Japan

Using GS1 standards to trace surgical and dental instruments

Challenge

There are around 40,000 surgical instruments at Tokyo Medical and Dental University Hospital. Keeping track of these by visual inspection presented problems from a risk management and workload perspective. Indeed the hospital had experienced recurring issues in managing the instruments, including the loss of important devices such as dental handpieces.

Approach

The hospital has acquired its own GS1 Company Prefix and directly marked a GS1 DataMatrix encoding GS1 Global Individual Asset Identifier (GIAI) on all 40,000 surgical instruments, including dental equipment such as handpieces. This has made it possible to track and trace items.

86% reduction in the time required to set up surgical instruments

No dental handpieces lost since the implementation of GS1 standards

Achieved in-hospital traceability of surgical instruments

Increased staff productivity and improved patient safety

Introduction

Tokyo Medical and Dental University Hospital has achieved in-hospital traceability of all surgical instruments by scanning GS1 DataMatrix barcodes directly marked on the instruments. This has enabled the hospital to visualise the use histories of the instruments. Using GS1 standards in this way has helped to reduce staff workload, prevent instrument loss, and to enhance patient safety. Work is now underway to further improve single-use medical devices (SUDs) management in the hospital, including through the implementation of RFID to support digital transformation.

Using GS1 barcodes on surgical instruments

In Japan, the revised Pharmaceutical and Medical Devices Act came into effect on December 1 2022, mandating GS1 barcode marking on the packaging of pharmaceuticals and medical devices to ensure traceability. However, the law does not currently include marking on medical devices itself or direct marking.

At Tokyo Medical and Dental University Hospital, staff manage approximately 40,000 surgical instruments. Traceability for those instruments had relied on visual inspection by staff and paper records. This caused problems from both a workload and risk management perspective, considering the complicated processes involved in the use of instruments – including inspection, cleaning, assembly, sterilisation, storage, and distribution (see Figure 1).

Hideo Kubota, the director of the hospital's central supply department, has addressed this by obtaining a GS1 Company Prefix and directly marking all surgical instruments with a GS1 DataMatrix barcode encoded with the GS1 Global Individual Asset Identifier (GIAI).
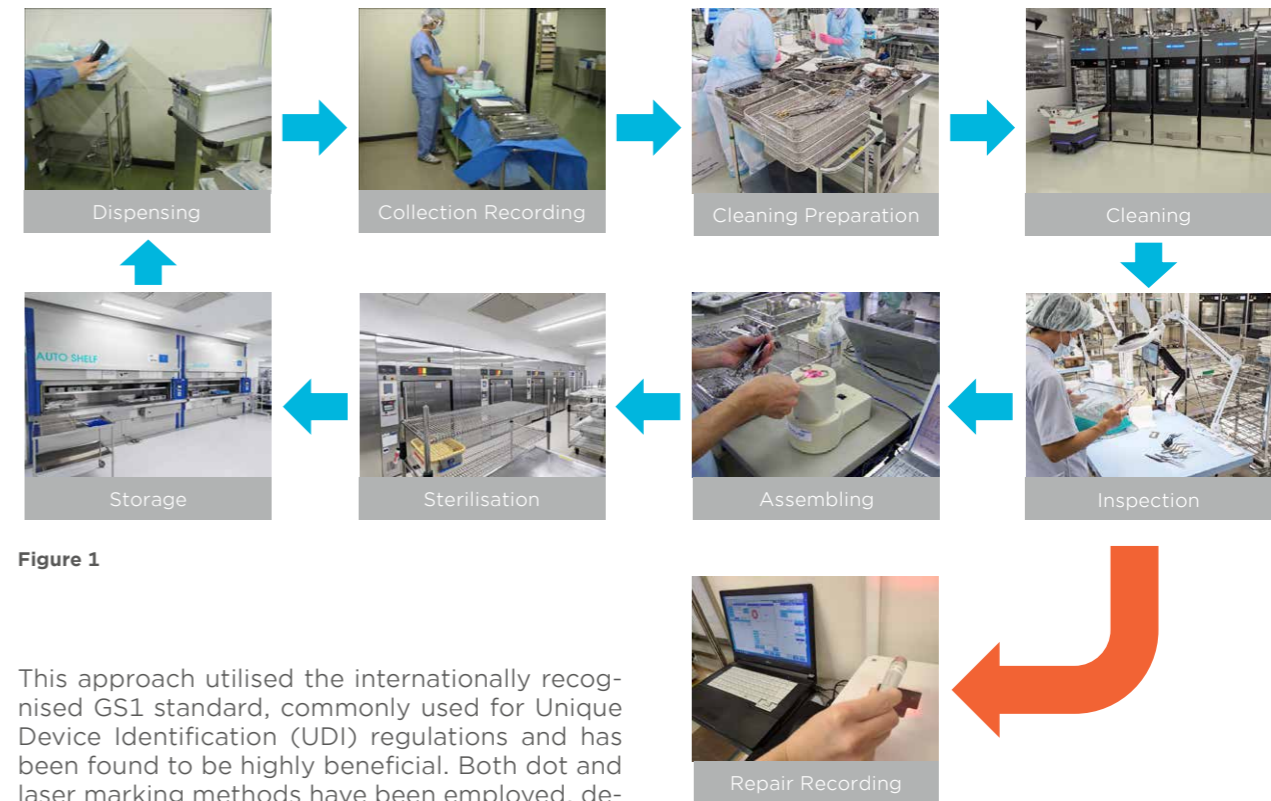
Figure 1

