

Field Safety Notice

Optergo ProSpec™ eyeglasses, Optergo PrismSpec™ eyeglasses, Optergo Ultralight™ Flip-up loupes, Optergo Ultralight™ TTL loupes, Optergo VinKep™ loupes, Optergo KepLite™ loupes

This field safety notice concerns users of the abovementioned optical solutions manufactured by Optergo. Users of Optergo PrismSpec™ eyeglasses and Optergo Ultralight™ Flip-up loupes with prism lenses, who have received their devices during the period of May 2022 – March 2023, are concerned by special instructions (see *Actions to reduce the risk*).

Contact details

Contact details of local distributor:

Name: <Please add details here>
Contact person: <Please add details here>
E-mail: <Please add details here>
Telephone: <Please add details here>
Address: <Please add details here>

Contact details of the manufacturer:

Name: Optergo AB
Contact person: Per Johan Pettersson
E-mail: perjohan@optergo.com
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Address: Furuhällsvägen 1
435 44 Mölnlycke, Sweden

Affected devices

Commercial name and device models:

- Optergo ProSpec™ eyeglasses
- Optergo PrismSpec™ eyeglasses
- Optergo Ultralight™ Flip-up loupes
- Optergo Ultralight™ TTL loupes
- Optergo VinKep™ loupes
- Optergo KepLite™ loupes

Device type and intended purpose: The devices affected by this field safety notice are of the types eyeglasses with or without prism lens, and eyeglasses with or without flip-up loupes or through-the-lens (TTL) loupes. The devices are intended to be used by medical professionals or lay persons for providing magnification (when including loupes), visual acuity and an ergonomically enhanced working position.

Affected manufacturing dates: All models and manufacturing dates are affected by the part of the field safety notice that concerns an update of the instructions for use (IFU). The part that specifically concerns Optergo PrismSpec™ eyeglasses and Optergo Ultralight™ Flip-up loupes with prism lenses affects devices with delivery date from the manufacturer during the period May 2022 – March 2023.

Reason for the Field Safety Notice

Background and description of the device problem: The lenses in all Optergo optical solutions are kept in place in the eyeglass frames by a screw clamping the frames around the lens. As with all eyeglasses, these screws may after some time start to unscrew because of movements during use, when the eyeglasses are taken on and off, due to uncareful handling etc. If the screws would loosen completely there is a risk that the lenses come loose and fall out from the frame. To prevent this from happening, Optergo provides a tool with all devices, to be able to check and retighten screws regularly. It has however not been clear enough in the IFU how and when this tool shall be used.

In addition to the above, a glue (Loctite) is used in the manufacturing of Optergo products, to further mitigate the risk of the screws loosening. It has come to the knowledge of Optergo that the subcontractor who mounts the glasses in Optergo PrismSpec™ eyeglasses and Optergo Ultralight™ Flip-up loupes with prism lenses, during a period has been using an expired glue in manufacturing, which has caused the glue to not achieve its intended effect. The problem was discovered after an incident where a prism lens fell out from a user's frames.

Hazard giving rise to the field safety notice: Without regular maintenance and retightening of the screws, as well as with inadequate gluing of the screw, the risk for the screw unscrewing from its threads after a period of use increases. This could in a worst case scenario lead to the lens falling out from the eyeglass frame and potentially causing harm to a patient hit by the lens.

Actions to reduce the risk

Actions to be taken by the user:

- Read through the attached updated instructions for use carefully and check the screws on your eyeglasses regularly according to current instructions.
- For users who have received Optergo PrismSpec™ eyeglasses or Optergo Ultralight™ Flip-up loupes with prism lenses during the above-defined period, the following also applies: Check the screw using the tool that was provided when you bought the device, as described in the updated instructions for use. Carefully try to turn the screw counterclockwise. If you feel a resistance, the screw is glued as it should be and you do not need to do anything else. Do not apply excessive force, since this may pull out the screw even if it is glued.

Is a reply required from the user?

- No reply is required regarding the updated instructions for use. Contact your local distributor if you have any questions.
- For users who have received Optergo PrismSpec™ eyeglasses or Optergo Ultralight™ Flip-up loupes with prism lenses during the above-defined period, the following also applies: If you feel a resistance the screw is properly glued, and you do not need to reply or do anything else. If you do not feel a resistance and the screw can easily be untightened, contact your local distributor to have the problem corrected.

Actions taken by the distributor and the manufacturer: The manufacturer has updated the attached instructions for use, and additional controls have been implemented to prevent the problem from arising in newly manufactured devices. The affected subcontractor has replaced the glue and updated their routines for manufacturing of the devices.

General information

Type of field safety notice: New

Further advice or information in follow-up field safety notice: No, no follow-up is expected.

Transmission of this field safety notice

This field safety notice shall be forwarded by the local distributor to all affected users who have received any of the devices described under *Affected devices*.

Please report all device-related incidents to the manufacturer or the local distributor, and the national competent authority if appropriate, as this provides important feedback.

The national competent authority in your country has been informed about this communication to distributors and users.

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Mölnlycke, 2023-05-02