

# NEW PRODUCT APPLICATIONS

BY KAREN APPOLD, CONTRIBUTING WRITER

## TissueBlue Is a Game Changer for Staining the ILM

*Brilliant blue G has been clinically proven to be reliable, predictable, and safe.*

**D**ORC International's TissueBlue, a 0.025% brilliant blue G ophthalmic solution, is the first FDA-approved dye designed to aid in ophthalmic surgery by selectively staining the internal limiting membrane (ILM).

"The ILM's transparent nature makes it difficult to visualize and peel," says James Burckhardt, global marketing director of DORC International. "TissueBlue is injected onto the inner retinal surface, enabling the ILM to be clearly stained and distinguished from the unstained retina, which facilitates its removal."

TissueBlue was launched outside the United States in 2010. "Since then, US retinal surgeons have been asking for access to the same dye to avoid using unapproved or off-label dyes," Burckhardt says. DORC has worked for several years to make the stain available in the United States.

### BENEFITS ABOUND

Jorge A. Fortun, MD, an associate professor of ophthalmology at Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, was eager to try DORC International's one-of-a-kind dye.

"Unlike compounded drugs, TissueBlue doesn't need to be mixed prior to surgery — it's ready for use," Dr.

Fortun says. "This limits the potential for errors in dilution and risk of infection." Furthermore, it doesn't require any additional procedures in order to stain the retina.

Prior to TissueBlue's approval, Dr. Fortun says that options available in the United States for staining the ILM were

### HOW IT WORKS

TissueBlue's formulation is unlike any other product in the United States. It features pharmaceutical-grade dye material, which ensures a higher level of purity than lower-grade compounded dyes, Burckhardt says.

The dye's unique formulation contains 4% polyethylene glycol (PEG), a carrier that increases the stain's weight and ensures that it forms a cohesive ball that sinks directly to the back of the eye. This ensures that it stains the target ILM tissue, without dispersing in the globe, Burckhardt continues. In addition to increasing both the viscosity and density of the dye, PEG does not significantly impact the osmolarity, ensuring higher stability of the dye compared to dyes formulated with other excipients. In addition, TissueBlue is the first ILM stain available in the United States that is sold in a terminally sterilized, prefilled syringe for improved convenience and consistent formulation, ensuring sterile delivery of the dye.



TissueBlue box and syringe.  
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limited. For example, suspension of triamcinolone acetonide uses steroids, has to be used off label, and has limitations when identifying tissues. Indocyanine green, designed for angiography, has to be used off label and has toxicity issues if it's used at a high concentration level or for a prolonged period of time. Compounded brilliant blue dye isn't FDA approved for medicinal use.

### CLINICAL APPLICATIONS

Outside of the United States, TissueBlue (called ILM Blue outside of the United States) has been used for more than 350,000 surgical procedures since its launch. It can be used in any macular surgery that requires peeling of the ILM. Dr. Fortun uses the dye for macular hole repairs, epiretinal

membrane (ERM) peeling, myopic traction myelopathy, and any other vitreoretinal procedure that requires identifying the ILM.

“Although removing the ILM can relieve symptomatic macular distortion caused by ERMs and macular holes, the transparent nature of the ILM makes it difficult to visualize and peel,” Burckhardt says. “By re-staining during surgery, TissueBlue can be used to confirm removal of the ILM, because it’s selective to the ILM. It also provides negative contrast staining of the ERM.”

ILM peeling is performed in approximately 40% of all vitrectomies. It has been shown that peeling the ILM improves postoperative best corrected visual acuity.<sup>1-3</sup>

## PATIENT BENEFITS

Patients benefit when their surgeons use TissueBlue because the dye is an FDA-approved stain with a proven safety profile superior to the nonapproved dyes that are currently used.<sup>3</sup>

In addition, because TissueBlue is supplied pre-mixed in a pre-filled syringe, it is both easier and safer in use—reducing the documented risk<sup>4</sup> of endophthalmitis and contamination from drawing medication from vials.

Dr. Fortun concurs, and says that TissueBlue’s biggest advantage is that it’s a safe and effective replacement to compounded or off-label staining agents previously used in the United States.<sup>3</sup>

“It’s efficacious, consistent, and ready to use in a syringe,” Dr. Fortun says. “It performs the same every time.”

## WHAT STUDIES SHOW

Studies have shown that TissueBlue is a safe dye for use in ILM staining. One study showed that ILM peeling with TissueBlue improved postoperative best-corrected visual acuity. In addition, the dye can be injected into a fluid-filled vitreous cavity and may facilitate staining and removal of the ILM and/or ERMs in macular surgery without an additional fluid-air exchange.<sup>1</sup>

“We’re delighted to make this game-changing product available as a standard of care for macular surgery in the United States,” Burckhardt concludes. **RP**

## REFERENCES

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