iNterra™

Inoffice Nightguard

DENTSPLY CAULK

DIRECTIONS FOR USE – ENGLISH

For Dental Use Only.
USA: Rx only.

1. PRODUCT DESCRIPTION

iNterra™ Inoffice Nightguard is a nightguard material combined with an impressionless technique designed for fabrication of resilient nightguards/splints directly in the oral cavity. The visible light cured resin material is adapted to the teeth and the occlusal contacts generated directly in the mouth. Following a tack cure with a handheld curing light, the adapted nightguard is removed from the mouth, stabilized, and final cured in an extraoral VLC light curing unit. Accurate fit and function is ensured since the nightguard is formed directly on and against the patient's dentition. The nightguard may be completed and delivered in a single office visit, without the need for cast fabrication, lab fees, or a second, delivery appointment.

1.1 Delivery forms

iNterra™ Nightguard is provided in individual, single-use packages and is available in small, medium and large arch shapes.

1.2 Composition

iNterra™ Nightguard is a visible light cured polymerizable resin comprised of a blend of aliphatic and aromatic urethane methacrylate resins, ethoxylated dimethacrylate ester, acrylate ester, and light cure initiators. iNterra™ Nightguard contains no methyl methacrylate monomer.

1.3 Indications for use

iNterra™ Nightguard is indicated for the fabrication of therapeutic dental appliances (such as occlusal guards and similar devices) used to mitigate damage associated with parafunctional dental habits.

1.4 Contraindications

iNterra™ Nightguard is contraindicated for use in appliances to treat disordered sleep.

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.

2.1 Warnings

1. This product contains polymerizable materials. It does not contain methyl methacrylate (MMA) monomer. It is possible that some dental health care workers may develop an allergy or sensitivity to the product.
   Avoid skin contact to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitisation or rash, discontinue use and seek medical attention.
2. Do not immerse iNterra™ Nightguard appliance in boiling water or steam autoclave. Exposure to extreme temperature will allow distortion and compromise accuracy. Clean and disinfect appliance according to instructions in Section 4.
3. iNterra™ Nightguard should not be used with patients who have a history of severe allergic reaction to any of the components.

2.2 Precautions

1. This product is intended to be used only as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
2. Do not contaminate iNterra™ Nightguard surfaces with debris, liquids, or powder from latex gloves. Wash hands before removing material from packaging.
3. Before use, make certain the material is at room temperature. High temperatures will make the material sticky and more difficult to handle and form. Cold temperatures will make the material stiff and hard to handle.
4. Severe undercuts need to be blocked out prior to fabrication of appliance.
5. Insufficient data exist to support use of iNterra™ Nightguard in the treatment of temporomandibular or myofascial pain dysfunction syndromes. iNterra™ Nightguard is designed to result in flat-plane, non-indexed occlusal contacts. iNterra™ Nightguard is not designed to be constructed as or to perform as a definitively indexed mandibular repositioning appliance.
6. Patient's dentition should be inspected prior to fabrication of the iNterra™ Nightguard to identify compromised restorations, such as, poorly bonded (compromised bond) crowns, bridges, onlays, fillings, etc… or restorations with material overextended beyond the preparation. Compromised restorations should be repaired otherwise the restoration could be damaged during removal of a well-fitting tack cured splint. Some patients may not be appropriate for an iNterra™ Nightguard appliance.
7. Users with special skin problems, cuts or abrasions may choose to wear protective non-latex gloves.
8. When grinding finished appliance, proper ventilation, masks and vacuum systems should be used.
9. Unused, uncontaminated iNterra™ Nightguard material should be cured prior to disposal. Expose material to direct sunlight or cure in an extraoral curing unit until hardened then dispose of in regular trash.

2.3 Storage conditions

Store in sealed packs at temperatures between 10°C/50°F and 24°C/75°F. Keep out of direct sunlight and protect from moisture. Refrigerated storage is acceptable when not in use. Allow material to reach room temperature prior to use. Do not freeze. Do not use after expiration date. Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

2.4 Adverse reactions

1. Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.
2. Dust will be generated when grinding these materials. Eye, skin and respiratory irritation may occur if appropriate engineering controls are not used.

