GS1 Japan

The Global Language of Business

GS1 DataMatrix Direct Marking Guideline for Surgical Steel Instruments

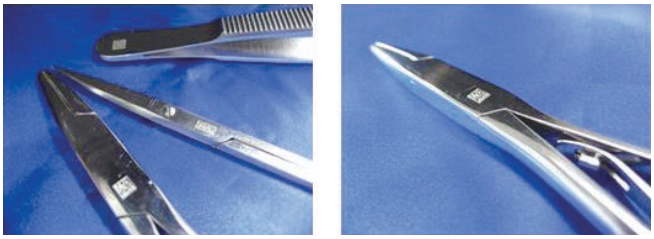
The Japan Association of Medical Devices Industries (JAMDI), a member of GS1 Healthcare Japan, released the "Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments (ver.1.2)" in July 2015. This guideline shows the recommended methods for manufacturers to mark their products, as well as helps medical institutions to mark the instruments inside hospitals (in-hospital marking). The guideline was introduced at the GS1 Global Healthcare Conference in Budapest in October 2015.

Background

A lot of surgical steel instruments are arranged and used in an operation. Preparation of correct instruments and complete sterilization of them are essential to patient safety. Direct marking, which enables the identification of each instrument, is expected to contribute to improve reliability for these processes. Furthermore, direct marking enables traceability of each instrument and the traceability will enhance both patient safety and cost efficiency, by preventing instruments remaining in a patient body after an operation,and reduction of unnecessary instruments etc.

The necessity of direct marking for medical devices including steel instruments are described in the UDI (Unique Device Identification) guidance of IMDRF (International Medical Device Regulation Forum) and the U.S. FDA (Food and Drug Administration) UDI rule.

Fig. 1 GS1 DataMatrix directly marked on steel instruments



Outline of the Guideline

This guideline was written for the direct marking method on surgical steel instruments such as forceps, knives, scissors, complying with the rules of GS1 standards and in the consideration of long-term repetitive uses of marked instruments.
The guideline consists of the following sections.

1) Introduction
2) Conditions necessary for direct marking of

two-dimensional symbols on steel instruments
3) Material suitable for marking and marking methods
4) Surface finishing and marking qualification for steel
5) Various marking and their adequacy
6) Marking quality
7) Attentions for marking technique
8) Manufacturing responsibility and user responsibility associated with marking
9) Companies that provides cooperation to prepare this guideline and their devices

Key Points of the Guideline

There are 18 of direct marking methods described in ISO/IEC TR24720 (Information technology - Automatic identification and data capture techniques - Guidelines for direct part marking (DPM)). Of these methods, the laser method and the dot peen method were selected for the guideline, because of their durability.
Some examples of the technical recommendation are as follows.

1) Marking a 3 to 5 mm square for GS1 DataMatrix of 18 x 18 cells. In this case, the minimum cell size becomes a 0.166 mm square.
2) Marking with n-by-n dots per one cell, because a precise marking technique has been established.
3) Marking with a depths of approximately 10 μm on a flat surface.
4) Rectangular symbol is suitable for thin rod-shaped instruments.
5) Marking a symbol on two surfaces, usually on the both sides of an instrument.

Fig. 2 Square and rectangular symbols of GS1 DataMatrix

a) When 3 mm or more square of marking area is assured.

b) When 3 mm square of marking area cannot be assured due to its shape

Utilization at Hospitals

Surgical steel instruments marked according to the guideline have already been used in several medical institutes. At present, it is usual that steel instruments are marked by each hospital (in-hospital marking).
Therefore, the hospitals use their own GS1 Company Prefix to identify the instruments with GIAI (Global Individual Asset Identifier) for example at NTT Medical Center Tokyo and University of Fukui Hospital. They use the dot peen method.
Direct marking on steel instruments are expected to increase as a result of expansion of UDI regulation all over the world. This guideline will support manufacturers corresponding to these regulations.
The guideline in English is on JAMDI web site.
http://www.jamdi.org/business/index_en.html

Fig. 3 Mr. Murata, the chairman of JAMDI DPM committee, introducing the guideline at GS1 Global Healthcare Conference in Budapest

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