



Optimizing Each Step of Membrane Staining



- Favourable Safety Profile
- Enhanced Surgeon Control
- Effective Membrane Staining
- End to End Portfolio

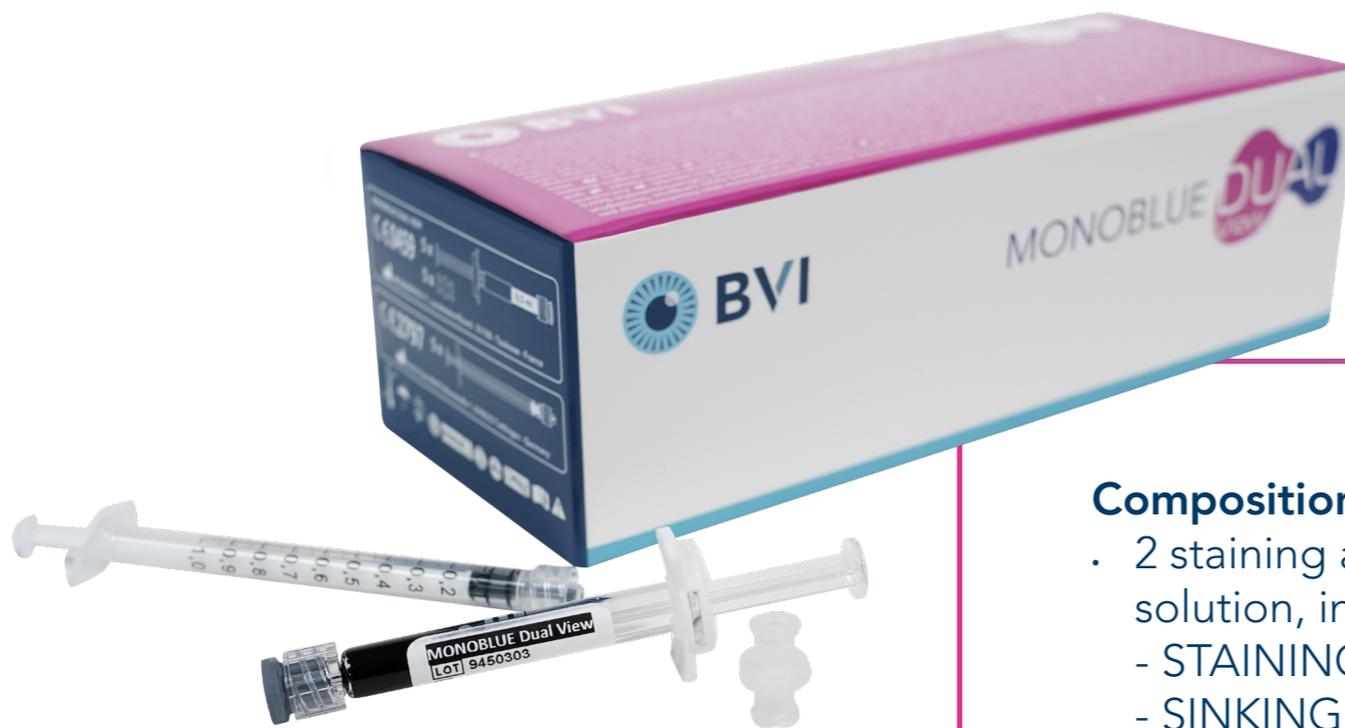


MONOBLUE **DUAL**
View

bvimedical.com



MONOBLUE DUAL View is indicated for the staining of the Epi-Retinal Membrane and the Internal Limiting Membrane (ERM/ILM).



Composition:

- 2 staining agents in 0.5 ml isotonic sterile non pyrogenic solution, in a 1 ml single-dose glass syringe
 - STAINING AGENTS Trypan Blue 0.09% + DDG¹ 0.025%²
 - SINKING AGENT Diglycerol 2.6%
- 5 syringes/box
- 5 sterile tuberculin syringes/box

