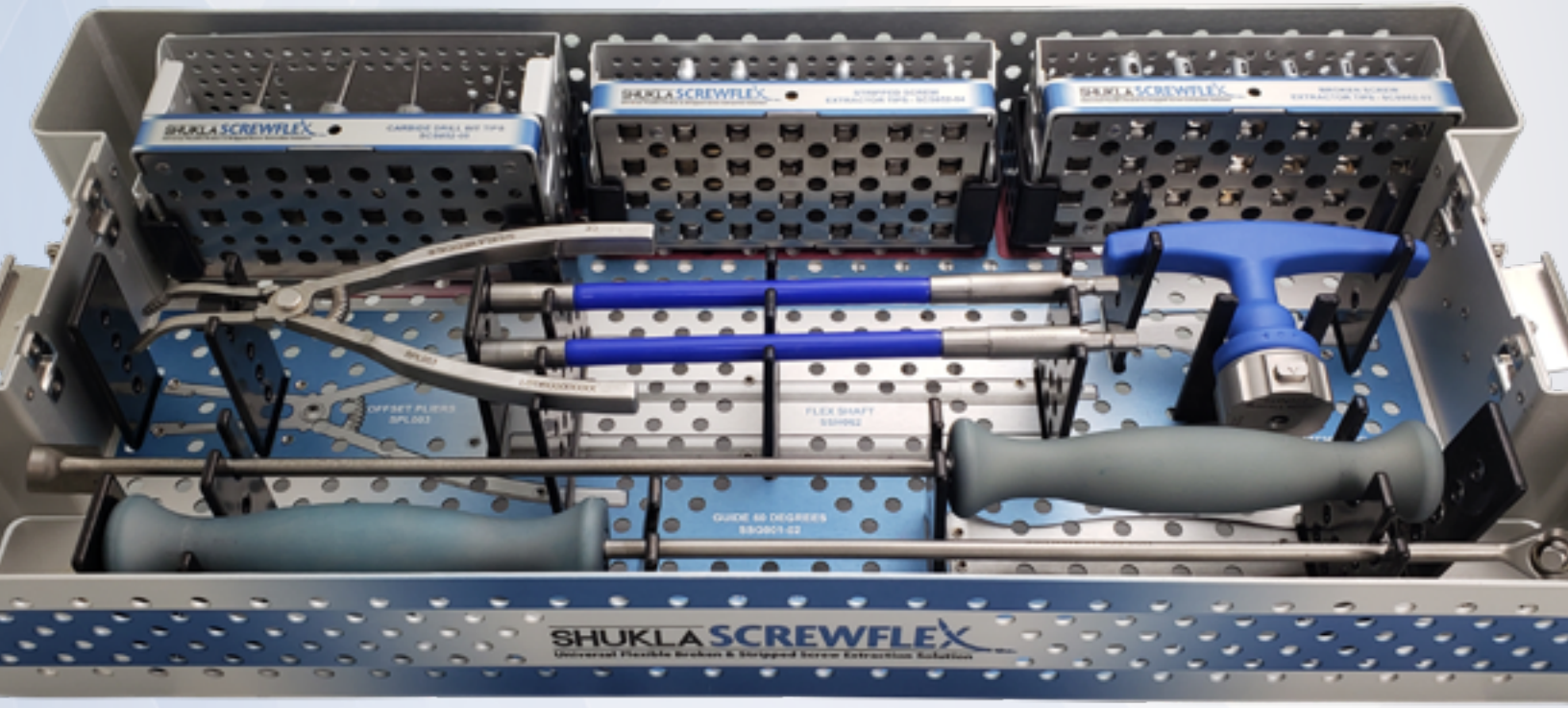
SURGICAL TECHNIQUE GUIDE

#20
System 20 of 25

SHUKLA SCREWFLEX

Universal Flexible Broken & Stripped Screw Extraction System



SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

THE EXTRACTION EXPERTS

CONTENTS

1

SHUKLA SCREWFLEX

Universal Flexible Broken & Stripped Screw Extraction System

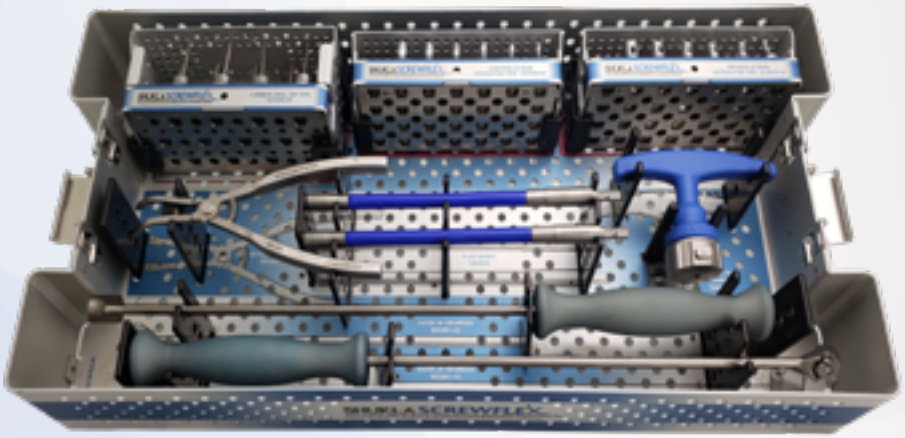
1.1 System Name: SHUKLA ScrewFlex

Part Number: S9SCREWFLEX

Version: 1

1.2 Primary Use

The SHUKLA Broken & Stripped ScrewFlex system is a universal screw removal system designed to remove all broken, stripped, and seized bone screws with minimal bone loss to the patient. This set is perfect for acetabular cup revision procedures.

