Ortho Solutions Non-Sterile Device Lifetime Manual

All Ortho Solutions devices that are supplied non-sterile **MUST** first be reprocessed prior to use. Ortho Solutions devices have been designed to facilitate their safe cleaning, disinfection, and re-sterilisation per EU MDR Annex I, Chapter II, Section 11.2. The cleaning and sterilisation methods recommended by Ortho Solutions are documented in the Reprocessing Instructions For Use, *OS TD 00019_18.*

OS TD 00019_18 recommends that all non-sterile devices are visually inspected and functionally tested prior to sterilisation as part of reprocessing. The purpose of this document is to provide visual and functional information to the intended user to aid in the identification of any end of life indicators during this process, which identify when a non-sterile device should no longer be reused. This document is applicable Non-Sterile Devices manufactured by Ortho Solutions UK Ltd West Station Business Park, Spital Road, Maldon, CM9 6FF, United Kingdom, Phone: +44(0)1621 843599, Fax: +44(0)1621 858953, www.orthosol.com.

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This document is subject to change. Users are advised to consult the latest version available at www.orthosol.com/eifu or contact Ortho Solutions directly to confirm that they are using the most up-to-date Instructions for Use.

Please verify that the current printed version is identical to the one at www.orthosol.com/eifu

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'Reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.

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1. Purpose

The purpose of this manual is to provide visual and functional information on end of life indicators that may present on a non-sterile device following repeated use and reprocessing, in order to assist the intended user in determining whether the device is no longer suitable for its intended use, and therefore should no longer be reused.

If following inspection and functional testing an Ortho Solutions non-sterile device presents an end of life indicator, please contact Ortho Solutions Customer Services or your Sales Representative for a replacement.

For additional non-sterile device maintenance information along with the recommended reprocessing instructions, please refer to the Ortho Solutions Non-Sterile Device Reprocessing Instructions, *OS TD 00019_18*, which can be accessed at the following: https://www.orthosol.com/eifu/.

For guidance on the correct disassembly for the applicable Ortho Solutions non-sterile devices that is required for reprocessing, please refer to the Disassembly Instructions, *OS TD 00081_25*, which can be accessed at the following: https://www.orthosol.com/eifu/.

2. Scope

This manual provides information applicable to the Ortho Solutions non-sterile devices that are intended for use in orthopaedic surgery to enable implantation of the associated Ortho Solutions implant(s) when used in accordance with the surgical technique. These devices are supplied non-sterile and are intended for reprocessing in a healthcare facility setting prior to use. This information is **NOT APPLICABLE** to Ortho Solutions single use, sterile devices.

3. Instructions for Using the Non-Sterile Device Lifetime Manual

Ortho Solutions defines no maximum number of reuses for its non-sterile devices, as this is dependent on multiple parameters from each individual use. End of life of a device is normally determined by damage, wear and loss of function due to surgical use, reprocessing and/or handling.

Evidence of damage and wear on a device may include but is not limited to the end of life indicators contained within this manual. Ortho Solutions non-sterile devices should be thoroughly inspected for the identification of any end of life indicators after cleaning but prior to sterilisation as part of every reprocessing cycle. This document describes and contains representative images of different types of damage and wear a device might experience during its lifetime, such as but not limited to:

- Bending
- Deformation
- Corrosion
- Surface Damage
- Blunt cutting edges
- Damaged threads
- Broken

The manual within **Section 5** is separated by the listed end of life indicators, with each indicator section containing the following:

- **Images** representing the specific end of life indicator type. Note: the images are intended to document representative examples of the specific type of end of life indicator, which can be applicable to multiple non-sterile devices not just the ones pictured.
    - **Symbol legend** the following symbols are contained in the lower right side of the images:

      Suitable for its Intended Use.

      Not Suitable for its Intended Use.

- **Descriptions** of the end of life indicator type as shown in the images.
- **Potential Effects of Wear** on any non-sterile device specific to the end of life indicator type described, not particularly to those as shown in the representative images provided, to aid in evaluating if the non-sterile device remains suitable for its intended use.

