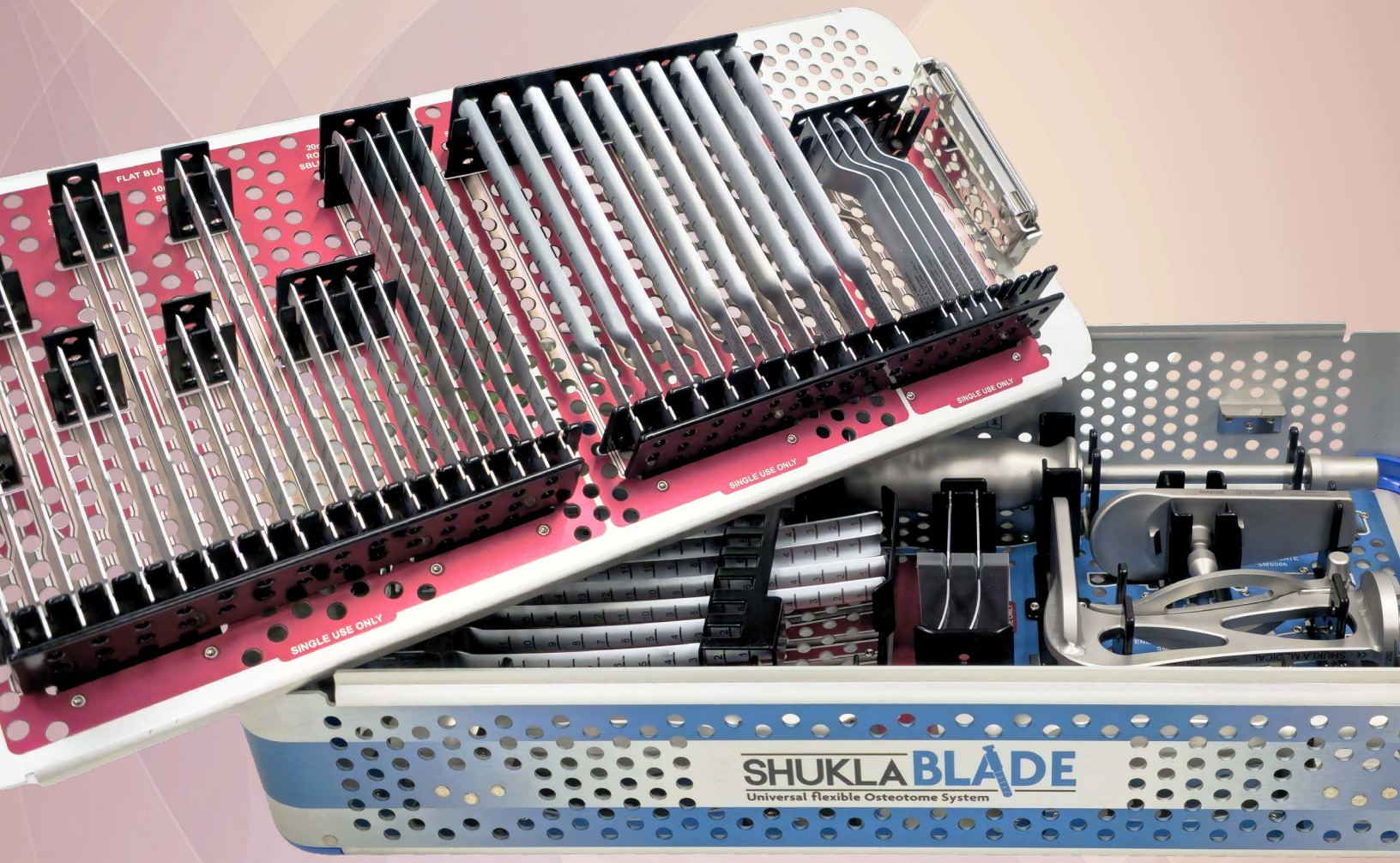
PRODUCT GUIDE

SHUKLA BLADE™

Universal Flexible Osteotome System

#4

System 4 of 25



SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

THE EXTRACTION EXPERTS

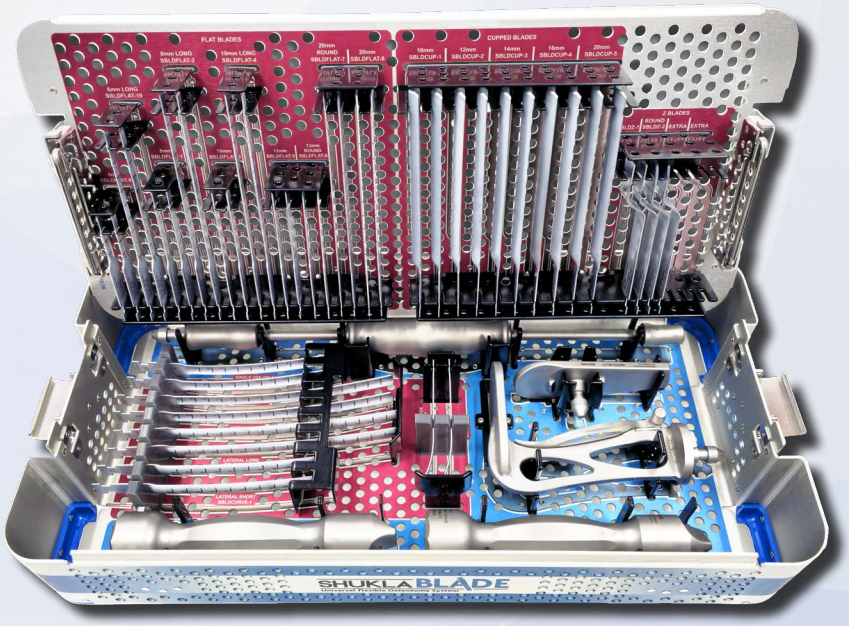
SHUKLA BLADE™

Universal Flexible Osteotome System

System Name: SHUKLA Blade v1

Primary Use

The SHUKLA Blade (Universal Flexible Osteotome System) is designed to be used in any 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 general orthopedic, knee and hip 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 implants for removal and to ensure minimal bone loss.



System History

In development since 2017, our engineers have been hard at work making sure that our flexible osteotome system is the best in the business. What began as an initial request by Dr. Peter Chiang from Colorado's SCL Good Samaritan soon became a universally desired product from Shukla. Thanks to field feedback from sales representatives, surgeons, and professionals, our v1 SHUKLA Blade system was released in August 2019.

Version History

- **2019: 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.
- Calcar Blade is designed to reach the previously difficult-to-reach calcar region of the femoral neck.
- 44 blades in 22 different configurations - rounded tip blades, flat tip blades, curved blades, straight blades. We offer more lengths, more widths, and more types than any on the market.
