

VisionBlue®

0.5ml Syringe



- Trusted for over 9 million cataract surgeries since launch.
- The only trypan blue stain for anterior use approved by the FDA.
- Now approved for staining of Descemet's membrane and trabecular meshwork.

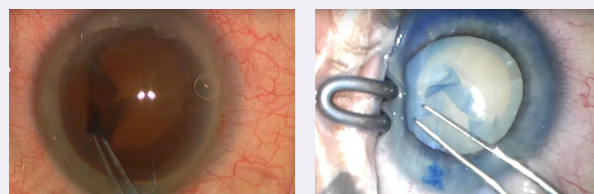
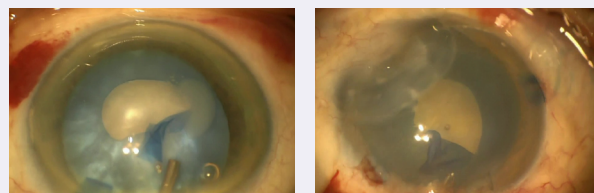
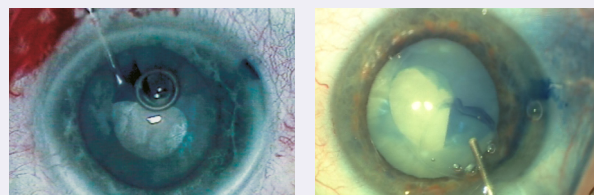


Mr. Sathish Srinivasan, Consultant Corneal Surgeon at University Hospital Ayr, Scotland.

"I have used VisionBlue® for over 10 years and in at least 350 cases, I greatly appreciate the staining performance of the dye for dense and complex cataract cases or where the capsulorrhexis is compromised. As an FDA approved stain, I also trust the purity of VisionBlue® and know I am minimizing any risk to endothelial cells."

See the difference

- **Assuring the complete**, circular capsulorhexis required for a safe phaco-emulsification procedure ¹³⁻¹⁶
- **High success** rates in performing anterior capsulotomy in cases of mature or brunescant cataracts ^{5, 6, 7, 11, 12}
- **Enhanced contrast** between the capsulorhexis rim, instrumentation and the adjacent nucleus ¹²⁻¹⁶
- **Reduced risk** of radial capsule tears and helps ensure a stable intraocular lens platform ^{1, 2, 3, 8}
- **Effective and safe** recovery of 'lost' capsulorhexis edge ⁴
- **Improved efficacy** in performing capsulorhexis in cases of narrow pupil ^{9, 10}
- **Improves visualization** in cases of vitreous hemorrhage and hazy or scarred cornea ^{4, 5}



Arie Marcovich, MD, senior ophthalmic surgeon at the Kaplan Medical Center, Israel

"All surgeons should be concerned about the purity of the stain they use for any anterior segment surgery. Low purity dyes were associated with severe inflammatory response and can compromise the endothelial cells during surgery and pose an unacceptable risk to patient outcomes. In my view, surgeons should use an FDA-approved dye like VisionBlue® or demand a purity analysis if generic trypan blue is used."

VisionBlue® usage description

VisionBlue® is indicated for use as an aid in ophthalmic surgery by staining the anterior capsule of the lens. Inadequate visualization of the anterior lens capsule may result in an incomplete capsulorhexis, which carries a high risk of radial capsule tears and associated complications.

VisionBlue® capsule staining therefore facilitates the performance of a capsulorhexis in the absence of a red fundus reflex, and reduces the risk of capsulorhexis-related complications by better visualization of radial capsule tears. VisionBlue® can be injected directly onto the anterior lens capsule and stains the capsule instantly. The capsule staining procedure is therefore quick and easy to perform.



Know what you are putting in the eye

- VisionBlue® is the **only trypan blue stain** for anterior use approved by the FDA
- **No confirmed adverse** events reported since launch in 2004
- **Highly purified trypan blue** with lowest recorded levels of mono-azo dye – known for carcinogenic properties in medical use*
- **High purification** reduces the reported TASS risk from lower purity generic trypan blue use
- **Batch level HPLC testing and Certificate of Analysis** provides purity assurance and traceability for every lot produced

HPLC Testing (High Performance Liquid Chromatography)	Trypan Blue Purity Content (%)	Monoazo Dye Impurity Content (%)
VisionBlue® (D.O.R.C.)	≥96%	0,4
Competitor 1	94,8	3,2
Competitor 2	92,9	3,9
Competitor 3	92,5	3,3
Competitor 4	91,4	5,4
Competitor 5	90,0	3,0
Competitor 6	89,6	2,8
Competitor 7	76,8	1,7

Purity analysis (test protocol available upon request)

* Typical VisionBlue® purity value – available in batch level Certificate of Analysis

* Unidentified impurities within trypan blue have been linked to cases of toxicity in cataract surgery^{17,18}



0,8%

1,7%

Monoazo dye impurity content: visual comparison

Important Safety Information

Following the procedure, excess dye should be removed by thorough irrigation of the anterior chamber. Adverse reactions reported following use of trypan blue include discoloration of high water content hydrogen intraocular lenses and inadvertent staining of the posterior lens capsule and vitreous face. Staining of the posterior lens capsule or staining of the vitreous face is generally self limited, lasting up to one week.