Optimizing Each Step of Membrane Staining



Favourable Safety Profile



Enhanced Surgeon Control



Effective Membrane Staining



End to End Portfolio



Technical Information



Favourable Safety Profile



Clinically proven comparable intra-operative and post-operative safety³



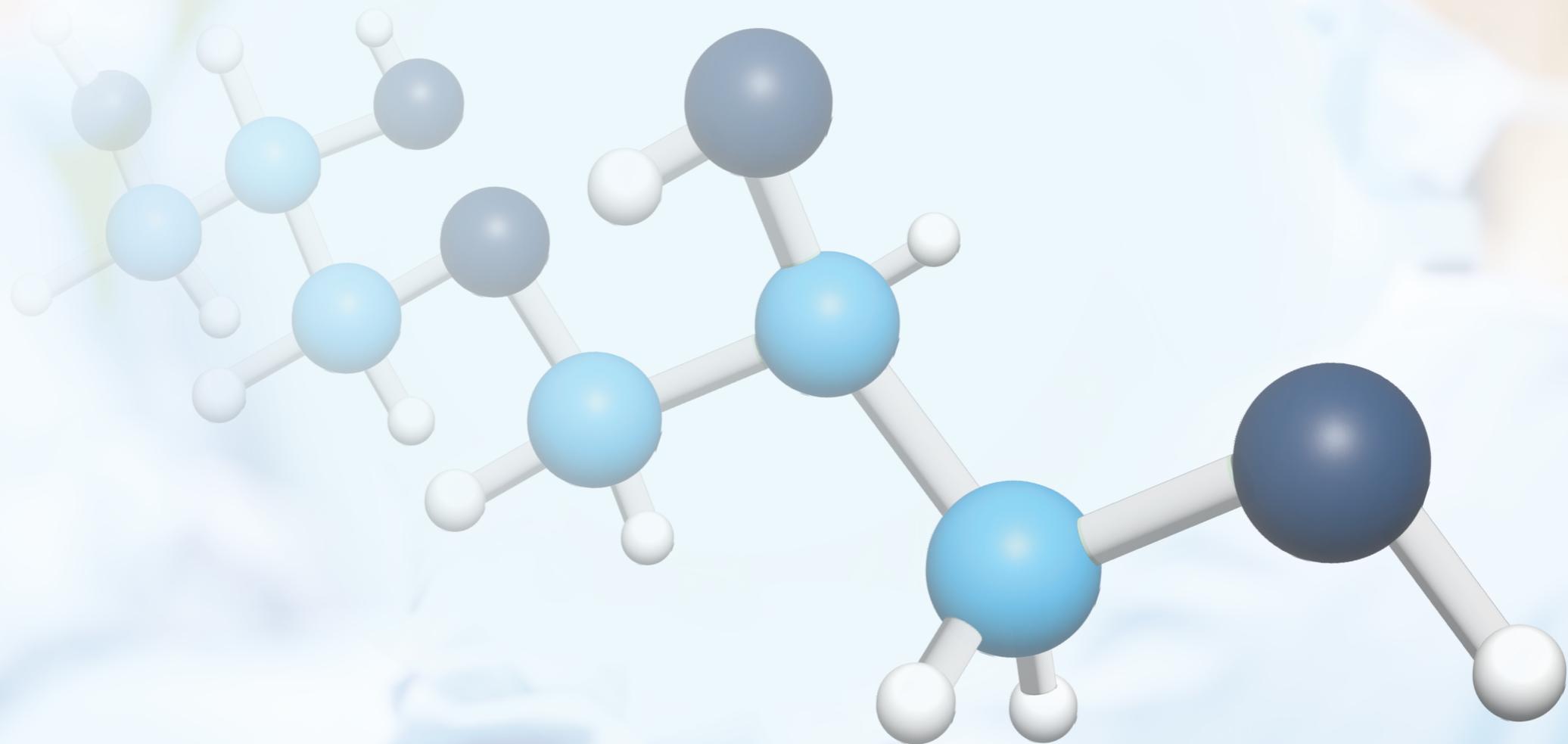
Non phototoxic and non cytotoxic compounds⁴



Clinically proven comparable intra-operative and post-operative safety³

Non phototoxic and non cytotoxic compounds⁴

MONOBLUE DUAL View composition preserves membrane staining performances even at 40% lower concentration of Trypan blue, along pre-clinical and clinical development stages, safety and efficacy profiles were compared to the reference product in the market.





Clinically proven comparable intra-operative and post-operative safety³

Non phototoxic and non cytotoxic compounds⁴

Cytotoxicity and Phototoxicity

DDG evaluation of toxicity and phototoxicity on ARPE-19 cells shows that DDG is non toxic/phototoxic in clinically relevant concentration.

Cell survival rate and standard deviations for different exposures to two staining agents at their indicated concentrations, and results of F-test and t-test comparisons.**

	light immediate	light delayed	dark immediate	dark delayed
BBG 0.025%	92.5 ± 2.6	96.3 ± 7.1	111.6 ± 4.5	98.7 ± 9.7
DDG 0.025%	102.1 ± 11.8	93.5 ± 16.5	117.3 ± 9.2	94.5 ± 8.1
F-test BBG/DDG 0.025%	0.10	0.32	0.39	0.82
t-test BBG/DDG 0.025%	0.39	0.24	0.56	0.80

* Test conditions:

Immediate = 5 min exposure at 37°C under light and dark

Delayed = 24 hours exposure at 37°C under light and dark

Reference standard for "non-toxicity", cells' survival rate above 70% (ISO 10993-5 2009)

** data referring to: Mohr A, Cendoya P, Wilinska J, Apostu M, et al. New dual dye for vitreoretinal surgery with increased transparency. *BMJ Open Ophthalmol.* 2022;7(1):e001116

