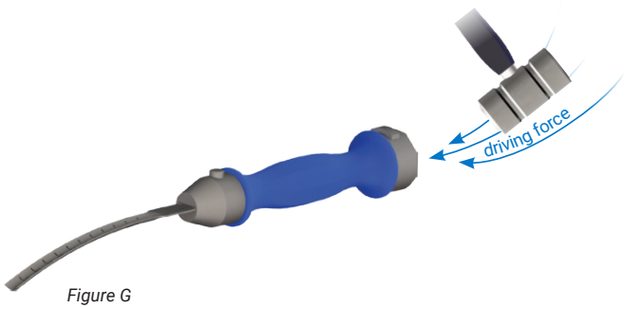


Figure G

- Impaction force, especially retrograde force, may also be applied with the use of an attachment (i.e. Slide Hammer, Strike Plate, or Extended Strike Plate; Fig H).
  - Driving force applied via attachments, while still effective, may be dampened slightly due to the PTC chuck connection. Maximum driving force will be achieved by striking the handle directly.

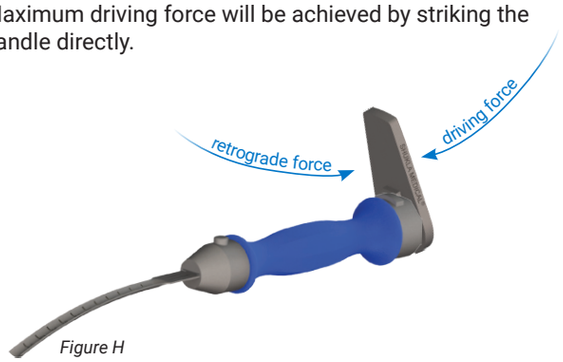


Figure H

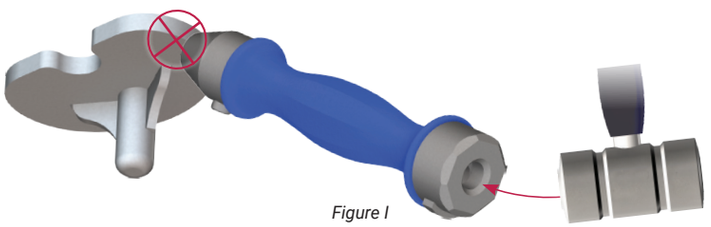


Figure I

Only use the handle with a blade attached

- Osteotome handles are intended to be used **only** with a blade inserted.
- Do not use osteotome handles in direct contact with any implant (as if to drive it out like a punch; Fig I), as this can damage the PTC mechanism of the handle, preventing normal use.

Slide Hammer

The Slide Hammer may be used to apply impact force in either antegrade or retrograde directions.

- Reduces user fatigue due to ergonomic grip
- Can be readily attached or removed from the rear PTC chuck on the handle (Fig. J)

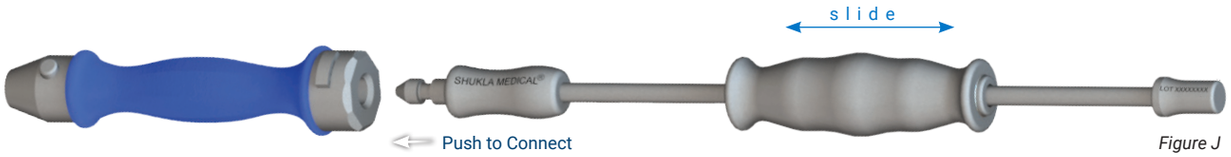


Figure J

Attachment Orientation

The rear chuck edge is surrounded by 8 chamfers (Fig K), allowing 8 functional orientations for the Strike Plate & Extended Strike Plate, which may be used in the surgeon-preferred orientation.

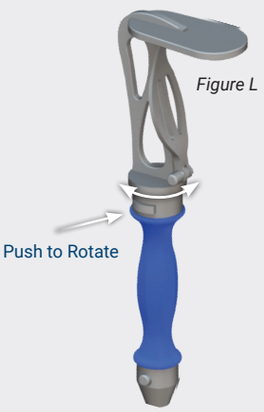


Figure L

Changing Attachment Orientation (Fig L, M)

1. Press and hold the handle release button.
2. Rotate the device to the desired position.
3. Release the button.
4. Check that the device is secure in the new position.

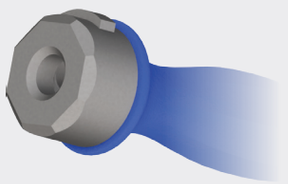


Figure K

Figure M

Strike Plate

The primary use of the Strike Plate (Fig N) is to extract a lodged blade.

- Double-sided impact surface allows the surgeon to apply driving or retrograde force.
- Allows quick change of direction for crucial impaction force.
- Can be readily attached or removed from the rear PTC chuck on the handle (Fig O).

