Thermo Fisher
S C I E N T I F I C

Single-use technology

Fill Finish Solution
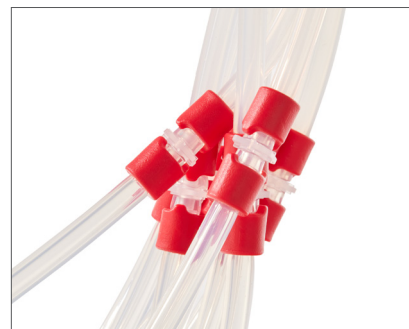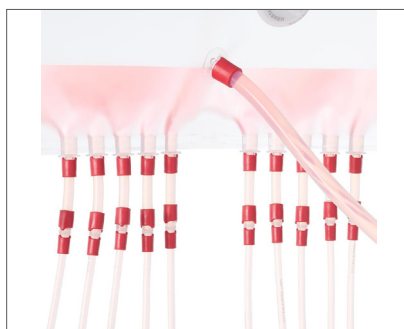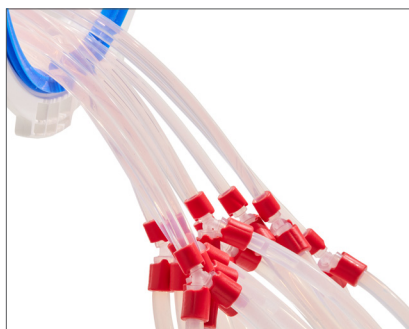## Maximize drug product recovery

Keywords
BioTitan Retention Device, Labtainer Pro surge bag, bioprocess container, Aegis film, aseptic filling, drug product, 100% assembly integrity test

The Thermo Scientific™ Fill Finish Solution offers advanced integrity assurance through a complete, configurable solution for biopharma and CDMOs looking to help maximize drug product recovery. With industry-leading integrity testing, exceptional lead times, and a range of easy-to-use single-use consumables for compounding, sterile filtration, and aseptic filling applications, the Fill Finish Solution can support high product quality while helping to optimize your workflow. Customizable with standard products and engineered to order, the Fill Finish Solution provides an end-to-end means to help meet your fill finish application needs.

Applications
Final drug product fill into containers such as prefilled syringes or vials for:

- Vaccine production

- Biologic production

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Key advantages

Designed with maximizing drug product recovery in mind, the Fill Finish Solution offers key features:

- **Trusted integrity assurance:** 100% of the assembly is tested for leaks using helium at a 10 µm detection limit to minimize leakage risk.

- **Exceptional lead times:** Standard and configurable product design options are supported by our global manufacturing network for supply assurance.

- **Thermo Scientific™ BioTitan™ Retention Device:** Consistent 360° seal reduces the risk of leaks and simplifies the setup process.

- **Maximum drainage from surge bag:** Surge bag design facilitates optimal drainage and has been leak tested to provide 99% product recovery.

- **High-quality film:** Choose from widely used single-use films (Aegis™ 5-14 film and CX5-14 film), which offer durable, puncture-resistant material.

- **Sustainability profile:** Reduction in packaging material, which creates a more environmentally friendly product.

User benefits

- **100% helium-tested assembly:** Helps ensure product integrity, minimizing leakage from the filling assembly.

- **Upgraded packaging:** Easy-peel tape on the shipping box and an easy-open polyethylene (PE) outer bag help simplify setup.

- **Waste management:** Cardboard reduction of up to 25%. Improved outer polyethylene bag—manufactured in a controlled environment—results in cleaner packaging with less risk of particulates.

- **Lot-based testing:** Implementation of lot-based bacterial endotoxin (BET) testing and particulate testing of Thermo Scientific™ Labtainer™ Pro BioProcess Container (BPC) products performed according to USP <788> and USP <85> standards.

Product features

The Fill Finish product family provides configurable single-use assemblies from a standard component catalog for drug product final fill applications. Products include compounding, final filtration, and aseptic filling assemblies.

