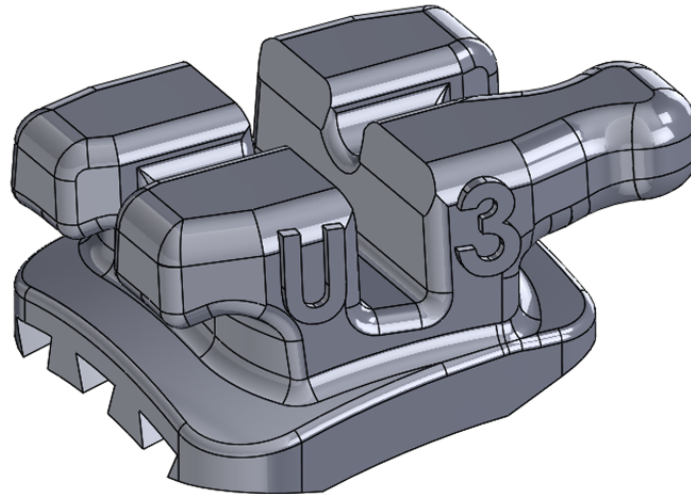




BRACES
on demand



Braces On Demand™ Modular Orthodontic Appliances

INSTRUCTIONS FOR USE - Rev. D

Braces On Demand Modular Orthodontic Appliances

INSTRUCTIONS FOR USE

CAUTION U.S. Federal law restricts this device to sale by or on the order of a licensed Dentist.

INDICATIONS FOR USE

The Braces on Demand Appliance System is intended for use as a clear, resin appliance system to provide orthodontic movement of natural teeth.

CONTRAINDICATIONS

- Persons who are allergic to biocompatible resins.

WARNINGS

- Braces On Demand appliances are for single patient use only.

PRECAUTIONS

- Braces On Demand appliances are capable of withstanding all normal orthodontic torque requirements. However, care should be taken when making a torquing activation. Large corrections with full size stainless steel archwires may result in appliance failure and should be avoided.
- Instruct patients not to chew hard substances such as hard candy, ice, or carrots. Careful and thorough patient instruction is key to avoiding appliance or tooth damage.
- Bonding to porcelain crowns or veneers may cause chipping or breakage of the crown or veneer during orthodontic treatment or bracket removal.
- Debonding of Braces On Demand appliances can be achieved with a ligature cutting plier*
**Any ligature cutting plier is suitable.*

ADVERSE REACTIONS

None known

BRACES ON DEMAND MODULAR ORTHODONTIC APPLIANCES

Braces on Demand modular orthodontic appliances are used to correct malocclusions in orthodontic patients using a doctor-derived, modular appliance design.

Braces On Demand brackets can be configured to the following orthodontic prescriptions:

- MBT*
- Roth*
- Doctor-customized prescription

Braces On Demand standard brackets can be configured to the following archwire slot size range:

- 0.018 inches
- 0.022 inches

Braces On Demand doctor-customized brackets can be configured with these additional archwire sizes:

- 0.014 inches
- 0.016 inches
- 0.018 inches
- 0.020 inches
- 0.022 inches
- 0.024 inches

Braces On Demand does not provide commercially available archwires, ligatures, or adhesives. All use of such products should be used according to the manufacturer's instructions.

**Braces On Demand version of this prescription. No endorsement by the Doctor is implied.*

BRACES ON DEMAND 3D PRINTING INSTRUCTIONS

STEP 1: Log into www.bracesondemand.com. Enter your username and password.

STEP 2: Follow the Braces On Demand online workflow. Select the desired appliance(s), make specific prescription selections and add the desired appliance(s) to the current print.

STEP 3: Verify that the correct dental resin is loaded into the printer. Prime the printer.

STEP 4: Check out and select the 3D Printer that will be used. Select Buy & Print to initiate the printing process.

STEP 5: Once the print is complete, place the build platform and newly-printed appliance(s) into the Form Wash™, and wash appliances for 10 minutes with 99% IPA.

STEP 6: Once the wash is complete, immediately remove the appliance(s) from the build platform and dry completely with compressed air.

STEP 7: Place the Braces On Demand appliance(s) into a glass bowl filled with glycerine. Insert glass bowl into the Form Cure™ and post-cure appliance(s) for 30min at 60°C.

STEP 8: Rinse Braces on Demand appliance(s) in water to remove any remaining glycerine. Dry completely with compressed air.

STEP 9: Store the Braces On Demand appliance(s) in a dark, dry area until they are needed.

WARNING regarding software, 3D printers, denture tooth resins, and post-cure units:

- The printers validated for use with Braces On Demand appliances are:
 - Formlabs Form 3 3D Printer, and
 - Formlabs Form 3B 3D Printer.
- The software interface used with the FormLabs printers is:
 - Pre-Form Software
- The resin options for 3D printing the brackets include 6 tooth shades:
 - Denture Tooth A1, A2, A3, A3.5, B1 and B2
- The auxiliary units validated for use are:
 - Form Wash™ – for washing after printing
 - Form Cure™ – for post-curing after printing
- No other software, equipment, or tools should be used with this bracket system.

Please refer to the OEM (Formlabs) Manuals, Quick Start Guides and Safety Booklets before printing the brackets.

BRACKET BONDING INSTRUCTIONS

STEP 1: Polish, dry, and isolate the patient's teeth from saliva.

STEP 2: Etch/prime the teeth using the Orthodontist's method of choice.

STEP 3: Add the light-cured orthodontic adhesive of your choice to the Braces On Demand bracket base.

STEP 4: Following the manufacturer's instructions, light cure the brackets from all angles to ensure full bond strength.

STEP 5: Ligate initial wire to brackets using conventional elastomeric "O-rings" or steel ligatures.

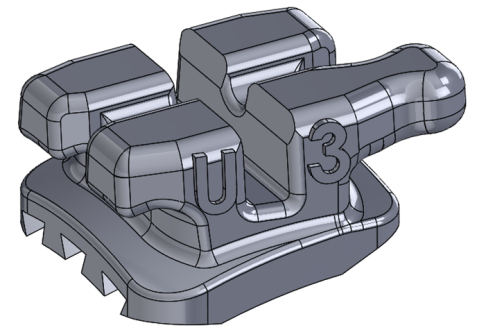
BRACKET DEBONDING INSTRUCTIONS

STEP 1: Place ligature cutting plier* diagonally across the bracket to engage the angled undercuts on each bracket pad.

**Any ligature cutting plier is suitable.*

BRACES ON DEMAND BRACKET IDENTIFICATION

Braces On Demand brackets are easily identifiable by tooth # and quadrant on the distal tie wings.



CYBERSECURITY

For Braces On Demand software users, it is very important to keep in mind the following recommendations:

- Default firewall settings are in place
- Built in virus scanner is enabled in default configuration
- Keep Antivirus scanner up to date
- Enable passwords on all accounts and to enable another functionality to reduce the risk of unauthenticated users (such as adding automatic logout or lockout)
- Keep credentials safe