SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

INSTRUCTIONS FOR USE CLEANING & STERILIZATION

&

PREOPERATIVE INSTRUMENTATION INSPECTION GUIDE

SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

INSTRUCTIONS FOR USE

CLEANING & STERILIZATION

Manual Surgical Orthopedic Instruments

THE EXTRACTION EXPERTS

1. **INTRODUCTION:** The processing instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of both hospital owned and Pay Per Surgery(PPS) Shukla Medical instrument sets.

   a. Title of this document is Instruction For Use (IFU): "Manual Surgical Instruments. Recommendations for Care, Cleaning, Maintenance and Sterilization."

   b. The ID number for this document is L3-IFU-INS-REVISED: JULY-03-25. The Rev number indicates the date when this version was approved for release.

   c. This document is controlled by a Document Management System (DMS) as LIT-1063. If any contents in here need to be updated, the changes shall be processed through an internal DMS process. Upon approval, Rev # in 1-b will be updated.

   d. The most current version of this document is available on the Shukla Medical website.

2. **WARNINGS AND PRECAUTIONS:** Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.

   a. Caution should be exercised when handling devices with sharp points or cutting edges.

   b. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes a gown, mask, goggles or face shield, gloves and shoe covers.

   c. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments.

   d. Soft-bristled, nylon brushes and pipe cleaners should be used.

   e. Do not place heavy instruments on top of delicate devices.

   f. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments.

   g. Remove excess body fluids and tissues with a disposable, non-shedding wipe and cover with a damp cloth.

   h. Automated cleaning alone may not be effective. A thorough manual cleaning process is recommended.

   i. Instruments should be removed from trays and cleaned separately.

   j. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

INSTRUCTIONS FOR USE

3. POINT OF USE PREPARATION, CONTAINMENT AND TRANSPORTATION

a. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
b. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning. Instruments should be disassembled (when applicable) and cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
c. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

4. PREPARATION OF CLEANING AGENTS

a. Neutral pH enzymatic and low foaming cleaning agents are preferred and recommended by Shukla Medical.
b. All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer.
c. Water used to prepare cleaning agents and for cleaning and disinfection (as described in the cleaning and disinfection steps) should meet the general quality recommendations outlined in AAMI TIR34:2014 or an equivalent standard. Suitable types include utility water or critical water that has undergone appropriate treatment, such as purification, deionization (DI), softening, or reverse osmosis (RO).
d. Use of recommended temperatures is important for optimal performance of cleaning agent and fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

5. RECOMMENDED MANUAL CLEANING PROCESS

a. Devices should be cleaned within 30 minutes of use to minimize the potential of soil drying prior to cleaning. Device must be disassembled before cleaning.
b. Wipe device using a soft, disposable non-shedding wipe.
c. Prepare (25-40°C) neutral pH enzymatic detergent (Recommended detergent for usage - Prolystica® HP Enzymatic Manual Cleaner) using tap (utility) water, per manufacturer's instructions.
d. Completely submerge device in enzymatic detergent and allow it to soak for a minimum of 20 minutes.
e. Using a soft nylon bristle brush, scrub all device surfaces until gross soil is no longer visually observed while submerged. Clean lumens of the device with a long narrow, soft-bristle brush.
f. Rinse device using DI water for a minimum of 3 minutes, thoroughly flushing lumens, holes and other difficult to reach areas.
g. Repeat rinse for 3 minutes with DI water.
h. Dry instruments with a clean, disposable, absorbent, non- shedding wipe.
i. Inspect instruments for any sign of residual soils. Repeat cleaning steps 2-8 until no residue is observed.
j. Apply lubricant in accordance with lubricant manufacturer instructions, such as STERIS Hinge-Free Instrument Lubricant.

