POSTERIOR SURGICAL DYES: FOCUS ON PURITY

MEMBRANEBLUE-DUAL® and ILM-BLUE®
ILM-BLUE®

• ILM-BLUE® is a dye to stain the ILM in vitreoretinal surgery.

• By injecting ILM-BLUE® in the vitreous cavity the ILM will be clearly stained and easily distinguished from the underlying, unstained retina and can be removed selectively.

• Due to an integrated carrier 4% PEG solution, ILM-BLUE® can be injected in a BSS filled eye and sinks immediately as a cohesive ball to the fundus of the eye and only stains the targeted tissue without diffusion throughout the whole globe.

Specifications:
Composition of one 0.5ml syringe:
• 0.125 mg • Brilliant Blue G
• PEG • 4% PEG 3350
• Density kg/l • 1.01

Concentration: 0.25 g/l
pH-value: 7.3 – 7.6
Osmolality: 301 - 369 mOsm/kg H2O

ILM-BLUE®: Posterior Dye for staining the ILM consists of:
• BBG 0.025% + 4% PEG
• Highly purified BBG – minimum 97% purity

EFFECTIVE ILM STAINING DUE TO HIGH PURIFICATION - MINIMUM 97% PURITY

SAFETY TESTS

• Toxicity tests on ARPE-19 human retinal pigment epithelium cells showed an advantageous safety profile of MEMBRANEBLUE-DUAL® and ILM-BLUE®.

• Increased purity of the dyes as well as the addition of PEG3350 results in even safer products.

• Safety testing was complemented by electron microscopy ultrastructural analysis and in vitro cytotoxicity tests according to ISO-10993.
MEMBRANEBLUE-DUAL®

- MEMBRANEBLUE-DUAL® is a dye to stain both the ILM as well as the ERM and PVR membrane, without compromising the staining effect within one injection.

- By injecting MEMBRANEBLUE-DUAL® in the vitreous cavity the membrane will be clearly stained and easily distinguished from the underlying, unstained retina and can be removed selectively.

- MEMBRANEBLUE-DUAL® is a stable mix and stains the ILM at the same level as ILM-Blue® and stains the ERM and PVR at a higher level than the classic MembraneBlue.

- Due to a new integrated carrier 4% PEG solution, MEMBRANEBLUE-DUAL® can be injected in a BSS filled eye and sinks immediately as a cohesive ball to the fundus of the eye and only stains the targeted tissue without diffusion throughout the whole globe.

Specifications:
Composition of one 0.5ml syringe:
- 0.125 mg • Brilliant Blue G
- 0.75 mg • Trypan Blue
- PEG • 4% PEG 3350
- Density kg/l • 1.01

Concentration: 1.75 g/l
pH-value: 7.3 – 7.6
Osmolality: 338 mOsm/kg H2O

MEMBRANEBLUE-DUAL®: Dye for staining ILM, ERM & PVR membranes consists of:
- Combination of TrypanBlue 0.15%
  + BBG 0.025% + 4% PEG
- Highly purified TB + BBG - minimum 97% purity

PURITY & SAFETY

- ILM-BLUE® & MEMBRANEBLUE-DUAL® are produced according to Current Good Manufacturing Practice (CGMP)
- ILM-BLUE® & MEMBRANEBLUE-DUAL® are produced with highly purified BBG + Trypanblue at a drug substance level.