

Instruction for use

AddOn IOL® - hydrophilic sterile intraocular lens for implantation into the ciliary sulcus

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Content:

One sterile foldable single-piece intraocular lens (AddOn IOL) for single use consisting of highly purified hydrophilic acrylate with covalently bounded UV absorber.

Description:

This intraocular lens (IOL) is an optical product of the highest precision. The manufacturing and the quality management system of 1stQ is in accordance with international standards and is certified according to ISO 13485 and 93/42/EEC.

AddOn® Spherical IOL provides vision in the distance.

AddOn® Progressive IOL (apodised multifocal diffractive) provides addition for near vision.

AddOn® Toric IOL provides correction of astigmatism.

AddOn® SML IOL provides addition for ultra-near vision by a magnifying function.

AddOn IOLs are designed with four rounded flexible haptics and a rounded optic.

The soft acrylic lens material is capable of being folded prior to implantation, allowing implantation through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance.

The optical properties, e.g. refraction power (spherical equivalent for toric lenses), power of cylinder of toric lenses, added power of progressive lenses, as well as the dimensions of the lens, e.g. size of optics, total size of IOL, are indicated on the labels on the primary and secondary packaging.

Indications of use:

All 1stQ AddOn IOLs - unless differently stated on the folding box - are indicated for implantation into the ciliary sulcus of the pseudophakic eye after implantation of an intraocular lens into the capsular bag.

- Spherical AddOn IOLs are intended to provide adjustment to the dioptric power of the pseudophakic eye.
- Diffractive AddOn IOLs are intended to provide far, intermediate and near vision capabilities with increased spectacle independence and to provide adjustment to the dioptric power of the pseudophakic eye.
- Toric AddOn IOLs are intended to provide adjustment for astigmatism and to the dioptric power of the pseudophakic eye.
- AddOn SML IOLs are intended to provide ultra-near vision with increased spectacle independence and adjustment to the dioptric power of the pseudophakic eye of patients with dry form of Age-related Macular Degeneration (AMD).

Contraindications:

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list(s) must be respected:

For all types of AddOn IOL:

- Microphthalmia or shallow anterior chamber, narrow angle, congenital eye abnormality
- Amblyopia, long-term anti-inflammatory treatment
- Active ocular diseases (chronic severe uveitis, proliferative diabetic retinopathy, retinal detachment, chronic glaucoma not responsive to medication, iris atrophy, severe zonulopathy)
- Children under the age of 18 years
- Corneal decompensation or diseases involving the central cornea, endothelial insufficiency
- Pseudophakic patients with a malpositioned or unstable capsular bag fixated intraocular lens
- Inability to achieve secure placement in the designated location e.g. due to absence of a secure peripheral anterior capsule, absence of intact zonules, or irregular anatomy of the ciliary sulcus

Additionally for AddOn Progressive IOL:

- Patients with ocular disorders, other than cataract, that could potentially cause future acuity losses up to a level of 0.63 or worse in either eye
- Patients who are expected to require retinal laser treatment
- Patients unlikely to achieve less than 1.5 diopter of post-operative astigmatism
- Patients unlikely to adopt to simultaneous multiple retinal images
- Patients with a multifocal capsular bag fixated IOL
- Patients who drive at night occupationally or occupation/hobbies depend on good night vision
- Patients who need very good near vision in semidarkness
- Patients who are non-professional or professional airline pilots
- Patients with keratoconus, age-related macular degeneration (AMD) or any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. amblyopia, nystagmus, retinitis pigmentosa, aniridia, eccentric pupil)
- one-eyed patients or patients with reduced or loss of vision in one eye
- Patients who are happy wearing glasses

Additionally for AddOn SML IOL:

- Severe Conulopathy
- Active neovascular AMD or dry form AMD if the BCDVA < 0.1
- Subluxation
- Aphacia
- Non-treated glaucoma
- Iris neovascularization
- Poor retinal function
- Amblyopia
- Patients with a multifocal capsular bag fixated IOL
- long-term anti-inflammatory treatment
- corneal diseases involving the central cornea
- inadequate visualization of the fundus on preoperative examination
- preoperative ineffective miotic pupillary reaction or non-mydriatic pupil size or more than 4 mm under photopic conditions

**Packaging:**

The hydrated hydrophilic acrylic lens is held by a lens holder fixed in the plastic screw cap of a glass vial/plastic container containing sterile water.

