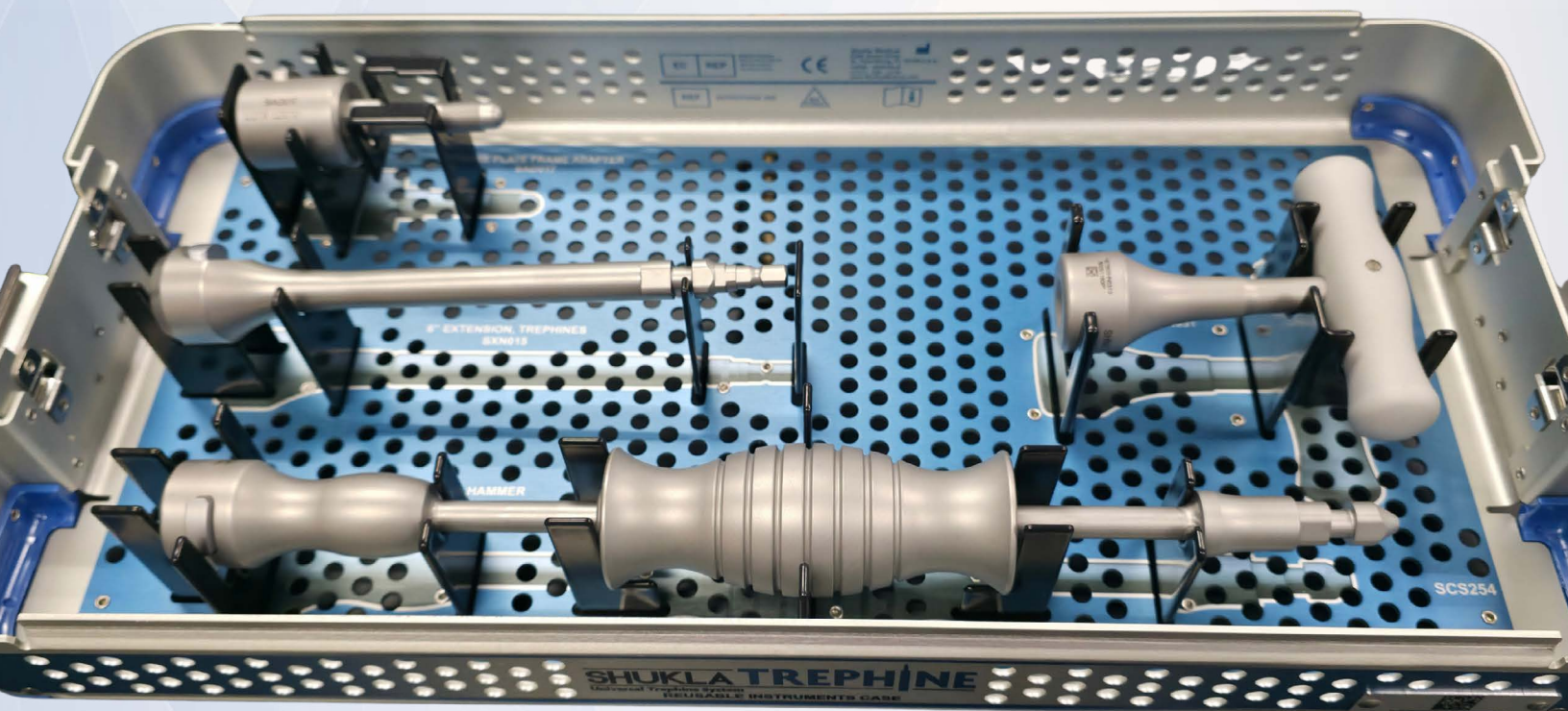


SHUKLA TREPHINETM

Universal Trephine System



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SHUKLA TREPHINETM

Universal Trephine System

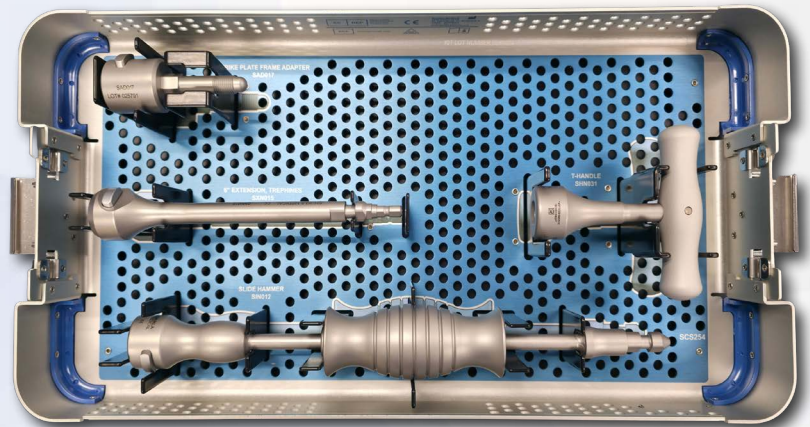
1.1 System Name: SHUKLA Trephine

Part Number: S9TREPHINE

Version: 1

1.2 Primary Use

The SHUKLA Universal Trephine system is designed for the coring over of IM Nails to break up the bone-implant interface. While primarily engineered for IM Nail revision surgeries, the trephines are also capable of coring over pins, broken stems, and screws as needed. The trephines can be used either by hand or under power.



1.3 System History

Engineering first began on the SHUKLA Trephine system in 2019. For years, surgeons had asked Shukla Medical if they intended on releasing a trephine set, and eventually enough demand was shown for the product that the company made the move to make it a reality. Our engineers ended up trying over twenty different trephine designs in order to maximize the cutting power and chip removal of the final product compared to the current products on the market. Development on the Strike Plate Frame Adapter utilized within the SHUKLA Trephine also began over the course of the system's development.

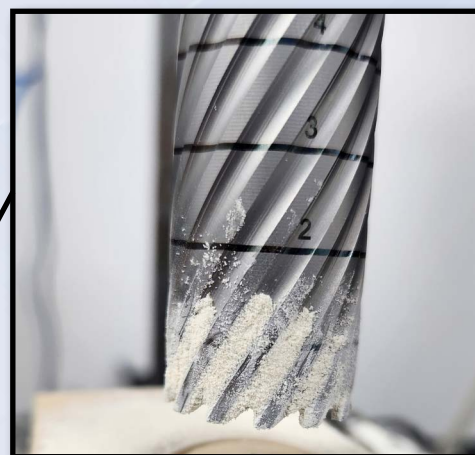
2.1

TREPHINE

With sizes ranging from 6mm to 26mm, our trephines are designed with teeth that flare outwards. This increases the cutting speed and reduces the heat generated while in use. Each trephine has 180mm of cutting length.



