

# CLEARFIL™

## 40th Anniversary



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**Kuraray Noritake Dental Inc.**

# CLEARFIL™ 40th Anniversary

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## The 40th anniversary of CLEARFIL™

Since the launch of CLEARFIL™ BOND SYSTEM-F in January 1978, we have developed and released a variety of products under the CLEARFIL™ brand, including bonding agents, as well as filling and core build-up materials. This year we are marking the 40th anniversary of the CLEARFIL™ brand. We appreciate all the support we have received from everyone.

CLEARFIL™’s history very closely follows the overall history of our dental materials business. As we developed our CLEARFIL™ products, we also developed various basic technologies, including monomer synthesis, color matching, and filler surface treatment. There have been continuous improvements of these technologies, and they are now used not only in the CLEARFIL™ series, but also in other series, such as our PANA VIA™ adhesive resin cement, CESEAD™ crown and bridge resin, ESTENIA™ hybrid ceramics, and TEETHMATE™ pediatric sealant.

CLEARFIL™ Bond System F, the first-generation product in the CLEARFIL™ series, consisted of a combination of a dental bonding material and a composite filling resin. The development of this product started as follows: In the late 1970s, we were introducing the "GK-101 system", a product that was developed in the U.S. for the purpose of selectively removing caries with medication. Then we recognized the need for a new treatment system that consisted of filling and adhesive materials that could be applied in cavities without the use of a retention form. The concept of retaining a filling restorative material by its "adhesion" to cleaned out cavities without the use of a retention form was a revolutionary idea, which led to a big change in this dental treatment modality. Through the development of this product, we were also able to develop the Phenyl-P adhesive monomer, a new type of monomer which provides a adhesion to tooth structure that facilitates a firm hold between the filling material and tooth structure. After that, to improve the bond’s adhesive properties further, we developed a new adhesive monomer called MDP, which was used for the first time in CLEARFIL™ NEW BOND developed in 1984. Subsequently, this new type of adhesive monomer has been adopted for use in many of our dental bonding materials. We also developed a self-etching system that, as it penetrates the tooth structure, demineralizes it through the acidity of the adhesive monomer. This etching

system is often used as an alternative to the conventional Etch & Rinse technique that demineralizes both the enamel and dentin with a phosphoric acid solution. In addition, we improved the performance of our bonding agents by using the antibacterial MDPB monomer as an ingredient.

Our adhesion technologies, including MDP, became applied as dental cements, as well as dental bonding materials. In 1983, we released a dental cement PANA VIA™ EX that contained MDP. This contributed to the establishment of new treatment procedures, such as the adhesive bridge technique. The spread of the CAD/CAM system has recently promoted the popularity of zirconia as a dental alternative to metal. It has been reported that MDP bonds strongly to zirconia, so that PANA VIA™ V5 containing MDP, the latest product of the series, is drawing attention with its fine performance in this regard, in addition to its ability to bond strongly to tooth structure.

At Kuraray Noritake Dental Inc., the slogan "prolonging the life of teeth" has been our consistent guide. We perform the research and development of our products in cooperation with related clinical and research institutions, in a collaborative network that exceeds the framework of one single business. We have been involved in the development of original and leading-edge technologies that include our core adhesion systems, the development of fluoride-releasing and antibacterial monomers, and the achievement of low polymerization shrinkage of composites through a technique for successfully adding large amounts of filler. We are proud that our activities have contributed a great deal to the advancement of dental treatment not only in Japan, but literally around the world.

The innovative spirit of our R&D activities has been passed down unbroken from generation to generation of dedicated researchers. This has led to the development of various new breeds of products. These include CLEARFIL™ Universal Bond Quick ER, which features both easy handling and excellent usability while maintaining high performance, CLEARFIL™ MAJESTY™ ES-2, which offers both superior color matching and ease of handling, and CLEARFIL™ MAJESTY™ ES Flow, which has a life-like gloss as well as sufficient mechanical strength to be used even in posterior applications.

## Envisioning the Future of Our Business

In April 2012, the merger of Kuraray Medical Inc. of the Kuraray Group and Noritake Dental Supply Co., Ltd. of the Noritake Company Group resulted in the formation Kuraray Noritake Dental Inc. One of the strengths of Kuraray Noritake Dental is its ability to use and take advantage of the many technologies related to both organic and inorganic materials that these two groups have accumulated.

