Surgical Instrument Marking Operations Guide

GS1 Healthcare Japan

Instrument Marking WG

Contents

Introduction

The importance of traceability is becoming recognized due to the necessity of treatment course re-evaluation and risk management in medical care. In the U.K. there are examples of hospitals that have commenced traceability, particularly of surgical instruments used in neurosurgery, in order to prevent mad cow disease infection. The Japanese Ministry of Agriculture, Forestry and Fisheries is also changing laws concerning the traceability of food products, and the tracing of beef from outbreaks of mad cow disease is now carried out in Japan.

The WHO (World Health Organization) launched the "Safe Surgery Saves Lives" program and "WHO Patient Safety" was established as one of its activities in order to reduce the number of surgical patient deaths around the world. In addition, at GS1[note] we are trying to construct an international goods management system in the field of medical care due to the necessity of "patient safety" through confirming the time-line of medical instruments up until patient use and traceability in the event problems arise with patients, etc. Traceability management has already been made possible for some drugs and medical instruments in leading medical facilities.

Amidst such circumstances, the Japanese Ministry of Health, Labour and Welfare also issued their "Ministry of Health, Labour and Welfare Enforcement Regulations" concerning medical care safety and then in 2006 the Japan Association of Medical Devices Industries (JAMDI) issued the "Surgical Instrument Two-dimensional Symbology Standard Guidelines". The creation of unique device identification (UDI) through a unique individual identification symbol created by direct marking in order to identify re-used surgical instruments is now considered necessary. The marking devices and readers that make up this system are continuously being developed, however it is believed that some companies have already established such a system and have entered a stage where traceability management is possible. It is a common understanding between medical personnel and industry that the management of drugs and medical instruments, etc. is expected to be able to contribute to patient safety in medical treatment.

GS1 Healthcare Japan's "Instrument Marking WG" has compiled all the latest UDI-related information with a focus on the foreign and domestic response to UDI in a basic Q&A format, and is now publishing the "Surgical Instrument Marking Operations Guide". We sincerely hope that this guide can be of use for traceability management in medical treatment. You can download the "Surgical Instrument Marking Operations Guide" in PDF form from the GS1 Healthcare Japan homepage. If you have any questions or wishes regarding future understanding, please don't hesitate to contact our council secretariat (Email: dsh13@dsri.jp)

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GS1 Healthcare Japan
Instrument Marking WG
Chief, Seizoh Nakata

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Q&A collection

Q1: What is direct marking?

Direct marking is not the attachment of a display label to products (goods, components and packaging) but rather is the generic term for the technique of directly marking a bar code and symbol to products by various methods and automatically identifying marked bar codes and symbols. Direct marking is used for (1) products that are extremely small and where there is no space for traditional marking and (2) when durability of the display is required. Surgical instruments such as surgical instruments, etc. are usually small and precise and go through a cleaning and sterilization process. As a result the space for the attachment of normal paper or film display labels and their long-term durability becomes a major issue. In addition, there is also the risk that the display label could fall off during surgery and remain as a foreign body in the patient – this is a risk that should never exist in medical practice. For reasons such as this, direct marking is being utilized for surgical instruments both in Japan and abroad.

Examples of direct marking on various instruments

Q2: Why is direct marking necessary for surgical instruments?

1. **Expected results from direct marking of surgical instruments and their tracing**
   (1) Ordering efficiency
   It becomes possible to automate the re-ordering of damaged surgical instruments and save time and effort.
   (2) Efficiency and standardization of surgical instruments assembled as a set
   By reading the two-dimensional label on each individual surgical instrument, it is possible to completely reconcile surgical instruments assembled as a set from the computer management menu screen and significantly improve the accuracy of instrument sets. Instrument set "surgical instrument identification" and "quantity count operations" are even possible for staff with little surgical instrument expertise resulting in improvements in safety.
   (3) Quality management
   After surgery it is possible to classify surgical instruments into used and unused. Set review and streamlining of set content (non-used instruments are not included in a set) can be achieved.
   (4) Understanding of individual surgical instrument data
   It is possible to precisely understand the number of times a surgical instrument has been used, its service life and its degradation in quality as digital data. In particular, an understanding of the frequency of use by surgery, department and patient contributes in terms of medical economics and is useful in the proper arrangement and leveling of instrument use. It also becomes basic information used in the replacement purchase of instruments.
   (5) Analysis of required surgical instrument sets and elimination of waste
   The content of surgical instrument sets required for each surgery/site can be analyzed from cases of surgery and it becomes possible to limit the purchase of unnecessary or non-urgent surgical instruments based on the data.

2. Effect of introduction

(1) Location management
- Identification of instrument location management necessary for surgery
- The time to prepare instruments to be used can be decreased

(2) Improvement of work efficiency
- Any member of the operations staff can easily handle the work

(3) Infection prevention
- Speedy identification of patients and target instruments during breakouts of bacterial infection
- Prevention of secondary infections

(4) Loss/theft analysis
- Instrument loss/theft analysis by traceability

(5) Maintenance control
- Maintenance operations are refined by clarifying damaged equipment

(6) Cost reduction
- Maintenance and inventory is reduced in advance through the identification of re-used instruments and unused instruments.
- Reduction in training costs

(7) Safety measures
- Safety measures and preparation against bacteria is made possible
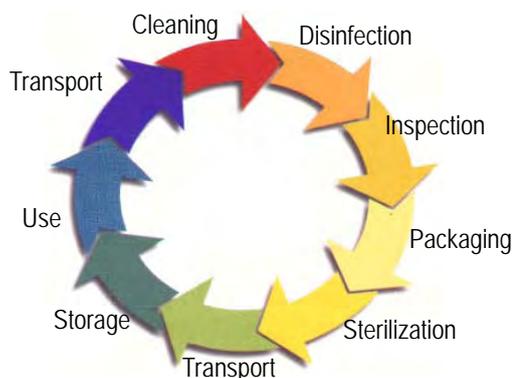
3. An example of a hospital that has introduced direct marking

(Source: Donald Gordon Medical Center, U.K.)

Prerequisites
- Central supply staff hourly rate: @2000 yen base (yearly rate of approx 5 million yen)
- Total number of instruments (target instruments for direct marking): 17,500
- Instrument loss: 2% yearly
- Instrument management education: Five days per year
- Number of managers: Five
- About 200 operations per year + recording time - 30 minutes is required for each instance

No	Item / content	Effect converted to time (H)	Effect: (1000yen / year)
1	Reduction of surgical instrument usage record keeping work (duty)	110H	210
2	Reduction of record keeping work for patients and instruments associated with Creutzfeldt-Jakob disease	100H	200
3	Reduction of monthly stocktaking man-hours	60H	120
4	Reduction of instrument disinfection-related record keeping	100H	200
5	Instrument loss related savings (17,500 x 0.02 x @10,000yen		3,500
6	Reduction of instrument management man-hours (including preparation man-hours)	300H	600
7	Reduction of equipment identification training, etc	400H	800
8	Reduction in time spent searching for instruments, ordering and organizing work	800H	1,200
9	Sterilization record management-related reductions	300H	600
10	Reduction of instrument set, etc. confirmation work	400H	800
11	Asset reduction effect from reviewing the instruments in the container		
Total		1,960H	8,230

As seen above, introduction of direct marking has brought about time savings of **1,960 hours per year** and significant cost savings of **8.23 million yen.**

Q3: What is the two-dimensional symbol used in marking display?

Since 2005, GS1 - The global standard for bar code, two-dimensional symbol and electronic data exchange headquartered in Belgium and with 110 member countries - has been examining two-dimensional symbols for display on surgical instruments together with regulatory authorities, medical device manufacturers, wholesale businesses and medical institutions around the world, etc. The **GS1 data matrix** [(Note)] has been decided upon as GS1's standard specification for the type of two-dimensional symbol that is marked onto surgical instruments and GS1 is promoting the standardization and spread of marking to relevant industries in Japan, U.S.A, Europe, Asia and South America. In addition, U.S. and European regulatory authorities are also welcoming the standardization and spread of the data matrix as well as the resulting improvements in patient safety resulting from standardization and commonality and the increased distribution and logistics efficiency.

In Japan, although the Japan Association of Medical Devices Industries (JAMDI) "Surgical Appliances Two-dimensional Symbology Standard Guidelines" lists two types of two-dimensional symbols – data matrix and QR code, the GS1 Healthcare Japan Instrument Marking Division has decided to standardize display symbols with the GS1 data matrix format after taking into account consistency with the rest of the world and actual use around the world as well as factoring in the lack of JAMDI QR code marking quality verification and reading verification.

Data matrix display example:	 (01)04977766654302 (21)42345B-2	**In this display example, the standard product code (04977766654302) and the serial number (42345B-2) is displayed, however these can be omitted if there is a lack of display space**

(Note): What is the difference between the term "GS1 data matrix" and the term "data matrix"?

The "GS1 data matrix" regulates the two technical specifications of "data items, order and number of digits" and "symbol display" according to the GS1 general specifications. On the other hand the "data matrix (ISO/IEC16022)" merely regulates the "symbol" (information display) medium (=mosaic pattern).

Q4: What kind of data is stored in a two-dimensional symbol?

The storage and display of the two items – the surgical instrument standard product code and the instrument serial number - in the two-dimensional symbol data matrix is set by the GS1 standardization body and the Japan Association of Medical Devices Industries (JAMDI) standard guidelines. The data matrix display items are the standard product code and the unique instrument serial number. This standard product code is a 14-digit code with a global name of GTIN (pronounced "Jiitin")

Data matrix display items	**Standard product code (GTIN)**
	Serial number

What is GTIN?

GTIN is pronounced as "Jiitin" and is an abbreviation of Global Trade Item Number. It is a uniform name for the common product code in data format which is obtained by standardizing product codes with different digit numbers such as the presently used 13-digit JAN code, the 12-digit UPC code popular in the U.S and the 14-digit ITF logistics products code, etc. on the product master file. It is an international standard product code used to identify the product itself in purchase, delivery, billing and payment operations and it is used in the worldwide consumer goods industry including for drugs and medical instruments. Efforts are already underway for worldwide standardization and commonization of products that are circulated and distributed internationally such as drugs and medical instruments, etc. In addition, the product identification codes in the Japanese Ministry of Health, Labour and Welfare's "pharmaceutical product bar code display notification" and "medical instrument bar code display notification" are all in GTIN format for the purpose of international compatibility. The product identification codes for surgical instruments are also in GTIN format.

What are the Japan Association of Medical Devices Industries (JAMDI) surgical instrument display guidelines?

Display items and display digits are standardized as follows by the Japan Association of Medical Devices Industries "Surgical Instrument Two-dimensional Symbology Standard Guidelines" enacted in November 2006:

Display item	Number of digits	Notes
Application identifier (01)	2 ("01" = 2 digits)	Previously fixed 2 digits (numerals)
Surgical instrument standard code	14	Previously fixed 14 digits (numerals)
Application identifier (21)	2 ("21" = 2 digits)	Previously fixed 2 digits (numerals)
Serial number (set by the manufacturer)	8	8 digit display recommended by JAMDI
Total digits	**26**	

JAMDI : Japan Association of Medical Devices Industries

Setting the number of serial code digits

It is recommended under the JAMDI's display guidelines that "0" be added to the front of the product serial number to create an eight-digit number if the original product serial number is less than eight digits. However, it is important for the reading system constructed to be able to read the numbers and respond flexibly in the case that a foreign product has a product serial number of nine digits or more. Therefore it is recommended that the reading system be able to read more than eight digits.

The relationship between number of data digits and cells (Note) in the data matrix

Symbol size changes according to whether the data digits written into the data matrix are numbers only or include roman characters, but in general a large number of data digits will result in an increase in the number of cells and naturally a bigger overall symbol. In the case of 26 digits recommended by the JAMDI "Surgical Instrument Two-dimensional Symbology Standard Guidelines" (as seen in the table above), the two-dimensional symbol is 18 x 18 cells.

(Note): Cells are individual squares, both in black and white, that comprise the two-dimensional symbols.

[How big is a two-dimensional symbol when its cells are 1mm?]
For example, with total of 26 numeral digits (18 cells)

Cell size		Actual No. of cells		Free space		Symbol size
1mm	x	(18 cells	+	2 cells)	=	20mm square

(There are two empty white spaces in the leftmost and rightmost cells)

(This image doesn't necessarily reflect the actual dimensions)

<18 cells>
Cell counting method
Empty white space = quiet zone
At least one empty white space is required to surround the data matrix
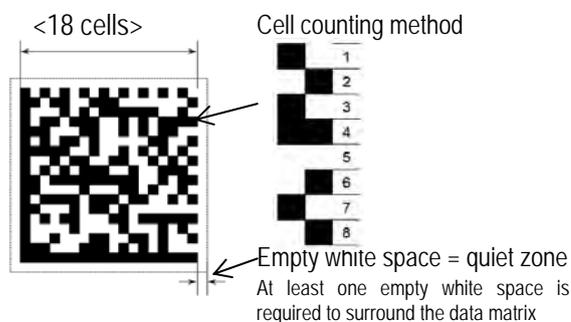
[The relationship between the number of cells and symbol size] *μm = micrometer (1/1000mm)

| Number of digits / data content / number of cells			Data matrix size		
Number of digits	Data content	Number of cells	Cell size: 1mm	Cell size: 100μm	Cell size: 25μm
26	Numerals only (recommended)	18 x 18 cells	20mm square	2.0mm square	0.5mm square
	Roman characters	20 x 20 cells	22mm square	2.2mm square	0.55mm square
30	Numerals only	18 x 18 cells	20mm square	2.0mm square	0.5mm square
	Roman characters	20 x 20 cells	22mm square	2.2mm square	0.55mm square
50	Numerals only	22 x 22 cells	24mm square	2.4mm square	0.6mm square
	Roman characters	24 x 24 cells	26mm square	2.6mm square	0.65mm square

* Application identifiers are included in the number of digits

Q5: What methods are used for the direct marking of surgical instruments?

A laser method or pin dot method is employed for the direct marking of surgical instruments.

(1) Laser method

The laser method is a marking method that employs a laser. Condensing a laser through a lens onto the surface of a surgical instrument can result in surface discoloration and the marking is possible to scrape off. However, by scanning the laser with a scan mirror it is possible to draw the outline of a two-dimensional symbol in a single motion.
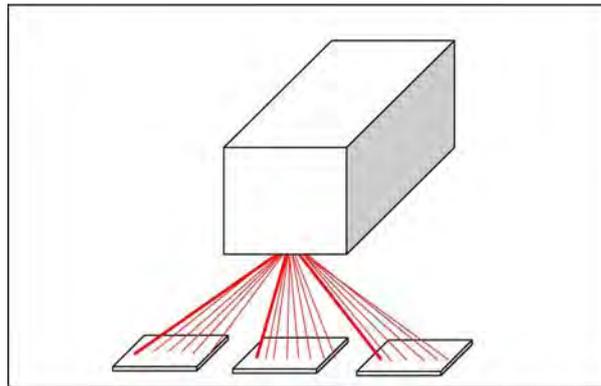

Changes to the marking method are made possible by changing the conditions in which the laser is condensed. There are various marking methods (changing the color to white, expanding the resin, and others), however the methods used in surgical instrument marking in the health care industry are "black marking method" which involves applying heat to the target surface and producing a black color and the "impression marking method" which involves removing parts of the surface by focusing the laser and increasing its intensity.
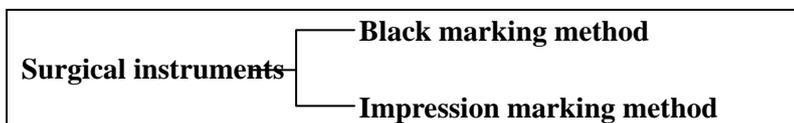
Because surgical instruments have a long usage life and are repeatedly sterilized and cleaned, rust must be avoided in the marked area. Through experimentation it has been determined that the "impression marking method" is more resistant to rust and as a result it is the recommended method.
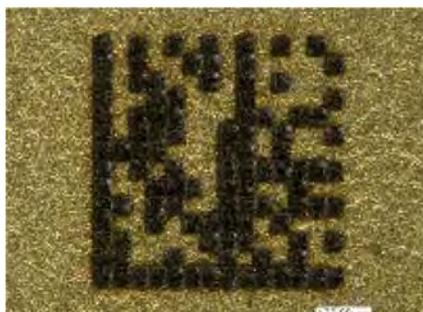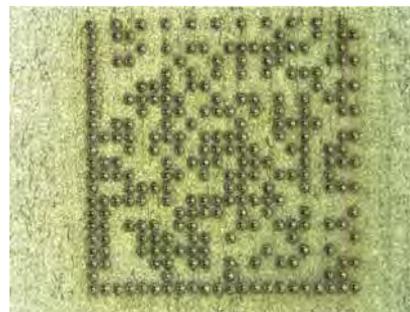

| Black marking method | Impression marking method |

(2) Dot pin method

The dot pin method is also known as the micro dot method. In this method an impression is left in the target object through the up and down vibration and movement of a pin and a marking created. The pin moves vertically at an approximate frequency of 200-300Hz according to the pin type and these vibrations make it possible to draw any type of character, logo or two-dimensional symbol.

