Boston Scientific GS1 / GTIN Transition
Frequently Asked Questions & Answers
July 2014

Boston Scientific is moving to the GS1/GTIN labeling and bar code standards as part of our continuing efforts to meet customer expectations and improve supply chain efficiency. This document contains answers to some of the more frequently asked questions. If you need additional information or support or would like to speak with someone regarding this activity, please contact either your local sales representative or Boston Scientific Customer Service at GS1CustomerInquiries@bsci.com or (800) 345-2498.

1. **What are the GS1 Standards?**
   GS1 standards are the most widely used supply chain systems in the world, spanning many industries. They drive supply chain efficiency, traceability and accuracy. Examples of GS1 supply chain applications include Global Trade Item numbers (GTIN), Global Location Numbers (GLN) and the Global Data Synchronization Network (GDSN.)

   To learn more about GS1 Healthcare, please visit, www.gs1.org/healthcare.

2. **What is a GTIN?**
   A GTIN (Global Trade Item Number) is a globally unique identification number of an item in the supply chain that identifies a product from manufacturing through distribution and use. The GTIN is typically a 14-digit numeric code which includes a company prefix followed by product identification numbers. The GTIN, as well as other key product attributes, are automatically identified when a bar code is scanned.

3. **Why is BSC moving to the GS1/GTIN now?**
   Boston Scientific is moving to the GS1/GTIN Healthcare Standard as part of our continuing efforts to meet customer expectations and improve supply chain efficiency. We recognize the value of standardization for the medical device industry and are working closely with healthcare providers to ensure that we are delivering what they need related to GS1 standards.

4. **How does this change impact healthcare providers?**
   It primarily impacts healthcare providers that, a) currently scan or plan to scan product labeling bar codes to manage inventory and product movement within their supply chain, or b) rely solely on the use of the previous "short-code / catalog number" to re-order products.

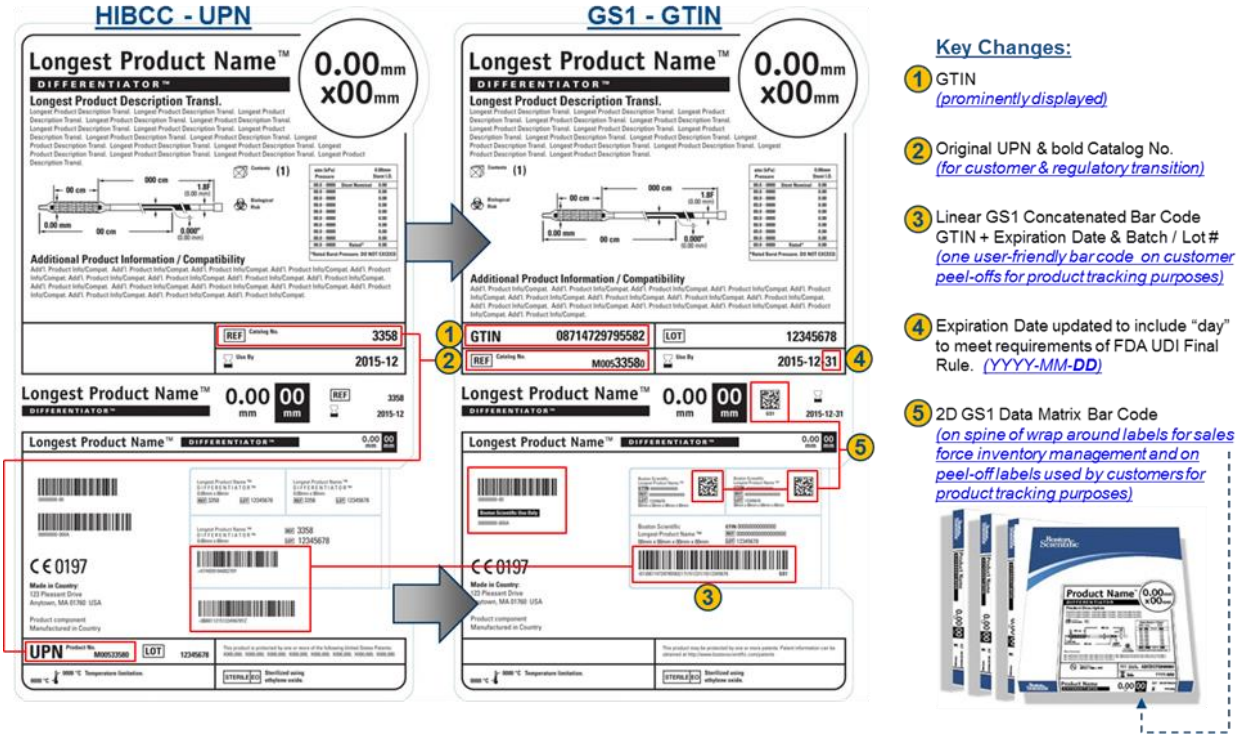
   a) For healthcare providers that scan product label bar codes, their Materials Management Information System (MMIS) will need to be updated to either add the new GTIN part numbers in addition to the existing UPN part numbers or replace the UPN part numbers with the new GTIN part numbers (if their MMIS cannot accommodate dual part numbers.)

