

Reusable Instrument Lifespan Manual



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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. This document is provided in conjunction with the cleaning and sterilization instructions for reusable instruments. For additional reusable instrument instructions, see the Instructions For Use for Biomet 3i Kits and Instruments (Doc No. P-ZBDINSTRP). For Zimmer Dental reusable instruments Instructions for Use, refer to labeling.zimmerbiomet.com.

Scope

This manual provides information applicable to the reusable instruments used to place and restore dental implants and accessories. This information is NOT APPLICABLE to instruments labeled as single use (sterile and non-sterile). Devices labeled “for single use only” must not be reprocessed for re-use as they are not designed to perform as intended after the first usage. When single-use devices are supplied non-sterile and require sterilization before use, the appropriate sections of the Instructions for Use may be applied unless other specific instructions are provided in the package insert. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use and/or cleaning and re-sterilization release.

Glossary

Condition – 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.

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 re-use.

Understanding Document Structure

This manual describes several types of wear including:

- | | |
|---------------------------|-------------------------|
| I. Bending | V. Discoloration |
| II. Surface Damage | VI. Corrosion |
| III. Dull Edges | VII. Fracture |
| IV. Color Coding | |

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

- **Images** representing the condition category to which it belongs. Images are only a representation of possible wear and/or damage.
- **Descriptions** of the condition shown in the image and content specific to the condition.
- **Potential Effects of Wear** on any reusable instrument specific to the condition 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



Not Suitable for Use

Inspection/Function Testing

After cleaning and prior to sterilization, reference this manual and follow the instructions below.

1. Instruments should be inspected for function.
2. Inspection includes:
 - a. Inspecting for all forms of wear outlined in this manual. Generally un-magnified, visual inspection under good light conditions is sufficient.
 - b. Functional check should be performed, where possible.
3. 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 this manual, the instrument should be replaced.

Prior to sterilization, inspect instrument kit tray and its components for wear and damage such as bending, bowing and warping as these may lead to:

- Insufficient function of handles and lids
- Can allow free travel of contents
- Interference between case components and contents
- Inadequate reprocessing
- Inadequate engagement of components
- Inadequate disengagement of components

If the kit tray is determined no longer suitable for use or if the suitability for use is still in question after inspection, the kit tray should be replaced.

Note: Zimmer Biomet Dental does not specify the maximum number of uses appropriate for re-use. The useful life of the reusable instrument depends on many factors including the method and duration of each use as well as the handling between uses.

Returning the Reusable Instrument(s)

If a complaint is made related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device at any other time for any reason outside of the scope of this manual, please complete and submit a Product Experience Report (CF04001) which can be found on zimmerbiometdental.com and return the reusable instrument(s) to Zimmer Biomet Dental for investigation.

Straight Osteotome



Angled Osteotome



Description

- Bent
- Kinked
- Crooked

Potential Effects of Wear

- Inadequate force applied
- Unintended contact with soft tissue or bone
- Inaccurate feedback
- Inadequate compression of bone
- Incorrect angle



Description

- Bent
- Kinked end
- Crooked/uneven end
- Blunt/dull tip

Potential Effects of Wear

- Inadequate force applied
- Unintended contact with soft tissue or bone
- Inaccurate feedback
- Inadequate compression of bone/bone graft
- Potential to fracture or split bone

Bent Direction Indicator/Paralleling Tool



Description

- Bent
- Crooked/uneven end

Potential Effects of Wear

- Inaccurate feedback
- Potential to fracture or split bone



Description

- Rounded edges
- Blunt/dull edges

Potential Effects of Wear

- Inaccurate feedback
- Unable to engage intended tissue
- Inadequate force applied

Rounded Hex

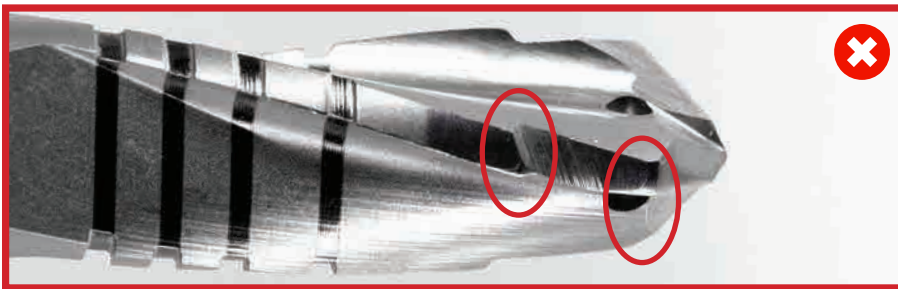


Description

- Rounded Hex/tip
- Blunt/dull edges

Potential Effects of Wear

- Inaccurate feedback
- Unable to engage intended component
- Ingestion/aspiration



