

# Direct Part Marking on Steel Instruments in Japan



**Chairman of DPM Committee, JAMDI**

**Akio Murata**

# History of standardization for Barcode Marking

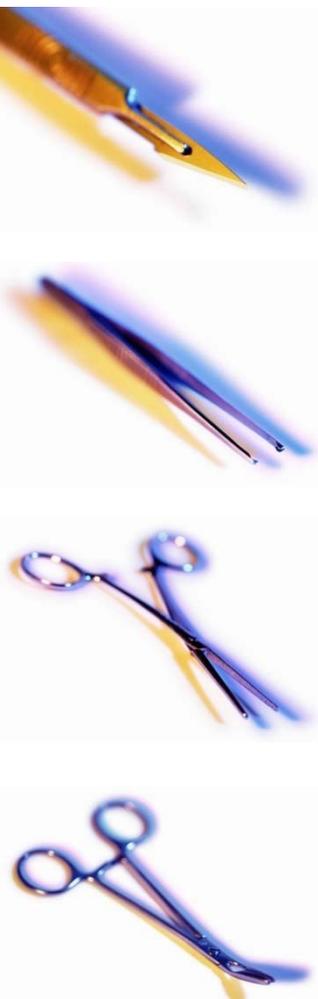
Guidelines for Standardizing Product Codes & Barcodes for  
 Medical/Surgical Materials in Japan  
*by JFMDA (The Japan Federation of Medical Devices Associations)*

- 1999 Released
  - 2000 Manual for the Guidelines (ver. 1)
  - 2002 Manual for the Guidelines (ver. 4)
  - 2005 Manual for the Guidelines (ver. 5)
  - 2006 Nov. **JAMDI issued Guideline for the indication of two dimensional (2D) symbol on steel instruments**  
JAMDI: Japan Association of Devices Industries
  - 2007 Sept. MHLW invited public comments on the draft Notification.
  - Oct. GS1 HUG and GS1 Japan submitted comments.
  - 2008 Mar. MHLW issued Notification
- ## for Bar Coding on Medical Devices
- MHLW (Ministry of Health, Labour and Welfare)
- 2008 Apr, **Manual for the Guidelines (NEW )**



Manual

# 2-D Direct Part Marking on Steel instruments



Guideline for the indication of two dimensional (2D) symbol on steel instruments

Guideline issued November 2006 by JAMDI

Objectives: Patient safety, Traceability/Recall & Asset Management

Metal Apparatus:

Made of stainless, aluminum, copper alloy, titanium, ceramics, etc.

Used for operation, medical treatment, etc.

Symbol: Data Matrix (ISO/IEC 16023) ECC 200  
or QR Code (ISO/IEC 18004)

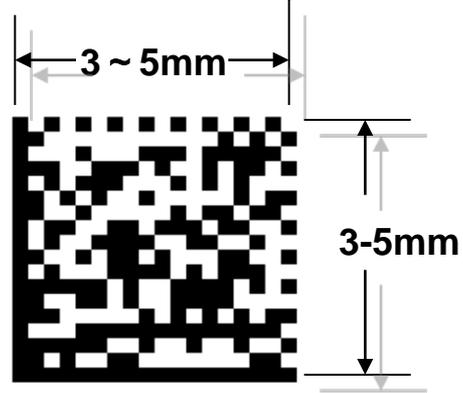
Data : AI (01) 14 digits GTIN  
AI (21) 8 digits Serial No.

**Two symbols !**

# Guideline for the indication of two dimensional (2D) symbol on steel instruments (DataMatrix)

*(a) 3mm square or larger space can be secured for indication*

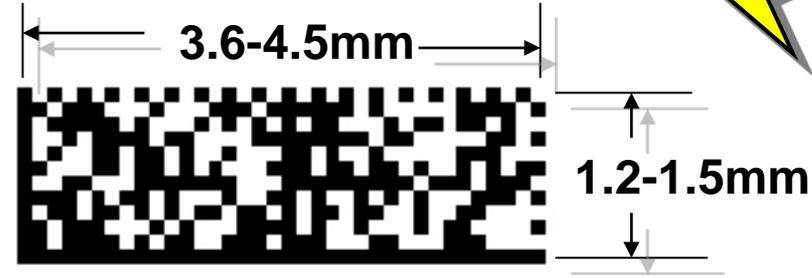
**DataMatrix ECC200**  
26byte, 3mm  
18×18、 0.166mm/cell



