SURGICAL TECHNIQUE GUIDE

#18
System 18 of 25

SHUKLA BLADE SHOULDER

Universal Flexible Osteotome System

SHUKLA MEDICAL®
Universal Orthopedic Extraction Technologies
Revolutionizing the Art of Revision Surgery

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SHUKLA SHOULDER BLADE

Universal Flexible Osteotome System

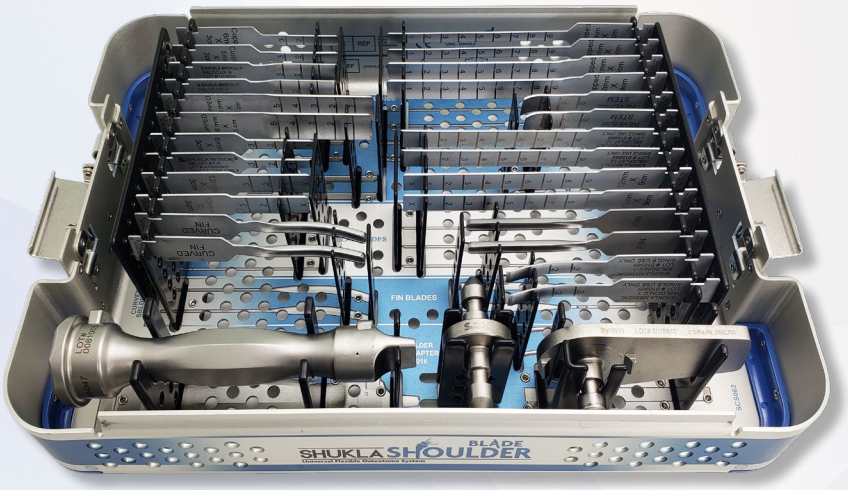
1.1 System Name: SHUKLA Shoulder Blade

Part Number: S9SHLDR-BLADE

Version: 1

1.2 Primary Use

The SHUKLA Shoulder Blade (Universal Flexible Osteotome System) is designed to be used in any shoulder orthopedic revision surgery that calls for osteotomes in order to loosen the interface between the implant and the bone or bone cement. The system includes blades for shoulder specific applications as well as numerous tip and blade configurations that all flex to conform to the implant geometry. This system was designed to prepare shoulder implants for removal as well as to ensure minimal bone loss.

