Application package:
Surgical Instrument Traceability
Version 6

Department of Health

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Dear adopter,

Since the beginning of the Auto Identification and Data Capture (AIDC) programme in February 2007, when the "Coding for success" document was first published, GS1 UK and I have been actively encouraging adoption and development of the GS1 UK standards within healthcare. Whether this is in pharmacy work, the decontamination of sterile surgical instruments, patient identification or any other area where an opportunity has arisen.

As I write this we have more than 185 hospitals using the standards in many ways and I think you will agree this is a great achievement; however, we are always looking for other opportunities. Whether you have received these guidelines from a workshop, a visit, by request or directly from GS1 UK or myself, I would encourage you to use them and feed your thoughts and comments back to us so that we can build upon and improve them. This will help other adopters, like you, to implement the standards as smoothly as possible.

So thank you for adopting the GS1 UK standards and may I wish you every success with your project.

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Foreword

The GS1 System is an integrated system of global standards that provides unique accurate identification using bar codes and other data carriers for products, assets, locations and services. This then forms the secure basis for onward communication of information. It is the most implemented standards system of its kind in the world.

A more responsive, efficient and accurate healthcare supply chain will reduce errors, process time and cost and enable healthcare professionals to provide an even higher quality of patient care.

The main benefit is improved patient safety through:

- Recording of information which is scanned at point-of-use
- Improved traceability
- Enabling checks on usage
- Fewer adverse events and critical errors
- Reduced error rates in administration
- More efficient processes
- Better medicines management
- Simplification and enhanced accuracy of order processing and receipt

Please see the Department of Health's 'Coding for Success' policy for more information. This can be downloaded at **http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082.**

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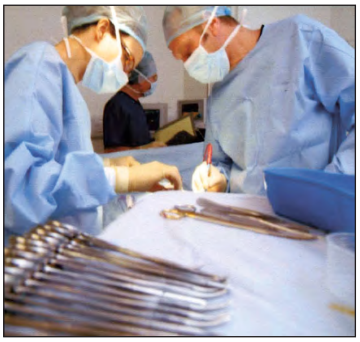
1. Introduction

1.1 Project background: 'Coding for Success'



There is clear evidence that using automatic identification and data capture (AIDC) systems to match patients to their care leads to real improvements in patient safety. These AIDC systems use globally unique identifiers encoded within especially dedicated bar codes to identify all the items involved in healthcare: the improvements are the result of fewer medication errors and much better record keeping. Using unique identifiers to manage supplies and purchase electronically can cut costs dramatically as well as improving efficiency.

Unique identifiers shown in bar codes provide the means to differentiate in a machine readable form, all the items involved in the healthcare supply chain. This ability, when linked with the providing of an item's batch number and serial number together with its expiry date, enables the traceability of all healthcare products from production to delivery to the patient (point-of-care).

The case for the use of unique identifiers shown in bar codes is compelling, but all stakeholders need to work to commonly agreed standards if the benefits are to be realised fully. The Department of Health has recommended that the GS1 System of standards should be adopted throughout the healthcare system in England, both for manufactured products and for identification systems used within healthcare settings. For example, this would include individually marking instruments and trays, patient identification numbers on wristbands and batch numbers on medicines.

To support this initiative, the Department of Health has published a policy position backed by an action plan to support both the NHS and the medicines and devices industries in realising the benefits for patients. It will include:

- Membership of GS1 UK for all NHS organisations, with demonstrator projects and further support to help organisations implement the technology locally
- Further encouragement to the medicines and devices industries to identify and bar code products supplied to the NHS using the GS1 System
- Engagement in the GS1 Healthcare User Group (GS1 HUG), which is reviewing the GS1 System to ensure it meets the needs of healthcare providers and manufacturers worldwide

Surgical instrument traceability and management have been identified as an important area where significant benefits including improved patient safety can be gained from using AIDC. This document aims at supporting the 'Coding for Success' policy document by providing guidance to hospitals, third party decontamination services and providers of instrument marking and management systems embarking on AIDC projects. This surgical instruments traceability guideline also provides technical guidance on how to implement the GS1 System.

2. Overview

In the UK, the Department of Health guidance is for hospitals to track instruments to at least tray level. A significant number of hospitals have decided to extend the traceability to single instrument level. Third party sterile services are also required to use GS1 standards for traceability to instrument level.

2.1 Cross contamination

The fear of cross-contamination between patients through surgical instruments (one example being variant Creutzfeldt-Jakob disease) and the need to manage valuable assets have been stated as the main reasons for tracking single instruments.

NHS trusts mark trays and surgical instruments in a variety of different ways, employing a range of different systems including bar code supported systems. However, there is a clear increase in the use of bar code and Radio Frequency Identification (RFID) supported systems to track and trace surgical instruments. GS1 compliance is now a requirement for contracts for super centres.

