Installation Instructions

# Opta® SFT Sterile Connector

85034-535-93

SARTORIUS

The purpose of this document is to outline the appropriate standard operating procedure for identifying and using a Sartorius Opta® SFT Sterile Connector. Operators must be trained to follow this operating procedure for assuring the correct use of the product.

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# 1 Labelling

The part number and the lot number of an Opta® SFT Sterile Connector are printed on the body of each connector. The identical specification and product name are printed on the label of the plastic bag.

# 2 Sterilization Instructions

The Opta® SFT Sterile Connector may be sterilized using gamma irradiation to a maximum 1 cycle of ≤ 50 kGy or alternatively using autoclaving for maximum two cycles of 40 minutes at 125°C.

**NOTICE**

Opta® SFT Sterile Connector products cannot be in-line steam sterilized.

## 2.1 Autoclaving

### NOTICE

Only autoclave Opta® SFT Sterile Connector in an unconnected state. Autoclaving in connected state could cause a reduction of sealing force of the elastic seal and lead to leakage.

Condensation can occure during the heating and exposure phases in the autoclaving processes. In an ideal case the condensate flows to the waste line at the bottom of the autoclave. If the condensate flows into a dead end, it will collect there.

A connector with a hydrophobic membrane can act as a dead end. Condensate can cover the membrane completely and make it impermeable. This can lead to the evacuation and steam pulse generating a large force on the membrane (due to pressure difference behind and in front of the membrane) so that the heat sealing of membrane can be damaged.

### NOTICE

To avoid damaging the Opta® SFT Sterile Connector membrane while autoclaving in the assembled state ensure that the generated condensate does not flow onto the membrane.

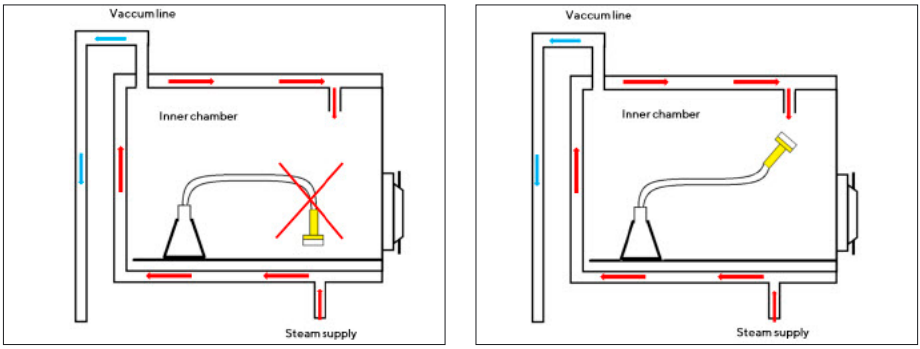



Abb. 1: Position of Opta® STR Sterile Connector while autoclaving

# 3 Maximal Allowable Operating Pressure

The following table indicates the pressure-temperature resistance values in operation:

| | |
|---|---|
| Opta® SFT | 3 bar (43.5 psi) |

**NOTE**

For the tubing assembly qualification, please refer to the validation guide.

# 4 Making the Connection

The female and the male part of the connector are supplied with protective caps.

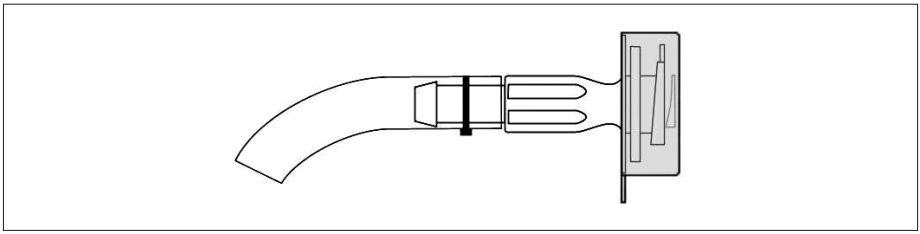


Abb. 2: Male connector

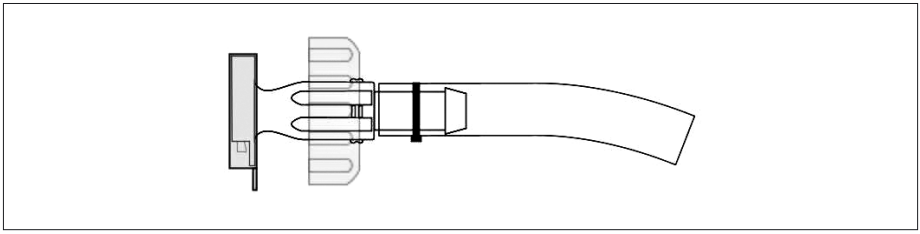


Abb. 3: Female connector

### Step 1

Remove the protective caps by pulling on the flaps that are located at the bottom of each cap. Visually check that the locking pins are in a proper state. After removal of the caps membrane tapes will be released. These membrane tapes should always hang down to assure the correct assembly of the male and female connector bodies.

