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To our customers:

In 2013, the FDA released its final rule establishing a unique device identification system. This requires the labeling of most medical devices to include a unique device identifier (UDI). A UDI is basically a string of numbers and letters which must also be machine readable (e.g., barcode). These numbers and letters identify the manufacturer and the product. For some devices, they also include production information such as the lot number and expiration date. For more detailed information, please visit the FDA's UDI website:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

#### **How Does This Affect You?**

The FDA's establishment of a unique device identification system will have little or no impact on our customers. Long before the FDA published its final rule establishing a unique device identification system, Dynarex established UPC numbers and barcodes for all products at each packaging level. As a result, Dynarex' devices require little or no change to meet the FDA's requirements.

#### **No Changes to Class I Devices**

All of Dynarex' US FDA class I medical devices already comply with UDI labeling requirements; the UPC is the UDI for these devices.

#### **Additional Barcode on Existing Class II Devices**

You will begin to see an additional barcode on Dynarex' US FDA class II medical devices. This barcode will use either the GS1-128 (UCC/EAN-128) standard or the GS1 Data Matrix standard. If you would like to know more how GS1 standards are used to meet FDA UDI requirements, visit GS1's website:

<http://www.gs1us.org/industries/healthcare/gs1-healthcare-us-initiative/fda-udi>

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The additional barcode will look similar to one of the examples below:

**GS1-128 (UCC/EAN-128) Barcode**



**GS1 Data Matrix**



This additional barcode is derived from a product’s existing UPC and other production information. Specifically, the device information (DI) part, or the number after “(01)”, is simply the UPC number with two leading zeros. The existing UPC is highlighted in red in the examples below:



The numbers after (10) are the lot number, the numbers after (11) are the manufacturing date, and the numbers after (17) is the expiration date. Numbers appearing after (21) is the serial number (not shown in the example above).

The existing UPC will remain on the packaging. This means that customers using our UPC’s now can continue to use them. Customers who wish to use the new barcodes may transition according to their own timetable. We anticipate all US FDA class II devices manufactured on or after September 24<sup>th</sup> will have this additional barcode.

**No UPC on New Class II Devices**

New US FDA class II medical devices marketed by Dynarex which are released after the fourth quarter of this calendar year may no longer have UPC barcodes. These devices will only have a GS1-128 barcode or GS1 Data Matrix.



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We expect the impact of this change to be minimal as there will be no existing UPC's associated with these products. However, you may need to obtain the necessary equipment and/or software to utilize these barcodes depending upon how you use them.

### Questions?

Dynarex' transition plan was developed with our customers' needs in mind. The changes described above should have little or no effect on our customers. It is important to us to meet both the FDA's requirements as well as our customers' requirements. If you have any questions or concerns, please feel free to contact us. We thank you for your business and to look forward to the opportunity to serve you in the future.

Sincerely,

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