### **MANI Value Creation**

MANI products around the world, as we aim to contribute to the welfare of our stakeholders including doctors and patients, society, employees, and shareholders, and of people worldwide. Value Creation Story **Business Model** Changes in management capital and the social environment Output Outcome Our values and aims **Corporate Philosophy Management Capital** Improve the Value drivers "Contributing to the welfare of people worldwide" That Supports Growth peed of nev Contributing to the welfare of people worldwide **Business segment** evelopme **Human Capital** Eyeless needles through the development, Utilize multinational personnel production and distribution of products with advanced technical Pursue beneficial to patients and doctors. Surgical capabilities gh-quality Value chain **Intellectual Capital** Development ☐ P. 27–31 Advanced technology capabilities **Doctors & Patients** that competitors cannot copy Medical instruments that will benefit patients Off-Limits **Manufacturing Capital** Improvement of the quality of life (QOL) of Management In-house development of proprietary manufacturing High-quality medical instruments that will \_\_\_\_ P. 23 benefit doctors equipment **Essence of Value Creation Social Capital** of custome Partner with local communities, Society **DNA of Aiming** and provide ongoing support for Manufacturing doctors from when they are to Be the Best Community-based medical & healthcare Strategy medical students in the World including overseas P. 24 Contribution to local communities **Financial Capital** ☐ P. 23–24 High profitability, and a QUALITY IN subsequently high equity THE WORLD, capital ratio O THE WORLD **Employees** Quality assurance **Key Measures** Workplace environment that is comfortable and rewarding Required for Changes in Opportunities to develop and grow skills **Dental & GDF** Cultivate new and capabilities the Social Environment MANI Sustainability domains Shareholders Carbon neutrality
 Utilization of diverse human resources P. 25–26 Green supply chain that considers the environment **Build up strengths** Stable and continuous shareholder returns Medium-Term Management Plan Key Measures Investment for sustainable growth **Collaborating** Personnel **Global marketing** with KOLs **Smart Factory R&D Center** development around the world

MANI has been leveraging the management capital we have accumulated over many years to provide high-quality products based on our strengths in three areas: "Off-Limits Management," "Manufacturing Strategy," and "DNA of Aiming to Be the Best in the World." We will continue to build on these strengths and provide high added value

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Create new pipelines <

### **Essence of MANI Value Creation**

-Off-Limits Management, Manufacturing Strategy, DNA of Aiming to Be the Best in the World-

In our product strategy, we are clarifying and implementing the trade off, or the "Off-Limits" fields in R&D. This "Off-Limits Management" derives the company's notable strengths, that is an extremely high operating income margin and equity capital ratio. While it is important to adapt technology strategies in accordance with technological changes in the markets we face, we will continue to inherit the core concept of our management, and aim for sustainable growth. In the technical field where we excel, we will continue to produce "the world's highest quality products." We believe this is the one way in which we can contribute to society, and is also the significance of our existence.

## We do not deal in products other than medical equipment

n Off-Limits
Management

In 1961, MANI successfully produced the world's first stainless-steel surgical needles. Since we achieved "rust-proof suture needles," which was an issue in the medical equipment industry at that time, we have adopted a consistent strategy. This means that medical equipment, which is small and consumable and has a long product life, is made "the best quality in the world" with its original technology centered on microfabrication technologies for wires and sold in global niche markets. We have arrived at this strategy by learning from our past failures. In the 1970s we developed surgical scalpels; however, as they were inferior in quality to the scalpels made by our competitors, we failed to enter the market. This was not one of our specialty fields like wire, and the scalpels used plates that involved materials and processing technologies that were completely different to those used for wire. That was what caused our failure. This experience taught us the importance of competing on the technologies that MANI excels at; therefore, we have been specializing in the development of instruments with delicate structures and that are made from wire.



#### Products created based on "Off-Limits Management"

# From the development failure of scalpels to success in the dental instrument's domain

From the development failure of surgical scalpels, we started to specialize in the development of instruments with delicate structures and that are made from our specialty field of wire; this resulted in the emergence of a new business in dental instruments. In 1976, we launched barbed and smooth broaches. Since then, we have deepened our technologies, and also developed reamers, files, and diamond burs that are currently some of the main products of MANI.