Compounding assembly:

- Buffer to compounding BPC

- Compounding to holding BPC

- Bioburden reduction filter assembly

Filtration assembly:

- Pre-use post-sterilization integrity testing (PUPSIT)

- Double sterilization filter assembly

Filling assembly:

- Beta bag

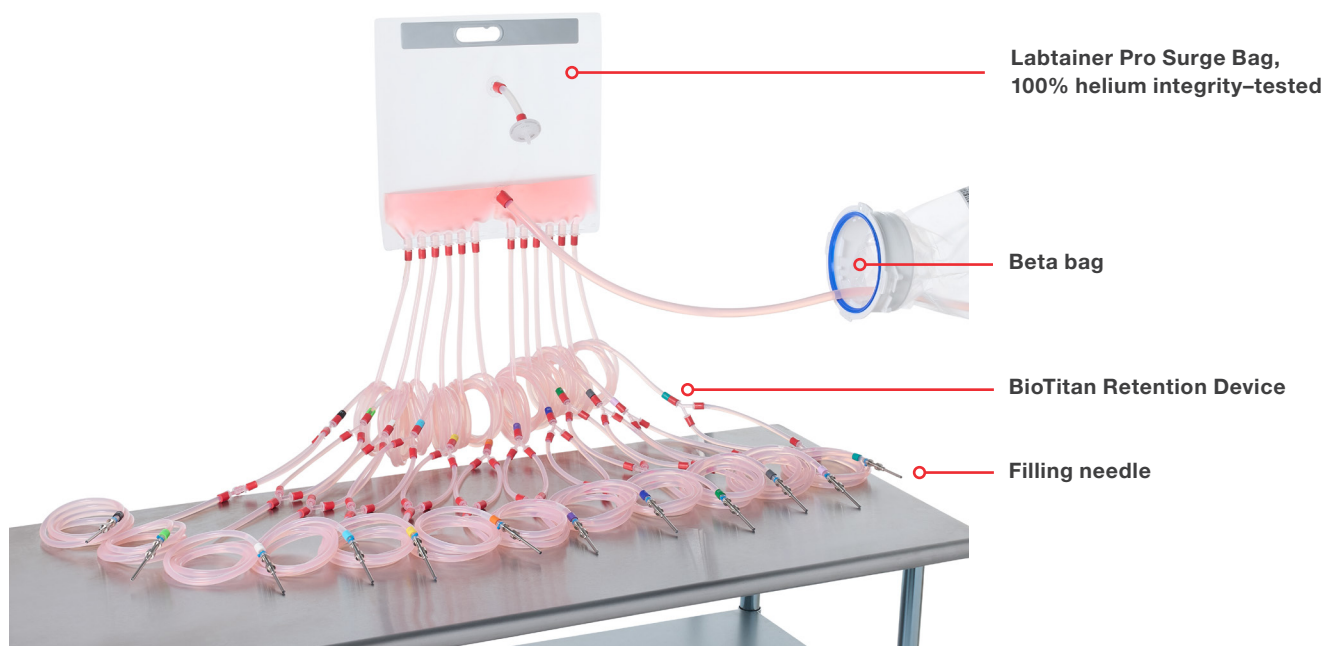- Drug surge bag

- Tubing assembly

- Filling needle

Labtainer Pro Surge Bag, 100% helium integrity–tested

Beta bag

BioTitan Retention Device

Filling needle

Table 1. Aseptic filling assembly, standard part numbers.

Assembly description	Cat. No.
Aseptic filling assembly, 1 L surge bag, 2 edge port (1/8 in.)	SUT17339
Aseptic filling assembly, 5 L surge bag, 6 edge port (1/8 in.)	SUT17342
Aseptic filling assembly, 5 L surge bag, 12 edge port (3/16 in.)	SUT19396
Aseptic filling assembly, 5 L surge bag, 6 edge port (1/8 in.)	SUT19649
Aseptic filling assembly, 5 L surge bag, 10 edge port (3/16 in.)	SUT19782
Aseptic filling assembly, 5 L surge bag, 8 edge port (1/8 in.)	SUT19783

Table 2. Filter options. Table 1. Aseptic filling assembly, standard part numbers.