**X-module=0.166mm**

*(b) Steel instruments in bar shape on which 3mm square indicator cannot be affixed.*

**DataMatrix ECC200**  
26byte,  
12×36、 0.1mm/cell

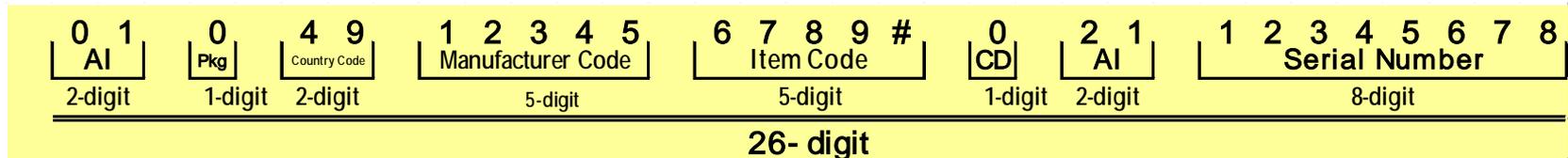


**Extra small steel instruments**

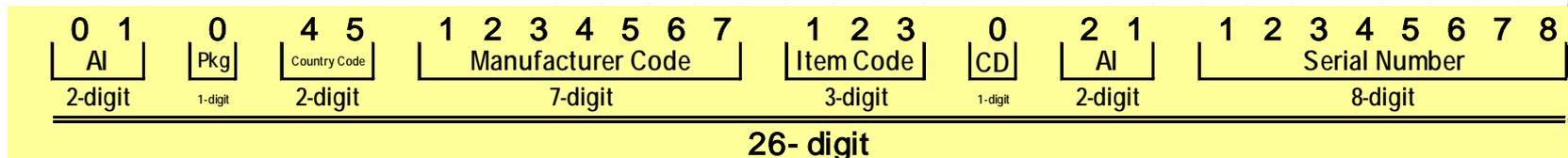
**X-module=0.10mm**

# Note 1: Standard specifications of manufacturer code and item code

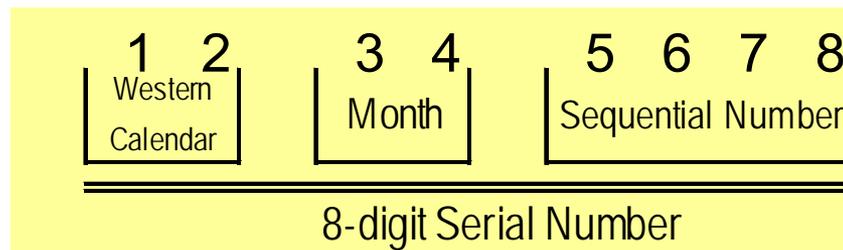
- A. In case of 5 digit manufacturer code



- B. In case of 7 digit manufacturer code

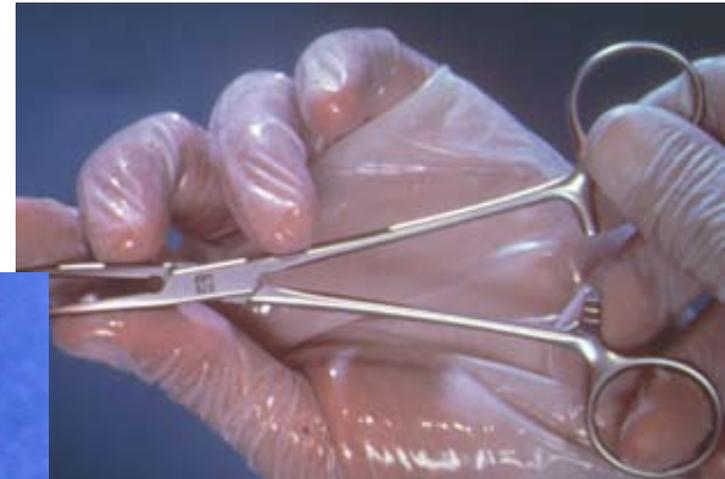
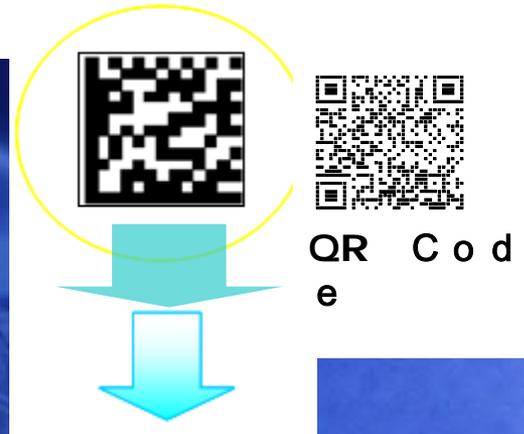


