Hitachi Metals
NEWSLETTER
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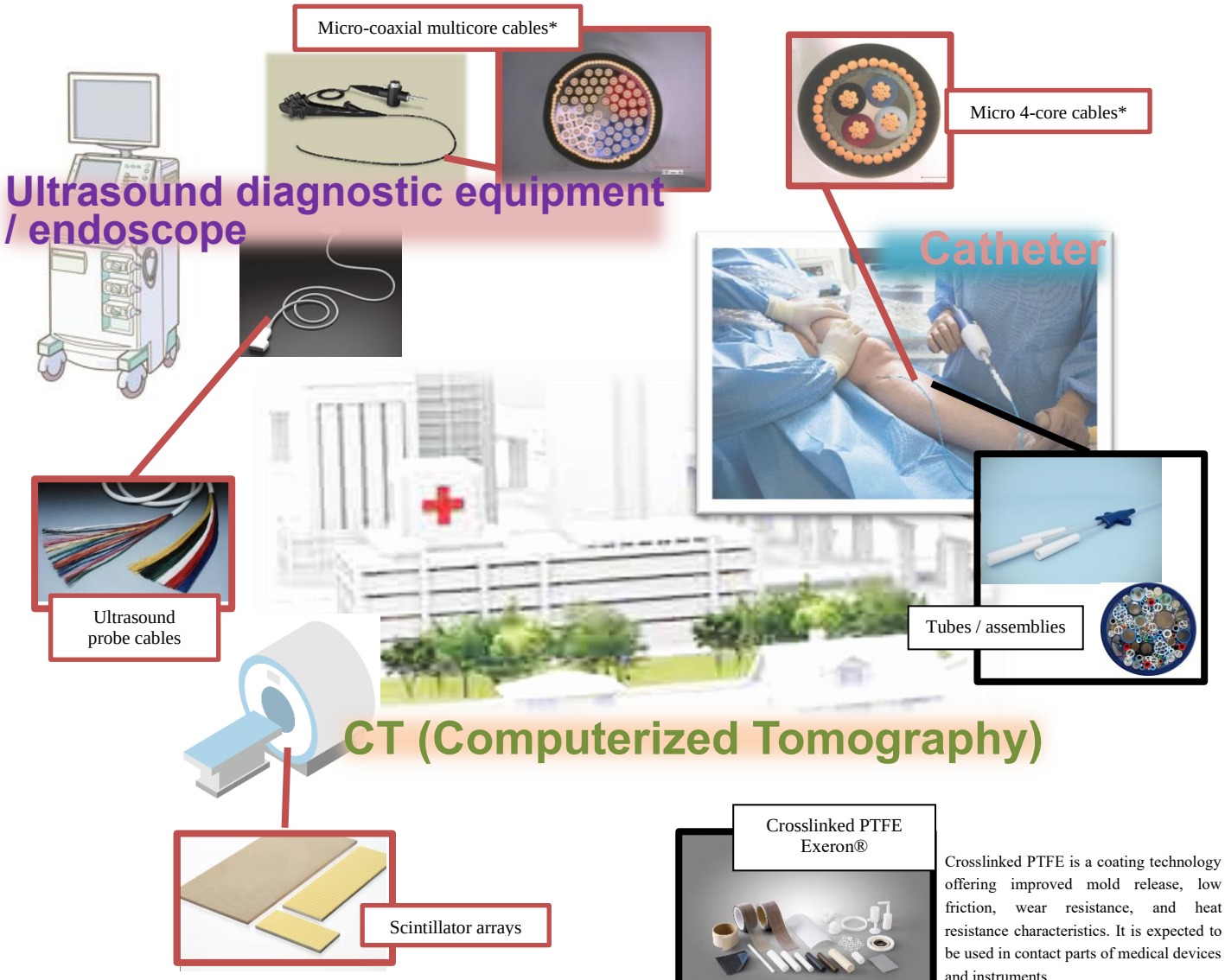
Hitachi Metals, Ltd.

