

Линза интраокулярная
акриловая торическая
однокомпонентная TECNIS®,
следующих моделей: ZCT375,
ZCT450, ZCT525, ZCT600,
ZCT700, ZCT800

Номер и дата РУ:	№ РЗН 2019/8911 от 06 октября 2023 года.
Назначение:	Линза предназначена для визуальной коррекции зрения при афакии у взрослых пациентов, у которых пораженный катарактой хрусталик удален посредством экстракапсулярной экстракции катаракты. Это устройство помещается в капсульный мешок.
Производитель:	«Джонсон & Джонсон Серджиал Вижн, Инк.», США, Johnson & Johnson Surgical Vision, Inc., 31 Technology Drive, Suite 200, Irvine, CA 92618, USA.
Уполномоченный представитель производителя в РФ:	ООО «Джонсон & Джонсон», Россия, 121614, г. Москва, ул. Крылатская, д. 17, корп. 2.
Место производства:	См. на упаковке. 1. AMO Groningen B.V., Van Swietenlaan 5, 9728 NX Groningen, The Netherlands. 2. AMO Puerto Rico Manufacturing, Inc., Road 402 N, Industrial Park Anasco, 00610, Puerto Rico.



Diopter Suggested "A" constant	Диоптрия Поправочный коэффициент («А»-константа)	Стерилизация этиленоксидом
Optical biometry	Оптическая биометрия	Повторное использование запрещено
Ultrasound biometry	Ультразвук	Не подлежит повторной стерилизации
Overall diameter (D _o)	Общий диаметр (D _o)	См. инструкции по применению
Optic diameter (D _o)	Оптический диаметр (D _o)	Верхний предел температуры
Use by (YYYY-MM-DD)	Срок годности (ТТТ-ММ-ДД)	Не использовать, если упаковка повреждена.
Serial number (SN)	Серийный номер (SN)	Хранить вдали от солнечных лучей.
Manufactured on (YYYY-MM-DD)	Дата производства (ТТТ-ММ-ДД)	Только для продажи только врачам
		Аллергенно неопасно

ИОЛ однокомпонентная двояковыпуклая имплантируемая в заднюю камеру: акриловая асферическая оптика с поглотителем УФ-излучения

TECNIS® Toric Intraocular Acrylic
Lenses, complete with container
and accessories, design versions:
TECNIS® Toric 1-Piece Intraocular
Acrylic Lens , models: ZCT 375,
ZCT 450, ZCT 525, ZCT 600, ZCT 700,
ZCT 800



DEVICE DESCRIPTION:

The TECNIS® Toric intraocular 1-piece acrylic lens is an ultraviolet-light absorbing posterior chamber intraocular lens (IOL) which compensates for corneal spherical aberrations and corneal astigmatism. It is designed to be positioned in the lens capsule where the lens should replace the optical function of the natural crystalline lens. The TECNIS® Toric intraocular 1-piece acrylic lens incorporates a proprietary wavefront-designed toric aspheric optic with a squared posterior optic edge designed to provide a 360 degree barrier to epithelial cells. The edge of the IOL optic has a frosted design to reduce potential edge glare effects. The anteriorly located cylinder axis marks denote the meridian with the lowest optic power.

INDICATIONS FOR USE:

The TECNIS® Toric intraocular 1-piece acrylic lens is indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia, in whom a cataractous lens has been removed by extracapsular cataract extraction and who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision. This device is intended to be placed in the capsular bag.

PRECAUTIONS:

- Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.
- Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
- Do not store the lens in direct sunlight or at a temperature

greater than 113°F (45°C). Do not autoclave the intraocular lens.

- Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded.
- When the insertion system is used improperly, the haptics of the TECNIS® Toric intraocular 1-piece acrylic lens may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

WARNINGS:

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

- Patients with recurrent severe anterior or posterior segment inflammation or uveitis.
- Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
- Surgical difficulties at the time of cataract extraction that may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).
- A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
- Circumstances that would result in damage to the endothelium during implantation.
- Suspected microbial infection.
- Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
- Children under the age of 2 years are not suitable candidates for intraocular lenses.
- The TECNIS® Toric intraocular 1-piece acrylic lens should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.
- TECNIS® Toric intraocular 1-piece acrylic lens away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.
- Carefully remove all viscoelastic from the capsular bag. Residual viscoelastic may allow the lens to rotate, causing misalignment of the TECNIS® Toric intraocular 1-piece acrylic lens with the intended axis of placement.
- AMO IOLs are single-use medical devices and are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. The reuse/sterilization/reprocessing of AMO single-use medical devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility.

ADVERSE EVENTS:

Potential adverse events during or following surgery of the TECNIS® Toric intraocular 1-piece acrylic lens may include but are not limited to:

- Endophthalmitis
- Hypopyon
- Pupillary block
- Retinal detachment
- Acute corneal decompensation
- Secondary surgical intervention (including implant repositioning, removal, AC tap or other surgical procedure).

DETAILED DEVICE DESCRIPTION:
Lens Optic:

- Optic Material: Optically clear, soft foldable acrylic with a covalently bound UV absorber.
- Power: +5.0 to +34.0 diopter powers in 0.5 diopter increments.
- Cylinder Power: 1.00 diopter, 1.50 diopter, 2.25 diopter, 3.00 diopter, 3.75 diopter, 4.00 diopter, 4.50 diopter, 5.25 diopter, 6.00 diopter, 7.00 diopter and 8.00 diopter (as measured in the IOL plane).

DETAILED DEVICE DESCRIPTION:

Lens Optic:

- Optic Material: Optically clear, soft foldable acrylic with a covalently bound UV absorber.
- Power: +5.0 to +34.0 diopter powers in 0.5 diopter increments.
- Cylinder Power: 1.00 diopter, 1.50 diopter, 2.25 diopter, 3.00 diopter, 3.75 diopter, 4.00 diopter, 4.50 diopter, 5.25 diopter, 6.00 diopter, 7.00 diopter and 8.00 diopter (as measured in the IOL plane).

Conversion table for cylinder powers:

	IOL Plane (labeled)	Corneal Plane
Cylinder Powers (D)	1.00	0.69
	1.50	1.03
	2.25	1.54
	3.00	2.06
	3.75	2.57
	4.00	2.74
	4.50	3.08
	5.25	3.60
	6.00	4.11
	7.00	4.80
8.00	5.48	

- Optic Edge Design: PROTEC 360 Square posterior edge.
- Index of Refraction: 1.47 at 35°C.
- Light Transmittance: UV cut-off at 10% T for a +5.0 diopter lens (thinnest) and a +34.0 diopter lens (thickest) are shown in Figure 1.
- **Haptics:**
 - Material: Soft foldable acrylic with a covalently bound UV absorber.
 - 1-piece lens.
 - Configuration: TRI-FIX design, Modified C, integral with optic.
 - Haptic Thickness: 0.46 mm.

LENS POWER CALCULATIONS:

Accurate keratometry and biometry is essential to successful visual outcomes.

Preoperative calculation of the required spherical equivalent lens power for these posterior chamber intraocular IOLs should be determined by the surgeon's experience, preference, and intended lens placement. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. The physician should determine preoperatively the spherical equivalent and cylindrical power of the lens to be implanted.

TECNIS® Toric intraocular 1-piece acrylic lenses are labeled with the IOL spherical equivalent power. Lens power calculation methods are described in the following references:

- Hoffer, K.J. The Hoffer Q formula: a comparison of theoretic and regression formulas. Journal of Cataract and Refractive Surgery. 1993; 19:700-712; ERRATA; 1994; 20:677.
- Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, R.S. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery. 1988; 14:17-24.
- Holladay, J.T. Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. Journal of Cataract and Refractive Surgery. 1997; 23:1356-1370.
- Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay, J.T. Journal of Cataract and Refractive Surgery. 1998; 24:433-434.
- Olsen, T., Olesen, H., Thim, K., and Corydon, L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery. 1992; 18: 280-285.
- Retzlaff, J.A., Sanders, D.R. and Kraff, M.C. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery. 1990; 16:333-340; ERRATA, 1990; 16:528.

