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GS Device

Design Principles and Benefits

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Technical Details – GS system

General Description

The GS System is a glove support system that positions the glove and sleeve assembly of the barrier isolator system during the Vapor Hydrogen Peroxide decontamination process.

The GS System positions the glove concentrically to the sleeve. The glove is supported by a "hand" that features three fingers. These fingers maintain the fingers of the glove separated from each other during the VHP gassing process.

The GS system also includes a stainless steel forming ring that keeps the glove/sleeve concentric to the hand.

The GS system's interface to the gloveport is adapted to fit the specific application.

Application specific and gloveport modification

Although the basic design and configuration of the GS device are always the same, the geometry and interface to the gloveport is adapted to the specific application (either the isolator manufacturer's gloveport or DDP's gloveport).

Included in the contract

- Fabrication and assembly of the devices, per order.

Excluded from the contract

- Installation and testing activities at the customer's facility
- Validation activities.

Features

- Positive lock of the GS structure onto the gloveport's available features, for example its internal diameter.
- "Hand" with separating fingers that positions and spreads the fingers of the glove during gassing
- Stainless steel forming ring that forms the sleeve concentric to the "hand" therefore optimizing gas distribution and minimizing the protrusion of the glove into the isolator
- Additional cuff support for those applications that feature a sleeve/cuff/glove assembly rather than a single piece gauntlet

Specification

- GS structure: machined PVC plastic.
- Sleeve supporting ring: 303 stainless steel.
- Glove support/"hand": machined PVC plastic.
- Protrusion into isolator (maximum): As required
- Hydrogen Peroxide compatible = No

- Autoclave sterilization compatible = No

Documentation

- Assembly drawing

Figure 1 - Typical glove support design (two finger unit shown)

Example of Application specific details

The following defines the requirements of the GS devices for a typical application

- Gloveport/glove details
    - Geometry/Shape: Round
    - Glove configuration: with cuff (sleeve/cuff/glove assembly
    - Internal diameter: 310mm
    - Thickness = 50mm
    - Gloveport diameter (inside chamber) = 330mm
    - Gloveport diameter (outside chamber) = 360mm
    - Sleeve length = 565 mm
    - Internal diameter of the cuff: 50mm
    - Three support fingers – Spreadable and positioned by friction
- Installed geometry
    - Maximum allowable protrusion into isolator: 330mm
- Operation
    - The device locks onto the internal diameter of the glove port by means of two spring loaded locking latches
    - The operator needs to squeeze the latches together to release the lock and install/remove the GS device from the gloveport