Supporting improvements in the performance of medical devices and making the impossible possible in medical care
–Forward-looking medical lineup that addresses issues for the future–

Hitachi Metals, Ltd. (“Hitachi Metals”) supplies high-performance materials to the medical devices business field, contributing to improvements in the performance of medical devices and resulting advancements in medical care. In particular, provision of these materials has led not only to contributions in improving the performance of medical devices—to which Hitachi Metals’ high-performance materials contribute directly—but also to micro-scale technological contributions with the awareness of improving usability in the medical workplace—making what was once impossible with conventional medical techniques possible. In this issue, the newsletter introduces Hitachi Metals’ medical products lineup, which has been created with a view to the future, addressing issues, and continuing to take on challenges together with medical professionals.



Crosslinked PTFE is a coating technology offering improved mold release, low friction, wear resistance, and heat resistance characteristics. It is expected to be used in contact parts of medical devices and instruments.

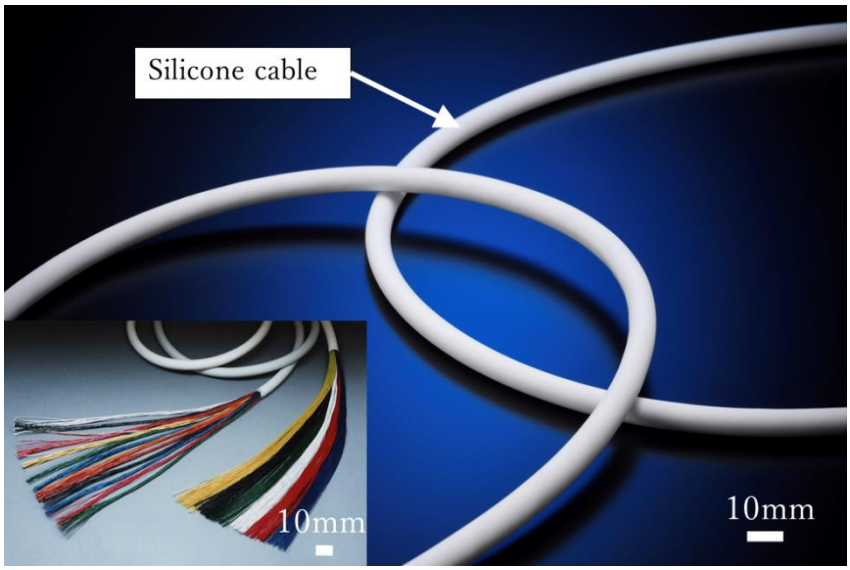
* Coaxial cable and multicore cables: Coaxial cable is type of insulated electrical wire. It is called “coaxial” because both the outer insulator ~~coating~~ and the conductor nested inside share the same geometric axis.

What needs exist for high-performance materials in the medical business field? What are the market trends??

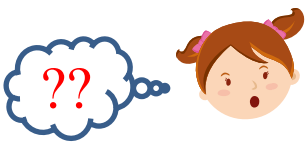
★ Growing needs such as social aging and infrastructure development

Despite a temporary decline in the global medical devices market in 2020 as a result of patients refraining from visiting medical institutions due to the COVID-19 pandemic and the postponement of non-urgent surgeries and medical procedures, the market is still expected to expend in the future, with high-level growth expected in the medium to long term due to the digital transformation of medical care in anticipation of social aging in developed countries and the development of medical infrastructure in emerging countries. The industry growth rate of around 5% is anticipated (2019–2027, according to research by Hitachi Metals). The endoscopy and catheter markets in particular—which are considered minimally invasive medical treatments[*1]—continue to grow at an especially high rate as some of the latest medical technologies, and demand is expected to increase further with the progress of medical technologies in the future.
Hitachi Metals has been supplying probe cables for many years, refining its micro-fabrication technologies and micro-coaxial cables for medical use, based on its expertise in materials development and coating technologies for the manufacture of electrical wiring. Hitachi Metals has utilized its reliable technologies and trusting relationships with customers built based on this track record to develop the market for minimally invasive medicine, which is displaying remarkable growth.

