

# Publication of the Direct Marking Operations Guide for Medical Devices



GS1 Healthcare Japan published “Surgical Instrument Marking Operations Guide” in 2011. Since then, Unique Device Identification (UDI) regulations have been implemented globally, while direct marking technology has improved. Based on these situations, GS1 Healthcare Japan newly published “Direct Marking Operations Guide for Medical Devices” in 2017.

## 1. What is direct marking?

Direct marking is the process of marking a symbol directly onto an item using intrusive or non-intrusive method instead of applying a label or using another indirect marking process.

Direct marking is used for products such as those below;

- (1) Products that are extremely small and have significant space constraints to place a barcode label on them,
- (2) Products that are intended reprocessed and reused.

Most medical devices are reused repeatedly after

cleaning and/or sterilization. If a barcode label is pasted on those products, there is a risk of peeling-off from a product during a surgery and being left inside a patient’s body. For the reasons above, direct marking is being adopted worldwide for medical devices, especially for surgical instruments.

Fig. 1 Direct Marking Operations Guide for Medical Devices



## 2. What is required to introduce direct marking?

Proper assignment of GS1 identification keys, appropriate marking methods, and a full understanding of reading equipment are necessary for direct marking. Therefore, the new guide mentions the latest information on the above points. In addition, the guide includes use cases of several medical institutes that are improving their medical safety and efficiency using direct marking on surgical instruments.

## 3. Use cases of Direct Marking at Medical Institutions

The guide shows two cases of medical institutes that implemented GS1 Standards and direct marking: NTT Medical Center Tokyo and the University of Fukui Hospital.

### 1) NTT Medical Center Tokyo

In 2011, NTT Medical Center Tokyo obtained GS1 Company Prefix to mark Global Individual Asset Identifiers (GIAI) on its endoscope components using GS1 DataMatrix.

At the hospital, GIAIs on endoscope components are read at the assembling process before sterilization and the collection process after surgery. These processes enable the hospital to assemble the components properly and record the use history of all endoscope components for each operation.

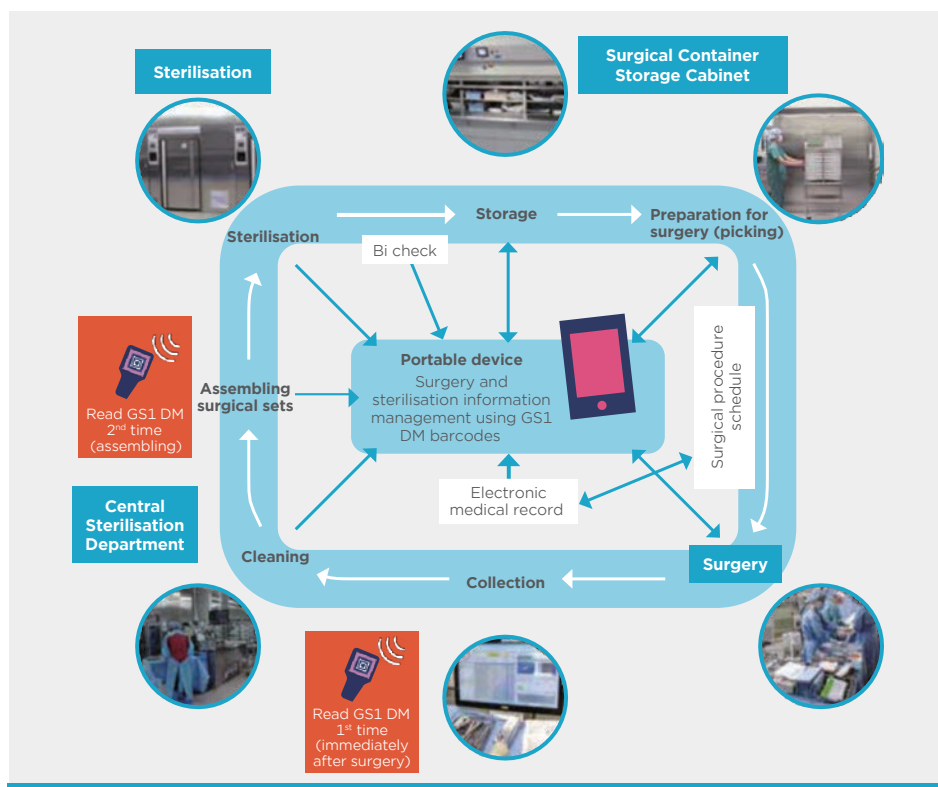
Thanks to the use history, the hospital could reduce the number of instruments prepared for surgery and avoid unnecessary sterilization which could hasten the deterioration of instruments. In addition, the information improved inventory management by appropriate component exchange and purchase schedules.

### 2) University of Fukui Hospital

University of Fukui Hospital implemented an integrated sterilization management system when the hospital moved its wards, the surgery division, and the sterilization control division into new buildings in 2014.

The hospital uses GIAI for accurate identification of surgical instruments and Global Location

Fig. 2 Workflow of the Integrated Sterilization Management System



Numbers (GLN) for location control.

University of Fukui Hospital installed a special storage cabinet to store surgical instruments. The cabinet automatically rotates and stops at the position where the necessary instrument is stored. The cabinet has 600 shelves and GLNs are allocated to them to identify their location. The usage of GIAI and GLN enables the hospital to securely manage instrument and significantly reduce working hours.

#### **4. Conclusion**

With more and more countries/regions adopting UDI regulations, direct marking is expected to be used globally in the future. GS1 Healthcare Japan makes efforts to deliver appropriate methods of direct marking in accordance with GS1 standards. In addition, GS1 Healthcare Japan will promote the use of direct marking at healthcare facilities to improve patient safety and efficiency of healthcare services.



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