

The Making of a Product

A Peek Behind the Scenes

R&D is serious business at BISCO. The team takes a comprehensive approach to product development that's led to the high-quality materials so many dentists know and love. Here's an inside look at how it all comes together.



A Passion for Science

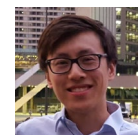
BISCO has been a pioneer in dental materials development for decades. A commitment to science and innovation is a big part of the company's success and is why dentists know they can trust any material with the BISCO name.

A focus on science and innovation has been at the core of BISCO product development since the company was founded by Dr. Byoung Suh in 1981. Dr. Suh's extensive background in chemistry served as a strong foundation for pioneering adhesive material development back then, and his commitment to advancing restorative dentistry remains a driving force for the entire team today.

Over the years, BISCO has become an industry leader thanks to its innovative restorative products, from groundbreaking adhesives to calcium-releasing materials. Its proven track record empowers dentists with confidence the materials will do exactly what they're designed to do, addressing common pain points and helping to achieve the best possible results for patients.

The R&D that goes into every BISCO product is what makes these materials so special. At a time when many companies outsource product development, BISCO continues to focus on it—a source of pride for the team members who put so much work into every product the company launches. And getting to that launch date is a lengthy process. Product development typically spans three to five years, with more complex innovations taking even longer. But the 20-plus members of the R&D team will tell you it's time well spent.

"We value quality products that are backed by



"We all have the same end goal: designing a good product for the patient."

Dr. Erick Yu, Manager of R&D Technology

science," said Nikki Janes, Manager of R&D Product Lifecycle. "We don't want to just go with the latest trends; we want to make sure it works."

Throughout product development, the R&D team works closely with all departments to make sure they're on the right track. Manager of R&D Technology Dr. Erick Yu said the goal is not only to provide dentists with a product that works, but one they really want. Feedback from outside sources is critical. This includes input from the dentists who will use the products every day, university researchers who can help with the testing in those early stages, and even other companies who are trying to solve the same problems.

"If you have a closed mind and only focus on the research within the company, you'll have a single-minded route to developing the product," Dr. Yu shared. "Dentistry should advocate an open learning space. We all have the same end goal: designing a good product for the patient."

EXPERTS IN PRODUCT DEVELOPMENT

Before any new product development can begin, the team presents to the leadership group for approval. These gatekeepers must be convinced to invest time and resources into a project. This is even more challenging as biocompatibility requirements have become more stringent, making product development more difficult.

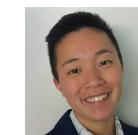
"Between testing and characterization, it's a big task," said Patrick Park, Director of R&D. "And a lot of companies are going away from manufacturing because of that. They don't have the manpower, time, or knowledge, where BISCO has decided to take that on. We are very good at that. I'm not saying it's easy for us, but we know how to get products through the clearance process."

From Concept to Market

There's a lot that goes into product development. Here's a closer look at the BISCO approach to dental material innovation—from the idea stage to development, to ultimately launching in the marketplace.

Product development at BISCO starts with an idea. And that idea can come from many different sources, whether it's a key opinion leader (KOL) who sees a need in daily practice, a conversation a sales representative had with a clinician at a tradeshow, or an "aha" moment a BISCO chemist has while thinking through a problem. Even concerns raised about current products can spur innovation.

Ideas are presented to key players during routine meetings, and once those gatekeepers decide something is worth pursuing, the R&D team gets to work. Park, who started his career at BISCO as a product manager 20 years ago, describes it as a comprehensive process that's rooted in science.



"At every point of contact, we can make small adjustments, but at some point, we have to say this is what we're looking for and we're moving forward."

Nikki Janes, Manager of R&D Product Lifecycle

"Our president, Dr. Suh, started this company as a chemist," Park said. "That's his passion, and he doesn't want to take shortcuts. He wants to make sure what he sells is true and genuine."

