Biolon™ OVD FAQ's

1. What is Biolon OVD?

Biolon OVD (Ophthalmic Viscosurgical Device) is a fermentation-based, sterile, optically clear, 1% (10mg/mL), sodium hyaluronate viscoelastic, provided in a sterile prefilled syringe.

2. What is Biolon's indication for use?

Biolon is indicated for use as a surgical aid to protect corneal endothelium during cataract extraction (extra-capsular) procedures, intraocular lens (IOL) implantation, and anterior segment surgery. When introduced in the anterior segment of the eye during these surgical procedures, Biolon serves to maintain a deep anterior chamber. In addition, Biolon helps to push back the vitreous face and prevent formation of a post-operative flat chamber.[1]

3. How is Biolon OVD classified?

Biolon OVD is classified as a Mid-Level Cohesive Viscoelastic. It has an average molecular weight of 3.0 million daltons, and an average viscosity of 105K cps at zero shear rate (0.1/sec).[1,3,6]

4. What are the properties of a Mid-Level Cohesive?

Mid-Level Cohesive viscoelastics are able to protect the corneal endothelium, maintain the space in the anterior chamber, and allow manipulation of the surgeon's instruments during phacoemulsification (removal of the old lens) and replacement of a new IOL (Intraocular lens). They can also be easily dispensed in the patient's eye at the beginning of surgery and can be readily removed after completion of the procedure.[6]

5. How is Biolon supplied?

Each Biolon kit consists of a sterile prefilled syringe containing 1mL of 1.0% NaHA viscoelastic, a sterile 27-gauge cannula, patient chart stickers, and an Instructions for Use leaflet.

The prefilled syringe is equipped with a rotating finger grip. The prefilled syringe and 27-gauge dispensing cannula are each supplied in their own sterile blister pack.

6. How is Biolon manufactured?

Biolon's viscoelastic is a highly purified, hyaluronic acid (NaHA) (1%), derived from fermentation of bacterial cells, which undergoes precipitation, redissolving and re-precipitating the hyaluronate in a phosphate buffered saline. The resultant material produced is ultra-pure, noninflammatory hyaluronic acid suitable for clinical use.[2]

7. What are the components found in Biolon?

Each mL of Biolon viscoelastic contains: 10 mg of Sodium Hyaluronate, in addition to sodium chloride (8.5 mg), disodium hydrogen phosphate dodecahydrate (0.56 mg), sodium dihydrogen phosphate dehydrate (0.045 mg), and water for injection q.s.

8. How is the Biolon syringe prepared for surgery?

The Biolon OVD syringes features an easy "Snap, Attach, Ready" tamper evident closure. Just before use, the white tip-cap is snapped off and the luer-lock cannula is secured on the tip. This tip cap ensures sterility until ready for use. For additional information on assembly, visit our website at: www.biolonusa.com.

9. How is Biolon managed after the cataract surgery?

After surgery, all Biolon viscoelastic should be removed from the eye. As with all OVDs, not retrieving the product after surgery could result in an increase in the intraocular pressure.

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10. What is the shelf life and storage temperature for Biolon?

Biolon OVD has a 3-year shelf life from the date of manufacture when stored refrigerated.

Biolon **can be stored at room temperature, 25ºC (77ºF), for up to one month.** Biolon can have room temperature excursions (up to 30 days) within the refrigerated shelf life of the product, (multiple excursions not to exceed a total of 30 days), allowing overnight and weekly procedure tray preparation.

Biolon OVD should be removed from refrigeration 20-30 minutes prior to surgery to allow the product to reach the desired temperature.

11. Can the Biolon syringe or cannula be reused?

No, avoid re-use of any of the kit components to ensure that there is no cross contamination. Cannulas are intended for single patient use only.

If reuse becomes necessary on the same patient during the surgical procedures, rinse the cannula thoroughly with sterile distilled water to remove all traces of residual material.

To guarantee that the contents of the syringe are completely sterile, a tamper evident closure is on the tip of the syringe. Do not use the syringe if the tamper evident cap is missing or broken.

12. How do fermentation-based, bacterial derived viscoelastics differ from those that are avian sourced?

Hyaluronic acid can be extracted from rooster combs or produced by microbial fermentation.[5] Resident proteins in OVDs made from rooster combs are high, and special storage conditions are required (2-8ºC) to keep their chemical integrity.[3] Raw materials used in fabricating sodium hyaluronate based OVDs, which are of a biological origin can be a source of endotoxins.[7] High molecular weight sodium hyaluronate obtained from microorganisms of the genus Streptococcus, fermented with a sugar-based carbon source, produce an ultra-pure, noninflammatory hyaluronic acid suitable for clinical use.[2] Note that physicians should be aware of immunological, allergic, and other potential risks of can occur from the injection of any biological substance since the presence of minute quantities of impurities cannot be totally excluded.

13. What is the background behind BTG, the manufacturer of Biolon?

Biolon is manufactured by Bio-Technology General (Israel) Ltd., who has been manufacturing NaHA based products for over 25 years. Bio-Technology General (Israel) LTD's facility is registered with the FDA. BTG currently supplies NaHA for use in more than 30 countries.

14. What is the safety record of Biolon OVD?

BTG (Israel) Ltd, has supplied over 7.5 million NaHA syringes for surgery across the globe. There has never been a product safety recall and less than 0.001% adverse events have been noted.[4]

15. What are the Biolon's Contraindications?

When used as recommended, there are no known contraindications to the use of Biolon. Refer to Biolon™ Package Instructions for additional information including Precautions and Warnings.

16. Product Use Warnings

Mixing of quaternary ammonium salts such as benzalkonium chloride with sodium hyaluronate results in the formation of a precipitate. The eye should not be irrigated with any solution containing benzalkonium chloride if Biolon is to be used during surgery.

References:

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6. Market Scope 2017 Single-Use Ophthalmic Surgical Product Report, p.93-104
7. Endotoxin testing recommendations for single use intraocular ophthalmic devices Issued August 17, 2015 US Dept of Health and Human Services

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