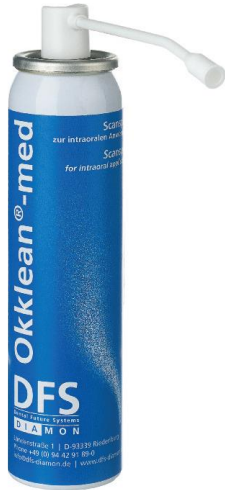


Okklean[®]-med
(Intraoral scan spray)

Date of issue: 20.02.2019

Last revision date: 01.02.2021



*Example

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1. User group

The intraoral scan spray Okklean[®]-med may only be used by appropriately qualified personnel in dental surgery, clinics and dental labs.

- Dentists
- Dental technicians

2. Target patient group

Patients with dental medical indications in the area of the described indications and applications.

3. Materials / Components

- Propellant
- Ethanol
- Micro-pulverized food coloring, white (titanium dioxide)

4. Product description

Okklean[®]-med spray serves as matting agent for reflective surfaces such as natural teeth and crowns before digital optical imprints. It can be applied both intraoral and on the dental model.

5. Indication

- Intraoral surface matting of teeth and crowns before digital optical imprints (intraoral scan)
- Intraoral fit and friction control of denture
- Extraoral matting of the dental model (before lab-side scanning)

6. Contraindication

- Use for any other than the described indication or application area
- Treatment of patients with asthmatic syndrome should be pondered in order to avoid respiratory distress

7. Application mode (Step-by-Step)

1. Place the dispenser with integrated atomizer onto the valve of the can
2. Shake the can vigorously before use
3. Clean and dry well the surfaces which are to be matted
4. Ask the patient to inhale deeply and then stop breathing
5. Apply the spray evenly and sparingly onto the areas to be matted, with short spray jets at a distance of approx. 3-5 cm. (Make sure not to apply several layers uncontrolled)
6. Let the patient exhale and repeat the procedure if necessary
7. Take an exposure with the 3D camera in the usual manner
8. Let the patient rinse thoroughly after scanning
9. The dispenser should be replaced after each use.
Replacement-Dispenser // DFS Art. no 11171 (3 pcs)

8. Protective measures / Warnings

- Caution! The can is under pressure
- Do not attempt to pierce or force open the can
- Protect yourself by wearing appropriate protective gear (mask)
- Recommended protective equipment for the patient: Eye protection

9. Side effects

In case of increased inhalation, sleepiness and/or drowsiness may occur.

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10. Residual risks

- Inhalation of the spray may cause respiratory distress or similar side effects in connection with chronic pulmonary disease (e.g. asthma).
- Sensitive reactions of the patient, user and/or third parties to the ingredients/substances of the spray cannot be completely excluded.

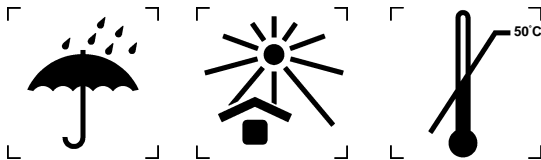
These residual risks are highly unlikely and are not expected in case of appropriate use and handling over the lifecycle of the product.

11. Traceability

Traceability via the lot number during the product lifecycle is ensured by the information on the label.

12. Storage

- Store in dry conditions
- Do not expose to direct sunlight (explosion hazard)
- Protect from warming up over 50°C



13. Disposal

Dispose only completely emptied cans with general laboratory waste (cans).

14. Notification to competent authorities

Competent national authorities and the manufacturer need to be notified about all serious incidents occurring in the context of the product without delay.



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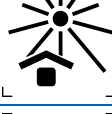

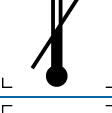
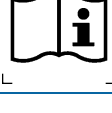
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15. Explanation of symbols

Pictogram	Standard / Directive	Explanation
	EU RL 93/42/EWG (MDD)	Proof of product conformity with the mentioned European directive/regulation.
	DIN EN ISO 15223-1 (Reference number 5.1.1)	Manufacturer
	DIN EN ISO 15223-1 (Reference number 5.1.3)	Date of manufacture
	DIN EN ISO 15223-1 (Reference number 5.1.5)	Batch code
	DIN EN ISO 15223-1 (Reference number 5.1.6)	Article number
	DIN EN ISO 15223-1 (Reference number 5.3.2)	Keep away from sunlight
	DIN EN ISO 15223-1 (Reference number 5.3.4)	Keep dry
	DIN EN ISO 15223-1 (Reference number 5.3.6)	Upper limit of temperature 50°C
	DIN EN ISO 15223-1 (Reference number 5.4.3)	Consult instructions for use