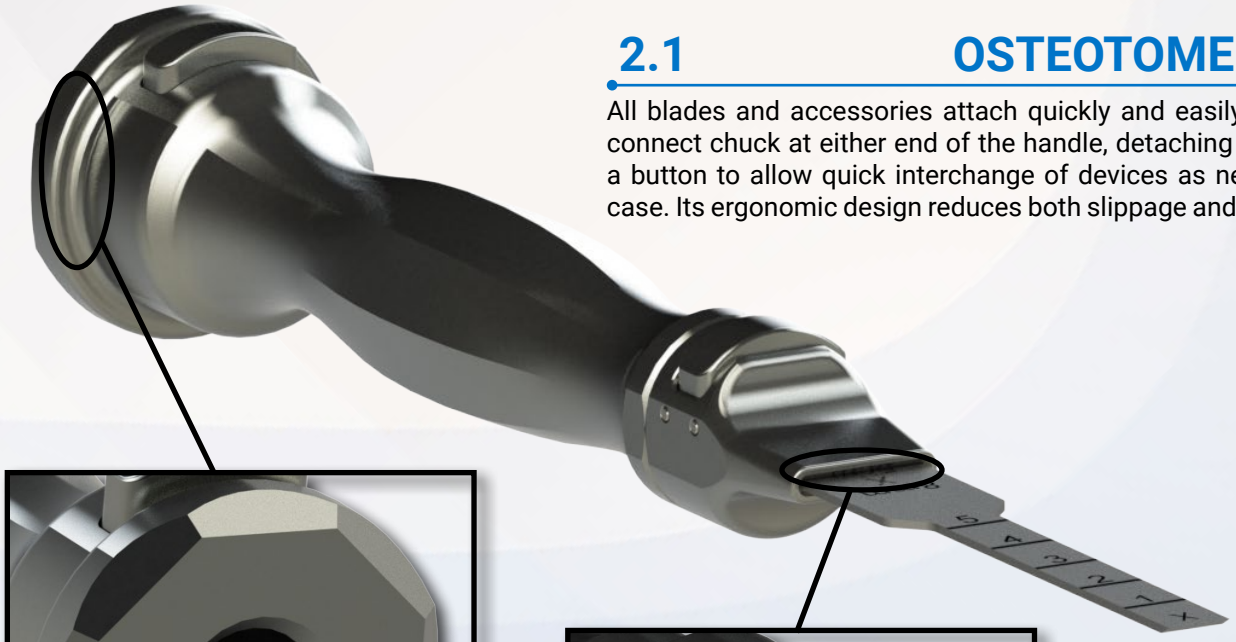


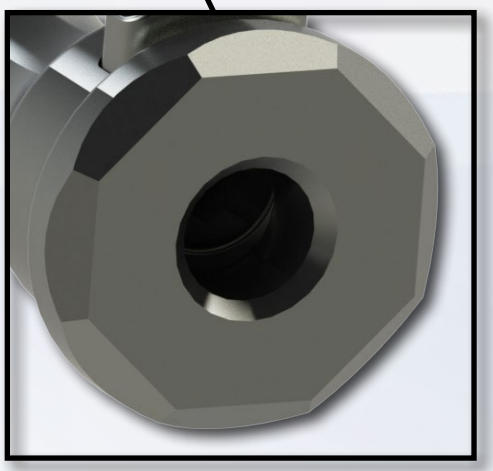
1.3 System History

Over the years numerous surgeons were asking Shukla Medical if a shoulder implant extraction system was available, and if not, when would it be? That level of demand led to our engineers to begin development of the SHUKLA Shoulder system in 2017. Shortly after, the Shoulder Blade system followed suit. Shukla Medical engineers worked alongside surgeons to make sure that the SHUKLA Shoulder Blade would be universal and intuitive to use. Building off the success of our SHUKLA Blade system, the Shoulder Blade system was launched in early 2022.

2.1 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 quick interchange of devices as needed during the case. Its ergonomic design reduces both slippage and surgeon fatigue.



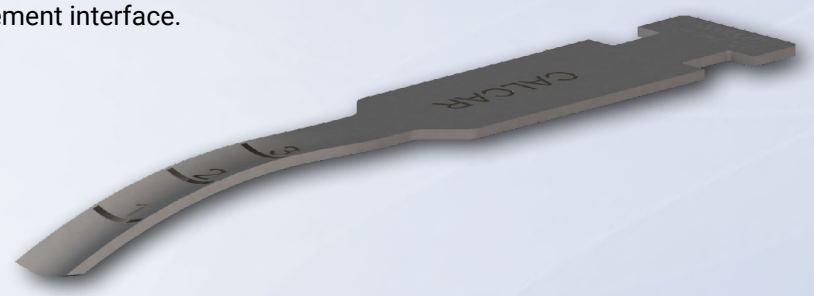


Osteotome Handle back push-to-connect chuck for Attachments.

Osteotome Handle front push-to-connect chuck for Osteotome Blades.

2.2 CALCAR BLADE

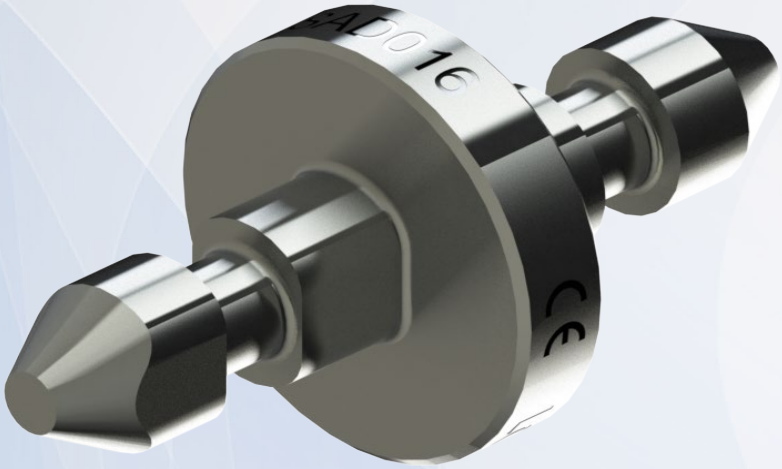
Designed to reach the difficult calcar region of medial calcar. The calcar blade easily breaks up proximal bone or bone cement interface.



Parts not shown to scale

2.3 SHOULDER HUB ADAPTER

The shoulder hub adapter allows for the connecting of the osteotome handle to the slide hammer. The slide hammer in the SHUKLA Shoulder system has a female connection, necessitating the use of the adapter.



2.4 FIN BLADE

Fin blades are designed to be used to break up the interface around shoulder stem fins. The Fin blades come in both a straight and a curved configuration.

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 *Reusable Instrument Inspection Manual,* FCD-17089). 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.
- The surgeon should be cautious with limb position change and/or excessive torque or twisting 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. Always inspect instrumentation for visible wear prior to use.

