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Icon[®]



CE 0482

Icon is an innovative product for the micro-invasive treatment of dental lesions in the proximal region and on smooth surfaces.

Icon is available in two variations:

Icon Resin Infiltrant – Proximal is specially developed for proximal dental lesions.

Icon Resin Infiltrant – Smooth Surface is specially developed for the infiltration on smooth surfaces, it is particularly well-suited for orthodontic patients after bracket removal. Unless white spots are being treated shortly (1-2 months) after bracket removal, it is recommended that the etching process is performed two times. If a white spot is still visible after the Icon-Dry has been applied, then a third etching process is recommended.

Indication

Micro-invasive treatment of early lesions in the proximal region (lesion depth up to D1*) and lesions on smooth surfaces limited to enamel (white spots e. g., after bracket removal).

Contra-indication

This material must not be used for deeper-seated lesions (D2–D3*) or on cavitated enamel.

Use Icon-Etch only on enamel surfaces. Do not use on exposed dentin or on cementum. Failing to observe these instructions, may cause pain to the patient.

The use is contra-indicated in case of developmental lesions or lesions due to fluorosis, hypoplasia, erosion or trauma.

Lesion depth classification*



* Radiographic lesion depth classification according to bite-wing x-rays.

RECOMMENDED USE

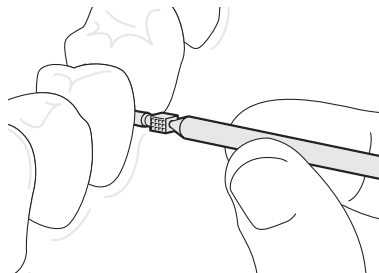
Treatment of proximal surfaces with Icon Resin Infiltrant – Proximal

The syringes included in each patient pack contain sufficient material for treating two proximal lesions. Discard syringes after use. If additional proximal surfaces require treatment during one visit treat these lesions consecutively.

1. Before the start of treatment, clean the affected tooth and adjacent teeth. Remove any cleaning residue with water spray. Place a rubber dam. Do not use rubber dams made from thermoplastic elastomers such as Flexi Dam (Coltène Whaledent/Hygenic). Insert one of the enclosed dental wedges into the interdentalium. For better access to the proximal region the wedge handle can be bent or twisted off.

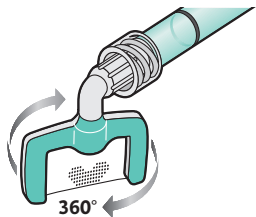
In order to obtain sufficient separation of the teeth, the wedges must be seated at an adequate depth in the interdentium. To ensure a successful treatment, a separation of approx. 50 μm is recommended.

Leave the wedge in the proximal space during the entire treatment procedure.



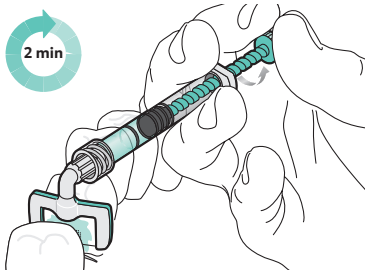
2. Screw a Proximal-Tip onto the Icon-Etch syringe, and place the application foil in the interdentium. Be sure to align the green side of the Proximal-Tip with the area to be treated.

The material will dispense only on the green side of the application tip.



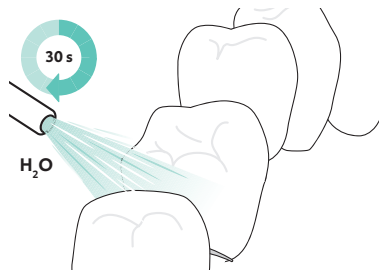
3. Apply an ample amount of Icon-Etch onto the lesion site. 1 ½ to 2 turns of the shaft correspond approximately to the amount to apply. Let Icon-Etch sit for 2 minutes. If necessary, remove any excess material.

The screw syringe can be operated with one hand.

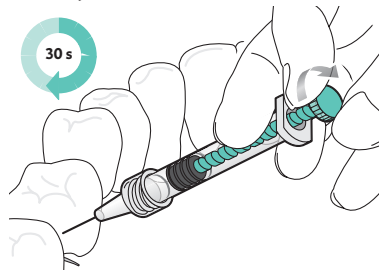


4. Remove the application foil from the interdentium and rinse off Icon-Etch immediately

with water for at least 30 seconds. Dry with oil-free and water-free air.

