

# The protection of respiratory tracts at the level of tracheostoma in laryngectomy patients

## Advantages of CYRANOSE<sup>®</sup>, Artificial nose or H.M.E.\*

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First of all, in order to understand the interest and appreciate the efficiency of a device restoring an air-processing system thanks to an artificial nose for laryngectomy patients, it is essential to emphasize the mechanisms of natural physiological breathing and, on the contrary, the consequences of direct breathing via a tracheostoma without an air passage through the upper respiratory tract.

### Introduction

#### 1/ The physiological device

The main organ used for breathing is the peripheral effector, i.e. the lung. At this level, there must be an efficient air-processing system so as to ensure correct gaseous exchange.

Alveolar gas is vapour-saturated with an approximate level of moisture of 1 (or 100%). Its temperature is of 37°C. The gas therefore contains 44 mg/dm<sup>3</sup> of water-vapour gas.

This conditioning is all the more important since, in this part of the organism, the internal environment (blood) is as close as ever to the external environment.

Furthermore, the particles and microorganisms are filtrated at the level of the upper respiratory tract thanks to the mucus covering the ciliated cells all over the respiratory mucous membrane. This mucus is a protecting carpet that orients particles and microorganisms towards the pharynx and œsophagus at the level of the upper respiratory tract and towards the œsophagus, from the bronchial tubes to the trachea and the larynx thanks to the lift system performed by mucociliary activity. The role of the latter is even more important here than at the level of upper respiratory tract.

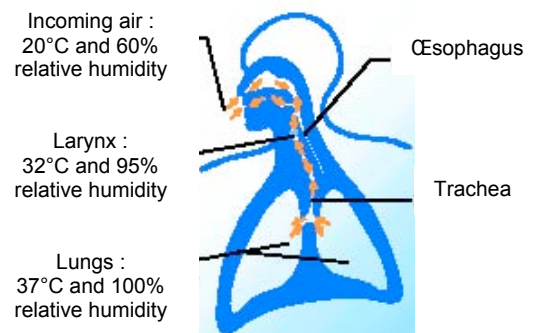
The efficiency of cilia depends on their beat frequency which itself depends on nervous

mediators and the physical quality of the mucous, that is to say its fluidity and volume. Indeed, nervous fibres regulate the activity of the mucous glands.

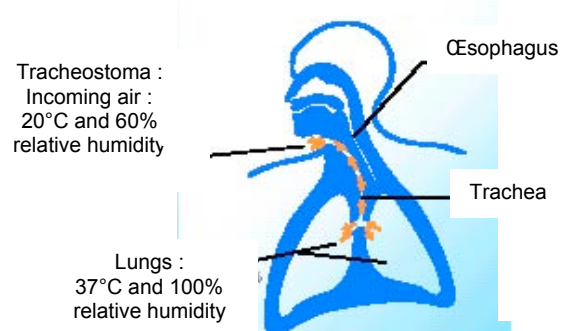
The nerve endings of the respiratory epithelium are sensitive to physical (air temperature) and chemical factors (presence of nitrates, for example). These nerve endings are also the origin of COUGHING, which is a defence reflex.

#### 2/ The consequences of a total laryngectomy

##### Before the operation



##### After the operation



(\*) Heat and Moisture Exchanger

The lack of air conditioning through the nose, but also through the pharynx and larynx, brings every inhaled particle and microorganism directly into the trachea and the tracheal tubes.

- There is consequently an important dusting with an increase of articular pollution at the level of the lower respiratory tree.
- External air temperature is 20°C and, for a 60% humidity, one litre of air contains 10 to 12 mg of water. The action of the nose and pharynx raises the temperature and humidity to 32°C and 95% at the level of the larynx, then to 37°C and 100% humidity for 44 mg of water per litre at the level of the alveolus.
- After a total laryngectomy, the direct contact between respiratory mucous and external air implies the evaporation of the periciliar liquid, provoking a drop in the air temperature and a lack of warming. The cold stimulates the nerve endings of the trachea and broncheal tubes respiratory epithelium, generates a stimulation of the mucus glands and therefore a rise of the mucus volume which is difficult to eliminate because of the inefficiency of coughing without a laryngeal sphincter.

The phenomenon is even more significant during winter. The reduction of the vapour suspended in the air linked with an improvement of the secreted mucus quality generates a subjective feeling of dryness of the respiratory tract. It also creates an intratracheal mucous plug. As soon as the volume of water increases, the laryngectomee feels much better.