The GS1 System of standards is an integrated system of global standards that provides unique identification and communication of information regarding products, services, assets and locations. The GS1 System provides sets of unique identification numbers and standard ways to encode these numbers in a machine-readable from. These numbers are usually represented as bar codes but they can also be represented in other data carriers such as RFID tags, and used with electronic business messages. The GS1 System is used all over the world and can be used by all industries and in all parts of the supply chain, from supply of raw materials through manufacturing, warehousing, and distribution and to end points such as hospital bedsides or operating theatres.

The use of the standards for product identification, bar coding and electronic communications has the potential to significantly improve the accuracy and speed of response of healthcare services. A more efficient and accurate healthcare supply chain will reduce errors and cost, and enable healthcare professionals to provide even higher quality patient care. Benefits include increased patient safety and improvement in the quality of care from:

- More efficient management of surgical instruments
- Reduction in errors and increase in quality
- Easier and earlier identification of missing items
- Avoidance of instrument migration from set to set
- More efficient utilisation of resources in assembling operations in CSSD
- Improved availability and planned usage of instruments

3. Surgical instrument identification and traceability

3.1 Surgical instrument identification and traceability

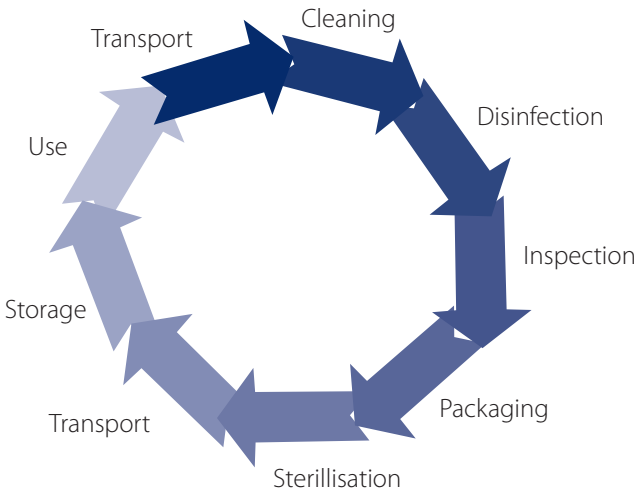
Instruments are either purchased or loaned from other hospitals or third party providers. It is estimated that the UK NHS has at least nine million individual surgical trays in circulation with each tray containing at least half a dozen separate instruments. Therefore the number of surgical instruments can be counted in tens of millions.

Re-usable instruments go through a cleaning and maintenance lifecycle shown below that can be performed by the hospital, another hospital or specialised third party. In the UK there is an increase in the use of specialised centres commonly known as super centres.

3.2 Surgical instrument maintenance lifecycle

Aquisition

1. Purchase
2. Loan



Disposal

1. Scrap
2. Return to lender

Before a re-usable surgical instrument is used for the first time, it goes through a number of processes including packaging, sterilisation, transport, storage and use. During the re-use cycle, it goes through a decontamination process which involves cleaning, disinfection and inspection. This means that there is a need to keep track of where the items are in the decontamination process and to guarantee that the instruments have gone through the correct process.

AIDC can support the whole process: bar codes tags on trays and/or individual instruments can be scanned before and after each activity in the cycle.

4. Current situation

4.1 Current situation

Different hospitals have different tracking practices ranging from manual systems to automated systems. Some track instruments at tray or group level while others track them at individual instrument level.

Currently very few manufacturers mark instruments for hospitals with a globally unique identifier and those who do often have used proprietary identification systems. A number of hospitals have implemented AIDC-supported systems, with some marking individual instruments.

Below are some of the key findings from a recent survey of the systems used for surgical instruments tracking[1] :

- Almost all respondents reported that tracking systems were in place in sterile services, theatre and endoscopy
- Among sterile services, almost 40% reported a paper based system in place, while almost 50% reported a bar code system, mainly at tracking tray level
- In theatre, 60% reported a paper based system and only 25% used bar codes. In endoscopy, paper dominated with 69% reporting this method
- Use of RFID tags was reported in a small number of cases for theatre and endoscopy

A number of studies have been done investigating the management of instruments highlighting the following:

- Need for traceability
- Need for management of valuable assets

4.2 Need for traceability

HSC 2000/032 states: "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 the instrument sets have been used. This is important so that the relevant patients can be identified in the event of exposure to potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instruments is in addition to the measures for identification and tracking of flexible endoscopes set out in Health Service Circular 1999/178."

Currently the Department of Health guidance is for trusts to track instruments to at least tray level. One recent study revealed that few systems used for medical device management relied on each individual item being identified and marked in a way that would allow information on that instrument to be captured as it passed through the different processes. The survey results showed that most of the respondents felt that there was a need for tracking and tracing instruments at individual instrument level for patient safety and that there was a need to automate this process.

One of the respondents in the survey said

"Tracking and traceability is nonsense until all instruments are properly coded. Unless each individual item is clearly marked/bar coded for tracking, no system will work."

