



Supporting craniotomy clipping for half a century: History and future

The Sugita Clip was launched in 1976. This single small clip has supported brain aneurysm surgery at home and abroad for half a century, saving countless lives. To commemorate the 50th anniversary of the launch, a special conversation was held between Dr. Nobuhito Saito, President of the Japan Neurosurgical Society, and Mr. Hiroshi Nemoto, Representative Director and President & CEO of Mizuho Corporation, manufacturer and distributor of Sugita Clip products. They reviewed the progress of the Sugita clip and discussed its clinical value and future prospects.



Left: Dr. **Nobuhito Saito**
President, Japan Neurosurgical Society
Professor, Department of Neurosurgery, The University of Tokyo Hospital
Right: Mr. **Hiroshi Nemoto**
Representative Director and President & CEO, Mizuho Corporation

The story of the Sugita Clip

Saito: In the mid 1970s, when the Sugita clip was introduced, there were very few high-quality clips for cerebral aneurysms produced in Japan. Although imported products were available, these typically had issues in terms of operability, safety, and grip strength. Even skilled doctors were being held back by the inherent limitations of medical instruments. It was the passion and conviction of Dr. Kenichiro Sugita that led to the creation of the ideal clip, a high-quality product designed to meet the needs of the medical industry.

Nemoto: Looking back through The Story of the Sugita Clip, which was published in 2005, I was reminded of the passion that Dr. Sugita had put into the development process. What impressed me most was his guiding ethos of producing a device that would work equally well with surgeons of all skill levels, and that would first and foremost help save the lives, rather than simply making life easier for doctors.

He visited the Gosen Plant in Niigata Prefecture many times to tell the workers there about the key attributes that medical professionals were seeking: smooth opening and closing action, reliable grip strength, compact size, a wide variety of profiles, and



biocompatible materials. To meet each of these needs, numerous prototypes and improvements were made. Constant iteration of effort is the story of our manufacturing journey.

Saito: The way that the manufacturing process, including patented technology, was established and has been continuously improved is a very interesting example of successful development of medical devices.

Nemoto: I believe that Dr. Sugita had a strong sense of mission and enthusiasm. He was convinced that Japanese manufacturers should be capable of producing medical devices that were ahead of the world and supplying them to the global marketplace. At that time in Japan, it was a rare and extremely challenging task for medical professionals and industry to work together to develop products for global markets.

Education and promotional campaigns in the domestic market

— Market penetration and institutional barriers

Nemoto: The Sugita Clip was first presented at the Japan Neurosurgical Society in Nagoya in 1975, and went on sale the following year. The original lineup comprised 14 different models, including standard and large sizes.

Saito: There was a marked increase in treatment of cerebral aneurysms in Japan from that time onward. Reliable, standardized instruments are essential for

safe clipping procedures, and the Sugita clip played an important role.

Nemoto: I think that the fact that the Sugita Clip was compatible with MRI, which was introduced in the 1980s, was also a major factor behind its popularity.

At that time, stainless steel clips were the norm, but the Sugita Clip has always been made of cobalt-chrome alloy, a material which is generally considered suitable for MRI. Later, in the late 1990s, cobalt-chrome alloy was replaced with a titanium alloy. The slimmer Sugita Titanium Clip II, currently the most popular model, appeared in 2007. Although the basic profile has changed little since the Elgiloy version released in 1976, it is the evolution of the material that represents a major turning point.

Saito: I am particularly impressed by the titanium clip, though I understand it was quite difficult to develop.

Nemoto: Yes, it certainly was. Titanium is a difficult material to work with, and we encountered many issues in relation to the shape, particularly the blade and the spring design of the grip. Nevertheless, our expert craftsmen were able to make a number of enhancements and improvements based on input from medical professionals, resulting in a viable product. At present, there are 134 different models, including mini sizes as well as versions with windows. I am proud that we were able to realize Dr. Sugita's vision of a product suitable for a variety of brain aneurysms.

Saito: Being able to maintain a consistent supply of high-quality clips available in a wide range of variations is also significant from an educational standpoint. If up-and-coming doctors can all learn using the same equipment, this enhances the process of passing on medical techniques.

Nemoto: At the same time, the continuing popularity of the Sugita Clip, combined with factors such as standardization requirements, presented us with a number of new challenges as a manufacturer. The insurance reimbursement scheme, for instance, resulted in price control and we were obliged to reduce our retail prices. The Sugita Clip is a precision product made by highly skilled craftsmen. Despite rapid increases in material and labor costs, we are unable to raise prices under the insurance reimbursement scheme, and this represents a major financial burden.

Saito: If domestic manufacturers can't continue operating, it will be a catastrophic loss for Japanese neurosurgery. I hope that we can continue to provide a consistent supply of critical medical equipment over the long term.



