



ADDITIONAL INSTRUCTIONS FOR GV18 OFFSET PLATE 40-50MM EN

- This document should always be read in conjunction with the general GV18 instructions for use, to which this is an addition.
- Please read this document carefully before using the product.
- Follow the safety instructions to avoid injuries.

0. Introduction

Before using the GV18 and accessories study the following recommendations, warnings and instructions carefully, as well as the general GV18 instructions for use and the product-specific in depth installation manual. The manufacturer does not accept liability in the case of non-compliance with these instructions. This includes but shall not be limited to the following cases;

- assembling this device with components, other than recommended by the manufacturer.
- using instrumentation other than recommended by staff of OsseoIntegration or appointed distributors.

1. Product Descriptions / Materials

1.0 General

The GV18 OFFSET PLATE 40-50MM is an addition to the GV18 to increase the achievable amount of offset.

1.1 Indications/contraindications for Use

A. Indications

- This product is to be used solely in combination with the GV18 in cases the standard offset is not sufficient.

B. Contraindications

- Please refer to the GV18 IFU.

1.2 Directions for Use

- The fitting of this device to a patient may only be carried out by an orthopaedic technician.
- The fitting of the device may only be carried out after proper instruction.
- Inspect the product every 30 days to ensure safe use.
- As the bolts used are not stainless steel, additional care should be taken to avoid corrosion (rust). In case corrosion does occur, replace the bolts.

1.3 Description of the device

- Please refer to **Figure 1** in Annex I on the next page.
- Note there are two different bolts: 014C4014 (item 2) and 1000201 (item 4).
- The bolts 014C4014 (item 2) are positioned upside down.
- All bolts should be used in conjunction with the 0500219 NORD-LOCK rings (item 3) **EXCEPT** the middle 1000201 bolt (item 4).

2. Warnings

2.1 Cleaning

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

2.2 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 performed, 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, acids, chlorination.

2.3 Service life

- The device service level is 2 years.
- The bolts should be replaced whenever visible corrosion occurs.

2.4 Disposal

This product may not be disposed of with regular waste.

3. Additional information

3.1 Warranty

The 24-month warranty of the adapter commences from the day of the initial fitting. 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.

The warranty is only valid were product has been installed by an certified and trained orthopaedic technician.

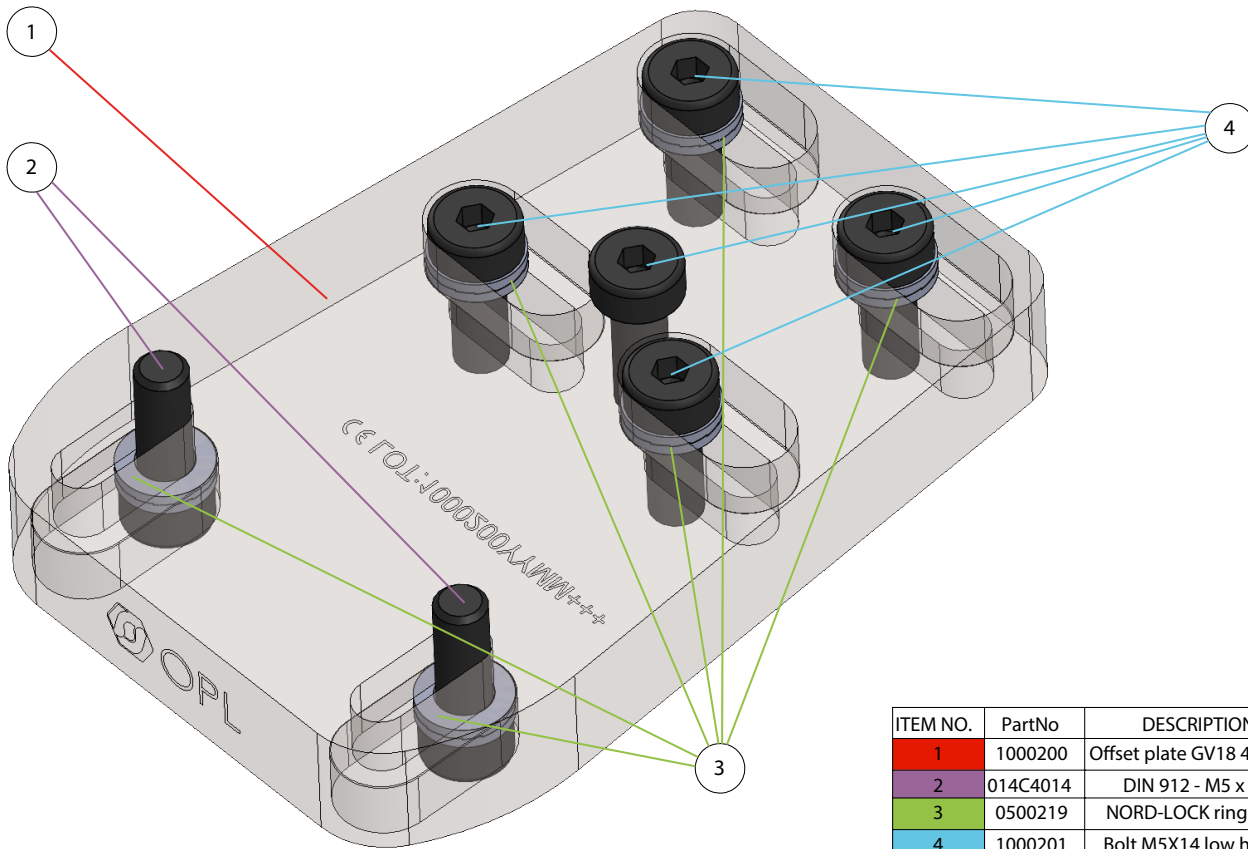
Products excluded from warranty:

- 014C4014 : DIN 912 - M5 x 14
- 0500219 : NORD-LOCK ring m5
- 1000201 : Bolt M5X14 low head



ANNEX I to

ADDITIONAL INSTRUCTIONS FOR GV18
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ITEM NO.	PartNo	DESCRIPTION	Default/QTY.
1	1000200	Offset plate GV18 40-50	1
2	014C4014	DIN 912 - M5 x 14	2
3	0500219	NORD-LOCK ring m5	6
4	1000201	Bolt M5X14 low head	5

▫ **Figure 1**