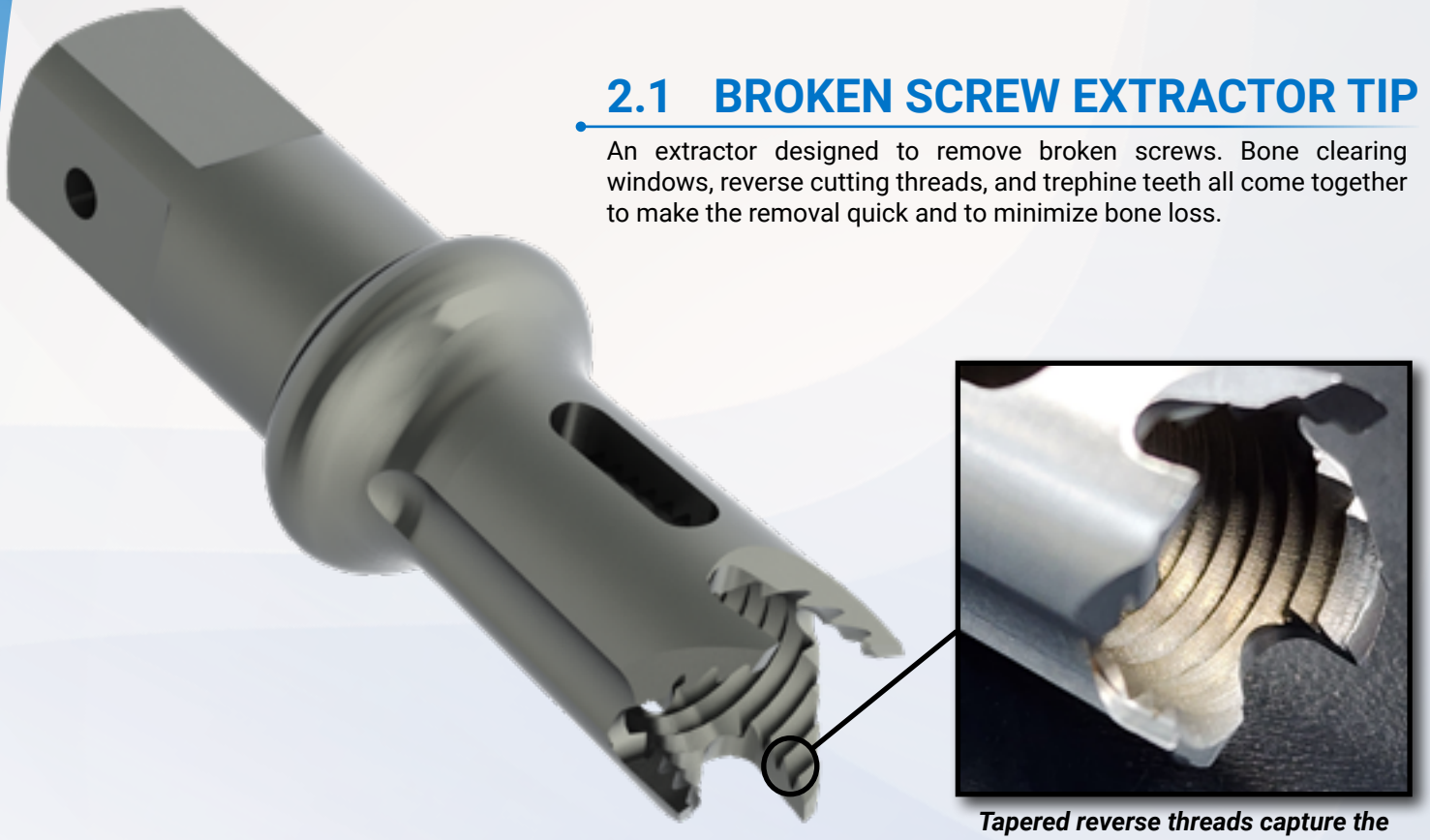


1.3 System History

Over the years, as more and more surgeons began using our SHUKLA Screw system, we noticed that during acetabular cup and shoulder revisions, it was difficult for surgeons to properly access the screws that needed removing. Normally, our SHUKLA Maxi system was used on those cases, but when a screw ended up broken or stripped, it presented a problem. In 2018, our engineers began development on the SHUKLA ScrewFlex to provide surgeons with a solution. In 2023, they realized their vision - the same industry leading broken and stripped screw removal capabilities as our SHUKLA Screw married with the patented flexible shaft technology of our SHUKLA Maxi.