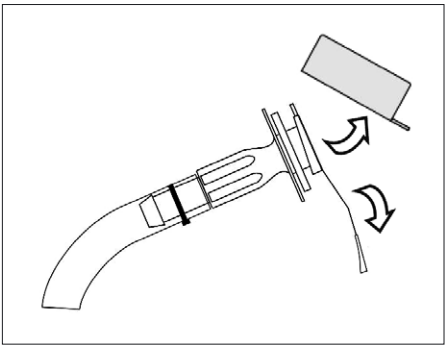
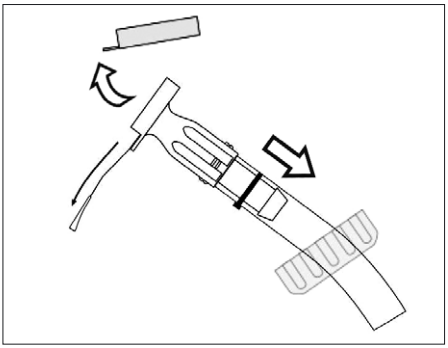


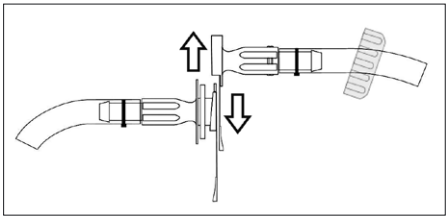
Abb. 4: Male connector



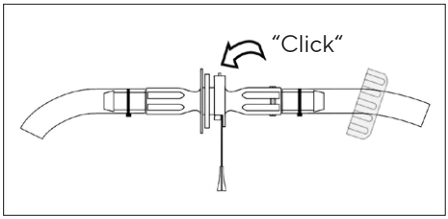
Female connector

If the connector was stored in refrigerated or frozen conditions, condensation can cause water droplet formation on the membrane. In that case, gently dry the membrane with a soft tissue after removing the protective cap.

### Step 2

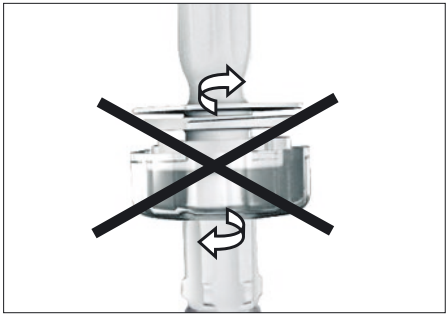


Retract the collar that is fixed on the female connector to prepare for assembly. Assemble the two connectors by sliding the two connector heads together until the two pins of the male connector click into place. Once the female and the male connectors are assembled they should not be disassembled.




The integrity of the male and female connectors is ensured by the membrane sterile barrier. Each membrane tape is equipped with a mating gripper to assure simultaneous removal of the sterile barrier.

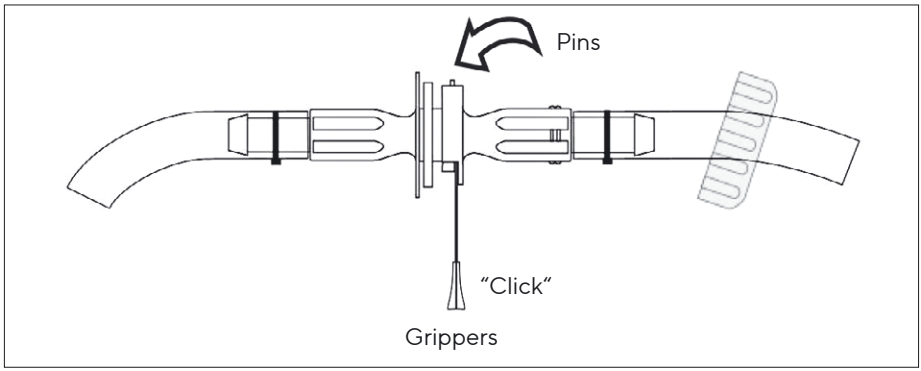
## NOTICE



Do **not** rotate Opta® male or female during the sliding step as it could bend a pin resulting in defective connection.