# Note 2: Recommended specification of serial number



# Academic-industrial alliance between Meijo University and JAMDI TESTING 1

- symbol quality
- reading performance



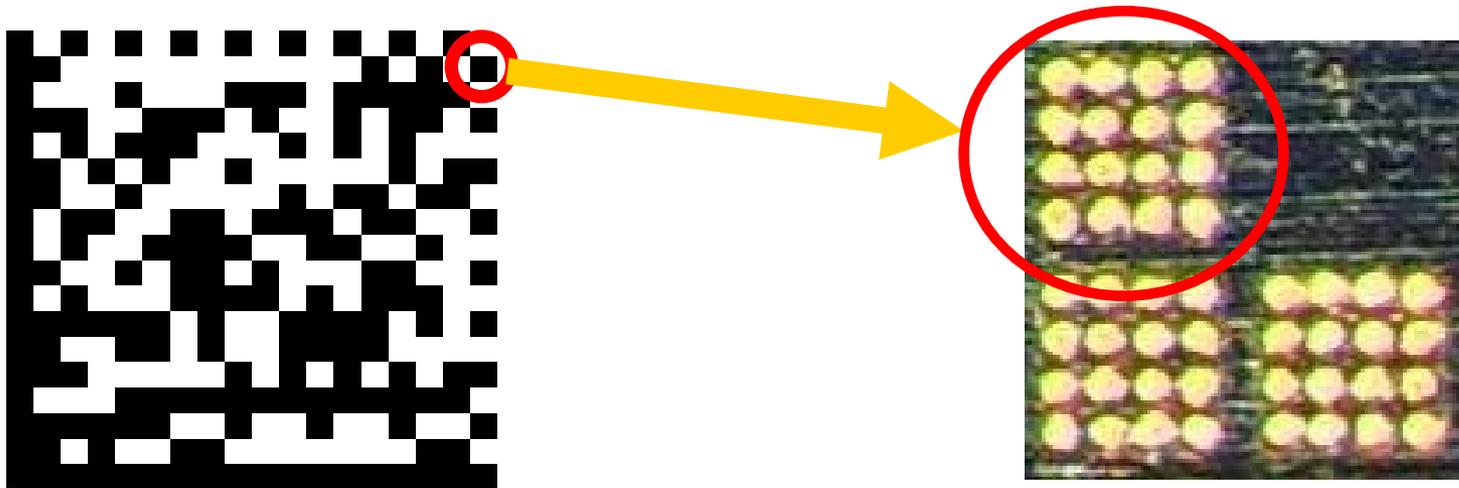
# Technical guidelines for 2D symbol marking

- \*Barcode reader should have continuous readability for 2mm to 5mm symbols.
- \*Symbols should be made by white pattern marking.
- \*Cells should be made by dot pattern marking.
- \*DPM quality should be secured over B level on quality guidelines provided by A I M

**ISO16022:**Information technology -- Automatic identification and data capture techniques

– Data Matrix bar code symbology specification

# Marking Method recommended by JAMEI



- White pattern marking (laser marking by melting the surface of metal)
- 4 × 4 dot makes one sell

