

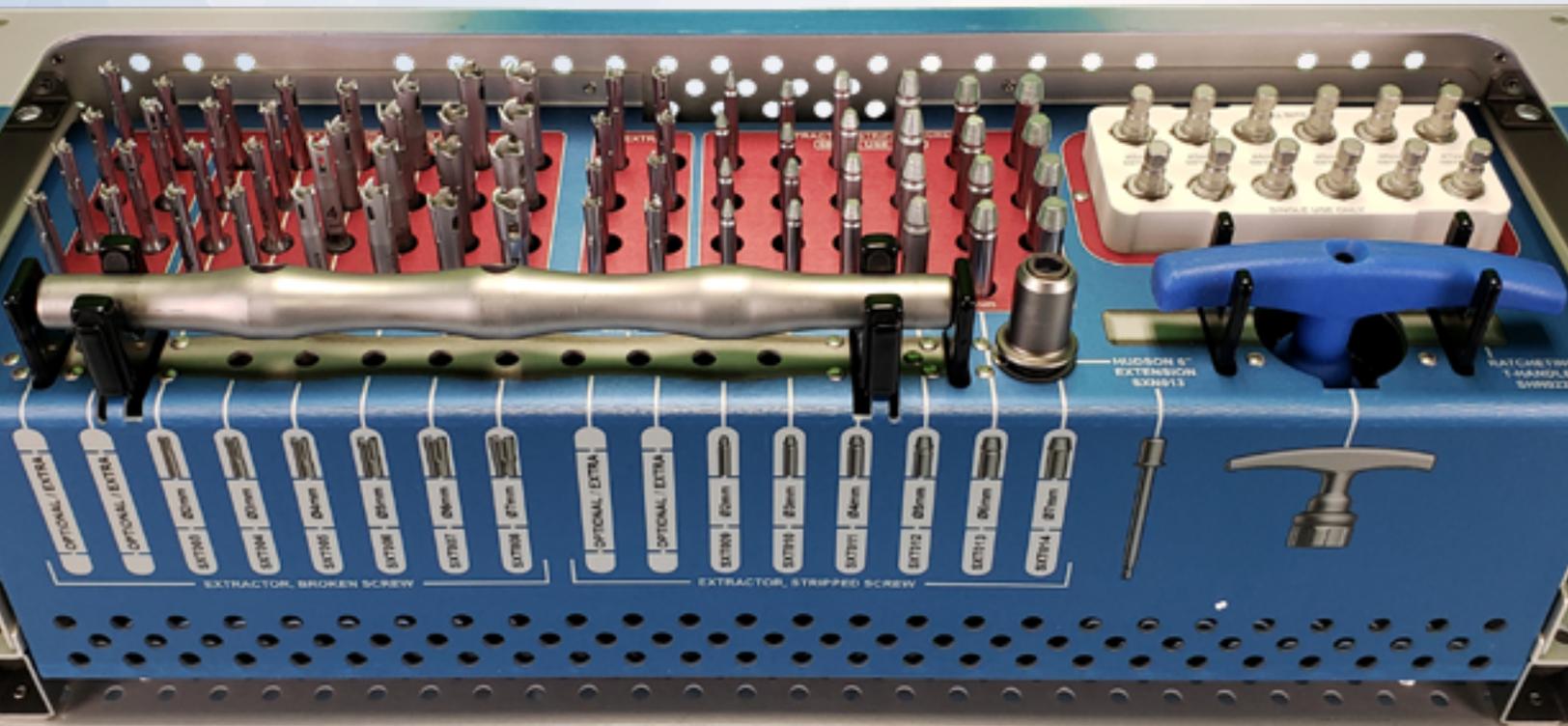
SURGICAL TECHNIQUE GUIDE

#3

System 3 of 25

SHUKLA SCREW^{V.3}

Universal Broken & Stripped Screw Extraction System



SHUKLA MEDICAL[®]
Universal Orthopedic Extraction Technologies
THE EXTRACTION EXPERTS

