

## Current clinical studies:

Status	Study	Indication	Medication
Recruitment ongoing	Sinonasal inhalation of 6% saline solution by patients suffering from cystic fibrosis and chronic rhinosinusitis	Cystic fibrosis	6% hypertonic saline solution
Recruitment ongoing	Sinonasal inhalation of colistin by patients with cystic fibrosis and Pseudomonas aeruginosa infection	Cystic fibrosis	Colistin

## References:

- 1) On the penetrability of the maxillary sinus ostium for conventional and vibrating ultrasonic aerosols in the treatment of chronic sinusitis maxillaris.
- 2) Schuschnig U. et al (2006): Comparison of delivery efficiency in a nasal cast model of fluticasone propionate suspension and a novel solution aerosolized via the PARI VibRENT™. Poster presentation RDDX
- 3) Keller M. et al (2010): Pulsating Aerosols for sinus drug delivery: new treatment options & perspectives in chronic rhinosinusitis. ONdrug Delivery: 20-24
- 4) Tiffin N. et al (2006): A novel compressor/nebulizer system to delivery aerosol to the paranasal sinuses. Poster presentation ATS
- 5) Mainz J. et al (2011): Sinonasal inhalation of dornase alfa in CF: A double blind placebo controlled cross-over pilot trial. Auris Nasus Larynx
- 6) Mainz J. et al (2011): Sinonasal inhalation of tobramycin in cystic fibrosis patients with P. aeruginosa colonization of the upper airways – results of a multicentric placebo controlled pilot study. Poster presentation ECFC
- 7) Geppé N. et al (2009): Nebulizer therapy of rhinosinusitis in Children. Poster presentation ERS



Specialists in effective inhalation **PARI**

## PARI Service Center

+49 (0) 8151 279-279

Call us...

...if you have any questions about using, handling, cleaning or servicing your PARI inhalation device.

...if you need any information about spare parts for current or older PARI products and/or would like to know where they can be ordered from.

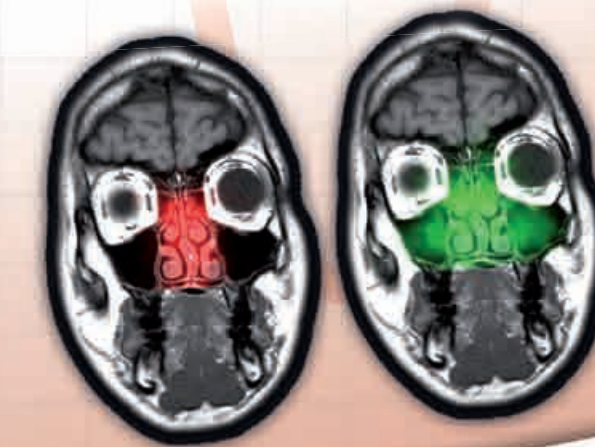
...if your PARI product needs to be serviced or repaired. With the PARI 48-hour repair service, your device will be shipped by our Service department within 48 hours.

...if you need a loan device while your PARI inhalation device is being repaired or while you are abroad on holiday.

**PARI** GmbH – Spezialisten für effektive Inhalation  
 Moosstraße 3 · 82319 Starnberg  
 Telephone +49(0) 8151 279-0 · Fax +49(0) 8151 279-101  
 E-mail: info@pari.de · [www.pari.de](http://www.pari.de)

