AnsellCARES™

InTouch™
CLINICAL UPDATE

MEDICAL DEVICE PACKAGING

A continuing education self-study for healthcare workers with an interest in patient and healthcare worker safety and infection prevention.

ISSUE 7

INSIDE THIS ISSUE

LEARNING OBJECTIVES

After completing this continuing education activity, you should be able to:

1. Describe key features of medical device packaging;
2. Discuss how the various stages of a medical device lifecycle dictate various packaging requirements;
3. Understand how state-of-the-art glove packaging is enhancing user experience, improving safety and benefitting the environment; and
4. Appreciate the views of a panel of clinical experts in regard to medical device packaging.

Cathryn Murphy PhD, CIC
Executive Director – Infection Control Plus
Honorary Adjunct Associate Professor,
Faculty of Health Sciences and Medicine
Bond University
Gold Coast, Queensland, Australia.

Associate Professor Murphy provides consulting services to Ansell worldwide and is the editor of this edition of AnsellCares™ InTouch™.

The opinions expressed in this edition are the editor's only and may not represent the official position of Ansell or Bond University.

Disclaimer: Infection Control Plus has performed paid consulting work for Ansell and/or its affiliates. CathrynMurphy is Chief Executive Officer and Creative Director at Infection Control Plus

GUEST FACULTY

In this edition, we welcome contributions from clinical and industrial healthcare experts.

Sue Barnes RN, BSN, CIC, FAPIC
With more than 30 years' infection prevention and control experience in healthcare environments, Sue now provides independent consulting services to professional organizations, manufacturers and others to support patient safety through prevention and control of healthcare associated infection. From 2007-2016 Sue was the National Program Leader, Infection Prevention and Control for Kaiser Permanente. She has served in senior elected positions as a member of the Association for Professionals in Infection Control and Epidemiology (APIC) National Board of Directors and as 2016 President of her local APIC chapter. Sue has a deep appreciation for OR-related aspects of infection prevention.

May Karam, BSN, RN, IBODE, CCRN
Currently the President of the European Operating Room Nurses Association, May Karam has extensive nursing leadership experience in a variety of specialty areas including central sterile supply (CSS), haemodialysis, intensive care, heart surgery unit, and the operating room. She also completed study on risk management, health quality and security in healthcare facilities (master degree).

Dr Monica Sagardoy PhD., Senior Director of Global Marketing, Surgical Gloves, Ansell
Monica has been involved in medical device manufacturing for almost two decades. In her current role Dr Sagardoy oversees packaging options for Ansell's surgical glove range and we welcome her insights into the manufacturers' perspective on medical device packaging.

Bit New Yee, Bachelor Degree Polymer Technology, R&D, Ansell
Yee is currently the Quality Management Representative for Ansell Melaka and Sri Lanka R&D innovation center (medical glove). Her current focus at Ansell is in product development, which includes supporting the R&D team in global regulatory submission and design dossiers. Her innovative work on the in-vitro antibacterial efficacy test methodology earned her team the Ansell 2016 Gold Award for Innovation.

Seow Lan Hoon, MSc., B.Tech., Regulatory Affairs Director, Europe-Middle East- Africa, Asia-Pacific Emerging Markets, Ansell
Lan Hoon, MSc. National University of Singapore, Bachelor of Technology University of Science Malaysia and Six Sigma Black Belt Motorola University, has 27 years working experience in the protective barrier medical device and food and beverage industry; holding various positions in Regulatory, QA and Technical. She is a committee member of AMMI (Association of Medical Device Manufacturers Malaysia) and MMDA (Malaysia Medical Device Association) and member of the AHWP (Asia Harmonization Working Party) a group of medical device experts to harmonize medical device regulations in Asia.

MEDICAL DEVICE PACKAGING GENERAL OVERVIEW

Have you ever stopped to think about the packaging surrounding commercially provided medical devices used in your organization? Like most of us you probably answered "no" and so in this edition of AnsellCares InTouch we take an in depth look at medical device packaging. Our discussion begins by addressing medical device packaging in general before narrowing down to focus on single-use glove packaging and in particular, surgical gloves.

