

# TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

PERFLUORODECALIN INSTRUCTIONS FOR USE  
Read the instructions for use cautiously!

## 1.PRODUCT INFORMATION

Product Name: Perfluorodecalin

Product Model: See the catalog or website for models  
BUDI-DI: 868054899023NF

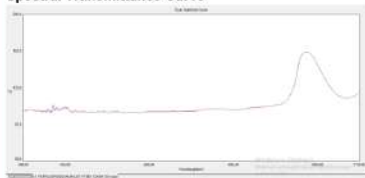
Size: 5, 7, 10 ml (in glass vial or glass syringe)

Shelf Life: Shelf life is 3 (three) years. Stated on the product.

Class: Ila

| Technical Features   |                                     |
|----------------------|-------------------------------------|
| Boiling Point:       | 141-143°C                           |
| Molecular Mass:      | 462.08 g/mol                        |
| Appearance:          | Clear, colorless liquid             |
| Smell:               | Odorless                            |
| Purity:              | 99% and above                       |
| Density:             | 1.883-1.912 g/cm <sup>3</sup>       |
| Kinematic Viscosity: | Calculated depending on the density |
| Dynamic Viscosity:   | 5 mPa.s (at 23/22°C)                |
| Molecular Formula:   | C <sub>10</sub> F <sub>18</sub>     |
| Refractive Index:    | 1.313 - 1.314 (at 25°C)             |
| Spectral:            | Measured between 300 nm and 1100 nm |

## Spectral Transmittance Curve



Perfluorodecalin is a sterile, single use, surgically invasive medical device. The product is designed for short-time temporary use. It is considered to be used as an auxiliary liquid used in vitreoretinal surgery. The product contains 100% fluorinated perfluorocarbon liquid. Perfluorodecalin is fluorocarbon and hydrogen atoms are substituted by fluorine. Purified, sterile and apyrogenic. These products do not contain phthalates and latex. Structurally inert, non-toxic. Do not dissolve in the eye.

## 2.PACKAGING AND STERILIZATION

Products are sterilized by steam sterilization. The products are offered in glass vial as 5, 7 and 10 ml, sealed with a polymer stopper and metal lid, or with a sterile cannula in a syringe. Supplied in the box with the glass vial with a sterile silicone injection cannula or dual bore cannula, depending on the product code. A sterile silicone injection cannula is offered in the box with the syringe, depending on the product code. Product amount is stated on the product packaging.

## 3.INTENDED PURPOSE

Perfluorodecalin is used as a short-time ocular tamponade. The main functions of perfluorodecalin are to flatten a detached retina and attach it towards the choroid. The main functions of perfluorodecalin are substitution of the vitreous substance and flatten retina approached towards the choroid during this substitution. The product must be used in ophthalmic surgery by surgeons who have specially vitreoretinal education.

### 3.1.Clinical Benefit

Provides short-time stabilization of the retina or protection of the macula during operations such as macular holes in all retinal detachments (RD with giant tears, traumatic RD, RD with PVR, Regmatogen RD), diabetic PVR, intraocular hemorrhage, removal of vitreous luxated intraocular lens or IOLs, removal of foreign bodies in the vitreous.

## 4.INDICATIONS

Perfluorodecalin is used for effective retinal reattachment, the release of subretinal fluid from the existing hole or tear while the retina is attached as a temporary tamponade to control fibro-vascular proliferation dissection and retinal hemorrhage. The product is used for short-time stabilization of the retina in all retinal detachments, (RD with giant tears, traumatic RD, RD with PVR, Regmatogen RD) during surgeries such as macular holes, diabetic PVR, intraocular hemorrhage, removal of vitreous luxation intraocular lens fragments or IOLs, removal of foreign bodies in vitreous or as a temporary intraocular tamponade during vitreoretinal surgeries to protect the macula.

### 4.1.Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population when needed for vitrectomy surgeries without indicating any weight restrictions.

### 4.2.Patient Preparation

The patient is prepared for the surgical procedure in line with the doctor's instructions. The product does not require

any special preparation and training

## 5.CONTRAINDICATIONS

As a result of the lack of any study of its tolerance, it should not be allowed to flow into subretinal tissues. The surgeon should use careful pre- and peri-operative evaluation and solid clinical judgment to decide the benefit/risk ratio before administering a perfluorodecalin injection to a patient with one or more of the following conditions. The evaluation of each individual case is at surgeon's discretion.

