

Allegro™ Single-Use Filling Needles Instructions For Use



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1 Types of Safety Symbols

All safety symbols: warning, prohibition, mandatory and GHS can /will be accompanied by additional text and signs to explain the reason for the warning, explain the nature of the prohibition, and explain the reason for the action required.

Table 1





ISO 7010 safety signs and symbols

Colour	Meaning / Purpose	Example	Description	Instruction and Information
Red	Prohibition / Danger		Red ring and diagonal bar with black symbol on white background	Specifies behaviour that is prohibited because it would result in an immediate or potential risk of personal injury or threat to health / life.
Yellow	Warning / Caution		Yellow triangle with black border and black symbol	Warns of hazards which could result in personal injury or threat to health.
Blue	Mandatory / Information		Blue circle with white symbol	Specifies an action required or informs of information to safeguard personal health and /or avoid risk of personal injury.
Red	GHS Hazards		Red diamond, white background with a black symbol	Classifies the hazards of chemical products and communicates health and safety information.

1.1 Safety Symbols Within This IFU

Table 2

Safety signs and symbols within this document

Symbol	Instruction and Information
	Prior to operating, the instructions must be read in entirety.
	Mandatory information
	General Warning
	Prohibited action that could



2 Introduction

Prior to use it is essential to read all instructions, and the following procedures must be followed. It is recommended to consult the appropriate data sheet for the product in use. For any queries, please consult Pall or your local distributor.

implement within your SOP's these general service instructions and the instructions for use of any other components supplied as an integrated item within your system. (e.g. Kleenpak™ sterile connectors, tubing sets, filters etc). Contact your Pall representative if you have any questions regarding correct use of your systems before using them in your process.

Pall can assist with training and the implementation of correct usage instructions for our systems and components within your SOPs through our Scientific and Laboratory Services.



Use of this product in a manner other than in accordance with Pall's current recommendations may lead to injury or loss. Pall cannot accept liability for such injury or loss.

3 Specifications



This product is not suitable for direct injection in human or veterinary use.

The working temperature range for the Allegro single-use filling needle is 2 °C to 40 °C. There is no operating pressure as the needle is an open-ended system. Please check the product datasheet for all other operating parameters or contact Pall or your local distributor. Operation outside the specifications or with fluids incompatible with construction materials may cause personal injury and result in damage to the equipment.

Incompatible fluids are fluids which chemically attack, soften, stress, attack or adversely affect the materials of construction. Please refer to Pall for exact limits.

4 Receipt of Equipment

The Allegro single-use filling needles are available in different internal diameter sizes.

Ensure that the diameter is suitable for the application.

Allegro single-use filling needles are supplied either non-irradiated (non-sterile) or sterilized by gamma irradiation (as an integral component of a pre-sterilized Allegro single-use system). Please check the product label prior to use to ensure product part numbers correspond to the application. If unsure as to whether the system has been irradiated or sterilized, or if unsure of suitable sterilization method, contact Pall.

- Store the Allegro single-use needles or Allegro systems in a clean, dry conditions between 0 and 30 °C without exposure to irradiation sources such as direct sunlight, and, wherever practical, in the packaging as delivered.
- Do not remove from packaging until just before installation.
- Check that the packaging is undamaged prior to use.
- Gamma-irradiated and sterile needles / assembled systems are double-bagged. Check that the inner bag is undamaged prior to use.
- Ensure that the needle selected is suitable for the application.

5 Installation and Operation

Before installation, it is essential to verify that the Allegro single-use filling needle selected is suitable for the fluid to be processed and to follow the appropriate instructions listed below.

5.1 Package Opening

To open the package, ensure that any cutting tool used does not damage any of the components of the needle or Allegro system. Take care not to puncture the packaging when handling.

Ensure that the needles are always handled with care and that the protective sheath is only removed prior to fitting in the filling machine.

When removing the protective sheath, take care not to damage the needle and to only hold the needle by the hub when inserting it into the associated hardware.

5.2 Installation

Install the Allegro single-use filling needle in-line using compatible connections. Ensure that it is installed in the correct orientation for flow from the inlet to the outlet and that it is adequately supported if needed. When Allegro single-use filling needles are used in conjunction with hardware, please ensure that the needle is correctly installed in the hardware.

5.3 Operation

Check in the Pall documentation file for further details regarding the operation of the Allegro single-use filling needle or system. If you do not have the Instructions for Use (IFU) related to Pall individual components and hardware, please contact Pall or your local distributor. See www.pall.com/allegro for more information.

6 Sterilization

This only applies to needles that are supplied non-gamma irradiated.

Sterilize the Allegro Single-use filling needles with the protective sheaths on.



Allegro single-use filling needles supplied gamma irradiated or sterilized by gamma irradiation must never be re-irradiated or autoclaved.

6.1 Autoclaving

The maximum cycle time for autoclaving is at 75 mins at 130 °C.

6.2 Gamma Irradiation

If the non-sterile Allegro single-use filling needle requires gamma-irradiation prior to use, the maximum allowable radiation dose is 50 kGy. Gamma irradiation above the maximum allowable dose or carried out on a product not specified for gamma irradiation, can result in degradation of the materials of construction and may lead to personal injury. The efficiency of the sterilization cycle should be validated using an appropriate method. Please refer to Pall Corporation for the minimum and maximum allowable dose.

7 Allegro Single-Use Needles Replacement



Do not re-use Allegro Single-Use filling needles.

Allegro single-use filling needles are designed and intended for single use only; therefore, they should be replaced after their first use. Allegro single-use needles should be replaced in accordance with the cGMP requirements for the process. Discard the system in compliance with local Health and Safety and Environmental procedures. No attempt should be made to clean and re-use Allegro single-use needles.

8 Scientific and Laboratory Services

Pall operates a technical service to assist in the application of our products. This service is readily available to you and we welcome your questions so that we can help. In addition, an extensive network of technical representatives is available throughout the world.

9 Warranty

Pall warrants that Allegro single-use filling needles manufactured by Pall, when properly stored and installed, and operated within recommended ratings, specifications, and design conditions, will be free from defects in material and workmanship during their shelf life.

Pall liability under any warranty is limited solely to replacing, or issuing credit for, the Allegro single-use filling needles that may become defective during the Warranty Period.



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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

IF APPLICABLE Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use.

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