4. Inspection & Function Testing

After cleaning and prior to sterilisation as part of every reprocessing cycle for the non-sterile devices, reference this lifetime manual to help in the identification of any end of life indicators, and follow the recommended visual inspections and functional testing as described below.

Note: the results of visual inspection, functional testing and the extent of all forms of damage and/or wear should be considered in determining whether a device remains suitable for its intended use.

4.1. Visual Inspection

Generally, visual inspection with the naked eye under good lighting conditions will suffice. The following visual inspections are recommended to be performed at minimum:

- Check all visible contamination has been removed. If contamination is still visible, repeat the cleaning process.
- Check for completeness of the device and correct assembly, disassembled devices should be reassembled prior to sterilisation.
- Check for damage such as cracks, fractures, parts being broken off and/or excessive wear. Pay attention to welded joints, assembly joints and pivot joints for signs of damage and/or wear.
- Check devices that form part of a larger assembly or assemble with mating components.
- Check for illegible, missing and /or removed direct part markings.
- Check for bending and kinking. Pay close attention to devices with cannulations (to ensure they are not blocked), those that are long and slender, and devices that contain components/features that must remain straight in order for it to achieve its intended use e.g. depth gauge probe/body.
- Check for deformation, twisting and severely rounded edges, pay close attention to features that engage with other components e.g. driver tips
- Check for corrosion and pitting.

- Check for severe discolouration. If discolouration has caused the direct part markings for device identification and/or the measuring scale to become illegible, this would be considered an end of life indicator. Note: minor discoloration and/or water marks are to be expected as part of repeated reprocessing of a reusable device and as they do not impact the functionality and/or safety of the device, this would not constitute an end of life indicator.
- Check for surface damage such as excessive scratches, dents and/or chips.
- Checking devices with internal mechanisms such as, springs or ball bearings for signs of damage and/or wear.
- Checks devices with internal and/or external threads for signs of damage and/or stripping.
- Check devices with cutting edges for sharpness and damage.

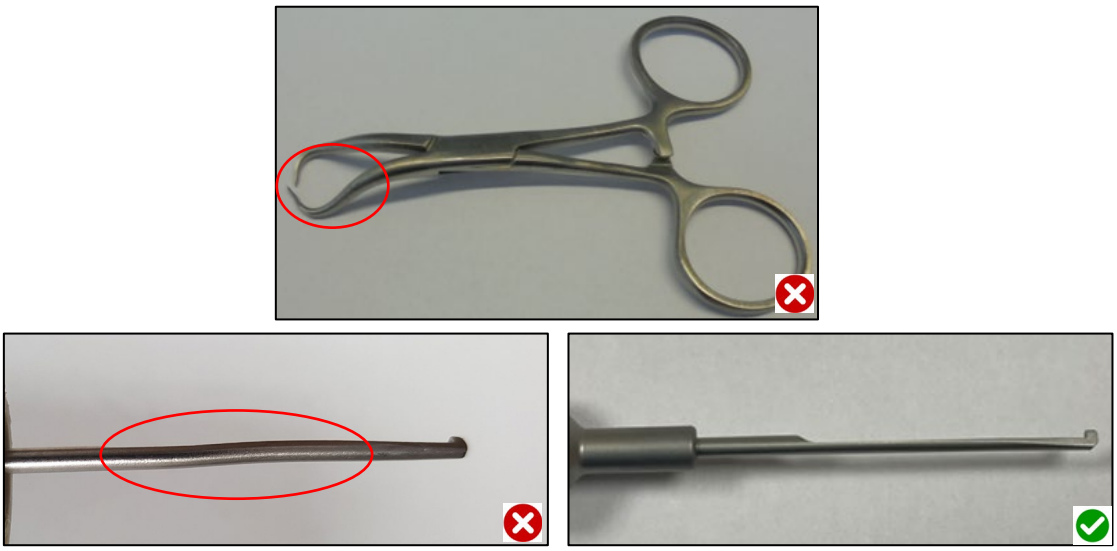
4.2. Functional Testing

The following functional tests are recommended to be performed at minimum:

- Test the action of moving parts such as hinges/joints and moveable features such as handles, ratcheting, couplings, and sliding parts, to ensure smooth operation throughout the intended range of motion e.g. can fully open and close and has no seizing.
- Test locking mechanisms fasten securely and detach easily throughout the intended range of motion e.g. ratchets.
- Test for correct alignment e.g. jaws and teeth align correctly.
- Test devices with cannulations (e.g. drill guides, cannulated drivers) for free passage without obstructions. e.g. free from blockages and damage.

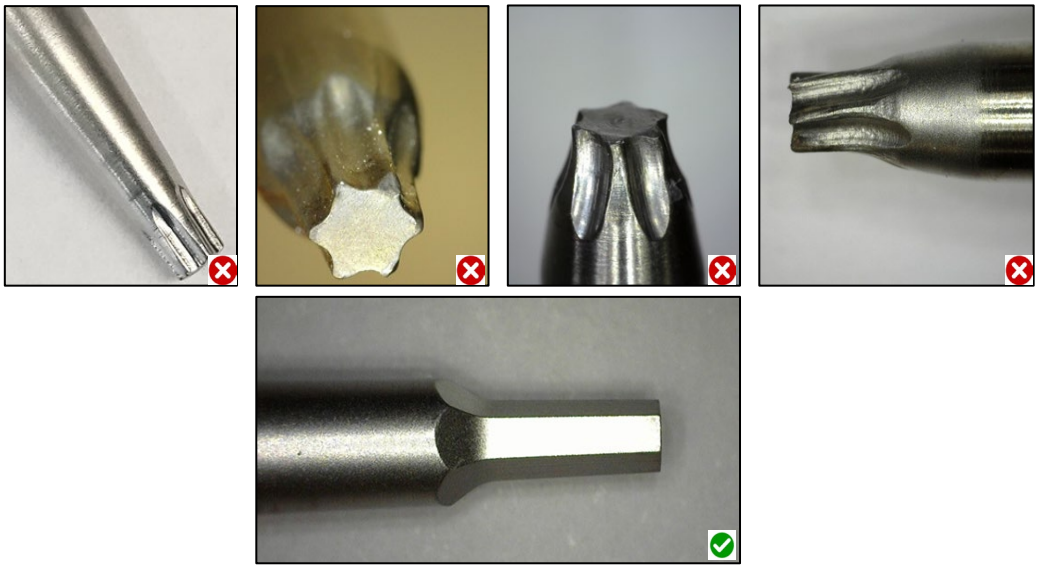
5. General End of Life Indicators

