Operating Instructions

SART System™

Gammasart Aseptic Transfer Device (ATD™) and SART Port

85030-531-26

SARTORIUS

Contents

1 The SART System™

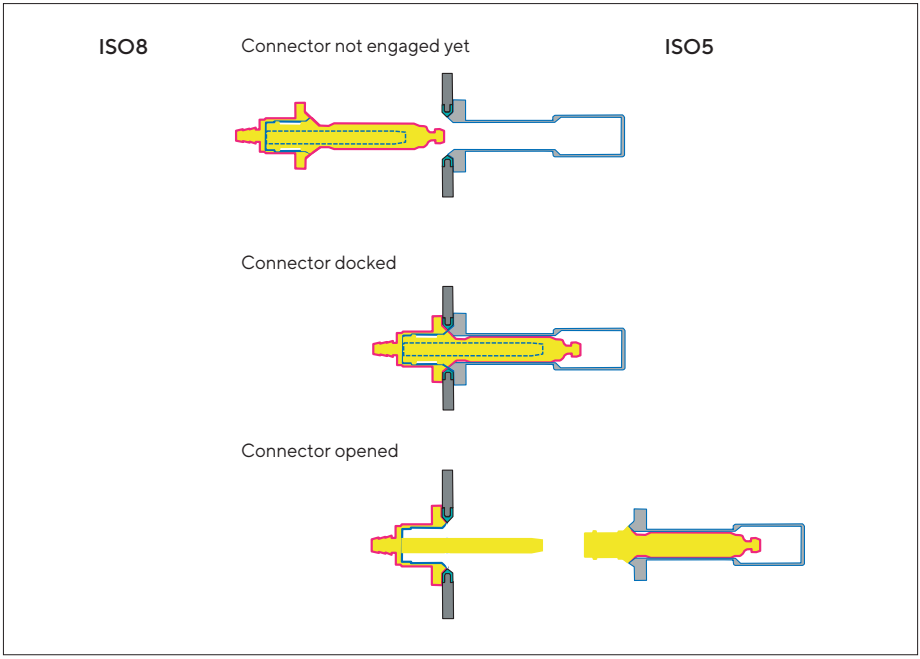
1.1 Introduction

The SART System™ is designed to allow liquid transfer between two areas with different containment classification. Among the most common applications are:

- Transfer from a clean room class ISO8 | Grade C to an isolator or a RABS (class ISO5 | Grade A). The isolator could be e.g., a filling isolator, a formulation isolator or a glove box for research;
- Distribution of liquid in multiple containers (e.g., division of a formulation lot in multiple sub-lots for storage);
- Aseptic transfer for research application (e.g., cell culture)
- Elimination of waste solution;
- Etc.

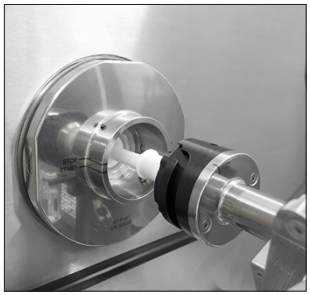
For these purposes, the SART Port is associated with a disposable connection device.

The following table describes the process of aseptic transfer between ISO8 and ISO5 environments using a Gammasart Aseptic Transfer Device (ATD™).



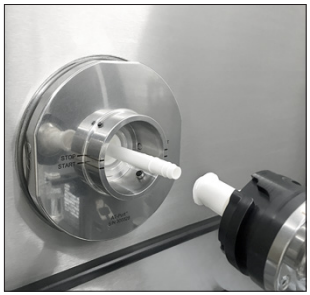
The connector device (1) is connected to the bulk container.

The device is introduced and locked into the external port mounted on the wall between the ISO8 and ISO5 areas.



Inside the ISO5 chamber, the connector cover is clamped within the internal port (2), and then the internal port is opened by rotation.

The connector cover is enclosed and locked within the internal port (3), and the connecting tube hosebarb is uncovered and exposed in the ISO5 chamber.



