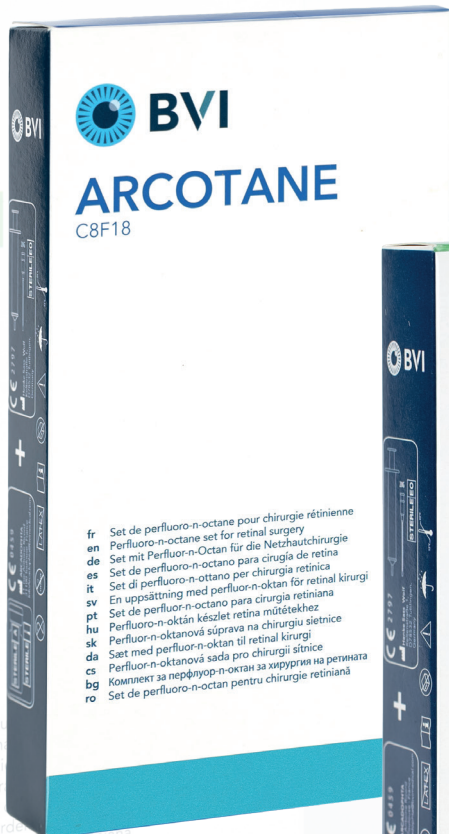


BVI

Safety Assured with Cytotoxicity Tests by IOBA* Perfluorocarbon Liquids



Purity
99%



BVI

ARCOTANE

Purity
97%



BVI

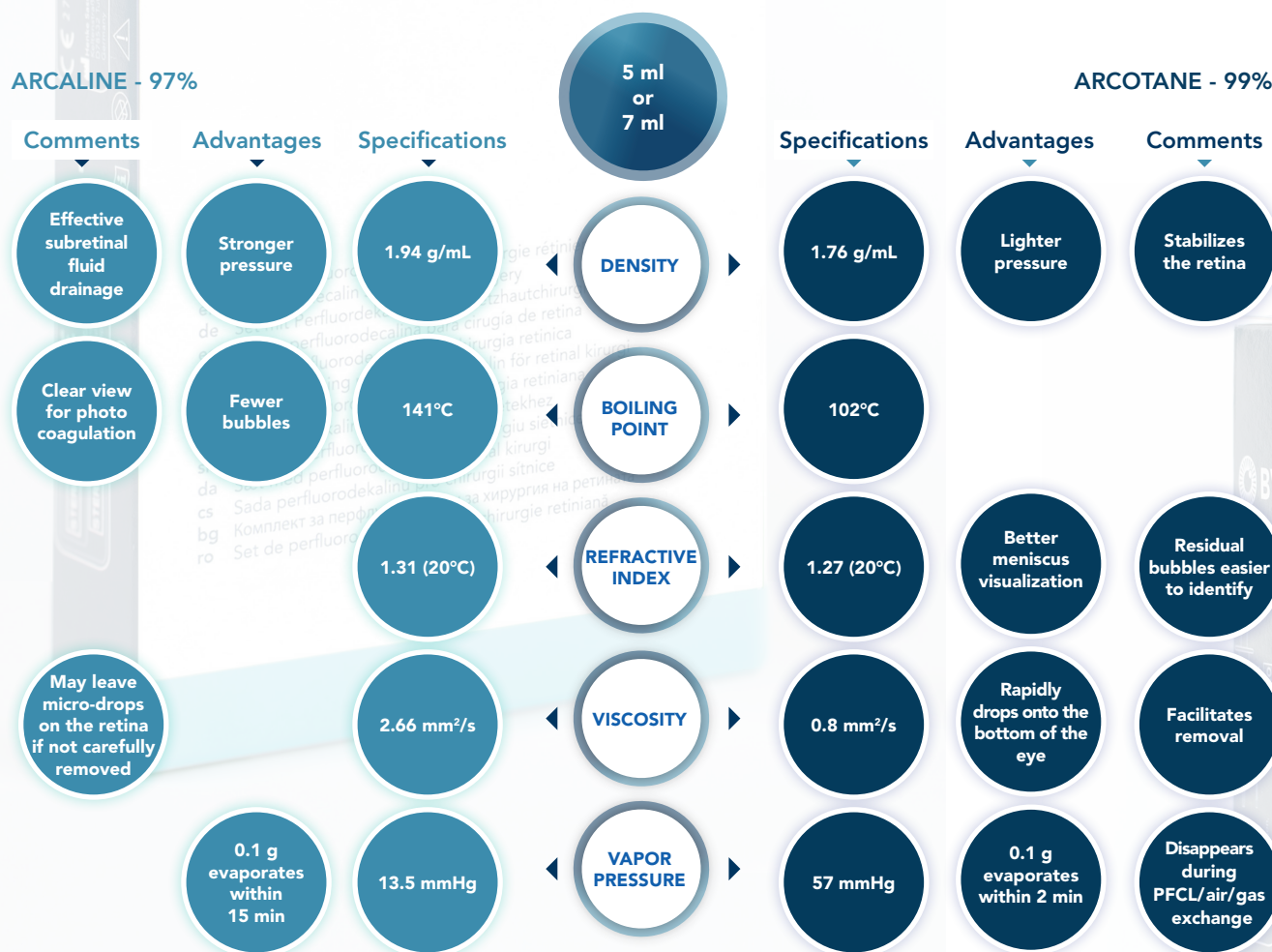
ARCALINE

C10F18

ARCOTANE C_8F_{18}
ARCALINE $C_{10}F_{18}$

ARCOTANE and ARCALINE Introduction

The highly purified perfluorocarbon liquids (PFCLs) have several indications in vitreo-retinal surgery, including drainage of subretinal fluids to favor re-adhesion of detached retina to the underlining tissue. Limiting the presence of free fluoride anions and any other toxic compound like fluoro-acid, fluoro-alcohol is key to ensure perfluorocarbon liquids are safe for use¹.