3.4 Intended Use

The SHUKLA Shoulder Blade (S9SHLDR-BLADE) Universal Flexible Osteotome Solution is intended for use during shoulder revision procedures for the loosening of implant-to-bone interface or implant-to-bone cement interface to facilitate implant extraction during shoulder revision surgery.

Instrumentation from Shukla Medical is recommended for use only within the intended design and only by licensed orthopedic surgeons and SPD staff. Any uses other than those indicated may cause adverse results to the instrumentation or to the patient.

3.5 Indications for Use

The SHUKLA Shoulder Blade (S9SHLDR-BLADE) Universal Flexible Osteotome Solution is indicated for use during any shoulder revision procedure in which the implant to bone or bone cement interface must be loosened prior to shoulder implant extraction.

3.6 Additional Recommendations

During shoulder revision procedures, the SHUKLA Shoulder Blade (S9SHLDR-BLADE) system is recommended for use in conjunction with the SHUKLA Shoulder (S9SHLDR) system.

STEP 1

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.
- The 'X' marking on each Flat Blade denotes the side of the osteotome blade that should be up against the implant.

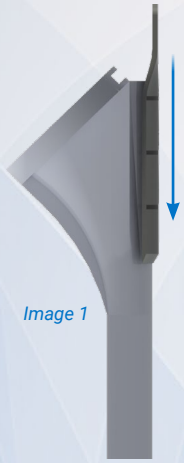


Image 1

Blade Direction

Blade edges are beveled, with one side longer than the other. Use blades with the longer side against the implant (Image 1). This creates a force that helps to keep the blade against the implant as the surgeon drives it forward.

For Flat Blades, make sure the side marked with an 'X' is against the implant.

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.
- **Approximate 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 with the blade tip flush against the anticipated obstruction.
    2. Note the marking near the edge of the implant; this shows how deep the blade can penetrate before reaching an obstruction.

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

Flat Blade Styles

Flat blades are available with various diameters, lengths, and tip styles to satisfy any surgical need (Image 2).

- **6 mm flat blades** are ideal for narrow pockets of implant to bone or bone-cement interface.
- **Regular flat blades** are ideal for loosening shoulder stems 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.

Image 2

Flat Tip

Note: Flat tips transfer all of the impaction force evenly across the entire length of the tip edge.

STEP 2

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 (Image 3).

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.

Image 3

Driving the Osteotome Blade

- Direct impact should be applied to the rear of the handle using the slotted mallet, included in the S9SHLDR system (Image 4). This is the most effective way to apply driving force to any osteotome blade.

Image 4

- Impaction force, especially retrograde force, may also be applied with the use of an attachment (i.e. Slide Hammer, Strike Plate; Image 5).
  - 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.

Image 5

Image 6

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; Image 6), as this can damage the PTC mechanism of the handle, preventing normal use.

STEP 3

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. (Image 7)

Image 7

Attachment Orientation

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

Changing Attachment Orientation (Image 9)

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.

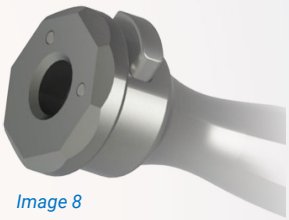


Image 8

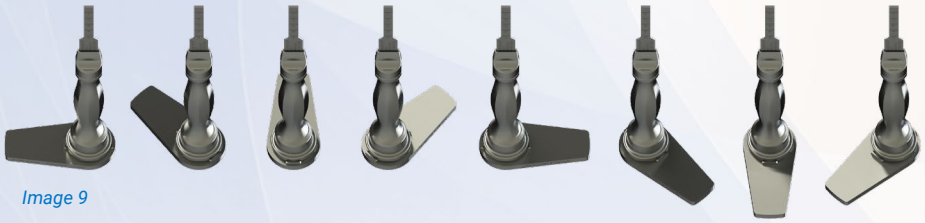


Image 9

Strike Plate

The primary use of the Strike Plate (Image 10) 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 (Image 11).

Image 10

Image 11

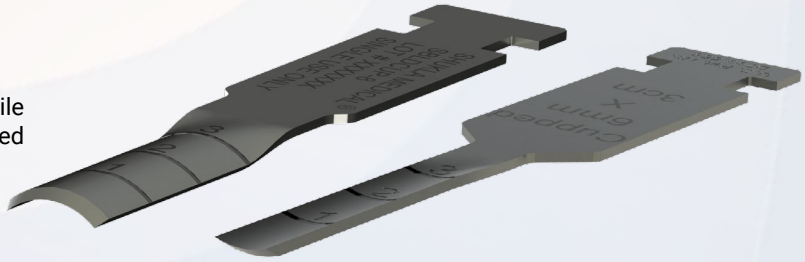
Blade Configurations

Flat Blade (SBLDFLAT-9/10/11/12)

Flat blades are available in various lengths and widths. They can be used to reach down the sides of the shoulder stem. Their flexibility allows the blade to follow the curvature of the implant.

