Reusable Instrument Lifespan Manual

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INTRODUCTION

Purpose

This manual is intended to assist the user in determining whether a reusable instrument has worn to an extent that it is no longer suitable for use. For additional reusable instrument care instructions, see the Zimmer Instrument Care, Cleaning, Maintenance and Sterilization Instructions (Doc No. 97-5000-170-00).

Scope

This manual provides information applicable to the reusable instruments used to implant hip, knee, shoulder, elbow, ankle, and trauma implants. This information is NOT APPLICABLE to single use instruments (sterile and non-sterile).

Glossary

Indicator – A term used to describe damage to a device that can indicate the instrument is no longer suitable for use.

Feedback – Refers to any specific visual, auditory, or tactile feedback that serves as an indicator of decision/action.

Quick Check – An assessment of the instrument's condition to detect the presence of wear.

Reprocessing – The necessary validated processes including cleaning, disinfection, and sterilization to render a medical device, which has been previously used or contaminated, fit for its intended subsequent single use.

Understanding Document Structure

This manual describes several types of wear including:

i. Bending

ii. Discoloration

iii. Corrosion

iv. Fracture

v. Thread Damage

vi. Surface Damage

Understanding Document Structure (cont.)

The indicators identified above are signs of wear and damage on reusable instruments. The manual is separated by the aforementioned indicators. Each indicator section contains:

- **Images** representing the indicator category to which it belongs. Images are only a representation of possible wear.
- **Descriptions** of the indicator shown in the image and content specific to the indicator.
- **Quick Check Methods** to assist in assessing the instrument for the presence of said indicator.
- **Potential Effects of Wear** on any reusable instrument specific to the indicator described, not particularly those shown in the images provided, to aid in assessing if the instrument is suitable for use.
- **Symbol legend**

  ✓ Suitable for Use

  X Not Suitable for Use

Inspection/Function Testing

While loading instruments into their respective instrument cases *after cleaning and prior to sterilization*, reference the manual and follow the instructions below.

1. Instruments should be inspected for completeness and function.
2. Inspection includes:
   a. Checking instruments that form part of a larger assembly or assemble with mating components.
   b. Checking internal mechanisms such as o-rings, springs, and subcomponents, if the device is intended to be disassembled for proper reprocessing.
   c. Actuating moving parts such as hinges/joints and moveable features such as handles, ratcheting, couplings, and sliding parts.
   d. Inspecting for all forms of wear outlined in this manual.
3. Results of assembly, actuation, and extent of all forms of wear should be considered in determining whether an instrument is suitable for use.
4. If the reusable instrument is determined no longer suitable for use or if the suitability for use is still in question after inspecting the instrument and referencing the Reusable Instrument Lifespan Manual, initiate the process to return the instrument(s) to the manufacturer.

Returning the Reusable Instrument(s)

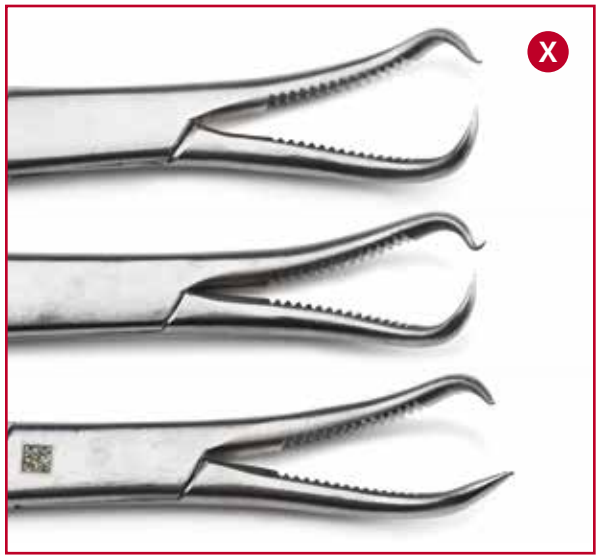
If an allegation is made related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device at any other time, please complete and submit a Product Experience Report (CF04001) and return the reusable instrument(s) to the manufacturer for investigation.