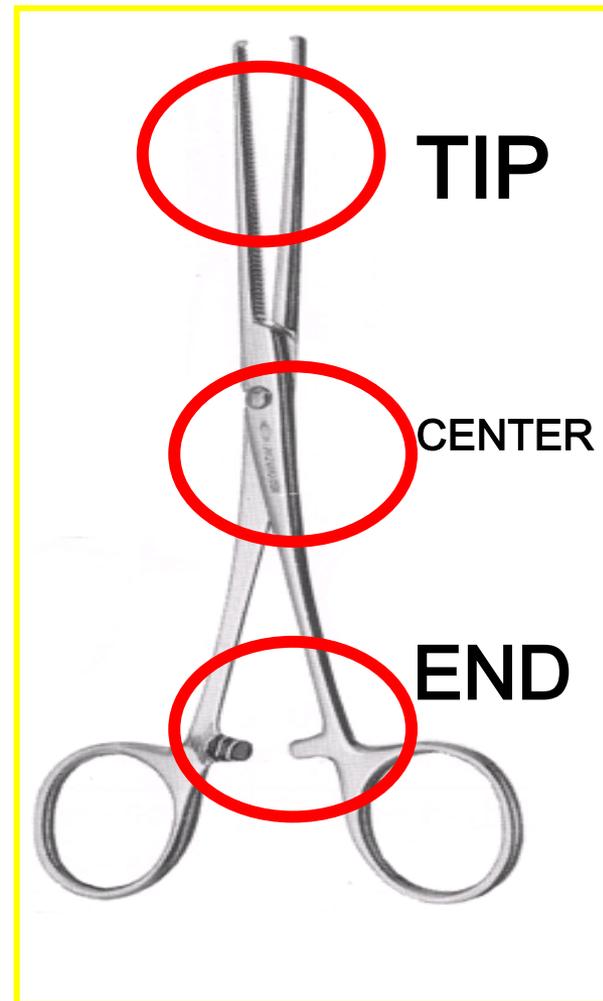
# We are testing used steel instruments.

## Testing 2

### Why we need testing?

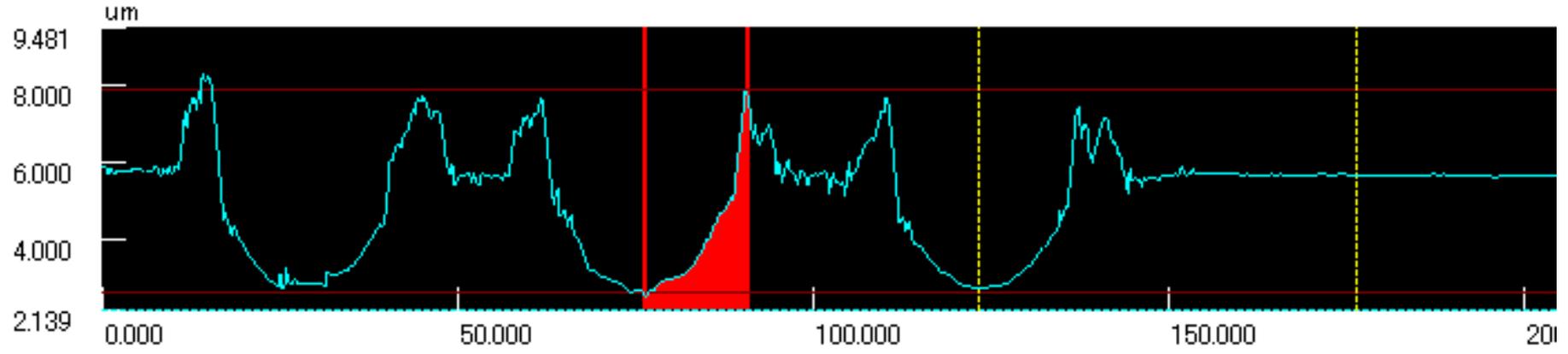
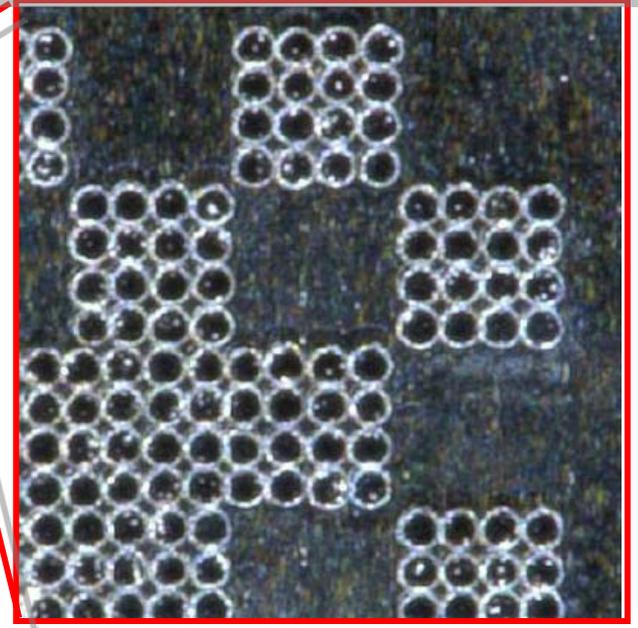
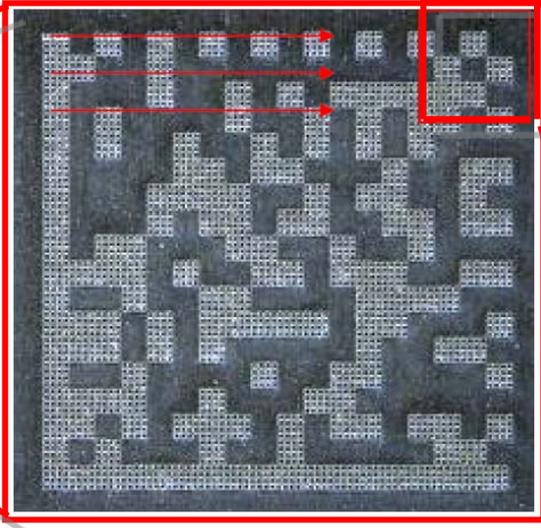
- \*The UDI carrier should be readable at useful life.
- \*or It should be a permanent UDI