Filter description*	Cat. No.
Meissner™ filter, PP/PVDF, 0.2 µm, 1/4 in. SHB x 1/4 in. SHB	SV21270.01
Millipore™ filter, PC/PVDF, 0.22 µm, 1 1/2 in. SF x 9/16 in. HB	SV20062.06
Millipore™ filter, PC/PVDF, 0.22 µm, 1/4 in. SHB x 1/4 in. SHB	SV20292.02
Millipore™ filter, PC/PVDF, 0.22 µm, 1/4 in. SHB x 1/4 in. SHB	SV20560.02
Millipore™ filter, PC/PVDF, 0.22 µm, 9/16 in. HB x 9/16 in. HB	SV20062.01
Millipore™ filter, PC/PVDF, 0.22 µm, 9/16 in. HB x 9/16 in. HB	SV20681.03
Millipore™ filter, PET/PES, 0.2 µm, 1/4 in. SHB x 1/4 in. SHB	SV21414.01
Millipore™ filter, PP, 0.2 µm, 1/2 in. SHB x 1/2 in. SHB	SV20696.02
Millipore™ filter, PP/PES, 0.2 µm, 1 1/2 in. SF x 9/16 in. HB	SV21198.22
Millipore™ filter, PP/PES, 0.2 µm, 1 1/2 in. SF x 9/16 in. HB	SV21198.18
Millipore™ filter, PP/PVDF, 0.1 µm, 9/16 in. HB x 9/16 in. HB	SV20685.01
Millipore™ filter, PP/PVDF, 0.22 µm, 9/16 in. HB x 9/16 in. HB	SV20686.01
Millipore™ filter, PP/PVDF, 0.22 µm, 1 1/2 in. SF x 1/2 in. HB	SUT30148.01
Millipore™ filter, PP/PVDF, 0.22 µm, 1 1/2 in. SF x 1/2 in. HB	SUT30148.02
Millipore™ filter, PP/PVDF, 0.22 µm, 1 1/2 in. SF x 1/2 in. HB	SUT30148.03
Millipore™ filter, PP/PVDF, 0.22 µm, 1 1/2 in. SF x 9/16 in. HB	SV20685.04
Millipore™ filter, PP/PVDF, 0.22 µm, 1 1/2 in. SF x 9/16 in. HB	SV20686.02
Millipore™ filter, PP/PVDF, 0.22 µm, 9/16 in. HB x 9/16 in. HB	SV20685.03
Pall™ filter, PP/PES, 0.2 µm, 3/4 in. SF x 1/4–1/2 in. SHB	SV20707.04
Pall™ filter, PP/PVDF, 0.2 µm, 3/4 in. SF x 3/4 in. SF	SV20734.01
Pall™ filter, PP/PVDF, 0.2 µm, 1/4–1/2 in. SHB x 1/4–1/2 in. SHB	SV20518.02
Sartorius™ filter, PP/PES, 0.2 µm, 1/2 in. HB x 1/2 in. HB	SV21288.63

* Acronyms for materials are defined as follows:

HB = hose barb

PC = polycarbonate

PES = polyethersulfone

PET = polyethylene terephthalate

PP = polypropylene

PVDF = polyvinylidene fluoride

SHB = stepped hose barb

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Table 3. Tubing options.

