

## Press release from Toulouse University Hospital (CHU de Toulouse)

Toulouse, 22<sup>nd</sup> February 2017

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### Innovation: world's first made to measure airway stent

Researchers in Toulouse have successfully developed and implanted several customized stents that are anatomically identical to patients' trachea and/or bronchi, offering hope to patients for whom standard prostheses do not fit. This has been achieved through a collaboration between the Pulmonology department<sup>1</sup> at Toulouse University Hospital and a Toulouse-based start-up company, AnatomikModeling<sup>2</sup>.

The first results from a clinical trial in which these new generation stents have been implanted have just been published in the most prestigious international pneumology journal, the *American Journal of Respiratory and Critical Care Medicine*<sup>3</sup>.

#### Indications for the implantation of a tracheobronchial prosthesis

Narrowing (or stenosis) of the trachea and/or bronchi leads to breathing difficulties and requires specific management through the implantation of a stent. Stenosis can occur due to a variety of reasons, such as post-intubation and post-tracheotomy problems, post-lung transplantation complications, diseases of the tracheal tissue and anatomical idiosyncrasies of the trachea. Obstruction of these upper airways is also a common complication in lung cancer patients.

#### The limits of standard prostheses

Currently, the standard prostheses used are suitable for most patients. However, they are not appropriate for some patients in terms of size, diameter, etc. or in cases with complex tracheal or bronchial anatomy. Poorly adapted prostheses present a risk of stent migration, inflammatory reaction and/or perforation. Thus, there is a great need for innovation in this field in order to overcome these issues.

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<sup>1</sup> The medical team of pulmonology at Toulouse University Hospital which realized this world premiere was composed with Pr A. Didier - Pr J. Mazières - Dr N. Guibert - Dr C. Hermant (Larrey hospital - 24, chemin de Pourville - TSA 30030 - 31059 Toulouse Cedex).

<sup>2</sup> AnatomikModeling (19, rue Jean Mermoz - 31100 Toulouse – [www.anatomikmodeling.com](http://www.anatomikmodeling.com)) was established in May 2015 to provide innovative solutions to health challenges using 3D technologies. It develops customized medical devices for reconstructive surgery, maxillofacial surgery, pneumology and thoracic surgery. Through applying 3D technologies, AnatomikModeling provides solutions that are 100% tailored to each patient, optimizing the aesthetic and functional results and minimizing intervention time and complications. The design of this new prosthesis won the « Coup de coeur – Life, Health and Well-being » category at the 36<sup>th</sup> Concours des Inn'Ovations (Innovations Competition). The trophy was presented on the 26<sup>th</sup> January 2017 at the Salon Midinnov, organized by Madeeli and the Occitanie region.

<sup>3</sup> Guibert N., Didier A., Moreno B., Mhanna L., Brouchet L., Plat G., Hermant C., Mazieres J. - Treatment of post transplant complex airway stenosis with a three-dimensional, computer-assisted - *Am. J. Respir. Crit. Care Med.* 2017 - en ligne le 16 février 2017 : <http://dx.doi.org/10.1164/rccm.201611-2361IM>

### A remarkable innovation: initial clinical trial results promising

These new prostheses are custom-made in three steps: first, a **3D reconstruction of the patient's airways** is produced from CT-scan images. This virtual reconstruction is then used to create a mould. Finally, a patient-specific prosthesis is manufactured from medical grade silicone elastomer.