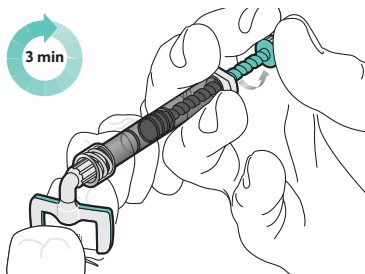


5. Screw the syringe tip onto the Icon-Dry syringe. Apply an ample amount of the Icon-Dry onto the lesion site and let sit for 30 seconds. Dry with oil-free and water-free air.



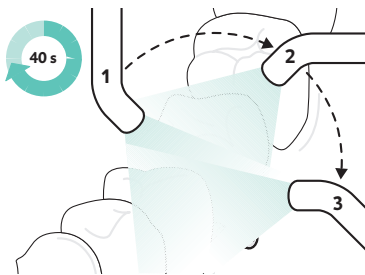
6. Screw a new Proximal-Tip onto the Icon-Infiltrant syringe and place the application foil in the interdentium. Be sure to align the green side of the Proximal-Tip with the area to be treated.

The material will dispense only on the green side of the Proximal-Tip.



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

7. Apply an ample amount of Icon-Infiltrant onto the lesion site. 1 ½ to 2 turns of the shaft correspond approximately to the amount to apply. Let Icon-Infiltrant sit for 3 minutes.
8. Remove the application foil from the interdental. Remove excess material with dental floss.
9. Light-cure Icon-Infiltrant from all sides for at least 40 seconds (total).



10. Screw a new Proximal-Tip onto the Icon-Infiltrant syringe and apply the material for a second time (repeat steps 7–9). Let the material sit for 1 minute. Then light-cure from all sides for at least 40 seconds (total).
11. If a second lesion needs to be treated repeat steps 1 through 10 for the affected site.
12. Remove wedge and rubber dam. Use polishing strips for the surface finish.

Treatment of smooth surfaces with Icon Resin Infiltrant – Smooth Surface

The syringes included in each patient pack contain sufficient material for treatment of two to three lesions on smooth surfaces.

Discard syringes after use. If required, multiple lesions can be treated at the same time.

1. Before the start of treatment, clean the affected tooth and adjacent teeth. Remove any cleaning residue with water spray. Place a rubber dam.

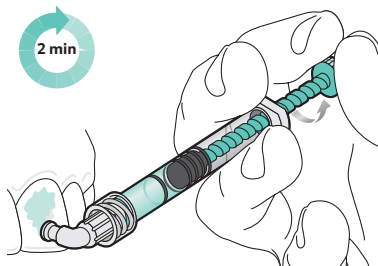
Do not use rubber dams made from thermoplastic elastomers such as Flexi Dam (Coltène Whaledent/Hygenic).

2. Screw a Smooth Surface-Tip onto the Icon-Etch syringe.
3. By turning the syringe shaft carefully apply an ample amount of Icon-Etch onto the lesion site and let sit for 2 minutes. If necessary, remove excess material with a cotton roll.

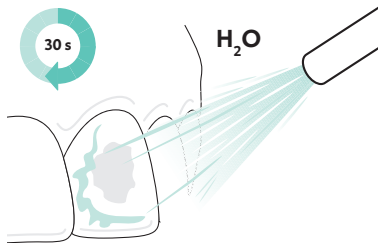
Unless white spots are being treated shortly (1-2 months) after bracket removal, it is recommended that the etching process is performed two times. If a white spot is still visible after the Icon-Dry has been applied, then a third etching process is recommended.

For topical 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 in case of large area white spots as they occur after bracket removal.

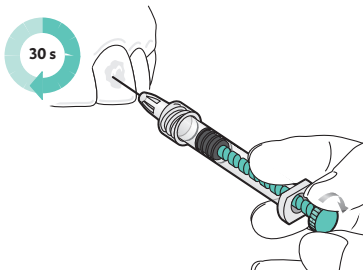
The screw syringe can be operated with one hand.