That passion trickles down to each member of the BISCO team, Janes said, and it shows in the work they put into every product. It takes years for an idea to actually come to fruition, requiring commitment and dedication from the development team and other departments throughout the company.

Here's a closer look at the extensive R&D process that has led to ground-breaking innovations such as All-Bond Universal and TheraCal LC:

The First Steps

To get a project off the ground, R&D works with many different departments, including marketing, sales, and regulatory. The marketing team helps define the product based on what customers want and the competitive landscape. Regulatory helps ensure they're meeting stringent FDA requirements for the product, with the focus on biocompatibility making that more difficult in recent years (and a reason many companies are spending more time in the development process).

Product development is divided into five phases. The initial phases are the longest and most difficult, as the team must prove they have the technological ability and resources to pursue the project of interest. R&D may go

THE PHASES OF PRODUCT DEVELOPMENT:

Phase 0: The R&D team must prove the project is feasible and that they have the resources and technological ability to pursue it.

Phase 1: R&D works with a task force to determine design inputs and material requirements. The first prototype is created and sent to dentists in BISCO's Clinical Research Network for testing on models.

Phase 2: The product, once cleared by the FDA, moves from nonclinical to clinical testing as part of design and development. Clinicians in BISCO's Clinical Research Network use the product on patients.

Phase 3: Finalizing documentation and transferring the design into an actual product for large-scale production.

Phase 4: The product is officially launched. Post-market surveillance begins, ensuring the product is performing as intended.

through this process only to find the idea is not feasible economically. They look at market research, competitive products, and the chemistry required to make the material work. An exploratory survey is also completed to make sure what the team thinks the market wants aligns with what the market actually wants.

Once an idea is deemed feasible, it goes back to those key players to get the go-ahead to move on to Phase 1.

"Phase 1 is a close circle between R&D and marketing," Dr. Yu said. "We have very specific needs and wants, called design inputs, as well as requirements for the material, such as physical strength. So, in Phase 1, we're checking off what we need to have in the product and creating that first prototype."

Prototypes are sent to dentists in BISCO's Clinical Research Network along with tooth models for them to test the product on, Janes said. The team will then make adjustments to the product based on clinician feedback. They work with both KOLs and other dentists from across the country, giving them a wide range of perspectives. Partners at universities also weigh in during this phase and throughout the development process, providing another outside source of feedback and knowledge.

"We put value into getting good data at the start," Dr. Yu said. "We have hundreds of dentists across the nation who test our prototypes in-vitro, so we're

DESIGN PHASE ADJUSTMENTS

There can be revelations during the design phase that push the development timeline back. For example, during TheraCal PT's development, the team decided to add calcium silicate during this phase to further enhance the material. Materials with calcium silicate are moisture sensitive, so secondary packaging had to be created to protect it.

Other times, marketing has asked to add indications. That can have a big regulatory impact, so the team must reassess performance metrics and conduct user verification surveys to ensure the product can be safely used in that way.

getting a lot of early market data. Ultimately, our products need fewer revisions because we're making the right decisions at the start. That saves time during the development cycle."

At the end of Phase 1, the team looks at product shelf life and, more importantly, biocompatibility to ensure the product is safe for patients, which Dr. Yu said is a "massive investment" that could take upwards of a year. This is also when smaller projects may arise, such as packaging for the material, which requires collaboration with manufacturers and distributors.

Phase 1 could take one to three years of testing and product development, Dr. Yu said, but the reward at the end is submitting that work to the FDA for clearance. After clearance comes through, usually in approximately three months, the clinical testing can begin. Of course, if the FDA doesn't grant clearance, the team will then make adjustments and conduct further testing.

Production Testing

By the end of the initial phases, most products have had anywhere from one to four years of development. The timeline begins to move faster, though, when they're transferred to production. Design validation is a critical step that Janes' team handles as part of Phase 2.

The goal in Phase 2 is to prove the product can perform as intended—and that means getting it into dentists' hands so they can use the material on patients.

