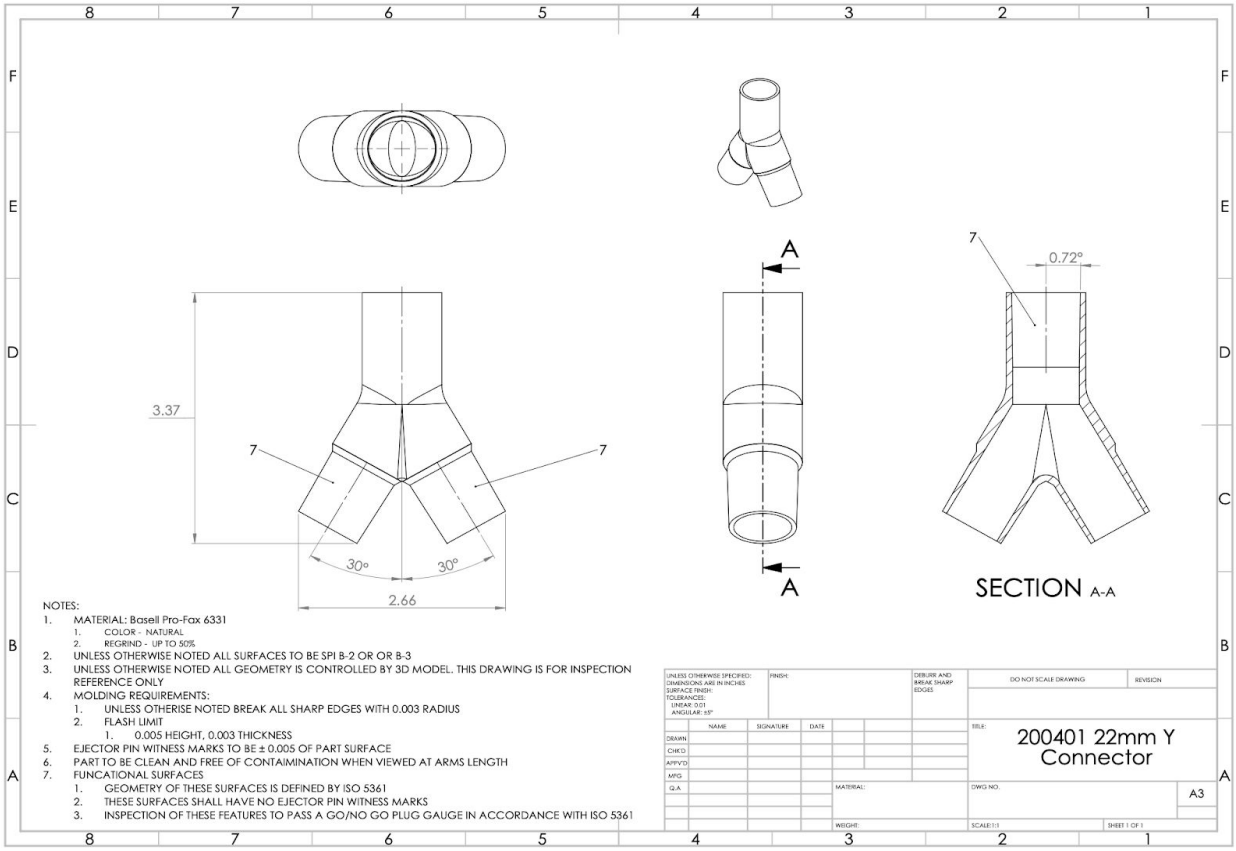
GENERAL CONSIDERATIONS FOR VENTILATOR TUBING CONNECTORS
PEUA200552 - Sparrow COVID-19 Co-Ventilator Assist Device

1. Device description/specification

1. Please describe the mechanism of action for any device functionality beyond flow splitting (e.g., flow restriction, pressure regulation, direction of flow regulation, flow and pressure monitoring, tidal volume estimation PEEP titration, etc.)

The Sparrow COVID-19 Co-Ventilator Assist Device ("Sparrow") is a single part, modular splitter. It is reversible, for inspiratory and expiratory use. It can be configured to adapt a single continuous ventilator for use by up to three patients simultaneously. It has no other functionality.