P1 = Marking depth
P2 = Penetration depth
P3 = Cleve depth

Deep material
Cross section A-A

Thin steel plate
Hammering
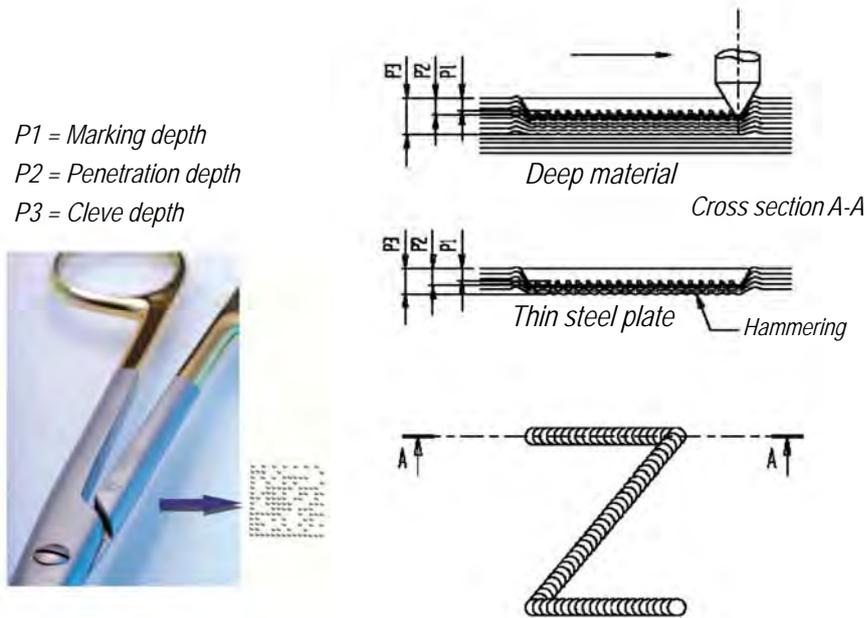
The main unit of the dot pin method marking equipment is characterized by its sturdy, safe and difficult to break design as well as its extremely easy operability. Because the pin pot method marks the data matrix more deeply into the target instrument than the laser method and it is resistant to scratches, etc., the marking remains over the lifetime of the instrument without disappearing and can almost permanently be read by a reader.

The dot pin method is a technique that was originally developed approximately 30 years ago to ensure marking didn't disappear over time in the traceability management of automotive, aviation and machinery parts.

Q6: In how much detail can a data matrix be created by direct marking?

(1) Laser method

It is possible to produce fine spots by condensing a laser through a lens and at present the smallest display size readable by commercial readers is 0.5mm×0.5mm (0.5mm squares). With 0.5mm squares, a reading test must be performed to verify readability. Reading trouble could occur if reading verification is not carried out. When the data matrix marked on surgical instrument is composed of a total of 26 digits including the GTIN (previously mentioned) and serial numbers, etc. it will consist of 18 x 18 cells.

In addition, it is possible to adjust the overall size of the data matrix by adjusting individual cell size.

*µm = micrometer (1/1000mm)

Breakdown of the 26 digits	Cell size: 25µm	Data matrix size: 0.5mm x 0.5mm
AI(01): 2 digits **GTIN: 14 digits** **AI(21): 2 digits** **Serial number: 8 digits**	Cell size: 50µm	Data matrix size: 1mm x 1mm
Total: 26 digits	Cell size: 100µm	Data matrix size: 2mm x 2mm

* A one cell or larger white margin is required surrounding the data matrix

Images of each size impression-method marking and the images displayed by the reader.

1) Marking image   (the sample photographs don't reflect the actual dimensions)
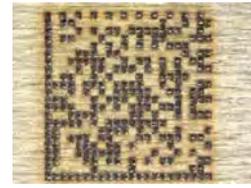

*One cell: 25μm*   *One cell: 50μm*   *One cell: 100μm*

2) Black and white image displayed by the reader
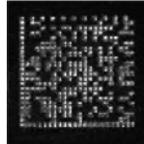
One cell: 25μm   *One cell: 50μm*   *One cell: 100μm*

It is possible to further reduce the data matrix display by narrowing the laser. However, it's not practical for the cell size to be less than 25μm as reading problems may occur.

In addition, it is thought that any surface unevenness of the surgical instruments results in data matrix reading difficulties.

It is possible to improve reading identification in such a case by smoothing and specularizing the foundation on which the data matrix will be marked (the background) with a laser in advance.
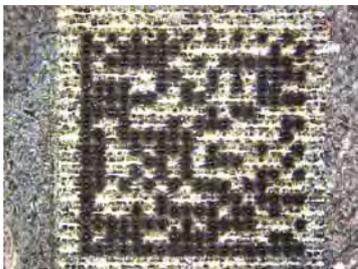

Image of impression-method marking on   *Reader display image*
a specularized background
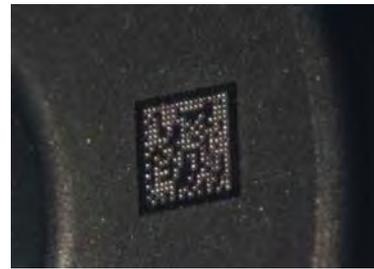
(2) Dot pin method

It is possible to change depth and dot size according to the material quality of the surgical instrument and the stamping strength setting settings of the marking device. The minimum readable cell size of data matrixes created with the dot pin method is 0.17mm. However, If marked with 26 digits, relatively stable readability is possible with a total square size of 3mm or more consisting of 18 x 18 cells.

Marking: 26 digits, 18 x 18 cells, 3mm or larger square = stable readability
However, readability of 1mm squares is possible depending on the marking device used

3mm square display image   *4mm square display image*

Q7: When should you use the laser method and when should you use the dot pin method?

Marking by dot pin and YAG laser is beginning to be adopted for the data matrix marking of surgical surgical instruments for medical facilities and implant company loaned surgical instruments.

The laser method marking size is small (0.5mm – 2.5mm squares) and suitable for data matrix marking. Because marking is carried out with pins that have a physical diameter in the dot pin method, this method is suitable for markings where the square size is 3mm or larger.

In practical use, the laser method is used for small and/or thin surgical instruments and surgical instruments where baking of the oxide film is necessary. The marking depth used for such instruments ranges from 1µm - 10µm (deeper marking is possible but extremely time consuming). Because of the relative shallowness of the marking, it is vulnerable to scratches, etc. and it is therefore is important to create a marking in an area of the surgical instrument that is less likely to receive direct contact.

The marking depth of the dot pin method ranges from 10µm - 50µm (depth is selectable by changing pins). Because of the resistance to scratches of marking carried out in this method, an efficient technique is to first mark the surgical instrument using the dot pin method and then treat it with laser engraving.

Q8: If re-marking becomes necessary, how should such repairs be carried out?

(1) Laser method
The marking repair method differs depending on the method of marking that was used

1) Black marking method

With the black marking method where the color of the target object surface is changed, the effect is only superficial. If re-marking is required, it is unnecessary to perform laser irradiation or sandblasting to smooth the marking surface. Rather, the existing marking is erased and a new black marking is added in the same position or to the side.
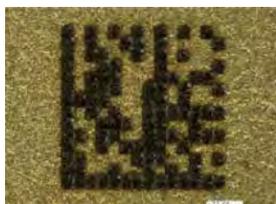
*Re-marking becomes necessary* / *The surface is smoothed* / *A new black marking is added in the same position or to the side*

2) Impression marking method

With the impression marking method it is impossible to smooth the marking surface and add a new marking in the same position. The new mark must be created in a separate position.
The old mark must be erased in order to ensure it is unreadable.
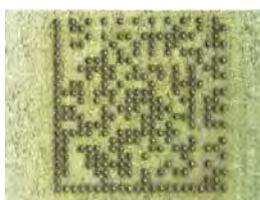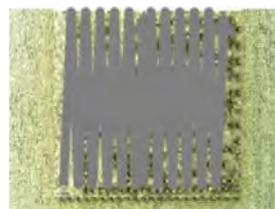
Re-marking becomes necessary / *The old marking is erased* / *A new impression marking is created in a different position*
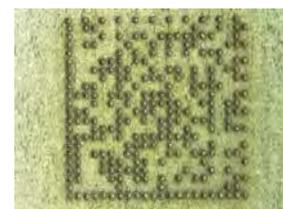
(2)　　　Dot pin method

Because dot pin marking was developed to be semi-permanent, the existing marking basically has to be shaved off and a new marking created in a separate location.

| *Re-marking becomes necessary* | *The old marking is shaved off* | *A new marking is created in a different position* |

Q9: What types of readers exist?

Two-dimensional symbols directly marked on metal differ from a printed label in that the print colors are basically weak, contrast is low and they are easily susceptible to the effects of specular reflection and ambient light, etc. due to the color of the material's metal (silver, etc). As a result, it is essential that a stable reading be obtained using a two-dimensional symbol reader specifically developed for direct marking reading.

In terms of reader types there are fixed readers, hand scanners and hand-held terminals

1) Fixed readers

Because fixed readers use a camera to read the marking, they support a wide range of reading as particular illumination (lighting) and lenses, etc. can be selected and combined depending on the reading environment. In surgical equipment application, they can be fixed to the work bench and used for reading when setting instruments.

2) Hand scanners

In recent years, the development of cable-free hand scanners in addition to the hand scanners with a USB cable allowing computer connectivity is becoming easier. With hand scanners a relatively cheap reading environment can be constructed if there are methods of improving reading conditions such as increasing the shading contrast or the size of the symbol.

3) Hand-held terminals

Because hand-held terminals have display functions, a numeric keypad and memory, etc., are equipped with business application programs and can be used as individual units, they don't necessarily need to be used in a location where a control instrument such as a computer, etc. is on hand. In addition, they can wirelessly transfer data from the location in which they are used thanks to their wireless capabilities.

Q10: What is the most important know-how for carrying out on-site stable reading?

Performing an actual reading test and verification is the most important step. Because surface discoloration occurs in surgical instruments as a result of cleaning and sterilization, etc., there are times when the area marked by laser or dot pin will become unreadable.

Marking is not normally erased on other stainless surgical, titanium or plated surgical equipment. The leading cause of reading failure is damage to the two-dimensional symbol due to scratching, etc.

Q11: Where should the marking be created on the surgical instrument?

It's desirable to consider the following points for surgical instrument marking in an easy-to-recognize area:
(1) Make a mark close to the logo on surgical instruments that have a logo
(2) Make a mark close to the hinge on surgical instruments that have a hinge
(3) In order to ensure long-term readability, mark on a flat surface where scratching is difficult
(4) It is also beneficial to mark one instrument in two or more areas as a practical measure against scratching

(1) Example of marking near the logo (marked by rectangular data matrix format)

Enlarged view
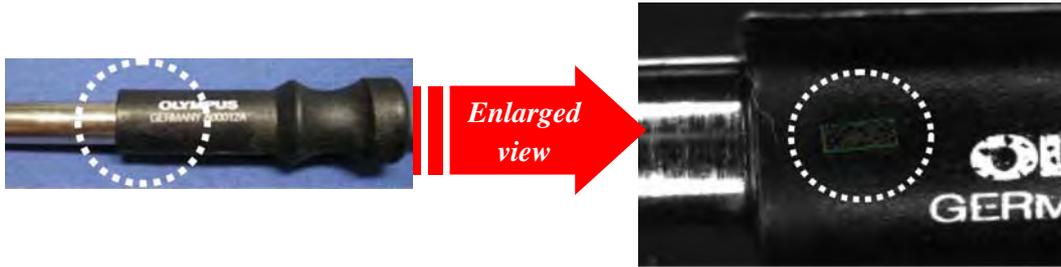
| **What is a rectangular data matrix format?** |

The rectangular data matrix format has the benefit of allowing marking in smaller vertical spaces in comparison to the square format as well as allowing <u>vertical marking on a cylindrical object.</u>

Rectangular format

Square format

**(2) Example of marking near the hinge**

(3) Example of marking after locating the flat portion of a cylindrical object

(4) Example of rectangular data matrix marking in multiple locations as a result of the object being a small-diameter cylinder

Enlarged view

Enlarged picture of the marking in multiple locations
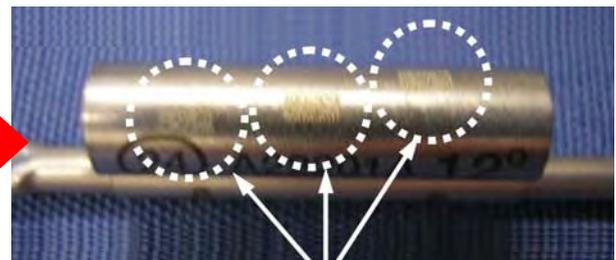
Rectangular marking has been performed in three locations

Q12: The trend of direct marking standardization in European industry?

German and U.S. surgical instrument manufacturers account for approximately 70% of the Japanese domestic surgical instrument market. In other words, Western products already play a leading role in Japan including in clinical practice. Accordingly, Western manufacturers have been actively creating of standardization specifications together with national industry associations and the GS1 international standardization body. Given this situation, the data matrix has been selected as the standard for two-dimensional symbols and a standard of two display items – the surgical instrument standard product code (GTIN) and serial number – has been developed. For example, German company B Braun – the world's largest surgical instrument manufacturer – is now preparing a data matrix marking system for its products as a result of a board decision.

Because there are several marking methods such as the laser method and dot pin method, several techniques are recognized without standardizing marking to the one method only. The reason for this is that specifying a specific method to be standardized amidst the rapid developments in marking technology would hinder technological progress. Therefore it is common sense not to standardize a specific method.

Two dimensional symbol type: data matrix
Display items: surgical instrument standard code (GTIN: 14 digits) + serial number (max 20 digits – letters and numbers)

Q13: The spread of direct marking in domestic and foreign medical industries

Medical staff of Europe-U.S. medical industry have a greater awareness of infection prevention and traceability than their Japanese counterparts. The western medical industry can be said to be actively involved in reliable direct marking as a countermeasure against paying large sums of compensation to patients, etc. The European industry has introduced direct marking of surgical equipment in hospitals across Europe, more so than the U.S. industry, based on:

(1) Measures against prion diseases such as mad cow disease and Creutzfeldt-Jakob Disease (CJD) since the 1990s

(2) The urgent clinical need of surgical appliance identification in the case of surgical site infection (SSI)

Within Europe, direct marking is used for instrument setting operations, understanding usage data, proper inventory management and appropriate instrument purchasing, etc. in the central sterile and supply department of **U.K., France and Germany** medical institutions. Guidelines and standards have been issued by the U.K. Ministry of Health and the French national standards as a legal backing to this.

U.K.	U.K. Ministry of Health: "Medical Equipment Contamination Prevention". Document Number: HSC2000/032. Issued March 31, 2001 *** A summarized Japanese translation is listed in reference collection #6 at the end of these materials**
France	French national standards: XP S 94-467 "Recording Specification Definition with the aim of Surgical Instrument Traceability". Issued January 2006 *** These standards are listed in reference collection #7 at the end of these materials**

Article introducing surgical instrument management by data matrix at the St. George Medical Center in the U.K.

Marking instrument setting operation. The left black frame is the black and white confirmation monitor screen.

Surgical instrument setting at Guy's and St Thomas Hospital, U.K.

Instrument tray label reading at Guy's and St Thomas Hospital, U.K.
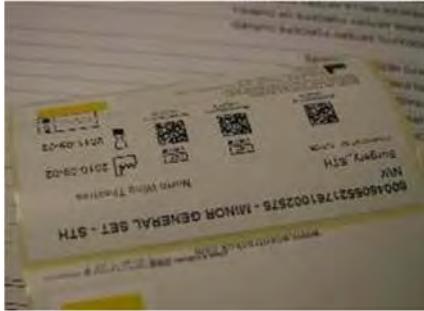
Instrument package label data matrix at Guy's and St Thomas Hospital, U.K.

Sterile container reading (with a reader) at Aarau state hospital, Switzerland

Instrument assembly support / traceability management system at Robert Ballanger Hospital, France

Instrument tray and withdrawal list bar code verification at Robert Ballanger Hospital, France
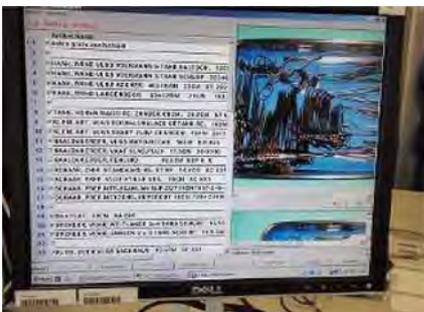
Assembly support system computer screen at Erasmus Medical Center, Netherlands

Setting while confirming with the computer screen at Erasmus Medical Center, Netherlands

Q14: Future developments

As mentioned in the response to Q13, European regulatory authorities are preparing their own respective safety regulations and guidelines as a measure against prion diseases such as mad cow disease and Creutzfeldt-Jakob Disease (CJD). These regulatory authority policies promote the joining together of the executives, doctors, nurses and staff of each medical institution to create a system of hospital safety standards, the introduction of an information network system and surgical instrument traceability management.

Essentially, it is expected that direct marking initiatives will increase extensively in future from both (1) the medical viewpoint of infection prevention for patient safety and (2) the medical economy viewpoint of understanding the amount of use of surgical instruments. The Japanese medical industry needs to focus on trends in the European healthcare industry from both a medical viewpoint and a medical economy viewpoint.

