

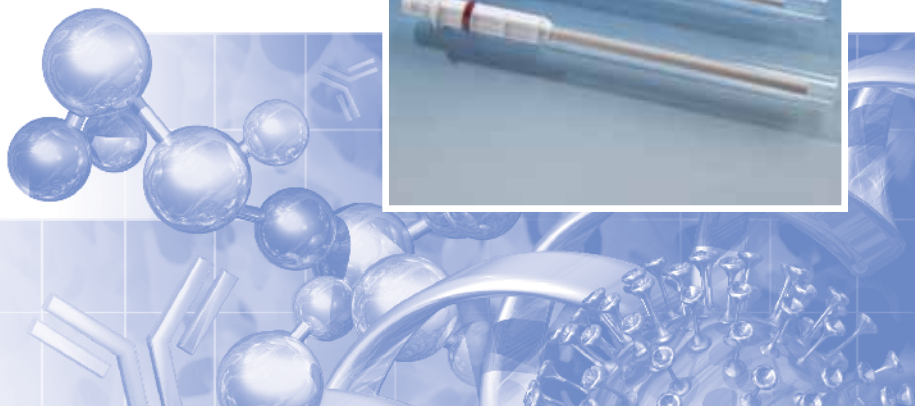


Life Sciences

Instructions for Use

USD 2835²

for Allegro™ Single-Use Filling Needles



1. Introduction



Important: The following procedures must be followed for the installation of Allegro single-use filling needles. The product data sheets must be read thoroughly because they contain valuable information gained by extensive experience. It is very important that all instructions are carefully followed, and where appropriate, they should be incorporated into the end user's standard operating procedures (SOP).

If some of the procedures do not suit your needs, please consult Pall or your local distributor before finalizing your system. 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.

It is essential that you read, understand and 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 SOP's through our Scientific and Laboratory Services.

2. Specification

This product is designed to be used for filling applications only.



Warning: 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 data sheet 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.

3. 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.

1. 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.
2. Do not remove from packaging until just before installation.
3. Check that the packaging is undamaged prior to use.
4. Gamma-irradiated and sterile needles / assembled systems are double-bagged. Check that the inner bag is undamaged prior to use.
5. Ensure that the needle selected is suitable for the application.

4. 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.

When handling the needles in the packaging, take care not to puncture the packaging.

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.

4.1 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.

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

4.2 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.

4.3 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.

5. Sterilization

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



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

5.1 Autoclaving

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

5.2 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.

6. Allegro Single-use Needles Replacement

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.



Warning: Allegro single-use filling needles should not be re-used.

7. 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.

8. 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.