Frequently Asked Questions about Expiration Dating

Question
What is expiration management?

Answer
Expiration management starts at the design stage of our products. Zimmer evaluates many factors that help determine the appropriate shelf life of the product.

Question
What exactly expires?

Answer
Expiration dating refers to the establishment of a date by which the product should be removed from inventory to ensure the integrity of the product. The date is established from many inputs including but not limited to product material, packaging and sterilization method. In the case of Metal, the product outlives the packaging; while with Polyethylene, the packaging outlives the product.

Question
How do I know if a product has expired?

Answer
If an implant package has an expiration date, Zimmer utilizes internationally recognized ISO symbology to denote the month and year of expiration. It is expressed as a four digit year, followed by a two digit month code. The month and year code appear to the right of an hourglass symbol.

Example: YYYY-MM

An expiration date of April 2016 would indicate the product expires that last day of the month and would be reflected as 2016-04.

If the product label does not contain the hourglass symbol and YYYY-MM code, the product is not expiration dated and can be used if package is not opened or damaged.

Question
Can expired product be implanted?

Answer
No. If the product has exceeded the expiration date on the product label, then the product must not be used.

Question
Why do I have similar items with different expiration dates?

Answer
Zimmer has initiated a process to evaluate and manage expiration dates. This is why some older products do not indicate an expiration date.

Question
Who can I call if I need help?

Answer
1 Contact your sales associate
2 Contact your Field Office
3 Call Customer Service
Subject: Expiration Dating for Sterile Metal Products

Within the United States, packaging sterility is not considered to be “time related” but rather to be “event related”. Packaged metals are considered to remain sterile unless the sterile barrier has been damaged or otherwise compromised. The packaging materials and methods used by Zimmer to sterile-package metal implants have remained tightly controlled and constant for many years. Thus, our sterile-packaged product is designed to retain its integrity, provided the sterile barrier has not been damaged or otherwise compromised.

Zimmer has been expiration dating products manufactured in, or destined for Europe to comply with the requirements of the Medical Device Directive since June 14, 1998. This European Directive required expiration dating for all sterile packaged products.

Zimmer now expiration dates all sterile metal products and not just those destined for Europe. The purpose of adding this date to sterile metals was to provide consistent packaging for Zimmer products in all markets, and to assist with inventory management.

Zimmer utilizes the event related approach but has changed to include an expiration date on all sterile metal produced. Sterile metals received their first expiration dates in April of 2001 with a 5 year shelf life. In 2003, Zimmer was able to complete real time aging studies that provided objective evidence allowing the packaging and product to be extended to the appropriate shelf life depending on the individual product. Since the 1st quarter of 2003, Zimmer has been expiration dating Metals with a 10 year shelf life.

With the different scenarios presented above, there are two conditions of packaging configurations for sterile metals that will be in the distribution supply chain.

Condition I: Metals that have been sterile packaged without an expiration date on the label.

Condition II: Metals that have been sterile packaged with expiration date on the label.

Any product that is not labeled (Condition I) with an expiration date may be used at any time so long as the packaging is intact. However, Zimmer expects that all product labeled with an expiration date (Condition II) will not be used past the stated expiration date. Please contact your sales representative for the current return policy.
