



BOND FILL SB

EN

INSTRUCTIONS

IMPORTANT :
READ ALL INSTRUCTIONS THOROUGHLY BEFORE USE.
KEEP THIS LEAFLET AND REFER TO IT PERIODICALLY.

Dental Adhesive Resin for Filling
 Polymer-based Pit and Fissure Sealant, Class 1

Bondfill SB

FOR DENTIST USE ONLY

1. What is Bondfill SB?

Bondfill SB is a self-cure, self-adhesive resin for dental restorations. It contains 4-META/MMA-TBB. Though it requires no bonding agent, Bondfill SB forms strong bonds to enamel, dentin, and restorative materials without gapping and discoloration. It is also designed to absorb intense, complicated complex external stresses and greatly resist wear. The Powder contains PMMA and TMPT reactive organic filler which creates a tough restoration that is hard yet still very resilient. The inorganic filler loading is 1.2 vol% (as powder) with a particle size range of 5 to 50 nm.

Typical Applications:

Bondfill SB is indicated wherever resilience is required, such as:

- Restoration of tooth wear, such as attrition, abrasion, abfraction, wedge-shaped defects
- Secondary caries at a restoration margin
- Repair of fractured prostheses and damaged restorations
- Sealing incipient pit and fissure caries

Note: Bondfill SB is not indicated to use for the restoration of occlusal surface.

2. Contents of the kit

2.1 Bondfill SB Kit:

- ① Base ----- 1 (8mL)
- ② Catalyst V----- 1 (0.7mL)
- ③ Powder Cervical (approx. Shade A4) ----- 1 (3g)
- ④ Powder Medium (approx. Shade A3.5)----- 1 (3g)
- ⑤ Teeth Primer ----- 1 (3mL)
- ⑥ Sponge (L•S)----- 1
- ⑦ Dispensing Stand ----- 1
- ⑧ Dispensing Cups----- 20
- ⑨ Brush Handle (Bent) ----- 1
- ⑩ Brush Tips (Brush-dip L) Label color: Pink ----- 10
- ⑪ Brush Tips (Brush-dip LL) Label color: Purple ----- 10

Attached documents : Instructions / Pictorial Instruction Card

2.2 Refills:

- Base----- 8mL
- Catalyst V-----0.7mL
- Powder Light (approx. Shade A2) ----- 3g
- Powder Medium (approx. Shade A3.5)----- 3g
- Powder Cervical (approx. Shade A4) ----- 3g
- Powder Opacious (approx. Shade A3 Opaque)----- 3g
- Teeth Primer----- 3mL
- Sponge (L•S)----- 1
- Dispensing Stand ----- 1
- Dispensing Cups ----- 40
- Brush Handle (Straight) ----- 1
- Brush Handle (Bent) ----- 1
- Brush Tips (Brush-dip S) Label color: Green ----- 10
- Brush Tips (Brush-dip L) Label color: Pink ----- 10
- Brush Tips (Brush-dip LL) Label color: Purple----- 10

3. Precautions : Read all instructions thoroughly before use.

3.1 Safety

- Sensitivity**
 Bondfill SB should not be used by clinicians or on patients who are sensitive to methacrylates or acetone. If signs of irritation such as redness appear, stop using Bondfill SB immediately and consult a physician.
- Avoid contact**
 Avoid contacting soft tissues, skin or eyes by Bondfill SB components. The use of rubber dam is recommended. Contaminated skin or mucosa should be wiped immediately with alcohol and then rinsed thoroughly with copious amounts of running water. If Bondfill SB components enter the eye, rinse immediately and thoroughly with running water and have the patient examined by an ophthalmologist. Clinicians should use dental gloves.
- Flammability**
 Catalyst V, Base, and Teeth Primer are flammable. Do not store where they may be exposed to open flame.
- Applications**
 Use Bondfill SB only for the applications recommended in these instructions.

3.2 Precautions on Catalyst V

Catalyst V reacts with air and water to generate heat and lose activity.

Please abide by the following.

- Storage conditions**
 Avoid high temperature, high humidity and direct sunlight. The repeated temperature changes may cause the syringe to aspirate air, thereby shortening the Catalyst V's shelf-life.
 *After prolonged storage, the first drop of the Catalyst V may be inactive due to exposure to air, though the rest of the material remains active. Express and dispose of a drop before making the mix.
 *The syringe is made of glass, therefore it must be handled with care to prevent shock, dropping, and other physical damage.
- Cap closure**
 The cap simply slides on and off. Recap the syringe immediately after each use. Air (oxygen and humidity) deactivates the Catalyst V. Do not leave the cap off during the bonding procedure.
- Expressing the Catalyst**
 If the Catalyst V does not come out of the syringe because the tip is blocked or the screw is tight, do not try too hard to turn it. The contents may splash as the syringe breaks.
- After use**
 Unscrew the syringe screw two turns counter-clockwise after each use to relieve pressure on the Catalyst. (Pressure buildup can cause leakage of the Catalyst V or even crack the syringe.)
- Clean spilled Catalyst V immediately with wet towels**
 The Catalyst V reacts with oxygen. If absorbed by a flammable material, it may raise the temperature enough to cause smoldering. If the Catalyst V is spilled, wipe it up immediately with a WET (not dry) disposable towel. Then rinse the towel to deactivate the Catalyst V thoroughly in running water.
- Cleaning syringe**
 Wipe the tip of the syringe with a dry gauze after each use to prevent residue buildup. Then rinse the gauze with water to kill any remaining activity. Buildup of the residue may prevent the cap from seating properly.

3.3 Storage

Please take the following precautions to maintain the quality.

- Storage conditions**
 Store Catalyst V, Base and Teeth Primer in a cool and dark location. High temperature, high humidity and direct sunlight will shorten their shelf-life.
- Volatility**
 Teeth Primer and Base are highly volatile. Recap the bottle immediately.
- Contamination**
 To avoid contamination, do not mix the components with other materials. Firmly recap the containers immediately after use. Dispose of any excess of mixed materials after use. Once dispensed do not return materials to the containers. Both Dispensing Cups and Brush Tips are for one-time use. Dispose of them after use.

As in any dental treatment, the patient's individual constitution and the unique requirements of clinical case at hand must be considered before selecting materials and conditions for use.