2. Please provide a complete list of all the components contained in your device

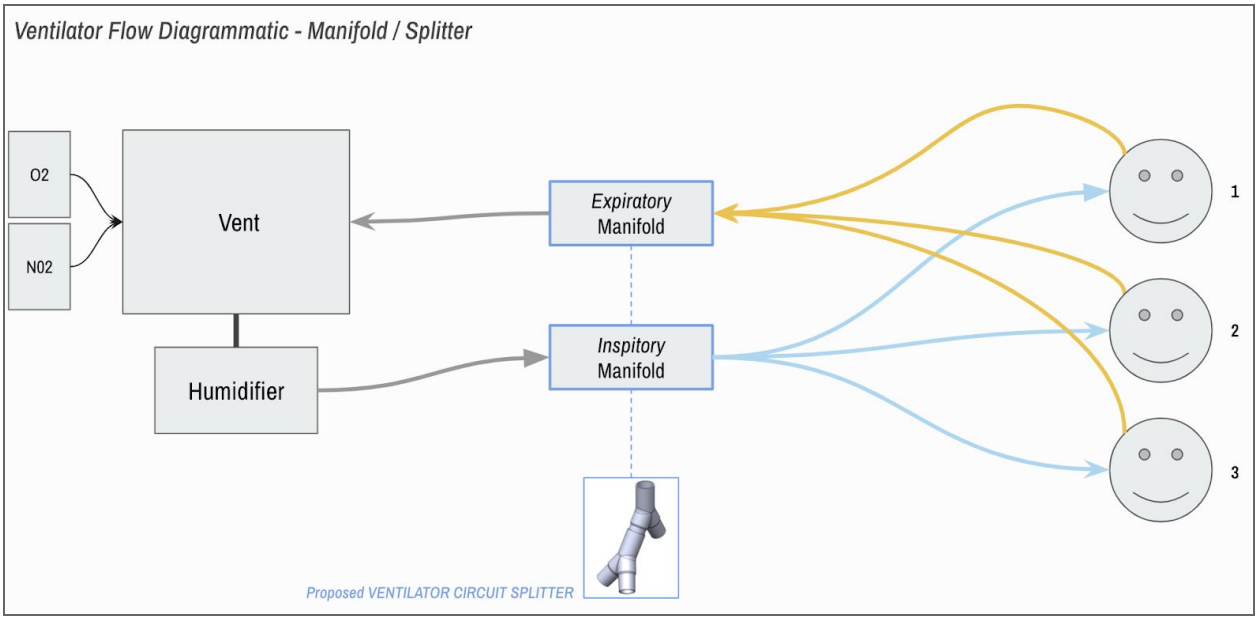
Sparrow is a single part device providing universal 22 mm standard female connection to a continuous ventilator. It will be made of Pro-Fax 6331 polypropylene homopolymer and produced through an industrial injection molding process. There are no other components.

3. For each component please provide appropriate material specifications and dimensional specifications --

N/A

4. **Please provide a complete schematic of the breathing circuit which specifies the configuration of your device and the required accessories (one-way valves, HMEF/viral filters, etc.).**

   Sparrow is reversible and can be used in either inspiratory or expiratory positions in the circuit. Bacterial/viral filters may be added to each circuit.



5. **Please specify the ventilation modes that your device is intended to be compatible with (e.g., pressure control, volume control, spontaneous ventilation)**

   Sparrow should only be used when the ventilator is set to pressure control mode.

2. Risk Assessment & Performance Testing

1. **Risk assessment and mitigation for device causing undue harm (e.g., barotrauma, volutrauma, insufficient tidal volume delivery, patient cross-contamination, aerosol generation)**

   The tests below were performed at Keck Hospital at the University of Southern California ("USC") Department of Respiratory Care.

Test	Date	Time	Device	Flow Sensor	Circuit Leak	Expiratory Filter	Circuit Resistance	Compliance Calibration
1	03/28/2020	22.57	1 Adult Circuit Fisher & Paykel RT-380 Evaqua 2	Passed	Passed	Passed	Passed	Passed
2	03/28/2020	23.06	2 Adult Circuit Fisher & Paykel RT-380 Evaqua 2	Passed	Passed	Passed	Passed	Passed
3	03/28/2020	23.09	3 Adult Circuit Fisher & Paykel RT-380 Evaqua 2	Passed	Passed	Passed	Passed	Passed
4	03/28/2020	23.44	4 Adult Circuit Fisher & Paykel RT-380 Evaqua 2	Passed	Passed	Passed	Passed	ALERT
5	03/28/2020	23.58	4 Flexi-Care Adult Expandable Circuit 96" w Y piece Luer elbow, 038-01-852U	Passed	Passed	Passed	Passed	Passed

After the initial testing reported above, the device was redesigned to accommodate the use of standard bacterial/viral filters. Two additional SST safety tests were performed at Keck Hospital of USC Department of Respiratory Care.