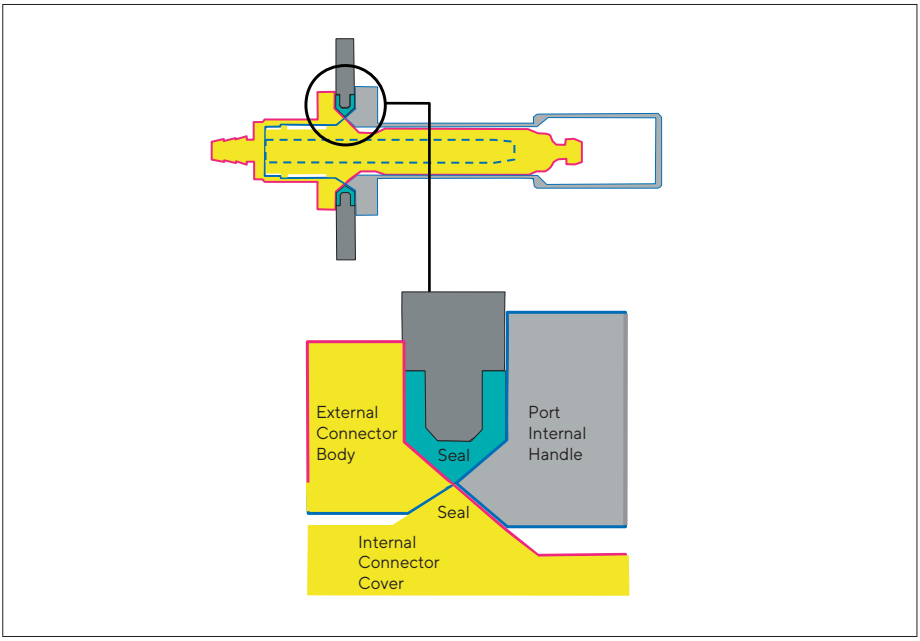
An aseptic connection is manually made to the connecting tube (4) in the ISO5 chamber.

Liquid transfer can start immediately.

1.2 The Alpha-Beta Concept

The SART System™ for fluid transfer is based on the Alpha-Beta concept – a well-accepted concept for transfer to a contained area – based on the principle that four V-points come together at the top and that all surfaces are in close contact with another one at a moment of time.

The extremities of each point make a line called “ring of concern”. The close contact between surfaces is ensured by having two opposite flexible joints, i.e., the thermoplastic elastomer seal on the connector cover and the silicone seal on the port.



This concept leads to the existence of two different surface conditions: one is less clean and exposed to the lowest containment classification spaces | areas and the other one is sterile and exposed to the highest containment classification spaces | areas, highest containment classification space | area is defined as the one having the highest ISO classification.

When the connector is not yet engaged in the port, the surfaces of the connector are exposed to the area with the lower level of environmental classification (ISO 8) and the sterile, interior surfaces are protected by connector seal edges being in tight contact with each other.

Once the connector is opened, the surfaces of the connector are exposed and the exterior connector surfaces are protected by tight contact. This prevent the surfaces from contaminating each other.

2 Overview of the SART System™

2.1 Description of the SART Port

The SART Port consists of 4 elements:

- The external port, which is permanently installed on the wall separating the two areas.
  - The purpose of the external portion of the port is first, to secure the connector body and, second, to secure the docking of the internal port on the other side of the wall. Interlocks are managed by the external port.
- The internal port, which can be unscrewed and separated from the external port.
  - The purpose of the internal port is to encapsulate the connector cover. This is accomplished by clamping onto the end of the connector by means of the handle and screwing it from the connector body.
- The internal port plug, which is added to the internal port to close it.
  - The purpose of the internal port plug is to protect the internal port mechanism during cleaning and sanitization.
- The external port cover, which is designed to seal the transfer port during cleaning and sanitization.

Fig. 1: Overview of the external port from outside the containment (left) and from inside the containment (right)

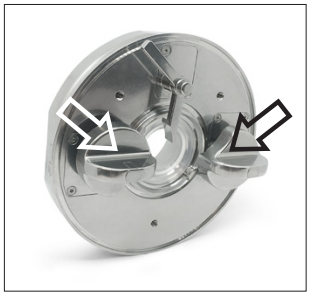
Fig. 2: View of the internal port (left), the external port **cover** (middle) and internal port **plug** (right)

2.2 Interlocks

To ensure the maximum safety in operation, the SART Port is equipped with the following interlocks:

- Connector presence:
  The internal port cannot be manipulated without a connector fully engaged in the external port. Presence of a connector fully engaged is detected by **the lever**. To engage a connector into the external port, the lever that obstructs the entry must first be moved to the correct position.

  This is to prevent opening of the internal port on the inside of the contained area when a connector is not fully secured in the external port, even if the two clamping buttons are in the closed position by mistake.



- Connector locking mechanism:
  The internal port can be manipulated only when both **clamping buttons** are in closed position.

  This is to prevent opening of the internal port on the inside of the contained area when a connector is fully engaged but is not fully secured by both clamping buttons.

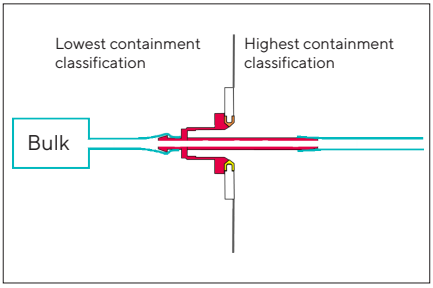
- Internal port detection:
  Both clamping buttons are blocked in the closed position until the internal port is fully docked to the external port. This is to prevent removal of the connector from the outside of the contained area while the internal port is not – or not totally – docked. This would jeopardize the integrity of the containment.