## We do not aim for quality other than the best in the world

DNA of Aiming to Be the Best in the World

The basic business policy of MANI is "THE BEST QUALITY IN THE WORLD, TO THE WORLD." All MANI Group employees carry this policy with them as they do their daily work. As part of our efforts to realize this policy, we hold a "The Best in the World or Not" conference once every six months, and run programs aimed at being the best in the world for each required characteristic of quality. We segmentize each product and scrutinize each characteristic to determine if we are the best in the world or not, and then we make improvements. If a competitor's product is superior to a MANI product, the sale of the superior product is for the benefit of patients and the world. We make every effort to pursue high-quality products that are well received by as many users as possible, and we strive to bring profits to all relevant parties by delivering these products to the world.

## We do not deal in products with a short product lifecycle

Manufacturing Strategy

MANI develops and produces only basic medical equipment with a long product lifecycle. This allows us to achieve cumulative quality improvements and cost reductions over a long term. It also generates the unique technologies to achieve the particular level of quality required in medical equipment, and allows us to establish even more efficient production technologies. This is how we are maintaining an organizational structure that achieves high quality and high income margins. MANI also develops in-house machines for evaluating the quality of our production machinery and products, and through this in-house development system we are refining our specific technologies.



#### Original structure from the "Off-Limits Management"

## In-house development of production machinery and machinery for evaluating the quality of products

Our engineers, who are very knowledgeable about the wire developed at MANI and the machinery to process and evaluate that wire, work daily on making improvements so that we can provide even better quality. Currently we are training many engineers both in Japan and at our overseas production bases, and it is the MANI employees at overseas bases that are playing a central role at present.

#### We do not enter markets other than niche markets

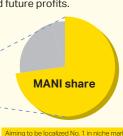
(annual global market scale of around ¥500 billion or less)

As a manufacturer of instruments with delicate structures, we do not have special resources compared to our large rival companies located overseas. We maximize the limited resources we have in our company, and so rather than directly competing with these large companies, we are aiming to be number one in the world in the niche markets where we can leverage our core technologies. By specializing in products where added value is required so as to avoid unnecessary price competition, and by patenting the creative technologies we have developed from our accumulated technologies, we are striving to secure both immediate and future profits.



We do not enter markets with an annual global market scale of around ¥500 billion or more. We also do not develop large-sized products and instruments that have no connection with MANI products or our proprietary technologies.





Manufacturing

**Strategy** 

#### Proprietary verification system to support MANI quality

#### "The Best in the World or Not" conference

To evaluate if a product is the best in the world or not, we look at more than just the product's performance; we also score aspects such as market price and availability, and then compile objective data that is used to do comparisons and data verification with competitors' products. We formulate action programs for the characteristics that need improvement and use it as we strive to provide high-quality products to realize even better treatments. We ask ourselves if the products that were once best in the world are really still the best, and the reasons why we can say so. While asking ourselves these harsh questions, we have been working enthusiastically and persistently to develop products, with a healthy sense of urgency.



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### Medium-Term Management Plan —Business Model Innovation—

In April 2021, we announced MANI Group's Medium-Term Management Plan ending August 31, 2026. This plan is for the Group's sustainable growth and strengthening the business base to support that. The outline of this plan is achieving our corporate philosophy of "Contributing to the welfare of people worldwide through the development, production and distribution of products beneficial to patients and doctors." We will move forward with the six corporate policies of (1) Business model innovation, (2) R&D with key opinion leaders (KOLs) in the world, (3) Expand global market shares through regional-oriented sales, (4) Global production system: High-quality and low-cost production, (5) Introduce a new personnel system, and (6) Promote MANI Sustainability.

#### Progress in the Fiscal Year Ended August 31, 2022

Recovery from the impact of the COVID-19 pandemic and the effect of a weaker yen resulted in net sales, operating income and ordinary income all reaching their highest ever levels. We have also been making steady progress in our key measures.

- Expanded dental products in the Indian market (the market itself has expanded, and at the same time we have added more sales staff and carried out an aggressive sales strategy. Subsequently, we have succeeded in cultivating customers and increasing market share.)
- Began construction of a new Head Office and Factory for GDF

- Doing what we say of delivering "the best quality in the world, to the world" >
   Achieving the MANI corporate philosophy
- Transforming MANI from a collection of development-based niche companies into a true global company that meets the demands of customers worldwide

			FY2022 (Results)	FY2026	FY2031
Numerical targets	Profitability	Operating income ROE	¥6.1 billion 12.5%	¥10.0 billion 12%	¥15.0 billion 16%
	Growth	Net sales	¥20.4 billion	¥30.0 billion	¥50.0 billion
	Shareholder returns	Dividend per share	¥30.0	Stable increase in dividends	Stable increase in dividends