In this issue, this newsletter explores the importance of medical cables and the background of their development, which Hitachi Metals has tackled with particular attention to quality, to make what was once considered impossible in the medical field a reality. The letter also introduces ceramic scintillators used in CT machines, which are one of the very latest kinds of medical devices.



Example structure of a medical probe cable (multi-core cable)
(Silicone cable with micro-coaxial cable for ultrasound diagnostic equipment inside)



What the "probe cable" is, anyway. What do you mean by "probe"?

A probe is an exploratory instrument (typically a transducer) that is placed in contact with or inserted into an object for measurement or experimentation. The probe cable is a cable that connects the transducer to the main unit of the diagnostic device, as is commonly seen in medical ultrasound equipment.

What functionality and performance are required?

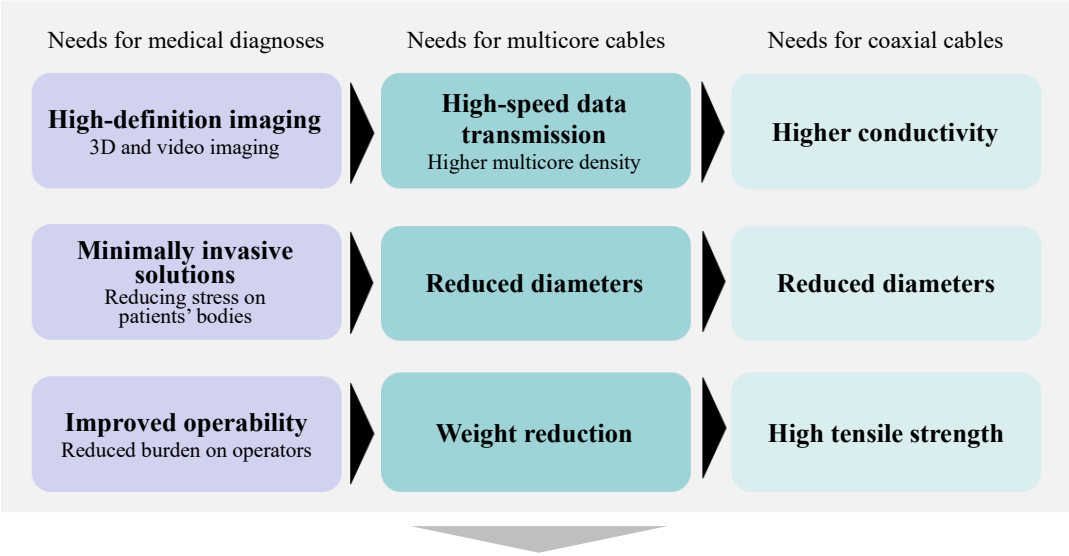
Due to the nature of diagnostic devices, the clarity of the image projected is a key point for identifying symptoms or physiological changes caused by diseases. To enable high-definition image quality, the cables for diagnostic imaging equipment consist of very large numbers of micro-coaxial cables (around 200 cables). Since they are used frequently, another key point is operability by medical professionals and general ease of management in the medical workplace.

Tackling challenges in healthcare: introducing high-performance products and solutions in the medical field!

It was in the early 2000s that Hitachi Metals first considered applying its high-performance electrical wiring technologies in the medical field, and basic research also began around this time. As a result of exploring the wider application of expertise and technical philosophies for wire manufacturing that Hitachi Metals (formerly Hitachi Cable) had cultivated up to that point, Hitachi Metals arrived at the possibility that aspects such as material development and cable diameter reduction technologies could be applied in medical applications, where the highest quality is required to save lives, and launched research efforts to tackle various challenges in this new field.

A typical application of copper alloy wire in the medical field is in multicore cables used in medical ultrasound equipment and endoscopes. Various needs in the medical field are shown in the figure below. Based on these needs, Hitachi Metals realized that further improvements to the high-strength copper alloy wires—which Hitachi Metals had worked on up until that point—would be required to produce ultra-fine copper alloy wires with high conductivity and high strength.