1. Introduction	3
1.1 System Name	3
1.2 Primary Use	3
1.3 System History	3
2. Key Component Description	4
2.1 Broken Screw Extractor	4
2.2 Extractor Extension	4
2.3 Stripped Screw Extractor	5
2.4 Ratcheting T-Handle	5
3. Preoperative & Intended Use	6
3.1 Preoperative	6
3.2 Operative	6
3.3 Storage	6
3.4 Intended Use	6
3.5 Indications for Use	6
3.6 Additional Recommendations.....	6
4. Surgical Technique	7
4.1 Identify Screw Problem	7
4.2 Remove Broken Screws	8
4.3 Remove Stripped Screws	9
4.4 Extractors	10
4.5 Carbide Drill Bits	11
4.6 Special Situations	13
5. Cleaning & Sterilization	14
6. Components	14
7. Notes	15

1

SHUKLA SCREW^{V.3}

Universal Broken & Stripped Screw Extraction System

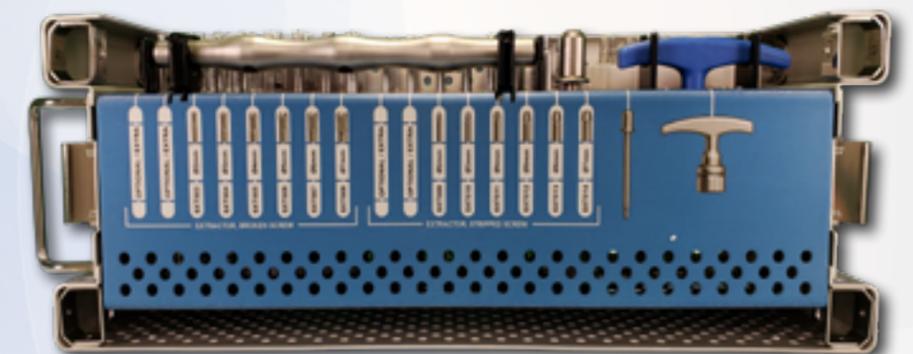
1.1 System Name: SHUKLA Screw

Part Number: S9SCREW

Version: 3

1.2 Primary Use

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



1.3 System History

The original version of the SHUKLA Screw system was the first system developed internally after the acquisition of Snap-On Medical. The original Screw was born from the frustration of surgeons trying to remove a screw that had been broken or stripped prior to or during the revision surgery.

In 2007, the SHUKLA Screw version 1 (v1) made the smart move towards disposable extractors, eliminating the issue of metal on metal galling ruining the integrity of the extractors. The v1 was so effective at removing broken & stripped screws that surgeons and hospitals found it difficult to imagine, believing the claims of removing screws in seconds to be absurd. Our Product Manager then created the Bone Block Demo, which proved to be a complete game changer.

The v2 of the system launched in 2016 and added a ton of improvements to an already stellar set such as carbide drill bits and increased extractor lengths.

Screw v3 began development in early 2019 thanks to surgeon feedback. New features like hudson ends for extractors and reverse carbide drill bits were combined with a brand new breaker bar to make our latest SHUKLA Screw set the most comprehensive and feature rich one to date.

2.1 BROKEN SCREW EXTRACTOR

An extractor designed to remove broken screws, with an extended neck length to help reach screws that are deeply buried. Bone clearing windows, reverse cutting threads, and trephine teeth all come together to make the removal quick and to minimize bone loss.



Bone clearing window to allow bone to pass through to prevent blockage.

