Functional Control Document

End of Life Indicators (EOLi) of Reusable Instruments

This instruction for use is not intended for distribution in the USA.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Important note for medical professionals and OR staff: This document does not include all the information necessary for selection and use of a device. Please read the instructions for use and the DePuy Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Purpose

The purpose of this document is to provide visual and functional information (i.e., End of Life Indicators) to the intended user to identify when the device should no longer be reused. In addition, this document provides recommended care information which may help to prevent or delay occurrence of the listed EOLi; however, devices that exhibit EOLi are not fit for use any longer. Consult your local Depuy Synthes 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. Evidence of damage and wear on a device may include but is not limited to the EOLi contained within this document. DePuy Synthes 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 within the recommended limits of its intended use (i.e., "Serviceable Device"), indicated by a green checkmark in the box in the lower right side of the picture, or outside its recommended limits of its intended use (i.e., "Defective Device"), indicated by a red 'X' in the box in the lower right side of the picture. When using this document, it is important to focus on the descriptive words for each feature as opposed to the accompanying picture only, as the picture is intended to document representative examples of types of wear and can therefore be applicable to multiple devices.

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Device Type

1. There are no unique EOLi for this device type – see Generic and Feature indicators, as applicable.
2. Torque Limiting devices require periodic maintenance and calibration to ensure that the device is performing as intended. Refer to device specific IFU to determine service frequency and other applicable information. If the audible click stops functioning or other concerns regarding functional performance, immediately return and replace the device to your DePuy Synthes representative.

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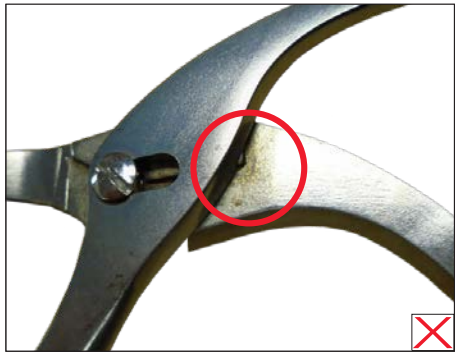
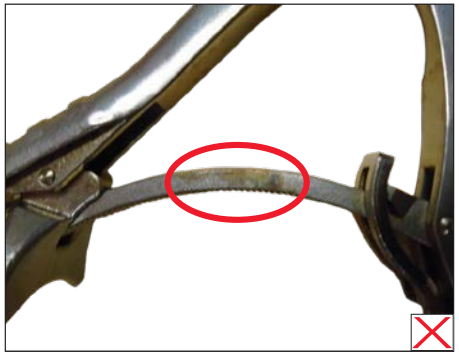
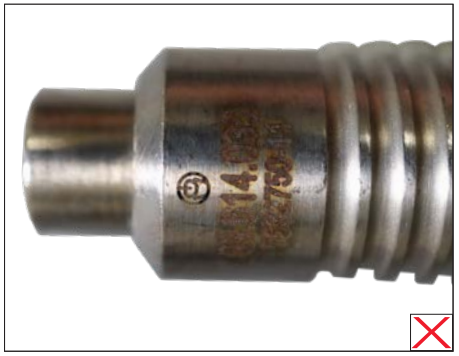
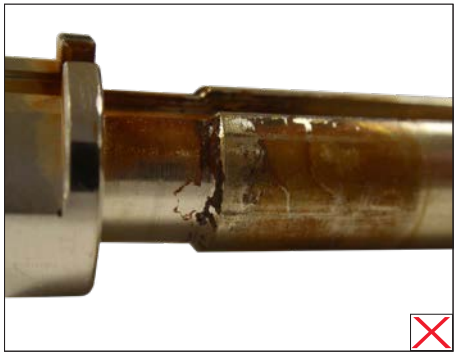
1.0 Generic EOLi (As Applicable)

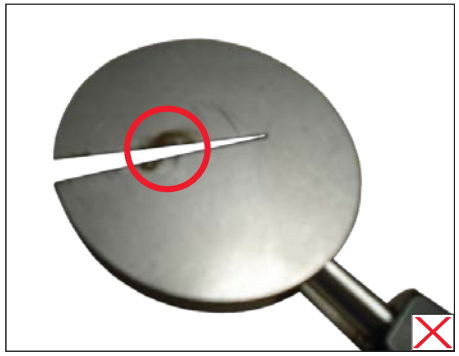
1.1 Corrosion, Rusting, Pitting

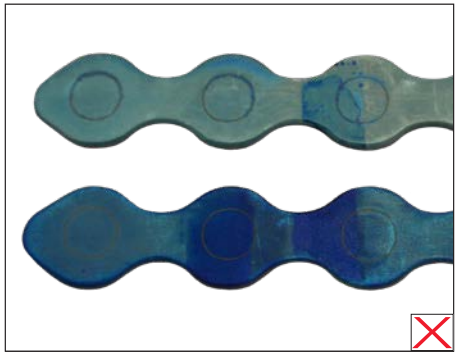




EOLi	Recommended Care
• Corrosion that effects traceability or functionality, corrosion on patient contact surfaces	• Follow "Important Information" for reprocessing instructions of reusable devices

1.2 Discoloration/Fading





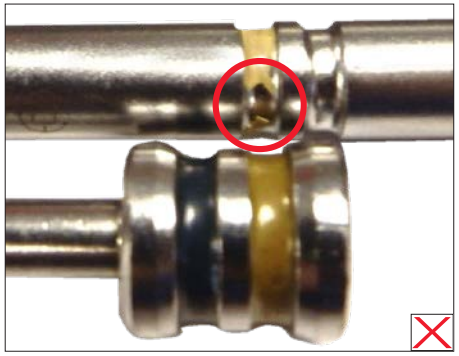
EOLi	Recommended Care
• Discoloration on plastic, anodized (i.e., color coded) aluminum and titanium devices	• Follow "Important Information" for reprocessing instructions of reusable devices

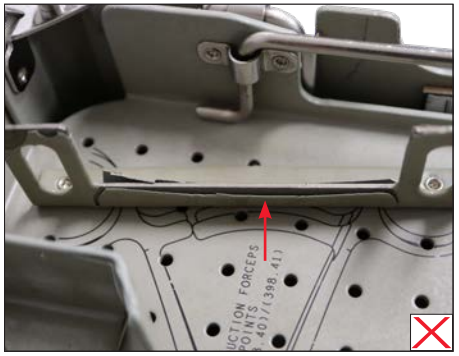
1.3 Excessive Scratches, Dents

EOLi

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

1.4 Flaking/Peeling

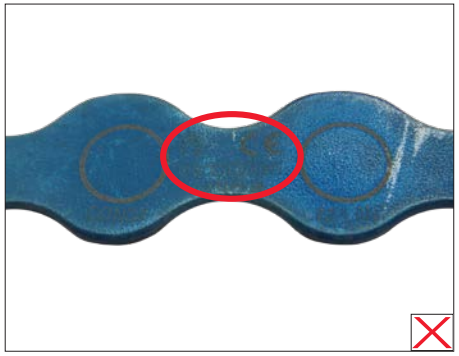




EOLi

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

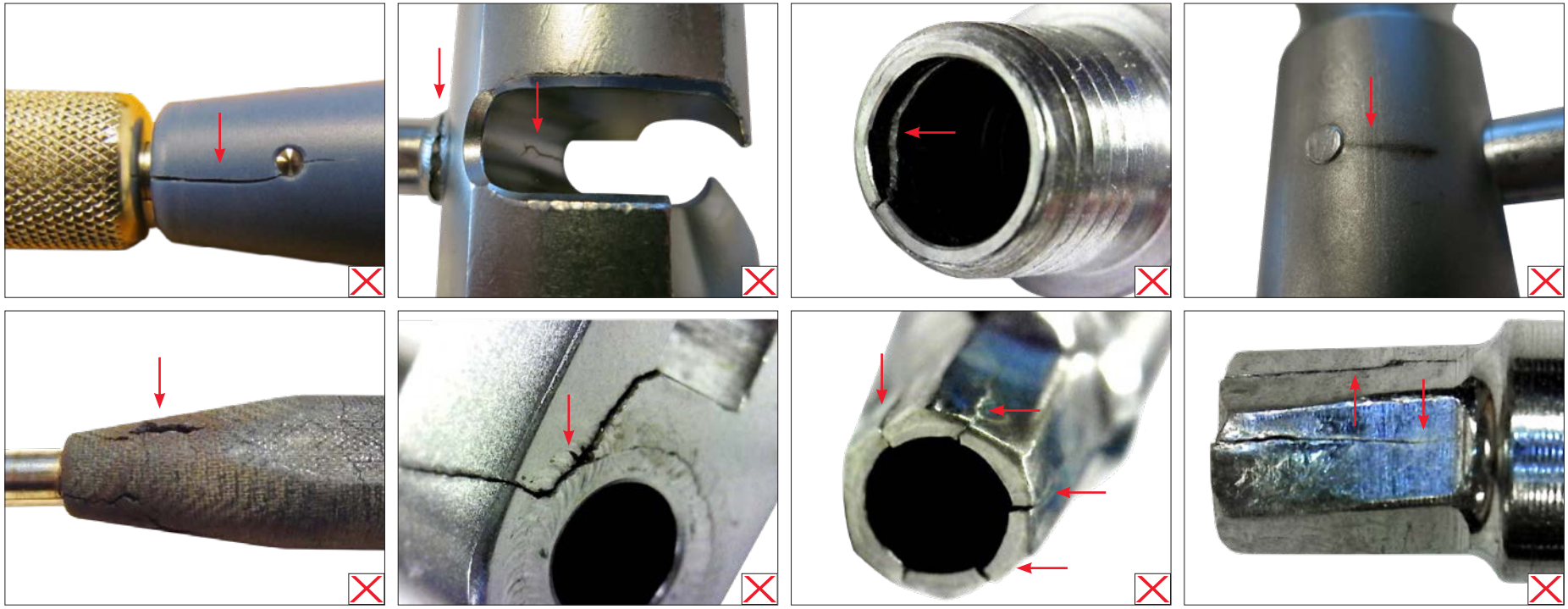
1.5 Devices With Unrecognizable Markings, Etches/Buffed off or Missing Part Numbers