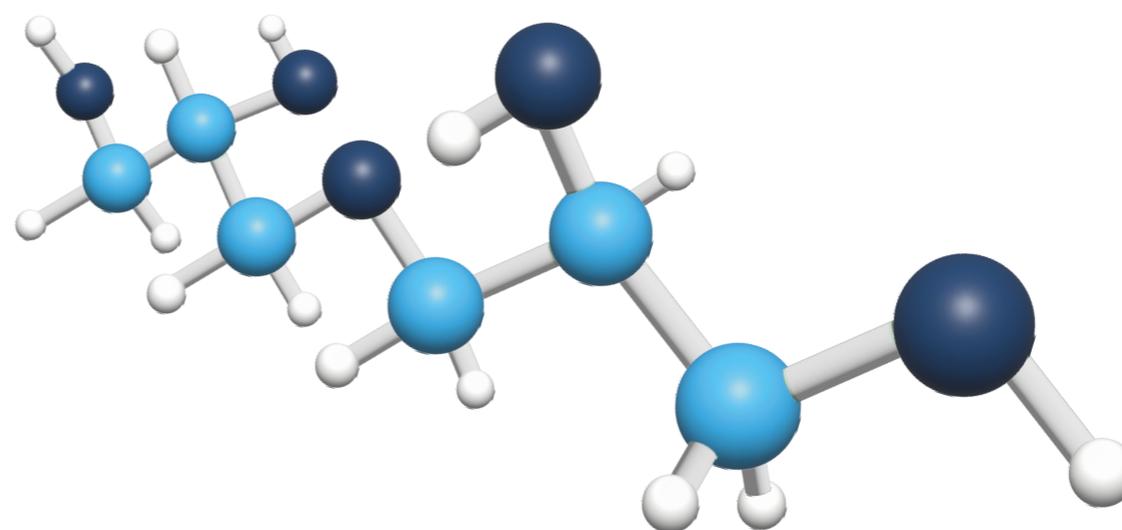
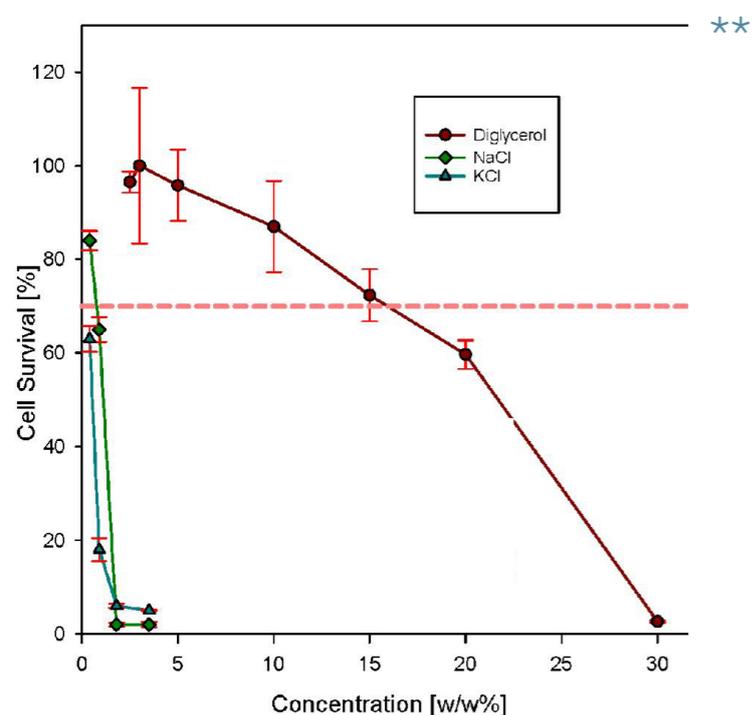


Clinically proven comparable intra-operative and post-operative safety³Non phototoxic and non cytotoxic compounds⁴

Cytotoxicity Test

Survival of ARPE-19 cells after exposure to the indicated compounds shows that in presence of diglycerol the osmotic stress of cells is very well tolerated.

Survival rate declines when diglycerol reaches three times higher concentrations (15% w/w) than the commercial product