Test	Date	Time	Device	Flow Sensor	Circuit Leak	Expiratory Filter	Circuit Resistance	Compliance Calibration
1	04/08/2020	13.45	2 Flexi-Care Adult Expandable Circuit 96" w Y piece Luer elbow, 038-01-852U	Passed	Passed	Passed	Passed	Passed
2	04/08/2020	14.05	1 Flexi-Care Adult Expandable Circuit 96" w Y piece Luer elbow, 038-01-852U	Passed	Passed	Passed	Passed	Passed

2. **Please provide performance testing to support any device functionality beyond flow splitting (e.g., flow restriction, pressure regulation, flow and pressure monitoring, tidal volume estimation). ICU ventilators are capable of delivering significantly higher flow than anesthesia gas machines, therefore please consider performing testing on ICU ventilators or other ventilators capable of delivering comparable flow. Tests should be performed for all ventilation modes for which your device is labeled to be compatible. Please also justify how your test conditions represent a reasonable worst-case condition for the indicated use of your device (e.g., high or low respiratory rate, inspiratory to expiratory ratio, peak pressures, patient lung compliance and tidal volume mismatch).**

   Three circuits were constructed using a Flexi-Care Adult Expandable Circuit 96" with Y piece Luer elbow, 038-01-852U. The circuits were connected to the Sparrow COVID-19 Co-Ventilator Assist Device, and then connected to the AVEA ICU ventilator. A Wright Spirometer was calibrated using a BD 60ml syringe.

   Maquet 190 test lungs were used. Tidal Volume max 1 liter, 60 06 832 E037E, times 3. The test lungs were new, out of the box from Maquet.

Ventilator settings for performance testing were:

- Pressure Control Mode
- Inspiratory Pressure 25 cmH2O
- Positive End Expiratory Pressure 5 cmH2O
- I-Time 1.0 seconds
- Rate of Respiration 12 breaths per minute

- **Test 1**: 16:02 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

Measurements of 10 breath cycles per lung were taken using the calibrated Wright Spirometer.

The test showed even distribution of gases between the three test lungs in the circuit.

- **Test 2:** 16:41 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

A rubber band was added to decrease compliance of one test lung. Test lung compliance was decreased from 18 ml/cmH^2O of driving pressure to 9 ml/cmH^2O using the calculator on the ICU ventilator. (This is effectively a 50% decrease in compliance.) The same 10 cycle breath measurements were run and results using the calibrated Wright Spirometer were recorded.

The test showed uneven distribution of gases between patients with differing lung compliance.

- **Test 3:** 17:03 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

Finally, two more sets of 10 breath cycles were measured on the test lung with the highest compliance characteristics. The Wright Spirometer was placed on all three sections of the circuits.

This test showed that varying positions in the circuit did not yield changes to distribution of gases.

3. **If your device contains any moving (non-static) components, please provide durability testing for the labeled usage duration. Please also justify your chosen sample size.**

Sparrow does not contain any moving components.

3. Please fill out the attached Biocompatibility Information for EUA Review sheet for each item listed.

- The New Bureau has requested a Letter of Authorization from Equistar LyondellBasell, the manufacturer of the Pro-Fax 6331 material that will be used for injection molding of the device.
- LyondellBasell has DMF # 1963 on file with FDA.
- The UL Technical Sheet for Pro-fax 6331 can be found in the Appendix to this document.

4. Quality System

1. **Have you ever had any quality assessment that reviewed your ability to oversee or assess manufacturing activities associated with: actions to address risks and opportunities; operational planning and control; control of externally provided processes, products and services; and performance evaluation activities? Please describe.**

   While The New Bureau is responsible for design specifications for the Sparrow COVID-19 Co-Ventilator Assist Device, it has not itself been the subject of any ISO 13485:2016, 21 CFR Part 820, MDSAP or other quality audit, nor has it been audited by regulators in any other jurisdiction. However, The New Bureau has engaged a contract manufacturer to produce and distribute the device:

   Tessy Plastics Corporation
   700 Visions Dr
   Skaneateles Falls, NY 13153
   P: 1-315-689-3924

   Tessy is registered with FDA (Owner/Operator No 1317202). Its facility is ISO 13485:2016 certified and compliant with 21 CFR Part 820. It currently manufactures two non-metal vaginal specula (K120743, K022948) and blood bank supplies (BK950026). A copy of the Supplier Agreement with Tessy will be made available for FDA inspection.

