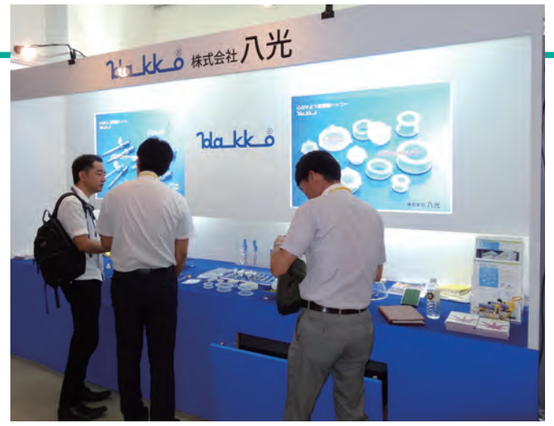
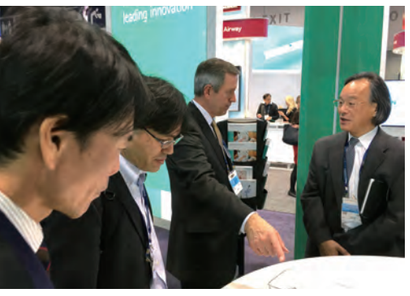
More accurate information to the medical field

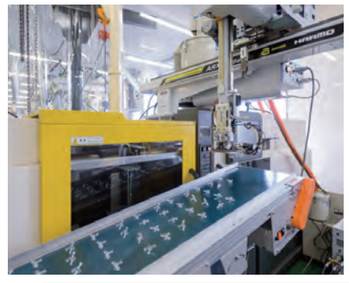
Our responsibilities are provide the information related to new medical technologies that contribute to improving patient quality of life and reducing the burden on healthcare professionals, and timely safety information to prevent health hazards by mitigating any invasiveness associated with medical practices. Our motto is “providing more accurate information faster to medical field through daily MR (Medical Representative) activities, academic conferences, exhibitions, and our Hakko websites.



More global

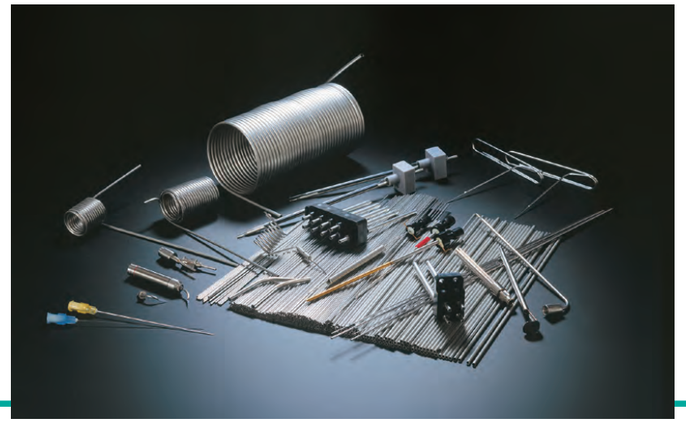
With a quality management system compliant with the global standard ISO13485 as the core, it also meets the requirements of the US Quality System Regulations, the European Medical Device Directive, the Korean GMP, etc. Clearing inspections by the US Food and Drug Administration (FDA) and the Korea Food and Drug Administration, and unannounced audits of European Notified Body, the company has expanded its sales channels worldwide.
We are also preparing to a new international QMS program in anticipation of global harmonization.

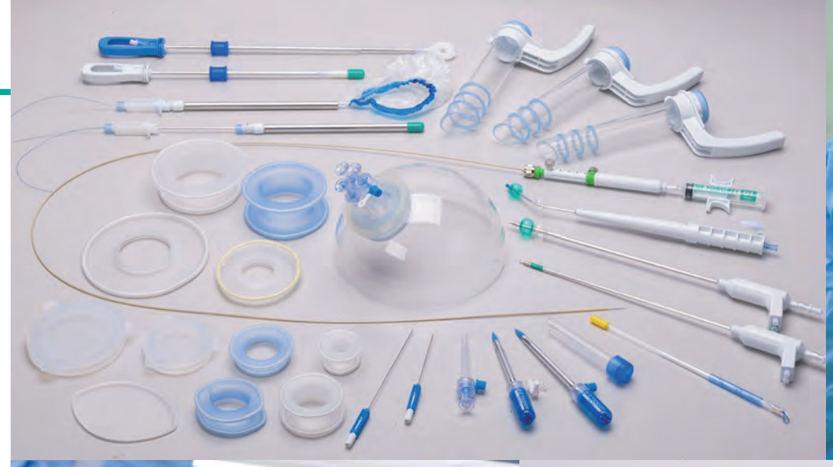




Transfer Medical device technology to other industrial fields

Various products produced by manufacturing and processing technologies for stainless steel tubes developed for medical use are actively used in the general industry due to their high quality and precision.The processing technology for precise plastic molds is widely used not only in the medical equipment field but also in the electrical and electronic fields.





Hakko Co.,Ltd. Medical Device Division

http://www.hakko-medical.com

Medical device with connecting heart

Our Mission
The medical division boasting high technological capabilities cultivated as a pioneer of single-use medical devices business has continued to provide original medical devices that accurately meet market needs since its establishment, and has been highly evaluated in Japan and overseas. Established a flexible innovative system in the head office factory that can quickly respond to new needs in the medical field as medical technology advances.Highly reliable medical device is manufactured by hand-made from the production line set up in a clean environment required by ISO13485(International standard for medical equipment quality management system).

With GLP (Good Laboratory Practice) facilities to provide safety and security, our mission is to be a value-creating company with the theme of “Medical device with connecting hearts together”.

Masaru Maruyama
Chairman

2017.01.01

Aiming to develop original and reliable medical devices

By developing original and reliable minimally invasive medical devices, we contribute to the improvement of patients' QOL and medical development.In order to accurately grasp the new needs of medical devices that are required as medical technology advances and to quickly deliver products from the patient's standpoint, close collaboration with medical sites is essential.We aim to make progress on a daily basis by closely exchanging information with medical professionals who are at the forefront, and we devote ourselves to creating novel product with unwavering efforts.

Providing products that are trusted in a clean environment and advanced quality system to the medical field

Under the advanced management system, Hakko's medical devices manufactured in a clean environment backed by ISO13485 * certification are highly evaluated both in Japan and overseas.

* ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is an International Organization for Standardization (ISO) standard.

Pursuing safety and ensuring reliability

Safety required for medical devices! We are making extra effort to ensure the safety of our products. The GLP test facility, which was established in the hope of delivering safe, secure and effective medical devices to patients as soon as possible, passed conformance test by the Pharmaceuticals and Medical Devices Agency in 2006. We have an in-house system for biological tests (GLP tests) necessary for obtaining manufacturing approval, such as cytotoxicity tests, sensitization tests, intradermal reaction tests, and acute systemic toxicity tests in accordance with ISO10993*.
We also equipped with FTIR, gas chromatography, atomic absorption analyzers, etc., and make every possible effort to ensure the chemical stability of products as well as to confirm the quality of parts material.

* ISO10993: International standard for biological testing of medical devices