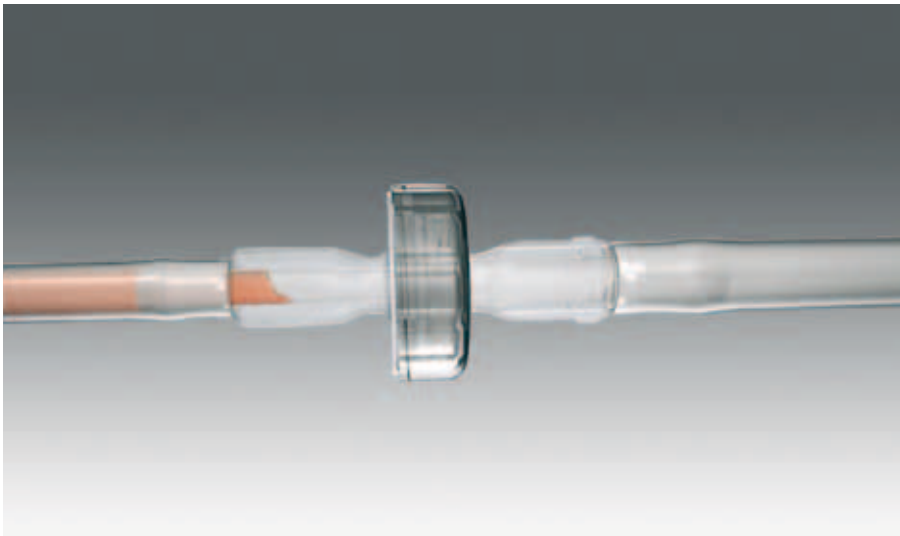




# Opta® SFT

Sterile Connector to be integrated into Sartorius Stedim Biotech Fluid Management assemblies (Opta® SFT-I) and also available as individual device for end-user assembly with silicone tubing (SFT-I) or TPE tubing (SFT-D) and autoclave sterilization



## Features & Benefits

Male and female connector couplings sealed with sterilizing grade membrane	Allows for sterile fluid transfer in non classified & classified environments
Male and female connector couplings	Allows for "error proofing" of designs to prevent mistaken connections.
Sterilizable by Gamma irradiation & Autoclave	Flexible implementation of Hybrid single-use and multiple use technologies.
100% integrity tested	Highest security
Claimed size equivalent to tubing ID size	No flow restriction
3-step operation	Easy, Robust, Repeatable Operation
All hose barb connections intensively qualified (SFT-I only)	Safe and robust tubing connections
Fully integrated supply chain for Opta® SFT-I incorporating single-use assemblies from Sartorius Stedim Biotech	Streamlined supply chain, high security of supply

### Description

The Opta® SFT Sterile Connector is a single-use device that allows a sterile connection between two separate, pre-sterilized components in biopharmaceutical manufacturing processes. Opta® SFT Sterile Connectors are quick and easy to use, and are backed by extensive validation work and 100% in house integrity testing.

The Opta® SFT-D is available as individual device for end-user assembly with TPE tubing and autoclave sterilization.

### Ultra Safe Hose Barb Design

The dimensions of Opta® SFT-I hose barbs have been specifically designed to assure the robustness and the integrity of the engagement between hose barb and various types of tubing. This is a key requirement for sterile fluid transfer in critical biopharmaceutical applications. Special tools in manufacturing guarantee the proper attachment to any type of tubing. Thus the Opta® SFT-I Sterile Connector is supplied with Flexel® 3D and Flexboy® bags as part of integrated Sartorius Stedim Biotech Fluid Management assemblies. The Opta® SFT-I is also available as individual device for end-user assembly with silicone tubing and autoclave sterilization.

Ready to Autoclave or Gamma sterilised transfer sets with Opta® SFT-I are also available to ensure the counter connection to customers process equipment.

