Recommendations by the quality task group (113)

Unambiguous traceability of medical device reprocessing – Part 2

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4. Processes

RECORDED DATA of automated processes can serve as an important data source.

The automated cleaning, disinfection and sterilization processes are **RECORDED** virtually everywhere in Germany and can thus serve as a data source for other important topics:

- What instruments / sets are used for which patients?
- What preparatory steps are undertaken for cleaning in the WD (precleaning, dismantling)?
- Control and packing processes

PAPER-BASED RECORDS in a RUMED could result in hygiene issues.

From a legal perspective the unmistakable individualization of MDs in the reprocessing process can be effected in paper or software format. However, the use of **PAPER-BASED RECORDS** in a RUMED could result in hygiene issues since it could be difficult to forward them with the set from the cleaning / disinfection area (unclean side) to the packing area (clean side). In general, unambiguous and unmistakable recording is done digitally using sector-oriented software to meet all hygiene requirements.

5. Traced medical devices

Unambiguous identification of the MDs or set is a precondition for unambiguous traceability.

Unambiguous:

- Basic Surgical Tray No. 8: precisely that tray.
- An unambiguous designation is based as a rule on the article (here basic surgical tray) and a serial number (in the example, the number 8).

Ambiguous:

- Basic surgical tray: any basic surgical tray.
- The contents are defined but there can be many (such basic surgical trays).

THE UNAMBIGUOUS IDENTIFICATION of sets is viewed as standard practice.

In the meantime, the **UNAMBIGUOUS IDENTIFICATION** of sets and transport containers is viewed as standard practice. This means that information can also be assigned to certain sets, e.g. missing items. Without unambiguous identification traceability (which instruments were used on patient X) is virtually impossible.

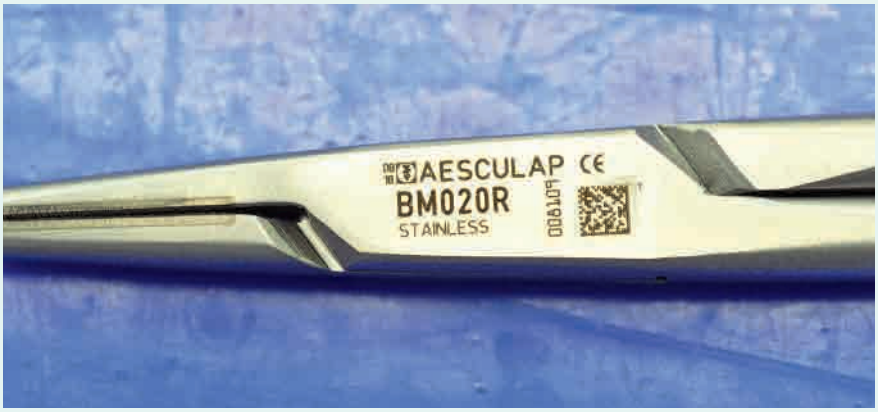

Figure 1: Instruments with Data Matrix code

In reality, however, instrument identification is generally not unambiguous. Increasingly often instruments have machine-readable identifications (Data Matrix or RFID) also featuring a serial number. However, it takes a lot of time to register these numbers at the respective checkpoints because of the size of the instruments.

Often, the **IDENTIFICATION** is not resistant to the process in the long term and can no longer be read. Likewise, changes made to the identification after repairs or because of surface changes present problems.

OFTEN, THE IDENTIFICATION OF SINGLE INSTRUMENTS is not resistant to the process in the long term.

Besides, some of the medical devices to be reprocessed are too small or are composed of a material to which codes cannot be easily affixed. In particular in the case of implants traceability is at least desirable, if not even necessary, to counter any problems arising after implantation.

Having to deal with ambiguous identification creates traceability uncertainty. Control procedures entail only checking whether any instrument of that type is present in the set (e.g. 14 cm curved, article number BH111R)

- Instruments can, e.g. during the operation, migrate between different sets containing them.
- It remains unclear whether instruments were repaired or replaced.

In general traceability during the process is carried out at set level Strictly speaking that is only correct if the entire contents of that set undergo the same process. Which individual medical devices are e.g. cleaned and disinfected separately is then no longer recorded.

Figure 2: Scanning barcodes to sets

Figure 3: Scanning barcodes

Electronic systems can be used for verification purposes (checking the inventory, withdrawals and used medical devices). Discipline is of paramount importance when using the systems

In general sets are registered in a RUMED by scanning them. However, because of the large number of sets it is possible that not all codes will be registered or labels may no longer be legible or may be missing

In most systems the user can specify in the software configuration the **PROCEDURE TO BE USED FOR A SET** if a previous step was not registered. In addition to

THE PROCEDURE TO BE USED FOR A SET if a previous step was not registered can be specified in the software configuration.

Table 4: Dealing with omitted scans

Example: Set was not recorded during cleaning, set should be packed		
Variant 1: The previous step is compulsorily enabled	**Variant 2:** The previous step is ignored	**Variant 3:** Subsequent assignment
Set cannot be packed	Set can be packed	Set cannot be packed initially
Set must be recleanned	Based on traceability information, the set has not been cleaned	Set can be assigned to a WD batch (when detected, possibly mistake)
Delay: 1 – 1.5h	No delay	Delay: approx. 10 min

a compulsory repeat of the step, subsequent assignment is generally also possible at the request of authorized personnel or simply on confirmation. Scenarios where an omitted step is ignored are also conceivable and release is based on only the last step.

The implications of these options in the respective RUMED should ideally be defined and documented in risk analysis.

The traceability process can be monitored using electronic batch documentation systems and, by comparing with the database entries, the number of cleaned, packed and sterilized sets can be checked against that of the sets delivered.

6. Outlook

Due to the difficulties related to identification and the vast number of medical devices, traceability is currently beset by numerous limitations and gaps.

THE UDI will improve traceability.

The situation is set to improve in the coming years with the advent of **UNIQUE DEVICE IDENTIFICATION (UDI)**. This universal, machine-readable code for all medical devices is based on an American regulation and will be gradually introduced over the next years. As from 2020, to the extent technically feasible, the UDI must be affixed to all instruments placed on the market in the USA. In the EU the introduction of the UDI will be enforced only at a later date, with an enforcement period of up to 2027, depending on the product.

However, only time will tell how great will be the practical benefits since no definite form of marking has been prescribed (barcode, data matrix, etc.). That could mean that one scanner may not be enough to read all the different codes. But scanner handling and the associated time investment will play an important role.

THE RFID TECHNOLOGY is able to simultaneously recognize several instruments.

In that respect the **RFID (RADIO-FREQUENCY IDENTIFIER DEVICE) TECHNOLOGY** has the great advantage of being able in principle to simultaneously recognize several instruments regardless of their position. That could be used to scan the entire contents of a set in minimal time on the basis of the serial numbers. But there is no guarantee that all items will be read (e.g. defective RFID) or of general acceptance of **SUBSEQUENTLY AFFIXING RFIDS** to all instruments (guarantee issues). Hence, there are still some technical and organizational hurdles to be overcome before its market readiness.

SUBSEQUENTLY AFFIXING RFIDS to all instruments will pose some technical and organizational problems.

A more realistic prospect for the future is precise location of trays via RFID systems. That can help to track inventories and dispense with many scanning operations.

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