4. How to use Bondfill SB

a. Surface preparation

1) Cleaning

Remove contaminants and stains using a polishing bur or oil-free, fluoride-free pumice to expose fresh tooth surface. Rinse thoroughly and dry. A rubber dam is highly recommended to reduce the chance of contamination by saliva, breath humidity or blood.

2) Priming

Dispense Teeth Primer into one of the small recesses on the Dispensing Stand. Using a pledget, keep the surface to be bonded saturated with a copious amount of Teeth Primer for approximately 20 seconds. Care should be taken not to contact the gingiva with the pledget. Then air dry. Rinsing is not needed.

Standard application time

Surface	Teeth Primer	Enamel Etchant Gel	Dentin Etchant Gel
Enamel	Approx. 20 sec	30 sec	30-60 sec
Dentin		—	5-10 sec
After application	Dry without rinsing	Rinse and dry	

*If the surface is cut enamel, use either Teeth Primer or Enamel Etchant Gel. If the surface is uncut enamel, however, Enamel Etchant Gel is recommended. If the surface is dentin, use either Teeth Primer or Dentin Etchant Gel.
 *Both Enamel Etchant Gel and Dentin Etchant Gel are sold separately by Sun Medical Co., Ltd. Unlike the Teeth Primer (which should not be rinsed from the tooth surface), Enamel Etchant Gel and Dentin Etchant Gel must be rinsed off the proper etching period (see table above).

*If a precious metal or ceramic restoration is present on the tooth surface to be treated, prime the metal or ceramic surface after priming the tooth surface with Teeth Primer.

3) Metal Surface

Rinse the metal surface thoroughly and dry. Applying the Enamel Etchant Gel helps remove surface contaminants. Air-abrade the metal surface with 50-micron aluminum oxide. If the surface is precious metal, apply a metal primer such as V-PRIMER on the metal surface to be bonded in order to increase bond strength and durability. V-PRIMER is sold separately by Sun Medical Co., Ltd. For application details refer to the instructions for the metal primer.

4) Ceramic (porcelain and zirconia) surface

Depending on the case at hand, clean the porcelain/zirconia surface with abrasive wheels and points or a prophyl cup with fluoride-free, oil-free pumice. Rinse thoroughly with water and dry. Applying the Enamel Etchant Gel helps

remove surface contaminants. An ultrasonic cleaner is also effective. Then, apply a porcelain primer such as Porcelain Liner M on the porcelain/zirconia surface to be bonded in order to increase bond strength and durability. Porcelain Liner M is sold separately by Sun Medical Co., Ltd. For application details refer to the instructions for the porcelain primer.

b. Preparation of Bondfill SB

Place two Dispensing Cups into two of the three holes in the Dispensing Stand. Dispense 2-3 drops of the Base into one of the Dispensing Cups. Hold the Catalyst V syringe vertical, and turn the screw to dispense a drop into the Base. Stir lightly with a brush. This mixture is called "activated liquid." The activated liquid gradually deactivates. Use it within 3 minutes after preparation.

Activated Liquid

Intended Use	Base	Catalyst V	Operartion time
Restoration and Build-up	2-3 drops	1 drop	3 minutes after mixing
Pit and Fissure Sealant	2 drops		

c. Restoration/Build-up/Pit and Fissure Sealant

- Dispense the appropriate amount of Powder into the other Dispensing Cup.
- Wet the surface to be bonded with the activated liquid.
- Soak the brush with ample activated liquid, then dip the brush into the Powder to form a ball of powder on the tip. Brush the powder ball onto the pre-wet surface to be bonded.
- Repeat the procedure until the restoration or the build-up is completed. When you repeat the procedure, clean the brush tip with gauze before you dip it again.

d. Setting and finishing

Wait approximately 10 minutes before finish and polish. If complete setting is desirable, wait to polish until the next day.

Working time and Setting time of Sealant

Item	Specification	Standard
Working time	≤5 minutes	ISO6874(2005)
Setting time	≥40 seconds	ISO6874(2005)

BOND FILL SB

본드필 SB

K R

INSTRUCTIONS

IMPORTANT :

반드시 이 설명서를 사용 전에 잘 읽고 바르게 사용해 주십시오.

사용 후 잘 보관하고, 필요할 때에 참고해 주십시오.

Dental Adhesive Resin for Filling

class 1, 치면열구전색제에 기초한 polymer

Bondfill SB

치과의사전용

1. Bondfill SB란?

Bondfill SB는 4-META/MMA-TBB가 포함되어 있는 자가중합형 치과용수복재료입니다. Bonding Agent를 사용하지 않아도 에나멜질·상아질·수복재료와 미세한 틈이나 번색없이 뛰어난 접착력을 발휘합니다. 또한 강력하고 복잡한 외부충격(교합압)을 흡수하고, 마모에 견디는 것이 가능합니다. Powder에 함유된 PMMA와 TMPT는 유기필러와 결합하여 단단하지만 탄력성이 강한 수복물을 형성합니다. 무기Filler는 5~50nm 정도 입자 크기로1.2vol%의 파우더가 함유되어 있다.

사용목적, 효능 또는 효과 :

Bondfill SB는 다음과 같은 목적에 사용된다 :

- a. 교모, 마모, 치질췌기결손부위 등의 보수
- b. 치경부이차우식의 충전
- c. 수복물의 보수
- d. 치과소와열구의 봉쇄 (초기우식 소와열구전색을 포함)

참고 : Bondfill SB는 교합면 수복에 사용하지 않는다.