With the rapid advancement of digital dentistry, the dental CAD/CAM restoration market has expanded substantially in recent years. This has led to an increased demand for CAD/CAM materials. In response to this demand, we have commercialized KATANA™ AVENCIA™ Block. This CAD/CAM material for crown restorations was created by combining the technology that grew from the development of ESTENIA™, a high-strength crown restoration material that had been developed as part of our composite technology, with techniques for molding inorganic materials. Thus, it can be said that KATANA™ AVENCIA™ Block is a promising example of the technological fusion of the two companies.

Dental treatment will continue to change substantially in the future, due to changes in the nature of disease in a population characterized by a higher average age, and also the diversification of the requirements of patients. We are committed to devoting our efforts to developing and supplying revolutionary and innovative dental materials and systems. These should help provide a longer healthy life expectancy, as well as reduce the burdens during treatment, on dental care providers and patients alike. We do hope that in the future you will continue to give us the benefits of your guidance and encouragement.

Kuraray Noritake Dental Inc.  
President Kiyoyuki Arikawa





### The advent of adhesive resin

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**Fig. 9**  
Long-term clinical follow-up of a posterior restoration carried out by a new graduate dentist using CLEARFIL™ POSTERIOR. Although color changes, surface air bubbles and surface roughness were detected after long-term, it is still clinically acceptable.  
(Photo courtesy of Prof. Shisei Kubo, Nagasaki University.)

## 2. The advent of the mild-etching primer

### 2-1 The mild-etching primer system

In the 1980's, dentistry's understanding of the structure of the bond interface between dentin and composite resin deepened and the field recognized the importance of having adhesives penetrate into the demineralized layer on the tooth surface. This accelerated efforts to develop a primer, a surface treatment agent to facilitate the effectiveness of adherents. There was concern, however, that phosphoric acid etching was severely damaging the tooth collagen exposed by demineralization, making it difficult for adhesives to penetrate into the tooth structure. This problem prompted recognition of the need for the development of a milder conditioning agent. These were the circumstances under which CLEARFIL™ PHOTO BOND, a light-cure adhesive resin, was developed in 1987. To get the best performance out of CLEARFIL™ PHOTO BOND, a new adhesive resin system called the CLEARFIL™ LINER BOND SYSTEM (Fig. 10) was developed in 1991. This system essentially consists of a sequence of four treatment steps :mild etching with a citric acid solution, application of a primer containing calcium chloride, application and light-curing of PHOTO BOND, and light-curing of a low-viscosity resin. The gentler conditioning and the primer treatment improve the penetration of the bond into the tooth structure, while the application and light-curing of the low-viscosity resin also helps improve the polymerization of the bond. It could be said that these improvements proceeded along a basic path that started with the first stage: "deep penetration and firm curing". That is, the development of adequate bond penetration into tooth structure, and then went on to the successful achievement of sufficient curing. It is of note that the use of PROTECT LINER low-viscosity resin in LINER BOND SYSTEM was achieved with the cooperation of Professor Yasuhiro Hosoda, and that this was the idea that led to recognition of the value of adhesives, like the current flowable resins. In addition, the finding that mild conditioning of tooth structure was found to result in improved bond performance, then brought about by the advent of self-etching primer. All of this makes the LINER BOND SYSTEM a very important step in the history of the CLEARFIL™ series.

### 2-2 Light-cured composite resin

PHOTO CLEARFIL™ A (Fig.11), a light-cured composite resin, was developed in 1985. As light-cured composite resins became popular restorative materials, their physical properties and color matching ability were also substantially improved. Improving the color matching of composite resin seemed to hinge on bringing the refractive indexes of the filler and the matrix resin closer to each other, and on being able to laminate multiple shades of resin. Pursuing these led to the release of CLEARFIL™ PHOTO ANTERIOR. Following this, in response to clinical needs, Photo CLEARFIL™ BRIGHT (Fig.12) with its excellent surface smoothness, and CLEARFIL™ PHOTO POSTERIOR featuring improved physical properties for the treatment of posterior teeth were launched in succession. The advent of these products helped the composite resin restoration to attain rapid popularity as an esthetic restorative material, as well as one that withstands the heavy loads required of a large restoration in the posterior region. CLEARFIL™ AP-X(Fig. 13), a composite resin suitable for posterior and anterior restorations, which is still clinically in use today, was developed 1994.