■ Medical needs and required improvements



Ultra-fine copper alloy super thin wire (diameter 0.013 mm or less)
with high conductivity and high strength was required

A key condition for applications in the medical field was that the wire must have a diameter of 0.013 mm or less, which was even thinner than the fine diameter wire (0.016 mm) manufactured by Hitachi Metals up until that time.

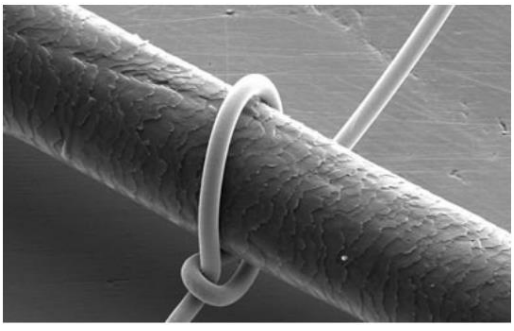
Since electrical resistance also increases simply by reducing the diameter, due to the decrease in cross-sectional area, high conductivity of the copper alloy itself was also required. It was also necessary to increase the strength of the copper alloy so that breaks in the wire would not occur during manufacturing and use, even if the diameter is reduced. However, there is a trade-off between conductivity and strength, and it was a major challenge to achieve both.

Identify needs and lead the medical industry!
Pursuing copper alloy wire technologies to develop medical-grade micro-coaxial cables to make the impossible possible

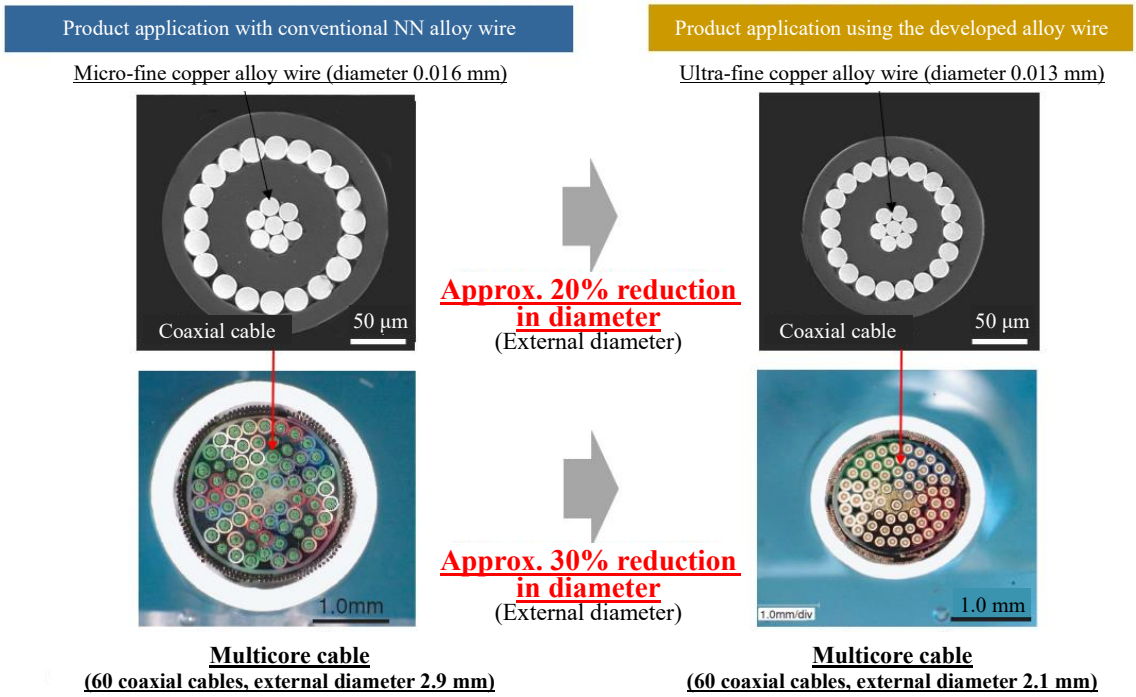
Although Hitachi Metals initially considered the application of existing NN alloy[*2] products, which offered high strength and workability, they did not reach the target conductivity, since conductivity decreased due to an increase in the solid solubility limit of the alloying elements.