5.1. BENDING



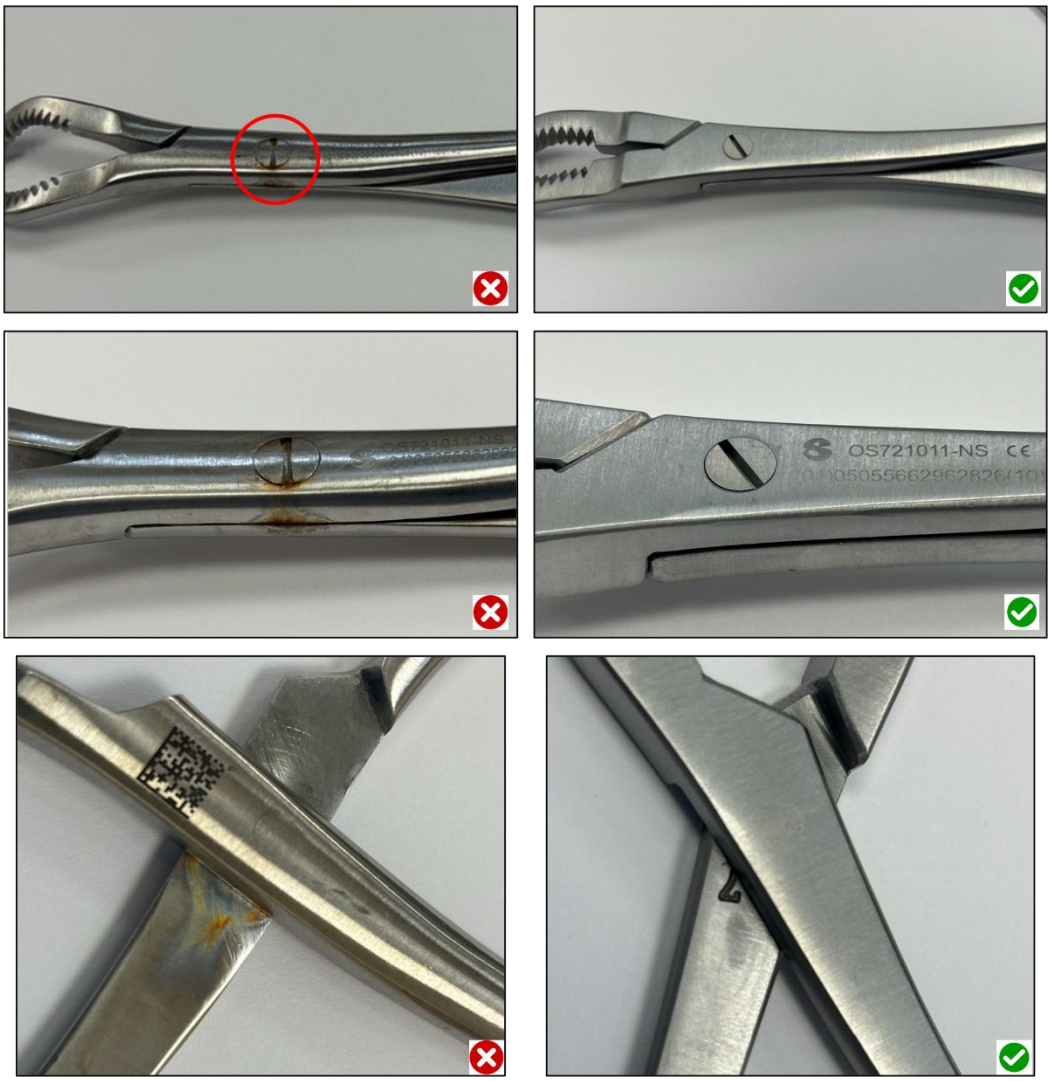
End of Life Indicator Description	Potential Effects
• Bent • Kinked	• Inadequate force applied • Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Inaccurate feedback • Inaccurate measurements • Inaccurate guidance • Blocked cannulation • Restricted range of motion

5.2. DEFORMATION



End of Life Indicator Description	Potential Effects
• Deformed • Twisted • Severely rounded edges	• Inadequate force applied • Inadequate removal of bone • Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Inaccurate feedback • Inaccurate measurements • Restricted range of motion • Inaccurate alignment