#### Key Policies for Our Future Evolution

### Pursue customer orientation by collaborating with KOLs around the world P.31

In our conventional product development, we have been focusing our development of MANI products with doctors in Japan, who are quite fastidious about the tools and instruments they use. This was based on our belief that if we can produce quality products that satisfy doctors in Japan, then doctors around the world will also use those products. However, as we strengthened our regional-oriented

sales worldwide, it became clear that the way our products are used and the needs associated with them vary by country and region. Therefore, we have been collaborating with KOLs around the world, and creating policies in the MTMP for product development that is based on doctors and surgical techniques worldwide. By utilizing the network of global sales bases that we have built, and meeting the various needs of doctors worldwide that are funneled through this network, we are aiming to achieve a system where MANI products are used in even more places in the world.

# Aim for a much faster development of new products at the R&D Center P.20

The R&D Center aims to create more innovative value by bringing together employees from bases in each country under with the keyword of aiming for the best quality in the world. By bringing together our

various functions, we believe that we will not only further promote our conventional development projects, but also accelerate the cycle of product development and production manufacturing by taking on the challenge of entering new minimally invasive treatment domains and developing new technologies.

### Establish a high-quality, low-cost global production system

P. 29

With a focus on the company's further growth from here on, we are also planning to build a new Head Office, R&D Center, and Smart Factory in Takanezawa, our founding site. At the Smart Factory, we will start using automated lines for each process to achieve manufacturing that

maintains high quality without being affected by labor costs.

We are also implementing the MANI Production System (MPS), which are activities to improve production efficiency, so as to achieve further cost price reductions at the Vietnam Factory. And at our German subsidiary GDF, we are scheduled to complete the construction of a new Head Office and Factory in 2023 and build a system for the increased production of dental restoration materials

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Value Chain

Development

Production

Quality Assuranc

Sales

### **Development Capabilities that Support the Best Quality in the World**

MANI has successfully developed the world's first Austenite stainless steel (an alloy including 18% chrome and 8% nickel) suture needles, which are made from "MANI hard-fiber stainless steel." These needles do not easily rust, and they are tough, hard, and sharp. Based on this new material, we developed micron-unit ultra microfabrication technologies and nanolevel surface treatment technologies. We are delivering over 10,000 types of medical equipment in the dental, ophthalmic, and surgical fields worldwide. We are also focusing on the development of new technologies and products based on the innovations of nano-level materials engineering and ultra microfabrication technologies, including dental treatment products made of NiTi (nickel-titanium) alloy with excellent flexibility, high strength, and shape memory. Also, dental caries restoration products made of (organic/inorganic) composite materials that polymerize and cure under ultraviolet (UV) light.

At the same time, thanks to recent advancements in medical technologies, minimally-invasive treatments are now a reality and a global trend, allowing for reliable surgeries with superior safety and excellent efficacy using endoscopes and surgical

MANI will continue to develop equipment for minimally-invasive treatment through the development of ultra microfabrication technologies and next-generation, innovative metal materials and composite materials.

### What Makes MANI Development Distinctive

1

### **Development of Proprietary Materials**

MANI developed the world's first Austenite stainless steel medical-use suture needles. We developed a new material to realize creating rust-proof and unbreakable suture needles. We have also created original and optimal processing methods, even for materials that are unsuitable for processing, which we use to make these materials into products. Within the company, we refer to that material as "MANI hard-fiber stainless steel."

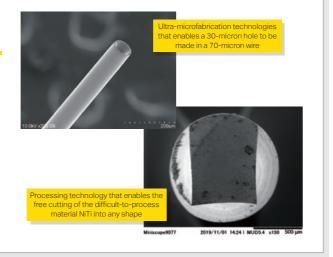
Now we have products that are made not only of stainless steel, but also of tungsten carbide (super steel), nickel titanium, and multiple types of metal materials, as well as products made of composite resins. We use multiple types of materials and processing methods to develop a diverse range of products.



otrength

# Microfabrication Technologies for Metals

An increase in the use of minimally-invasive treatments is also facilitating an expansion of the areas where MANI's specialty of microfabrication technologies are used. The core of MANI's manufacturing and processing equipment is our proprietary development and design. Due to this, we were able to make materials into products, carry out high-mix production, achieve a stable level of high quality, and realize cost competitiveness and mass production. MANI products are also distinctive for their long product life, and the continual improvements we make to the products are also our major competitive strength. We will continue the challenge of incorporating advanced technologies that are one step ahead, and continually evolving our microfabrication technologies.