Hitachi Metals therefore selected a copper-silver alloy—which was expected to deliver the necessary strength—and created a fine fibrous structure[*3] by optimizing the concentration of the alloying element silver (Ag) to achieve a high level of strength (suppressing the solid solubility limit of the alloying element to control the decrease in conductivity). However, although high strength was achieved, a large amount of processing strain accumulated in the fibrous structure, still resulting in a decline in conductivity.

By controlling the amount of strain in the micro-scale structure through the application of a new heat treatment process that removes strain in the processing of the material, Hitachi Metals was eventually able to achieve high strength while maintaining the high conductivity of the fibrous structure. With this pioneering, industry-leading new material technology, Hitachi Metals finally succeeded in the practical commercialization of fine-diameter cable for medical devices while at the same time maintaining the performance of each coaxial cable.



Human hair and 10 μm diameter copper alloy wire



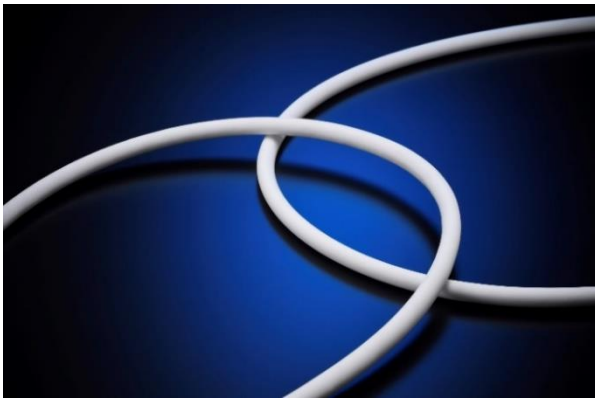
With the development of this product, in 2005, Hitachi Metals began providing high-performance materials in the medical field. Since then, Hitachi Metals has overcome high-level obstacles to contribute to medical needs in areas such as minimally invasive medicine and high-definition imaging. The quality and reliability of our products have been recognized and rated highly by many medical device manufacturers, our customers, and we have received messages expressing expectations for future development efforts.

The medical field, which is directly linked to human life, has extremely high-quality standards for equipment used. Hitachi Metals has earned the trust of medical device manufacturers around the world by responding proactively to these medical needs with high quality products that make the impossible possible and has led the market in cables for medical applications.

Medical cables are subject to very careful judgments over a certain certification period, from initial product development right up until they are adopted for use in medical devices. For this reason, Hitachi Metals must develop our products from a long-term perspective with an eye to the future. Hitachi Metals continues to engage in daily development efforts and provide solutions, as an unsung ally supporting people's health.

> Contributing not only to relieving the burden placed on patients, but also improving operational efficiency in the medical workplace!

Development of medical-use silicone cable SilMED®, also useful in preventing COVID-19 infections.



In medical diagnostic equipment, image quality is very important, since it can relate directly to the patient's life. Another key point is operability—ease of management and usability of diagnostic equipment in the medical workplace. Hitachi Metals has provided a new solution that dramatically enhances operability. That solution is the silicone cable SilMED.

Since medical devices demand measures against nosocomial (in-hospital) infections and require frequent disinfection, the adoption of silicone cables—which offer excellent chemical resistance, sterilization resistance and biocompatibility—is becoming increasingly widespread. However, silicone has also posed various issues in its use, such as difficulty in handling for medical professionals due to the stickiness of its surface, which makes it prone to attract dust and become dirty, and discomfort to patients due to the feeling of stickiness on their skin.

Hitachi Metals has achieved a high level of surface slipperiness by applying a unique treatment to the outer sheath of silicone cables.

With built-in micro-coaxial cable, SilMED offers advanced mechanical and transmission characteristics, making it possible to achieve the impossible—with both improved slipperiness of cable sheath and high chemical resistance.