Tubing description	Cat. No.
Pharma-50 tubing, silicone, 1/4 in. ID x 1/2 in. OD x 1/8 in. wall	SV20791.08
Pharma-65 tubing, silicone, 1/4 in. ID x 3/8 in. OD x 1/16 in. wall	SV21060.04
Pharma-65 tubing, silicone, 2/17 in. ID x 17/72 in. OD x 1/17 in. wall	SV21060.58
Pharma-50 tubing, silicone, 1/2 in. ID x 3/4 in. OD x 1/8 in. wall	SV20791.10
Pharma-50 tubing, silicone, 1/8 in. ID x 1/4 in. OD x 1/16 in. wall	SV20791.02
Pharma-50 tubing, silicone, 3/8 in. ID x 5/8 in. OD x 1/8 in. wall	SV20791.09
Pharma-APT tubing, silicone, 0.5 in. ID x 0.75 in. OD x 0.125 in. wall	SUT30120.14
Pumpsil™ tubing, silicone, 1/2 in. ID x 3/4 in. OD x 1/8 in. wall	SV20682.17
Silicone tubing, 1/2 in. ID x 3/4 in. OD x 1/8 in. wall	SV20019.10
Silicone tubing, 1/4 in. ID x 7/16 in. OD x 3/32 in. wall	SV20019.07
Silicone tubing, 1/8 in. ID x 1/4 in. OD x 1/16 in. wall	SV20019.02
Silicone tubing, 3/8 in. ID x 5/8 in. OD x 1/8 in. wall	SV20019.09
Sani-Tech™ STHT™-R tubing, braided silicone, 0.250 in. ID x 0.515 in. OD x 0.133 in. wall	SV20348.02
Sani-Tech™ STHT™-R tubing, braided silicone, 0.375 in. ID x 0.687 in. OD x 0.156 in. wall	SV20348.03
Sani-Tech™ STHT™-R tubing, braided silicone, 0.500 in. ID x 0.847 in. OD x 0.174 in. wall	SV20348.04
Thermoplastic elastomer (TPE) tubing, 1/2 in. ID x 3/4 in. OD x 1/8 in. wall	SV21678.10
TPE tubing, 1/4 in. ID x 1/2 in. OD x 1/8 in. wall	SV21678.08
TPE tubing, 1/8 in. ID x 1/4 in. OD x 1/16 in. wall	SV21678.02
TPE tubing, 3/8 in. ID x 5/8 in. OD x 1/8 in. wall	SV21678.09
Trelleborg™ tubing, braided silicone, 1/2 in. ID x .800 in. OD x .150 in. wall	SV21585.04
Trelleborg™ tubing, braided silicone, 1/4 in. ID x .520 in. OD x .135 in. wall	SV21585.02

Table 4. Fastener and fitting options.

Description*	Type	Material	Cat. No.
Fastener: cable tie, beaded, 10 in.	10 in. beaded CT		SV20030.12
Clamp: polyester, snapper clamp, 3/16–3/8 in.	Snapper clamp	Polyester	SV20031.02
Clamp: polyester, snapper clamp, 1/2–3/4 in.	Snapper clamp	Polyester	SV20031.03
Fitting: silicone, sanitary flange gasket, 1 1/2 in.	SF gasket	Silicone	SV20189.04
Fitting: silicone, sanitary flange gasket, 3/4 in.	Mini SF gasket	Silicone	SV20189.06
Fitting: silicone, sanitary flange gasket, 3 in.	XL SF gasket	Silicone	SV20189.07
Fitting: SmartSite™ needle-free valve port	SmartSite port		SV20271.01
Clamp: nylon, sanitary flange screw clamp, 1 1/2 in.	SF screw clamp	Nylon	SV20420.01
Clamp: nylon, sanitary flange screw clamp, 3/4 in.	Mini SF screw clamp	Nylon	SV20420.02
Clamp: nylon, sanitary flange screw clamp, 3 in.	XL SF screw clamp	Nylon	SV20420.03
Clamp: nylon, Pharmalok™ sanitary flange, 1 1/2 in.	Pharmalok SF	Nylon	SV20420.12
Clamp: nylon, Pharmalok™ sanitary flange, 3/4 in.	Pharmalok mini SF	Nylon	SV20420.13
Fitting: PC, female Luer lock, 1/8 in.	Female Luer lock	PC	SV20421.02
Fitting: PP, end plug, 1/8 in.	End plug	PP	SV20503.01
Fitting: PP, end plug, 1/4 in.	End plug	PP	SV20503.04
Fitting: PP, end plug, 3/8 in.	End plug	PP	SV20503.07
Fitting: PP, T connect, 1/8 in.	T connect	PP	SV20504.01
Fitting: PP, T connect, 1/4 in.	T connect	PP	SV20504.02
Fitting: PP, T connect, 1/2 in.	T connect	PP	SV20504.04
Fitting: PP, T connect, 1/2 in. x 1/2 in. x 1/4 in.	T connect	PP	SV20504.24
Fitting: PP, T connect, 1/2 in. x 1/2 in. x 3/8 in.	T connect	PP	SV20504.25
Fitting: PP, straight connect, 1/4 in. x 1/8 in.	Straight connect	PP	SV20505.03
Fitting: PP, straight connect, 1/2 in.	Straight connect	PP	SV20505.07
Fitting: PP, straight connect, 3/8 in. x 1/4 in.	Straight connect	PP	SV20505.11
Fitting: PP, straight connect, 1/2 in. x 1/4 in.	Straight connect	PP	SV20505.12
Fitting: PP, straight connect, 1/2 in. x 3/8 in.	Straight connect	PP	SV20505.13
Fitting: PP, male Luer lock, 1/8 in.	Male Luer lock	PP	SV20507.01
Fitting: PP, female Luer lock, 1/8 in.	Female Luer lock	PP	SV20507.02
Fitting: PC, stemless male Luer cap	Male Luer cap	PC	SV20613.01
Fitting: PP, cross connect, 1/8 in.	Cross connect	PP	SV20650.02
Fitting: PP, cross connect, 1/2 in.	Cross connect	PP	SV20650.06
Clamp: nylon/PSU, heavy duty clamp, 3/16–1/2 in. ID with 0.085–0.200 in. wall	Heavy duty clamp	Nylon/PSU	SV20664.01
Fitting: PSU, male Lynx™ S2S, 1/2 in.	Male Lynx S2S	PSU	SV20710.02
Fitting: PC, PendoTECH™ pressure sensor press-N-050-B, 1/2 in.	PendoTECH pressure sensor	PC	SV20826.11
Fitting: PC, PendoTECH™ pressure sensor press-N-050-30, 1/2 in.	PendoTECH pressure sensor	PC	SV20826.12

