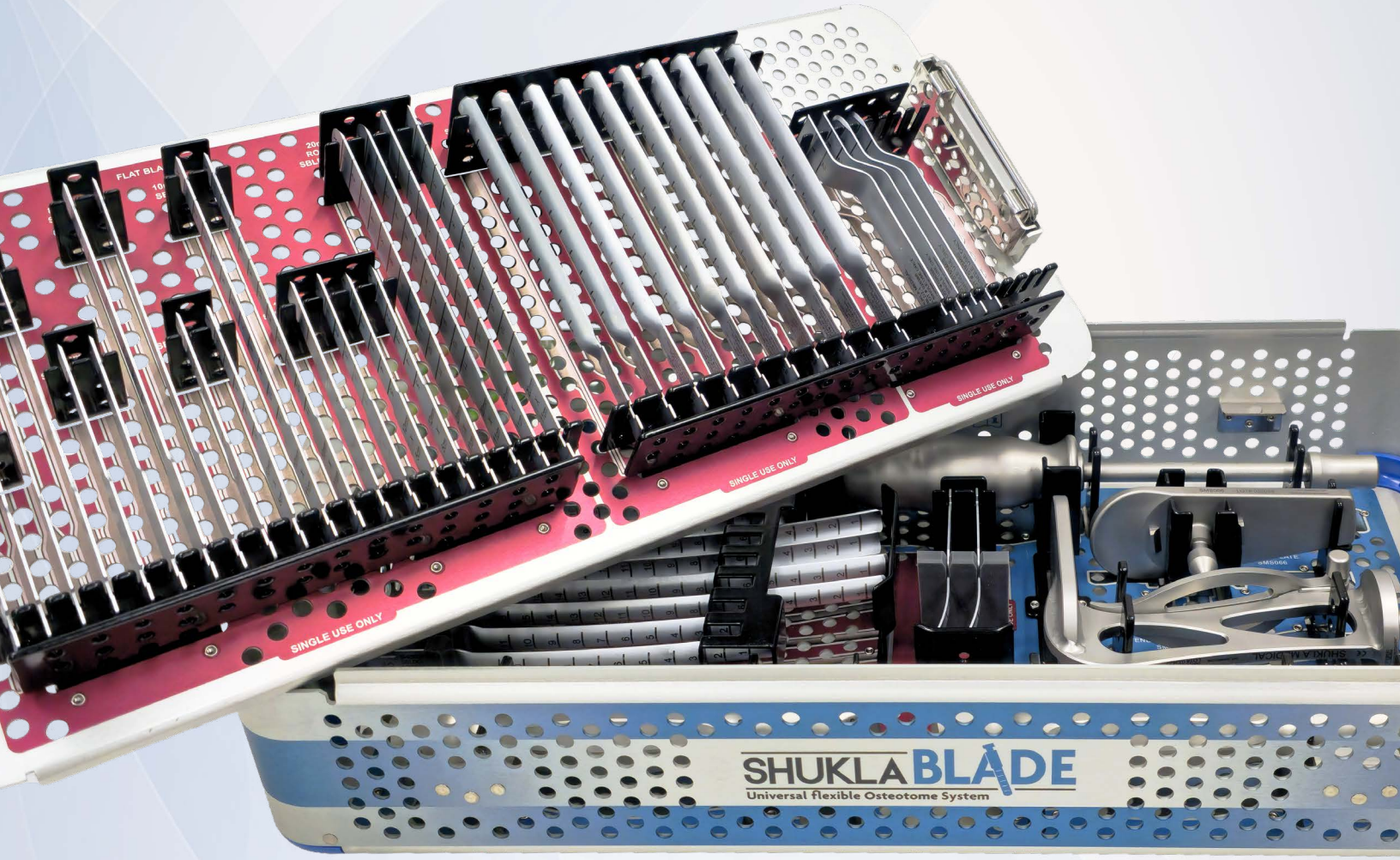
SURGICAL TECHNIQUE GUIDE

#4
System 4 of 25

SHUKLA BLADE™

Universal Flexible Osteotome System



SHUKLA MEDICAL®
Universal Orthopedic Extraction Technologies
THE EXTRACTION EXPERTS