- Strike Plate attachment allows blades to be tapped into the bone or tapped out if stuck in bone.
- Z Blades use their unique shape to bypass hard to get around soft tissue in the knee.
- Minimize lost time searching for the right osteotome.
- Single use blades guarantee the sharpest osteotome blade every time.
- Strike Plate attachments can be set in any of eight configurations allowing it to position at any angle that is appropriate for a given case.

Strike Plate Orientation

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

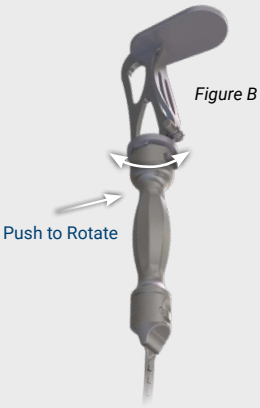


Figure B

Changing Strike Plate Orientation (Fig B)

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.



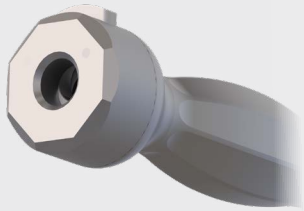


Figure A

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

Ergonomic Design

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

Universal Designs

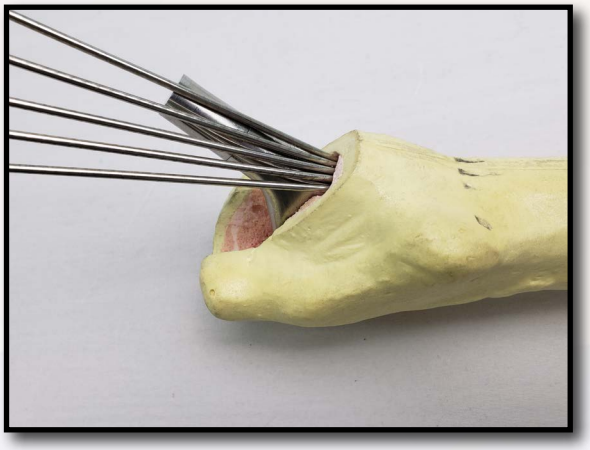
- Less prep time for surgeons
- Less space taken up in the O.R.
- Reduces need for other systems or tools

Comprehensive Design

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

Alternative Method Comparison

Before our calcar blade was made, the only reliable method of breaking apart the bony interface of the calcar region was by running k-wires down side-by-side since a traditional osteotome wouldn't reach. Other sets on the market lack our comprehensive range of blades as well as the simple push-to-connect capability of our handle.