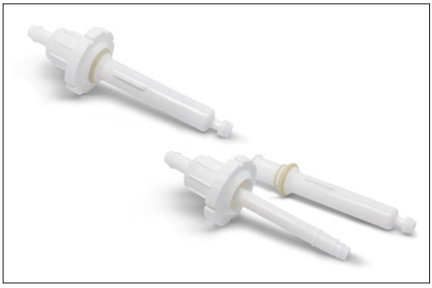
As a consequence, the external port hole is always closed, either by a connector properly secured or by the internal port totally docked.

2.3 Description of the Gammasart Aseptic Transfer Device (ATD™)

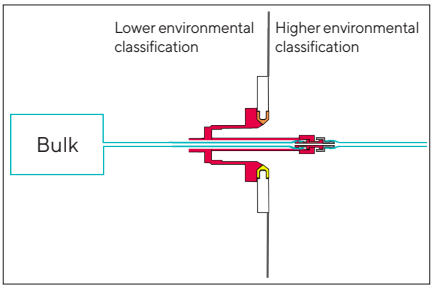
Different disposable connection devices can be operated with the SART Port, depending on the application.

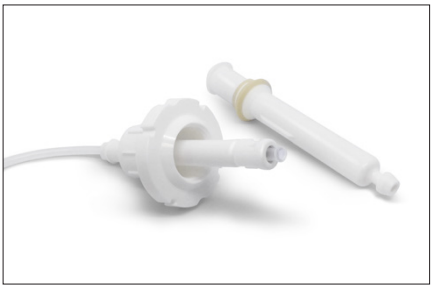
- The Gammasart ATD™ is a connector designed for the transfer of significant quantities of liquids thanks to its ⅜ inch internal diameter.





- The AT-Connect™ is a connector designed for the transfer of small quantities of product. The connection inside the containment is ensured via a Luer-lock to a tube connected to the bulk on the other side. There is no product contact with the connector device material. This connector is distributed by Aseptic Technologies.





All these connecting devices are made of PBT with an over-molded seal made of a thermoplastic elastomer. Refer to the relevant connector device specification for more details.

Connecting devices can be delivered either gamma-irradiated or ready for gamma sterilization. Irradiated devices may not be re-irradiated.

3 Preparation and Installation

3.1 Preparing the Gammasart ATD™

3.1.1 Gamma Irradiation

Gammasart ATD™ are supplied in two packaging formats: the blister packaging is used for connectors that have undergone gamma-irradiation and the shrink-band packaging is used for assemblies that will undergo the irradiation process later when installed onto a single-use bag or tubing assemblies.

Since one-time gamma-irradiation is mandatory, it is important that each type of packaging be used for its intended purpose.

It is also critical that an irradiated Gammasart ATD™ is not subjected to any additional irradiation procedure that has not been validated. The maximum validated irradiation dose is 45 kGray.

3.1.2 Assembling onto Containers

The connector device is designed to allow liquid transfer from an area with a lower environmental classification to an area with a higher environmental classification.

To protect the liquid, the connector device should be connected to the container located in the lowest environmentally classified area, with the final connection done inside the area with the higher environmental classification.

The following recommendations should be observed to ensure optimal assembly of the Gammasart ATD™:

- Always assemble before the last sterilization step (for non pre-irradiated connectors only)
- Perform the assembly in the higher classified environment to avoid particle contamination or introduction of viable particles.

- Verify that the blue mark located on the joint is still straight and complete. Any small separation of the mark should be considered as accidental opening of the connector device and means that the device should not be used.
- Install tubing with an internal diameter of ⅜ inch (9.52 mm) or $^{5}/_{16}$ inch (7.93 mm)
- Once the connector is secured to tubing, attach clamping component to the tubing to prevent any accidental transfer of liquid inside the connector before being opened (e.g., during transportation)
- After assembly, secure the connection with a tightening component to avoid accidental dismantling during operations (e.g., cable tie tightening).

3.1.3 Sterilization

- Gammasart ATD™ devices attached to containers supporting irradiation (e.g., pouches) are submitted to gamma irradiation on the condition that the connector device has not undergone previous irradiation treatment.
  NOTE Sterilization of Gammasart ATD™, supplied irradiated in a blister packed with 5 units for on-site connection, was initially validated for the first version of the connector according to the AAMI TIR 27:2001 VD MAX method.
- If Gammasart ATD™ are connected to containers not designed for gamma irradiation (e.g., stainless steel vessels), they may undergo a steam sterilization process.
  The steam sterilization of the assembly should be validated to meet GMP requirements.
  If long lengths of tubing are used to connect the container to the connector device, the sterilization procedure should be adapted to ensure that steam spreads throughout the entire tubing length, for example, by the following procedures:
  - Installing a vent filter close to the connector with a closing device
  - Performing pressure cycles to force the vapor into the tubing

IMPORTANT

Never hold the connector by the cover once it is connected to a container. Gravity, weight or resistance to movement could cause it to become unscrewed. Operators should be trained to always handle the connector by the connector body.