EOLi

- Scratches, fading, anodization

1.6 Cracks



EOLi

- Cracks at welded joints, cracks at assembly joints (e.g., pins), cracks in cannulated devices (e.g., threads, screwdriver tips)

1.7 Broken (2+ Pieces)

EOLi

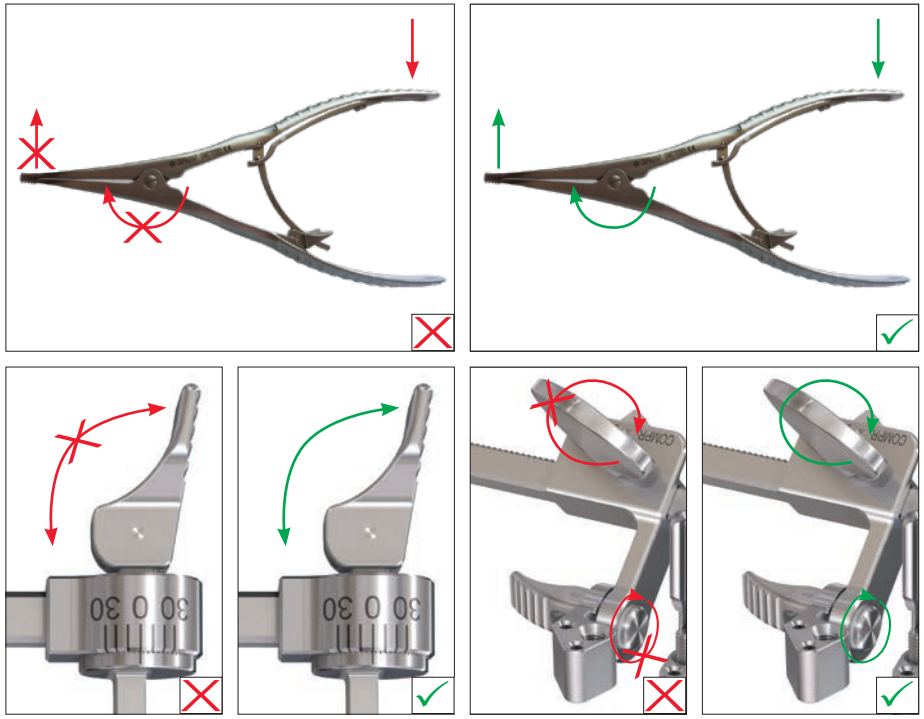
- Broken at welded joints, driver/tip breakage, broken at assembly joints (e.g., plastic handles)

1.8 Bent/Deformed/Twisted

EOLi

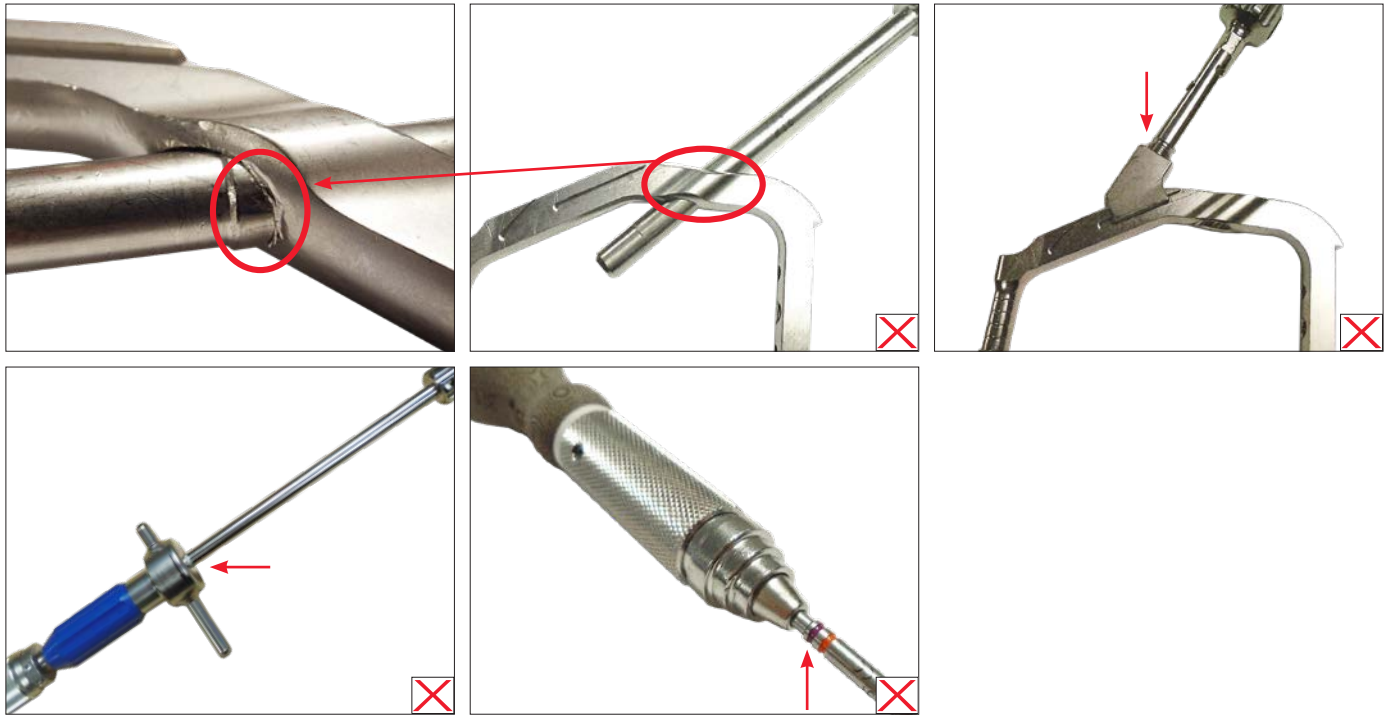
- Bent shaft or body, tips/drivers deformed or twisted

1.9 Seized (Multi-Component Device)



EOLi	Recommended Care
• Restricted range of motion • Will not open or close	• Clean and lubricate hinges and joints

1.10 Seized (2+ Instruments)



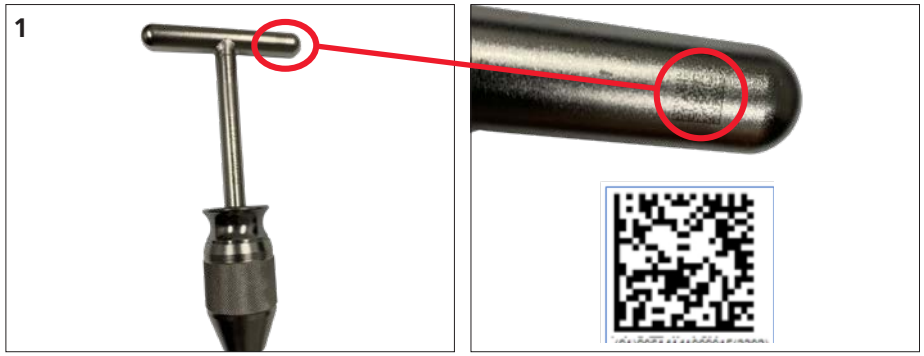
EOLi

- Seized coupling, bent shaft or deformed holes, threads deformed or stripped

1.11 Missing Components; Assembly/Disassembly

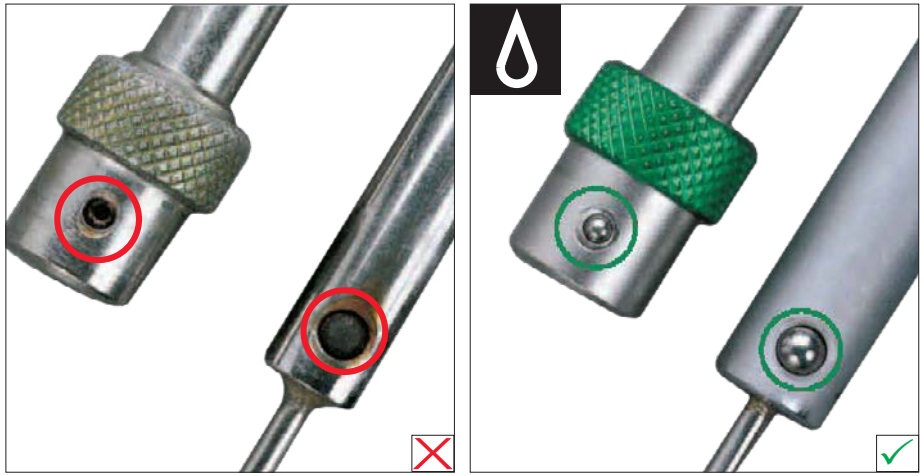
Disassembled devices should be reassembled prior to sterilization unless otherwise noted or the case is not configured. Further detailed instrument dismantling instructions are available from your local sales representative or for download at http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance.