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



Calcar Blade inserted into the calcar region, causing minimal bone loss alongside image of Calcar Blade.

Return On Investment Justification

According to a study published in JAMA Surgery, the cost of one minute in an O.R. can vary anywhere from $36 per minute to $100 per minute with the average cost of a minute in the O.R. a staggering $66! Taking just the lowest estimate of time savings, the savings per surgery can be estimated at 60 minutes x $36 per minute = $2,160. A SHUKLA Blade set at the current (2019) price sells at $13,500. At this price, when you use the system a mere 7 times, the full purchase price is recovered.

When You Don't Have It

Picture this scenario: You are doing a hip revision. You discover that the hip stem has gotten integrated with the bone through its porous interface. You happen to have a generic osteotome. However, not only is the width not right, but it isn't long enough. It gets stuck because the tip is flat instead of curved. You could try k-wires to break up the interface, but that would result in unnecessary bone loss.

Or, you get the SHUKLA Blade system, and have the most comprehensive and capable osteotome system on the market on hand for every case where it is needed.

How We Compare

Most orthopedic implant manufacturers provide revision/extraction tools suited *only* for their own implants. Even suppliers that claim to offer extraction sets basically have an assortment of tools thrown together as an afterthought. For Shukla Medical, ***extraction is what we do***. Our engineers design truly universal tools to help remove any implant/hardware out there, making our competition essentially nonexistent. Our patented designs are revolutionizing the art of revision surgery; we proudly stand alone. We have still tried to provide a comparison to other systems on the market.

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 Blade system makes single-use blades ensuring surgeons always have the sharpest blade possible. The SHUKLA Blade not only provides flat and curved blades but also procedure-specific blades. Blades such as Z-Blades for knee implants, Calcar Blades for the calcar region, along with a wide range of blades tailored for hip implants.

Shukla blades come in a set allowing surgeons to visualize how each blade would apply to their specific scenario. With the SHUKLA Blade, surgeons can look at the blade options, feel the blades in their hands, and evaluate if it is the right blade for the task at hand. The SHUKLA Blade 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 Blade flexible osteotome system.

Our engineers work hard - the tools and instruments they come up with make every step of the process easier.

PATENTS

- Osteotome Handle
- Extended Strike Plate
- Calcar Blade
- ESSE Blade
- Slide Hammer

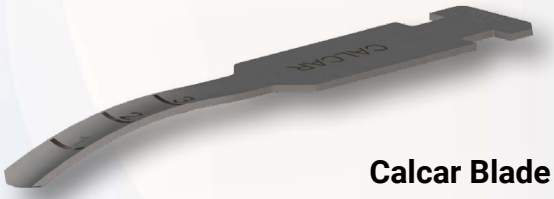


Extended Strike Plate

The distance from the handle to the impact surface allows for a greater range of motion for mallet strikes. This increases crucial impaction force. A retractable hand guard protects the user from possible injury during mallet strikes.

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.

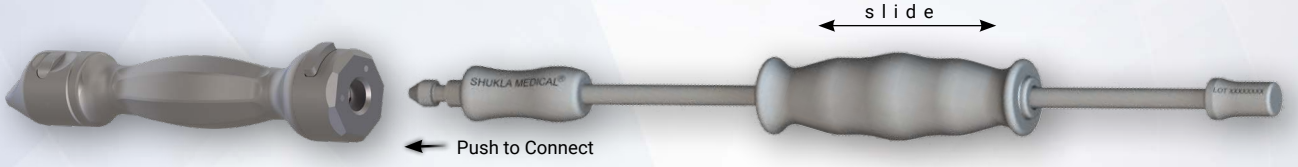


Z Blade

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

Slide Hammer

The Slide Hammer may be used to apply impact force in either antegrade or retrograde directions. Its ergonomic grip reduces user fatigue. It can be readily attached or removed from the rear Push-To-Connect chuck on the osteotome handle.



Attention to Detail

The patented osteotome handle allows attachments to pivot into eight different positions without the need to even remove it from the push-to-connect mechanism. The calcar blade was engineered for a specific issue many surgeons had to face. The blades were created with a variety of shapes, widths, and lengths to ensure that no matter the bone that appears before you, you can osteotome it. Our blades are beveled only on one side to maximize alignment force to the implant to minimize risk of bone loss.

