



**Icon<sup>®</sup>**



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**CE** 0482

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## Product description

Icon is an innovative product for the micro-invasive treatment of dental lesions in proximal regions and on smooth surfaces and is available in two variations:

**Icon Resin Infiltrant – Proximal** is a specially developed hard tissue preserving treatment for incipient proximal dental lesions.

**Icon Resin Infiltrant – Smooth Surface** is a specially developed infiltration product for smooth surfaces, particularly well-suited to remove white spots and treat incipient caries, especially those related to orthodontic treatment.

## Indications

- Micro-invasive treatment of non-cavitated dental enamel lesions (lesion depth up to D1\*).

- Esthetic improvement of non-cavitated lesions caused by demineralization and/ or mild to moderate fluorosis (on smooth surfaces).

## Lesion depth classification\*



- \* Radiographic lesion depth classification according to bite wing images.

## Contraindications

Do not use this material:

- for deeper seated lesions (D2 – D3) (see »Lesion depth classification\*« on page 1) or on cavitated enamel (enamel defects).
- in case of known allergies to any material component or existing contact allergies.

## General safety information

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- ▶ For dental use only!
- ▶ Keep out of reach of children!
- ▶ **Caution!** Icon-Etch can cause chemical burns. Avoid contact with soft oral tissue, eyes, and skin. In case of inadvertent contact rinse with copious amounts of water, and, if necessary, consult a physician.
- ▶ Limit the application to the surface to be treated. Avoid contact of the etching gel with the gingiva and adjacent teeth.
- ▶ Use only the syringe and application tip provided to apply the etching gel in the patient's mouth.
- ▶ Discard the application tip after use and cap the syringe.

**Caution!** Avoid contact of Icon-Infiltrant and Icon-Dry with eyes and skin.

- ▶ In case of eye contact, rinse with copious amounts of water, and, if necessary, consult a physician.

- ▶ In case of skin contact, wash the areas thoroughly with water and soap.

**Caution!** Improper use or incorrect application of Icon-Etch may cause pain in patients.

- ▶ Use Icon-Etch on enamel surfaces only. Do not apply onto exposed dentin or cementum.

## Please note

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- Light-curing units should have an output of 450nm and should be checked regularly.
- The light intensity should be at least 800mW/cm<sup>2</sup>.
- Place the light unit as close to the material as possible.
- The etched surface must not be touched or contaminated with saliva or moisture during treatment. If contamination occurs after drying, re-etch for approx. 10 s and repeat drying with Icon-Dry.
- Create a dry working field. Take appropriate measures; such as rubber dam, liquid dam or similar, to protect the gingival tissue. Do not

use thermoplastic elastomers such as Flexi-Dam (Coltène Whaledent/Hygenic).

- Discard syringes after use.
- On heavily remineralized, older white spots, the remineralized surface layer may be fairly thick. In this case, a 2 minute etching step to remove the surface layer may not be sufficient and etching and rinsing will have to be repeated. The teeth are then dried with Icon-Dry and infiltrated.

### **Proximal surface treatment**

- The syringes included in the treatment unit contain sufficient material for treating two proximal lesions.
- Additional proximal surfaces can be treated consecutively during one visit.

### **Smooth surface treatment**

- The syringes included in the treatment unit contain sufficient material for treating two to three smooth surface lesions. Multiple smooth surface lesions can be treated at the same time.

- For smooth surface applications, a liquid dam (Liquid Dam) can be used as well.
- Treating orthodontic patients after bracket removal: Unless white spots are treated early, i. e. 1 to 2 months after bracket removal, it is recommended to repeat the etching step. A third etching is recommended if a white spot is still visible after Icon-Dry is applied.
- In total, a lesion can be etched up to three times for 2 minutes each with Icon-Etch.
- For topical cariogenic white spots, an area of 2 mm beyond the lesion site is etched. At the discretion of the dentist, the entire smooth surface area ought to be etched and infiltrated, as in cases of large area white spots as they may occur after bracket removal.
- The overall esthetic result might be enhanced by a bleaching treatment prior to infiltration, especially when treating fluorosis. Please follow the manufacturer's specifications and instructions when bleaching.