The introduction and use of sterile services super centres will increase the need for better traceability systems as the services will be out-sourced to third parties who may be handling instruments from different hospitals. A hospital using the decontamination services will need to know that it is getting the same instruments that it sent out for processing.

Fear of cross contamination is another key driver for instrument traceability especially in regards to variant Creutzfeldt-Jakob Disease (vCJD). This has increased the need to identify which instruments have been used on which patients and to keep a history of the instruments, making it possible to identify instruments that have been contaminated and the patients the instruments have been used on.

4.3 Management of valuable assets

With surgical supplies among the highest expenses in the hospital inventory, accurate instrument tracking is key. Lost instruments can cost a 500-bed hospital an average of over £100,000 per year. Problems with instruments are amongst the ten most frequent causes of operating theatre delays. These delays, due to incorrectly assembled or unavailable instrument sets, cost an average of £500 per hour.

[2] http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4002990
[3] Patients Association, Tracking Medical Devices and the Implications for Patient Safety, 'A survey of hospital practices and opinions'

5. GS1 standards: Identification

5.1 Why GS1 standards

Because of the large number of manufacturers who supply the NHS with surgical instruments, the variety of instruments and the number of existing instruments in use, it is vital that the approach taken for identification is the use of a single global system of standards. The use of third party decontamination centres also increases the need for standards, as the centres will be processing instruments for different hospitals. If different individual systems are adopted it would lead to a lack of interoperability:

- The manufacturers would have to know which hospital the instruments will be going to and what the data and bar code requirements of each hospital were before any marking could be done resulting in added costs and unnecessary processes for the manufacturer
- The hospital would have to make sure that it develops its data requirements and ensures that these are communicated to all suppliers. Alternatively it will have to accept different standards from different suppliers and either approach adds costs and complexities. The sterilisation centres dealing with instruments from different hospitals would also need to maintain different systems

These types of proprietary approach lead to broken traceability links which can affect patient safety and increase the costs of re-identification if a change of ownership or responsibility occurs.

As product marking will be done by different organisations including hospitals, manufacturers and sterilisation services, it is very important that a single data standard and bar code are used. Failure to implement this will result in a number of disadvantages and give rise to additional costs.

In 2003 the NHS Purchasing and Supply Agency (NHS PASA) researched methods for identifying surgical instruments from cradle to grave and concluded that the most effective method would be to use a unique product identification system. The study concluded the GS1 system (then known as EAN.UCC) should be the standard used.

In 2007, The Department of Health published a policy document which recommended the use of GS1 standards for AIDC application in the NHS . The GS1 System includes specifications for surgical instrument identification (asset tracking) and these are summarised in this document. It includes a standard identifier and a corresponding data carrier, a two-dimensional matrix symbol called GS1 DataMatrix. The NHS, hospitals, solution providers and trade associations support this.

5.2 The basic principles of identification

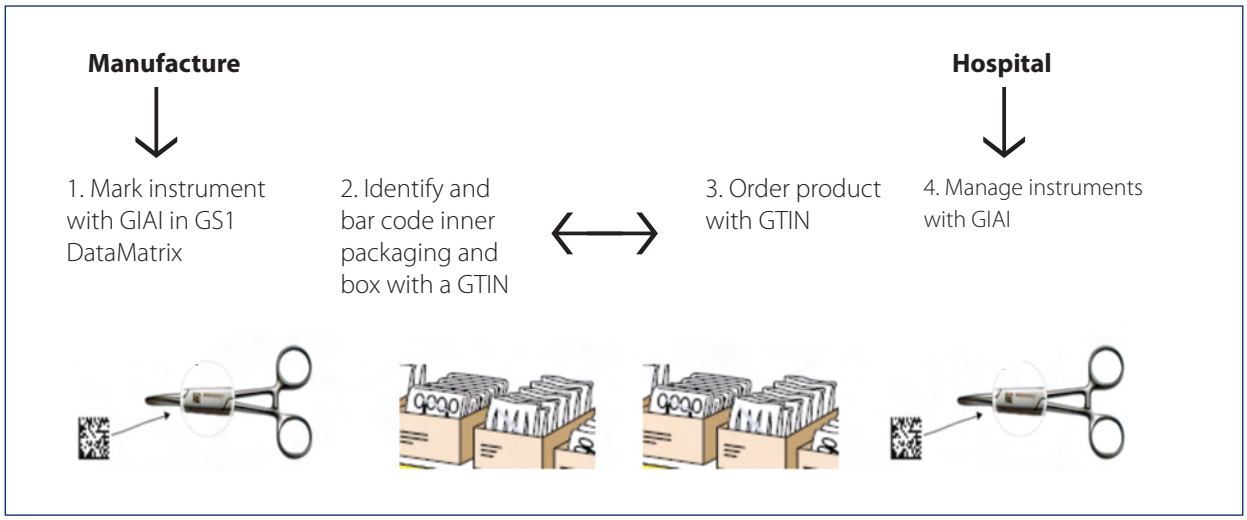
Whenever a surgical instrument set or an individual instrument is ordered by a clinician, the set or instrument will be identified by a unique Global Trade Item Number (GTIN). When the set or instrument is supplied it may be packed and identified with the relevant GTIN plus extra information such as a serial number (which may cross refer to a listing of all the individual items in the set) and an expiry date which relates to the sterilisation of the item. The use of GTINs means that these items can be accurately ordered, and where appropriate, invoiced correctly.