1.12 UDI Marking Unable to be Read



EOLi	Recommended Care
• Scanner does not read/recognize the UDI marking	• A Direct Part Marking (DPM) scanner is required. Prior to replacing the device, try scanning another device, clean the part surfaces, adjust the scan distance/angle, or adjust lighting distance/angle

2.1 Instruments With Spring-Loaded Ball Bearings



EOLi	Recommended Care
• Ball-bearing jammed	• Lubricate as needed
• Ball-bearing lost	

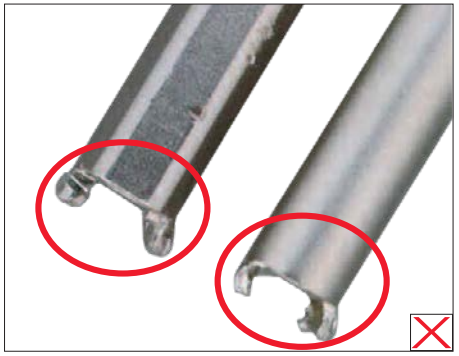
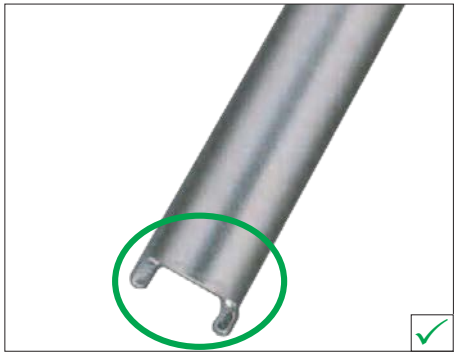
2.2 Instruments With Hexagon Sockets or Bolt Heads

EOLi

- Hexagon bolt head worn or damaged
- Hexagon socket widened

2.3 Instruments With Cams




EOLi

- Cams bent, twisted or broken off
- Misalignment between mating features

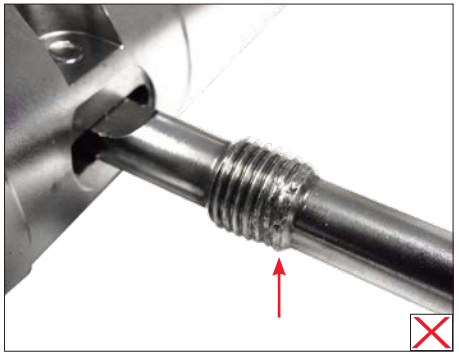
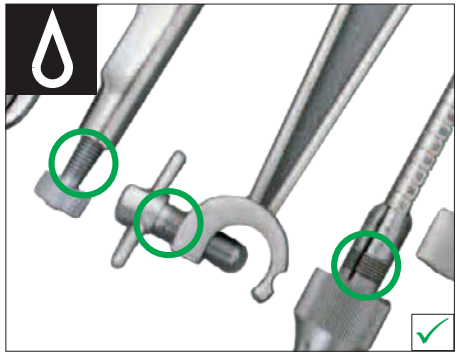
2.4 Instruments With Shanks or Sleeves

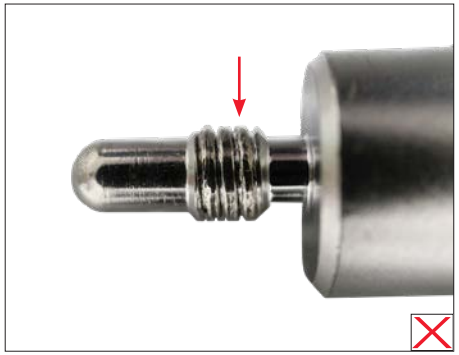
EOLi

- Shank or sleeve bent or blocked

2.5 Threaded Instruments

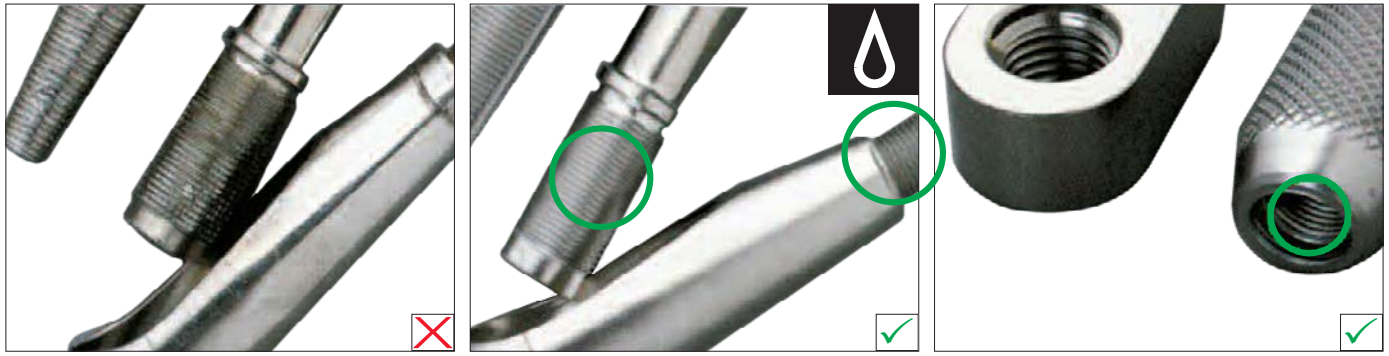




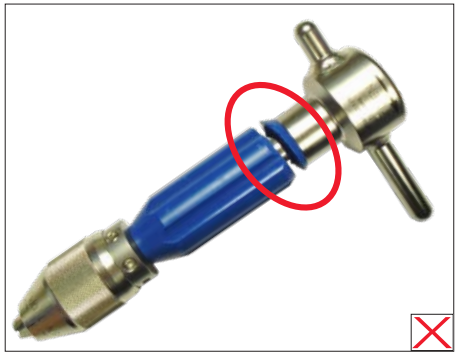
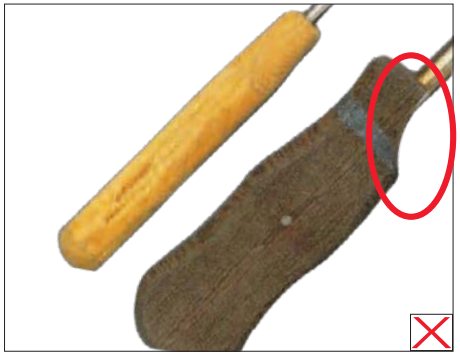
EOLi	Recommended Care
• Difficulty in screwing in and unscrewing	• Remove any incrustations with a suitable detergent. Then carefully clean instrument and apply lubrication regularly
• Threads damaged/peeling	• Clean the threads carefully. Always fully unscrew the screws • Do not use excessive force

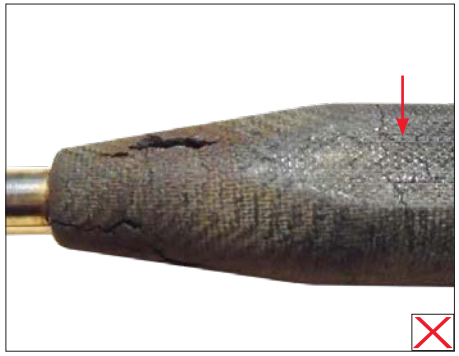
2.6 Instruments With Interlocking Threads



EOLi	Recommended Care
• Threads damaged, stripped or destroyed (e.g., hammer blows)	• Ensure that the instruments are securely screwed together before use • Do not subject the instruments to excessive force • Do not grip threads with pliers
• Difficulty in screwing in and unscrewing	• Dissolve any incrustations with a suitable substance. Then carefully clean the instrument and apply lubrication to threads • Do not grip threads with pliers