Dispensing → Collection Recording → Cleaning Preparation → Cleaning → Inspection → Assembling → Sterilisation → Storage

Repair Recording

This approach utilised the internationally recognised GS1 standard, commonly used for Unique Device Identification (UDI) regulations and has been found to be highly beneficial. Both dot and laser marking methods have been employed, depending on the instrument's shape.

With the implementation of a GS1 DataMatrix directly marked on surgical instruments, the sterilisation process has become more efficient and accurate. When instruments are returned from a theatre after a surgery, the GS1 DataMatrix on the instruments is scanned to ensure all items have been collected. During the assembly of surgical sets, the GS1 DataMatrix on every required instrument is scanned and automatically verified against the preparation list displayed on the PC screen. If the wrong instrument is then scanned before the procedure, the subsequent steps in the process cannot be performed.
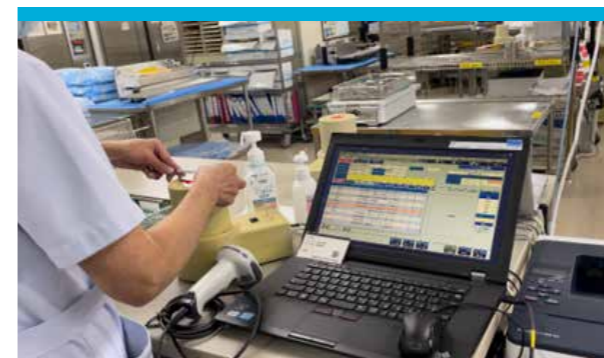
The hospital uses the barcodes to link instruments, staff, and facilities. During the cleaning and sterilisation steps, barcodes are affixed to the cleaning machines, sterilisation machines, and to the case of the assembled set. Barcode scans are used to establish links between the instruments that need to be cleaned or sterilised and the machine. Before surgery, the nurse also

> *"Surgical instruments must undergo complicated sterilisation processes, so they should be managed with GS1 standards."*
>
> **Hideo Kubota,**
> Director of Central Supply Department, Tokyo Medical and Dental University Hospital

scans the barcode on the set, along with the barcode on the surgical request form, which contains encoded patient information data. Additionally, the staff ID barcode is scanned before these processes to record who is responsible for the work.

Patient safety has been increased through improved traceability, and the system has streamlined and standardised the workload of the staff, leading to increased efficiency.

GS1 barcodes on dental handpieces

Building on the success achieved in the medical hospital, GS1 standards have also been implemented in the dental hospital.

The hospital directly marked a GS1 DataMatrix encoding GIAI on every handpiece for individual identification management. Additionally, unique

codes were assigned to each dentist to whom handpieces are distributed. During the supply process, a handy terminal is used to scan the barcode on the handpiece label, along with the dentist ID barcode, linking them together. Similarly, after surgery, the directly marked GS1 DataMatrix is scanned to record the device's collection during the sterilisation process.

