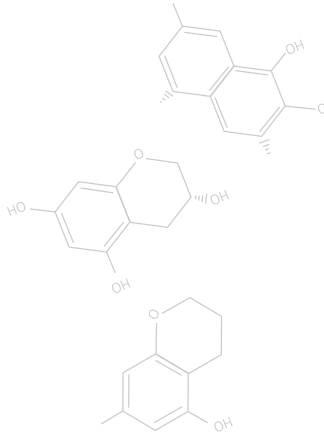




MAIN Biz
주요사업 분과업

Guideline for the use of Medical Devices



Multifunctional Universal Adhesive



MEDICLUS

EASY & FAST
RESTO SOLUTION

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The background image shows a close-up of a dental procedure, likely a root canal treatment, with a hand holding a dental instrument. Overlaid on this is a circular infographic with a central clock-like face. Six white circular icons are arranged around the center, each containing a different dental symbol: a tooth with a magnifying glass, a dental chair, a tooth with a crown, a tooth with a root canal, a tooth with a filling, and a tooth with a crown. The infographic also includes labels for 'E Type', 'D Type', and 'Q Type' around its perimeter.

5. Clinical guidelines

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- Clinical procedure
- Convenience of clinical application
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6. Storage Instruction

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- Storage method
- Storage condition

Hi-Bond Universal (Dentin bonding system)

Hi-Bond Universal is a universal dentin bonding system from Medclus. As the importance of the preservation aesthetic area has recently emerged, interest in adhesives for the success of aesthetic restoration is also increasing. Dentin adhesive plays a role in bonding the tooth's dentin surface to the restorative material through chemical bonding. There should be no microleakage between dentin and the restorative material, which requires sufficient adhesive strength. It facilitates mechanical bonding through resin infiltration into the demineralized layer and dentinal tubules and helps to exclude moisture and tissue fluids from the dentinal tubules, making adhesion between the tooth and the restoration material more effective.

The 6th generation dentin adhesive, in contrast, consisted of a self-etching primer and an adhesive resin, requiring a two container system where the adhesive had to be stored separately and mixed just before use. However, with the 7th generation dentin adhesive, all components, including the conditioner, primer, and adhesive resin, are pre mixed in a single container. While both the 6th and 7th generations are 1-step systems that compress the three restorative processes of Etching, Primer, and Adhesive into a single step, the 7th generation goes further by combining Etching, Primer, and Adhesive in a single bottle, creating a 1-bottle system. This adhesive system streamlines the clinical process, optimizing speed and efficiency, eliminating the need for mixing and precise ratio adherence, reducing chair time, and lowering the technical sensitivity of the operator. Due to its convenience, Universal dentin adhesive has garnered significant attention in the market.

This guideline provides information about Medclus's Hi-Bond Universal Dentin Adhesive and handles the clinical application guidelines.

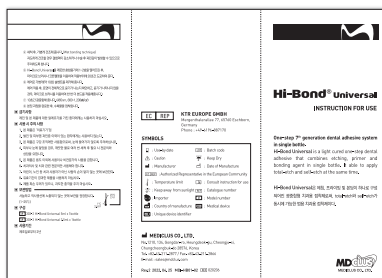
This guideline was prepared by the Seoul National University Center for Future Dentistry (Tel : 822-740-8735, E-mail : snucfd@snu.ac.kr), funded by the Ministry of Trade, Industry and Energy of the Republic of Korea (Medical Device Commercialization Promotion Project) in 2023.

Packaging

1



2



No	Name	Quantity
1	Hi-Bond Universal 5ml	1
2	Instruction for use	1

Components



- Volume 5ml.
- **Convenient flip-style lid.**
- Etching + Primer + Adhesive (1 step, 1 bottle system).
- **Applied in any of the total-etch, self-etch, selective-etch modes.**
- Excellent adhesion strength regardless of etching mode.
- With the function of Mesoporous Bioactive Glass (MBG), remineralization, hypersensitivity alleviation, matrix metalloproteinases (MMPs) inhibition, and adhesion to hard and soft tissues could be enhanced.
- Containing 10-MDP for chemical bonding with various indirect restorative materials such as zirconia, ceramics, and metals.
- Ultra mild pH(pH3.2), compatible with dual cure and self cure products.
- The solvent is ethanol, which has a less unpleasant odor.

Compositions

Product composition
Methacrylate resin monomers
10-MDP*
Silanized MBG
PVP (Polyvinyl pyrrolidone)
Camphorquinone
Ethyl 4-(dimethylamino)benzoate
2, 6-di-tert-butyl-4-methylphenol
Ethanol
Distilled water