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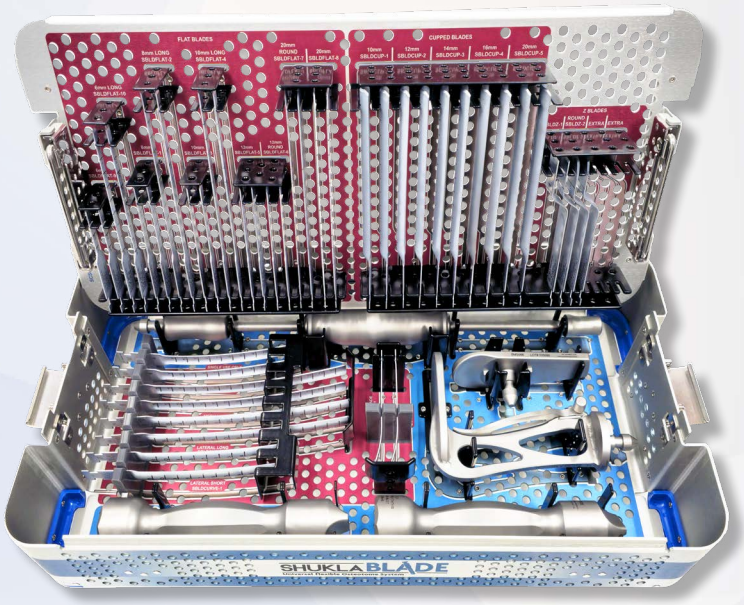
SHUKLA BLADE™

Universal Flexible Osteotome System

1.1 System Name: SHUKLA Blade

Part Number: S9BLADE

Version: 1



1.2 Primary Use

The SHUKLA Blade (Universal Flexible Osteotome Solution) 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 specific 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 as well as to ensure minimal bone loss.

1.3 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, we developed the debut v1 of the SHUKLA Blade system.

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. It's ergonomic design and silicone molding reduce both slippage and surgeon fatigue.

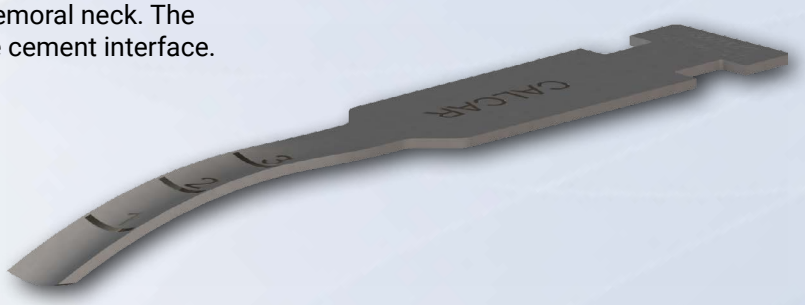


Osteotome Handle back push-to-connect chuck for Attachments.