2.7 Instruments With Plastic Handles

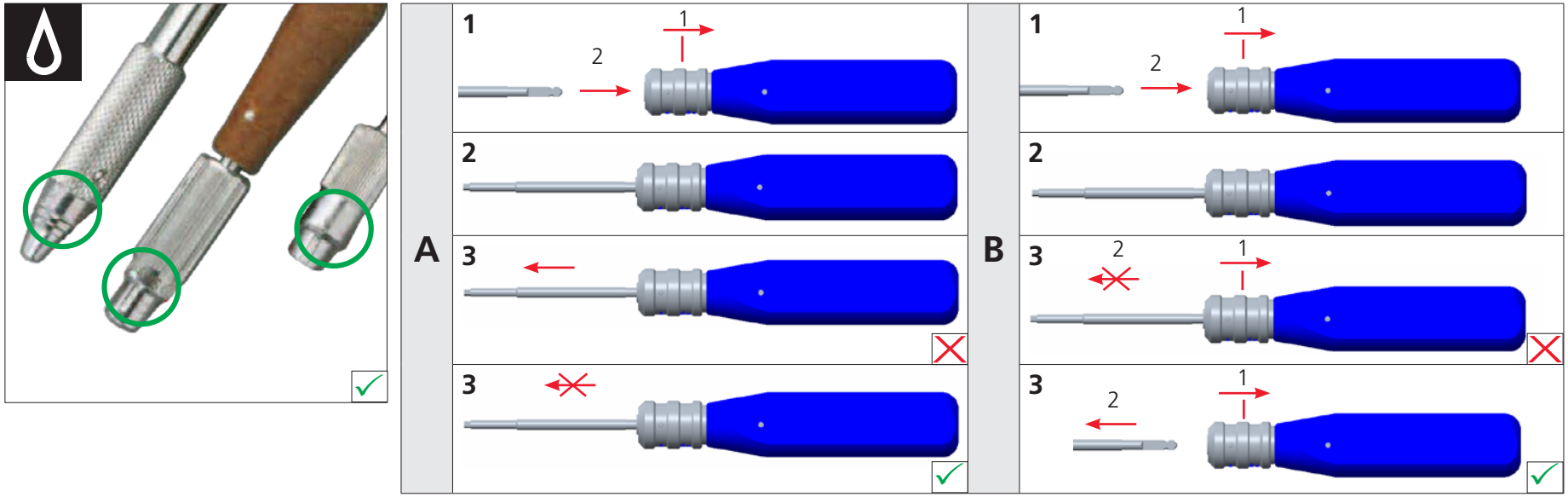



EOLi	Recommended Care
• Parts cracked or broken off • Surface is brittle, soft or has a burnt appearance • Discoloration or delamination of handle	• Do not sterilize instrument in hot air • Avoid using excessively strong disinfectants or detergents
• Shank is loose in the handle	• Do not drop instrument

2.8 Anodized Aluminum Items

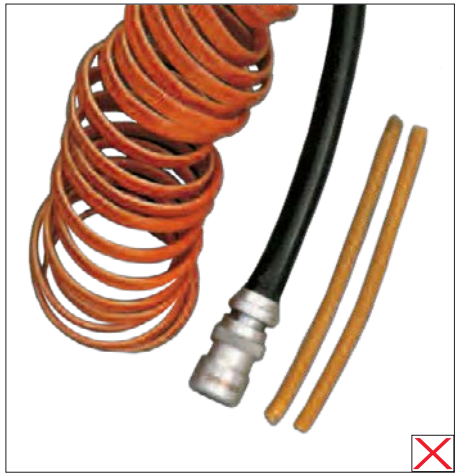
EOLi	Recommended Care
• Anodized surface discolored or flaky	• Do not use disinfectants or detergents containing iodine and metal salts such as mercury, or strongly alkaline solutions
• Surface scratched	• Never use wire brushed or steel wool for cleaning

2.9 Instruments With Coupling Features (e.g., Quick Coupling)



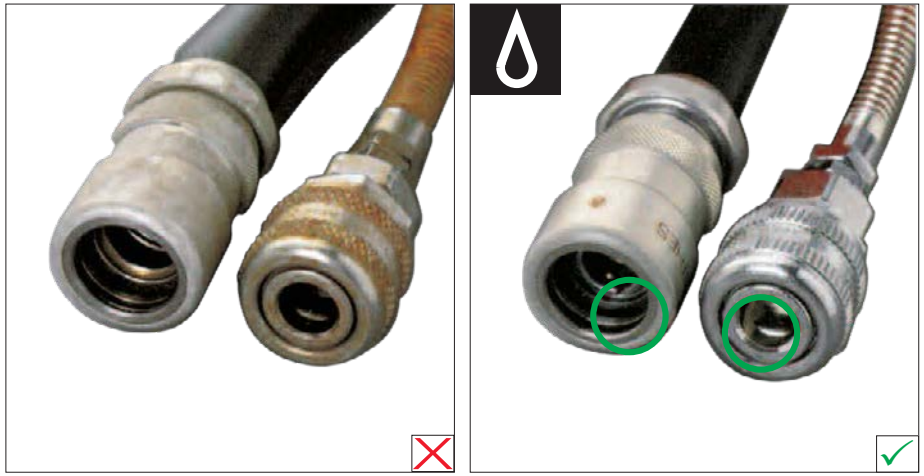
EOLi	Function Check	Recommended Care
• Will not hold/retain (A) • Will not release (B)	Check for proper functioning as follows: A. Insert the shaft into the coupling (1) and engage the locking mechanism (2). Pull onto the shaft in the opposite direction and ensure that the assembly is secure (3). Replace 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.	• Lubricate the coupling joints as needed
• Flexibility of coupling piece impaired or restricted • Instrument cannot be fitted		

2.10 Plastic Items and Rubber Hoses



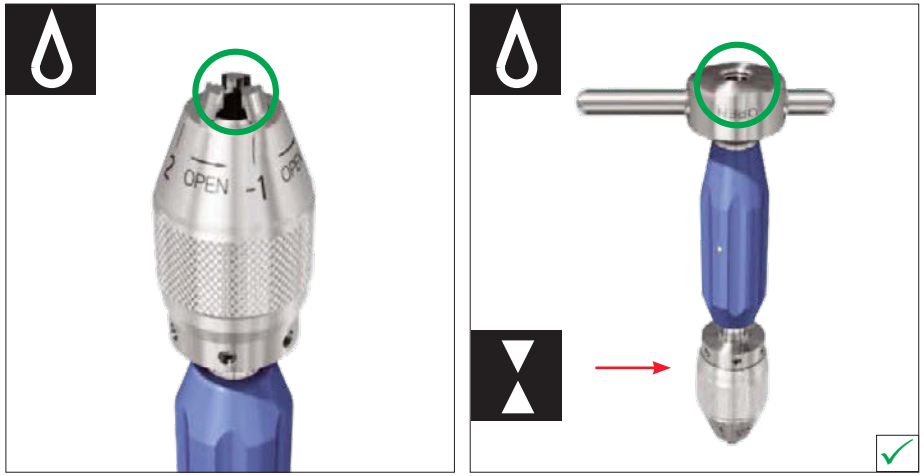
EOLi	Recommended Care
• Helical or rubber hose deformed, split, soft or brittle due to overheating	• Allow hose to cool down before use • Never lay metallic items on top of hoses during sterilization • Do not attach couplings together and never sterilize in hot air • When disconnecting a hose, never pull on the hose itself but on the connector • Never use a double air hose when blowing an air and oil mixture through an air drill
• Medullary tube discolored, hard or brittle	• Check the flexibility of a plastic medullary tube regularly. Do not sterilize in hot air

2.11 Compressed Air Hose Couplings



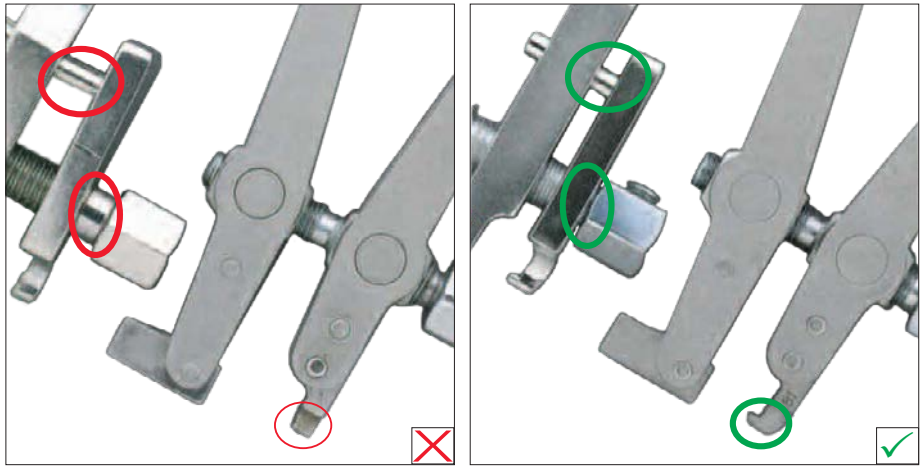
EOLi	Recommended Care
• Sleeves difficult to move	• Clean all couplings thoroughly while moving parts
• Retention pins jammed or air valve blocked	• Apply lubrication

2.12 Instruments With Chuck



EOLi	Recommended Care
• Chuck jamming	• Lubricate the chuck and the cannulation at the back of the instrument previous to sterilization with autoclavable Synthes oil
• Device will not open or close	• Fully open and close the chuck without implants and check its frictionless function before and after each use