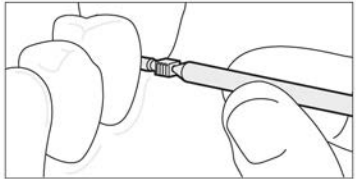
## Recommended use

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### Proximal surface treatment with Icon Resin Infiltrant – Proximal Preparation

1. Before the start of treatment, clean the affected tooth and adjacent teeth. Remove any cleaning residue with water spray.
2. Create a sufficiently dry working field. Take appropriate measures such as rubber dam, liquid dam or similar, to protect the gingival tissue. Please follow the manufacturer's specifications and instructions.

## Separation

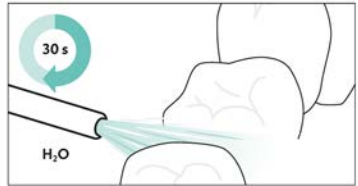


3. To ensure a successful treatment, a proximal separation of approximately 50 microns is required. Introduce one of the enclosed dental wedges into the treatment site.
  - ▶ For better access to the proximal region, the wedge handle can be bent or detached with a twisting motion. In order to obtain sufficient separation of the teeth the wedges must be seated at an adequate depth interproximally.
  - ▶ This should be done gradually: Insert the wedge to the point of resistance. Wait 3 to 5 s and gradually move the wedge deeper until sufficient separation is achieved.

- ▶ The material can only be dispensed on the green side of the application tip.



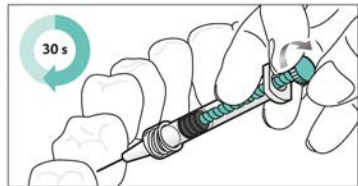
5. Apply an ample amount of Icon-Etch onto the lesion site (1 ½ to 2 turns of the shaft). Let Icon-Etch set for 2 minutes. The etching gel will be activated by slightly moving the applicator. Remove excess material.

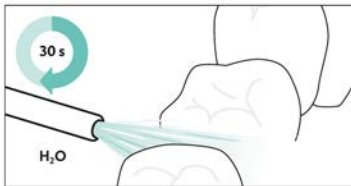


6. Remove the application tip from the proximal area. Suction off Icon-Etch and rinse with water for a minimum of 30 s. Dry thoroughly with oil-free and water-free air.

### Drying

For best treatment results the lesion must now be desiccated.

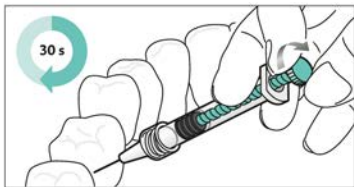




6. Remove the application tip from the proximal area. Suction off Icon-Etch and rinse with water for a minimum of 30 s. Dry thoroughly with oil-free and water-free air.

### Drying

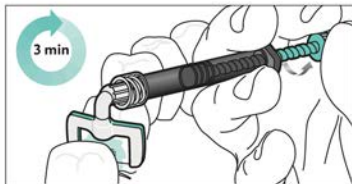
For best treatment results the lesion must now be desiccated.



7. Screw the application tip onto the Icon-Dry syringe, apply an ample amount of material onto the lesion and allow to sit for 30 s. **Dry thoroughly with oil-free and water-free air.**

### Infiltration

Now that the lesion is completely desiccated, it is ready to absorb the infiltrating resin when applied.



- ▶ **Do not apply Icon-Infiltrant under direct operating light as this may cause the material to set prematurely.**
8. Screw a new Proximal-Tip onto the Icon-Infiltrant syringe and introduce the application tip into the treatment site. Be sure to align

the green side of the Proximal-Tip with the area to be treated.

- ▶ **The material can only be dispensed on the green side of the Proximal-Tip.**
9. Apply an ample amount of Icon-Infiltrant onto the lesion site (1 ½ to 2 turns of the shaft).
  10. Let Icon-Infiltrant penetrate fully for 3 minutes. Infiltration will be enhanced by slightly moving the applicator. Add small amounts of material during the three minutes.
  11. Remove the application tip from the treatment site. Remove excess material with dental floss.



