# **PRODUCT GUIDE** SHUKLA SHOULDER Universal Flexible Osteotome Sutton









## System Name: SHUKLA Shoulder Blade v1

## **Primary Use**

The SHUKLA Shoulder Blade (Universal System) Flexible Osteotome is designed for use in any orthopedic shoulder revision surgery 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 is designed to prepare shoulder implants for removal as well as to ensure minimal bone loss.



## **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.

**Version History** 

2022: Version 1 Introduced

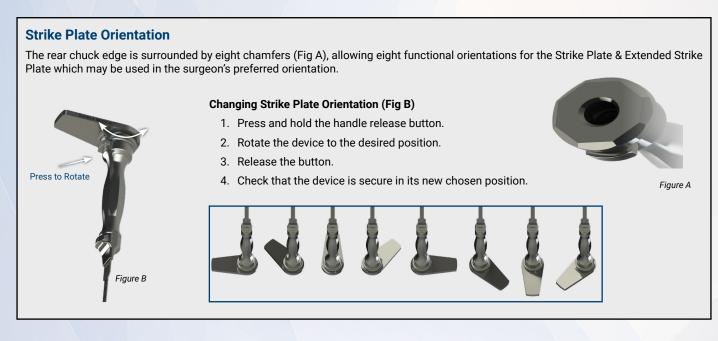


## **Key Benefits**

- Osteotome handle is push-to-connect on both ends. In the front for the blades themselves and in the back for attachments.
- Fin Blades designed to break up bone interface around shoulder stem fins.



- 26 blades in 13 different configurations rounded tip blades, flat tip blades, curved blades, straight blades. We offer more lengths, more widths, and more types than anything available on the market.
- Strike Plate attachment allows blades to be tapped into the bone or tapped out if stuck in bone.
- Single use blades guarantee the sharpest osteotome blade every time.
- Strike Plate attachments can be set in eight different configurations allowing it to be positioned at any angle that is appropriate for a given case.



### **Universal Shukla System Benefits for Better Patient Outcomes**

#### Less Time Spent in O.R.

- Reduces risk of infection to patient
- Reduces time spent under anesthesia
- Reduces cost to the hospital

#### **Universal Designs**

- Less prep time for surgeons
- Less space taken up in the O.R.
- · Reduces need for other systems or tools

#### **Ergonomic Design**

- Reduces surgeon stress
- Reduces surgeon fatigue
- Better grip/reduces slippage

#### **Comprehensive Design**

- Addresses all known challenges
- Tools ensure surgery is a success
- · Provides backup solutions during surgery





PRODUCT GUIDE SHUKLA Shoulder Blade (S9SHLDR-BLADE) Universal Flexible Osteotome System

## **Alternative Method Comparison**

Before we introduced our calcar blades, the only reliable method of breaking apart the bony interface of the calcar region was by running k-wires down side-by-side because a traditional osteotome couldn't reach.



K-Wires inserted into the calcar bone, causing a much higher rate of bone loss.



Fin Blade inserted into the fin of an implant, causing minimal bone loss. (Alongside image of Fin Blade)

## **Return On Investment Justification**

According to a study published in JAMA Surgery, the average cost for one minute in an O.R. is a staggering \$66! The median time spent in an O.R. per surgery is 75 minutes per surgery. Therefore, the typical per surgery cost could be calculated as 75 minutes per surgery x \$66 per minute for a total of \$4,950. The SHUKLA Shoulder Blade system would pay for itself in less than two surgeries.

## When You Don't Have It

We've all been there before. You're doing a shoulder revision only to discover the implant has become integrated with the bone through its porous interface. You happen to have a generic osteotome set on hand. However, not only are they not the width you needed, none of them are long enough. Since the non-Shukla blades were not designed for single use, they were too dull from your last surgery to be effective for you when you needed them to be. You could try k-wires to break up the interface, but that would result in unnecessary bone loss.

