

SureSmile® IDB Trays

Instructions for Use

Table of Contents

1	General Information	1
1.1	Introduction	1
1.2	Device description	1
1.3	Intended use/Performance characteristics	1
1.4	Indications for use	1
1.5	Contraindications	1
1.6	Warnings	2
1.7	Precautions	2
1.8	Adverse reactions	2
2	Designing and using SureSmile IDB Trays	3
2.1	IDB tray components	3
2.2	IDB cap components	4
3	Prepare for the IDB appointment	5
3.1	Organize your workspace	5
3.2	Inspect the tray	6
3.3	IDB tray hygiene	7
3.4	Seat brackets in the trays	8
4	Bracket category overview	9
4.1	Bracket categories, insertion directions and seating requirements	10
4.1.1	Brackets with parallel shape (wings)	10
4.1.2	Brackets with angled shape (wings)	11
4.1.3	Smart clip brackets	12
4.1.4	Round shaped brackets	13
4.1.5	Self-ligating brackets	14
4.1.6	Single tubes (straight types): 1 st and 2 nd molar tubes with or without distal extension	15
4.1.7	Single tubes (funneled type): 1 st and 2 nd molar tubes with or without distal extension	16
4.1.8	1 st molar tubes	17
5	IDB appointment	19
5.1	Chairside setup	19
5.2	Suggested instructions for using light-curing adhesive	19
6	Storage	25
7	Safe disposal	25
8	Symbols used in this manual	25
9	Learning resources	26

1 General Information

1.1 Introduction

These instructions only cover the clinical protocols associated with preparing, inserting and removing IDB trays. Please refer to SureSmile's training materials and online help for information about designing and ordering IDB trays.

1.2 Device description

The Indirect bonding (IDB) trays offer three-point contact for brackets with no customized pads. The unique tray design has individual caps that are combined into a sectionable tray. IDB trays are based on bracket heights and are thus suitable for the straight wire method of treatment. The SureSmile software allows you to visualize straight-wire treatment and highlight potential interferences. You can then create custom-printed trays based on your simulation using a 3D printing process that allows for more accurate bracket positioning than traditional methods.

Your IDB solution includes:

- Bracket placement simulation to view and adjust brackets on a diagnostic model
- 3D simulation to visualize the effects of straight-wire therapy
- Upper and/or lower labial IDB trays shipped to your practice.
- Set of initial SureSmile wires (SureSmile customers with Standard w/IDB case type only).

1.3 Intended use/Performance characteristics

Indirect bonding (IDB) tray is a transfer tray that is intended to facilitate the placement of brackets on the surface of patient's teeth by holding the brackets in position during the bonding process. By placing the brackets in the pre-allocated slots of the trays, the doctor can then add adhesive and light cure the brackets onto the patient's teeth without needing to perform additional measurements or adjustments.

1.4 Indications for use

Indicated for patients who have been prescribed orthodontic brackets and who will have brackets indirectly bonded onto enamel.

- **Clinical benefits:** Clinical benefits of orthodontic treatment include overall improvement of tooth health and correction of malocclusion.

1.5 Contraindications

This product is contraindicated for patients with a history of allergic reactions to acrylics.

Do not use the trays on patients with uncontrolled biting behavior.

1.6 Warnings

In rare instances, some patients may be allergic to the trays. Patients with a history of allergic reactions to acrylics should not be prescribed this product.

Do not use damaged or broken IDB trays, as their parts can be accidentally swallowed or aspirated and may be harmful.

Report serious incidents that have occurred in relation to the device to the device manufacturer and the Competent Authority in member state of residence, or other applicable regulatory agency.

If the IDB tray is damaged or incorrect, replace in container and immediately contact SureSmile Customer Care for a replacement.

1.7 Precautions

Make sure that only alcohol-based cleaning fluid comes in contact with the plastic tray.

Do not sterilize the trays in an autoclave. Dentsply Sirona only guarantees compatibility of its SureSmile IDB trays with isopropyl alcohol. If you use acetone to clean the bracket bases, make sure that no acetone comes in contact with the plastic tray.

Patient should be bonded within six weeks of scan used for IDB.

Make sure that no trays, tray parts, or brackets fall inside the patient's mouth.

Each IDB tray is a custom-made device for a particular patient and should be handled with care.

Do not reuse the product. Risks of reuse include infection and cross-contamination to patient and healthcare provider.

Brackets are not supplied with the IDB tray.

When cleaning the bracket base or applying adhesive, use only mesial-distal strokes. Otherwise, you risk dislodging the bracket from the cap.

If using self-ligating brackets with IDB tray, ensure the "door" is firmly shut.

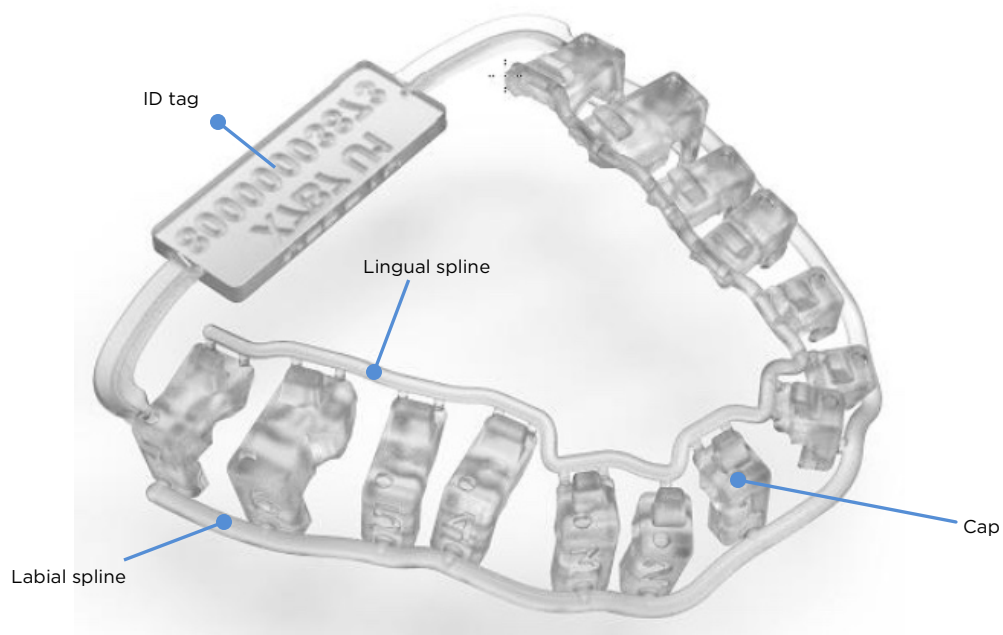
Remove any paint or wax markings on the bracket face prior to use with IDB tray, as these may cause the bracket to seat incorrectly. Supplemental treatment may be required for severe open bite/overjet or skeletally narrow jaw.

1.8 Adverse reactions

Allergic reaction to acrylics.