Table 4. Fastener and fitting options (cont.).

Description*	Type	Material	Cat. No.
Fitting: PC, PendoTECH™ pressure sensor press-N-050-60, 1/2 in.	PendoTECH pressure sensor	PC	SV20826.13
Fitting: PC, PendoTECH™ pressure sensor press-N-025-30, 1/4 in.	PendoTECH pressure sensor	PC	SV20826.21
Fitting: SS, straight connect, 1/8 in. x 1/8 in.	Straight connect	SS	SV20849.01
Fitting: PP, 3/4 in. sanitary flange, 1/4 in.	Mini SF	PP	SV21011.02
Fitting: PP, 3/4 in. sanitary flange, 3/8 in.	Mini SF	PP	SV21011.03
Fitting: PP, 3/4 in. sanitary flange, 1/2 in.	Mini SF	PP	SV21011.04
Fitting: PP, 1 1/2 in. sanitary flange, 3/8 in.	SF	PP	SV21011.08
Fitting: PP, 1 1/2 in. sanitary flange, 1/2 in.	SF	PP	SV21011.09
Fitting: PP, 1 1/2 in. sanitary flange cap	SF cap	PP	SV21011.14
Fitting: PP, 3/4 in. sanitary flange cap	Mini SF cap	PP	SV21011.15
Fitting: HDPE, 3/4 in. SF x 1/4 in. HB, with SterilEnz™ gasket	SterilEnz II with gasket	HDPE	SV21012.11
Fitting: HDPE, 3/4 in. SF x 1/2 in. HB, with SterilEnz™ gasket	SterilEnz II with gasket	HDPE	SV21012.13
Fitting: HDPE, 1 1/2 in. SF x 1/2 in. HB, with SterilEnz™ gasket	SterilEnz II with gasket	HDPE	SV21012.16
Fitting: PC, AseptiQuik™ G fitting, 1/4 in.	AseptiQuik G	PC	SV21289.01
Fitting: PC, AseptiQuik™ G fitting, 1/2 in.	AseptiQuik G	PC	SV21289.03
Fastener: nylon, PharmaLok™ tube clamp, 1/2 in. to 7/8 in. ID tubing (1/8 in. or greater wall)	PharmaLok clamp	Nylon	SV21453.01
Fastener: nylon, PharmaLok™ tube clamp, 1/2 in. OD tubing max (1/32–3/32 in. wall)	PharmaLok clamp	Nylon	SV21453.03
Fitting: PC, sanitary flange cap, 3 in.	XL SF cap	PC	SV21469.01
Fitting: silicone temperature probe and sampling insert for 1 in. port	Temperature probe	Silicone	SV21487.01
Clamp: NovaSeal™ clamp, crimp, 3/8 in. ID x 5/8 in. OD	NovaSeal clamp		SV2A038.02
Clamp: NovaSeal™ clamp, crimp, 3 mm ID x 6 mm OD	NovaSeal clamp		SV2A038.04
Polybag: PE, resealable polybag	Extra polybag		SV50031