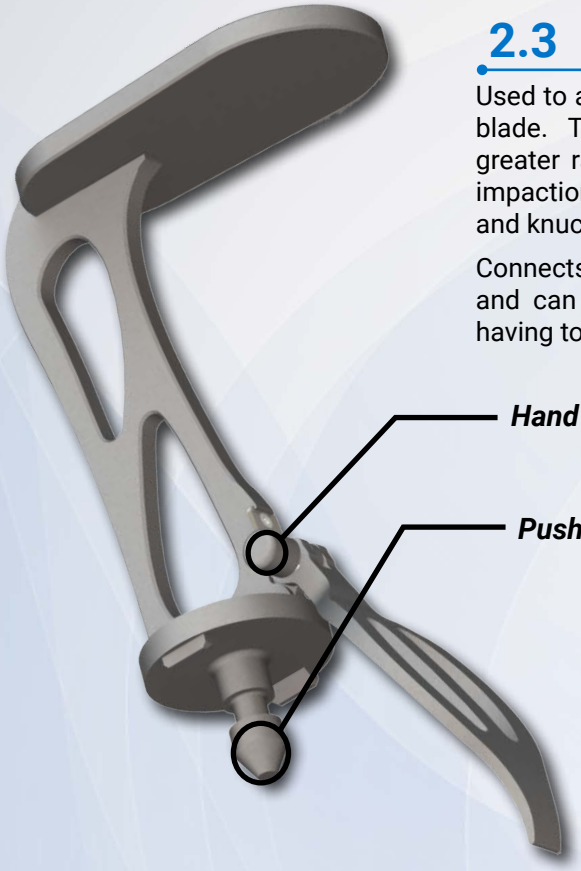
Osteotome Handle front push-to-connect chuck for Osteotome Blades.

2.2 CALCAR BLADE

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



Parts not shown to scale



2.3 EXTENDED STRIKE PLATE

Used to apply greater impact force to the equipped osteotome blade. The distance from handle to impact surface allows a greater range of motion for mallet strikes, increasing crucial impaction force. A retractable hand guard protects user's hand and knuckles during heavy mallet strikes.

Connects quickly to the Osteotome Handle with a simple push, and can be realigned in eight different orientations without having to remove it from the handle.

2.4 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.





2.5 LATERAL & MEDIAL HIP BLADES

Curved blades that are designed to break up the interface on the medial & lateral sides of the hip stem. Their flexible nature means they will conform to fit the geometry of the implant when used. Even though they are designated as Hip Blades, they are also highly effective on IM Nail geometries as well. After the implant has been removed, they can be used to clear remaining bone cement.

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.

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 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.

3.5 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.

3.6 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).

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.

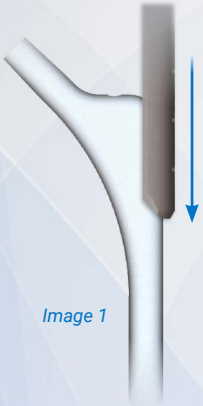


Image 1

Blade Direction

Blade edges are beveled, with one side longer than the other. Use blades with the longer side against the implant (Image 1, 2). This creates a force that helps to keep the blade against the implant as the surgeon drives it forward.

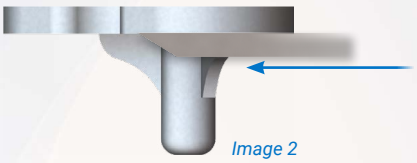
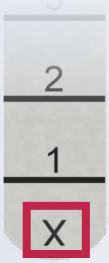


Image 2



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.
- **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 (3A) 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 (3B); this shows how deep the blade can penetrate before reaching an obstruction.

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

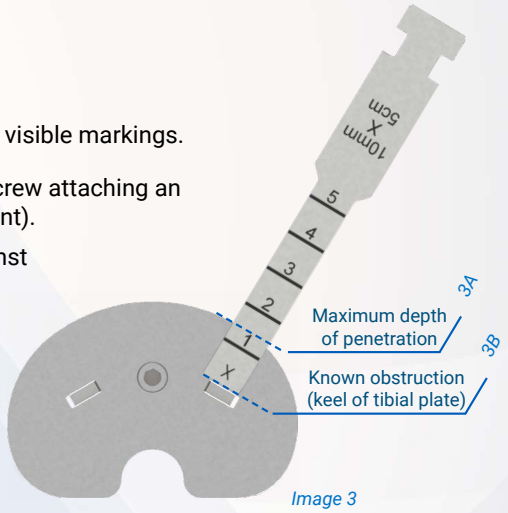


Image 3

Flat Blade Styles

Flat blades are available with various diameters, lengths, and tip styles to satisfy any surgical need (Image 4).

- **6 mm 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 and 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.