DIRECTIONS FOR USE:

- Prior to implanting, examine the lens package for IOL type, power, proper configuration and expiration date.
- Open the peel pouches and remove the lens in a sterile environment. Verify the dioptric power and cylinder power of the lens.
- Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens' optical surfaces for other defects.
- If desired, the lens may be soaked or rinsed in sterile balanced salt solution until ready for implantation.
- AMO recommends using the UNFOLDER Platinum 1-Series implantation system with the 1MTEC30 cartridge, the ONE SERIES Ultra implantation system with the 1VIPR30 cartridge, the UNFOLDER Emerald AR Series implantation system with the iCART30 cartridge, or an equivalent insertion instrument or system to insert the TECNIS® Toric intraocular 1-piece acrylic lens. Only insertion instruments that have been validated and approved for use with this lens should be used. Please refer to the directions for use with the insertion instrument or system for additional information.

SELECTION AND PLACEMENT OF TECNIS® TORIC INTRAOCULAR 1-PIECE ACRYLIC LENSES:

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, AMO provides a web-based tool (www.TecnisToricCalc.com) for the surgeon. Preoperative keratometry and biometry data, incision location, and estimated surgically induced corneal astigmatism are used to determine the appropriate TECNIS® Toric intraocular 1-piece acrylic lens model, spherical equivalent lens power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The anterior surface of the IOL is marked with indentations (four at opposite sides) at the haptic/optic junction that identify the flat meridian of the TECNIS® Toric intraocular 1-piece acrylic lens optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The TECNIS® Toric intraocular 1-piece acrylic lens cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Prior to surgery the operative eye should be marked in the following manner: With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the web-based www.TecnisToricCalc.com to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the TECNIS® Toric intraocular 1-piece acrylic lens with the marked axis of lens placement. Carefully remove all viscoelastic from the capsular bag. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual technique may be used, if preferred, to ensure removal of viscoelastic from behind the IOL. Special care should be taken to ensure proper positioning of the TECNIS® Toric intraocular 1-piece acrylic lens at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate, causing misalignment of the TECNIS® Toric intraocular 1-piece acrylic lens with the intended axis of placement.

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the TECNIS® Toric intraocular 1-piece acrylic lens during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS® Toric intraocular 1-piece acrylic lens after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

CAUTION: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

PATIENT CARD:

An implant identification card, to be supplied to the patient, is included in the package. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

REPORTING:

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as IOL-related and that were not previously expected in terms of their nature, severity or rate of occurrence must be reported to AMO.

This information is being requested from all surgeons in order to document potential long-term effects of intraocular IOL implantation, especially in younger patients.

Physicians are required to report these events in order to aid in identify-

ing emerging or potential problems with posterior chamber IOLs. These problems may be related to a specific lot of IOLs or may be indicative of long-term problems associated with these IOLs or with intraocular lenses in general.

HOW SUPPLIED:

The TECNIS® Toric intraocular 1-piece acrylic lens lenses are supplied sterile within a double aseptic transfer peel pouch. The double aseptic transfer peel pouch is sterilized with ethylene oxide and should be opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the outer pouch are not sterile.

EXPIRATION DATE:

The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

RETURN / EXCHANGE POLICY:

Contact the local AMO representative for the return policy. Return the IOL with proper identification and the reason for the return. Label the return as a biohazard. Do not attempt to resterilize the IOL.