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

2.2 EXTRACTOR EXTENSION

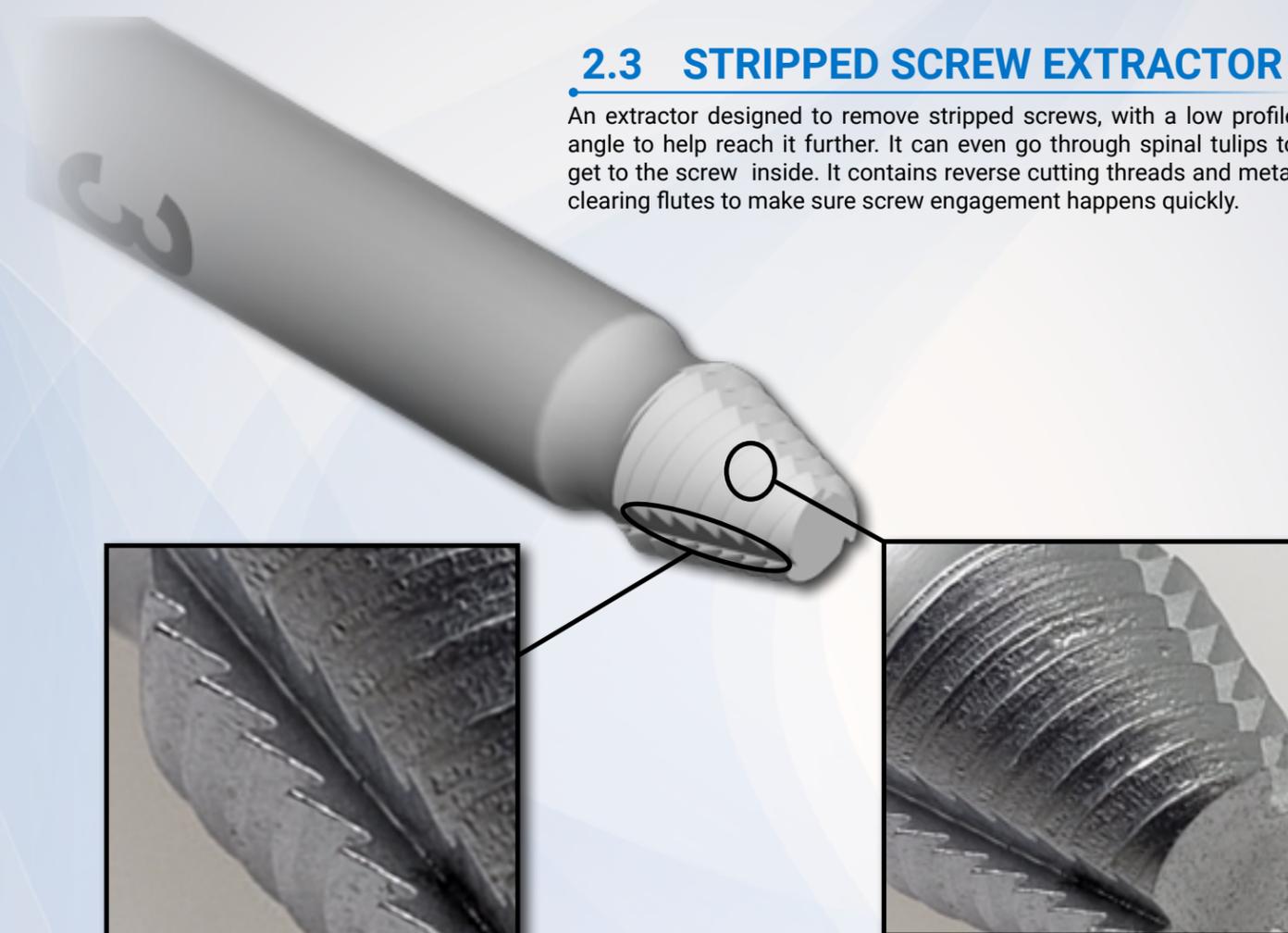
The six inch extension for the broken and stripped screw extractors allows surgeons to engage with hard to reach screws. The hudson connection allows for rapid use of an orthopedic drill.



Parts not shown to scale

2.3 STRIPPED SCREW EXTRACTOR

An extractor designed to remove stripped screws, with a low profile angle to help reach it further. It can even go through spinal tulips to get to the screw inside. It contains reverse cutting threads and metal clearing flutes to make sure screw engagement happens quickly.



Metal clearing flutes remove the excess chips from the screw as the stripped well becomes engaged.

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

2.4 RATCHETING T-HANDLE

Ratcheting push-to-connect T-Handle with an ergonomic design grants easier and simpler screw removal with less fatigue.



3.1 Preoperative

- Clear 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 and techniques for the removal of orthopedic implants.
- The instruments should be inspected for visible damage prior to use. Do not use the product if damage is suspected.
- Only validated cleaning and sterilization procedures 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.

3.3 Storage

- It is recommended to store all Shukla Medical instrumentation in a clean, dry environment. Under 50% relative humidity; $\leq 75^{\circ}\text{F}/24^{\circ}\text{C}$.
- Proper handling and storage of the instrumentation is mandatory. Always inspect instrumentation for visible wear prior to use.