The Hudson Hub on the back of the trephine allows it to connect to both a drill or our instrumentation without any secondary steps required.



Helical grooves provide a path for the bone chips to be cycled up and out during usage.

2.2 STRIKE PLATE FRAME ADAPTER

If a trephine becomes stuck, the Strike Plate Frame Adapter allows the Shukla Medical Strike Plate Frame to be connected to the end of any size of trephine.



2.3 HUDSON HUB EXTENSION

Trephine Extension allows trephines better access through soft tissue when the situation requires it.



2.4 T-HANDLE

Designed with ergonomic comfort in mind. Allows for the trephine to be twisted and pulled free if it ever becomes stuck.

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 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 Preoperative Instrumentation Guide, 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; $\leq 75^{\circ}\text{F}/24^{\circ}\text{C}$.
- 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 Trepine (S9TREPINE) is intended for use during revision procedures to remove IM nail implants, knee implants, hip implants, pins, and screws.

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 Trepine (S9TREPINE) is indicated for use during any orthopedic revision procedure in which an IM nail, knee, or hip implant or other orthopedic hardware requires removal of bone in order to be explanted.

3.6 Additional Recommendations

During orthopedic revision procedures, the SHUKLA Trepine system is recommended for use in conjunction with the SHUKLA Nail, SHUKLA Knee, and/or the SHUKLA Hip and Anterior Hip systems.