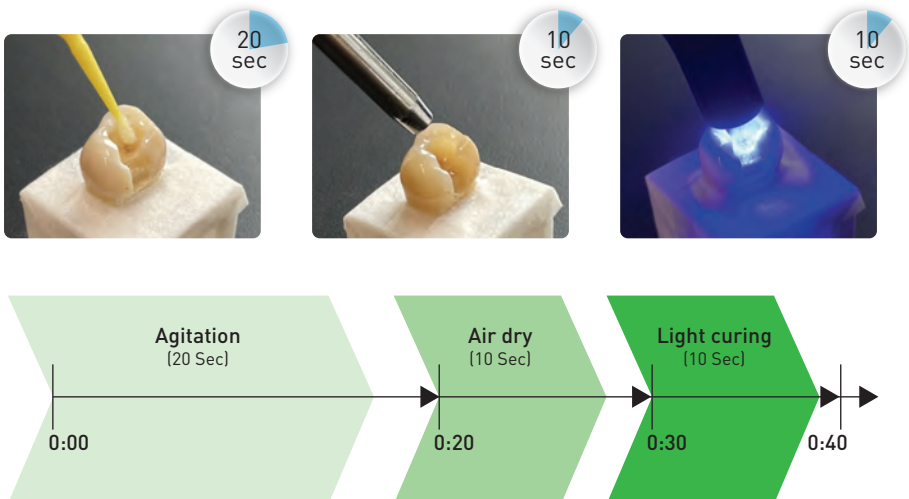
* 10-MDP : 10-Methacryloyloxydecyl dihydrogen phosphate

Compositons and Properties

Purpose of Use

- ① **Direct restoration**
 - Resin based composite
 - Resin modified Glass Ionomers
 - Core build-up resin
- ② **Indirect restoration**
 - Metal
 - Ceramics
 - Zirconia
 - Porcelain
 - Veneer
- ③ **Hypersensitivity treatment**

Application method



How to apply

Dental treatment method		Adhesive etching mode		
		Total etch	Selective etch	Self etch
Direct restoration	Composite			
	Core (dual-cure)			
Zirconia				
PFM, PFG				
All Ceramics				
Desensitization				
Sealant				



highly recommended



recommended



available

Properties

pH

- The pH was measured using a pH meter, and the table below displays the obtained values.

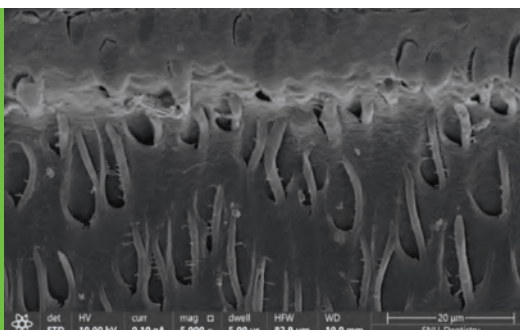
Products	pH (mean $\pm$ standard deviation)		
	Manufacturer's data	Measured pH	Difference(%)
Hi-Bond Universal	3.2	3.16 $\pm$ 0.03	-1.27
Product S	2.7	3.11 $\pm$ 0.01	13.18
Product P	> 2.5	2.48 $\pm$ 0.01	-0.81
Product A	3.2	3.20 $\pm$ 0.01	0
Product E	2.2	3.64 $\pm$ 0.03	39.56

- The pH Meter electrode was placed in a Conical Tube filled with dentin adhesive, and we waited for approximately 20 seconds until the pH meter displayed a constant value. Then, we recorded the stable measurement value.
- Actual measurement results, Product E had the highest measurement, while Product P showed the lowest pH value.

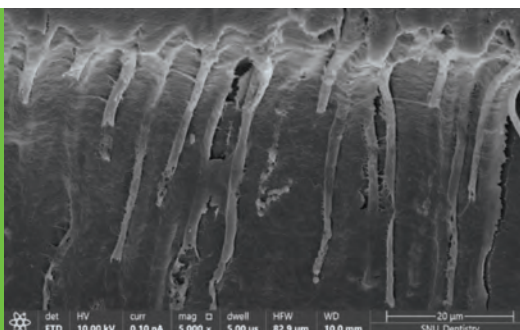
Dentin-adhesive interface

- The hybrid layer formed in dentin plays a crucial role in dentin adhesion strength.
- Universal adhesive can be used in both total-etching (etch & rinse) and self-etching modes. The microstructure of the hybrid layer formed on the dentin adhesive interface treated with total-etching and self-etching was observed using SEM.
- The microstructure of the hybrid layer formed at the dentin adhesive interface exhibited a similar pattern with little variation.

Self-etch



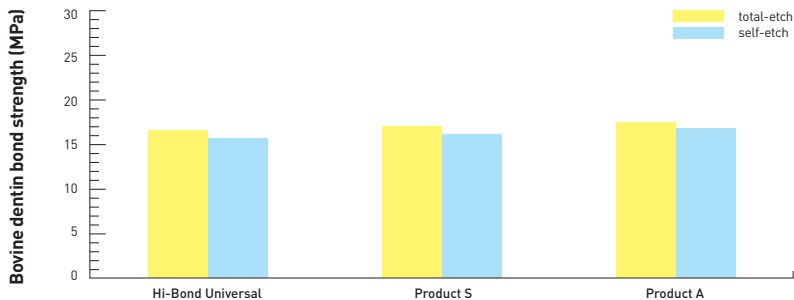
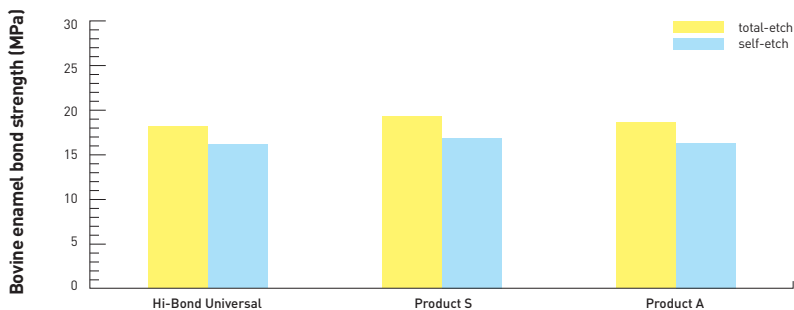
Total-etch
(etch & rinse)