[4] The Department of Health, 'Coding for success: Simple technology for safer patient care', February 2007

In addition each of the components of the surgical instrument set needs to be identified with a unique asset number, a Global Individual Asset Identifier (GIAI) so that the use of each instrument can be accurately recorded against any particular procedure. The GTIN and serial number will together provide a unique reference that will be used to cross refer to all the relevant asset numbers.

The use of GTINs is reserved for items that are ordered and may be priced and invoiced, while GIAIs simply identify each of the instruments and trays involved.

The diagram below outlines how manufacturers and hospitals should mark individual instruments with Global Individual Asset Identifiers (GIAIs) and Global Trade Item Numbers (GTINs)



1. The manufacturer identifies individual instruments with GIAIs and marks the instrument with a GS1 DataMatrix symbol.
   - The hospital will have to mark existing instruments and new instruments that come from the manufacturer unmarked

2. The manufacturer identifies each product grouping with a Global Trade Item Number (GTIN). The GTIN is bar coded on the packaging.
   - Some of these instruments or groupings may be distinguished with serial numbers, that when used with the GTIN will enable the manufacturer to trace the history of the manufacture of each instrument individually
   - Each GTIN will have to be linked to the individual GIAI
   - Each level of packaging for surgical instruments, for example, inner packaging and box will have a different GTIN
   - If it is possible for an instrument to be supplied from three different manufacturers, each manufacturer will need to allocate a different GTIN

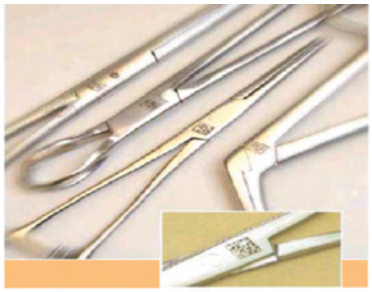
3. The hospital orders from the manufacturer using the GTIN of the product required.

4. The GIAI of each instrument is used to manage it throughout its maintenance lifecycle (see section 3.2 Surgical Instrument maintenance lifecycle).

5.3 Instrument traceability

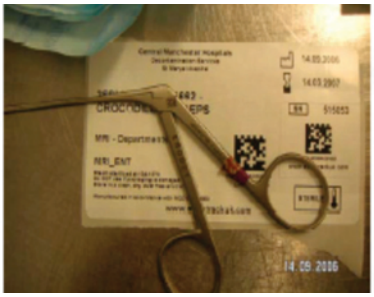
Traceability process

1. GIAI on individual instrument



2. GIAI on trays

3. GTIN, serial number and expiry date on the tracker/production label



1. Each individual instrument is identified with a GIAI
2. Each tray is identified with a GIAI
3. Each tracker/production label shows a GTIN, serial number and expiry date

These GIAIs will be scanned on instruments and trays throughout their daily cycle, and when packed into sets and sterilised.

The use of GTINs on the tracker/production label enables the operating theatre to order sterilised instruments in sets or individually from an in-house or out-sourced provider. The GTIN will be used to identify the sterilised set ordered by a clinician. The GTIN identifies the service of providing these particular instruments ready for a particular operation. Each set or instrument that can be ordered individually has a different GTIN. For example, a small hip replacement set has a different GTIN to a large hip replacement set.

- The serial number identifies that instance of the operation set/instrument. The serial number will be used to distinguish one set from another of the same type.
- The expiry date enables the hospital or service provider to identify if the sterilisation has expired and to manage stock rotation.
- All the GIAIs that comprise the set will be recorded against the GTIN and serial number.

Only instruments or sets that can be ordered for use by a clinician will need to be assigned GTINs for use within the hospital. If a tray can never be requested by itself, it will be sufficient to identify it with a GIAI. (The asset register will record all the relevant details about this item, including its manufacturer and the GTIN that was used to buy it.)

6. Creating Global Trade Item Numbers (GTINs)

6.1 Creating Global Trade Item Numbers (GTINs)

Each organisation that wishes to use GTINs to identify its products or services will obtain a GS1 company prefix number by becoming a member of a GS1 member organisation. In the UK this is GS1 UK. GTINs are created by allocating different item reference digits to identify each product line as shown below and then calculating the last check digit.

GS1 company prefix number	Item reference element	Check digit	Format
5012345	67890	0	n13*
50551234	7890	3	n13*
506009876	123	3	n13*

*GTINs may be eight, twelve, thirteen or fourteen digit numbers. The table above shows how 13-digit GTINs are created. All these GTINs are unique, and they may be treated as fixed-length 14-digit numbers in any database record if this is required. In effect any GTIN of less than 14 digits may be prefixed with leading zeroes.

