INSTRUCTIONS FOR USE

Spectacle frames - Accessory for a medical device

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1. General information

These Instructions for Use apply to a spectacle frame intended to be combined with corrective lenses. The spectacle frame is an accessory for a medical device and is intended to hold corrective lenses in the correct position in front of the user's eyes. Before using the device, read these Instructions for Use and retain them for future reference.

2. Device name

Spectacle frames

3. Intended purpose

The spectacle frame is intended to be combined with corrective lenses. As an accessory for a medical device, it is intended to hold corrective lenses correctly in front of the patient's eyes, thereby supporting the correction of refractive errors of vision.

4. Indications for use

The device is intended for use where correction of refractive errors of the eye is required, in particular:

- myopia,
- hyperopia,
- astigmatism,
- presbyopia,
- other indications for the use of corrective lenses as determined by an ophthalmologist or optometrist.

5. Target patient population

The device is intended for:

- adults,
- children from 3 years of age,

requiring optical correction using spectacle lenses selected on the basis of a prescription issued by an ophthalmologist or a qualified optometrist.

6. Intended user

The intended user of the device is primarily a professional user, in particular:

- optician,
- optometrist,
- another person qualified to select and fit corrective lenses in accordance with the prescription and professional practice.

A lay user may purchase the spectacle frames; however, its functional selection and combination with corrective lenses should be carried out by a professional user.

7. Description of device operation

The spectacle frame constitutes a mechanical frame holding corrective lenses in the proper position in front of the user's eyes. The device operates by physically supporting the corrective lenses, which correct refractive errors by appropriately focusing or diverging light falling on the retina.

The spectacle frames is fitted by a professional user to the anatomy of the patient's face by adjusting the nose pads and temples.

8. Main components of the device

The spectacle frame may include in particular:

- frame front,
- temples,
- bridge,
- nose pads or integrated saddle bridge,
- hinges,
- temple tips.

The device is available in various design and material variants, including frames that are:

- full-rim,
- half-rim,
- rimless,

and made of:

- metal,
- plastic,
- combined materials,
- other permitted materials.

9. Instructions for safe use

1. Before use, ensure that the frame has been correctly selected and prepared by a professional user.
2. The frame shall be used only in accordance with its intended purpose.
3. The device should only be used after properly selected corrective lenses have been fitted.
4. Do not perform adjustments yourself if they could lead to damage to the frame or impair its fit.
5. In the event of loosening, deformation or damage to the device, contact an optician or another professional user.
6. The device should be put on and taken off carefully so as not to deform its structural components.
7. The device should not be used if its technical condition is questionable.

10. Contraindications

Do not use the device in the case of:

- allergy to frame materials,
- inflammation or irritation of the nose, temples, ears or eyes,
- hypersensitivity to components that come into contact with the skin,
- skin lesions at the points of contact with the frame if use may exacerbate symptoms.

11. Warnings and precautions

- Any use of the device other than its intended purpose is improper and may be dangerous for the user.
- The device should be correctly selected and fitted by a professional user.
- The user or caregiver should consult a healthcare professional if uncertain whether the device is suitable for the particular patient.

- Do not use a damaged, deformed or incomplete frame.
- Do not use the device in a manner that may cause excessive pressure, friction or unstable positioning on the face.
- If pain, irritation, skin redness, allergic reaction or other concerning symptoms occur, discontinue use and consult a professional user or a physician.
- Protect the device from moisture and excessive exposure to sunlight.
- Do not expose the frame to extreme temperatures.
- The device should be stored out of the reach of small children if there is a risk of misuse or damage.

12. Possible undesirable side-effects

Undesirable side-effects may occur during use, such as:

- contact dermatitis caused by an allergic reaction to the frame material, in particular nickel in metal alloys,
- local irritation of the skin of the nose, temples or ears resulting from pressure or friction,
- pressure sores or abrasions of the epidermis at the contact points of the nose pads or temples during prolonged improper use,
- skin reactions to residues of cleaning agents or substances coming into contact with the frame.

If an undesirable side-effect occurs, discontinue use of the device and contact a professional user or a physician.

13. Cleaning and maintenance

The frame should be cleaned with:

- a soft, lint-free cloth, preferably microfibre,
- water or a spectacle-cleaning solution.

Do not use:

- aggressive chemical agents,
- solvents,
- acetone,
- abrasive agents,
- preparations that may damage the surface of the device.

Additional recommendations:

- store the device in a protective case when not in use,
- regularly inspect the condition of hinges and components in contact with the skin,
- where necessary, seek assistance from a professional user for adjustment and maintenance.

14. Storage conditions

The device should be stored:

- at a temperature from 5°C to 40°C,
- at relative humidity below 90%,
- in a manner protecting it against mechanical damage, moisture and direct sunlight,
- preferably in a protective case or unit packaging.

15. Transport conditions

During transport, the device should be protected against:

- mechanical damage,

- moisture,
- contamination,
- excessive temperature,
- direct sunlight.

16. Device lifetime

The declared lifetime of the device is a total of 5 years, including:

- 3 years of storage,
- 2 years of use,

provided that storage, transport, use, cleaning and maintenance are carried out in accordance with these Instructions for Use.

17. Disposal

After use, the device should be transferred to selective waste collection in accordance with local recycling regulations.

It is recommended to:

- transfer metal frames to metal collection points,
- transfer plastic frames to plastic recycling,
- dispose of cardboard packaging as paper waste.

18. Incident reporting

Any serious incident related to the device should be reported to the manufacturer and to the competent national authority in accordance with applicable regulations.

WARNING

Any serious incident related to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user or patient is established.

Explanation of the symbols used in the labelling template

	Device compliant with Regulation (EU) 2017/745 on medical devices		Medical device manufacturer
	Unique catalogue number (REF)		Batch / lot number expressed as the date of manufacture (YYMMDD), where YY means the last two digits of the relevant calendar year
	Consult the Instructions for Use		Warning
	Unique Device Identifier		Medical device
	Keep dry		Keep away from sunlight

Manufacturer

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