Properties

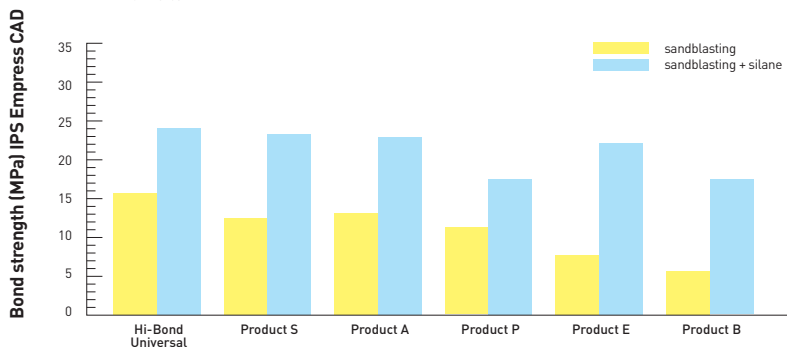
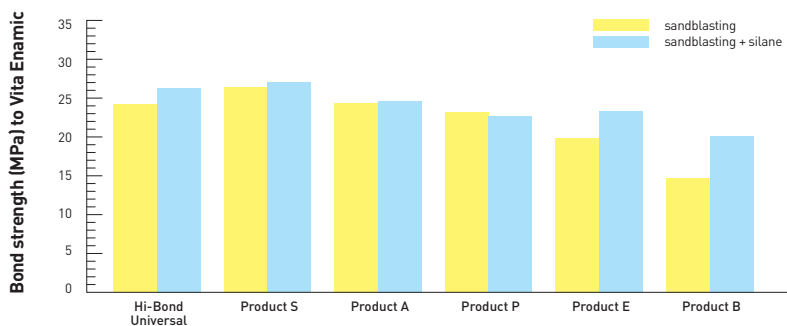
Bond strength (1) Bovine tooth structure (enamel & dentin)

- Dentin adhesive is used for the purpose of bonding restoration or prosthetic materials to damaged dentin.
- Universal adhesive can be used in both total-etching and self-etching mode.
Therefore, the bond strength tests were conducted to evaluate the enamel and dentin bond strength subject to etching modes.
- The bond strength of Hi-Bond Universal on dentin and enamel did not show a significant difference compared to imported products (S, A) ($p>0.05$).
Total-etching showed slightly higher values compared to the self-etch mode, although the difference was not significant ($p>0.05$).



Bond strength (2) CAM blocks (Vita Enamic, IPS Empress CAD)

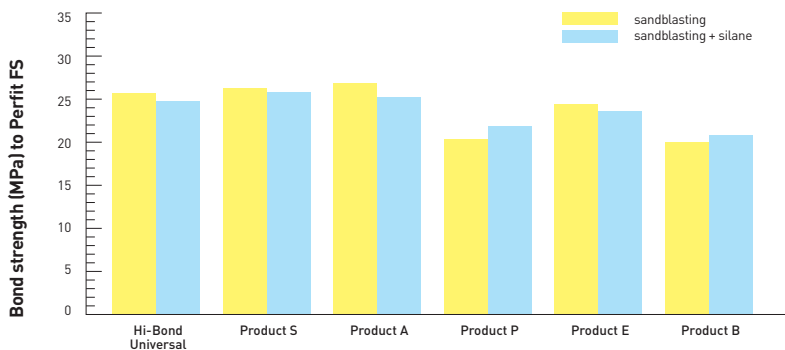
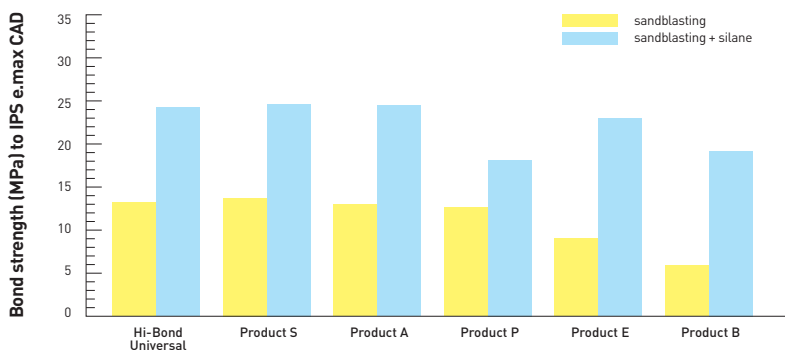
- Recently, the use of Universal adhesive for bonding CAD/CAM blocks is being widely reported. Therefore, adhesive strength evaluation experiments were conducted on various type of CAM blocks (after 24hrs immersed in 37°C water).
- In the case of adhesive strength for the **Hybrid composite resin block** (Vita Enamic), Hi-Bond Universal exhibited adhesive strength that did not significantly differ from the popular imported products (S, A, P), but it showed higher adhesive strength compared to domestic products (E, B). Additionally, the increase in adhesive strength due to silane treatment was not significant, except for domestic products.
- The adhesive strength for the **Leucite glass-ceramic block** (IPS Empress CAD) significantly increased with additional silane treatment ($p < 0.05$). The average adhesive strength of Hi-Bond Universal was the highest, but there was no significant difference compared to the popular imported products (S, A) ($p > 0.05$).