3.4 Intended Use

The SHUKLA Screw (S9SCREW) Universal Broken & Stripped Screw Removal System is intended for use during revision procedures for the removal of any implanted orthopedic screws that have become broken or stripped in order 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

For use by, or as directed by, a surgeon in any hardware removal case in which broken, stripped, or seized screws must be removed. Includes extractors and drill bits ranging in size from 2.0mm-11.5mm to remove any orthopedic screw.

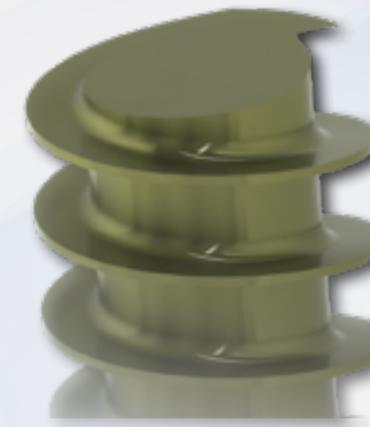
3.6 Additional Recommendations

During revision procedures, the SHUKLA Mini and the SHUKLA Maxi are recommended for use in conjunction with the SHUKLA Screw for universal screw removal capabilities.

For difficult to reach screws due to implant or body geometry, the SHUKLA Screw Flex is recommended for use in conjunction with the SHUKLA Screw.

STEP 1

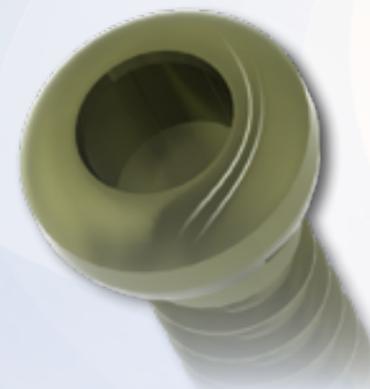
Determine if the screw is broken. If it is broken, skip to **Step 4**. If it is not broken, proceed to **Step 2**.



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 a plate. If it is cold-welded, skip to **Step 18**. If it is not cold-welded, refer to the Surgical Technique Guide for the S9MAXI.

STEP 4

Determine if the screw is broken mid shaft. If it is, skip to **Step 24**. 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 Extractors

SXT003-SXT008 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

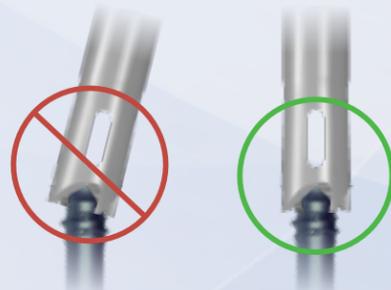
Select the appropriate size of extractor

- Should fit completely over the screw shaft
- Should engage with sides of shaft before bottoming out
- If screw is too large to remove, skip to **Step 25**.



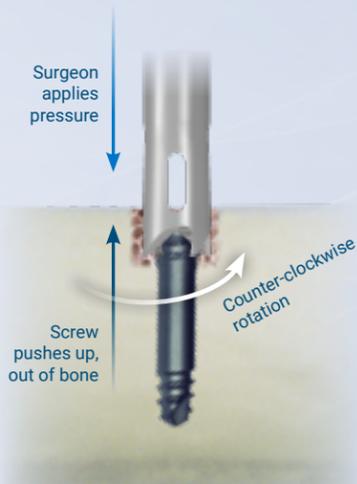
STEP 7

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. Trepine-like cutting teeth will dig into proximal bone 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 14 through 17**.

Stripped Screw Extractors

SXT009-SXT014 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 Bits (SBT001-SBT006) 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 (SXT003-SXT008)



STEP 10

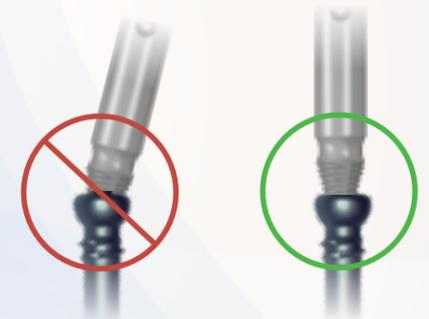
Select the appropriate size of extractor

- 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 25**.