- How many scratches on the surface?
- How is the depth of the scratch?
- Which part of the instrument has many scratches?

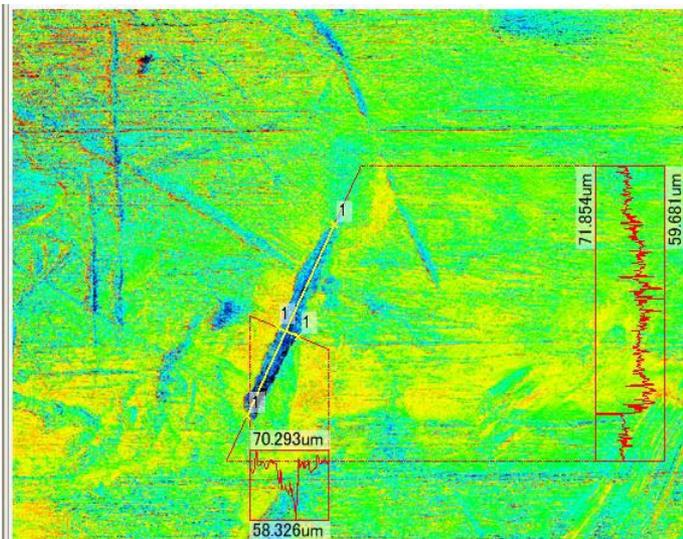


# Laser Microscope

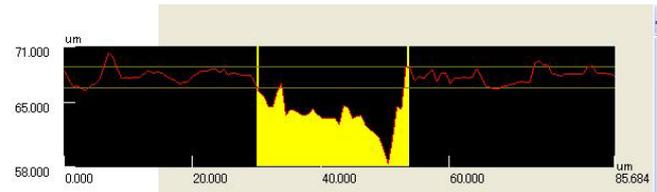
Laser Microscope (VK-9700 KEYENCE)  
3D Color Analyzer (VK-Analyzer KEYENCE)



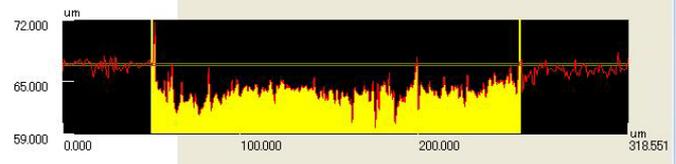
# Surface of the steel instruments



magnifying power of a microscope : 400  
 Image of 506x675 μm (1.7mm<sup>2</sup>)



プロフィール1	水平距離	高度差	高さ平均	角度	断面長さ	断面積	コメント
全体	85.684um	0.552um	66.692um	0.369°	120.549um	1456.35...	
区分1	23.305um	2.326um	63.728um	5.699°	43.734um	336.088...	

