

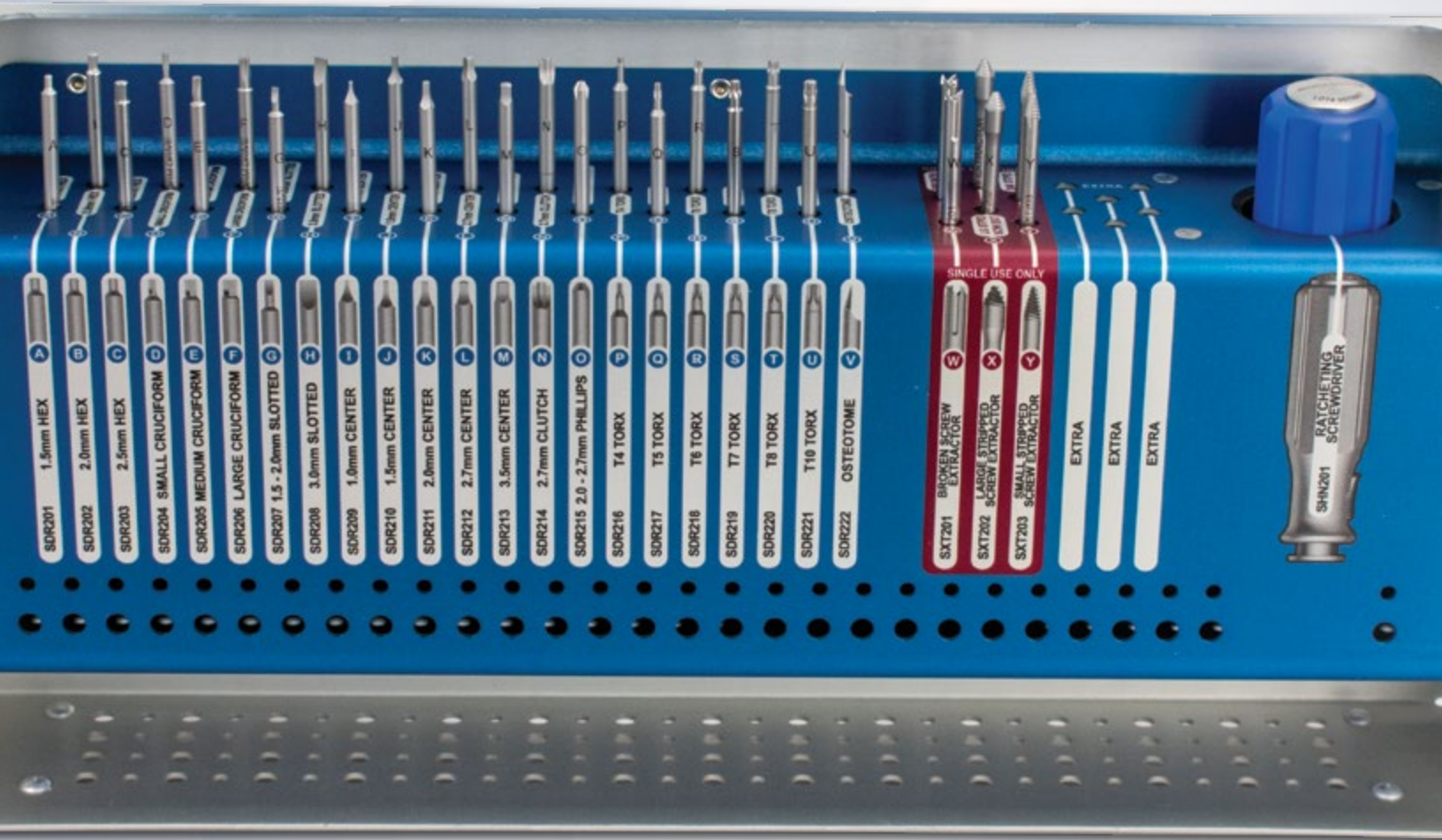
SURGICAL TECHNIQUE GUIDE

#1

System 1 of 15

SHUKLA mini

Universal Small Screw Removal Solution



SHUKLA MEDICAL[®]

