New as of: 2023-10

Dentsply Sirona

CEREC Optispray

Operating Instructions (not valid for USA)

English



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1 General data

1.1 Symbols used

CE mark

This product is compliant with EU Medical Device Regulation 2017/745 including all amendments.

MD — This product is a medical device.

For the USA only

Rx only — **CAUTION:** According to US Federal Law, this product may be sold only to or by instruction of physicians, dentists, or licensed professionals.

Legend

REF ABC123 — Article number

LOT ABC123 — Batch number

Observe accompanying documents

The accompanying documents are available on the Dentsply Sirona homepage.

www.dentsplysirona.com/manuals

YYYY-MM-DD — Date of manufacture: Year-Month-Day

YYYY-MM-DD — Can be used until: Year-Month-Day

XXX ℮ — Filling volume of packaging

XXX ml ℮ — Nominal filling quantity

Keep out of direct sunlight

+50 °C — Temperature during storage and transport

Only the special nozzle and the stabilization tube are disposable components.

1.2 Contact information

Dentsply Sirona Product service

Log in to register your units and make service requests:
https://dentsplysirona.service-pacemaker.com/

Dentsply Sirona Product service

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https://dentsplysirona.service-pacemaker.com/

Manufacturer's address



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This product complies with the requirements of the technical regulations for medical devices adopted by the Cabinet of Ministers of Ukraine by resolution No. 753 on October 2nd of 2013.

Representation:
Dentsply Ltd.
Welyka Wasylkiwska St. 9/2, office 40
01004 Kiev, Ukraine

1.3 General information about these operating instructions

Observe the operating instructions.

Familiarize yourself with the spray using these operating instructions before applying it. It is essential that you comply with the specified warning and safety information.

The operating instructions are available online at www.dentsplysirona.com/manuals.

Always keep the operating instructions handy in case you or another user require(s) information at a later point in time. Print out the operating instructions and note where they are stored on the unit or online.

Online portal for technical documents

We have set up an online portal for technical documents at www.dentsplysirona.com/manuals. From here, you can download these operating instructions along with other documents. Please complete the

online form if you would like a hard copy of a particular document. We will then be happy to send you a printed copy free of charge.

Help If you continue to have difficulties despite having thoroughly studied the operating instructions, please contact your dealer.

1.4 General conventions and structure of the document

1.4.1 Structure of the document

1.4.1.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these operating instructions. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in minor or moderate bodily injury.

NOTICE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information on making work easier.

1.4.1.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Identifies an action sequence with prompt and result.
see “Formats and symbols used [→ 6]”	Identifies a reference to another text passage and specifies its page number.
• List	Identifies a list.
"Command / menu item"	Identifies commands, menu items or a quote.

2 Hazard and safety information

IMPORTANT

Shake before using!

Failure to observe the specified application restrictions and procedure may result in measuring errors.

⚠ CAUTION

No side effects are known to date. Allergic reactions may occur in individual cases. CEREC Optispray should not be used if it is suspected or known that the patient may be allergic to any of its ingredients.

CEREC Optispray must not be used on infants. Infants must not be present during a CEREC Optispray treatment.

Hazard warnings

- The can is pressurized: it can burst if exposed to heat.

Safety instructions

- Keep away from heat, hot surfaces, sparks, naked flames and other ignition sources. Do not smoke.
- Do not pierce or burn, even after use.
- Only use outdoors or in well-ventilated spaces.
- Protect from sunlight.
  Do not expose to temperatures over 50 °C/122 °F.
- Contains 2% by weight of flammable components.
- Keep out of reach of children.

IMPORTANT

Immediately notify the manufacturer and the national competent authority of any serious incident that has occurred with the product.

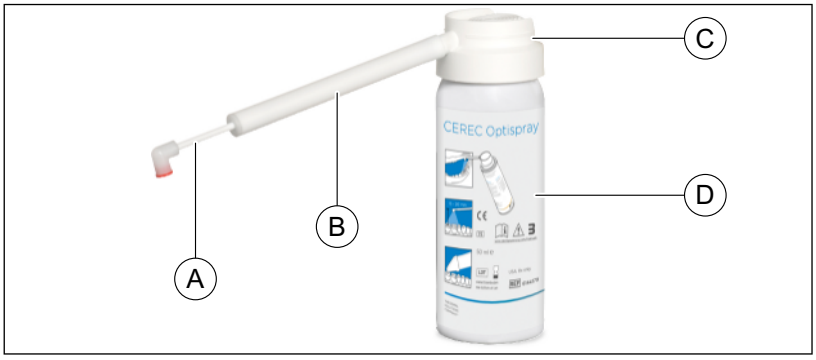
3 Product description

CEREC Optispray enables easy and perfect optical impressions to be taken of CAD/CAM restorations. CEREC Optispray is designed for (chairside) intraoral application. Due to its optimized dispensing and a special nozzle, it always ensures homogeneous coating of the object to be recorded.

3.1 Composition

- Pigment suspension based on zinc sulfide, pentane and ethanol
- Trans-1,3,3,3-Tetrafluoro-1-propene as propellant
- Peppermint oil as flavoring

3.2 Components



A	Special nozzle
B	Stabilization tube
C	Spray head
D	Aluminum can

3.3 Applied standards

- Directive 75/324/EEC
- ISO 10993-1
- ISO 13485
- ISO 62366-1
- ISO 14971

4 Intended use, indications and contraindications

4.1 Intended use

CEREC Optispray is used as the coating for optical impressions with the CEREC system. It is used for the intraoral measurement of prepared and unprepared teeth and the surrounding area.

4.2 Indication

Intraoral application (prepared and unprepared teeth and the surrounding area)

4.3 Contraindications

- on uncleaned surfaces,
- on wet surfaces,
- on heavily bleeding wounds that cover a large area.

5 Application procedure

⚠ CAUTION

Avoid inhaling spray mist

Inhalation of spray mist must be avoided at all times.

1. The surface to be coated must be thoroughly cleaned and dried.
2. Take the spray head with special nozzle and slide it into the spray head until the colored marking on the special nozzle disappears inside the spray head. Before every application, the secure fit of the special nozzle must be checked by pulling it gently.
3. Shake the can well before use.
4. The special nozzle can be rotated as required to enable optimal coating from all directions. For coating in the posterior tooth region, the stabilization tube can be used to push the patient's lip to one side without deforming the special nozzle.
5. Cover the exposure area with a thin even layer by targeting the spray jet.
6. The spray nozzle should be held approx. 10-15 mm away from the object.
7. During the application process, suction must be used in the patient's mouth.
8. Take an exposure with the 3D camera in the usual manner.
9. As soon as the optical 3D exposure has been taken, the surface must be cleaned with air/water spray.
10. The special nozzle and the stabilization tube must be replaced after every use.

6 Spare parts and consumables

REF	Designation
6203819	Special nozzle CEREC Optispray, 25 pieces
6321850	Stabilization tube CEREC Optispray

7 Disposal

Information on disposal can be found in the safety data sheet.

8 Storage and transport

Information on storage and transport can be found in the safety data sheet.

We reserve the right to make any alterations which may be required due to technical improvements.

© SIRONA Dental Systems GmbH
D3344.201.04.16.02 2023-10
Sprache: englisch
Ä.-Nr.: 134 472
Printed in Germany

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Order No 66 87 466 D3344