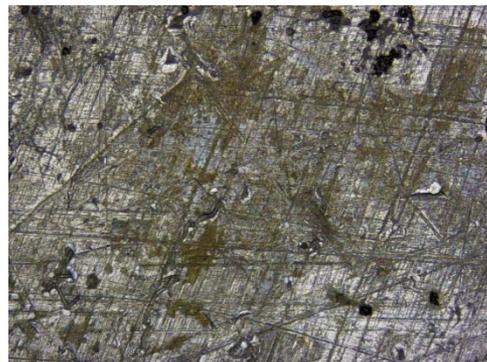


プロフィール2	水平距離	高度差	高さ平均	角度	断面長さ	断面積	コメント
全体	318.55...	1.550um	64.840um	0.279°	487.72...	4791.4...	
区分1	206.90...	0.230um	63.915um	0.064°	340.54...	2919.6...	

Image of steel instruments surface



TIP



CENTER



END

# Findings

- \*Most of the width of scratches are  $10\mu\text{m}$  or less. As X-module of 2D symbol is  $166\mu\text{m}$ , most scratches are enough small compared with X-module. (less than 1/16)**
- \*Lots of scratches are concentrated in the center of instruments. Researchers think this shows the scratches are caused mainly by cleanings.**
- \*The depth of marking (hole) should be  $10\mu\text{m}$  or deeper.**

We are ready to start marking  
on steel instruments !!



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# Use Case 1. Osaka University Hospital

Evolution for patient safety using laser marking on surgical instruments in Japan

Report on the verification of the instrument traceability system at Osaka University Hospital and example of system implementation at another health care institution

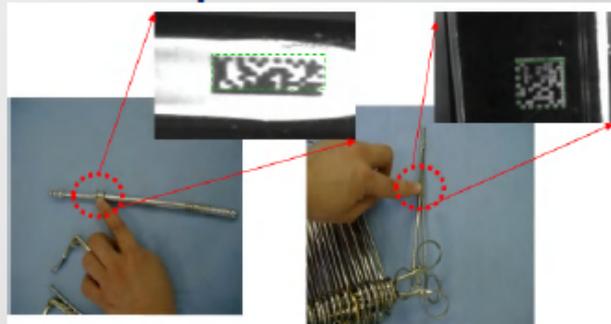


Original Data by Former Director of Surgical Center, Osaka University Hospital  
Dr. Seizoh NAKATA

# Verification of direct marking of DataMatrix barcodes on surgical instruments -1-

In October 2005, we started to mark two-dimensional DataMatrix barcodes directly on the surgical instruments for laparotomies in the Department of Obstetrics and Gynecology. Direct marking was expanded to endoscopic equipment in the Department of Urology in June 2006. And then we conducted verification on the practical performance of our surgical instrument traceability system featuring the sterilization management function using the DataMatrix barcode symbology.

## Surgical instrument set for laparotomies in the Department of Obstetrics and Gynecology



## Endoscopic equipment set in the Department of Urology



DataMatrix barcode



# Report on Practical Use (Application and Engraving Method)

- Laparotomy container for Obstetrics and Gynecology: 5sets
- Surgical instruments per container: 88 items
- 5 Containers × 88 instruments = 440 instruments under serial number management
- Structure of DataMatrix marked on surgical instrument