PATIENT INFORMATION:

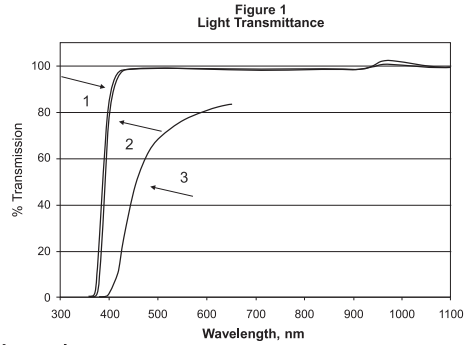
Each patient should receive information regarding intraocular lenses prior to the decision to implant an intraocular lens.

Symbol/Explanation:

SYMBOL	ENGLISH
	Sterilized using Ethylene Oxide
	Do Not Reuse
	Use By (YYYY-MM: Year-Month)
	Caution: See Instructions for Use
	Manufacturer
	Authorized Representativein the European Union
	Do Not Resterilize
	Upper Limit of Temperature 45°C (113°F)
	Keep Away from Sunlight
	Do Not Use if Package is Damaged

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	Johnson & Johnson Surgical Vision, Inc. 31 Technology Drive, Suite 200, Irvine, CA 92618, USA	
	Block B Liffey Valley Office Campus Quarryvale, Co. Dublin, Ireland	0344



Legend:

- Curve 1: Spectral Transmittance curve of a typical 5 diopter IOL (thinnest), UV cut-off at 10% T is 375 nm
- Curve 2: Spectral Transmittance curve of a typical 34 diopter IOL (thick-est), UV cut-off at 10% T is 380 nm
- Curve 3: Spectral Transmittance (T Curve) Corresponding to 53 year-old Phakic Eye

Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance of IOLs (5-34 diopter) made with this material. Spectral transmission measurements were taken in water (aqueous) at room temperature.

*Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.

Addition to Directions for Use of Medical Device (MD)

TECNIS® Toric intraocular 1-piece acrylic lens, models: ZCT375, ZCT450, ZCT525, ZCT600, ZCT700, ZCT800

1. Purpose of the medical device

1.1 Name of the medical device

TECNIS® Toric intraocular 1-piece acrylic lens, models: ZCT375, ZCT450, ZCT525, ZCT600, ZCT700, ZCT800 (here and after referred to as lens, IOL, device, product).

1.2 Purpose of the medical device

Lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. This device is intended to be placed in the capsular bag.

1.3 Indications

Lens is indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia, in whom a cataractous lens has been removed by extracapsular cataract extraction and who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

This device is intended to be placed in the capsular bag.

1.4 Contraindications

There are no known contraindications.

1.5 Possible side effects associated with this medical device

Potential adverse events during or following surgery of the Toric 1-Piece lens may include but are not limited to:

1. Endophthalmitis
 2. Hypopyon
 3. Pupillary block
 4. Retinal detachment
 5. Acute corneal decompensation
- Secondary surgical intervention (including implant repositioning, removal, AC tap or other surgical procedure).
- 1.6 Indication of possibility and peculiarities of using the medical device by people with implanted medical device, pregnant women, breastfeeding women, children, adults with chronic diseases
- People with other medical devices implanted into their body, pregnant women, breastfeeding women, and adults with chronic diseases should consult their physician prior to the implantation of this lens.
- Children under the age of 2 years are not suitable candidates for intraocular lenses.

1.7 Information about the potential effects of this device on the ability to drive and operate machinery

Not applicable.

1.8 Conditions of using the medical device

This device is intended for use by an ophthalmologist experienced in the use of such products in specialized areas of medical and health care institutions in aseptic conditions.

