INSTRUCTIONS FOR USE
Contact lenses
Goldmann/Diagnostics/Laser
Introduction
Thank you for choosing a HAAG-STREIT device. Provided you comply carefully with the regulations in this instructions for use, we can guarantee the reliable and unproblematic use of our product.

Purpose of use
The Haag-Streit contact Lenses are a family of diagnostic / therapeutic contact lenses used in the examination of eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

Contraindication
There is no absolute contraindication for the use of contact lenses. Appropriate professional assessment and caution are necessary.

WARNING!
Read the instruction manual carefully before commissioning this product. It contains important information regarding the safety of the user and patient.

NOTE!
Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.
Contents

1. Safety ................................................................. 4
  1.1. Areas of application ................................................ 4
  1.2. Ambient conditions ................................................ 4
  1.3. Shipment and unpacking ......................................... 4
  1.4. Operation, environment ........................................... 4
  1.5. Cleaning and disinfection of contact lenses ............... 4
  1.6. Visual inspection of the contact lenses for damage ....... 5
  1.7. Warranty and product liability ................................. 5
  1.8. Description of symbols ............................................. 6

2. Use of contact lenses .............................................. 6
  2.1. Fundamentals ...................................................... 6
  2.2. Product overview ................................................ 7
  2.3. Product description ................................................ 8

3. Direct contact lenses for diagnostic purposes ....... 9
  3.1. Contact lens 901 .................................................. 9

4. Mirror contact lenses for diagnostic purposes ... 10
  4.1. One-mirror contact lens 902/902 S ......................... 10
  4.2. Two-mirror contact lens 905/905 S ......................... 11

5. General information on three-mirror contact lenses .......... 12
  5.1. Three-mirror contact lens 903/903 S ....................... 12
  5.2. Three-mirror contact lens 630/630 L ....................... 12
  5.3. Three-mirror contact lenses for infants and children 906/906 S and 907 ............................................. 13

6. Contact lens 1210 endothelium according to Eisner ........ 14
  6.1. Using the contact lens 1210 ..................................... 14
  6.2. Locating specular reflections ................................... 14
  6.3. Examination of the specular reflections ..................... 14
  6.4. Examination of the periphery of the cornea ................ 14
  6.5. Disinfecting the contact lens 1210 ......................... 14

7. Use of oculars with reticle according to McIntyre and contact lens 1210 ............................................. 15
  7.1. Ocular 25x for HAAG-STREIT slit lamp BM 900 ................ 15
  7.2. Ocular 12.5x for HAAG-STREIT slit lamp BQ 900 .......... 15
  7.3. Estimating the cell density of the endothelium .......... 15

8. Mirror contact lenses for laser use .......................... 16
  8.1. Gonioscopy contact lens CGAL ............................. 16

9. Three-mirror contact lenses for laser use ............... 17
  9.1. 903 L and 630 L .................................................. 17
  9.2. 906 L and 907 L .................................................. 17

10. Direct contact lenses for laser use ......................... 18
  10.1. Retina contact lens CGRL .................................... 18
  10.2. Iridectomy contact lens CGIL ............................... 19
  10.3. Vitrectomy contact lens CGVL ............................. 20
  10.4. Capsulotomy contact lens CGPL ............................ 21
  10.5. Contact lens RETINA 145 L ................................. 22

11. Technical data ....................................................... 23
  A. Legal regulations .................................................. 23
  B. Classification ........................................................ 23
  C. Standards ............................................................ 23

1. **Safety**

**DANGER!**
Failure to comply with these instructions may result in material damage or pose a danger to patients or users.

**WARNING!**
These warnings must absolutely be complied with to guarantee safe operation of the product and to avoid any danger to users and to patients.

**NOTE!**
Important information: please read carefully.

1.1. **Areas of application**
Contact lenses are used in combination with a slit lamp, in doctor's practices, hospitals and universities under normal ambient conditions. The procedure requires contact with the anaesthetized eye, therefore contact lenses shall be clean and disinfected.