Universal Orthopedic Extraction Technologies

Revolutionizing the Art of Revision Surgery

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SHUKLA mini

Universal Small Screw Removal Solution

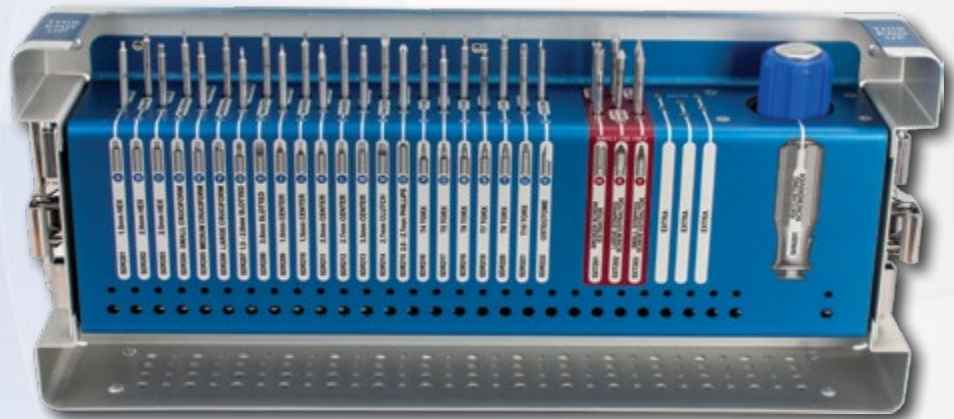
1.1 System Name: SHUKLA Mini

Part Number: S9MINI

Version: 4

1.2 Primary Use

The SHUKLA Mini is a comprehensive screwdriver system designed to simplify removal of virtually all small bone screws found in craniomaxillofacial, hand, wrist, foot, ankle, & spine procedures.



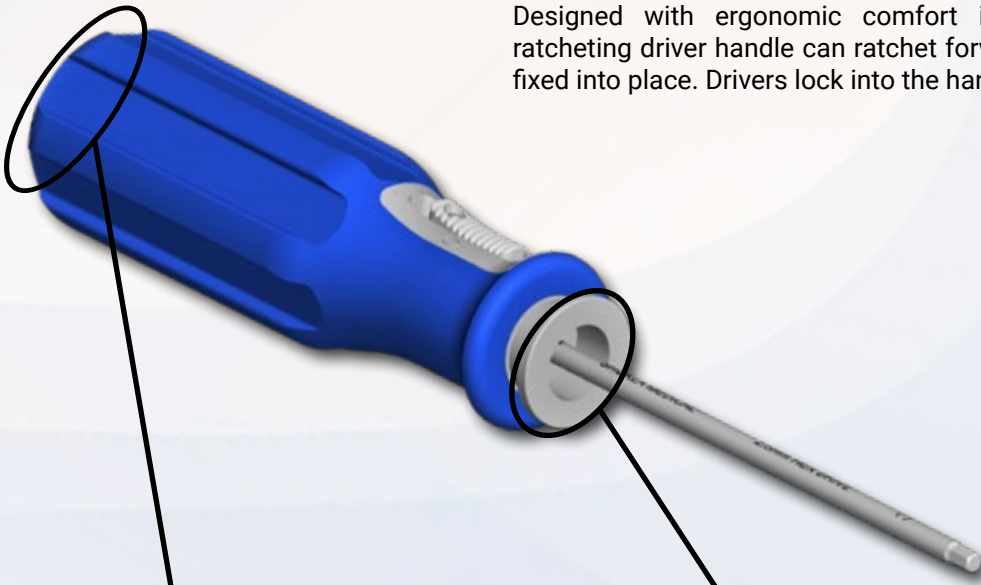
1.3 System History

The original Mini system was a byproduct of the original acquisition of the Medical Products Division of Snap-On by S.S. White Technologies. The first version (v1 system) was in a laydown tray and debuted in 1996. The product manager at that time paved the way, but it was an employee of S.S. White Medical at the time, who spearheaded the development of the second version (v2) in 2008. The v2 added broken & stripped screw capabilities as well as brand new tip configurations. In 2011 the third version (v3) was an update that brought with it even more drivers, a newly designed vertical case, and a brand new ergonomic handle. Finally, the current version, version 4 (v4), was introduced in 2017, further refined the handle design and added even more drivers and tip configurations.

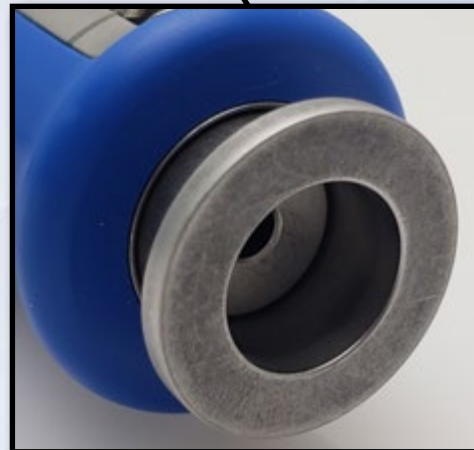
Parts not shown to scale

2.1 RATCHETING HANDLE

Designed with ergonomic comfort in mind. The quick-connect ratcheting driver handle can ratchet forward and in reverse, or can be fixed into place. Drivers lock into the handle with a simple push.