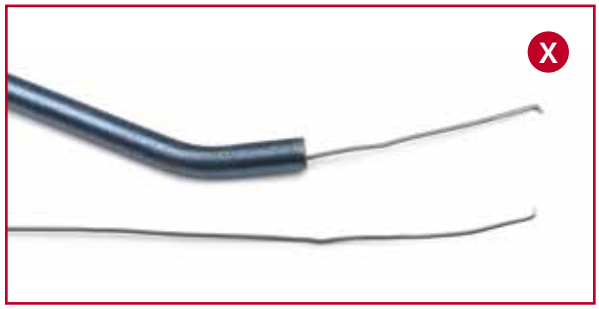
If the instrument to be returned is not a complaint, complete and submit a Worn Instrument Return Form (F-01413 D).

The Worn Instrument Return Program is not a replacement for the Complaints Submission Process.

Please do not attempt to dispose of the reusable instrument(s) through any other means.

BENDING





Description	Potential Effects of Wear
• Bent • Kinked • Crooked • Unraveled coils	• Inadequate force applied • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing • Contact unintended soft tissue or bone • Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Inadequate application/removal of bone cement

Roll Quick Check –
Action: Instrument is rolled back and forth on flat surface.
Result: If instrument wobbles, wear is present and the instrument must be returned to the manufacturer.

Inclined Quick Check –
Action: Instrument is rolled down an incline.
Result: If instrument does not roll freely, wear is present and the instrument must be returned to the manufacturer.

Free End Lift Quick Check –
Action: Allow instrument to lay flat on a surface.
Result: If deflection is observed at the free end, wear is present and the instrument must be returned to the manufacturer.

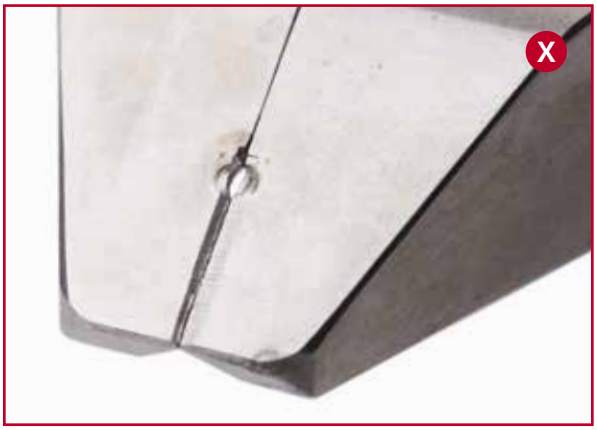
Description	Potential Effects of Wear
• Bowed • Curved • Warped • Unraveled coils	• Inadequate force applied • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing • Contact unintended soft tissue or bone • Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Inadequate application/removal of bone cement

Roll Quick Check –
Action: Instrument is rolled back and forth on flat surface.
Result: If instrument wobbles, wear is present and the instrument must be returned to the manufacturer.

Inclined Quick Check –
Action: Instrument is rolled down an incline.
Result: If instrument does not roll freely, wear is present and the instrument must be returned to the manufacturer.

Free End Lift Quick Check –
Action: Allow instrument to lay flat on a surface.
Result: If deflection is observed at the free end, wear is present and the instrument must be returned to the manufacturer.

Camber Quick Check –
Action: Place instrument on a flat surface with either end on a straight edge.
Result: If there is deflection in the width direction, wear is present and the instrument must be returned to the manufacturer.



Description	Potential Effects of Wear
• Curled cutting edges	• Inadequate force applied • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing • Contact unintended soft tissue or bone • Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Inadequate application/removal of bone cement

Description	Potential Effects of Wear
• Bent light pipe or cable **Light Quick Check –** *Action:* Hold end of light pipe or cable against a light source and look into pipe or cable at the other end. *Result:* If light will no longer travel through the pipe or cable, wear is present and the instrument must be returned to the manufacturer.	• Inadequate light for guidance • Inadequate engagement of components • Inadequate disengagement of components

Description	Potential Effects of Wear
Bent, bowed or warped: • Cases • Bases • Trays • Lids • Brackets or posts	• Insufficient function of handles, lids, and rotating components • Can allow free travel of contents • Interference between case components and contents • Inadequate reprocessing • Inadequate engagement of components • Inadequate disengagement of components

DISCOLORATION

Description	Potential Effects of Wear
• Discolored product markings	• Illegible product markings • Inaccurate feedback

Readability Quick Check –
Action: Read instrument markings.
Result: If instrument markings are illegible or difficult to read, wear is present and the instrument must be returned to the manufacturer.