1.2. **Ambient conditions**

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<td>Relative humidity from 30% to 90%</td>
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1.3. **Shipment and unpacking**

* Before unpacking the contact lenses, check whether the packaging shows traces of incorrect handling or damage. If this is the case, notify the transport company that delivered the goods to you. Unpack the contact lenses together with a representative of the transport company. Prepare a report of any damaged parts. This report must be signed by you and by the representative of the transport company.

1.4. **Operation, environment**

**DANGER!**

* Never look directly into the sun with the contact lenses.
* Never use damaged contact lenses.

**WARNING!**

* Only use clean and disinfected contact lenses!
* The contact lenses may only be serviced by qualified personnel. The user is responsible for such training.
* The contact lenses may only be used in accordance with the descriptions in the "Purpose of use."
* The contact lenses must be inspected following any external force (e.g. accidental impact, dropping) and should be sent to the factory for repair if required or where possible.
* In case of eye infections or cornea injuries, the examinations should be carried out at the discretion and judgement of the medical professional, since the medical condition of the patient might be affected by the examination.

**NOTE!**

Only HAAG-STREIT accessories may be used.

1.5. **Cleaning and disinfection of contact lenses**

**DANGER!**

- Do not disinfect with alcohol
- Do not clean with acetone
- Do not disinfect using UV radiation
- Do not sterilise using steam or ethylene oxide
- Do not expose to temperatures above 60°C

* After unpacking, check the contact lenses for damage.
* Return defective contact lenses in the appropriate packaging.
* Store packaging material carefully, so that it can be used for possible returns or when moving.

WARNING!
Contact lenses are not shipped in disinfected state and must be cleaned and disinfected before their first use in accordance with the separate instructions for use on the cleaning and disinfection of tonometer measuring prisms, contact lenses and Desinset.
- Preparation may only be conducted by qualified and trained personnel. Their training is the responsibility of the user.
- Appropriate professional assessment and caution are necessary.
- The operator will be liable in the event of non-observance of the cleaning and disinfecting process!

NOTE!
- Only those disinfectants tested by HAAG-STREIT for material compatibility may be used for disinfection.
- The current list is enclosed with every contact lens and can also be found on the HAAG-STREIT AG website (www.haag-streit.com).
- The separate instructions for use on the cleaning and disinfection of tonometer measuring prisms, contact lenses and Desinset must be consulted regarding the exact mode of action, contact time and dwell time.
- Improper preparation can result in the transmission of diseases to the patient and user as well as damage to the contact lenses.
- Residue from cleaning agents and disinfectants may irritate and burn the patient’s eye.
- As a rule, the contact lenses may be treated together with each other, but not with any other products.
- In order to achieve efficient disinfection and storage of contact lenses, we recommend use of our Desinset as well as the disinfectant ‘Sekusept Forte’. This set was successfully used by the accredited testing laboratory HS System- und Prozesstechnik GmbH, 65779 Kelkheim, Germany, when validating the cleaning and disinfection processes – see separate instructions for use on the cleaning and disinfection of tonometer measuring prisms, contact lenses and Desinset.
- The validation report is available from HAAG-STREIT on request.
- A summary of the validation report can be found on the HAAG-STREIT website (www.haag-streit.com).
- The operator accepts all liability for the use of other disinfectants.

NOTE!
Contact lenses which are used with the Stery Cup need not be disinfected. Rinse the contact lens thoroughly with cold or lukewarm water immediately after use. Put a few drops of mild liquid soap (i.e. neutral pH value of 7.0) on a moistened cotton pad and gently wipe it over the contact lens in circular motions. Then rinse thoroughly with cold or lukewarm water and dry off with a lint-free cloth. The contact lens is now ready for another use with the Stery Cup.

1.6. Visual inspection of the contact lenses for damage

DANGER!
Never use damaged contact lenses.

