

## OPTIMISED PRODUCT IDENTIFICATION AT BEGO IMPLANT SYSTEMS

From February 2019 the labels on our products will have an improved layout. This means that they will be compliant with the latest international regulatory requirements, provide better information and make the products safer to use. In the following we explain everything you need to know and provide advice about changes that may need to be made (understanding the label, scanning the code).

### Why have the label layouts been changed?

The changes were made to comply with new national and international regulatory requirements. During the regulatory transition phase, both the old and new label layouts comply with regulatory requirements. Products that BEGO Implant Systems have already brought to market can still be used without restriction.

### How have the label layouts changed?

1. The exact expiry date is shown (Year – Month – Day/YYYY-MM-DD).
2. The number of products sold in a pack is indicated (Quantity/QTY).
3. The HIBC healthcare barcode has been changed from a linear barcode to a data matrix code; the content sequence has changed, and the expiry date includes the day (see following pages).
4. There is a product description in five languages on the label.
5. There is now a URL to view and download digital versions of instructions ([ifu.bego.com](http://ifu.bego.com)).
6. The manufacturing date is no longer listed after the batch number, but rather below the manufacturer's symbol.
7. Symbols that are already covered thematically by other, in some cases new, symbols are omitted.
8. Some other symbols have been added to standardise the layout. The omission of symbols on existing labels is not an error and does not mean there is an increased risk for the product, patients, users or any third party.
9. The colour coding has been standardised in line with other media, e.g. catalogue. Some products are designed for specific diameters, but are additionally compatible and applicable with components of other diameters. Therefore, in such cases, the other compatible sizes are also indicated by the color coding.
10. Every label has been given a unique reference number.



## What is the difference between a linear barcode and a data matrix?

	Linear Barcode	Data Matrix Code
Structure	One-dimensional linear	Two-dimensional rectangular
Coding form	Information coded in the form of lines of different widths	Information very compactly coded in a square or rectangular area as a pattern of dots
Coding standard	HIBC	HIBC
Reader	1D and 2D scanners	2D scanners (image scanners)

## What do linear barcodes and data matrix codes look like?

Linear Barcode

Data Matrix Code

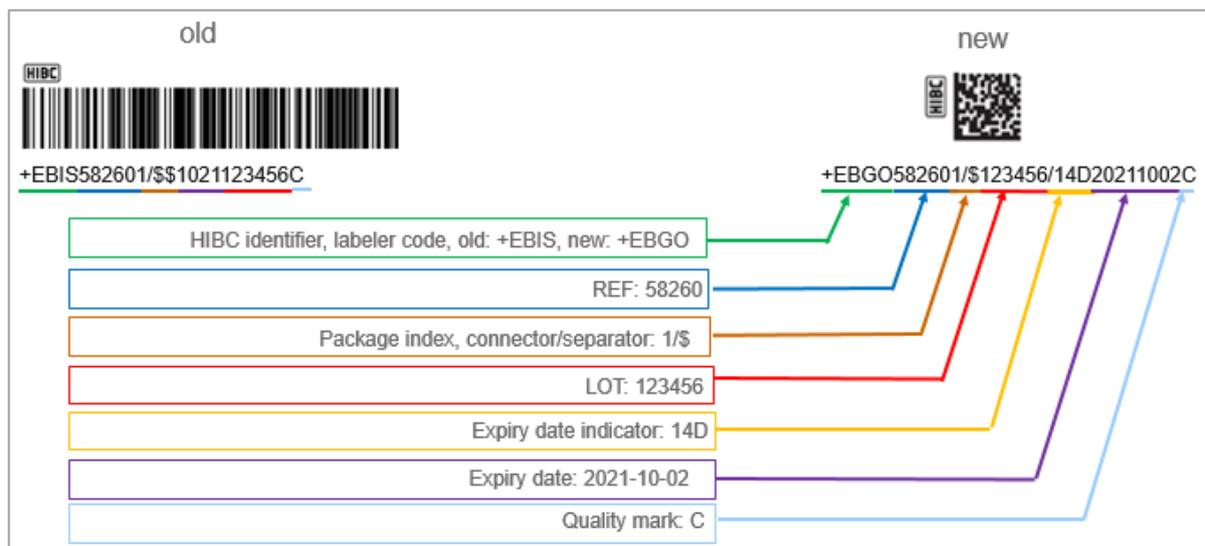


Fig. 3: Data contained in the code

## Why has the linear barcode been replaced by a data matrix code?

Changes needed to be made to comply with requirements in the latest EU regulations. One of requirements of the EU's Medical Device Regulation (MDR, 2017/745) is that medical product identifiers include a UDI (Unique Device Identification). The UDI allows products to be tracked. Because of this and other international regulations, the data matrix code has been designed to comply with the latest UDI requirements. Functionally secure and space-saving, data matrix codes are state of the art, and they are recommended for the healthcare sector, instead of linear bar codes.

