



**ARCAD**  
SAFETY FIRST

PERFLUOROCARBON LIQUIDS  
Tested on retinal cells



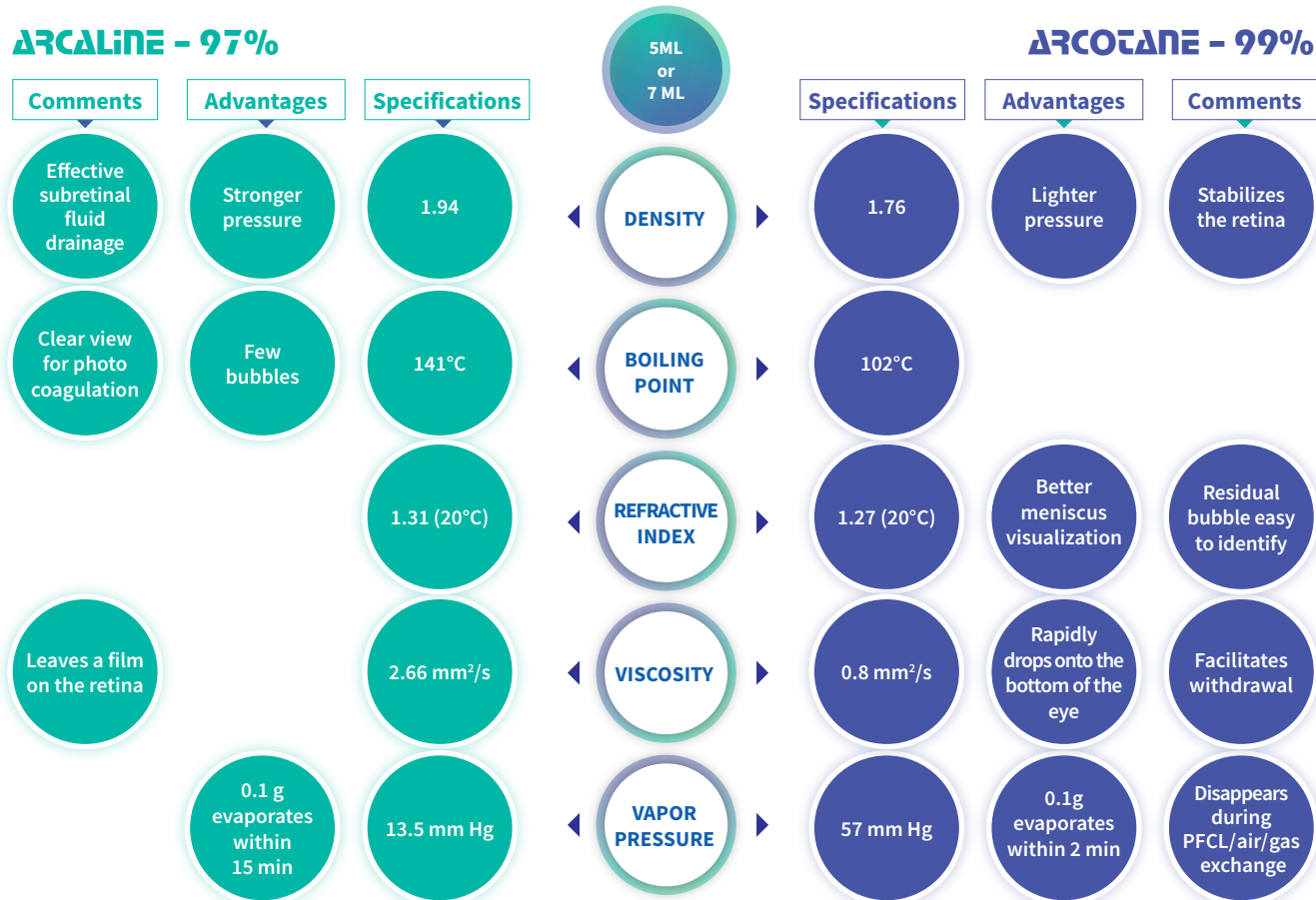
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97%

[www.arcadophta.com](http://www.arcadophta.com)

# Product specifications

The highly purified perfluorocarbon is used as a per-operative tool during retinal surgery, to drain subretinal fluid, and reapply the retina.