The general definition of a medical device includes articles manufactured specifically for diagnostics, monitoring, treatment, or modification of the human body and are not solely pharmaceutical goods.[1] Packaging of medical devices varies depending on factors such as the type and size of the device and its intended use, as well as its transportation, handling, storage conditions and expiration period. In 2009 when considering medical packaging standards, the American Society for Testing and Materials (ASTM), an international standards organization responsible for developing and publishing a wide variety of technical standards, recognized that "Packaging can perform a function as simple as separating products into individual or multiple units and as complex as providing specialized environments for highly perishable items."[2]

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One of the complexities of device packaging is that the medical device industry market is now global. Device manufacturers serve customers throughout the world and often have a global infrastructure underpinning provision of their product. Operations are carried out in multiple regions, countries and sites and there is often variation in operating procedures and capacity. Integration and standardization of systems including packaging and labelling across these platforms can be beneficial. A medical device you use today may have been manufactured in a region of the world far from where you are using it. In these cases, manufacturers must meet the requirements of multiple jurisdictions and parties across the supply chain including regulatory bodies, distributors, transportation services, stores, end users and waste disposal. At a practical level, medical device packaging labels are increasingly required to be both multi-language and language-specific.[3] Pictograms that have universal meaning and understanding are sometimes included.

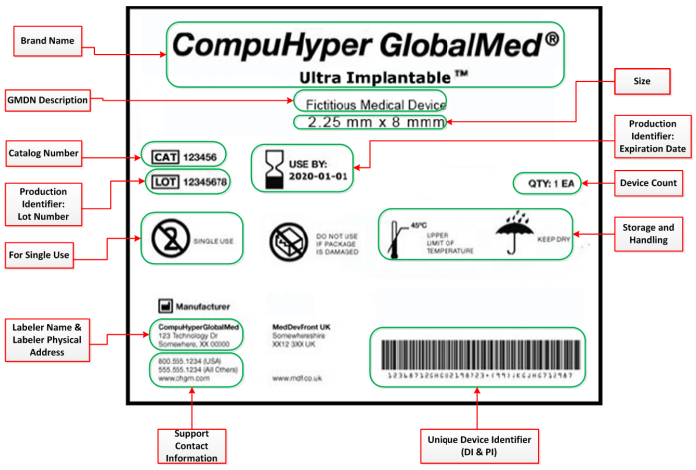
Medical device packaging is also influenced by labelling requirements some of which may be universal and others dependent on national and local requirements.

An important and recent development in medical device packaging is integrated label lifecycle management (LLM) solutions, a system that can capture, store, and disseminate data safely,[4] quickly and accurately. LLM has been driven primarily by commercial and regulatory requirements. Improvements in medical device packaging and labelling may reduce the number of voluntary recalls caused by labelling and packaging defects which has significant benefits for both manufacturers and medical device users.

MEDICAL DEVICE PACKAGING GENERAL OVERVIEW

A more specific medical device labelling requirement is the use of a Unique Device Identifier (UDI) which includes coded information facilitating easy and accurate identification of any specific product or product batch throughout their distribution and use. The UDI acts as a key to unlock device-specific details in a global UDI database (GUDID), which is in the public domain and easily accessible to patients, caregivers, healthcare providers, hospitals, and industry. On July 20, 2016, the US Food and Drug Administration (FDA) released a draft guidance pertaining to the use of UDI. When the guidance is final, the UDI system will go into effect in stages, over a period of seven years, to ensure a smooth transition and to spread the costs and burdens of implementation over time.

As of May 1, 2017, the GUDID had received 1.4 million submissions.[5] UDI use enables valuable information to be used in the standard form or barcode which facilitates more efficient and secure medical device commercialization, distribution and use. Secondary benefits from the UDI include better understanding of information related to medical device adverse event reports, easier traceability and fewer errors.[3,6]



GUDID Attributes Mapped to a Fictitious Medical Device Label

The intended use of a medical device, including requirements for sterility also impact medical device packaging. Further, increasing global awareness of the need to protect the environment and escalating waste disposal costs have and continue to influence the design, composition and manufacture of medical device packaging.[1,7] This is most evident in the increasing use of environmentally friendly products, including recyclable-packaging. Another emerging trend is for more compact and smaller sized packaging for medical devices. This has come about through the need to reduce required storage space and overall weight of packaged medical devices. Designs which are user-friendly, intuitive and promote lean and standardized workflows are particularly appealing as they reduce healthcare worker variability and potentially support patient safety and better outcomes.

Other common characteristics of medical device packaging may include the need for the packaging to be:

- Traceable
- Non-toxic, non-leaching and odorless
- Protective and free of cracks, creases, holes, tears, local degradation and other threats to the integrity of contents
- Able to withstand specific sterilization processes and maintain a sterile state until use, and
- Capable of being presented aseptically [8]

PACKAGING OF STERILE MEDICAL DEVICES

At its core, the medical device package must ensure that the packaged device arrives efficiently, safely, and effectively to the end user. For sterile devices, medical device packaging must allow its contents to be sterilized and then must maintain that sterility until the time of use. Accordingly, there are strict requirements for packaging systems and packaging materials used to preserve the sterility of medical devices, protect their functionality and retain their biological safety. This process typically begins when medical devices are packaged, boxed, cased then sent to the sterilizer – which could be in the same facility or a facility across the city/country. The process continues throughout the life of the product including its handling, distribution and eventual use.