## Specifications

### Materials for Male and Female coupling

Connector body & collar:	Polycarbonate
Seal:	
Seal small connector:	Santoprene
Seal large connector:	EPDM
Membrane:	Hydrophobic polyethersulfone
Protective cap:	Polypropylene

### Connections

Small connector body:	1/4", 3/8" and 1/2" Hose Barb
Large connector body:	3/4" Hose Barb

### Pressure resistance

Max. operating pressure:	3 bar (43.5 psi) at 40°C (104°F)
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### Sterilization Methods

Gamma irradiation:	≤ 50 kGy
Autoclaving:	20 minutes at 121°C (250°F)

### Simple & fast operation principle

The Opta® SFT Sterile Connector consists of a female and a male coupling body that once assembled create the sterile fluid path via an easy 3-step operation. The removal of the protective plastic caps attached to each coupling prepares for assembly. After sliding the male and female coupling heads together, the sterile barrier membrane is pulled out to create the sterile fluid path. Finally, the locking collar is screwed into place. The Opta® SFT Sterile Connector is now ready for the sterile fluid transfer.

## Operating Sequences



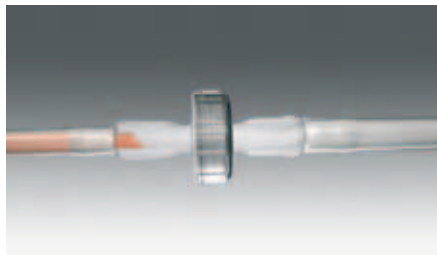
1. Remove protective cap and connect the Opta® SFT male and female connectors – correct connection validated by a click



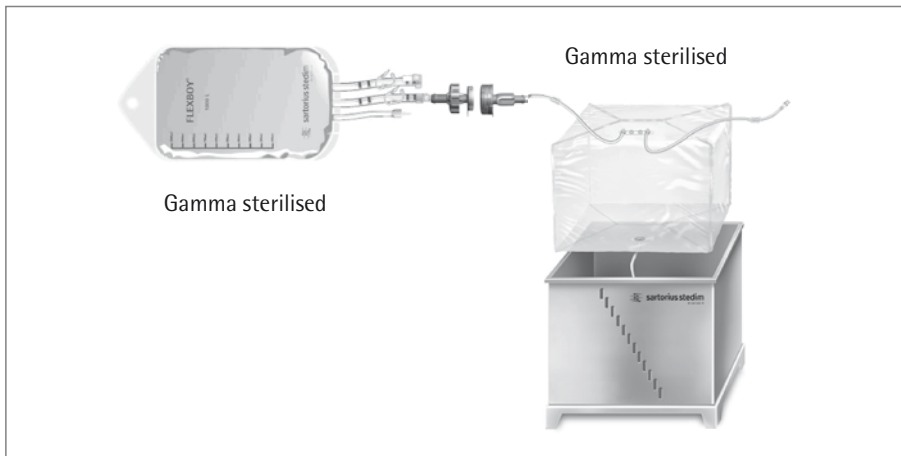
2. Remove membranes



3. Screw the collar – correct screwing validated by a click



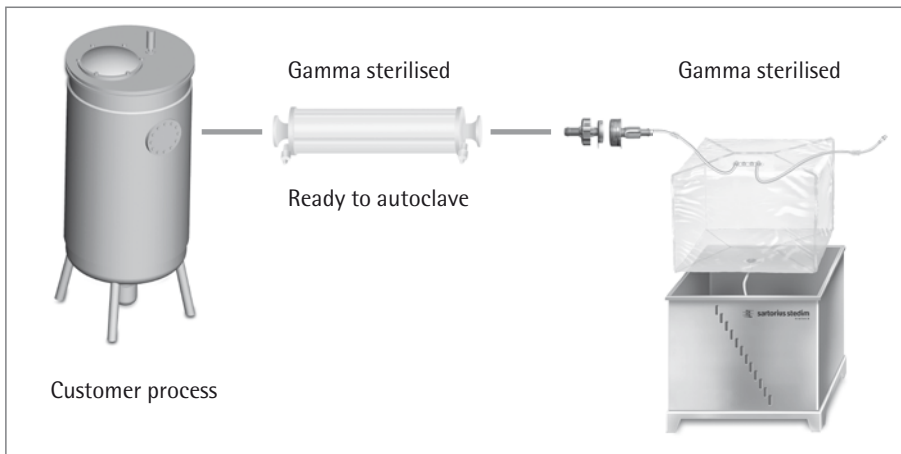
Transfer fluid



Details on methodologies and equipment used as well as further tests performed are available in the Validation Guide.