12. Light-cure Icon-Infiltrant from all sides for at least 40 s (total).
13. Screw a new Proximal-Tip onto the Icon-Infiltrant syringe, repeat the application, and allow to penetrate for 1 minute. Remove the application tip from the site. Remove excess material with dental floss.
14. Light-cure Icon-Infiltration from all sides for at least 40 s (total).
15. Screw a new Proximal-Tip onto the Icon-Infiltrant syringe, repeat the application, and allow to penetrate for 1 minute. Remove the application tip from the site. Remove excess material with dental floss. Then light-cure from all sides for at least 40 s (total).
16. If a second lesion needs to be treated repeat steps 1 through 13 for the affected site.
17. Remove the wedge and rubber dam. Use polishing strips for the surface finish.



## Smooth surface treatment with Icon Resin Infiltrant – Smooth Surface Preparation

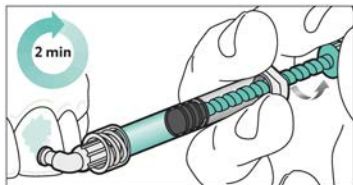
1. Before the start of treatment, clean the affected tooth and adjacent teeth. Remove any cleaning residue with water spray.
2. Create a sufficiently dry working field. Take appropriate measures; such as rubber dam, liquid dam or similar, to protect the gingival tissue. Please follow the manufacturer's specifications and instructions. Do not use rubber dams made from thermoplastic elastomers. Ensure that the treated lesion is completely accessible.

### Uncovering the lesion body

For successful elimination of white spots, it is imperative that the surface layer of the lesion is completely removed in order for the Infiltrant to gain access to the lesion body.

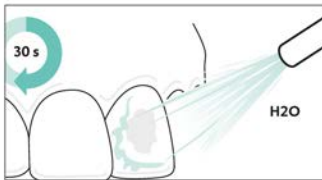
The light application of a medium grit abrasive disk can be utilized in cases of highly demineralized white spot lesions prior to etching.

3. Screw the Smooth Surface-Tip onto the Icon-Etch syringe.



4. Apply an ample amount of Icon-Etch onto the lesion site by turning the syringe shaft carefully. Periodically massage the Etch over the 2 minute period. Remove excess material with a cotton wad.

**Note:** Unless white spots are treated early, i. e. 1 to 2 months after bracket removal, it is recommended to repeat the etching step up to three times.

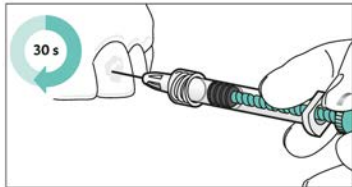


5. Suction off Icon-Etch and rinse with water for at least 30 s. Dry with oil-free and water-free air.

### Visual Inspection

To ensure successful infiltration, the lesion must now be desiccated and inspected.

- ▶ **In this step, a preview of the final result is shown. When wetted with Icon-Dry, the whitish-opaque coloration on the etched enamel should diminish. If this is not the case, repeat the etching step once or twice for 2 minutes each, and rinse and dry the teeth again (steps 3-5).**



6. Screw the application tip onto the Icon-Dry syringe, apply an ample amount of material onto the lesion, and allow to set for 30 s.

### Drying

For best treatment results, it is necessary to dry the lesion in-depth.

7. After the visual inspection, dry the lesion thoroughly with oil-free and water-free air.

### Infiltration

Now that the lesion is completely desiccated, it is ready to absorb the infiltrating resin when applied.

8. Screw a new Smooth Surface-Tip onto the Icon-Infiltrant syringe.

- ▶ **Do not apply Icon-Infiltrant under direct operating light as this may cause the material to set prematurely.**



9. Apply an ample amount of Icon-Infiltrant onto the etched, dried surface by turning the shaft.
  10. Allow Icon-Infiltrant to penetrate for 3 minutes adding material to keep the surface wet. The infiltration will be enhanced by slightly massaging with the applicator.
- ▶ **In case of deeper and larger defects the esthetic result can be improved by extending the exposure time up to 6 minutes.**
11. Remove excess material with a cotton wad and dental floss.



