



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.

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BENDING

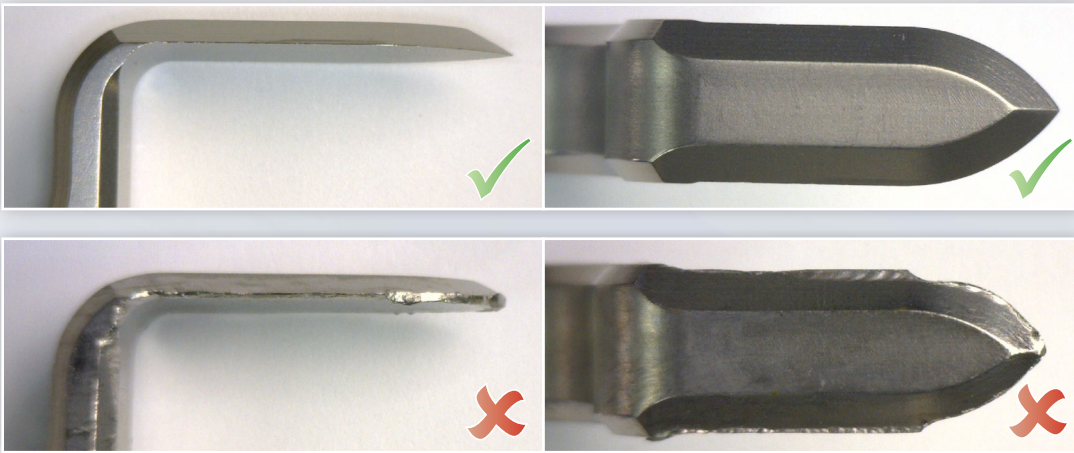
Description

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

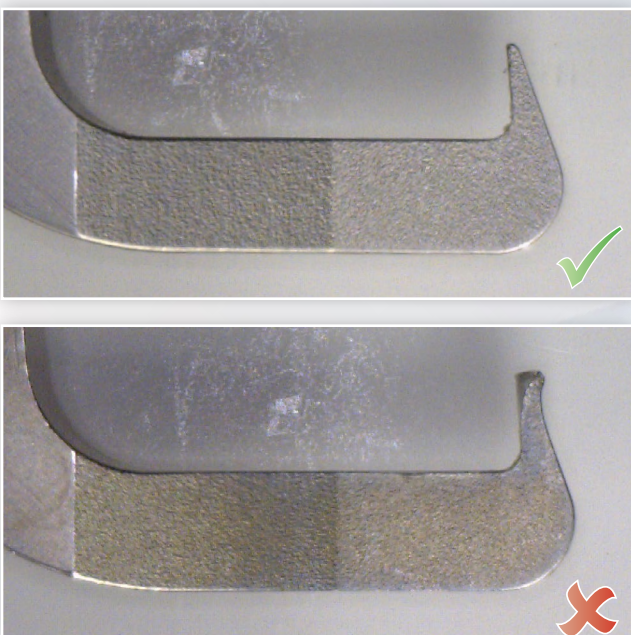
Inspection Test Method

- Visual Inspection

Warped



Bent



THREAD DAMAGE

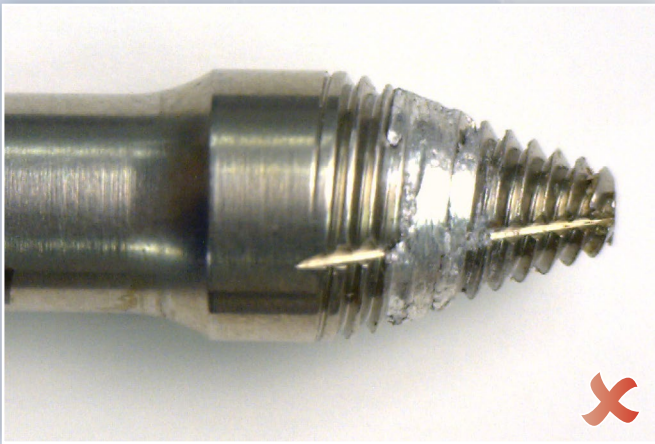
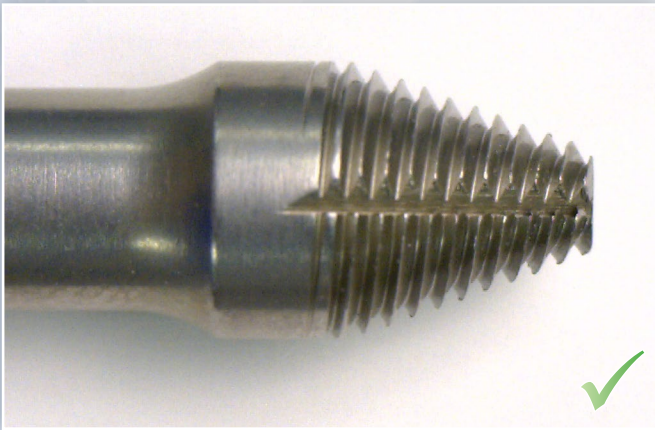
Description