3. STEP-BY-STEP INSTRUCTIONS FOR USE

1. Inspect patient's dentition for compromised restorations or severe undercuts. Unavoidable undercuts can be blocked out using a silicone such as Regisil® Rigid Bite Registration Material (see complete Directions for Use). Repair compromised restorations or segregate patients who are not appropriate for iNterra™ Nightguard construction.
2. Open the package at the tear point, and remove the iNterra™ Nightguard arch form from the silicone mold. Remove, but do not discard the release film. Set it aside to be used in the curing process later (Step 10). Be sure to keep the arch shaped piece of flexible film attached to the top (facing opposing arch) side of the iNterra™ Nightguard material.
3. If necessary to size the arch for the particular patient, reform the arch using slight finger pressure to pull (stretch) or use scissors to trim the arch to the desired shape and length. For additional thickness, if needed, two arch forms may be used together to form one appliance (see Step 15a below).
4. Make sure the teeth are wet by pre-rinsing with water or mouthwash. Application of lubricating medium is not required or recommended. Place the exposed resin side of the arch against the teeth. With finger pressure, adapt the facial and lingual resin extensions onto the mid-facial tooth surfaces while covering most of the lingual surfaces. Adapt the material into the tooth embrasures. Avoid adapting the resin into deep undercuts taking care to avoid infrabulge areas of fixed restorations. **Technique Tip:** Do not over-compress material while adapting. Material thickness should be no less than 1.0 mm after adaptation.
5. Have the patient bite lightly and observe points where the teeth contact the flexible film on the surface of the material. Ask the patient to lightly bite down and open, then bite again and open in various excursive jaw positions. "Stepping" the occlusal contacts through excursions rather than "dragging" contacts will assist in creating a smooth, functionally generated disclusive surface. **Technique Tip:** Do not allow patient to occlude through uncured material. Occlusal contact registrations should be limited to minimal cusp indentations only. These indentations will be smoothed and polished after curing for flat-plane, point contacts. Maintain a minimum occlusal thickness of 1.0mm.
6. When it is confirmed that occlusal contacts and excursive paths have been lightly registered into the flexible film surface, ask the patient to bite lightly in centric occlusion and hold that position while the handheld curing light tip is directed against the facial surfaces. The curing light must have a minimum curing output of 500mW/cm^2 and a spectral output containing 470nm. If desired, use the light guide tip to press iNterra™ Nightguard against tooth surfaces. Step-cure (5 to 10 seconds each area for single thickness, 10 to 20 seconds for double thickness if applicable) across the facial of the entire arch for 1 minute (2 minutes for double thickness). Hold the light as close to the material surface as possible at all times. **NOTE:** Quartz halogen lights cure the material most efficiently; about 50% additional cure time will be needed for most LED curing units.

Inadequate polymerization due to insufficient curing
- Check compatibility of curing light
- Check curing cycle
- Check curing output before each procedure

7. Ask the patient to open, confirm adequate lingual adaptation, and step-cure lingual surfaces of the arch for 1 minute (2 minutes for double thickness) with same technique. Finally, step-cure the occlusal surface for 1 minute (2 minutes for double thickness).
8. After 3 minutes (5-6 minutes for double thickness) total of intra-oral curing (4½ minutes for LED's, corresponding increase for increased thickness), remove the partially cured nightguard with a snap release. Seat/reseat partially cured nightguard at least 3 times to assure proper removal and fit. With appliance seated, re-cure (5-10 seconds only) any soft areas.
9. Remove the partially cured iNterra™ Nightguard arch from the mouth. Do not separate the flexible film from iNterra™ Nightguard at this time. Do not squeeze, twist or distort nightguard.

10. Fill the internal aspect, including all tooth spaces with Regisil® Rigid Bite Registration material. Extend the rigid silicone 4-6mm above/beyond the edge of the splint. Invert the iNterra™ Nightguard filled with silicone onto the square celluloid sheet from original packaging (silicone side down) and wait 2 minutes until the silicone has completely set.
11. Place inverted and filled iNterra™ Nightguard into a recommended extraoral curing unit and cure according to the table below (see curing unit manufacturer's complete Directions for Use).

