

Case Study: Integrated sterilization management system using GS1 standards in University of Fukui Hospital Surgical Center



Since 2014, University of Fukui Hospital had focused on the cost-effective management of its surgical operations by using GS1 standards. The hospital has successfully achieved the traceability of surgical instruments in its surgical center's sterilization process by identifying each of 20,000 instruments with the GIAI (Global Individual Asset Identifier) encoded in a laser-engraved GS1 DataMatrix. To date, the Hospital has reduced the error rate along with the time required when assembling instruments for surgical operations by 2,000 hours per year. The Hospital is the first hospital in Japan to use GLN (Global Location Number) to identify each of its locations. By using GLNs as part of its surgical container setting system, they reduced overall operation time by 500 hours per year.

Aiming to ensure the safe use of instruments

There had long been calls for safety management of surgical instruments using two-dimensional barcodes from the perspective of preventing surgical instruments from being left in a patient's body as well as eliminating any concerns about

infections via contaminated surgical instruments, especially triggered by Creutzfeldt-Jakob disease. With the aim of ensuring the safe use and traceability of instruments, the Japan Association of Medical Devices Industries (Jamdi) released the *Guideline for Marking for Two Dimensional Symbol on Steel Instruments* in 2006. This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of GTIN (Global Trade Item Number) plus serial numbers and direct marking with GS1 DataMatrix. However, direct marking on surgical instruments by manufacturers has not yet reached satisfactory level.

Outline of University of Fukui Hospital and adoption of GS1 standards

University of Fukui Hospital is located in the Fukui region of Japan with a population of around 400,000. It is the central hospital of the region with 600 beds and approximately 5,000 surgical operations performed annually.

From 2010 to 2014, the hospital was preparing to

Fig. 1 GIAI on steel instruments



relocate its wards—the Surgical Center and the Central Sterilization Department—to a new building. During this period, the hospital introduced the “Integrated sterilization management system,” which through unique identification ensures traceability of steel instruments, for enhancing patient safety and the quality of infection control.

This system enables the linkage of patient IDs, surgical operation schedule and surgical instruments information within a hospital information system. For the identification of surgical instruments and sterilization related equipment, the hospital decided to adopt GS1 standards and obtained GS1 Company Prefix.

Adoption of the GIAI and GLN

University of Fukui Hospital adopted the GIAI as an identification key and the GS1 DataMatrix as a data carrier for UDI on steel instruments. The hospital has a laser-marking machine in place, which marks steel instruments with GIAI encoded in GS1 DataMatrix (Fig. 1). At the beginning of the system, the number of steel instruments marked with GS1 standards totalled approximately 18,000. The hospital spent nearly one year on the direct marking and registration of all instruments in the hospital database.

They have also adopted GLNs to identify locations. GLNs are assigned to each operating room, every location in the surgical container storage cabinet that accommodates sterilized containers and items, fixed shelves and storage

Fig. 2 The surgical container storage cabinet assigned GLN



racks at the hospital wards, and more (Fig. 2). In total, more than 1,000 of the hospital’s locations have GLNs.

The integrated sterilization management system

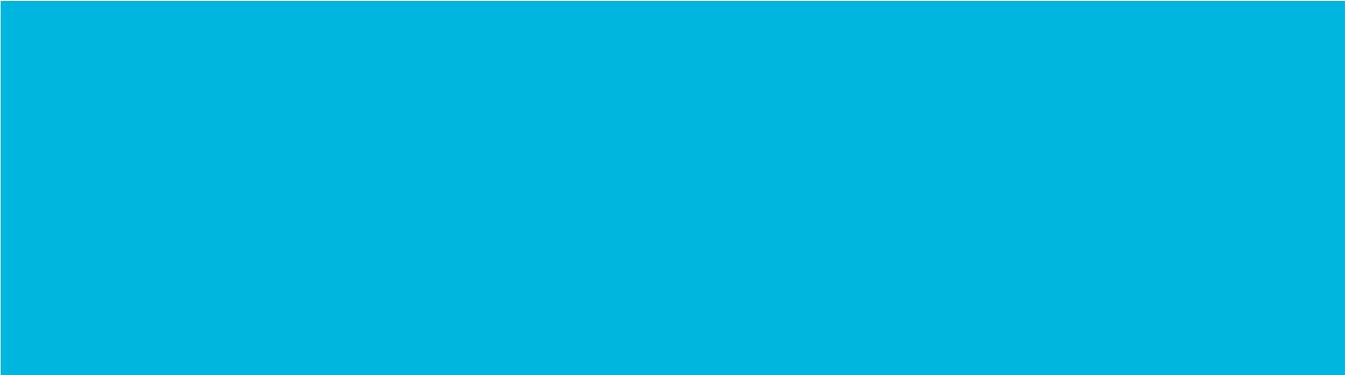
The workflow of the integrated sterilization management system is illustrated in Fig.3. By using portable digital devices, the system allows them to manage information during each step of a surgical operation: the collecting, cleaning, sterilizing and storing the surgical instruments along with preparing for operations.

As shown in Fig.3, the GS1 DataMatrix that is directly marked on each steel instrument is read twice—during the collection step after a surgical operation and during assembly.

University of Fukui Hospital has scanned the GS1 DataMatrix more than 2 million times in 3 years. By scanning barcodes, they can obtain various information about their sterilization process which achieves safer and more efficient care.

Benefit

Specific benefits of the new system using GS1 standards include improved medical safety measures by ensuring traceability on individual steel instruments. This includes the prevention of leaving surgical instruments in a patient’s body, the prevention of errors in counting, the more precise assembly of surgical sets, and the prevention of loss and unauthorized takeout. The system also enables easy analysis on the frequency of use or turnover as well as the status of stock instruments at piece and set levels,



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