FORM FIT®
INTRACANALICULAR PLUG

HOW DOES THE HYDROGEL PLUG WORK?

Once inserted into the punctum, the dry hydrogel plug will absorb tear fluids and swell (approximately 20 times in volume) to fill and conform to the vertical canaliculus. The hydrated plug will remain in dynamic equilibrium with the tear fluids surrounding it in the canaliculus.

HOW LONG UNTIL THE PLUG IS FULLY HYDRATED?

Form Fit® will swell to 3 times its size within 45 seconds and become fully hydrated over a 10-minute period.

HOW LONG WILL THE PLUGS LAST?

Form Fit® is designed for long-term closure of the punctum similar to other forms of punctal occlusion.

CAN THE PLUG BE REMOVED?

Yes. Form Fit® can be removed by using a lacrimal cannula and flushing balanced salt solution through the lacrimal system.

HOW DO YOU KNOW IT'S IN?

Like all plugs that are situated below the punctum (Medennium and Lacrimedics®), you will not be able to visually confirm that Form Fit® is in place. Only through patient evaluation, Schirmers test, etc. or patient satisfaction, will a doctor be able to confirm the product's placement.

IS DILATION NECESSARY?

Dilation is not recommended, however it may be necessary in patients with very small puncta.

ARE THERE ANY SPECIAL INSERTION INSTRUMENTS TO PURCHASE?

No. Form Fit® comes pre-loaded in an inserter.

IS THERE ANY SPECIAL STORAGE REQUIRED?

No. Form Fit® can be stored at room temperature.

IN ITS SOLID STATE IS THERE CONCERN FOR SNAPPING OR BREAKING THE PLUG?

No. Form Fit® is securely positioned inside the inserter.

OASIS®
514 S. Vermont Avenue • Glendora, CA 91741 • (909) 305-5400 • www.oasismedical.com

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DOES THE HYDROGEL BECOME BRITTLE?

No. During the hydration period Form Fit® becomes more gel-like.

HAS THIS MATERIAL BEEN USED BY OTHER PLUG MANUFACTURERS?

No. This is a patent pending product unique to OASIS® and no other company has used this form of hydrogel for punctal occlusion.

IS IT POSSIBLE FOR THE MATERIAL TO ABSORB BACTERIA?

Bacteria will not absorb into the hydrated canalicular plug. The hydrogel material forming the hydrated canalicular Form Fit® is a homogenous material that does not have micro porosity.

The porosity in the hydrated hydrogel is in the molecular level (measured in Angstroms) which is too small to allow bacteria penetration.

Additionally, since the plug is hydrophilic, it will absorb the tear soluble components of the tear fluid. It will not absorb any oil or oil-based components of the tear fluid.

WILL THIS PLUG ABSORB DRUGS?

DRUG PLACED ON AN EYE WITH A PREVIOUSLY INSERTED HYDROGEL PLUG – Most drugs placed on the eye will dissolve in the tear fluid, and may ultimately diffuse into the hydrated hydrogel plug. The diffusion of the drug components from the tear fluid into the hydrated Form Fit® will be very slow, and will ultimately depend on the length of time the drug is in contact with the hydrated plug.

The diffusion rate of the drug depends on the difference between its concentrations in the tear fluid and in the hydrated Form Fit®. It also depends on the surface area of the plug actually exposed to the tear fluid, which is very small. If the drug has a short residency in the tear fluid, the diffusion of the drug into the hydrated plug will be minimal to non-existent.

The volume of the hydrated hydrogel plug equals about 1/10 of a drop. Diffusion of any absorbed drug out of the hydrated plug will also be very slow. The net effect of the outward diffusion of any drug from the hydrated plug is that it will occur over an extended period of time and will not be clinically significant.

HYDROGEL PLUG INSERTED IN AN EYE WITH DRUG ALREADY ON IT – In this scenario, the dry hydrogel plug will absorb the tear fluid which already contains a drug dissolved in it. The hydrogel plug will not intensify the concentration of the drug components. The drug concentration in the hydrated plug will not exceed the drug concentration in the tear fluid.

WILL THE HYDROGEL PLUG ABSORB PROTEINS?

Proteins will deposit on the surface of hydrated hydrogel plugs. This also occurs for other punctal and canalicular plugs. However, this will not affect either the performance or the safety of this or other competitive plugs.

The water content of the hydrated canalicular plug is approximately 95% compared to contact lenses, which range from 50% to 70%. This higher water content presents less foreign material (plastic) to the protein in the tear film, so protein absorption onto the surface of the hydrated Form Fit® will be less than for contact lenses.

Patent No. 5,116,371 Additional Patents Pending

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