Description

- Discolored product markings due to corrosion

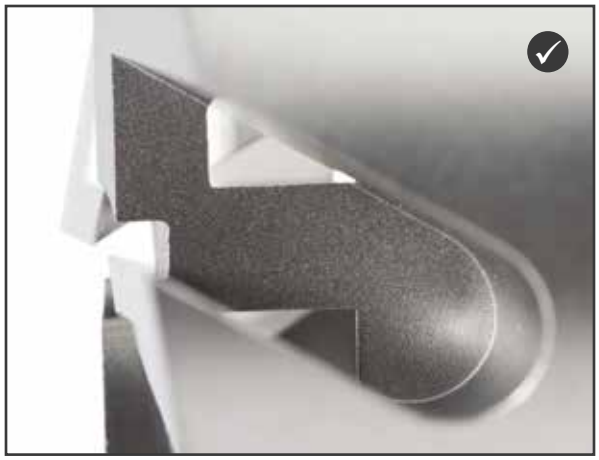
Pencil Eraser Quick Check –
Action: Rub a pencil eraser on the affected area.
If the discoloration is removed by the eraser, it is a stain.
Result: If the discoloration is not removed by the eraser or reveals pitting, wear is present and the instrument must be returned to the manufacturer.

Readability Quick Check –
Action: Read instrument markings.
Result: If instrument markings are illegible or difficult to read, wear is present and the instrument must be returned to the manufacturer.

Potential Effects of Wear

- Illegible product markings
- Inaccurate feedback

CORROSION



Description	Potential Effects of Wear
• Surface corrosion • Pitting **Pencil Eraser Quick Check –** *Action:* Rub a pencil eraser on the affected area. If the discoloration is removed by the eraser, it is a stain. *Result:* If the discoloration is not removed by the eraser or reveals pitting, wear is present and the instrument must be returned to the manufacturer.	• Inaccurate feedback • Inadequate reprocessing • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Inadequate engagement of components • Inadequate disengagement of components

Description	Potential Effects of Wear
• Crevice corrosion • External/Internal thread corrosion **Threading Quick Check –** *Action:* Thread the components. *Result:* If there is difficulty fastening or unfastening components, wear is present and the instrument must be returned to the manufacturer. **Pencil Eraser Quick Check –** *Action:* Rub a pencil eraser on the affected area. If the discoloration is removed by the eraser, it is a stain. *Result:* If the discoloration is not removed by the eraser or reveals pitting, wear is present and the instrument must be returned to the manufacturer.	• Inaccurate feedback • Inadequate reprocessing • Inadequate engagement of components • Inadequate disengagement of components • Inadequate removal of bone, soft tissue, or bone cement to a specific/nonspecific shape • Excessive torque to engage threads • Excessive torque to disengage threads

Description	Potential Effects of Wear
• Discolored product markings due to corrosion	• Illegible product markings • Inaccurate feedback

Pencil Eraser Quick Check –
Action: Rub a pencil eraser on the affected area.
Result: If the discoloration is removed by the eraser, it is a stain. If the discoloration is not removed by the eraser or reveals pitting, wear is present and the instrument must be returned to the manufacturer.

Readability Quick Check –
Action: Read instrument markings.
Result: If instrument markings are illegible or difficult to read, wear is present and the instrument must be returned to the manufacturer.