2. Information about the manufacturer of the medical device:

- 2.1 Name and address of the manufacturer
Name Johnson & Johnson Surgical Vision, Inc.
Address 31 Technology Drive, Suite 200, Irvine, CA 92618, USA
- 2.2 Information about the manufacturer and production sites
1. AMO Groningen B.V., Van Swietenlaan 5, 9728 NX Groningen, The Netherlands.
2. AMO Puerto Rico Manufacturing, Inc., Road 402 N, Industrial Park Anasco, 00610, Puerto Rico.
- 2.3 Information about authorized representative of the manufacturer in Russia
Name Johnson & Johnson Russia LLC
Address 17, Krylatskaya str., bld. 2, Moscow, 121614
Telephone +7 (495) 580-77-77
Fax +7 (495) 580-78-78

3. Description of the principles underlying the work of the medical devices and their features

The TECNIS® Toric 1-Piece lens is an ultraviolet-light absorbing posterior chamber intraocular lens (IOL) which compensates for corneal spherical aberrations and corneal astigmatism. It is designed to be positioned in the ens capsule where the lens should replace the optical function of the natural crystalline lens. The TECNIS® Toric 1-Piece IOL incorporates a proprietary wavefront-designed toric aspheric optic with a squared posterior optic edge designed to provide a 360 degree barrier to epithelial cells. The edge of the IOL optic has a frosted design to reduce potential edge glare effects. The anteriorly located cylinder axis marks denote the meridian with the lowest power.

4. Method of application

DIRECTIONS FOR USE:

1. Prior to implanting, examine the lens package for IOL type, power, proper configuration and expiration date.
2. Open the peel pouch and remove the lens in a sterile environment. Verify the dioptric power and cylinder power of the lens.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. If desired, the lens may be soaked or rinsed in sterile balanced salt solution until ready for implantation.
5. AMO recommends using the DK7786 injector and an implantation system with a One Series Ultra cartridge or a similar insertion instrument or system for implanting TECNIS® Toric intraocular 1-piece acrylic lenses. Only insertion instruments that have been validated and approved for use with this lens should be used. Please refer to the directions for use with the insertion instrument or system for additional information.

LENS OPTICAL POWER CALCULATION:

Accurate keratometry and biometry is essential to successful visual outcomes. Preoperative calculation of the required spherical equivalent lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended use of the camera lens assembly. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. The physician should determine preoperatively the spherical equivalent and cylindrical power of the lens to be implanted.

TECNIS Toric Intraocular 1-piece acrylic lenses are labeled with the IOL spherical equivalent power. Lens power calculation methods are described in the following references:

- 1) Hoffer, K.J. The Hoffer Q formula: a comparison of theoretic and regression formulas. Journal of Cataract and Refractive Surgery. 1993; 19:700-712; ERRATA; 1994; 20:677.
- 2) Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, Y., and Ruiz, R.S. A three-part system for refining intraocular lens

power calculations. Journal of Cataract and Refractive Surgery. 1988; 14:17-24.

3) Holladay, J.T. Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. Journal of Cataract and Refractive Surgery. 1997; 23:1356-1370.

4) Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay, J.T. Journal of Cataract and Refractive Surgery. 1998; 24:433-434.

5) Olsen, T., Olesen, H., Thim, K., and Corydon, L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery. 1992; 18: 280-285.

6) Retzlaff, J.A., Sanders, D.R. and Kraff, M.C. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery. 1990; 16:333-340; ERRATA, 1990; 16:528.

7) Lowery, M.D., Makker, H., Lang, A. Effect of the speed of sound in Sensor acrylic lenses on pseudophakic axial length measurements. Journal of Cataract and Refractive Surgery. 2002 Jul; 28(7):1269-70.

8) Haigis W. "The Haigis formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 41-57.

