

# PACTRYS™

## DISPOSABLE SWIVEL CONNECTORS

Accessory of NIV Face Mask  
INSTRUCTIONS FOR USE

### Intended Use:

Hans Rudolph, Inc., Swivel Connectors are intended for use as scientific tools or components for life science applications in educational and research environments. Swivel Connectors are intended to be used under the supervision of an appropriately qualified life science researcher. Swivel Connectors are not intended to be used in clinical medical applications to diagnose, prevent, monitor, predict, prognose, treat, alleviate, or compensate for a disease, injury, or disability.

### Warnings:

1. This product is not for home care use.
2. These Connectors are for Disposable Single Test Subject Use only. Attempts to disinfect or sterilize will result in the deterioration of the connector materials which will compromise their use.
3. For proper function of the 115401 and 115402 Models, do not block the AAV or Vent Holes.
4. If supplemental oxygen is supplied within the circuit, the inhaled percentage oxygen could vary depending upon flow, pressure, test subject breathing pattern and circuit leakage rate.
5. Oxygen flow must be turned off when the circuit is inactive or not connected to a test subject.
6. Do not use if the mating device 22 mm Male or Female medical taper does not engage properly and stay connected. Mating connectors should comply with ISO 5356-1 Conical Connectors for respiratory equipment.

### Residual Risks:

Reference the primary device data sheet which the Connector is attached.

### Connector Components (fig. 1, 2, 3, 4):

1. All Swivel Connectors have a 22 mm Male medical taper and a 22 mm Female medical taper ports per ISO 5356-1.
2. Two of the Swivel Connectors have Anti-Asphyxia Valves (AAV) (fig. 3, 4)
3. One of the Swivel Connectors has Vent Holes (fig. 4)

### Application & Fitting:

Fitting Medical Tapered connectors (22 mm Male & Female) especially when made of plastics requires a significant push-in and twist connection between mating connectors for a good tight leak-free engagement.

### Safety Features Verification:

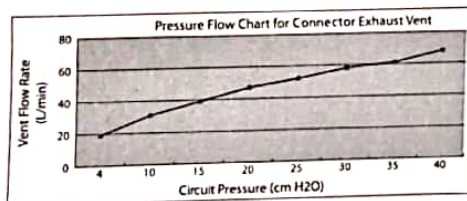
The AAV closes the room air port in circuit pressures >3 cmH<sub>2</sub>O and opens the circuit when pressures are <3 cmH<sub>2</sub>O.

### Functional Check:

1. Swivel Connector taper fit with mating device is engaged fully and will not come apart without significant force.
2. AAV is installed completely with the locking tabs fully engaged and diaphragm flexing freely with no obstruction as received from the manufacturer. There is no reason to remove this valve (fig. 5, 6).

### Technical Specifications

1. Swivel Connectors Resistance to Flow (cm H<sub>2</sub>O @ LPM):
  - a. Straight & Elbow type No AAV: 0.1 @ 50, 0.5 @ 100
  - b. Elbow type with AAV: 2.0 @ 50, 4.0 @ 100
2. AAV Resistance to Flow (open port): 3.5 cm H<sub>2</sub>O @ 50 LPM
3. AAV opening/closing pressure: 3 cm H<sub>2</sub>O
4. Unintended leak rates for Swivel Connectors (LPM @ cm H<sub>2</sub>O)
  - a. Straight & Elbow type No AAV: 1.5 @ 10, 2.5 @ 20, 3.5 @ 30
  - b. Elbow type with AAV: 5 @ 10, 8 @ 20, 10 @ 30
5. Sound Pressure Level: <25 dB(A) at 15 cm from vent
6. Material: Polycarbonate plastic
7. Medical OD & ID Tapered connections: per ISO 5356-1



### Order Part Numbers:

1. 115404 – Straight Swivel Connector 22 mm OD X 22 mm ID (fig 1)
2. 115403 – Elbow Swivel Connector 22 mm OD X 22 mm ID (fig 2)
3. 115402 – Elbow Swivel Connector 22 mm OD X 22 mm ID with AAV (fig 3)
4. 115401 – Elbow Swivel Connector 22 mm OD X 22 mm ID with AAV and VENT (fig 4)

### Service Life:

These Swivel Connectors are disposable after use and are incapable of being disinfected or sterilized.

### Environment:

1. Operational: -18 to 50 °C; 0-95% RH (non-condensing)
2. Extreme Ambient Transport Conditions (Temporary): -40 to 70 °C; 0-95% RH (non-condensing)

### Disposal

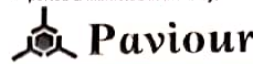
Treat as conventional solid waste in accordance with local and federal regulations.

### Manufactured by:

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