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# End of Life Indicators (EOLi) of Reusable DePuy Synthes Spine Instruments

## Attachment 1

## Purpose



The purpose of this document is to provide visual and functional information (i.e. End of Life Indicators, EOLi) to the intended user to identify when the reusable device should no longer be reused. Devices that exhibit EOLi are not fit for use any longer; consult your local Depuy Synthes Spine representative to replace the device.

## Basic Instructions for Using the End of Life Indicator (EOLi) Document

End of Life (EOL) of a device is normally determined by wear and damage due to use. DePuy Synthes Spine instruments should be inspected for the applicable EOLi of the device after processing but prior to sterilization.

This document contains representative images of the device type. It captures common design features within the device type that are pertinent to the function and safe use of the device. Each device may have one or more criteria provided that can be used to determine if the device is still serviceable. When using this document, it is important to focus on the descriptive words for each feature as well as the accompanying images.

Evidence of damage and wear on a device may include but is not limited to the End of Life indicators contained within this document; this document is therefore not a definitive list of End of Life indicators. These indicators may also present themselves different visually from the images provided within this document. When using this document, it is important to note that the images are intended to provide representative examples of types of wear and can therefore be applicable to multiple devices and device features.

-  -Devices deemed to be outside of their recommended limits of intended use (i.e. 'Defective Device') are indicated by a red 'X' in the box.
-  -Appropriately functioning devices are indicated by a green checkmark in the box.

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Device Types not listed above have no unique EOLi - see  
Generic and Feature Indicators, as applicable.

## 1. Generic EOLi (As Applicable)

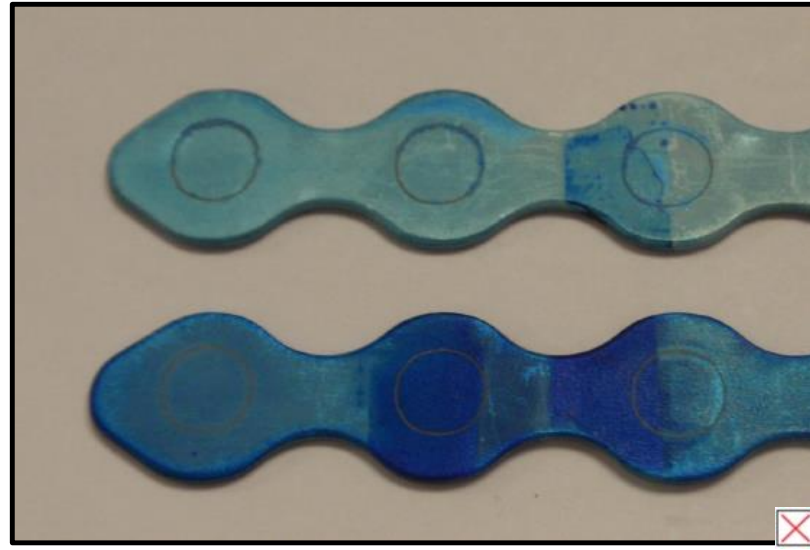
### 1.1 Corrosion, Rusting, Pitting



EOLi: Corrosion that effects traceability or functionality, corrosion on patient-contacting surfaces

## 1. Generic EOLi (As Applicable)

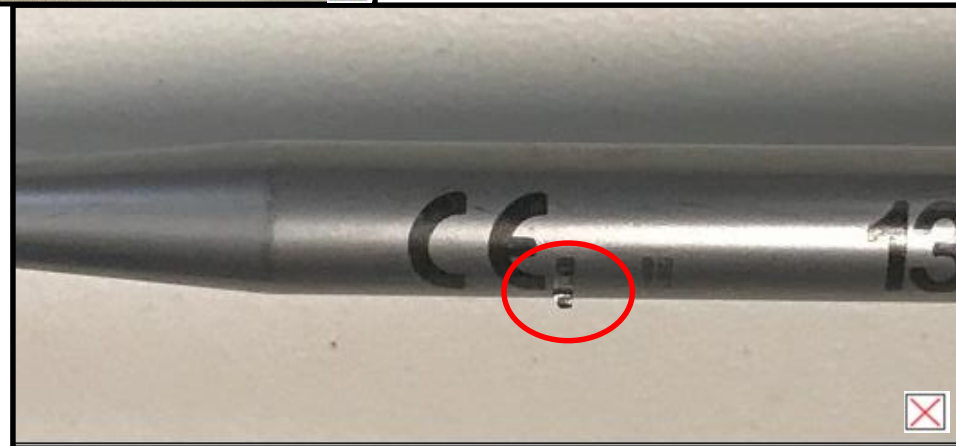
### 1.2 Discoloration / Fading



EOLi: Discoloration on plastic, anodized (i.e., color coded) Aluminum and Titanium devices

## 1. Generic EOLi (As Applicable)

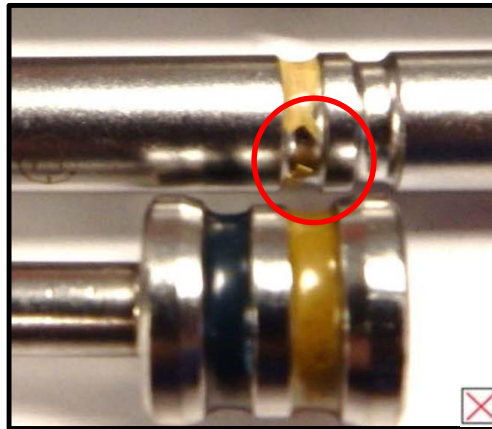
### 1.3 Excessive Scratches, Burrs or Dents



EOLi: Excessive scratches, burrs or dents on surfaces that mate with other instruments or surfaces held by the user (e.g., handles).

## 1. Generic EOLi (As Applicable)

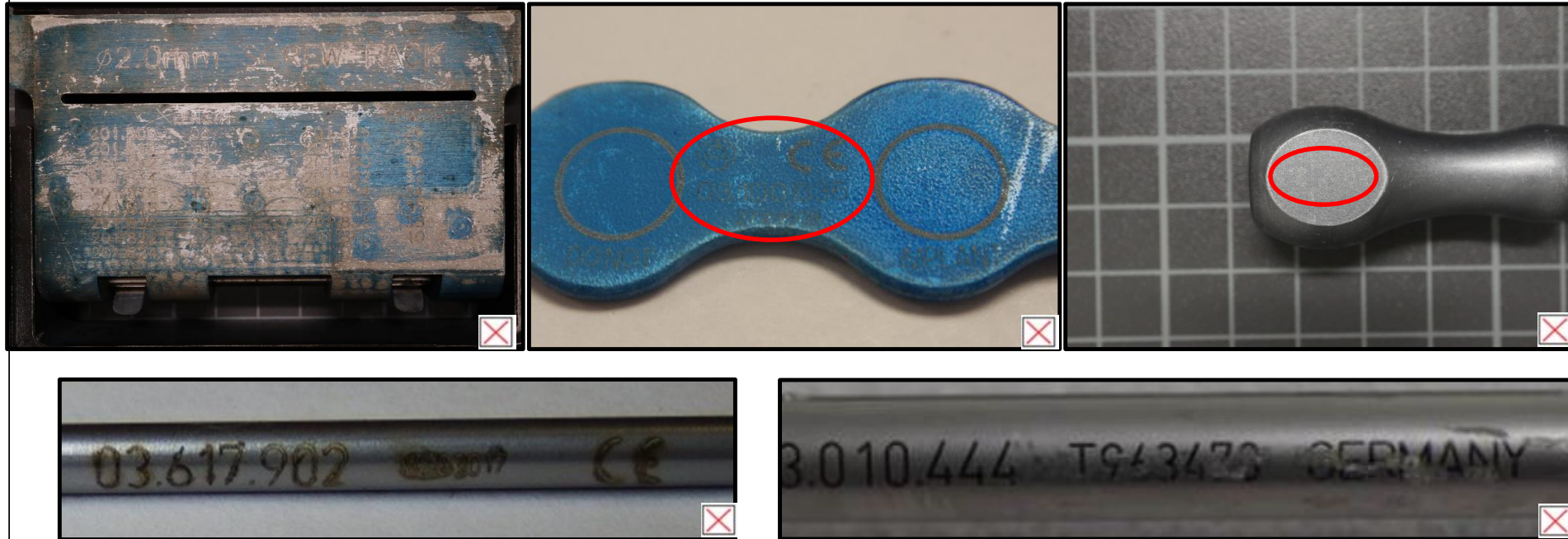
### 1.4 Flaking / Peeling



EOLi: Paint coating peels off (e.g., color-coded devices and graphic cases)