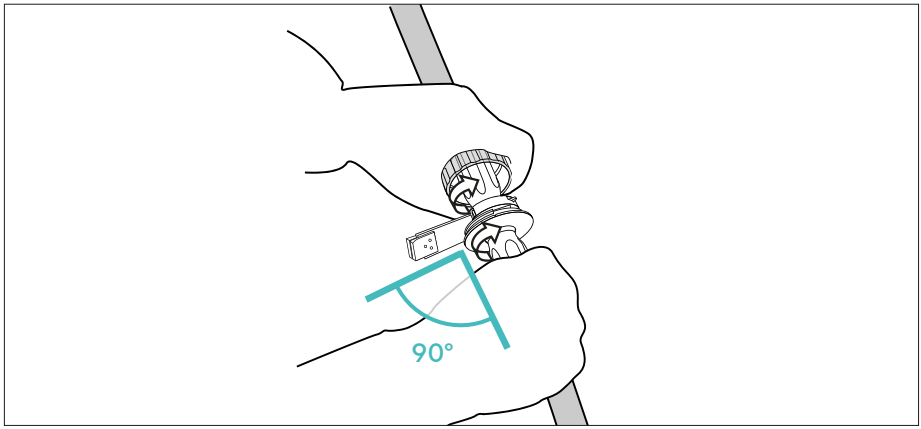
### Step 3

After the two pins of the male connector are “clicked” into place, join the grippers at the bottom of each membrane tape together. The grippers should also “click” into place.



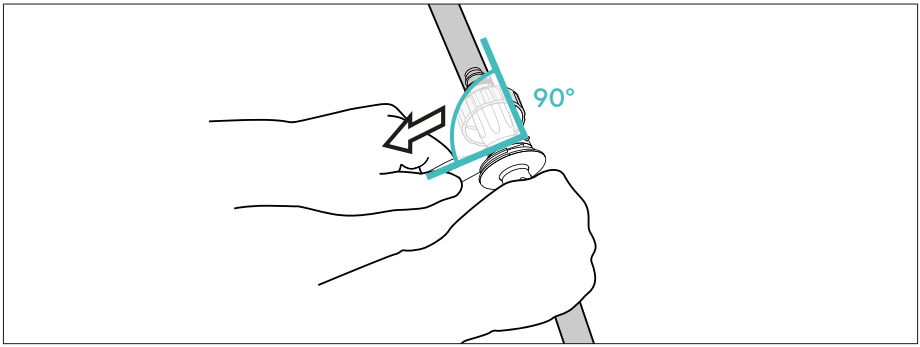

### Step 4

Hold on the grippers perpendicular to the connector bodies, and rotate the device by 90° to get the membrane in the horizontal position.



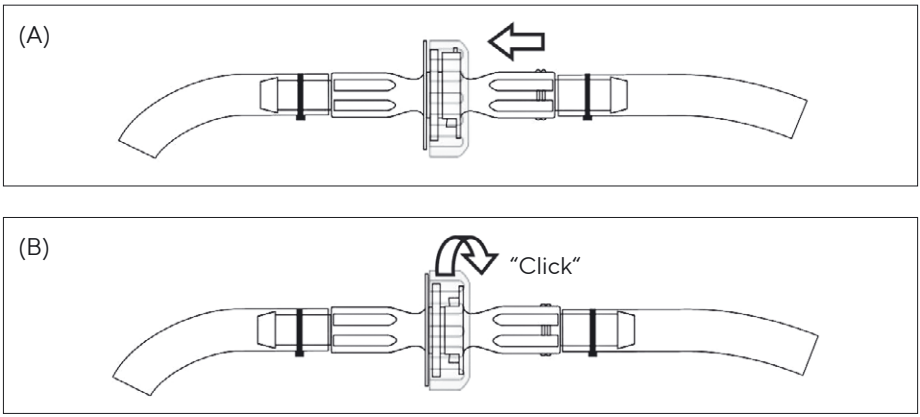
### Step 5

Take the handle in one hand and gently remove the membrane horizontally with the other hand.




### Step 6

(A) Slide the collar that has been retracted back in place and (B) turn it clockwise until the lock "clicks" into place.




### Step 7

A sterile fluid path has now been achieved. The Opta® SFT Sterile Connector is now ready for the sterile fluid transfer.

# 5 Applications Support

Please contact your local Sartorius representative to obtain more detailed information and technical data. Our application specialists distributed around the globe have been trained to support your trials and develop your application.

We support users from the design and implementation phase of biopharmaceutical manufacturing processes with the most comprehensive support program that ensures successful design, implementation and validation of Single-Use Manufacturing.