# PARI SINUS

## Pulsating Aerosol



© PARI GmbH - Spezialisten für effektive Inhalation · 02BD0011 · 11/2011

## Making waves in the nasal sinuses

Specialists in effective inhalation **PARI**

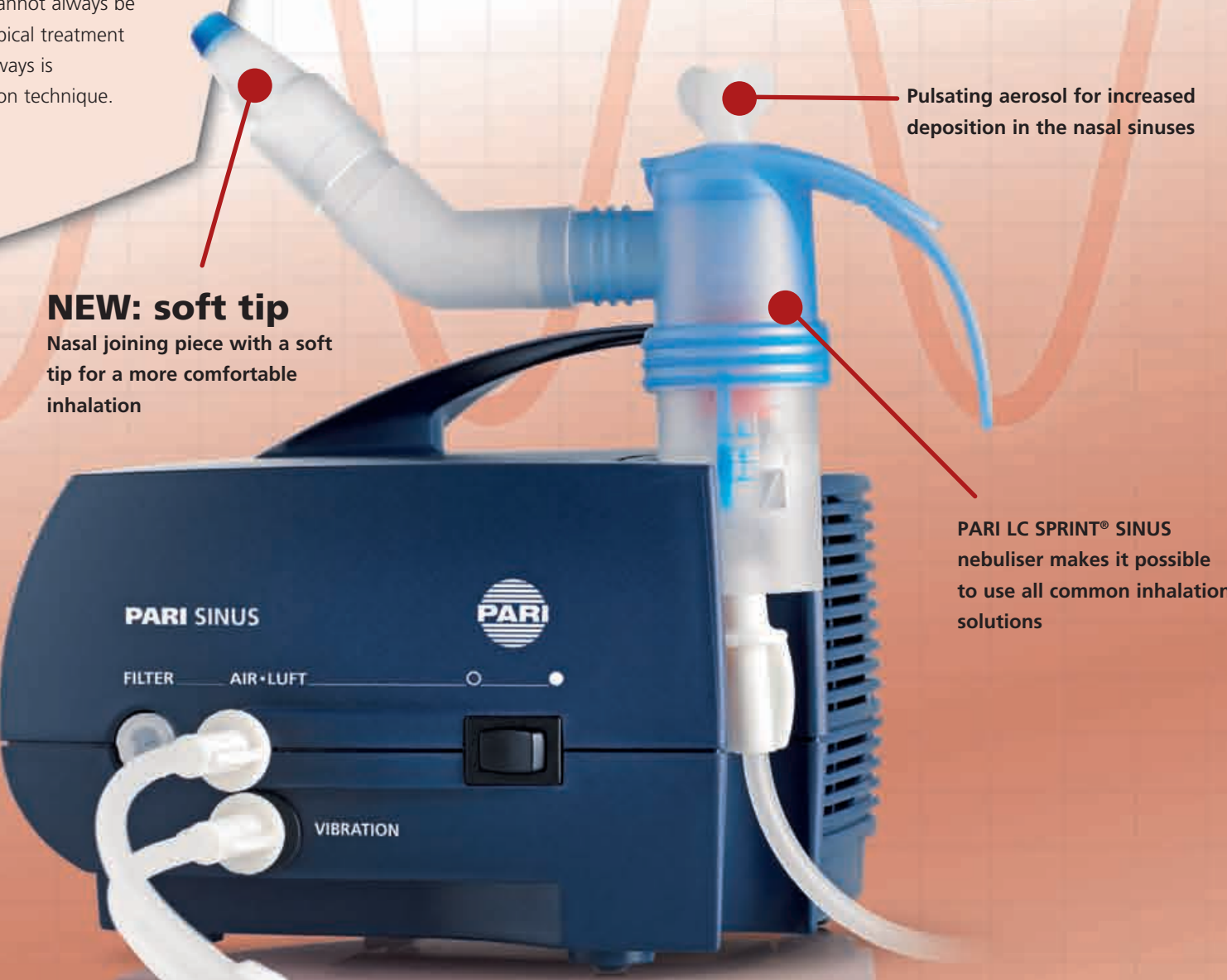




## Efficient medication deposition in the nasal sinuses

Treatment of the nasal sinuses with classic nasal sprays is a standard therapy for rhinosinusitis. But it very often happens that the rhinosinusitis cannot be treated efficiently because the nasal sinuses cannot always be reached satisfactorily with this form of therapy. Now, topical treatment of these practically unventilated cavities in the upper airways is possible with a specially developed, new type of inhalation technique.

**Tip:** The PARI SINUS compressor can also be used for treatment of the lower respiratory tract. To treat the lower respiratory tract, the PARI LC SPRINT® nebuliser is required. Available from chemists, medical supply specialists or medical equipment dealers.