- Inspect the contact surface of the contact lenses for contamination or damage (scratches, cracks, chips or sharp edges). To do so, it is best to use the slit lamp microscope at 10x to 16x magnification.
- Disinfectants may seep into cracks or defective sealant at the front part of the contact lenses, causing eye irritations for the patient.
- Contact lenses that have allowed condensation to penetrate to the interior may no longer be used.

1.7. Warranty and product liability

Haag-Streit products must be used only for the purposes and in the manner described in the documents distributed with the product.
- The product must be treated as described in the ‘Safety’ chapter. Improper handling can damage the product. This would void all guarantee claims.
- Continued use of a product damaged by incorrect handling may lead to personal injury. In such a case, the manufacturer will not accept any liability.
- Haag-Streit does not grant any warranties, either expressed or implied, including implied warranties of merchantability or fitness for a particular use.
- Haag-Streit expressly disclaims liability for incidental or consequential damage resulting from the use of the product.
- This product is covered by a limited warranty granted by your seller.

For USA only:
- This product is covered by a limited warranty, which may be reviewed at www.haag-streit-usa.com.
1.8. **Description of symbols**

- Read the instructions for use attentively
- European certificate of conformity
- Manufacturer
- Date of manufacture
- LOT number
- HS reference number

2. **Use of contact lenses**

**WARNING!**
It is imperative to read the “Safety” chapter and to observe its precautions before using the contact lenses.

2.1. **Fundamentals**

* A prerequisite for the successful use of contact lenses is good anaesthetisation of the cornea and conjunctiva with an agent that does not damage the corneal epithelium.

* The space between the eye and contact lens is filled with Methocel 2%, an isotonic fluid that is innocuous to the cornea and conjunctiva.
### 2.3. Product overview

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<th>Scleral flange</th>
<th>Laser</th>
<th>Mirror</th>
<th>Central (pupil)</th>
<th>Central (vitreous)</th>
<th>Mirror 66°</th>
<th>Mirror 59° (funus)</th>
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<th>Magnification(*)</th>
<th>Laser spot magnification(*)</th>
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<th>Height [mm]</th>
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<th>Antireflex coating</th>
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<th>450 – 810 nm R&lt;1%</th>
<th>1064 nm R&lt;0.3%</th>
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<td>1.24x (**)</td>
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<td>RETINA 145 L</td>
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(*) = The magnification is determined by the eye model used and the microscope. With other eye models, these values could differ. Information on the eye model used can be made available upon request.

(**) = 1mm behind the lens
2.4. **Product description**

The renowned Goldmann three-mirror contact lens is an all-rounder which allows examining the entire retina and the irido-corneal angle with the slit lamp.

**Name**

* Laser contact lenses are designated with an "L".
* Contact lenses designated with an "S" feature a special scleral flange that serves as an eyelid block.

L = Laser  
S = Scleral

**Material**

* Contact lenses for exclusively diagnostic purposes are made out of acrylic lens.
* Contact lenses for laser treatments consist of mineral lens or acrylic lens with a mineral lens with anti-reflection coating (see Table 2.3).

**Stery Cup**

* Contact lenses which are marked with the following symbol may be used in combination with Stery Cup.
3. Direct contact lenses for diagnostic purposes

3.1. Contact lens 901

This lightweight contact lens provides a direct image of the central fundus (30°). It is a lens made up of two parts: the optically-active lens with haptic, and the funnel for comfortable handling of the contact lens. The optically-active surface has a diameter of 12 mm.

Examination of the ocular fundus

Before examination with the fundus contact lens, a maximum mydriasis is desirable. Anaesthesia and positioning of the contact lens using Methocel 2%, see section ‘Fitting of contact lenses’ (chapter 2, page 6).

