Zimmer, Inc.

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To: Zimmer Customer

Subject: Unique Device Identification (UDI) Regulations and GS1^{R} Standards

In 2013, the FDA issued a 'final rule' to establish a system to adequately identify medical devices through distribution and use. This final rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. During this time, the FDA also accredited GS1, a global standards organization, and as an issuing agency to assign Unique Device Identifiers (UDIs) and standards across the industry. The UDI system will also facilitate healthcare product data synchronization and accurate reporting of adverse events by making it easier to identify the device. Synchronizing healthcare product data globally allows the healthcare industry to know when and where products are produced and to manage recall and adverse event reporting to a global standard. This FDA mandated UDI regulations and GS1 standards provide a central framework to improve patient safety and enable efficient business processes worldwide.

Zimmer is proud to support the healthcare industry's adoption of the **Global Location Number** (GLN), **Global Trade Identification Number** (GTIN) and the **Global Data Synchronization Network** (GDSN). These standards are not only imperative to meeting the requirements of the FDA's UDI rule, but they also support our commitment to our customers and improving the quality of life for patients around the world.

- **GLN** (Global Location Number): A GS1 endorsed method for identifying a company in e-commerce transactions.
- **GTIN** (Global Trade Item Number): A GS1 endorsed method for uniquely identifying a part at its various saleable units.
- **GDSN** (Global Data Synchronization Network): A GS1 endorsed global database to maintain key descriptive elements for parts assigned to GTIN numbers.

To comply with the timeline and expectations of the FDA's final rule on UDI, Zimmer has reviewed our product portfolio and adapted our business processes and systems to meet UDI implementation requirements. At this time we are utilizing the GLN number in our e-commerce transactions. In addition, a new GTIN assignment process has been developed and we have

begun labeling and communicating the GTIN information for Class III devices. GHX Health ConneXion[tm] was selected as our certified data pool provider and Class III products have now been synchronized and are available for our trading partners via the GDSN subscription process.

Please review the summary and timeline below. For labeling information, frequently asked questions and other Zimmer UDI and GS1 related information, please visit www.zimmer.com.

Device	Label/GUDID/Date Format	Direct Mark (When Required)
Class III (including class III LS/LS) Implantable Devices licensed under the PHS Act	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II)	September 24, 2015	N/A
LS/LS (class II)	September 24, 2015	September 24, 2016
Class II (other than I/LS/LS)	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24, 2020

LS/LS = life-supporting or life-sustaining

I/LS/LS = Implantable, life-supporting or life-sustaining

Direct Mark requirements apply to products that are intended to be used more than once and intended to be reprocessed before each use. Direct mark compliance dates are in addition to label/GUDID/date format compliance dates.