Image 4

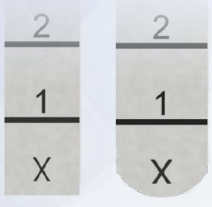


Image 5

Tip Styles: Flat vs Curved (Image 5)

- 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.

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 6).

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.

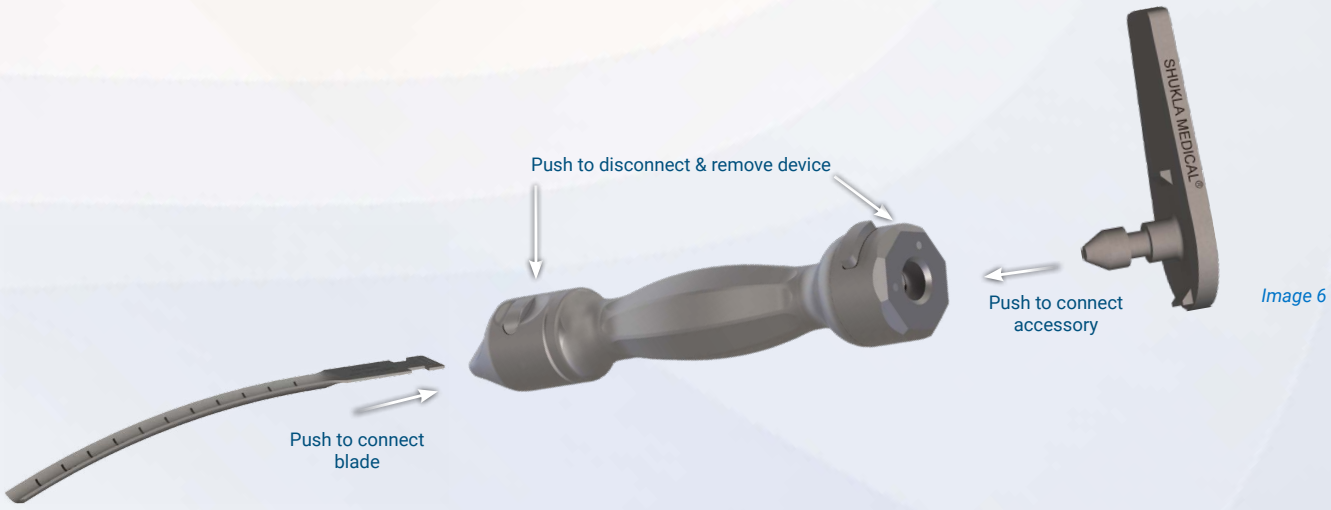


Image 6

Driving the Osteotome Blade

- Direct impact should be applied to the rear of the handle using a general surgical mallet, not included (Image 7). This is the most effective way to apply driving force to any osteotome blade.



Image 7

- 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; Image 8).
  - 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.

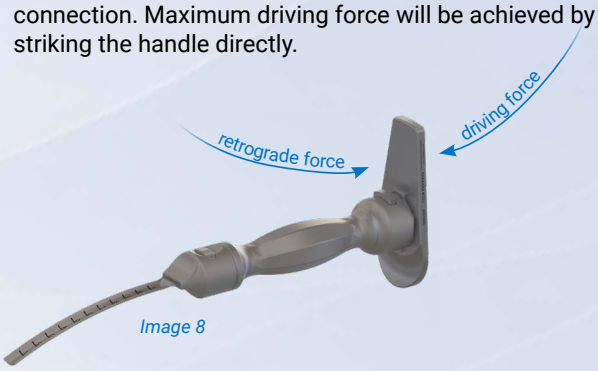


Image 8



Image 9

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 9), 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 10)



Image 10

Attachment Orientation

The rear chuck edge is surrounded by eight chamfers (Image 11), allowing eight functional orientations for the Strike Plate & Extended Strike Plate, which may be used in the surgeon-preferred orientation.