2. **Explain how your experiences with the above listed quality management activities would allow you to adequately control the manufacturing activities associated with manufacturing ventilators capable of providing ventilatory support.**

   Tessy Plastics Corporation has implemented a quality management system for its manufacturing processes. The QMS will help the manufacturer ensure that products produced meet or exceed applicable standards for quality and consistency.

3. **How does your experience with your quality activities as described allow you to ensure reliable and consistent delivery of therapy and function of any safety alarms?**

   The Sparrow COVID-19 Co-Ventilator Assist Device is a vent splitter that can be used to modify a facility-based continuous ventilator for use by more than one patient at the same time. The Instructions for Use indicate that if patients are co-ventilated, a ventilator alarm will not be able to identify which patient triggered the alarm. As a result, co-ventilated patients should be monitored closely. When an alarm sounds, each patient should be evaluated immediately.

4. **How would you appropriately identify/account for/assess/and mitigate particular risks (e.g., hypoxemia, barotrauma, electrical or thermal shock, etc.)**

   The New Bureau will identify to FDA a qualified Third Party to track and investigate product complaints and report device-related adverse events according to standard operating procedures ("SOPs") and timelines applicable to emergency use authorization and consistent with the requirements set forth at 21 CFR Part 803 and 21 CFR Part 820. That Party will also be tasked with records retention according to 21 CFR 820.180. We intend to execute a Supplier Agreement with the Party and make copies of the executed Supplier Agreement and relevant SOPs available for FDA inspection.

5. **Please identify how your experiences allow you to provide oversight of supplier activities given the significance of supplied services/products to the operating of ventilator devices.**

   The New Bureau intends to execute supplier agreements with the manufacturer, distributor, and any other parties that may be engaged in preparation and use of the Sparrow COVID-19 Co-Ventilator Assist Device. We intend to monitor supplier compliance with applicable quality controls and regulations in a manner consistent with ISO 13485:2016 and 21 CFR Part 820.

APPENDIX: UL TECHNICAL SHEET FOR PROFAX 6331

Pro-fax 6331

Polypropylene, Homopolymer

Product Description Pro-fax 6331 general purpose polypropylene homopolymer is available in pellet form. This resin is typically used in injection molding applications.

For regulatory compliance information see Pro-fax 6331 Product Stewardship Bulletin (PSB).

Product Characteristics

Status Commercial: Active

Test Method used ASTM

Availability North America

Processing Methods Extrusion Compounding, Injection Molding

Features Good Colorability, Good Flow, Good Stiffness

Typical Customer Applications Containers, Other Industrial, Sports, Leisure and Toys

Typical Properties Method Value Unit Physical Density -Specific Gravity ASTM D 792 0.90
Note: 23/23°C Method B Melt Flow Rate (230°C/2.16kg) ASTM D 1238 12 g/10 min Mechanical Flexural Modulus ASTM D 790
(0.05 in/min, 1% Secant, Procedure A) 210000 psi (1.3 mm/min, 1% Secant, Procedure A) 1450 MPa Tensile Strength @ Yield ASTM D 638
(2 in/min) 4900 psi (50 mm/min) 34 MPa Tensile Elongation @ Yield ASTM D 638 11 % Impact Notched Izod Impact ASTM D 256
(73 °F, Method A) 0.6 ft-lb/in (23 °C, Method A) 32 J/m Thermal Deformation Temperature Under Load ASTM D 648
(66 psi) 200 °F (0.45 MPa) 93 °C Note: Unannealed

Notes Typical properties; not to be construed as specifications.

LyondellBasell markets this product through the following entities:
Equistar Chemicals, LP Basell Sales & Marketing Company B.V. Basell Asia Pacific Limited Basell International Trading FZE LyondellBasell Australia Pty Ltd

For the contact details of the LyondellBasell company selling this product in your country, please visit http://www.lyb.com/.

Before using a product sold by a company of the LyondellBasell family of companies, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

SELLER MAKES NO WARRANTY; EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY) OTHER THAN AS SEPARATELY AGREED TO BY THE PARTIES IN A CONTRACT.

This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices, without prior notification to Seller for each specific product and application; or

(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: (1) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (2) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; (3) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (4) tobacco related products and applications; (5) electronic cigarettes and similar devices; and (6) pressure pipe or fittings that are considered a part or component of a nuclear reactor.

(iii) Additionally, the product(s) may not be used in: (1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; (2) applications involving permanent implantation into the body; (3) life-sustaining medical applications; and (4) lead, asbestos or MTBE related applications.

All references to U.S. FDA, Health Canada, and European Union regulations include another country's equivalent regulatory classification.

Users should review the applicable Material Safety Data Sheet before handling the product.

Release Date: 07 May 2013