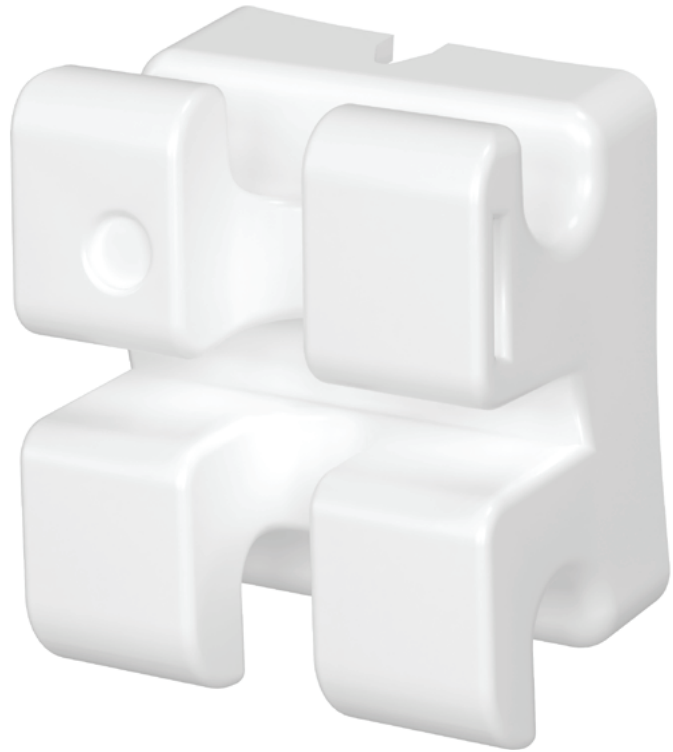
LightForce ORTHODONTICS



LightForce System
INSTRUCTIONS FOR USE

LightForce Orthodontic Bracket System

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

Indicated for orthodontic movement of natural teeth.

The LightForce Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient specific orthodontic appliances.

A .STL file must be submitted to plan.lightforceortho.com to initiate treatment.

There are some clinical scenarios that fall outside the scope of the LightForce system

** Case Scenarios **not** currently supported:*

- *a quadrant has no clinically bondable molars*
- *more than one tooth missing from a single quadrant*
- *missing canine cases where canines will be replaced by implants*
- *rotations or crowding is so severe that an insufficient labial surface is available for bonding*
- *existing appliances such as molar tubes or bands are present*

** Final determination on case capabilities will be at the discretion of the LF Treatment Planning Technicians*

The LightForce Orthodontic System consists of patient-specific ceramic brackets, patient-specific bracket placement jigs, arch wire templates, and instructions for use. The use of bracket placement jigs (indirect bonding, IDB, jigs) is optional and instructional steps are below. If choosing to directly bond brackets, follow standard orthodontic office procedures.

LightForce Orthodontics does not provide commercially available arch wires, ligatures, or adhesives. All use of such products should be used according to the manufacturer's instructions.

Standard buccal tubes are included in the indirect bonding jig with custom placement relative to the existing arch plane.

	TORQUE	ANGULATION	OFFSET
Upper 6	-10°	0°	8° Distal
Lower 6	-20°	0°	0°

BONDING INSTRUCTIONS

STEP 1 Add light-cured orthodontic adhesive* of choice to the LightForce Orthodontic bracket base and ensure brackets are positioned correctly in the IDB jigs. Store in a light-shielded area.

** Due to the customized bonding base the adhesive layer required is less than typically required for a non-custom application. Only a thin layer is adhesive is recommended.*

STEP 2 Polish, dry, and isolate the patient's teeth from saliva.

STEP 3 Etch/prime the teeth using Orthodontist's method of choice.

STEP 4 Place IDB jigs* on patient's teeth with mild occlusal and labial pressure and cure with UV light

** Always place Central jigs prior to placing right and left quadrants.*

STEP 5 Remove IDB tray and cure brackets again from all angles for final cure.

STEP 6 Ligate initial wire to brackets using conventional elastomeric "O-rings" or steel ligatures.

BRACKET REBONDING PROCEDURE

If a spontaneous bond failure occurs, it may be necessary to re-bond a bracket. The following steps are recommended:

- Carefully inspect the bracket for any damage.
- Contour cured adhesive on bracket base with a bur.
- Leave a thin layer of adhesive on the bracket base when removing any excess adhesive. An adhesive-to-adhesive bond is necessary when re-bonding brackets.
- If bracket has been contaminated, rinse the bracket in isopropyl alcohol or acetone and allow it to dry.
- Prepare the tooth surface and bond the bracket using standard direct bond procedures.

BRACKET DEBONDING PROCEDURE

STEP 1 Place the direct bond bracket remover* mesial-distally over the bracket and apply pressure to the breakaway base. The bracket will collapse and release.

** Any direct bond bracket remover is suitable. If a specific instrument is desired, the Unitek™ Self-Ligating Bracket Debonding Instrument (REF 804-170) is recommended*

CONTRAINDICATIONS

LightForce Orthodontic Ceramic Brackets should not be bonded to dental porcelain, restorative or compromised enamel surfaces.

WARNINGS

- Lightforce Orthodontic Ceramic Brackets are for single patient use only.
- Due to the hardness of ceramic brackets, bonding brackets in occlusion should be avoided to prevent wearing of enamel surfaces during all phases of treatment..
- Bonding of ceramic brackets to compromised teeth (i.e., with large restorations, peg laterals, or preexisting pathological conditions) can increase the risk of tooth damage.

