

ReddyPort™ Elbow

Compatible with Philips Respironics AF541 mask Instructions for Use (IFU)

- ⚠ **Caution**—U.S. federal law restricts this device to sale by or on the order of a physician.
- ⚠ **Caution**—This is an emergency use authorized device. The safety of the device has not been fully evaluated
[Fact sheet for healthcare providers](#)
[Fact sheet for patients](#)
- ⚠ **Caution**—Drugs should not be injected in the gas pathway when this device is used.

Intended use

The ReddyPort™ Elbow is intended to provide an interface for application of CPAP or bi-level therapy to be delivered to the patient during a care procedure by hospital/institutional clinicians (e.g. oral care, suctioning, bronchoscopy). The elbow is for single patient use in the hospital/institutional environment. For adults (>40lbs/18.2 kg) where CPAP or bi-level therapy has been prescribed.

Contraindications

The ReddyPort Elbow should not be used on patients who need life support ventilation.

Mask compatibility

The ReddyPort Elbow model number RP-541-L1 is compatible with the Philips Respironics AF541 mask.

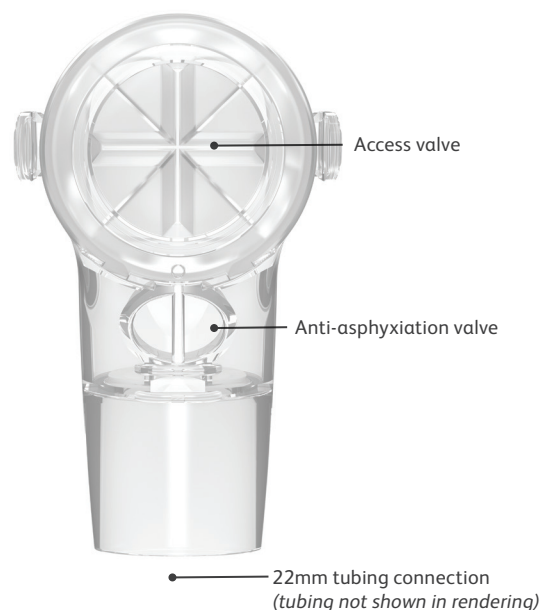
DO NOT use ReddyPort Elbow with masks other than those identified as this could decrease safety and performance of the mask.

Important notes

- A separate exhalation device must be used with the ReddyPort Elbow. When replacing the conventional elbow, verify the necessary leak rates are achieved for proper CO₂ flushing. 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. The elbow includes an anti-asphyxia valve for added safety in the event of a ventilator failure.

⚠ Warnings

- 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.
- **DO NOT** block or try to seal the anti-asphyxia valve on the ReddyPort Elbow
- The 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.



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Warnings (continued)

- 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.
- **DO** instruct the patient or family not to introduce anything through the valve.
- Avoid severe shock, vibration, and rain/snow splash during the transportation process.

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 1. 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 1.

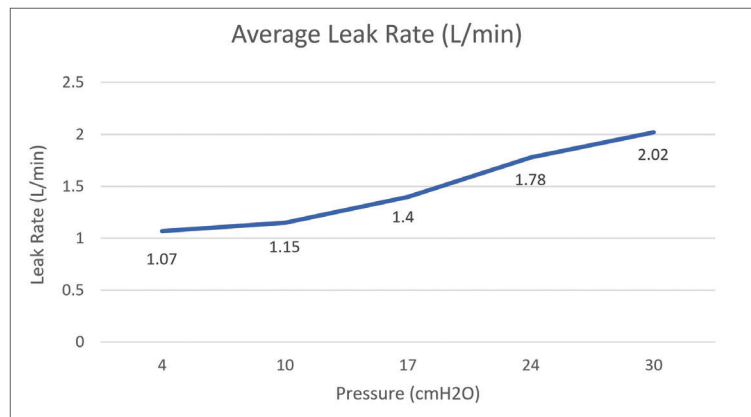


Figure 1

Use of ReddyPort Elbow and mask

1. Before being placed on patient, acquire a Philips Respironics AF541 mask.
2. Remove the existing elbow from the mask by pressing the release tabs and gently pulling off the elbow.
3. Press the ReddyPort elbow into the faceplate hub and tug on elbow to ensure secure connection.
4. Ensure the separate exhalation port is placed at the 22mm connection on the ReddyPort Elbow.

Specifications

- Please refer to the specifications provided with the mask that is being used with the elbow.
- Added resistance to flow (pressure drop) is .2 cmH₂O at 50l/min and .96 cmH₂O at 100l/min
- Inspiratory resistance to flow (single fault) is 1.0 cmH₂O and expiratory resistance to flow (single fault) is .8cmH₂O.

For any inquiries contact ReddyPort at **1.801.899.3036**
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