2 Designing and using SureSmile IDB Trays

2.1 IDB tray components



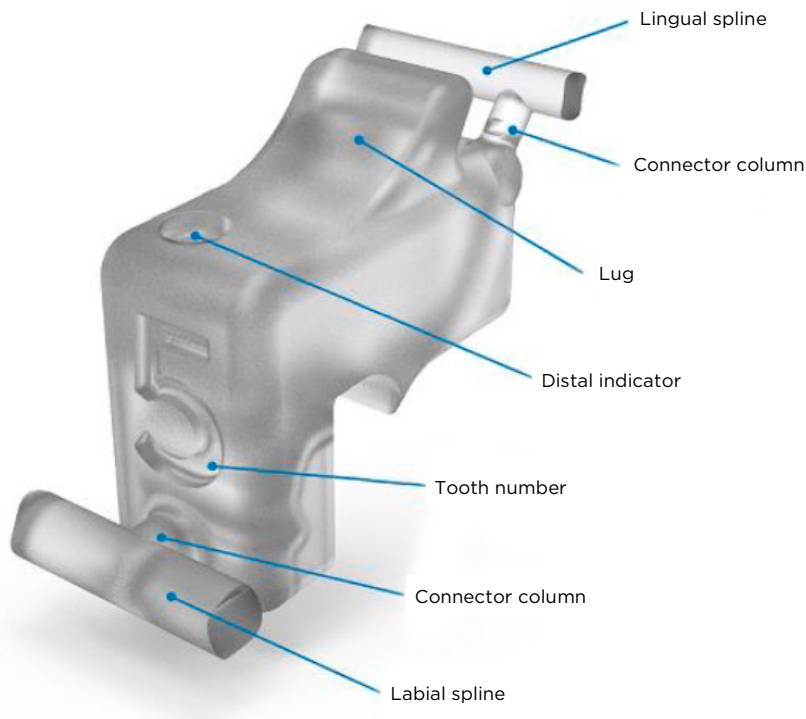
ID tag - serial number for tray

Lingual spline - connects the lingual side individual caps to assist in holding the tray together

Cap - fits to the individual tooth and holds the bracket in place

Labial spline - connects the labial side of the individual caps to assist in holding the tray together

2.2 IDB cap components



Lingual spline - connects the lingual side individual caps to assist in holding the tray together

Connector columns - columns have an indented snap-off point for removing the lingual spline after bonding

Lug - use lug as lever to pry cap away from bracket

Distal indicator - indentation on top of cap indicates distal side that ensures correct placement if cap is removed from the spline and placed independently

Tooth number - number of tooth imprinted on the cap face (Palmer Notation numbering system used)

Labial spline - connects the labial side of the individual caps to assist in holding the tray together

3 Prepare for the IDB appointment

Before you begin the IDB appointment prepare the trays:

1. Find the IDB tray package, unpack and verify the trays are for the patient.
2. Seat the brackets in the tray.
3. Remove the patient ID labels.
4. Clean the bracket bases with alcohol.
5. Apply the bonding adhesive just before insertion.

3.1 Organize your workspace

1. Find an uncluttered, well-lit workspace next to a computer running SureSmile.
2. Open SureSmile to the patient's IDB simulation.
3. Have at your workspace:
 - **Patient's IDB trays** in their containers
 - **Patient's bracket set** or a supply of the brackets being used
 - **Tools** to insert brackets into the tray (e.g., cotton pliers or pincers, tweezers, scaler, direct bond bracket holder, etc.)
4. **Recommended** but not required:
 - Lighted magnifying glass
 - Wearing medical grade gloves is recommended to reduce contamination of bracket bonding surface.

CAUTION



Patient should be bonded within six weeks of scan used for IDB.

3.2 Inspect the tray


1. Double check the IDB box label before opening to make sure you have the patient's trays.
2. Remove trays from bubble wrap packaging.
3. Visually inspect the IDB tray or tray segments to ensure nothing is damaged.
4. Compare each tray or tray segment to the IDB simulation in SureSmile to make sure it matches the simulation.



IDB box




IDB trays (detail)

	<p>NOTICE</p> <p>If the IDB tray is damaged or incorrect, replace in container and immediately contact SureSmile Customer Care for a replacement.</p>
---	--

3.3 IDB tray hygiene

SureSmile IDB trays are not sterile when delivered. Disinfect the trays according to the hygienic protocol of your practice before placing in the patient's mouth. SureSmile IDB trays are compatible with alcohol.

<p>CAUTION</p> 	<p>Dentsply Sirona only guarantees compatibility of its SureSmile IDB trays with isopropyl alcohol.</p>
	<p>Do not sterilize the trays in an autoclave.</p>
	<p>If you use acetone to clean the bracket bases, make sure that no acetone comes in contact with the plastic tray.</p>

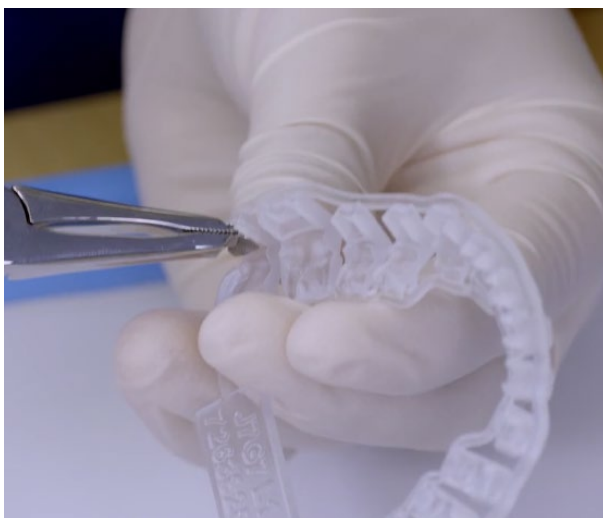
3.4 Seat brackets in the trays

Select a bracket. If self-ligating, make sure the door is firmly shut. Remove any paint or wax markings on the bracket face as these may cause the bracket to seat incorrectly.

Remove paint marking
before inserting bracket
into IDB tray

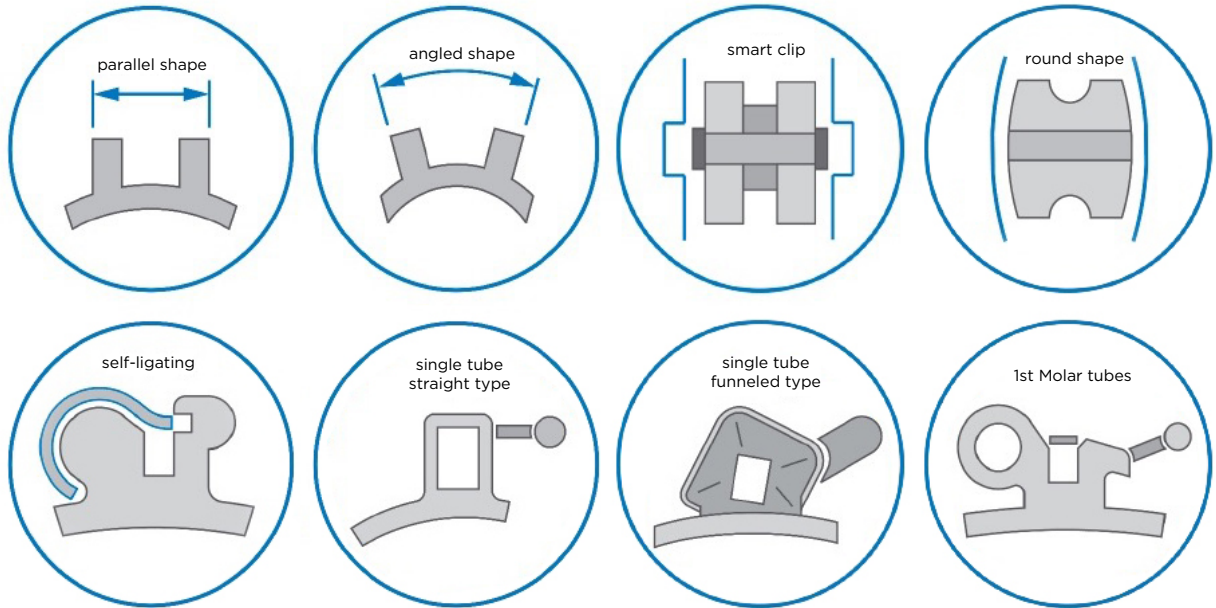


Using the following directions and recommendations, insert each bracket carefully using your fingers or a tool of your choice. The order or sequence you use to seat the brackets is up to you.