6. RECOMMENDED AUTOMATIC CLEANING PROCESS

a. At point of use take appropriate measures to ensure contaminants do not dry on soiled device.
b. Device must be disassembled before cleaning.
c. Pre-rinse the device with cool water for a minimum of 1 minute until gross soil is no longer visually observed.
d. Load devices into a mesh basket.
e. Automated washing shall be performed using a validated washer-disinfector in accordance with ISO-15883 or equivalent recognized standards.

6.1 AUTOMATED CLEANING WITH AN ALKALINE SOLUTION

a. Execute the cycle using a pH alkaline detergent (Recommended detergent for usage - Prolystica® Ultra Concentrate HP Alkaline Cleaner) according to the following process:

Motor Speed: High			
Step	**Description**	**Minimum Temperature**	**Minimum Cycle Time**
1	Pre-wash	Cold tap water (Facility)	2 minutes
2	Enzyme wash	Hot tap water (Facility)	4 minutes
3	Wash (Detergent % according to manufacturer specification)	65.5°C (149.9°F)	2 minutes
4	Rinse	Hot tap water	15 seconds
5	Thermal rinse with lubricant (% according to manufacturer specification)	90.0°C (194.0°F) Purified Water (Heated)	1 minute
6	Hot Air Dry	HIGH	6 minutes

b. Upon completion, unload the washer-disinfector.
c. Visually inspect the Devices for remaining soil.

6.2 AUTOMATED CLEANING WITH A NEUTRAL pH SOLUTION

a. This should follow **Recommended Manual Cleaning Process**
b. Execute the cycle using a pH neutral detergent according to the following process:

Motor Speed: High			
Step	**Description**	**Minimum Temperature**	**Minimum Cycle Time**
1	Pre-wash	Cold tap water (Facility)	2 minutes
2	Enzyme wash	Hot tap water (Facility)	4 minutes
3	Wash (Detergent % according to manufacturer specification)	65.5°C (149.9°F)	2 minutes
4	Rinse	Hot tap water	15 seconds
5	Thermal rinse with lubricant (% according to manufacturer specification)	90.0°C (194.0°F) Purified Water (Heated)	1 minute
6	Hot Air Dry	HIGH	6 minutes

c. Upon completion, unload the washer-disinfector.
d. Visually inspect the Devices for remaining soil.

7. INSPECTION, MAINTENANCE AND LUBRICATION

a. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

b. Visually inspect per the Preoperative Instrumentation Inspection Guide section (pages 6 - 15) for device integrity, damage and/or excessive wear NOTE: If damage or wear is noted that may compromise the function of the instrument, contact Shukla Medical for a replacement.

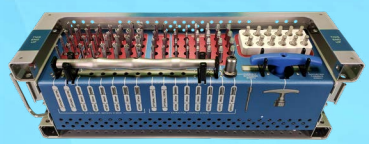
c. Check the action of moving parts (e.g. hinges, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion. Hinged, rotating, sliding or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized.

d. Recommended detergent for usage - Prolystica® Ultra Concentrate HP Instrument Cleaning Chemistries

e. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use dilution concentrations NOTE: Mineral oil or silicone lubricants should not be used because they 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

8. STERILIZATION INSTRUCTIONS

a. Orientation of Shukla Medical Cases - For any stand up cases the case needs to be laid horizontal on its side for proper sterilization. If placed properly the lid of the case will still be removable but parts inside will no longer orient vertically. An example of a stand up case is S9SCREW-V3:



b. Steam sterilize using a pre-vacuum cycle for 3 minutes at a minimum temperature of 134°C (273.2°F) for EU/UK based facilities, as appropriate.

c. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded.

d. Drying times will vary according to load size and should be increased for larger loads.

e. "Flash" sterilization is not recommended for SHUKLA Medical instruments and systems.

f. Following Table 1 summarizes the minimum exposure times and temperatures that have been validated for SHUKLA Medical systems. If a system is not listed, parameters for S9KNEE should be followed.

g. For US use, there are two options for wrapping the system for sterilization. If double blue wrapping, refer to table 1A. If placed in a rigid sterile container, refer to table 1B.

h. For EU/UK use, there are two options for wrapping the system for sterilization. If double blue wrapping, refer to table 2A. If placed in a rigid sterile container, refer to table 2B.

i. Steam sterilization shall be performed using a validated steam sterilizer in accordance with EN 285 or equivalent local standards.