3.1 Tension Devices

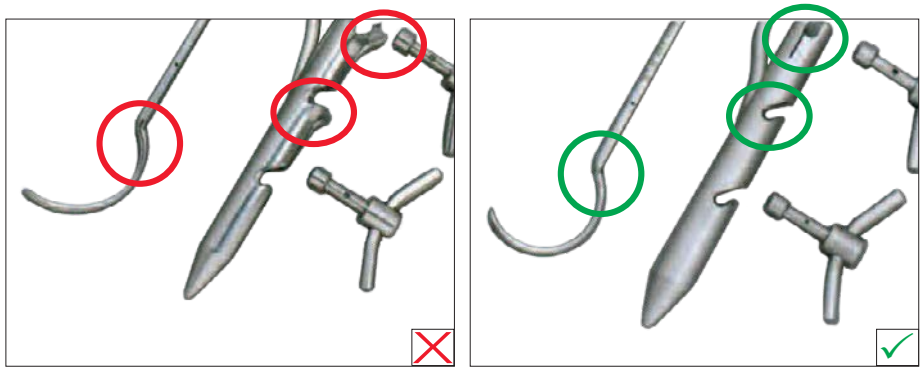


EOLi

- Distraction or tensioning hooks are bent or broken
- Guide pin bent
- Hexagonal nut damaged

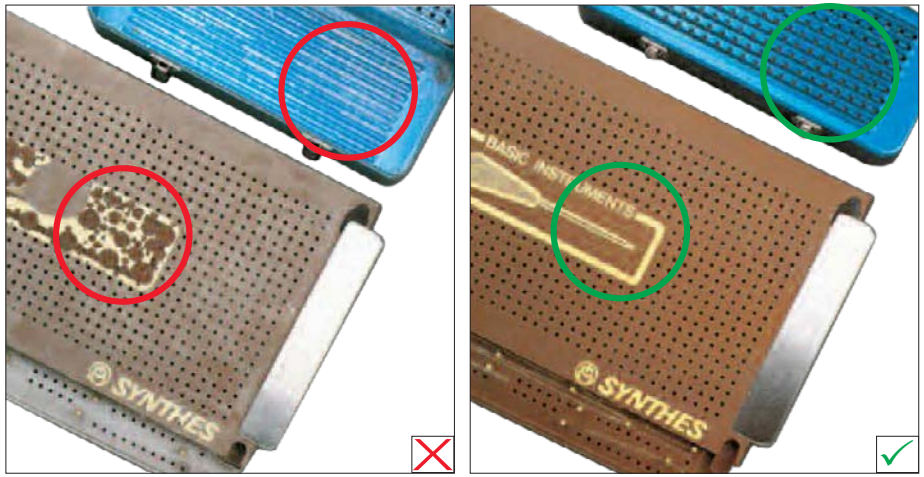
- Movement of the nut is impaired
- See also *2.2 – Instruments With Hexagon Sockets or Bolt Heads and 2.5 – Threaded Instruments*

3.2 Cerclage Instruments (Wire Tightener, Passer, Twister…)



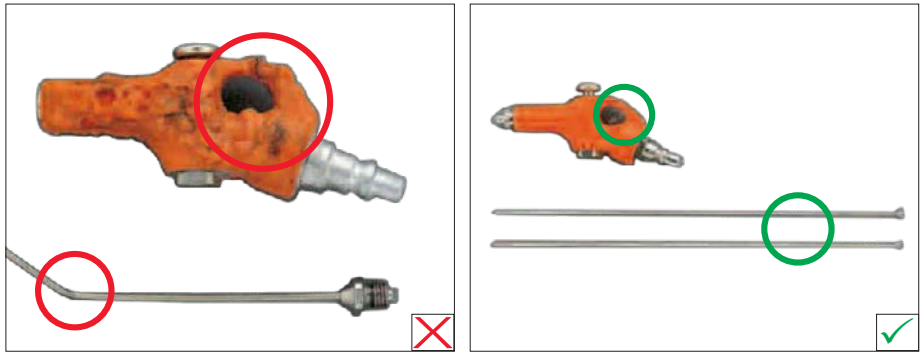
EOLi	Recommended Care
• Wire passer bent or flattened • Guide tube of the wire tensioner split or deformed	• Slightly deformed slots can be bent back into position • Do not hold the guide tube of the wire passer with forceps • Feed the instrument around the bone without tilting it • Thread appropriate size cerclage wires into the coil • Before tightening wires, fit the coil fully into the slots in the guide tube • Do not apply excessive force to the instrument • Remove wire residues
• Wire passer blocked	• Dissolve incrustations in the tube of the wire passer thoroughly with a suitable substance. Thoroughly clean and flush instrument

4.1 Anodized Aluminum Cases



EOLi	Recommended Care
• Surfaces discolored, flaky or scratched	• Do not use disinfectants or detergents containing iodine or heavy-metal salts such as mercury, etc • Do not use strongly alkaline solutions • Never use wire brushes or steel wool for cleaning • Treat surfaces with care. Lay instruments in the cases carefully

5.1 Air Jet and Air Tube

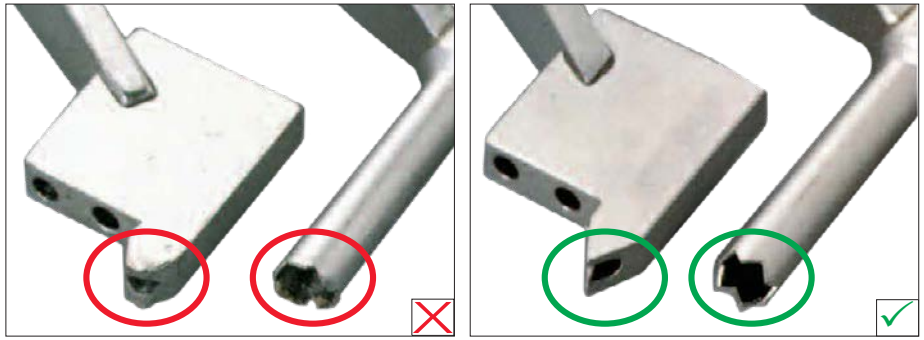


EOLi	Recommended Care
• Plastic deformed or melted	• Never sterilize the nozzle
• Tube bent, broken or blocked	• Move the tube carefully back and forth when cleaning flexible shafts • Rinse the air tube thoroughly after use

6.1 Cutting Instruments

EOLi	Recommended Care
• Cutting edges damaged, chipped, or blunt	• Regrinding is possible provided the cutting edges are not too badly damaged. Consult your Synthes representative • Do not misuse instruments. The very function of these instruments means that such damage and wear is to be expected

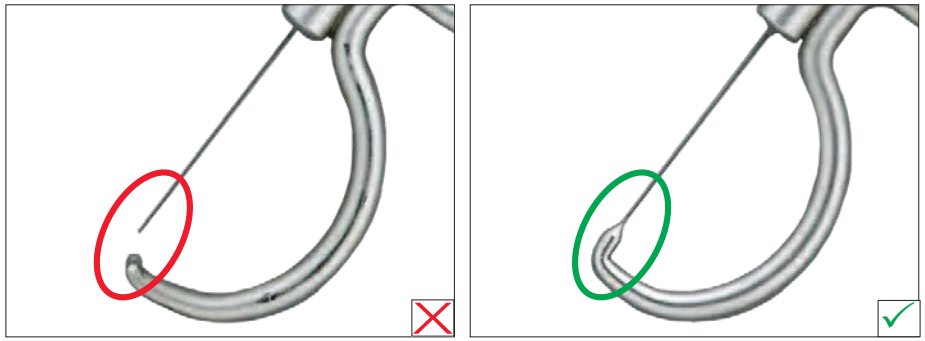
8.1 Drill Sleeves With Serrated Ends



EOLi

- Teeth damaged or worn
- The guide sleeve or drill cylinder bent and blocked

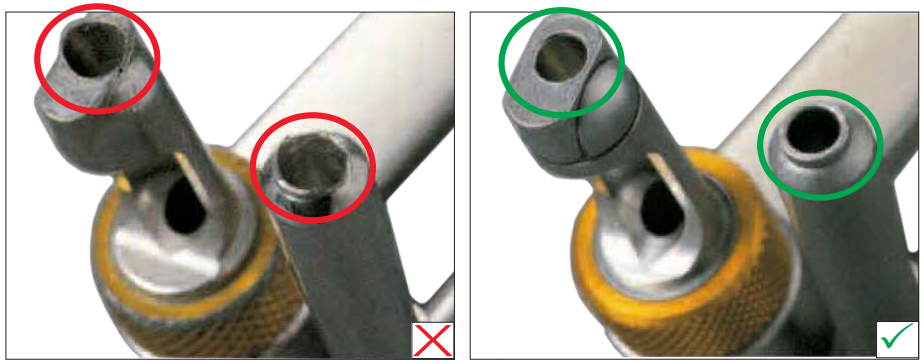
8.2 Pointed Drill Guide



EOLi

- Alignment error—drill guide and tip not in line
- Tip damaged
- Guide damaged by drilling