Properties

Bond strength (3) CAM blocks (IPS e.max CAD, Perfit FS)

- In the case of adhesive strength for the **Lithium disilicate glass-ceramic block (IPS e.max CAD)**, the adhesive strength significantly increased with additional silane treatment before applying all the evaluated Universal adhesives ($p < 0.05$). The adhesive strength of Hi-Bond was measured at a high value with no significant difference compared to the popular imported products (S, A, P) ($p > 0.05$).
- The adhesive strength for the **Zirconia block [(Y, Nb)-TZP] (Perfit FS)** was as high as that for the Hybrid composite resin block, and there was no significant impact of silane treatment ($p > 0.05$). The adhesive strength of Hi-Bond Universal was measured at a high value with no significant difference compared to imported products (S, A) and domestic products (E).



Cytotoxicity test

1. Test Background

- Dentin adhesives is applied intraorally not only for restorations but also for purposes such as treating dental hypersensitivity. Therefore, it must have appropriate biological compatibility in relation to human gingival fibroblasts.
- The cell culture technique is used to evaluate the effects of dentin adhesives or their diluted culture medium on cell lysis (necrosis), growth inhibition, and other effects.

2. Test Products

- Hi-Bond Universal (HBU), Product S, Product P, Product A, Product E, Product B (Total of 6 products).

3. Test method

- ISO 10993-5:2009 Biological evaluation of medical devices-Part 3 : Tests for in vitro cytotoxicity 8.4.1 Agar diffusion.
- ISO 7405:2008 Dentistry Evaluation of biocompatibility of medical devices used in dentistry.
- Agar diffusion assay : The assessment of cell proliferation or death by the exact count or measurement of remaining active cells in contact with discs made of testing adhesives.
- Cell viability test (Cell counting kit-8) The assessment of cell cytotoxicity and cell count, after treating cells with a reagent related to cell metabolism or the activity of enzymes within the cell.

Properties

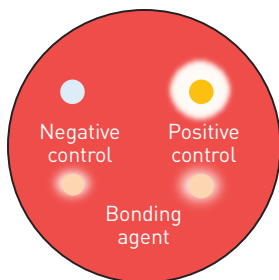
Cytotoxicity test method

1. Agar diffusion assay

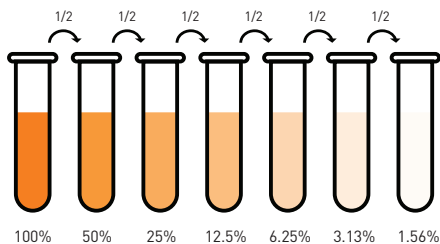
- The test is designed to demonstrate the nonspecific cytotoxicity of test materials after diffusion through agar or agarose.
- Place an appropriate number of samples and control groups in a cell culture dish with an appropriate spacing ($>20\text{mm}$) between adjacent specimens.
- This involves cultivation under a water saturated environment containing 5% carbon dioxide at $(37\pm 2)^{\circ}\text{C}$ for 24 hours.
- A glass disc was used as the negative control, and latex was used as the positive control.

2. Cell viability test (Cell counting kit 8)

- CCK-8 utilizes a chemical substance processed by mitochondrial oxidation reduction enzymes.
- At a wavelength of 450nm, optical density values were measured using a microplate reader to indirectly reflect the number of live cells.
- Using serial dilution, the bonding agent was diluted by $\frac{1}{2}$ and cells were treated with chemicals for 72 hours at 3,000 cells/well to confirm cell viability.



Agar diffusion assay



Serial dilution

1) Agar diffusion assay results

Group	Directly below sample	Zone index	Sample boundary	Lysis index
Hi-Bond Universal		1		2
Product S		1		0
Product A		2		1
Product E		2		1
Product P		2		2
Product B		3		4
Positive control		4		5
Negative control		0		0

Properties

Decolorization zone index (ISO 7405)

Index	Description of zone
0	No detectable decolorization zone around or under specimen
1	Zone limited to area under specimen
2	Zone not > 0.5cm beyond specimen
3	Zone not > 1.0cm beyond specimen
4	Zone not > 1.0cm beyond specimen, but not involving entire dish
5	Zone involves entire dish

Lysis index (ISO 7405)

