Bar codes and Co.

ABSTRACT

Today, we are facing an alarming array of bar codes on the packaging of implantable medical devices. Some packages have up to five different bar codes with quite different information and even different symbologies. In the Consumer Goods sector, global standards are enforced by the retail chains; in Healthcare, we see hospitals and suppliers beginning to take action and working together. We are working towards a uniformly usable system, whereby all relevant data will be made safe and readable by scanner. GS1 DataMatrix bar codes appears to fulfil the requirements most favourably.

By **Dr. Thomas Rothe**, University Hospital of Dresden (Germany)

Background

Vast rows of shelves with screws, bolts, nails, plates, clamps – in hundreds, no, thousands of different sizes, shapes and materials. Add to this bizarre-looking mechanical parts in the strangest forms made out of various metals or plastics, neatly lined up in large cabinets behind glass doors. We are in the operating theatre preparation rooms of the Orthopaedic Clinic at the University Hospital in Dresden. We watch as nurses pull out a gigantic assortment of implant parts and place them on metal screens or roller tables. All parts are clearly marked, and yet now and again we see that where items have long names, only a letter or a digit serves to distinguish a slightly different part in terms of its shape or make-up. It takes someone with considerable expertise to be able to distinguish between these items and understand their medical purpose. And we are not talking about the assembly of inanimate machines; a mistake could have disastrous consequences for a human being's health, as doctors and nurses well know. This is a place where experts work in shifts in several operating rooms at a time; 60 operations per week are the norm, sometimes many more. And in the neighbouring accident and reconstructive surgery, as well as in the neurosurgery just next door, the situation is scarcely different. And this is not just the case at the University Hospital in Dresden.

Automatic identification of implants

After a successful operation, all implants must be clearly documented with coherent descriptions for the medical records and, of course, they must be reordered from the manufacturer, ready for the next operation. The manufacturer delivers the correct supplies for the shelves within the next 24 hours – provided the right one out of thousands of items was ordered from them – worldwide. A vast network is required in order to do this, a network of information and logistics.

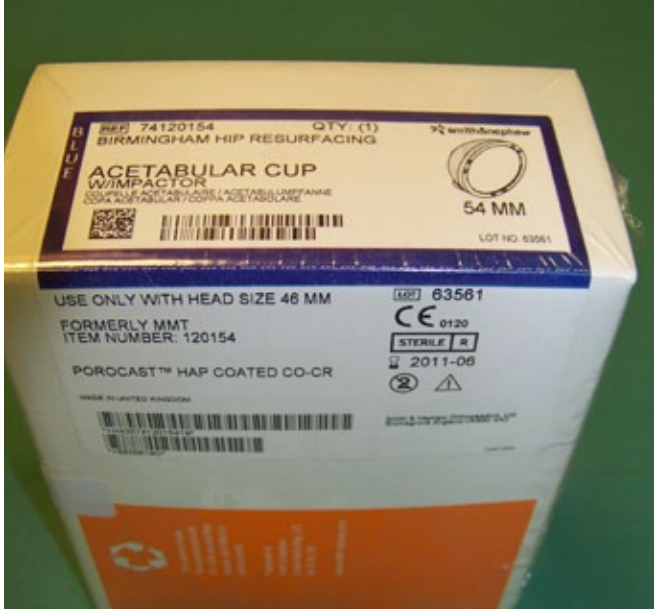
But who is keeping track of all this? Which theatre nurse will be able to distinguish between the items in the future when the cabinets grow even bigger, the shelves even longer? Bar codes on the implant packaging, at least on most of them, remind us of being at the supermarket. So we begin our search, is there a kind of "scanner checkout" here, too?

No, we don't find one; none of the implants are scanned.

Let us take a closer look at the labels on the implants. We quickly realise that all bar codes are not created equal. What at first looked similar, upon closer inspection shows that the manufacturers use very different systems. The system of machine-readable labels is almost fifty years old and there are many different systems around the world. People talk about different "symbologies". We also see that some packages have up to five different bar codes with quite different information and even different symbologies. What should a scanner read here and what shouldn't it read? We even find implants from one and the same manufacturer with different bar code symbologies. How can that be?

Rows of cabinets with implants

That's a very long bar code



Five different bar codes on one package?

Let us first attempt to compare with the retail sector. Why does a system that works there, not work for implants (and, unfortunately, not just for implants)? In global terms, the everyday items in retail are often much easier to replace than very specialised medical products. Retail chains exert high pressure on manufacturers to include the goods in their range, or even not to. For these retailers the logistics are the crucial cost element, as every minute in the warehouse and at the checkout counts. So retailers agreed long ago on a globally uniform bar code system and anyone who wants to be in it must participate. When it comes to implants, as a rule, sales do not go through retail chains: manufacturers normally supply consumers directly, that is, the hospitals. For production and sales, manufacturers have built and optimised their own systems, but each manufacturer for himself. This has contributed to the fact that implants cannot yet be scanned in hospitals using a simple system like the one used in the supermarket.

Not yet, but this is beginning to change!

Hospitals operate under cost constraints with more and more responsibility falling upon medical staff. There is no room for error. Making sure that people receive the correct treatment is always paramount. Should an implant be fitted incorrectly, it would not only be a personal tragedy for the patient but there would also be an additional and therefore extremely high financial burden on the company due to the necessary follow-up treatments, For all these reasons, these errors must be avoided.

Future outlook: GS1 DataMatrix

And in the case of labelling implants with bar codes, there are now proposals to solve the problem. For example, the standards organisation GS1 developed the GS1 DataMatrix. With the GS1 DataMatrix a system is defined which allows all necessary information such as article identification (GTIN), serial numbers, lot numbers, expiry dates and much more to be encoded within very small spaces and to be machine-readable. This is based on a small square graphic pattern in conjunction with a so-called data identification system. This 2D bar code is also regarded as particularly easy to read, due to the "Reed-Solomon error correction", it is even recognisable if it is partially damaged or covered. The problem of scanners for implants in the operating room is therefore not insurmountable.

The GS1 DataMatrix: extremely small, a lot of information, very easily read by camera scanners.

UNICO and GS1 Germany have already discussed bar code identification of implants with 13 university hospitals from Germany and the Netherlands and the 10 largest manufacturers of implants. The manufacturers were both interested and willing to invest in modern methods of machine-readable labels that followed a uniform standard in the future – so long as the hospitals also pressed for a globally consistent system. Because of its special properties, the GS1 DataMatrix appears to fulfil the requirements most favourably.

Also the providers of hardware and software for the bar code scanners need to come on board, because integration with the existing major HIS and ERP healthcare systems is the hospitals' primary objective. Eventually a global recommendation for the machine-readable identification of implants will be published, offering both manufacturers and hospitals a uniformly usable system, whereby all relevant data will be made safe and readable by scanner.

ABOUT THE AUTHOR

Dr. Thomas Rothe studied at and obtained a doctorate from the Technical University of Dresden. From 1992 to 2003, he has worked in a large German pharmaceutical company in various positions, where he had already initiated a number of organisational and IT projects.
In 2003 he became Project Manager at the University Hospital Carl Gustav Carus, Dresden, where he was responsible for the introduction of SAP. Since that time, he has worked on various IT projects as a management staff member. Within the UNICO purchasing group (of which the University Hospital of Dresden is also a member), he does committee work in GS1 and other organisations.