Strengt 3

### **Culture that Values Customer Satisfaction**

We hope to advance the progression of minimally-invasive treatment through the development of products that are easy to use for doctors, and medical equipment that can reduce the physical burden on patients as much as possible. In hand-held medical equipment, there are also various needs depending on the doctor and treatment method. In the development of such products, we are collaborating with KOLs and other partners around the world to acquire detailed information on these various needs, and building a system for low-volume high-mix product development.

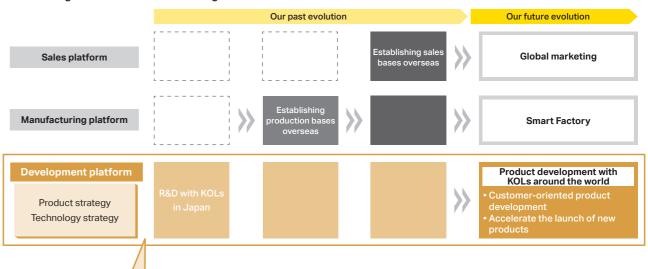


### **▶** Growth Strategy

We are taking on a new challenge of entering the minimally-invasive treatment domain, with the keyword of "the best quality in the world." We will move forward with expanding new business domains through challenging product development by deepening our joint development with KOLs around the world, industry-academia collaboration, and medicine-engineering collaboration. Additionally, we will strengthen initiatives, including research new materials and processing technologies.

We will also accelerate the cycle of product development and production in Japan by investing in R&D centers. And we will step up the training of development personnel to support these initiatives.

#### Positioning in the Medium-Term Management Plan



(ey Measures

Create new development themes	<ul> <li>Expand joint development with KOLs in the domain of dental, ophthalmic, and medical-use suture needles, where we have the resources of customers, technologies, and products, and deepen our product range and businesses</li> <li>Make more active use of external resources, such as industry-academia collaboration, medicine-engineering collaboration and companies that have other technologies, and promote the development of new domains and technologies, as well as create new products and businesses</li> </ul>		
Speed up development	<ul> <li>Create a roadmap of businesses, products, and technologies, based on changes in society and medical &amp; healthcare</li> <li>Actively introduce new elemental technologies, use Finite Element Analysis (FEA) and other technologies in product desig develop an original analysis and evaluation system, strengthen the foundation for the creation of prototypes and processit technologies</li> <li>Strengthen management of the product development process</li> </ul>		
Human Resource Development	<ul> <li>Strengthen skills in personal relations, specializations, commercialization promotion, and management</li> <li>Accelerate growth by building a structured education and training system, providing planned opportunities for growth, and creating a culture that enables for scientific discussions</li> <li>The new Head Office will organically link the R&amp;D Center and Smart Factory to provide a place for learning and practice</li> </ul>		

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Sales

Value Chain

Production

Quality Assurance

Sales

### Manufacturing for the Best Quality in the World

MANI's production activities are mainly characterized by how we utilize the long product life of our products, make continual improvements to our proprietary equipment that we have developed, and keep working on increasing production efficiency over the long term.

In ordinary manufacturing industries, equipment needs to be modified and updated every few years when new products are developed; this makes it difficult to continue using original equipment. As for MANI, since we can continue to produce the same products for a decade and longer, we are able to use our original equipment over a long period while continually updating it. Continual use also creates many opportunities for improvements, which leads to improvements in production efficiency as well. Such an approach means we can also enjoy for a long period the benefits of progressive increases in efficiency, and this also contributes greatly to cost price reductions.

Furthermore, we have made the Vietnam Factory our main manufacturing base, and incorporated labor-intensive aspects as well. This allows us to also maintain a precise production and a quality assurance system, which leads to balancing sustained high quality with low-cost production.

### Policies going forward

We will promote the following three key measures going forward, to further improve efficiency and quality, and strengthen collaborations with other departments.

### **Build a Smart Factory**

With a focus on further growth in the future, first we will build a Smart Factory in Japan to achieve efficient production that maintains high-quality and is not affected by labor costs. At the Smart Factory, we will start using automated lines to enable the manufacture of products of the same quality, regardless of which country they are manufactured in and without being affected by labor costs. In the future, we are also considering the possibility of building smart factories in multiple regions, so as to keep up with the expansion of our sales regions.

The R&D Center and Smart Factory will first integrate development and production in Japan, and facilitate our aim of setting up a system for a speedy cycle of development to production.