The vial/container is packed in a sterile peel-pouch or sterile blister.

The overall packaging contains the product, a set of stickers for administrative purposes identifying the lens and a patient card to be completed and given to the patient.

Sterilization:

This IOL has been sterilized by steam after being packed under clean room conditions.

Sterility is guaranteed only when the packaging is neither opened nor damaged.

Conditions of storage, transportation and waste management:

Handle with care.

Store at room temperature.

Do not expose to direct sunlight or extreme temperatures.

Do not freeze.

Keep dry, protect from moisture/water.

The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

Expiration:

Do not use this medical device after the expiry indicated on the carton/pouch/blister and the primary container.

Warnings:

- Do not use if the sterilized package is open, wet or damaged.
- Do not re-sterilize by any means.
- Do not use if expired.
- Do not re-use. Any occasional re-use must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.
- Use only sterile intraocular rinsing solutions such as sterile Ringer's solution or sterile BSS solution.
- Do not use any hydrophilic acrylic IOL if there is no fluid in the lens container.
- The storage fluid must not be used.
- If a hydrophilic acrylic 1stQ IOL has been stored below room temperature prior to implantation, a temporary opaqueness of the lens may occur. This physical reaction does not harm the lens material and clears after equilibration in each case.

Precautions:

High level of surgical skill is required for proper implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more appropriate courses before attempting to perform implantation.

The accurate power calculation is the key to the success of the implantation. Especially for progressive AddOn IOL the surgeon should target emmetropia and carefully position the IOL centrally to avoid visual impairments.

Careful preoperative evaluation and clinical judgment should be made by the surgeon prior to surgery to decide the benefit/risk ratio of the implantation in the following pre-existing conditions as described in the relevant medical literature (some may reduce the postoperative visual improvement, especially in case of progressive AddOn IOL):

- one-eyed patients or patients with loss or reduction of vision in one eye
- colour vision deficiencies
- bleeding disorders
- retinal detachment, retinopathy of prematurity in the medical history
- current or recent treatment with any anticoagulant or antiplatelet medication or systemic alpha-1a adrenergic antagonists (e.g. tamsulosin)
- prior ophthalmic surgery e.g. keratorefractive surgery, penetrating keratoplasty, pars plana vitrectomy, scleral buckling surgery
- diabetes including its complications, e.g. proliferative diabetic retinopathy
- anatomical variances e.g. difficult access to the eye (e.g. deep-set eyes), microphthalmos, extremely shallow anterior chamber, small myotic pupil
- any concomitant severe eye disease including uveitis, glaucoma, high hyperopia and myopia, pseudo-exfoliation syndrome
- corneal diseases, like Fuch's corneal endothelial dystrophy, severe corneal dystrophy, irregular corneal astigmatism
- iris disorders, like synechiae, essential iris atrophy, rubeosis iridis
- zone laxity or dehiscence and potential phacodonesis and lens subluxation
- special cataract types, e.g. dense (brunescent) nuclear cataract, posterior polar cataract, white (mature cortical) cataract, cataract due to rubeola, non-age related cataract
- disorders of the choroid, retina and the optic nerve, e.g. choroidal hemorrhages, retinal detachment, macular degeneration, severe optic nerve dystrophy

For optimal results, aim to achieve perfect IOL centration.

Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or may necessitate additional surgical intervention.

Additional precautions for toric AddOn IOL:

Misalignment of the flat meridian of the IOL with the steep axis of the cornea may compromise the astigmatic correction. Such misalignment can result from inaccurate keratometry, inaccurate marking of the cornea, inaccurate placement of the IOL during surgery, unanticipated surgically induced change in the cornea or physical rotation of the IOL after implantation.

To minimize this effect the surgeon should ensure an accurate preoperative keratometry and biometry and should take care that the toric IOL is properly oriented at the end of the surgery.

Additional precautions for progressive AddOn IOL:

Some visual effects can be expected due to the superposition of the focused and unfocused images. These may include the perception of halos or radial lines around point sources of light under low lighting conditions. A reduction of contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions.

