**Manufacturer:**
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# INSTRUCTION FOR USE OPL LLC Toolkit

EN

- Please read this document carefully before using the product
- Follow the safety instructions to avoid injuries
- Document is only for general information, please read document "Installation instructions" for full instructions

## 1. Introduction

Before using the OPL LLC Toolkit (also known as Sleeve Extractor Toolkit, reference 1009043), study the following recommendations, warnings and instructions carefully, as well as the product-specific information (Operational Manual). The manufacturer does not accept liability in the case of non-compliance with this package insert.

## 2. Product Descriptions

### 2.1 General

The OPL LLC Toolkit is used to assemble and disassemble the OPL System Components. It is used outside the operation theatre by end users, including patients and prosthetists, in ways prescribed in the Operational Manual. Compatible product groups are:

- OPL-FIF Stems
- OPL-TIF Stems
- OPL-DCA
- OPL-LLC-M8
- OPL connector
- GV connectors
- OPL-LLC-M10 connectors
- Permedica OPL stems and dual cones
- AQ Implant stems, dual cones and connectors

### 2.2 Indications/contraindications for Use

**A. Indications**

- This product is to be used to assemble and disassemble various composition of OPL System Components, including the GV connector.

**B. Contraindications**

- Do not use the toolkit with products other than the compatible product groups as described under 1.0 of this IFU.

### 2.3 Directions for Use

- Two persons are needed to properly assemble and disassemble the components.
- The device should only be used outside the operating theatre. Whenever it is used inside the operating theatre, handling and cleaning instructions of the Osseointegration International OSIS kit should be followed.
- Ensure grease is available when planning to remove the taper sleeve. It should be applied to the thread of the extractor screw to avoid cold welding of the thread.

### 2.4 Parts included

- 1x Taper sleeve extractor body M14 (1000164)
- 1x Taper sleeve extractor shaft M14 (1000165)
- 4x Handles for Holders/Extractor M10 (1000170)
- 1x Taper sleeve holder grub screw (1000147)
- 1x Taper sleeve holder (1000168)
- 1x Allen key 4mm (0500420)
- 1x Allen key 5mm (0500425)
- 1x Allen key 6mm (0500421)
- 1x Allen key 8mm (0500422)
- 1x Case (1000174)

### 2.5 Installation and maintance instructions

Please read the illustrated assembly/disassembly instruction as provided in the Operational Manual before using the OPL LLC Toolkit.

### 2.6 Regular use

The toolkit can be used until there are clear signs of wear. A longer lifetime is ensured with the regular use of grease on the thread of the excrator screw.

## 3. Warnings

### 3.1 Precautions

- Ensure all parts are readily available.
- Always use grease on the thread of the extractor screw when operating the toolkit.
- Do not use the device whenever it appears damaged or shows wear. Inspect the product before and after each use.
- A second person should be available to assist during the procedure. This person should be strong enough to tightly hold the handles, providing a counter-rotational torque of the patients leg and/or stem.
- Never use extensive force when tightening the components. Maximum torque per step of the procedure is specified within the Operational Manual.

### 3.2 Cleaning

- Clean the product with a damp cloth.
- Dry the product with a soft cloth.
- Allow to air dry to remove residual moist.
- Apply grease to the extractor screw.

### 3.3 Environmental conditions

**A. Allowable user conditions:**

- Temperature range for use: -10 °C to +60 °C.
- Allowable relative humidity 0% till 94%, non-condensing.
- Dust, sand allowable when regularly torque testing is perfomed, according to 2.5 service life.

**B. Allowable conditions for transport:**

- Temperature: -40 °C to +60 °C.
- Allowable relative humidity: 0% till 94%, non-condensing.

**C. Unallowable conditions:**

- Mechanical vibrations or impacts.
- Perspiration, urine, salt water, acids, chlorination.

### 3.4 Disposal

This product may not be disposed of with regular waste.

## 4. Additional information

### 4.1 Warranty

The 12-month warranty of the OPL LLC Toolkit commences from the day purchase. The warranty covers defects that are the result of flaws in the material, production or construction. The warranty shall cover repair or replacement at no charge, but at the discretion of the manufacturer. To make use of the warranty, please return the toolkit to the manufacturer or authorized representative through which the device was bought.

The warranty is only valid when product has always been used in line with this IFU and the Operational Manual.

### 4.2 Adverse events or incidents

Please report any adverse events to the legal manufacturer or a local authorized representative.

When a serious incident occurred in relation to the device, please contact Manufacturer, and the competent authority of the member state (EU) where the user/patient is established. See link for relevant competent authority: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

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For determination whether a incident should be reported, see vigilance guidance documentation of the European Union: MEDDEV 2.12/1 rev.8 or link for guidance documents: **https://ec.europa.eu/docsroom/documents/32301 reporting form: https://ec.europa.eu/docsroom/documents/41681**

**4.3 Symbols used**

 Symbol for «Manufacturer»

 Symbol for «Date of Manufacturing»

 Symbol for «Consult instructions for use»

 Symbol for «Caution»

Symbol for «Non-Sterile»

 Symbol for «Do not use if package is damaged»

Symbol for «Catalogue number»

Symbol for «Batch code»

 Symbol for «Conformity according to the applicable European directive»

Symbol for «medical device, indicates the item is a medical device»

Symbol for «Unique Device Identifier»

Symbol for «UK Conformity Assessed»