GTINs have this administrative structure to ensure that all product lines and services are identified uniquely, but the complete number has no meaning. The GTIN is not intended ever to be divided into its components. Although the company prefix number can only be used by one organisation and is unique, it is not regarded as a company identifier.

The item reference elements should be allocated sequentially, with the complete GTIN being used as an identifier or key in an internal database that may also record an in-house code or classification for this item. The GTIN contains no information about the item being identified: it is a non-significant identifier.

6.2 GTIN data structures

The table below shows the position of each individual digit in a given data structure for a GTIN.

	Global Trade Item Number													
Data structures	Indicator	Company prefix plus item reference												Check digit
GTIN-14	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}	N_{14}
GTIN-13	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}
GTIN-12	0	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}
GTIN-8	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8

*N represents the position of each individual digit in a given data structure and 0 represents a filler digit for those data structures that are not 14 digits long.

GTIN-13

GTIN-13 numbers are formed by adding an item reference after the company prefix and then calculating a check digit and placing it at the end. The complete GTIN is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information.

GTIN-14

GTIN-14 numbers are only used on bulk packs. GTIN-14 numbers are formed by adding an indicator digit to the GTIN-13 for the single item within the pack and recalculating the check digit.

The indicator digit can take any value from 1 to 8 and simply creates a different item number for a different packaging configuration. (The number 9 is only ever used when identifying outer cases of products of a continuously variable measure which is usually weight.)

7. Creating Global Individual Asset Identifiers (GIAIs)

7.1 Creating Global Individual Asset Identifiers (GIAIs)

The GIAI is simply a unique serial number that is used to identify individual assets, and it incorporates a GS1 company prefix number to guarantee this uniqueness.

Global Individual Asset Identifier		
GS1 company prefix number	Asset serial number	Format
5012345	123456789012345	an…30
50551234	abc123456e	an…30
506009876	123456abcde123	an…30

*Please note that there is no check digit for the GIAI.

7.2 Distinguishing GTINs from GIAIs: Application Identifiers (AIs)

The GS1 standards specify AIs which are used to ensure that a GTIN is always processed as a GTIN when it is scanned or read from a data carrier such as a bar code or RFID tag. The application identifiers are two, three or four digit numbers, and they denote the format of the data that follows them. Below is a table listing the GS1 application identifiers that relate to surgical instruments.

Application identifier	Title
01	Global Trade Item Number (GTIN)
10	Batch Number
17	Expiry Date
21	Serial Number
8004	Global Individual Asset Identifier (GIAI)

7.3 Marking instruments and trays for asset tracking purposes

Global Individual Asset Identifier (GIAI)

Example: (8004) 5012345123456789012345

- The issuing organisation must ensure that the asset serial number element remains unique.
- The application identifier is not part of the GIAI; it is used when encoding this identifier in a bar code so that it can be correctly processed when the bar code is scanned.

7.4 Production labels

GTIN + expiry date + unique serial number

Example: (01) 05012345678900 (17) 051231 (21) ABCD1234567890

- Each different set of instruments will be identified with a unique GTIN.
- The expiry date (specified by the application identifier 17) will allow for accurate rotation of stock.
- The serial number, together with the GTIN will identify the record that provides all the GIAIs of all the items that comprise each individual set and any other information that relates to the cleaning, packing and sterilising process.

8. Bar coding individual items

8.1 Bar codes

One way of automatically tracking and tracing each individual instrument is by the use of bar codes where each instrument is given a unique number, which is then bar coded onto the instrument. There are a number of benefits of using such a system:

- Each instrument has a unique number which allows its history to be recorded and retrieved as required
- Bar coding each instrument allows the data to be captured more quickly as the bar code is simply scanned whenever it passes a point where the instrument needs to be identified
- As the bar code is machine readable, there are fewer errors when reading the code
- Permanent ways of marking the bar code on the instrument mean that once this is done, it stays with the instrument throughout its life
- With the introduction of super centres where instruments from different hospitals are processed together, hospitals can be sure that the instruments that go out for processing are the same as those that come back from the super centres

8.2 Bar code enabled system issues

- The bar code needs to be permanent, and should not interfere with the decontamination process which means that the method used for marking the instrument is important.
- Most manufacturers are currently not bar coding instruments. Any hospital thinking of using such a system should make decisions on when the bar coding is done.
- If a hospital does not require suppliers to bar code the instruments, then the bar coding can be done at the hospital before their first use. However, this adds a lot of cost for the hospital and even if the hospital decides to do the bar coding at the beginning, the long-term aim should be to encourage the manufacturers/suppliers to do the bar coding.
- Existing instruments will need to be marked.

Initially the hospital will have to do some marking whether it is just for the existing instruments or for both the existing and new instruments if the manufacturer is not doing the marking on new instruments.