** Source: A new dual dye for vitreoretinal surgery with increased transparency - BMJ Open Ophthalmology



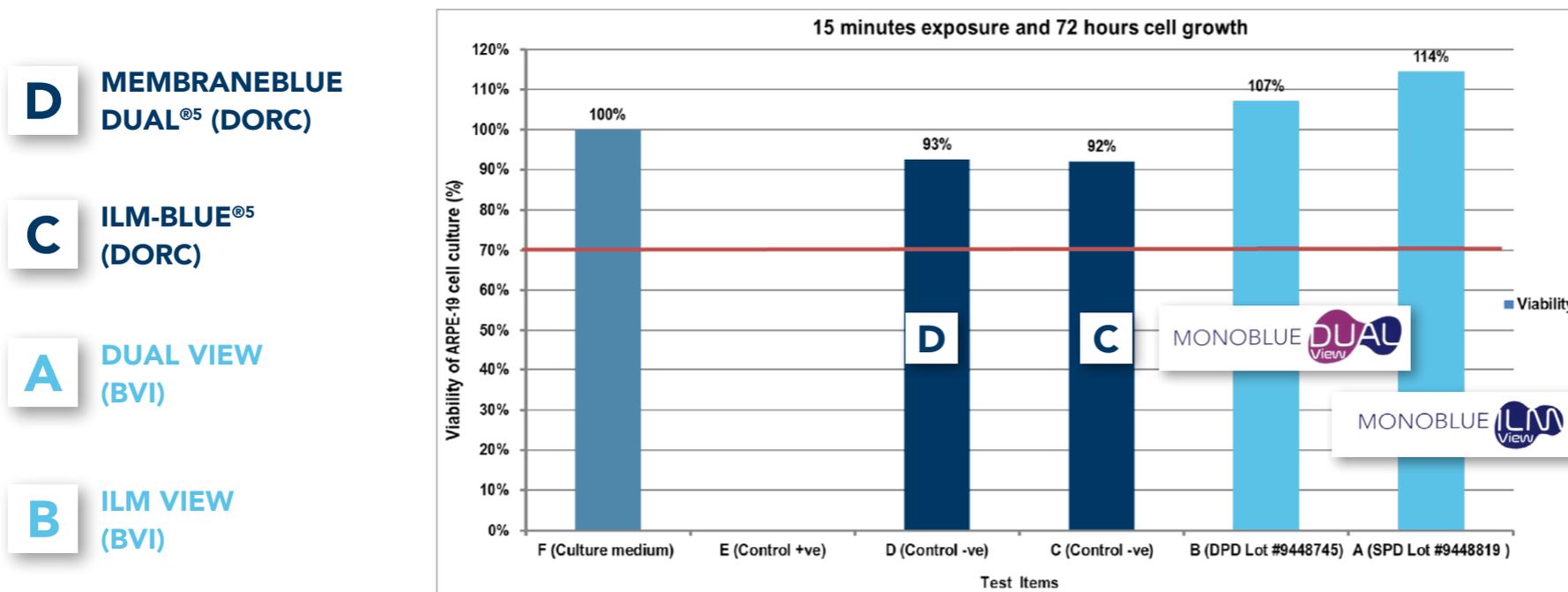


Clinically proven comparable intra-operative and post-operative safety³

Non phototoxic and non cytotoxic compounds⁴

Cytotoxicity and Phototoxicity

In vitro comparative evaluation of ARPE-19 cell survival shows that Monoblue DUAL/ILM View is not cytotoxic after 15min exposure and 72 hours cell growth⁶.



The horizontal dashed line indicates the cell survival level below which a compound is considered cell-toxic

- Under ISO 10993-5 2009 4 criteria, (cell survival >70%), MONOBLUE ILM/DUAL view is non-toxic
- No significant difference in toxicity between MONOBLUE ILM/DUAL VIEW and controls

** data referring to: 1. Mohr A, Cendoya P, Wilinska J, Apostu M, et al. New dual dye for vitreoretinal surgery with increased transparency. BMJ Open Ophthalmol. 2022;7(1):e001116.



Enhanced Surgeon Control

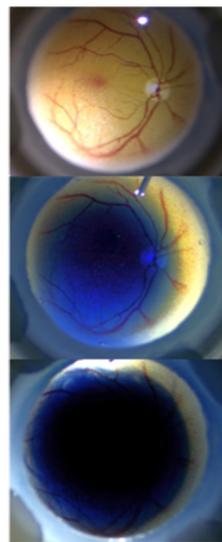
- Fingertips-pressure driven drops with packaged tuberculin syringe or complementary squeezer



Enhanced Surgeon Control

- Enable enhanced visualization of vitreous-cavity⁴

TEST WITH BIONIKO EYE-MODEL



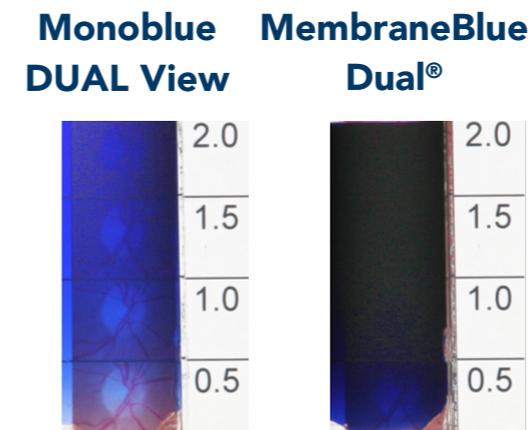
**100 µL PHOSPHATE
BUFFERED SOLUTION
NO TRYPAN**

