



## Allegro™ Single-Use Filling Needles



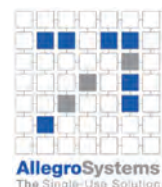
### *For single-use final filling applications*

The Allegro single-use filling needle offers a cost-effective, unique direct replacement alternative to the stainless steel filling needles that are currently used for aseptic filling of liquids. This versatile needle is easily integrated into new or existing single-use filling lines, where the fluid path is either autoclaved or gamma irradiated. Complete single-use assemblies incorporating the needles simplify filling machine operation, reduce assembly time and needle installation risks.

The Allegro single-use plastic filling needle consists of a Polyether Ether Ketone (PEEK) shaft reinforced with non-fluid contact stainless steel and a polypropylene hub with female luer connection. The needle shaft is 75 mm (2.95 in.)

in length and is available in three lumen diameters: 0.8, 1.6 and 3.2 mm ID. For use in a disposable sterile filling system, it can be either autoclaved or gamma irradiated.

The Allegro single-use filling needle is ready to use (after sterilization where required) and offers a completely disposable solution for final filling that avoids the cost and resource of filling needle cleaning verification and validation. Its use increases available manufacturing time and decreases down time of filling machines and associated equipment.



## Features and Benefits

- ▶ Ready to use, single-use
  - No cleaning verification or validation needed
  - Increase manufacturing up time and decreases turnaround and cleaning time
  - Particulate and endotoxin claims per USP methods remove the requirement for pre flushing and drying
- ▶ Plastic needle reinforced by stainless steel
  - Autoclavable and gamma irradiatable and ready to use
  - Product contact portion is PEEK / Polypropylene for Stainless Steel sensitive biologics
- ▶ Straightness of needle
  - Allows bottom up high speed filling
- ▶ Control of shaft diameter
  - No drip formation<sup>1</sup>
  - Accurate volumetric filling
- ▶ Female Luer connection with O-ring seal
  - Allows for easy integration in filling lines or systems
  - O-ring prevents slippage in filling head assembly
- ▶ Available in a range of lumen diameters
  - Facilitates a range of filling volumes
- ▶ Every needle is laser marked with part number and batch number
  - Easy identification
  - Fully traceable production history

## Applications

The Allegro single-use filling needle can be used in a variety of ways.

- ▶ In existing filling machines where the needle can replace its stainless steel counterpart
- ▶ Integrated in a single use system for final formulation and filling with other Allegro components, such as product feed and surge vessel biocontainers, Kleenpak™ sterile disconnectors, Kleenpak sterile connectors, and tubing sets
- ▶ Can be used for a broad range of filling applications<sup>2</sup>:
  - Liquid injectable pharmaceuticals
  - Biopharmaceuticals pre-lyophilization
  - High potency drug filling
  - Blood derivatives
  - Vaccine vialing
- ▶ Used to fill vial volumes  $\geq 0.5$  mL

<sup>1</sup> Subject to other filling machine parameters

<sup>2</sup> Subject to fluid compatibility studies

Contract manufacturing and filling organizations accrue additional benefits with fast turn around and removal of the need to control needle inventory for different batches and different clients.

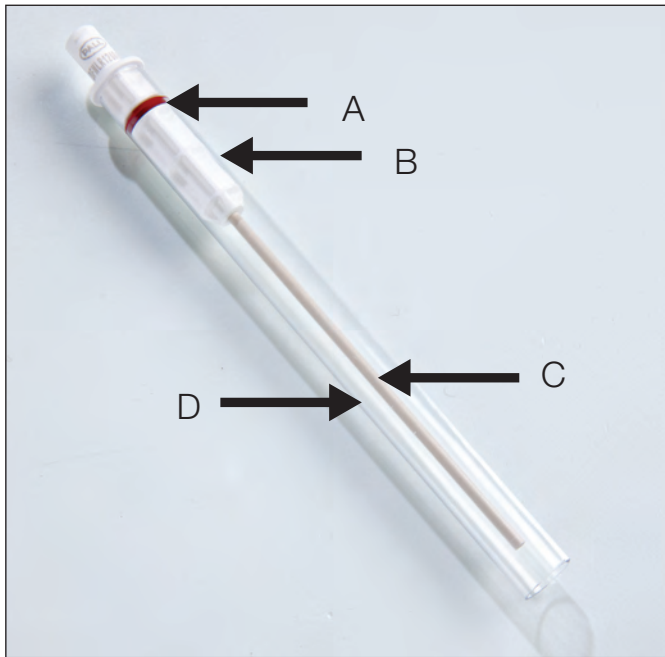
Clinical trials and other smaller batches can be economically filled with less preparation work.