## 1. Generic EOLi (As Applicable)

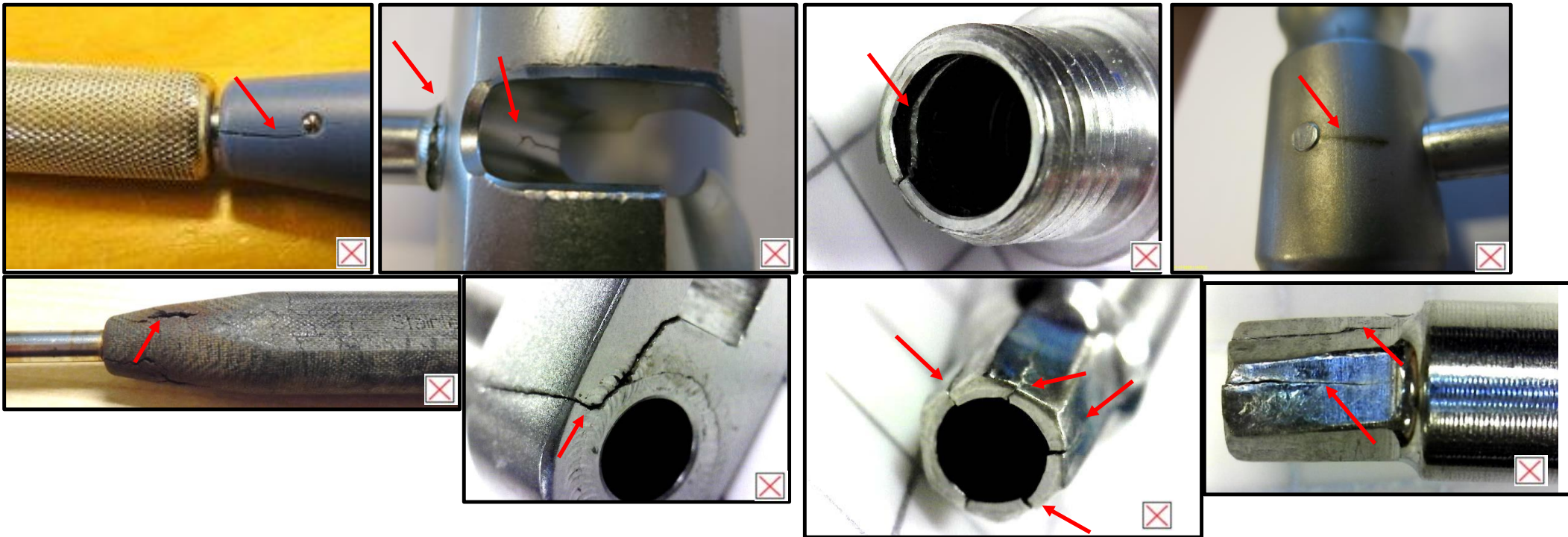
### 1.5 Devices with Unrecognizable Markings, Etches/Buffered off or Missing Unique Device Identifier Numbers



EOLi: Scratches, fading, Illegible markings

## 1. Generic EOLi (As Applicable)

### 1.6 Cracks



EOLi: Cracks at welded joints, cracks at assembly joints (e.g., Pins), cracks in cannulated devices (e.g., Threads, screwdriver tips) \_

## 1. Generic EOLi (As Applicable)

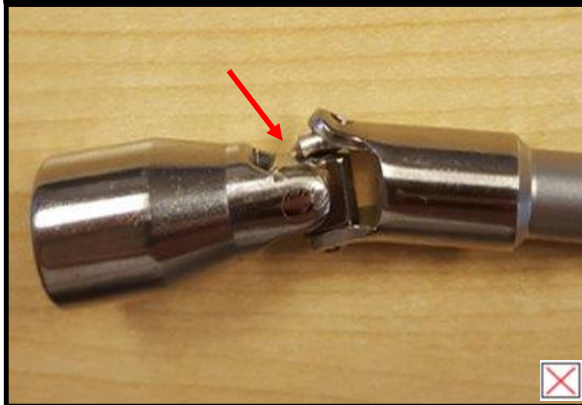
### 1.7 Broken (2+ Pieces)



EOLi: Broken at welded joints, driver/tip breakage, broken at assembly joints (e.g., Plastic handles)

## 1. Generic EOLi (As Applicable)

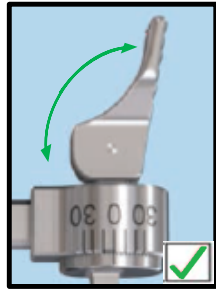
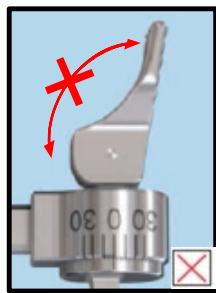
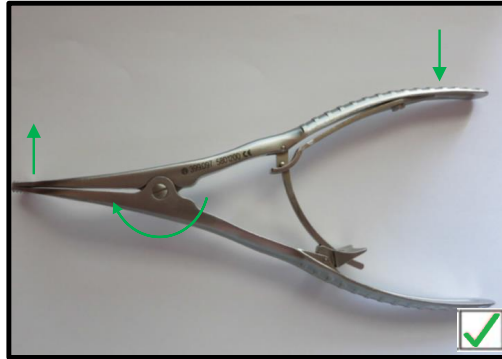
### 1.8 Bent / Deformed / Twisted



EOLi: Bent shaft or body, tips/drivers deformed or twisted

## 1. Generic EOLi (As Applicable)

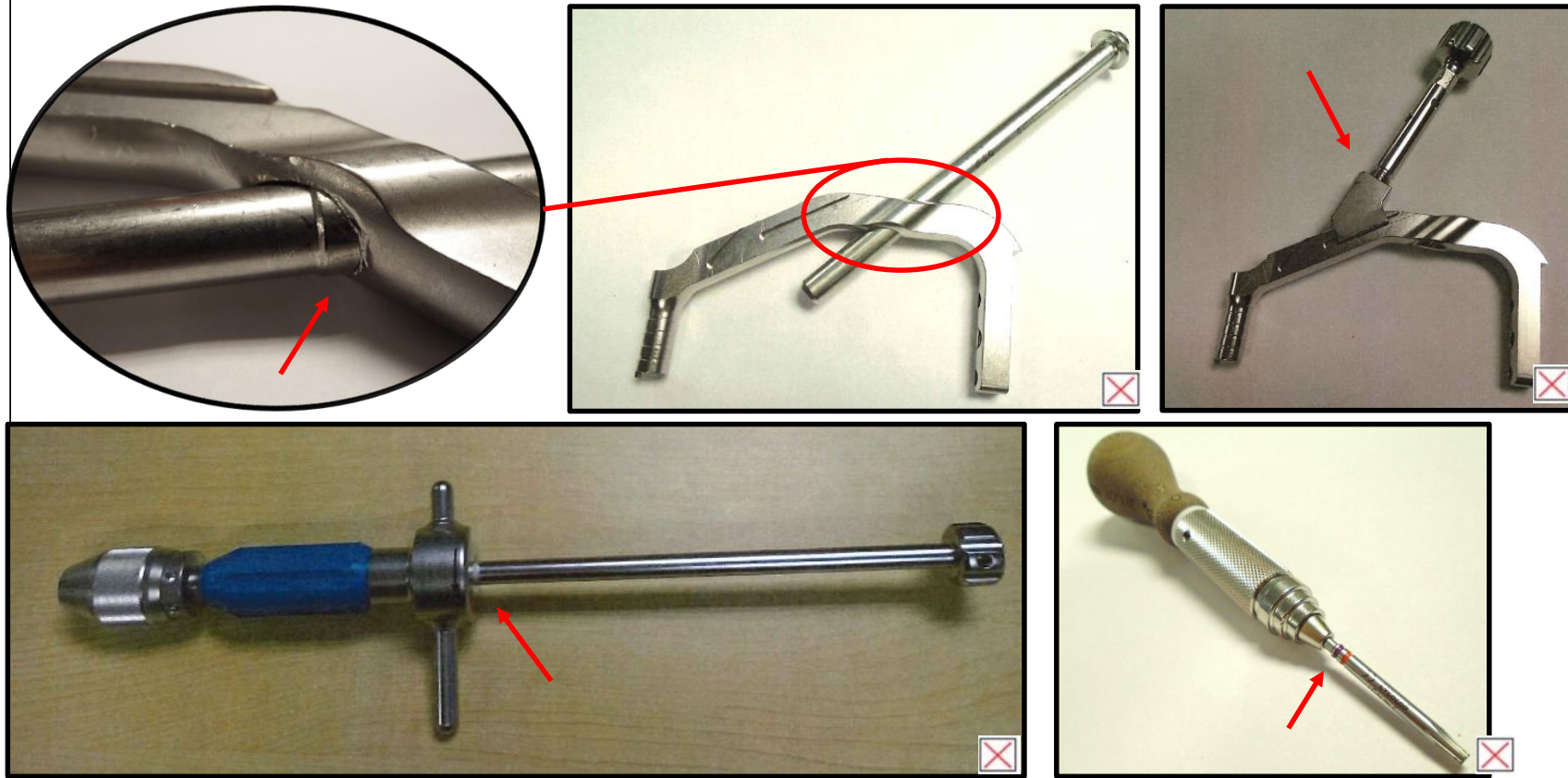
### 1.9 Seized (Multi-Component Device)



EOLi: Restricted range of motion. Will not open or close or function as required.