2. 세트구성 :

2.1 Bondfill SB Kit:

- ①Base ----- 1 (8mL)
- ②Catalyst V ----- 1 (0.7mL)
- ③Powder Cervical (approx. Shade A4) ----- 1 (3g)
- ④Powder Medium (approx. Shade A3.5)----- 1 (3g)
- ⑤Teeth Primer ----- 1 (3mL)
- ⑥Sponge (L·S) ----- 1
- ⑦Dispensing Stand ----- 1
- ⑧Dispensing Cups ----- 20
- ⑨Brush Handle (Bent) ----- 1
- ⑩Brush Tips (Brush-dip L) Label color: Pink ----- 10
- ⑪Brush Tips (Brush-dip LL) Label color: Purple ----- 10

Attached documents : Instructions / Pictorial Instruction Card

2.2 Refills:

- Base ----- 8mL
- Catalyst V ----- 0.7mL
- Powder Light (approx. Shade A2) ----- 3g
- Powder Medium (approx. Shade A3.5)----- 3g
- Powder Cervical (approx. Shade A4) ----- 3g
- Powder Opacious (approx. Shade A3 Opaque) ----- 3g
- Teeth Primer ----- 3mL
- Sponge (L·S) ----- 1
- Dispensing Stand----- 1
- Dispensing Cups ----- 40
- Brush Handle (Straight) ----- 1
- Brush Handle (Bent) ----- 1
- Brush Tips (Brush-dip S) Label color: Green ----- 10
- Brush Tips (Brush-dip L) Label color: Pink ----- 10
- Brush Tips (Brush-dip LL) Label color: Purple ----- 10

3. 사용상의 주의 : 사용 전에 아래의 내용을 잘 읽어 주십시오.

3.1 안전

- ①**과민증상**
Bondfill SB 또는 메타크릴산 에스테르계모노모, 아세톤에 대해서 발진, 피부염 등의 과민증의 과거병력이 있는 술자, 환자에게는 사용하지 말 것. 또 본 재료의 사용에 의해 발진 등의 과민증상을 일으킨 경우에는 바로 사용을 중지하고, 의사의 진단을 받게 할 것.
- ②**부착·접촉**
구강점막과 피부에 묻지 않도록 주의 할 것. 러버댐의 사용을 추천한다. 묻었을 경우에는 곧바로 알코올솜 등으로 닦아낸 후, 다량의 흐르는 물로 씻어낼 것. 만일, 눈에 들어갔을 경우는 곧바로 다량의 흐르는 물로 씻어내고 필요에 따라서 안과 의사의 진단을 받게 할 것.
- ③**화기**
화기 근처에서 사용하거나 놓아두지 말 것. Catalyst V, Base, Teeth Primer는 가열성이기 때문에 특히 주의 할 것.
- ④**사용범위**
취급설명서에 기재된 용도 이외에 사용하지 말 것.

3.2 Catalyst V사용상의 주의

Catalyst V는 공기나 물에 닿으면 발열 분해되고 활성이 저하된다. 성능을 유지하기 위해 아래의 주의사항을 지킬 것.

- ①**저장·보관방법**
다습, 직사광선, 화기를 피해 실온(1℃~30℃)에서 보관할 것. *장기간 사용하지 않았던 경우, 남은 Catalyst는 활성을 유지하고 있으나 처음 한 방울은 활성이 저하되어 있을 수 있다. *Catalyst 용기는 Glass제 이다. 충격·낙하 등으로 인해 파손될 우려가 있으므로 취급에 주의할 것.
- ②**CAP의 개폐**
CAP은 슬라이드 형태이다. TIP 앞부분의 공기접촉을 피하기 위해 CAP은 사용직전에 개봉하고, 사용 후 즉시 밀폐할 것. CAP을 열어둔 채 두지 말 것.
- ③**압출 시 주의**
나사를 돌려 Catalyst V를 적하 할 때, 나사가 뿔뿔하여 액이 용기의 선단에서 나오지 않을 때에는 무리하게 나사를 돌리지 말 것. 용기가 파손되어 액이 뿔 수 있다.
- ④**사용 후의 처리**
사용 후, 나사를 2회 반대로 돌려서 내압이 생기지 않도록 할 것. 내압이 상승하면 액이 새거나 용기가 파손될 우려가 있다.
- ⑤**홀러내린 Catalyst V의 처치**
Catalyst V는 산소와 반응한다. 마른 종이, 티슈페이퍼, 거즈, 탈지면, 스폰지 등 불에 타기 쉬운 물질과 접촉하면 발화될 우려가 있다. **실수로 홀린 경우나 액이 새 경우는 티슈페이퍼, 거즈, 탈지면 등을 반드시 물에 적셔서 닦아 낼 것. 마른 티슈페이퍼 등으로 닦아내거나 그대로 방치하면 발화할 우려가 있다.** 의류 등에 묻은 경우에는 즉시 세척할 것.
- ⑥**CAP과 침부분의 청소**
CAP과 침부분에 하얀가루가 묻어있는 경우가 있다. 부착물은 CAP의 밀폐성을 저해하기 때문에 마른 거즈 등으로 닦아 낼 것. 사용 한 거즈는 수세할 것.

3.3 보관

품질을 유지하기 위해서 아래의 주의사항을 지켜주십시오.

- ①**저장·보관방법**
고온, 다습, 직사광선을 피해 실온(1℃~30℃)에서 보관할 것.
- ②**취발성**
Teeth Primer와 Base는 취발성이 높다. 사용 후에는 곧바로 CAP을 닫을 것.
- ③**오염**
오염을 피하기 위해 다른 제품과 혼합해 사용하지 말 것. 사용 후에는 곧바로 밀폐할 것. 사용 후의 잔존물은 파기 할 것. 한번 사용한 내용물은 용기에 다시 넣지 말 것. Dispensing Cups와 Brush Tip은 일회용이므로 사용 후 파기 할 것.

사용에 있어서는 환자의 개인차도 고려해 증례에 적합한지 판단하여 사용할 것.

4. Bondfill SB의 사용방법

- a. **표면처리**
 - CLEANING**
통법대로 치면 청소를 하고 수세·건조한다. 타액, 습기, 혈액 등과의 오염을 피하기 위해 러버댐의 사용을 추천한다.
 - PRIMING**
Teeth Primer를 Dispensing Dish 등에 채취하고 스폰지로 잇몸에 묻지 않도록 주의하면서 피착면에 도포한다. 도포하고 나서 20초간 젖은 상태를 유지시킨 채 놓아둔 후, Air로 충분히 건조시킨다. 세척은 필요하지 않다.

표준처리시간

Surface	Teeth Primer	Enamel Etchant Gel	Dentin Etchant Gel
에나멜질	Approx. 20 초	30초	30-60 초
상아질		—	5-10 초
도포 후 처리	건조 (세척불필요)	세척 및 건조	

*에나멜질의 경우, Teeth Primer 또는 Enamel Etchant Gel 등으로 치면 처리를 한다. 단, 미삭제 에나멜질의 경우, Enamel Etchant Gel 등의 적용을 권장한다.