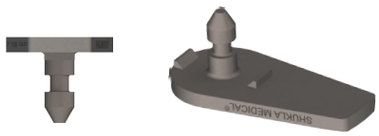


Figure N

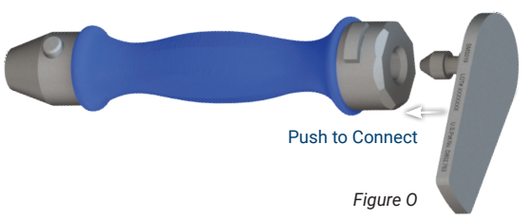


Figure O

Extended Strike Plate

If the Strike Plate and Slide Hammer are not effective when extracting a lodged osteotome blade, the Extended Strike Plate may be used to apply the greatest impact force to the blade (Fig P).

Example: A long blade driven to maximum depth along a hip stem can become wedged and may require greater impact force to remove the blade than can be achieved with the Strike Plate or Slide Hammer.

- Distance from handle to impact surface allows a greater range of motion for mallet strikes, increasing crucial impaction force.
- Retractable hand guard protects user during heavy mallet strikes.

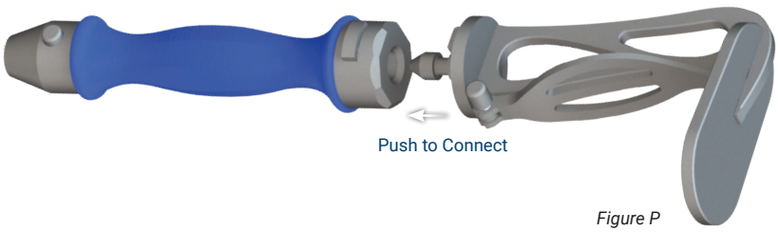


Figure P

Retractable Hand Guard

Extend the retractable hand guard for user protection when swinging with a mallet (Fig Q).

1. Depress the button at the hinge of the hand guard.
2. Pull down the guard until fully extended. The guard should lock in place with an audible click.
3. Press the hand guard button to retract.

Figure Q

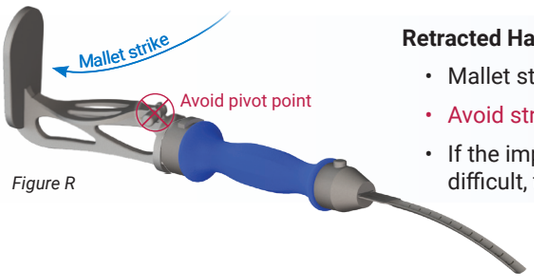


Figure R

Retracted Hand Guard (Fig R)

- Mallet strike must land on impact surface only.
- Avoid striking other components (i.e. pivot point or safety lock).
- If the impact force or angle of approach make strike accuracy difficult, the hand guard must be extended.

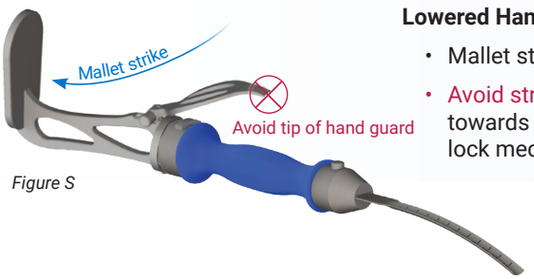
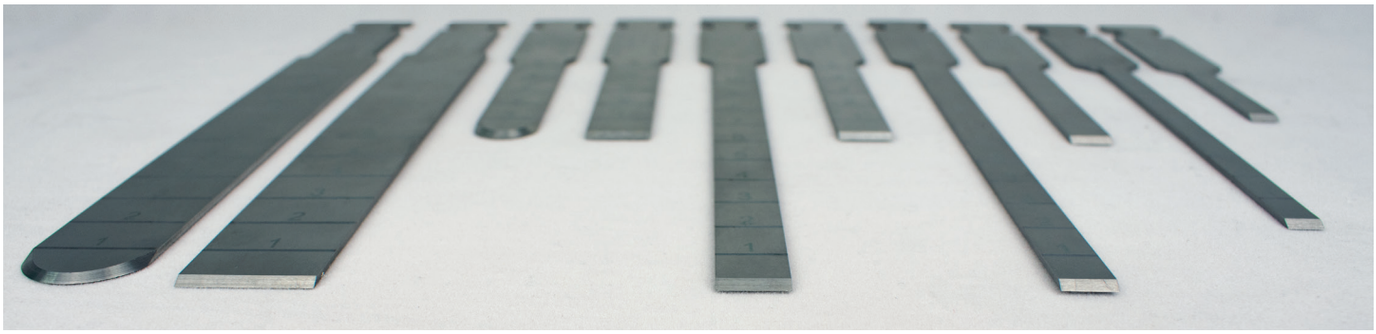


Figure S

Lowered Hand Guard (Fig S)

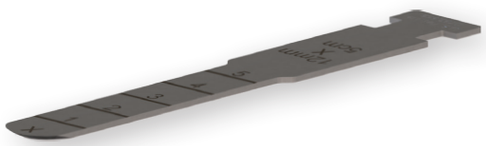
- Mallet strike must land on impact surface only.
- Avoid striking the bottom edge of the hand guard, as this can force it towards the retracted position and can damage the pivot point and safety lock mechanisms.