STEP 11

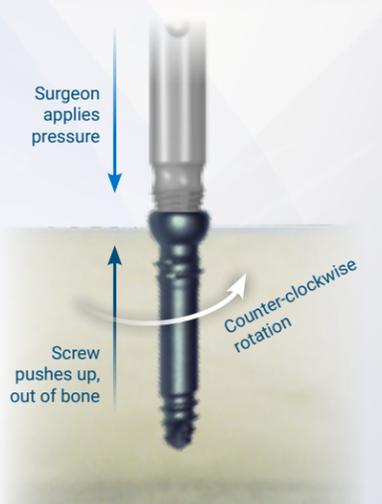
Set extractor tip into socket of stripped screw. Extractor must be aligned with screw shaft.



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 14 through 17**.

Stripped screw extractors (SXT009 through SXT014) are single-use only and must be discarded after case completion.

STEP 14

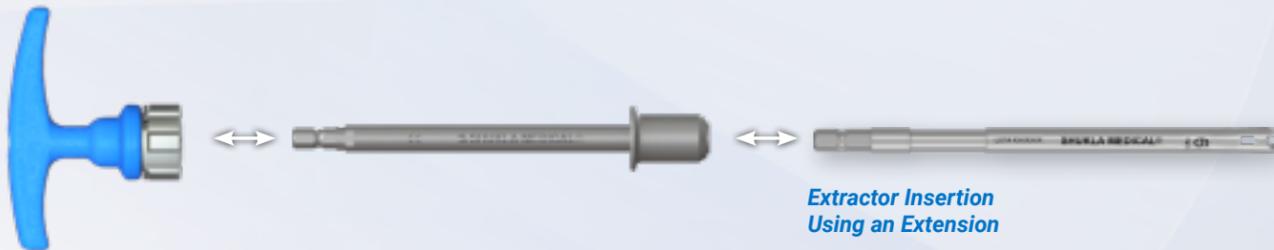
Determine shaft size of exposed screw and assess whether a Broken or Stripped Screw Extractor is required for removal. Select single-use extractor in corresponding size and type. If screw is embedded, estimate diameter of screw shaft using x-ray imaging with applied scale factor.



STEP 15

Attach extractor to T-Handle or drill by inserting extractor directly into the chosen method. To disconnect the extractor, remove the extractor by pushing the Unlock Button (T-Handle), or removing the extractor from the drill chuck (drill).

- **Manual Use:** Attach Extractor to Ratcheting T-Handle (SHN022). Choose ratcheting direction by turning arrow to forward, neutral, or reverse position on handle. If more torque is required, skip to **Step 17**.
- **Powered Use:** For use under power, connect extractor to drill.
- **Extended Reach:** If needed, use the Hudson End Quick Connect Extension (SXN013) to attach Extractor to T-Handle or surgical drill.



STEP 16

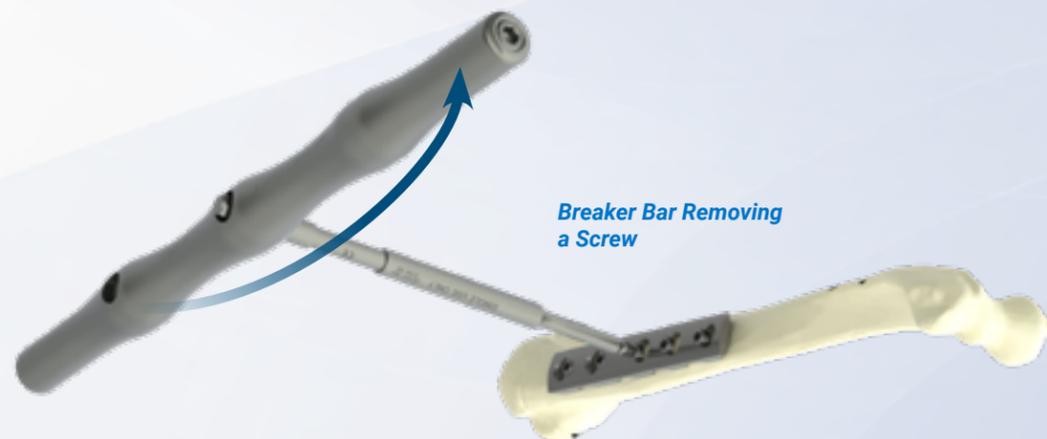
Align extractor tip with screw. Apply torque in a **counter-clockwise** direction. Reverse threads on extractor should engage screw and immediately back screw out of bone or plate.