- Stripped Threads
- Damaged Threads
- Crevice Corrosion

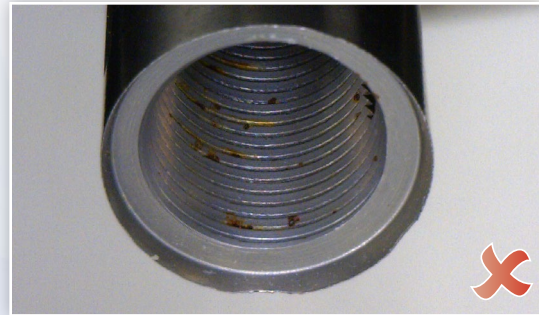
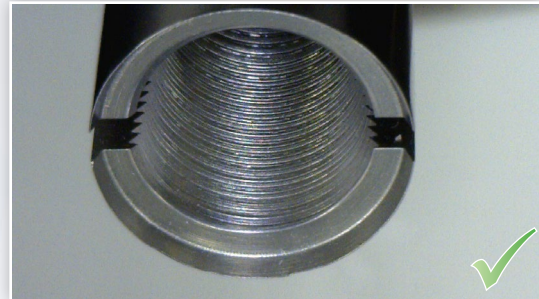
Inspection Test Methods

- Visual Inspection
- Functional Inspection

Stripped/Damaged Threads



Crevice Corrosion



DISCOLORATION

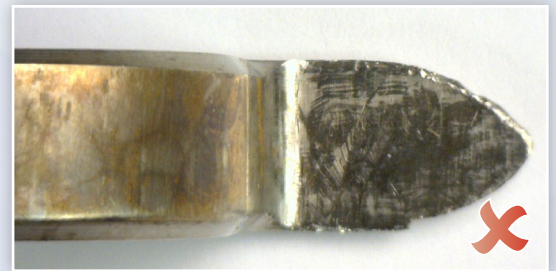
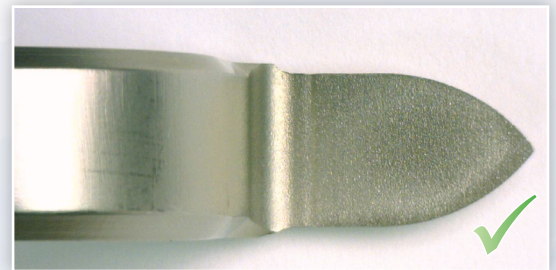
Description

- 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

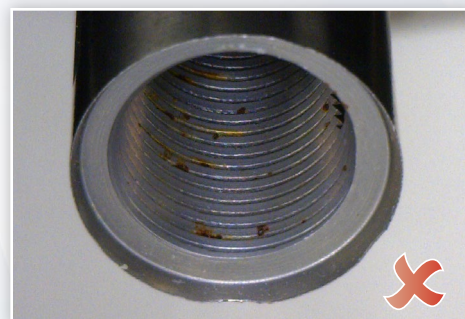
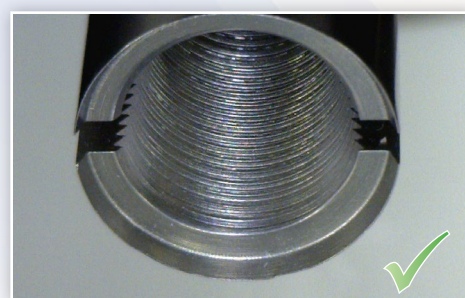
Surface Corrosion



Corrosion of Laser Markings



Thread Corrosion



SURFACE DAMAGE [GENERAL]