Description Potential Effects of Wear

- Blunt/dull edges

- Inadequate cutting/under prepared osteotomy



Description

- Paint chips
- Coating peeling/flaking

Potential Effects of Wear

- Wrong size instrument selected
- Inadequate reprocessing



Description

- Coating chips
- Coating peeling/flaking

Potential Effects of Wear

- Possible dull cutting edges
- Inadequate cutting/under prepared osteotomy



Description

- Corrosion
- Contamination
- Illegible marking

Potential Effects of Wear

- Illegible product markings
- Wrong size instrument selected
- Irritation/infection
- Inadequate reprocessing
- Permanent viral infection



Description

- Discolored product markings
- Illegible marking
- Faded marking
- Deterioration

Potential Effects of Wear

- Illegible product markings
- Wrong size instrument selected
- Incorrect sequence is followed, if applicable



Description

- Surface corrosion
- Pitting
- Rust

Potential Effects of Wear

- Inaccurate feedback
- Inadequate reprocessing
- Inadequate compression of bone or bone graft
- Wrong size instrument selected
- Permanent viral infection
- Irritation/infection



Description

- Discolored product markings due to corrosion
- Corrosion
- Pitting
- Contamination
- Illegible marking

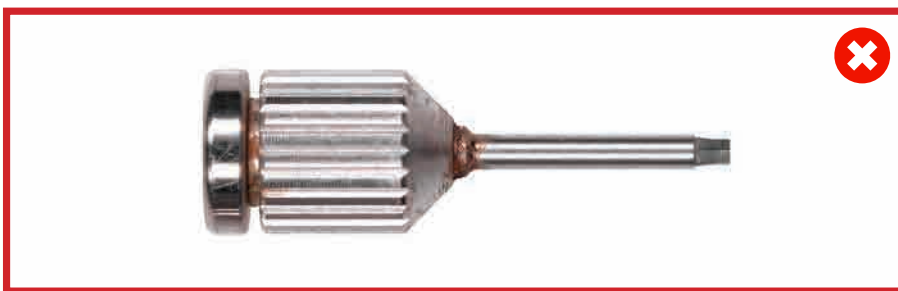
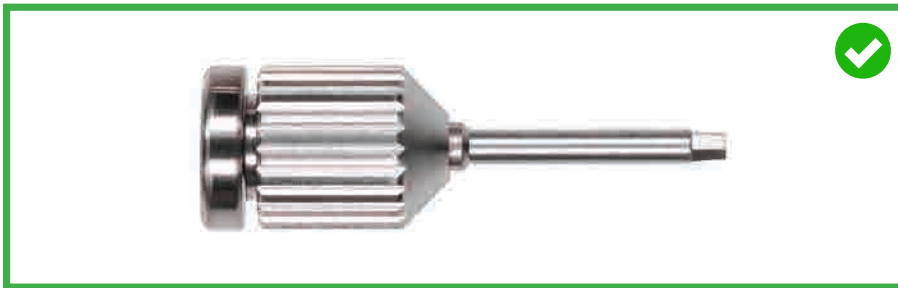
Potential Effects of Wear

- Illegible product markings
- Wrong sized instrument selected
- Irritation/infection
- Inadequate reprocessing
- Permanent viral infection

Corrosion Burr



Corrosion Driver



Description

- Surface corrosion
- Pitting
- Rust

Potential Effects of Wear

- Inadequate reprocessing
- Permanent viral infection
- Irritation/infection



Description

- Fractured
- Broken
- Chipped

Potential Effects of Wear

- Inadequate feedback
- Inadequate force applied
- Bone fracture and/or splitting
- Ingestion/aspiration/foreign body reaction



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Contact us at 1-800-342-5454 or visit

zimmerbiometdental.com

Zimmer Biomet Dental
Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Tel: +1-561-776-6700
Fax: +1-561-776-1272



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