



opt-on® 2.7/3.3 TTL

Instructions for Use

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SDDI inside

1. DEAR CUSTOMER

1.1. Prologue

The product that you have purchased – the **opt-on^{2.7}/opt-on^{3.3}** is state-of-the-art technology and has been produced in accordance with the strictest quality criteria. As we are constantly developing our products further, it is possible that the illustrations and drawings in this document may differ slightly from the product that you have purchased.

These instructions contain an exact description and explain how to use the **opt-on^{2.7}/opt-on^{3.3}**. If you have any additional questions or ideas, we would be pleased to help you by telephone or by email.

These instructions accompany the **opt-on^{2.7}/opt-on^{3.3}**. Please keep them to hand. If you pass this product on to a third party, please give them this document too as it contains important information on commissioning and handling the product.

Please use these instructions to familiarize yourself with the product before you use it during treatment.

1.1.1. Responsibility of the Manufacturer

The **opt-on^{2.7}/opt-on^{3.3}** is manufactured in accordance with the state-of-the-art technology and the recognized safety-related rules and regulations.

orangedental GmbH & Co. KG [hereafter referred to as orangedental] only considers itself responsible for the effects on safety, reliability and performance of the device, if:

- >> Assembly, add-ons, readjustments, alterations or repairs are only carried out by persons authorized by orangedental,
- >> the device is used in accordance with the instructions for use.

1.1.2. Responsibility of the Operator

Among other things, the operator is responsible for:

- >> adherence to the accident prevention regulations as well as the regulation concerning the installation, operation and use of active medical products (German regulation MPBetreibV).
- >> the operation.
- >> the maintenance.

- >> the proper and safe condition of the product.
- >> the storage of the instruction manual at the location of use.
- >> following the safety instructions contained in these instructions (see chapter 1.3: Conventions, Symbols Used).

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1.3. Conventions, Symbols Used

In these instructions, the conventions set out below indicate important information:

WARNING: This symbol is used if deviating from the procedure described can lead to physical injury or death.



CAUTION: This symbol is used if deviating from the procedure described can lead to damage to the product or to loss of data.



IMPORTANT: The usage of the term **IMPORTANT**, formatted in bold capitals, provides instructions about the use of the device or a process.

Note: Notes are used to highlight important or unusual points.

The meaning of the symbols, which are used on this product, its packaging or in these instructions, is listed below.

CHECK INSTRUCTIONS

This symbol indicates that this user manual contains important, mandatory instructions which must be followed to comply with the safety standards for the medical product.



ATTENTION

This symbol indicates that there are warnings or regulations concerning the product which are not specified on the label. It advises the reader to consult the accompanying documents.



MANUFACTURER

This symbol is used in order to display the name and address of the manufacturer of the medical product.



DATE OF MANUFACTURE

This symbol indicates the date of manufacture.



UDI-DI

This symbol indicates the UDI-DI number and the GTIN.



SERIAL NUMBER

This symbol is used to indicate the serial number.



MEDICAL DEVICE

This symbol is used to indicate that the product is a medical device.



CE MARKING

This symbol, attached by the manufacturer, indicates that the medical product is in conformity with and fulfills all requirements of the medical device regulation (EU) 2017/745.



2. ABOUT THE PRODUCT

2.1. Intended Use

The loupe **opt-on^{2.7}/opt-on^{3.3}** is solely used to support the visual inspection / to survey findings/ to aid in treatment by dental professionals using optical magnification in a dental treatment room. There are no known contraindications for the use of the magnifying glasses. There are no restrictions regarding the intended patient group.

2.2. System Components

| | |
|---|---|
| Loupe Incl. one pair of Varioclips for the needed working distance | lup0499000 (2.7) resp. lup0499100 (3.3) |
| lanyard | 00.001.934 |
| micro fiber tissue | zub0498210 |
| Box | zublup0499290 |
| manual | 00.000.527 |



2.3. Accessories/ Spare Parts

All parts can be ordered at your dealer or [orangedental](http://orangedental.com).

