



Pediatric Tracheo-bronchomalacia Stent and Deployment System

IP Status: Issued US Patent; **Application #:** 15/946,901

3D Printed Pediatric Airway Stent

A 3D printed airway stent and delivery system can be rapidly customized and atraumatically inserted into pediatric airways to provide temporary internal support for the airway (or other duct or plenum) to treat tracheo-bronchomalacia (TBM). The stent is made of silicone, an FDA approved material that is conformable, biocompatible and suitable for additive manufacturing. The length and outer diameter of the stent are customizable based on the size of the patient's airway. After measuring the airway, the stent is 3D printed and the deployment system (stent, applicator, torque connector and drive catheter) is assembled. Rotating the driver engages the torque connector into the inner wall of the applicator, which engages with the stent to place it in position. After advancing the stent, the other components can be removed by driving the components in reverse, leaving the stent in the airway (or other passage benefitting from added support) when the applicator is removed.

Avoids Tracheostomy and Ventilators for Children

Tracheo-bronchomalacia (TBM) causes abnormal compression or collapse of the trachea or bronchi and affects 1 in 2000 children. Most will outgrow it, but a temporary internal support is often needed to avoid tracheostomy, ventilators, and other treatments whose side effects often include morbidity rates similar to that of TBM itself. Currently, no commercially available airway stents specifically for infants and small children exist. This technology is ideal for treating pediatric TBM because as the trachea grows wider and becomes less pliable, TBM symptoms become less pronounced, so this temporary approach can prevent airway collapse without the adverse effects of intubation, tracheal stents or other invasive therapies.

BENEFITS AND FEATURES:

- Airway stent for infants and small children
- Treats tracheo-bronchomalacia (TBM)
- 3D printed
- FDA cleared material (silicone)
- Temporary implant (510k predicate)
- Custom and/or on-shelf range of sizes

APPLICATIONS:

- Pediatric stents
- Adult GI applications or palliative trach/broch
- Replacement for current difficult-to-place products
- Improving adult airway stent design and customizability
- Deployment system could be used in GI applications that use a seldinger technique

Phase of Development- Prototype made and bench tested in ex vivo swine trachea-bronchus

Researchers

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20170050

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