8.3 Bar coding instruments

A bar code is marked directly on the surgical instrument. The bar code to be used on surgical instruments is the two-dimensional GS1 DataMatrix symbol. There are different methods of marking instruments and common methods include dot peening, laser etching, electro-chemical etching, and ink jet marking. Some solution providers offer marking services for hospitals. The main advantage of this kind of service is that the hospital does not need to invest in marking equipment and find qualified people who understand the marking technology and data requirements. This is especially attractive for hospitals that are only thinking of doing the marking at hospital level as a short term measure and expecting new products to come in already marked by the manufacturer.

Laser etching

Laser etching, or laser engraving, uses precisely controlled lasers to engrave or mark the bar code on the product. A computer controlling a series of mirrors and lenses focuses the laser to burn or etch the bar code. The process allows a product to be directly and permanently marked but is only suitable for 'laserable' materials. The power of the laser needs to be set based on the volume printing required as well as the speed of printing. The power must be adapted to substrates and commonly ranges from 10 to 100 watts.

Dot peening

The technology is used to directly mark the material and is particular suitable for solid materials (metals, plastics, wood, etc). It can be used for all the information to be marked on the item (text, date, logo, etc.) as well as the GS1 DataMatrix symbol. A small head, normally made from a very strong material such as tungsten, is computer controlled to make a defined series of identical punch marks in the surface of the substrate. The depth of marking can be carefully controlled to ensure all indents are identical, making this technique particularly suited for printing GS1 DataMatrix directly on items made of metal or other material with very hard flat surfaces.

Electro-chemical etching

Electro-chemical etching is a process whereby the mark is produced by oxidizing metal from the surface being marked through a stencil impression.

Ink jet marking

Ink jet printers precisely propel ink drops to the part surface, after which the fluid evaporates and leaves a coloured die that creates the pattern of modules that make up the mark.

9. Marking surgical instruments

9.1 Marking new instruments

Instruments should ideally be marked at source for a number of reasons. Firstly, the marking of instruments can be done as part of the production process. Also, marking of instruments by parties other than the manufacturer may affect the product's warranty.

The manufacturers can use different marking methods but all systems will have to use GS1 coding standards. The introduction of this by all manufacturers will mean that as old instruments are replaced, all instruments within the NHS will be identified with a GS1 number.

9.2 Marking existing instruments

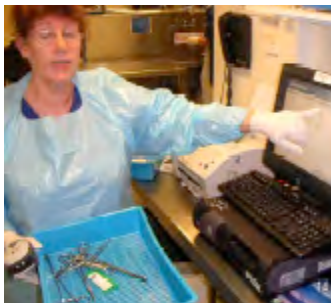
Some hospitals in the UK have already decided to mark their existing instruments. The main solution providers who provide marking products and services have bought into the GS1 UK system and their solutions are therefore GS1 compatible. The cost for marking will vary depending on the technique used.

It should be noted that by marking the instruments, the organisation carrying out the marking could be interfering with the integrity of the instrument and therefore the liability for the instrument passes from the manufacturer.

Hospitals in England wishing to mark their instruments are able to join GS1 with no membership charges as part of the contract agreement between Connecting for Health and GS1 UK. Remember that the GS1 system is used to identify both surgical instruments and surgical trays.

10. Instrument management process

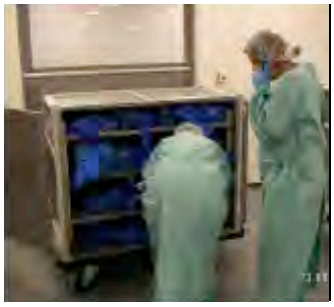
Once you have registered with GS1 UK and received your unique company prefix number and marked your instruments the process normally proceeds as follows:



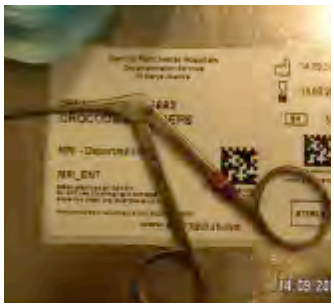
Step one: Collection and transportation of contaminated items
After a medical device has been used, it is usually placed on a collection container which is collected by the sterile services department at agreed times. The items are collected and a link is made to the patient. Containers and trolleys that are used to transport items to and from sterile services also need to be tracked.

Step two: Receipt of contaminated item by Sterile Services Department (SSD)
The department receives items for reprocessing in the designated 'dirty' section of the decontamination area. Staff must check each item and notify the user if any part of the equipment is missing or damaged on receipt.

Step three: Reprocessing
The items are placed in the appropriate container for decontamination. The items are then washed by the washer/disinfector, which also dries the items following the disinfection stage of the automated process. Once the cycle is complete, the machine transfers the cleaned and disinfected medical devices into the production room. Should devices require manual cleaning only, they are cleaned in accordance with the manufacturer's written instructions prior to transfer to the production room.