3.2 Installation of the SART Port

The external port is installed onto a flat surface made of either stainless steel, Plexiglas, or other acceptable material that can afford holes. It is not recommended to install the external port on a glass surface.

Depending on the material, the minimum thickness of the installation surface will be selected to ensure the required rigidity and appropriate flatness, e.g. 2 mm minimum for stainless steel. The maximum thickness of the installation surface may not exceed 6 mm. There is no additional stainless stell support required depending on the surface thickness between 2 to 6 mm.

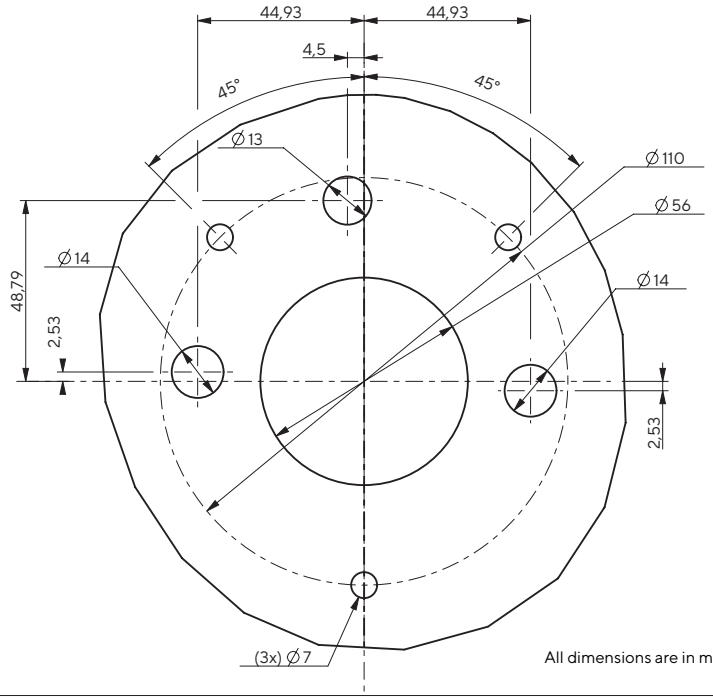
It is recommended that the port is installed with the clamping buttons in the horizontal position, with the lever on the top, provided there is enough space for free movement. However, the port can work in any other position.

Tightness between the external port and the inner surface of the contained area is ensured the double gasket part of the external port.

Appropriate flatness of the surface is important to ensure tightness.

The here below pattern describes the size and the position of the required piercings in the surface when viewed from the outside of the contained area.

View from the outside of the containment



All dimensions are in millimeter.

After installation of the external port on the wall, the internal port must be re-engaged.

The procedure is the following:

1. Turn both clamping buttons to the “close” position.

2. Lift the lever and hold it in this raised position.

3. Dock the internal port.

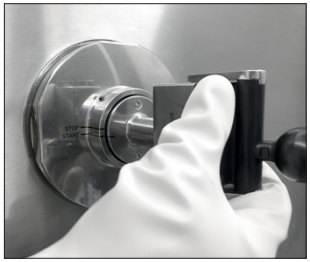
4. Release the lever.

5. Turn both clamping buttons to the “open” position.

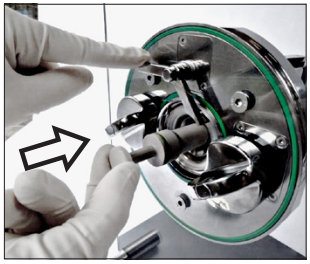
4 Sanitization of the Port

During sanitization, the objective is to treat all parts of the port that will be in contact with the inside of the contained area, in particular the V-points of the equipment, while preventing from deterioration of the port's precision mechanism by potential aggressive decontamination agents. To sanitize the port, the following steps are recommended.

Initial conditions: internal port engaged in the START position with no connector inside, and the handle in "open" position.

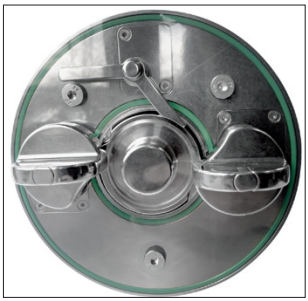


1. Initial conditions.

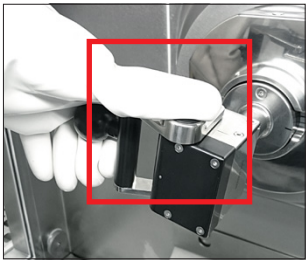


2. From the outside: introduce the internal port plug into the port (like a connector).

3. Close the external port with the external port cover.



4. Secure the external port cover by closing the two clamping buttons.



5. From the inside, rotate the handle of the internal port 90° (closed position) to clamp the internal port plug inside the internal port.