- In patients known to be allergic to any of the product ingredients
- Should not be used for long-term intraocular use or as a permanent vitreous backup.

## 6.SIDE EFFECTS

Temporary high intraocular pressure, hypotonia, glaucoma, cataracts, and corneal or iris abnormalities may occur following the surgery. In case the product residues remain in front of the retina, it may affect refraction and temporarily alter visual acuity for this reason. Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

## 7.USAGE

Should not be left in the eye after the procedure is completed. Care should be taken to ensure that the cannula delivering the product remains inside the balloon first formed while administering the product and behind the retinal tear during injection. This way, spreading of the product and penetration of the subretinal tissues are prevented. The amount to be injected varies in each specific case and should be designated by the surgeon during the operation. Do not mix with any other substance before use.

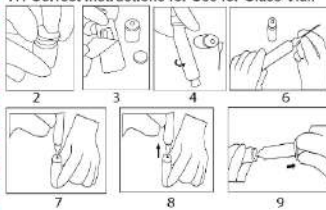
- Take out the products from the box.
- Open the product packaging just before use.
- Open the sterile packaged products taken out of the box to a sterile area by following the sterile opening rules and the opening direction shown on the package. (Picture A)



Picture A: Symbol of Roll Pack Open Direction

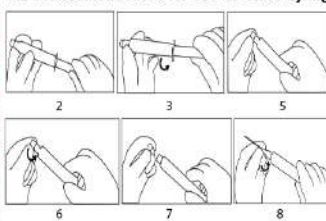
- Replace the product with the preferred endotamponade (gas or silicone) after the surgery, switching or not switching to the air first.

## 7.1 Correct Instructions for Use for Glass Vial:



1. Take the glass vial in the box out of its package.
2. Remove the cap of the glass vial.
3. Take the cannula from the box out of its package.
4. Hold the syringe.
5. Place the cannula on the syringe. (dual bore cannula or silicone injection cannula)
6. Twist and secure.
7. Perforate the polymer plug with the syringe.
8. Pull the plunger rod back to draw the product into the syringe.
9. Transfer the product from the vial to the syringe.

## 7.2 Correct Instructions for Use for Glass Syringe:



1. Take the syringe out of its package with its plunger rod.
2. Move the plunger rod to the appropriate space on the syringe.
3. Place the plunger rod by twisting it to the appropriate space and fix it.
4. Take the cannula from the box out of its package.
5. Hold the syringe luer as shown.
6. Carefully twist the syringe luer cap.
7. Remove the syringe luer cap.

8. Place the cannula on the syringe. Twist the cannula and secure. The product is ready to use.

## 8.WARNINGS and PRECAUTIONS

|   |                                                                                                                                                                                                       |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ⚠ | It is for single use.                                                                                                                                                                                 |
| ⚠ | Do not shake the product.                                                                                                                                                                             |
| ⚠ | Do not re-sterilize. Reuse and/or resterilization may adversely affect device performance, which could seriously harm patient health and safety.                                                      |
| ⚠ | Do not use the product whose sterile package has been opened or damaged.                                                                                                                              |
| ⚠ | Apply with a sterile single use syringe and a sterile single use cannula.                                                                                                                             |
| ⚠ | Do not use expired products.                                                                                                                                                                          |
| ⚠ | The product is restricted for use by surgeons trained in ophthalmic surgery.                                                                                                                          |
| ⚠ | Stop the application if any side effects occur. In case of any adverse reaction, notify the manufacturer.                                                                                             |
| ⚠ | Conduct the application according to the instructions written in the instructions for use. Otherwise the manufacturer is not responsible.                                                             |
| ⚠ | Glass injectors are potentially fragile and should be used carefully.                                                                                                                                 |
| ⚠ | In case of air bubbles, clean the syringe before use.                                                                                                                                                 |
| ⚠ | Subretinal migration may occur during injection. Special attention should be paid to remove and inspect subretinal residues before completing the surgery.                                            |
| ⚠ | Before opening the retina sing perfluorodecalin, all tractions should be taken into consideration so that the added weight of perfluorocarbons does not lead to iatrogenic retinal tears.             |
| ⚠ | If the eye is continually irrigating, ensure that the perfluorodecalin is flowing along the irrigation line.                                                                                          |
| ⚠ | Use for children, pregnant or lactating women is under the initiative of the ophthalmic surgeon.                                                                                                      |
| ⚠ | It should not be used in conjunction with other devices and/or general purpose equipment.                                                                                                             |
| ⚠ | In case residual PFCL bubbles are detected in the anterior chamber following the retinal surgery, removal is recommended to prevent damage to the corneal endothelium.                                |
| ⚠ | If its residues remain in front of the retina, it can affect refraction and temporarily change visual acuity for this reason. Make sure that the product is completely removed after the application. |