INSTRUCTIONS FOR USE

1) STERILIZATION INSTRUCTIONS FOR ALL SHUKLA SYSTEMS (US)						
SHUKLA Part Numbers:	**Prevacuum Pulses**	**Min. Temp.**	**Min. Exposure Time Wrapped**	**Min. Dry Time**	**Min. Open Door Dry Time**	**Min. Cool Down Time**
1A) Wrapped in 2 Layers of Single-Ply Polypropylene Wrap Using Sequential Envelope Folding Techniques						
MKS1031*, S9SPINE, S9COPTER	4	132°C/ 270°F	4 min.	30 min.	-	-
MKS1022*, S9BLADE, S9MAXI, S9MINI	4	132°C/ 270°F	4 min.	45 min.	-	-
S9KNE*/S9KNEE, 120-00*/S9HIP-MOD, S9NAIL/ S9WINQ*, S9NAIL-BR, S9LAG, S9SHLDR, S9SHLDR-BLADE, S9CUP, S9VISE, S9TREPHINE, S9SCREWFLEX, S9HIP-ANT	4	132°C/ 270°F	4 min.	45 min.	-	30 min.
104-00*/S9HIP, MKS1017*, S9SCRW*/S9SCREW, S9SCREW-V3	4	132°C/ 270°F	4 min.	60 min.	-	30 min.
1B) Placed in Aesculap Sterile Container Systems (JK444 or JK446) w/ Lid (JK486) + Single-Use Filters US751 or Equivalent						
All Systems	4	132°C/ 270°F	4 min.	30 mins.	-	-

* Legacy Systems - No Longer Sold

2) STERILIZATION INSTRUCTIONS FOR ALL SHUKLA SYSTEMS (EU/UK)						
SHUKLA Part Numbers:	**Pre-vacuum pulses**	**Temp. min.**	**Min. Exposure Time Wrapped**	**Min. Dry Time**	**Min. Open Door Dry Time**	**Min. Cool Down Time**
1A) Wrapped in 2 Layers of Single-Ply Polypropylene Wrap Using Sequential Envelope Folding Techniques						
All Systems	4	134°C/ 273°F	3 min.	90 mins.	30	90
1B) Placed in Aesculap Sterile Container Systems (JK444 or JK446) w/ Lid (JK486) + Single-Use Filters US751 or Equivalent						
All Systems	4	134°C/ 273°F	3 min.	30 mins.	-	-

i. For the above table, please note items (ii to v) below:

ii. The temperature listed is the minimum validated steam sterilization temperature required to achieve a 10^-6 sterility assurance level (SAL).

iii. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.

iv. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.

v. The sterilization and cleaning cycles are also compatible with Health Technical memorandum 01-01 (HTM 01-01 per Medicines and Healthcare products Regulatory Agency - UK)

vi. Drying times vary according to load size and should be increased for larger load.

9. STORAGE INSTRUCTIONS

a. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes. Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

b. For Non-Sterile Systems: Store in ambient room conditions (Cool and dry)

c. For Sterile Packaging: As per packaging instructions

d. For Non-Sterile Packaged Parts for Stock Boxes: Store in ambient room conditions (Cool and dry)

e. For Sterile Packaged Parts for Stock Boxes: As per packaging instructions

10. FOR LOANER/RENTAL SETS

a. Loaner/rental sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and sterilization before being returned to Shukla Medical.

b. All rental sets are sent out with a Decontamination Certificate (FCD-0360) that is to be filled out and returned with the set along with any supplementary evidence of decontamination. Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to Shukla Medical to ensure that the missing/damaged instrument(s) are backfilled.