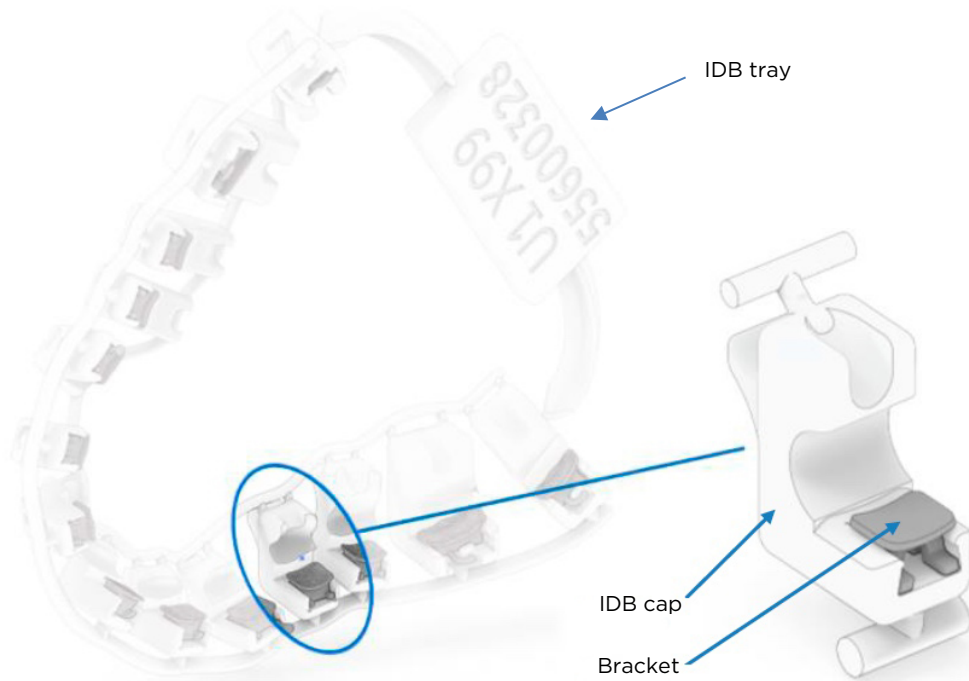


4 Bracket category overview

Different bracket types need a specific way to insert the bracket into the tray. The bracket category overview helps to identify your bracket type.



The following figure shows the simplified view to an IDB tray and single cap which is used in the instructions below.

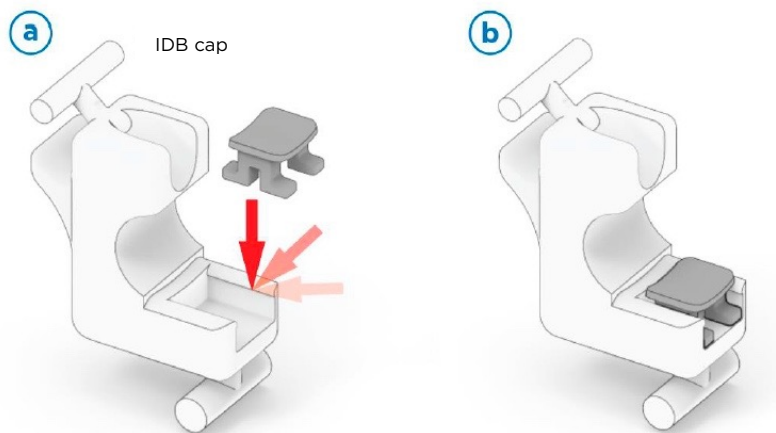


4.1 Bracket categories, insertion directions and seating requirements

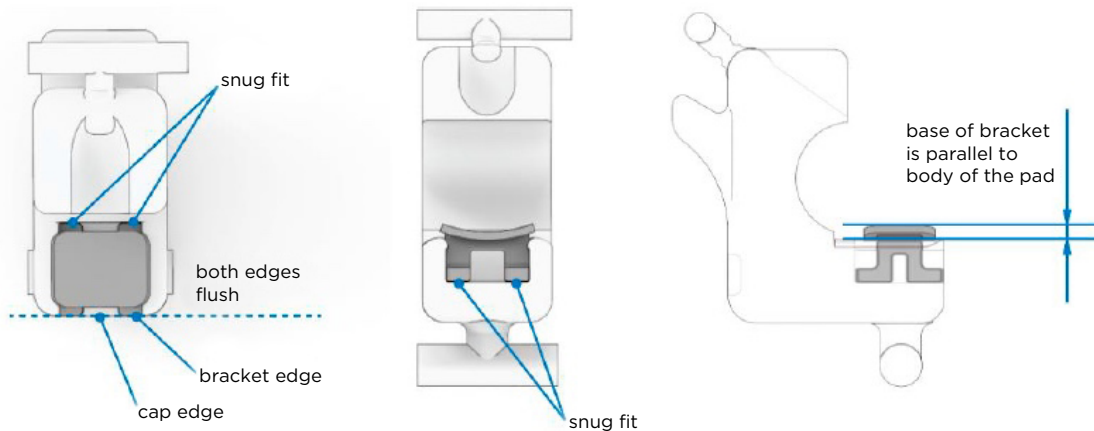
4.1.1 Brackets with parallel shape (wings)



Inserting direction for brackets with parallel shape may vary. The recommended direction is indicated by the red arrow.



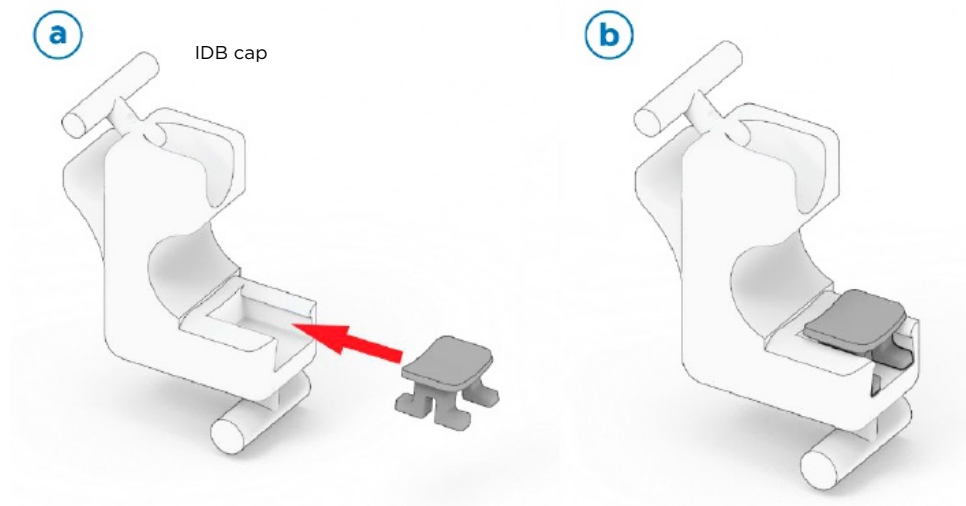
Bracket seating requirements:



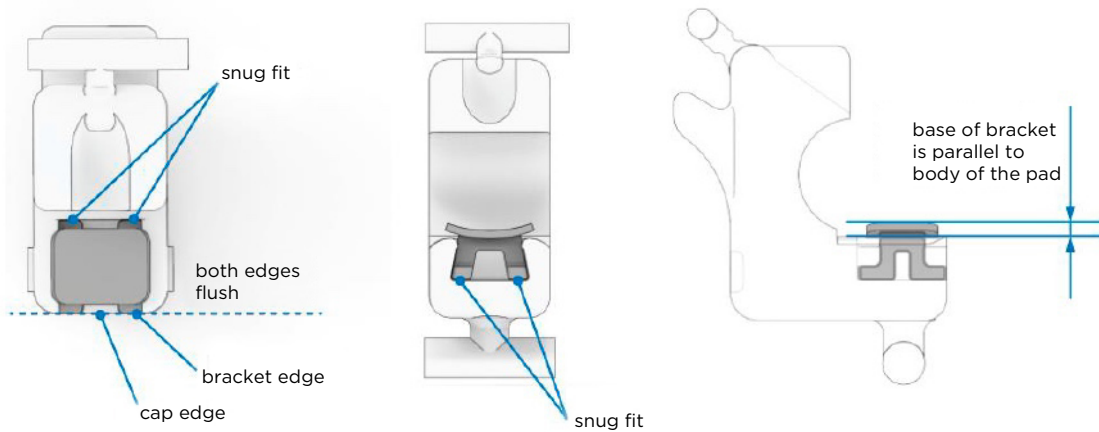
4.1.2 Brackets with angled shape (wings)



