

Medical Professional's Name: _____ Contact Number: _____

INFORMED CONSENT FOR TREATMENT OF DRY EYE SYNDROME WITH USE OF SMARTPLUG®

A consent form should give you sufficient information to be able to make a decision. This consent form may contain words you do not understand. If you have any questions, please make sure to ask your medical professional.

BACKGROUND & PURPOSE

You have two canals in each eye that allow tears to drain from your eye. Each canal is called a punctum and a punctum plug slows the outflow of tears from the eye surface by blocking the punctum. You are considering have a punctum plug, SmartPlug®, inserted into your punctum. SmartPlug® was developed to treat patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, and foreign body sensations. SmartPlug® may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases. SmartPlug® may also be used after ocular surgery to prevent complications due to dry eye and to enhance the retention of topical ocular medications on the eye. Patients experiencing dry eye related contact lens problems may also be aided by SmartPlug®.

PROCEDURES

Your medical professional will describe the plug, the insertion technique, and the follow-up care required after the insertion. You will be asked questions about your medical history and your eye problems. You will have your eyes examined, have tests performed to see how dry your eyes are and whether tears flow easily enough through your tear ducts.

You should not have this device inserted if:

1. You have excessive or overflow tearing (epiphora).
2. You have inflammation of the eyelid or tear (lacrimal) sac.
3. You have a permanent closure of the punctum or tear (lacrimal) ducts. The plug will be ineffective and trapping fluid within the tear (lacrimal) ducts may lead to other problems.
4. You have had a significant eye injury in the last 6 months.
5. Your immune system is compromised due to a medical condition or therapy, such as radiation or chemotherapy.

ALTERNATIVE TO SMARTPLUG®

There are alternative treatment for dry eye symptoms. Alternative treatments include eye drops, other punctum plugs, and permanent closure of the punctum (cauterization). You should ask your medical professional to explain these alternatives to you. You may also choose to change your treatment at any time, but before changing your treatment, please consult with your medical professional.

RISKS AND COMPLICATIONS

SmartPlug® is inserted into the punctum. You may feel some pressure when the plug is first inserted, but this sensation is expected to stop and will not continue to bother you.

The possible risks with the use of the plug are irritation, granulomas, infection (canaculitis) and/or difficulty in removal. If you feel irritation, itching or notice redness in your eyes, call your medical professional immediately. There is no guarantee or assurance that SmartPlug® will remedy your condition and it may cause excessive tearing. If you or your medical professional are not satisfied, the plug may be removed by irrigation or in exceptional cases by surgical intervention.

By signing this, I attest that I understand that there is no guarantee of the outcome either stated or implied. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction.

You must be given a signed copy of this consent form to keep.

Signature of patient

Date

Signature of witness

Date

Printed name of patient

Printed name of witness