**100 µL MONOBLUE
DUAL VIEW - TEST
TRYPAN BLUE @ 0,09%**

**100 µL MEMBRANEBLUE
DUAL® - REFERENCE
TRYPAN BLUE @ 0,15%**

TEST WITH WEDGE SHAPED CUVETTE

Transparency of reference cuvette filled with solution dye, the numbers gives the thickness of the liquid layer in mm⁴



- Monoblue DUAL View solution, 0,09% of Trypan Blue is more transparent than MembraneBlue Dual® solution, 0,15% of Trypan blue
- Most of eye-fundus anatomy is still visible with Monoblue DUAL View whereas MembraneBlue Dual® allows only minimal visibility of blood vessels
- Translucent appearance of Monoblue DUAL View allows a safe aspiration of the dye solution with lower risk of touching retina surface

** data referring to: 1. Mohr A, Cendoya P, Wilinska J, Apostu M, et al. New dual dye for vitreoretinal surgery with increased transparency. BMJ Open Ophthalmol. 2022;7(1):e001116.



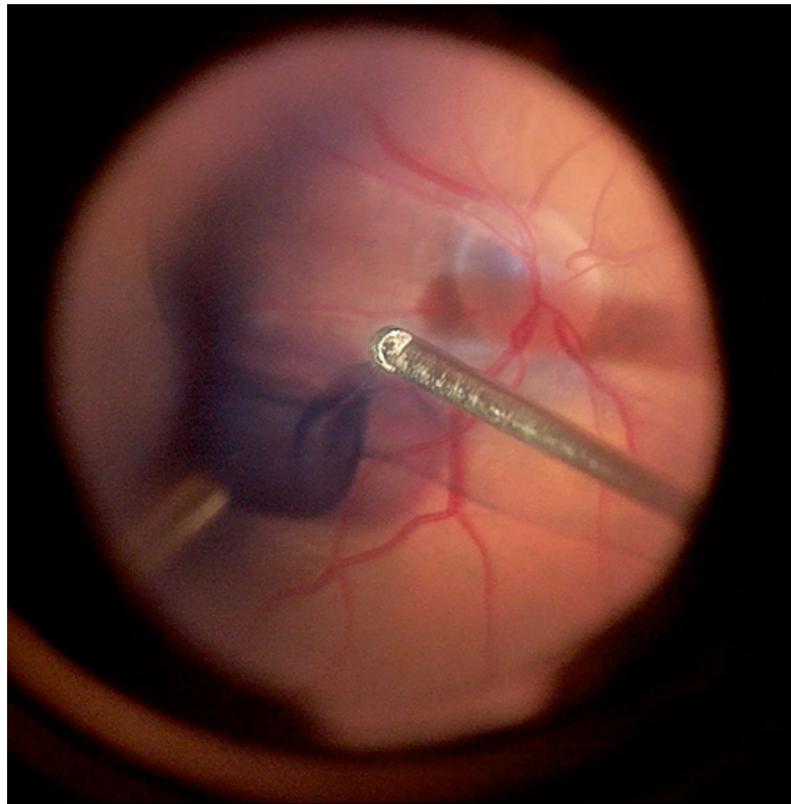


Methods and Materials:

- Comparative tests SPD (Monoblue ILM View) and DPD (Monoblue DUAL View) vs ILB (ILM-Blue®) and MBD (MembraneBlue Dual®)
- Applying 50 μ L of dye solution into filter and membrane for 30sec
- Removing dyes solution by vacuum filtration
- Washing membrane and filter (x 3) with PBS⁷
- Recording photographically and grading (0-3) stained membrane
- Recording absorbance spectrum of DMSO extracts of TB stained membrane's

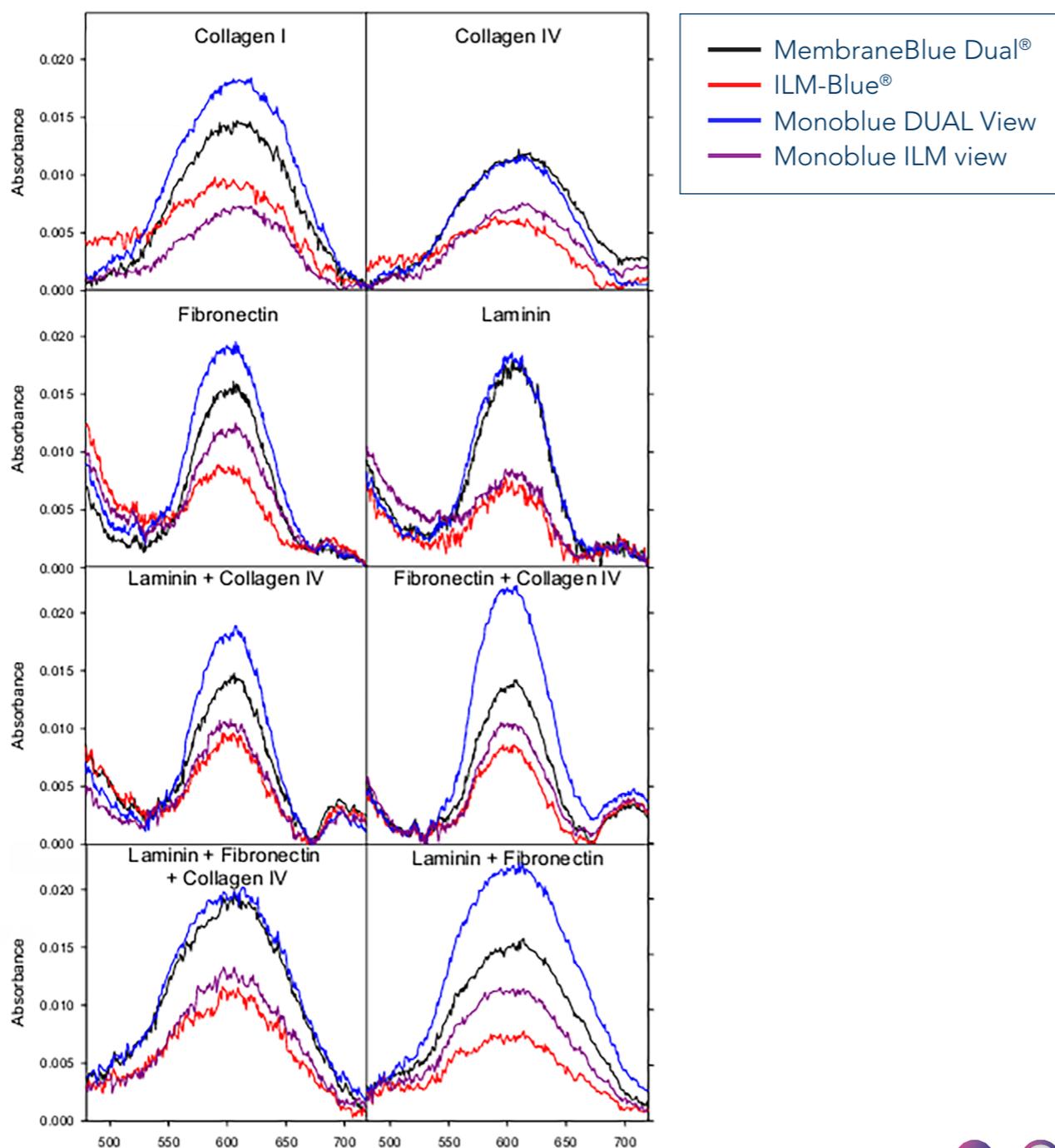
Enhanced Surgeon Control

- Easier aspiration of dye solution in excess (product specification).



Lower viscosity for easier aspiration of excessive dye solution with less viscous solution

Effective Membrane Staining



In vitro binding study with coated proteins on plastic support (ERM/ILM)