IMPORTANT

A safety system prevents accidental opening: it is necessary to push on the safety button to allow handle rotation.

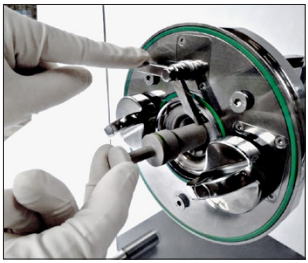
6. Open the internal port and let it in its rest position inside the contained area.

7. Perform cleaning and sanitization (wiping with bleach and | or alcohol, H_2O_2 cycle in an isolator, ...).

8. After sanitization, with the external port cover and the internal port plug still in place, the internal port is re-assembled with the external port and rotated to the STOP position.

9. When the internal port is fully docked on the external port, the handle must be re-aligned in order to release the internal port plug.

10. The external port cover can be removed from the outside.



11. Next withdraw the internal port plug from the external port. The port is ready for operation.

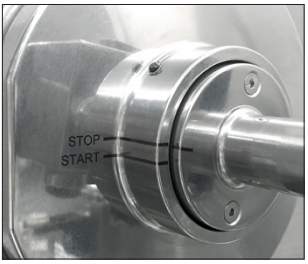
5 Connector & Port Operation

5.1 Installing the Internal Port and Gammasart ATD™

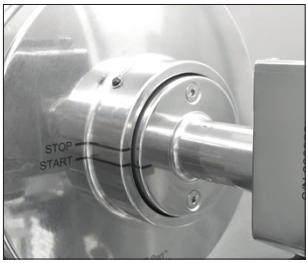
The following procedure should be followed for optimal use of the SART Port and associated Gammasart ATD™:

Operation inside the area with the highest containment condition

1. After finalization of sanitization and withdrawal of the cover and plug, the two clamping buttons remain in open position.



2. The internal port should be in the STOP position (see chapter „6 QA | QC Release“, page 29).



3. The internal port must be rotated back to the START position. Once the START position is reached, the internal port is blocked by the interlocks.

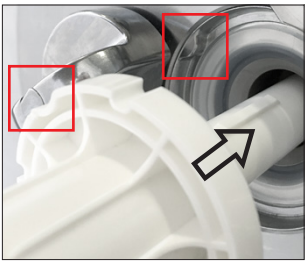
4. The handle of the internal port should be in open position, i.e the handle is aligned with the internal port.

Operation in the area with the lowest containment condition

It is recommended to wipe with alcohol both confidence lines located on the port and on the connector to minimize presence of viable particles on these critical areas.

1. With the two clamping buttons in the open position, lift the lever and engage the connector device inside the port.

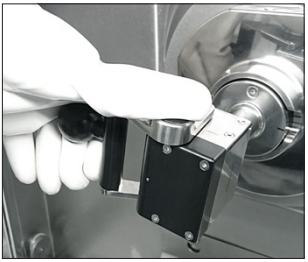
2. When the connector is slightly engaged, rotate the connector to align it with the **two bumps** (framed on the picture), then engage it straight and completely.



NOTE The other grooves that are present around the connector body (see the arrow on the picture) ensure compatibility of the device with the former versions of the SART Port.

3. Secure the connector device by rotating the two clamping buttons to the close position.

Operation inside the area with the highest containment condition

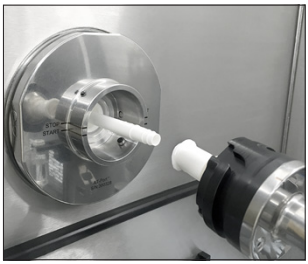


1. Rotate the handle of the internal port 90° (closed position) to clamp the connector cover inside the internal port.

2. Rotate the internal port counterclockwise until it cannot move any further.

IMPORTANT

It is **NOT** recommended to use the handle to rotate the internal port as this can introduce unwanted torques on the system.



3. Withdraw the internal port and place it in the designed location (to be defined by the user).

   The connector is now free for connection inside the area having the highest containment conditions.

5.2 Release of the connector

Operation inside the area with the highest containment condition

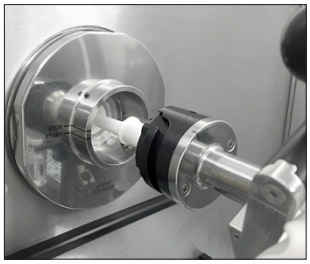
The connector device can be closed and released without creating an opening in the wall separating the two areas. To that end, the following procedure must be followed:

1. Empty the tubing and the connector to avoid leakage of liquid. This can be achieved by using the pump in reverse direction or by clamping the tubing.