## 9.WASTE DISPOSAL

Used products must be disposed of properly to avoid possible risks of infection. Disposal of the products after use should be performed by authorized persons in line with hospital procedures. Manufacturer is not responsible for waste disposal procedures.

## 10.STORAGE AND TRANSFER CONDITIONS

Store at temperatures between 10°C (50°F or 283.15°K) and 25°C (77°F or 298.15°K). Store in a dry place. Protect against light and impact. Do not use after the expiry date. If it is wanted to be transferred, it can be transported in the boxes belonging to the product.

## 11.WARRANTY AND LIMITATION OF LIABILITY

Teknomek Medikal is not responsible for any injuries or damages that may arise from non-compliance with the recommendations and suggestions in the instructions for use and that are not suitable for the patient in the specified criteria. The risk of contamination which may arise from re-sterilizing the product by ignoring its single use quality is not the responsibility of the manufacturer. Teknomek Medikal is not responsible for the injuries or damages that the patient may suffer if it is not used by the doctor in line with the instructions for use.

## 12.SAFETY and CLINICAL PERFORMANCE

The product does not contain tissue, cell or derivatives of human or animal There are no accessories and software for the device. There are no medicinal substances or biological materials included in the device as an integral part of the device. No CMR substances or materials that contain or consist of endocrine disruptors as an integral part of the device or that may cause sensitization or an allergic reaction to the patient or user are included in the device. Please contact the manufacturer for detailed safety and performance information.

## 13.RETURN AND EXCHANGE POLICY

Please contact the manufacturer or your local distributor for the return or exchange of the product.

## 14.SYMBOLS

The symbols given on the product box and in the instructions for use are listed below

|                                                                    |                                                                    |
|--------------------------------------------------------------------|--------------------------------------------------------------------|
| Manufacturer                                                       | Manufacturer                                                       |
| LOT                                                                | Batch Code                                                         |
| 10°C - 25°C                                                        | Temperature Limit                                                  |
| 30% RH                                                             | Humidity Limitation                                                |
| Do not re-use.                                                     | Do not re-use.                                                     |
| Do not re-sterilize.                                               | Do not re-sterilize.                                               |
| Use-by Date                                                        | Use-by Date                                                        |
| Caution                                                            | Caution                                                            |
| Keep away from sunlight                                            | Keep away from sunlight                                            |
| Sterilized using steam. Single sterile barrier system.             | Sterilized using steam. Single sterile barrier system.             |
| Keep dry.                                                          | Keep dry.                                                          |
| Consult instructions for use.                                      | Consult instructions for use.                                      |
| Do not use if package is damaged and consult instructions for use. | Do not use if package is damaged and consult instructions for use. |
| MD                                                                 | Medical device                                                     |
| UDI                                                                | Unique Device Identifier                                           |
| Does not contain natural rubber latex.                             | Does not contain natural rubber latex.                             |

## 15. ABBREVIATIONS

| IFU               | Instructions for Use                                   |
|-------------------|--------------------------------------------------------|
| EN                | English                                                |
| %                 | Percentage                                             |
| °K                | Kelvin                                                 |
| °C                | Centigrade                                             |
| °F                | Fahrenheit                                             |
| ml                | Milliliter                                             |
| g                 | Gram                                                   |
| nm                | Nanometer                                              |
| g/mol             | Gram/mol                                               |
| mPas              | Milli pascal second                                    |
| IOL               | Intra-Ocular Lens                                      |
| CMR               | Carcinogenic, mutagenic, reprotoxic substances         |
| RD                | Retinal Detachment                                     |
| PVR               | Proliferative vitreoretinopathy                        |
| PFCL              | Perfluorodecalin                                       |
| BUDI-DI           | Basic Unique Device Identification - Device Identifier |
| g/cm <sup>3</sup> | Grams/Cubic Centimeters                                |

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