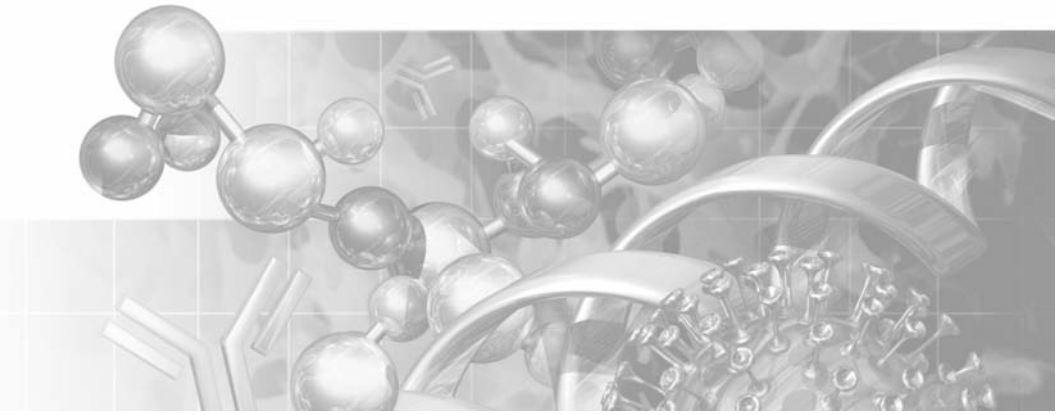
Life Sciences

Instructions For Use

USD 2421b

Assembly and Installation Procedures Pall Allegro™ Single-use Systems



*Filtration. Separation. Solution.*SM

1. Introduction

Important: The following procedures must be followed for the installation of Pall Allegro single-use systems. 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, Allegro totes, 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 you SOP's through our Scientific and Laboratory Services.

2. Specification

The maximum working pressure and temperature can vary among Allegro single-use systems. The working limits are defined as a result of the operating parameters of the individual components and the assembly process. The working limit for each individual Allegro system is defined in the engineering drawing. Please check the documentation file, 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.

Warning:
The use of solutions containing low molecular weight alcohol, especially isopropyl alcohol, to decontaminate the exterior of the Allegro biocontainers may, in circumstances where significant stress (repetitive bending and twisting) is applied during use, cause damage to the molded LDPE inlet and outlet ports. The flexible LDPE film of the Allegro biocontainers is not affected.

3. Receipt of Equipment

Allegro single-use systems are supplied either non-irradiated (non-sterile), gamma-irradiated (non-sterile, microbially controlled), or sterilized by gamma irradiation. 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 system in 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 Allegro single-use systems are double-bagged. Check that the inner bag is undamaged prior to use.
5. Ensure that the Allegro system selected is suitable for the application.
6. In addition to the part number, each system assembly is identified by a unique identification batch number.

4. Installation and Operation

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

4.1 Package Opening

To open the package, ensure that the cutting tool used does not damage any of the components of the Allegro single-use system.

4.2 Installation

Install the Allegro system 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 systems are used in conjunction with hardware, please ensure that the system is correctly installed in the hardware.

4.3 Operation

Check in the Pall documentation file for further details regarding the operation of the whole Allegro system. If you do not have the Instructions of Use related to Pall individual components and hardware, please contact Pall or your local distributor.

5. Sterilization

This only applies to Allegro systems that are supplied non Gamma irradiated

Warning: Allegro systems supplied Gamma irradiated or sterilized by gamma irradiation must never be re-irradiated or autoclaved

5.1 Autoclaving

Please refer to the Pall documentation file for the maximum recommended cumulative autoclave exposure time if the Allegro system needs to be autoclaved prior to use.

Warning: If the Allegro system contains capsule filters, autoclave sterilization procedures for the capsules are detailed in Pall publication USTR 805. Do not autoclave the Allegro system in the bags provided. When sanitary connections are used within the Allegro system, it is recommended that the sanitary clamps are not fully tightened prior to autoclaving. The clamps should be fully hand-tightened when autoclaving is completed.

5.2 Gamma Irradiation

If the Allegro system requires Gamma-irradiation prior to use, consult Pall for maximum allowable radiation dose. Gamma irradiation above the maximum allowable doses, 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 the Pall documentation file for the minimum and maximum allowable dose.

6. Integrity Testing

If integrity testable membrane filter capsules are used within the Allegro system, their integrity should be verified between the sterilization and the filtration step, and also after the filtration step, by means of an appropriate test method. Contact Pall for recommended integrity test procedures and integrity test values.

7. Allegro Single-use System Replacement

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

Warning: Allegro systems should not be re-used.

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 systems 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 systems 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.

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