*상아질의 경우, Teeth Primer 또는 Dentin Etchant Gel 등으로 치면 처리를 한다.

*Enamel Etchant Gel과 Dentin Etchant Gel은 Sun Medical Co., Ltd.에서 별도 판매하고 있다. 이 제품들은 Teeth Primer와 달리 표면처리 후(표준처리시간을 참조) 수세가 필요하다.

*금속이나 세라믹, 치질이 혼재할 경우에는 연마 등에 따라 각 피착면의 깨끗한 면이 나오게 한 후, 처음에 Teeth Primer로 치면 처리를 한다. 그 후, 금속면에 귀금속용 Primer(예를 들면 V-PRIMER)를, 세라믹면에는 Porcelain Primer(예를 들면 Porcelain Liner M)를 각각 도포한다.

- 금속면**
금속의 표면을 수세·건조한다. 금속면의 표면처리를 하기 전에 금속면의 세척을 목적으로Enamel Etchant Gel를 적용하고 수세 건조하는 것을 권장한다. 비귀금속인 경우는, 피착면에 Alumina Sandblast 처리를 한다. 귀금속인 경우는, 피착면에Alumina Sandblast 처리를 한다. 수세·건조 한 피착면에 귀금속용 Primer(예를 들면V-PRIMER)를 도포한다. V-PRIMER는 Sun Medical Co., Ltd.에서 별도 판매하고 있다. 사용에 있어서는 재료의 첨부문서에 따라주십시오.

- 세라믹 (도재, 지르코니아)면 및 레진면**
도재·지르코니아인 경우는 필요에 따라서 피착면 Alumina Sandblast 처리 등을 하고, 수세·건조한다. 도재면의 표면처리를 행하기 전에 도재면의 청소를 목적으로 Enamel Etchant Gel을 적용해 수세 건조하는 것을 권장한다. 초음파세척기 등의 사용도 가능하다. 그 후, Porcelain Primer(예를 들면 Porcelain Liner M)를 도포하고 가볍게 Air Blow 한다. Porcelain Liner M은 Sun Medical Co., Ltd.에서 별도 판매하고 있다. 사용에 있어서는 재료의 첨부문서에 따라주십시오.

- b. **Bondfill SB 활성화액의 조제**
Dispensing Stand (3홀)에 2개의 Dispensing Cup을 세팅한다. 한쪽에 Bondfill SB의 액제 2~3방울에 Catalyst V 1방울의 비율로 채취하여 활성화액을 만든다. 활성화액은 공기와 반응하여 천천히 활성이 저하되기 때문에 조제 후 3분 이내에 사용해주십시오.

사용목적	Base	Catalyst V	활성화액의 사용가능시간
충전과 수복	2~3방울	1방울	조제 후 3분 이내
Pit and Fissure Sealant	2방울		

c. 충전/축성 / Pit and Fissure Sealant

- Dispensing Cup에 소정의 분체를 채취한다.
- Disposable Tip으로 조제한 활성화액을 피착면에 한층 도포한다.
- Disposable Tip에 활성화액을 스며들게해 그 붓 끝을 분체에 묻혀 레진볼을 만들어 피착면에 올려 축성한다.
- 목적한 형태가 될 때까지 조작을 반복한다. 반복하기 전에는 Brush Tip을 닦으면서 조작을 한다.

d. 완성

레진 경화 후 통법에 따라서 형태수정·연마를 한다. (완성시간 : 약10분) 레진의 완전경화를 기다린 경우는 익일 이후의 연마조작을 권장한다.

sealant의 작업시간과 셋팅시간

제품명	사양	규격
작업시간	5분 이상	ISO6874(2005)
셋팅시간	40초 이하	ISO6874(2005)

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BONDFILL SB

INSTRUCTIONS IMPORTANT : READ ALL INSTRUCTIONS THOROUGHLY BEFORE USE. KEEP THIS LEAFLET AND REFER TO IT PERIODICALLY.

Dental Adhesive Resin for Filling Polymer-based Pit and Fissure Sealant, Class 1 Bondfill SB FOR DENTIST USE ONLY

1. **What is Bondfill SB?** Bondfill SB is a self-cure, self-adhesive resin for dental restorations. Bondfill SB is chemically activated with extra-oral. It contains 4-META/MMA-TBB. Though it requires no bonding agent, Bondfill SB forms bonds to enamel, dentin, and restorative materials without gapping and discoloration. It is also designed to absorb insect, complicated complex external stresses and resist wear. The Powder contains PMMA and TMTPT reactive organic filler which creates a tough restoration that is hard yet still resilient. The inorganic filler loading is 1.2 w0% (as powder) with a particle size range of approx. 0.02µm.

Indications: Bondfill SB is indicated wherever resillience is required, such as:

a. Restoration of tooth wear, such as attrition, abrasion, abrasion, wedge-shaped defects.

b. Secondary caries at a restoration margin.

c. Repair of fractured prostheses and damaged restorations.

d. Sealing incipient pit and fissure caries.

Note: Bondfill SB is not indicated to use for the restoration of occlusal surface.

2. **Contents of the kit**

2.1 **Bondfill SB Kit:**

① Base ----- 1 (8mL)
② Catalyst V ----- 1 (0.7mL)
③ Powder Light (approx. Shade A2) ----- 1 (3g)
④ Powder Medium (approx. Shade A3.5) ----- 1 (3g)
⑤ Teeth Primer ----- 1 (3mL)
⑥ Sponge (L·S) ----- 1

⑦ Dispensing Stand ----- 1

⑧ Dispensing Cups ----- 1

⑨ Brush Handle (Bent) ----- 1

⑩ Brush Tips (Brush-dip L) Label color: Pink ----- 1

⑪ Brush Tips (Brush-dip LL) Label color: Purple ----- 10

Attached documents : Instructions / Pictorial Instruction Card

2.2 **Refills:**
① Base ----- 8mL
② Catalyst V ----- 0.7mL
③ Powder Light (approx. Shade A2) ----- 3g
④ Powder Medium (approx. Shade A3.5) ----- 3g
⑤ Powder Cervical (approx. Shade A4) ----- 3g
⑥ Powder Opaque (approx. Shade A3 Opaque) ----- 3g
⑦ Teeth Primer ----- 3mL
⑧ Sponge (L·S) ----- 1
⑨ Dispensing Stand ----- 1

⑩ Dispensing Cups ----- 40

⑪ Brush Handle (Straight) ----- 1

⑫ Brush Handle (Bent) ----- 1

⑬ Brush Tips (Brush-dip S) Label color: Green ----- 10

⑭ Brush Tips (Brush-dip L) Label color: Pink ----- 10

⑮ Brush Tips (Brush-dip LL) Label color: Purple ----- 10

3. **Compositions.**
Base: Methacrylate monomers, others.
Powder: Poly(methyl methacrylate, others.
Catalyst V: Partially oxidized Tri-n-butylborane, others.
Teeth Primer: Methacrylate monomers, Aceton, Water, others.