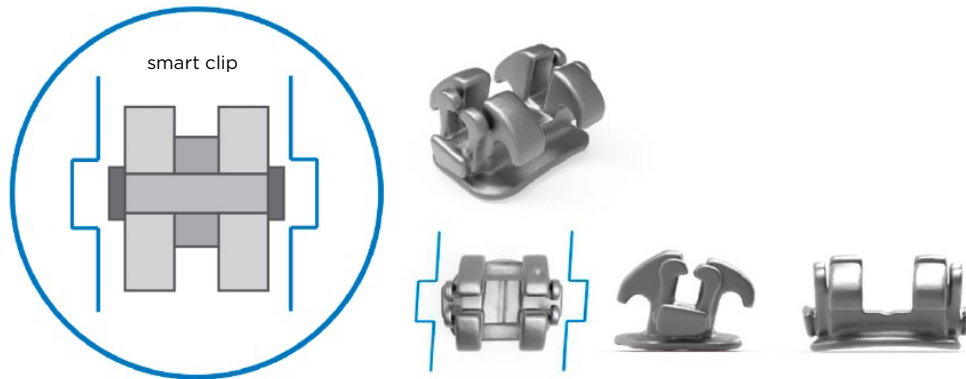
The recommended direction for inserting brackets with an angled shape is indicated by the red arrow.



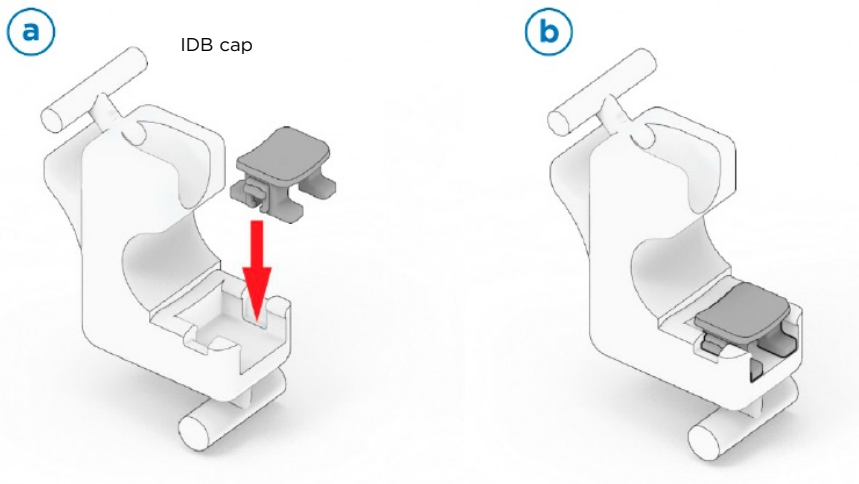
Bracket seating requirements:



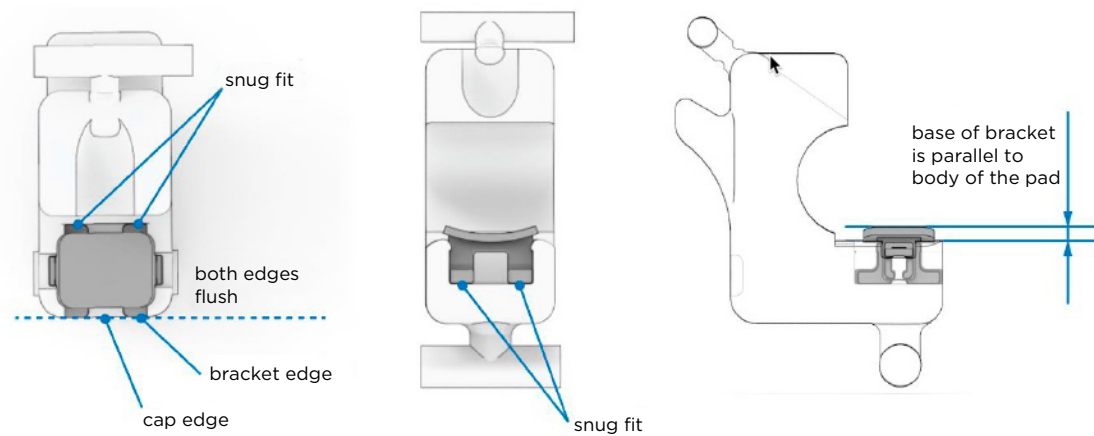
4.1.3 Smart clip brackets



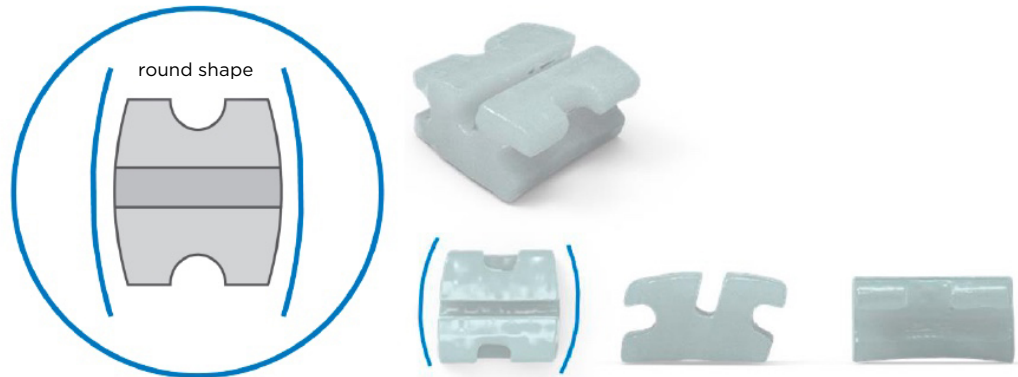
The recommended direction for inserting smart clip brackets is indicated by the red arrow.



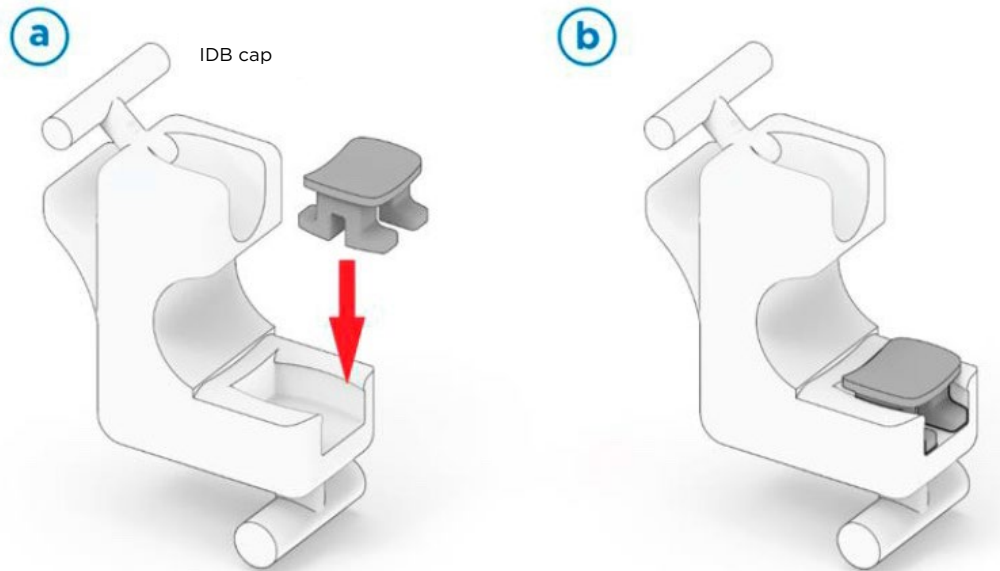
Bracket seating requirements:



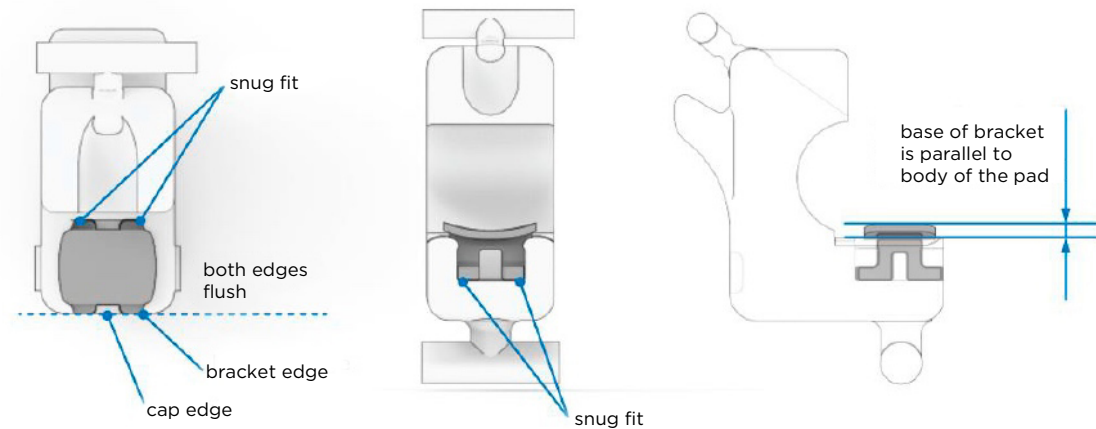
4.1.4 Round shaped brackets



The recommended direction for inserting brackets with a round shape is indicated by the red arrow.



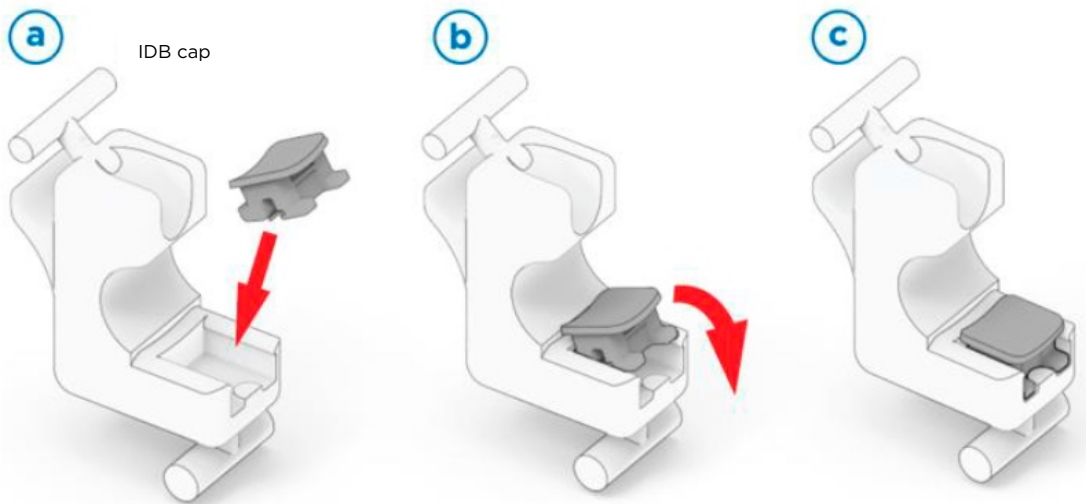
Bracket seating requirements



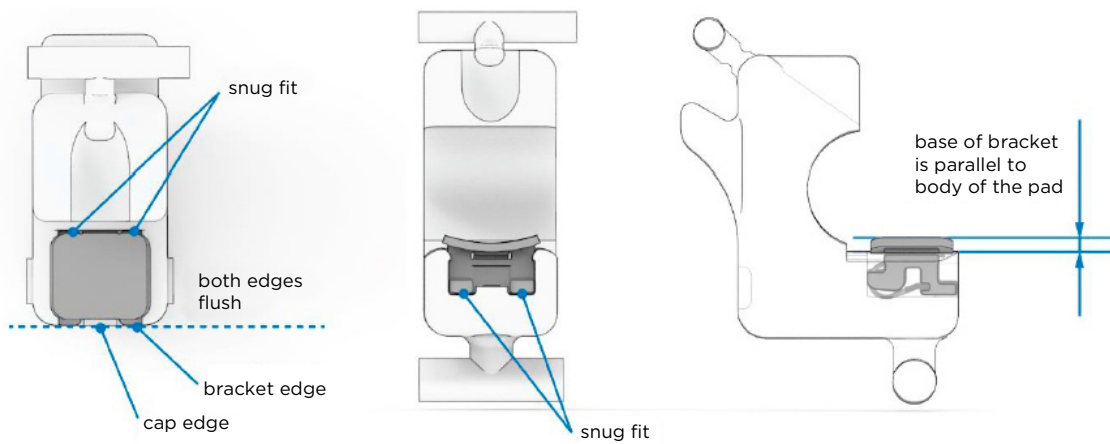
4.1.5 Self-ligating brackets



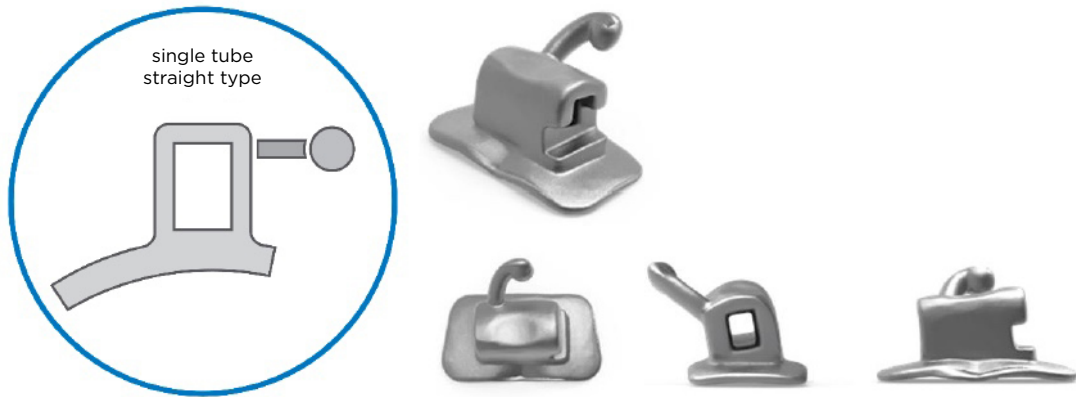
The recommended direction for inserting self-ligating brackets is indicated by the red arrow. **Make sure bracket slider is closed completely before inserting.**



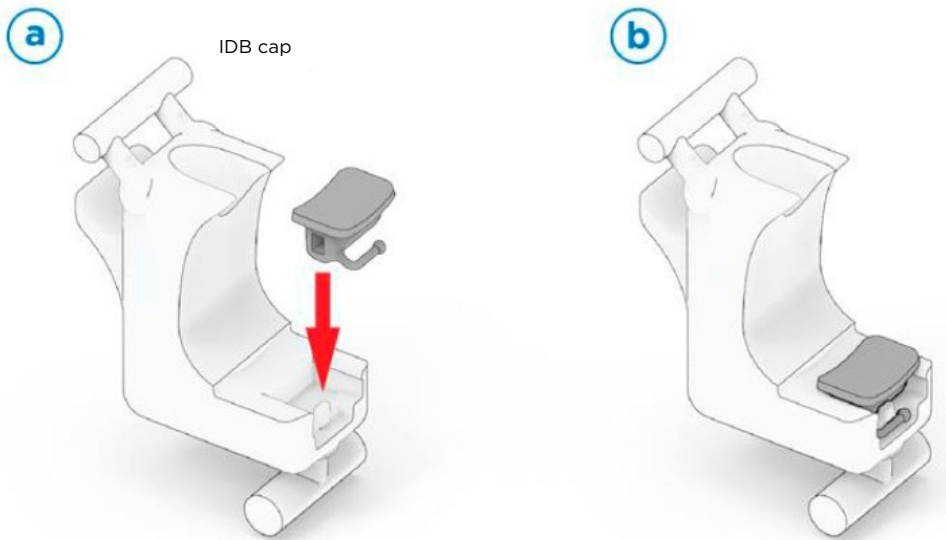
Bracket seating requirements:



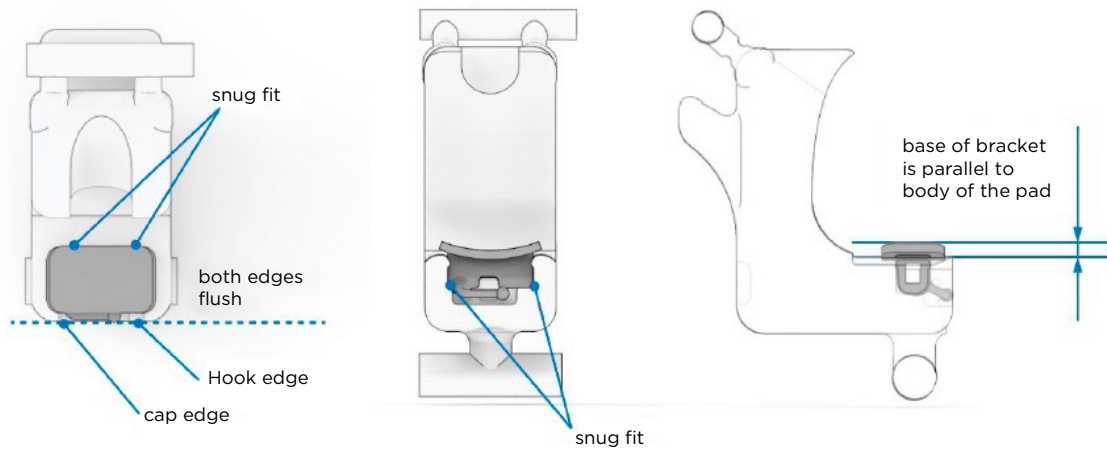
4.1.6 Single tubes (straight types): 1st and 2nd molar tubes with or without distal extension



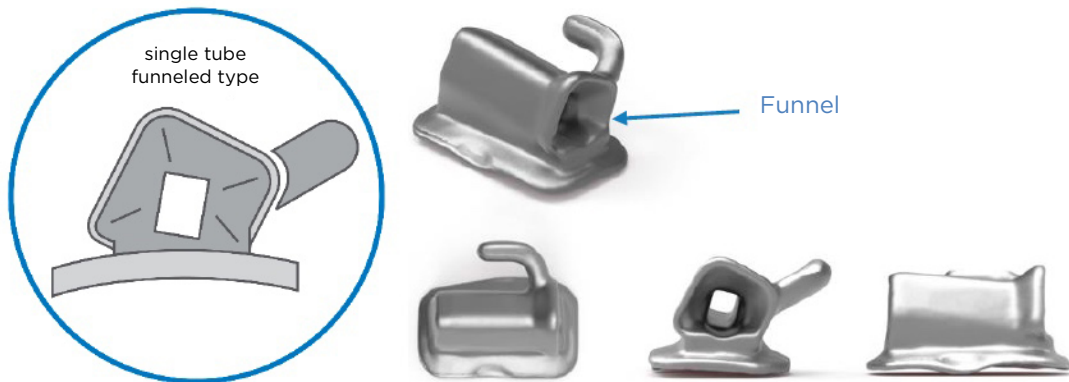
The recommended direction for inserting single tube molar brackets is indicated by the red arrow.



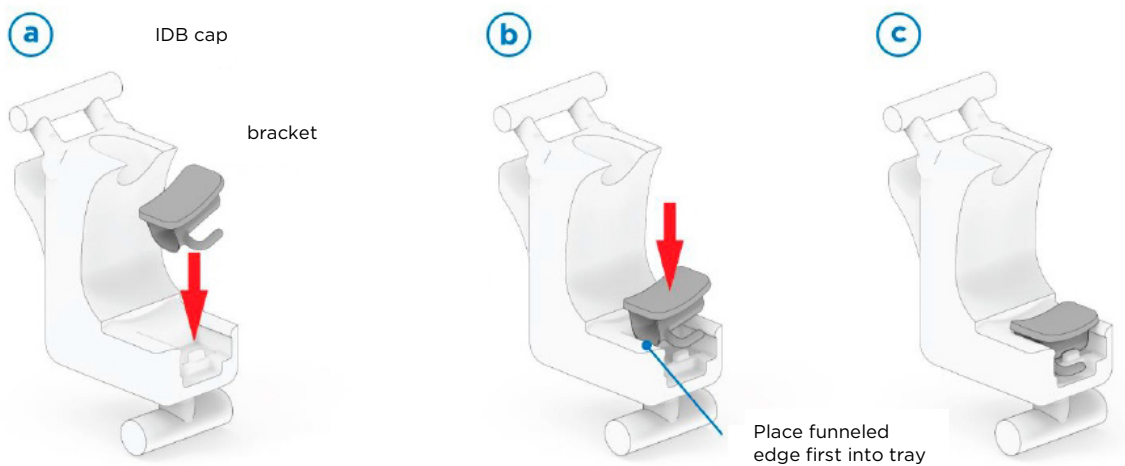
Bracket seating requirements:



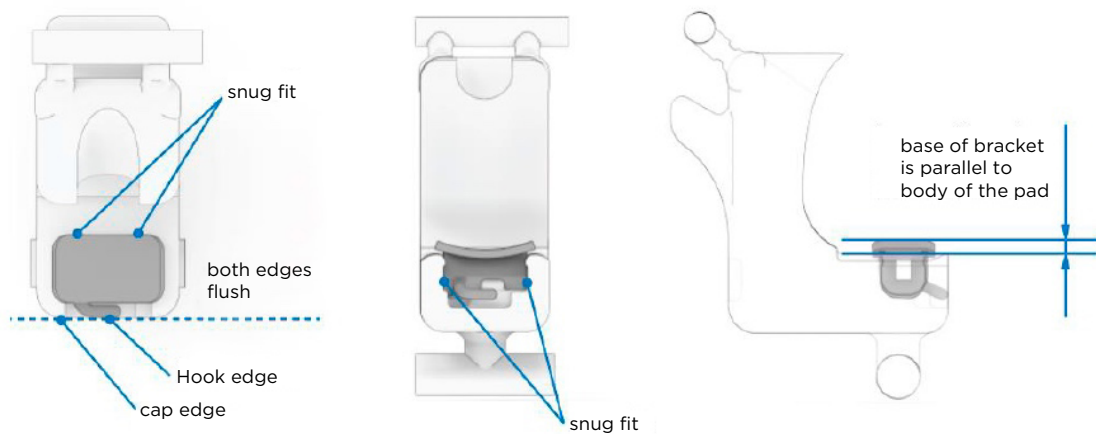
4.1.7 Single tubes (funneled type): 1st and 2nd molar tubes with or without distal extension



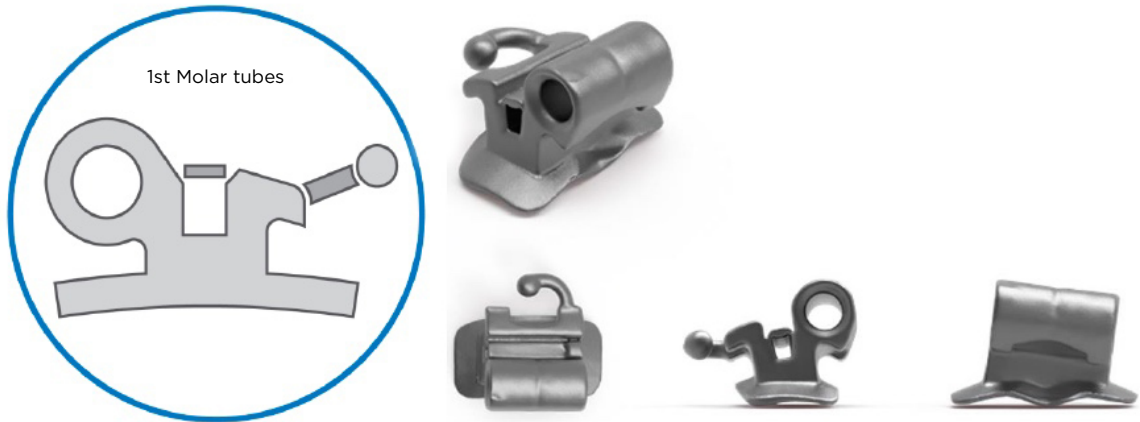
The recommended direction for inserting single tube molar brackets is indicated by the red arrow.