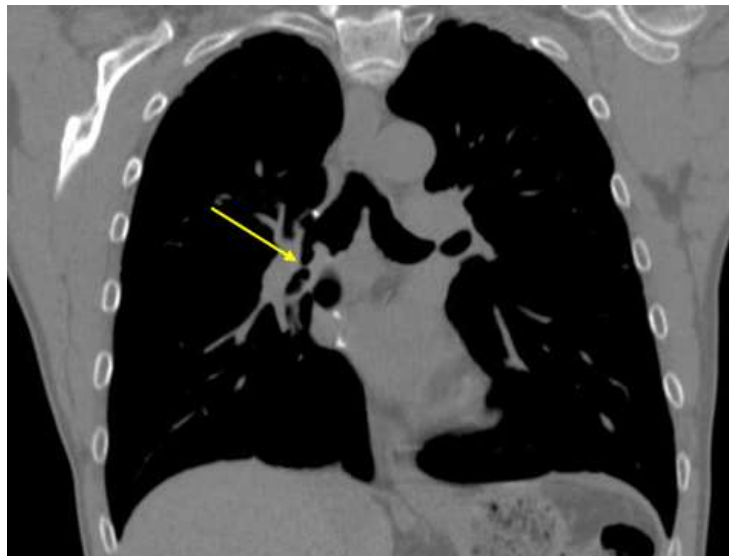


Figure 1 – Scanner image (image credit: Toulouse University Hospital 2017)

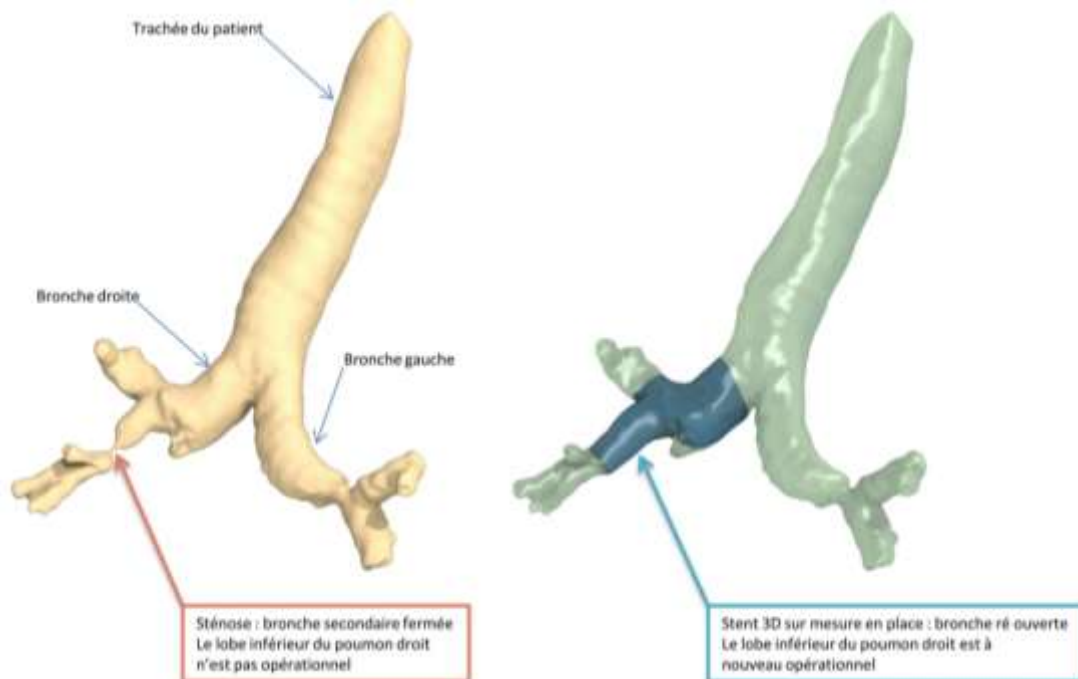


Figure 2 - Virtual 3D reconstruction (image credit: AnatomikModeling 2017)



Figure 3 – Corresponding implant (image credit: AnatomikModeling 2017)

The prosthesis is implanted by conventional bronchoscopy with the help of a prosthesis pusher, in the operating room under general anesthesia. In addition, the rigidity of the stent can be calculated as a function of the stenosis.

This new technology is being evaluated in an ongoing clinical trial. Through this, several patients have successfully received these implants, resulting in markedly improved quality of life with no complications so far.

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