



Doctor/Dentist **Instructions For Use**

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1. Device Description:

DynaFlex CS Bondable system is built to facilitate correction of Class II and Class III cases through the use of bondable pivots that allow for the placement of low force springs to create directional movement. The CS System is direct bonded to the teeth for patients wearing aligners to aid in dental correction of misaligned teeth.

2. Indications For Use:

- CS Bondable System should be placed in the mouth by a trained dental professional only.
- CS Bondable System are bonded to teeth to hold springs and could be used in conjunction with aligners leveling and aligning teeth regarding Class II and Class II corrections.

3. Contraindications:

CS Bondable Systems are contraindicated for patients known to have:

- Sensitivity to nickel titanium.
- Active dental disease.

4. Warnings:

- Root resorption or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the tempromandibular joint.
- Excessive salivation.
- Should not be bonded to restorative or compromised enamel surfaces.
- Single use only.

5. Precautions:

- Dentist/Clinician should consider the medical history of the patient, including history of asthma, breathing, respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device. Dentist/Clinician should take into account patients' sensitivity to material compositions for irritation.
- Bonding of pivots to compromised teeth (i.e., with large restorations, to peg laterals, or preexisting pathological conditions) can increase the risk of tooth damage.
- Do not use product for anything other than orthodontic purposes.
- Instruct patients not to chew or bite hard substances like hard candy, ice or carrots.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.
- If deformation or deterioration is recognized, do not use.
- If an allergic reaction occurs, discontinue use immediately and direct the patient to consult a physician.

6. Appliance Fit & Adjustments - Dentist:

- Only trained dental professionals may insert orthodontic pivots.
- If an allergic reaction occurs, discontinue use immediately and direct the patient to consult a physician.

7. Exclusions For Use:

Orthodontic pivots should be placed in the mouth by trained dental professionals only.

- Product Life & Replacement– Orthodontic pivots are not reusable and are intended for Single Use Only. Use as directed by a dental professional.
- Do not reuse the product. Risks of reuse include infection and cross-contamination to patient and healthcare provider.

8. Other:

For proper product storage, handling and usage, refer to product instructions on packaging.

9. Bonding Instructions:

1. Pivot should be placed at the beginning of aligner treatment in a Class II or Class III Position.
 2. If applicable, scan patient with pivots in place to allow for aligner cut outs.
 3. Prepare the tooth surface and bond the pivot using the procedure as described by the orthodontic adhesive manufacturer.
 4. Pivots should be placed close to the gingival margin; however, it should not impinge on the tissue.
 5. The pivots are designed to be placed with the pad in a vertical or horizontal position to the gingival margin depending on the dentition. This will not have any effect on the performance of the CS System.
 6. Once pivots have been placed, slide the spring keyhole end over the pivot and secure to the pivots using the low profile screw.
- NOTE: Magnetic allen pencil is specifically designed to hold the low profile screw when inserting intraorally.

Important Tips

- Seat Aligners (with placement for pivot cutout) using aligner seaters or similar to ensure aligners are seat adequately.
- Patient should not open mouth too during CS Bondable System treatment. This will increase the possibility of NiTi Springs Breaking.

10. De-Bonding Instructions:

NOTE: Never attempt to debond the low profile pivot by putting pressure on the stem.

1. Using a bracket removal plier, grasp the edge of the base and apply a torquing motion to debond the pivot.
2. Once debonded, remove excess adhesive as normal.

General Information For The Dentist/Orthodontist:

As part of developing a treatment plan, and prior to appliance placement, assess the need for inter- disciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists. Follow manufacturer's instructions for any orthodontic bonding agents, instruments or other materials used in treatment. Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement and removal. Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Patients using retainers, which can be applied for a longer period, should schedule periodic follow-up visits as recommended by their orthodontist. For immunocompromised patients, oral hygiene is of particular importance, and should be monitored by the orthodontist and dentist. In the presence of root resorption, assess whether further treatment is advisable. Disposal of all orthodontic appliances must follow regional and national regulations.



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