

Safety Communication

رسالة سلامة

**Identified risk linked to the use of
Per-Fluor-Carbon-Octane liquids in ophthalmic surgery**

Device/ Product Description:	EFTIAR Octane, syringes and vial, 5 ml and 7 ml
Lot/Serial Number:	EFT05-OCT, EFT-07-OCT, EFT-OCT5-S, EFT-OCT7-S
Manufacturer:	D.O.R.C. Dutch Ophthalmic Research Center
Problem:	Use of Eftiar Octane into the vascular system may cause a fatal air embolism after uneventful choroidal melanoma endoresection without air infusion.
Recommendation/Actions:	<p>- The benefits of the use of EFTIAR Octane continue to outweigh the risk, providing that users take into account the following additional warning and precaution:</p> <p><u>Warning</u> Eftiar Octane should not be injected directly into the vortex vein. In addition, inadvertent leakage of intraocular perfluoro-octane into the vortex vein should be avoided.</p> <p><u>Precaution</u> Special precautions are indicated when Eftiar Octane may enter the vascular circulation (e.g. during endoresection of intraocular tumors and ocular trauma). Rare cases of air embolisms potentially related to the PFCL ingress have been reported.</p>

	<p>For more information, Please click here</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>	
Authorized Representative Details	AR name:	Albasar for Medical Supplies
	Assigned Contact Person:	Abdulaziz Abdullah AlFadda
	Mobile/Phone:	(966) 505450967
	Email:	info@albasarmedical.com.sa