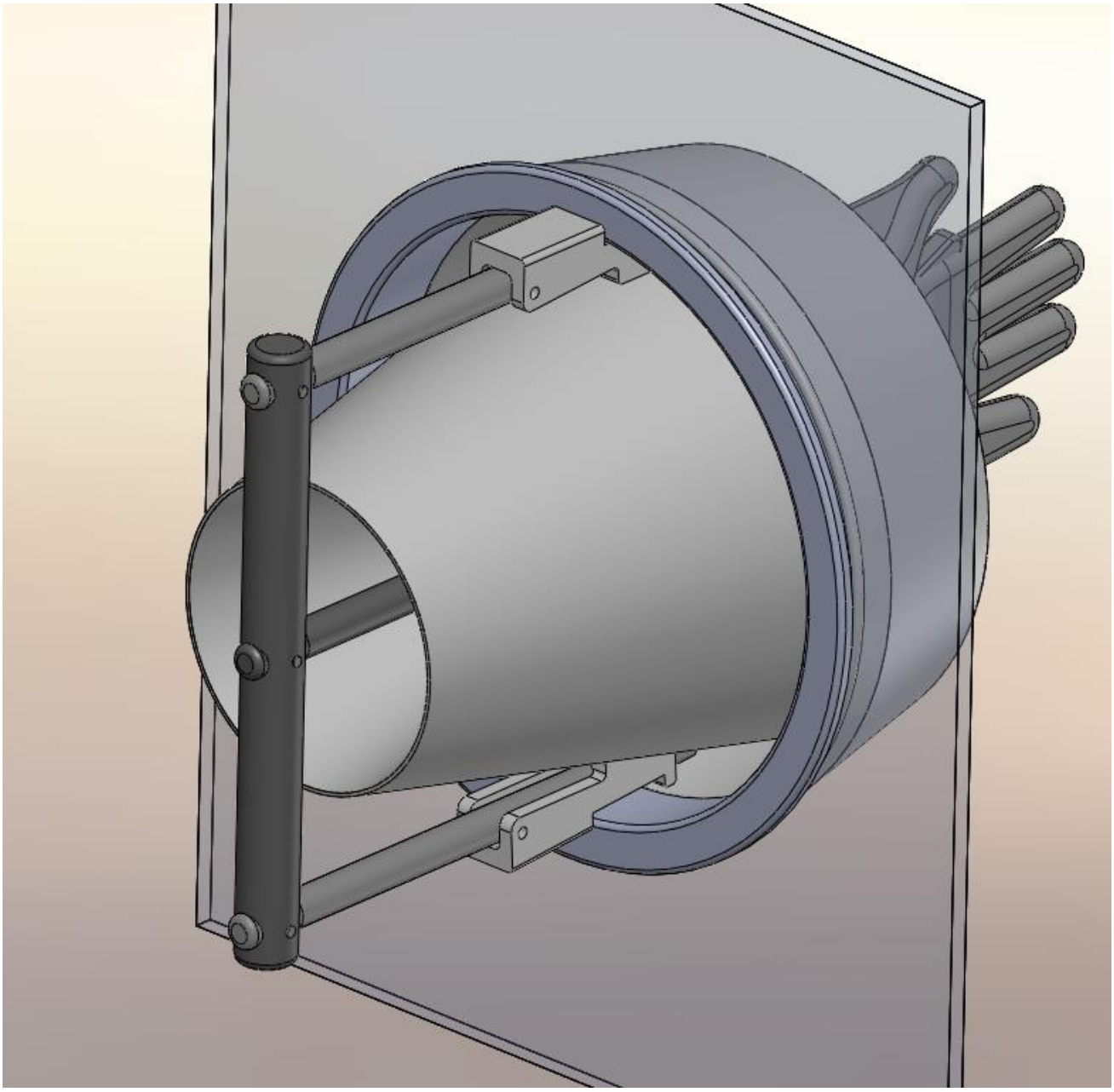

Figure 2 - Operator side

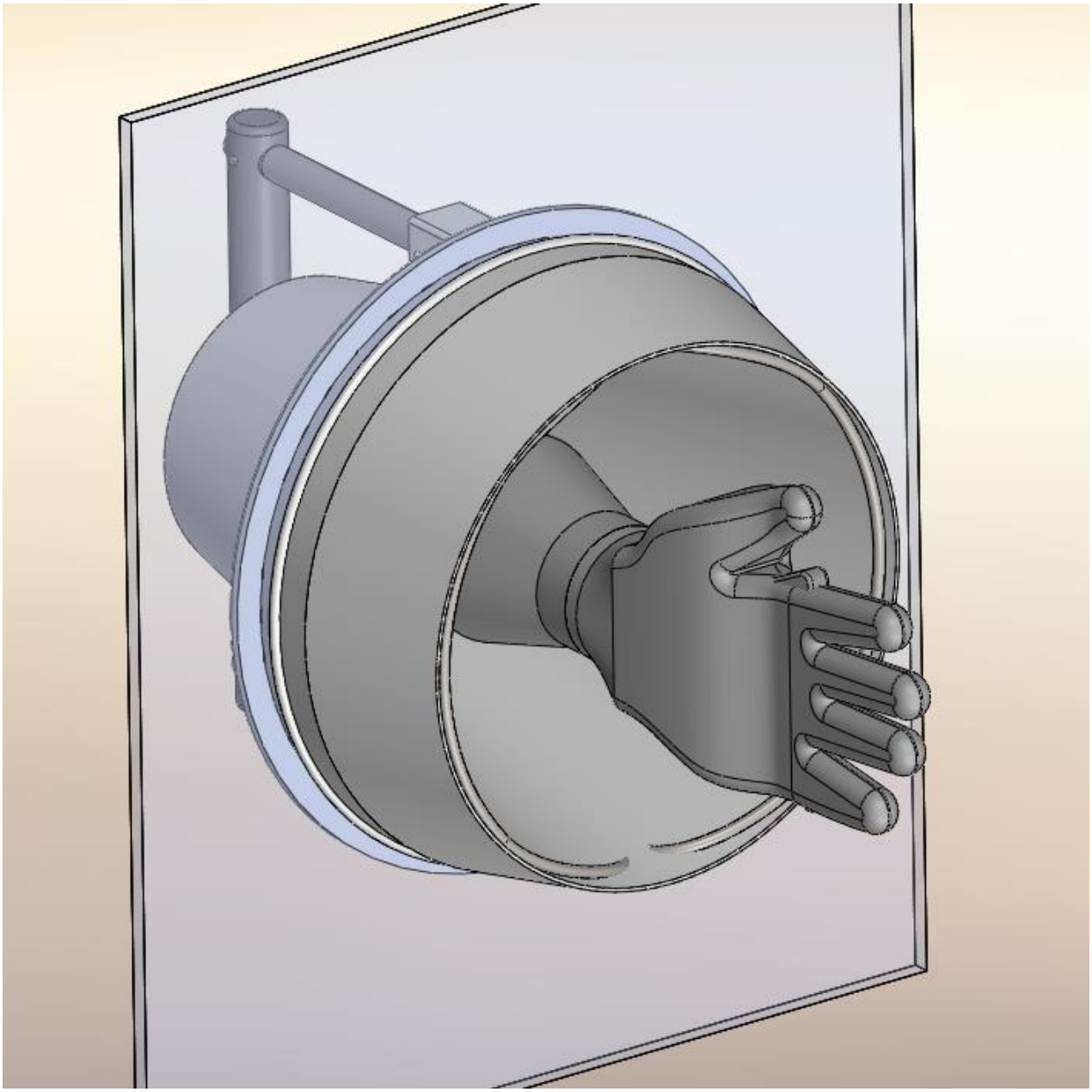

Figure 3 - Sterile side view

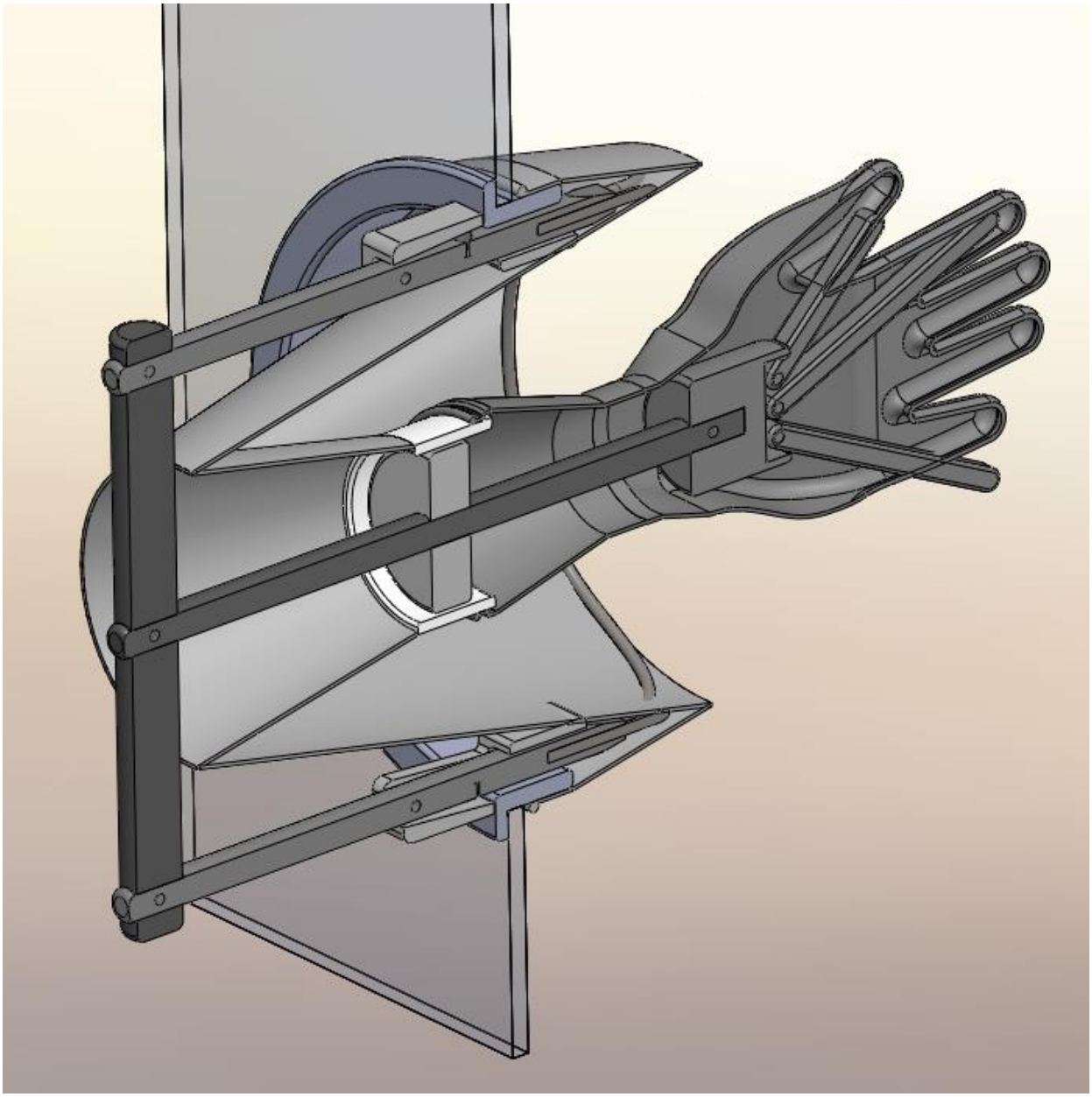

Figure 4 - Cut out view through the center

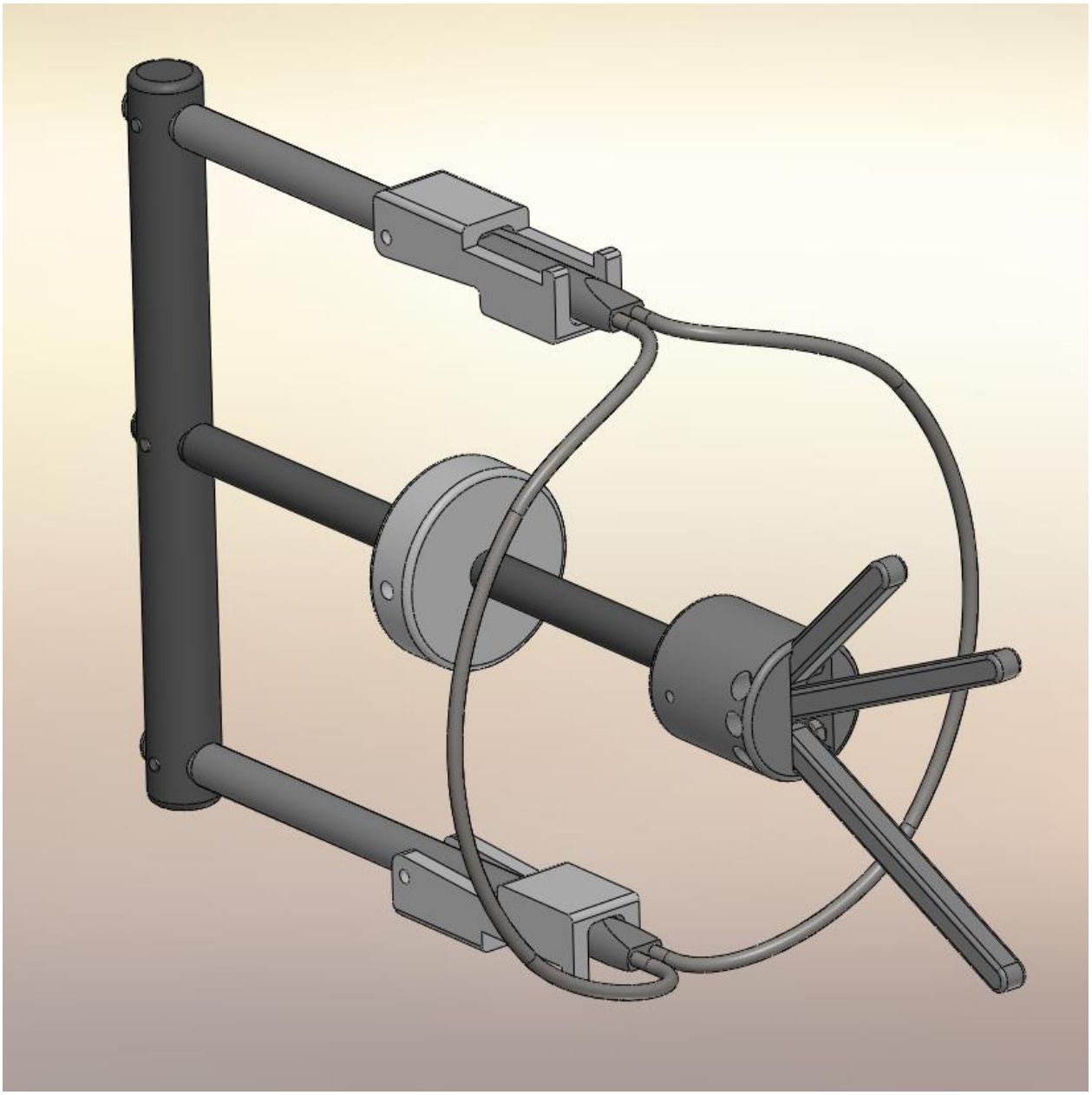

Figure 5 - GS device - uninstalled

GS device design drivers

Primary reason for implementing the GS device

The ultimate purpose of the GS device is to position of the glove inside the isolator system in such a way that is repetitive and optimizes coverage of all surfaces by the VHP gas

As background information, the VHP decontamination process is a surface phenomenon. Surfaces that exposed to the gas will be decontaminated while surfaces that are not exposed to the gas will not be decontaminated.

The lack of exposure may be caused by, for example, fingers touching each other or any part of the glove touching components internal to the isolator

“Hand” design principle

DDP’s GS device integrates a “hand” that features three spreadable fingers that, when compressed together, facilitate the installation process while, when spread, create a visible gap between the five fingers of the glove.

The following photos show how the three finger design resolve this VHP gas surface coverage problem.

Figure 6 - Unsupported glove held by the cuff

Figure 7 - Glove held by cuff without finger support

Figure 8 - Two finger support - (Thumb and little finger)

Figure 9 - Three finger support (thumb, index and little fingers)

Minimal protrusion into isolator

DDP's GS device integrates a stainless steel forming ring that allows the glove/sleeve to be folded onto itself and be concentrically positioned around the glove itself. By folding the glove onto itself, the protrusion of the glove itself into the isolator is kept within the design limits driven by the application

The figure below shows a graphic representation of the principle behind this design configuration