4. **Precautions :**

4.1 **Safety**

This product contains substances that may cause allergic reactions. Read the following points below.

① **Sensitivity**
Bondfill SB should not be used by clinicians or on patients who are sensitive to methacrylates or acetone. If signs of irritation such as redness appear, stop using Bondfill SB immediately and consult a physician.
② **Avoid contact.**
Avoid contacting soft tissues, skin or eyes by Bondfill SB components. The use of rubber dam is recommended. Contaminated skin or mucosa should be wiped immediately with alcohol and then rinsed thoroughly with copious amounts of running water. If Bondfill SB components enter the eye, rinse immediately and thoroughly with running water and have the patient examined by an ophthalmologist. Clinicians should use dental gloves.
③ **Avoid ingestion**
Avoid accidental ingestion while applying and rinsing this material. If ingested, the patient must seek medical attention.

④ **Flammability**
Catalyst V, Base, and Teeth Primer are highly volatile and flammable. Do not store where they may be exposed to open flame.

⑤ **Avoid inhalation**
Handle Bondfill SB in a well ventilated area (air to be replaced several times per hour). In case of inhalation of the vapor, move for fresh air.

⑥ **Applications**
Use Bondfill SB only for the applications recommended in these instructions. If necessary, for deep cavities with only a minimal layer of dentin, the pulp must be indirectly capped liquid.
Don't use in conjunction with other materials.
Brush Tips is for one-time use only. Do not reuse and should be discarded after using.

4.2 **Precautions on Catalyst V**

Catalyst V reacts with air and water to generate heat and lose activity. Please abide by the following.

① **Storage conditions**
Avoid high temperature, high humidity and direct sunlight. The repeated temperature changes may cause the syringe to aspirate air, thereby shortening the Catalyst V's shelf-life.
*After prolonged storage, the first drop of the Catalyst V may be inactive due to exposure to air, though the rest of the material remains active. Express and dispose of a drop before making the mix.
*The syringe is made of glass, therefore it must be handled with care to prevent shock, dropping, and other physical damage.
② **Cap closure**
The cap simply slides on and off. Recap the syringe immediately after each use. Air (oxygen and humidity) deactivates the Catalyst V. Do not leave the cap off during the bonding procedure.
③ **Expressing the Catalyst V**
Bondfill SB does not come out of the syringe because the tip is blocked or the screw is tight, do not try too hard to turn it. The contents may splash as the syringe breaks.
④ **After use**
Unscrew the syringe screw two turns counter-clockwise after each use to relieve pressure on the Catalyst V. (Pressure buildup can cause leakage of the Catalyst V or even crack the syringe.)

⑤ **Clean spilled Catalyst V immediately with wet towels**
The Catalyst V reacts with oxygen. If absorbed by a flammable material, it may raise the temperature enough to cause smoldering. If the Catalyst V is spilled, wipe it up immediately with a WET (not dry) disposable towel. Then rinse the towel to deactivate the Catalyst V thoroughly in running water.

⑥ **Cleaning syringe**
Wipe the tip of the syringe with a dry gauze after each use to prevent residue buildup. Then rinse the gauze with water to kill any remaining activity. Buildup of the residue may prevent the cap from seating properly.

4.3 **Storage**
Please take the following precautions to maintain the quality.

① **Storage conditions**
Store Catalyst V, Base and Teeth Primer in a cool (1°C - 30°C) and dark location. High temperature, high humidity and direct sunlight will shorten their shelf-life.

② **Volatility**
Teeth Primer and Base are highly volatile. Recap the bottle immediately.

③ **Contamination**
To avoid contamination, do not mix the components with other materials. Firmly recap the containers immediately after use. Dispose of any excess of mixed materials after use. Once dispensed do not return materials to the containers. Both Dispensing Cups and Brush Tips are for one-time use. Dispose of them after use.

④ **shelf life**
3 years in a room temperature.

*See outer package for expiration date. Do not use after expiration date.

4.4 **Disposal**
① Soak the empty syringe of Catalyst V in water overnight. Dispose it appropriately according to the law about the waste.
② Dispose of empty container or package except Catalyst V according to the law about the waste.

As in any dental treatment, the patient's individual constitution and the unique requirements of clinical case at hand must be considered before selecting materials and conditions for use.

5. **How to use Bondfill SB**

a. **Surface preparation**

① **Cleaning**
Remove contaminants and stains using a polishing brush or oil-free, fluoride-free pumice to expose fresh tooth surface. Rinse thoroughly and dry. A rubber dam is highly recommended to reduce the chance of contamination by saliva, breath humidity or blood.

② **Priming**
Dispense Teeth Primer into one of the small recesses on the Dispensing Stand. Using a pledget, keep the surface to be bonded saturated with a copious amount of Teeth Primer for approximately 20 seconds. Care should be taken not to contact the gingiva with the pledget. Then air dry. Rinsing is not needed.

Standard application time

Surface	Teeth Primer	Enamel Etchant Gel	Dentin Etchant Gel
Enamel	Approx. 20 sec	30 sec	5-10 sec
Dentin	-----	-----	5-10 sec
After application	Dry without rinsing	Rinse and dry	-----

③ **If the surface is cut enamel,** use either Teeth Primer or Enamel Etchant Gel. If the surface is uncut enamel, however, Enamel Etchant Gel is recommended.
④ **If the surface is dentin,** use either Teeth Primer or Dentin Etchant Gel.
⑤ **Both Enamel Etchant Gel and Dentin Etchant Gel are sold separately by Sun Medical Co., Ltd.** Unlike the Teeth Primer (which should not be rinsed from the tooth surface), Enamel Etchant Gel and Dentin Etchant Gel must be rinsed off the prep etching period (see table above).
⑥ **If a precious metal or ceramic restoration is present on the tooth surface to be treated,** prime the metal or ceramic surface after priming the tooth surface with Teeth Primer.