Bracket seating requirements:



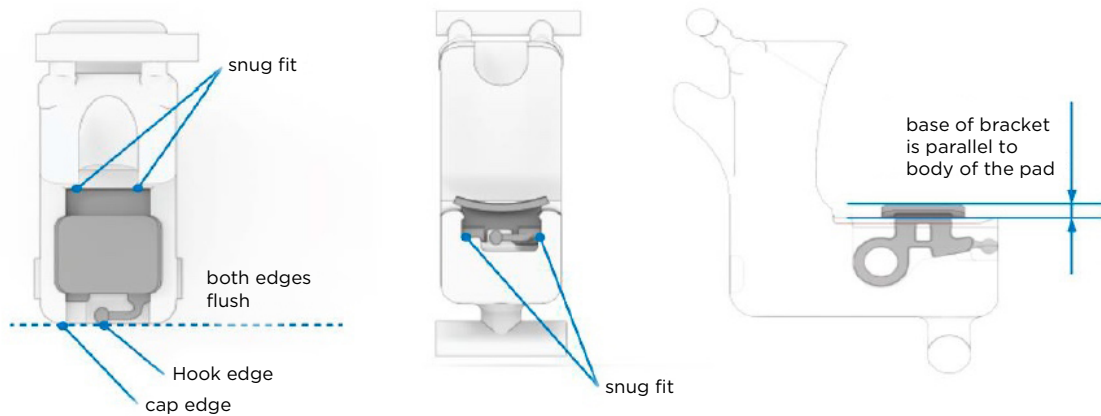
4.1.8 1st molar tubes



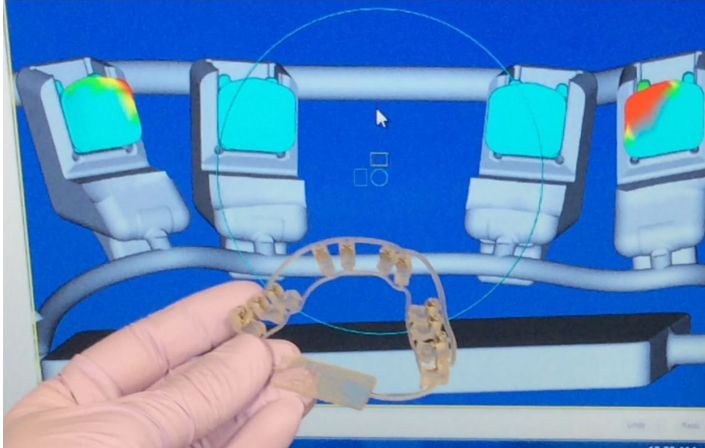
The recommended direction for inserting single tube molar brackets is indicated by the red arrow.



Bracket seating requirements:




Check the bracket seatings under magnification and compare the target of the 3D IDB tray simulation in SureSmile against the actual position of the bracket you just seated.



Brackets should fit snugly against the cap.

Tip: When you finish seating all brackets in a tray, check that all brackets are still snugly seated.

	Check the seated brackets against the simulation in SureSmile to verify fit.
--	--




When you are finished seating all the brackets in a tray, put the tray back into its container. Seat the brackets for the other tray using the steps just described.

5 IDB appointment

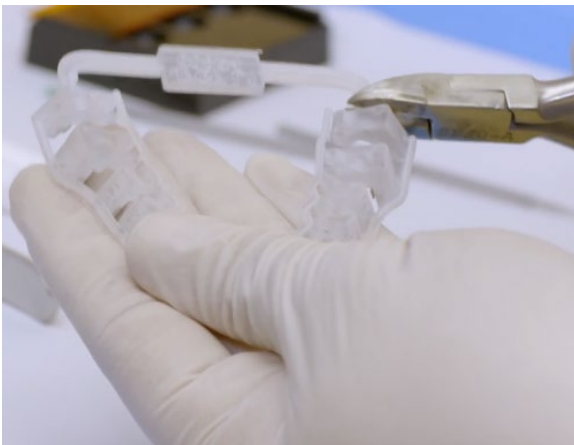
5.1 Chairside setup

1. Open SureSmile to the patient's IDB simulation.
2. Make sure you have the following items chairside:
 - **Patient's IDB trays** in their package
 - **Bracket adhesive**
 - Use an **applicator** or **micro brush** for cleaning excess adhesive flash.
 - **Instruments** to insert tray (e.g., cotton pliers or pincers, tweezers, scaler, direct bond bracket holder, etc.)
 - **Curing light**. Use of a small light cure tip (6-8 mm) is recommended.

<p>CAUTION</p> 	<p>Make sure that only alcohol-based cleaning fluid comes in contact with the plastic tray.</p>
	<p>When cleaning the bracket base or applying adhesive, use only mesial-distal strokes. Otherwise, you risk dislodging the bracket from the cap.</p>

5.2 Suggested instructions for using light-curing adhesive

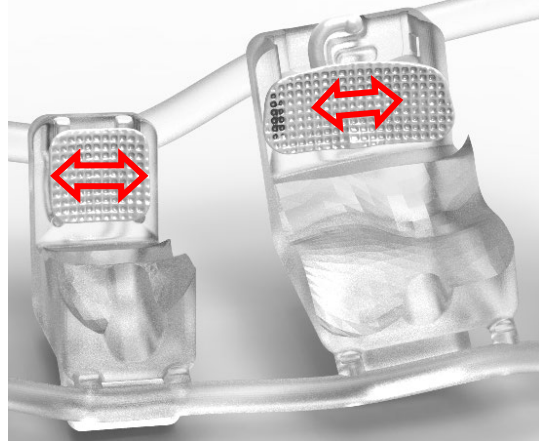
1. Trim the IDB tray labels: Use ligature or wire cutters to snip off the tray ID tag.
2. Clean each bracket pad with alcohol and let dry.



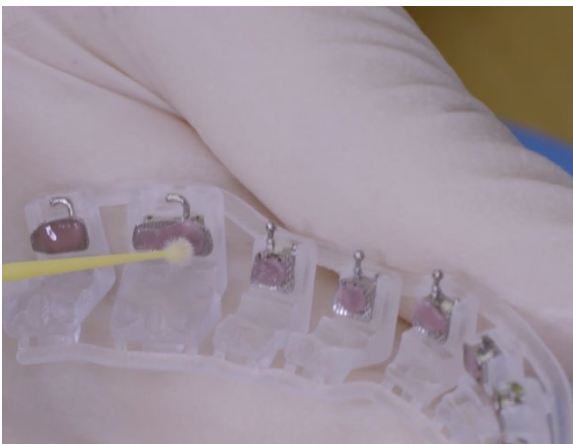
3. Apply bracket adhesive to each pad:



4. Use only mesial-distal strokes to clean the bracket base or apply adhesive.



5. Apply adhesive: Use primer/sealant to push adhesive into pad mesh. Cover the tray with a light filter, place under the IDB shipping container box, or cover in some other way to block light and prevent premature curing.



6. Prophyl all teeth.



7. Rinse and dry well.



8. Apply Etch. Leave on for 30 seconds.



9. Rinse and dry well second time. Teeth should appear chalky.



10. Use tooth dryer 3-5 seconds per tooth.



11. Apply a thin layer of primer/sealant on the entire tooth surface.



12. Apply light air to thin out the primer/sealant.



13. Seat Tray: Apply firm pressure on the occlusal surface to ensure tray is completely seated. Push labially and buccally to ensure bracket pad is pressed into the tooth surface well.