Therefore, multifocal patients should exercise caution when driving at night or in poor visibility conditions. The physician should consider the following important aspects that are unique to the use of multifocal IOLs:

- The surgeon must target emmetropia to achieve optimal visual performance.
- Patients with significant preoperative (determined by keratometry) or expected postoperative astigmatism ≥ 1.0 D may not achieve optimal visual outcome.
- Care should be taken to achieve IOL centration, as a decentration may result in visual disturbances under certain light conditions.
- Patients with pupil size less than 2.5 mm may not obtain any near vision benefit.
- Patients may require a neuroadaptation period up to approximately 6 months to experience full visual benefits of the implanted multifocal lens.

Use of intraocular air/gas tamponade:

The deterioration of the transparency of the IOL implanted into the human eye has been observed after the intraocular administration of SF₆ or C₃F₈ gases. Visually significant haze may develop, that may lead to IOL exchange.

Calcification of IOLs:

Several reports - almost exclusively in diabetic patients - describe the calcification of intraocular lenses in the postoperative period.

Laser treatment:

Focus the laser beam precisely on the action site behind the lens. A laser beam focused on the implant itself will lead to a damage of the lens.

Interactions:

No direct interactions of the implanted IOL with drugs are known.

However, the current or previous treatment with systemic alpha-1a adrenergic antagonist (tamsulosin) may increase the perioperative complications of the cataract surgery.

The use of antiplatelet and anticoagulant medications may increase the risk of haemorrhagic anaesthetic or perioperative complications.

In reasonably foreseeable environmental conditions, no significant interaction or possible damage caused by exposition to magnetic fields, external electrical influences, electrostatic discharge, pressure or variation in pressure, thermal ignition sources, and acceleration are known.

Patient information:

The surgeon performing the implantation must inform the patient about the implant and all known side-effects and risks.

The patient should be instructed to inform the doctor in charge properly about any side-effects after implantation.

**Patient card:**

The relevant details should be entered onto the patient card enclosed. One of the stickers with the IOL details from the label set enclosed should be affixed on the back of the patient card. This card is to be given to the patient, who should take care of it so as to present it to any eye specialist in the future.

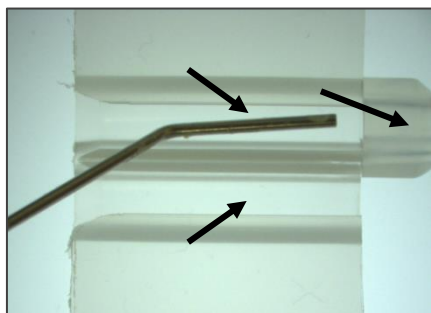
Implantation devices:

For implantation use the 1stInject 2.0 HB instrument. For toric AddOn with cylinder > 6.0 D use the 1stInject 2.4 HB instrument.

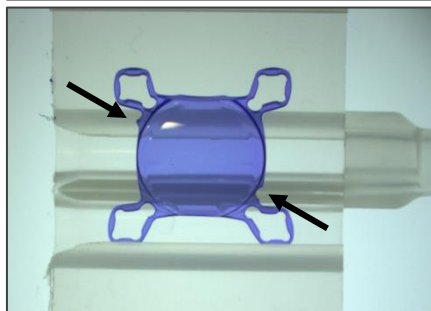
Handling:

- It is recommended to store the lens the day before implantation at room temperature.
- Make sure that the appropriate unexpired sterile injection system is present.
- Check the label on the outer package to ensure that an unexpired, proper lens model with the necessary power is selected.
- Ensure that the IOL model and power corresponds with the results of the preoperative biometry.
- Open the outer package to remove the peel-pouch or blister and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, serial number).
- Open the pouch/blister at the marked end and remove the lens container from the packaging in a sterile environment.
- Hold the vial or vessel vertically, carefully open the cap and remove the lens holder from the fluid.
- Thoroughly rinse the lens with a sterile intraocular irrigating solution (BSS).
- Hydrophilic IOLs should not be kept in open air for longer than 1 minute. Neither type of IOL should be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.
- Carefully load the lens to an appropriate injection device, avoid any trapping or damaging of the lens optic or haptics. Non-toothed, polished instruments must be used when handling the IOL. Do not grasp the optical area with forceps.
- Discard the injector after use.