## What are the benefits of a data matrix?

- The data matrix code has a very high data density, as a lot of information can be encoded in a very small area.
- The code is highly secure since it can be read even if 25% of it is damaged.
- Data matrix codes support electronic activity recording with a high degree of user security, e.g. for automatic entries in an electronic patient file, which leads to a reduction of potential errors by eliminating manual entries and time expenditure.

### I cannot read the data matrix – what should I do?

- Ensure you have the right reader – a scanner with a camera (image scanner).
- Vary the distance and the angle between the scanner and the data matrix code. Experience shows that the data matrix is often more legible with a scanning angle of less than 90°.
- Changing the lighting may also improve legibility.
- As a backup, in case digital scanning fails, all the data is also provided in text below the code (see Fig. 3)

### My software cannot read the data – what should I do?

Check whether you have commercially available or individually programmed software (e.g. Excel programming).

Commercial software which has been designed to read HIBC data matrix codes should be able to process the data because the code content is addressed by control symbols. If you still encounter any problems reading the code please contact the software manufacturer.

With programmable software, e.g. Excel programming, the data may need to be reassigned to the data fields in the software. If this is the case, we recommend programming using control symbols. When programmed, it will be able to read data from both data matrix and linear barcodes.

### What is the system behind the data matrix, and how can one be sure that everyone is using the same one?

ISO/IEC 16022 standardises the coding. This norm ensures that all data matrix users (coders and decoders) use the same code.

As was the case with linear barcodes, the HIBC standard is used. The HIBC differentiates between the primary and secondary data segments. The primary data segment, the UDI-Device Identifier (UDI-DI), essentially contains the manufacturer ID, product code and package index. The secondary data segment, the UDI-Production Identifier (UDI-PI), contains the batch number and the expiry date. All the content in the code is addressed by control symbols and software can read it using a scan function.

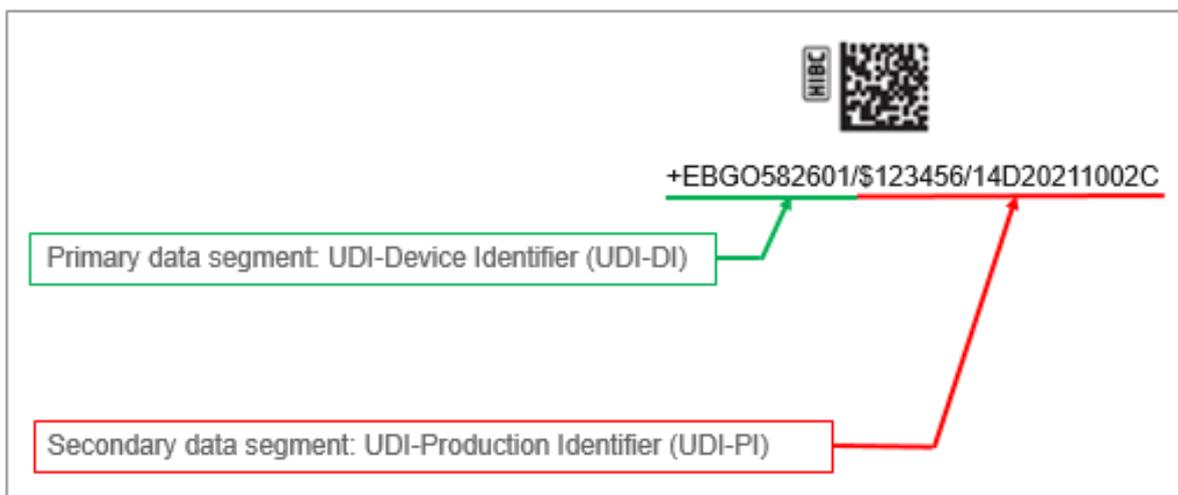


Fig. 4: UDI Primary and secondary data segments

### **Which BEGO Implant Systems products have the data matrix so far?**

All products made after February 20<sup>th</sup> 2019 come with a data matrix. All batches produced prior to that come with a linear barcode. During the transition phase, batches will be supplied with both the linear barcode and the data matrix.

In some cases, depending on the order, a delivery of different products may contain products with both codes. Switching over so that deliveries only go out with data matrix codes will take a little time.

### **Can the data matrix also be used without an electronic patient file?**

Yes. The data matrix offers benefits at every stage in product management and product use, e.g. in storage management.

- Improved security, because the reference number, batch and expiry date no longer need to be written by hand
- Time savings, as the relevant data is no longer recorded manually, but using a scanner
- A control mechanism (four-eyes principle) is dispensed with by the scanning function, and reduced to the two-eyes principle by user and computer