# 6 Return of used Opta® SFT Sterile Connectors

All used connectors should be properly sterilized prior to shipping to Sartorius. This allows our technical staff to handle them with minimal risk during the inspection. The German law requires that a return shipment form (available through your local Sartorius representative) must be completed prior to shipping of used products.

# 7 Liability

Sartorius cannot assume liability if the Opta® SFT Sterile Connectors are subjected to improper use. In the interest of product development we reserve the right to make changes.

# 8 Ordering Information

This document pertains to Sartorius Opta® SFT Sterile Connector products with the following part numbers:

**Opta® SFT-I Small body for assembly with Silicone tubing**

| Product code | Description | Pack size |
|---|---|---|
| 640MS014M---D | Opta® SFT-I Sterile Connector, ¼" Hose Barb, Male Small Connector Body | 10 |
| 640FS014M---D | Opta® SFT-I Sterile Connector, ¼" Hose Barb, Female Small Connector Body | 10 |
| 640MS038M---D | Opta® SFT-I Sterile Connector, ⅜" Hose Barb, Male Small Connector Body | 10 |
| 640FS038M---D | Opta® SFT-I Sterile Connector, ⅜" Hose Barb, Female Small Connector Body | 10 |
| 640MS012M---D | Opta® SFT-I Sterile Connector, ½" Hose Barb, Male Small Connector Body | 10 |
| 640FS012M---D | Opta® SFT-I Sterile Connector, ½" Hose Barb, Female Small Connector Body | 10 |

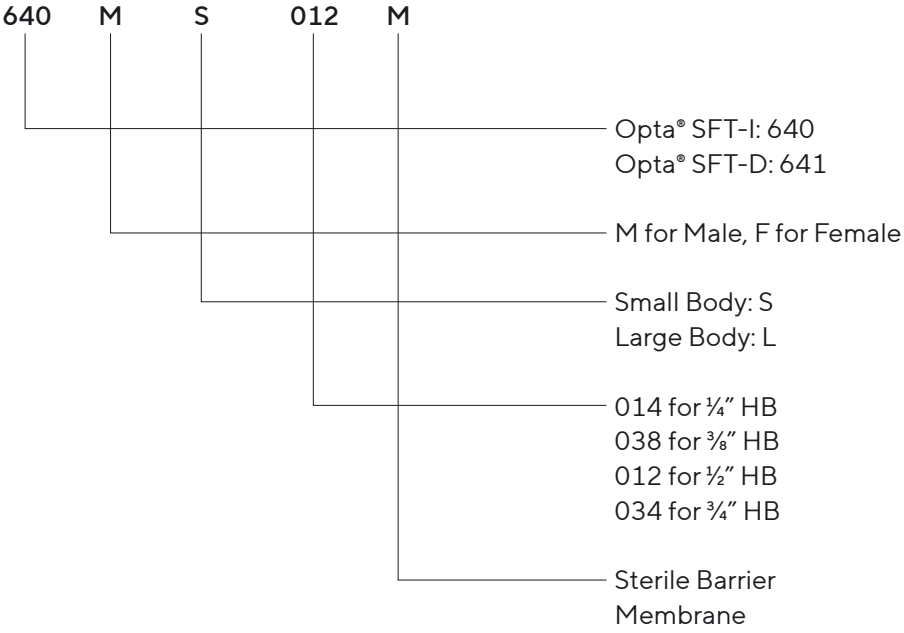
### Opta® SFT-I Large body for assembly with Silicone tubing

| Product code | Description | Pack size |
|---|---|---|
| 640ML034B---D | Opta® SFT-I Sterile Connector, ¾" Hose Barb, Male Large Connector Body | 10 |
| 640FL034M---D | Opta® SFT-I Sterile Connector, ¾" 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, ¼" Hose Barb, Male Small Connector Body | 10 |
| 641FS014M---D | Opta® SFT-D Sterile Connector, ¼" Hose Barb, Female Small Connector Body | 10 |
| 641MS038M---D | Opta® SFT-D Sterile Connector, ⅜" Hose Barb, Male Small Connector Body | 10 |
| 641FS038M---D | Opta® SFT-D Sterile Connector, ⅜" Hose Barb, Female Small Connector Body | 10 |
| 641MS012M---D | Opta® SFT-D Sterile Connector, ½" Hose Barb, Male Small Connector Body | 10 |
| 641FS012M---D | Opta® SFT-D Sterile Connector, ½" Hose Barb, Female Small Connector Body | 10 |

**Example for part number codification:**



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The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.



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