8.3 Drill Guides for Plates



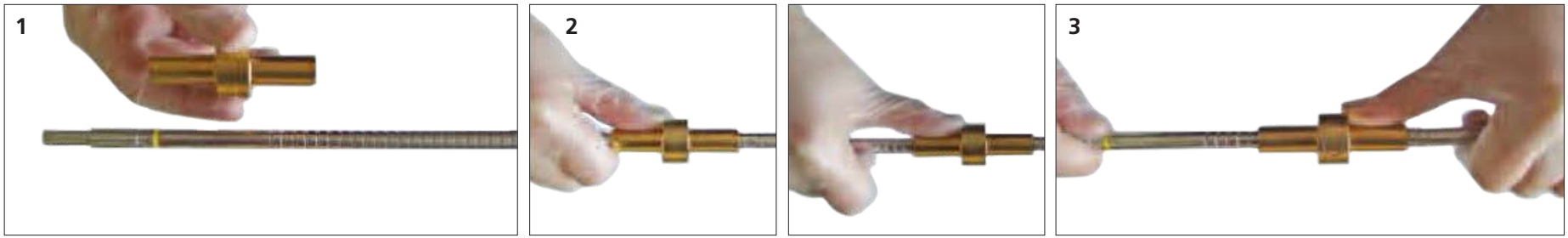
EOLi

- The base of the drill guide is damaged
- Guide cylinder blocked
- See also 2.1 – *Instruments With Spring-Loaded Ball Bearings*

EOLi

- Blunt, bent, broken, rounding of sharp edges
- Chipped, gouged, deep scratches
- Does not rotate concentrically; circular scratching due to intended rotation of the device
- Knocks and can thus break; damage due to impact

9.1 Fixation Sleeve/Drill Stop for Reamers and Drill Bits



EOLi

- The fixation sleeve allows the reamer to stop at a predetermined depth. After multiple use, however, the holding force may become insufficient and the fixation sleeve may move under pressure

Function Check

- Check the stop of the fixation sleeve before use

Proceeding:

1. Slide the fixation sleeve on the reamer
2. Press with the thumb onto the fixation sleeve without pressing the button. If the fixation sleeve moves under pressure, replace it
3. Do the same test into the opposite direction. If the fixation sleeve moves, replace it

Recommended Care

- Drill only under periodic image intensifier control
- While reaming, do not use excessive force

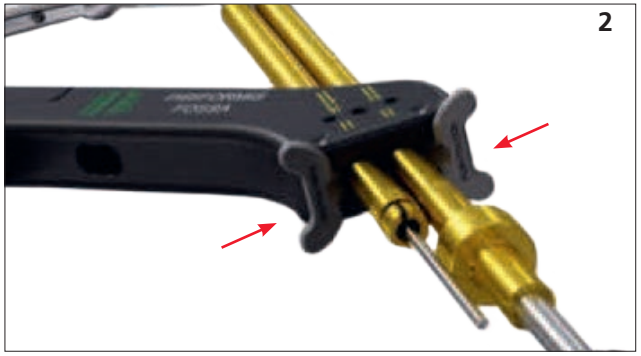
EOLi	Recommended Care
• Jaws deformed or worn	• Do not subject forceps to excessive force
• Ratchet or adjuster spindle bent	• Always use the correct size forceps according to the size of bone being held
• Joint damaged or corroded	• Carefully clean and lubricate joints
• Forceps member bent	• Sterilize instrument only with locks open
• Does not hold, retain, loose	

EOLi

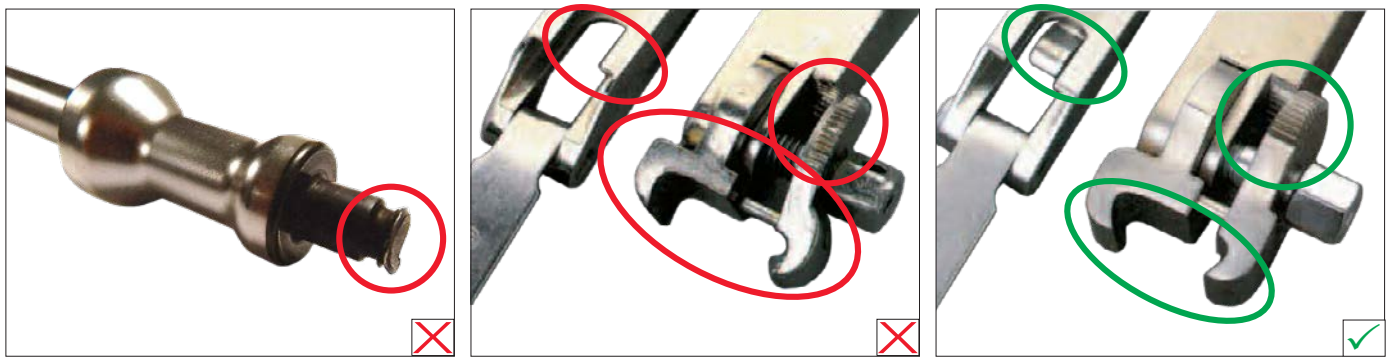
- Aiming accuracy impaired
- Tube damaged.
- Hole widened

- *See also 2.3 – Instruments With Cams*

14.1 Radiolucent Aiming Arms With Cam Lock Levers

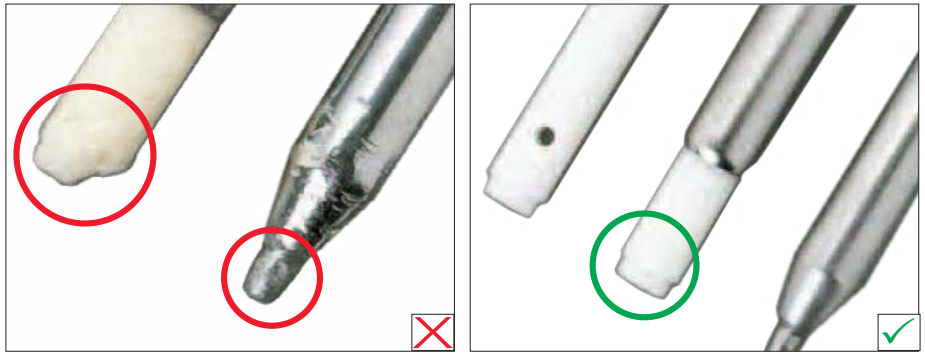


EOLi	Function Check	Recommended Care
• The cam lock lever holds the protection sleeve in the aiming arm in place. After multiple use, however, the holding force may become insufficient and the protection sleeves may move under pressure	• Check the cam lock lever of the aiming arm before use: 1. Ensure the cam lever is not depressed. Insert the combination assembly with the protection sleeve into the aiming arm. 2. After assembly, press the cam lock lever to secure the protection sleeve in the aiming arm. 3. Slightly push and pull onto the protection sleeve to ensure it's held in place. If the protection sleeve moves, replace the aiming arm.	• Do not exert excessive force on the aiming arm assembly. These forces may prevent accurate targeting through the proximal locking holes and damage the drill bits

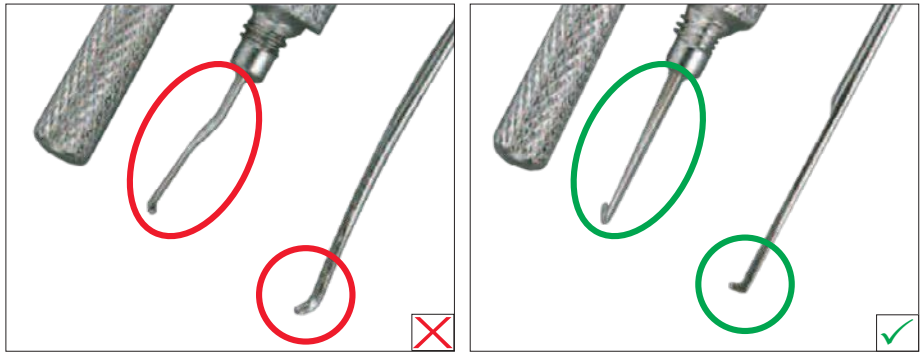


EOLi	Recommended Care
• Damaged teeth • Instrument with jaws: jaw grippers worn or widened	• Arrange angle plates so that several teeth are engaged (if necessary, turn or shift through 180°) • Firmly tighten the locking nut
• Instrument with flat spring: flat spring of guide plate bent or broken off	• If the guide plate spring no longer provides a grip, it can be slightly bent into position to regain tension • Do not bend flat springs to and fro
• Instrument with drive pin: drive pin bent	• Do not subject drive pin to excessive force
• Instrument with guide plate: plate is deformed	• Do not subject guide plate to excessive force
• See also *2.2 – Instruments With Hexagon Sockets or Bolt Heads and 2.6 – Instruments With Interlocking Threads*	