In the U.S. there have been fewer specific examples of mad cow disease and Creutzfeldt-Jakob disease outbreak and surgical countermeasures. In addition, the fact that U.S. medical institutions generally have an ample budget for equipment and a lower recognition of individual item data management, etc. are also reasons why regulatory initiatives are not being introduced and medical institution introduction is not actively progressing to the extent of European countries.

# "Application identifier" explanation

(1) Application identifier setting standards for surgical instruments

The use of two-dimensional symbol data matrix display and reading has commenced in the domestic medical instrument industry and the Japan Association of Medical Devices Industries (JAMDI) issued the "Surgical Instrument Two-dimensional Symbology Standard Guidelines" in November 2006. Since then direct laser marking, reading and data management has been progressing within the market as a result of the demands for safety, traceability and precise and detailed equipment management of surgical instruments from medical institutions, etc. Under the guidelines, products manufactured by manufacturers are guided by specification standards, however there are a large amount of surgical instruments not manufactured by manufacturers circulating in the market in various business forms such as property commissioned for sterilization and cleaning, rental property and lease property, etc.

ISO/IEC15418 standard GS1 application identifiers are defined by the following business types and ownership. These application identifiers are similarly displayed in the European industry where they have begun to be used. The display of application identifiers on surgical instruments has great benefits for the end user medical institutions and facilities from the perspective of international conformity as well as precise and detailed data management for each form of business such as replacement purchasing, equipment management, depreciation management and loss prevention, etc. Accordingly, the following setting, display and reading of application identifiers tailored to the business is recommended.

Marking device manufacturers, reader manufacturers and users are strongly urged to set, display and read application identifiers based on the ISO/IEC15418 standards.

Business type	Target product	Application identifier, data item	Explanation
Manufacturer	 Manufacturer — Sales → Medical institution		
	Goods manufactured by a manufacturer	**AI 01** **GTIN 14 digits** **AI 21** **Serial number: Eight digits recommended (alphanumeric support)**	The data configuration is the same as listed in the "Surgical Instrument Two Dimensional Symbology Standard Guidelines". * Refer to (P.90-) of the Japan Federation of Medical Devices Association's "Standard Code Operation Manual for Medical Instruments, etc"
	Display **FNC1 01 04977766654302 21 42345B-2** **(Note): Spaces are for explanation purposes only and not included in the row of data** (01)04977766654302 (21)42345B-2		(Note): Visual data is not required in cases where display is impossible

Medical Institution — Outsourcing — Sterilization & Cleaning Outsourcer

| Sterilization and cleaning outsourcing | Goods commissioned by medical institutions and facilities | **Current display:**
AI 90
Serial number: Any number of digits (alphanumeric support) | As they own the goods, the GTIN corporate code shall be the code of the medical institution. However as the medical institutions in Japan don't have seven or nine-digit JAN corporate codes, the display shall be the AI "90" defined by agreement between the two companies until the medical institution acquires the aforementioned JAN corporate code.
* The relationship between the medical institution and the sterilization/cleaning center is a "company/company" relationship, and therefore the AI "90" is set under the GS1 standards. Please refer to the "table of application identifiers" |

Current display

> **FNC1 90 XXXXXXXXXXXXXXXXXXXXXXXXXXXX**
> **(Note): Spaces are for explanation purposes only and not included in the row of data. X is the alphanumeric character data**

(90)xxxxxxxxxx
xxxxxxxxxxxxxx

(Note): Visual data is not required in cases where display is impossible

| Goods commissioned by medical institutions and facilities | **Future display**
AI 8004
JAN corporate code + Global Individual Asset Identifier (alphanumeric support)
Up to 30 digits | The AI 8004 Global Individual Asset Identifier (GIAI) is set. This identifier consists of the JAN corporate code acquired by the medical institution/facility (seven or nine digits) plus an arbitrary global individual asset identifier to create a total of up to 30 digits. |

Future display

> FNC1 8004 497776665 42345B-2
> **(Note): Spaces are for explanation purposes only and not included in the row of data**

(8004)49777665
42345B-2

(Note): Visual data is not required in cases where display is impossible

Rental / leasing business	Rental & leasing Company — Rental & leasing — Medical Institution		
	Rental / lease of their owned products	**AI 8004** **JAN corporate code + Global Individual Asset Identifier (alphanumeric support)** **Up to 30 digits**	As they own the goods, the rental/leasing company shall acquire a JAN corporate code. The AI 8004 is the Global Individual Asset Identifier. The display shall be the seven or nine-digit JAN corporate code plus an arbitrary global individual asset identifier to create a total of up to 30 digits.
Rental / leasing business	**Display** FNC1 8004 497776665 42345B−2 **(Note): Spaces are for explanation purposes only and not included in the row of data**		(8004)497776665 42345B-2 (Note): Visual data is not required in cases where display is impossible
Medical institutions	Medical Institution — In-hospital marking		
	In-hospital unique arbitrary marking	**Current display** **AI 91** **Serial number: Any number of digits (alphanumeric support)**	As they own the goods, the GTIN corporate code shall be the code of the medical institution. However as the medical institutions in Japan don't have seven or nine-digit JAN corporate codes, the display shall be the AI "91" used internally by the medical institution/facility until the medical institution acquires the aforementioned JAN corporate code. * The in-hospital independently set hospital code and serial number AI is set as AI "91" under the GS1 standards. Please refer to the "table of application identifiers"

|	**Current display**		
	FNC1 91 XXXXXXXXXXXXXXXXXXXXXXXXX **(Note): Spaces are for explanation purposes only and not included in the row of data. X is the alphanumeric character data**	 (91)XXXXXXXXX XXXXXXXXXXXXX	(Note): Visual data is not required in cases where display is impossible
In-house unique arbitrary marking	**Future display** **AI 8004** **JAN corporate code + Global Individual Asset Identifier (alphanumeric support)** **Up to 30 digits**		The AI 8004 is the Global Individual Asset Identifier. The display shall be the seven or nine-digit JAN corporate code plus an arbitrary global individual asset identifier to create a total of up to 30 digits.
	Future display		
	FNC1 8004 497776665 42345B-2 **(Note): Spaces are for explanation purposes only and not included in the row of data**	 (8004)497776665 42345B-2	(Note): Visual data is not required in cases where display is impossible

[Inter-company AI "90" and medical facility in-house AI "91" settings]

90	**Data agreed to between companies**	When companies have agreed on the data to be displayed (the intra-medical institution/center commissioned for sterilization/cleaning hospital code and serial number), AI "90" is set.	**n2+an…30**
91	**Used in-house by facilities/companies**	When companies/facilities display data for used on their own assets (hospital code and serial number), "91" is set. After "91" is "92" and "93", etc. Sequential AI can be set.	**n2+an...30**

(2) Application identifier setting standards for returnable vessels such as sterile containers, etc.

ISO/IEC15418 standard GS1 application identifiers for returnable vessels (that are recovered and recycled) such as sterile containers, etc. are defined by the following business types and ownership. These application identifiers are similarly listed in the European industry where they have begun to be used. The display of application identifiers on returnable vessels (that are recovered and recycled) such as sterile containers, etc. has great benefits for the end user medical institutions and facilities from the perspective of international conformity as well as precise and detailed data management for each form of business. Accordingly, the following setting, display and reading of application identifiers tailored to the business is recommended.

Business type	Target product	Application identifier, data item	Explanation
Manufacturer	Goods manufactured by a manufacturer	**AI 01** **GTIN 14 digits** **AI 21** **Serial number: Eight digits recommended (alphanumeric support)**	The data configuration is the same as the "Surgical Instrument Two Dimensional Symbology Standard Guidelines". * Refer to (P.90-) of the Japan Federation of Medical Devices Association's "Standard Code Operation Manual for Medical Instruments, etc"
	Display FNC1 01 04977766654302 21 42345B−2 **(Note): Spaces are for explanation purposes only and not included in the row of data** (01)04977766654302 (21)42345B-2		(Note): Visual data is not required in cases where display is impossible
Sterilization and cleaning outsourcing	Goods commissioned such as sterile containers, etc.	**Current display** **AI 90** **Serial number: Any number of digits (alphanumeric support)**	As they own the goods, the GTIN corporate code shall be the code of the medical institution. However as the medical institutions in Japan don't have seven or nine-digit JAN corporate codes, the display shall be the AI "90" defined by agreement between the two companies until the medical institution acquires the aforementioned JAN corporate code. * The medical institution and the sterilization/cleaning center is a "company/company" relationship, and therefore the AI "90" is set under the GS1 standards. Please refer to the "table of application identifiers"

Sterilization and cleaning outsourcing	Goods commissioned such as sterile containers, etc.	**Current display** FNC1 90 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX **(Note): Spaces are for explanation purposes only and not included in the row of data. X is the alphanumeric character data** (90)XXXXXXXXXX XXXXXXXXXXXXXX	(Note): Visual data is not required in cases where display is impossible
		Future display **AI 8003** **0 + JAN corporate code + asset type code + check digit + serial number (maximum of 16 digits)** **Maximum total digits: 30**	AI 8003 is the Global Returnable Asset Identifier. (GRAI) This identifier consists of the number "0" followed by the JAN corporate code (seven or nine digits), the asset type code (three or five digits), the check digit (one digit) and the serial number (maximum of 16 digits) to create a total of up to 30 digits.
	Future display FNC1 8003 0 4977766 63333 8 42345B-2 **(Note): Spaces are for explanation purposes only and not included in the row of data** (8003)04977766633338 42345B-2		(Note): Visual data is not required in cases where display is impossible
Rental / leasing business	Rental / lease of their owned products	**AI 8003** **0 + JAN corporate code + asset type code + check digit + serial number (maximum of 16 digits)** **Maximum total digits: 30**	AI 8003 is the Global Returnable Asset Identifier. (GRAI) This identifier consists of the number "0" followed by the JAN corporate code (seven or nine digits), the asset type code (three or five digits), the check digit (one digit) and the serial number (maximum of 16 digits) to create a total of up to 30 digits.
	Display FNC1 8003 0 4977766 63333 8 42345B-2 **(Note): Spaces are for explanation purposes only and not included in the row of data** (8003)04977766633338 42345B-2		(Note): Visual data is not required in cases where display is impossible
Medical institutions	In-hospital unique arbitrary marking	**Current display** **AI 91** **Serial number: Any number of digits (alphanumeric support)**	As they own the goods, the GTIN corporate code shall be the code of the medical institution. However as the medical institutions in Japan don't have seven or nine-digit JAN corporate codes, the display shall be the AI "91" used internally by the medical institution/facility until the

			medical institution acquires the aforementioned JAN corporate code. * The in-hospital independently set hospital code and serial number AI is set as AI "91" under the GS1 standards. Please refer to the "table of application identifiers"
Medical institutions		**Current display** FNC1 91 XXXXXXXXXXXXXXXXXXXXXXXXXX **(Note): Spaces are for explanation purposes only and not included in the row of data. X is the alphanumeric character data** (91)XXXXXXXXX XXXXXXXXXXXXX	(Note): Visual data is not required in cases where display is impossible
	In-house unique arbitrary marking	**Future display** **AI 8003** **0 + JAN corporate code + asset type code + check digit + serial number (maximum of 16 digits)** **Maximum total digits: 30**	AI 8003 is the Global Returnable Asset Identifier. (GRAI) This identifier consists of the number "0" followed by the JAN corporate code (seven or nine digits), the asset type code (three or five digits), the check digit (one digit) and the serial number (maximum of 16 digits) to create a total of up to 30 digits.
		Future display FNC1 8003 0 4977766 63333 8 42345B–2 **(Note): Spaces are for explanation purposes only and not included in the row of data** (8003)04977766633338 42345B-2	(Note): Visual data is not required in cases where display is impossible

[Inter-company AI "90" and medical facility in-house AI "91" settings]

90	**Data agreed to between companies**	When companies have agreed on the data to be displayed (the intra-medical institution/center commissioned for sterilization/cleaning hospital code and serial number), AI "90" is set.	n2+an…30
91	**Used in-house by facilities/companies**	When companies/facilities display data for used on their own assets (hospital code and serial number), "91" is set. After "91" is "92" and "93", etc. - sequential AI can be set.	n2+an...30

AI8003 and AI8004

Extract from the GS1 General Specifications Vol.9: "Chapter 3: GS1

application identifier"

Global Returnable Asset Identifier (GRAI): AI (8003)

The Application Identifier (8003) indicates that the GS1 Application Identifier data field contains the GRAI (Global Returnable Asset Identifier). The GRAI is used to identify returnable assets. The GS1 Company Prefix is the one allocated to the owner of the asset (see Section 1.5). It makes the number unique worldwide. The zero in the leftmost position is added to generate 14 digits in the asset identification number field.

The Asset Type is a number assigned by the owner of the asset to uniquely identify each type of asset.

The Check Digit is explained in Section 7.10. Its verification, which must be carried out in the application software, ensures that the number is correctly composed. The optional serial number is assigned by the owner of the asset. It identifies an individual asset within a given Asset Type. The field is alphanumeric and may contain all characters contained in Figure 7.12 – 1.

Figure 3.9.3 – 1

Format of the Element String				
Application Identifier	Global Returnable Asset Identifier (GRAI)			
	GS1 Company Prefix $\longrightarrow$	Asset Type $\longleftarrow$	Check Digit	Serial Number (Optional)
8 0 0 3	0 N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12}		N_{13}	X_1 variable X_{16}

The data transmitted from the bar code reader means that the GRAI has been captured. It may be processed according to the particular application requirements.

When indicating this Element String in the human readable section of a bar code label, the following Data Title should be used (see also Section: **GRAI**

Global Individual Asset Identifier (GIAI): AI (8004)

The Application Identifier (8004) indicates that the GS1 Application Identifier data field contains a GIAI (Global Individual Asset Identifier). This Element String may be used for the unique identification of individual assets to provide a means to store relevant data.

✔ **Note:** This Element String must never be used to identify the entity as a trade item or logistic unit. If an asset is transferred between parties, the GIAI cannot be used for ordering the asset. However, asset identification may be exchanged between parties for the purpose of traceability

The GIAI uses the GS1 Company Prefix of the company assigning the Individual Asset Reference. The structure and numbering of the Individual Asset Reference is determined by the holder of the GS1 Company Prefix. It may contain all characters contained in Figure 7.12 – 1.

Figure 3.9.4 - 1

Format of the Element String		
Application Identifier	Global Individual Asset Identifier (GIAI)	
	GS1 Company Prefix ──────────▶	Individual Asset Reference ──────────────────────▶
8 0 0 4	N_1 ... N_i	X_{i+1} ... variable length $X_{j\,(j<=30)}$

The data transmitted from the bar code reader means that the Element String of a GIAI has been captured. It may be processed according to the particular application requirements.

When indicating this Element String in the human readable section of a bar code label, the following Data Title should be used (see also Section): **GIAI**

Case study guide

1) "A" hospital case study in Japan

(1) Summary

Surgical instruments are investigated if surgical site infection occurs and if surgical instruments suspected to have been used on patients with Creutzfeldt - Jakob Disease have been used on other patients as well, it is necessary to confirm those patients. In facilities that add a symbol to distinguish individual containers and keep usage records in cases of surgical department surgery, it is often possible to trace the individual container unit used in a surgical procedure. However, sometimes the swapping of instruments between containers has been observed when there are multiple surgical instruments such as Kocher, etc. housed in a single container. Because unique identification numbers are not attached to individual surgical instruments that are used as an individual unit and not housed in a container, accurate traceability is not possible when there are multiple surgical instruments of the same type.

For accurate traceability, it's necessary to ultimately attach a unique identification number to individual surgical instruments that are reused. Seal attachment, RFID installation and direct engraving have been considered as marking methods for reused surgical instruments, however direct marking that can never fall off into the body is thought to be the most appropriate method from the perspective of preventing residual foreign bodies during surgery.

Management and operation of surgical instruments by direct marking has been considered for basic sets of surgical instruments for obstetrics and gynecology, sets of surgical instruments for urological endoscopy and for rental orthopedic surgical instruments.

(2) Size of facility

Beds: 1,076
Operating rooms: 17
Outpatient departments: 29
Number of surgical procedures: Approximately 8,500
Number of outpatients: 2,555 (daily average)

(3) System aims

The creation of a system to make traceability of medical care possible is considered necessary as a measure to ensure the safety of medical care and in order to examine the root cause and prevent recurrence if a problem occurs in treatment. In particular, attaching a unique device identification symbol to individual surgical instruments and keeping a history of their use is considered beneficial in preventing medical accidents from surgical instruments. The decision has been made to examine the future direction of data storage media and the minimum required data from a broad perspective taking into account current technology.

(4) System summary

1) Marking and marking method

The currently used data matrix marked data is basically 16 digits (fig.1) of which the first two digits are the country code (e-mail country identification code: Germany = DE, Japan = JP, U.S.A. = US, etc.), the following three digits are the corporate/hospital code and the remaining 11 digits (alphanumeric) are used arbitrarily (fig.2). It is believed this is a sufficient number of digits for equipment/instruments that require marking.

The size of the marking is the minimum marking size of 1 x 1mm and the hospital have proceeded with a maximum of 16 digits. Metallic surgical instruments can be marked with YAG laser, but some surgical instruments are made of synthetic resin and can be marked with 2mm markings by CO_2 laser.