Fig. 10  
CLEARFIL™ LINER BOND SYSTEM



Fig. 11  
PHOTO CLEARFIL™ A



Fig. 12  
PHOTO CLEARFIL™ BRIGHT



Fig. 13  
CLEARFIL™ AP-X

## 3. The advent of the self-etching system

### 3-1 CLEARFIL™ LINER BOND 2

Immediately after the development of the CLEARFIL™ LINER BOND SYSTEM in 1991, the company began working on self-etching primer. This was an extremely important milestone in the history of adhesive resins, comparable to the development of the CLEARFIL™ BOND SYSTEM-F in 1978. It was not until around this time that the concept of a total-etch technique using phosphoric acid was finally accepted in Europe and the U.S., under the name of the etch and rinse technique. This brought about a blossoming of the number of researchers engaged in adhesion dentistry worldwide. Dental materials manufacturers began to promote the advantages of their products globally. The adhesive resin monomer has a phosphoric acid group and a carboxylic acid group at the terminals. It is also sometimes referred to as an acidic monomer. It was well known that an adhesive resin monomer was also an effective primer. Self-etching primer was born by taking advantage of the principle that an acidic group will be ionized in the monomer solution, to make the primer acidic. The primer itself, thus, serves as the etching agent. In 1993, this technique was commercialized in PANA VIA™ 21 and CLEARFIL™ LINER BOND 2 (Fig. 14). The combination of PANA VIA™ 21 and CLEARFIL™ LINER BOND 2 secured restorations to the dentin so firmly that the adherents underwent cohesive failure before the restorative materials themselves, making it difficult to determine the strengths of the bonds correctly using a standard bond strength test method (Fig. 5). This problem was resolved at a later date by adopting the micro-tensile or micro-shear bond strength test method devised by Sano and coworkers<sup>4)</sup>, as well as Shimada and coworkers<sup>5)</sup>.

### 3-2 CLEARFIL™ SE BOND

CLEARFIL™ LINER BOND 2 uses a 2-liquid self-etching primer containing Phenyl-P. In CLEARFIL™ LINER BOND 2V (Fig. 15) developed in 1998, the adhesive monomer was switched from Phenyl-P to MDP and the polymerization method was changed from light-curing to dual-curing. In 1999, CLEARFIL™ SE BOND was developed (Figs. 16 & 17: composition. Hereafter, referred to simply as SE BOND). This is a bond system consisting of a single-liquid, self-etching primer and a single-liquid, light-cured bond. In a report<sup>6)</sup> that examined the bond strength of six types of adhesives including SE BOND, the SE BOND product had the highest stable bond strength regardless of bond strength test type, making this product the gold standard for dental adhesives worldwide. In addition, many researchers often cited the name SE BOND as a control in their reports on dental adhesion. Around this time, the total-etch technique became popular worldwide, and research into the strength of bond to dentin was vigorously conducted by many researchers. One such type of research was the study of the durability of adhesive action. Through such research activities, it was found<sup>7)</sup> that when phosphoric acid etching was used, the resin-



Fig. 14  
CLEARFIL™ LINER BOND 2



Fig. 15  
CLEARFIL™ LINER BOND 2V



Fig. 16  
CLEARFIL™ SE BOND

PRIMER
<ul style="list-style-type: none"><li>• 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)</li><li>• 2-Hydroxyethyl methacrylate (HEMA)</li><li>• di-Camphorquinone</li><li>• Water</li></ul>
BOND
<ul style="list-style-type: none"><li>• Bis-phenol A diglycidylmethacrylate (Bis-GMA)</li><li>• 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)</li><li>• 2-Hydroxyethyl methacrylate (HEMA)</li><li>• di-Camphorquinone</li><li>• Silanated colloidal silica</li></ul>

Fig. 17  
Principal ingredients of CLEARFIL™ SE BOND



impregnated layer has fine nanoleakage, into which the bond does not penetrate sufficiently. This finding contributed greatly to the recognition of the value of SE BOND's characteristic of using a primer instead of an acid etching agent. It was also recognized that the hydrolysis of collagen fibers by matrix metalloproteinases (MMPs) is strongly implicated in the deterioration of adhesion of bonds to dentin<sup>8)</sup>. The involvement of MMPs, however, seems to be limited when such a bond system like SE BOND is used, which provides mild etching, penetrates deep into the tooth structure, and cures firmly there. CLEARFIL™ SE PROTECT (Fig. 18, named CLEARFIL™ PROTECT BOND at the time of the release) was developed in 2005, as an evolutionary step after SE BOND. This bond system contained an antibacterial monomer, and also released fluoride. That is to say, this product was provided with what you could call a bio-active function. The primer contained MDPB, an antibacterial monomer, and the bond contained surface-treated sodium fluoride filler.

As far as bond performance is concerned, it is reported that CLEARFIL™ SE PROTECT has more durable adhesion to dentin than SE BOND. This is probably because fluoride released after the curing of the bond modifies the dentin near the adhesive interface.