17.1 Impactors



EOLi	Recommended Care
• Front end damaged	• Ensure that the end of impactor fits exactly into the hole of the plate before driving in the plate • Do not tilt the instrument during impacting • Avoid using excessive force
• Plastic heads broken off	• Ensure that the end of impactor fits exactly into the hole of the plate before driving in the plate • Do not tilt the instrument during insertion • Avoid using excessive force

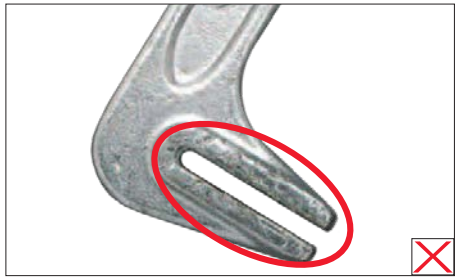


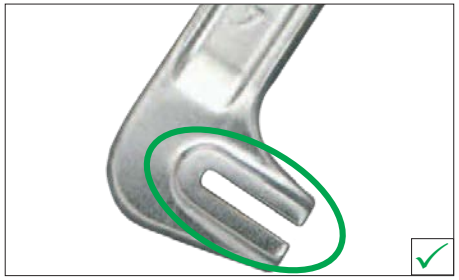
EOLi	Recommended Care
• Measuring hook bent out of alignment or broken off	• Insert gauge correctly • Adequate care should be taken of the measuring hook
• Scaling no longer visible	
• See also *2.1 – Instruments With Spring-Loaded Ball Bearings*	

EOLi

- Poor light transmission

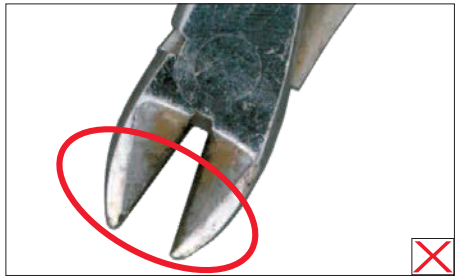
22.1 Bending Iron

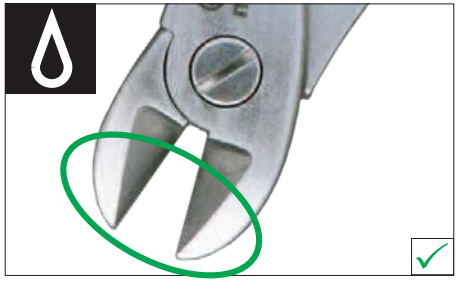




EOLi	Recommended Care
• Jaws damaged or widened	• Use the irons only for twisting plates • Do not use excessive force
• Leg or pin broken off	• Do not use excessive force

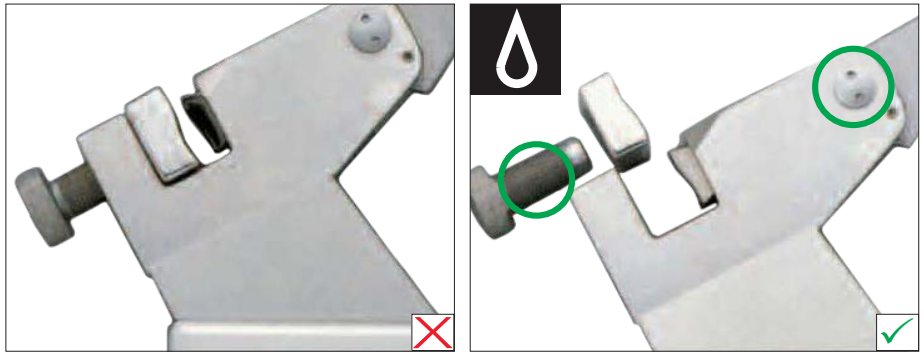
22.1 Cutting and Bending Pliers





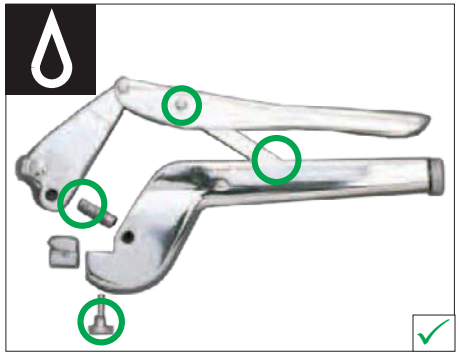
EOLi	Recommended Care
• Cutting edges damaged	• Do not apply excessive force to pliers • Ensure that the appropriate cutting and bending pliers are used for the various diameters of wire • Use lubrication
• Jaw deformed	• Do not apply excessive force to pliers • Ensure that the appropriate cutting and bending pliers are used for the various diameters of wire

22.3 Bending Press



EOLi	Recommended Care
• Screw jammed or difficult to turn	• Dismantle press for cleaning (screw and anvil) • Carefully clean the thread of the adjuster screw • Lubricate the screw, lever joint and punch
• Anvil cannot be detached • Surface damaged • Punch damaged • Lever stiff	• Never force adjuster screw and anvil together. Punch profile must correspond to anvil profile

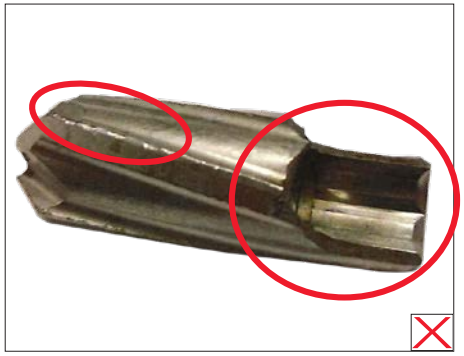
22.4 Plate Bending Pliers



EOLi	Recommended Care
• Adjuster screw or thrust member damaged	• Dismantle the pliers when cleaning and carefully clean threaded parts • Apply lubrication
• Anvil damaged	• Use the correct size anvil according to plate size

- See also 2.5 – *Threaded Instruments*

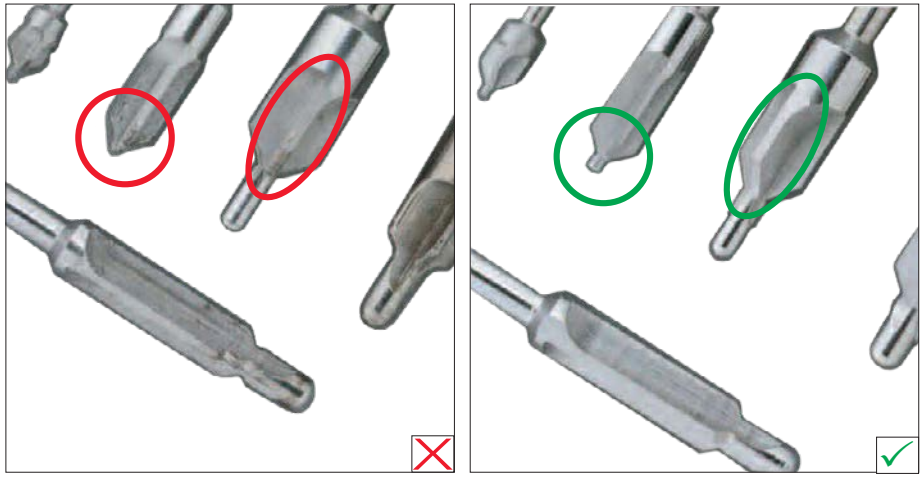
24.1 Medullary Reamer Heads



EOLi

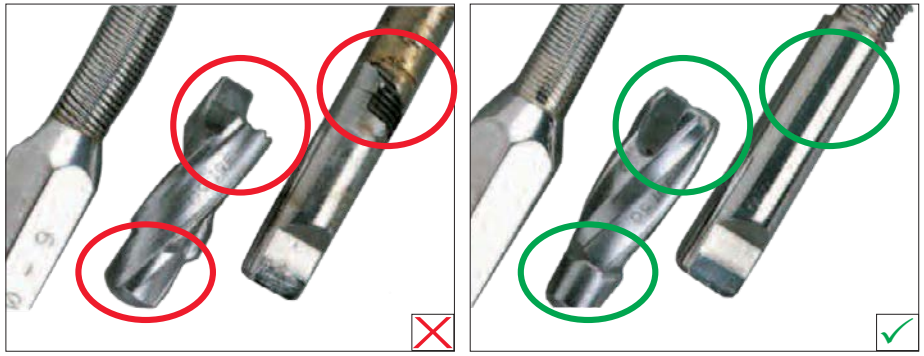
- Chipped, gouged, deep scratches
- Circular scratching due to intended rotation of the device
- Cutting edge damaged; cutting edge corners broken off
- Rounding of sharp edges
- T-groove of drilling heads damaged or broken off