2.1 BROKEN SCREW EXTRACTOR TIP

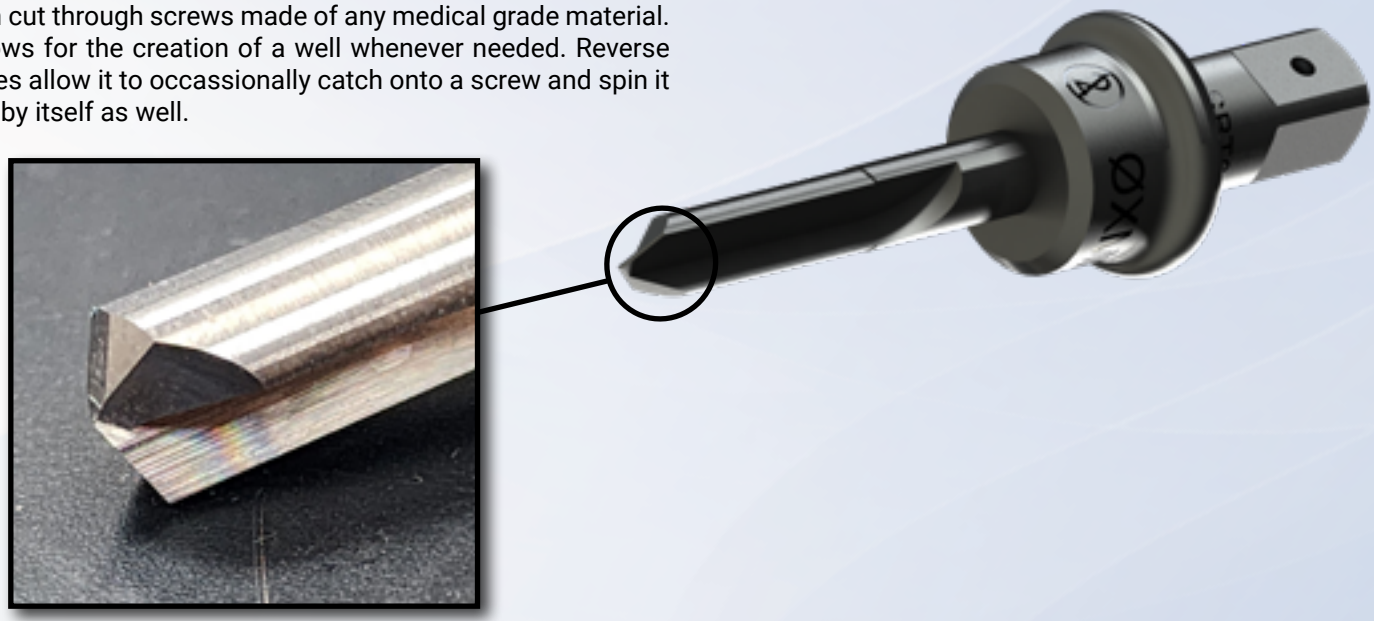
An extractor designed to remove broken screws. Bone clearing windows, reverse cutting threads, and trephine teeth all come together to make the removal quick and to minimize bone loss.



Tapered reverse threads capture the screw quickly while trephine teeth cut through bone.

2.2 CARBIDE DRILL BIT TIP

Can cut through screws made of any medical grade material. Allows for the creation of a well whenever needed. Reverse flutes allow it to occassionally catch onto a screw and spin it out by itself as well.



Reverse flutes to either burr off a screw head, deepen a well, or catch onto the screw and remove it.

Parts not shown to scale

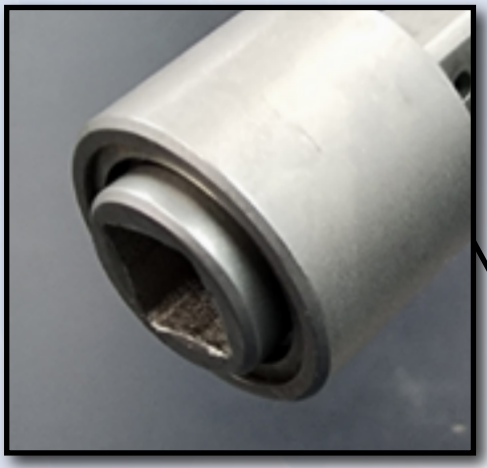
2.3 STRIPPED SCREW EXTRACTOR TIP

An extractor designed with a taper to remove stripped screws. It contains reverse cutting threads and metal clearing flutes to make sure screw engagement happens quickly.

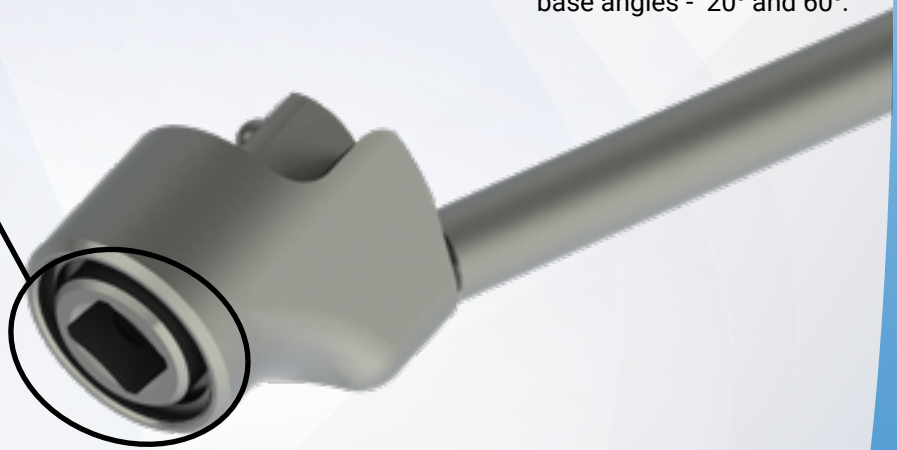
Reverse threading cuts new threads into the wall of the stripped screw well.

2.4 FLEXIBLE SHAFT GUIDE

Allow surgeons to hold the perfect angle when removing screws from hard-to-reach areas. Comes with two different base angles - 20° and 60°.



Push-to-Connect ends on both the front and back of the Shaft Guide allow both extractor tips and flexible shafts to be attached quickly.



3.1 Preoperative

- Appropriate x-rays and surgical notes may be used to identify the manufacturer, brand, location, & condition of implanted hardware.
- The surgeon should be familiar with the general principles of revision surgery and techniques for the 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

- Proper handling and storage of the instrumentation is mandatory. Damage to the instrumentation may produce stresses and cause defects, which could become a focal point for failure.
- 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; ≤75°F/24°C.
- 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.

3.4 Intended Use

The (S9SCREWFLEX) SHUKLA Broken and Stripped Screw Flexible is intended for use during revision procedures to remove broken, stripped, or seized bone screws with minimal bone loss in hard-to-reach places.

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 the patient.