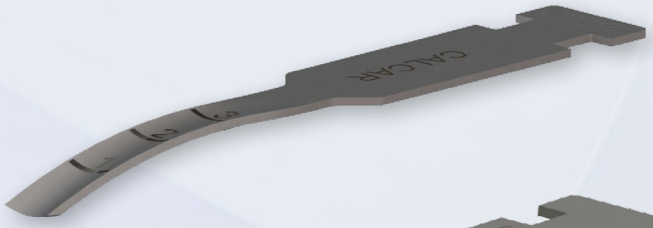
Cupped Blade (SBLDCUP-6/7/8/9/10)

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



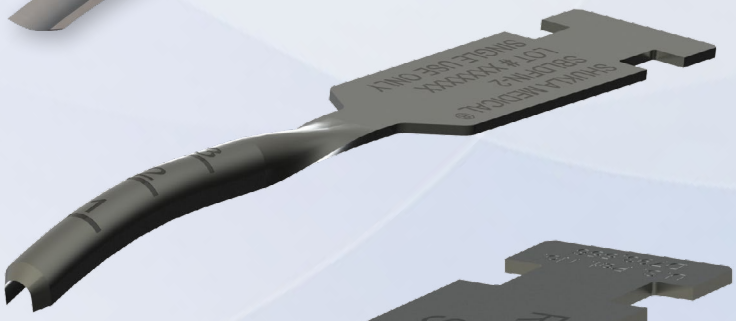
Calcar Blade (SBLDCALC-1)

The calcar blade is designed to break up the interface on the medial calcar surface of shoulder stems.



Fin Blade (SBLDFIN-1/2)

Fin blades are used to break up the interface around shoulder stem fins. They come in both a straight and a curved configuration.



Reverse Stem Blade (SBLDCUP-11)

The reverse stem blade is designed to be used with reverse shoulder stem implants. The blade clears out bone from underneath the shell.

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

5 TIPS and TRICKS — SHUKLA Shoulder Blade

- The Strike Plate can be rotated to different orientations without the need to fully remove it from the handle.
- The Hub Adaptor can be used for the slide-hammer attachment found in the S9SHOULDER system. It can be used to both impact an osteotome in or to help dislodge or remove it if needed.
- Flexible nature of the osteotomes means that they will conform to the geometry of the implant, making them universally compatible.

6 CLEANING & STERILIZATION

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. 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

CE

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The Netherlands

REF S9FLEX
S9BLADE

SHUKLA Medical
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St. Petersburg, FL 33709
USA

CONSULT INSTRUCTIONS FOR USE

NON STERILE NON-STERILE PRODUCT

7 COMPONENTS LIST

Part #	Description	Std Qty
SCS062	Case, Shoulder Blade System	1
SCS063	Tray, Shoulder Blade System	1
SHN047	Handle Assy, Osteotome, Push-to-Connect, Low-Profile	1
SMS019	Strike Plate	1
SAD005	Hub Adapter, Male to Male, Shoulder	1
SBLDFLAT-9	Blade, Flat, 6mm x 3cm, Single Use	2
SBLDFLAT-10	Blade, Flat, 6mm x 9cm, Single Use	2
SBLDFLAT-11	Blade, Flat, 12mm x 3cm, Single Use	2
SBLDFLAT-12	Blade, Flat, 12mm x 9cm, Single Use	2
SBLDCUP-6	Blade, Cupped, 6mm x 3cm, Single Use	2
SBLDCUP-7	Blade, Cupped, 6mm x 9cm, Single Use	2
SBLDCUP-8	Blade, Cupped, 12mm x 3cm, Single Use	2
SBLDCUP-9	Blade, Cupped, 12mm x 9cm, Single Use	2
SBLDCUP-10	Blade, Cupped, 16mm x 5cm, Single Use	2
SBLDCUP-11	Blade, Cupped, Reverse Stem, Single Use	2
SBLDFIN-1	Blade, Fin, Straight, Single Use	2
SBLDFIN-2	Blade, Fin, Curved, Single Use	2
SBLDCALC-1	Blade, Calcar, 8mm x 3cm, Single Use	2

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

SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

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

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CE

FDA REGISTERED

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.

L3-SHLDR-BLADE-STG-REVISED: OCT-24-21