Step four: Packaging and sterilisation
The medical devices are wrapped in medical packaging material and the packaged products sterilised.



Step five: Storage
After sterilisation, the products are allowed to cool before being stored or re-issued. A record is kept of items in storage and these items are despatched on a *'first in first out'* basis. The SSD should retain a record within the storage administrative area of items in the store and available for use. A record must be made of the dispatch of any item from this area and stock is issued on a 'first in first out' basis.

Step six: Tracking and tracing
A link needs to be made between the instruments and patients. This traceability to decontamination and sterilised equipment is made by labelling all records/documents that are used in the patient's medical records.

Appendix one: Bar codes

Bar codes

Bar codes help organisations to capture data automatically via scanners. Automatic data capture (AIDC) is less error prone and faster than manual data capture with statistics indicating 1 error per 300 characters entered using a keyboard as opposed to 1 error per 1,000,000 for data entered through scanning of bar codes.

The GS1 System uses the following bar code symbologies:

1. EAN/UPC symbology family (EAN-13, EAN-8, UPC-A and UPC-E)
2. ITF-14
3. GS1 DataMatrix
4. GS1-128
5. GS1 DataBar (formerly known as Reduced Space Symbology)

GS1-128

The GS1-128 bar codes together with the application identifier standards enable companies to provide additional information about a product along with the GTIN for the product itself. GS1-128 is a subset of Code 128.

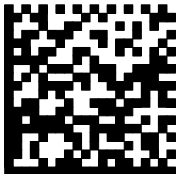
Below is an example of a GS1-128 encoded with a GTIN and best before date. The different types of data are specified by AIs, which normally appear in brackets in the human readable characters (the brackets are not encoded in the bar codes).

GS1 DataMatrix

GS1 DataMatrix is a two dimensional machine readable code, which is capable of encoding the same information as any other GS1 codes but in a fraction of the space. The code also has the advantage of built in error correction so that could still be read with only 75% of the code remaining. It can be used where the marking area will preclude the application of ink, thus requiring the symbol to be applied by means of direct part marking. GS1 DataMatrix cannot be read by laser scanners and older versions of robotic dispensing systems.

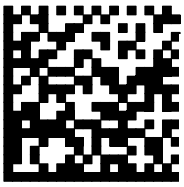
Below are two examples of GS1 DataMatrix symbols:

GS1 DataMatrix Symbol Encoded with GTIN, expiry date and batch number (AIs 17 and 10)



(01)04012345678901
(17)050101
(10)ABC123

GS1 DataMatrix Symbol Encoded with GTIN and Serial Number (AI 21)



(01)04012345678901
(21)ABCDEFG123456789

Appendix two: Check digit calculation

Check digit calculation

The last digit of any GTIN is a check digit to make sure the number is correctly composed. The check digit is calculated by a modulo 10 algorithm from all the other digits in the number through the following steps:

1. Starting with the digit on the right of the number (excluding the check digit) sum all the alternate digit values, reading right to left.
2. Multiply the result of step one by three.
3. Sum all the remaining digit values.
4. Add the result of step 2 to the result of step three.
5. The modulo 10 check digit is the smallest number, which when added to the result of step four, produces a multiple of 10.

	501234576421_
Step 1	1 + 4 + 7 + 4 + 2 + 0 = 18
Step 2	18 x 3 = 54
Step 3	2 + 6 + 5 + 3 + 1 + 5 = 22
Step 4	54 + 22 = 76
Step 5	76 + C = 80
Answer	C = 4

The complete GTIN–13 number is **50123456764214**

A check digit calculator is available on the GS1 UK website at **www.gs1uk.org**.