Tip: Broken and stripped screw extractors (SXT003 - SXT014) must be discarded after completion of the surgery. **Extractor tips and drill bits are not reusable.**

STEP 17

Attach extractor to Breaker Bar (SHN049) at either of the two connection points. Both connections offer the same increased torque levels - simply apply surgeon preference when deciding.

Align extractor tip with screw. Apply torque in a **counter-clockwise** direction. Reverse threads on extractor should engage screw and immediately back screw out of bone or plate.

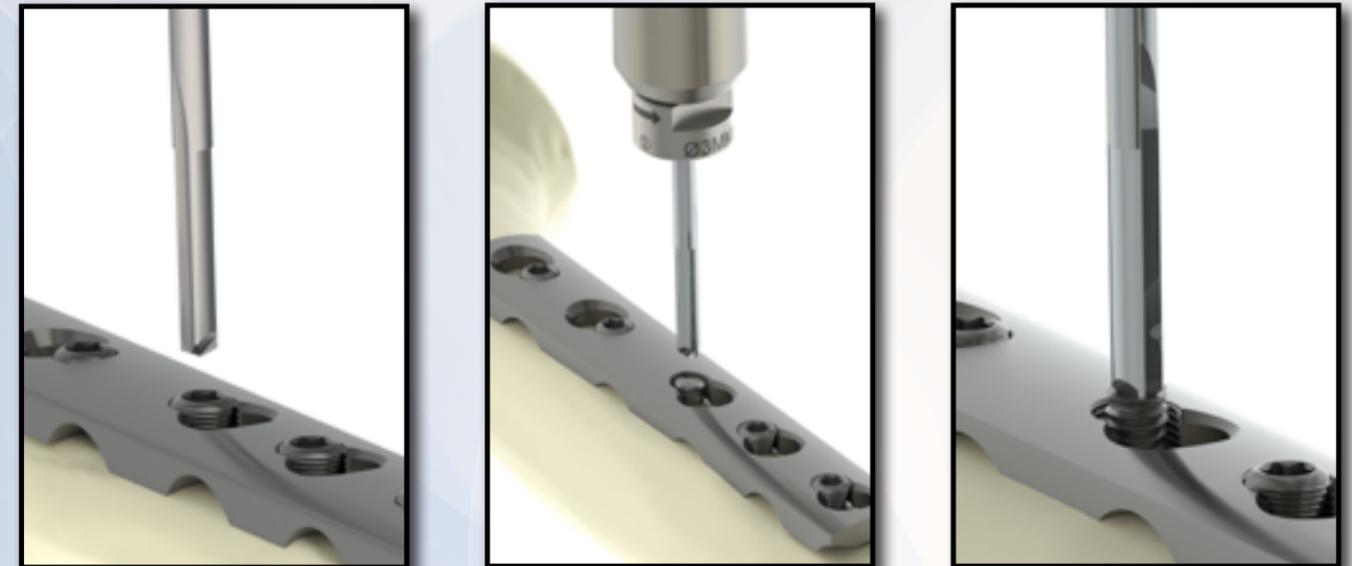


When to Use a Carbide Drill Bit

STEP 18

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 19 through 22**.
- To drill the head off a screw if it is cold welded with a plate. This allows the plate to be removed once all of the screw heads are removed. If this is the case, proceed to **Steps 19 - 21, and skip to Step 23**.



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

Right: Carbide drill bit catching onto screw and backing it out by itself.

Drill Bits

SBT001-SBT006

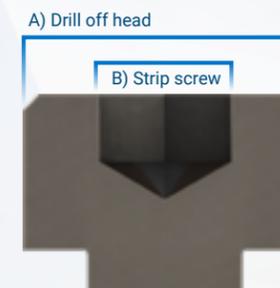
Facilitate screw extraction by drilling out and deepening a screw well, or by completely removing the screw head.