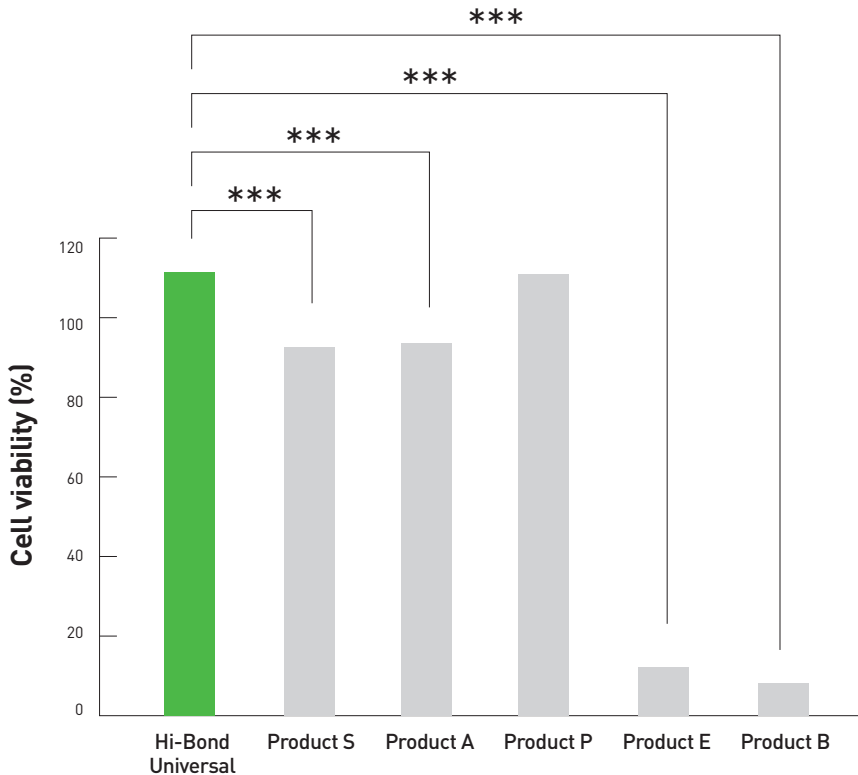
Index	Description of zone
0	No observable lysis
1	Up to 20% of zone lysed
2	20-40% of zone lysed
3	40-60% of zone lysed
4	60-80% of zone lysed
5	Over 80% lysed within zone

2) Agar diffusion assay results

Group	Product	Decolorization Zone Index	Lysis Index	Cytotoxicity	
				Zone index	Lysis Index
Universal bonding system	Hi-Bond Universal	1	2	1	2
	Product S	1	0	1	0
	Product A	2	1	2	1
	Product E	2	1	2	1
	Product P	2	2	2	2
	Product B	3	4	2	3
Positive control	Rubber Latex	4	5	3	3
Negative control	Slide Glass	0	0	0	0

- In the agar overlay method results, Decolorization Index was observed in the following order : Hi-Bond Universal and Product S < Product A, Product E, Product P < Product B The Lysis Index was observed in the following order Product S < Product A, Product E < HBU, Product P < Product B.

3) Cell viability test results



- In Hi-Bond Universal, the number of surviving cells was the highest, followed by Product E, Product A, Product S, Product P, and Product B in that order. Hi-Bond Universal showed a significant difference compared to Product S, Product A, Product P, and Product B, except for Product E ($p < 0.001$).

Clinical procedure



1. Tooth preparation

- Rinse with water to remove any contaminated material and debris from tooth preparation.
- Dry with air but do not dry excessively.
- When excessively dry, incomplete adhesion may indicate the possibility of hypersensitivity.



2. Bonding

- Apply it to cavity on the inner part with a micro brush.
- Agitation 20 seconds.



3. Dry

- Lightly remove the solvent with air.
- After applying air, check if the surface shows uniform gloss. (If the shine does not appear, apply the adhesive once more using a micro brush.)
- Dry 10 seconds.



4. Curing

- Light curing for 10 seconds.
(465nm, 800~1200 mW cm²)

Clinical Guideline



5. Resin filling

- Place an appropriate amount of composite resin into the cavity using a resin applicator.
- Apply a 2 mm layer incrementally.



6. Curing

- Light curing for 20 seconds.
(465nm, 800~1200 mW cm²)



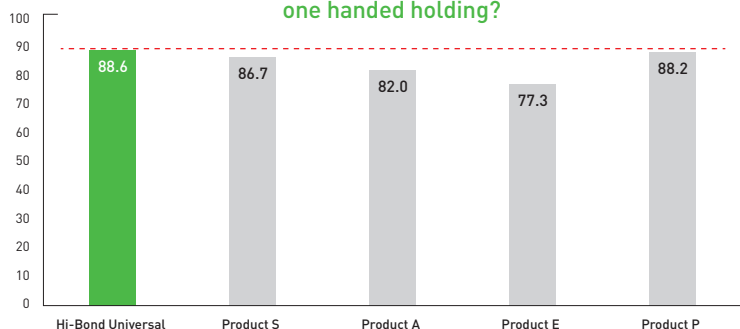
7. Finishing and polishing

Usability test

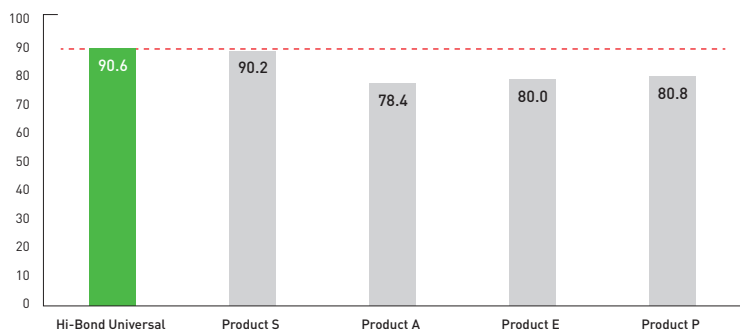
Packaging and Labelling

- A User Convenience Test was conducted with 50 licensed practicing dental professionals, and the evaluation content was based on their assessments following product use.
- The score was calculated by converting User the Convenience Test measurements, which were conducted on a 5-point scale, into a 100-point score.
- A baseline was marked at the top rank for each item.
(※ In the case of the blue baseline, the lowest score is ranked as 1st place.)