### 3-3 The development of CLEARFIL™ SE BOND 2, the most recent 2-step type bond system from Kuraray Noritake Dental

From detailed analyses of the adhesion interfaces among SE Bond, dentin, and restorations, it was found that there was room for improvement concerning fracture resistance inside the bond layer, and at the interface between the bond and the composite resin. Kuraray Noritake Dental, therefore, developed a new catalyst system with the goal of improving the polymerization of the bonds and copolymerization of bonds and composite resin. They released CLEARFIL™ SE BOND 2 (Fig. 19), a bond system incorporating a new catalyst system that had just been developed. This new bond system thus achieves an even stronger bond than that of SE BOND, due to improved post-cure physical properties and reduced water sorption<sup>9)</sup>.

They report that the development of this new catalyst system was possible because they were able to make use of knowhow accumulated through the development of their preceding 1-step, self-etching bonding agent (the all-in-one bond system). The 1-step self-etching agent contains various components, including an adhesive monomer, a hydrophilic resin monomer, a hydrophobic resin monomer, a solvent to dissolve them, water that is used to make the solution acidic, and a polymerizing catalyst. It had been reported that use of 1-step self-etching agents was likely to result in inadequate removal of the solvent and insufficient polymerization of the bond, thus often resulting in problems such as the occurrence of air bubbles in the adhesive interface.

### 3-4 CLEARFIL™ Universal Bond Quick

CLEARFIL™ S3 BOND (Fig. 20) was developed in 2005 in the form of a one-bottle, 1-step bond system. Such 1-step bond systems are very popular among dental clinicians because they are very easy to handle and the thin bond layer makes them suitable for the esthetic restoration of anterior teeth.

Following the release of CLEARFIL™ S3 BOND, the dual-cure type CLEARFIL™ DC BOND (Fig. 21) was developed, followed by CLEARFIL™ S3 BOND PLUS (Fig. 22. Hereafter, this will be referred to as "S3 PLUS"). This has a "touch cure" quality which improves the polymerization of the interface between the bond and the composite resin. It was recommended for use with CLEARFIL™ DC CORE PLUS (Fig. 23). It is reported<sup>10)</sup> that S3 PLUS maintains an extremely high bond strength. There is no significant drop in bond strength after 8 years of in-water storage, and only slight defects appear at the interface between the bond and the composite resin after that period.

In recent years, some 1-step type bond systems, referred to as "universal bonds", have been commercialized by several dental materials suppliers. They are basically the same as a conventional 1-step bond system. The definition of "universal bonds" is not clear, but they are becoming popular because they bond to virtually all types of adherents, including the restorative materials used for various restorative methods, including the "indirect method".

Kuraray Noritake Dental developed CLEARFIL™ Universal Bond as a universal bond system (Fig. 24.). Following this product, two other universal bond products were launched in succession: CLEARFIL™ Universal Bond Quick (Fig. 25. Hereafter, referred to collectively as "UBQ"). UBQ was developed as a new type of universal bond system by taking advantage of a new revolutionary bond technology.

The polymerization and physical properties of the UBQ's bond were improved by the use of a hydrophilic amide-based monomer and a new type of catalyst, in addition to MDP and sodium fluoride. The amide-based monomer is highly hydrophilic and has excellent physical properties. Good penetration of the primer into the tooth structure is achieved, with no waiting time after application<sup>11)</sup>. Besides that, it should be noted that UBQ's bond strength is close to that of SE BOND. Figure 26 shows the results of bond strength tests of Kuraray's self-etching bond systems conducted in our department. It was found that even products launched quite a while ago have higher bond strengths than the tensile strength of the dentin-enamel junction. UBQ also has excellent adhesion durability; the development of these products suggests that in the near future, bonding systems will shift completely from 2-step self-etching to 1-step self-etching.



