



The Global Language of Business



Surgical Instrument Traceability Guidelines





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About the Healthcare User Group

The Healthcare User Group (HUG) is made up of invited senior representatives from healthcare trade associations, providers, suppliers, solution and service companies and other related organisations. The objectives of the group are:

- To actively support and accelerate the adoption of GS1 standards throughout healthcare, by sharing learnings and best-practice solutions from local implementations
- To help healthcare providers comply with Unique Device Identification (UDI) and Falsified Medicines Directive (FMD) regulations
- To identify and review opportunities that enhance efficiency and patient safety
- To provide feedback and advice on GS1 UK's healthcare plans and activity
- To act as the UK point of contact for the GS1 Global Healthcare Group, and to provide feedback to the GS1 Global Standards Management Process



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Foreword

The GS1 system is an integrated set of global standards that provide unique, accurate identification using barcodes 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 global standards system of its kind and is endorsed by the Department of Health, Health and Social Care Information Centre (HSCIC), NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA).

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 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 eProcurement Strategy for more information on the need to adopt GS1 standards: <https://www.gov.uk/government/publications/nhs-e-procurement-strategy>

1 Surgical Instrument Traceability Summary

The "Surgical Instrument Traceability Guidelines" document was originally issued by GS1 UK in collaboration with Connecting for Health (CfH) back in 2008. Since then GS1 standards have been updated to meet increased business requirements within the healthcare sector. The information needed by manufacturers, hospital sterile services departments and other hospital departments has also increased and these guidelines have been amended to meet these changes. The document was reviewed and involved discussions and site visits with three NHS Trusts (University Hospital Southampton NHS Foundation Trust, Isle of Wight NHS Trust and Portsmouth Hospitals NHS Trust), as well as the MHRA and decontamination system providers.

Document summary:

Manufacturers will need to identify all their products using a GTIN with an appropriate barcode on the packaging, including the appropriate attribute information e.g. serial number, expiry date etc. Instrument trays should be marked with an appropriate barcode and use either a GTIN or GIAI, depending on who has marked the product and who owns it. Instruments should be marked with a GS1 barcode with the appropriate data structure, depending on where the instrument was marked (by product manufacturer or product owner.)

Sterile Service Departments will need to:

- order products from their suppliers using a GTIN
- create an asset database using appropriate GS1 identifiers for each product
- link their products to the instrument trays
- ensure all trays are uniquely identifiable and each reprocessing cycle can be matched to the instruments and trays used in that cycle.

Hospital theatres need to:

- be able to identify and check the trays that are used
- have trays tracked in and out of the operating theatres and theatres need to be able to manage their inventory accordingly.
- the instruments and instrument trays used to be associated with the patient and recorded in that patients care records
- Track used instruments and trays back to the decontamination / sterile services facility to ensure full traceability

2 Introduction

2.1 Project background

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 barcodes 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 barcodes 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 barcodes 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 *mandated* 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 includes 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 suppliers in realising the benefits for patients. It includes:

- 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 barcode 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 was one of the first application areas that was implemented within the NHS in England using GS1 standards, with guidelines first issued in 2007. This document is an update of that original document which provided initial guidance to hospitals, third party decontamination services and providers of instrument marking and management systems embarking on AIDC project, and aims to provide technical guidance on how to implement the GS1 System in a decontamination centre.



This document, and a second document called "*Technologies for Marking Surgical Instruments*" - detailing the technologies currently available and typically used within the healthcare sector to identify surgical instruments, form the complete guidance for Surgical Instrument Traceability.

"Technologies for Marking Surgical Instruments" can be downloaded here: "[*Download link to be provided*](#)"

3 Overview

In the UK, the Department of Health and MHRA 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.

3.1 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. However, there is a clear increase in the use of barcode and Radio Frequency Identification (RFID) supported systems to track and trace surgical instruments. GS1 compliance is now a requirement for all decontamination centres in England.