Or, you use the SHUKLA Shoulder Blade system and have the most comprehensive, capable osteotome system on the market available for every shoulder revision case you come across.



## **How We Compare**

Most orthopedic implant manufacturers provide revision/extraction tools suited only for their specific implants. Suppliers that claim to offer extraction systems for a variety of implants really only offer an assortment of tools thrown together as an afterthought. At Shukla Medical, **extraction is what we do**. Our engineers design truly universal tools to help remove any implant/hardware available on the market today. Our comprehensive, patented designs are revolutionizing the art of revision surgery; we proudly stand alone. That being shared, we did our best to provide a competitor comparison below.

Osteotome blades are by far the most used tools in revision surgery. Most of the blades currently available in the market are reusable and only provide flat or curved blades. The SHUKLA Shoulder Blade system offers single-use blades ensuring surgeons will always have the sharpest blade possible. The SHUKLA Shoulder Blade not only provides flat and cupped blades but also procedure-specific blades, such as Fin Blades and Calcar Blades.

With the SHUKLA Shoulder Blade, surgeons can visually check the available blade options and evaluate what the right blade would be for the task at hand. The system offers an advanced ergonomic handle that features push-to-connect chucks at both ends for blades and accessories.

The engineers at Shukla worked hard to create several ingenious patented items just for the SHUKLA Shoulder Blade flexible osteotome system. The tools and instruments they develop make every step of the process easier.

#### PATENTS

- Osteotome Handle
- Strike Plate
- Calcar Blade
- Fin Blade

#### **Strike Plate**

Features eight different possible positioning configurations, allowing surgeons to orient the strike plate in the ideal direction no matter what the situation.

#### **Osteotome Handle**

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

#### **Calcar Blade**

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

#### Fin Blade

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





## **Attention to Detail**

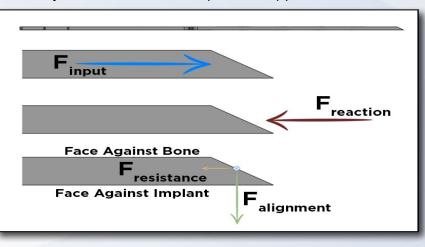
The patented osteotome handle allows attachments to pivot in eight different positions without the need to remove it from the push-to-connect mechanism. The Calcar Blade and Fin Blades have been engineered for specific issues many surgeons face. The blades have been created with a variety of shapes, widths, and lengths to ensure that no matter the shape of the bone, surgeons can take care of it. Our blades are beveled only on one side. This one-sided bevel design was developed to maximize the alignment force to the implant and minimize the risk of bone loss.

The blades are designed to be and marked as single-use items. They should be replaced after each use. By designing the blade system with the surgeon in mind, we created an easy-to-use, no-need-to-open-a-packet format allowing the surgeon to look at, hold, and determine the right option for each surgery.

The blades are made of SS410 steel ideally suited for surgical instruments. It allows for the sharpest edge possible and is treated with chrome plating to aid in the prevention of rusting due to sterilization. Since the blades are open and accessible, any unused blades must be sterilized after each use, and may be re-sterilized multiple times. *Please note: The sterilization process, over time, may cause any unused blade(s) to corrode. Frequent inspection of blades is recommended.* 



A single bevel blade may seem like a standard, simple way of sharpening an object, but why is it done this way?



For every action, there is an equal and opposite reaction.

The input force is the force put on the blade (the force from the mallet or slap hammer). The bone is imparting a reaction force on this. The resistance force in the diagram is very small; this is the force that needs to be overcome in order to drive the blade into the bone.

The interesting force here is the alignment force. This is a substantial force that is pushing the flat side of the blade against the implant to keep it from migrating out into bone. This simple force is one of the keys to bone preservation in the osteotome blades.



## **Components List**

Part #	Description	Std Qty
SCS062	Case, Shoulder Blade System	1
SCS063	Lid, 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, <mark>Single Use</mark>	2

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





## 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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CONSULT INSTRUCTIONS FOR LISE

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.



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.