## Quality Standards

- ▶ Manufactured in an ISO class 8 clean room facility
- ▶ Manufactured under a quality management system certified to ISO13485
- ▶ Supplied with a Certificate of Test confirming the quality standards and quality control tests performed by Pall (including endotoxin per USP <85> and particulates per USP <788>)
- ▶ Validation tests include:
  - Dimensional accuracy
  - Leak test
  - Shelf life
  - Autoclave / irradiation
  - Extractables
  - Hub integrity
  - Batch number marking
- ▶ The fluid path meets all regulatory requirements for:
  - Biological Reactivity Tests (*In Vitro*) for Class VI-121°C Plastics, USP <88>
  - Biological Reactivity Tests (*In Vitro*) for Cytotoxicity, USP <87>
  - Particulate Matter in Injections, USP <788>
  - Physiochemical Tests for Plastics, USP <661>
  - Bacterial Endotoxins Test, USP <85>



## Technical Specifications



### Aqueous Extractables (NVR)

Water at 20 – 25 °C after autoclaving and gamma irradiation	Typically < 1 mg
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### Sterilization Methods

Gamma irradiation	Maximum 50 kGy
Autoclave	1 cycle @ 75 mins at 130 °C

### Operating Conditions

Range of operating temperature	2 - 40 °C
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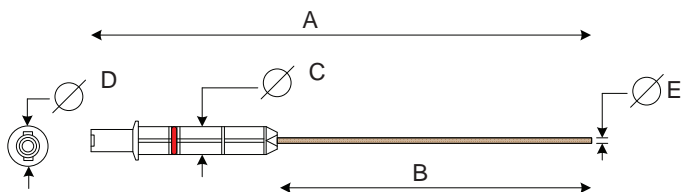
### Nominal Dimensions

Description	Dimensions		
	0.8 mm	1.6 mm	3.2 mm
Internal diameter (ID)	0.8 mm	1.6 mm	3.2 mm
	(0.03 in.)	(0.06 in.)	(0.13 in.)
Overall length (A)	120 mm	120 mm	120 mm
	(4.72 in.)	(4.72 in.)	(4.72 in.)
Shaft length (B)	75 mm	75 mm	75 mm
	(2.95 in.)	(2.95 in.)	(2.95 in.)
Hub diameter (C)	8.6 mm	8.6 mm	8.6 mm
	(0.34 in.)	(0.34 in.)	(0.34 in.)
Flange diameter (D)	12 mm	12 mm	12 mm
	(0.47 in.)	(0.47 in.)	(0.47 in.)
Shaft outer diameter (E)	2.2 mm	2.2 mm	3.8 mm
	(0.09 in.)	(0.09 in.)	(0.15 in.)

### Allegro Single-Use Filling

Needle Component	Material of Construction
A O-Ring	Silicone
B Hub	White polypropylene (TiO <sub>2</sub> colorant)
C Shaft	PEEK with stainless steel reinforcement
D Packaging sheath	Glycol polyethylene terephthalate (PET-G) <sup>2</sup>

<sup>2</sup> Terephthalates are a safe and well established class of polyesters unrelated to phthalate excipients or PVC plasticizers.



## Ordering Information

Part Number	Description	Packaging
DFNLR1208608	0.8 mm ID needle	12 per tray
DFNLR1208616	1.6 mm ID needle	12 per tray
DFNLR1208632	3.2 mm ID needle	12 per tray



## Life Sciences

### Corporate Headquarters

Port Washington, NY, USA  
+1.800.717.7255 toll free (USA)  
+1.516.484.5400 phone  
biopharm@pall.com e-mail

### European Headquarters

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone  
LifeSciences.EU@pall.com e-mail

### Asia-Pacific Headquarters

Singapore  
+65 6389 6500 phone  
sgcustomerservice@pall.com e-mail

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E-mail us at [allegro@pall.com](mailto:allegro@pall.com)

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