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 form. These numbers are usually represented as barcodes 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, barcoding and electronic communications has proved 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:

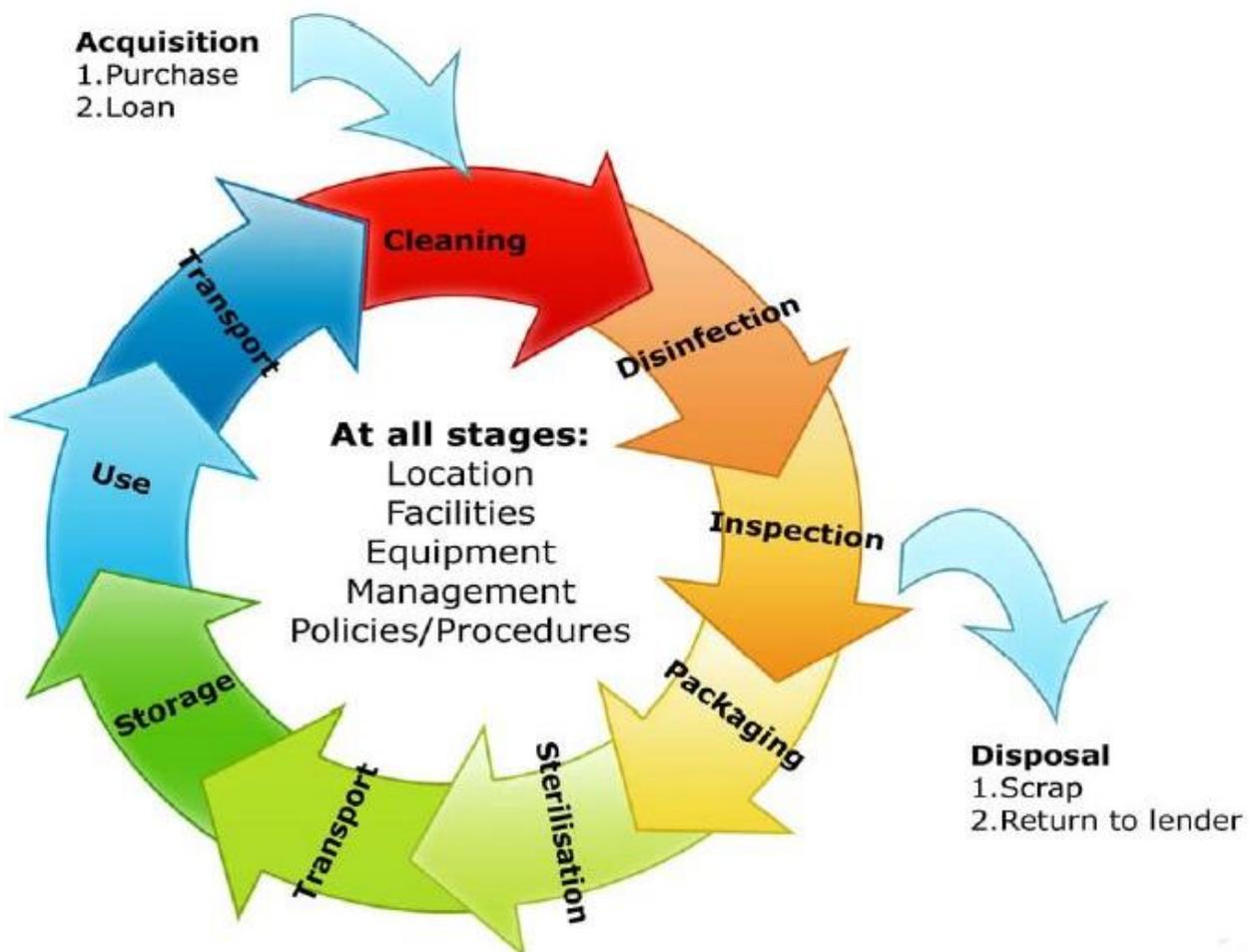
- More efficient management of surgical instruments
- Reduction in errors and increase in quality
- Easier and earlier identification of missing items
- Avoidance of instrument migration from set to set
- More efficient utilisation of resources in assembling operations in CSSD
- Improved availability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

4 Surgical instrument identification and traceability

4.1 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.

4.2 Surgical instrument maintenance lifecycle



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: barcode or RFID tags on trays and/or individual instruments can be scanned before and after each activity in the cycle.