PRECAUTIONS

- Lightforce Orthodontic Brackets are capable of withstanding all normal torque requirements. However, care should be taken when making torquing activations. Large corrections with full size stainless steel wires may result in bracket failure and should be avoided.
- Instruct not to chew or bite hard substances such as hard candy, ice, or carrots. Careful and thorough patient instruction is a key to avoiding appliance or enamel damage.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.
- Debonding of LightForce Orthodontic Ceramic Brackets can be done using a direct bond bracket remover or similar instrument.

ADVERSE REACTIONS

None known.

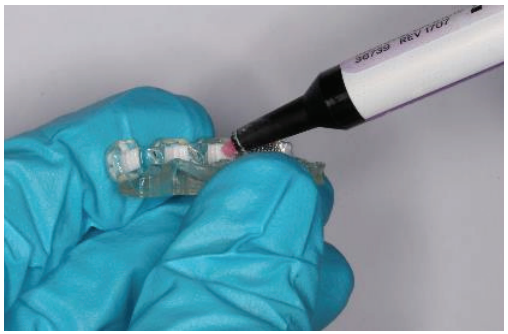
LIGHTFORCE CERAMIC BRACKET IDENTIFICATION

Lightforce Orthodontic brackets are easily identifiable by a tooth # identification on the tie wing

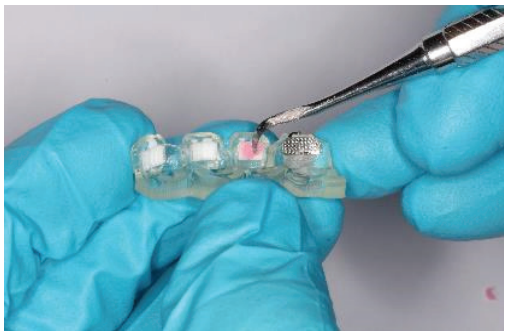
BONDING GUIDE

NOTE Lightforce custom bracket bases require less cement than stock bracket bases. Adjust accordingly to avoid excess flash.

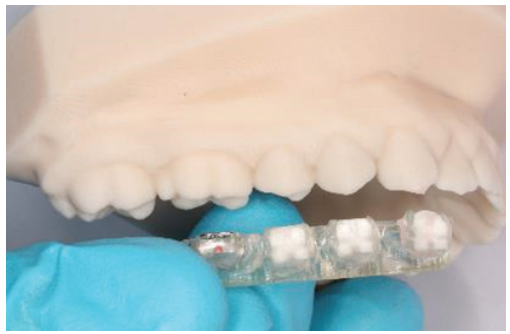
STEP 1



STEP 2



STEP 3



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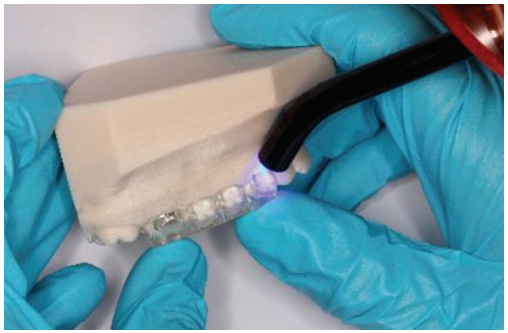

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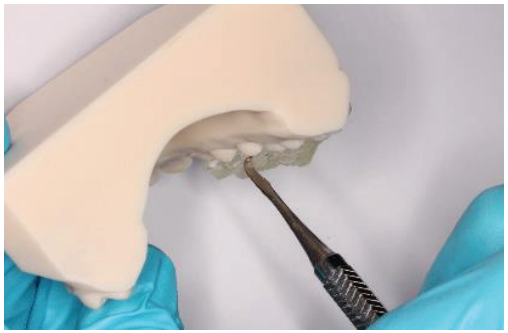
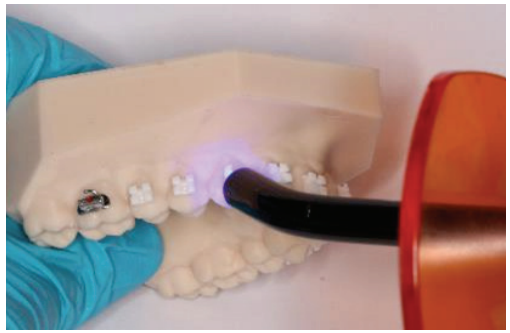
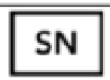


STEP 6



LIGHTFORCE ORTHODONTICS

SYMBOL GLOSSARY

Symbol	Title / Designation No. of Standard	Title of Symbols	Reference No.	Description
	ISO 15223-1[1]	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93'42/EEC and 98/79/EEC.
	ISO 15223-1[1]	Date of Manufacture	5.1.3	Indicates the date when the medical device was manufactured
	ISO 15223-1[1]	Serial Number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	21CFR801.109 (b)(1)	Prescription device labeling statement	NA	CAUTION: Federal law (USA) restricts this device to sale by on on order of a physician.
	ISO 15223-1[1]	Do not re-use	5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1[1]	Non-sterile	5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1[1]	Consult instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use.

(1) ISO 15223-1: 2012
Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied