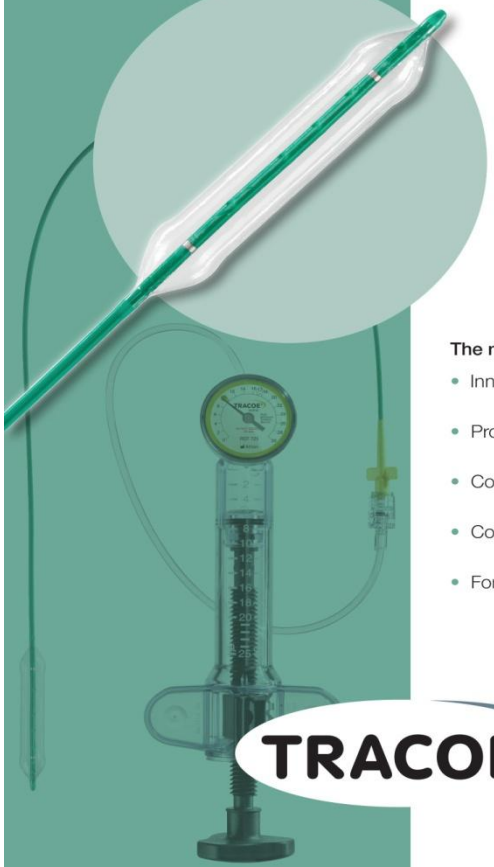
TRACOE aeris®
Balloon Dilation Catheter

For Treatment of
Laryngotracheal
Stenoses



The next Generation

- Innovative non-slip design
- Provides safe, secure placement
- Controlled, radial dilation
- Constant dilation of strictures
- For adults & children

TRACOE®

Laryngotracheal Stenosis gently treated

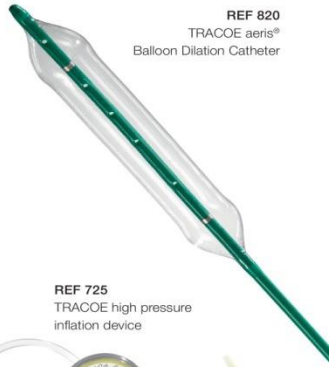
What does it mean?

Narrowing of the airway, the trachea or the larynx is called laryngotracheal stenosis. This may cause stridor, retractions or shortness of breath on exertion. Shortness of breath at rest implies a more severe narrowing of the airway. Due to the reduced dimension of their airways children are at higher risk than adults. Stenoses are differentiated by their grade of constriction, their length and consistency.

Classification of Laryngotracheal Stenosis [1]:

- **Grade I** = 0 – 50 % constriction of airway profile (no treatment necessary)
- **Grade II** = 51 – 70 % constriction of the airway profile (dyspnoe under stress)
- **Grade III** = 71 – 99 % constriction of the airway profile (dyspnoe at rest)
- **Grade IV** = complete occlusion of tracheal lumen (dilation contraindicated)

REF 820
TRACOE aeris®
Balloon Dilation Catheter



What is the etiology of subglottic stenosis?

- Due to scarred tissue after endotracheal tubes have been used or after an occlusion of a tracheostoma
- Due to injuries, inflammations or other ailments in the airway
- Due to radio-therapeutic treatment

REF 725
TRACOE high pressure
inflation device

How to treat them?

Typically a short, soft, young stenosis has a good chance of being treated endoscopically. This type of stenosis may be removed by balloon dilation as it is more gentle for the patient.

Balloon dilation may improve even severe stenosis of the airway and may prevent the need for open airway reconstruction. Surgery is often not necessary with soft and/or young stenosis. Improvement is often temporary but symptoms and quality of life will be optimised and the patient has time to decide whether a surgery should be performed by specialists.

The TRACOE aeris® balloon dilation catheter will be your first choice with stenosis, except for highly fibrous strictures.

TRACOE® select

TRACOE aeris® Balloon Dilation Catheter

Balloon dilation is a quick and safe procedure

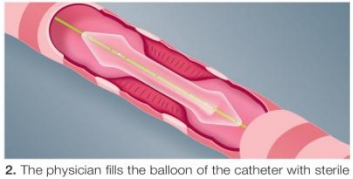
The minimal invasive balloon dilation of stenosis using the TRACOE aeris® balloon catheter offers an efficient, atraumatic method of treatment. It offers great benefits to the physician and patients [2].