14. Using an explorer or another favorite adhesive removal instrument, clean up any excess glue from around the brackets.



15. Seat tray: Use the curing light to cure the brackets on the labial/buccal surface and on the gingival surface. Once the tray is removed cure each bracket again. Make sure you meet or exceed your light manufacturer's recommendations for curing time per tooth.



16. Seat Tray: Hold the tray in position while curing the brackets



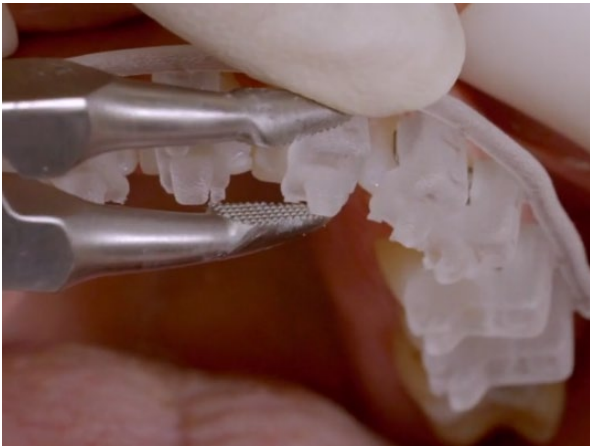
17. Remove Tray: Use tip of scaler or plier to leverage lingual spline and release from the seating lug.



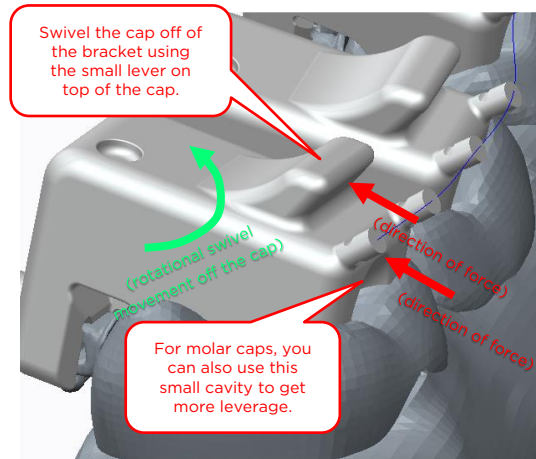
18. Remove Tray: Remove lingual spline.



19. Remove Tray: Release each cap from the bracket as shown.



20. Remove Tray: Use the small lever on top of the cap. For the molars you can also use the small cavity as shown. Swivel each cap as shown to release the bracket.



21. Remove Tray: Remove tray by gently pulling occlusally.



22. Remove Tray: Remove tray.



Completed upper and lower arch





6 Storage

The SureSmile IDB trays are suitable for use in a standard office environment. Store the trays in their original container or in a dark environment. Direct sunlight can damage the tray.

7 Safe disposal

Used dental appliances may be considered a biohazard. Follow your country-specific laws, directives, standards and guidelines for the disposal of used devices.

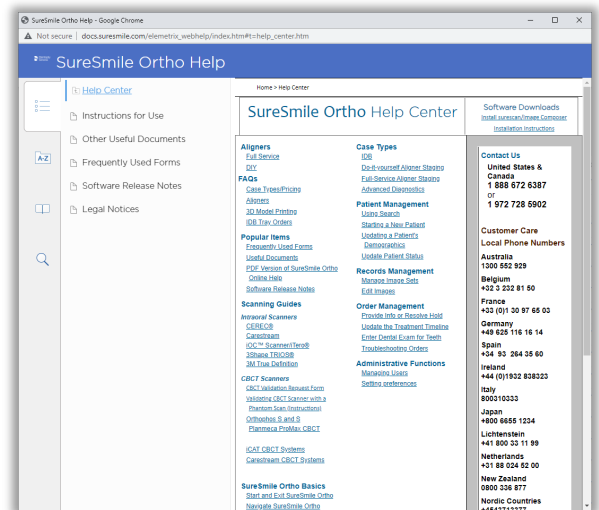
8 Symbols used in this manual


	<p>CAUTION</p> <p>Indicates a potentially hazardous situation, which if not avoided, may result in minor or moderate injury, product or property damage.</p> <p>It may also be used to alert against unsafe practices.</p>
	<p>NOTICE</p> <p>Indicates important information that is required to use the system properly.</p>

9 Learning resources/Training

Search the [Help Center](#) in SureSmile for:


- Online help topics with step-by-step instructions
- Downloads including forms and reference documents
- Video demonstrations of software features

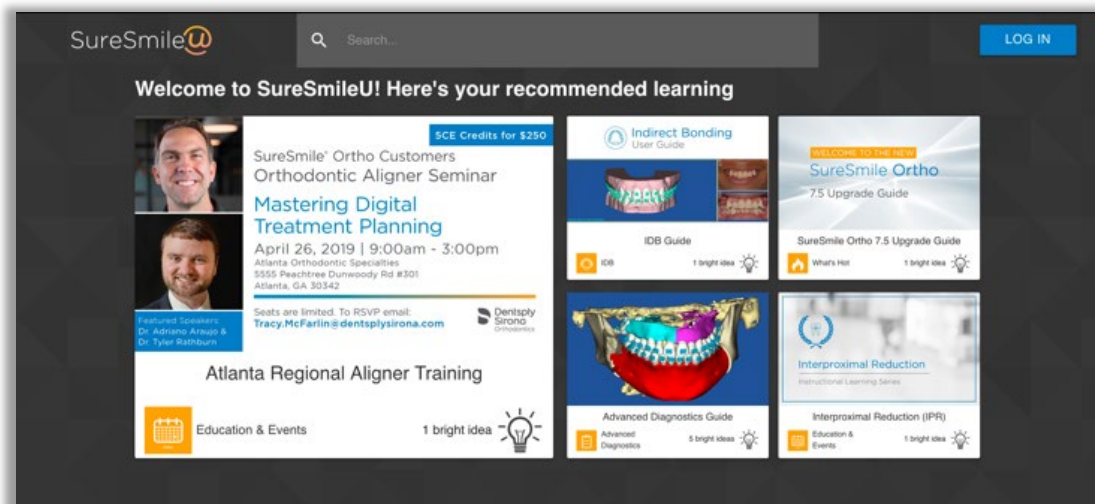
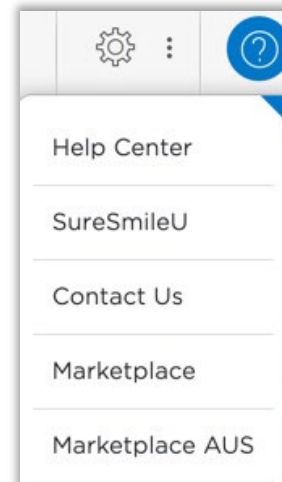


To open the Help Center, click the question mark button  and select **Help Center**.

Visit www.suresmileu.com for online learning resources including:

- Archived SureSmile webinars
- Recordings of presentations from events
- Class materials

To open SureSmileU from the SureSmile software, click the question mark button  and select **SureSmileU**.





Manufacturer

OraMetrix

2350 Campbell Creek Blvd., Suite 400
Richardson, TX 75082, U.S.A.



Authorized EU Representative

Orametrix GmbH

Rungestrasse 19,
10179 Berlin, Germany

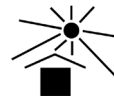
Australian Sponsor

Dentsply Sirona Pty Ltd.

11-21 Gilby Road
Mount Waverley VIC 3149 Australia
1300 55 29 29



Do not
reuse



Keep away
from sunlight



www.dentsplysirona.com/ifu

All rights reserved. SureSmile is a registered trademark of Dentsply Sirona, Inc.

© 2021 Dentsply Sirona Inc.

0281-IFU000060 Rev. 12

Issued 12-2021