3.5 Indications for Use

The SHUKLA Broken and Stripped Screw, Flexible (S9SCREWFLEX) is indicated for use during any orthopedic revision procedure in which a broken, stripped, or seized bone screws in a hard-to-reach place must be removed.

3.6 Additional Recommendations

During acetabular cup revision procedures, the SHUKLA Broken and Stripped Screw Flexible system is recommended for use in conjunction with the SHUKLA Cup (S9CUP) system.

During shoulder revision procedures, the SHUKLA Broken and Stripped Screw Flexible system is recommended for use in conjunction with the SHUKLA Shoulder (S9SHOULDER) System.

STEP 1

Determine if the screw is broken. If it is broken, skip to **Step 4**. If it is not broken, proceed to **Step 2**.

Example of a Broken Screw

STEP 2

Determine if the screw is stripped. If it is stripped, skip to **Step 5**. If it is not stripped, proceed to **Step 3**.

Example of a Stripped Screw

STEP 3

Determine if the screw is cold-welded to the cup, a well is needed to be formed in the screw head, or if the screw head needs to be burred off. If yes, skip to **Step 14**.

STEP 4

Determine if the screw is broken mid shaft. If it is, skip to **Step 20**. If it is not, skip to **Step 6**.

STEP 5

Determine if the screw well is too shallow. If it is too shallow, skip to **Step 18**. If it is not too shallow, skip to **Step 10**.

Broken Screw Extractor Tips

SXT051-02 - SXT051-07 **USE ALL EXTRACTORS IN REVERSE**

Reverse threads inside extractor tip will capture shaft of broken screw and then back screw out of bone. Extractor must be large enough to fit over shaft of screw, and small enough that screw shaft will not bottom out inside extractor.

- Always operate in a counter-clockwise direction
- If the screw head is intact, but the correct driver is not present, use a larger size extractor to capture the screw head. This technique is popular with square-headed Knowles pins.

Caution: If extractor tip is larger than necessary, excess bone removal will occur. Choose smallest functional extractor size to achieve minimal bone loss.

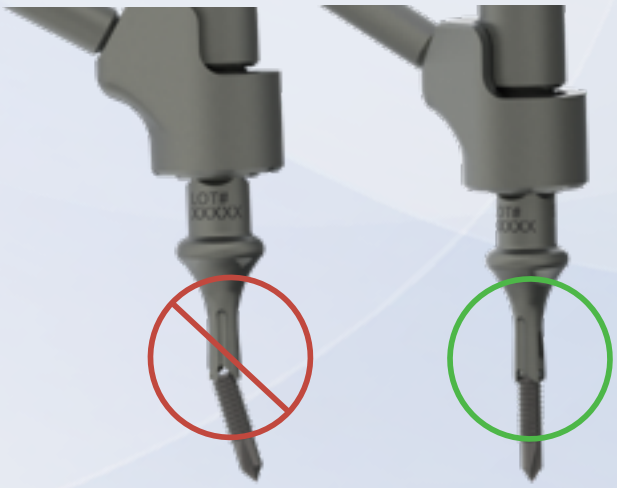
STEP 6

Select the appropriate size of extractor

- Should fit completely over the screw shaft
- Should engage with sides of shaft before bottoming out

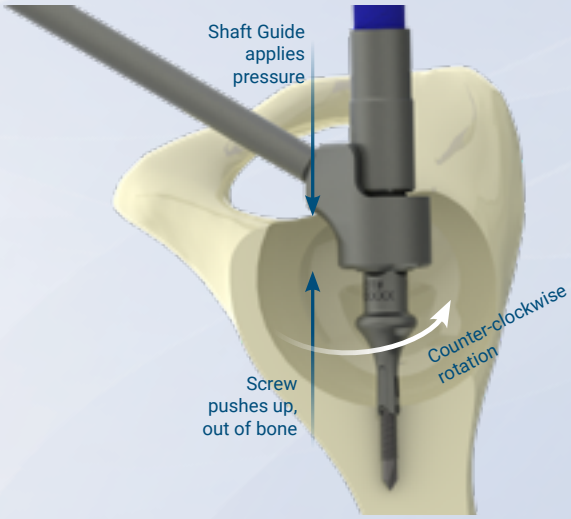
STEP 7

Center extractor tip over shaft of broken screw. Extractor must be aligned with screw shaft. Avoid side-bending, which can cause extractor tip to break.



STEP 8

Apply downward pressure with counter-clockwise torque. Trephine-like cutting teeth will dig into proximal bone only until reverse threads inside extractor grip onto screw shaft and immediately back screw out of bone.



STEP 9

Continue applying torque until screw is completely freed.

If additional assistance is needed in regards to the extractors, skip to **Steps 22 through 25**.

Broken Screw Extractors (SXT051-02 through SXT051-07) are single-use only and must be discarded after case completion.

Stripped Screw Extractor Tips

SXT052-02 - SXT052-07 USE ALL EXTRACTORS IN REVERSE

If screw socket is intact but cannot engage with standard drivers, use Stripped Screw Extractors to remove screws from bone.

Reverse threads on extractor tip will bite into screw head socket and back screw out of bone. Extractor must fit into screw head so that the threads at the tip engage with side walls of screw socket without striking bottom of socket.

- Always operate in a counter-clockwise direction
- It may be necessary to test multiple extractors before correct size is identified. If extractor tip fits into screw socket but does not engage, go up one size and try again.
- Drill Bit Tips (SBT034-02 - SBT034-07) can be used to deepen, clean up, and better define the screw well socket.
- If the Stripped Screw Extractor does not properly seat, it is recommended to try a Broken Screw Extractor.

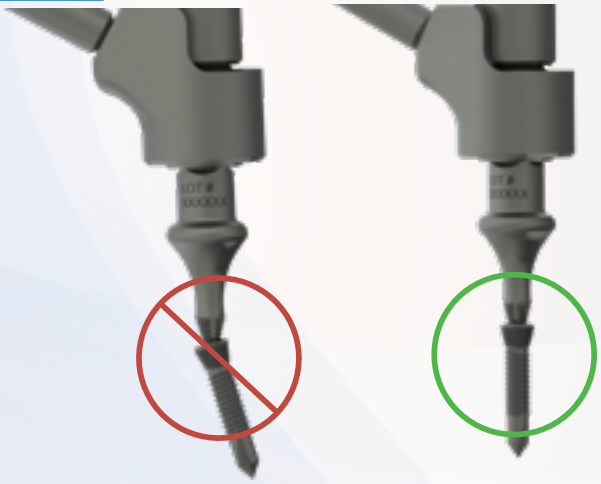
STEP 10

Select the appropriate size of extractor

- Should fit into the screw socket
- Should engage with sides of screw well before bottoming out
- If screw is too large to remove, skip to **Step 21**.

STEP 11

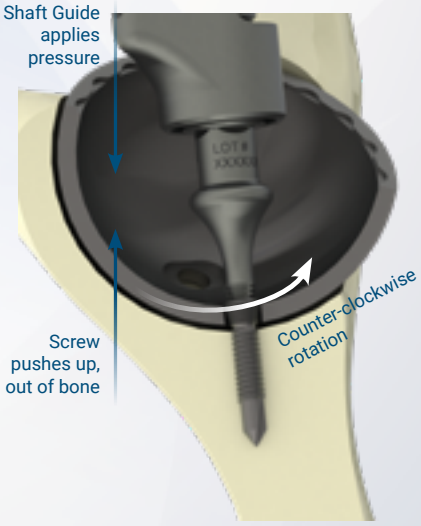
Set extractor tip into socket of stripped screw. Extractor must be aligned with screw shaft.



STEP 12

Apply downward pressure with counter-clockwise torque. Reverse threads on extractor tip will bite into stripped screw socket and immediately back screw out of bone.

- If extractor bottoms out in the screw head socket before biting deep enough, it is too small. Use the next size up.
- If extractor does not go deep enough into screw head to get a good bite, it is too large. Try a size smaller.
- If the Stripped Screw Extractor cannot achieve a good connection with the screw, and all above methods have been tried, then use a Broken Screw Extractor to engage the entire screw head.



STEP 13

Continue applying torque until screw is completely freed.

If additional assistance is needed in regards to the extractors, proceed to **Steps 22 through 25**.

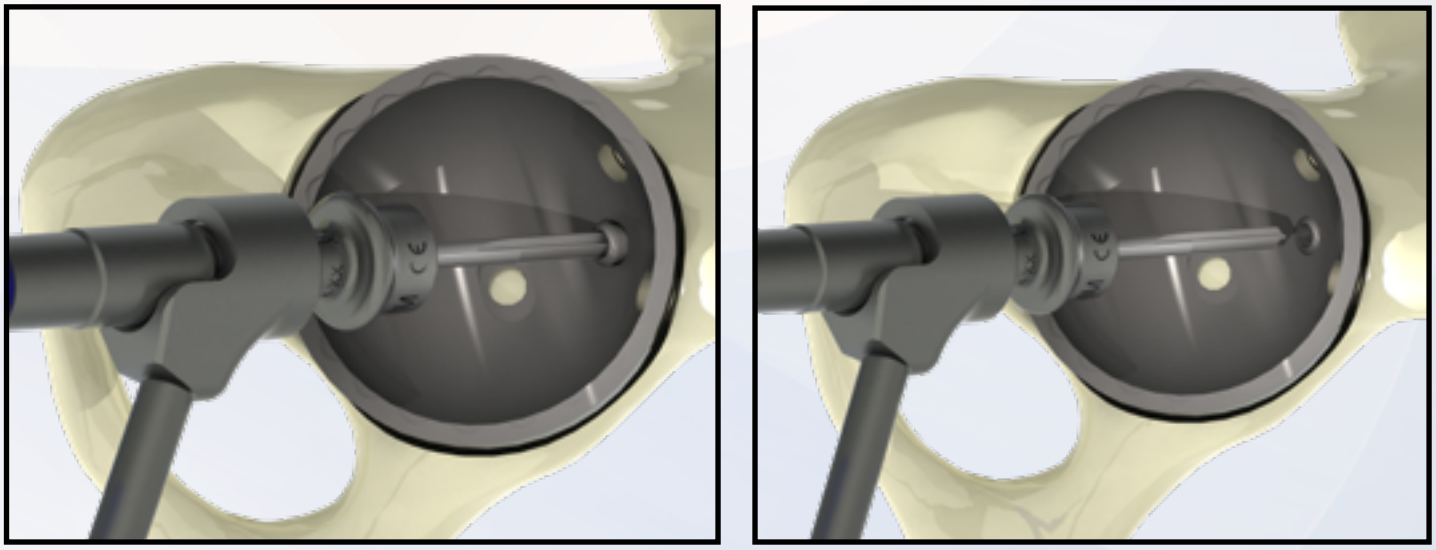
Stripped Screw Extractors (SXT052-02 through SXT052-07) are single-use only and must be discarded after case completion.

When to Use a Carbide Drill Bit

STEP 14

If a screw needs to be modified first before using an extractor, a carbide drill bit may be used. Carbide is an extremely hard material that can cut through any titanium or steel orthopedic screw. Some reasons a screw may need to be modified are:

- To deepen, clean up, and better define the screw well to allow an extractor to properly bite into the screw. If this is the case, proceed to **Steps 15 through 18**.
- To drill the head off a screw if it is cold welded with the cup or a plate. This allows the cup to be removed once all of the screw heads are removed. If this is the case, proceed to **Steps 15 - 17, and skip to Step 19**.