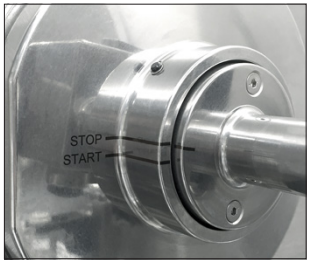
2. Disconnect the tubing from the connector.

IMPORTANT

When using connectors with hose barb tube connections, it is mandatory to pull the tube in the alignment with the connector to avoid breakage.

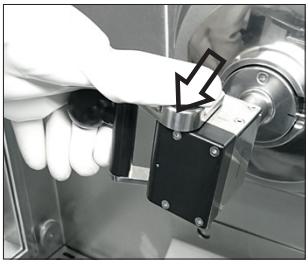


3. Engage the internal port until the two guiding pins are fully engaged in the grooves.



4. Then rotate the internal port clockwise until the STOP position is reached.

The fact that the rotation goes beyond the "START" position allows for a slightly longer screw path and therefore, over-compresses the joint of the connector cover onto the connector body. This over-compression compensates for the possible deformation of the joint following a long period of compression during storage.



5. Release the handle by aligning it with the axis of the internal port.

IMPORTANT

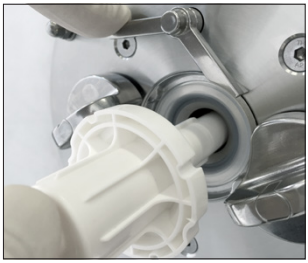
A safety system prevents from accidental opening: it is necessary to push on the safety button to allow handle rotation.

Operation in the area with the lowest containment condition

1. Open the two connector clamping buttons.

IMPORTANT

The two clamping buttons are blocked until the internal port is fully closed.



2. Take the connector device out of the port.

IMPORTANT

Pull the connector out of the port without any rotation movement because this can open the connector

5.3 Re-use of the connector device

The connector device can be re-used in rare but valuable situations. For example when an assembly has been done on a filling line in an isolator and, rapidly, the filling line presents a major break-down which requires a long repair with breakage of the isolator's condition. The connector can be closed and the formulated batch can be safely returned to a storage area. Once the line is repaired, the connector opening can be performed again.

Nevertheless, this operation should be done in strict conditions:

- The connector can never be disassembled from the initial bulk container and assembled onto another one.
- The opening and closure has been validated with the following conditions:
  - Three series of opening and closing cycles maximum (tested with 5 series, therefore a validation is claimed for 3);
  - The last opening and closure should happen within one week from the initial opening.
- To operate the connector the following instructions have to be followed:
  - For the second and third openings, the instructions in chapter 5.1, page 22 are applicable with some modifications:
    - The line on the internal port should not be aligned with the "START" position but with the "STOP" position (as the connector has already faced a closing process with over-compression), otherwise the connector cannot be fully introduced.
    - The rotation of the internal port will start from the STOP position but will reach the same release point.
    - All other operations are identical.
  - For the second and third closings, the process is identical to chapter 5.2, page 25. Nevertheless, it is important to note that there will be no more over-compression after closing. This is the reason for recommending not to store an open and re-closed connector device for a long period as the closure integrity cannot be guaranteed once the joint has adopted the new deformation due to the over-compression.

NOTE that the connector can be engaged in different ports in case of re-use (e.g., start filling on line 1 and re-start on line 2).

6 QA | QC Release

6.1 SART Port

The port is released by the supplier after completion of the following tests:

- Checking the stainless steel certificates provided by the suppliers.
- Measuring the critical dimensions as CD8*
- Control of the quality of the surface finish.
- Ensure presence of all seals and all components on the external port, internal port and plugs.
- Roughness of the major surfaces of the port facing the area with the higher containment classification (Ra below 1.2 µm).
- Absence of cutting edges.
- Leak test of all ports: test for leakage of the internal port at 350 mbar and a maximum allowable leakage rate of 1 mbar/4 sec. Correct any ports that fail the test until they pass or are rejected.
- Check port function (insert and open the connector, check interlock function, ensure that the connector is a tight secured in the port and the rotation marks are located properly).
- External port lever dimensional check.