* Abbreviations:

CT: cable tie

EPDM: ethylene propylene diene monomer

HDPE: high-density polyethylene

PC: polycarbonate

PE: polyethylene

PP: polypropylene

PSU: polysulfone

S2S: sterile-to-sterile

SF: sanitary flange

SS: stainless steel

XL: extra large

Table 5. Beta bag options.*

Description	Size	Flange	Cat. No.
DPTE beta bag	30 L	190 mm	SUT30048.01
DPTE beta bag	30 L	105 mm	SUT30048.02
DPTE beta bag, autoclavable	30 L	190 mm	SUT30182.01
Aseptic transfer single-use bag	15 L	110 mm	SUT21566

* More options will be added.

Table 6. Surge bag options.

Description	Size	Film	Cat. No.
Labtainer Pro Surge Bag with 3/8 in. and 1/4 in. face ports	5 L	Aegis5-14 film	SUT21897
Labtainer Pro Surge Bag with 1/4 in. face port	5 L	Aegis5-14 film	SUT21896

Table 7. Needle options.

Description	Inner diameter	Material	Cat. No.
Syntegon™ PreVAS single-use filling needle	1.2 mm	Stainless steel	SV21217.01
Syntegon™ PreVAS single-use filling needle	1.6 mm	Stainless steel	SV21217.02
Syntegon™ PreVAS single-use filling needle	2.1 mm	Stainless steel	SV21217.03
Syntegon™ PreVAS single-use filling needle	3.0 mm	Stainless steel	SV21217.04
Syntegon™ PreVAS single-use filling needle	3.8 mm	Stainless steel	SV21217.05
Syntegon™ PreVAS single-use filling needle	4.6 mm	Stainless steel	SV21217.06
Syntegon™ PreVAS single-use filling needle	5.5 mm	Stainless steel	SV21217.07
Allegro™ filling needle	1.6 mm	PEEK	SV2A094.02
Allegro™ filling needle	0.8 mm	PEEK	SV2A094.01
Allegro™ filling needle	4.0 mm	PEEK	SV2A094.05
Allegro™ filling needle	2.4 mm	PEEK	SV2A094.08
Allegro™ filling needle	1.2 mm	PEEK	SV2A094.09
IMA filling needle (MPA/OVLK)	1.0 mm	Stainless steel	SUT30073.01
IMA filling needle (MPA/OVLK)	3.0 mm	Stainless steel	SUT30073.02
OneShot™ single-use IMA filler needle with spool hub	1.0 mm	Stainless steel	SUT30091.01
OneShot™ single-use IMA filler needle with spool hub	3.0 mm	Stainless steel	SUT30091.02
OneShot™ single-use IMA filler needle with spool hub	5.0 mm	Stainless steel	SUT30091.03
OneShot™ single-use IMA filler needle with spool hub	1.5 mm	Stainless steel	SUT30091.04
OneShot™ single-use IMA filler needle with spool hub	0.8 mm	Stainless steel	SUT30091.05
OneShot™ single-use IMA filler needle with spool hub	4.0 mm	Stainless steel	SUT30091.06
OneShot™ single-use IMA filler needle with spool hub	1.6 mm	Stainless steel	SUT30091.11
OneShot™ single-use IMA filler needle with spool hub	2.0 mm	Stainless steel	SUT30091.12
OneShot™ single-use IMA filler needle with spool hub	2.1 mm	Stainless steel	SUT30091.13
OneShot™ single-use IMA filler needle with spool hub	2.5 mm	Stainless steel	SUT30091.14
OneShot™ single-use IMA filler needle with spool hub	3.2 mm	Stainless steel	SUT30091.15
OneShot™ single-use IMA filler needle with spool hub	3.4 mm	Stainless steel	SUT30091.16
OneShot™ single-use IMA filler needle with spool hub	3.5 mm	Stainless steel	SUT30091.17
OneShot™ single-use IMA filler needle with spool hub	4.4 mm	Stainless steel	SUT30091.18
OneShot™ single-use IMA filler needle with spool hub	4.8 mm	Stainless steel	SUT30091.19