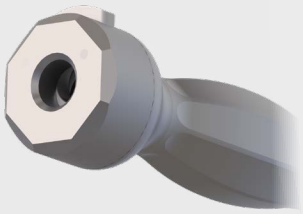


Image 11

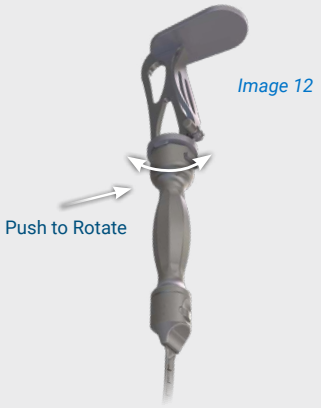


Image 12

Changing Attachment Orientation (Image 12, 13)

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 13

Strike Plate

The primary use of the Strike Plate (Image 14) 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 15).



Image 14



Image 15

STEP 4

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 (Image 16).

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.

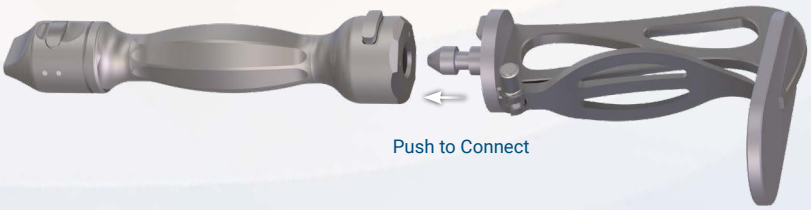


Image 16

Retractable Hand Guard

Extend the retractable hand guard for user protection when swinging with a mallet.

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.

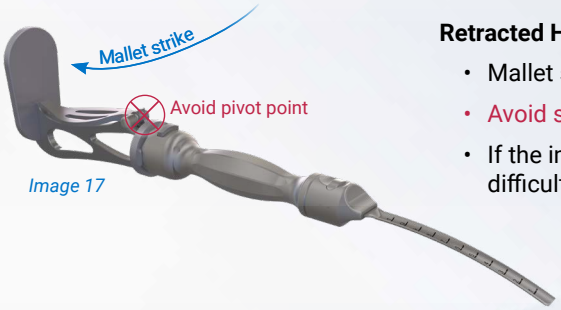


Image 17

Retracted Hand Guard (Image 17)

- 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.



Image 18

Lowered Hand Guard (Image 18)

- 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.

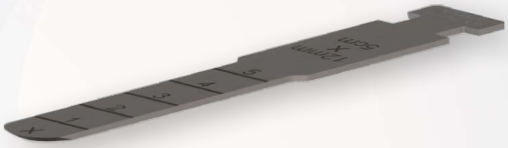
Image 17



Blade Recommendations: Tibial Component

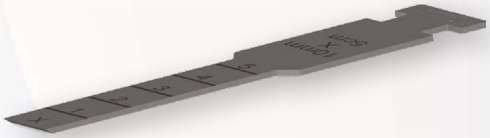
12 mm Flat Blade with Curved Tip (SBLDFLAT-6)

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



Regular Flat Blade (SBLDFLAT-1/3/5)

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.

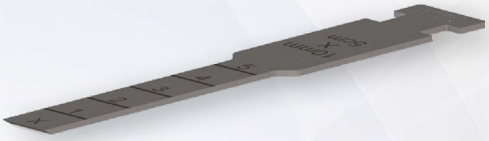
Z Blade (SBLDZ-1/2)

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.



6 mm Flat Blade (SBLDFLAT-9/10)

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



Long Flat Blade (SBLDFLAT-2/4/7/8)

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

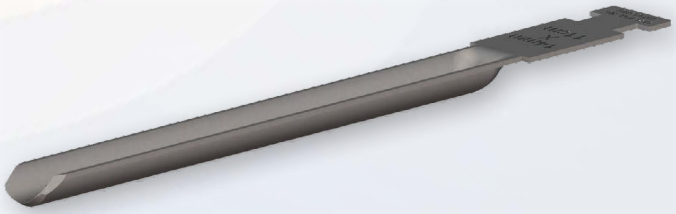
Long Flat Blade (SBLDFLAT-2/4/7/8)

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.