These modifications of air conditioning also entail an increase of infectious phases and, finally, the deterioration of the respiratory function.

In the whole system, cilia are the most sensitive elements since their activity decreases with the cold or with a hygrometry drop. With the passing years, structures of the respiratory epithelium suffer from modifications.

The monolayer of epithelial cylindrical cells turns into a structure that consists of several layers of squamous cells : malpighian METAPLASIA of the epithelium with an inflammation of the chorion, œdema and progressive disappearance of the ciliar function.

Keratinisation may appear entailing the destruction of the basis membrane, fibrosis, and stenosis.

At the phase of mucous metaplasia, the damage is reversible if normal air conditioning is restored. At the phase of fibrosis, regeneration becomes impossible.

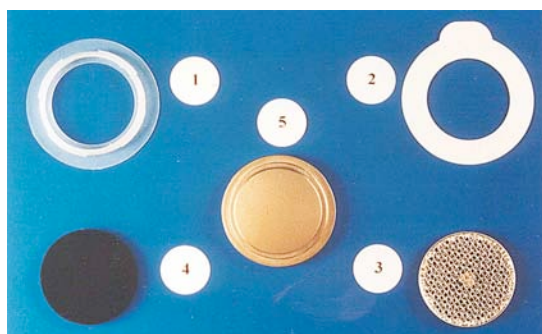
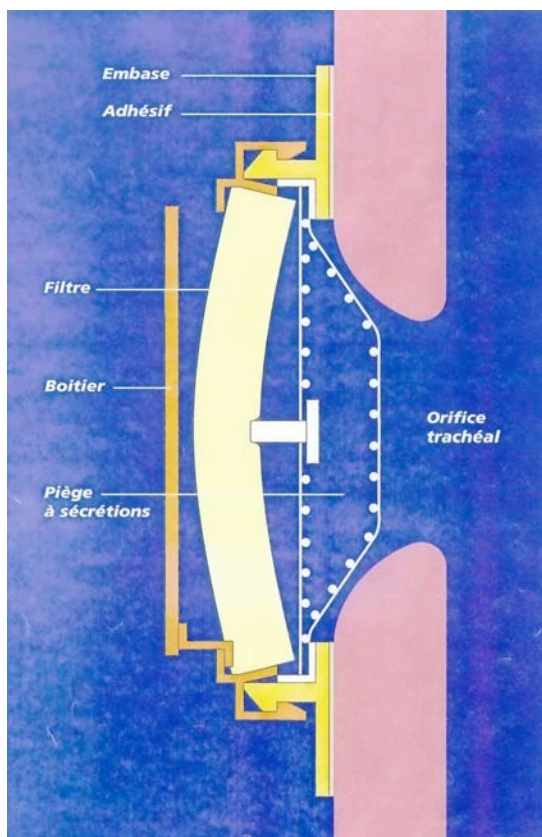
## **Presentation**

### **The artificial nose or H.M.E. (Heat and Moisture Exchanger)**

The main goal of the artificial nose is to restore an air-conditioning system not unlike natural breathing.

- The "artificial nose" at the level of the tracheostoma must not only be a protection for the respiratory tract – classical tracheal protections take on this function – but also, if possible, a genuine air-conditioning system, while remaining very discreet.
- The air-conditioning system must generate a reheating and moistening of inhaled air. There are also some useful atmosphere moistening systems but they are bulky and usable only in a closed room.
- Current artificial noses are usually unpractical, prominent and become easily clogged. Their use in a hospital environment is possible and their efficiency is rather good, however, they cannot be used for outpatient care. As seen before, with regard to classical tracheal protections, if they protect correctly the entrance of the tracheostoma, they do not offer a real air-conditioning system.
- Since the temperature of the exhaled gas is 35°C with 40 mg of water per litre, the main point is to recover the water vapour suspended in the air and the exhaled heat so as to release it in the inhaled air. This heat and moisture retriever must be able to retain these elements long enough to modify the inhaled air. Similarly, the secretions and expectoration must be trapped in a system easy to clean.
- Finally, this artificial nose must be as discreet as possible in order for the patient to dress with a round-neck pullover without discomfort.

CYRANOSE®  
 (fig. 2 cross-section and fig. 3)



- 1 - Embase - Collar
  - 2 - Adhésif - Adhesive
  - 3 - Piège à sécrétions - Secretion Trap
  - 4 - Filtre - Filter
  - 5 - Boîtier - Casing
- Orifice trachéal - Tracheal Orifice

The ambition of the CYRANOSE® respiratory prosthesis, made by CEREDAS, is to meet the following requirements :

- Be an efficient filter for microparticles suspended in the air,
- Be an efficient retriever of the heat and moisture in exhaled air,

- Be an efficient trap for expectoration, while remaining easy to clean,
- Finally, be small enough to be easy and discreet to wear in your everyday use.