Curing Unit	Program	Cure Time
iNterra™ VLC	Night Guard Cycle	10 minutes
Triad® 2000*	Two 10-minute cycles **NOTE:** not more than 3 minutes between cycles	20 minutes
Enterra® VLC*	Night Guard Cycle	10 minutes
Eclipse® Processing Unit*	Menu 5 (Full BP Repair)	6 minutes

*DENTSPLY Prosthetics

Technique Tip: Immediately following curing, iNterra™ Nightguard will be hot, and thermally plastic. Avoid squeezing bending or twisting. Allow iNterra™ Nightguard to cool prior to handling or removal of injected silicone to minimize potential distortion.

12. After the iNterra™ Nightguard is completely cured and cooled, remove the injected silicone and peel away the flexible film. Disinfect iNterra™ Nightguard as outlined in Section 4. After disinfection, remove any gross flash with laboratory carbide burs or abrasive wheels/bands. Rinse and air dry.
13. Check the fit of the iNterra™ Nightguard in the patient's mouth. Adjust the borders to obtain the necessary fit and adjust the occlusion as necessary.
14. Finish and polish with laboratory carbide burs and polishing brushes and pumice with rag wheel.
15. Adding on to the iNterra™ Nightguard (if necessary)
    a. Adding 2 iNterra™ Nightguard Pieces Together (e.g, for added initial thickness) prior to initial fabrication: Remove the two iNterra™ Nightguard materials from their packaging molds. Press the two sides together that do not contain the flexible film. Remove the flexible film from one side and fabricate the iNterra™ Nightguard as described above. Technique Tip: Increased thicknesses and/or surface areas typically require a corresponding increase in intraoral tack-curing times (see Curing Step-by-Step 6, 7, and 8 above). Additional curing time in extraoral curing unit is not necessary.
    b. Adding Onto a Fully Cured iNterra™ Nightguard (during initial fabrication or repair of appliance after use): Use a bur to roughen the surface. Clean any debris with running water and dry. Apply fresh iNterra™ Nightguard material (flexible film removed) to the roughened area and complete the fabrication and/or curing process.
    c. Adding to a Tack Cured iNterra™ Nightguard (during initial fabrication): Remove the flexible film and ensure the surface is clean. Adapt additional iNterra™ Nightguard material and complete the fabrication and curing process as outlined above.

4. HYGIENE

4.1 Initial appliance construction – following final curing and cooling

Following completion of final cure and removal of silicone stabilizer, the iNterra™ Nightguard should be disinfected prior to finishing, polishing and delivery. The following disinfectants have been used successfully and are recommended:

- Glutaraldehyde-based disinfectants
- Quaternary ammonium chlorides
- Quaternary ammonium chlorides/isopropyl alcohol (low concentration)
- Spray-based phenolics

Use of other disinfectant products may not be suitable with iNterra™ Nightguard. Avoid disinfectants containing iodine.

1. Follow the disinfectant manufacturer's directions properly for optimum results.
2. After disinfection, clean the iNterra™ Nightguard by scrubbing with warm water and soap or detergent.
3. After disinfection, thoroughly rinse and dry the nightguard before finishing, polishing and delivery.
4. Do not autoclave the iNterra™ Nightguard material or completed appliance.
5. Disinfect curing units according to manufacturer's instructions.
6. Disinfect and/or properly dispose of removed silicone stabilizer according to manufacturer's instructions.

CAUTION

Cross-contamination

- Do not attempt to clean or disinfect for reuse any excess iNterra™ Nightguard material introduced intraorally.
- Properly dispose of the excess contaminated iNterra™ Nightguard and silicone spacer material in accordance with local regulations

4.2 Cleaning and maintenance instructions for patients

Routine disinfection after use is not typically required. After use, iNterra™ Nightguard should be cleaned by gentle scrubbing with a soft bristled brush (e.g., toothbrush dedicated for this purpose) with warm water and toothpaste or mild soap. iNterra™ Nightguard should be rinsed thoroughly and dried prior to storage. iNterra™ Nightguard is compatible with most commercially available denture or orthodontic appliance cleansers. Refer to manufacturer's directions for use for compatibility and usage.

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard is used: "YYYY/MM"
2. The following numbers should be quoted in all correspondence:
   - Reorder Number
   - Lot number

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