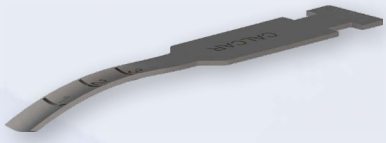
Cupped Blade (SBLDCUP-1/2/3/4/5)

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 (SBLDCALC-1)

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



Curved Blade for Lateral & Medial Hip (SBLDCURVE-1/2/3/4)

Curved blades are designed to break up the interface on the medial and 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.

5 TIPS and TRICKS SHUKLA Blade

- Lateral and Medial Hip Blades work especially well around the geometry of Intramedullary (IM) Nails.
- A second Osteotome Handle is provided to allow for rapid swapping of blade configurations during surgery.
- The Strike Plate and Extended Strike Plate can be rotated to different orientations without the need to fully remove it from the handle.
- The slide-hammer attachment 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

For detailed cleaning and sterilization instructions, please consult the SHUKLA Medical Instructions For Use (IFU) document or visit www.ShuklaMedical.com/Sterilization

CE

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

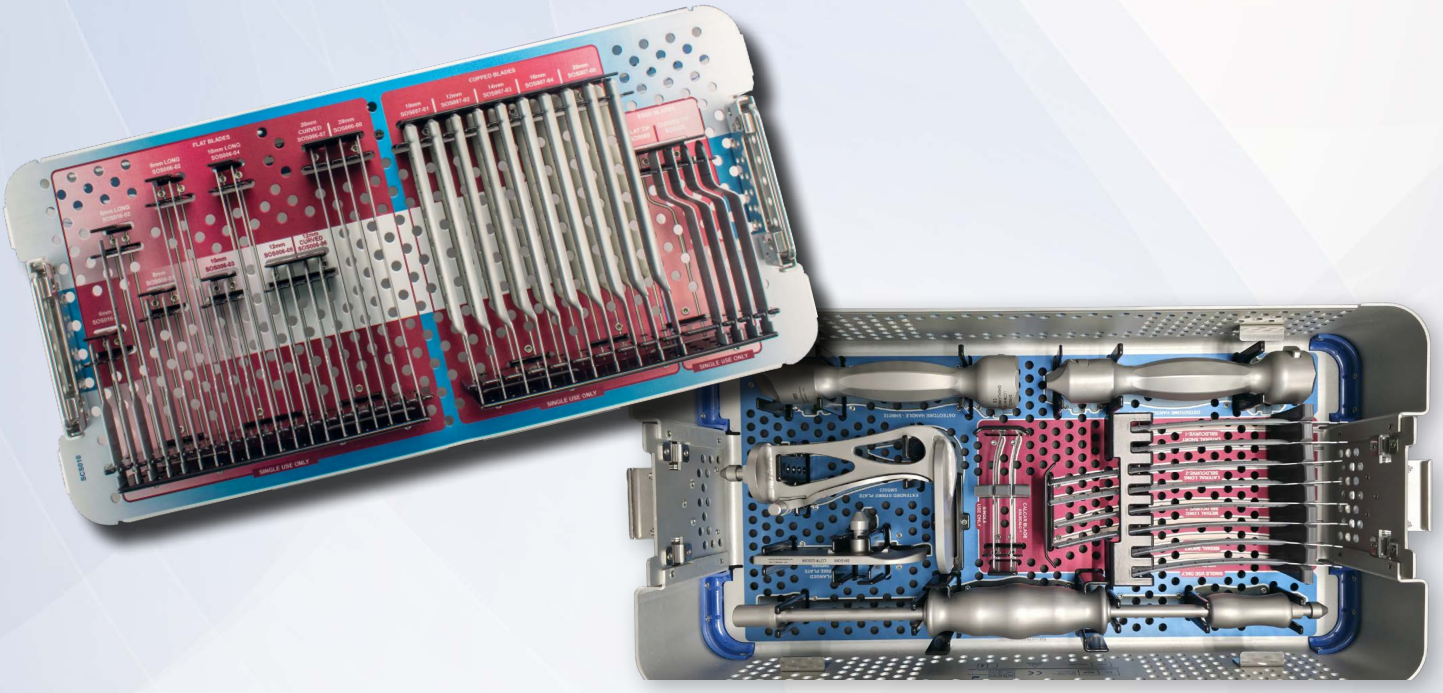
CONSULT INSTRUCTIONS FOR USE

NON STERILE NON-STERILE PRODUCT

7 COMPONENTS LIST

S9BLADE Universal Flexible Osteotome Solution					
Part #	**Description**	**Qty**	**Part #**	**Description**	**Qty**
SCS009	Case, Blade System	1	SBLDFLAT-9	Blade, Flat, 6 mm x 3 cm, Single Use	2
SCS010	Tray, Blade System	1	SBLDFLAT-10	Blade, Flat, 6 mm x 9 cm, Single Use	2
SCS011	Lid, Hip, Knee, Broken & Stripped, Blade Systems	1	SBLDCUP-1	Blade, Cupped, 10 mm x 11 cm, Single Use	2
SHN012	Handle Assy, Osteotome, Push-to-Connect	2	SBLDCUP-2	Blade, Cupped, 12 mm x 11 cm, Single Use	2