Data matrix
Marking content: 16 digits (alphanumeric)
Country code (two digits) + hospital code (three digits)
+ serial number (11 digits)
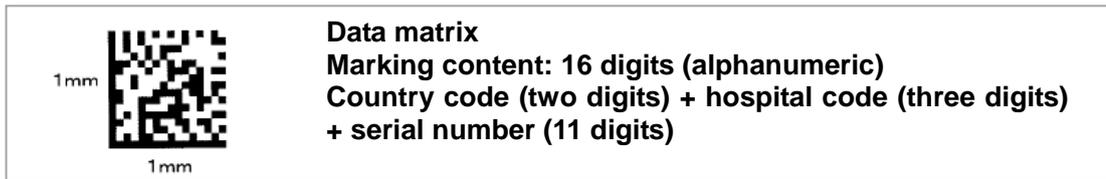
Figure 1: Marking content

Corporate/ hospital classification symbol **(EX: Osaka University = H0)**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
J	P	H	0	0											

Used arbitrarily by the company / hospital
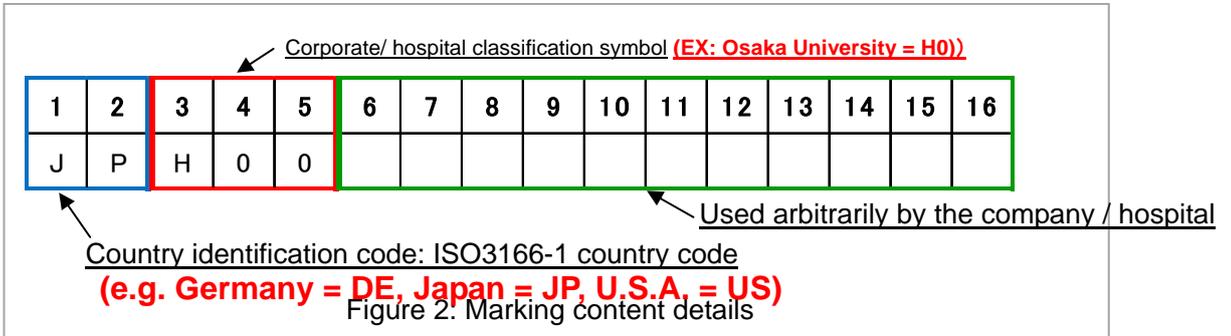
Country identification code: ISO3166-1 country code
(e.g. Germany = DE, Japan = JP, U.S.A. = US)
Figure 2: Marking content details

2) Target departments and surgical instruments
(1) Basic sets of surgical instruments for obstetrics and gynecology
First the size of the marking on the various metallic surgical instruments and the number of digits (in bytes) was examined. Then the hospital verified that the markings could continue to be read even after sterilization and cleaning, etc. Based on the results, two-dimensional symbol data matrixes were created on five containers of surgical instruments (fig.3, fig.4) for basic laparotomy in obstetrics and gynecology and tested with approximately one year of continuous reading.
One container contained 88 surgical instruments, making a total of 440 instruments subject to marking.
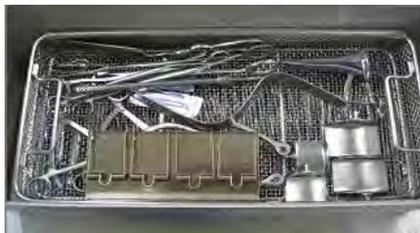
Figure 3: Obstetrics and gynecology surgical instruments in a sterile container (1)

Figure 4: Obstetrics and gynecology surgical instruments in a sterile container (2)

(2) Surgical instruments for urological endoscopy

The basic sets of surgical instruments for obstetrics and gynecology were all metallic items, a lot of them were relatively large and the marking position could be selected after sufficient consideration. However, the surgical instruments for urological endoscopy are not all metallic – some synthetic resin products are included. In addition, there are also some small, cylindrical surgical instruments. Here examination of small surgical instruments and surgical instruments for urological endoscopy incorporating plastic materials where marking is considered difficult was carried out.

The target instruments are the instruments of the endoscopy system's transurethral resection system which include very small and thin instruments, instruments with complex shapes, detached parts (all parts will be marked), instruments consumable electrodes and instruments with multiple sterilization methods (autoclave sterilization, low temperature plasma sterilization), etc (fig.5, fig.6).

Figure 5: Endoscopic surgical instruments treated with autoclave sterilization (approximately 30 instruments)

Figure 6: camera head treated with ethylene oxide or low temperature plasma sterilization

(3) Rental orthopedic surgical instruments

In recent years the Ministry of Health, Labour and Welfare have been seeking measures to prevent defects in rental instruments such as setting a service life or a limit on use based on scientific evidence. Here 1.0mm square, 16-digit base marking was applied to two types of stainless surgical and two types of plastic rental orthopedic surgical instruments and the possibility of establishing traceability was verified by the reading of markings with a reader when setting the instruments after return from the hospital.

3) The overall flow of the traceability management system

Figure 7 displays the overall flow of the traceability management system. After surgery is completed, the surgical instruments are transported directly to the cleaning process. It is possible for some sets to be divided into used and unused instruments and transported in two patterns. For example, in the case of a partial endoscopy, etc. the consumables, etc. are divided into used and unused equipment after surgery and the instruments recovered/sorted from the cleaning division are placed in a washing machine and it is possible to keep a cleaning history.

After cleaning, the instruments are then returned again to the surgical container. By reading the two-dimensional symbol marked on each instrument at this time, it's possible to accurately set instruments without the presence of an expert. The mistaken return of instruments to the container is checked and the serial number and linking of the container and its instruments are automatically stored in a database.

When setting is complete, all instruments are processed as a container unit. By reading the two-dimensional symbol marked on the container plate with a hand-held two-dimensional symbol-reading PHS terminal and entering the number of the sterilization equipment, the sterilization equipment data is linked with the container number and sterilization management is established for the container unit and the surgical instruments inside.

Following this, the two-dimensional symbol marked on the container plate is read with a hand-held two-dimensional symbol terminal, the container is stored in a warehouse and sterilization deadline management and location management is carried out.

Each patient's surgery order number allocated by the surgical ordering system is received at the hand-held two-dimensional symbol-reading PHS terminal. The two-dimensional symbol marked on the container plate is read and a check is performed to see whether the container matches the patient's surgery order number. If there is a match, the container is transported to the operating room.
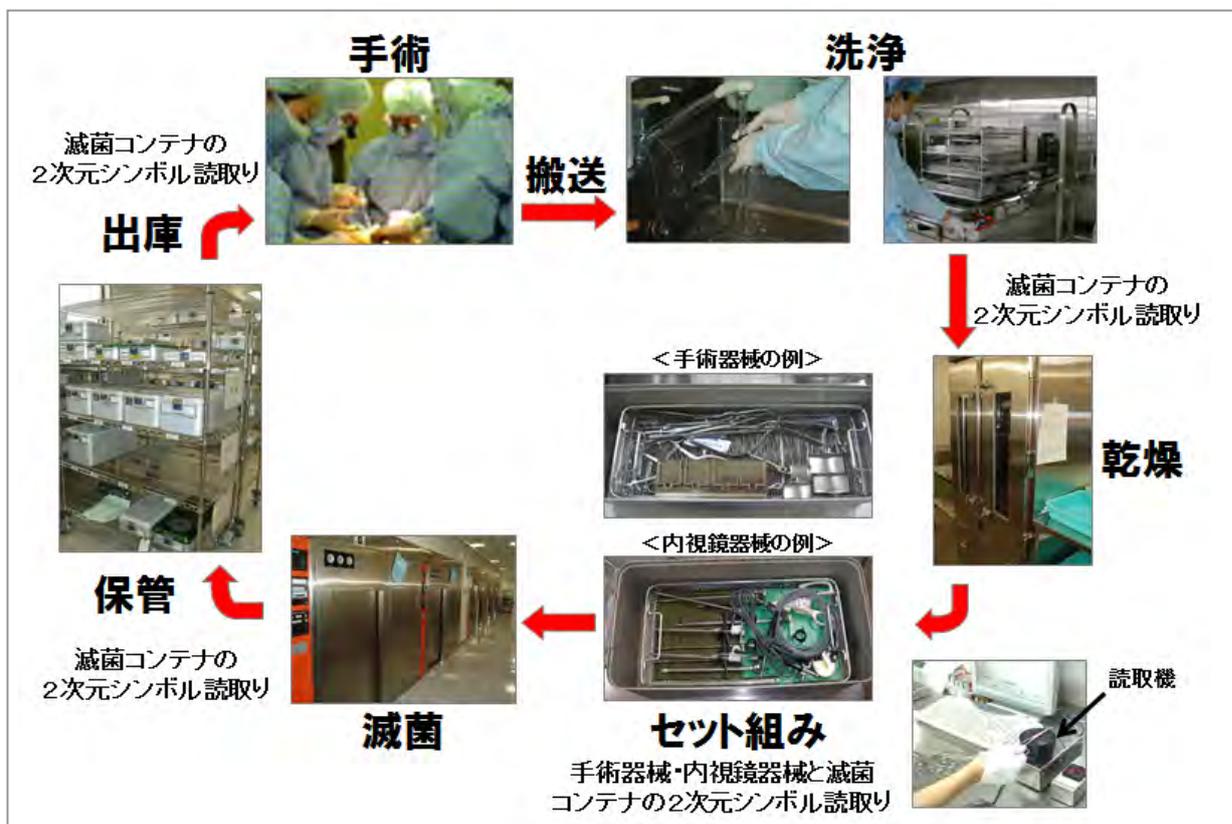
(5) Result of introduction and future prospects

It is necessary to be able to refer to more detailed materials if the marked content has been read, however the materials for instruments already possessed by the facility basically need to be created in the user's computer.

It is essential that newly purchased equipment can be checked via an official database center from its marking content. To make this possible, it is thought that each manufacturer needs to commit to determining items and creating materials.

Approximately 3,000 different kinds of instruments are used in the surgical department each year. Generally the instrument manufacturers name and instrument name is already known, so it would be beneficial if the individual instrument identification code and relevant materials were understood by reading the marking with a reader. For example, a Kocher instrument is visually distinguishable as a Kocher so it would be beneficial to identify which Kocher instrument it is out of the many Kocher instruments (by confirming the specific product from the identification symbol) and confirm and record its usage history (patients / cleaning / sterilization / storage), purchase history, disposal history and repair history, etc. for the purpose of surgical instrument management.

The creation of two-dimensional symbols on surgical instruments and their use for the confirmation of sales/logistics (packing unit symbols are OK) and recovery time due to damage/repair (individual identification is required) is presumed to be for the purposes of the instrument maker. However, in addition to this, the medical care side must use the unique identification code for surgical instrument management such as usage history and disposal, etc. In order for them to do this, the instrument manufacturers must be requested to provide a long-term guarantee for their two-dimensional symbol markings and create a

database.

The Japan Association of Medical Devices Industries (JAMDI) "Surgical Instrument Two-dimensional Symbology Standard Guidelines" has been developed and manufacturers' newly sold instruments are believed to be marked, however it is desirable to create a database that contains information such as the instrument's overall length, whether the tip is straight or curved and whether there are hooks, etc. in addition to the product name and standard format.

2) "B" hospital case study in Japan

(1) Summary

　　Two-dimensional printed sterile labels and a traceability system using plates have been created as a "sterilized product quality control system" to manage traceability information and quality control of sterile items. Using this "sterilized product quality control system" as a base, this hospital is now introducing a sterile container management system using additional RFID tags and an instrument reading system utilizing two-dimensional symbols marked on instruments.

(2) Size of facility

Beds: 801
Operating rooms: 15
Outpatient departments: 32
Number of surgical procedures: 4,949 (per year)
Number of outpatients: 1,210 (daily average)

(3) System aims

The aim of this system is to achieve a traceability system for small surgical instruments through two-dimensional symbols and data matrixes, implement individual instrument management from individual instruments to sterile container sets and ensure the quality and safety of sterile instruments. In addition, the system aims to support the sterility assurance of sterile instruments that have been the source of even one infection through a system that prevents accidents such as the use of sterile instruments past their expiry date and instruments with defects in sterilization before they occur as well as reduces work through automatic input with RFID tags.

(4) System summary

　　1) Systems being introduced:
- Sterilized product quality control system (traceability system)
- RFID tag sterile container management system
- Instrument marking reading system (container / individual instruments)
　　2) Equipment
- Database server, web server, five computer terminals
- Four hand-held terminals for data matrix reading
- Nine RFID tag gate-type antennas, three antennas for electronically tagged cleaning equipment
- Three RFID tag stand-type antennas
- 12 instrument marking readers, approx. 100,000 marked instruments

　　Using the "sterilized product quality control system" as a base, a system is being introduced where RFID tag plates are attached to sterile containers and data matrixes marked on surgical instruments are utilized. Figure 1 displays the reading of the RFID tags in four phases – "recovery", "cleaning", "sterilization" and "withdrawal" and movement management.

　　A dedicated reader reads the surgical instruments with marked data matrixes in recovery and setting operations and transmits the data as count information. Individual instruments are also marked with a data matrix and, based on label management, a dedicated reader reads the surgical instruments in recovery and labeling and transmits the data.
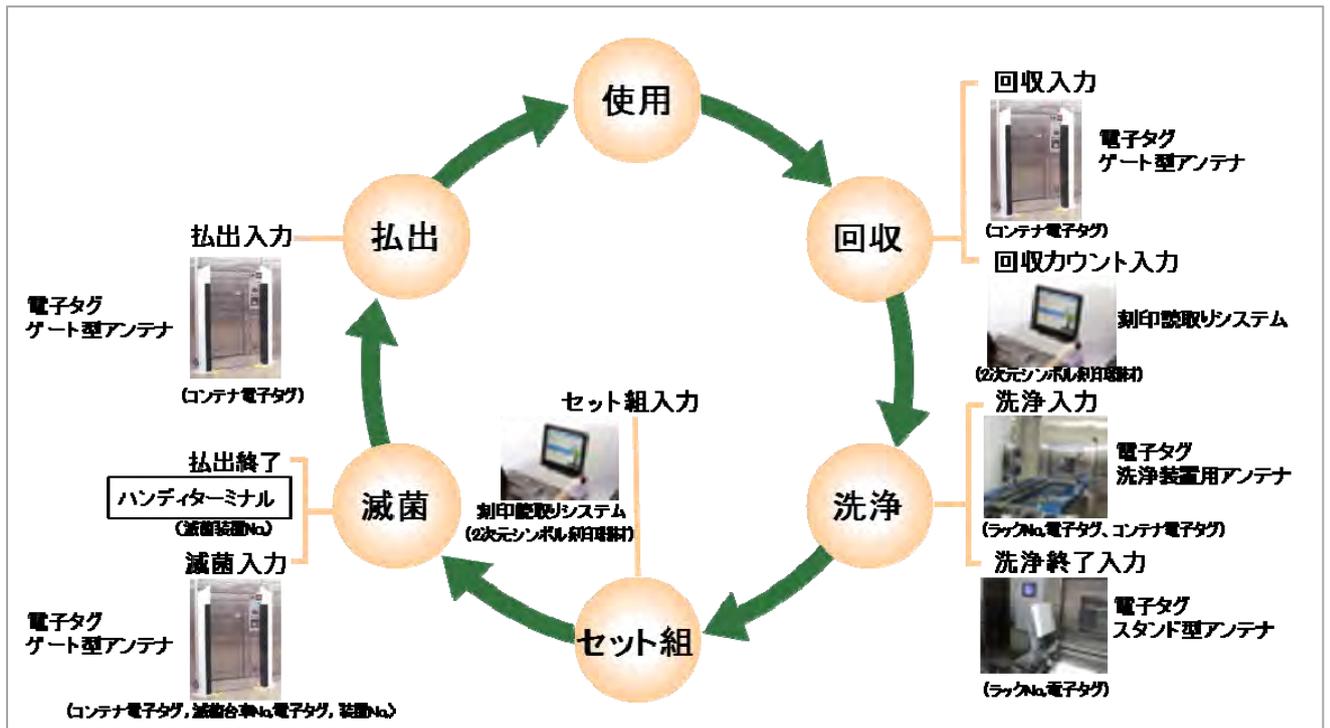
Figure 1: Sterile container operation flow
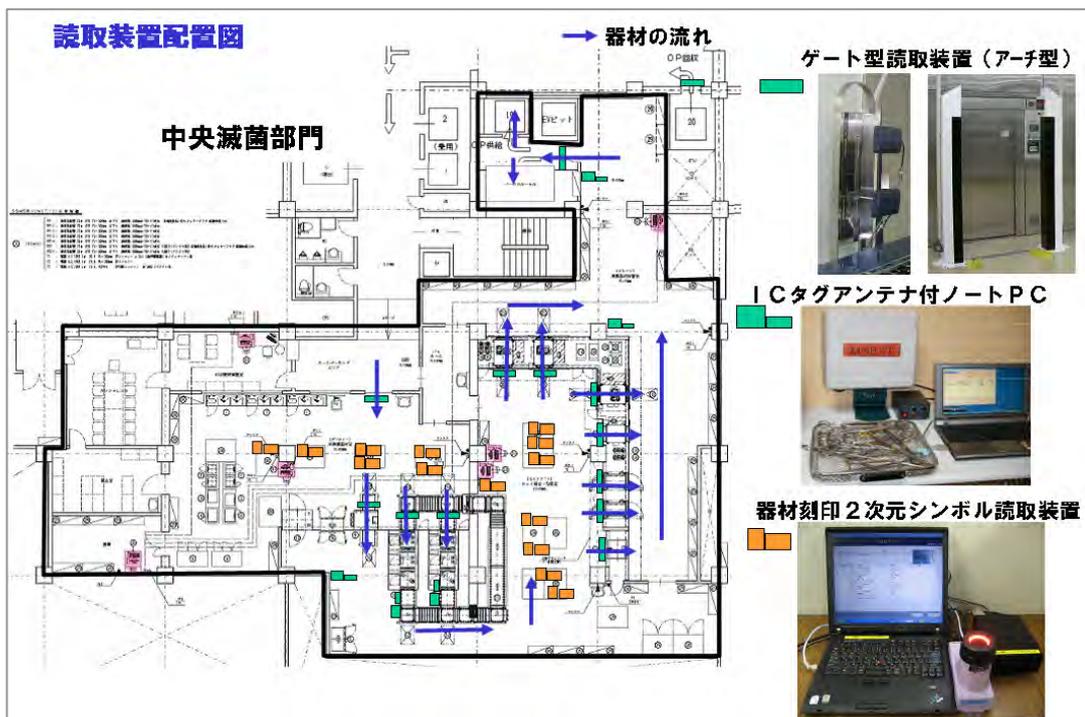
Figure 2: Reading equipment, RFID tag antenna placement
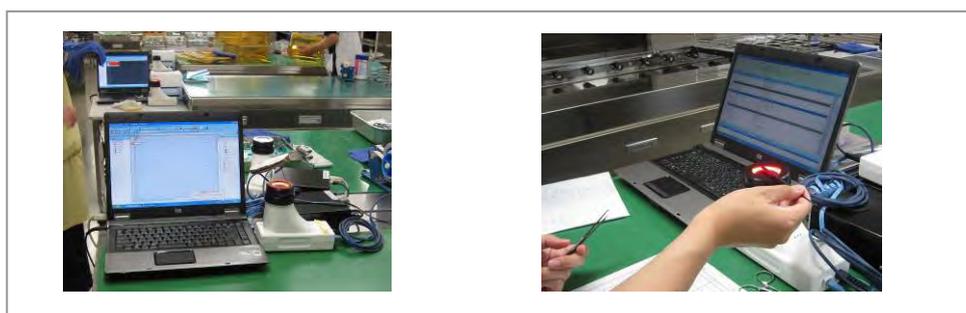
Figure 3: Marked surgical instrument reader

3) RFID tags and surgical instrument two-dimensional symbols

Stress is applied to RFID tags and markings as a result of heating during the cleaning and sterilization process.