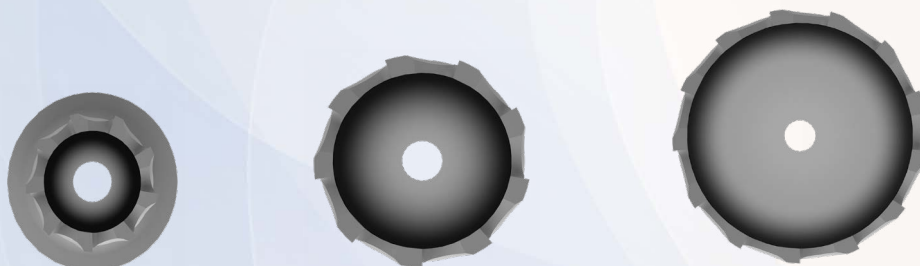
Notes About Shukla Medical Trephines

- The trephines are used to cut over implants in order to break up bone interface for easier extraction in conjunction with other SHUKLA systems.
- The trephines can chuck into a Hudson chuck or into any of the Shukla components with quick-connects in the system.
- The cutting teeth are designed to maximize cutting efficiency.
- Each trephine has 8 inches of cutting length.
- The flutes along the length of the trephines bring chips out of the cutting area and reduce heat buildup at the cutting site.
- The trephines have depth markings along the side for visual confirmation of plunge depth. *Depth markings are not calibrated, and are intended for visual reference only.*
- Trephines are **single use** in order to keep teeth sharp for each revision. Dull teeth will cut slower and create more heat, allowing for more chances to damage the bone.

STEP 1

Choosing the Proper Size Trephine

For the implant you are cutting over, choose a trephine size as close as possible to the implant diameter to reduce the amount of bone that is cut. Use an x-ray or preoperative notes to ascertain the size of the implant. Once the proper trephine has been determined, proceed to **Step 2**.



Small, Medium, and Large Trephine Sizes

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

SURGICAL TECHNIQUE

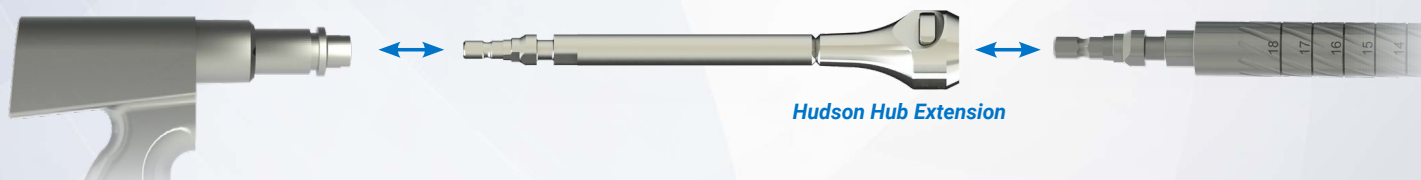
SHUKLA Trephine | Drilling

STEP 2

Chuck the Hudson end of the selected trephine into an orthopedic drill (or attach the T-Handle). Proceed to **Step 3**.



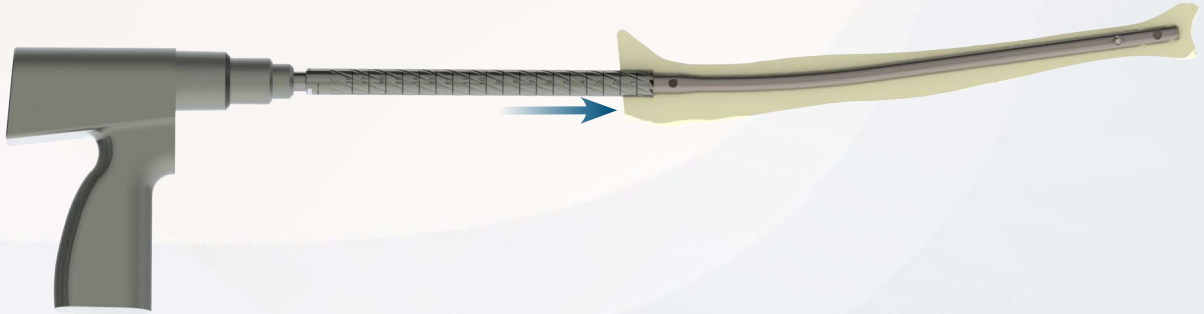
Note: If additional reach is needed, use the Hudson Hub Extension (SXN015) to attach drill bit to surgical drill (or T-Handle).



