



ARDIEN
Consulting Services
Your Partner in Isolator Validation

**Non-Viable Particulate Air Adapter Ports for Use
with SKAN Isolators**

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Non-Viable Particulate Air Adapter Ports for Use with
SKAN Isolators, Rev. 1

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Non-Viable Particulate Air Adapter Ports for Use with SKAN Isolators



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1.0 Description and Assembly

- 1.1 As part of routine compendial sterility testing, Non-Viable Particulate (NVP) Air sampling is often performed.
- 1.2 The standard connection from SKAN is open directly to the room; there is no in-line protection from the room and the Grade A internal isolator environment. See the photograph on the previous page for clarification. The adapters specified within this document provide a sanitary connection to the NVP Port on the isolator and allow it to be capped off when not in use.
- 1.3 The **Non-Viable Particulate Air Adapter Ports** comprise the following items:

PHOTO 1: Adapter 1 Connected to Isolator

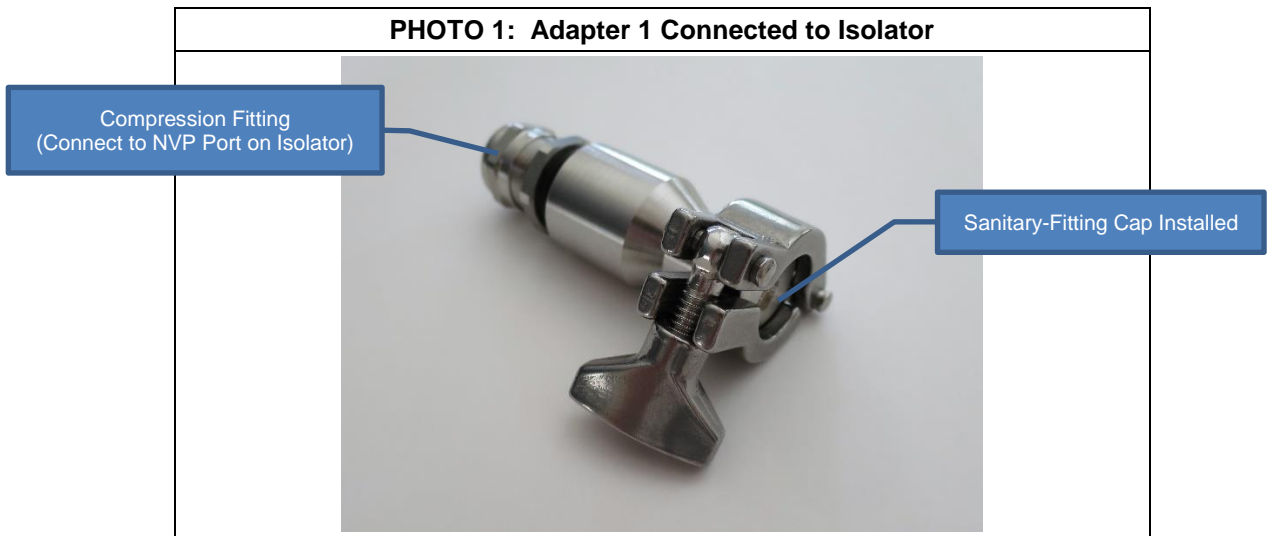
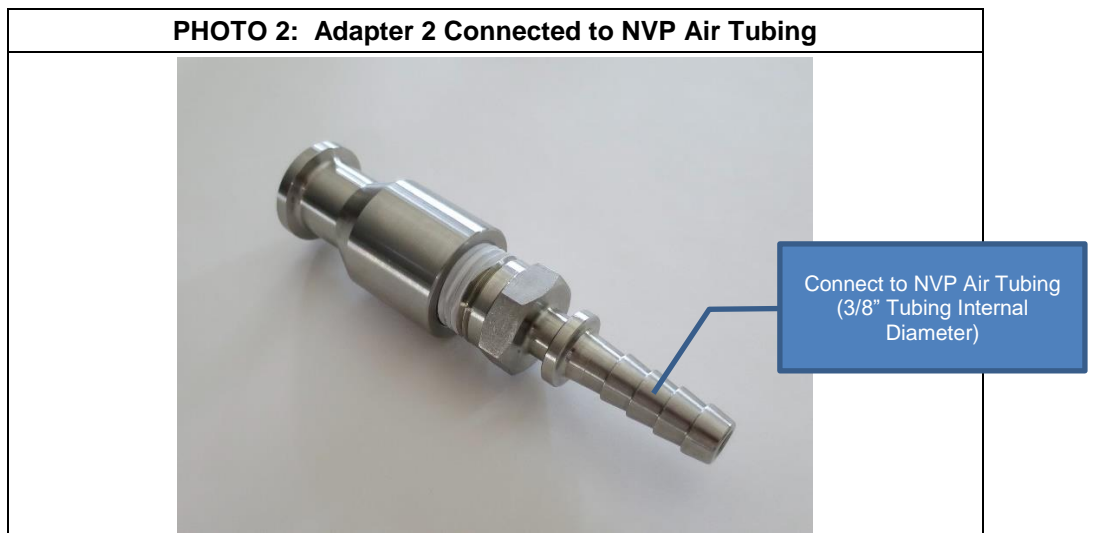