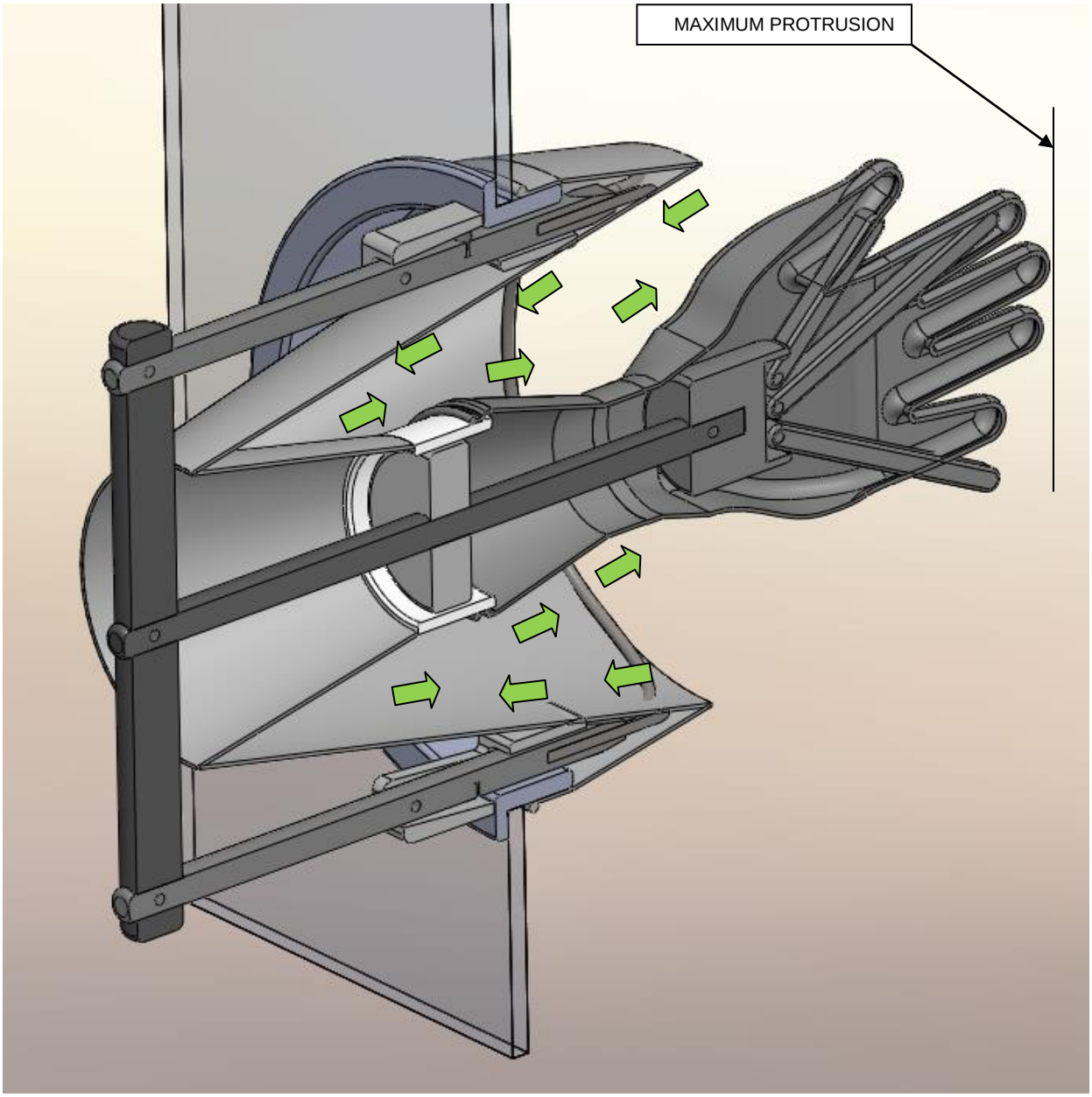

Figure 10 - VHP gas distribution and protrusion into isolator

Summary

Dynamic Design Pharma's GS device resolves the two most impacting issues related to VHP gas distribution and total surface coverage. Although not the most inexpensive glove extender device available in the market, it includes features that make it a system that can be validated and that can produce reproducible results.