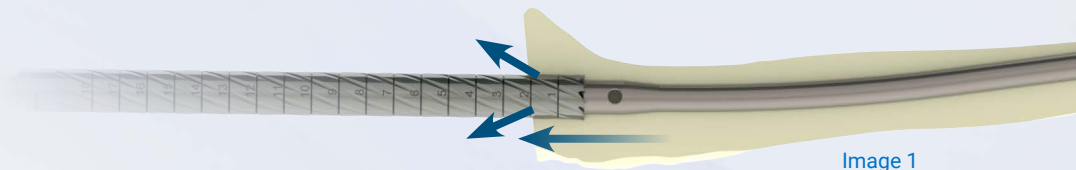
STEP 3

Using the Trephines

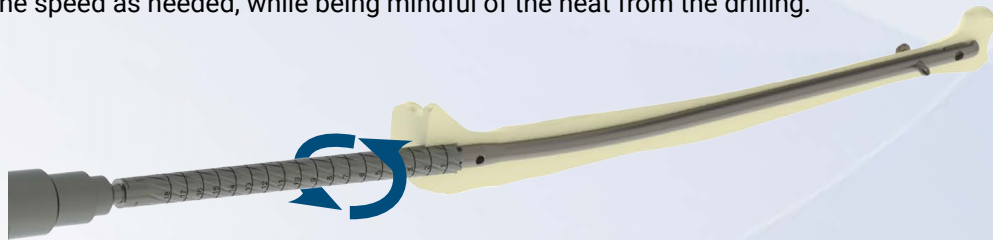
Set the drill in forward and in ream speed. Line up the trephine over the implant so that the trephine will cut around the circumference of the implant. Start drilling slowly and apply pressure to the drill so that the trephine starts to cut the bone.



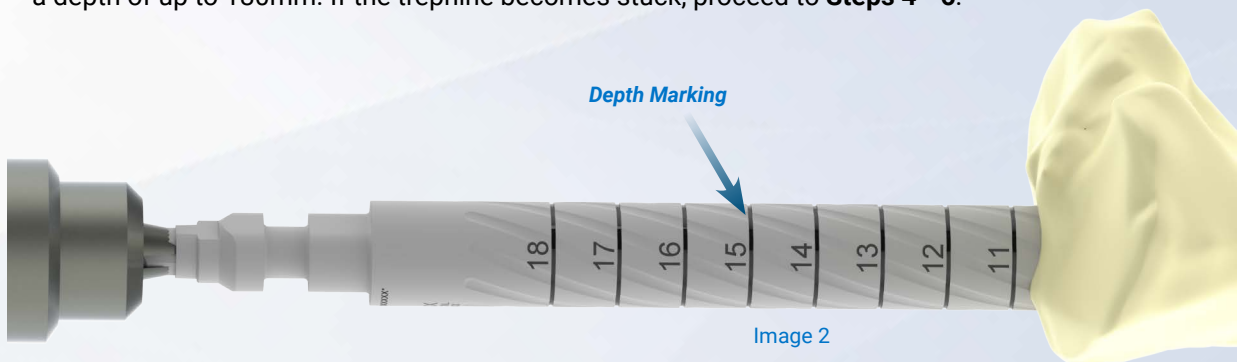
Note: Periodically lift the trephine out of the surgical site to relieve cut chips. (Image 1) This will help to maintain high cutting efficiency and reduce heat buildup.



Increase the speed as needed, while being mindful of the heat from the drilling.



Monitor the depth of the trephine by using the depth markings on the side. (Image 2) The trephines can reach a depth of up to 180mm. If the trephine becomes stuck, proceed to **Steps 4 - 6**.



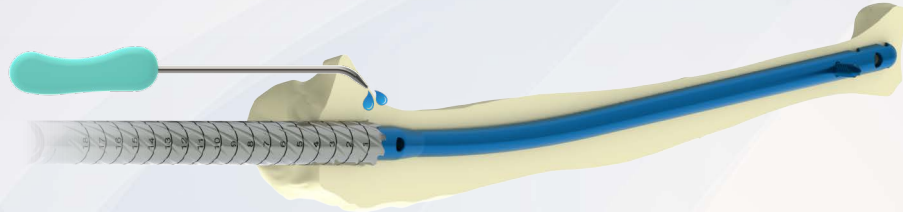
Note: Stop drilling when you reach the distal end of the implant.
Do not drill any deeper than the length of the implant.

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

Notes About Overheating

Drilling or sawing creates heat and it is very important to keep temperatures low enough to prevent any bone damage. **Temperatures above 50°C may cause irreversible thermal damage to the patient's bone and/or surrounding tissue.**

- Be sure to take all necessary steps to reduce heat buildup when drilling or sawing bone cement such as cooling with saline solution, utilizing a lower drill speed (ream speed), and frequent relieving of the chips.