Hot water treatment is carried out for ten minutes at 93°C in machine cleaning followed by drying for 60 minutes at a maximum of 105°C. Stress is also applied in hand-cleaning as the process of drying for 60 minutes at a maximum of 105° is still followed. During sterilization, vapor pressure is used to heat the instruments at 135°C for ten minutes resulting in heat and pressure stress. A maximum heating load of 110°C is applied for 15 minutes during drying. Heat-resistant RFID tags that can withstand the above stress during cleaning and sterilization are being developed through experimentation. The RFID tags have a unique 17-digit number. This unique number is read and linked with the sterile container management master data recorded in the management system and a sterilized product quality control system is implemented.

RFID tag unique number example: H0084E3C04137E003 HE004000000267D05
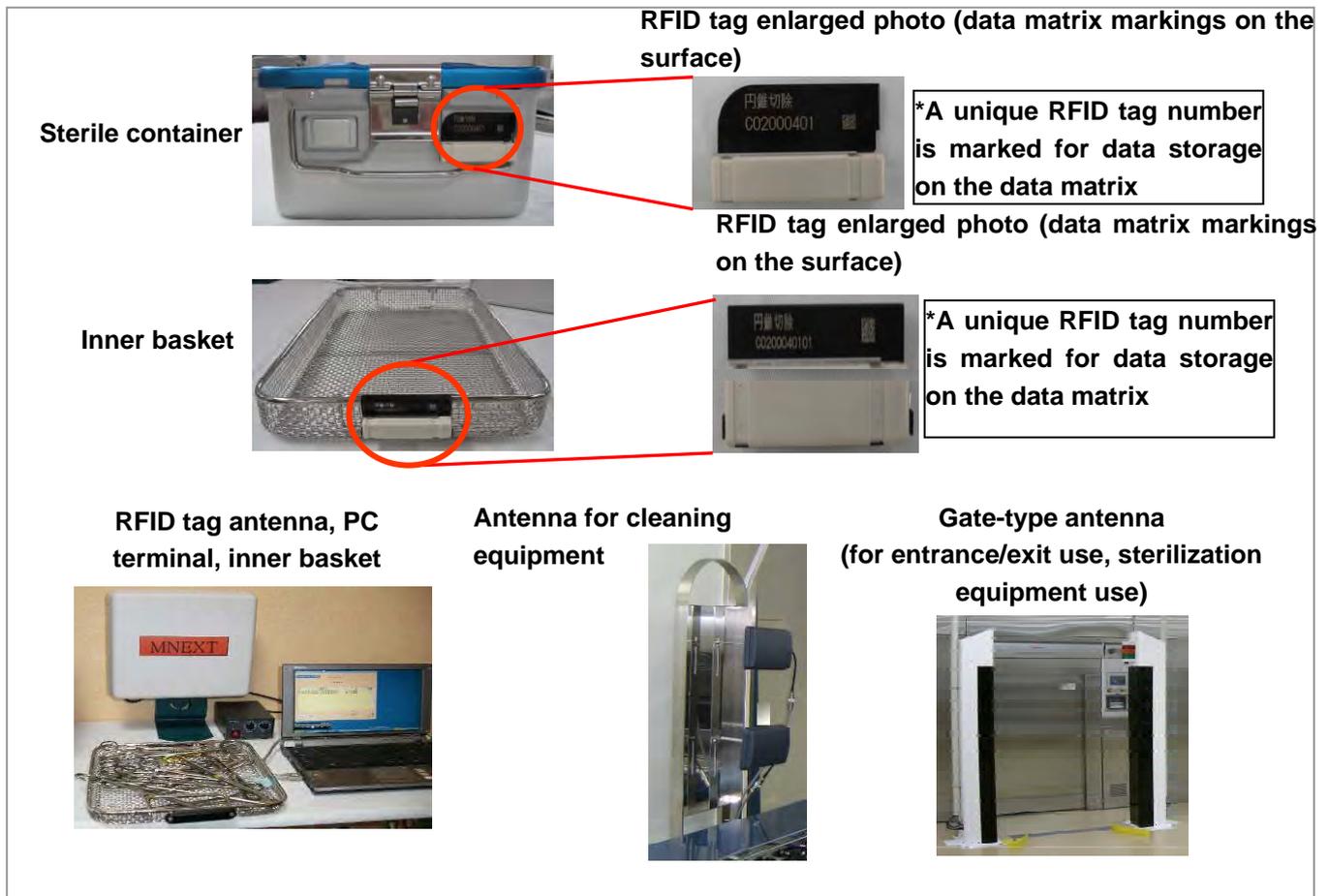
Figure 4: RFID tag and RFID tag antenna

The hospital carries out their own data matrix marking on surgical instruments in accordance with the Surgical Instrument Two-dimensional Symbology Standard Guidelines. They mark 16 digits such as an AI (Application Identifier): 90 and serial number: any number of digits (alphanumeric). Surgical appliances can be marked to a size of a 1.2mm square, so even small instruments can be marked and their readability will be good.

Marking example	AI (Application Identifier)	Country code	Hospital code	Serial number (sequence number)
	90	JP	A01	000000001
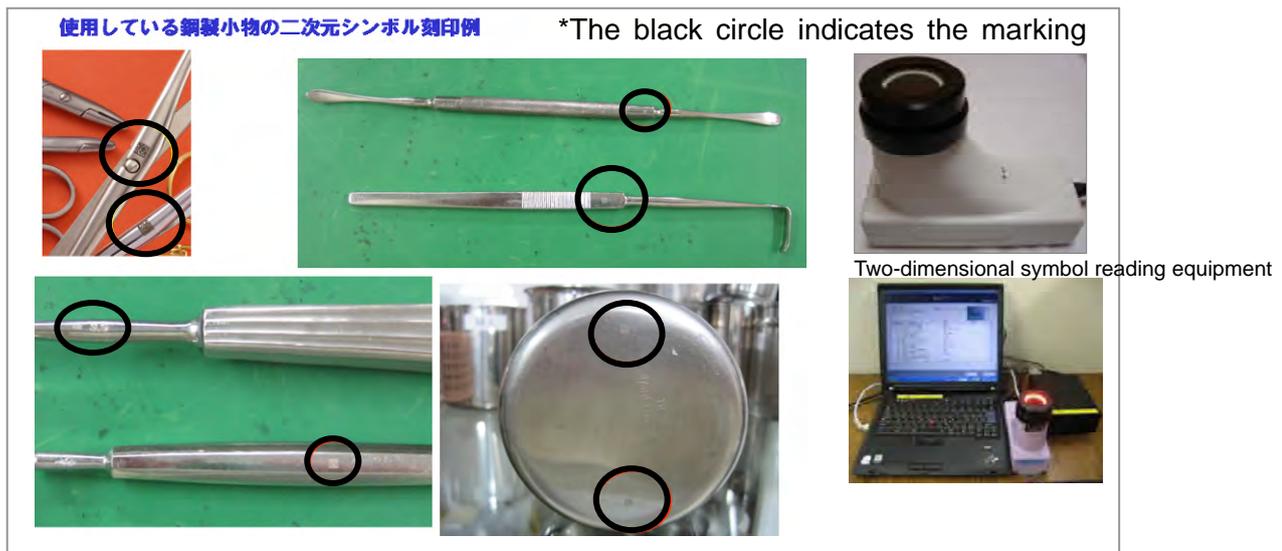
Figure 5: Data matrixes marked on surgical instruments and dedicated reading

(5) Benefits of introduction

- Reduction of working time for staff in the sterilization department

A reduction of central sterilization department staff working hours from 462,960 minutes to 453,960 minutes as a result of the introduction of the "sterilized product quality control system" was reported at the 2004 Medical Instrument Society of Japan conference (Tokushima University Hospital).

At this point input was mainly done through hand-held terminals at seven locations. In this case study, the hand-hand terminal entry point was reduced to a single location (sterile containers) through the use of RFID tags and the workload and working time of the central sterilization department staff has been reduced.

- Improvement of operation precision as a result of converting instrument management to data

Instruments can easily be identified by reading the data matrix. As a result, while the time for setting input operations hasn't noticeably changed from the approximate five minutes per container (88 instruments), the accuracy of these operations has significantly improved.

- Improvement of work efficiency and data management level

In terms of business, a cooperative framework has been established from work orders and work prediction and work efficiency and data management levels have improved. Instrument processing through a combination of RFID tags and the "sterilized product quality control system" has allowed for the quantification of each process and a reduced workload thanks to automatic input. In addition, operation accuracy and instrument management levels have improved along with individual management through surgical instrument data matrix reading.

(6) Future Issues

Due to the wide variations in material quality of surgical instruments, it is important to select a marking method, marking shape and marking size that are suitable for the material quality when marking. In this case study, marking was carried out by laser and engraving.

Scuffing or scratching may damage the marking but this can be dealt with to an extent depending on the marking method and marking size. However, there are also cases where a marking may become unreadable, so it is important to determine the marked data storage and re-marking methods in advance.

One measure of the lifespan of RFID tags is 1,000 readings. It is important to store data for RFID tag replacement in advance by displaying a data matrix such as the sterile container code, etc. on the RFID tag itself.

(7) Summary

A traceability system was introduced as a sterilized product quality control system and hand-held terminal input by barcode made the basis for data entry with combined use of an instrument two-dimensional marking reading system and RFID tag reading system.

RFID tag plates and antennas to read the RFID tags are required for the RFID tag system. In the instrument marking reading system it is important that the markings have been created on the surgical equipment in advance and the reading equipment is highly accurate.

The sterilized product quality control system, RFID tag system and instrument marking reading system allowed for quantification of each process in surgical instrument processing and was linked to a reduced workload. In addition, operation accuracy and instrument management levels also improved. This improves surgical instrument quality control and guarantees quality and it thought that such a system contributes significantly to the improvement of a hospital's medical care safety.

References

1. Marking examples

2. Japan Association of Medical Devices Industries
   "Surgical Instrument Two-dimensional Symbology Standard Guidelines"

3. The Guidelines of Japanese Ministry of Health, Labour and Welfare(Japanese)

4. U.K. Ministry of Health Regulations Summary "Pollution Prevention Guidelines for

   Medical Equipment"

5. French specification standards: "Insruments chirurgicaux Definition des
   specifications d'immatriculation a des fins de tracabilite"(French)

1. Marking examples

(1) Laser marking examples:

The black marking method and impression marking method can be used to mark metals. The black marking method has good visibility but is shallow compared to the impression marking method. The impression marking method, where marking of a greater depth can be created, is suitable for surgical equipment as the equipment can be scratched when it rubs against other items of equipment and it is often subject to cleaning and sterilization.

（1）Black marking
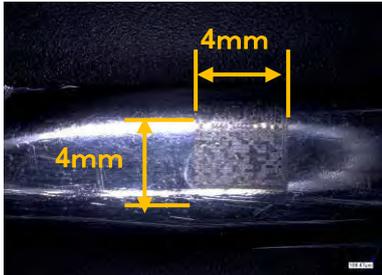
Marking size: 4mm square
Digits: 26
Marking depth: 11.2μm

（2）Impression marking
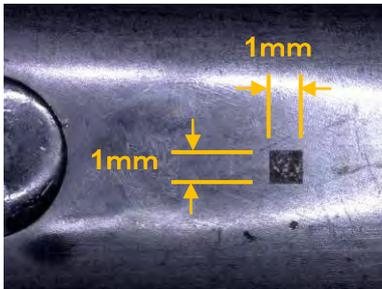
Marking size: 1mm square
Digits: 26
Marking depth: 41.0μm
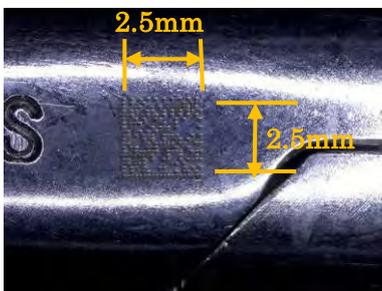
Marking size: 2.5mm square
Digits: 26
Marking depth: 20.0μm

（2）Dot pin marking
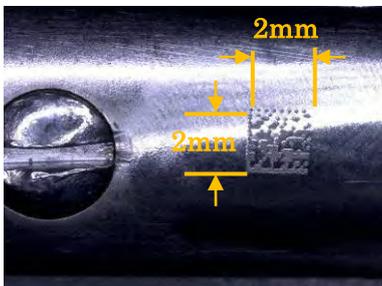
Marking size: 2mm square
Digits: 26
Marking depth: 36.6μm
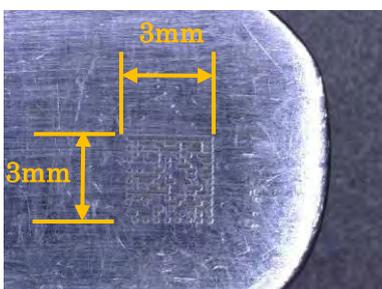
Marking size: 3mm square
Digits: 26
Marking depth: 29.4μm

2. Japan Association of Medical Devices Industries "Surgical Instrument Two-dimensional Symbology Standard Guidelines"

Surgical Instrument Two-dimensional Symbology Standard Guidelines

1. Purpose

The display of two-dimensional symbols on surgical instruments is becoming essential to ensure medical safety and for traceability in the case trouble arises. In particular, from the viewpoint of both marketing authorization holders and medical institutions it is essential to create a display on the body of a surgical instrument that can be used to for identification in order to identify and recover of bad lots, for sterilization management of surgical instruments that have been used on patients with Variant Creutzfeldt-Jakob disease (vCJD) and to enable on-site approval of rental instruments.

These guidelines are standard guidelines that lay out the coding schemes such as data carriers and data structure in order to avoid traceability confusion in the two-dimensional symbology standards supplied by each marketing authorization holder and make them useful for the safety management of medical institutions. We ask for the cooperation and understanding of all marketing authorization holders both domestically and internationally.

2. Definition of surgical instruments

The "surgical instruments" that are the target of these guidelines are surgical instruments made from materials such as stainless steel, aluminum, copper alloy, titanium or ceramics, etc. and are reused in surgery or treatment and subject to regenerative treatment such as cleaning and sterilization, etc.

In addition, instruments used in surgery or treatment that don't fall under the category of medical instruments as prescribed in the Pharmaceutical Affairs Act may still be subject to these guidelines.

3. Basic code system

The basic code system adopted under these guidelines conforms to the UCC/EAN-128 data structure of the "Medical Instrument Product Code / UCC/EAN-128 Bar Code Standardization Operation Standards Manual (volume 5)" jointly formulated and published in September 2005 by the Japan Federation of Medical Devices Association, the Distribution System Research Institute and Medical Information System Development Center and is a two-dimensional symbol data carrier under ISO standards.

（1）Data structure
In the UCC/EAN-128 code system, the GTIN (Global Trade Item Number: 13-digit EAN with the "0" packaging indicator added to the front to create 14 digits) and serial number is composed of the following items in order and is 26-36 digits (26 digits is recommended.