4. Rinse Icon-Etch with water for at least 30 seconds. Dry with oil-free and water-free air.

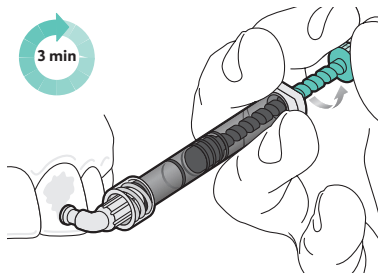


5. Screw the syringe tip onto the Icon-Dry syringe. Apply an ample amount of the Icon-Dry onto the lesion site and let sit for 30 seconds. Dry with oil-free and water-free air.



When wetted with Icon-Dry the whitish opaque appearance of the enamel should diminish. If this is not the case repeat the etching step a second or third time for 2 minutes each and rinse and dry the teeth again (steps 3-5).

6. Screw a new Smooth Surface-Tip onto the Icon-Infiltrant syringe.
Do not apply the Icon-Infiltrant under direct operating light as this may cause material to set.
7. Apply an ample amount of Icon-Infiltrant on the etched surface by turning the shaft and let sit for 3 minutes. Remove excess material with a cotton roll or similar.



8. Light-cure Icon-Infiltrant for 40 seconds.



9. Screw a new Smooth Surface-Tip onto the Icon-Infiltrant syringe and apply the material for a second time (repeat steps 7–8). Let the material sit for 1 minute and then light-cure for at least 40 seconds.

10. Remove the rubber dam. Use polishing cups (or similar) for the surface finish.

Safety information for handling Icon-Etch

- * Icon-Etch can cause caustic burns. Limit the application to the surface to be treated. Avoid contact of the etching gel with the gingiva and adjacent teeth.
- * Use only the enclosed syringe and application tip to apply the etching gel in the patient's mouth.
- * Discard the application tip after use and cap the syringe.
- * 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.

Use of a rubber dam

- * For best treatment results, a sufficiently dry working area is critical. Therefore, placement of a rubber dam is imperative. For application on smooth surfaces a liquid dam can be used as well.

Please note

- * Light-curing units should have an output of 450 nm and should be checked regularly. The light intensity should be at least 800 mW/cm². Place the light as close to the material as possible.

- * On superficially remineralized, mostly older white spots the pseudo-intact surface layer can be fairly thick. In this case a 2 minute etching step to remove the surface layer may not be sufficient and may have to be repeated before the teeth are rinsed and dried again and then infiltrated. In total, the etching step may be performed up to three times for 2 minutes each.
- * The etched surface must not be touched or contaminated with saliva or moisture until the treatment resumes. If contamination occurs after drying re-etch for approx. 10 seconds.

Contra-indications

Allergies or intolerance to material components.

Side effects

In some cases contact allergies with similar products have been reported. Do not use this material in case of known allergies to one of the material components or existing contact allergies.

Avoid material contact with eyes, skin and the oral mucosa. In case of contact with eyes rinse with copious amounts of water, and, if necessary, consult a physician. In case of contact with skin clean affected areas thoroughly with water and soap.

Contact of Icon-Etch with the oral mucosa causes a white surface coloration. This will subside after a few days.

Interaction

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

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 room temperature not exceeding 25 °C/77 °F. Do not use after expiration date.

Patient card + sticker

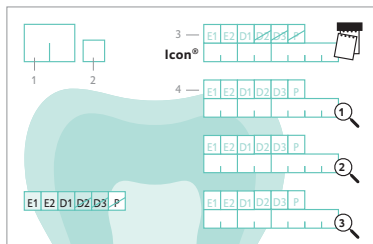
This material is not radiopaque. To document the infiltrated surfaces and lesion depths, the enclosed patient card can be filled out at the time of treatment and at follow-up visits and handed to the patient. In addition, the enclosed sticker supports the documentation in the patient's record.

1. Front: Enter name of the patient and apply 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].

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!



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

* For lesion depth classification, see »Indication«

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:

1 Icon-Etch syringe @ 0.3 ml fluid

1 Icon-Dry syringe @ 0.45 ml fluid

1 Icon-Infiltrant syringe @ 0.45 ml fluid



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