Features of silicone rubber
- No discoloration
- Good biocompatibility
- Allows application of sterilization processes
- Stickiness → Can be resolved with Hitachi Metals' proprietary silicone rubber coating

Hitachi Metals' proprietary non-sticky silicone rubber

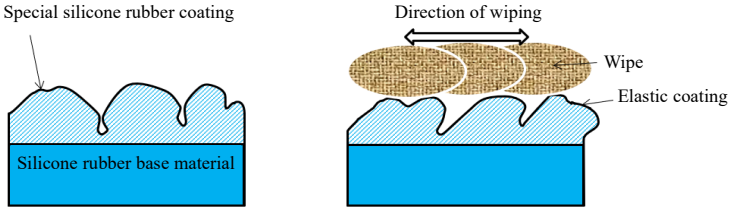


Figure: Cross-sectional schematic diagram of non-sticky silicone rubber

Going forward, by applying this product to various medical devices in applications such as ultrasound probe cables, endoscope cables and catheters—for which demand is expected to increase in the future—it will also be effective in preventing infectious diseases such as nosocomial infections.

■ Comments of development engineer of the medical cables

(Detian Huang, Ibaraki Works, Electric Wire & Cable business unit)

>> Do you have any interesting stories from your efforts in developing products for patients and medical professionals that you can share now?

One thing I have felt through my 20 years of participating in development efforts until now is that to be involved in the medical field means facing the future with sincerity. When I started my research in the early 2000s, I made my own predictions of what medical care would look like ten years later and felt my way along as I designed my image of the future. As a result of steadily gathering information from customers and other market stakeholders and thinking through how Hitachi Metals could approach the business field, my projections included the prediction that ultra-fine micro-cables would make an active contribution in terms of improving usability. I was conscious that the first issue to be addressed in order to achieve this was to create materials that matched the needs of medical care.

At the time, the former Hitachi Cable was taking the classic route of electrical wire manufacturers, using copper to produce and sell high-performance electrical wires. Because the company is a manufacturer with a firm belief in technology, however, the company also believed that it was important for their future to contribute to society by creating further added value through the efforts as a company.

At that time, the finest specification for cables applied to medical devices was a core wire diameter of 25 μm. While cables with a core wire diameter in the 10 μm-range were ideal for high-definition images, their application to medical care was a domain that no one could even imagine due to the high-level obstacles involved. Additionally, research and development for such wires required clean manufacturing site management that would allow not even the slightest bit of dust. Mass production would also require the same careful management for the entire manufacturing site, so there was great concern about the feasibility of developing such facilities. Even so, my team continued in the research and development efforts because my team believed that this research would be a force to support the company ten years in the future. Firstly, in materials research, which was the first task, my team succeeded in developing an alloy that fit the requirements for medical applications. That is the copper alloy material for the medical-grade coaxial cables introduced in this newsletter. Based on the development of this material my team was able to make the electrical wires thinner to fit medical needs, and the manufacture of ultra-fine micro-scale conductors with an outer diameter of 10 μm became a reality. Since then, my team has made use of this material in various applications and delivered numerous products to the medical workplace. Hitachi Metals' latest product, SilMED silicone cable, is one of them. My team has been aware of both the usefulness and challenges of silicone since the beginning of the development of medical cables, and I have been considering effective ways to improve the material to reduce stickiness and combat infectious diseases since that time. Although my team faced various hardships in the development of the product during the COVID-19 pandemic, including issues with communication between the development workplace and production locations, I am confident that it has become a product that is particularly useful in combating infectious diseases.

>> What were the key points and difficulties in the development of SilMED?

Cables with silicone sheaths have chemical resistance, but the sticky, adhesive nature of the surface has presented

issue. It can lead to discomfort when the cable touches the patient's skin, difficulty in handling by medical staff, and adhesion of dust to the surface. One key point in the development of SilMED was that Hitachi Metals was able to solve the problem of the surface stickiness of silicone using the own proprietary surface treatment, maintaining a high level of slipperiness even after 10,000 cable wiping tests, simulating disinfection in a hospital setting. In the early stages of the development, there was a difficulty in that slipperiness declined as the number of wipes increased. Hitachi Metals eventually succeeded in satisfying the condition of resistance to wiping 10,000 times by devising a surface structure shape that essentially absorbs the stress imparted by wiping with non-woven fabric impregnated with a disinfectant solution.