This implementation of GS1 standards in the dental field, specifically utilising GIAI, was likely the first of its kind in Japan. This comprehensive tracking system has allowed for the recording of the distributing details for any device, including when, to whom, where, and what was distributed. Before GS1 implementation eight of the 741 dental handpieces had been lost over a period of 18 months. The number of lost handpieces fell to zero within the first 18 months of operation of the new system. During this period there were 24 instances in which the handpieces were misplaced. However, the system could track their users and narrow down the search locations, and so all were soon found. The barcode scanning process has also streamlined routine tasks such as checking inventory counts, significantly reducing the time required.

Currently, the system is operational only in the outpatient department, but there are plans to expand its implementation to the entire dental department.

> "Hospitals need to know where and how much of each disposable items is in stock, when and by whom it was used, and the GS1 standards are an effective identifier for the purpose".
>
> **Hideo Kubota,**
> Director of Central Supply Department, Tokyo Medical and Dental University Hospital

RFID utilisation and the data flow

To further advance digital transformation and improve the efficiency of total SUDs management, the hospital is now also using RFID technology.

RFID tags are attached to SUDs at the hospital, so reducing the workload of management staff. After being used in surgeries, empty SUDs packages are discarded in a designated waste bin equipped with an RFID scanner.

The SUDs information is then sent to the hospital's logistics system, where they are linked to the GS1 barcode data of the respective SUDs for simplifying the recording process. This approach ensures traceability of the SUDs used, while also streamlining data preparation for insurance claims.

The visualisation of SUDs data enables the hospital to access detailed information, such as which SUDs were used in specific procedures, the number of products used, products that remain unused, and unexpected usage patterns that deviate from the manufacturer's expectations. Data is uploaded to the cloud, and this information used for automatic SUDs ordering and providing feedback to manufacturers to enhance product development. The data obtained from RFID scanning is recorded in the hospital's logistics

system, and consumption data is registered by cross-checking with master data. When the inventory quantity falls below a predetermined threshold, an automatic order is placed with the manufacturer. Additionally, SUDs usage data is integrated with surgical data, and the frequency of SUDs usage is stored for reference. Required information can be extracted from this data and uploaded to the cloud for sharing with manufacturers.

By incorporating RFID technology and utilising cloud-based data analysis, the hospital is optimising its total SUDs management, improving inventory control, and fostering collaboration with manufacturers for continuous improvement and innovation of product developments.

> "Source tagging by GS1 standards has begun in Japan, mainly for orthopaedic materials by manufacturers and I hope in due course for other items as well".
>
> **Hideo Kubota,**
> Director of Central Supply Department, Tokyo Medical and Dental University Hospital

Next steps

In January 2025, the hospital's master system will be replaced and medical and dental master data will be integrated. As part of this change, the hospital aims to eliminate the use of paper and embrace GS1 standards in inventory management. This will ensure accurate tracking of materials usage histories and efficient inventory control.

The adoption of GS1 standards has enabled the hospital to visualise the frequency of instrument usage in each surgery. The hospital intends to share this information with manufacturers. This feedback aims to encourage the development of better products, while also generating additional revenue for the hospital via a fee to access the data.

Conclusion

By implementing GS1 standards, the hospital has reduced staff workload and enhanced patient safety. GS1 standards have ensured traceability for each instrument, including information on which instruments were used, when, and by whom. The time required for setting up surgical instruments has been reduced by 86%, and errors have been eliminated. The visualisation of each instrument's usage status has been accomplished and reduced the number of unnecessary instrument setups by 12%.

About the author

Hideo Kubota
Director of Central Supply Department, Tokyo Medical and Dental University Hospital

Hideo Kubota is leading the implementation of the GS1 standards as a Director of Central Supply Department at Tokyo Medical and Dental University Hospital. He has more than 15 years' experience in the field of medical material management and has established traceability systems for surgical instruments and SUDs in cooperation with many solution providers. Outside of the hospital, he is actively involved in writing articles and giving lectures related to the utilisation of GS1 standards and is also a board member of the Japanese Society of Medical Instrumentation.

About the organisation

Tokyo Medical and Dental University Hospital
Tokyo Medical and Dental University Hospital is a national university hospital located in Tokyo and is well-known as one of the most advanced hospitals in Japan. It consists of medical and dental hospitals, with a total of 813 beds. There were 7,794 medical surgeries and 961 dental surgeries performed at the hospital in the 2022 financial year.

www.tmd.ac.jp/medhospital/english