Blade Recommendations: Tibial Component

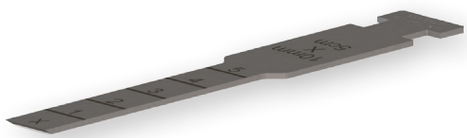
12mm Flat Blade with Curved Tip (SOS006-06)

Begin loosening the tibial component using the curved tip 12mm blade.



Regular Flat Blades (SOS006-01/03/05)

Use the square tip of a regular flat blade to clear remaining interface between the keel or stem and the bone or bone cement interface.



Blade Recommendations: Femoral Component

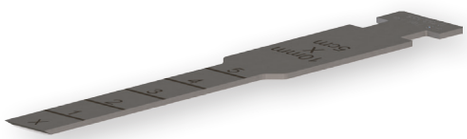
The below blades, in addition to those noted above for tibial plates, are recommended for loosening a femoral component. Blades that work well for tibial components may also be effective for femoral components.

ESSE Blades (SOS009 & SOS026)

The offset geometry of the ESSE blades is able to bypass soft tissue surrounding the femoral component without requiring retraction, allowing faster access to the implant interface.

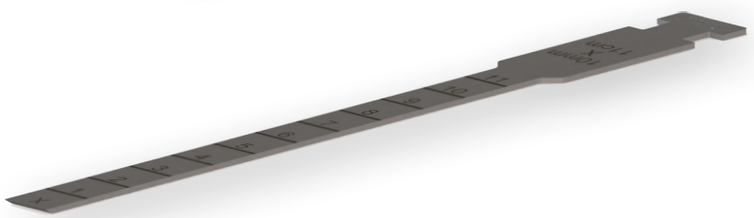
6mm Flat Blades (SOS016-01 & SOS016-02)

The narrow width of 6mm flat blades are ideal for breaking up interface beneath narrow chamfers of a femoral component.

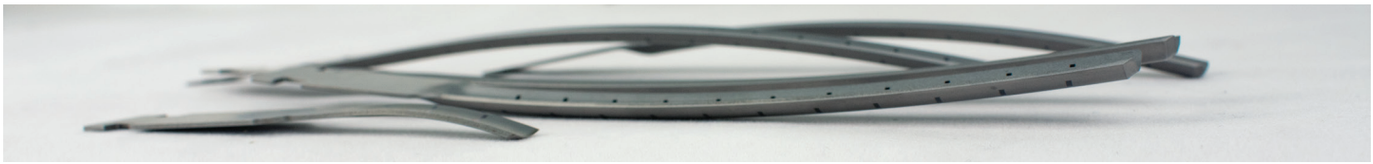


Long Flat Blades (SOS006-02/04/07/08)

Longer flat blades may be driven across the entire width of the femoral component, breaking up the entire interface from one side of the surgical site.



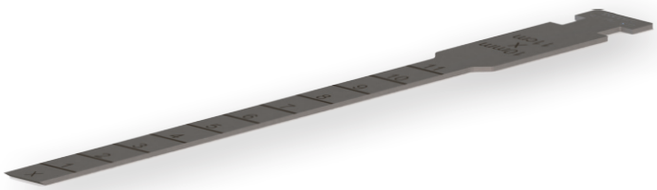
Single-use Only: Always use new blades in every procedure. Discard any used blades at the conclusion of the case.



Blade Recommendations: Hip Stems

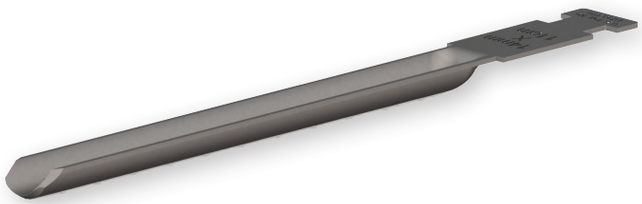
Long Flat Blades (SOS006-02/04/07/08)

Longer blades can be used to reach down the sides of the stem. Blade flexibility also allows the blade to be driven down the calcar, following the curvature of the hip stem.