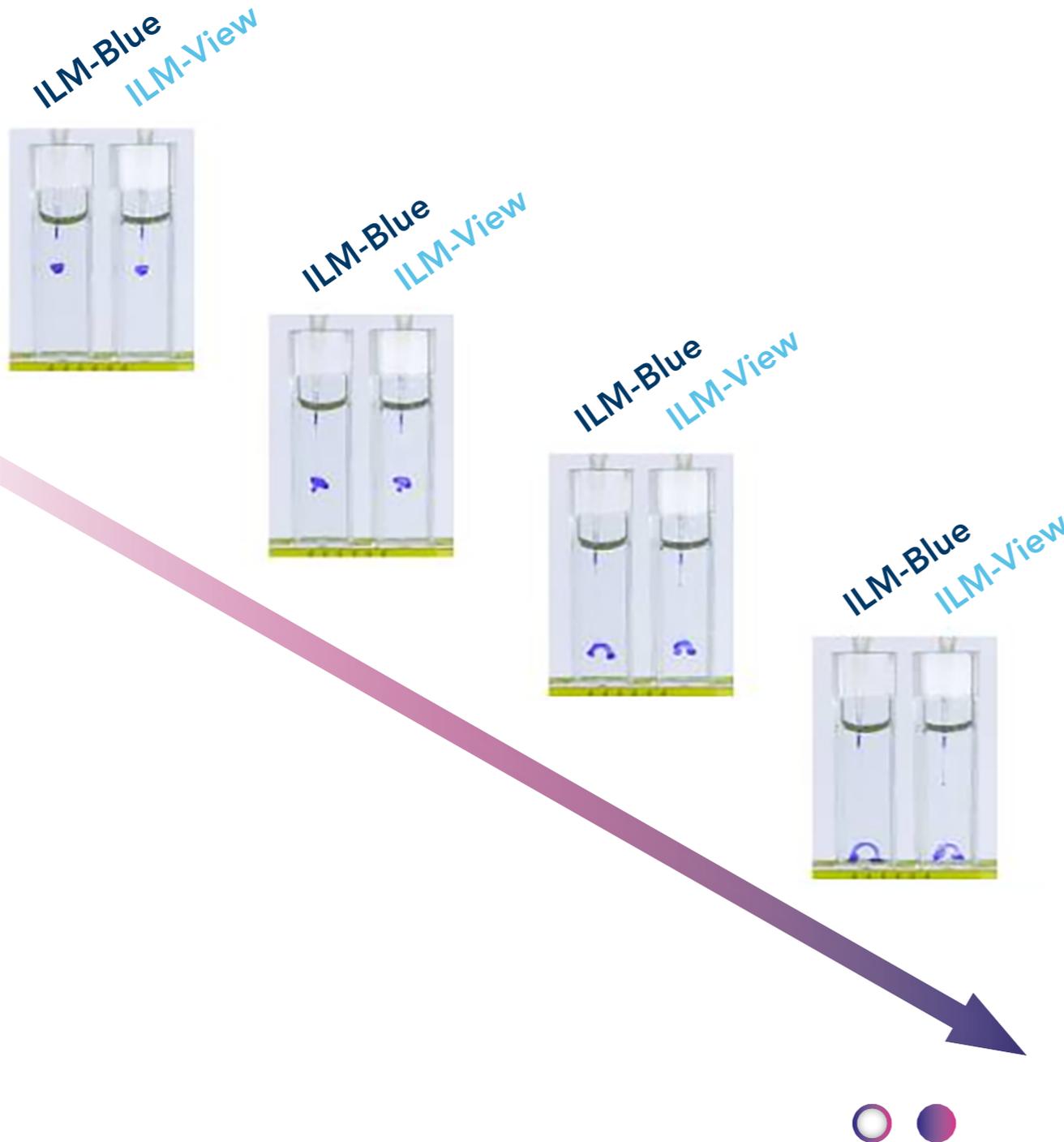
Monoblue DUAL View with -40% Trypan Blue vs product reference on the market stains equally/superiorly for Collagen I staining.⁴



Methods and Materials:

- Comparative tests Monoblue ILM View and Monoblue DUAL View vs ILM-Blue® and MembraneBlue Dual®
- Stains of individual / mixture of proteins adsorbed on plastic surfaces
- Recording at 600 nm absorbance spectrum of stained protein-coated surfaces
- ERM contains collagen type I proteins
- ILM contains collagen type IV and laminin proteins (among others)

Effective Membrane Staining



Cohesively sinks to eye fundus to stain targeted tissue without diffusion throughout the whole globe

Comparable sinking/removal time vs reference product on the market



End to End Portfolio

BVI portfolio has a large panel of consumables and equipment related to VR environment.
Main part of the consumables are available in 23G/25G and 27G

MONOBLUE DUAL

MICRO-FORCEPS

FC23.D03
FC25.D03
FC27.D03



Improved visualization for grasping thin membranes

BLUNT CANNULAS

CN25.D01



CN23.D01



Optimal control over surgical maneuvers



609

DYE SQUEEZERS



SQ00.D1

3 drops only

SURGICAL EQUIPMENT



R-Evolution®
Ref. 121012

23G

25G

27G



End to End Portfolio

BVI portfolio has a large panel of consumables and equipment related to VR environment.
Main part of the consumables are available in 23G/25G and 27G

MONOBLUE DUAL



MICRO-FORCEPS

- FC23.D03
- FC25.D03
- FC27.D03



Improved visualization for grasping thin membranes

DYE SQUEEZERS



SQ00.D1

3 drops only

BLUNT CANNULAS

CN25.D01



CN23.D01



Optimal control over surgical maneuvers



Technical Information



Preference of Use



Instruction of Use



Technical Data Sheet



Figure 1. Attach the connector to the luer on the glass syringe and connect the tuberculin syringe to the other end of the connector



Figure 2. Gently push the plunger of the glass syringe to transfer the contents of the glass syringe into the tuberculin syringe



Figure 3. When the transfer is complete, remove the connector from the tuberculin syringe and replace it with a blunt-tipped injection cannula

Preparation of the syringe by sterile user:

1. Remove the stopper from the glass syringe;
2. Attach the connector to the luer on the glass syringe;
3. Connect the tuberculin syringe to the other end of the connector;
4. Gently push the plunger of the glass syringe to transfer the contents of the glass syringe into the tuberculin syringe;
5. When the transfer is complete, remove the connector from the tuberculin syringe and replace it with a blunt-tipped injection cannula (not supplied).



- Under saline irrigation, carefully apply Monoblue DUAL View to the retinal membrane by gently pushing the plunger of the tuberculin syringe.
- 30 to 60 seconds of application under saline irrigation could be necessary to get an appropriate staining once the retina has been cleared of vitreous and posterior hyaloid residues.
- After application, the Monoblue DUAL View is carefully removed from the vitreous cavity by rinsing with saline solution.
- No Air Fluid Exchange required.