(1) Product code identifier (AI): 01 (two digits, fixed)
(2) Packaging indicator: 0 (one digit, fixed)
(3) Manufacturer code: The corporate code given by the Distribution System Research Institute (*Note #1)
(4) Item code: The product identification code registered by each company (*Note #1)
(5) Check digit: A single digit determined by the numbers from (2) – (4)
(6) Serial number identifier (AI): 21 (two digits, fixed)
(7) Serial number: The ID identification code registered by each company, eight digits recommended (*Note #2)

*Note #1: Manufacturer code and item code standard specifications:

A. If a manufacturer code (five digits) was obtained before December 2000:

0 1	0	4 9	1 2 3 4 5	6 7 8 9 10	0	2 1	1 2 3 4 5 6 7 8
AI	包装	国コード	メーカーコード	アイテムコード	CD	AI	シリアルナンバー
2桁	1桁	2桁	5桁	5桁	1桁	2桁	8桁
				26桁			

B. If a manufacturer code（seven digits）was obtained from January 2001:

0 1	0	4 5	1 2 3 4 5 6 7	1 2 3	0	2 1	1 2 3 4 5 6 7 8
AI	包装	国コード	メーカーコード	アイテムコード	CD	AI	シリアルナンバー
2桁	1桁	2桁	7桁	3桁	1桁	2桁	8桁
				26桁			

*Note #2: Serial number recommended specifications:

Our recommended specification is an eight-digit serial number display as seen below. Companies that manage their serial numbers under other specifications may continue to do so; however this is undesirable from the perspective of serial number validity as increasing the number of digits may result in an unreadable display.

1 2	3 4	5 6 7 8
西暦	月	連番
	シリアルナンバー8桁	

(2) Data carrier type and display position and size

We recommend the following two ISO standard two-dimensional symbols as the data carrier.

Promotion of Data Matrix (ECC200) as the data carrier has become common in the western medical equipment/instrument industry. As the data matrix (ECC200) will be displayed and circulated on future imported equipment/instruments, use of the data matrix (ECC200) together with the domestic industry QR code is already seen and therefore a QR code is recommended.
A single scanner can read both data matrixes and QR codes and circulation of both two-dimensional systems in a standardized basic system code wouldn't cause confusion in use. However, advance confirmation of reading specifications is a prerequisite for data carrier type selection.

The use of RFID tags, etc. will also be examined at a later stage based on future technology trends and reading accuracy.

1) Data Matrix (ECC200) (ISO/IEC 16023)
2) QR Code (ISO/IEC 18004)

As a rule, there are two display positions for the data carrier.
In addition, a 3-5mm square is an appropriate size for a data carrier considering display and recognition

accuracy. However, any of the following display methods may be selected according to the size and shape of the surgical instrument.

(1) When a display area of a 3mm square or above can be secured on the surgical instrument

3～5mm	3～5mm
3～5 mm	3～5 mm
a）Data Matrix（ECC200）	b）QR Code
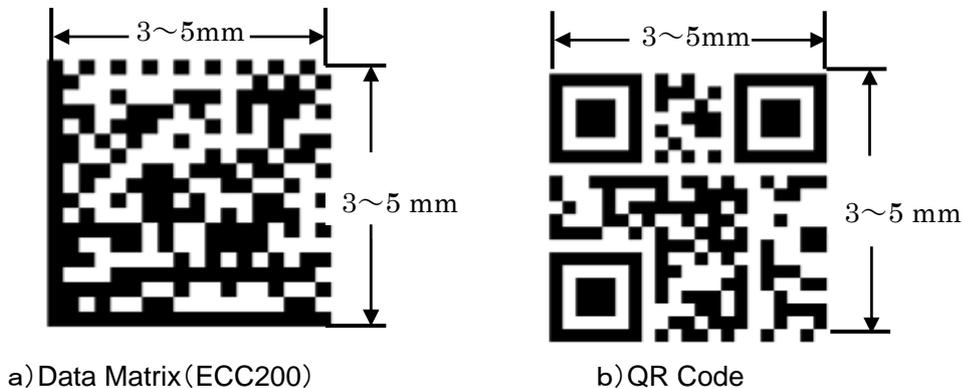
(2) When the surgical instrument is cylindrical and a display area of a 3mm square cannot be secured

3.6～4.5mm

1.2～1.5mm
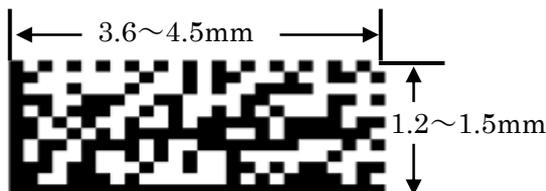
(3) Product code registration in the medical instrument database

As a rule, the product code portion of the GTIN (13-digit EAN) displayed under these guidelines is registered in the Medical Information System Development Center medical instrument database. It's important to note that the check digit differs at this time.

(4) Other

These guidelines were formulated as surgical instrument manufacture and sale industry association standard specifications but they do not constitute a legal display as specified by the Pharmaceutical Affairs Law. However, the display of two-dimensional symbols on surgical appliances possessed by medical institutions and rental companies, etc. should conform to these guidelines in order to avoid confusion with new two-dimensional symbology standards supplied by marketing authorization holders.

In addition, these guidelines don't refer to marking devices, two-dimensional symbol readers or regeneration management systems.

3．The Guidelines of Japanese Ministry of Health, Labour and Welfare (Japanese)

厚生労働省施行規則　　　　　　　　　（出典：医療機器情報コミュニケーター(MDIC)標準テキスト）

（1）医療安全に係る施行規則
医療法の規制の方針に従い、省令（医療法施行規則）において医療機関の管理者に医療安全確保に関する体制の整備をし、それに基づく管理を求めている。（表 1-1.）

表 1-1．医療安全に係る施行規則

第一条の十一　病院等の管理者は、法第六条の十の規定に基づき、次に掲げる安全管理のための体制を
　確保しなければならない（ただし、第 2 号については、病院、患者を入院させるための施設を
　有する診療所及び入所施設を有する助産所に限る。）
一　医療に係る安全管理のための指針を整備する
二　医療に係る安全管理のための委員会を開催すること。
三　医療に係る安全管理のための職員研修を実施すること。
四　医療機関内における事故報告等の医療に係る安全の確保を目的とした改善のための方策を講ずること。

2　病院等の管理者は、前項各号に掲げる体制の確保に当たっては、次に掲げる措置を講じなければならない。
一　院内感染対策のための体制の確保に係る措置として次に掲げるもの（ただし、ロについては、病院、患者
　を入院させるための施設を有する診療所及び入所施設を有する助産所に限る。）
　イ　院内感染対策のための指針の策定
　ロ　院内感染対策のための委員会の開催
　ハ　従業者に対する院内感染対策のための研修の実施
　ニ　当該病院等における感染症の発生状況の報告その他の院内感染対策の推進を目的とした改善のため
　　　の方策の実施
二　医薬品に係る安全管理のための体制の確保に係る措置として次に掲げるもの
　イ　医薬品の使用に係る安全な管理（以下この条において「安全使用」という。）のための責任者の配置
　ロ　従業者に対する医薬品の安全使用のための研修の実施
　ハ　医薬品の安全使用のための業務に関する手順書の作成及び当該手順書に基づく業務の実施
　ニ　医薬品の安全使用のために必要となる情報の収集その他医薬品の安全使用を目的とした改善のため
　　　の方策の実施
三　医療機器に係る安全管理のための体制の確保に係る措置として次に掲げるもの
　イ　医療機器の安全使用のための責任者の配置
　ロ　従業者に対する医療機器の安全使用のための研修の実施
　ハ　医療機器の保守点検に関する計画の策定及び保守点検の適切な実施
　ニ　医療機器の安全使用のために必要となる情報の収集その他の医療機器の安全使用を目的とした改善
　　　のための方策の実施
（以下略）

（2）医療機器に係る安全管理のための体制の確保（施行規則第 1 条の 11 第 2 項第 3 号関連）

改正法の施行にあたり、実施に係る事項に関して、下記に掲げる通知で詳細を示している。

「良質な医療を供給する体制の確立を図るための医療法等の一部を改正する法律の一部の施行について（2007 年 3 月 30 日　医政発第 0330010 号（医政局長））」

「医療機器に係る安全管理のための体制確保に係る運用上の留意点について（2007 年 3 月 30 日　医政指発第 0330001 号（医政局指導課長）医政研発第 0330018 号（医政局研究開発振興課長））」

これらの通知に示されている医療機器の安全確保対策に関する主要事項について、以下に述べる事にする。

なお、ここに掲げた法律、省令及び通知の詳細については、厚生労働省法令データベースで検索できる（http://www.hourei.mhlw.go.jp/hourei/）

1）医療機器安全管理責任者等について

①医療機器安全管理責任者の設置

医療機関の管理者は、医療機器安全管理責任者を設置しなければならない。

②医療機器安全管理者の資格

医療機器の適切な使用方法、保守点検の方法等医療機器に関する充分な知識を有する常勤職員で下記に掲げる資格を有する者を「医療機器安全管理者」として設置しなければならない。

資格：医師、歯科医師、薬剤師、助産婦（助産所に限る）、看護師、歯科衛生士（歯科診療所に限る）、診療放射線技師、臨床検査技師又は臨床工学技士の資格を有する者。なお、病院にあっては、管理者との兼務は認められない。

③安全管理の対象となる医療機器

薬事法第 2 条第 4 項に規定する医療機器で病院が管理するもの。なお、当該医療機関が管理する在宅等で使用するために貸し出された医療機器も対象とする。

＊保守・修理等を要さないような医療機器も安全使用管理が必要なことから、この法律に定める管理が求められて

いる。

④医療機器安全管理責任者の業務

・従業者に対する医療機器の安全使用のための研修の実施

・医療機器の保守点検に関する計画の策定及び保守点検の適切な実施

・医療機器の安全使用のために必要となる情報の収集その他の医療機器の安全使用を目的とした改善のための方策の実施

2）従業者に対する医療機器の安全使用のための研修について

①研修の定義

個々の医療機器を適切に使用するための知識及び技能の習得方法の向上を目的とする。

イ　新しい医療機器の導入時に行う研修

ロ　特定機能病院における定期研修

特に安全使用のために技術の習得が必要な医療機器に関し、年 2 回程度の定期的研修を行い、その実施記録を作

成する。

対象機器の例：

・人工心肺装置及び補助循環装置

・人工呼吸器

・血液浄化装置

・除細動装置（自動体外式除細動器AEDを除く）

・閉鎖式保育器

・診療用高エネルギー放射線発生装置（直線加速器等）

・診療用放射線照射装置（ガンマナイフ等）

②研修の実施形態

研修の形態は問わない

研修の例：

・医療機関において、知識を有するものが主催する研修

・当該医療機関以外の場所での研修、外部講師による研修

・製造販売業者等による取扱い・保守等に関する説明等

③研修対象者

対象医療機器の使用に携わる医療従事者等の従業者

④研修内容

研修の内容は、以下に掲げる事項

・医療機器の有効性安全性に関する事項

・医療機器の使用方法に関する事項

・医療機器の保守点検に関する事項

・医療機器の不具合が発生した場合の対応（施設内での報告、行政機関への報告等）に関する事項

・医療機器の使用に関して法令上遵守すべき事項

⑤研修において記録すべき事項

・開催・受講年月日

・出席者名

・対象機器の名称

・研修項目（内容）

・実施場所

・その他

3）医療機器の保守点検に関する計画の策定及び保守点検の適切な実施について

①保守点検計画の策定

保守点検計画の策定に当たっては、当該医療機器の添付文書に記載されている保守点検に関する事項を参照すること。また、必要に応じて、当該医療機器の製造販売業者に対して情報の提供を求めるとともに、これらの情報をもとに研修等を行い安全な使用を確保すること。

イ　保守点検計画をすべき医療機器

保守点検が必要と考えられる医療機器について、機種別に保守点検計画を策定すること。

ロ　保守点検計画に記載すべき事項

・医療機器の名称

・製造販売業者名

・医療機器の形式

・保守点検実施時期、間隔条件等

②保守点検の適切な実施
　保守点検の記録
　個々の医療機器ごとに、保守点検に関し以下の事項が把握できるよう記載すること。
　　・医療機器の名称
　　・製造販売業者名
　　・医療機器の形式
　　・保守点検の記録（実施年月日　保守点検結果の概要及び保守点検実施者の氏名）
　　・修理の記録（修理年月日　修理の概要及び修理実施者）
　なお、上記以外にも保守点検の実施により得られた当該機器に関する情報は出来る限り記録・保存をし、
　以後の適正な保守点検に活用すること。
③保守点検の実施状況等の評価
　医療機器の特性を踏まえ、保守点検の実施状況、使用状況、修理状況等を評価し、医療安全の観点から、
　必要に応じ医療機器の導入・更新等に関する助言を行うとともに、保守点検計画の見直しを行うこと。
④保守点検の外部委託
　保守点検業務を外部の者に委託する場合には、医療法第 15 条の 2 に規定する基準を遵守すること。なお、
　医療機器安全管理責任者は、保守点検を外部に委託する場合にも、保守点検の実施状況等の記録を保存
　し、管理状況を把握すること。

(3)院内感染のための体制の確保（施行規則第 1 条の 11 第 2 項第 1 号関連）
　医療機器に係る安全管理のための体制の確保と同様、「良質な医療を供給する体制の確立を図るための医
　療法等の一部を改正する法律の一部の施行について（2007 年 3 月 30 日　医政発第 0330010 号）」で詳細を
　示している。その概要を下記に示す。

 1）病院等における院内感染対策について
 ①院内感染対策のための指針
　指針は、次に掲げる事項を文書化したもので、院内感染対策委員会の議を経て策定・変更するものである。
　・院内感染対策に関する基本的事項
　・院内感染対策のための委員会、その他の組織に関する事項
　・院内感染対策のための従事者に対する研修に関する基本方針
　・感染症の発生状況の報告に関する基本方針
　・院内感染発生時の対応に関する基本方針
　・患者等に対する当該指針の閲覧に関する基本方針
　・その他院内感染対策の推進のために必要な基本方針
②院内感染対策のための委員会
　院内感染対策のための推進のために設けるものであり、以下の基準を満たす必要がある。
　・管理及び運営に関する規定を定めていること
　・重要な検討内容について、管理者へ報告すること
　・院内感染が発生した場合、速やかに原因を分析し、改善策の立案及び実施、従業者への周知
　・月1回程度開催するとともに、必要に応じ適宜開催する
　・委員は職種横断的に構成する

③従業者に対する院内感染対策のための研修

院内感染対策のための基本的考え方及び具体的方策について、従業者に周知徹底を行うことで、ここの従業者の院内感染に対する意識を高め、業務遂行のための技能・知識の向上を図るものである。

④感染症の発生状況の報告その他院内感染対策の推進を目的とした改善のための方策

院内感染の発生状況を把握するため、感染症の発生動向の情報を共有することで、院内感染の発生の予防及びまん延の防止を図るものとする。

２）特定機能病院における院内感染対策

従前より医療法施行規則に規定する体制の一環として実施されてきたところであるが、今般、安全管理のための措置に院内感染対策のための措置が含まれることが明確にされたことを踏まえ、引き続き院内感染対策の体制の充実強化に取り組むこと。

以上の法的要求事項をまとめたものが、表 1-2 である。

表 1-2. 医療感染対策の医療法施行規則等における規定
（2007 年 3 月 15 日　院内感染対策中央会議資料より）

内　　容	特定機能病院	臨床研修病院	病院	有床診療所助産所（入所あり）	無床診療所助産所（入所なし）
指針の整備	◎	◎	◎	◎	◎
委員会の開催	◎	◎	◎	◎	－
職員研修の実施	◎	◎	◎	◎	◎
発生状況の報告等	◎	◎	◎	◎	◎
部門の設置	◎	◎	－	－	－
担当者の配置	○	◎	－	－	－

◎：今回新たに規定、　○：既に規定、　－：規定なし

（参考）マニュアル作成のための指針として【医療機関における院内感染対策マニュアル作成の手引き】が、事務連絡として、医政局指導課から平成 19 年 5 月 8 日に発出されている。

（4）医薬品に係る安全管理のための体制の確保（施行規則第 1 条の 11 第 2 項第 2 号関連）

医薬品の安全管理に関しても院内感染対策及び医療機器安全管理と同様、管理体制の確保をするよう求められている。ここでは詳細は割愛するが、体制確保に係る措置について、下記の事項を掲げている。

１）医薬品の使用に係る安全な管理のための責任者の配置

２）従業者に対する医薬品の安全使用のための研修の実施

３）医薬品の安全使用のための業務に関する手順書の作成及び当該手順書に基づく業務の実施

４）医薬品の安全使用のために必要となる情報の収集その他医薬品の安全使用を目的とした改善のための方策の実施

（5）手術室における手洗いの設備について

手術室の手洗い設備について、医療法施行規則で次のように規定している。

> 第 20 条の 3
> 手術室は、なるべく準備室を附設し、塵埃の入らないようにし、その内壁全部を不浸透室のもので
> 覆い、適当な暖房及び照明の設備を有し、清潔な手洗いの設備を附属して有しなければならない。

さらに、厚生労働省医政局指導課長通知（医政指発第 0201004 号　平成 17 年 2 月 1 日）で以下の通り示している。

「近年の知見によると、水道水と滅菌水による手洗いを比較した場合でも有意な手指の滅菌効果の差が認められず、清潔な流水で十分であるとされていることから、必ずしも滅菌水を使用する必要はないこと。」