ISO 11607 *Packaging for terminally sterilized medical devices*[9] is the ISO Standard specifying requirements for sterile medical device packaging. It consists of two parts — *Part 1: Requirements for materials, sterile barrier systems and packaging systems* and *Part 2: Validation requirements for forming, sealing and assembly processes.*

ISO 11607 refers to three components of packaging which ensure its sterility. The first, is the *packaging system* which comprises the other two which are the *protective packaging* and the *sterile barrier system*. The *packaging system* must minimize potential safety hazards by: 1) maintaining sterility of the packaged device; 2) providing protection against biological risks; and 3) preventing damage that could lead to device malfunction.

As for non-sterile medical devices, the device *packaging system* must also protect the device while in transit and use, be easily identifiable, have expiry dating, and successfully communicate the manufacturer's branding (generally through the use of colours and/or icons).

The *protective packaging* is a "configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use." The *sterile barrier system* is the "minimum package that prevents ingress of micro-organisms and allows aseptic presentation of the product at the point of use." Examples include pouches, bags, and containers. The *sterile barrier system* must of course be compatible with and able to withstand both the labelling and sterilization processes.

In everyday use, the ISO Standard infers that the *packaging system* and particularly *protective packaging* should also provide sufficient protection from sharp and/or penetrating objects, moisture, dust etc. This degree of protection and the *sterile barrier system* must be strong enough to ensure the integrity of the packaging up to the point of use regardless of the fact that the risks for contamination, degradation, loss of package integrity and the like vary between production, distribution and eventual use. Although beyond the scope of this edition of InTouch, readers are reminded that Part 2 of ISO 11607 stipulates the validation processes required for medical device packaging.

This label indicates that the product has been through the sterilization process, and usually found on the case or inner dispenser.

STATE OF THE ART MEDICAL DEVICE PACKAGING CASE STUDY

In the last few years, commercial, environmental, infection prevention, regulatory and occupational health and safety (OH&S) concerns have prompted some glove manufacturers to review their device packaging options. These reviews have led to innovative, safer, more environmentally-friendly and ergonomically designed device packaging.

Because of the substantial and unprecedented increase in the single-use disposable medical device market, hospitals and specialty areas such as the operating room and delivery suites, day procedural centres, intensive care units, dental clinics and emergency departments are facing increased pressure for storage space.

Responding to these demands in the surgical glove market, Ansell designed packaging that not only incorporates a smaller pouch, and a dispenser box and more gloves per box, but also offers versatility with shelving configuration and box storage by either storing vertically or horizontally. In practice, this enables more gloves to be stored in less space thereby freeing up space for either additional storage or alternate use. It also reduces the number of times the glove boxes must be changed. A box that is also lightweight and easy to move around provides handlers and users with less risk of ergonomic handling and transportation-related injuries. Smaller sized cartons, dispensers and/or pouches all contribute to reductions in the amount of and costs of generated waste. This enables users to better comply with waste minimization and environment-saving programs.

Larger dispenser transition to SMART pack (smaller dispenser)

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Additionally, the sterile device packaging must be designed so that neither the sterile device, the recipient, nor the sterile field is inadvertently contaminated in the transfer process. Studies conducted to-date suggest that packaging and the opening process are potential indirect routes for contamination of medical devices. Research that evaluated the effect of pouch size on contamination rates concluded that larger pouches produced higher contamination rates of the contents compared to smaller pouches.[10] Acknowledging this situation, Ansell changed their surgical glove pouch size to a small pouch to reduce risk of inadvertent contamination.

Surgical Glove Sterile Pouch

SURGICAL GLOVE STORAGE RECOMMENDATIONS

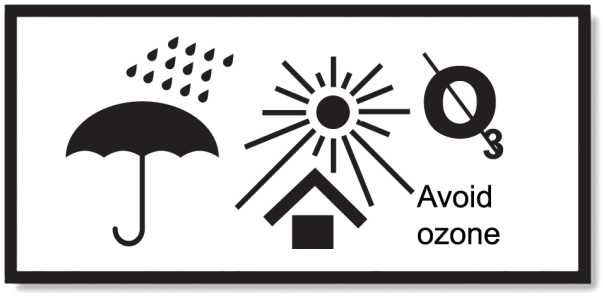
BIT NEW YEE, ANSELL

Surgical gloves may be stored for long periods before being used, and thus it is important that they are stored in conditions that minimize changes in their physical properties. Such changes may result in degradation, which may include excessive hardening, softening, cracking, crazing and other surface effects that will affect the performance and barrier protection of the glove.

