Allegro™

SINGLE-USE FILLING NEEDLES

For single-use final filling applications

Filling inaccuracy, dripping and needle clogging lead to costly product losses and process downtime at a critical stage in the manufacture of drug products.

Allegro™ single-use filling needles overcome these challenges through the inherent hydrophobicity of their reinforced polyether ether ketone (PEEK) construction and their availability in a wide range of internal diameters. These features combine to deliver accurate and reliable dispensing across a broad range of drug products and dosing volumes, as part of an autoclaved assembly or when integrated into a gamma-irradiated single-use system.

Complete single-use assemblies incorporating Allegro needles simplify filling machine operation, and reduce assembly time and needle installation risks.

The needles are available in different sizes:

- 0.8, 1.2, 1.6, 2.4, and 3.2 mm with female luer connection
- 3.2, 4.0, 5.0, and 6.0 mm with a direct connection

Fig 1. Single-use filling needles highlighting sizing range and different connections.

Features	Benefits
Ready to use, single-use	No cleaning verification or validation needed
	Increase manufacturing up time and decrease turnaround and cleaning times
	Particulate and endotoxin claims per USP methods remove the requirement for pre-flushing and drying
Plastic needle reinforced by stainless steel	Autoclavable, gamma irradiatable and ready to use
	Product contact portion is PEEK (and polypropylene for luer connection)
Straightness of needle	Allows bottom-up high-speed filling
Control of shaft diameter	No-drip formation [1]
	Accurate volumetric filling
Female luer connection for sizes 0.8, 1.2, 1.6, 2.4, and 3.2 mm and direct connection for sizes 3.2, 4.0, 5.0, and 6.0 mm	Allows 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 product code and batch number	Easy identification
	Traceable production history

[1] Subject to other filling machine parameters

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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
- In a broad range of filling applications [(2)]:
  - liquid-injectable pharmaceuticals
  - biopharmaceuticals pre-lyophilization
  - high-potency drug filling
  - blood derivatives
  - vaccine vialling
  - high-viscosity biological fluids (monoclonal antibodies, polysaccharides, etc.)
  - high-concentration drugs
- To fill a variety of fill volumes, depending on customer requirements

Contract manufacturing and filling organizations accrue additional benefits, with fast turnaround 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.

[(2)] Subject to fluid compatibility studies

Quality standards

- Manufactured in an ISO class 8 cleanroom facility
- Manufactured under a quality management system certified to ISO9001
- Supplied with a certificate of test confirming the quality standards and quality control tests (including endotoxin per USP <85> and particulates per USP <788>)
- Validation tests include:
  - dimensional accuracy
  - leak test for luer-connected needles
  - shelf life
  - autoclave / irradiation
  - extractables
- 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>

Fig 2. Final filling assembly with Allegro single-use filling needle.

Fig 3. Final filling assembly including a surge biocontainer and multiple Allegro single-use filling needles.

Technical specifications

		Fluid contact material	
Component	**Materials of construction**	**Luer connection needle**	**Direct connection needle**
O-ring [1]	Silicone	–	–
Hub [2]	White polypropylene (TiO_2 colorant)	✓	–
Shaft [3]	PEEK with stainless steel reinforcement	✓	✓
Packaging sheath [4]	Polycarbonate	–	–
Aqueous extractables (NVR)			
	Water at 20°C to 25°C after autoclaving and gamma irradiation	Typically < 1 mg	
Sterilization methods			
	Gamma irradiation	Maximum 50 kGy	
	Autoclave	1 cycle at 75 minutes at 130°C	
Operating conditions			
	Range of operating temperature	2 to 40°C	

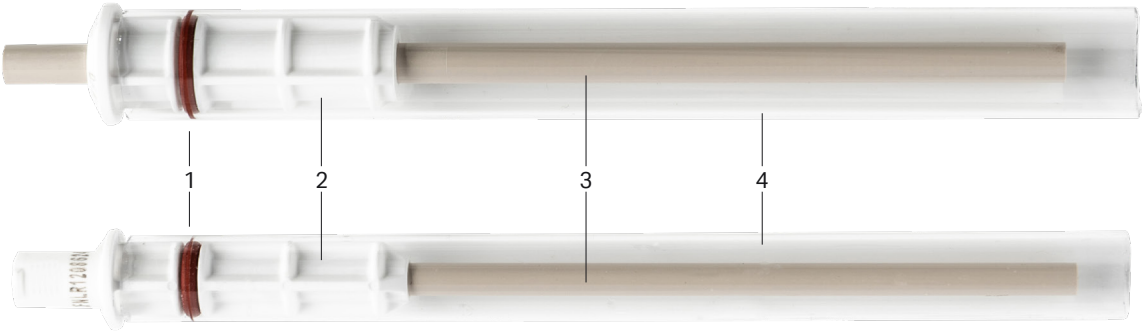
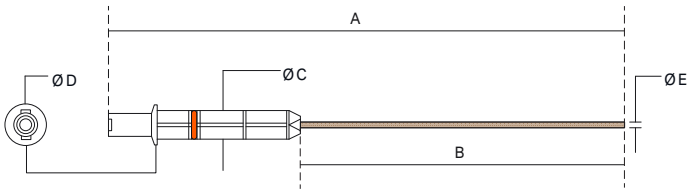


Fig 4. Allegro single-use filling needle with direct connection (top) and luer connection (bottom).

Dimensions	**Luer connection needle**					**Direct connection needle**			
Internal diameter (ID)	0.8 mm (0.03 in.)	1.2 mm (0.05 in.)	1.6 mm (0.06 in.)	2.4 mm (0.09 in.)	3.2 mm (0.13 in.)	3.2 mm (0.13 in.)	4.0 mm (0.16 in.)	5.0 mm (0.20 in.)	6.0 mm (0.24 in.)
Overall length [A]	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)	120 mm (4.72 in.)
Shaft length [B]	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)	75 mm (2.95 in.)
Hub diameter [C]	8.6 mm (0.34 in.)	8.6 mm (0.34 in.)	8.6 mm (0.34 in.)	8.6 mm (0.34 in.)	8.6 mm (0.34 in.)	10.9 mm (0.43 in.)	10.9 mm (0.43 in.)	10.9 mm (0.43 in.)	10.9 mm (0.43 in.)
Flange diameter [D]	12 mm (0.47 in.)	12 mm (0.47 in.)	12 mm (0.47 in.)	12 mm (0.47 in.)	12 mm (0.47 in.)	14 mm (0.55 in.)	14 mm (0.55 in.)	14 mm (0.55 in.)	14 mm (0.55 in.)
Shaft outer diameter [E]	2.2 mm (0.09 in.)	2.2 mm (0.09 in.)	2.2 mm (0.09 in.)	3.8 mm (0.15 in.)	3.8 mm (0.15 in.)	4.6 mm (0.18 in.)	5.4 mm (0.21 in.)	6.4 mm (0.25 in.)	7.4 mm (0.29 in.)



Ordering information

Product	Packaging	Product code
0.8 mm ID needle with luer connection	12 per tray Non-sterile, gamma irradiatable / autoclavable	DFNLR1208608
1.2 mm ID needle with luer connection		DFNLR1208612
1.6 mm ID needle with luer connection		DFNLR1208616
2.4 mm ID needle with luer connection		DFNLR1208624
3.2 mm ID needle with luer connection		DFNLR1208632
3.2 mm ID needle with direct connection		DFNST1201132
4.0 mm ID needle with direct connection		DFNST1201140
5.0 mm ID needle with direct connection		DFNST1201150
6.0 mm ID needle with direct connection		DFNST1201160

Fig 4. Tray of single-use filling needles.

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