### **Promote the MANI Production System (MPS)**

Even as we move forward with the Smart Factory concept, the existing Vietnam Factory will continue to function as our main factory, and we will focus once again on achieving cost price reductions in the Vietnam Factory.

So far, we have focused on cost price reductions, mainly through automation in the production processes. However, as an effort to reduce losses overall, we will also pursue efficiency in other areas, such as the management of labor time, overhead expenses, and costs associated with the purchase of consumable items.

### **3** Strengthen the Supply Chain Management

Since all of the MANI products are small-sized items, storage costs can be contained even if we storage large amounts of stock. This also means that if we secure a large inventory of stock, we do not need to keep a close eye on lead times up to the completion of manufacturing.

However, as we aim to improve development speed of new products and to further raise productivity as outlined in the MTMP, we will also continue to update the ERP (core system) and shorten the lead time for commercialization. To achieve that as well, we will strengthen the collaboration between the Sales and Marketing Division and Production Division, and move forward with optimizing the balance of production and sales volumes.

Furthermore, we will introduce logistics centers in main sales bases, such as Asia and Europe, and finally work on optimizing product commercialization and delivery in each sales area.

### **Quality Assurance That Supports the Best Quality in the World**

MANI regularly undergoes inspections and reviews by third party certification institutions. We have acquired and are maintaining various certifications, such as ISO 13485 and MDSAP.

As for the quality assurance system, we reflect the three elements of the medical device regulations (MDR), which are "product safety and efficacy," "quality management system," "post-market safety management," to maintain and improve the company's internal standards: Through these mechanisms, we are able to launch on the market safe and effective medical equipment. This includes working with various divisions to try and obtain the latest information on the medical device regulations of other countries.

The Quality Vigilance and Safety Division provides support to other divisions that manage the design and development, manufacturing, logistics, and post-market processes, and helps to ensure their work proceeds smoothly.

### ▶ Policies going forward

The MANI quality policy also includes the Quality Assurance activity (duty) of all employees to ensure the quality of their own post, and the method of abiding by the laws, regulations, and standards to create and provide quality that customers trust the most in the world. To achieve this, we are educating and training each department and employee level about the medical device regulations and other measures that are applied in the company. We are striving to strengthen the company-wide quality assurance system including in development, production, and sales, by seeking a mutual understanding and deeper awareness of the quality assurance work done among each division.



## MPS Activities in MANI HANOI CO., LTD.

MANI HANOI CO., LTD. is the company's main production base, and it is also much more than just a production base. It is where we proactively carry out activities aimed at improvement, including updating manufacturing equipment and reviewing the production processes using automation, etc.

Since 2021 we have been working on a productivity-improvement initiative called the MANI Production System (MPS), which is being promoted mainly by the department managers and leaders at MANI HANOI CO., LTD.

By repeatedly identifying the issues in each segment and making improvements, visualizing results of these activities, we are ensuring the quality of MANI products while also

achieving continuous cost price reductions.





Value Chain

### Sales Capabilities That Spread the Best Quality in the World

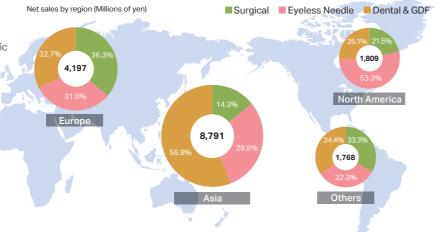
The strengths of MANI include our development capabilities and microfabrication technologies in metal materials, which we use to develop even more minimally-invasive medical instruments. Minimally-invasive treatments reduce the burden on a patient's body, more than conventional treatments do. These treatments are a major trend for their ability to increase the efficacy and safety of treatments.

Micro-sized medical instruments are used particularly in delicate medical procedures done under microscopes and endoscopes. When these instruments become micro size, the metal materials tend to lose their strength, and it is no longer possible to make use of the instruments' inherent performance and features. To resolve this issue, we developed proprietary metal materials, and used microfabrication technologies and a special design to manufacture the materials into products. Going forward, as we keep in line with the trends in the medical equipment industry, we will continue to develop our regionaloriented sales worldwide to accurately and promptly grasp the needs of doctors and patients in each country and region, and strive to expand sales and market share.

#### Activities in 2022

FY2022 was a year of resuming the marketing activities that had dropped off during the COVID-19 pandemic, such as seminars, academic meetings, and exhibitions, and strengthening systems in our existing sales bases. It was also possible to make some business trips overseas, so we actively worked on strengthening direct sales overseas as well, including opening a new representative office in Malaysia for the South-East Asia region. And in GDF in Europe, we set up the MANI European Business Development Division to drive forward sales of GDF products and MANI products.