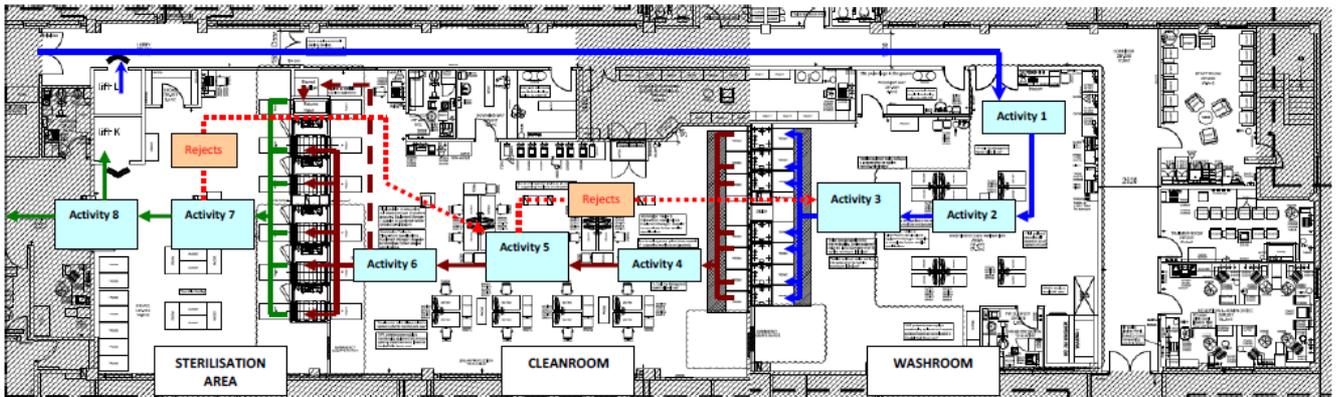
5 Instrument management process

Decontamination is the combination of processes including cleaning, disinfection and sterilization used to render a reusable item safe for further use on a patient and handling by staff. The effective decontamination of reusable surgical instruments is essential in minimising the risk of transmission of infectious agents.

Further information here: <http://www.wales.nhs.uk/sites3/Documents/254/InstrDecontamguide.pdf>

- NICE (National Institute for Health and Care Excellence) Interventional Procedure Guidance IPG 196 - <https://www.nice.org.uk/guidance/ipg196> - The Chief Medical Officers of England, Scotland, Wales and Northern Ireland have asked NICE to develop guidance on the prevention of transmission of Creutzfeldt-Jakob-Disease (CJD). The National Institute for Health and Clinical Excellence (NICE) has issued full guidance to the NHS in England, Wales, Scotland and Northern Ireland on patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures.
- ISO 13485:2016 Medical devices – Quality Management systems – Requirements for regulatory purposes http://www.iso.org/iso/catalogue_detail?csnumber=59752 - ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.
- MHRA - Guidance on legislation "Borderlines with medical devices" - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284505/Borderlines_with_medical_devices.pdf Article 12 – kits and procedure packs / assembling and processing Article 12 of the MDD provides for manufacturers who put together medical devices already carrying the CE mark into kits or procedure packs for specific uses. Kits or procedure packs will come within the remit of the regulations and manufacturers need to comply with specific elements of the regulations, although the kit or procedure pack itself does not need to carry an additional CE mark. Such kits may also include non CE marked products. For example, such a kit may contain a medicinal product, which must meet the requirements of the regulations covering medicinal products, including those covering labelling, packaging etc. Where such kits / procedure packs are sterilised after completion, the assembler will require certification via a notified body for the sterilisation process. If any of the medical devices contained in such a kit are not CE marked by the original manufacturer, then the person putting the kit on the market is considered to be the manufacturer and the whole kit would need to be CE marked as a medical device in its own right under Article 11 of the MDD. That is, the 'assembler' in such cases would be regarded as the manufacturer of the whole kit.
In addition, if the CE marked devices are placed in the kit for a purpose not compatible with the original manufacturer's stated intended purpose then the person assembling the kit will be deemed to be placing a medical device on the market in its own right and therefore must meet the full requirements of the MDD. The assembling of medical devices is likely to come within the remit of the MDD, for example the assembling of CE marked spectacle frames and lenses for specific patients, along with associated processes such as glazing, and surfacing. MHRA's website contains specific guidance on these types of products and activities.
- HTM 01-01 provides guidance about the management and decontamination of reusable surgical instruments and medical devices used in acute care.
<https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care>