6.2 Gammasart ATD™

The table below lists the different tests performed on the Gammasart ATD™:

Tests conducted for initial validation	Routine tests on randomly selected samples	100 % individual tests

– Leak test after ageing
– Leak test after multiple openings | closures
– Fitting and traction test
– Burst pressure test
– Packaging integrity test
– Particle detection
– USP class VI criteria
– Extractable profile
– Endotoxin contamination
– Media fill simulation in worst case condition
	– Critical dimensions
	– Weight of all parts
	– Visual inspection:
	  – general on connector body
	  – connector body | 4 square & 2 round notches
	  – outer tubes | 2 short ribs
	  – absence of filaments
	– Resistance test of body | inner tube welding
	– Documentation review (plastic molder batch record and release, incoming QC record)
	– Packaging integrity
		– Packaging identification
		– Air leak test on closed connectors
		– Visual inspection:
		  – check of the absence of filaments
		  – visual check of the presence and quality of the 2 straight painted lines
		– Functional test with a dummy port

7 Maintenance & Repair

This section only refers to the internal and external port of the SART System™.

The Gammasart ATD™ is a disposable component requiring no maintenance.

7.1 Servicing

If the port is damaged, return it to Sartorius and receive a replacement so that operation can continue during the repair period. The following types of damages are critical and must be repaired immediately:

- Damage to the “V point” of the internal port based on the alpha-beta concept. If not repaired, there is a significant risk that viable particles could be introduced inside the area with the higher containment classification
- Damage or torsion to the internal mechanism to clamp the connector cover in the internal port. If not repaired, this could expose the contaminated surface of the connector cover inside the area with the higher containment classification
- Damage or torsion to the interlock. The interlock function is necessary to prevent accidental release of the internal port when the connector body disengaged
- Damage to the silicone joint. If not repaired, it could create a leak into the area with the higher containment classification

7.2 Maintenance of the port

The port requires little maintenance. To facilitate operation, some silicone could be added to the pins used for rotating the internal port.

The joint in the external port needs to be inspected during each preparation of the equipment. In case of damage, the joint must be changed.

IMPORTANT

For closure integrity, it is critical that the face of the seal with the two edges is located in the area where it is in contact with the internal port. If not, rotation of the internal port may be very difficult.

For greater safety, inspect the joints on rotating clamps every two years under normal use (500 – 1000 openings | year).

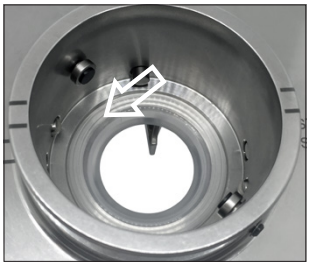
7.2.1 External port

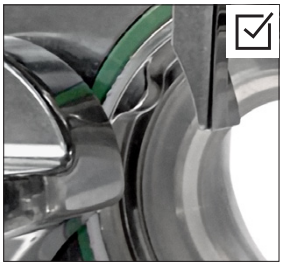
The external port requires the following preventive maintenance and | or repair:

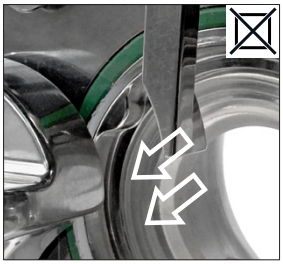
1. The large seal on the external port needs to be inspected during each preparation of the equipment. In case of damage, it must be replaced by a spare part.

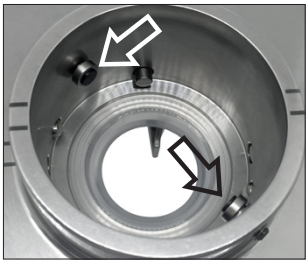
IMPORTANT

The seal must be placed in such a way the face showing two ribs is on the internal port side. If not, it could be that the rotation of the internal port becomes difficult.

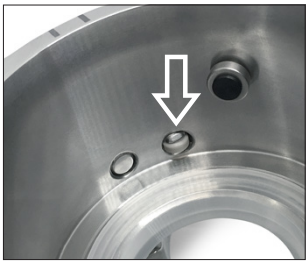








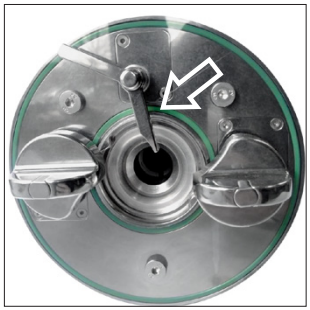
2. The two rollers that guide the internal port into the external port should be regularly checked to avoid difficulty to screw the internal port. In case of malfunctioning, the complete guiding pin made of the axis, the rollers and the locker, should be replaced.



3. The rollers that participate in the interlock system should be regularly checked to avoid any malfunctioning of the interlocks. They must freely roll and easily come back when released after having been pushed to the inside.

4. It is recommended to regularly verify that the connector body is well pressed to the large seal of the external port as this ensures closure integrity. In case of mechanical play it is recommended to contact Sartorius Service.

   Also any significant increase of the mechanical play in the rotation of the clamping buttons should be considered a sign of forcing or abnormal wear of the internal locking mechanisms and should be reported to Sartorius Services.