2.3.1. Spare Parts Loupe Frame

| Frame | No. frame | No. right temple | No. left temple | No. frame front |
|--|------------|------------------|-----------------|-----------------|
| frame A (164) <i>size: L; color: white</i> (6554) | 00.002.013 | 00.002.283 | 00.002.327 | 00.002.248 |
| frame A (165) <i>size: S; color: white</i> (6554) | 00.002.024 | 00.002.294 | 00.002.338 | 00.002.226 |
| frame A (164) <i>size: L; color: glossy black</i> (6550) | 00.002.035 | 00.002.261 | 00.002.305 | 00.002.250 |
| frame A (165) <i>size: S; color: glossy black</i> (6550) | 00.002.046 | 00.002.272 | 00.002.316 | 00.002.237 |
| frame A (170) <i>size: L; color: clear</i> (6053) | 00.004.263 | 00.005.051 | 00.007.367 | 00.006.063 |
| frame A (171) <i>size: S; color: clear</i> (6053) | 00.004.195 | 00.005.062 | 00.004.948 | 00.006.074 |

| Frame | No. frame | No. right temple | No. left temple | No. frame front |
|--|------------|------------------|-----------------|-----------------|
| frame A (164) <i>size: L; color: brown (former copper matt) (6051)</i> | 00.004.296 | 00.005.073 | 00.004.950 | 00.006.085 |
| frame A (165) <i>size: S; color: brown (former copper matt) (6051)</i> | 00.004.230 | 00.005.084 | 00.004.961 | 00.005.872 |
| frame A (164) <i>size: L; color: red (6064)</i> | 00.004.285 | 00.005.095 | 00.004.972 | 00.006.096 |
| frame A (165) <i>size: S; color: red (6064)</i> | 00.004.228 | 00.005.106 | 00.004.983 | 00.006.107 |
| frame A (164) <i>size: L; color: black matt (6071)</i> | 00.004.274 | 00.005.117 | 00.004.994 | 00.004.871 |
| frame A (165) <i>size: S; color: black matt (6071)</i> | 00.004.217 | 00.005.128 | 00.005.005 | 00.004.882 |

| Description | No. |
|--------------------------------------|---------------------------------|
| hinge right | 00.002.340 |
| hinge left | 00.002.351 |
| Pads Euro (1pair) | 00.002.362 |
| Pads Asia (1 pair) | 00.006.120 |
| 1 pair protection lenses with ocular | individual |
| 1 pair Varioclips | working distance 250 mm=10 inch |
| 1 pair Varioclips | working distance 300 mm=12 inch |
| 1 pair Varioclips | working distance 350 mm=14 inch |
| 1 pair Varioclips | working distance 400 mm=16 inch |
| 1 pair Varioclips | working distance 450 mm=18 inch |
| 1 pair Varioclips | working distance 500 mm=20 inch |

2.3.2. Accessories

| Description | No. |
|---|---------------|
| lanyard | 00.001.934 |
| box | zublup0499290 |
| micro fiber tissue | zub0498210 |
| clip in prescription adapter | zublup0499100 |
| clip in prescription adapter for long eye lashes | zublup0499101 |
| individual prescription lenses for clip in prescription adapter | zublup0499250 |
| Protect-on face shield complete system incl. 10 face shields | lup0499300EN |

3. INDIVIDUAL FITTING

Your **opt-on**^{2.7}/**opt-on**^{3.3} has been produced individually for your interpupillary and working distance. You can take the following additional fittings:

3.1. Fitting of Nose Pads

There are two different nose pad positions:

>> click in: loupe position high



>> click out: loupe position low



3.2. Inclination

There are three inclination positions. You can change the inclination of your loupe or compensate different height of ears.



3.3. Mounting of Lanyard

You can use your loupe with or without lanyard. The lanyard can be slid over the earpiece. By tightening the lanyard you achieve weight relief for your nose.

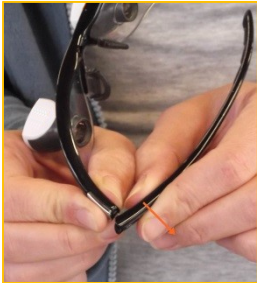


4. INSTALLATION OF EXPENDABLE PARTS AND ACCESSORIES

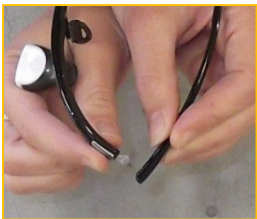
If your loupe needs to be repaired, you can send the loupe to your dealer or orangedental. Often it is possible just to order the spare parts and mount the parts on your own, to save time and money. You can also change the Varioclips to change the working distance.

4.1. Change the Temple

Retract the temple and hold it as shown at the picture.



Push the temple.



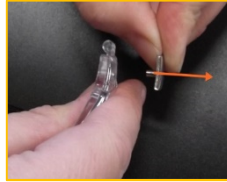
To mount the new temple, just press it to the hinge.

4.2. Change the Hinge

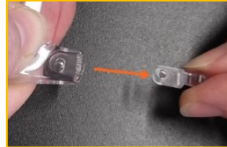
Remove the temple (see section 4.1: Change the Temple)
Push a solid, pointed tool (e.g. little screw driver) against the small silver round area.



Push the part outside



Remove the broken hinge.



To mount the new hinge, do the same procedure in reverse order.