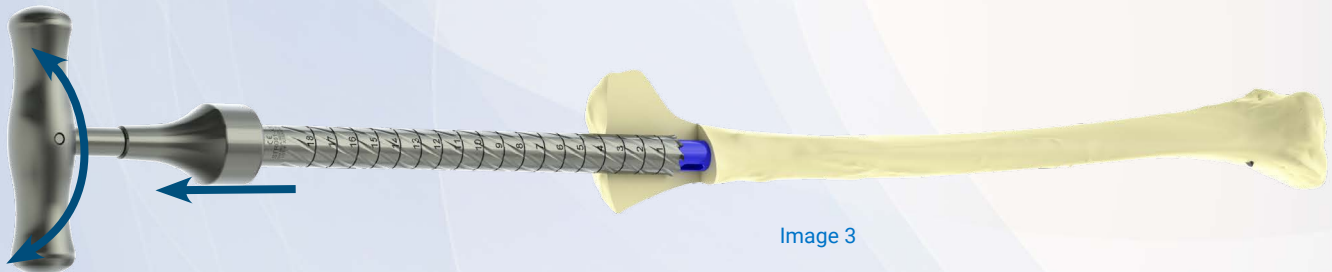


SURGICAL TECHNIQUE

SHUKLA Trephine | Stuck Trephines

STEP 4

If the trephine becomes stuck, attach the T-Handle (SHN031) to the back of the trephine. Using the T-Handle, twist the trephine back and forth while pulling on the T-Handle. This motion should loosen up the trephine and allow you to remove it. (Image 3)



STEP 5

If the trephine is stuck and needs a bit more impaction force to dislodge, attach the Slide Hammer (SIN012) to the back of the trephine. Slide the handle on the Slide Hammer back and repeat until the trephine is removed. (Image 4)