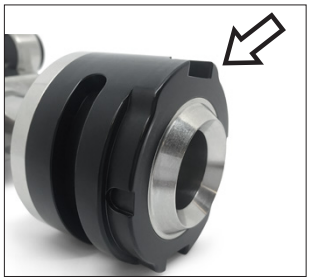


5. Damage or torsion to the lever may affect the functionality of the corresponding interlock and the internal port could be blocked. The lever can easily be replaced by a spare part.

   In case the internal mechanism is damaged, it is recommended to contact Sartorius Services.

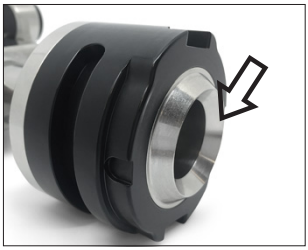
7.3 Internal port

The internal port requires the following preventive maintenance and | or repair:



1. The cylindrical head of the internal port, made of PEEK material, should be checked every year, or after 500 manipulations whichever occurs first, or after being dropped, to verify that its shape and its guiding grooves are not altered. This is important because such alterations could lead to difficulty to properly rotate the internal port, or could lead to some play along the main axis when the internal port is fully rotated and therefore, closure integrity could be jeopardized.

   The cylindrical head component can be easily replaced.



2. The “V-point” of the internal port should be regularly checked as any damage could jeopardize the efficacy of the alpha-beta concept and could lead to a risk of introduction of viable particles inside the area with the highest containment condition. Such damage usually cannot be repaired and leads to replacement of the complete internal port.

3. Damage or torsion to the internal mechanism of the internal port that it used to clamp the connector cover in the internal port, is to be considered as critical as this could jeopardize the integrity of the internal port when disconnected from the external port. Usually such damage cannot be repaired and it is recommended to replace the complete internal port.

7.4 External port cover

The external port cover requires the following preventive maintenance and | or repair:

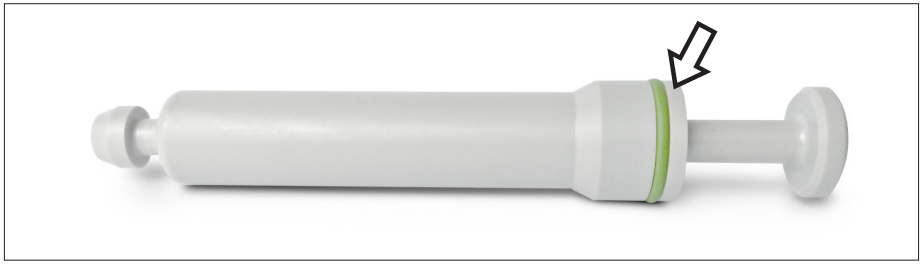
Damage to the conical surface that presses on the large seal could affect the closure integrity. Therefore, it is recommended to inspect that surface before use. Usually such damage cannot be repaired and it is recommended to replace the external port covert.

7.5 Internal port plug

The internal port plug requires the following preventive maintenance and | or repair:

The green seal needs to be inspected before each installation of the equipment as it ensures the closure integrity of the internal port when the internal port is removed for decontamination.

In case it is damaged or missing, that green seal must be replaced.



7.6 Spare parts List

The following spare parts are available:

Item	Order number
Complete Port	AN-CON-385025
External Port Seal	AN-CON-207025
Internal Port Complete	AN-CON-433025
Internal Port head + 2 fixing screws	AN-CON-432025
Internal port Lever + screw + seal	AN-CON-431025
Internal port rollers (×2)	AN-CON-430025
Internal Port Plug	AN-CON-420025
Internal Port Plug Seal	AN-CON-218025
External Port Cover	AN-CON-384025

8 Do’s and Don’ts

8.1 Do’s

Assembly

Use appropriate tubing with the recommended internal diameter dimension for the connector and secure the tubing with a tightening device.

Manipulation

- Handle the connector by the body, not the cover.
- Check that the blue mark is still aligned until first opening.

Port preparation

Check the integrity of the seal and the absence of damages.

Port manipulation

- Take your time, do not rush and think before acting.
- Rotate the internal port by handling the box (not the handle) to avoid torsional movement.
- Place the port in the START position when a new connector device is used.
- Engage or disengage the connector with a straight movement.
- Go up to the STOP position when closing a connector device.

Second use of connector device: begin in STOP position.

8.2 Don’ts

Manipulation

- Handle the connector by the cover.
- Re-close the connector manually in case of accidental opening.

Port manipulation

- Rotate the internal port by using the handle (leads to undesirable torque).

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone: +49 551 308 0
www.sartorius.com

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 the other gender as well.

Last updated:
12 | 2020

Printed in the EU on paper bleached without chlorine. | MB
Publication No.: SLO6001-e201205