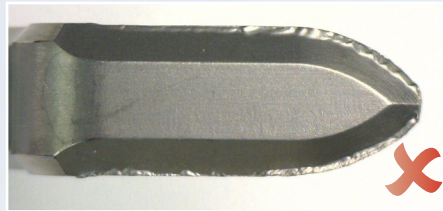
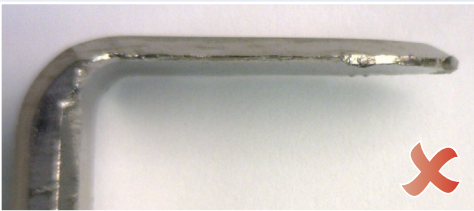
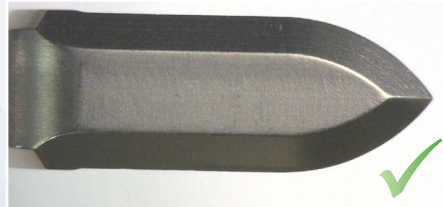
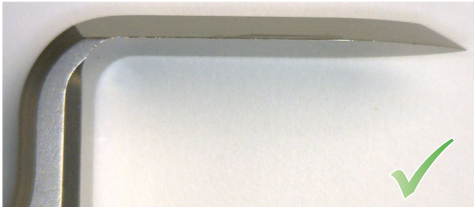
Description

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

Inspection Test Methods

- Visual Inspection

Burred



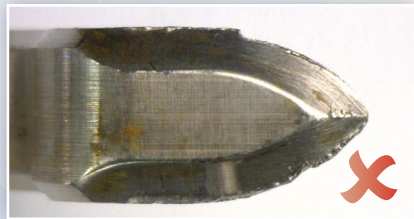
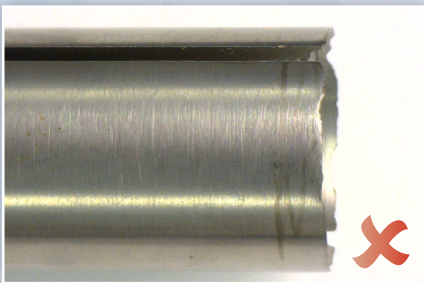
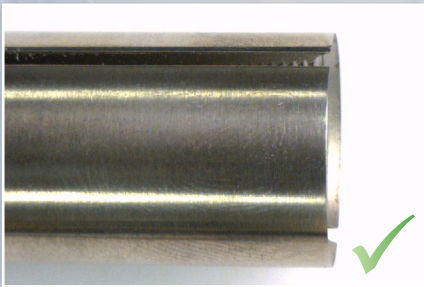
Scratched



Nicked



Chipped



Loss of Laser Markings



FRACTURE

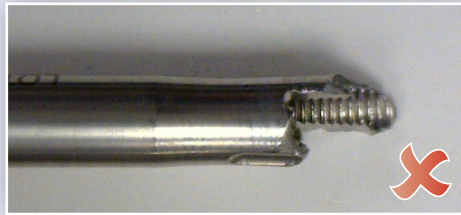
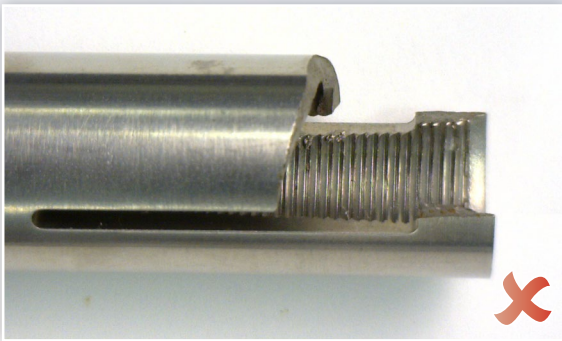
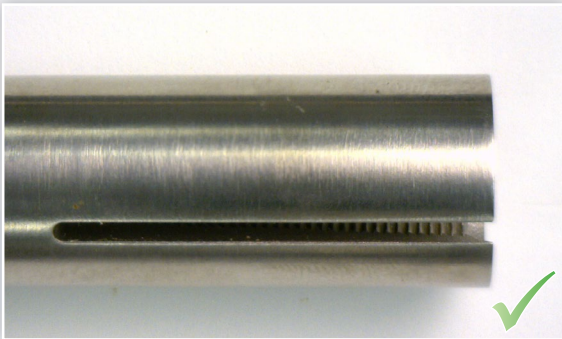
Description

- Fractured
- Cracked

Inspection Test Method

- Visual Inspection

Fractured





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
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands



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.