12. Light-cure Icon-Infiltrant for 40 s.
13. Screw a new Smooth Surface-Tip onto the Icon-Infiltrant syringe, repeat the application, and allow penetration for 1 minute. Remove excess material with a cotton wad and dental floss, and light-cure for a minimum of 40 s.
14. Remove the rubber dam. Use polishing cups (or similar) for the surface finish.

### Side effects

- In some cases, contact allergies with similar composite products have been reported.
- Contact of Icon-Etch with the oral mucosa causes a white surface coloration. This will subside after a few days.

## Interaction

Polymerization inhibiting substances such as products containing eugenol (e. g. temporary cements) must not be used in combination with this material.

## Composition

- Icon-Etch: Hydrochloric acid, pyrogenic silicic acid, surface-active substances
- Icon-Dry: 99% ethanol
- Icon-Infiltrant: Methacrylate-based resin matrix, initiators, additives

## Storage

- ▶ Store at 2 to 25 °C / 36 to 77 °F!
- ▶ Protect from direct sunlight!
- ▶ Do not use after the expiration date!

## Patient card + sticker

This material is not radiopaque. To document the infiltrated surfaces and lesion depths, the

enclosed patient card can be filled out at the time of treatment, follow-up visits, and retained by the patient. In addition, the enclosed sticker supports the documentation in the patient's record.

1. Front: Enter the name of the patient and office stamp.
2. Tooth diagram: Mark the treated area.
3. Record the treated tooth [1], the treated surface [2] (d = distal, m = mesial, v = vestibular (buccal, cervical, labial), l = lingual or palatal), lesion depth\*, and the treatment date [3].

The diagram illustrates the layout of the patient card and sticker. The card is divided into several sections:

- Zahn | Tooth:** A box labeled '1' with a vertical line indicating the tooth number.
- Fläche | Surface:** A box labeled '2' with a vertical line indicating the surface.
- Läsionstiefe | Lesion depth:** A box labeled '3' with a grid of cells for recording lesion depth.
- Behandlungsdatum | Treatment date:** A box labeled '4' with a grid of cells for recording the treatment date.
- Kontrolldatum 1 | Follow-up appointment 1:** A box labeled '4' with a grid of cells for recording the first follow-up appointment.
- Kontrolldatum 2 | Follow-up appointment 2:** A box labeled '4' with a grid of cells for recording the second follow-up appointment.
- Kontrolldatum 3 | Follow-up appointment 3:** A box labeled '4' with a grid of cells for recording the third follow-up appointment.

The sticker is a grid with columns labeled E1, E2, D1, D2, D3, P.

4. Follow-up visit [4]: Record the lesion depth\* and date of the follow-up appointment. Annual check-ups are recommended.

\*see »Lesion depth classification\*« on page 1

## Packaging

Icon Resin Infiltrant – Proximal	
Mini-Kit @ 2 Patient Packs	REF 220400
Cube @ 7 Patient Packs	REF 220401

Icon Resin Infiltrant – Smooth Surface	
Mini-Kit @ 2 Patient Packs	REF 220402
Cube @ 7 Patient Packs	REF 220403

### Each Patient Pack includes:

Icon Resin Infiltrant – Proximal

- 1 Icon-Etch syringe @ 0.3 ml fluid
- 1 Icon-Dry syringe @ 0.45 ml fluid
- 1 Icon-Infiltrant syringe @ 0.45 ml fluid
- Accessories

Icon Resin Infiltrant – Smooth Surface

- 1 Icon-Etch syringe @ 0.45 ml fluid
- 1 Icon-Dry syringe @ 0.45 ml fluid
- 1 Icon-Infiltrant syringe @ 0.45 ml fluid
- Accessories

Caution: US Federal law restricts this device to sale by, or on the order of a dentist, or other practitioner licensed by law of the state in which he or she practices to use or order the use of this device.

Keep away from children! For dental use only!