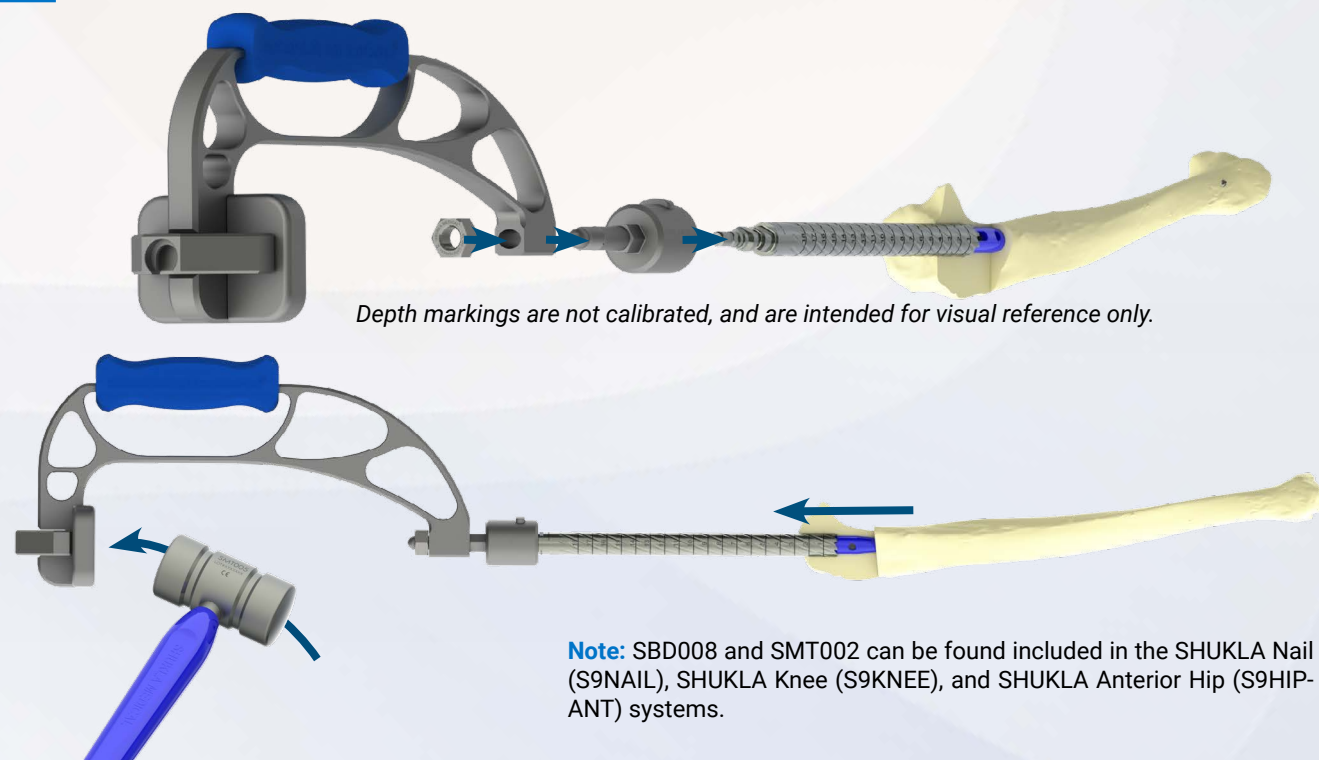


5 SURGICAL TECHNIQUE

SHUKLA Trephine | Stuck Trephines

STEP 6

If the trephine is stuck and needs more significant impact force to dislodge, attach the Strike Plate Frame Adapter (SAD017) to the back of the trephine. Connect the Strike Plate Frame (SBD008) (**Not Included**) to the adapter. Using a Large Mallet (SMT002) (**Not Included**), impact the Strike Plate Frame until the trephine is removed.



6 TIPS & TRICKS

SHUKLA Trephine

- The trephine will be less likely to get stuck if the chips are cleared out as the revision progresses.
- Using a saline solution will not only keep the trephine cool, but will also make the chips easier to vacuum up.
- You can use the T-Handle and Slide Hammer together to remove a stuck trephine if either one has difficulty on its own.
- You may not have to drill all the way to the distal end of the implant. Partially drilling may still relieve enough pressure from the bone on the implant to make extraction easier.
- Be mindful of any curves in an implant; the trephines are straight and may cut into the implant or break through bone.
- Depth markings are not calibrated, and are intended for visual reference only.

7 CLEANING & STERILIZATION

SHUKLA Trephine

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



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S9TREPHINE



SHUKLA Medical
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St. Petersburg, FL 33709
USA



CONSULT
INSTRUCTIONS
FOR USE



NON-STERILE
PRODUCT

S9TREPHINE Component List		
Std Qty	Part Number	Description
1	SCS011	Universal Case Lid
1	SCS254	Trephine Case
1	SAD017	Adapter, Strike Plate Frame
1	SHN031	T-Handle Assy, Female Chuck
1	SIN012	Adapter Cap, Female Chuck, Slide Hammer
1	SXN015	Extension, 6", Trephines
Sterile Pack Component List		
Std Qty	Part Number	Description
1	STR001-06-SP	Trephine, 06mm, Single Use
1	STR001-07-SP	Trephine, 07mm, Single Use
1	STR001-08-SP	Trephine, 08mm, Single Use
1	STR001-09-SP	Trephine, 09mm, Single Use
1	STR001-10-SP	Trephine, 10mm, Single Use
1	STR001-11-SP	Trephine, 11mm, Single Use
1	STR001-12-SP	Trephine, 12mm, Single Use
1	STR001-13-SP	Trephine, 13mm, Single Use
1	STR001-14-SP	Trephine, 14mm, Single Use
1	STR001-15-SP	Trephine, 15mm, Single Use
1	STR001-16-SP	Trephine, 16mm, Single Use
1	STR001-17-SP	Trephine, 17mm, Single Use
1	STR001-18-SP	Trephine, 18mm, Single Use
1	STR001-19-SP	Trephine, 19mm, Single Use
1	STR001-20-SP	Trephine, 20mm, Single Use
1	STR001-21-SP	Trephine, 21mm, Single Use
1	STR001-22-SP	Trephine, 22mm, Single Use
1	STR001-23-SP	Trephine, 23mm, Single Use
1	STR001-24-SP	Trephine, 24mm, Single Use
1	STR001-25-SP	Trephine, 25mm, Single Use
1	STR001-26-SP	Trephine, 26mm, Single Use

Single-use Only: Always use new trephines 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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For the most up-to-date version of this literature, please refer to our website at <https://shuklamedical.com/Products>



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.