3) **Metal Surface**
Rinse the metal surface thoroughly and dry. Applying the Enamel Etchant Gel helps remove surface contaminants. Air-abrade the metal surface with 50-micron aluminum oxide. If the surface is precious metal, apply a metal primer such as V-PRIMER on the metal surface to be bonded in order to increase bond strength and durability. V-PRIMER is sold separately by Sun Medical Co., Ltd. For application details refer to the instructions for the metal primer.

4) **Ceramic (porcelain and zirconia) surface**
Depending on the case at hand, clean the porcelain/zirconia surface with abrasive wheels and points or a prophy cup with fluoride-free, oil-free pumice. Rinse thoroughly with water and dry. Applying the Enamel Etchant Gel helps remove surface contaminants. An ultrasonic cleaner is also effective. Then, apply a porcelain primer such as Porcelain Liner M / Super-Bond Universal Ceramic Primer on the porcelain/zirconia surface to be bonded in order to increase bond strength and durability. Porcelain Liner M / Super-Bond Universal Ceramic Primer is sold separately by Sun Medical Co., Ltd. For application details refer to the instructions for the porcelain primer.

b. **Preparation of Bondfill SB**
Place two Dispensing Cups into two of the three holes in the Dispensing Stand. Dispense 2-3 drops of the Base into one of the Dispensing Cups. Hold the Catalyst V syringe vertically, and turn the screw to dispense a drop into the Base. Stir lightly with a brush. This mixture is called "activated liquid." The activated liquid gradually deactivates. Use it within 3 minutes after preparation.

2) **Dispense the appropriate amount of Powder into the other Dispensing Cup.**
1) Wet the surface to be bonded with the activated liquid.
3) Soak the brush with ample activated liquid, then dip the brush into the Powder to form a ball of powder on the tip. Brush the powder ball onto the pre-wet surface to be bonded.
4) Repeat the procedure until the restoration or the build-up is completed. When you repeat the procedure, clean the brush tip with gauze before you dip it again.

d. **Setting and finishing**
Wait approximately 10 minutes before finish and polish. If complete setting is desirable, wait 10 points until the next day.
*Use carbide burs or super-fine diamond points for finishing.
*Use white silicone points for polishing.
Working time and Setting time of Sealant

Item	Specification	Standard
Working time	≤5 minutes	ISO6874(2005)
Setting time	≥40 seconds	ISO6874(2005)

2) **Restoration/Build-up/Pit and Fissure Sealant**

1) Dispense the appropriate amount of Powder into the other Dispensing Cup.
2) Wet the surface to be bonded with the activated liquid.
3) Soak the brush with ample activated liquid, then dip the brush into the Powder to form a ball of powder on the tip. Brush the powder ball onto the pre-wet surface to be bonded.
4) Repeat the procedure until the restoration or the build-up is completed. When you repeat the procedure, clean the brush tip with gauze before you dip it again.

d. **Setting and finishing**
Wait approximately 10 minutes before finish and polish. If complete setting is desirable, wait 10 points until the next day.
*Use carbide burs or super-fine diamond points for finishing.
*Use white silicone points for polishing.
Working time and Setting time of Sealant

Item	Specification	Standard
Working time	≤5 minutes	ISO6874(2005)
Setting time	≥40 seconds	ISO6874(2005)

FR

INSTRUCTIONS IMPORTANT : LIRE ATTENTIVEMENT LES INSTRUCTIONS AVANT L'USAGE. CONSERVER CE DOCUMENT ET SY RÉFÉRER RÉGULIÈREMENT.

Résine adhésive pour obturations dentaires Bondfill SB pour le scellement des puits et fissures en Classe 1

FR

INSTRUCTIONS IMPORTANT : LIRE ATTENTIVEMENT LES INSTRUCTIONS AVANT L'USAGE. CONSERVER CE DOCUMENT ET SY RÉFÉRER RÉGULIÈREMENT.

Résine adhésive pour obturations dentaires Bondfill SB pour le scellement des puits et fissures en Classe 1

1. **Qu'est ce que Bondfill SB?**
Bondfill SB est une résine chémopolymérisable auto-adhésive pour les restaurations dentaires. Bondfill SB est activée chimiquement à l'extérieur de la cavité buccale. Bondfill SB contient du 4-META/MMA-TBB. Sans nécessiter d'adhésif, Bondfill SB procure une adhésion à l'émail, à la dentine et aux matériaux de restauration sans hiatus ni discoloration. Bondfill SB est également conçu pour absorber les contraintes externes et résister à l'usure. La poudre Polymère contient du PMMA et la charge réactive organique TMTPT pour former une restauration résistante mais également résiliente. Le pourcentage de charge inorganique est de 1.2 %(comme la poudre) avec une taille moyenne des particules de environ 0.02 µm.

Indications: Bondfill SB est indiqué dès que la résillience est un facteur clé:

a. Restauration des lésions d'usure, cas d'attrition, d'abrasion, d'abfraction et/defauts cunéiformes.
b. Caries secondaires marginales.
c. Réparation de fractures de prothèses et d'obturations endommagées.

① Soit le catalyseur ou de base et de la résine avant de l'usage.
② Soit le catalyseur ou de base et de la résine avant de l'usage.
③ Note: Bondfill SB n'est pas indiqué pour la restauration de la surface occlusale.