The patient’s eye is guided to the desired position using the fixation light, and the area to be examined is observed at 10x or 16x magnification using a narrow slit. During examination, a binocular, stereoscopic slit examination is primarily aimed for. For this purpose, the widest-possible angle between illumination and the microscope is advantageous. At the start of the examination the angle is small, and is enlarged as soon as the slit image is viewed binocularly.
4. Mirror contact lenses for diagnostic purposes

4.1. One-mirror contact lens 902/902 S

The 902 is a one-mirror lens (62°) which allows the examination of the anterior chamber.

Examination of the ocular fundus

A magnification of 10x is best for initial adjustments and 16x is best for the actual examination.

The chamber angle is illuminated with a narrow slit via the contact lens mirror. An angle of approximately 10° (lateral dwell position for the HAAG-STREIT slit lamp 900) is set between the illumination instrument and the microscope. If the angle between the microscope and the illumination instrument is larger than 15°, the slit image will no longer be sharp in the eyepiece’s normal setting.

Blurry slits at angles smaller than 15° may be corrected by altering the position of the chamber angle lens.

It is also possible to examine the lateral chamber angle sections using diffuse lighting on the scleral fold. To do so, the illumination must be removed from the centre (after loosening the centering screw on the HAAG-STREIT slit lamp 900).
4.2. Two-mirror contact lens 905/905 S
Two mirrored surfaces, each with an inclination of 62° towards the front surface, have been cut into the 17 mm long lens cone. This makes it possible to examine and compare both irido-corneal angles without rotating the contact lens.

Examination of the chamber angle
A magnification of 10x is best for initial adjustments and 16x is best for the actual examination.

The chamber angle is illuminated with a narrow slit via the contact lens mirror. An angle of approximately 10° (lateral dwell position for the HAAG-STREIT slit lamp 900) is set between the illumination instrument and the microscope. If the angle between the microscope and the illumination instrument is larger than 15°, the slit image will no longer be sharp in the eyepiece's normal setting. Blurry slits at angles smaller than 15° may be corrected by altering the position of the chamber angle lens.

It is also possible to examine the lateral chamber angle sections using diffuse lighting on the scleral fold. To do so, the illumination must be removed from the centre (after loosening the centering screw on the HAAG-STREIT slit lamp 900).
5. **General information on three-mirror contact lenses**

The Goldmann three-mirror contact lens allows the examination of the entire retina and the irido-corneal angle with the slit lamp.

**Zone 1** = Lens (1) Examination of the ocular fundus in the 30°-zone, mostly with a magnification of 10x

**Zone 2** = Mirror (2) with an inclination angle of 73°, observation of the area outside of the 30° range

**Zone 3** = Mirror (3) with an inclination angle of 66°, observation of peripheral sections of the ocular fundus, and under favorable conditions, of the ora serrata

**Zone 4** = Mirror (4) with an inclination angle of 59°, observation of the vitreous body and ocular fundus sections neighboring the ora serrata, and gonioscopic examination

5.1. **Three-mirror contact lens 903/903 S**

The classic contact lens from Professor Goldmann – with or without scleral flange.

5.2. **Three-mirror contact lens 630/630 L**

This contact lens is especially suited for slit lamps that feature a smaller distance between the eye and the reduction prism, as compared to the HAAG-STREIT slit lamp 900.
5.3. Three-mirror contact lenses for infants and children 906/906 S and 907

Infants: 906/906 S
Children up to 4 years of age: 907

The mirrors of these three-mirror contact lenses, especially designed for use on children, are smaller than the normal three-mirror contact lenses. The inclination angles are identical, however.

Two models are available. In the model for infants (model 906), the corneal portion has an internal diameter of 10 mm and in the model for children up to 4 years of age (model 907), it has a diameter of 11 mm.
6. **Contact lens 1210 endothelium according to Eisner**

For examination of the corneal endothelium and epithelium, magnification 1.93x.

6.1. **Using the contact lens 1210**

- After removing the protective plug (4) fill the liquid reservoir with Methocel 2 %.
- Insert into the eyelid gap with the release opening (1) or marking (2) facing upwards.