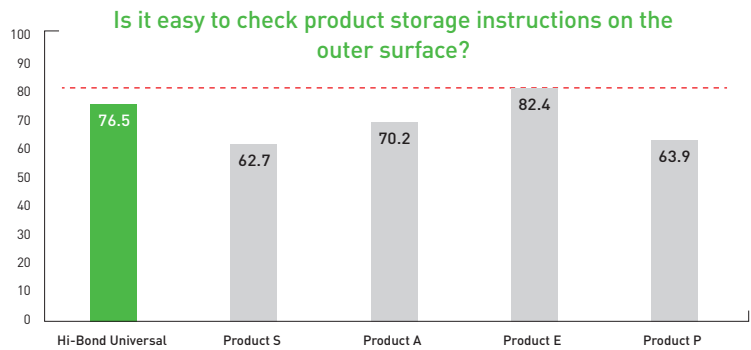
Is the external design convenient for one handed holding?



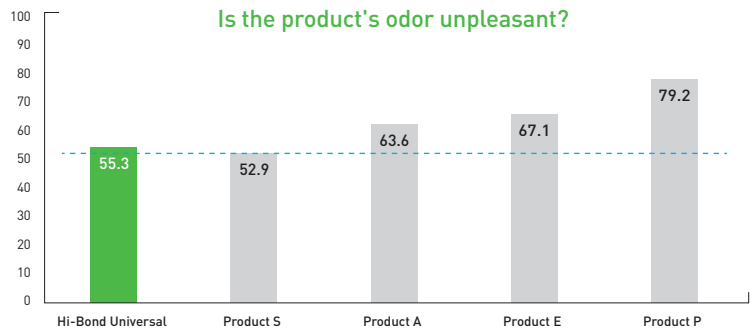
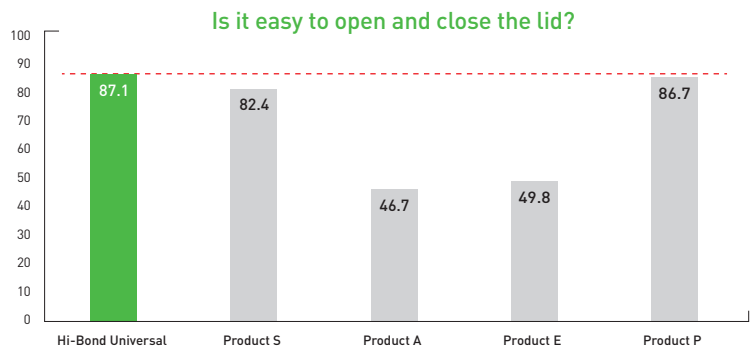
Does the product stand stably?



Clinical Guideline

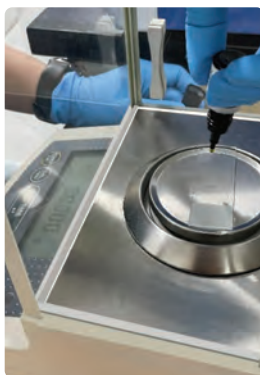
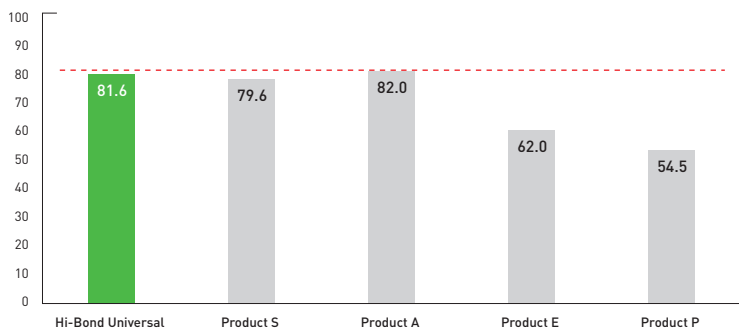


Operation convenience



* The lower the score, the less unpleasant the product's odor.

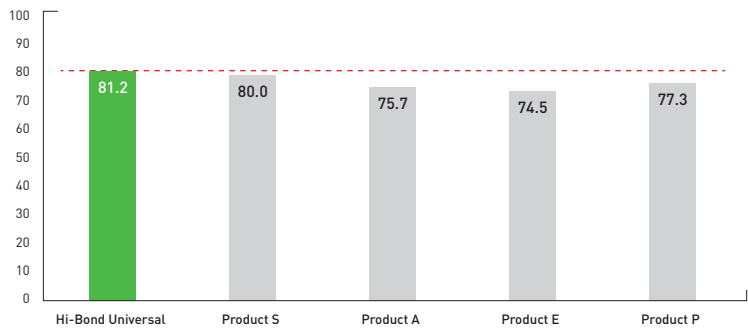
Is the volume of adhesive satisfactory?



- In a survey of User Convenience Test, Hi-Bond Universal ranked second, with a 0.4-point difference from the top, regarding the satisfaction of the adhesive volume.
- An evaluation experiment was conducted to confirm the DROP droplet technology of the Hi-Bond Universal one touch container. Hi-Bond Universal has a volume of 5ml, and the measurement results showed an average of 0.02g per droplet. This corresponds to the average of 200-250 droplets, as announced by Medclus for the number of uses.