2. **Composants du coffret:**

2.1 **Bondfill SB Kit:**

① Base ----- 1 (8mL)
② Catalyste V ----- 1 (0.7mL)
③ Poudre Light (approx. Teinte A2) ----- 1 (3g)
④ Poudre Medium (approx. Teinte A3.5) ----- 1 (3g)
⑤ Teeth Primer ----- 1 (3mL)
⑥ Eponges (L·S) ----- 1

⑦ Support de mélange ----- 1

⑧ Coupes de mélange ----- 20

⑨ Manche (Coudé) ----- 1

⑩ Brossettes (Technique du pinceau L) Couleur d'étiquette: Rose ----- 1

⑪ Brossettes (Technique du pinceau LL) Couleur d'étiquette: Violet ----- 10

Documents : Instructions / Carte illustrée

2.2 **Accessoirs:**
① Base ----- 8mL
② Catalyste V ----- 0.7mL
③ Poudre Light (approx. Teinte A2) ----- 3g
④ Poudre Medium (approx. Teinte A3.5) ----- 3g
⑤ Poudre Cervical (approx. Teinte A4) ----- 3g
⑥ Poudre Opaque (approx. Teinte A3 Opaque) ----- 3g
⑦ Teeth Primer ----- 3mL
⑧ Eponges (L·S) ----- 1
⑨ Support de mélange ----- 1

⑩ Coupes de mélange ----- 40

⑪ Manche (Droit) ----- 1

⑫ Manche (Coudé) ----- 1

⑬ Brossettes (Technique du pinceau S) Couleur d'étiquette: Vert ----- 10

⑭ Brossettes (Technique du pinceau L) Couleur d'étiquette: Rose ----- 10

⑮ Brossettes (Technique du pinceau LL) Couleur d'étiquette: Violet ----- 10

Documents : Instructions / Carte illustrée

3. **Composition**

Base: Monomères Methacrylates, autres.
Poudre: Polyméthacrylate de méthyle, autres.
Catalyseur V: Tri-n-butylborane partiellement oxydé, autres.
Teeth Primer: Monomères Methacrylates, Acétoène, Eau, autres.

4. **Précautions :**

4.1 **Sécurité**

Ce produit contient des substances pouvant causer des réactions allergiques. Bien lire les éléments suivants.

① **Sensibilisation**
Eviter l'usage de Bondfill SB chez les patients qui sont sensibles au monomère méthacrylique ou à l'acétone. Si une irritation ou une rougeur apparaît, stopper l'utilisation du Bondfill SB et consulter un médecin.
② **Contact à éviter**
Eviter tout contact du Bondfill SB avec les tissus mous, la peau ou les yeux. L'usage de la digue en caoutchouc est recommandée. Eviter le contact avec les muqueuses ou avec les vêtements. L'usage de gants est recommandé. Si la poudre se présente sur la peau, rincer abondamment à l'eau et sécher.
③ **Éviter l'ingestion**
Éviter l'ingestion accidentelle en appliquant et rinçant le matériau. En cas d'ingestion, le patient doit rechercher une aide médicale.
④ **Inflammabilité**
Catalyseur V, la Base, et le Teeth Primer sont fortement volatiles et inflammables. Ne pas stocker, ne pas stocker a proximité d'une flamme libre.

Surface	Teeth Primer	Enamel Etchant Gel	Dentin Etchant Gel
Email	Approx. 20 sec	30 sec	5-10 sec
Dentin	-----	-----	5-10 sec
Après application	SECHER	RINCEZ et SECHER	-----

*En cas d'émail préparé, utiliser soit le Teeth Primer soit le Enamel Etchant Gel.
*En cas d'émail non préparé, l Enamel Etchant Gel est recommandé.

⑤ **En cas de surface de dentine,** utiliser soit le Teeth Primer soit le Dentin Etchant Gel.
⑥ **Enamel Etchant Gel et Dentin Etchant Gel sont vendus séparément.** A l'inverse du Teeth Primer (qui ne doit PAS être rincé), le Enamel Etchant Gel et le Dentin Etchant Gel doivent être rincés après l'application (voir le tableau ci dessus).

*En cas de surface céramique ou en métal précieux, veuillez traiter ces surfaces APRES avoir appliqué le Teeth Primer sur la surface dentaire.

3) **Surface Métallique**
Rincer abondamment la surface métallique et sécher. Appliquer le Enamel Etchant Gel aide à décontaminer les surfaces. Sabler la surface avec de l'oxyde d'alumine à 50 microns. Si la surface est en métal précieux, appliquer le V-PRIMER pour améliorer le collage et sa durabilité. V-PRIMER est un produit de Sun Medical Co., Ltd. Se référer au mode d'emploi du V-PRIMER si nécessaire.

4) **Surface Céramique ou Zirconie**
Nettoyer la surface Porcelaine/Zirconie avec des meulettes/jointes abrasives ou une cupule et de la ponce émerise d'hulle et de fluorure. Rincer abondamment à l'eau et sécher. Appliquer le Enamel Etchant Gel aide à décontaminer les surfaces ainsi que l'usage des ultrasons. Appliquer un primer spécifique comme le Porcelain Liner M / Super-Bond Universal Ceramic Primer sur la surface Porcelaine / Zirconie pour améliorer le collage et sa durabilité. Porcelain

⑤ **Éviter l'inhalation**
Manipuler Bondfill SB dans une zone bien ventilée (où l'air est remplacé plusieurs fois par heure). En cas d'inhalation des vapeurs, sortir (ou par lavage) et sécher.
⑥ **Applications**
Utiliser Bondfill SB exclusivement pour les indications spécifiées dans le mode d'emploi. Si nécessaire, pour les caries profondes avec une couche de dentine minimale, la pulpe doit être localement couverte indirectement.
Ne pas utiliser conjointement à d'autres matériaux.
Les points de pinceau sont à usage unique. Ne pas réutiliser, et éliminer après utilisation.

d. **Setting and finishing**
Wait approximately 10 minutes before finish and polish. If complete setting is desirable, wait 10 points until the next day.
*Use carbide burs or super-fine diamond points for finishing.
*Use white silicone points for polishing.
Working time and Setting time of Sealant

Usage prévu	Base	Catalyseur V	Temps d'utilisation
Restauration et reconstitution	2-3 gouttes	1 goutte	3 minutes après le mélange
Scellement des puits et fissures	2 gouttes	-----	-----

c. **Mise en place/Scellement des puits et fissures**

① Déposer la quantité appropriée de Poudre dans la **deuxième** cupule de mélange.
② Moudre la surface à coller avec le mélange BASE/Catalyseur V.
③ Bien tremper le pinceau dans le mélange BASE/Catalyseur V puis plonger le pinceau dans la poudre pour former une boule de résine à son extrémité. Déposer au pinceau la résine sur la surface déjà mouillée.
④ Répéter cette procédure en nettoyant le pinceau avec une compresse avant de le replonger dans le liquide.

d. **Prise et finlton**
Attendre approximativement 10 minutes avnt la finlton et le polissage. Si une polymérisation complète est souhaitée, attendre 24h avant de polir.