#### Global sales results (Net sales for the fiscal year ended August 31, 2022)



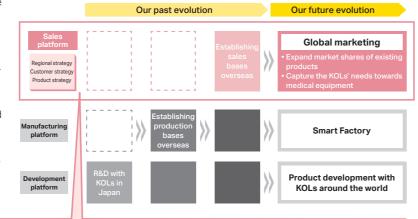
### Policies going forward

#### Develop Regional-Oriented Sales in South-East Asia and Europe

With the keyword of global regional-oriented sales, we are increasing the opportunities to communicate with doctors in various regions, and expand the range of direct sales. The mainstream treatment methods, easy-to-use products, and other aspects differ by region, so we are using feedback from KOL doctors to promote sales of products tailored to each region. As a new step toward achieving that, we have opened sales bases in South-East Asia and

We are also moving forward with global personnel development, so that it is possible to autonomously operate the sales bases as they expand, using both regional and product strategies.

Positioning in the Medium-Term Management Plan



## Key Measures

31

Using the China sales system as a model, we established the MANI European Business Development Division in GDF's new Europe Expand sales of mainly existing products North Explore the full-scale entry into advanced medical & America

Grasp the local medical & healthcare needs in bases in China and India Set up new sales bases in South-East Asia, and organize logistics

Expand sales of ophthalmic products with the launch of new products

Expand the market share of sales of NiTi files in the dental domain

## Medium-Term Management Plan

### **Key Development Products**

In order to further evolve new minimally-invasive treatments in domains such as dental and ophthalmology, we are carrying out joint development with KOLs around the world, and currently focusing on product development particularly in the following three domains.

### ▶ Develop Products by the Expansion of Business Domains

NiTi rotary files for dental and root canal treatment/ root canal shaping and expansion

Product name: JIZAI



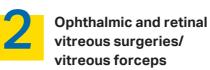
This dental treatment instrument is used in root canal shaping and expansion for removing caries-damaged dental pulp and cleaning the infected root canal area. This tool makes it possible to remove infected dental pulp and dentine, even in root canals that are curved and have complex formations. With the design of this product that uses NiTi material we have achieved better flexibility to follow the curvature of the root canal, while minimizing cutting of the dentine.

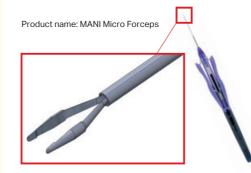


We have mostly dealt in manual root canal treatment instruments so far, and now we have produced new motorized root canal treatment products.

#### Policies going forward

These products are being increasingly used in university hospitals and other institutions, primarily in Japan, Webelieve that acquiring cases of these products being used in treatments will lead to even further expansion of their usage in other countries and clinics. We are carrying out joint development with KOLs around the world, and working on developing and enhancing advanced root canal formation and expansion instruments.



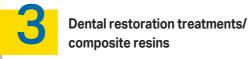


This surgical instrument is used in internal ocular procedures such as treatments for retinal detachment and diabetic retinopathy. Internal ocular diseases can substantially affect visual acuity, so such treatments are extremely important in improving patients' quality of vision (QOV). These surgeries require extremely delicate techniques, as the procedures are performed on the internal ocular tissues using small diameter surgical instruments. In this instrument, we have achieved a combination of high rigidity and high precision using microfabrication technologies and a product design for precise operation.

So far, we have mostly dealt in products in the domain of cataract surgeries, and now we are expanding into the domain of surgical instruments for procedures for vitreous and glaucoma surgeries

#### Policies going forward

The vitreous forceps have acquired pharmaceutical certification, and it is undergoing clinical evaluation. We will move forward with product development in the domain of vitreous and glaucoma surgeries, where we expect an expansion of the market particularly in



Product name: MANI EG Composite



The most commonly used dental restoration materials are restoration and filling materials made from composite resins. We have developed products that are made using materials free of environmental hormones. These products can easily create shapes and color tones, and have even higher esthetic properties. These products shorten treatment time. and add a sense of reassurance to materials that remain in the oral cavity for a long period.

#### Policies going forward

We have mostly sold composite resins in GDF to original equipment manufacturers

composite resins. In December 2022, we acquired European Union Medical Device Regulation (MDR) certification for this material. We are planning advance sales in Europe. We will successively launch sales in Vietnam and India in the Asia region, and once we acquire regulatory approval, we plan to introduce this material in Japan and China as well.

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