PHOTO 2: Adapter 2 Connected to NVP Air Tubing



1.4 Connect **Adapter 1** and **Adapter 2** as indicated below:

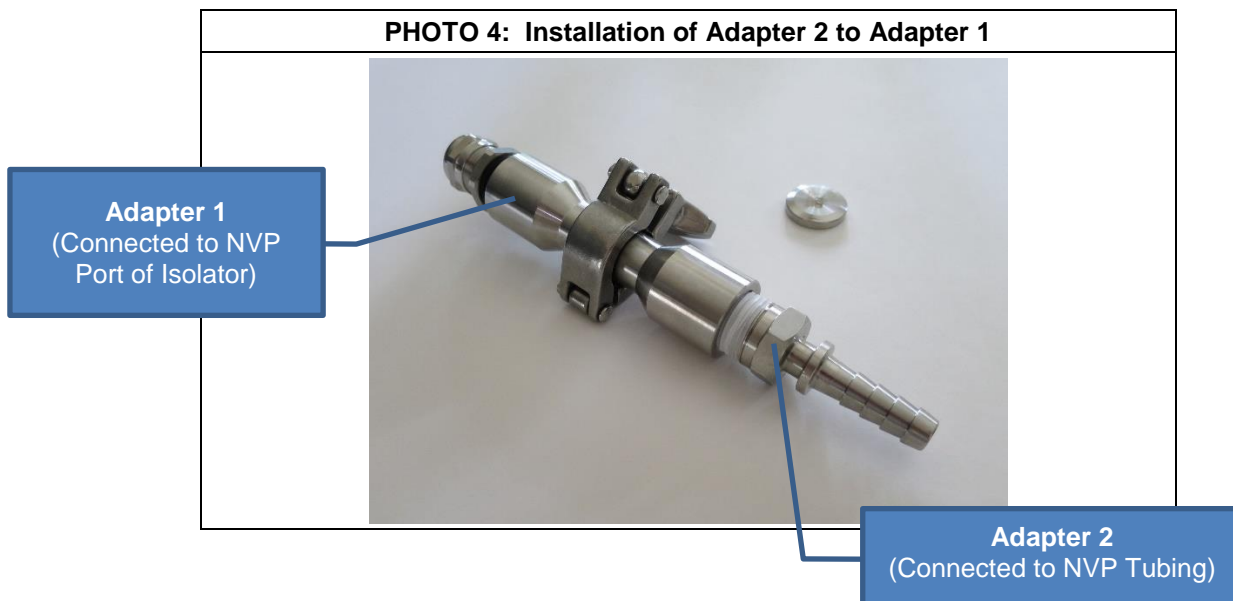
- 1.4.1 Connect **Adapter 1** to the NVP Port of the Isolator as indicated in **PHOTO 1**. Using a suitable wrench, open the compression fitting, if necessary. Push **Adapter 1** all the way in until it stops. Using the wrench, fully tighten the compression fitting of **Adapter 1** so it is secure around the NVP Port of the Isolator.
- 1.4.2 Remove the sanitary cap and clamp as shown in **PHOTO 3** below. Leave the sanitary gasket in place.

PHOTO 3: Removal of Sanitary Cap from Adapter 1



- 1.4.3 Connect **Adapter 2** shown in **PHOTO 2** to **Adapter 1** using the sanitary connection. Attach and secure the sanitary clamp as shown in **PHOTO 4** below. Set the sanitary cap aside.

PHOTO 4: Installation of Adapter 2 to Adapter 1



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1.4.4 Perform the NVP Air sampling as specified in the applicable SOP.

1.4.5 To re-cap the NVP Air Sampling Port, perform Steps 1.4.1 – 1.4.3 in reverse. When completed the assembly should look like **PHOTO 1**.

2.0 Safety

2.1 These connections present a potential tripping hazard because they extend slightly into the room. Exercise caution when walking around the isolator.

NOTE: *This can be slightly reduced by cutting the rigid stainless-steel tubing of the NVP port if deemed necessary.*

2.2 Due to the weight of these parts, it may be necessary to provide adequate support to prevent damage.

3.0 General Cleaning

3.1 Clean items/components using low-particulate wipe(s) saturated with 70% isopropyl alcohol. Allow to dry.

4.0 General Troubleshooting

4.1 Refer to this document.

4.2 Please feel free to contact Ardien Consulting Services if there are any technical questions related to the content of this document.

4.3 Contact Ardien Consulting Services.

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