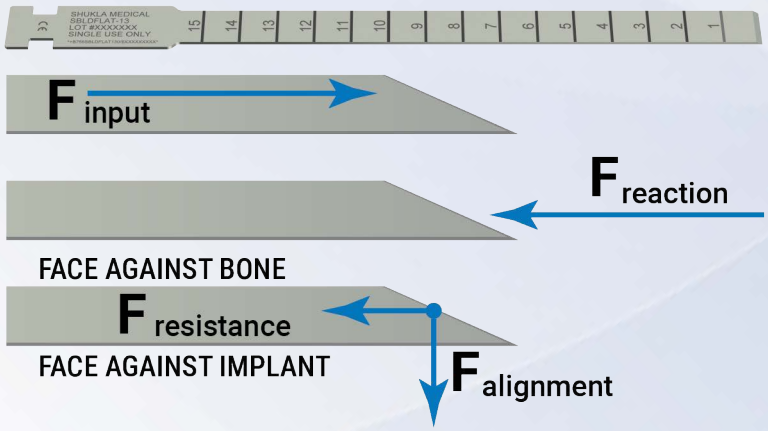
The blades are marked as 'single-use' items and should be replaced after each use. By designing the blade system with the surgeon in mind, we created an easy-to-use, no-need-to-open-a-packet format allowing the surgeon to look at, hold, and determine the right option for each surgery.

The blades are made of SS410 material to allow for the sharpest edge possible and are treated with chrome plating to aid in the prevention of rusting due to sterilization. Since the Shukla 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.

THE BEVEL

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.

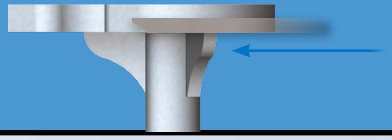


The input force is the force we are putting into the blade (the force from the mallet or slap hammer). The bone is imparting a reaction force on this. The resistance force in the diagram is very small and this is the force that needs to be overcome in order to drive the blade into the bone.

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.

Blade Direction

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



Components List

Part #	Description	Std Qty
SCS009	Case, Blade System	1
SCS010	Tray, Blade System	1
SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems	1
SHN012	Handle Assy, Osteotome, Push-to-Connect	2
SIN005	Hammer Assy, Slide	1
SMS066	Strike Plate, Flanged	1
SMS023	Strike Plate, Assy, Extended	1
SBLDFLAT-1	Blade, Flat, 8 mm x 5 cm, Single Use	2
SBLDFLAT-2	Blade, Flat, 8 mm x 11 cm, Single Use	2
SBLDFLAT-3	Blade, Flat, 10 mm x 5 cm, Single Use	2
SBLDFLAT-4	Blade, Flat, 10 mm x 11 cm, Single Use	2
SBLDFLAT-5	Blade, Flat, 12 mm x 5 cm, Single Use	2
SBLDFLAT-6	Blade, Flat, Round Tip, 12 mm x 5 cm, Single Use	2
SBLDFLAT-7	Blade, Flat, Round Tip, 20 mm x 11 cm, Single Use	2
SBLDFLAT-8	Blade, Flat, 20 mm x 11 cm, Single Use	2
SBLDFLAT-9	Blade, Flat, 6 mm x 3 cm, Single Use	2
SBLDFLAT-10	Blade, Flat, 6 mm x 9 cm, Single Use	2
SBLDCUP-1	Blade, Cupped, 10 mm x 11 cm, Single Use	2
SBLDCUP-2	Blade, Cupped, 12 mm x 11 cm, Single Use	2
SBLDCUP-3	Blade, Cupped, 14 mm x 11 cm, Single Use	2
SBLDCUP-4	Blade, Cupped, 16 mm x 11 cm, Single Use	2
SBLDCUP-5	Blade, Cupped, 20 mm x 11 cm, Single Use	2
SBLDCURVE-1	Blade, Curved, for Lateral Hip, 12 mm x 11 cm, Single Use	2
SBLDCURVE-2	Blade, Curved, for Lateral Hip, 12 mm x 16 cm, Single Use	2
SBLDCURVE-3	Blade, Curved, for Medial Hip, 12 mm x 11 cm, Single Use	2
SBLDCURVE-4	Blade, Curved, for Medial Hip, 12 mm x 16 cm, Single Use	2
SBLDZ-1	Blade, Z, Flat Tip, 16 mm x 2 cm, Single Use	2
SBLDZ-2	Blade, Z, Round Tip, 16 mm x 2 cm, Single Use	2
SBLDCALC-1	Blade, for Calcar, 8 mm x 3 cm, Single Use	2

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 USE

NON STERILE NON-STERILE PRODUCT

SHUKLA Surgical Tech Support

24 hours a day, 7 days a week
+1 (727) 293-5400

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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