Preference of Use

Instruction of Use

Technical Data Sheet

Minimally Invasive Staining Solution	Name	General Device Description	Qty/Bx	SKU#
	MONOBLUE DUAL View	GTIN 1 376013064 054 8 GMDN 45 180 – “Eye dye”, ophthalmology	5	609

Composition	MONOBLUE DUAL View: DDG 0.025% (m/v), Trypan blue 0.09% (m/v), Diglycerol 2.6% (m/v), Phosphate buffer qsp 0.5 mL MONOBLUE DUAL View contains no natural latex or preservatives.
Density	1.008 - 1.010 mg/mL
Volume	≥ 0.5 mL
Source	Chemical synthesis + high purification
Osmolality	350 – 400 mOsm/kg (H2O)
pH	7.0 – 7.5
BVI product code	609





Preference of Use

Instruction of Use

Technical Data Sheet

Packaging	General Device Description								
5 pre-filled glass syringes per box, individually packed in a paper peel pouch with a female/female connector 1 multilanguage Instructions for Use Supplied with 5x1mL tuberculin syringes in a peelable pouch.	<table border="0"> <tr> <td>Name</td> <td>MONOBLUE DUAL View</td> </tr> <tr> <td>Reference Code</td> <td>CT 230</td> </tr> <tr> <td>GTIN</td> <td>1 376013064 054 8</td> </tr> <tr> <td>GMDN</td> <td>45 180 – "Ophthalmic surgical dye"</td> </tr> </table>	Name	MONOBLUE DUAL View	Reference Code	CT 230	GTIN	1 376013064 054 8	GMDN	45 180 – "Ophthalmic surgical dye"
Name	MONOBLUE DUAL View								
Reference Code	CT 230								
GTIN	1 376013064 054 8								
GMDN	45 180 – "Ophthalmic surgical dye"								
Manufacturer	Product Class								
Arcadophta 11 rue Antoine Ricord 31100 Toulouse - France	Class IIa sterile, single use								
OR Requirements	Shelf Life								
Sterile medical devices intended for use as an aid in the vitrectomy procedure during vitreoretinal surgery adults: DUAL View is indicated for the staining of the epiretinal membrane and the internal limiting membrane (ERM/ILM). It is intended for ophtalmologists experienced in vitrectomy surgical procedures	Two (2) years from manufacturing date								
Certification Information	Absence of								
EC Certification: 37858 CE mark: CE 0459 FDA approval: NA Notified Body: GMED ISO: NF EN ISO 13485:2016	Natural latex or preservatives								
Sterilization	Packaging Material								
Steam sterilization (Autoclave)	Primary: Type I Glass Secondary: Paper peel pouch and carton box								
Weight of the Device	Storage & Transportation								
8 g	Storage: Clean and dry place (15°C - 25°C) protected from light. Do not refrigerate. Do not freeze. Transportation: Withstand to hot and cold condition excursions (5°C, 50°C) during shipping.								



SURGICAL FLUIDS PORTFOLIO

Safety first for our line of product



ARCEOLE

Ready-to-Use
Set of Ophthalmic Gas

New Packaging Coming Soon



ARCIOLANE

Fractionated and Purified
Silicone Oil



ARCALINE - ARCOTANE

Heavy Liquids for
Ophthalmic Surgery



MONOBLUE

Purified
Staining Solutions



OP'COVER

Long Lasting*
Corneal Protection

*Less than 1h



REFERENCES

1. DDG differs from BBG only by a single methylene group (the ethoxy substituent of BBG has been changed to a methoxy substituent in DDG, DDG is a patented molecule.
2. HPLC testing
3. Efficacy and safety evaluation of Monoblue Dual View and Monoblue ILM View vital stains during vitrectomy surgery, Gauthier Blanckaert, Joris Vander Mijnsbrugge, Ann-Laure Delbecq, Joyce Jansen, Peter Stalmans (corresponding author: peter.stalmans@uzleuven.be) – Submitted for publication
4. New dual dye for vitreoretinal surgery with increased transparency. A. Mohr, P. Cendoya, D. Gabel et Al - BMJ Open Ophthalmol. 2022 Sep;7(1):e001116. doi: 10.1136/bmjophth-2022-001116.
5. MEMBRANEBLUE DUAL® and ILM-BLUE® are trademark owned by DORC International BV
6. Study report - Annex 4 Cytotoxicity ARPE-19, IOBA report of 27 APRIL 2021 (DPD #9448745 and the batch SPD #9448819)
7. PBS stands for phosphate-buffered saline solution



At BVI we care about the Planet

This is why we decided save paper and help the Environment by providing digital versions of our printed material.

GO
DIGITAL



GO
GREEN!