**Structure of DataMatrix : [16 digits]**

***FNC1+AI90+Hospital (5) + AI21+ Consecutive numbers(7)***

GS1 Application Identifier 2 digits  
hospital

90: assets owned by the  
21: serial number

## ■ Engraving pattern

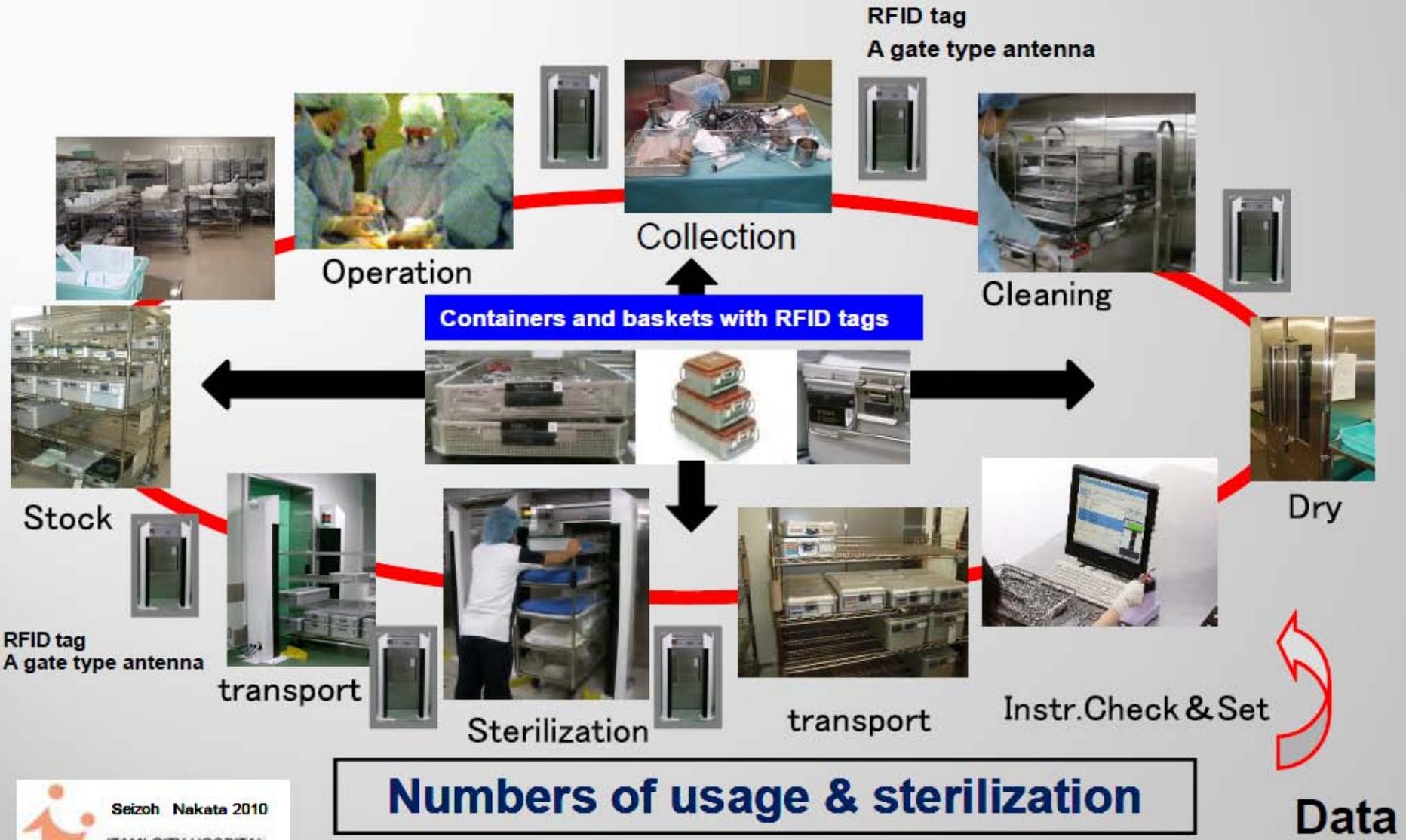
- ① 2.5mm × 2.5mm
- ② 1.2mm × 2.7mm
- ③ 1.0mm × 1.0mm
- ④ 0.8mm × 0.8mm

# Use Case 2. Metropolitan Hospital

- **Hospital capacity**
  - 880 general beds and 30 exclusive beds for patients with infections
- **Number of operating theatres**
  - 15 operating theatres (including 5 exclusive operating theatres for infectious diseases)
- **Number of surgical instruments owned by the hospital**
  - Approximately 100,000 instruments (markable surgical instruments only)
- **Equipment used in operating theaters and central supply department**
  - 3 steam sterilizers
  - 2 EOG sterilizers
  - 2 plasma sterilizers
  - 2 sets of automatic cleaning machines
  - 6 manually-operated cleaning devices
  - 2 drying machines