As was also true for the development of coaxial cable materials, I am not bound by the principle of dropping the trade-off condition when one condition is met. I strive to conduct research that makes the impossible possible, such as by overcoming difficulties and combining opposing characteristics.

>> What are the points that customers rate highly in Hitachi Metals products?

The characteristic technologies used in the creation of medical cables are copper alloy technology, for making materials used for conductors, and insulator coating technology, which is a production process technology. For many years, Hitachi Metals' workers and engineers in the manufacturing workplace have created these technologies by grasping the needs of medical professionals and customers, and I am confident that Hitachi Metals is one of the top-class manufacturers in the business field.

With this development history and the high reliability and quality of Hitachi Metals' products, customers and medical professionals have displayed expectations for Hitachi Metals' R&D capabilities and future potential to always be able to propose new solutions, and I feel that Hitachi Metals has been able to build trusting relationships with them as a partner. In particular, my team is mindful of the research stance of not rushing to achieve results, but approaching things steadily from a long-term perspective, and an eye to the future beyond. Hitachi Metals strives to engage in steady research efforts on a day-to-day basis, as a member of the team supporting medical care that helps people.

Hitachi Metals' supply capabilities and ability to respond in times of emergency has also been rated highly by customers. Hitachi Metals regards the supply of products to medical sites that are directly linked to human life as a great social responsibility. Hitachi Metals has created a system to supply the necessary quantities of products when needed, and do not fail to coordinate with customers as necessary.

I believe that Hitachi Metals will be able to deepen the trusting relationships with the customers by continuing to work closely with them going forward, thoroughly understanding their needs and making proposals that continue to tackle challenges together with customers so that they can reliably achieve their goals, without considering the choice of saying we "cannot do" something.

>> What are your future plans for the widespread popularization of SilMED and other future product development trends?

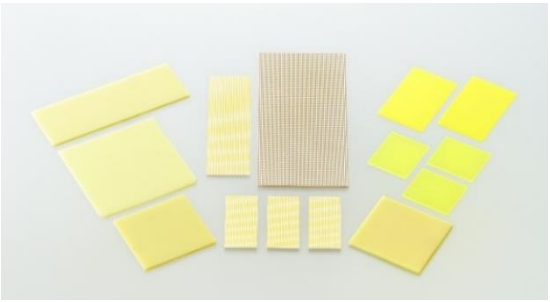
With Hitachi Metals' strengths in coaxial cable technology, created using the copper alloy technology, I expect to expand into a wide range of minimally invasive medical technologies which include catheters, lung ultrasound, rigid endoscopes, and next-generation gastrointestinal endoscope applications—contributing to reducing the burden placed on patients and medical professionals alike. Hitachi Metals is also planning to apply it to equipment for COVID-19 diagnoses.

In the future, I aim to penetrate the global market with this product as a new ultra-fine copper alloy wire developed in Japan and contribute as a product that facilitates minimally invasive medical technologies that support medical professionals and patients in many countries and regions, and from a wide range of age groups. Going forward, Hitachi Metals will train human resources with the spirit and skills needed for implementing reform and who can be constantly mindful of the future. At the same time, Hitachi Metals will work to establish a development system for identifying and understanding the needs of patients and medical professionals, as Hitachi Metals continues in the efforts to lead the business field and make the impossible possible.

Hitachi Metals continues to constantly provide solutions for the future, looking ahead many years from now and imagining ideal solutions for both patients and medical professionals. This is the essence of Hitachi Metals' business of tackling issues in medical care. With their pioneering spirit and dedicated efforts, Hitachi metals' developers and manufacturing personnel have continued to make the impossible a reality, supporting people's lives and health from the bottom up.

Below, the newsletter introduces another representative product that takes into account the burden placed on patients.