An example of activity flow and description is detailed below in Diagram A



Key:
← Sterile item flow
← Clean item flow
← Dirty item flow

	Activity description	Scanning activity
Activity 1	Receipt of used goods	Washing arrival scanning
Activity 2	Inspection, dismantling and cleaning	Pre-wash inspection
Activity 3	Loading of washers	Washing batch and Washer-In
Activity 4	Unloading of washers	Washer Out (including washer cycle number)
Activity 5	Inspection, assembly, packing and wrapping	Packing Inspection and Wrapping, double checking
Activity 6	Loading of sterilizers	Steriliser Batch and Sterilizer In
Activity 7	Unloading of steriliser	Steriliser Out (including steriliser cycle number)
Activity 8	Despatch	Sterile Store (including delivery location release)

Once you have registered with GS1 UK, 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.

6 Current situation

6.1 What is the current scenario?

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.

A number of hospitals have implemented AIDC supported systems, with some marking individual instruments whilst others have marked at the tray level and the instruments are unmarked.

6.2 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." – For more information

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4002990

Currently, the Department of Health guidance is for Trusts to track instruments to at least tray level. One recent study (Patients Association, Tracking Medical Devices and the Implications for Patient Safety, "A survey of hospital practices and opinions") 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/barcoded 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 outsourced 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.





6.3 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.

7 GS1 standards: Identification

7.1 Why GS1 standards

Because of the large number of manufacturers who supply the NHS with surgical instruments, and 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 barcode requirements of each hospital were, before any marking could be done. This results in added costs and unnecessary processes for the manufacturer
- The hospital would have to make sure that it develops its data requirements and ensure 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. This 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 barcode 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 NHS¹. 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.

7.2 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.

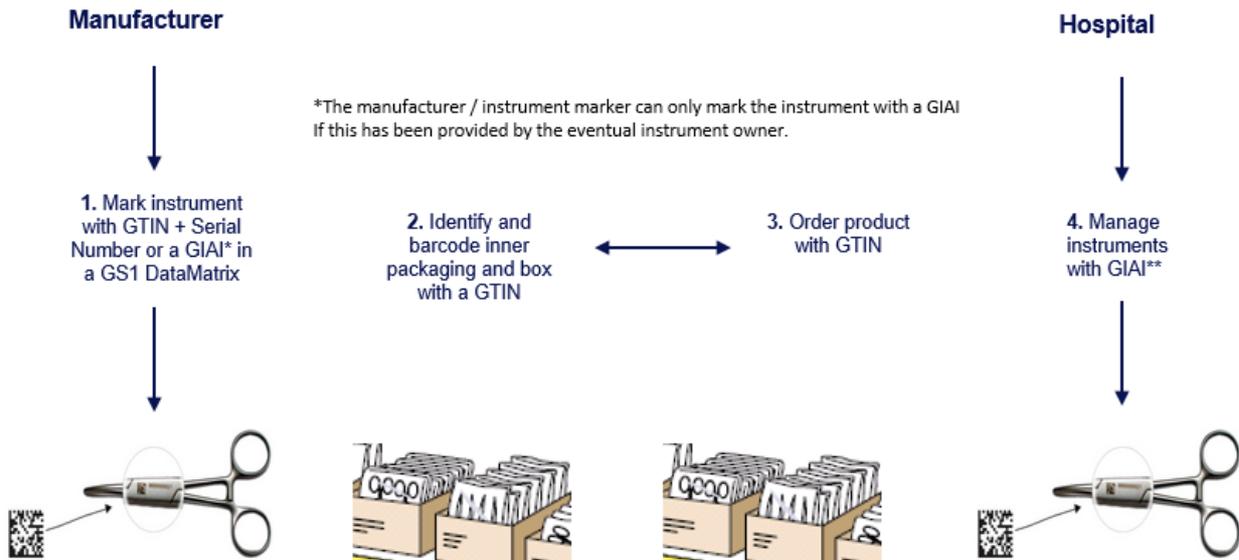
In addition, each of the components of the surgical instrument set needs to be identified with a unique asset number, a Global Individual Asset Identifier (GIAI), so that the use of each instrument can be accurately recorded against any particular procedure. The GTIN and serial number will

¹ The Department of Health, 'Coding for success: Simple technology for safer patient care', February 2007

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)



**The hospital needs to allocate asset numbers to all its instruments, if the instrument has no marking then this asset number is marked using a GIAI on the instrument. If the instrument has already been marked with a GTIN + Serial Number by the manufacturer then the hospital asset number need to be associated with this within their asset database.