Carbide drill bit removing the head of a screw, paving the way for a cup to be removed with minimal bone loss so that the screw shaft can then be extracted easily.

Drill Bit Tips

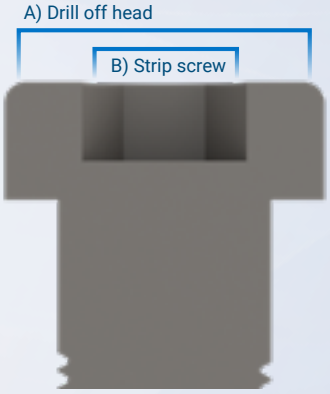
SBT034-02 - SBT034-07

Facilitate screw extraction by drilling out and deepening a screw well, or by completely removing the screw head.

- **ALWAYS USE CARBIDE DRILL BITS IN REVERSE**

A) To prep for a broken screw extractor, use a drill bit size that corresponds to diameter of screw head to drill off the entire screw head. The drill bit should be larger than the shaft diameter and smaller than the head diameter.

B) To prep for a stripped screw extractor, use a drill bit size that corresponds to the screw interface to clean up or deepen the well.



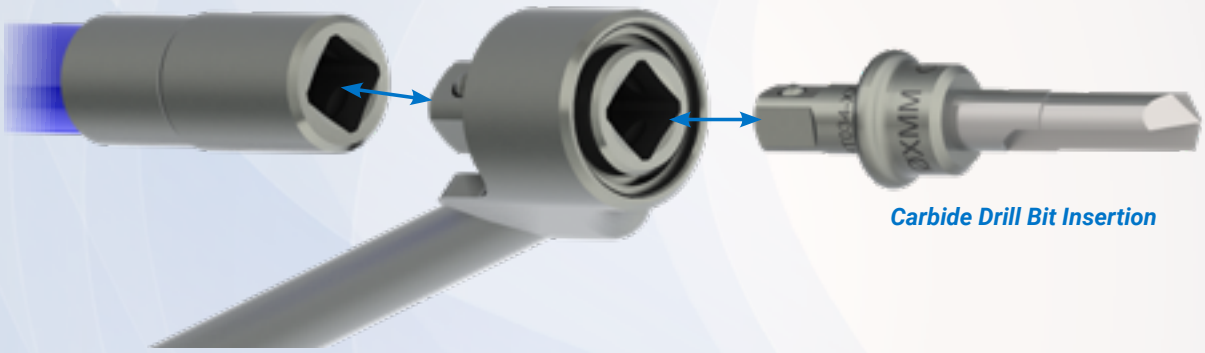
How to Use a Carbide Drill Bit

STEP 15

Determine shaft size of exposed screw and assess whether a Carbide Drill Bit is required for removal. Select single-use drill bit in corresponding size. If screw is embedded, estimate diameter of screw shaft using x-ray imaging using applied scale factor.

STEP 16

Attach Flex Shaft (SSH062) to drill. Connect the opposite end of the Flex Shaft to the preferred Flexible Shaft Guide (SSG001-01 or SSG001-02). Connect Carbide Drill Bit to the Flexible Shaft Guide's opposite end. To disconnect, remove the Flex Shaft by removing from the drill chuck (drill).



Carbide Drill Bit Insertion

STEP 17

- Set the drill bit in the well of the screw. Keep the drill bit aligned with the screw as much as possible. The drill bits are made of carbide which is extremely hard yet also brittle, and can break from excessive side-loads.
- Apply downward pressure and apply counter-clockwise torque. The drill bit will drill off the head of the screw. It might also catch the screw and back it out.

Instructions for Proper Drill Bit Tip Use

Since carbide is a brittle material it may shatter into small fragments when it breaks. Therefore, it is important to follow the suggested guidelines that will help you use your drill bit tips safely:

- Drill as straight as possible to reduce side loads.
- Use a drill bit that fits the screw well as much as possible to keep the drill bit aligned.
- Drill on ream speed to avoid breakage.
- Ensure that the drill is set in reverse.
- Continuously drill while the bit is in the well so it is always cutting.
- Don't turn or twist the drill while drilling to prevent snapping the bit.
- If the drill bit gets stuck, remove the bit from the drill and carefully remove the bit by hand or pliers.
- The smaller the drill bit, the more prone it is to breaking.

If the bit breaks, remove all of the broken pieces.

Carbide Drill Bits (SBT034-02 through SBT034-07) are single-use only and must be discarded after case completion.

Special Situations

You may encounter some scenarios which require special tecniques. Here are some ways to solve these issues.

STEP 18

Screw Well Too Shallow

When using a stripped screw extractor tip and the extractor can't securely attach to the screw to remove it, then the screw well may be too shallow. When this happens, there are several possible solutions.

1. Try the next size up stripped screw extractor and see if that one can engage the screw. Discard all used extractors.

2. If no stripped screw extractors are engaging, the screw well can be deepened or cleaned up with a carbide drill bit. Find the largest drill bit that can fit within the well and use it to deepen the well. Follow the procedure for using carbide drill bits. Ensure that the drill is in reverse. Discard all used drill bits.

3. An alternative to option 2 or if option 2 doesn't work, is to use a broken screw extractor that fits over the head of the screw.

STEP 19

Screws Cold-Welded to Cup/Plate/Locking Plate Removal

Over the course of time, some screws can become "cold-welded" to a plate. When this happens, the screws can be nearly impossible to remove with a driver or a screw extractor. To easily remove a plate and screws in this case, follow these steps:

1. Find a carbide drill bit that fits within the screw well but is smaller than the outer diameter of the screw head. It is important that it is smaller than the screw head so that you can use the screw well as a guide.