- **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 19

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 20

Attach Carbide Drill Bit to drill by inserting the carbide drill bit directly into the drill chuck. To disconnect, remove the Carbide Drill Bit from the drill chuck.

- **Powered Use:** Connect drill bit directly to surgical drill.
- **Extended Reach:** If needed, use the Hudson End Quick Connect Extension (SXN013) to attach drill bit to surgical drill.



STEP 21

- 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 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 bits 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.

Special Situations

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

STEP 22

Screw Well Too Shallow

When using a stripped screw extractor 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 23

Screws Cold-Welded to 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 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 24

Screw Break Mid-Shaft

If screw is broken mid-shaft and both sections are accessible, pieces may be removed separately. Use Broken Screw Extractors (SXT003-SXT008) 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 25

Screw Too Large to Remove

If the screws present in the implant are larger than 8 mm for broken screws or 7 mm for stripped screws, special larger extractors can be ordered.

Large special order Broken Screw Extractors (SXT015 - SXT018) can remove broken screws from 8 mm to 11 mm in diameter. Large special order Stripped Screw Extractors (SXT026 - SXT029) can remove stripped screws from 8 mm to 11 mm in diameter.

5 CLEANING & STERILIZATION

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



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



S9SCRW
S9SCREW



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



CONSULT
INSTRUCTIONS
FOR USE



NON-STERILE
PRODUCT



6 COMPONENTS LIST

Component List			
Std Qty	Part Number	Description	Effective Range
1	SCS054	Case & Lid, Broken & Stripped V3 System	
1	SHN049	Breaker Bar, Hex End	
1	SXN013	Extension, Hudson End, 6"	
1	SHN022	T-Handle Assy, Ratcheting, Hex, 1/4"	
2	SBT001	Drill Bit Assy, Carbide, Hudson End, 2 mm, <i>Single Use</i>	
2	SBT002	Drill Bit Assy, Carbide, Hudson End, 3 mm, <i>Single Use</i>	
2	SBT003	Drill Bit Assy, Carbide, Hudson End, 4 mm, <i>Single Use</i>	
2	SBT004	Drill Bit Assy, Carbide, Hudson End, 5 mm, <i>Single Use</i>	
2	SBT005	Drill Bit Assy, Carbide, Hudson End, 6 mm, <i>Single Use</i>	
2	SBT006	Drill Bit Assy, Carbide, Hudson End, 7 mm, <i>Single Use</i>	
4	SXT003	Extractor, Broken Screw, 2 mm, 6" long, <i>Single Use</i>	2.0-2.5mm
4	SXT004	Extractor, Broken Screw, 3 mm, 6" long, <i>Single Use</i>	2.5-3.5mm
4	SXT005	Extractor, Broken Screw, 4 mm, 6" long, <i>Single Use</i>	3.5-4.5mm
4	SXT006	Extractor, Broken Screw, 5 mm, 6" long, <i>Single Use</i>	4.5-5.5mm
4	SXT007	Extractor, Broken Screw, 6 mm, 6" long, <i>Single Use</i>	5.5-6.5mm
4	SXT008	Extractor, Broken Screw, 7 mm, 6" long, <i>Single Use</i>	6.0-8.0mm
4	SXT009	Extractor, Stripped Screw, 2 mm, 6" long, <i>Single Use</i>	2.0mm
4	SXT010	Extractor, Stripped Screw, 3 mm, 6" long, <i>Single Use</i>	2.5-3.5mm
4	SXT011	Extractor, Stripped Screw, 4 mm, 6" long, <i>Single Use</i>	3.5-4.5mm
4	SXT012	Extractor, Stripped Screw, 5 mm, 6" long, <i>Single Use</i>	4.5-5.5mm
4	SXT013	Extractor, Stripped Screw, 6 mm, 6" long, <i>Single Use</i>	5.5-6.5mm
4	SXT014	Extractor, Stripped Screw, 7 mm, 6" long, <i>Single Use</i>	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.*

7 NOTES



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



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



S9SCREW



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



CONSULT
INSTRUCTIONS
FOR USE



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.