*Utiliser des fraises au carbure ou des pointes en diamant super-fines pour la finlton.
*Utiliser des pointes en silicone blanc pour le polissage.

5) **Nettoyage immédiatement avec un tissu mouillé tout catalyseur renversé accidentellement**

Le catalyseur réagit avec l'oxygène. En cas d'absorption du catalyseur par un matériau inflammable, la température peut s'élever et provoquer une combustion du matériau. Essuyer immédiatement avec un tissu bien mouillé. Ensuite rincer abondamment le tissu sous l'eau courante avant de le jeter.

⑥ **Nettoyage de l'embout du seringue**
Essuyer l'embout de la seringue avec une gaze sèche après chaque usage afin d'éviter la formation d'un dépôt. Puis rincer à l'eau la gaze pour supprimer toute activité. L'accumulation d'un dépôt peut empêcher la bonne adaptation du bouchon de fermeture.

4) **Après l'usage**
Dévisser le piston de 2 tours afin de relâcher la pression interne sur le catalyseur. Une pression trop forte peut entraîner une fuite de catalyseur ou de la fracture de la seringue.

⑤ **Nettoyage immédiatement avec un tissu mouillé tout catalyseur renversé accidentellement**

Le catalyseur réagit avec l'oxygène. En cas d'absorption du catalyseur par un matériau inflammable, la température peut s'élever et provoquer une combustion du matériau. Essuyer immédiatement avec un tissu bien mouillé. Ensuite rincer abondamment le tissu sous l'eau courante avant de le jeter.

⑥ **Nettoyage de l'embout du seringue**
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4) **Après l'usage**
Dévisser le piston de 2 tours afin de relâcher la pression interne sur le catalyseur. Une pression trop forte peut entraîner une fuite de catalyseur ou de la fracture de la seringue.

⑤ **Nettoyage immédiatement avec un tissu mouillé tout catalyseur renversé accidentellement**

Le catalyseur réagit avec l'oxygène. En cas d'absorption du catalyseur par un matériau inflammable, la température peut s'élever et provoquer une combustion du matériau. Essuyer immédiatement avec un tissu bien mouillé. Ensuite rincer abondamment le tissu sous l'eau courante avant de le jeter.

⑥ **Nettoyage de l'embout du seringue**
Essuyer l'embout de la seringue avec une gaze sèche après chaque usage afin d'éviter la formation d'un dépôt. Puis rincer à l'eau la gaze pour supprimer toute activité. L'accumulation d'un dépôt peut empêcher la bonne adaptation du bouchon de fermeture.

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Dévisser le piston de 2 tours afin de relâcher la pression interne sur le catalyseur. Une pression trop forte peut entraîner une fuite de catalyseur ou de la fracture de la seringue.

⑤ **Nettoyage immédiatement avec un tissu mouillé tout catalyseur renversé accidentellement**

Le catalyseur réagit avec l'oxygène. En cas d'absorption du catalyseur par un matériau inflammable, la température peut s'élever et provoquer une combustion du matériau. Essuyer immédiatement avec un tissu bien mouillé. Ensuite rincer abondamment le tissu sous l'eau courante avant de le jeter.

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Indications: Bondfill SB est indiqué dès que la résillience est un facteur clé:

a. Restauration des lésions d'usure, cas d'attrition, d'abrasion, d'abfraction et/defauts cunéiformes.
b. Caries secondaires marginales.
c. Réparation de fractures de prothèses et d'obturations endommagées.

① Soit le catalyseur ou de base et de la résine avant de l'usage.
② Soit le catalyseur ou de base et de la résine avant de l'usage.

*En cas de surface de dentine, utiliser soit le Teeth Primer soit le Dentin Etchant Gel.
*Enamel Etchant Gel et Dentin Etchant Gel sont vendus séparément. A l'inverse du Teeth Primer (qui ne doit PAS être rincé), le Enamel Etchant Gel et le Dentin Etchant Gel doivent être rincés après l'application (voir le tableau ci dessus).

*En cas de surface céramique ou en métal précieux, veuillez traiter ces surfaces APRES avoir appliqué le Teeth Primer sur la surface dentaire.

3) **Surface Métallique**
Rincer abondamment la surface métallique et sécher. Appliquer le Enamel Etchant Gel aide à décontaminer les surfaces. Sabler la surface avec de l'oxyde d'alumine à 50 microns. Si la surface est en métal précieux, appliquer le V-PRIMER pour améliorer le collage et sa durabilité. V-PRIMER est un produit de Sun Medical Co., Ltd. Se référer au mode d'emploi du V-PRIMER si nécessaire.

4) **Surface Céramique ou Zirconie**
Nettoyer la surface Porcelaine/Zirconie avec des meulettes/jointes abrasives ou une cupule et de la ponce émerise d'hulle et de fluorure. Rincer abondamment à l'eau et sécher. Appliquer le Enamel Etchant Gel aide à décontaminer les surfaces ainsi que l'usage des ultrasons. Appliquer un primer spécifique comme le Porcelain Liner M / Super-Bond Universal Ceramic Primer sur la surface Porcelaine / Zirconie pour améliorer le collage et sa durabilité. Porcelain

Liner M / Super-Bond Universal Ceramic Primer est un produit Sun Medical Co., Ltd. Se référer au mode d'emploi du Porcelain Liner M / Super-Bond Universal Ceramic Primer si nécessaire.

b. **Preparation du Bondfill SB**

Clipser 2 cupules de mélange dans les trous prévus à cet effet du support de mélange. Déposer 2-3 gouttes de la BASE dans une des 2 cupules. Tenir la seringue de Catalyseur V verticalement, tourner la vis pour déposer UNE goutte de catalyseur dans la BASE. Mélanger rapidement avec un pinceau. Utiliser ce mélange dans les 3 minutes suivant sa préparation.

2) **Dispense the appropriate amount of Powder into the other Dispensing Cup.**
1) Wet the surface to be bonded with the activated liquid.
3) Soak the brush with ample activated liquid, then dip the brush into the Powder to form a ball of powder on the tip. Brush the powder ball onto the pre-wet surface to be bonded.
4) Repeat the procedure until the restoration or the build-up is completed. When you repeat the procedure, clean the brush tip with gauze before you dip it again.