Elena Barraquer, MD, Spain

“My preferred staining approach in cataract surgery is to use VisionBlue®. Some ophthalmic trypan blue solutions include clumps, and, in my experience, these may not stain the anterior capsule optimally and can compromise the entire procedure. I look for maximum purity in an ophthalmic staining liquid so that I can be confident that the injected vital dye will not damage the corneal endothelium. The purity of any substance injected into the anterior chamber must be extremely high.”

VisionBlue® product information

Ref. VBL.10S
BOX / 10 - STERILE
0.5ML SYRINGE – READY TO USE



For additional information please contact:
D.O.R.C. Dutch Ophthalmic Research Center
(International) B.V.
Scheijdelveweg 2, 3214 VN Zuidland, The Netherlands

Phone: +31 181 45 80 80 | Fax: +31 181 45 80 90
www.dorcglobal.com

VisionBlue®: Helping to save vision globally

“Without VisionBlue®, to perform phacoemulsification on “African cataracts” would be much more difficult and risky. Thank you D.O.R.C. for facilitating my work!”

Elena Barraquer, President of the FUNDACIÓN ELENA BARRAQUER, a non-profit organization that fights against blindness caused by cataracts in developing countries (www.fundacionelenabarraquer.com)



References

- (1) Neuhann T. [Theory and surgical technic of capsulorhexis]. *Klin Monbl Augenheilkd.* 1987 Jun;190(6):542-5.
- (2) Gimbel HV, Neuhann T. Development, advantages, and methods of the continuous circular capsulorhexis technique. *Cataract Refract Surg.* 1990 Jan;16(1):31-7.
- (3) Assia EI, Apple DJ, Barden A, Tsai JC, Castaneda VE, Hoggatt JS. An experimental study comparing various anterior capsulectomy techniques. *Arch Ophthalmol.* 1991 May;109(5):642-7.
- (4) de Waard PW, Budo CJ, Melles GR. Trypan blue capsular staining to “find” the leading edge of a “lost” capsulorhexis. *Am J Ophthalmol.* 2002 Aug;134(2):271-2.
- (5) Kothari K, Jain SS, Shah NJ. Anterior capsular staining with trypan blue for capsulorhexis in mature and hypermature cataracts. A preliminary study. *Indian J Ophthalmol.* 2001 Sep; 49(3):177-80.
- (6) Jacob S, Agarwal A, Agarwal A, Agarwal S, Chowdhary S, Chowdhary R, Bagmar AA. Trypan blue as an adjunct for safe phacoemulsification in eyes with white cataract. *J Cataract Refract Surg.* 2002 Oct; 28(10):1819-25.
- (7) Pandey SK, Werner L, Escobar-Gomez M, Roig-Melo EA, Apple DJ. Dye-enhanced cataract surgery. Part 1: anterior capsule staining for capsulorhexis in advanced/white cataract. *J Cataract Refract Surg.* 2000 Jul;26(7):1052-9.
- (8) Naidu TS. CAPSULAR STAINING IS HELPFUL IN ROUTINE AND COMPLEX CASES Safety is paramount. *CRSTEurope* October 2015.
- (9) Fridman G, Rizzuti AE, Liao J, Rolain M, Deutsch JA, Kaufman SC. Trypan blue as a surgical adjunct in pediatric cataract surgery. *J Cataract Refract Surg.* 2016 Dec;42(12):1774-1778.
- (10) Lotfy A, Abdelrahman A. Trypan blue-assisted posterior capsulorhexis in pediatric cataract surgery. *Clin Ophthalmol.* 2017 Jan 24;11:219-222
- (11) Saini JS, Jain AK, Sukhija J Gupta P, Saroha V. Anterior and posterior capsulorhexis in pediatric cataract surgery with or without trypan blue dye: Randomized prospective clinical study. *J Cataract Refract Surg* 2003; 29(9):1733–1737
- (12) Werner L, Pandey SK, Escobar-Gomez M, Hoddinott DS, Apple DJ. Dye-enhanced cataract surgery. Part 2: learning critical steps of phacoemulsification. *J Cataract Refract Surg.* 2000 Jul;26(7):1060-5
- (13) Melles GJR, de Waard PWT, Pameyer JH, Houdijn Beekhuis W, Trypan blue capsule staining to visualize the capsulorhexis in cataract surgery. *J Cataract Refractive Surgery* 1999; 25:7-9
- (14) Sturmer J, Cataract surgery and the “Blue Miracle”, *Klin. Monatsblatt Augenheilkunde* 2002; 219:191
- (15) Bhartiya P, Sharma N, Ray M, Sinha R, Vaypayee RB, Trypan blue assisted phacoemulsification in corneal opacities, *British J. Ophthalmology* 2002; 86:857-859
- (16) Dada T, Ray M, Bhartiya P, Vaypayee RB, Trypan blue assisted capsulorhexis for trainee phacoemulsification surgeons, *J. Cataract Refractive Surgery* 2002; 28:575-576
- (17) Buzard K, Zhang J, Thumann G, Stripecke R, Sunalp M. Two cases of toxic anterior segment syndrome from generic trypan blue. *J. Cataract Refractive Surgery* 2010; 36:2195-2199
- (18) Matsou A, Tzamalís A, MD, PhD, Chalvatzis N, Mataftsi A, Tsinopoulos I, Brazitikos P. Generic trypan blue as possible cause of a cluster of toxic anterior segment syndrome cases after uneventful cataract surgery. *J. Cataract Refractive Surgery* 2017; 43:848–852