"This gives us even more valuable feedback," Janes said. "It's FDA cleared, so dentists can place the material in the mouth where there's moisture and all the other noise. It makes it real."

The team ultimately moves on to Phase 3, which involves finalizing documentation and transferring the design into an actual product for large-scale production, and Phase 4: launching in the marketplace. "At every point of contact, we can make small adjustments," Janes said, "but at some point, we have to say this is what we're looking for and we're moving forward."

Launch Signals a New Chapter

The work doesn't stop once a product is launched. That's when the post-market monitoring begins. Janes' team performs clinical evaluations to ensure new products are performing as they should. They look at articles, competitor data, and complaints about performance. This information can be used to improve the prod-

uct, or possibly spur an idea for another new innovation. In the case of FluoroCal fluoride varnish, it led to new flavors.

"The line started with spearmint, a classic flavor, but we received feedback from dentists that they'd like other flavor options," Dr. Yu said. "So, after rounds of testing and discussion, we launched bubble gum and green apple. That came out of customer feedback, and maybe in future years we'll add other flavors. But a significant change, like adding a new feature or adjusting how the product is used, could take another two or three years to accomplish."

Even seemingly small changes, such as adding a shade or changing the tip, "triggers a slew of new testing" to verify that the product still performs the same, Park said.

What's Ahead for BISCO?

BISCO's legacy is built on adhesive materials, with the company pioneering the category and creating market-leading bonding materials for decades. But the R&D team also focuses on other areas, and the experts noted that a key restorative product is currently in development.



The Thera line is another major area of focus for BISCO, according to Park, who estimated that it accounts for the majority of the company's R&D efforts. The team will continue developing innovative calcium-releasing Thera products to complement the existing product line of TheraCal LC, TheraCal PT, TheraBase, and TheraCem.

"We're always building on those successors," Dr. Yu said. "The dental industry doesn't demand dental products to come out every year, but I'd expect that on a rolling five-to-10-year basis we'll always have a new version to supersede the current one."

Product innovation rooted in science will always be a focus for BISCO. The team will continue to do what they love

and what they're known for: developing innovative dental materials that advance the industry, make dentistry better, and improve the end result for patients.

Dr. Suh, who remains heavily involved in BISCO's industry-changing work, is looking forward to further product innovation.

"I am excited about BISCO's role in developing innovative new products that will enhance and improve restorative dental procedures," he said. "We have a great R&D team here at BISCO that I am confident will continue BISCO's track record of developing new products in adhesive dentistry, future THERA technology and products, and self-adhesive materials that will enhance the future of restorative dentistry."

IMPROVING CUSTOMER AWARENESS

One of the challenges the BISCO R&D team faces is balancing a product's technological feature with customers' understanding of it, Dr. Yu said. The key is to avoid buzz words and marketing hype, and to instead focus on educating dentists on how products work and the science behind them.

"Dentists want products that are faster with fewer steps. They want one product that can do everything," Dr. Yu said. "That takes sacrifices. We have to help them understand: If you want a good product with certain features, you have to do it this way and this is why."

FROM THE EXPERTS: POINTS OF PRIDE

"BISCO has always been on the cutting edge of adhesive dentistry, and that's how the company started over 40 years ago. This same pioneering tradition continues today with development of our line of Thera products, which has changed the industry."

Patrick Park
Director of R&D



"All-Bond Universal is the foundation of the adhesive legacy for BISCO and was launched before my tenure. However, a more recent product I enjoyed working with is Duo-Link Universal, a resin luting cement. A lot of people don't look too deeply into this category, but designing a good cement is equally as challenging as a universal adhesive."

Dr. Erick Yu
Manager of R&D Technology



"TheraBase, our dual-cured, calcium- and fluoride-releasing, self-adhesive base/liner, is a great demonstration of how we listen to our customers. Dentists told us they would love a liner and a base material, and our direct response to that was developing TheraBase."

Nikki Janes
Manager of R&D Product Lifecycle



ADDITIONAL RESOURCES