Table 7. Needle options (cont.).

Description	Inner diameter	Material	Cat. No.
OneShot™ 316L SS Inova filler needle	1.1 mm	Stainless steel	SUT30106.01
OneShot™ 316L SS Inova filler needle with 8 mm hub	2.1 mm	Stainless steel	SUT30106.02
OneShot™ 316L SS Inova filler needle with 8 mm hub	3.0 mm	Stainless steel	SUT30106.03
OneShot™ 316L SS Inova filler needle with 8 mm hub	2.5 mm	Stainless steel	SUT30106.04
OneShot™ 316L SS Inova filler needle with 8 mm hub	4.0 mm	Stainless steel	SUT30106.05
OneShot™ 316L SS Inova filler needle with 8 mm hub	5.0 mm	Stainless steel	SUT30106.06
OneShot™ 316L SS Inova filler needle with 8 mm hub	3.2 mm	Stainless steel	SUT30106.07
OneShot™ 316L SS Inova filler needle with 8 mm hub	1.6 mm	Stainless steel	SUT30106.08
OneShot™ 316L SS Inova filler needle with 13 mm hub	1.6 mm	Stainless steel	SUT30106.09
OneShot™ 316L SS Inova filler needle with 13 mm hub	2.1 mm	Stainless steel	SUT30106.10
OneShot™ 316L SS Inova filler needle with 13 mm hub	3.0 mm	Stainless steel	SUT30106.11
OneShot™ 316L SS Inova filler needle with 13 mm hub	3.2 mm	Stainless steel	SUT30106.12
OneShot™ 316L SS Inova filler needle with 13 mm hub	5.0 mm	Stainless steel	SUT30106.13
OneShot™ 316L SS Inova filler needle with 8 mm hub	1.5 mm	Stainless steel	SUT30106.14
OneShot™ 316L SS Inova filler needle with 13 mm hub	3.5 mm	Stainless steel	SUT30106.15
OneShot™ 316L SS Inova filler needle with 13 mm hub	4.8 mm	Stainless steel	SUT30106.16
OneShot™ 316L SS Inova filler needle with 8 mm hub	2.0 mm	Stainless steel	SUT30106.22
OneShot™ 316L SS Inova filler needle with 8 mm hub	3.4 mm	Stainless steel	SUT30106.23
OneShot™ 316L SS Inova filler needle with 8 mm hub	3.5 mm	Stainless steel	SUT30106.24
OneShot™ 316L SS Inova filler needle with 8 mm hub	4.4 mm	Stainless steel	SUT30106.25
OneShot™ 316L SS Inova filler needle with 8 mm hub	4.8 mm	Stainless steel	SUT30106.26
OneShot™ 316L SS Inova filler needle with 13 mm hub	1.5 mm	Stainless steel	SUT30106.34
OneShot™ 316L SS Inova filler needle with 13 mm hub	2.0 mm	Stainless steel	SUT30106.35
OneShot™ 316L SS Inova filler needle with 13 mm hub	2.5 mm	Stainless steel	SUT30106.36
OneShot™ 316L SS Inova filler needle with 13 mm hub	3.4 mm	Stainless steel	SUT30106.37
OneShot™ 316L SS Inova filler needle with 13 mm hub	4.0 mm	Stainless steel	SUT30106.38

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