6.2. **Locating specular reflections**

- Slit lamp settings:
  - Magnification: small
  - Slit width: small
  - Angle between slit lamp and microscope: small
- Sharply focus and centre the optical system with silver-coloured ring (3).
- Slide the slit lamp until the following appear successively in sharp focus: the reflection of the lens (5) and then the epithelium (6) and endothelium (7) corneal areas being examined.
- Adjust the contact lens until mirror reflections are illuminated.

6.3. **Examination of the specular reflections**

- Slit lamp settings:
  - Magnification: large
  - Slit width: large
  - Angle between slit lamp and microscope: large

6.4. **Examination of the periphery of the cornea**

- Guide the patient’s line of vision in the desired direction.
- Adjust the contact lens.

6.5. **Disinfecting the contact lens 1210**

- Insert protective plug (4) into the contact lens. Then, proceed according to the separate instructions for use on the cleaning and disinfection of tonometer measuring prisms, contact lenses and Desinset.
7. **Use of oculars with reticle according to McIntyre and contact lens 1210**

7.1. **Ocular 25x for HAAG-STREIT slit lamp BM 900**
* Insert ocular halfway into microscope tube and hold the cylinder housing firmly with one hand.
* With the other hand, loosen the knurled ocular refraction ring (2) by turning it anticlockwise about 10°.
* De-focus the reticle by turning the occluder (1) anticlockwise. The knurled ocular refraction ring should not turn with the occluder.
* Slowly turn the occluder clockwise until the reticle appears in sharp focus.
* Tighten the knurled ocular refraction ring.
* Slide in the ocular to the stop point in the barrel.
* Align centre marks vertically.
* Use knurled ocular refraction ring on microscope to adjust dioptre setting to zero.

7.2. **Ocular 12.5x for HAAG-STREIT slit lamp BQ 900**
When adjusting the ocular to the user’s refraction, look towards a light surface and adjust the ocular from the + side by turning the knurled ocular refraction ring with dioptre scale (3) until the eyepiece crosshairs appear sharply focused.

7.3. **Estimating the cell density of the endothelium without contact lens**
* Microscope magnification 40x.
* Reading taken in column 40x.

**with contact lens 1210 acc. to Eisner**
* Microscope magnification 25x (overall magnification: microscope magnification x contact lens magnification 48.25x).
* Take reading of control sample in column 1.93 x 25x.
8. Mirror contact lenses for laser use

8.1. Gonioscopy contact lens CGAL

The CGAL gonioscopy contact lens was developed by Roussel and Fankhauser for laser treatments of the chamber angle. It is made of laser-resistant lens and has anti-reflection coating. It reduces the laser spot by a factor of 1.44 as compared to Goldmann contact lenses. As a result, less energy is required to cut strands during the cataract incision with the YAG laser. Thanks to its magnifying effect, the CGAL contact lens also improves the aiming accuracy and success rate of laser trabecu-loplasty.

During office examinations, the CGAL contact lens allows for detection of the fine structures of the trabeculum thanks to its high resolution, and produces excellent photographs and video recordings due to the low-reflectivity coating in the visible spectral area.

The aiming point is the centre of curvature C of the spectral entrance surface and, as such, free of spherical aberrations and coma.

The beam aberration (φ) is significantly lower with the CGAL than with Goldmann contact lenses (φ: inclination angle of the contact lens).
9. Three-mirror contact lenses for laser use
For a description see section ‘General information on three-mirror contact lenses’
(chapter 2.7, page 13).

9.1. 903 L and 630 L

903 L and 630 L contact lenses for laser use.

9.2. 906 L and 907 L
Magnifications vary depending on eye size!

Fundus iridocornea (infants) contact lens 906 L.
Fundus iridocornea (child) contact lens 907 L.
10. Direct contact lenses for laser use
10.1. Retina contact lens CGRL

The CGRL retina contact lens is a wide angle contact lens designed for laser photocoagulation and diagnosis. It is a small, lightweight contact lens that expands the field of vision without increasing the working distance, while guaranteeing an excellent image quality and good resolution. The entire posterior pole, including the temporal vascular arcades, can be viewed simultaneously. It is used for axial and paraxial photocoagulation.

Optical attributes

The CGRL retina contact lens creates an upright virtual image of the ocular fundus. The cone angles of both beams (laser and observation) are reduced from 6° in air to 3.2° in vitreous. As a consequence, the visual field is expanded from 46° to 64°, allowing for observation of the entire posterior pole.

Dioptic power in air. –50 D
10.2. Iridectomy contact lens CGIL
The CGIL iridectomy contact lens was designed by Riquin, Fankhauser et al. to perform full-thickness peripheral laser iridectomies.

Optical attributes
The CGIL contact lens increases the cone angle of the laser beam and therefore also the beam diameter on out-of-focus structures, while decreasing the diameter of the focal spot. The effective focal spot reduction is achieved by minimizing spherical aberrations and coma through application of the Young-Weierstrass theorem: The contact lens was designed so that the aplanatic point of the entrance surface falls on the iris, three millimeters behind the cornea.

Dioptic power in air. +5 D
10.3. **Vitrectomy contact lens CGVL**

The CGVL vitrectomy contact lens was designed by Rol, Fankhauser et al., for photodisruptive YAG laser procedures in the posterior vitreous body.

**Optical attributes**

The CGVL vitrectomy contact lens increases the cone angle of the laser beam and therefore also the beam diameter on out-of-focus structures, while decreasing the diameter of the focal spot. The effective focal spot reduction is achieved by minimizing spherical aberrations and coma: the center of curvature of the entrance surface – a point free of spherical aberrations or coma – coincides with the center of curvature of the retina, while the other aplanatic point of the entrance surface is located on the retina.

Dioptric power in air.  

$$-33 \text{ D}$$
10.4. Capsulotomy contact lens CGPL

The CGPL capsulotomy contact lens was designed by Riquin, Fankhauser et al., for the dissection of opacified posterior lens capsules and membranes in the pupillary and retropupillary space with the YAG laser.

Optical attributes

The CGVL contact lens increases the cone angle of the laser beam and therefore also the beam diameter on out-of-focus structures, while decreasing the diameter of the focal spot. The effective focal spot reduction is achieved by minimizing spherical aberrations and coma through application of the Young-Weierstrass theorem: the contact lens was designed so that the aplanatic point of the entrance surface falls on the retropupillary space, eight millimeters behind the cornea.

Dioptric power in air. +9 D
10.5. **Contact lens RETINA 145 L**

The Retina 145 L contact lens is a panfundus wide-angle contact lens designed to facilitate the diagnosis and treatment of the retina as far as the aequator. With an image magnification of 0.7 x, this contact lens allows for a highly detailed assessment of even subtle changes in the fundus.

**Optical attributes**

The quality of the laser-scan image is as high on the periphery as it is in the centre. There are no major image distortions. Simultaneous visualization of the posterior pole and centre periphery permits optimum orientation toward the back of the eye at any time.

Dioptric power in air: 86.5 D

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11. Technical data
See section ‘Product overview’ (chapter 2.3, page 7) and the respective product description.

NOTE!
Subject to technical alterations.

A. Legal regulations
* According to Directive 93/42/EEC on medical devices, the contact lenses are in Class I.
* You can request a copy of the declaration of conformity for this contact lens from HAAG-STREIT at any time.
* Statutory accident regulations are to be observed.

B. Classification
CE Directive 93/42/EEC  
Class I

FDA  
Class II

C. Standards
EN ISO 10993-1  
EN ISO 17664
Should you have any further questions, please contact your HAAG-STREIT representative at:
http://www.haag-streit.com/contact/contact-your-distributor.html