Dr. Nobuhito Saito

Nemoto: In the same way, we see it as our mission and duty to ensure ongoing consistency of supply. I hope that the health insurance reimbursement scheme in Japan will be a mechanism to fairly evaluate products with proven future potential.

A global presence

— Japanese technology transcending borders

Nemoto: As clinical successes in Japan steadily accumulated, the Sugita Clip started to attract interest from overseas as well. Backed by Dr. Sugita's conviction that Japanese manufacturers should have a global presence, we took the lead in expanding into overseas markets. This required compliance with regulations and certifications in different countries and regions. The first turning point was the World Congress of Neurosurgery in Munich in 1981. Dr. Sugita's presentation to the congress was very well received, and Sugita Clip became an internationally known name.

The next step was to expand into the U.S. market. After a rigorous three-round screening process, the Gosen Plant was approved by the United States Food and Drug Administration (FDA) in 1984. From that point, the Sugita Clip was enthusiastically adopted by high-volume centers in the United States.

Recently the Sugita Clip was granted Class III certification, the highest ranking in the European Medical Device Regulation (MDR) scheme. Only a handful of products worldwide have received Class III certification. We see this as acknowledgment of our unwavering commitment to exacting quality standards and stability of supply. Although it takes a lot of time and effort to obtain certification, Mizuho has always been passionate about developing this very special product in conjunction with Dr. Sugita. Equally, we believe that maintaining a stable global supply system is an important responsibility.

Saito: The process of ensuring compliance with a succession of strict regulatory and certification systems has no doubt helped to make it a better product overall. It is the cumulative result of these efforts that sees us today celebrating this milestone 50th anniversary.

Clipping delivers real value in the era of mainstream endovascular treatment

Nemoto: In recent years, there has been a shift toward less invasive treatment modalities such as coil embolization, flow diverters, and stents in addition to clipping, both in Japan and in the West. How do you see the future of craniotomy and clipping procedures?

Saito: I think craniotomy and clipping will still be required in the future. Endovascular treatment is an important therapeutic option that delivers high patient satisfaction levels and is increasingly considered the first choice for unruptured aneurysms.

Although endovascular treatment is not necessarily suitable for all cases, clipping still tends to be the first choice for patients with complex or wide-necked aneurysms, recurrent cases, and younger patients. The more difficult the case, the more likely it is that craniotomy and clipping will be required. In this sense, we can say that demand for reliable clips will remain strong.

Nemoto: At the annual Sugita Memorial Forum, we run hands-on training sessions where young doctors can learn clipping techniques. These are as important and useful as ever.

Saito: Of course. Younger doctors looking to work in fields such as vascular disorders and strokes have to acquire specialist qualifications but they also want to learn craniotomy and endovascular therapy techniques. I feel that people increasingly understand that you need mastery of both of these in order to specialize in this field.

Nemoto: Whenever I see this in younger doctors, I feel a strong sense of responsibility to support their education as a manufacturer. We will continue to work closely with clinical settings by providing active support for hands-on training sessions as well as preparing technical materials and educational materials for young doctors.

The next 50 years — Our people, our future

Nemoto: For some 50 years now, the Sugita Clip has been provided to medical institutions thanks to the support of a great many people. I believe that a key reason for the consistent ongoing success of the Sugita Clip both in Japan and around the world is the work put in by our domestic distributors and overseas partners to learn about and develop a detailed understanding of the products.

Outside of Japan, we find that medical regulations

and approaches differ considerably among countries and regions. So we have set up distribution systems together with local partners that provide us with valuable feedback that we can use to tailor the products to local markets.

Saito: Health care is a team effort, and I feel that those responsible for product development and distribution are like the invisible members of the team. I am often reminded of the efforts of so many that underpin the supply chain.

Nemoto: Dr. Sugita was known to say that there should be not even one defect per million products. His words are the guiding principle that as medical device manufacturers we must always keep in mind. We will continue to honor his words by ensuring that the skills of our craftsmen are passed on.



Hiroshi Nemoto

Saito: The Sugita Clip is an exceptional medical instrument that has played a key role in the history of neurosurgery in Japan. It has steadily evolved over the three decades I have been involved in clinical practice. I am sure that the Sugita Clip will continue to play a unique role in therapeutic treatment for years to come, and I trust that you will remain the sole domestic manufacturer of this wonderful product.

The needs and expectations of the medical sector are always changing. I trust that the Sugita Clip will continue to evolve in response to these changes, based on input and suggestions from medical professionals.

Nemoto: Our mission over the next 50 years is to preserve and maintain Dr. Sugita's legacy, in particular his philosophy and his pride in Japanese craftsmanship. We look forward to supplying these life-saving devices well into the future, with gratitude to the medical professionals who have used our products for many years; our sales partners who have maintained a constant supply of products in occasionally difficult circumstances; and the skilled craftsmen at our manufacturing sites.

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History of the Sugita Clip

