

## FREQUENTLY ASKED QUESTIONS

### **What is UDI (Unique Device Identification) ?**

The U.S. Food and Drug Administration (FDA) is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. The UDI will be an industry standard in the very near future. The UDI is part of a global initiative for product identification.

The Unique Device Identification System, when fully implemented, will offer many benefits to industry, FDA, legislative agencies, consumers, health care providers and systems by (source: FDA.org):

- “Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reducing medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhancing analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Providing a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leading to the development of a medical device identification system that is recognized around the world.”

### **Why is LifeNet Health using UDI?**

LifeNet Health manufactures tissue-based medical devices and products classified as “361 HCT/PS” in the U.S. We are required to apply the UDI barcode to our products classified as medical devices. In an effort to provide the best possible customer service, we are also applying the UDI barcodes to all of our products. We feel the unique device identifier will improve product tracking in the industry, and fill information gaps that were lacking with older systems.

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### **When will UDI go into effect? When will LifeNet Health utilize the UDI on its labels?**

The FDA has mandated that all implantable class II medical devices be labeled with the new UDI code beginning September, 24, 2015. LifeNet Health has chosen to label all the allografts we produce with this new identification system. Any medical device products in LifeNet inventory with the former label configuration may continue to be distributed for up to 3 years without being relabeled. Note: you may receive grafts in your facility with both label configurations for a period of time, until all of the older system materials are depleted. LifeNet Health will begin using the new label scheme in August 2015.

### **What will change on the new labels?**

The UDI uses the GS1-128 format. This is an application standard of the GS1 implementation using the Code 128 bar code specification. GS1 is a neutral not-for-profit international organization that develops and maintains standards for supply and demand chains across multiple sectors. The UDI code is separated into three sections: 01 for GTIN, 17 for Expiration date and 21 for product serial number:

- **GTIN section (01)** – made up of 14 digits. The first digit is a packaging level code and is always 0 for LifeNet Health. The next 7 digits represent LifeNet Health’s unique company prefix (0889858) and will always remain the same. The next 5 digits correspond to a product code. One of the main building blocks of the GS1 System, a Global Trade Item Number (or GTIN) is a number that uniquely identifies trade items as they move through the global supply chain to the ultimate end-user.
- **Expiration Date section (17)** – in YYMMDD format
- **Product Serial Number (21)** – corresponds to the current product ID code – format is 7777777-4444

There will be a new look to LifeNet Health labels. They will contain an additional bar code, and they will continue to have all the previous bar codes. With minor exceptions, labels will contain the following information (reading downward):


- **Code** – with corresponding bar code to right
  - This is the Product Code as listed in the product catalog or other materials
- **Description**
  - As listed in the product catalog or other materials

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- **Size**
  - This may take up to two lines depending on the product
- **ID** - with corresponding bar code to right
  - unique identifier in the form of xxxxxxx-xxxx
- **Exp** - with corresponding bar code to right
  - expiration date in the form of YYYY-MM-DD – this is the biggest change from the older labels
- Storage conditions statement with reference to Instructions for Use
- **UDI** - with corresponding bar code to right
  - unique identifier number (both in machine and human readable forms) using GS1 standards

Please see the example LifeNet Health ReadigRAFT Cancellous label below to see what the new labels will look like.

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**ReadiGRAFT**  LifeNet Health  
Saving Lives. Restoring Health. Giving Hope.


Allowash XG Sterilized Adgraft Bio-Implants

**Code: CAN15** 

**CANCELLOUS (1-8 MM)**


**Size: 15 CC**


**ID: 777777-0009** 

**Exp: 2020-06-23** 

FREEZE DRIED - STORE AT AMBIENT TEMP


Caution: See package insert for precautionary and preparation information.


**UDI:**   
(01008695800587611)200623(21)777777-0009

For LNH Internal Use Only  PM:0642


CAN15


**CANCELLOUS (1-8 MM)**  
**15 CC**


LifeNet Health **ID: 777777-0009** 


LifeNet Health **Code: CAN15** 

LifeNet Health **CANCELLOUS (1-8 MM)**


LifeNet Health **Exp: 2020-06-23** 


LifeNet Health **UDI:**   
(01008695800587611)200623(21)777777-0009


LifeNet Health **ID: 777777-0009** 


LifeNet Health **Code: CAN15** 

LifeNet Health **CANCELLOUS (1-8 MM)**


LifeNet Health **Exp: 2020-06-23** 


LifeNet Health **UDI:**   
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LifeNet Health **ID: 777777-0009** 

LifeNet Health **Code: CAN15** 

LifeNet Health **CANCELLOUS (1-8 MM)**

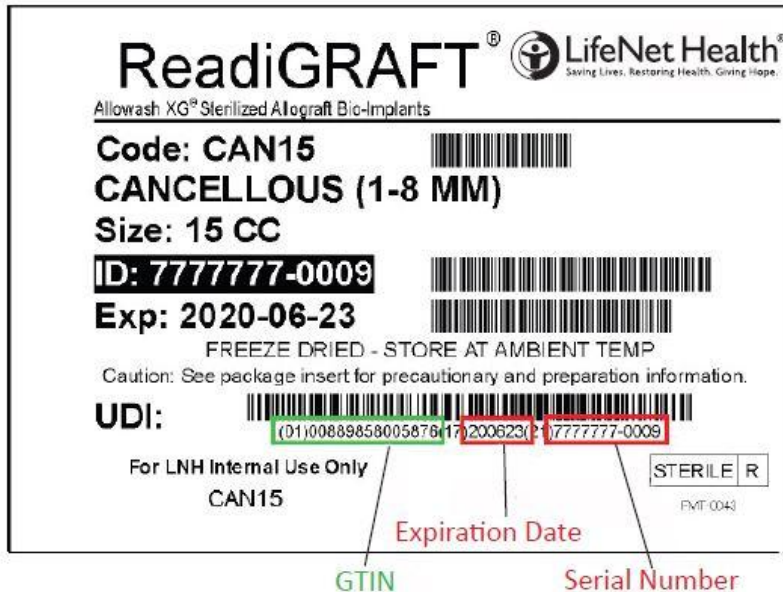
LifeNet Health **Exp: 2020-06-23** 

LifeNet Health **UDI:**   
(01008695800587611)200623(21)777777-0009

### UDI Bar Code Label:

- Bar Code Format: GS1-128
- Identifies Global Trade Item Number (GTIN), expiration date and product serial number

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### The UDI seems small --- will it scan correctly?

The UDI bar code appears small due to the area allotted. However, it has been extensively tested and will scan as well as the barcodes currently used.

### What do I need to do differently to receive LifeNet Health allografts?

You do not need to change how you receive LifeNet Health allografts. All of the bar codes you previously used will still be present. You can continue receiving LifeNet Health products just as you have in the past, or you can start scanning the new, additional UDI bar code. Where you will find improvement will be when you start scanning the UDI code. The UDI is a combination of a **GTIN number + expiration date + unique unit identifier number**. Therefore, much more information will be available with one scan. In addition, the product description part of the UDI will provide information on type of allograft, preservation method and much more.

## FREQUENTLY ASKED QUESTIONS

### **How can I get additional information related to UDI?**

For information from the FDA, go to:

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

To speak with someone from LifeNet Health, contact:

Client Services:

1-888-847-7831 (U.S. & Canada)

1-757-464-4761 ext.2000 (OUS)