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

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

ISO 13485:2016 CE FDA REGISTERED

SHUKLA MEDICAL®

Universal Orthopedic Extraction Technologies

PREOPERATIVE INSTRUMENTATION INSPECTION GUIDE

INTRODUCTION

1. Purpose

1.1. The purpose of this manual is to provide the user, criteria and guidance for the inspection of Shukla Medical surgical systems and instruments prior to each use. The manual will serve as a guidance in determining whether and when an instrument is or is not suitable for use.

2. Scope

2.1. The guidelines and inspection criteria in this manual are applicable to all Shukla Medical Products (with the exception of single use parts already used on patients in surgery).

3. Background

3.1. The following types of instrument nonconformities will be addressed in the manual: bending, discoloration, corrosion, fracture, surface damage, and thread damage. Each of these nonconformities indicate surface wear. The presence of any of the previously stated types of wear on any reusable component indicates said instrument is no longer suitable for use.

3.2. Each section of the manual will contain descriptions, definitions, and corresponding images indicating and displaying the types of damage being addressed, along with methods of verifying if that wear is present.

4. Definitions

4.1. Visual inspection: The process of looking for nonconformities/conditions on the parts against pictures/photographs in the guide for the specific conditions.

4.2. Functional inspection: The process of inspecting the instrument against its intended use. This has to be done in conjunction with the relevant surgical technique guide.

5. Inspection Process

5.1. Surgical systems/Rental kits should be inspected for both completeness of the set and functionality of the components with the set.

5.2. Inspection includes:

- 5.2.1. Checking the functionality of components that form a larger assembly or interaction with one another
- 5.2.2. Checking the functionality of moving parts (handles, ratchets)
- 5.2.3. Checking internal mechanisms when applicable if the device is to be disassembled for processing
- 5.2.4. Inspecting for all forms of damage and surface wear as indicated in this manual
- 5.2.5. Inspecting kit completeness

5.3. If a component is deemed not suitable for use it should be determined if it is to be scrapped.

5.4. If a component is deemed not suitable for use it should be replaced with a new component (of the same part number) from the Shukla Medical stock room.