2. Following the procedure for using carbide drill bits, drill through the head of the screw until it comes off. Ensure the drill is in reverse. Repeat this for each screw on the plate.

3. Once the screw heads are drilled off, the cup or plate can be removed.

4. Find a broken screw extractor that fits over the screws remaining in the bone. Follow the procedure for removing broken screws. Ensure the drill is in reverse.

STEP 20

Screw Break Mid-Shaft

If screw is broken mid-shaft and both sections are accessible, pieces may be removed separately. Use Broken Screw Extractors (**SXT051-02 - SXT051-07**) to capture exposed screw ends.

Follow the procedure for removing broken screws. Ensure the drill is in reverse to back pieces out of bone. Carbide Drill Bits can be used to clear a path to the buried broken distal screw. Then, a Broken Screw Extractor can be used to capture and remove the broken screw.

STEP 21

Screw Too Large to Remove

If the screws present in the implant are larger than 7 mm for stripped screws, special larger extractors can be ordered. Large special order Stripped Screw Extractors (**SXT052-08 - SXT052-11**) can remove stripped screws from 8 mm to 11 mm in diameter.

STEP 22

Determine shaft size of exposed screw and assess whether a Broken or Stripped Screw Extractor is required for removal. Select single-use extractor in corresponding size and type. If screw is embedded, estimate diameter of screw shaft using x-ray imaging with applied scale factor.

STEP 23

Attach Flex Shaft (SSH062) to Ratcheting T-Handle (SHN022) or drill by inserting extractor directly into the chosen method. Connect the opposite end of the Flex Shaft to the preferred Flexible Shaft Guide (SSG001-01 or SSG001-02). Connect desired extractor tip (Broken, Stripped, or Carbide Drill Bit) to the Flexible Shaft Guide's opposite end. To disconnect, remove the Flex Shaft by pushing the Unlock Button (T-Handle) or removing from the drill chuck (drill).

- **Manual Use**: Attach Flex Shaft to T-Handle. Choose ratcheting direction by turning arrow to forward, neutral, or reverse position on handle.
- **Powered Use**: For use under power, connect Flex Shaft to drill.

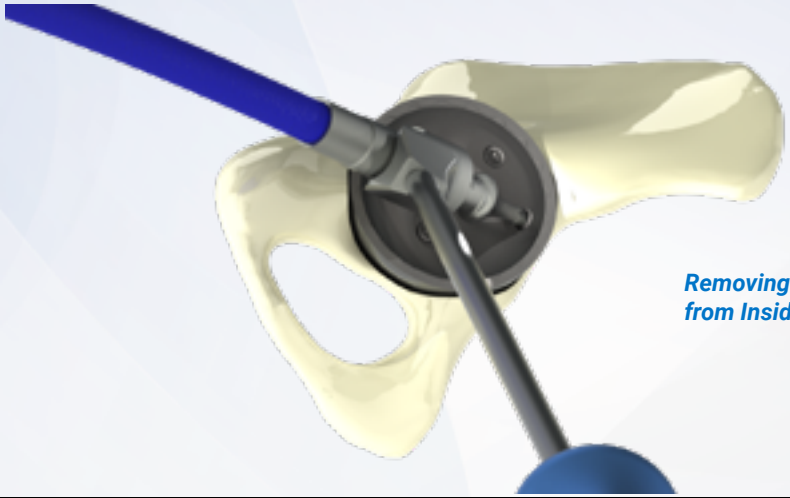
Assembling the Instrumentation

Finished Look When Assembled

STEP 24

Use the Flexible Shaft Guide to align extractor tip with screw inside the cup. Apply torque in a ***counter-clockwise (Reverse)*** direction. Reverse threads on extractor tip should engage screw and immediately back screw out.

Tip: All extractor tips (Broken, Stripped, and Carbide Drill Bits) (**SXT051-02 - SXT051-07, SXT052-02 - SXT052-07, and SBT034-02 - SBT034-07**) must be discarded after completion of the surgery. Extractor tips and drill bits are not reusable.