SIN005	Hammer Assy, Slide	1	SBLDCUP-3	Blade, Cupped, 14 mm x 11 cm, Single Use	2
SMS066	Strike Plate, Flanged	1	SBLDCUP-4	Blade, Cupped, 16 mm x 11 cm, Single Use	2
SBLDFLAT-1	Blade, Flat, 8 mm x 5 cm, Single Use	1	SBLDCUP-5	Blade, Cupped, 20 mm x 11 cm, Single Use	2
SBLDFLAT-2	Blade, Flat, 8 mm x 11 cm, Single Use	2	SBLDCURVE-1	Blade, Curved, for Lateral Hip, 12 mm x 11 cm, Single Use	2
SBLDFLAT-3	Blade, Flat, 10 mm x 5 cm, Single Use	2	SBLDCURVE-2	Blade, Curved, for Lateral Hip, 12 mm x 16 cm, Single Use	2
SBLDFLAT-4	Blade, Flat, 10 mm x 11 cm, Single Use	2	SBLDCURVE-3	Blade, Curved, for Medial Hip, 12 mm x 11 cm, Single Use	2
SBLDFLAT-5	Blade, Flat, 12 mm x 5 cm, Single Use	2	SBLDCURVE-4	Blade, Curved, for Medial Hip, 12 mm x 16 cm, Single Use	2
SBLDFLAT-6	Blade, Flat, Round Tip, 12 mm x 5 cm, Single Use	2	SBLDZ-1	Blade, Z, Flat Tip, 16 mm x 2 cm, Single Use	2
SBLDFLAT-7	Blade, Flat, Round Tip, 20 mm x 11 cm, Single Use	2	SBLDZ-2	Blade, Z, Round Tip, 16 mm x 2 cm, Single Use	2
SBLDFLAT-8	Blade, Flat, 20 mm x 11 cm, Single Use	2	SBLDCALC-1	Blade, for Calcar, 8 mm x 3 cm, 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

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

Shukla Medical
8300 Sheen Drive
St. Petersburg, FL 33709
www.ShuklaMedical.com

T: 888-4-SHUKLA
T: 888-474-8552
F: 727-626-2770
CS@ShuklaMedical.com

ISO 13485:2016

FDA REGISTERED

EC REP **Emergo Europe**
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

REF S9BLADE

SHUKLA Medical
8300 Sheen Drive
St. Petersburg, FL 33709
USA

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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L3-BLADE-STG-REVISED: JULY-22-20