5.5. If a single-use component has been used in a surgery, it should be discarded and replaced.

CONTENTS

BENDING

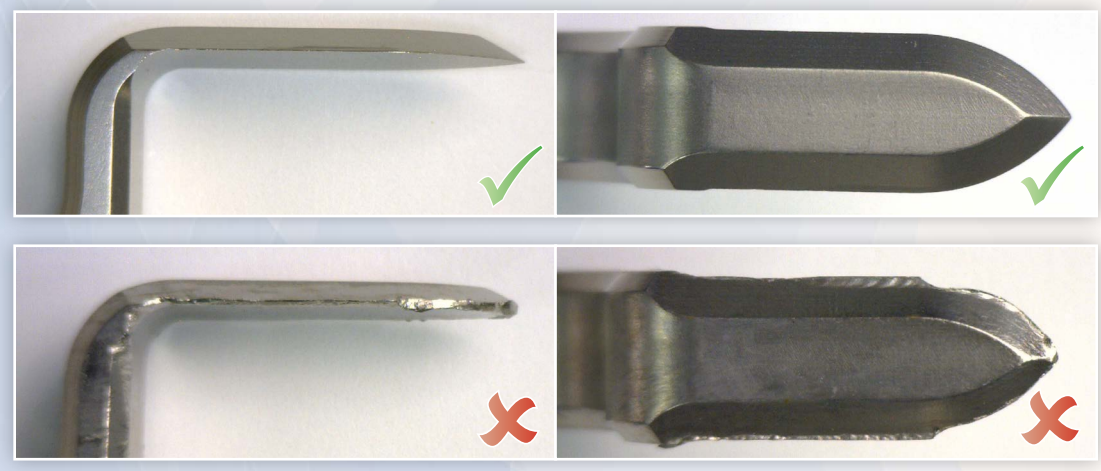
Description

- Bent
- Crooked
- Warped
- Curved (Out of Conformity)
- Bowed

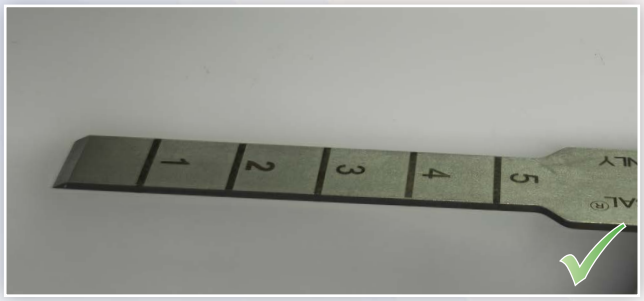
Inspection Test Method

- Visual Inspection

Warped



Bent



THREAD DAMAGE

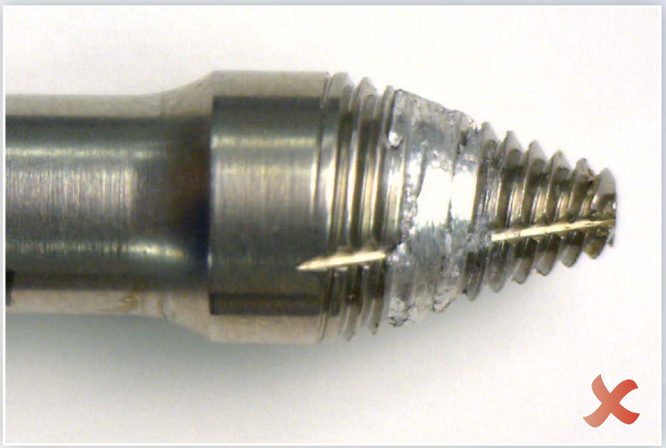
Description

- Stripped Threads
- Damaged Threads
- Crevice Corrosion

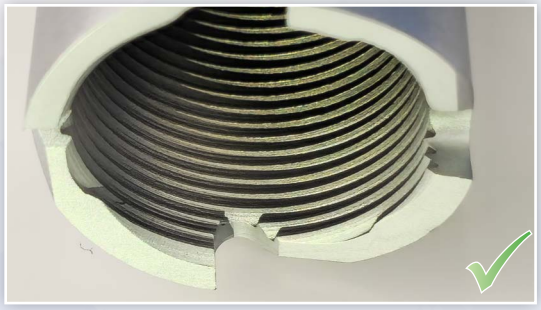
Inspection Test Methods

- Visual Inspection
- Functional Inspection

Stripped/Damaged Threads



Crevice Corrosion



DISCOLORATION

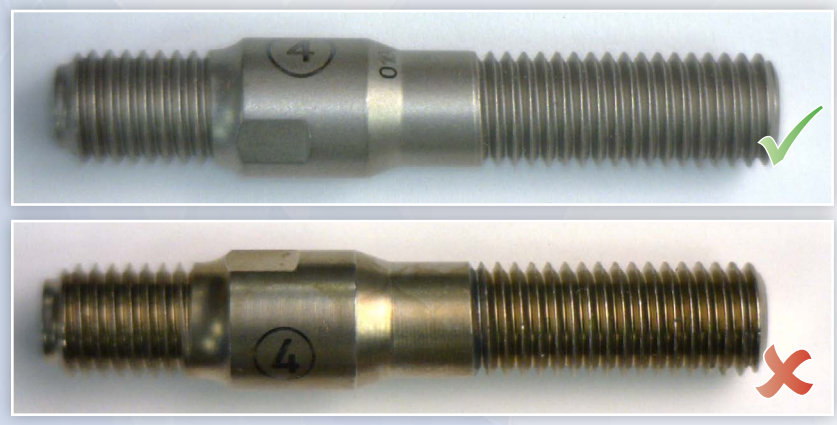
Description

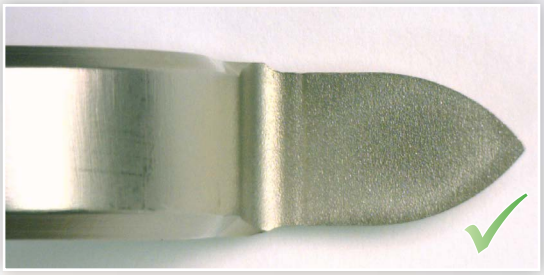