## 1. Generic EOLi (As Applicable)

### 1.10 Seized (2 or more Instruments)

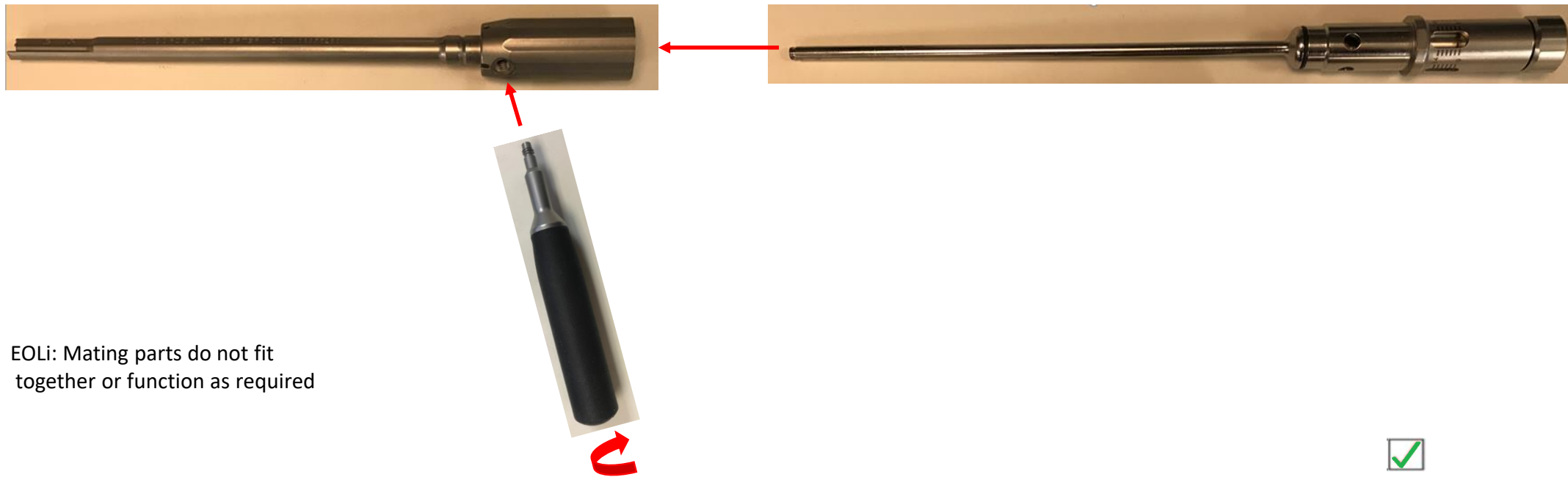


EOLi: Seized coupling, bent shaft or deformed holes, threads deformed or stripped

## 1. Generic EOLi (As Applicable)

### 1.11 Missing Components; Assembly / Disassembly

Disassembled devices should be reassembled prior to sterilization unless otherwise noted or the case is not configured.

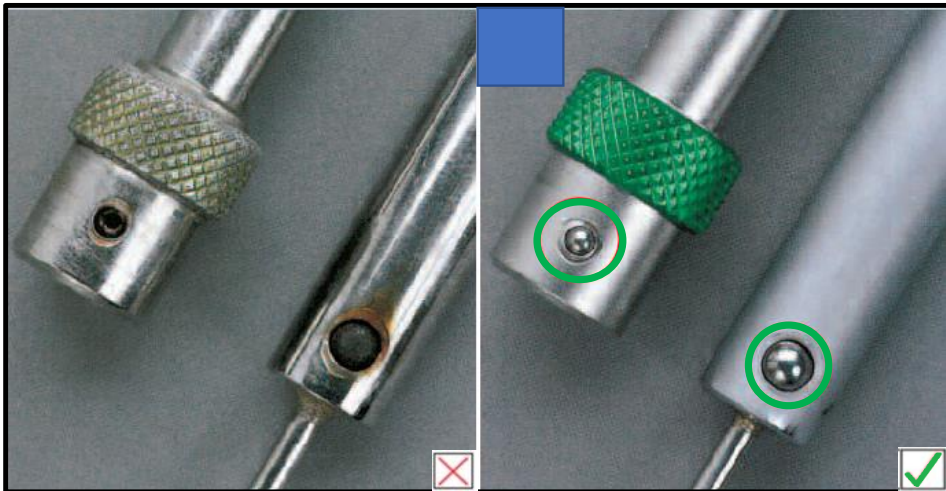


EOLi: Mating parts do not fit  
together or function as required



## 2. Feature EOLi (As Applicable)

### 2.1 Instruments with Spring-Loaded Ball Bearings

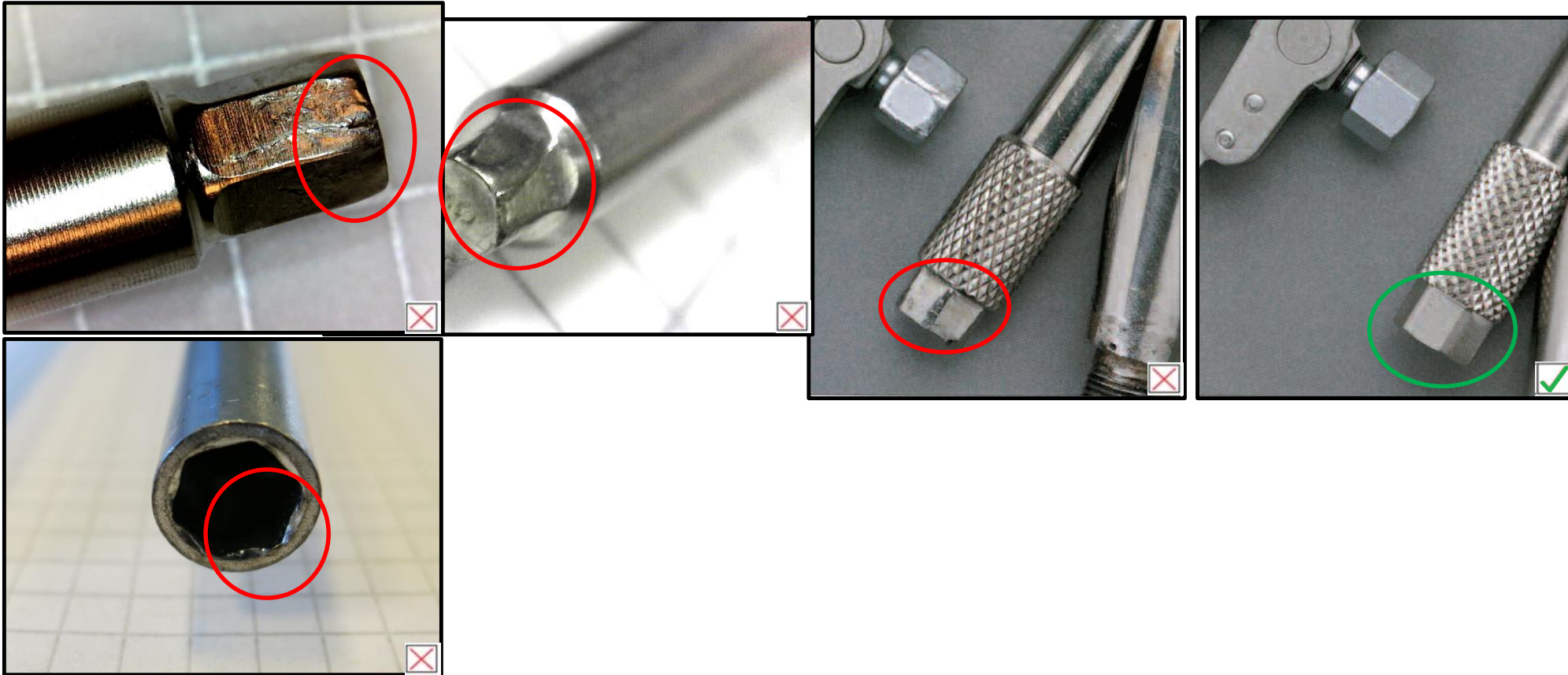


#### EOLi

- Ball-bearing jammed.
- Ball-bearing lost.

## 2. Feature EOLi (As Applicable)

### 2.2 Instruments with Hexagon Sockets or Bolt Heads

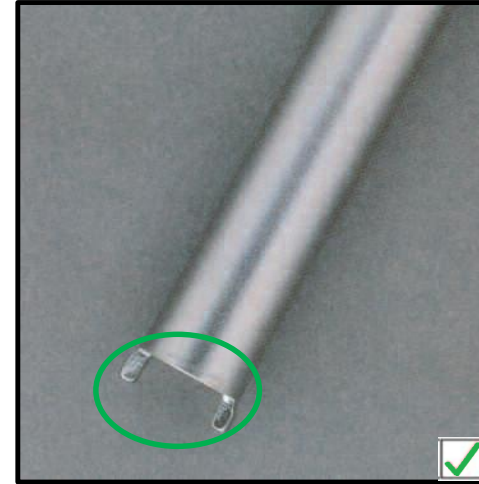
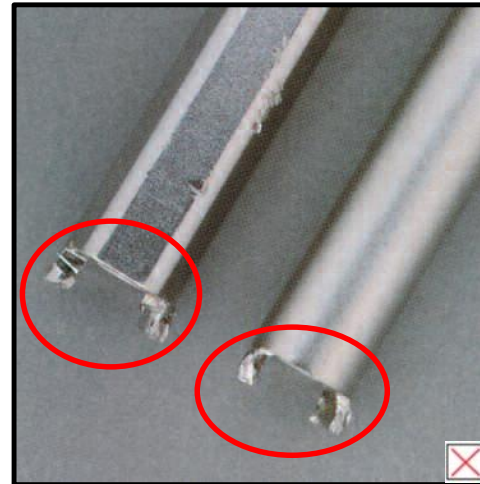
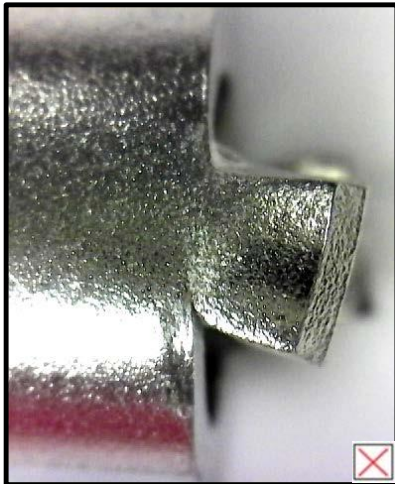