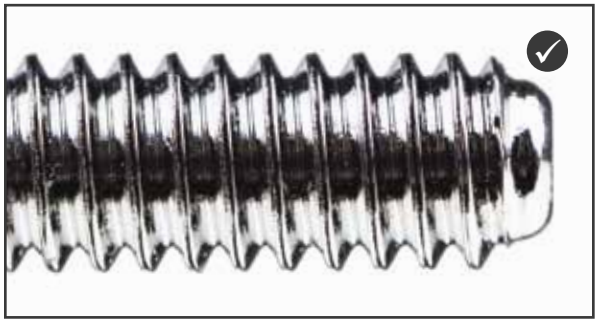
FRACTURE

Description	Potential Effects of Wear
• Fractured	• Inadequate reprocessing • Inadequate accommodation of hand use • Inadequate force applied • Inaccurate feedback • Inadequate engagement of components • Inadequate disengagement of components

Description	Potential Effects of Wear
• Cracked	• Inadequate reprocessing • Inadequate accommodation of hand use • Inadequate force applied • Fracture • Inaccurate feedback • Inadequate engagement of components • Inadequate disengagement of components

Description	Potential Effects of Wear
• Cracked/Fractured in flexible shaft body	• Inadequate reprocessing • Inadequate accommodation of hand use • Inadequate force applied • Fracture • Inaccurate feedback • Inadequate engagement of components • Inadequate disengagement of components

THREAD DAMAGE

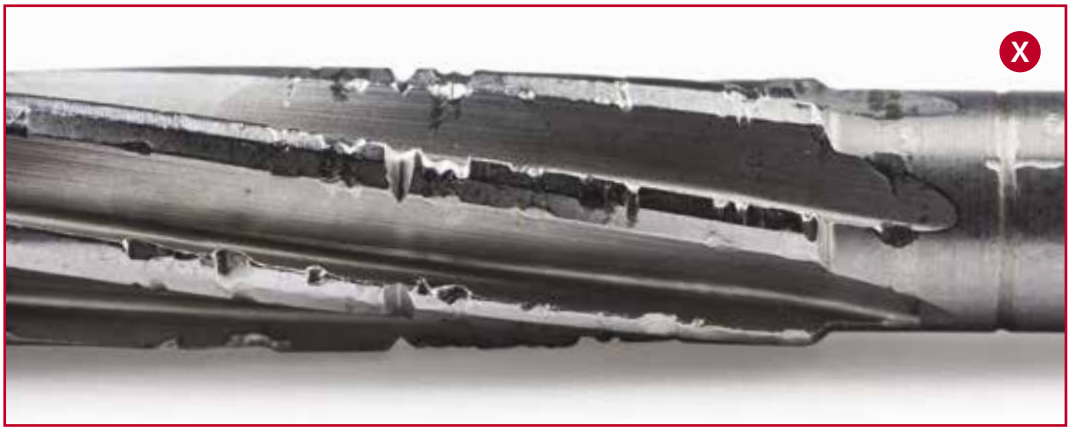


Description	Potential Effects of Wear
• Stripped external/internal threads • Damaged external/internal threads **Threading Quick Check –** *Action:* Thread the components. *Result:* If there is difficulty fastening or unfastening components, wear is present and the instrument must be returned to the manufacturer.	• Excessive torque to engage threads • Excessive torque to disengage threads • Inaccurate feedback • Inadequate engagement of components • Inadequate disengagement of components

Description	Potential Effects of Wear
• Crevice corrosion • External/Internal thread corrosion **Threading Quick Check –** *Action:* Thread the components. *Result:* If there is difficulty fastening or unfastening components, wear is present and the instrument must be returned to the manufacturer. **Pencil Eraser Quick Check –** *Action:* Rub a pencil eraser on the affected area. If the discoloration is removed by the eraser, it is a stain. *Result:* If the discoloration is not removed by the eraser or reveals pitting, wear is present and the instrument must be returned to the manufacturer.	• Inaccurate feedback • Inadequate reprocessing • Inadequate engagement of components • Inadequate disengagement of components • Inadequate removal of bone, soft tissue, or bone cement to a specific/nonspecific shape • Excessive torque to engage threads • Excessive torque to disengage threads

SURFACE DAMAGE

Description	Potential Effects of Wear
• Scratched • Damaged surface **Fingernail Quick Check –** *Action:* Slide fingernail on the surface. *Result:* If the nail is obstructed/resisted, wear is present and the instrument must be returned to the manufacturer.	• Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Contact unintended soft tissue or bone • Inadequate accommodation of hand use • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing • Inadequate force applied