#### The adhesive

The prosthesis is stuck on the skin thanks to a biological double-sided adhesive that avoids you to wear unaesthetic scarf around the neck. This adhesive, which is available in 6 sizes and different formats to fit the morphology of each neck, works with a collar stuck on the superficial side of the adhesive.

#### The collar

Silicone-made with an adhesive plane surface and cylinder to plug the other elements.

#### The secretion trap

The collar is intended to receive the secretion trap. The latter is composed of a metallic grid of fine mesh. This grid is made in nickel and chrome-plated surgical stainless steel. The meshes are designed to retain the secretion but also to be easy to clean using lukewarm soapy water. Therefore, it is not necessary to remove the prosthesis in order to clean it after every coughing fit.

However, in cases of extremely abundant secretion, the prosthesis is not easy to wear. We can nevertheless notice that the effect of the artificial nose reduces tracheo-broncheal irritation and consequently, decreases coughing. The secretion trap avoids the filter to clog up too quickly, moreover the latter is not in contact with the trap thanks to the spigot placed on the centre of the grid.

#### The filter

Made in open cell polyester foam, it is placed on the grid. The aim of this filter is to manage the exchange between external and tracheal air during inhalation and exhalation. Its dimension and its thickness have been conceived for a maximal efficiency.

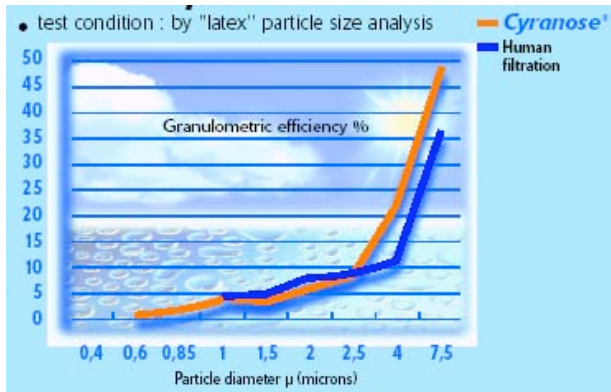
#### 1<sup>st</sup> role

It retains impurities. Studies show that the efficiency of the filter is close to physiological filtration (cf. Trial Curve G-Med/june 94 – Fig. 4). The result is thus an efficient protection of the respiratory tree thanks to a reduction of dusting and articular pollution.

(\* ) Heat and Moisture Exchanger

**FILTRATION**

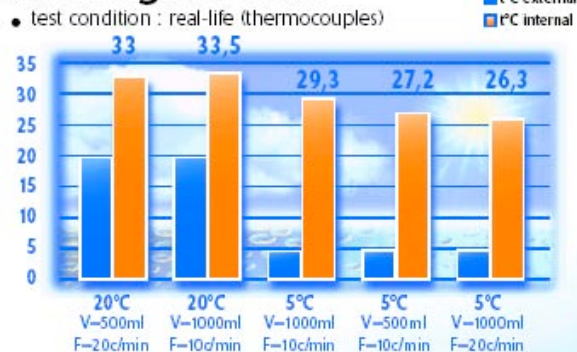
Efficiency of the filtration with regard to the size of the particles



Conventional Thoracic Fraction (according to AFNOR – Documentation Manual X 43-100)

2<sup>nd</sup> role

**Exchange of heat**



The metallic surfaces of the casing and of the secretion trap grid are highly sensitive to the heat exuded by exhalation. Therefore, they contribute to reheating the internal atmosphere of the prosthesis, in particular the filter.

Secretion trap for exhaled air, the filter immediately restores the heat to the inhaled air.

The tests carried out in the context of the trials of G-Med n° 31240264/15 appendix n° 3 of the report reveal that the temperature taken at a distance of 5 mm on either side of the prosthesis is on average 12,1 °C highest inside the prosthesis. An average curve made from constant data (cf. Curve Fig. 5) shows that the temperature within the trachea is 12°C above that of the external temperature.

3<sup>rd</sup> role

The capture of moisture in the exhaled air is based on the same principle. The moisture in the exhaled air settles on the metallic piece and on the filter which then become filled with micro-droplets of water recuperated by the inhaled air, therefore avoiding the desiccation of the tracheo-broncheal mucous membrane, but also the dehydration of secretions. Consequently, it is preventive treatment for tracheal plugs that are responsible for worrying and spectacular periods of distress.