#### EOLi

- Hexagon bolt worn or damaged.
- Hexagon socket widened

## 2. Feature EOLi (As Applicable)

### 2.3 Instruments with Cams

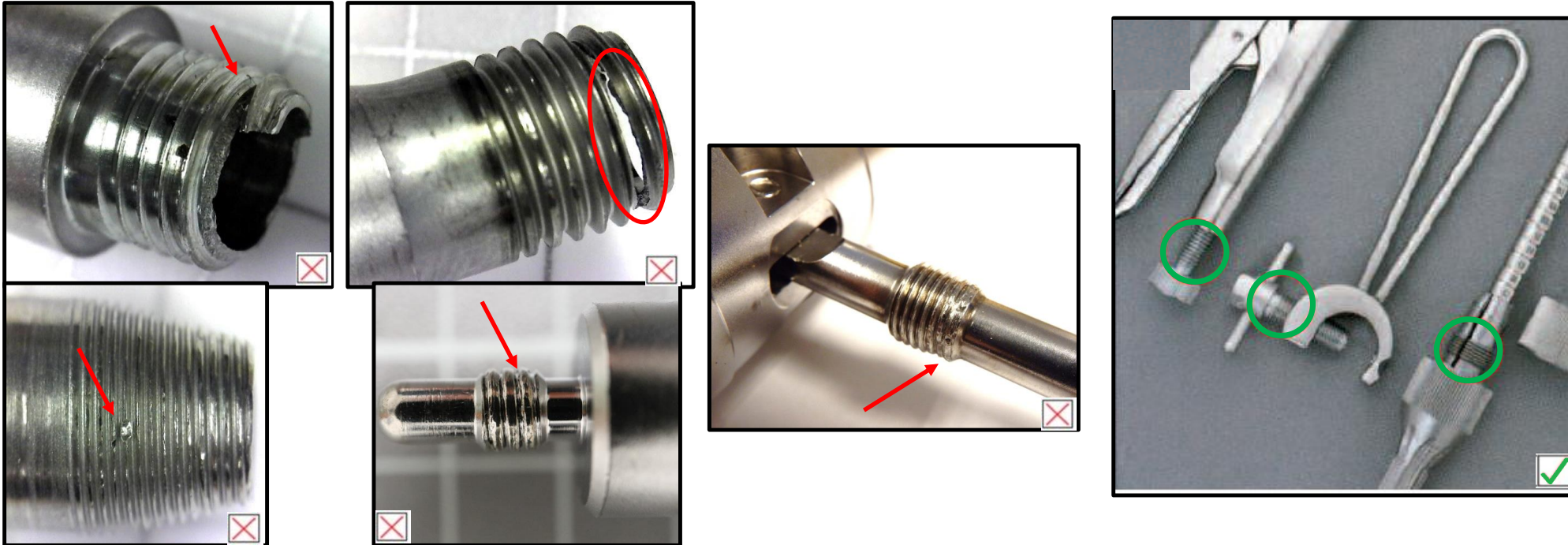


#### EOLi

- Cams bent, twisted or broken off.
- Misalignment between mating surfaces.

## 2. Feature EOLi (As Applicable)

### 2.4 Threaded Instruments

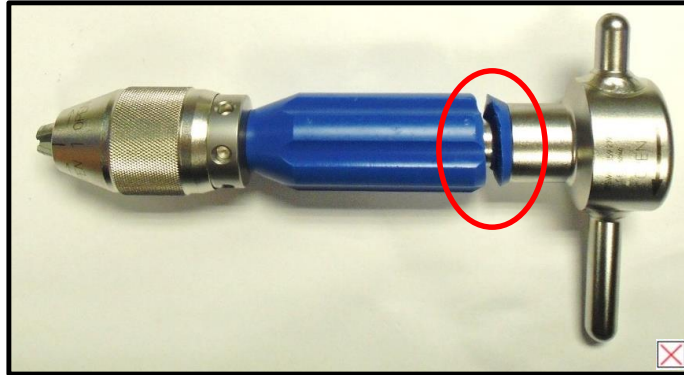


#### EOLi

- Difficulty in screwing or unscrewing.
- Threads damaged, peeling or stripped.

## 2. Feature EOLi (As Applicable)

### 2.5 Instruments with Plastic Handles or Silicone Coated Handles

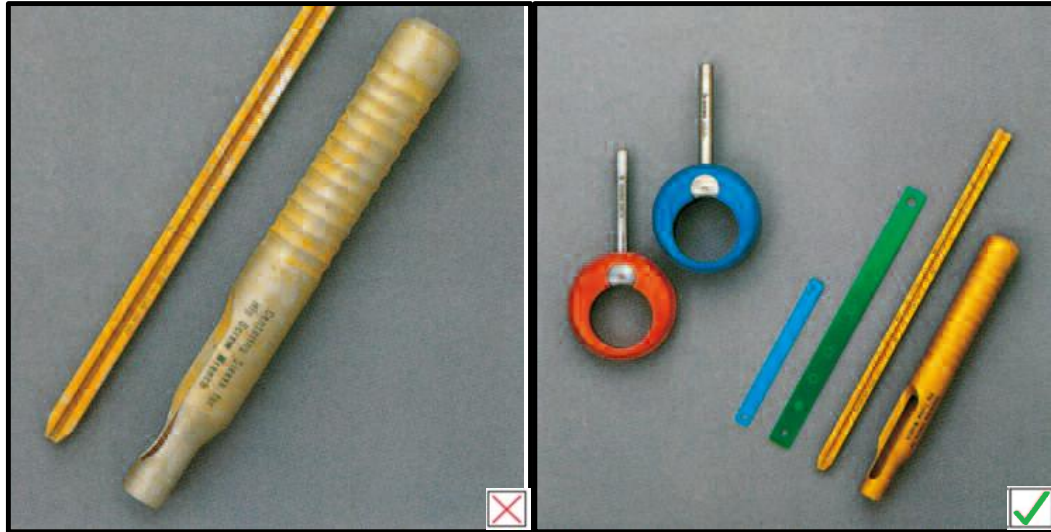


#### EOLi:

- Parts cracked or broken-off.
- Surface is brittle, soft or has a burnt appearance
- Discoloration or delamination of handle
- Silicone handle cut or peeling
- Shank is loose in the handle

## 2. Feature EOLi (As Applicable)

### 2.6 Color markers

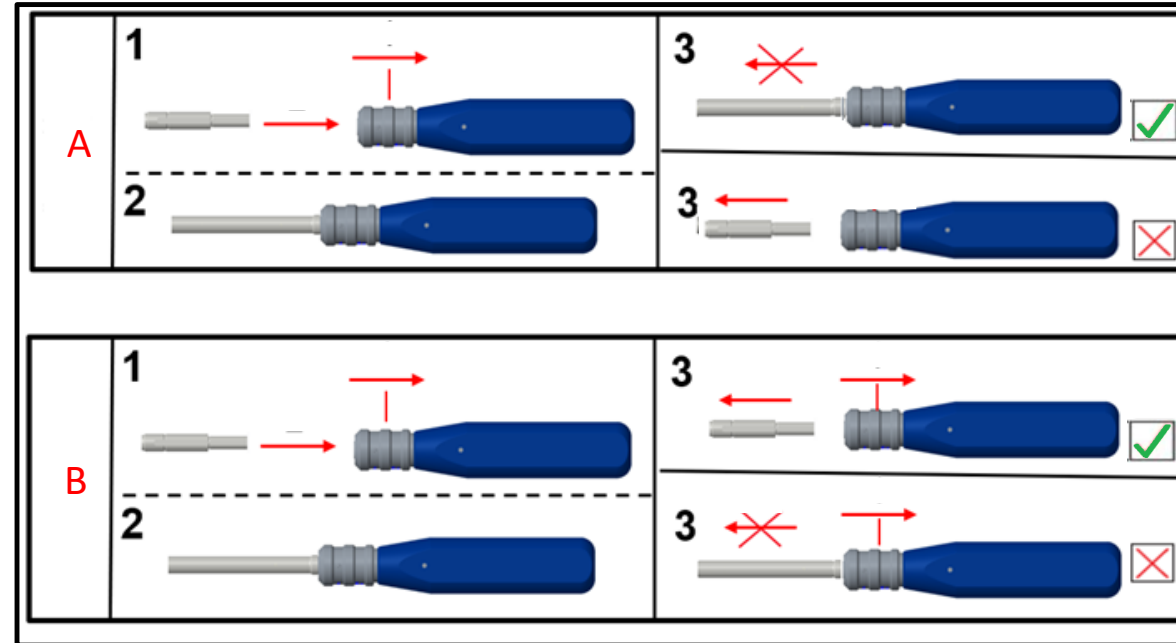
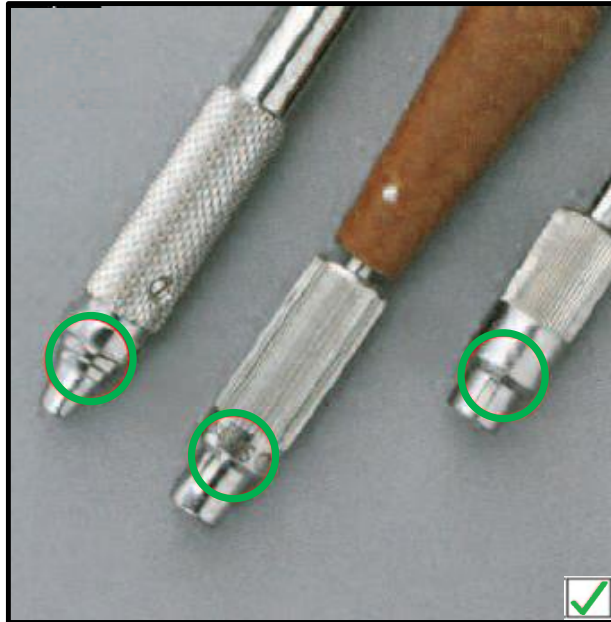


#### EOLi

- Anodized surface discolored or flaky.
- Color marker missing, faded or unrecognizable
- Surface scratched

## 2. Feature EOLi (As Applicable)

### 2.7 Instruments with Coupling Features (e.g., Quick Coupling)



#### Function Check

Check for proper functioning as follows:

A - Insert the shaft into the coupling (1) and engage the locking mechanism (2). Pull onto the shaft in the opposite direction and ensure that the assembly is secure (3). Replace the instrument if it does not retain the shaft.