To prevent glove degradation, surgical gloves should be stored in a cool, dark environment where they are shielded from sun light, ozone and ultraviolet (UV) light. This is especially important for natural rubber gloves, which are extremely susceptible to degradation from UV light, including the weak UV from fluorescent lamps and ozone that may be generated by motors and other electrical equipment.

To prevent glove degradation, surgical gloves should be stored in a cold, dark environment.

Gloves should always be stored away from radiators, air outlets or other heat sources and should not be stored long term in areas with temperatures above 90°F/32.2°C, as heat accelerates ozone damage and degradation. Exposure avoidance to these factors, in order not to adversely impact storage life, is indicated in the product packaging (refers to below diagram an example of symbols on product dispenser/carton).



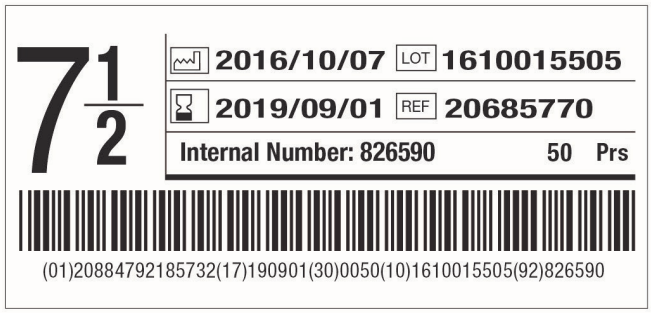
Example of Internationally recognised standards

The expiration date, in accordance with stability studies completed as per ASTM D7160 and/or EN455-4, is indicated on the packaging. Please note that manufacturer's expiration dating is not applicable when the product package seal has been broken, gloves have been removed from their original packaging or have been exposed to moisture.

Please note that manufacturer's expiration dating is not applicable when the product package seal has been broken.

Ansell surgical gloves have been challenged up to 90 days at 122°F/50°C to simulate the extreme possible condition in commercial supply chain. These include short term exposure to elevated temperature during sea shipment and land transportation in hot climates, or gloves storage during summer weather.

Most gloves have a three-year shelf life and stock rotation should be in a "first in, first out" basis. The label below indicates a manufacturing date of 2016/10/07 and an expiry date of 2019/09/01, reflecting a three-year shelf life.



Example of Product Barcode
Dates are displayed in year/month/day

REGULATIONS THAT IMPACT MEDICAL DEVICE PACKAGING

SEOW LAN HOON, ANSELL

Medical Device Labelling Requirements - APAC and Middle East Countries

Labelling is defined as "label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents."[11]

Labelling serves to identify a device and its manufacturer, and to communicate information on safety, use and performance. It is intended for users of medical devices, both professional and lay, as appropriate, and for relevant third parties. Regulatory Authorities require and specify information that manufacturers are expected to incorporate in the labelling when the device is placed onto the market.[9]

Labelling serves to identify a device and its manufacturer, and to communicate information on safety, use and performance.

The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). Users of medical devices must be provided with information about the medical device.[12] The information supplied by the manufacturer shall not be in such a way that it obscure other essential information.[13] A Regulatory Authority may authorize labelling to be in one or more language(s) other than its national language(s). In the case of single-use sterile devices, usually the labeling includes information about sterilization method, legend "Sterile" and advice against re-use.

Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Instructions for use may not be needed or may be abbreviated for devices if they can be used safely and as intended by the manufacturer without any such instructions for use. [14]

Users of medical devices must be provided with information about the medical device [14]

The use of internationally recognized symbols should be encouraged if device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.[15] If symbols are used on packaging, information, and marketing materials, the symbols shall meet the requirements in ISO 15223.