- Discoloration of Laser Markings
- Surface Discoloration

Inspection Test Methods

- Visual Inspection
- Eraser Test - If unsure it is discoloration, use a standard rubber eraser on the area; if the discoloration goes, away it was a stain

Surface Discoloration





Discoloration of Laser Markings

CORROSION

Description

- Rust
- Rust of Laser Markings
- Surface Corrosion
- Corrosion of Laser Markings
- Thread Corrosion

Inspection Test Method

- Visual Inspection

Surface Corrosion

Corrosion of Laser Markings

Thread Corrosion

Connection Threads Corrosion

SURFACE DAMAGE [GENERAL]

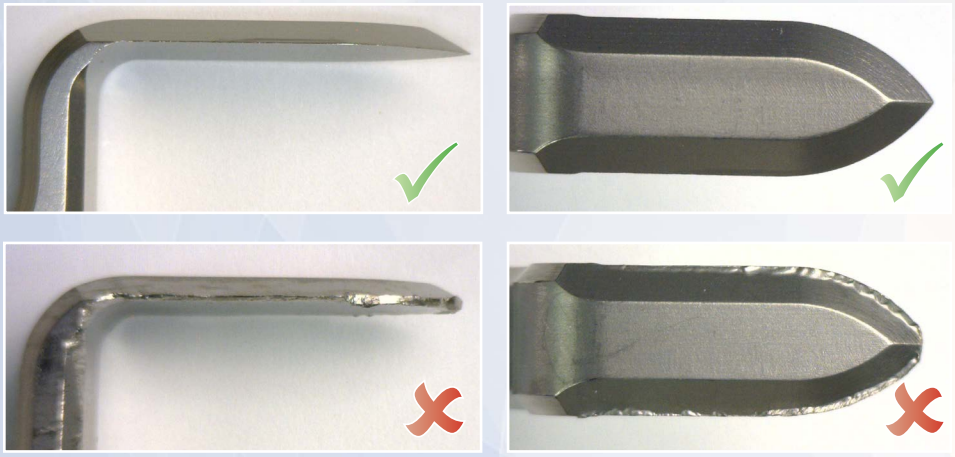
Description

- Burred
- Scratched
- Dented
- Chipped
- Nicked
- Loss of Surface Coating
- Rounded Edges
- Loss of Laser Markings