（6）医療機関の管理者の注意義務

医療法施行規則に医療機関の管理者の薬事法遵守に関する注意義務として、以下の事項が規定されている。（表 1-3）。また、添付文書の記載事項の遵守に関しても以下のような事務連絡が発出されているので、参考までに掲げる（表 1-4）

表 1-3. 医療機関の管理者の注意義務

> 第十四条
> 病院又は診療所の管理者はその病院又は診療所に存する医薬品及び用具につき薬事法の規定に違反
> しないよう必要な注意をしなければならない

表 1-4. 単回使用医療用具に関する取り扱いについて

> 医政発第 0209003 号
> 平成 16 年 2 月 9 日
>
> 各都道府県知事　殿
>
> 厚生労働省医政局長
>
> 単回使用医療用具に関する取り扱いについて
>
> 　表記については、先般行われた医療安全対策検討会議ヒューマンエラー部会（座長：矢崎義雄　国立国際医療センター総長）において、医療機関における単回使用の医療用具の再使用に関する実態が示されたところである。
> 　このため、ペースメーカーや人工弁等の埋め込み型の医療材料等については医療安全や感染の防止を担保する観点から、その性能や安全性を充分に保証し得ない場合は再使用しない等の措置をとるなど、医療機関として十分注意されるよう関係者に対する周知徹底方よろしくお願いする。
> 　なお、使用する医療用具が単回使用製品であることは、「医家向け医療用具添付文書の記載要領について」平成 13 年 12 月 14 日付け医薬発第 1340 号厚生労働省医薬局長通知及び、医薬安発第 158 号厚生労働省医薬局安全対策課長通知において添付文書上明示することとなっていることを申し添える。

4. U.K. Ministry of Health Regulations Summary "Pollution Prevention Guidelines for medical equipment"

Health Service Circular

NHS
Executive

Series Number:	**HSC 2000/032**
Issue Date:	**18 October 2000**
Review Date:	**31 March 2001**
Category:	**General Management**
Status:	**Action**
	sets out a specific action on the part of the recipient with a deadline where appropriate

Decontamination of medical devices

For action by:	Health Authorities (England) - Chief Executive
	NHS Trusts - Chief Executives
	Primary Care Trusts - Chief Executives
For information to:	Dental Postgraduate Deans
	Directors of Education & Training
	Health Authorities (England) - Directors of Nursing
	Medical Schools - Deans
	Post Graduate Deans
	Regional Advisers in General Practice
	Dental Schools - Deans
	Regional Directors
	Regional Directors of Public Health
	Regional Directors of Performance Management
	Regional Directors of Nursing
	Regional Dental Advisors
	Health Authorities (England) - Directors of Public Health
	Health Authorities (England) - Consultants in Communicable Disease Control
	Primary Care Groups - Chief Executives
	Primary Care Groups - Chairs
	NHS Trusts - Medical Directors
	NHS Trusts - Directors of Nursing
	NHS Trusts - Chief Pharmacists
	NHS Trusts - Chairs of Infection Control Committees
	PHLS - Directors

Further details from:	Regional decontamination leads
	Contact details within this circular

Additional copies of this document can be obtained from:

Department of Health
PO Box 777
London
SE1 6XH

Fax 01623 724524

It is also available on the Department of Health web site at
http://www.doh.gov.uk/coinh.htm

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Decontamination of medical devices

Summary

Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to make a re-usable item safe for further use on patients and handling by staff. The effective decontamination of re-usable medical devices* is essential in reducing the risk of transmission of infectious agents.

HSC 1999/179 emphasised the importance of implementing guidance on the cleaning and sterilization of medical devices, since this is of the utmost importance in reducing the risk of transmission of infectious agents. HSC 1999/178 stated that effective cleaning of surgical instruments prior to sterilization is of the utmost importance in reducing the risk of transmission of vCJD via surgical procedures.

Following the issue of HSC 1999/179 and the reissue, on CD-ROM and *NHSnet*, of Department of Health guidance on the complete process of decontamination of medical equipment, a snapshot survey of current decontamination practices in a small number of healthcare premises in England has been carried out. A more comprehensive review of decontamination provision across the health service now needs to take place so that plans for the future can be based on national findings. There are also some immediate steps that should be taken, without waiting for the outcome of the review, to minimise any risks associated with decontamination.

This circular identifies the immediate and medium-term actions required to ensure that decontamination is carried out effectively. It also sets out the information needed to gather a robust picture of decontamination provision nationally and describes the support available to assist NHS trusts, Health Authorities and Primary Care trusts in delivering the actions required.

Action

(The website referenced in the actions below can be found at http://www.nhsestates.gov.uk. It contains the annexes referred to, as electronic documents for downloading and completion either electronically or in printed form.)

Chief Executives of NHS trusts should:

Immediately (By 01 November 2000):

- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Regional Office decontamination lead (listed on page 6 of this circular). Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel including, where applicable, Infection Control Teams, Sterile Service managers, Estates and Facilities managers and Theatre managers;

By 17 November 2000:

- send a report to the Regional Office decontamination lead, using the checklist (Annex A) on the website, recording the actions being taken to ensure that appropriate management arrangements are in place to oversee and improve where necessary the overall process of decontamination;
- send a report to NHS Estates (which will be forwarded on to Regional Office decontamination leads), using the audit tool (Annex B) on the website, identifying any issues of immediate potential risk to patients and staff;
- ensure that the proforma (Annex C) on the website is completed to indicate the age and condition of decontamination facilities and equipment, and is returned to NHS Estates (who will forward it to the Regional Office decontamination lead).

By 15 December 2000:

- send a report to NHS Estates (which will be forwarded on to Regional Office decontamination leads), using the action plan (Annex D) on the website, recording the actions being taken to address any issues of immediate potential risk to patients and staff;

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* A medical device is any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of: control of conception; diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or physiological process. Surgical instruments are medical devices.

By 31 March 2001:
- ensure that a comprehensive review is carried out of all aspects of the overall process of decontamination, and use this to complete a baseline self-assessment and develop an action plan against the controls assurance decontamination standard.

By 31 March 2002:
- have taken steps towards having systems in place to enable the tracing of surgical instrument sets to patients on whom they have been used.

Chief Executives of Health Authorities should:

Immediately (by 01 November 2000):
- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Regional Office decontamination lead (listed on page 6 of this circular). Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel including, where applicable, Consultants in Communicable Disease Control, Directors of Public Health, Directors of Primary Care (or equivalent), Primary Care Medical Advisors, Pharmaceutical Advisors, Directors of Nursing and Infection Control Doctors and Nurses;

By 15 December 2000:
- working with PCG Chief Executives and Clinical Governance leads where appropriate, ensure that independent contractors, including GPs (GMS & PMS), Dentists (GDS & PDS), Pharmacists and Optometrists, are aware of and understand their responsibilities for ensuring compliance with the contents of this HSC and the associated website and are encouraged to review their own practice;
- ensure that all private and voluntary healthcare providers registered under the 1984 Registered Homes Act are aware of their responsibilities for ensuring compliance with the contents of this HSC and the associated website;
- arrange for the contact details of the senior member of staff responsible for decontamination in PCTs to be recorded in a local database so that further information can be disseminated as necessary (PCTs have been instructed to send details of their relevant senior member of staff to the HA Consultant in Communicable Disease Control by 01 November 2000);

By 31 March 2001:
- ensure that inspection of registered independent healthcare providers verifies adequate compliance with Department of Health guidance on decontamination.

Chief Executives of Primary Care trusts should:

Immediately (by 01 November 2000):
- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Health Authority Consultant in Communicable Disease Control. Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel, including Clinical Governance leads;

By 17 November 2000:
- where their organisation is a direct provider of community health services, send a report to the Health Authority Consultant in Communicable Disease Control, using the checklist (Annex A) on the website, recording the actions being taken to ensure that appropriate management arrangements are in place to oversee and improve where necessary the overall process of decontamination;
- where their organisation is a direct provider of community health services, send a report to NHS Estates (which will be forwarded on to the Health Authority), using the audit tool (Annex B) on the website, identifying any issues of immediate potential risk to patients and staff;
- where their organisation is a direct provider of community health services, ensure that the proforma (Annex C) on the website is completed to indicate the age and condition of decontamination facilities and equipment, and is returned to NHS Estates (who will forward it to the Health Authority).

By 15 December 2000:
- ensure through PCT Clinical Governance leads that GPs are aware of their responsibilities for ensuring compliance with the contents of this HSC and the associated website and are encouraged to review their own practice;

- where their organisation is a direct provider of community health services, send a report to NHS Estates (which will be forwarded to the Health Authority), using the action plan (Annex D) on the website, recording the actions being taken to address any issues of immediate potential risk to patients and staff;

By 31 March 2001:

- where their organisation is a direct provider of community health services, ensure that a comprehensive review is carried out of all aspects of the overall process of decontamination.

Further information and details of requirements

General

HSC 1999/179 emphasised the importance of implementing existing guidance on the cleaning and sterilization of medical devices and required Chief Executives of NHS trusts and Health Authorities to ensure that guidance was observed. A snapshot survey of current decontamination practices in a small number of NHS trusts, general medical and dental practices and private and voluntary sector hospitals has since been carried out. It is now important to ensure that any associated risks are effectively managed by all healthcare providers, at the same time as gathering a more comprehensive picture of decontamination provision across the NHS to inform medium-term action plans.

Effective management control systems

Decontamination is vital to the effective delivery of patient care. The overall decontamination process can include purchasing and acquisition of instruments and equipment, cleaning and disinfection of instruments, packaging of instruments, sterilization and transport, storage and disposal. It requires effective management systems, often spanning a range of disciplines and locations within one organisation.

The checklist (Annex A) at http://www.nhsestates.gov.uk identifies a number of management issues associated with decontamination. It should be used to confirm that appropriate management arrangements are in place.

Immediate risk issues

There are a number of health and safety issues associated with decontamination (including uncontrolled use of chemicals and inappropriate use of processes) that potentially put patients and staff at direct risk of injury. These apply to NHS hospitals, general medical and dental practices and private and voluntary hospitals. It is essential that all such practices should be identified and immediate checks made to ensure that they are adequately addressed. An audit tool and proforma action plan are available at http://www.nhsestates.gov.uk and should be used to confirm that the identified issues are being handled appropriately.

Comprehensive review of decontamination processes

Short-term actions taken to address management and immediate risk issues should be seen as the first step in a comprehensive review of decontamination practice. This review should include management arrangements, policies and procedures, facilities, purchasing (of both medical devices and decontamination equipment), washing, disinfection and sterilization practice, record-keeping, validation and maintenance. It should cover both existing practices and a strategic assessment of the way in which decontamination services are provided.

A technical manual of guidance will be published later this year. This will provide detailed support to assist individual organisations in carrying out a comprehensive review of decontamination practice. Details will be notified when available, via the website at http://www.nhsestates.gov.uk

An HSC to be issued shortly (Controls Assurance statements 2000/2001 and establishment of the Controls Assurance Support Unit) will require NHS trusts to complete a baseline self-assessment against a new controls assurance standard on the decontamination of re-usable medical devices. The technical manual may be used by organisations to assist in completing this assessment and in developing an action plan that clearly sets out how the required standards will be achieved and maintained.

Traceability

It is important that systems are in place to allow sets of surgical instruments to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively. Systems should also be implemented to enable the identification of patients on whom instrument sets have been used. This is important so that relevant patients can be identified in the event of exposure to a potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instrument sets is in addition to the measures for identification and tracing of flexible endoscopes set out in HSC 1999/178.

Implementing Changes

Short-term: The review of vulnerability to immediate risk issues may require provider organisations to make some immediate investment to replace individual pieces of equipment in order to avoid disruption to the delivery of patient care. It is expected that such investment will normally be managed within existing resources.

Medium and long-term: Further information will be required in order to establish service-wide requirements, consider the relative merits of central and local provision of decontamination services and to develop detailed feasibility plans and costs. Collection of this information will be co-ordinated by Regional Offices. Long-term investment, where necessary, will be based on a strategic review of the optimum method of providing decontamination services across an extended geographical area. Implementation arrangements will be decided in the light of the review's findings.

Support
Each Regional Office has identified a lead member of staff to co-ordinate the support available to organisations to ensure that the actions required can be met. The contact details for Regional Office leads are set out below.

A Support Taskforce is being set up to work with NHS trusts, HAs, PCTs and Regional Offices to assist in meeting the recommendations of the decontamination review. This taskforce will include technical advisors with a broad range of experience of practical decontamination issues. Access to the Support Taskforce will be co-ordinated via RO leads, and further details will be notified when available.

Further advice is also available from various parts of the Department of Health and there are various professional organisations that may be able to provide assistance. Information about the advice available can be obtained via Regional Office leads.

The technical manual is a tool to guide organisations, step by step, through the issues they need to address to ensure that decontamination practices meet acceptable standards. It will be able to be used as the basis for the comprehensive review of decontamination practices and assessment against the Controls Assurance decontamination standard.

A series of briefing sessions will be held for the nominated senior managers with overall responsibility for decontamination within their organisation. These sessions will be open to every NHS trust, Health Authority and Primary Care Trust. Dates and venues will be notified via Regional Offices.

Following publication of the technical manual, additional workshops will be held targeted at specialists within organisations (for example infection control doctors and nurses, sterile service managers, estates and facilities professionals, health and safety advisors, risk managers).

Regional Office decontamination leads

Northern & Yorkshire
Dennis Bastow: Estates Advisor
Tel: 0191 301 1300   Email: dennis.bastow@doh.gsi.gov.uk

Eastern
Stuart Denham: Head of Estates and Facilities
Tel: 01908 844562   Email: stuart.denham@doh.gsi.gov.uk

South East
Ann Merricks: Assistant Director of Performance
Tel: 0207 725 2542   Email: ann.merricks@doh.gsi.gov.uk

London
Terry Murphy: Head of Estates and Facilities
Tel: 0207 725 5423   Email: terry.murphy@doh.gsi.gov.uk

Trent
Jonathan Harris: Regional advisor - Pharmacy and Prescribing
Tel: 0114 282 0375   Email: jonathan.harris@doh.gsi.gov.uk

West Midlands
Dr Jeremy Hawker: Regional Epidemiologist
Tel: 0121 773 7077   Email: jhawker@phls.org.uk

North West
Dr Iqbal Sram: Consultant in Public Health Medicine
Tel: 01925 704256   Email: iqbal.sram@doh.gsi.gov.uk

South West
Dr Deidre Lewis: Regional Epidemiologist
Tel. 01452 – 413080   email: dlewis@phls.org.uk

Associated Documentation

"Decontamination Guidance" CD-ROM issued with HSC 1999/179, and available on *NHSnet* at
http://nww.doh.nhsweb.nhs.uk/health/decontamination-guidance.htm

HSC 1999/123:	Governance in the new NHS: Controls assurance statements 1999/2000 risk management and organisational control.
HSC 1999/178:	Variant Creutzfeldt Jakob Disease: minimising the risk of transmission.
HSC 1999/179:	Controls assurance in infection control: decontamination of medical devices.
HSC 2000/002:	The management and control of hospital infection.
Forthcoming HSC:	Controls assurance statements 2000/2001 and establishment of the controls assurance support unit.

MDA DB 2000(04):	Single-use medical devices: Implications and consequences of reuse.
MDA SN 2000(18):	Handling of surgical instruments on loan from another organisation

Guidelines for Implementing Controls Assurance in the NHS. Guidance for Directors. (Nov. 1999)

Controls Assurance Standards 1999/2000: Risk Management and Organisational Controls: Infection Control Standard.

Useful websites

NHS Estates:	http://www.nhsestates.gov.uk
Medical Devices Agency:	http://www.medical-devices.gov.uk
NHS Purchasing and Supply Agency:	http://www.pasa.doh.gov.uk

Controls Assurance:
Internet:	http://www.doh.gov.uk/riskman.htm
NHSnet:	http://nww.doh.nhsweb.nhs.uk/nhs/riskman.htm

This Circular has been issued by:

Neil McKay
Acting Chief Executive

Dr Pat Troop
Deputy Chief Medical Officer

5. French specification standards: "Insruments chirurgicaux Definition des specifications d'immatriculation a des fins de tracabilite"

(Definition of registration specifications for the traceability of surgical instruments)

Enacted January 2006 by AFNOR (Association Francaise de Normalisation) - XP S 94-467 standard.

XP S94-467

Janvier 2006

AFNOR
Association Française
de Normalisation

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XP S 94-467
Janvier 2006

Indice de classement : **S 94-467**

ICS : 11.040.30

Instruments chirurgicaux

Définition des spécifications d'immatriculation à des fins de traçabilité

E : Surgical instruments — Definition of immatriculation specifications
for tracability purposes
D : Chirurgische Instrumente — Definition der Immatrikulationsanforderungen
für Rückverfolgbarkeitszwecke

Norme expérimentale

publiée par AFNOR en janvier 2006.

Les observations relatives à la présente norme expérimentale doivent être adressées à AFNOR avant le 31 décembre 2009.

Correspondance

À la date de publication du présent document, il n'existe pas de travaux européens et internationaux traitant du même sujet.

Analyse

Le présent document spécifie des exigences pour identifier de façon unitaire et univoque chaque instrument chirurgical par un numéro d'immatriculation et s'applique aux instruments chirurgicaux utilisés dans les établissements de santé et les cabinets libéraux, depuis la réception jusqu'à la réforme.