Medical device manufacturers must incorporate in their quality assurance (QA) program several elements that relate to labeling to meet the Good Manufacturing Practice (GMP) requirements of the Quality System regulation. The QA program must be adequate to ensure that labeling meets the GMP requirements with respect to legibility, adhesion, etc., and ensure that labeling operations are controlled so that correct labeling is always issued and used. It applies to the application of labeling to ensure legibility under normal conditions of use over the expected life of the device; and also, applies to inspection, handling, storage, and distribution of labeling. US FDA considers a device to be adulterated if these requirements are not met.[16]

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REGULATIONS THAT IMPACT MEDICAL DEVICE PACKAGING

SEOW LAN HOON, ANSELL

Failure to comply with GMP requirements, such as proofreading and change control, could result in labeling content errors. In such cases, the device is misbranded and adulterated. Labeling is part of the device master record; therefore, all changes to labeling must be made under a formal change control system similar to that required for specification.[17] Any changes to labeling must be formally reviewed and authorized before implementation.

In APAC/ Middle East countries, medical device labeling generally follows the requirements of recognized international or national standards. In the case of medical gloves, compliance standard declared are ISO 10282 and ISO 11193. Other national standards which are aligned to ISO e.g. Australia / New Zealand standards (ASNZS), Japan standards (JIS), Korean standards (KS), China standards (GB) are generally required by the customers including tender bodies of the respective countries. In addition to these standards, some countries have their own specific national labeling requirements, e.g. local language, registration number, local sponsor details, font size of the text etc. The Regulatory Authorities in the Middle East Countries are elaborative about storage conditions due to their environment conditions and demand that additional storage conditions are specified.

In general, below are the key components of information included in a medical device labeling in this sub-region:

- Product name
- Device description
- Manufacturer details
- Importer/ local sponsor information
- Country of origin
- Storage conditions
- Instruction for use
- Caution/warning statement
- Registration number
- Sterility info – sterile legend, sterilization method
- Production information – manufacturing date, expiry date, lot number, product code
- Product related data – quantity, size, left / right, material (e.g. latex), powdered/ powder free, pair, textured/ smooth, straight / curve fingers

Example of labeling requirements.

WHAT'S IMPORTANT IN PACKAGING

SUE BARNES, MAY KARAM, AND MONICA SAGARDOY

InTouch asked our clinical experts how important medical device packaging was in terms of device usability. All experts agreed that it was highly important. Their reasoning was interesting and included that proper identification, selection and dispensing of devices needs to happen in environments where there are pressures on time and staff.

When asked to select the five most important features of device packaging our experts agreed that the number one feature was the ability of the device packaging to protect contents from moisture, tearing and/or degradation.

The remaining four features were equally ranked and included the following:

- Clarity of information included on the individual unit,
- Compliant with necessary regulations,
- Ability of sterile products to maintain sterility up to the point of use, and
- The ability of medical devices to be dispensed aseptically without contamination.

Our experts each agreed that in terms of influencing purchasing decisions it was highly important for a medical device to be packaged in recyclable or environmentally-friendly material.

When asked whether the requirements of medical packaging differed between specific clinical areas our clinical experts expressed opposing views. One commented that the same rules and regulations apply regardless of the clinical area whilst the other indicated that requirements were more strictly followed in surgical rather than medical departments.

After considering current "state-of-the-art" device packaging, our experts provided very thoughtful views on the key features that should be included such as documentation, labelling, guaranteed process for the life of the package, recyclability, bar coding and radio-frequency tracking of sterile packages until opening. For one respondent "state of the art packaging means a pack that takes into account clear identification, usability and disposal after consumption. Identification is determined by text and colours, while usability is determined by overall weight, ease and speed of dispense, "stockability" in limited shelf space and durability on use and dispensing together with adequate disposal and recyclable. All this needs to be done within the regulatory framework and its associated requirements".

Two of our experts noted that manufacturers must accommodate large amounts of text due to regulatory requirements while simultaneously keeping the font size big enough to read.

Despite being based on separate continents and coming from different clinical specialities, independent of each other, our clinically-based experts both indicated that some infection prevention protective feature would be a feature they would like to see engineered into new medical device packaging designs. Specific examples included a recyclable, antimicrobial barrier and some sort of contamination indicator.

InTouch is especially grateful to Sue, May and Monica for sharing their views on this important issue of medical device packaging and we look forward to hearing the views of others as we explore additional contemporary issues in future InTouch editions.

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North America
Ansell Healthcare Products LLC
111 Wood Avenue South
Suite 210
Iselin, NJ 08830, USA

Europe, Middle East & Africa
Ansell Healthcare Europe NV
Riverside Business Park
Blvd International 55
1070 Brussels, Belgium

Asia Pacific
Ansell Services Asia Sdn. Bhd.
Prima 6, Prima Avenue
Block 3512, Jalan Teknokrat 6
63000 Cyberjaya, Malaysia

Australia & New Zealand
Ansell Limited
Level 3, 678 Victoria Street
Richmond, Vic, 3121
Australia

www.ansell.com