## SAFETY ISSUES CONTROL <sup>(1)</sup>

- Control of free fluoride compounds
- Control the presence of any other toxic compounds like fluoro-acid, fluoro-alcohol.

## ARCAD WITH IN PROCESS CONTROLS

All the controls, especially gas chromatography and nuclear magnetic resonance, shows that **Arcad PFCL specifications comply with up-to-date norms.**

FDA approved products specification in US		ARCAD standard
FLUORIDE (F-)	≤ 3 ppm	≤ 2 ppm
NON VOLATILE RESIDUES	≤ 20 ppm	≤ 20 ppm
(C-H) Link IR	≤ 1	≤ 0,015
HYDROGENATED COMPOUNDS	≤ 1 ppm w/w	≤ 0.02 ppm w/w

(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



# ARCAD unique biological guarantee

with a specific cytotoxicity test on retinal cells (human ARPE cells and porcine-ganglionar cells)  
**for each new batch of production.**

  
Universidad de Valladolid

  
ioba  
Instituto Universitario de  
Oftalmobiología Aplicada

### CERTIFICATE OF PRODUCT CYTOTOXICITY

The University of Valladolid, Valladolid, Spain, through its Eye Institute (Instituto Universitario de Oftalmobiología Aplicada IOBA) which has implemented and maintains a Quality Management System which fulfills the requirements of the ISO-9001:2008 standards (valid up to 17-04-2018) registration number: ES-0101/2006.

**CERTIFIES THAT:** lot(s)/batch(es) number(s): 141125; 551477; 558231; 590929; 591057;

The product: PFCL Medical Devices 930766; 950418; 952216

provided by: ARCADOPHTA, 11 Rue Antoine Ricord, 31100, Toulouse, France. VAT: FR 54440530558.

**"does not produce cytotoxicity"**

on cultures of **retinal pigment epithelium** (RPE) cells from **human** origin (ARPE-19 cell line), and **neuroretina** explants from **porcine** origin in our experimental conditions performed following the UNE ISO guidelines (UNE-EN ISO 10993-5: 2009, 10993-12: 2012).

**Signed:**

<b>Sponsor</b> Signature:  Mr Gerard Reboul technical director Date: October 24, 2016	<b>Innovation and Transference Vicerector</b> Signature:  Prof. Dr. Celedonio Álvarez-González Date: October 24, 2016	<b>Head of Test Facility Management (Director of IOBA)</b> Signature:  Prof. Dr. Miguel J. Maldonado-López Date: October 24, 2016
<b>Study Director</b> Signature:  Dr. Girish Kumar-Srivatava Date: October 24, 2016	<b>Quality Assurance Manager</b> Signature:  D. Miguel Ángel García-Hontoria Date: October 24, 2016	<b>Head of Retina Group</b> Signature:  Prof. Dr. J. Carlos Pastor-Jimeno Date: October 24, 2016

  
FUNGE UVA

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R

  
UNET

IOBA Certificate

## ARCAD Safety Facts

- No case of cytotoxicity over 15 years of production and commercialization
- Over 600.000 products distributed
- Pharmaceutical environment production
- French manufacturer
- Distributed worldwide in more than 70 countries
- ISO 13485/2016 certified company by GMED



MANUFACTURED  
IN FRANCE

NO CYTOTOXICITY  
OVER 15 YEARS

## ARCAD PFCL instructions for use

- Injection of the PFCL with a long canula, close to the optic disc to create a single bubble.
- Smoothly inject the PFCL always in the same bubble, avoid jetstream to prevent damage of the retina.
- Let the bubble grow until you reach the bottom part of the tear and stop the injection to avoid any passage of the PFCL into the subretinal space
- Make your endophotocoagulation through the PFCL
- Thoroughly remove the PFCL passively before Gas or Silicone oil tamponade.



## Safety first for our product line

**ARCIOLANE**

Fractionnated and purified  
silicone oil



ARCEOLE

Ready-to-use set  
of ophthalmic gas

**NONOBLUE**

Ultra-purified  
trypan blue



## OP'COVER

## Corneal protection

**ARCAD**  
SAFETY FIRST

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Bibliography on the website : [www.arcadophta.com](http://www.arcadophta.com)