

**Boston Scientific GS1/GTIN Transition
Frequently Asked Questions & Answers
February 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 sales representative, GS1CustomerInquiries@bsci.com or Boston Scientific Customer Service at (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 hospitals?

It primarily impacts hospitals that currently scan or plan to scan product label bar codes. They will need to update their MMIS (materials management information systems) with the GTIN part numbers.

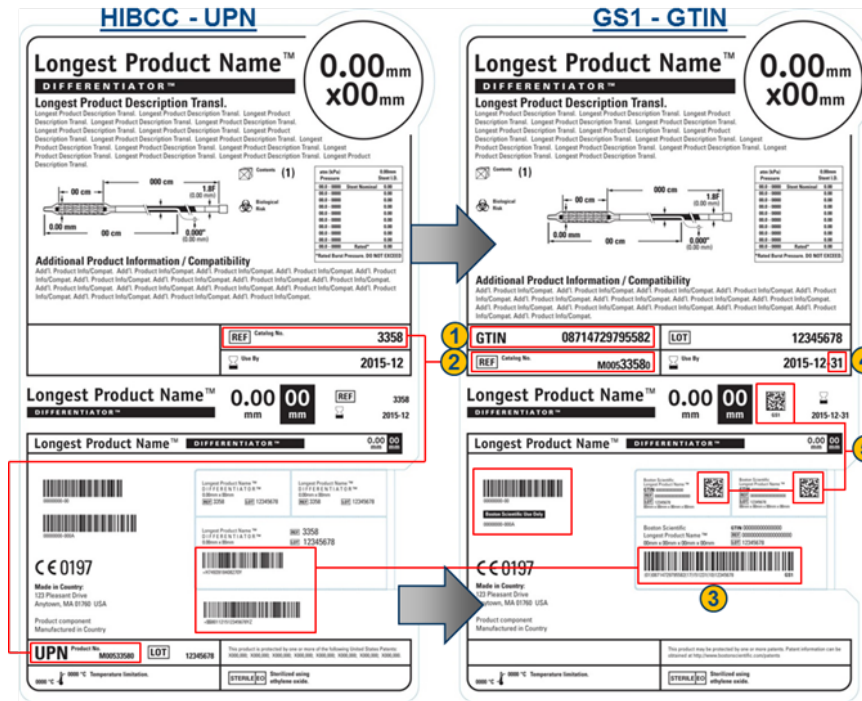
5. Is the GTIN replacing the HIBC numbers and bar codes on all current products?

The majority of Boston Scientific products are currently labeled with a Universal Product Number (UPN) and Health Industry Bar Codes (HIBC). The HIBC will be removed, and the UPN will remain on the label as a secondary device identifier to the GTIN & GS1 bar code.

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), and the removal of the HIBC bar code. Note that the previous part number is still present and may be found in the Reference/Catalog field of the label.



- Key Changes:**
- 1 GTIN (prominently displayed)
 - 2 Original UPN & bold Catalog No. (for customer & regulatory transition)
 - 3 Linear GS1 Concatenated Bar Code GTIN + Expiration Date & Batch / Lot# (one user-friendly bar code on customer peel-offs for product tracking purposes)
 - 4 Expiration Date updated to include "day" to meet requirements of FDA UDI Final Rule. (YYYY-MM-DD)
 - 5 2D GS1 Data Matrix Bar Code (on spine of wrap around labels for sales force inventory management and on peel-off labels used by customers for product tracking purposes)



7. **Where are GTINs used?**

GTINs are used on product packaging labels, invoices and packing slips.

8. **What is the timeline for products transitioning to GTINs?**

GTIN labeling begins 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 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.

10. **Are other companies using these GS1 Standards?**

Yes. Numerous companies across the healthcare industry have adopted GS1 standards.

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. You may continue to use UPN or Catalog Numbers to order products.

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.