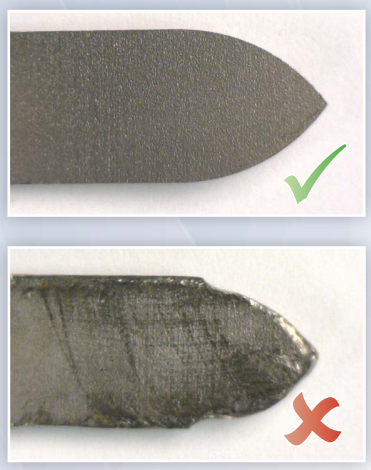
Inspection Test Methods

- Visual Inspection

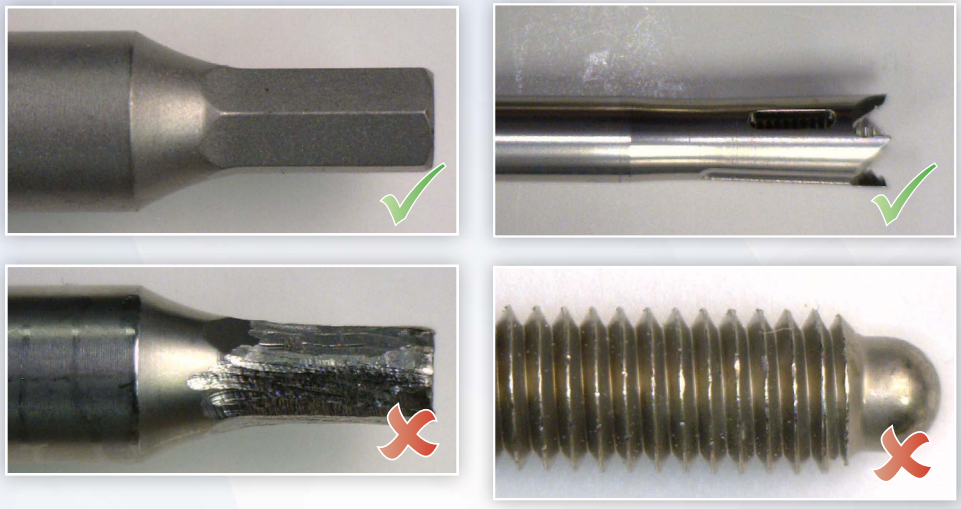
Burred



Scratched



Nicked



SURFACE DAMAGE [GENERAL]

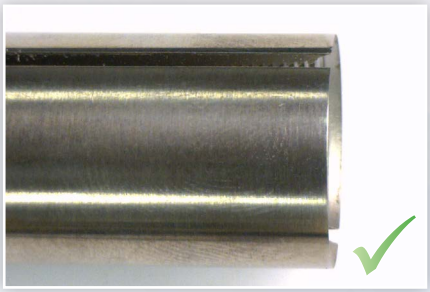
Description

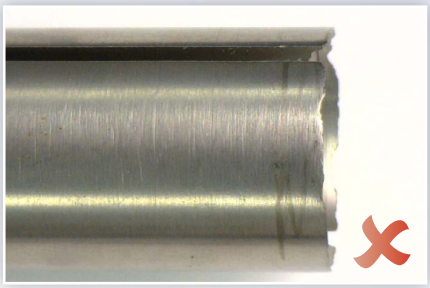
- Burred
- Scratched
- Dented
- Chipped
- Nicked
- Loss of Surface Coating
- Rounded Edges
- Loss of Laser Markings

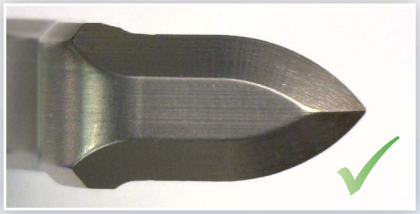
Inspection Test Methods

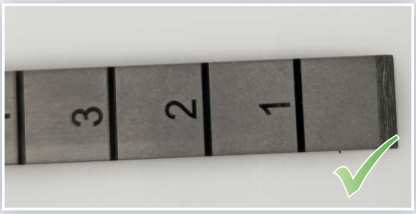
- Visual Inspection

Chipped









Loss of Laser Markings

FRACTURE

Description

- Fractured
- Cracked

Inspection Test Method

- Visual Inspection

Fractured

SILICONE DAMAGE [GENERAL]

Description

- Epoxy Damage
- Epoxy Displacement
- Silicone Damage

Inspection Test Methods

- Visual Inspection

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

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

CONSULT INSTRUCTIONS FOR USE

NON STERILE NON-STERILE PRODUCT

CE

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.

Once opened - sterile packages cannot be reprocessed or reused.

*Please see our website for the complete explanation of these terms and full details on our warranty.

L3-IFU-INS-REVISED: JULY-03-25