Clinical Guideline

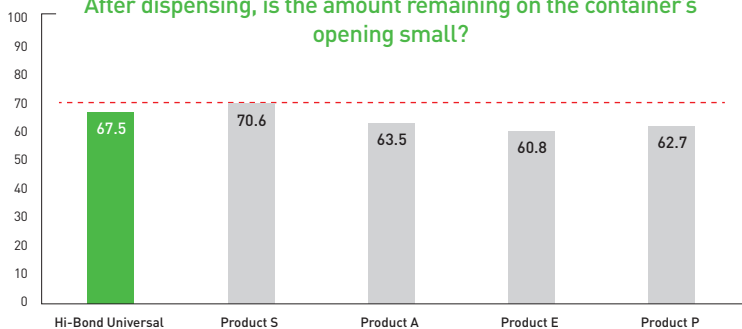
Is the container opening size appropriate?



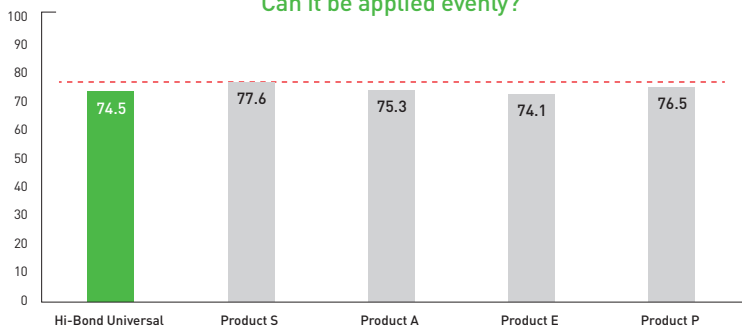
Hi-Bond Universal		A : 0.30mm B : 0.10mm
Product S		A : 0.35mm B : 0.10mm
Product A		A : 0.30mm
Product E		A : 0.40mm B : 0.20mm
Product P		A : 0.40mm B : 0.30mm

* The image is an observation of the bonding agent's entrance using a stereoscopic microscope.

After dispensing, is the amount remaining on the container's opening small?



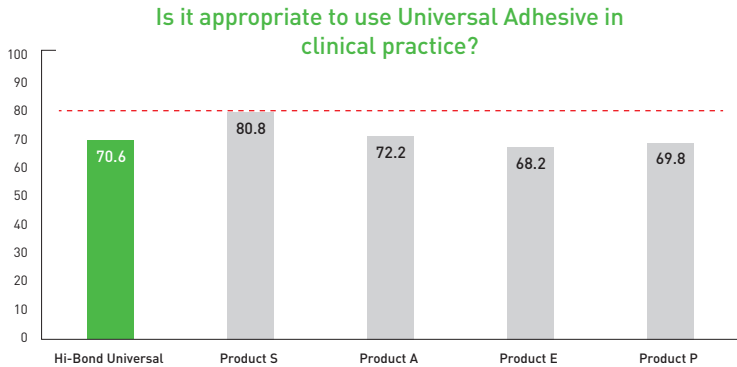
Can it be applied evenly?



Is the adhesion strength excellent after light curing?



Clinical Guideline

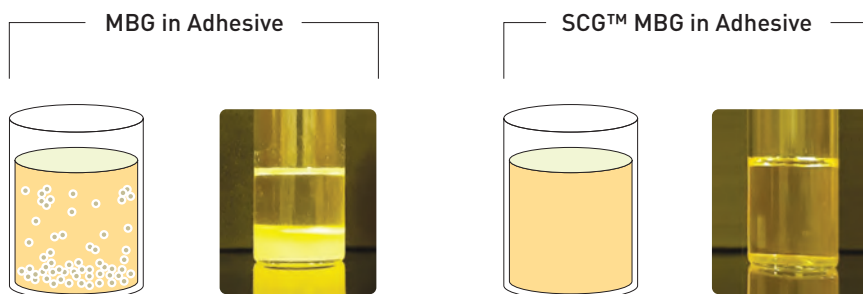


Open ended (key answers)

- A square design provides a comfortable grip.
- I can't feel a significant difference compared to the 3M product.
- The properties also seem to be similar to other products, and it looks good.
- The opening and closing mechanism is clear, so there's no worry about not closing it properly.
- It has a distinctive design that stands out from other products.
- The properties are similar to other products, but the lack of recognition makes me hesitant.
- The lack of sufficient clinical data results in a lack of confidence.
- It has almost no noticeable odor.
- It has excellent flowability, making it easy to dispense from the container, and it offers outstanding adhesive properties.
- The green exterior design is distinct and clear.
- Its good flowability results in minimal post-curing residue, reducing discomfort for patients around the gums.
- It disperses well due to its high flowability.
- Overall, it is easy to use.
- The viscosity is acceptable.
- It allows for even application on a microbrush. ●

Product Strength

- There's **no need to shake** (slight 1 or 2 shake make it more homogeneous), and **no need to store it in refrigerator**.



- With the one **touch container** and its **DROP control technology**, it can be used an average of 200-250 times.
- The solvent is **ethanol based**, and it has a mild odor, which is not off-putting.
- With its **10-MDP** content, it can be used with not only **self-etching** but also **any etching** techniques.