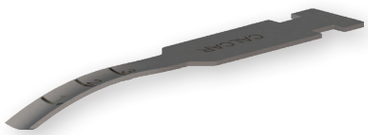
Cupped Blades (SOS007-01/02/03/04/05)

Cupped blades may be used as gouges to break up interface while hugging the curvature of the hip stem. They may also be used if there is a stem left behind.



Calcar Blade (SOS025)

The calcar blade is designed to break up proximal bone or bone cement interface at the calcar.



Curved Blades for Lateral & Medial Hip (SOS008-01/02/03/04)

Curved blades are designed to break up the interface on the medial & lateral sides of the hip stem. They may also be useful to clear remaining bone cement after the implant has been removed.

Single-use Only: Always use new blades in every procedure. Discard any used blades at the conclusion of the case.

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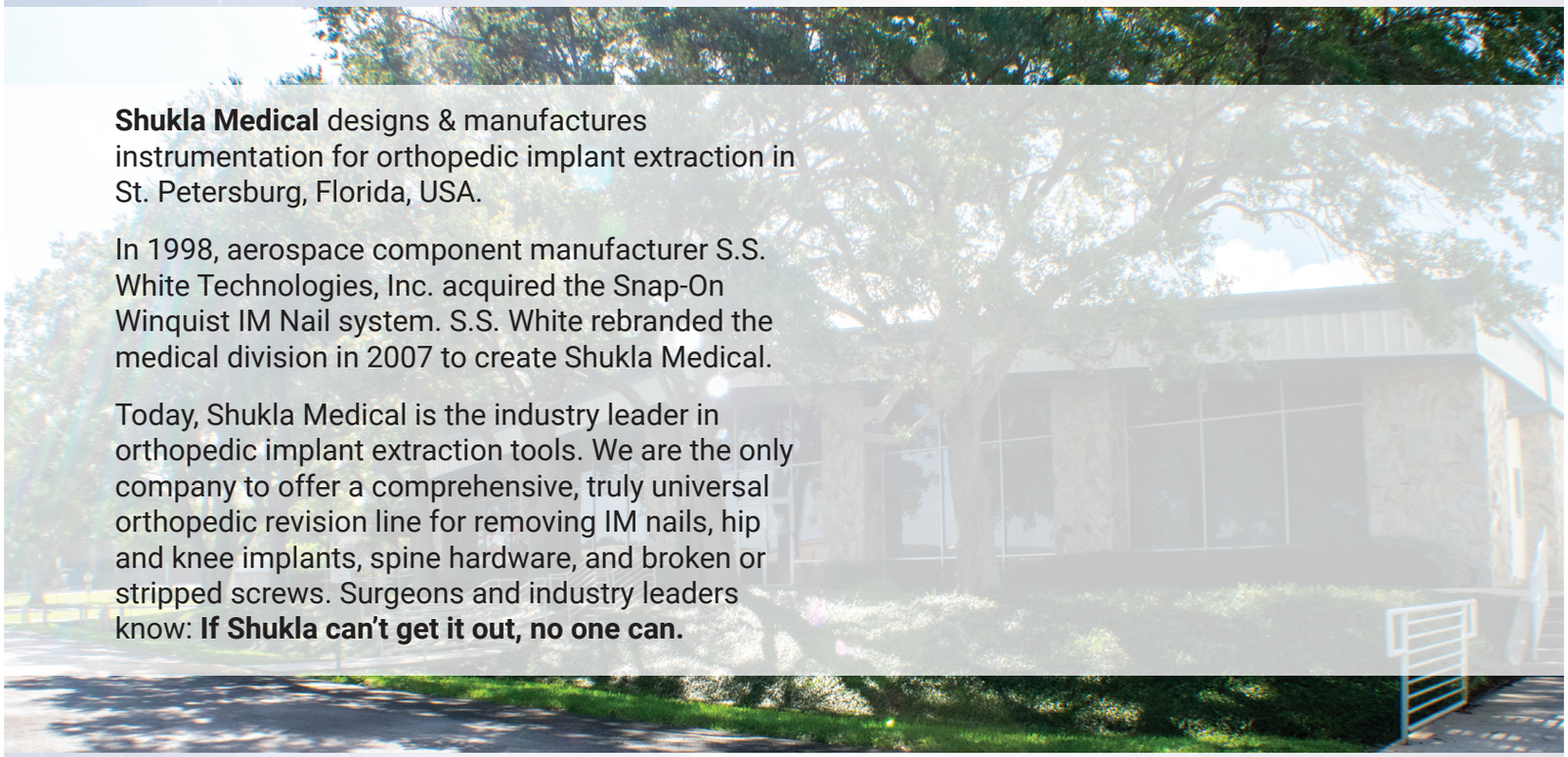
Universal Orthopedic Extraction Technologies

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.**

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