Important: The hinge for the right side is marked with R, the hinge for the left side is marked with L.

The right temple is placed at the right ear!
The letters R and L need to face inside the loupe.



4.3. Change of Varioclips

If changing the working distance of your loupe is necessary, please contact your dealer to order Varioclips for the needed working distance. Mounting of the new Varioclips is easy. Just follow the written steps:

Remove the Varioclips. Just slide your fingernail or the added enclosed tool between the white and grey/black part.



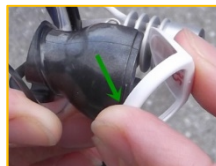
Slide until you hear CLICK and the Varioclip removes.



Take the Varioclip away.



Pose the new one at the bottom of the ocular.



Slightly push the orangedental logo on the upper side of the clip until you hear CLICK.



5. SAFETY, SERVICING AND MAINTENANCE

IMPORTANT: Please read safety instruction **opt-on^{2.7}/opt-on^{3.3}**

IMPORTANT: Please read manual attentively.

ATTENTION: When wearing the loupes do not look directly at the sun or any other bright light source to avoid injuries of your eyes.



ATTENTION: Do not leave the loupe where it is exposed to direct sunlight as this could lead to a fire.



ATTENTION: Do not use that loupe when working with laser light.



IMPORTANT: Do not use the loupe when the working area needs to be sterile.

IMPORTANT: Check that the loupe strap is fastened carefully before use.

IMPORTANT: Please note that your field of vision is restricted, while wearing the loupe and walking around.

5.1. Cleaning

Clean the loupes and eyepieces carefully using a micro fiber cloth. For coarse dirt, moisten the cloth with alcohol or water, and scrub the dirt off gently.

Note: Please clean the **opt-on^{2.7}/opt-on^{3.3}** immediately after use to prevent that blood or protein residues coagulate.

CAUTION: Only clean the loupe if the Varioclips are installed. Do not expose the plastic lens to any liquid as it could scratch the lens when drying it.



CAUTION: Only use soft cloths for cleaning and disinfecting. Do not use sharp or scratching objects.



5.2. Disinfection

CAUTION: Do not submerge the loupe **opt-on^{2.7}/opt-on^{3.3}** in water, sterilization, or other cleaning liquids. The loupe **opt-on^{2.7}/opt-on^{3.3}** is not waterproof.



CAUTION: Do not use aggressive solvents.



CAUTION: Any sterilization (autoclave/chemical clave procedures, iodinated agents or other proceedings) is not possible.



5.2.1. Disinfection Agents for **opt-on^{2.7}/opt-on^{3.3}**

The best way to disinfect your **opt-on^{2.7}/opt-on^{3.3}** is using a medically approved disinfection wipes, offering a broad spectrum of activity against bacteria, fungi and viruses e.g. disinfection wipes:

- Schülke kodan wipes [100g agent solution contain 30g Propan-2-ol and 30g Propan-1-ol]
- Schülke mikrozyd AF wipes [100g agent solution contain 25g Ethanol and 35g Propan-1-ol]

5.3. Disposal

Die **opt-on^{2.7}/opt-on^{3.3}** can be disposed with the normal waste.

6. SPECIFICATIONS AND CONFORMITY



orangedental GmbH & Co. KG
 Aspachstrasse 11 | 88400 Biberach / Riss



6.1. Requirements regarding the Practice Environment

Important: The loupe **opt-on^{2.7}/opt-on^{3.3}** is solely used to support the visual inspection / to survey findings / to aid in treatment by dental professionals using optical magnification in a dental treatment room.

6.2. Technical Data

6.2.1. Loupe Data

| | | | | | | |
|------------------|--|---------|---------|---------|---------|---------|
| magnification | 2,7x / 3,3x | | | | | |
| Working distance | 25 cm | 30 cm | 35 cm | 40 cm | 45 cm | 50 cm |
| | 10 inch | 12 inch | 14 inch | 16 inch | 18 inch | 20 inch |
| | The working distance of your loupe is written on your loupe ID card | | | | | |
| Ocular distance | The distance between the oculars has been calculated for your pupil and working distance | | | | | |
| weight | 32 gram | | | | | |

6.2.2. Ambient Conditions

Operation and Storage:

Temperature: +10°C to +40°C
 Rel. humidity: 25 to 75%
 Air pressure: 700 hPa to 1060 hPa

Transport

| | |
|----------------|---------------------|
| Temperature: | -40°C to +60°C |
| Rel. humidity: | 10 to 90% |
| Air pressure: | 500 hPa to 1060 hPa |

6.2.3. Conformity with Standards

Classification according to Regulation (EU)2017/745 I