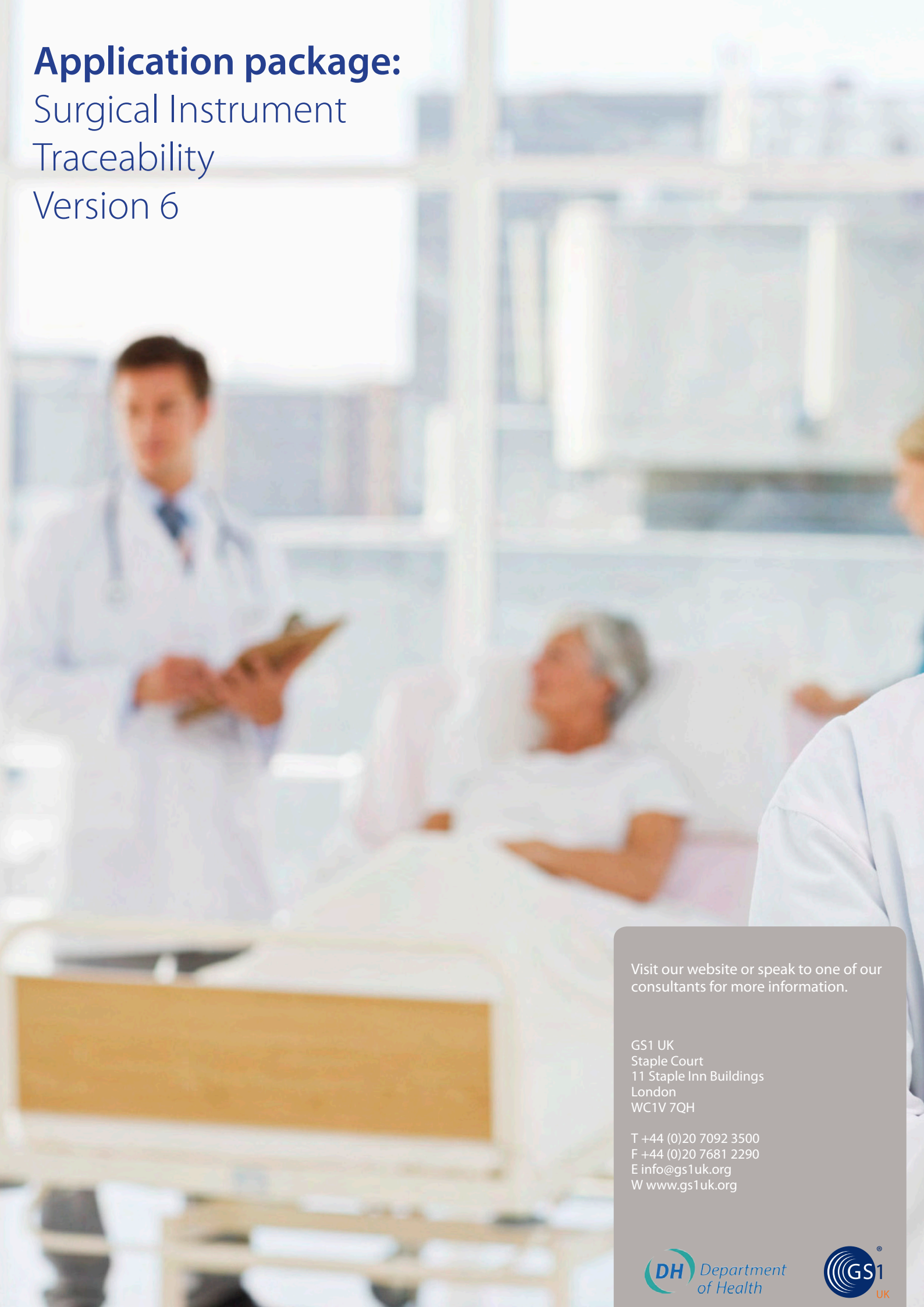
Appendix three: Glossary of terms

Data carrier	A means to represent data in a machine-readable form; used to enable automatic reading of data (element string) held within the carrier.
Global Individual Asset Identifier (GIAI)	The GS1 Identification Key used to identify individual assets.
Global Trade Item Number (GTIN)	The GS1 Identification Key for any pre-defined product or service that may be priced, ordered or invoiced at any point in the supply chain.
GS1 Check Digit Calculation	A GS1 System algorithm for the calculation of a Check Digit to verify accuracy of data.
GS1 Company Prefix	Part of the GS1 System identification number consisting of a GS1 Prefix and a Company Number, both of which are allocated by GS1 Member Organisation.
GS1 DataMatrix	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix ISO version ECC 200 is the only version that supports GS1 System identification numbers, including Function 1 symbol character. DataMatrix symbols are read by two-dimensional imaging scanners or vision systems.
GS1 General Specifications	Defines the GS1 Identification Keys, bar codes and supplementary data to be represented in bar code format.
GS1 Identification Key	A numeric or alphanumeric data field managed by GS1 to ensure the global, unambiguous uniqueness of the identifier in the open demand or supply chain
GS1 Member Organisation	A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in GSMP.
GS1 System	The specifications, standards and guidelines administered by GS1.
GS1–128	A subset of the Code 128 that is utilised exclusively for GS1 System data structures.
Human Readable Interpretation	Characters that can be read by persons, such as letters and numbers, as opposed to symbol characters within bar code symbols, which are read by machines.
Scanner	An electronic device to read bar code symbols and convert them into electrical signals understandable by a computer device.
Serial Number	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.
Supplier	The party that produces, provides or furnishes an item or service.

Appendix four: Abbreviations

AIDC	Automatic Identification and Data Capture
dm+d	Dictionary of Medicines and Devices
EPR	Electronic Patient Record
GTIN	Global Trade Item Number
HUG	Healthcare User Group
ISB	Information Standards Board (NHS
ISN	Information Standards Notice (issued by ISB)
MHRA	Medicines and Healthcare products Regulatory Agency (NHS)
NJR	National Joint Registry
NPSA	National Patient Safety Agency (NHS)
PASA	Purchasing and Supply Agency (NHS)
PSA/SPN	Patient Safety Alert and Safer Practice Notice
RFID	Radio Frequency Identification

Application package:
Surgical Instrument Traceability
Version 6



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