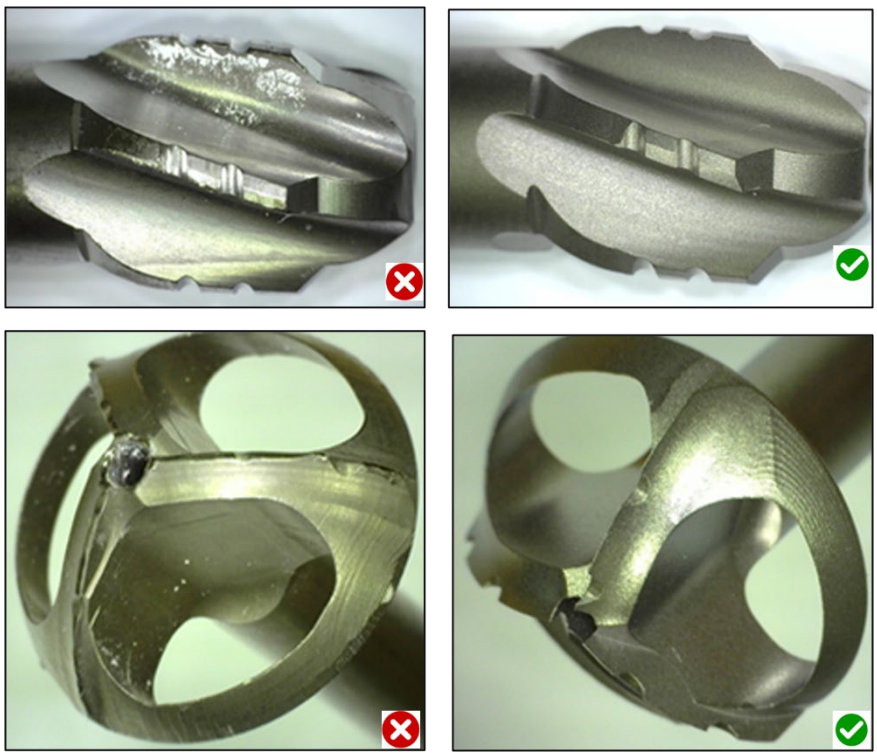
5.3. CORROSION



End of Life Indicator Description	Potential Effects
• External surface corrosion • Internal surface corrosion • Pitting • Severely discoloured / illegible direct part marking due to corrosion	• Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Excessive torque to engage components • Excessive torque to disengage components • Inaccurate measurements • Inadeqaute reprocessing • Inadequate biocompatibility

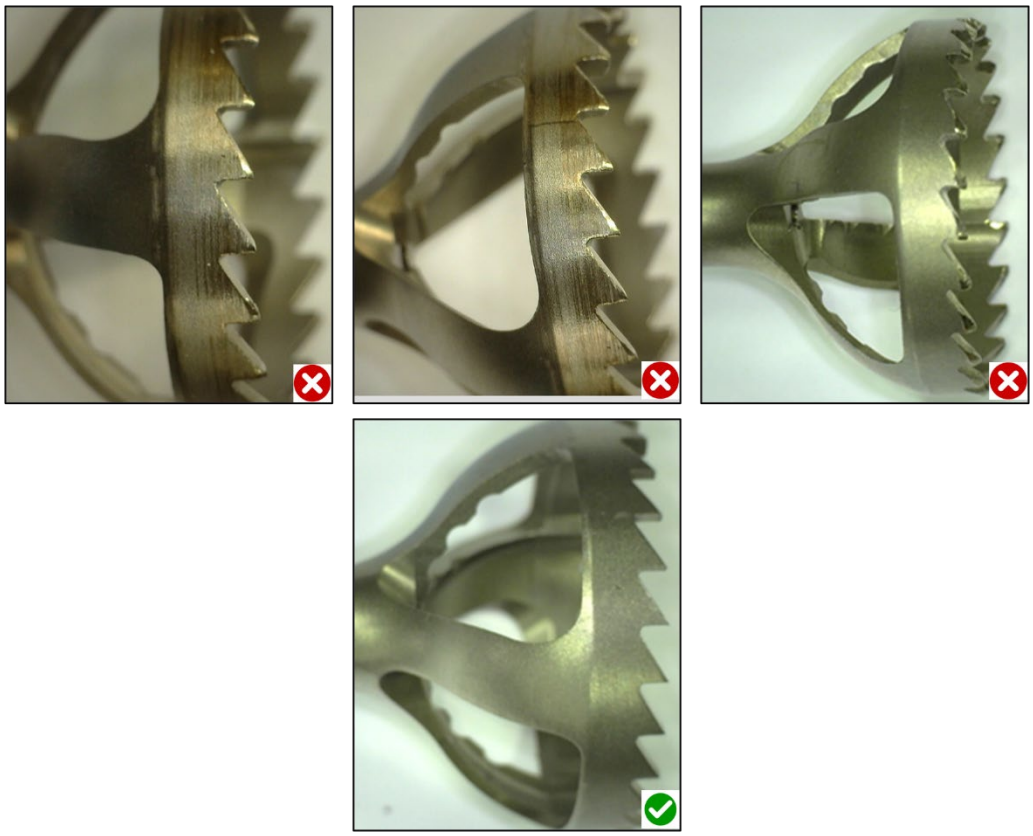
	• Inadequate identification / traceability

