



# ONE-DAM

EN Light curing liquid cofferdam  
LT Šviesioje kietėjantis skystas koferdamas



## INSTRUCTION FOR USE

EN

### DESCRIPTION

ONE-DAM is a Light Curing Liquid Cofferdam, indicated as barrier for the isolation of gingival tissues and replacement of the rubber dam sheet to protect the gingival tissue in some cases where there is a risk of irritation by contact with products used in the clinical procedures, such as dental bleaching with Hydrogen Peroxide. The product is sufficiently viscous and allows easy application and control over the place to be protected. It is blue or green in colour in order to make a contrast with the gingival tissues and the teeth and so facilitate its localization.

### COMPOSITION

ONE-DAM contains contains resins 80-90%, fillers 5-10%, excipients 0.01-6%, pigments <2%.

ONE-DAM does not contain medicinal substance, including human blood or plasma derivate; tissues or cells, or their derivatives, of human origin; tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No. 722/2012; substances which are carcinogenic, mutagenic, toxic to reproduction or having endocrine-disrupting properties.

### PERFORMANCE CHARACTERISTICS

Colour	Green/blue
Appearance	Paste
Setting time	20 sec

### INTENDED PURPOSE AND CLINICAL BENEFITS

ONE-DAM Light Curing Liquid Cofferdam protects biological structures of restorable tooth and adjacent tissues.

### CLINICAL INDICATIONS

- to provide protection for the gingival tissue and/or the adjacent tooth, restorations during clinical procedures, such as teeth whitening, bleaching with high concentration of Hydrogen Peroxide, air abrasion (sandblasting) or etching with strong acids.
- for complete isolation of the gingival tissue during cavity preparation or endodontic treatment.

### CONTRA-INDICATIONS

Patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients.

### RESTRICTIONS TO COMBINATIONS

None known.

### UNDESIRABLE SIDE EFFECTS

In susceptible individuals, ONE-DAM may cause allergic or irritation reactions (skin, eye, mucosa, respiratory tract).

### RESIDUAL RISKS

Risk control measures have been implemented and verified, risk is reduced as far as possible, the overall residual risk is judged to be acceptable.

### PATIENT TARGET GROUP

No restrictions known regarding patient population, their age and general health conditions. There may be children, middle aged or elderly patient.

### INTENDED PART OF THE BODY OR TYPES OF TISSUES OF BODY FLUIDS

Part of the body – mouth. Tissues or body fluids contacted by the device – tooth, saliva, mucosa.

### INTENDED USER

ONE-DAM is developed for professional use in dentistry only. Its user only licensed doctor who has knowledge how to use common dental materials. There is no need for specific training.

### STERILITY

ONE-DAM is delivered non-sterile. There is no need of any preparatory sterilization, cleaning or disinfection, preventive, regular maintenance or calibration to ensure that the device operates properly and safely during its intended lifetime. However, do not use if primary package is damaged.

### USE ENVIRONMENT

ONE-DAM is designed to be used in dental office where ambient temperature is 18-25°C. Dispensed amount is suitable for single use (only for one patient). Do not re-use. Dispensed amount kept not in original package may lead to loss of function.

### CONSUMABLE COMPONENTS AND ACCESORIES

No accessories are supplied with the device. Consumable components such as tips are supplied with the device.

### INSTRUCTION FOR USE

**NOTE!** Do not use if primary package is broken. It is recommended prepare syringe just before applying.

#### Syringe preparation:

1. Remove Luer cap.
2. Attach working tip to the syringe.
3. Verify resin flow prior to applying. If resistance is met, replace tip and re-check. Use only recommended tips.

**NOTE!** DO NOT APPLY product on gingival tissue in poor conditions, people who have undergone recent periodontal surgery or which contains a previously installed irritation.

1. Clean and dry the gingival tissues and the teeth in the area which you wish to protect.

2. Apply a fine layer (maximum of 1-2mm) of the product on the gingiva and the interdental papilla in a way that they are completely covered and there will be a good field of protection for the procedure to be applied.
3. Light cured for 20-40 seconds. It is advisable to proceed with the polymerization soon after applying the resin in order to prevent any possible irritation of gingiva. During the process of polymerizing a slight sensation of heat or burning may be felt on the gingiva owing to the reaction of the polymerization and contraction of the resin.
4. Verify that the product covers the entire gingiva surface and that it is completely polymerized. In order to see the rear part of the papilla and gingiva, use a clinical mirror looking from incisal to cervical. Avoid testing it by forcing it or trying to lift it as this can cause infiltration of the irritating substance.
5. Do clinical procedures.
6. In order to remove the polymerised product after procedures just move it forwards. It should come loose easily as a whole or in large pieces.

### WARNINGS

Do not use ONE-DAM for patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients. ONE-DAM does not emit radiation and does not cause any electromagnetic interferences.

### PRECAUTIONS

In susceptible individuals, product may cause allergic or irritation reactions (skin, eye, mucosa, respiratory tract). Product causes skin or mucosa irritation and serious eye irritation. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN OR MUCOSA: Wash with plenty of soap and water. If skin/mucosa irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. IF SWALLOWED: Rinse mouth. Call a Poison Center or doctor/physician if you feel unwell. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Wash hands thoroughly after handling. It is recommended to wear protective gloves/protective clothing/eye protection /face protection for doctor and patient.

#### Interaction with other substances:

Avoid interaction with eugenol, strong bases, strong oxidizing agents.

### SHELF-LIFE

Shelf-life of OEN-DAM is 3 years from the date of manufacture. Do not use after the expiry date. See packaging for expiry date.

### STORAGE

Keep product tightly closed in dry well-ventilated place at 4-28°C. Protect from direct sunlight and heat sources. Do not freeze. Keep out of the reach of children!

### DISPOSAL

Dispose of contents/container to as required by national regulatory requirements.

### VIGILANCE

If any serious incident that has occurred in relation to the device report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

### SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

ONE-DAM is safe and performs as intended if it is used in accordance to manufacturer's instruction for use.

### MANUFACTURERS RESPONSIBILITY

Our products have been developed for professional use in dentistry. As the application of our products is beyond our control, the user is fully responsible for the application. Of course, we guarantee the quality of our products in accordance with the applied standards.

### VALIDITY

Upon publication of this instruction for use, all previous versions are superseded.

### PACKAGING

**REF** DRMIDABP 3.5g syringe, 3 tips, instruction for use

### SIGNS EXPLANATION / EXPLICAȚIA SEMNELOR

	Caution /Ispėjimas
	Temperature limit /Temperatūros riba
	Consult instructions for use /Skaitykite naudojimo instrukciją
	Keep away from sunlight /Laikyti atokiau nuo saulės spindulių
	Do not re-use /Nenaudoti pakartotinai
	Non-sterile /Nesterilus
	Medical device /Medicinos priemonė
	Use-by-date /Tinka naudoti iki
	Catalogue number /Katalogo numeris
	Batch code /Partijos numeris



Manufacturer /Gamintojas



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