The measures realised for the trial G-Med n° 31240264/15 evaluate the quantity of water in inhaled air and calculate the moisture captured by the prosthesis (Ew). This last figure corresponds to the quantity of water per air volume unit for the patient.

The formula used was :

$$Ew = [1 - \left( \frac{m^1 - m_2}{m^3 - m^4} \right) \times \frac{V_2}{V^1}] \times 43,1$$

- Ew = moisture captured by the exchanger
- m1 = initial mass of the patient model before the trial with the exchanger
- m2 = final mass of the patient model after the trial with the exchanger
- m3 = initial mass of the patient model before the trial without the exchanger
- m4 = final mass of the patient model after the trial without the exchanger
- V1 = total volume of gas transferred during the trial with the exchanger
- V2 = total volume of gas transferred during the trial without the exchanger

Trial n°	Ew at 36,6°C (mg/l)	% Relative moisture at 36,6°C
1	6	17
2	8	19
3	15	35

The moisture gain varies between 6 to 15 mg of water per litre of air for the patient. Therefore, the moisture gain varies from 17 to 35%.

(\* ) Heat and Moisture Exchanger

### **The casing**

Metallic and flat, it covers the filter and secretion trap. The aim is to leave - laterally in periphery - an opening between the casing and the collar in order to let the inhaled and exhaled air pass systematically through the grid and filter.

The visible part of the circular casing may be standard for a common tracheostoma. It can also be stuck on the collar thanks to a spring closing hermetically the passage of exhaled air, which allows the exhaled air under pressure to pass through a phonatory implant or fistula, depending on the patient. (Fig. 6).

The advantages are very significant as it allows:

- to avoid touching the tracheostoma with fingers (increased hygiene, patient less reluctant, easier rehabilitation),
- to avoid irritation of the edge of the tracheostoma due to fingers and nails,
- to avoid leakage during exhalation and therefore improve the efficiency of the phonatory implant or fistula.

### **Clinical Trials**

Obviously, the results obtained in vitro must be verified in vivo.

Clinical trials were carried out, after having been approved by the Consultation Committee for People Protection in the Biomed Research of the Kremlin Bicêtre (Comité de Consultation de Protection des Personnes dans la Recherche Biomédicale du Kremlin Bicêtre). Professor LUBOINSKI was in charge of the coordination and professors LUBOINSKI, GEHANNO and TRAISSAC were responsible for research. The promoter was CEREDAS S.A., in Antony (92).

The clinical trials were carried out in 1994 and have been subject to consultations and general commentaries for the presentation file of the CYRANOSE® product in order to obtain the reimbursement. Favourable opinion has been obtained.

The clinical trials were carried out on 65 laryngectomy patients, 20 of which gave up the prosthesis:

- 9 due to psychological troubles or lack of interest,
- 3 due to carcinological recurrence,

- 2 due to bending of the tracheostoma which could no longer stick correctly to the skin,
- 3 due to extremely abundant secretion,
- 2 due to allergy to the adhesive tape or frequent unsticking (abundant sweating),
- 1 for having chosen an automatic tracheostoma valve to use with a phonatory implant.

A few weeks of adaptation are necessary, and after 3 months, the patients are almost unanimously satisfied :

- Fitting is considered easy in 82% of all cases, removal in 93%.
- Filtration has improved in 96% of all cases on the outside and 98% on the inside.
- Reheating is considered to have improved in 94 % of all cases.
- Moistening has improved in 94% of cases with non-dry mucus fluid, along with a decrease and even the disappearance of scabs.
- Breathing is considered easier in 84% of all cases, and 40% of the patients consider their oesophagien voice to have improved.
- The less obvious improvement, although it is noticed by 78% of patients, is the effect on the decrease of secretions. It appears that certain results, particularly among patients prone to tracheo-mucous plug, were spectacular but not regular.

In addition, the efficiency of the prosthesis seems to be very satisfactory although it needs an adaptation period. Furthermore, it is all the more efficient since the patient is informed thoroughly and attentively.

The use of the prosthesis with an obstructing lid appeared rather interesting and particularly appreciated by the patients equipped with phonatory implants or fistula.

Some conformations resulting from surgical operations or inherent to the subject do not allow the use of standardised material.

Finally, we must add that the information transfer system developed by CEREDAS S.A. is extremely personalised and seems to be very well adapted, efficient and dynamic.

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