1. The manufacturer identifies individual instruments with GTIN + Serial Number or a GIAI (if provided by the customer) and marks the instrument with a GS1 DataMatrix symbol. If the instrument has been pre-marked by the manufacturer then the hospital will need to allocate a GIAI to that instrument and map the two codes together *See Diagram B below.*



Diagram B

The hospital will have to mark existing instruments and new instruments that come from the manufacturer unmarked using a GIAI only.

2. The manufacturer identifies each product grouping with a Global Trade Item Number (GTIN). The GTIN is barcoded 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 4.2 *Surgical Instrument maintenance lifecycle*).

7.3 Instrument traceability

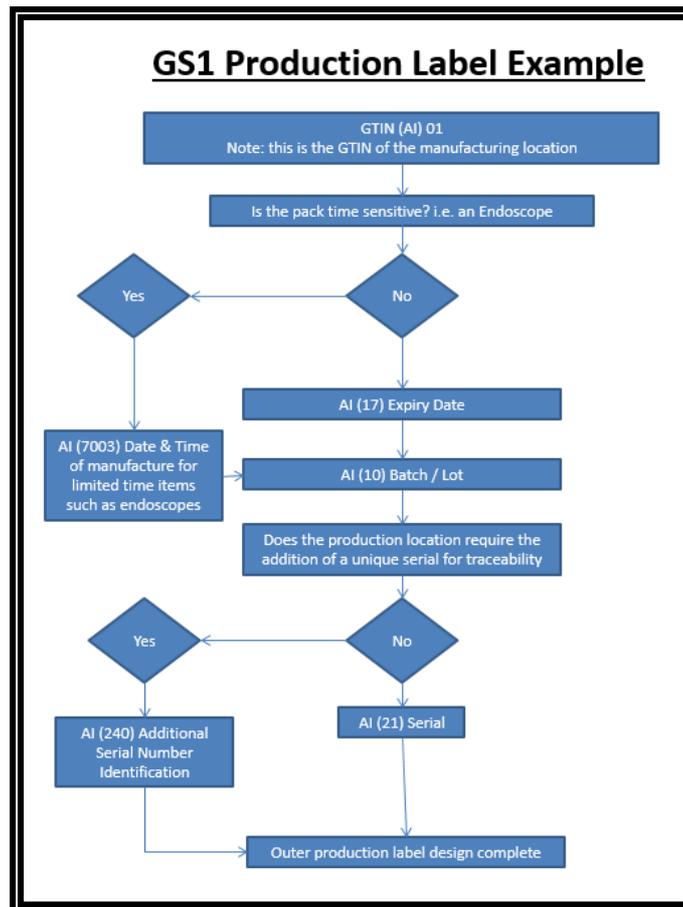


1. Each individual instrument is identified with a GIAI using AI (8004) which may be mapped to a GTIN + Serial Number if marked by the manufacturer.
2. Each tray is identified with a GIAI using Application Identifier - AI (8004) – typically barcoded using a tray tag.
3. Each tracker / production label needs the following mandatory and additional codes that may be required to achieve the desired outcome of tray identification.
 - a. GTIN – AI (01) N2+N14 – Mandatory
 - b. Batch / Lot Number – AI (10) N2+X..20 – Mandatory
 - c. Expiry Date - **AI (17) N2 + N6** in **YYMMDD** format - **Mandatory**
 - d. Serial Number - **AI (21) – N2 + X..20 – Mandatory (not mandatory if AI 7003 is used instead)**

- e. Additional Serial Number Identification - **AI (240) N3 + X...30** – this may be the Asset Number of the tray contained within the packing and if the GIAI is used must include the complete data string.
 - f. Expiry Date and Time - **AI (7003) N2 + N10** in **YYMMDDHHMM** format – **Mandatory if AI 21 not used, if AI 21 is used NOT required.**
4. To decide which data may be required on the production label see the process map below in Diagram C



Diagram C



An example Production Label showing information that can be used can be seen on Diagram D. Please note this diagram is for illustration purposes only and does not show the use of the GS1 application identifier for the serial number – AI 21). The Production label can be barcoded using a GS1-128 or GS1 DataMatrix barcode.