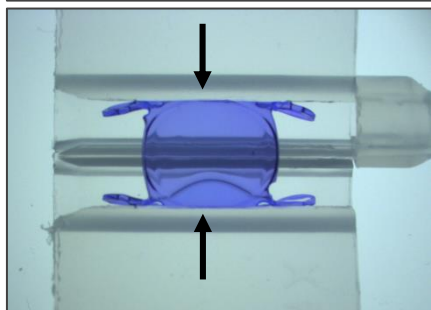
Loading of an AddOn IOL into the cartridge:



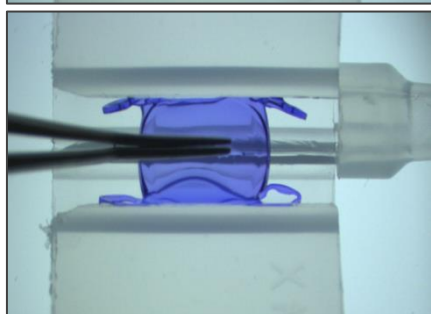
Fully open the wings of the cartridge to 180°. Apply a viscoelastic inside the nozzle and to both grooves of the loading chamber (see arrows). Balanced salt solution (BSS) should not be used as a lubricant.



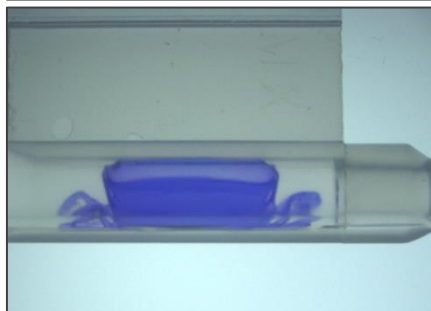
Position the AddOn in the cartridge: the markings at the optic edges should be at 4 o'clock to the right of the haptic and at 10 o'clock to the left of the haptic (see arrows).



Position the lens in the loading chamber in a “reverse U” configuration: ☾
Ensure that the edges of the haptics are securely positioned under the guiding rims (see arrows) and that they are not twisted.



With forceps hold the lens in position to ensure that the edge of the optic stays securely positioned under the rim of the flaps. Ensure the haptics and optic are completely within the loading chamber. Whilst keeping the lens in position with closed forceps, carefully close the flaps of the cartridge.



Visually observe that the lens is symmetrically folded within the loading chamber and not trapped. Insert the cartridge into the injector (follow the instruction for use of the injector).



Inject the lens in a slow and controlled manner. Do not stop after you have started implanting the lens. The pushing movement from start till end has to be done in a continuous non-interrupted way until the injection is completed. Never pull the plunger back! Anticipate an initial slight resistance. Excessive resistance could indicate a trapped lens. Do not use too much pressure. If the IOL blocks the injector system, discard the injector. The plunger should be pushed forward only until the lens has fully unfolded out of the cartridge.

Correct placement into the sulcus is achieved when the IOL can easily be rotated as is usual for posterior chamber IOLs.

The surgeon should implant the lens centrally without tilt into the ciliary sulcus with the correct anterior-posterior orientation and in case of a toric lens with the correct axes orientation.

Implantation of a toric IOL:

When implanting a toric lens the eye to be operated should be marked pre-operatively on its limbus prior to surgery in the following manner:

- Ensure that the limbus is dry before making these marks.
- During the usual preoperative measures mark the horizontal (0°-180°) axis of the cornea as the reference axis while the patient is in sitting position and is looking forward to avoid cyclotorsion.
- In the operating room mark the steep axis of the cornea while the patient is in supine position and has been prepared for the surgery.
- Mark the axis of the incision.
- Use operating microscope.

The toric AddOn IOLs of 1stQ are marked with 2 marking lines on the anterior surface to identify the flat meridian of the IOL which must be aligned with the steep axis on the cornea by rotating the IOL in the sulcus (Figure 2).

Carefully remove all viscoelastic material from both sides of the lens. Residual viscoelastic material may cause complications including lens rotation resulting in the misalignment of the IOL, which compromises astigmatic correction.

Check the correct orientation of the marking lines after the removal of the viscoelastic material once again.

Figure 1. The optical properties of the toric lens

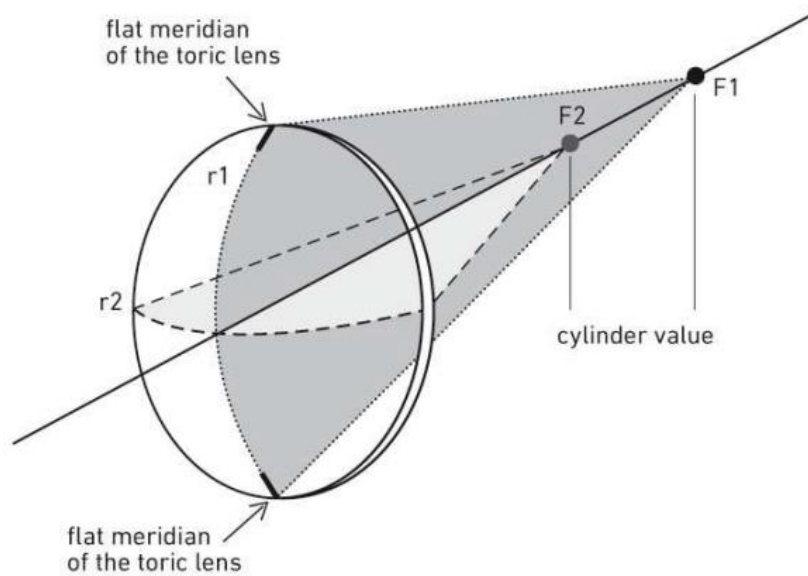
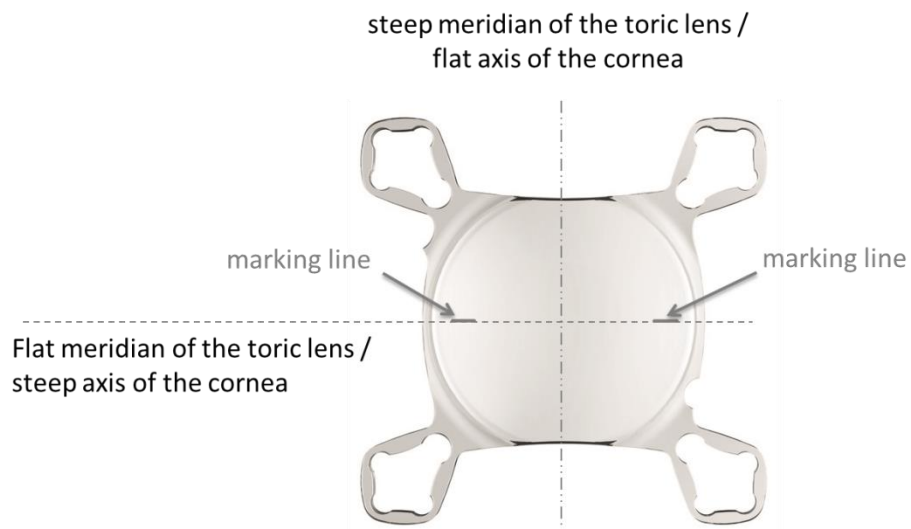


Figure 2. Positioning the toric lens in the ciliary sulcus



Possible perioperative and postoperative complications and undesirable effects

As with any surgical procedure, there is risk involved.

The most common potential complications and undesirable effects accompanying cataract or implant surgery - some of them may lead to a secondary surgical intervention or medication - are referred in the relevant medical literature. The following non-exhaustive list specifies the complications that have been associated with the implantation of IOLs:

- pigment dispersion syndrome
- recurrent iridocyclitis
- infections, vitritis
- transient or persistent glaucoma, secondary glaucoma
- corneal endothelial damage and/or oedema
- flat anterior chamber after lens extraction
- detachment of the Descemet's membrane
- wound leak/dehiscence
- thermal burns
- astigmatism, oedema/ bullous keratopathy
- uveitis
- haemorrhage in one or more segments of the eye
- radial tears of the anterior capsule
- rupture of the posterior capsule
- capsular phimosis and capsule block syndrome
- late tear of the capsule with posterior dislocation of the IOL
- posterior capsule opacification (PCO)
- damage to the zonules with consequential IOL dislocation including the sunset syndrome
- wound gape/iris prolapse
- iritis, iris trauma, iris prolapse, seclusio pupillae, iris capture, epithelial ingrowth, pupillary block
- damage to the IOL or capsular bag during insertion
- postoperative opacification or calcification of the IOL, deposits, discolouration
- incorrect positioning of the IOL during surgery
- retinal detachment
- vitreous loss
- raised intraocular pressure (angle closure/open angle glaucoma)
- cystoid macular oedema
- cyclitic membrane
- hypopyon
- endophthalmitis
- IOL dislocation
- corneal (stromal) oedema
- hyphema, synechia
- glares