24.2 Burrs



EOLi
• Conical or side-cutting edge damaged or blunt
• Centering tip damaged

24.3 Flexible Shafts

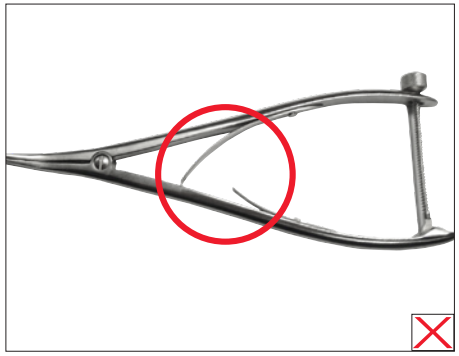


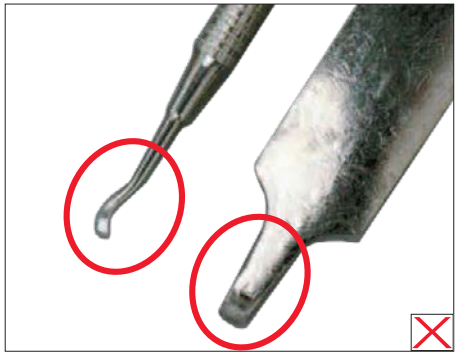
EOLi	Recommended Care
• Helix or shaft irregular or kinked • Connector worn at front or rear • Soldered point damaged	• Never reverse run a flexible shaft • Do not apply excessive pressure while drilling • Core drill in increments of 0.5 mm • Change shaft as required • Always core drill via the mandrel
• Shaft contaminated with dried-on drillings	• During surgery, flush the shaft directly after use with Ringer-Lactate solution or saline solution. Never leave the shaft submerged in the solution • At the conclusion of surgery, clean the shaft by hand under water with a water jet, nozzle and detergent. Close the distal opening with a finger to force the solution through the wire walls. During cleaning, bend the shaft to and fro. Then dry with warm air • Dissolve incrustations with suitable agent. Clean the instrument thoroughly

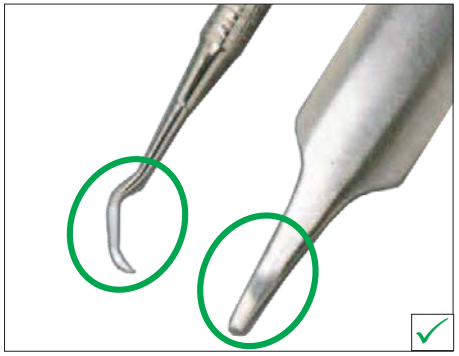
• See also *24.1 – Medullary Reamer Heads*

24.4 Fixation Sleeve/Drill Stop for Reamers and Drill Bits

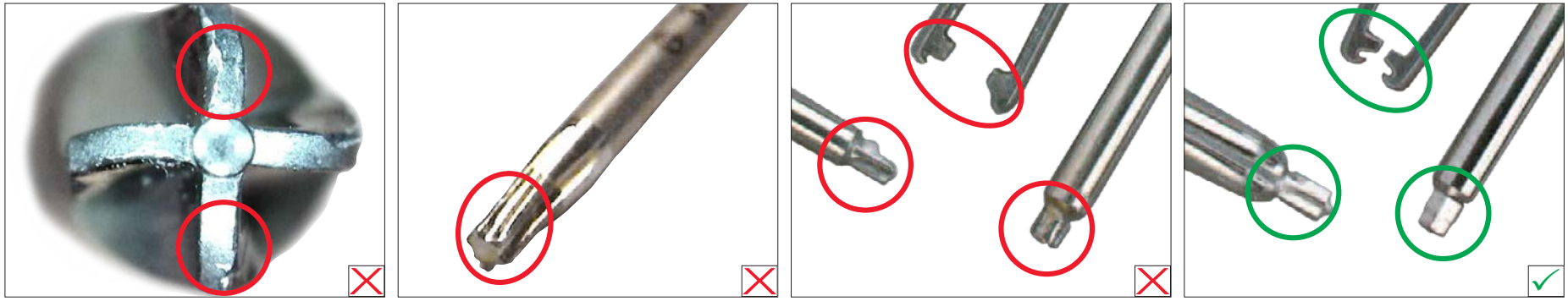
(See also *9.1 – Fixation Sleeve/Drill Stop for Reamers and Drill Bits)*







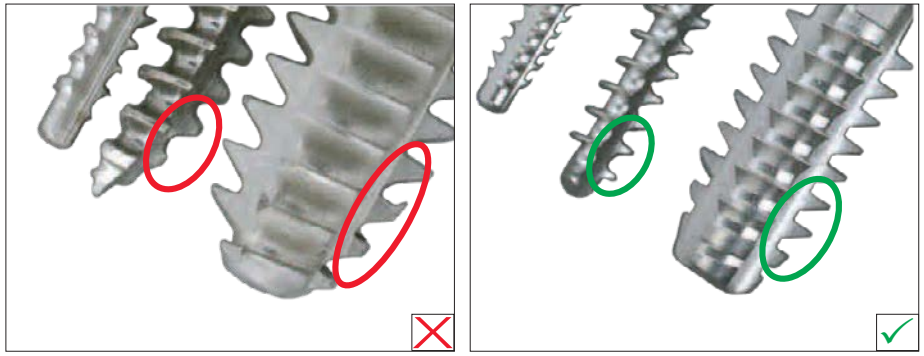
EOLi	Recommended Care
• Tips deformed or broken off	• Do not apply excessive force to bone hooks
• Retractor accidentally drilled, bent or has sharp edges	• Do not apply excessive force to retractors. Do not drill into retractors
• Spring on bone spreader damaged	



EOLi

- Hexagon/Stardrive™/Cruciform tip damaged
- Self-retaining screwdriver tips worn, do not retain

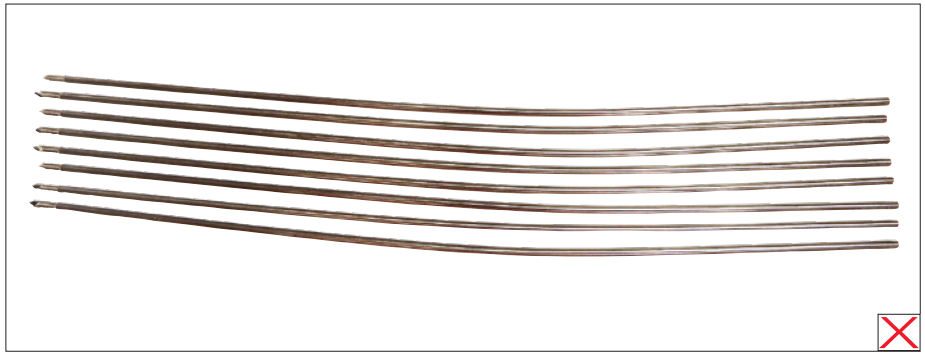
- Spring action or holding force of the holding sleeve ineffective; end damaged

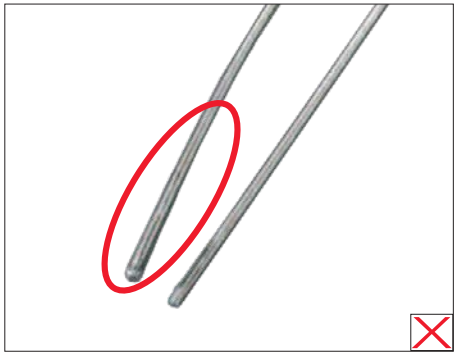


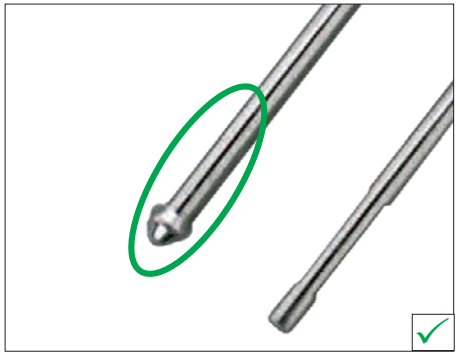
EOLi

- Thread damaged. Teeth blunt or broken
- Tap bent or twisted

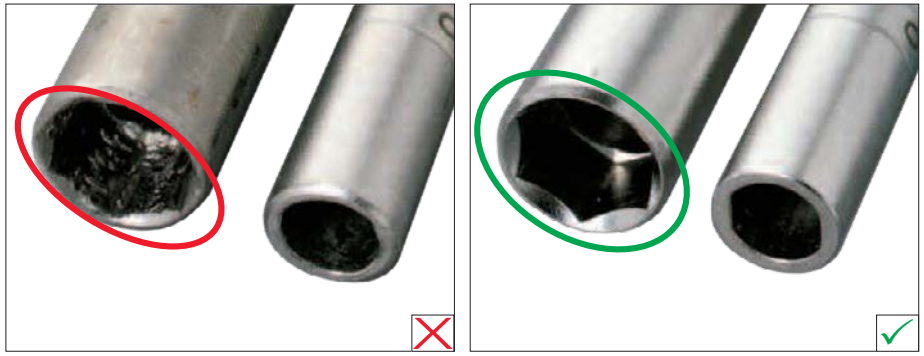
- Quick coupling end damaged







EOLi	Recommended Care
• Instrument bent, kinked or distorted	• Straighten slightly bent instrument • When drilling, do not tilt the drill over guide wire or rod • Do not apply excessive pressure during the drilling
• Ends damaged, e.g., drilled into or twisted	• Do not damage ballpoint end of guide pin during drilling. Take care with frontally cutting drill heads



EOLi

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

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