#### **Sterile Fluid Transfer Validation**

Opta<sup>®</sup> SFT Sterile Connectors has been validated to provide a sterile fluid transfer path under worst case conditions. In order to provide the assurance that the Opta<sup>®</sup> SFT can provide a sterile fluid path in your process, a comprehensive validation, including immersion of the male and female connector bodies in a bacterial suspension prior to connection, followed by the transfer and subsequent incubation of growth promotion medium has been performed. Complete details of this validation are available in our validation guide.



#### **Applications**

Opta<sup>®</sup> SFT Sterile Connectors are used to create a sterile fluid path between two pre-sterilized components in classified as well as non classified production environments. All operations in Up – and Downstream Processing that are using single-use or hybrid equipment can benefit from the Opta<sup>®</sup> SFT Sterile Connector from Sartorius Stedim Biotech.

#### **Quality Assurance**

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

#### **Integration**

All Opta<sup>®</sup> SFT-I connectors can be integrated into custom Sartorius Stedim Biotech assembly including a full range of additional disposable components.

Opta<sup>®</sup> SFT-I are pre-assembled to bags, filters and tubing and then Gamma sterilised to offer a ready to use solution. They can also be assembled on tubing and filtration sets without Gamma sterilisation to offer ready to autoclave solutions to end users when autoclaving is required in the process.

#### **100% integrity tested**

All Opta<sup>®</sup> SFT Sterile Connectors are 100% integrity tested to assure the highest quality for critical applications like sterile fluid transfer.

#### **Qualification**

Opta<sup>®</sup> SFT Sterile Connector has been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Opta<sup>®</sup> SFT sterile connectors with data representing a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of  $10^{-6}$  over the shelf life.

Opta<sup>®</sup> SFT Sterile Connectors are tested for compliance to:

- USP <85>: Bacterial Endotoxin testing
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <645>: pH and conductivity
- USP <788> and E.P. 2.9.19: Particulate
- ISO 11737: Bioburden
- ISO 11137: Sterilization of Medical Devices

#### **Security of Supply**

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes for its fully integrated disposable assemblies. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

## Ordering information

### OPTA® SFT-I Small body for assembly with Silicone tubing

Product code	Description	Pack size
640MS014M---D	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Male Small Connector Body.	10
640FS014M---D	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Female Small Connector Body.	10
640MS038M---D	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Male Small Connector Body.	10
640FS038M---D	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Female Small Connector Body.	10
640MS012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Male Small Connector Body.	10
640FS012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Female Small Connector Body.	10

### OPTA® SFT-I Large body for assembly with Silicone tubing

Product code	Description	Pack size
640ML034M---D	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Male Large Connector Body.	10
640FL034M---D	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Female Large Connector Body.	10

### OPTA® SFT-D Small body for assembly with TPE tubing

Product code	Description	Pack size
641MS014M---D	OPTA® SFT-D Sterile Connector, 1/4" Hose Barb, Male Small Connector Body.	10
641FS014M---D	OPTA® SFT-D Sterile Connector, 1/4" Hose Barb, Female Small Connector Body.	10
641MS038M---D	OPTA® SFT-D Sterile Connector, 3/8" Hose Barb, Male Small Connector Body.	10
641FS038M---D	OPTA® SFT-D Sterile Connector, 3/8" Hose Barb, Female Small Connector Body.	10
641MS012M---D	OPTA® SFT-D Sterile Connector, 1/2" Hose Barb, Male Small Connector Body.	10
641FS012M---D	OPTA® SFT-D Sterile Connector, 1/2" Hose Barb, Female Small Connector Body.	10

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