# Instrument Cycle



# Data traceability system using DataMatrix and RFID tags

## RFID TAGS on the sterilized containers



Cleaning



Sterilization

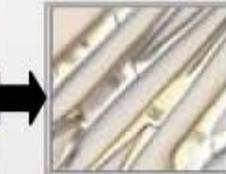


Auto scanning



Gate type antenna  
14 units

## Data Matrix engraved on the surgical instruments



Laser  
Marker  
Operation

## Data Matrix scanning for instrument Kitting



Fixed  
Mount  
Scanner



RFID Hand-held  
Terminals



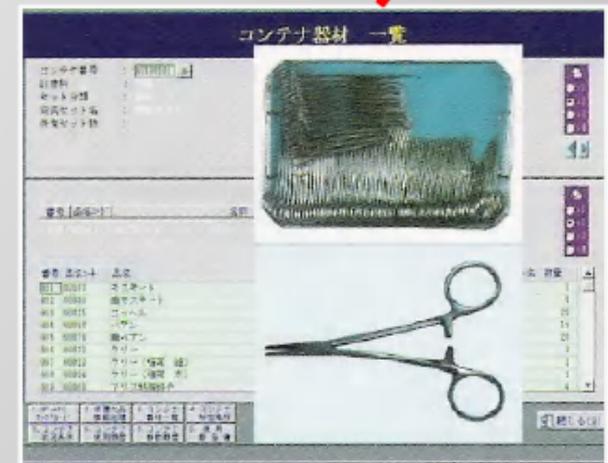
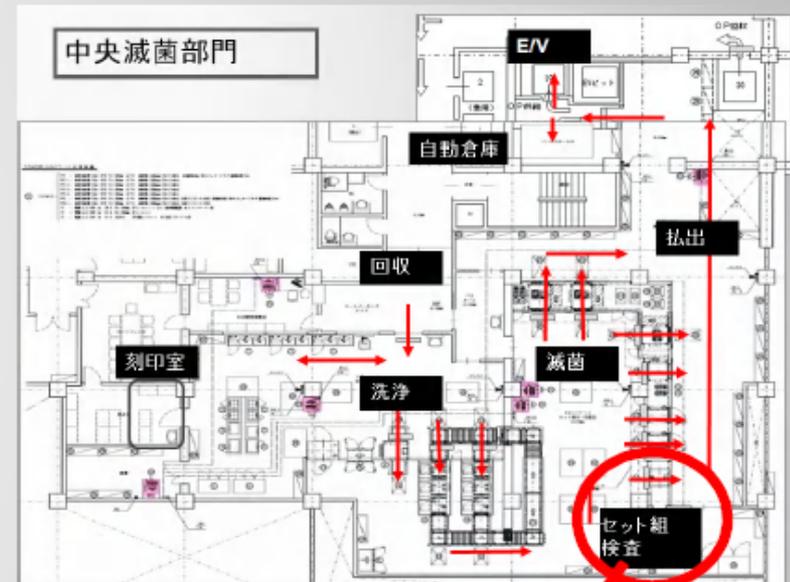
Antennas for  
Spread-Spectrum  
System

# Instrument set assembly

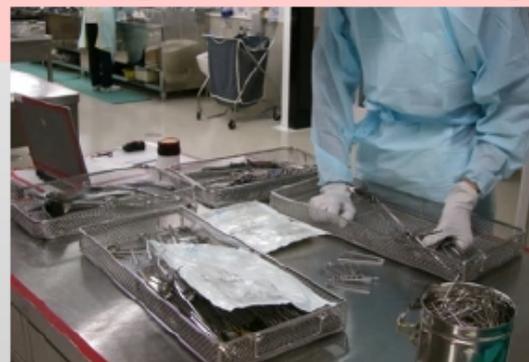
The number of surgical instruments for operating theatres, endoscopic equipment and other medical instruments used in the hospital ward is 100,000.

## Sizes of DataMatrix (mm)

Square symbols		Rectangular symbols	
Symbol sizes 	Data capacity in alphanumeric characters	Symbol sizes 	Data capacity in alphanumeric characters
0.80 x 0.80	16	0.96 x 2.08	16 by YV04 laser-marking machine
1.20 x 1.20		1.14 x 3.42	
1.92 x 1.92		1.62 x 2.10	
2.40 x 2.40			
3.20 x 3.20	by dot-marking machine		



## Instrument set assembly using direct marking



## Utilization of Data Matrix Using

1. The precise data of actual usage of the instruments
2. For right depreciation
3. Appropriate purchase controle
4. Adequate stock management
5. Leads to high motivation of the hospital staff.





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