

FACTRY'S™ DISPOSABLE SWIVEL CONNECTORS

Accessory of NIV Face Mask
INSTRUCTIONS FOR USE

Intended Use:

Intended Use: Swivel Connectors are rigid devices intended to deliver pressurized medical gases. They are designed for connecting respiratory circuits and tubing to masks and other respiratory devices. One end of these Connectors has a 22 mm OD Medical Taper and the opposite end has a 22mm ID Medical Taper. They are intended for single-patient-use only and are for use only by medical professionals. Swivel Connectors are sold clean non-sterile, and are disposable after use; the materials are incapable of being disinfected or sterilized.

Indications for Use:

Swivel Connectors are indicated for use when a means to connect a mask or other respiratory device to various patient circuits is required. Depending on the Connector model used, they can also provide a passive means for continuously cleaning or flushing patient rebreathed dead space within a patient circuit (using exhalation vent holes), as well as a separate means for a secondary patient breathing path or Anti-Asphyxia Valve (AAV), when flow in the patient circuit is cut off.

Cautions:

These Connectors are for use only by medical professionals.

Warnings:

1. This product is not for home care use.
2. These Connectors are for Disposable Single Patient 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 patient circuit, the inhaled percentage oxygen could vary depending upon flow, pressure, patient breathing pattern and patient circuit leakage rate.
5. Oxygen flow must be turned off when the patient circuit is inactive or not connected to a patient.
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):

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

Application & Fitting:

Fitting respiratory equipment 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:

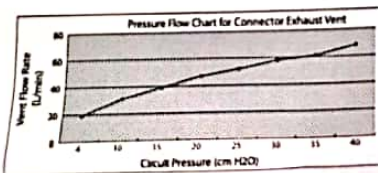
1. Connectors that incorporate an AAV (fig. 1, 2) are for use in CPAP/Bilevel respiratory circuits and allow room air breathing if the ventilator device stops. The AAV closes the room air port in circuit pressures >3 cmH₂O and opens the circuit when pressures are <3 cmH₂O.
2. Connectors that incorporate exhalation Vent Holes (fig. 2) are for use in CPAP/Bilevel respiratory circuits that do not have an exhalation vent port.

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. 3, 4).

Technical Specifications

1. Swivel Connectors Resistance to Flow (cm H₂O @ LPM):
 - a. Elbow type with AAV: 2.0 @ 50, 4.0 @ 100
2. AAV Resistance to Flow (open port): 3.5 cm H₂O @ 50 LPM
3. AAV opening/closing pressure: 3 cm H₂O
4. Unintended leak rates for Swivel Connectors (LPM @ cm H₂O)
 - a. 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. 115402 – Elbow Swivel Connector 22 mm OD X 22 mm ID with AAV (fig 1)
2. 115401 – Elbow Swivel Connector 22 mm OD X 22 mm ID with AAV and VENT (fig 2)

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.



EC Rep Ltd.
5 Fitzwilliam Square East
Dublin 2, D02 R744
Ireland
Tel: +353 1 2 544 944
Email: info@ecrep.ie

Manufactured by:
HANS RUDOLPH, INC.
8325 Cole Parkway
Shawnee, Kansas 66227 USA
Tel: (913) 422-7788
Toll Free: (800) 456-6695

Fax: (913) 422-3337
Web Site: www.rudolphkc.com
Email: hri@rudolphkc.com

Imported & Marketed in India by:



An ISO 9001:2015 Certified Company

Paviour Pharmaceuticals Pvt. Ltd.
311-312 Sunje Tower 1, District Centre
Janki Puri New Delhi-110058
Ph: +91-11-25542181, 82, Fax: +91-11-25542183
E-mail: info@paviour.org, Website: www.paviour.org

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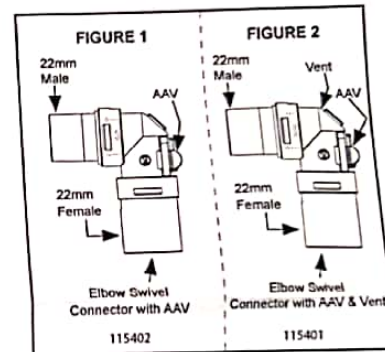
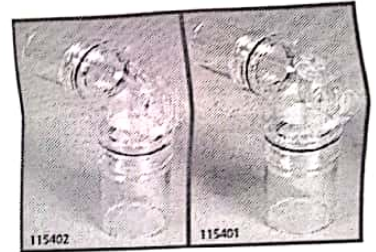


Figure 3

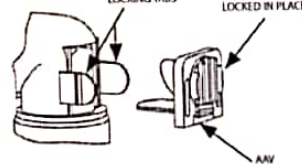


Figure 4