Fig. 18  
CLEARFIL™ SE PROTECT



Fig. 19  
CLEARFIL™ SE BOND2



Fig. 20  
CLEARFIL™ S3 BOND



Fig. 21  
CLEARFIL™ DC BOND



Fig. 22  
CLEARFIL™ S3 BOND PLUS



Fig. 23  
CLEARFIL™ DC CORE PLUS



Fig. 24  
CLEARFIL™ Universal Bond



Fig. 25  
CLEARFIL™ Universal Bond Quick

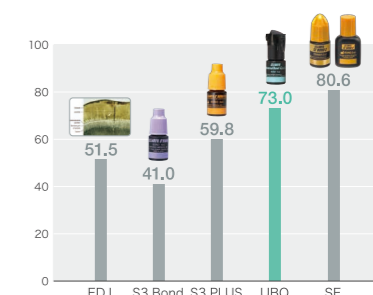


Fig. 26  
Bonding strength comparison of the CLEARFIL™ series by Self-Etch.  
EDJ: Enamel Dentin Junction,  
S3 BOND: CLEARFIL™ S3 BOND,  
S3 PLUS: CLEARFIL™ S3 BOND PLUS,  
UBQ: CLEARFIL™ Universal Bond Quick,  
SE: CLEARFIL™ SE BOND  
(Results from Cariology and Operative Dentistry, Tokyo Medical and Dental University's researches)

## 4. The 40th anniversary of CLEARFIL™

Since the development of CLEARFIL™ BOND SYSTEM F in 1978, Kuraray Noritake Dental Inc. has made incessant efforts toward even better refinements. As one of the front runners in the development of adhesive resin materials, the company has contributed greatly to the advancement of the world's academic and dental adhesive materials community, as well as worked hard for the betterment of the dental health of the world's populace. I would like to express my sincere gratitude and offer tribute to their researchers, employees and the company itself, for their constant, persistent efforts.

I became a dentist in 1980 and then joined the department of Professor Fusayama, and took a doctorate in dentistry. My doctoral dissertation was a study that involved the use of CLEARFIL™. After that was completed, I continued studying under the guidance of many professors, including Professors Hosoda and Masuhara, with the support of many researchers and others in Japan and abroad.

It is not an exaggeration to say that I have been living with CLEARFIL™ for the past 40 years. Every time I evaluate a new CLEARFIL™ product, supplied on a trial basis, I feel, "This is the ultimate bond. You cannot create anything better than this!" Looking back, all the products have been created with dedication to the concept of "deep penetration and firm curing". Once again, it is my personal opinion that the current bond systems are approaching the final stages of perfection. Given that my feelings on this point have been proven wrong many times, I suppose that a new technological innovation will create a totally new dental material or treatment modality. This may well turn out to be different from the idea we've focused on for quite a while: "deep penetration and firm curing".

Finally, I would like to express my gratitude once again to Kuraray Noritake Dental Inc. for giving me the chance to review and consider the history of CLEARFIL™ products, the succession of new products that have come along, and the interesting topic of dental product innovation in general.

### 3-5 The diversification of composite resins

As bond systems are undergoing increasing improvement, the indications for the use of composite resin restorations are also expanding. In addition, various composite resin products suitable for these indications have been developed, diversifying the types of composite resin available on the market. Flowable composite resin is gaining popularity with particular rapidity. Some products of this type have performance -- physical properties, color matching ability, surface smoothness -- equivalent to or better than those of paste-type composite resin. This has been attained through the accumulation of incessant basic research and development, including the improvement of the filler material, size, surface-treatment method, matrix resin type, and the formulation and refinement of catalysts.

In 2012, Kuraray Noritake Dental Inc. developed CLEARFIL™ MAJESTY ES-2, a paste-type composite resin that diffuses light very similarly to natural tooth structure. The conception of shades for this product was established on the basis of brightness. In 2013, in response to the popularity of flowable resin, the company developed CLEARFIL™ MAJESTY™ ES Flow, which achieves both high strength and gloss retention by a heavy load of microfiller. Thus, the range of indications for resin restoration techniques, which was limited to small, relatively light-load regions in the beginning, has thus expanded to large posterior restorations, including non-vital teeth. Regarding the restoration of anterior teeth, it also expanded to veneer restorations using the direct method and the restoration of teeth whose crowns have badly disintegrated (Fig. 27). It can therefore be said, that the composite resin restoration technique has become widely recognized as a very effective esthetic restoration method. Furthermore, the use of composite resin in a direct resin-bonded bridge technique has recently come into use for the treatment of missing teeth (Fig. 28) and there are some clinical reports available on the use of this in the medium to long term.

Given that composite resin, supported by excellent adhesives, has made it possible to freely reproduce and recreate the form and color of teeth, it is expected that dental treatment using composite resin will result in totally new treatment modalities that far exceed our present imagination.



Fig. 27 a



Fig. 27 b



Fig. 27 c

Eroded anterior teeth clinical case  
(Photo courtesy of PhD. Keiichi Hosaka, Tokyo Medical Dental University)



Fig. 28 a



Fig. 28 b



Fig. 28 c

Direct bridge clinical case  
(Photo courtesy of PhD. Hirofumi Tashiro)

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