Description	Potential Effects of Wear
• Nicked • Dented • Chipped **Fingernail Quick Check –** *Action:* Slide fingernail on the surface. *Result:* If the nail is obstructed/resisted, wear is present and the instrument must be returned to the manufacturer.	• Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Contact unintended soft tissue or bone • Inadequate accommodation of hand use • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing • Inadequate force applied

Description	Potential Effects of Wear
• Burr **Fingernail Quick Check –** *Action:* Slide fingernail on the surface. *Result:* If the nail is obstructed/resisted, wear is present and the instrument must be returned to the manufacturer.	• Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Contact unintended soft tissue or bone • Inadequate accommodation of hand use • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing

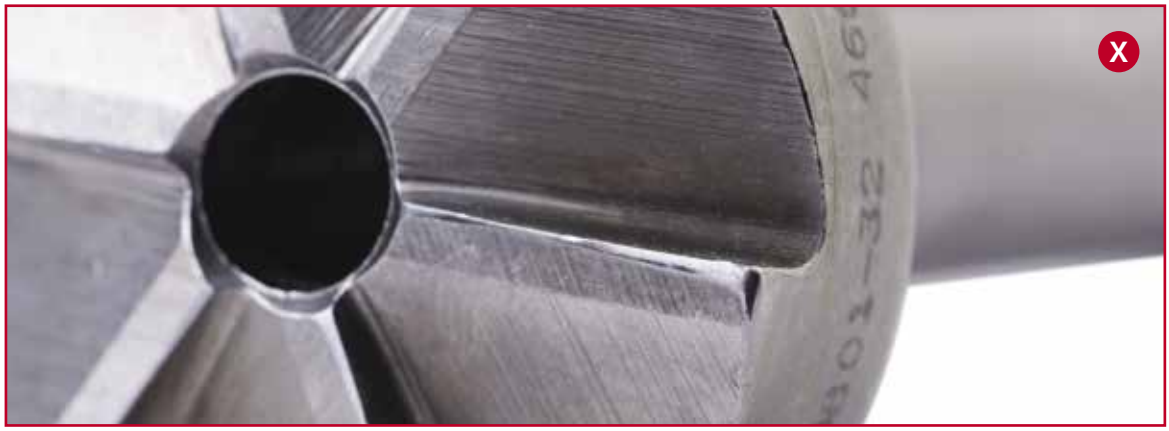
Description	Potential Effects of Wear
• Gouged • Scratched • Dented	• Inaccurate feedback • Inadequate accommodation of hand use • Inadequate engagement of components • Inadequate disengagement of components • Inadequate reprocessing

Fingernail Quick Check –
Action: Slide fingernail on the surface.
Result: If the nail is obstructed/resisted, wear is present and the instrument must be returned to the manufacturer.

Description	Potential Effects of Wear
• Loss of coating	• Inaccurate feedback • Inadequate removal of bone, soft tissue, or bone cement to a specific/non-specific shape • Inadequate reprocessing • Inadequate force applied

Description	Potential Effects of Wear
• Stripped drivers	• Inaccurate feedback
• Rounded edges	• Inadequate engagement of components
	• Inadequate disengagement of components
	• Inadequate reprocessing
	• Inadequate force applied

Description	Potential Effects of Wear
• Damaged cutting edges	• Inadequate removal of soft tissue, bone, or bone cement to a specific/non-specific shape • Excessive force to remove soft tissue, bone, or bone cement • Inadequate accommodation of soft tissue or bone



Description	Potential Effects of Wear
• Damaged cutting edges	• Inadequate removal of soft tissue, bone, or bone cement to a specific/non-specific shape • Excessive force to remove soft tissue, bone, or bone cement • Inadequate accommodation of soft tissue or bone

Notes

Notes

Notes

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EC REP **Authorized Representative**
Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP
UK

Legal Manufacturer
Biomet Sports Medicine
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet Trauma
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet Biologics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana 46580
United States

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