Diagram D

These GIAIs or GTIN + Serial Numbers 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.)



8 Creating Global Trade Item Numbers (GTINs)

8.1 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.

8.2 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	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13	N14
GTIN-13	0	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13
GTIN-12	0	0	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12
GTIN-8	0	0	0	0	0	0	N1	N2	N3	N4	N5	N6	N7	N8



*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.)



9 Creating Global Individual Asset Identifiers (GIAIs)

9.1 Creating Global Individual Asset Identifiers (GIAIs)

The GIAI is simply a unique serial number that is used to identify individual assets. 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.

9.2 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 barcode 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)
7003	Expiry Time
240	Additional ID



9.3 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 barcode so that it can be correctly processed when the barcode is scanned.

9.4 Production labels

GTIN + expiry date + unique serial number + batch number

Example: (01) 05012345678900 (17) 151115 (21) ABCD1234567890 (10) ABCD1234

- 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 (specified by the application identifier 21), 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.
- The batch number (specified by the application identifier 10) can be used to identify the sterilisation process cycle.
- Other information may be included as per Section 7.3.

10 Barcoding individual items

10.1 Barcodes

One way of automatically tracking and tracing each individual instrument is by the use of barcodes, where each instrument is given a unique number which is then barcoded 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
- Barcoding each instrument allows the data to be captured more quickly as the barcode is simply scanned whenever it passes a point where the instrument needs to be identified
- As the barcode is machine readable, there are fewer errors when reading the code
- Permanent ways of marking the barcode 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

10.2 Barcode enabled system issues

- The barcode 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 barcoding instruments. Any hospital thinking of using such a system should make decisions on when the barcoding is done.
- If a hospital does not require suppliers to barcode the instruments, then the barcoding 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 barcoding at the beginning, the long-term aim should be to encourage the manufacturers/suppliers to do the barcoding.
- 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.

10.3 Instrument identification

A barcode or an RFID tag is applied directly on the surgical instrument. The barcode 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. More information on the technologies available to identify surgical instruments titled "Technologies for Marking Surgical Instruments" can be downloaded here: "[*Download link to be provided*](#)"

11 Marking surgical instruments

11.1 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.

11.2 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 and technology 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.

All hospitals in England wishing to mark their instruments are already members of GS1 as part of the contract agreement between the Department of Health and GS1 UK. Remember that the GS1 system is used to identify both surgical instruments and surgical trays.

A Appendix A: Barcodes

Barcodes

Barcodes 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 barcodes.

The GS1 System in healthcare primarily uses the following barcode symbologies:

1. EAN/UPC symbology family (EAN-13, EAN-8, UPC-A and UPC-E)
2. GS1 DataMatrix
3. GS1-128

GS1-128

The GS1-128 barcode 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, expiry date and batch number. 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 barcodes).



GS1 DataMatrix

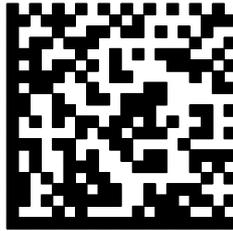
GS1 DataMatrix is a two dimensional machine readable code, which is capable of encoding the same information as any other GS1 codes but in a fraction of the space. The code also has the advantage of built in error correction so that could still be read with only 75% of the code remaining. It can be used 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 all hospitals are advised to procure camera based barcode scanners to ensure all barcode types can be scanned.

For further information on the implementation and use of the GS1 DataMatrix barcode please refer to the following document: www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

For the GS1 Healthcare Position Statement on GS1 DataMatrix Implementation please read the following document: http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf

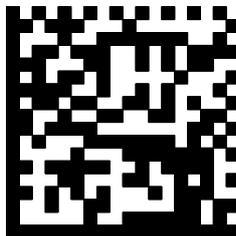
Below are two examples of GS1 DataMatrix symbols:

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



(01)05012345764214
(17)151122
(10)ABCDE12345

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



(01)05012345764214
(21)1234567

B Appendix B: 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	$18 \times 3 = 54$
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 **5012345764214**

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



C Appendix C: Glossary of terms

Application Identifier – GS1 (AI)	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
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, barcodes and supplementary data to be represented in barcode 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 barcode symbols, which are read by machines.
Scanner	An electronic device to read barcode 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.



D Appendix D: 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