5.4. SURFACE DAMAGE



End of Life Indicator Description	Potential Effects
• Excessively scratched internal or external surfaces • Excessively dented internal or external surfaces • Excessively chipped internal or external surfaces	• Inadequate removal of bone • Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Inaccurate feedback Inaccurate measurements • Inadequate reprocessing • Inadequate identification / traceability

5.5. BLUNT CUTTING EDGES

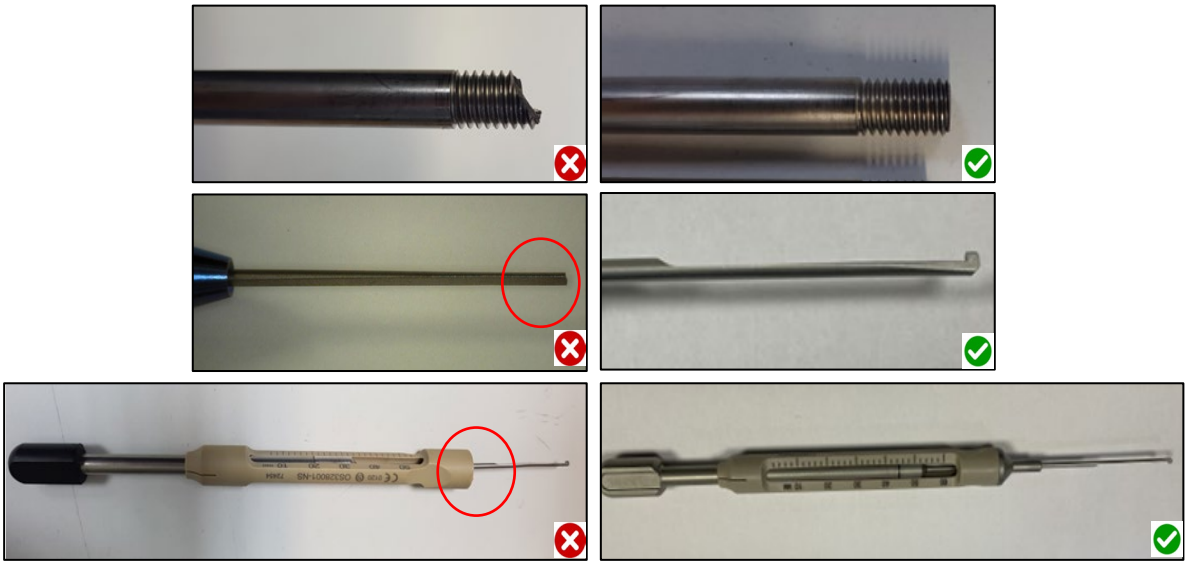


End of Life Indicator Description	Potential Effects
• Cutting edge blunt • Cutting edge damaged	• Inadequate force applied • Inadequate removal of bone • Inaccurate feedback

5.6. DAMAGED THREADS

End of Life Indicator Description	Potential Effects
• Internal or external threads damaged • Internal or external threads stripped	• Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Excessive torque to engage threads • Excessive torque to disengage threads • Inaccurate feedback • Inadequate assembly

5.7. BROKEN



End of Life Indicator Description	Potential Effects
• Fractured • Cracked • Broken (components broken off)	• Inadequate force applied • Inadequate removal of bone • Inadequate engagement with implant, instrument or bone • Inadequate disengagement with implant, instrument, or bone • Inaccurate feedback • Inaccurate measurements • Restricted range of motion • Inaccurate alignment