

ReddyPort® Elbow

Compatible with Philips Respironics AF541 mask and AF531 mask with clip-style connection
Instructions for Use (IFU)

⚠ Caution—U.S. federal law restricts this device to sale by or on the order of a physician.

Intended use

ReddyPort® Elbow is intended to provide an interface for application of CPAP or bi-level therapy to the patient including while the patient is simultaneously undergoing another care procedure (e.g. oral care, suctioning, bronchoscopy) by hospital/institutional clinicians. The elbow is for single patient use in the hospital/institutional environment. The elbow is to be used on patients (>40lbs/18.2 kg) for whom CPAP or bi-level therapy has been prescribed. The elbow can be used with Philips Respironics AF541 masks and AF531 masks with the clip-style connection.

Contraindications

ReddyPort Elbow should not be used on patients who need life support ventilation. The elbow should not be used on patients who are unsafe for oral care, suction, or bronchoscopy. **DO NOT** use the ReddyPort elbow if the patient is unsafe for flexible bronchoscopy due to a compromised respiratory status, per the discretion of the clinical provider. **DO NOT** use the elbow as an accessory to ventilators which do not have adequate alarms and safety systems for ventilation failure.

Mask compatibility

ReddyPort Elbow model number RP-541-SE is compatible with the Philips Respironics AF541 masks and AF531 masks with the clip-style connection, including both over-the-nose (OTN) and under-the-nose (UTN) cushion configurations, sizes Small, Medium, Large, and Extra Large (OTN) and A, B, C (UTN). See Leak and Port Settings below for additional information on usage and setup.

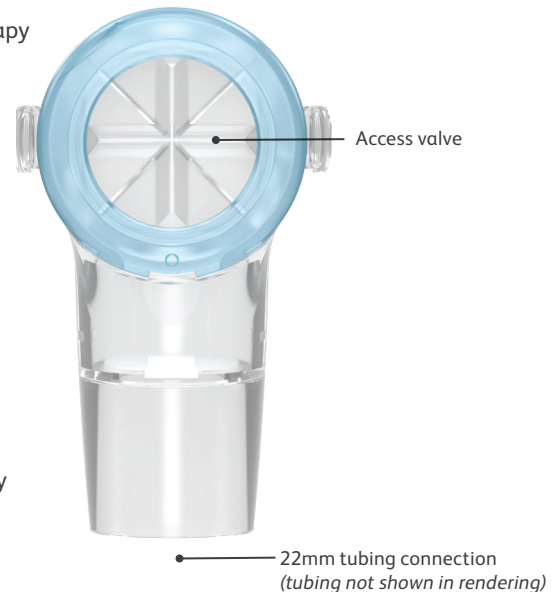
DO NOT use ReddyPort Elbow with masks other than those identified as this could decrease safety and performance of the mask.

Important notes

- A separate exhalation device must be used with the ReddyPort Elbow. This elbow does not include an anti-asphyxia valve that would allow a patient to breath if the ventilator fails. Please see (figure 1) on the next page for ReddyPort Elbow leak rates.
- ReddyPort Elbow is a permanent use elbow for replacement of conventional elbows. It should be left in the circuit for the duration of the patient's therapy.

⚠ Warnings

- The standard elbow should not be used with single-limb circuits.
- **DO NOT** use the elbow as an accessory to ventilators which do not have adequate alarms and safety systems for ventilation failure.
- ReddyPort Elbow is intended to provide an interface between the compatible masks listed above and CPAP or bi-level therapy devices.
- Placing an instrument through the access valve may cause ventilation disruption.
- ReddyPort Elbow must be used with an additional exhalation port device.
- Inspect the elbow for damage or wear (cracking, crazing, tears, etc.) and replace as necessary.
- Replace the elbow when considerable buildup of fluid or secretions accumulate.
- ReddyPort Elbow includes small parts that could present a choking hazard.
- Appropriate patient monitoring should be used as medically necessary.
- **DO** instruct the patient or family **NOT** to introduce anything through the valve.



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- ReddyPort Elbow is for single use only and is not intended to be disinfected or cleaned after patient use. Dispose of the elbow after patient use. Multi-patient use without disinfection between patients increases the risk of infection.
- ReddyPort Elbow is not designed for reuse. SMD Manufacturing cannot guarantee the performance specifications once these elbows have been disinfected or cleaned after patient use.
- If the elbow is used for bronchoscopy, follow standard oral intake protocols prior to the procedure.
- Dispose of in accordance with local regulations.
- If liquid is added to the mouth or airway, ensure quantities are low to prevent any asphyxiation risk.
- Avoid severe shock, vibration, and rain/snow splash during the transportation process.
- Store in a cool, dry place out of direct sunlight.
- If patient vomits, remove mask and suction / clear mouth and airway.
- During and after the end of a bronchoscopy procedure, close patient monitoring of vital signs (heart rate, respiratory rate, SpO₂) surveillance is essential.
- **Important Note:** Additional leak is expected while a care procedure is being performed. If leak is excessive, remove the care procedure tool and discard. Only use tools for the care procedure that is prescribed for the ReddyPort Elbow.

Before use please read and understand the instructions completely

- Check for damage, wear, or secretion buildup. Discard and replace the elbow as necessary.

Leak and port settings

Some ventilators may incorporate the use of a leak symbol and value in the mask selection setup procedures. The leak characteristic of the ReddyPort Elbow is leak 0 or SE. The leak symbol and value represent the intentional leak characteristic of the interface. On ventilators equipped with a mask selection control, enter the leak value of 0 or SE.

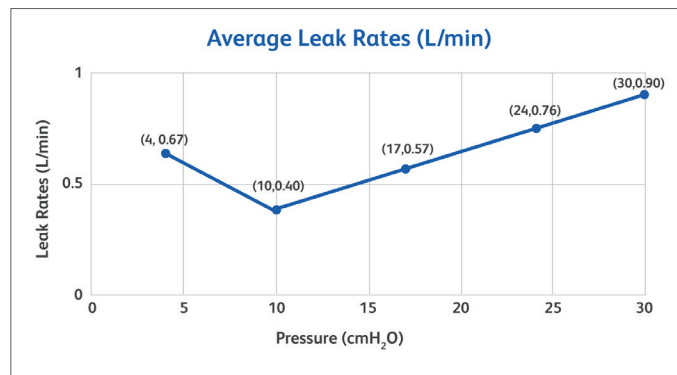
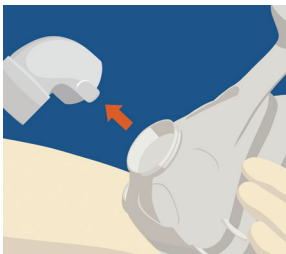


Figure 1

Use of ReddyPort Elbow and mask



SETUP: Before being placed on patient, acquire a Philips Respironics AF541 mask or AF531 with the clip-style connection. **PRESS** release tabs and gently pull off existing elbow.



STEP 1: **PRESS** ReddyPort Elbow into the faceplate hub until the clips snap into place (*audible click*) and gently tug on the elbow to ensure a secure connection.



STEP 2: Following hospital protocols, fit the non-invasive ventilation (NIV) mask onto the patient.



STEP 3: Ensure separate exhalation port is placed at the 22mm connection on ReddyPort Elbow.

Warning: If the elbow is used for bronchoscopy, follow standard oral intake protocols prior to procedure.

Specifications

- Please refer to the specifications provided with the mask that is being used with the elbow.
- Added resistance to flow (pressure drop) is 0.23 cmH₂O at 50L/min and 0.13 cmH₂O at 100L/min.

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