



**Arthrex**<sup>®</sup>  
GLOBAL ENTERPRISE  
LABELING SYSTEM



# What is the Global Enterprise Labeling System (GELS)?

GELS is an integrated platform that will provide consistency with Arthrex's label layout, enhance overall business and customer usability, and help lower patient risk regarding medical device selection and data management.

## Benefits for Arthrex and its Partners

- Improve operating leverage between Engineering, Regulatory, Quality and Operations
- Reduce errors and enhance label functionality
- Ensure consistency and standardization of label content across all products
- Compliance with ISO and GS1 industry standards
- Improved overall health care supply chain efficiency
- Increased visibility and traceability throughout the global distribution process
- Satisfy global regulatory requirements while concurrently increasing global production and distribution volume

## Global Health Care GS1 Standards and Arthrex

Arthrex is dedicated in the health care initiative to implement GS1 standards and establish unique identifiers for health care locations, products and services.



# Specific GS1 Identification Keys

## GS1 Identification Keys include:

- **GTIN** – Global Trade Item Number for product identification
- **GLN** – Global Location Number for identification of corporate entities, functional departments, and physical locations (Arthrex and subsidiary locations)



## Arthrex Bar Coding Changes

### Arthrex will...

- Start retiring the use of the HIBC bar code format and adopt the latest GS1 global health care labeling industry standard
- Transition to using both 2D DataMatrix and GS1-128 linear bar codes with this initiative; both bar codes contain the same device identification data

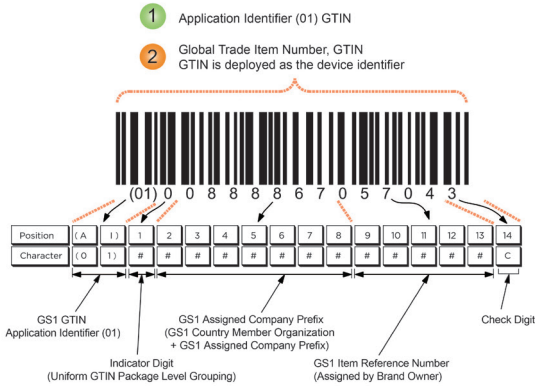
## GS1 Adoption Benefits

### Adoption of GS1 in the health care industry is intended to:

- Enhance traceability and facilitate authentication systems
- Fight counterfeiting
- Ensure effective and efficient product recalls
- Improve supply chain efficiency
- Enable AIDC (bar code) systems all the way from manufacturing to the point of care
- Reduce medical errors
- Establish regulatory compliance
- Efficient compliance with product registration
- Expedite product notifications



# Current Linear GS1 Format



- 3 Application Identifier (30), variable package quantity
- 4 Actual packaged quantity
- 5 Application Identifier (17), expiration date (YYMMDD)  
 Use By Date, UBD (Expiration date)  
 UBD is deployed as a production identifier. The date format will always be in the form of YYMMDD, (2 digit year, 2 digit month & 2 digit day)
- 6
- 7 Application Identifier (10) lot or batch number
- 8 Actual Lot or Batch number
- 9 Application Identifier (21) serial number
- 10 Actual serial number

GS1-128 Linear with GTIN, Quantity, Use by Date and Lot Control



GS1-128 Linear with GTIN, Use by Date and Lot Control



GS1-128 Linear with Serial Control



## Future 2D DataMatrix GS1 format

GS1 2D DataMatrix with Lot Control

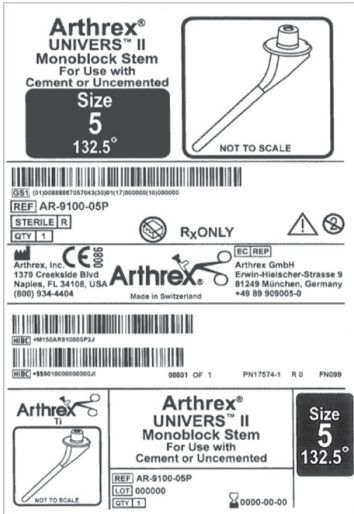


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# Global Labeling Impact

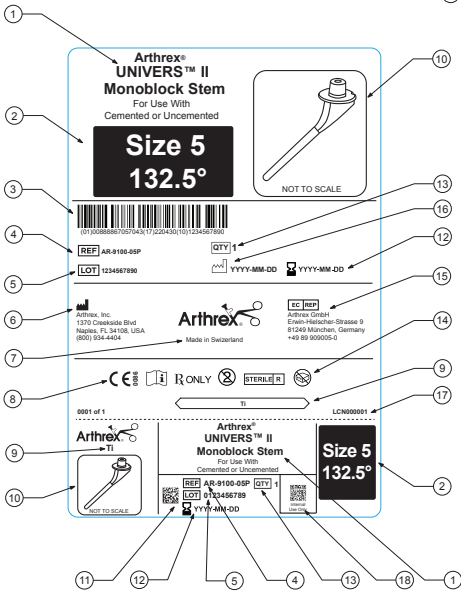
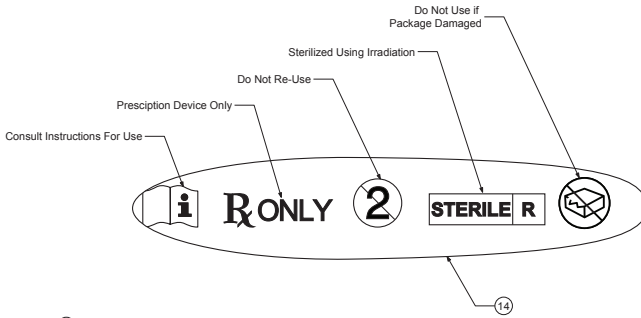
## Current Layouts



## Proposed Layouts



# Carton Label



Arthrex Label Interpretation Guide			
1	Device Description	10	Device Image
2	Device Size	11	GS1 2D DataMatrix
3	GS1-128 Linear Bar Code	12	Expiry Date
4	Catalog or Item Number	13	Packaged Quantity
5	Lot or Batch Number	14	Graphical Symbols
6	Manufacturer & Address	15	EU Representative Address
7	"Made In" Country of Origin	16	Manufacturing Date
8	European Conformity	17	Manufacturers Label ID No.
9	Implant Material	18	Arthrex use only



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Questions?

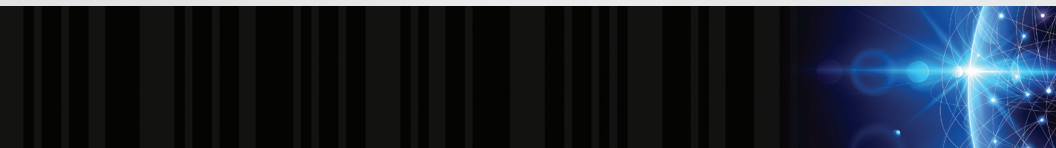
For questions or technical assistance, contact the Global Labeling Team at [Arthrex\\_GlobalLabeling@arthrex.com](mailto:Arthrex_GlobalLabeling@arthrex.com).

Use the bar code below to test your scanning equipment and ability to transact material.



(01)80888867999998(17)220731(10)1234567890

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Helping Surgeons Treat Their Patients Better





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