FortifEYE®

Capsular Tension Ring

CTR

The FortifEYE® preloaded single-use injector simplifies capsular tension ring (CTR) implantation by preloading the implant eyelet into the device, allowing for safe, immediate preparation and use.

Indications For the stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness (e.g., Marfan syndrome), secondary zonular weakness (e.g., trauma or vitrectomy), cases of zonulysis, cases of pseudoexfoliation, and cases of Weill-Marchesani syndrome.[1]

STREAMLINE **CTR** PLACEMENT

SIMPLY INNOVATIVE

CTRs have been shown to preserve the integrity of the capsular bag diameter, rhexis size, and IOL shape, allowing for good anatomical IOL centration.[2,*]

CTRs have been shown to be a safe and effective ancillary method to delay the incidence, onset, and magnitude of posterior capsular opacification.[3-6]

CTRs have been shown to reduce postsurgical decentration and tilt to allow for excellent optical performance of multifocal and plate-haptic IOLs.[7-9]

*Results from an in vitro study.

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FortifEYE® CTR

CTR10R 12.3mm, 10.0mm
CTR10L 12.3mm, 10.0mm
CTR11R 13.0mm, 11.0mm
CTR11L 13.0mm, 11.0mm
CTR12R 14.5mm, 12.0mm
CTR12L 14.5mm, 12.0mm

The FortifEYE® CTRs are sterile, non-optical implants made up of one continuous piece of polymethyl methacrylate (PMMA), available in both clockwise (right-handed) and counterclockwise (left-handed) implantation options.

MODEL NUMBER	SIZE (EXPANDED, COMPRESSIBLE)	BULBUS LENGTH	MATERIAL
CTR10R	12.3mm, 10.0mm	< 28mm	PMMA
CTR10L	12.3mm, 10.0mm	< 28mm	PMMA
CTR11R	13.0mm, 11.0mm	24 – 28mm	PMMA
CTR11L	13.0mm, 11.0mm	24 – 28mm	PMMA
CTR12R	14.5mm, 12.0mm	> 28mm	PMMA
CTR12L	14.5mm, 12.0mm	> 28mm	PMMA

A range of options to meet the various needs of your patients

FortifEYE® is a smart choice for your cataract patients with conditions associated with weak or partially absent zonules, such as[1]:

- Primary zonular weakness (e.g., Marfan's syndrome)
- Secondary zonular weakness (e.g., trauma or vitrectomy)
- Zonulysis
- Pseudoexfoliation
- Marchesani's syndrome (or Weill-Marchesani's syndrome)

1. FortifEYE [instructions for use]. Rochester, NY: Bausch & Lomb Incorporated; 2017.
2. Lee DH, Lee HW, Lee KH, Chung KH, Joo CK. Effect of a capsular tension ring on the shape of the capsular bag and opening and the intraocular lens. J Cataract Refract Surg. 2001;27(3):452-456.
3. Kim JH, Kim H, Joo CK. The effect of capsular tension ring on posterior capsular opacity in cataract surgery. Korean J Ophthalmol. 2005;19(1):23-28.
4. D'Eliseo D, Pastena B, Longanesi L, Grisanti F, Negrini V. Prevention of posterior capsule opacification using capsular tension ring for zonular defects in cataract surgery. Eur J Ophthalmol. 2003;13(2):151-154.
5. Halili I, Mutlu FM, Erdurman FC, Gündogan FC, Kiliç S. Influence of capsular tension ring on posterior capsule opacification in myopic eyes. Indian J Ophthalmol. 2014;62(3):311-315.
6. Summary of safety and effectiveness data. FDA January 2002, PMA P010059.
7. Alió JL, Elkady B, Ortiz D, Bernabeu G. Microincision multifocal intraocular lens with and without a capsular tension ring: optical quality and clinical outcomes. J Cataract Refract Surg. 2008;34(9):1468-1475.
8. Price FW Jr, Mackool RJ, Miller KM, Koch P, Oetting TA, Johnson AT. Interim results of the United States investigational device study of the Ophtec capsular tension ring. Ophthalmology. 2005;112(3):460-465.
9. Takimoto M, Hayashi K, Hayashi H. Effect of a capsular tension ring on prevention of intraocular lens decentration and tilt and on anterior capsule contraction after cataract surgery. Jpn J Ophthalmol. 2008;52(5):363-367.

Important Safety Information for FortifEYE® Capsular Tension Ring

DESCRIPTION: The Bausch + Lomb FortifEYE® Capsular Tension Ring is a sterile capsular tension ring (CTR) that is preloaded into a single-use injector. The FortifEYE® preloaded single use injector is an auxiliary device which simplifies the implantation of the FortifEYE® capsular tension ring.

INDICATIONS: For the stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness (e.g., Marfan's Syndrome), secondary zonular weakness (e.g., trauma or vitrectomy), cases of zonulysis, cases of pseudoexfoliation and cases of Marchesani's Syndrome.

CONTRAINDICATIONS: The capsular tension ring should not be used in children 12 years of age or younger since this device is contraindicated in eyes still growing. The FortifEYE® CTR is contraindicated for patients with perforated or damaged capsules.

WARNINGS: The effect of the capsular tension ring on the progression of zonular instability over time is unknown at this date. Eyes with pseudoexfoliation syndrome and decreased anterior chamber depth exhibit a greater likelihood of zonular instability at the time of surgery and an increased probability of intraoperative complications.

Since the number of eyes with zonular dehiscence greater than 50 % was very low (13/316, 4%), no scientific conclusions can be drawn regarding the probable visual outcome in this population, especially in the presence of other preoperative pathologies. The physician should use his/her own discretion in utilizing the FortifEYE® CTR in these cases.

PRECAUTIONS: Do not use the Bausch + Lomb FortifEYE® CTR if the sterilized package is open or damaged. The capsular tension ring should not be used after the expiration date indicated. Do not re-sterilize the implant or the injector by any method. Do not reuse the implant or the injector. Rinse the implant only with sterile intraocular rinsing solutions such as sterile Ringer's solution or sterile balanced salt solution. Store only at room temperature. Do not expose to extreme temperatures. The injector must only be used with the implant provided with it.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Contact your Bausch + Lomb Sales Representative for full Instructions for Use.

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