When there is bone ingrowth in the screw, the impact cap allows for taps of the driver into the screw head.



Depress the button in order to properly insert the driver and fully engage it.

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

- 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. 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 SHUKLA Mini (S9MINI) Universal Small Screw Extraction System is intended to install or remove virtually any small bone screw, especially those commonly used in hand, foot, craniomaxillofacial, & cervical spinal procedures.

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 Mini (S9MINI) is indicated for use during any revision procedure in which small bone screws must be inserted or removed.

Includes 25 distinct drivers & a ratcheting handle, allowing removal of any small screw in any location.

Driver Configurations:

- 3 sizes of hex driver (SDR201-203)
- ⊕ 3 sizes of cruciform driver (SDR204-206)
- ⊖ 2 slotted drivers (SDR207-208)
- 5 center drivers (SDR209-213)
- ⊖ Clutch driver (SDR214)
- ⊕ Phillips driver (SDR215)
- ⊕ 6 sizes of torx driver (SDR216-221)
- Osteotome (SDR222)
- Broken screw extractor (SXT201)
- 2 Stripped screw extractors (SXT202-203)

3.6 Additional Recommendations

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

STEP 1

Determine bone screw configuration & size (Image 1) and corresponding driver from the S9MAXI system.

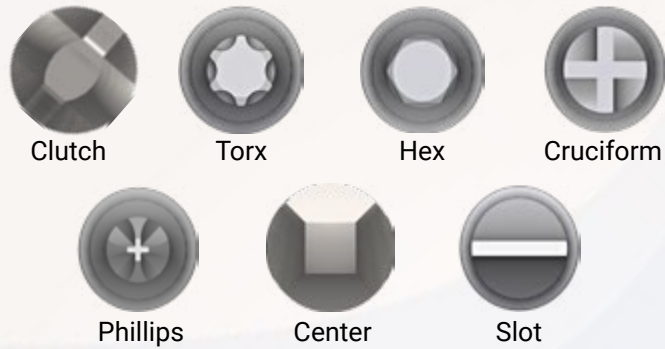


Image 1

STEP 2

Insert driver into Ratcheting Handle (SHN201) by depressing metal collar. Insert driver and release collar to lock. (Image 2) Exchange drivers by depressing collar to release and inserting the next driver.



Image 2

STEP 3

Set drive mode (Image 3) for Ratcheting Handle:

- Center:** Ratcheting disabled
- Forward:** Insert screws
- Back:** Remove screws



FORWARD: ← Insert screws → BACK: Remove screws

CENTER
Ratcheting
Disabled

Image 3

STEP
4

Remove or insert screws as required.

Stripped Screw Extractors

SXT202-SXT203

Extractor must fit into screw head so that threads at tip will capture side walls of screw socket, and will not reach the bottom of the screw shaft. (Image 4) Using some pressure, apply counterclockwise torque to create a secure attachment between the driver & stripped screw.



Image 4

Osteotome

SDR222

Can be used to clear debris from the screw head.

Drive mode must be locked in the middle position to prevent swiveling of the osteotome blade. (Image 6)



Image 6

Broken Screw Extractor

SXT201

Extractor must be centered over screw in order for screw to engage with reverse threads inside extractor tip. (Image 5) Using some pressure, apply counterclockwise torque to create a secure attachment between the driver & broken screw.

Caution: Contact between extractor teeth and broken screw may cause extractor teeth to break



Image 5

Impact Cap

If necessary, light force may be applied to the impact cap at end of handle to help seat driver into screw. Please note that excess force may damage ratcheting mechanism. (Image 7)



Image 7

STEP
5

Remove driver from handle by depressing the collar at the end of the handle to release (Image 8).



Image 8

- The Ratcheting Handle's (**SHN201**) Impact Cap can be used with the osteotome driver (**SDR222**) in order to help clear out bone ingrowth in and around screw heads.
- The staggered placement of the drivers and extractors in the case mitigate the chance of surgical gloves getting caught.
- The Ratcheting Handle (**SHN201**) can be set to ratchet in both forward and reverse directions, and can also be locked into place.
- The osteotome driver (**SDR222**) can be used as an atraumatic option for removing plates if the plate has formed ingrowth with the bone after all of the screws have been removed.

6 CLEANING & STERILIZATION

SHUKLA Mini

All Shukla Medical surgical instruments require manual cleaning with a neutral pH cleanser. Open and disassemble all instruments, making sure to remove all contamination during cleaning. Instruments must be reassembled prior to sterilization. Machine washing is not recommended. Maintenance and care using an autoclaveable lubricant on movable parts is required to preserve the life of the instrument. For more cleaning, inspection, maintenance, and care tips, contact Shukla Medical directly.