Descripteurs

Thésaurus International Technique : matériel médical, matériel chirurgical, matériel réutilisable, traçabilité, identification, numéro d'immatriculation, code, exigence, stérilité.

Modifications

Corrections

AFNOR 2006

1er tirage 2006-01-F

Instruments chirurgicaux

AFNOR S90N

Membres de la commission de normalisation

Président : M ROZENBAUM

Secrétariat :   M GIANG — AFNOR

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M	TIROUVANZIAM	SNITEM

Sommaire

1 Domaine d'application

Cette norme expérimentale spécifie des exigences pour identifier de façon unitaire et univoque chaque instrument chirurgical par un numéro d'immatriculation. Ce numéro d'immatriculation est un des éléments permettant d'assurer la traçabilité des instruments chirurgicaux.

La présente norme expérimentale s'applique aux instruments chirurgicaux utilisés dans les établissements de santé et les cabinets libéraux, depuis la réception jusqu'à la réforme.

La mise en place de cette norme expérimentale nécessite l'utilisation d'un système de capture automatique d'information.

Le numéro doit être constitué d'un identifiant du fabricant, de la référence du produit et d'un numéro de série unique.

Les instruments chirurgicaux dont la configuration ne permettent pas un support d'identification dans l'état actuel de l'art ne sont pas couverts par la présente norme.

2 Termes et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

2.1
instrument chirurgical réutilisable
instrument destiné à accomplir un acte chirurgical tel que couper, forer, scier, gratter, racler, serrer, rétracter ou attacher et pouvant être réutilisé après avoir été soumis aux procédures appropriées

2.2
traçabilité
aptitude à retrouver l'historique, l'utilisation ou la localisation d'une entité au moyen d'identifications enregistrées

> NOTE   Il existe plusieurs types de traçabilité selon les objectifs des entreprises ou d'une filière.

2.3
immatriculant
entité prenant en charge l'immatriculation de l'instrument de chirurgie dans le respect des normes européennes et internationales

3 Exigences

3.1 Généralités sur la traçabilité

Du point de vue de l'utilisateur, la traçabilité peut être définie comme le fait de suivre des produits qualitativement et quantitativement dans l'espace et dans le temps. Du point de vue de la gestion de l'information, mettre en place un système de traçabilité dans une chaîne d'approvisionnement, c'est associer systématiquement un flux d'informations et un flux physique.

L'objectif est de pouvoir retrouver, à l'instant voulu, des données préalablement déterminées relatives à des lots ou regroupements de produits, et ce, à partir d'un ou plusieurs identifiants clés.

L'entreprise doit préciser les objectifs de sa démarche de traçabilité afin de définir ensuite les moyens à mettre en œuvre pour les réaliser. Ils permettront également de déterminer les types de requêtes qui seront demandés dans le cahier des charges du système d'information.

3.1.1   Les objectifs de la traçabilité

Les objectifs sont directement liés aux enjeux de la mise en œuvre d'une démarche de traçabilité :

- Qualité : retrouver les caractéristiques d'un produit, identifier les lots, améliorer la qualité ;

- Sécurité sanitaire : effectuer des rappels de lots défectueux ;

- Logistique : rationaliser les processus liés aux flux logistiques, optimiser la gestion des stocks ... ;

- Aspects juridiques : respecter une réglementation, lutte contre la fraude ... ;

- Marketing commercial : protéger une image commerciale, améliorer le service au consommateur final ...

Le fabricant d'instruments chirurgicaux a pour objectif de fournir l'immatriculation à l'exploitant, celle-ci servant de base à la sécurité sanitaire. En cas de mutualisation des moyens entre les exploitants, sous-traitants et donneurs d'ordre, l'identification univoque des instruments chirurgicaux est rendue nécessaire.

3.1.2   Les éléments de traçabilité

Avant toute mise en place d'une démarche de traçabilité il est important de bien identifier les quatre principes clés du système : identifier, gérer des liens, enregistrer les données et communiquer.

Pour définir les différents éléments de traçabilité, il faut :

- définir intervenants et responsabilités à chaque étape ;

- permettre l'enregistrement des process de traitements d'un instrument chirurgical ;

- relier l'acte de soins et l'instrument chirurgical ;

- assurer les liens entre les différents intervenants d'instrument chirurgical.

3.1.2.1   *Identifier*

La codification des produits et des intervenants est le préalable obligatoire pour mettre en place un système de traçabilité.

3.1.2.2   *Gérer des liens*

Gérer des liens, c'est :

- Gérer la hiérarchie (lien entre le(s) contenant(s) et le(s) contenu(s)) entre les unités de bases et leurs différents niveaux de regroupement ;

- Assurer les liens entre les flux physiques et les flux d'information par l'utilisation d'identifiants uniques et communs et d'un même dictionnaire de données.

3.1.2.3   *Enregistrer les données*

Tout système de traçabilité repose sur la collecte d'informations, lui permettant de décrire l'ensemble des paramètres, qui garantissent les différents types de traçabilité.

Les données collectées sont soit :

- transmises par un partenaire,

- issues des étapes de transformation dans l'entreprise ou l'établissement de santé,

- calculées.

3.1.2.4   *Communiquer*

Afin d'assurer la continuité de la traçabilité, le système doit permettre la transmission des informations nécessaires aux différents acteurs de la chaîne. Elles sont transmises soit entre partenaires soit mises à disposition sur un système de consultation en ligne.

3.2 Responsabilités et mises à jour

L'exploitant doit assurer la continuité des informations pendant la durée de vie de l'instrument chirurgical. Il doit avoir mis en œuvre ou faire mettre en œuvre, les moyens pour garantir le suivi, la mise à jour et le transfert des données et ceci dans tous les cas possibles (réalisation des opérations par l'exploitant ou par tout organisme ou personne désigné contractuellement).

Le fabricant et/ou immatriculant doit s'engager à ce que l'identification du dispositif médical soit possible pendant toute la durée de vie de celui-ci en tenant compte des traitements de pré-désinfection, de désinfection, de stérilisation et de remise en état.

La gestion de la traçabilité doit reposer sur une organisation, une structure définie par l'organisme (cette organisation devra être décrite dans une procédure à l'aide d'un schéma synoptique et d'explications appropriées). Ces éléments pour être maîtrisés doivent faire l'objet d'une description au moins sommaire.

3.3 Architecture et codifications

Le but est d'identifier de façon unitaire et univoque les instruments de chirurgie en leur affectant un numéro d'immatriculation.

Le numéro d'immatriculation de chaque instrument de chirurgie doit être composé de :

*   l'identification de l'immatriculant défini par le système EAN.UCC ;

*   l'identification du produit ;

*   la sérialisation du produit pour une identification unitaire.

3.4 Modalités d'opération et interopérabilité

Le marquage univoque (immatriculation) permet la dématérialisation de l'information (définie comme l'échange entre deux entités distinctes d'informations sans support papier).

Pour la rendre possible, il est nécessaire de définir des protocoles de transfert des informations, permettant à l'émetteur et au récepteur l'échange de données.

Elle nécessite la mise en œuvre de moyens de sécurisation (limitation des accès) et l'identification des opérateurs (recours à des tiers certificateurs, aux signatures informatiques aux séquestres...).

Elle suppose l'interopérabilité des systèmes informatiques pour exploiter ces données transmises dont la structuration doit faire l'objet d'une standardisation des codifications et de la syntaxe utilisée. Dans le domaine de la santé, la dématérialisation doit concerner les achats (via E.D.I. échange de données informatisé), les factures, les marchés publics, le dossier médical informatisé la traçabilité de tous les produits sensibles : médicaments dérivés du sang, dispositifs médicaux implantables, instruments de chirurgie à usages multiples re-stérilisables. Pour ces derniers, le recours à des mises à disposition d'ancillaires, à des sous-traitances pour les opérations de stérilisation et au suivi des maintenances, doit nécessiter une identification univoque de l'instrument, une immatriculation invariable entre l'exploitant et ses partenaires.

3.5 Conditions environnementales et cycles de stérilisation

Les principaux objectifs de la traçabilité à l'instrument sont :

— de pouvoir répondre aux aspects normatifs (norme ISO 8402 (1995)) et réglementaires (circulaire DGS/DG n° 672 du 20 octobre 1997, arrêté du 22 juin 2001, circulaire DGS/DHOS n° 138 du 14 mars 2001),

— d'apporter une aide au conditionnement,

*   en permettant d'identifier les instruments complexes,

*   en informant sur le type d'emballage et/ou le traitement,

— de suivre les envois d'instruments en maintenance,

— de réceptionner les instruments aux blocs et à la stérilisation.

Les instruments re-stérilisés doivent suivre un cycle d'utilisation aux Blocs opératoires et de traitement à la Stérilisation. La traçabilité à l'instrument doit pouvoir être réalisée aux Blocs et à la stérilisation.

Un exemple de préparation stérile des instruments chirurgicaux est proposé en annexe C.

Aux Blocs opératoires, la traçabilité à l'instrument doit pouvoir permettre :	Conditions environnementales
d'effectuer la réception du matériel stérile provenant de la Stérilisation	Matériel stérile réceptionné et stockés dans différents types d'emballage (sachets, paniers emballés, conteneurs) ne permettant pas obligatoirement une reconnaissance à l'instrument
d'identifier les instruments stockés, de suivre les péremptions	
d'identifier les instruments utilisés pour un patient donné au moment de l'acte opératoire,	Installation d'un système de reconnaissance des instruments dans une salle d'opération. Temps supplémentaire pour réaliser cette étape dans des conditions d'urgence.
de suivre le matériel souillé – pré-désinfecté qui va être livré à la Stérilisation	Risques pour le personnel d'identifier des matériels «sales»

À la Stérilisation, la traçabilité à l'instrument doit pouvoir permettre :	Conditions environnementales
d'effectuer la réception du matériel souillé pré-désinfecté provenant des Blocs,	— Risques pour le personnel de manipuler des matériels «sales» pour effectuer leur traçabilité
de suivre les différentes étapes de préparation des Dispositifs Médicaux Stériles	Les systèmes de traçabilité à l'instrument doivent pouvoir s'interfacer avec les logiciels de traçabilité des étapes de préparation des dispositifs médicaux stériles à la Stérilisation.
— nettoyage	Risques pour le personnel d'identifier des matériels «sales»
— vérification après nettoyage et conditionnement	— Manipulation de matériel propre. — Intérêt de l'identification des instruments — Mise en place de matériel informatique dans une enceinte à empoussièrement contrôlé (ISO 8) — Temps supplémentaire pour réaliser cette étape
— stérilisation — libération	Matériel stérile conditionné dans différents types d'emballage (sachets, paniers emballés, conteneurs) ne permettant pas obligatoirement une reconnaissance à l'instrument
— stockage, livraison	
— préparation à l'envoi en maintenance	— Matériel conditionné et stérile
— envoi en maintenance	— Effectué à la Stérilisation ou dans le service effectuant cette activité.

Annexe A

(informative)

Système EAN•UCC : Codification, structure
et représentation des données

A.1   Codification : structure du GTIN

En France, la structure du code EAN•UCC 13 (GTIN) est la suivante :

Préfixe pays	Identification entreprise	Identification produit	Clé
attribué par GS1	attribuée par GS1 France	attribuée par l'entreprise	

NOTE   Exemple de code

3306560396841   006789

La première partie de l'immatriculation est un code à 13 caractères s'il respecte la structure internationale du GTIN (Global Trade Item Number ou code du produit) dans le système EAN•UCC. Ce code permet d'identifier de façon unique et non ambiguë le détenteur de la marque commerciale du produit (de 5 à 8 caractères selon la taille de l'entreprise) et l'identification du produit (de 4 à 6 positions selon le nombre de références à identifier). Ces informations étant bien entendu transmises par l'immatriculant et intégrées dans les bases de données de l'utilisateur. Un exemple de structure est proposé en annexe A.

La seconde partie du code est variable jusqu'à 20 caractères et représente le numéro de série qui permet d'identifier chaque produit de façon univoque.

Quel que soit le pays où le produit est codifié, le code, composé de 13 chiffres, comprend :

•   Un préfixe Pays

   Celui-ci identifie le pays de codification attribué par GS1 (anciennement EAN International).

   Cet indicatif n'implique pas systématiquement que le produit soit fabriqué ou même distribué dans le pays.

   Pour la France *, ce préfixe est le chiffre 3, suivi obligatoirement d'un chiffre compris entre 0 et 7.

•   L'identification Entreprise

   En France *, GS1 (anciennement Gencod EAN France) attribue un code national unique fabricant (CNUF) au moment de l'adhésion de l'entreprise

   Ce code identifie l'Entreprise responsable de la codification, propriétaire de la marque commerciale des produits. Il commence par un chiffre défini entre 0 et 7. Sa longueur variable est comprise, selon les besoins de codification de l'entreprise, entre 5 et 8 chiffres.

•   L'identification Produit

   L'entreprise attribue ensuite un Code Interface Produit. Ce code identifie chaque produit et prend en compte chaque variante : matières, coloris, taille, ... L'entreprise responsable de la codification attribue un seul et unique code à chaque produit.

   NOTE   Selon la longueur du CNUF qui lui a été attribué, l'entreprise définit des codes produits à 6, 5, 4 ou 3 chiffres. Ce code doit identifier l'article au niveau le plus fin, dans la mesure où il est ré-approvisionnable à ce niveau.

   La longueur de chaque zone n'a d'intérêt qu'à la création du code. Pour assurer l'unicité et l'aspect international des codes, les partenaires doivent gérer les 13 chiffres en une seule zone.

•   La Clé de contrôle sert à fiabiliser la lecture optique et se calcule en fonction des douze chiffres précédents.

Il est important de ne pas confondre codification (un code est attribué au produit ou à l'unité logistique) et la symbolisation (le mode de représentation qui va permettre l'identification automatique, qui peut être un code à barres ou une puce à radio fréquence).

La structure de codification est fournie aux entreprises lors de leur adhésion. Pour les entreprises adhérentes à l'Étranger, l'organisme local précisera la structure. Liste des organismes sur le site : www.GS1.org.

A.2   La structure et représentation des données

A.2.1   La structure des données

À partir des codes définis, ceux-ci seront représentés (par code à barres, RFID…) selon une structure standard et internationale des données (EAN•UCC 128).

Cette structure utilise une liste d'AI, sigle officiel pour «identifiants de données» — Application Identifier, défini par GS1 (anciennement EAN International) au niveau international. Cette liste est disponible auprès des organisations GS1 nationales.

L'AI introduit la donnée dans un symbole et en définit sa nature et sa structure. L'AI est un code numérique à 2, 3 ou 4 positions, et utilisable dans un code à barres EAN•UCC 128, Datamatrix ou puce RFID.

Pour des raisons de lisibilité, il est recommandé que l'AI soit inscrit entre parenthèses en clair sous le symbole.

A.2.2   La représentation des données

Il existe plusieurs technologies pouvant supporter l'immatriculation du dispositif médical (code à barres linéaire, Datamatrix, R.F.I.D., …).

A.2.3   Un exemple de structure du code EAN•UCC 128 :

- **(01)07612989001357   (21)HT9611**

(01) AI (Application Identifier – identifiant de donnée) indiquant que la donnée qui suit est un GTIN.	GTIN sur 14 caractères. Pour des raisons de compatibilité dans les bases de données, le GTIN à 13 caractères est calé à 14 positions dans la structure EAN•UCC 128.	(21) AI indiquant que la donnée qui suit est un numéro de série jusqu'à 20 caractères.	Numéro de série attribué par le fabricant.

A.3   Démarche pratique pour marquer les informations complémentaires

Contrairement aux codes EAN•UCC 13 (GTIN), les informations complémentaires peuvent, pour un même article, varier au fur et à mesure de la production (numéro de lot, de série, dates …). Elles ne peuvent donc pas être imprimées à l'avance sur les emballages.

Elles le seront au moment de la constitution de l'unité par des imprimantes programmées et reliées à un système informatique de gestion de production.

Annexe B

(informative)

Exemple d'identifiants EAN•UCC 128

Identifiant	Définition	Format
00	Numéro séquentiel de colis	n2+n18
01	Code EAN article	n2+n14
02	Code article contenu	n2+n14
10	Numéro de lot de fabrication	n2+an..20
11	Date de fabrication (AAMMJJ)	n2+n6
13	Date d'emballage (AAMMJJ)	n2+n6
15	Date minimum de validité (AAMMJJ)	n2+n6
17	Date maximum de validité (AAMMJJ)	n2+n6
21	Numéro de série (non structuré)	n2+an..20
22	Code HIBCC	n2+an..29
240	Identification complémentaire du produit	n3+an..30
241	Code article client	n3+an..30
30	Quantité unitaire	n2+n..8
37	Quantité	n2+n..8
422	Pays d'origine du produit	n3+n3

Signification des termes :

n   Caractère numérique

n2+..   **Valeur sur deux caractères numériques de l'AI suivi de la structure de la donnée**

an   Caractère alphanumérique

n2   Zone de 2 caractères numériques

an..18 Zone pouvant aller jusqu'à 18 caractères alphanumériques

Pour plus d'informations, se reporter à la documentation technique disponible sur le site de GS1 France.

Annexe C

(informative)

Exemple de préparation stérile des instruments chirurgicaux