PRODUCT IDENTIFICATION AT BEGO IMPLANT SYSTEMS

The labels on our products comply with the latest international regulatory requirements, provide comprehensive information and make the products safer to use. In the following we explain everything you need to know and offer advice on how to use the label (understanding the label, scanning the code).

Why have the label contents been changed?

The changes were made to comply with regulatory requirements, such as the EU Medical Devices Regulation (Regulation (EU) 2017/745 on Medical Devices (MDR)). During the regulatory transition phase, both the old and new labels comply with regulatory requirements. Products that BEGO Implant Systems have already brought to market can still be used without restriction.

What distinguishes the current labels?

1. There is a product description in twenty five languages on the label.

2. Further symbols introduced in the course of the EU Medical Devices Regulation (Regulation (EU) 2017/745 on Medical Devices (MDR)) can be found on the label.
   The existing labels, on which these further symbols were previously not required, therefore do not represent a defect or an increased risk for the product, the patient, the users or any third party.
3. The label, which is stuck into the implant identification card, allows the patient to find out about the product and the manufacturer.

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Label and sticker

1		Manufacturer
2		Article description/size information
3		Color coding □ Ø3.0 ■ Ø4.1 ■ Ø2.7/2.9/3.1 ■ Ø4.5 ■ Ø3.25 ■ Ø5.5 ■ Ø3.75
	REF	Article number
	LOT	Batch code
	QTY	Quantity
	UDI HIBC	Data Matrix Code Includes manufacturer and article number. If necessary, also batch number and/ or expiry date
4		Product description
5		Use by
	CE	CE marking
		Do not reuse
	STERILE R	Sterilized using irradiation
		Do not resterilize
	NON STERILE	Non-sterile
	ifu.bego.com	Consult instructions for use for electronic instructions for use
		Do not use if package is damaged
		Caution
		Temperature limit
		Keep away from sunlight
	RxOnly	According to US Federal law, this product may only be sold to trained physicians or on their behalf
		Speed of rotation
		Packaging system comprising non-sterile protective packaging and a sterile barrier system
	MD	Medical device
	MR	MR conditional
6		Product model
		Information website for patients

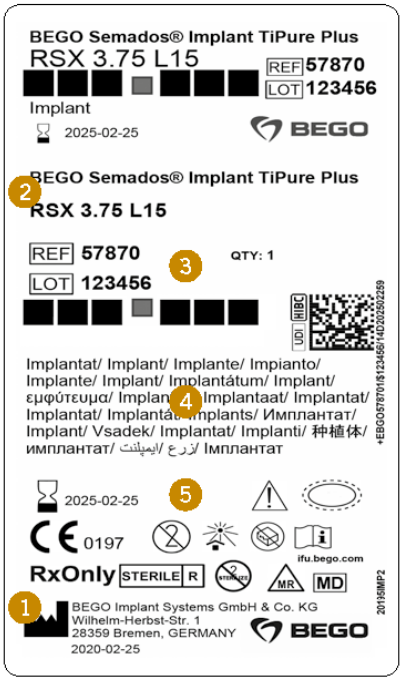

Fig. 2: Explanation of label contents

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What does the DataMatrix code consist of?

	Data Matrix Code
Structure	Two-dimensional rectangular
Coding form	Information very compactly coded in a square or rectangular area as a pattern of dots
Coding standard	HIBC
Reader	2D scanners (image scanners)

What does the DataMatrix code look like?