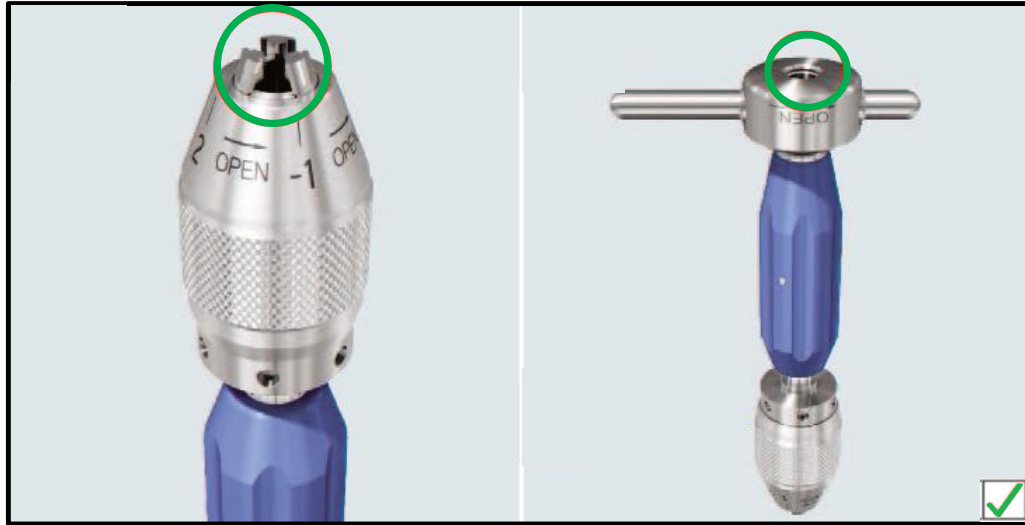
B - Insert the shaft into the coupling (1) and engage the locking mechanism (2) to ensure a secure assembly. Disengage the locking mechanism to pull the shaft out of the socket. Replace the instrument if it does not release the shaft.

#### EOLi

- Will not hold/retain (A)
- Will not release (B)
- Flexibility of coupling piece impaired or restricted.
- Instrument cannot be fitted

## 2. Feature EOLi (As Applicable)

### 2.8 Instruments with Chuck

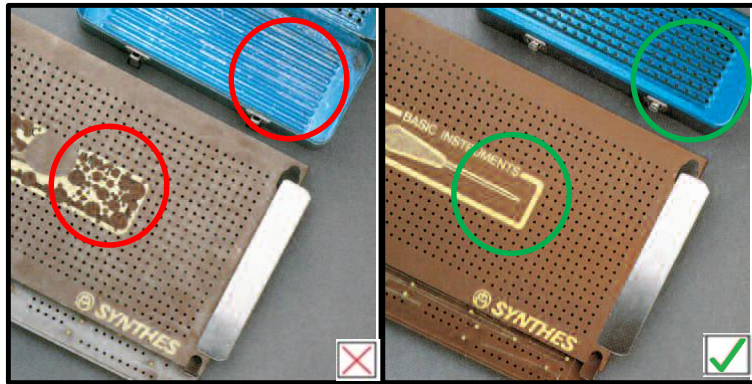


EOLi

- Chuck jamming.
- Device will not open or close.

### 3. Device Specific EOLi

#### 3.1 Cases (Anodized Aluminum Cases)

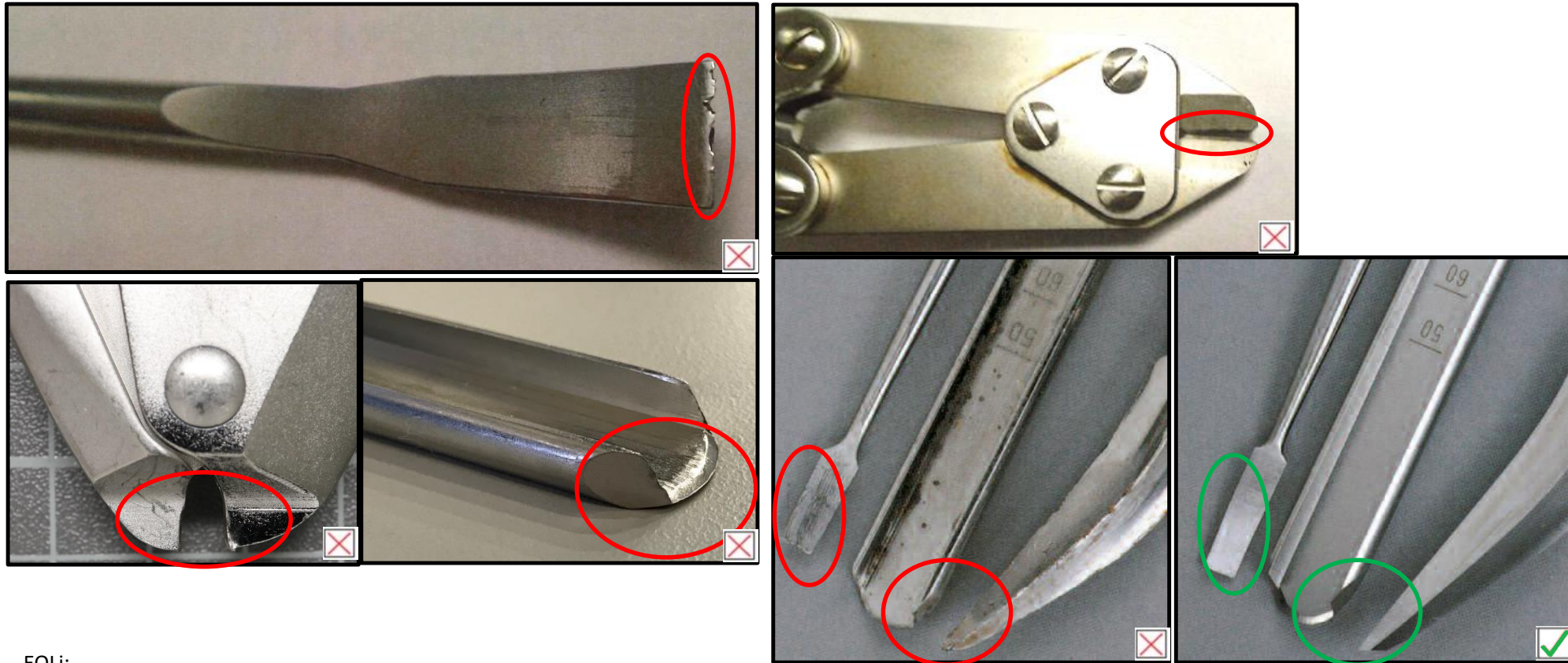


EOLi:

- Surfaces discolored, flaky or scratched

### 3. Device Specific EOLi

#### 3.2 Cutting and Bone Removal Instruments (Chisels, Gouges, Osteotome, Cutters, Countersinks)

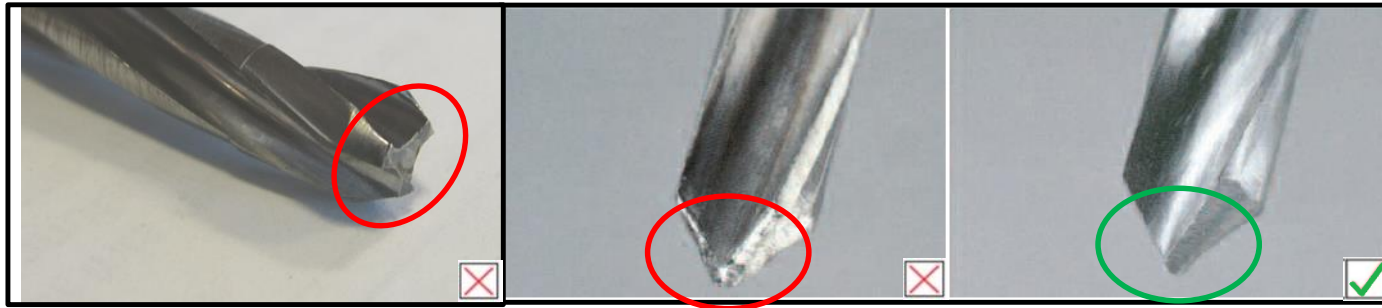


EOLi:

- Cutting edges damaged, chipped, or blunt

### 3. Device Specific EOLi

#### 3.3 Drill Bits

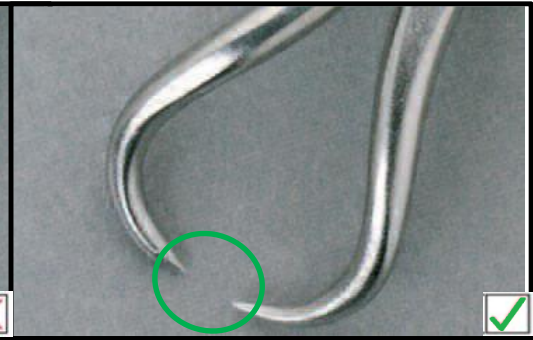
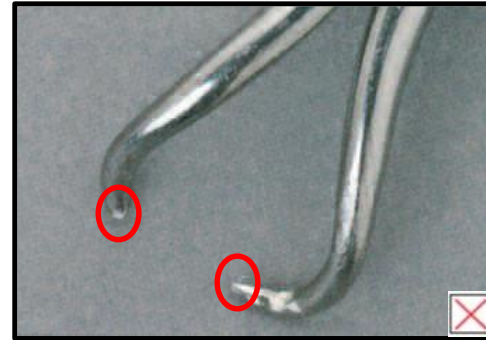


#### EOLi:

- Blunt, bent, broken, rounding of sharp edges
- Chipped, gouged, deep scratches
- Does not rotate concentrically

### 3. Device Specific EOLi

#### 3.4 Forceps, Pliers, and Holding Instruments

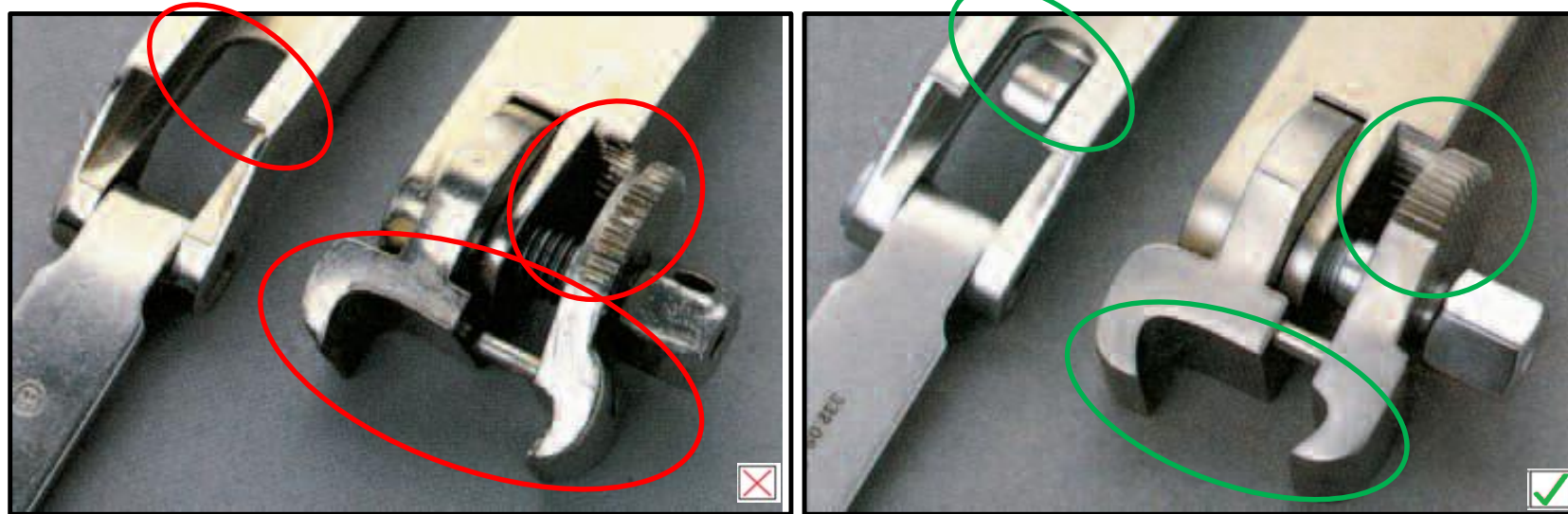


#### EOLi

- Jaws deformed or worn.
- Ratchet or adjuster spindle bent.
- Joint damaged or corroded.
- Forceps member bent.
- Does not hold, retain, loose

### 3. Device Specific EOLi

#### 3.5 Insertion and Extraction Instruments

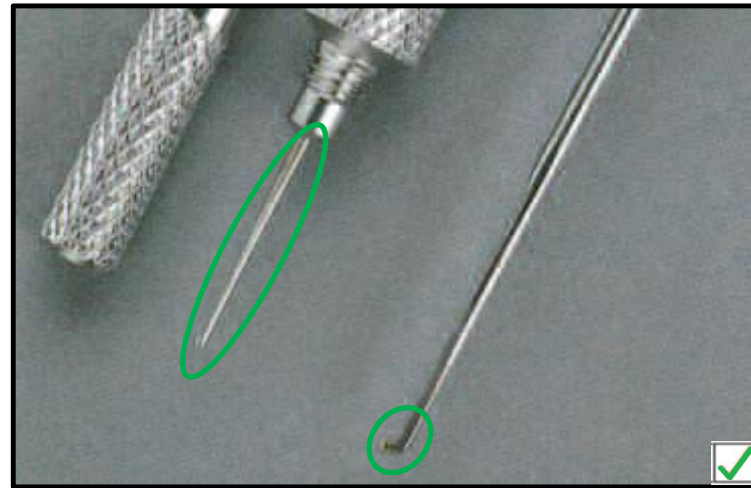
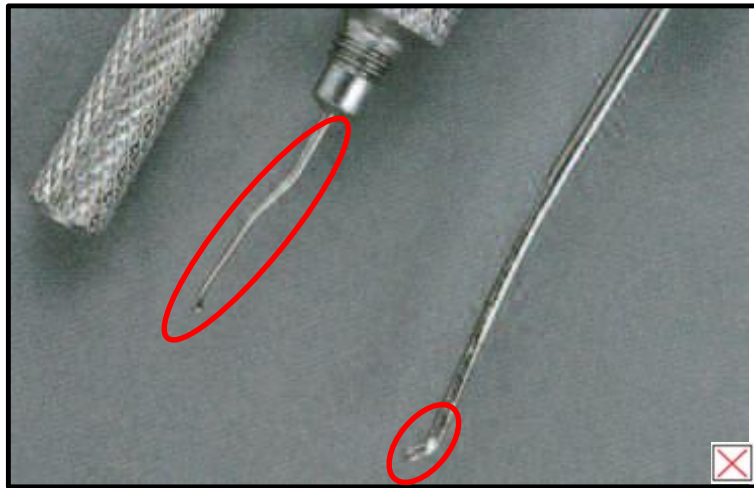


#### EOLi:

- Damaged teeth
- Instrument with jaws: jaw grippers worn or widened
- Instrument with flat spring: flat spring of guide plate bent or broken off
- Instrument with drive pin: drive pin bent
- Instrument with guide plate: plate is deformed

### 3. Device Specific EOLi

#### 3.6 Length Assessing Devices (Depth Gauges, Rulers/Estimators, Direct Measuring Devices)

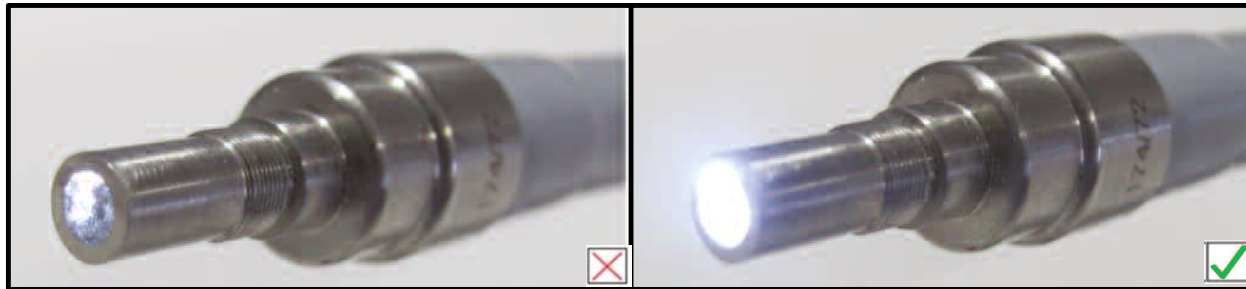


#### EOLi

- Measuring hook bent out of alignment or broken off
- Scaling no longer visible

### 3. Device Specific EOLi

#### 3.7 Light Cables

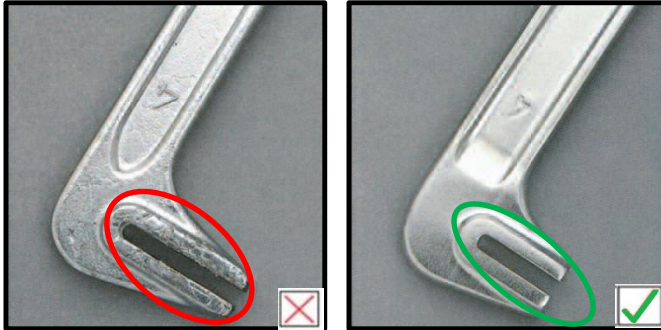


#### EOLi

- Poor Light Transmission

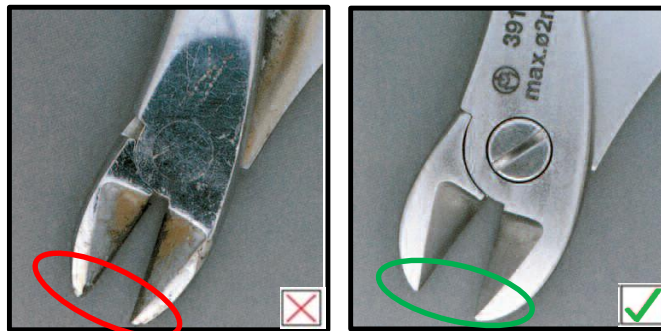
### 3. Device Specific EOLi

#### 3.8 Plate / Rod Bending and Cutting Instruments



EOLi Rod/Plate Benders:

- Jaws damaged or widened
- Leg or pin broken off

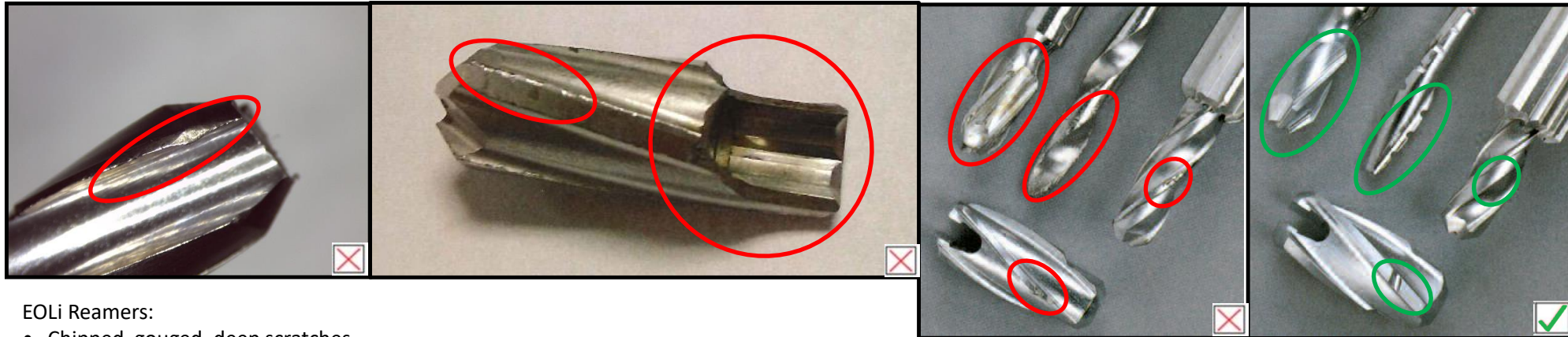


EOLi Cutting Instruments:

- Cutting edges damaged
- Jaw deformed

### 3. Device Specific EOLi

#### 3.9 Reamers and Awls



##### EOLi Reamers:

- Chipped, gouged, deep scratches.
- Circular scratching due to intended rotation of the device.
- Cutting edge damaged; cutting edge corners broken off.
- Rounding of sharp edges.

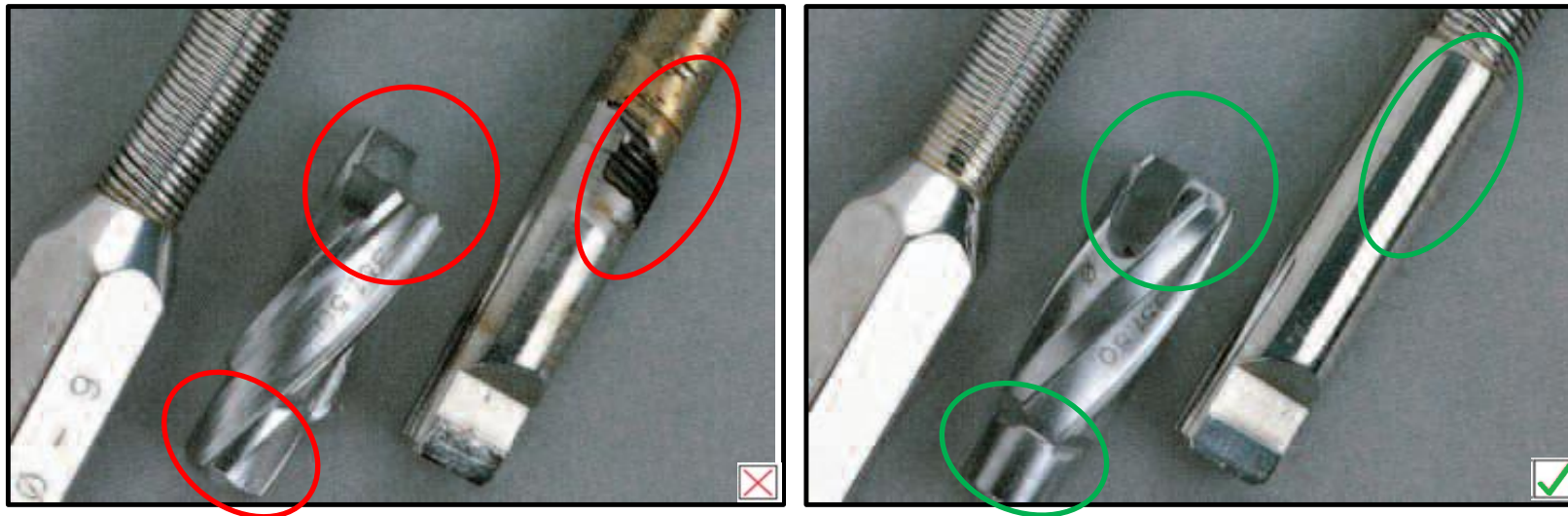
##### EOLi Awls:

- Awl Conical point damaged or blunt.



### 3. Device Specific EOLi

#### 3.10 Flexible shaft drives

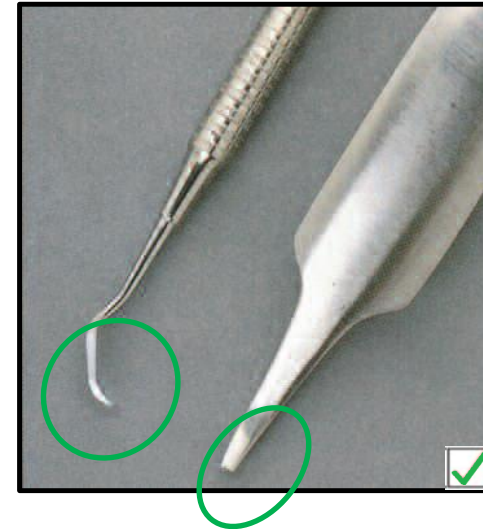
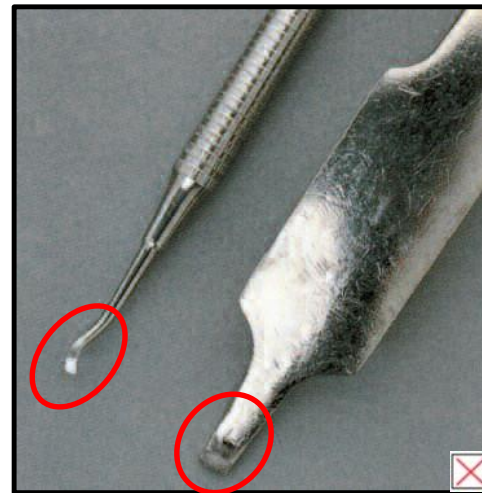
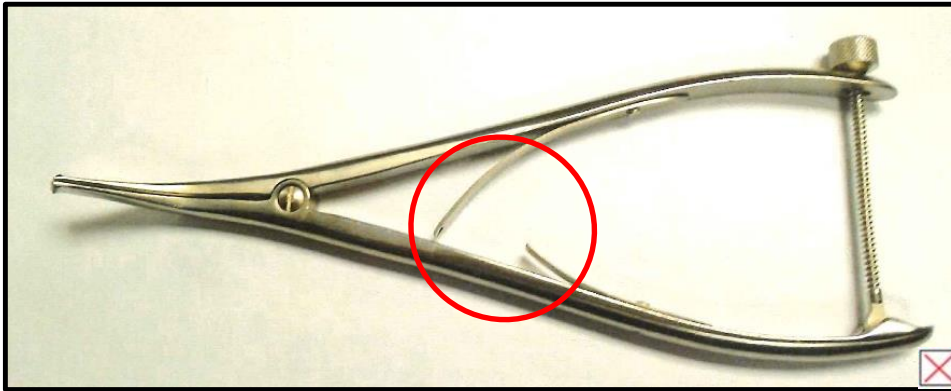


#### EOLi

- Helix or shaft irregular or kinked
- Connector worn at front or rear
- Soldered point damaged