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



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CONSULT
INSTRUCTIONS
FOR USE

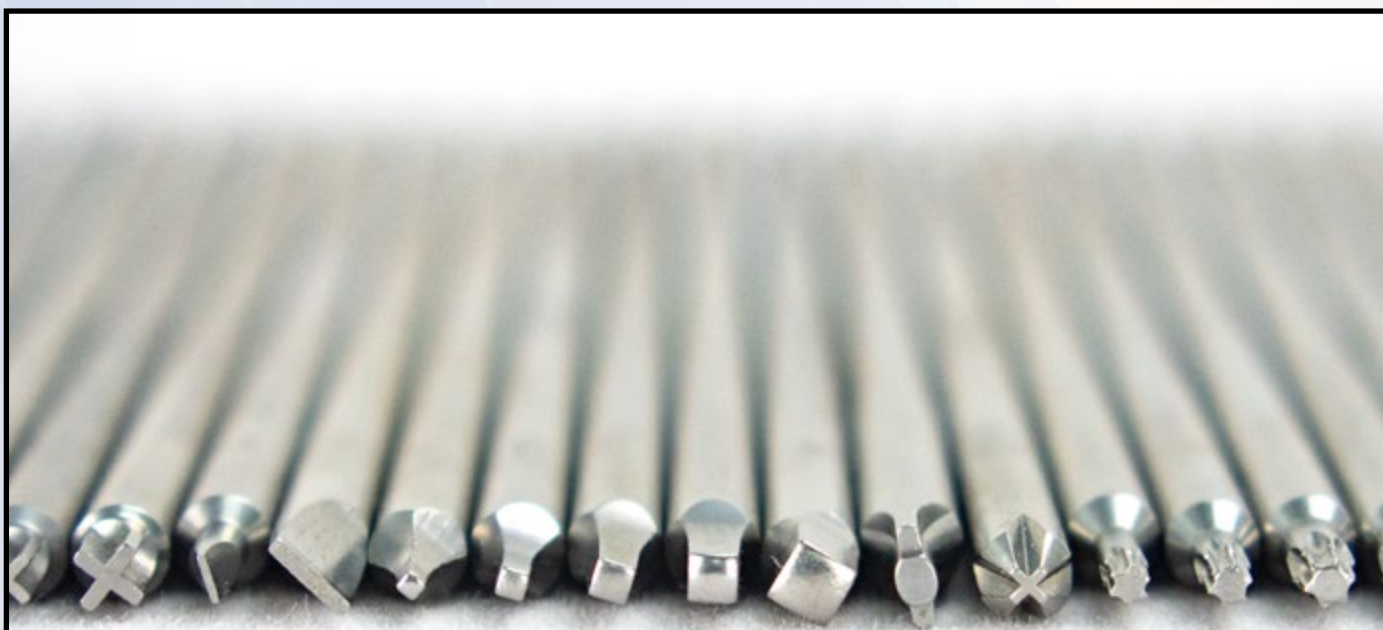


NON-STERILE
PRODUCT

7 COMPONENTS LIST

Component List		
Std Qty	Part Number	Description
1	SCS201	Case, Mini V3 Screw System
1	SDR201	Driver, Hex, 1.5 mm
1	SDR202	Driver, Hex, 2.0 mm
1	SDR203	Driver, Hex, 2.5 mm
1	SDR204	Driver, Cruciform, 1.37 mm
1	SDR205	Driver, Cruciform, 2 mm
1	SDR206	Driver, Cruciform, 2.5 mm
1	SDR207	Driver, Flat, 1.5 mm to 2 mm
1	SDR208	Driver, Flat, 3 mm
1	SDR209	Driver, Square, 1 mm
1	SDR210	Driver, Square, 1.5 mm
1	SDR211	Driver, Square, 2 mm
1	SDR212	Driver, Square, 2.7 mm
1	SDR213	Driver, Square, 3.5 mm
1	SDR214	Driver, Clutch, 2.7 mm
1	SDR215	Driver, Phillips, 2 to 2.7 mm
1	SDR216	Driver, Torx, T4
1	SDR217	Driver, Torx, T5
1	SDR218	Driver, Torx, T6
1	SDR219	Driver, Torx, T7
1	SDR220	Driver, Torx, T8
1	SDR221	Driver, Torx, T10
1	SDR222	Driver, Osteotome
1	SHN201	Handle Assy, Ratcheting, for MINI
2	SXT201	Extractor, Broken Screw, 2mm for MINI, <i>Single Use</i>
2	SXT202	Extractor, Stripped Screw, .157" for MINI, <i>Single Use</i>
2	SXT203	Extractor, Stripped Screw, .122" for MINI, <i>Single Use</i>

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





Revolutionizing the Art of Revision Surgery

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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SHUKLA Surgical Tech Support
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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.