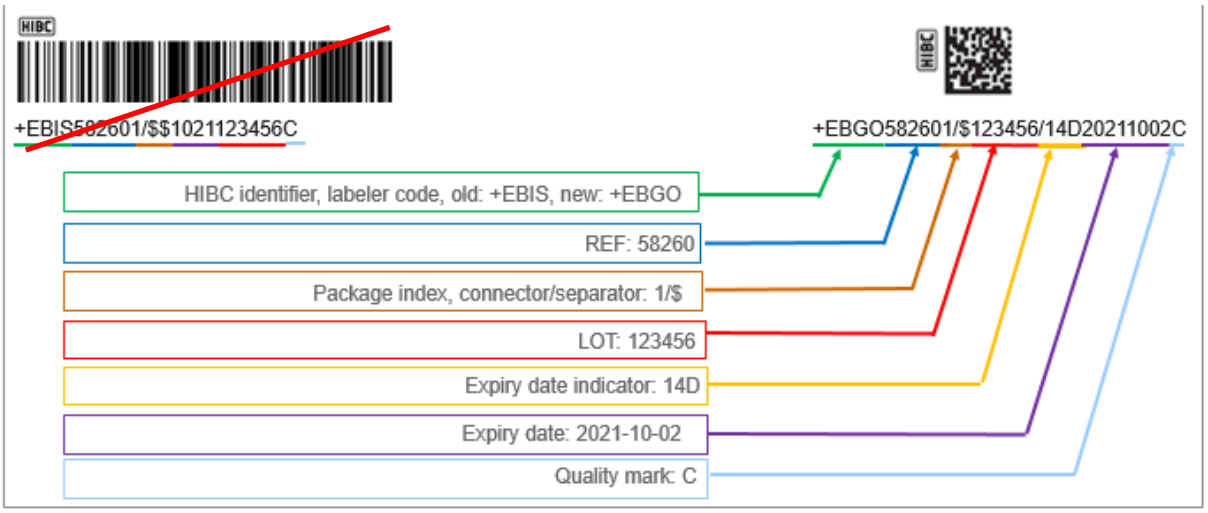

Fig. 3: Data contained in the DataMatrix code

What is the DataMatrix code used for?

One of requirements of the EU's Medical Device Regulation (Regulation (EU) 2017/745 on Medical Devices (MDR)).) 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.

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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.

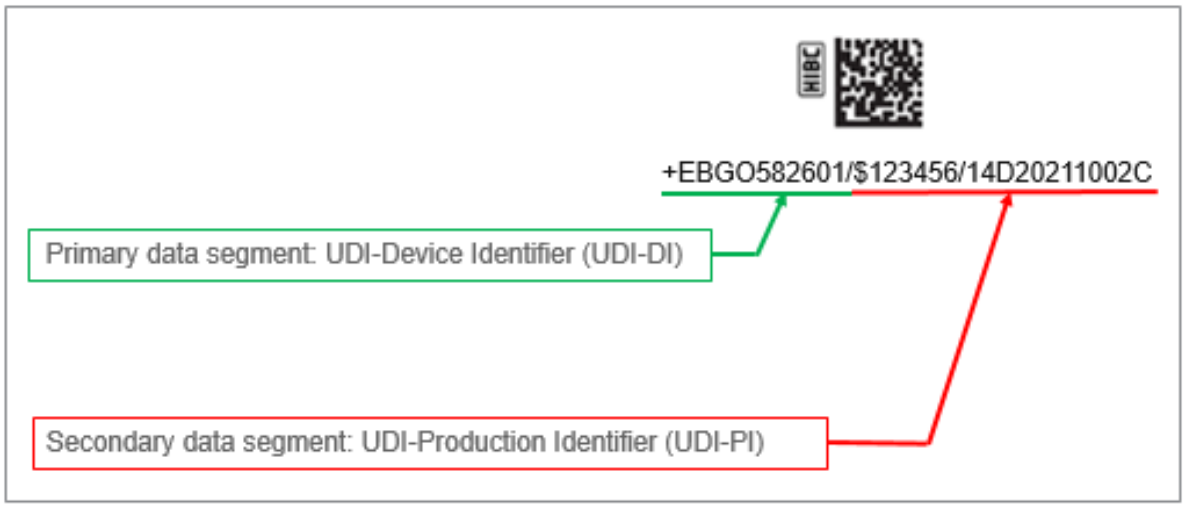

Fig. 4: UDI Primary and secondary data segments

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

All products made after February 20th 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

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