In many cases it may even completely replace a surgical intervention. Even in cases that require further treatment, the dilation with the TRACOE aeris® balloon catheter is an effective treatment for airway stenosis caused by scar tissue that has narrowed the airway.

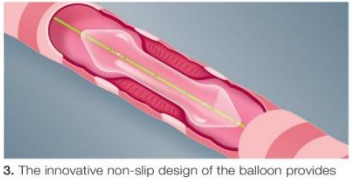
The innovative non-slip design of the balloon means that upon initial inflation, two hubs appear distally and proximately on the balloon. This locks the balloon in place over the stricture.

Patient Friendly Dilation

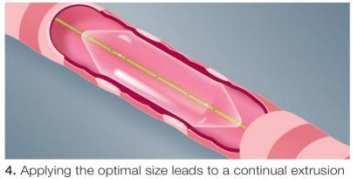
1. Under bronchoscopy surveillance the dilation catheter is introduced and placed exactly at the stenosis.



2. The physician fills the balloon of the catheter with sterile water. This will radially expand the balloon and dilate the stricture in a controlled manner.



3. The innovative non-slip design of the balloon provides safe, secure placement reducing the risk of slippage.



4. Applying the optimal size leads to a continual extrusion of the stenosis.

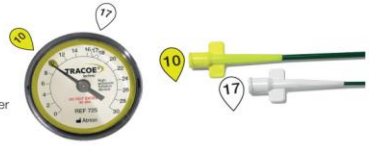
The dilation can be performed several times in a row during one treatment [3]. The inflation is performed with the TRACOE high pressure inflation device (REF 725) which is characterised by its safe and easy application.

⚠ **Please note, this brochure is neither intended to nor replaces the instructions for use. Please ensure you read the current valid instructions for use before using the product.**

1 Myer CM III, O'Connor DM, Cotton RT. Proposed grading system for subglottic stenosis based on endotracheal tube sizes. Ann Otol Rhinol Laryngol. 1994;103:319-323.
2 Michael Lang MD, Scott E. Brietzke MD, MPH. A Systematic Review and Meta-analysis of Endoscopic Balloon Dilation of Pediatric Subglottic Stenosis. Otolaryngology-Head and Neck Surgery 2014, Vol. 150(2) 174-179
3 K. Balakrishnan et al. Balloon dilation of the airway. Chap 12 Management of the Difficult Airway: A Handbook for Surgeons. JP medical publishers 2016

Colour Coding

The colour coded Luer connectors correspond to the proper pressure setting on the inflation device gauge.



Airway Balloon Dilation Sizing Guideline

REF Number	Patient Age				Balloon Size (diameter x length)	Max Inflation Pressure
REF 820-05	Premature < 30 weeks		Premature > 30 weeks	Neonates / Infants	5 x 30 mm	17 atm
REF 820-06					6 x 30 mm	17 atm
REF 820-07	1 year				7 x 30 mm	17 atm
REF 820-08	2 years	4 years			8 x 30 mm	17 atm
REF 820-09			6 years		9 x 30 mm	17 atm
REF 820-10	8 years	10 years			10 x 30 mm	17 atm
REF 820-12			12–14 years		12 x 40 mm	10 atm
REF 820-14	Adult Female			14–16 years	14 x 40 mm	10 atm
REF 820-16		Adult Male			16 x 40 mm	10 atm
REF 820-18					18 x 40 mm	10 atm

Based on clinical experience by MJ Rutter, MBChB, FRACS
Cincinnati Children's Hospital Medical Center, Ohio, U.S.A.

1 atm = 1.013125 bar = 101325 Pa

Ordering information

REF Number	Description	Packaging unit
REF 820-size (see above)	TRACOE aeris® Balloon Dilation Catheter	1 pc., sterile package
REF 725	TRACOE high pressure inflation device	1 pc., sterile package

Product Video
TRACOE aeris®
Balloon Dilation Catheter

For further information please contact your TRACOE representative

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