ARCALINE AND ARCOTANE IN PROCESS CONTROLS

All the controls, especially gas chromatography and nuclear magnetic resonance, show that **ARCALINE and ARCOTANE specifications comply with up-to-date standards.***

| FDA approved products specification in US* | | ARCALINE / ARCOTANE specification |
|--|-----------|-----------------------------------|
| FLUORIDE (F-) | ≤ 3 ppm** | ≤ 2 ppm |
| NON VOLATILE RESIDUES | ≤ 20 ppm | ≤ 20 ppm |
| (C-H) Link IR | ≤ 1 | ≤ 0,015 |


1. Ophthalmologica Review: Retinal Toxicity of Medical Devices Used during Vitreoretinal Surgery: A Critical Overview acute retinal damage after using a toxic perfluorocarbon for vitreoretinal surgery- retina 37:1140-1151, 2017.

* As per P950018 S019 Perfluoron PMA reported in the FDA website.


** Part Per Million, commonly used to express chemicals concentration.

ARCOTANE and ARCALINE Unique Biological Safety Guarantee

Each batch is tested for cytotoxicity on human retinal cells (ARPE*** cells) and on porcine-ganglionar cells.



IOBA | Cell Culture Lab: Preclinical In Vitro
Cytotoxicity study of PFO medical devices (-ARCADOPHTA XII-)



IOBA
Instituto Universitario de Oftalmobiología Aplicada

Study Report

In vitro cytotoxicity study of PFO medical devices on cultures of human retinal pigment epithelial cells and porcine neuroretina
-ARCADOPHTA-

Sponsor:

ARCADOPHTA

11 Rue Antoine Ricord
31100 Toulouse
France

Conclusions:

The product "PFO medical device" lot numbers 310832 and 400929 (A and B) were provided by the company ARCADOPHTA and tested with RPE cell cultures,

- Lots 310832 and 400929 are NON-CYTOTOXIC.

It was concluded based on the differences in terms of viability compared to the controls used in the experiments performed following the UNE-EN ISO 10993-5:2009 "Tests for in vitro cytotoxicity".

The product "PFO medical device" lot numbers 310832 and 400929 (A and B) were provided by the company ARCADOPHTA and tested with porcine neuroretina cultures,

- Lots 310832 and 400929 are NON-CYTOTOXIC.


It was concluded based on the differences in terms of the cell/tissue degeneration compared to the controls used in the experiments performed following the UNE-EN ISO 10993-5:2009 "Tests for in vitro cytotoxicity".

Version: 01

Date: 26/10/2020



Study Director:

JC Pastor Jimeno




Experiments Directors:

Cristina Andrés Iglesias
Iván Fernandez Bueno




Facilities Director:


MJ Maldonado López



Quality Assurance Unit:

MA Garcia Hontoria





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- The test results relate only to the items tested -
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IOBA Certificate

ARCOTANE and ARCALINE Advantages

- No reports of cytotoxicity² have been communicated to the manufacturer Arcadophta over 15 years of production and commercialization
- Over 600.000 units distributed in more than 70 countries
- Pharmaceutical environment production
- ISO 13485/2016 certified company
- European legal manufacturer

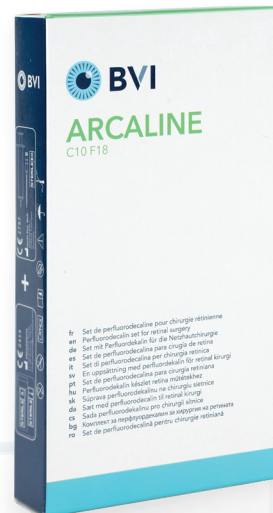
| Description | SKU # |
|--------------------|-------|
| Arcaline 5 ml vial | 102 |
| Arcaline 7 ml vial | 103 |
| Arcotane 5 ml vial | 104 |
| Arcotane 7 ml vial | 105 |

2. ARCAD_PMS-PMCF_01 Version 0 of the 27/04/2020* As per P950018 S019 Perfluoron PMA reported in the FDA website.

***Adult Retinal Pigment Epithelium cells.

ARCOTANE and ARCALINE PFCL Instructions For Use

- Use a long blunt cannula to inject PFCL close to the optic disc and create a single bubble
- Always inject PFCL smoothly into the same bubble, and avoid jet-stream to prevent damaging the retina
- Let the bubble expand until you reach the bottom part of the tear; Stop the injection to avoid any PFCL leakage into the subretinal space
- Apply laser endophotocoagulation through the PFCL
- Thoroughly remove PFCL passively before introducing gas or silicone oil tamponade



Safety First for Our Product Line



ARCIOLANE

Fractionated and Purified
Silicone Oil



MONOBLUE

Ultra-purified Staining
Solutions



ARCEOLE

Ready-to-Use Set
of Ophthalmic Gas

New Packaging Coming Soon



OP'COVER

Corneal
Protection

FOR COMPLETE PRODUCT INSTRUCTIONS, PLEASE REFER TO THE IFU SUPPLIED WITH THE PRODUCT

<https://www.bvimedical.com/customers-support/>