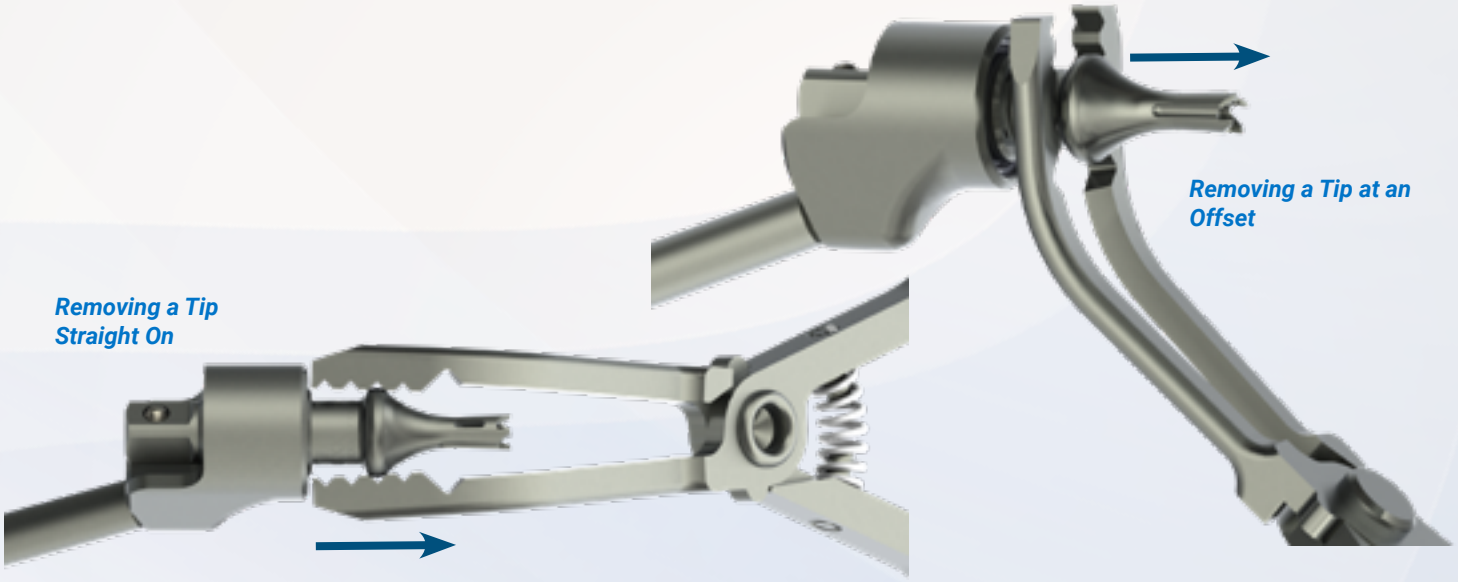


Removing a Screw from Inside a Cup

STEP 25

Removing Extractor Tips

To remove an extractor tip from the Flexible Shaft Guide, either to swap it out or because a screw was successfully removed, use the Offset Pliers (SPL003). Grab the tip either from an angle or straight on, depending on access and preference. Grip and pull away from the Flexible Shaft Guide until the extractor tip disengages.



5 TIPS and TRICKS SHUKLA ScrewFlex

- The Offset Pliers (SPL003) can be used to aid in connecting the Extractor Tip to the Flexible Shaft Guide.
- The reverse flutes of a Carbide Drill Bit can occassionally back out a screw all by itself while in use. This happens more often when the size of the drill bit is the same size as the screw well.
- Using a Carbide Drill Bit at a slower speed while on power increases the chances of it catching on and backing up the screw.
- When using Broken Screw extractor tips, it is best to start with a smaller size and work on up to best minimize potential bone loss.
- While used primarily during acetabular cup revisions, the SHUKLA ScrewFlex is perfect for any broken or stripped screw that is encountered in a hard to access area.

6 CLEANING & STERILIZATION SHUKLA ScrewFlex

All Shukla Medical surgical instruments can be cleaned using manual cleaning or automated cleaning processes per the 'Instructions for Use - Cleaning & Sterilization'

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

CE

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Prinsessegracht 20
2514 AP The Hague
The Netherlands

REF S9SCREWFLEX

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

CONSULT INSTRUCTIONS FOR USE

NON STERILE NON-STERILE PRODUCT

7 COMPONENTS LIST

Component List			
Std Qty	**Part Number**	**Description**	**Effective Range**
1	SCS052-01	Case, Broken and Stripped Screw, Flexible System	
1	SCS052-02	Lid, Broken and Stripped Screw, Flexible System	
1	SCS052-03	Caddy, Broken and Stripped Screw, Flexible System, Broken Extractor Tips	
1	SCS052-04	Caddy, Broken and Stripped Screw, Flexible System, Stripped Extractor Tips	
1	SCS052-05	Caddy, Broken and Stripped Screw, Flexible System, Carbide Drill Bit Tips	
2	SSH062	Flex Shaft with 1/4” Square Connection	
1	SSG001-01	Guide, 20 Degrees	
1	SSG001-02	Guide, 60 Degrees	
1	SPL003	Offset Pliers	
1	SHN022	Ratcheting T-Handle	
2	SBT034-02	Drill Bit Assy, Carbide, Hudson End, 2 mm, Single Use	
2	SBT034-03	Drill Bit Assy, Carbide, Hudson End, 3 mm, Single Use	
2	SBT034-04	Drill Bit Assy, Carbide, Hudson End, 4 mm, Single Use	
2	SBT034-05	Drill Bit Assy, Carbide, Hudson End, 5 mm, Single Use	
2	SBT034-06	Drill Bit Assy, Carbide, Hudson End, 6 mm, Single Use	
2	SBT034-07	Drill Bit Assy, Carbide, Hudson End, 7 mm, Single Use	
4	SXT051-02	Extractor Tip, Broken Screw, 2 mm, Single Use	2.0-2.5mm
4	SXT051-03	Extractor Tip, Broken Screw, 3 mm, Single Use	2.5-3.5mm
4	SXT051-04	Extractor Tip, Broken Screw, 4 mm, Single Use	3.5-4.5mm
4	SXT051-05	Extractor Tip, Broken Screw, 5 mm, Single Use	4.5-5.5mm
4	SXT051-06	Extractor Tip, Broken Screw, 6 mm, Single Use	5.5-6.5mm
4	SXT051-07	Extractor Tip, Broken Screw, 7 mm, Single Use	6.0-8.0mm
4	SXT052-02	Extractor Tip, Stripped Screw, 2 mm, Single Use	2.0mm
4	SXT052-03	Extractor Tip, Stripped Screw, 3 mm, Single Use	2.5-3.5mm
4	SXT052-04	Extractor Tip, Stripped Screw, 4 mm, Single Use	3.5-4.5mm
4	SXT052-05	Extractor Tip, Stripped Screw, 5 mm, Single Use	4.5-5.5mm
4	SXT052-06	Extractor Tip, Stripped Screw, 6 mm, Single Use	5.5-6.5mm
4	SXT052-07	Extractor Tip, Stripped Screw, 7 mm, Single Use	6.0-7.0mm

Single-use Only: Always use new extractors and drill bits in every procedure.
Discard any used single use parts 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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ISO 13485:2016

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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
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-SCREW-V3-STG-REVISED: MARCH-02-23