   b) For those that utilize the "short-code / catalog number" to re-order products, it is highly recommended that you begin transitioning away from this practice and start using the GTIN as the primary method for re-ordering product.

5. **Is the GTIN replacing the HIBC numbers and bar codes on all current products?**
   Yes. The majority of Boston Scientific products are currently labeled using the HIBC Universal Product Number (UPN) and bar code standard format. In transitioning over to the GS1 standards, the Global Trade Item Number (GTIN) will now be prominently displayed on the label and represented in both human readable and bar code format. The UPN will remain on the label as the Reference/Catalog.

   Note that our Cardiac Rhythm Management (CRM) products already utilize GTINs and GS1 bar codes. As such, these changes will not impact CRM products.

6. **What does the new label look like?**
   The new label features the addition of the Global Trade Item Number (GTIN) in both human readable and bar code format, and the removal of the UPN bar code. Note that the previous number (UPN) is still present and may now be found in the Reference/Catalog field of the label and label peel-offs where it has replaced the previous "short-code". The previous "short-code / catalog number" is now bolded in this field.



   Also note that all the information about the device, batch number, and expiration date is contained in one concatenated bar code (Item 3 above) and is collected with a single scan. If the healthcare provider does not require all of the information in the bar code, the software system or bar code scanner needs to be configured to accept only the needed portion of the information.

7. **Where are GTINs used?**
   GTINs are used on product packaging labels, invoices and packing slips alongside the original UPN number.

8. **What is the timeline for products transitioning to GTINs?**
   GTIN labeling began in February 2014. Each month additional products will transition to the new label. We anticipate that all BSC products will include the new GTIN identifier by the end of 2014.

   Over the next year, you will see a mixed inventory of products as our supply chain pipeline is flushed and all HIBC – labeled product is consumed. There is no difference between products that are HIBC labeled or GTIN labeled. As such, HIBC – labeled products need not be returned.

9. **Where can I get a list of GTIN bar codes?**
   A complete listing of our products transitioning to the GTIN part numbers along with their original HIBC UPN part number may be found on our website, www.bostonscientific.com/gs1. This list is known as the UPN to GTIN crosswalk. It also includes reference to the previous "short-code / catalog number" for transition.

10. **Are other medical device manufacturers using these GS1 Standards?**
    Yes. Most major medical device manufacturers across the healthcare industry have adopted GS1 standards and many will be transitioning.

11. **How do the GS1 standards relate to the new Unique Device Identification (UDI) rule?**
    The FDA recently published their final rule on a Unique Device Identification (UDI) System for medical devices. They will require that all medical device packaging labels contain Unique Device Identifiers from FDA Accredited Issuers. Both the GS1 GTIN and HIBC UPN unique identifiers and bar codes meet the requirements of the FDA UDI final rule.

12. **Do we have to use GTINs to order BSC products?**
    No. Orders can still be placed using the original UPN or the "short-code / catalog number". However, it is highly recommended that you begin transitioning away from using the "short-code / catalog number" for re-ordering product.

13. **Do I need to return inventory that doesn't have the new GTIN labeling?**
    No. You may receive inventory that contains the HIBC only product labels during the transition period to the new labeling. It is not necessary to return products that do not contain GTIN bar code labels.

14. **Who can I contact for more information or help with GTIN bar code scanning?**
    For more information, please contact your local Boston Scientific sales representative, or our Customer Service team, GS1CustomerInquiries@bsci.com or (800) 345-2498. You may also visit our website, www.bostonscientific.com/gs1 for more information on GS1 and GTIN bar codes.