FAQ

Q

What are the methods to increase the adhesive strength of dentin adhesives?

A

Clinically, the solvent drying process is very important when applying dentin adhesives. If polymerization occurs without sufficient evaporation of the solvent, the space occupied by the solvent limits monomer penetration and lowers the conversion ratio of the adhesive resin also, residual solvent that causes a dilution effect is another reason for decrease in adhesive strength.

Q

Is it okay to use Universal dentin adhesives on enamel?

A

That differs according to what kind one uses The self-etch technique can be divided based on the acidity of the primer into strong (pH 1 and below), moderate (about pH 1.5 and mild self-etch adhesive (about pH 2).

For strong types, the demineralization effect of the enamel is similar to etching with 30~40 phosphoric acid, but the bonding effect to dentin is significantly decreased due to its strong acidity On the other hand, mild types show better adhesion to dentin, but lack sufficient demineralization effect on enamel, therefore recommended to etch the enamel separately using 30~40 phosphoric acid.

[Conservative Dentistry 4th edition, Korean Academy of Conservative Dentistry, p 271]

Q

Can Universal dentin adhesive be used as a desensitizing agent?

A

They can Self-etching adhesives are not rinsed after demineralization of tooth structure. Initially, they are acidic, but interaction with demineralized tooth components results in chelation and neutralization, so the acidity does not pose a problem. It is said for deep dentin, they are less likely to cause post operative sensitivity than total-etch systems using phosphoric acid.

[Dental Materials, 8th Edition, Korean Association of Dental Materials, p 256]

Q

What is the appropriate thickness of a dentin adhesives layer?

A

When applied to the tooth, the number of applications varies according to the product, one must adjust the thickness by applying the adhesive 1~3 times until an even resin layer is sufficiently formed on the surface, giving the adhesive treated dentin surface a shiny appearance. Depending on the products, this process may need to be repeated multiple times for superior results, and this has been verified through extensive experiments on adhesive strength.

Q

Is proper agitation and drying sufficient to improve adhesion with dentin?

A

Indeed, there are additional points to consider.

- When air-drying, it's important to remove solvents like ethanol, acetone, and water.
- After applying self-etch adhesives, thorough drying is essential once they have sufficiently penetrated the dentin and allowed for interaction with the residual dentin components.
- Be cautious when dealing with adhesive strength on dentin adjacent to cured enamel or areas with demineralization.
- Depending on the adhesive, it may be necessary to apply 1~3 coats to ensure a uniform resin layer on the surface, giving the treated ivory enamel a glossy appearance.

[\[Dental Materials, 8th Edition, Korean Association of Dental Materials, p 257~258\]](#)

FAQ

Q

What is the recommended storage method for Universal dentin adhesive?

A

Caution must be taken to maintain the effective concentration of the volatile organic solvent included in the adhesive above a proper level. After use, the lid must be closed immediately. The bottle should be stored upright and gently

shaken before use.

Always follow the manufacturer's recommendation.

Q

Is it possible to use it without phosphoric acid etching?

A

The 7th generation employs the etching + primer + adhesive (1-step) method. Although the acidic monomer, 10-MDP, allows for both self-etch and total-etch modes, it is generally recommended to selectively etch the enamel using

phosphoric acid for optimal bonding to the enamel when used in self-etch mode.



Can the 7th generation dentin adhesive be used with all resins?



Hi-Bond Universal and similar ultra-mild pH products are suitable for use.

Generally, 7th generation dentin adhesives require caution when used with chemical polymerized or dual polymerized composite resins. Even after polymerizing self-etching adhesive, the surface is hindered by oxygen, forming a layer of incompletely polymerized acidic resin monomers. In this scenario, the amine polymerization accelerator (3rd amine) within the composite resin prioritizes reacting with the incompletely polymerized acidic resin monomer over forming free radicals with the polymerization initiator. This leads to the formation of charge-transfer complexes, preventing the composite resin from fully polymerizing and resulting in adhesive failure.

On the other hand, ultra mild pH products like Hi-Bond Universal have lower reactivity in acid-base reactions, allowing them to be used with chemical-polymerized or dual polymerized composite resins and cements containing amine polymerization accelerators.

Even when using light-curing composite resin, delaying its photopolymerization initiation time can have adverse effects. Self-etch adhesive resins do not have a separate hydrophobic bonding resin in the three-step bonding system they serve not only as bonding resins but also perform the roles of etching and priming in a single solution. Additionally, to facilitate penetration into moisture containing dentin, an acidic hydrophilic resin monomer is used, and the adhesive film thickness is kept thin. Therefore, if the initiation of photopolymerization is delayed after resin filling, moisture from the underlying dentin may diffuse through the adhesive resin, creating resin droplets containing moisture on the interface, leading to adhesive failure.

(Dental Materials, 8th Edition, Korean Association of Dental Materials, p 255~256)

Storage methods

- ① Microbrushes are single use only. Discard after use.
- ② Wipe the entrance of the bottle clean and close the lid.
- ③ To minimize evaporation, close the cap immediately after use.
- ④ Store in a dry, cool place.
- ⑤ Avoid exposure to direct sunlight.
- ⑥ Do not store near flammable substances.

Storage condition

- Store in a well ventilated place with no direct sunlight.
- Store at temperatures between 5-25°C.
- Do not use after the expiration date.