Additional possible complications for progressive AddOn IOL:

- asthenopic discomfort, adaption difficulties
- reduced best corrected visual acuity (distance)
- reduced contrast sensitivity
- reduced vision at night or in poor visibility conditions

- perception of halos or radial lines around point sources of light
- delayed neuroadaptation

Following complications (not limited to these) may lead to a secondary surgical intervention:

- dissatisfactory visual outcome, e.g. due to incorrect IOL refraction
- IOL dislocation (decentration, tilt, axial shift, rotation)
- pupillary block, iris capture
- wound leak
- retinal detachment

IOL power calculation:

The label of a 1stQ IOL contains the relevant optical parameters of the lens including (depending on type of AddOn IOL) the spherical equivalent power (SEQ) and/or the added power of the lens.

Accurate up-to-date and complete keratometry, biometry (axial length, anterior chamber depth, corneal radii) and visual acuity (s.c./c.c. and subjective refraction) are inevitable for a successful visual outcome. It is essential that the measurements are carried out in a consistent manner using standardized settings.

The surgeon should preoperatively determine the optimal power of the lens to be implanted according to his experience, preference and intended location. Calculation may need the contribution of properly qualified optometrists.

The power of the lens to be implanted can be calculated variously from the biometry and refraction of the eye according to different formulae described in the following references:

Cataract Surgery Guidelines - The Royal College of Ophthalmologists, September 2010

Güell JL et al: Phakic intraocular lenses Part.1-2. JCRS 2010, 36, 1976-93 and 2168-94

Retzlaff J., Sanders D. & Kraff M. Lens Implant Power Calculation. A Manual for Ophthalmologists & Biometrists. Third Edition, 1990

Holladay J. A Three-part System for Refining Intraocular Lens Power Calculations. J. Cataract Refract. Surg. V14: 17-24. 1988

Holladay J. Standardizing Constants For Ultrasonic Biometry, Keratometry & IOL Power Calculations. J. Cataract Refract. Surg. V23:1356 -1370. 1997

Hoffer K. The Hoffer Q Formula: A Comparison of Theoretic and Regression Formulas. J. Cataract Refract. Surg. V19: 700-712. 1993

Holladay J.T., Gills J.P., Leidlen J, Cherchio M. Achieving emmetropia in extremely short eyes with two piggyback posterior chamber intraocular lenses. Ophthalmology 1996, 103: 1118-1123

G.L. van der Heijde: Optical Consequences of Implanting of a Concave Intraocular Lens Correcting Myopia, Klin. Mbl. Augenheilk. 193 (1988)

Reporting customer complaints including quality complaints, adverse events and other medical device related observations:

Customer complaints including quality complaints, adverse events and other medical device related observations should be reported to 1stQ without delay. A report is requested describing the details of the complaint/event, the applied therapy, the product type, LOT/serial number of the medical device used.

**Return of product:**

If possible, return the medical device and/or its original container and/or any part of the packaging, as well as the used injection instrument to 1stQ or to your local distributor.

Contact for complaints:

1stQ GmbH
Quality Management
Harrlachweg 1
68163 Mannheim
Germany
Tel: +49 621 717 6330
Fax: +49 621 717 6333
E-Mail: info@1stq.de
Homepage: www.1stQ.eu

Liability:

1stQ does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material.

Several product types listed in these Instructions for use may not be marketed in your country.












Please keep these Instructions for use and read it carefully before you apply this medical device.

In case you are not in the possession of the Instructions for use, please request a copy. This IFU is also available electronically on our website: www.1stq.eu.

All translations of this text are derived from the original English text. Should you face any discrepancy or problem in interpretation, please consult the English version for guidance.

The content of this document is subject to change without prior notice.

Symbols used:

Do not resterilize	
For single use	
Keep away from sunlight	
Keep dry	
Use by (date)	
Consult Instruction for use	
Serial number	
Sterilized using steam or dry heat	
Do not used if package is damaged	
Manufacturer	
CE certified	

Manufacturer:



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 68163 Mannheim
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