### 3. Device Specific EOLi

#### 3.11 Retractors / Elevators (Bone Spreaders, Hooks, etc.)

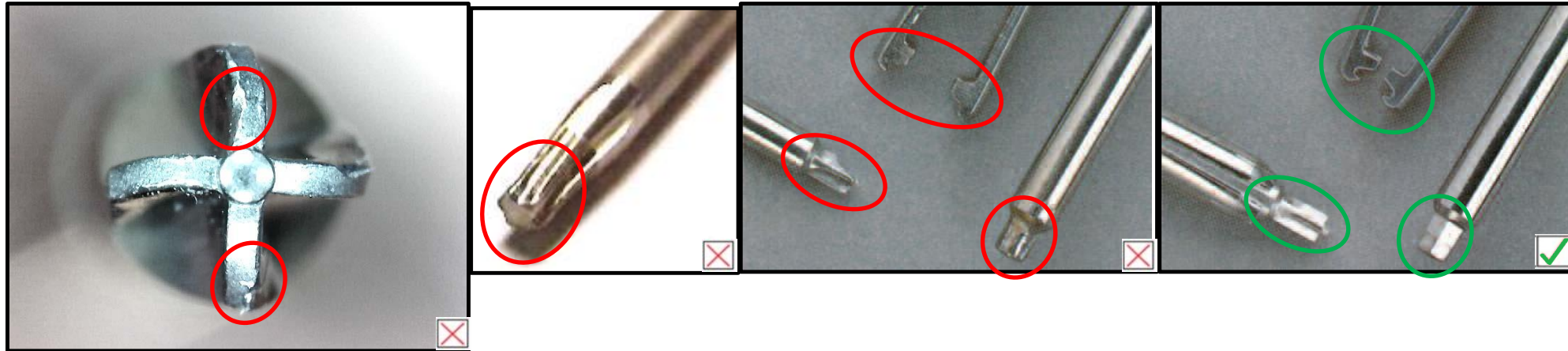


EOLi:

- Tips deformed or broken off
- Retractor bent or has sharp edges
- Spring on bone spreader damaged

### 3. Device Specific EOLi

#### 3.12 Screwdrivers

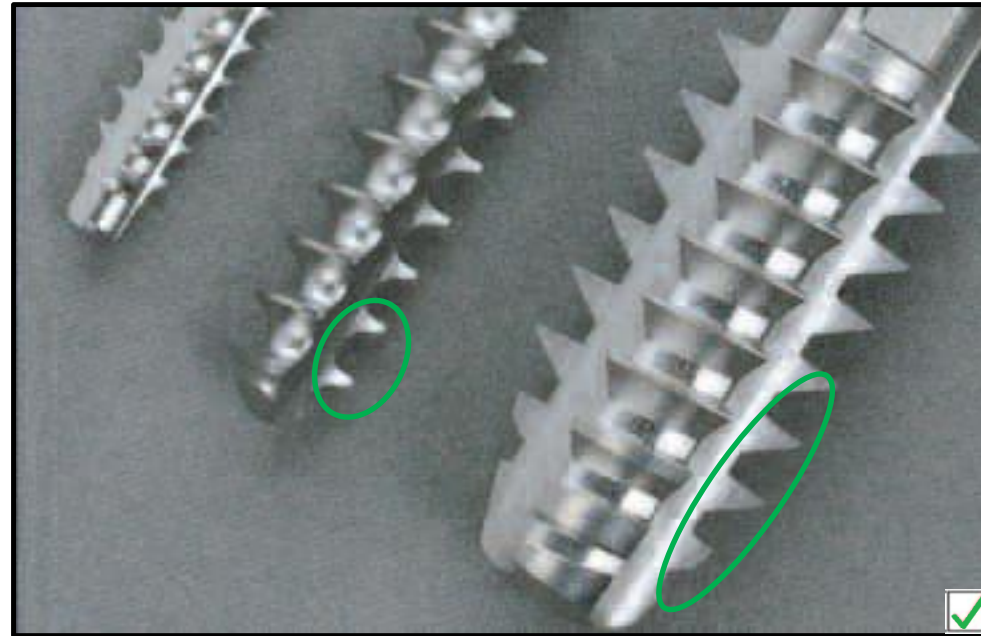
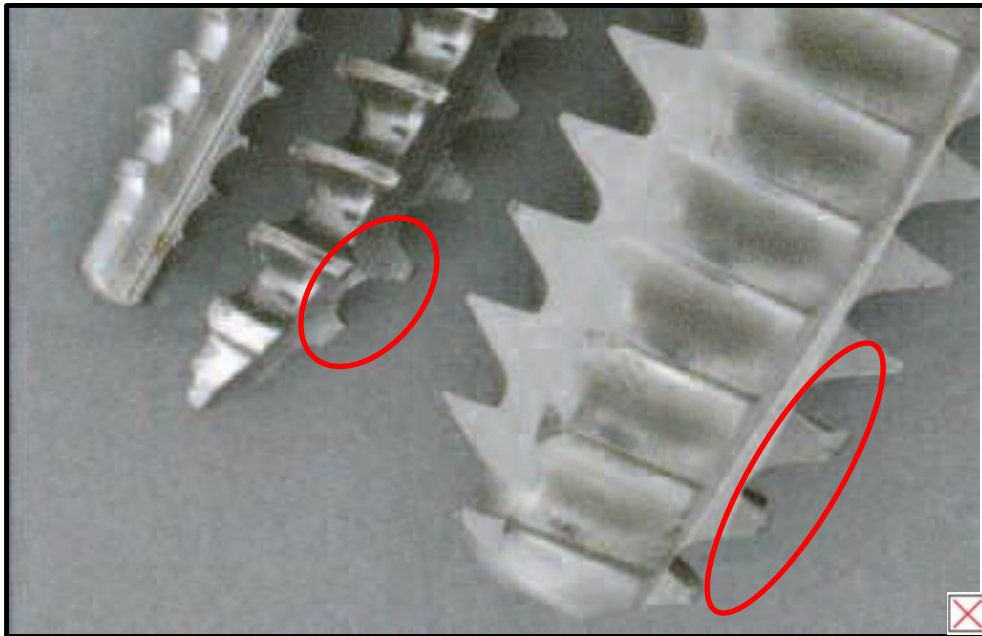


#### EOLi

- Hex drive/Torx drive / tip damaged
- Self-retaining tips worn, do not retain
- Spring action or holding force of the holding sleeve ineffective; end damaged

### 3. Device Specific EOLi

#### 3.13 Taps



#### EOLi

- Thread damaged. Teeth blunt or broken
- Tap bent or twisted
- Quick coupling end damaged

### 3. Device Specific EOLi

#### 3.14 Torque Limiting Devices

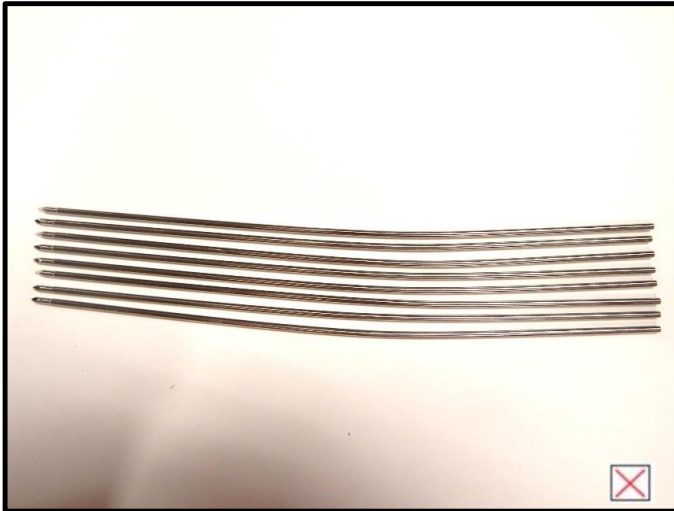


#### EOLi

- Torque mechanism out of torque tolerance
- Quick connect mechanism non-functioning
- Torque limiting devices require periodic inspection to ensure that the device is performing as intended. It is recommended that these devices be inspected every 12 months of use or 150 autoclave cycles. When either criterion is reached, or if any other concerns regarding functional performance of the torque limiting device occurs, return and replace the device to your DePuy Synthes Representative.

### 3. Device Specific EOLi

#### 3.15 Wires

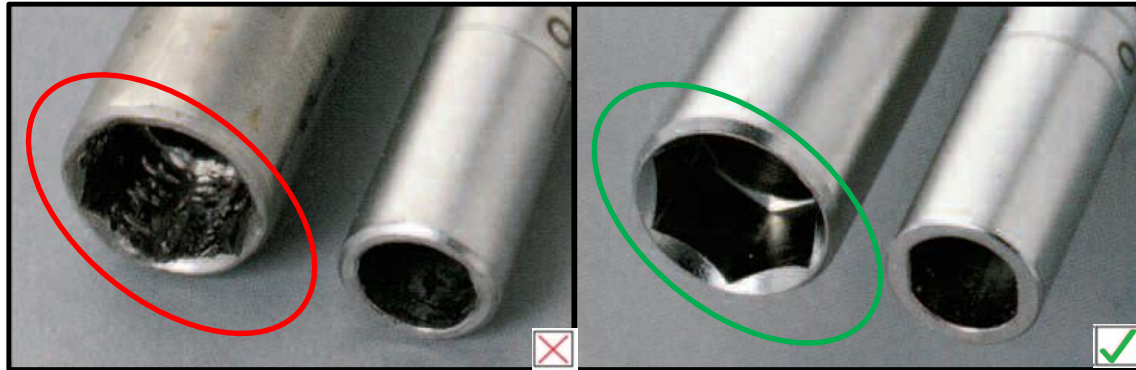


#### EOLi

- Instrument bent, kinked or distorted.
- Ends damaged

### 3. Device Specific EOLi

#### 3.16 Wrenches



#### EOLi

- Hexagon worn or widened.
- End of open-ended or box wrench damaged.
- The front end of the DHS/DCS wrench has been widened.

### 3. Device Specific EOLi

#### 3.17 Powered Instruments



#### EOLi

- See Technique Guide or IFU of specific powered instrument systems for End of Life Indicators