9) Olsen T. "The Olsen formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 27-40

10) Canovas C., Artal P. "Customized eye models for determining optimized intraocular lenses power". Biomed. Opt. Express 2011; 2:1649-1662

SELECTION AND IMPLANTATION OF THE TECNIS® TORIC MULTIFOCAL 1-PIECE IOL

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of astigmatism in the crystalline lens to be removed may affect the results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. To optimize the selection of IOL and its axis of implantation, Johnson & Johnson Surgical Vision, Inc. offers surgeons a web-based application (www.TecnisToricCalc.com). Preoperative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate TECNIS® Toric multifocal 1-piece IOL model, the spherical equivalent lens power, and the axis of implantation in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens in the capsular bag. The posterior surface of the IOL is marked with grooves (four at opposite sides) at the haptic/optic junction that identify the flat meridian of the TECNIS® multifocal toric multifocal IOL optical part. These grooves form an imaginary line that represents the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The TECNIS® multifocal toric multifocal IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of implantation).

Prior to surgery, the operative eye should be marked in the following manner: With the patient sitting upright, precisely mark the 12 o'clock and/or 6 o'clock position with a T-marker, a surgical skin marker, or a marking pencil for ophthalmic use. Use these marks as reference points. Use the axis mark immediately prior to or during surgery to mark the lens implantation axis.

After the lens is inserted, precisely align the axis marking grooves on the TECNIS® multifocal toric multifocal IOL with the marked axis of lens placement. Carefully remove all viscoelastic from the capsular bag. To that end, manipulate the IOL optic with the I/A tip or use a standard irrigation/aspiration method to remove all viscoelastic from the eye. Bimanual technique may be used, if preferred, to remove viscoelastic from behind the implanted lens. After the removal of viscoelastic, make sure to ensure the proper positioning of the TECNIS® multifocal toric multifocal IOL at the intended axis. Residual viscoelastic may allow the lens to rotate, causing misalignment of the TECNIS® multifocal toric 1-piece IOL from its intended axis of placement.

Misalignment of the axis of the lens with the intended axis of implantation degrades the quality of astigmatism correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate marking of the axis of the TECNIS® multifocal toric IOL during surgery, an unanticipated surgically induced change in the cornea, or rotation of the TECNIS® multifocal toric IOL. To prevent this, the surgeon must ensure the accuracy of preoperative keratometry and biometry, as well as the correct orientation of the IOL before the completion of surgery.

Caution: Do not use the lens if the package is damaged. The sterility of the lens may have been compromised.

5. Technical description of the medical device.

5.1 The basic composition and a list of accessories of the medical device TECNIS® Toric intraocular 1-piece acrylic lens, models: ZCT375, ZCT450, ZCT525, ZCT600, ZCT700, ZCT800 is supplied with the following components (see photo in section 6.1):

Contents of the consumers packaging (carton packaging):

- Device in a two-layer aseptic pouch;
- Operational documentation:
- 1. Directions for Use;
- 2. Patient Card;
- 3. Implant Identification Card;
- 4. Patient Label.

Sterile packaging (pouches) for lenses in a round daisy package

- Intraocular acrylic lens;
 - Round daisy packaging for storage of the lens.
 - 5.2 Possibility and ways of integration with other medical devices
- Please refer to 5. Method of application

5.3 The materials from which the medical device or its main parts are constructed

ZCT375, ZCT450, ZCT525, ZCT600, ZCT700, ZCT800: Hydrophobic acrylic with covalently bound UV absorber.

6. Information about packaging

Each lens is supplied sterile in a round daisy package for lens storage inside a double sterile transfer pouch. The sterile double transfer pouch has been sterilized by ethylene oxide and must be opened only in sterile conditions. The round daisy package is labeled with the serial number, catalog number, diopter power, and optic and overall dimensions. External surfaces of the package are not sterile.

The packaged IOL is placed along with Directions For Use (DFU), a patient identification card (this is a certificate of the implant), extra identification labels, and a card for business meetings in a folding carton. The patient should be instructed to keep the patient identification card (it is certificate of the implant) and to provide this card to their

ophthalmologist.

7. Transportation and storage conditions

This device can be carried by any mode of transport. Lenses are supplied sterile and preloaded into an aseptic double transfer pouch. The ase