> Ceramic scintillator arrays: contributing to the improvement of the image quality of CT machines for early detection of disease indicators



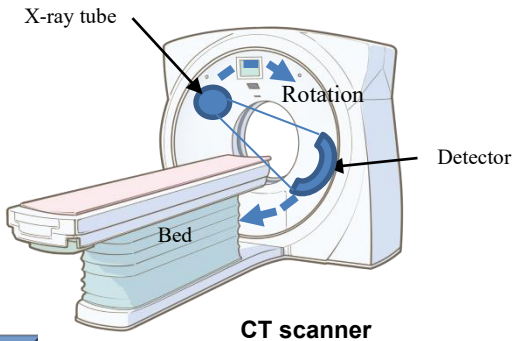
Ceramic scintillator arrays

A scintillator is a substance that absorbs energy and emits visible light when exposed to radiation, such as X-rays and gamma rays. A scintillator array is a product in which scintillators are arranged to correspond to a detector. Scintillator arrays are mainly used in medical equipment such as X-ray CT scanners, analysis equipment, non-destructive testing equipment using radiation and radiation leak inspection equipment. Hitachi Metals offers a lineup of high-density, high-performance ceramic scintillator arrays.

Key features of our high-performance ceramic scintillator arrays—which contribute to the improvement of CT scan image quality—are as follows.

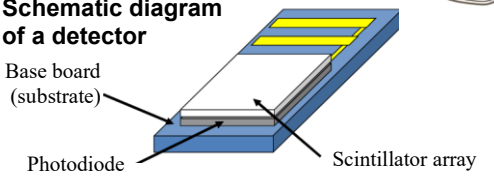
- Scintillator array elements are finely sized → CT scan image resolution is high
- Light emission output of the scintillator array is high (the elements shine brightly) → CT scan images are clear with high contrast
- Light emission output of each element in the scintillator array is uniform
  (there are no defects such as discoloration, scratches, voids, element misalignment or warping)
  → minimal disruption of the CT image
- Low afterglow after X-ray irradiation → less residual image in CT images

Higher performance of scintillator arrays leads not only to higher image quality but also to lower radiation exposure for patients. The maximum radiation exposure in CT imaging is around 10 mSv per dose. Exposure of 100 mSv or more per year also leads to an increase in the risk of cancer in patients, so minimizing exposure is a key requirement. At the same time, the higher the amount of X-ray irradiation (exposure) used to produce a CT image, the higher the image quality will be. When a high-performance scintillator array is used in a CT scanner it contributes to reducing the burden placed on the patient's body—such as by enabling higher image quality to be obtained with the same amount of X-ray irradiation as before or obtaining the same image quality with a smaller amount of X-ray irradiation.
Currently, Hitachi Metals is aiming to further improve the image quality of CT images using this product. Efforts are also being made to colorize monochromatic CT images (using composition analysis by multi-colorization of X-rays). In this way, Hitachi Metals will contribute to the further advancement of medical care making what was impossible until now a reality, such as making signs of disease easier to identify.



CT scanner

Schematic diagram of a detector



In addition to the products introduced this time, Hitachi Metals also offers numerous other product lineups (introduced on pg.1).

Hitachi Metals is not limited to simply being an extension of its business to date. Hitachi Metals is refining their product capabilities to open up new possibilities for the future by proposing ideas that anticipate the needs of society and customers' end products, and by creating product value through innovation in manufacturing processes. Going forward, Hitachi Metals will continue to make every effort to improve the quality of the products and enhance technologies that will enable the company to lead the business field and meet the needs of the customers better than ever before, thereby contributing to the development of society.

Inquiry contacts for the press: Corporate Communications Department, Hitachi Metals, Ltd. hmcc.sa@hitachi-metals.com

References:

*1. Minimally invasive medical treatment: Medical procedures that reduce the physical burden and impact of treatment on patients' bodies.
*2. NN alloy: Our copper-tin-indium alloy. It can be manufactured at fine diameters.
*3. Fibrous structure: A state in which the crystalline structures in the metal are miniaturized. When the structure is squeezed and narrowed down by pressure during the wire drawing process, the strength of the entire structure—including the mother phase—increases dramatically.

About Hitachi Metals NEWSLETTER

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Stories are aimed at enabling many readers to gain in-depth understanding.
We hope that this communication tool will help you gain a better understanding of the Group.