**NEW: soft tip**  
Nasal joining piece with a soft tip for a more comfortable inhalation

## PARI SINUS Pulsating Aerosol

The special features of the PARI SINUS

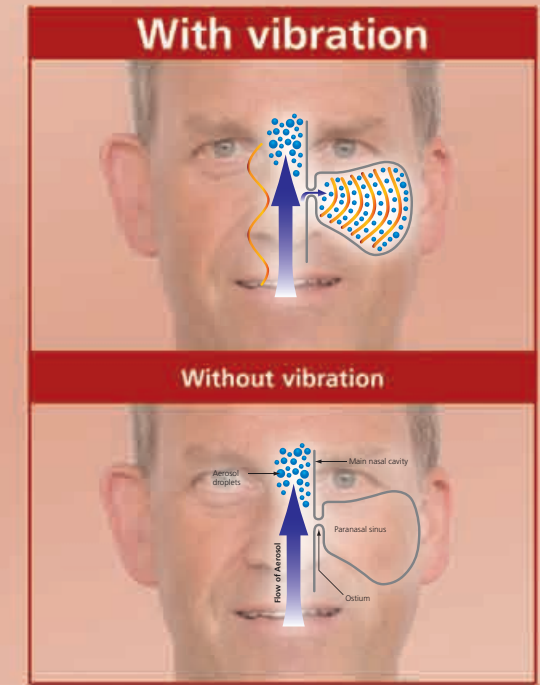
Pulsating aerosol for increased deposition in the nasal sinuses

PARI LC SPRINT® SINUS nebuliser makes it possible to use all common inhalation solutions

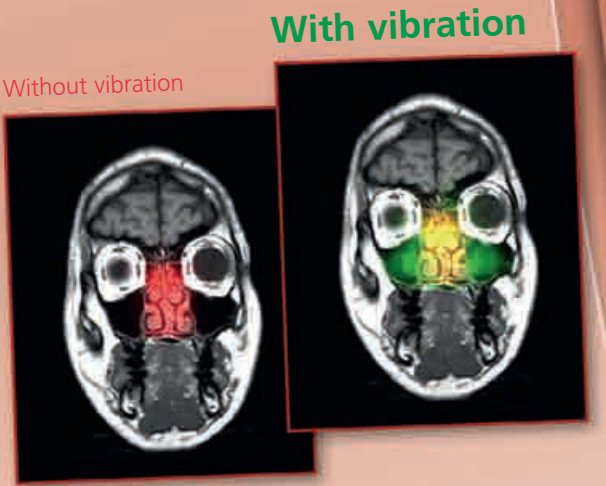
## Pulsating aerosol – why?

- Pulsating aerosols perform substantially better in penetrating the ostium of the maxillary sinus (one study showed that when pulsed aerosol is used the quantities (of medication) deposited are 25% greater than with non-pulsed aerosol<sup>1</sup>)
- Pump sprays achieve adequate nasal deposition, but almost none of the active agent is deposited in the sinus cavities<sup>2</sup>
- In an in-vivo „proof-of-concept study“ for PARI SINUS, it was demonstrated very clearly that the nasal sinuses can only be reached effectively by pulsation<sup>3</sup>

	Pump-action spray	Pulsating aerosol
Nose	193 µg	440 µg
Nasal sinuses	0,9 µg	29 – 38,7 µg



**Fig. 1: Operating principle of pulsating aerosol**  
This figure shows schematically that the aerosol is only able to pass through narrow openings of the ostia and thus reach the nasal sinuses if it is pulsed.<sup>4</sup>



**Fig. 2:** Gamma camera images superimposed on MRT imaging clearly show: the nasal sinuses are not ventilated unless additional pulsed pressure fluctuations (shown in green) are applied. Without this vibration, only the main nasal cavity (shown in red) is reached.<sup>3</sup>

## Useful information

Before using the PARI SINUS, it is recommended to carry out a nasal rinse, since the nose must be clear to allow effective treatment.



In order to ensure that pulsating aerosol is able to reach the nasal sinuses effectively, the soft palate must be closed.



The pressure resistance that builds up in the head when the PARI SINUS is used is unpleasant for some patients. This can be reduced by cutting off the inner tip of the nose plug with a pair of scissors.

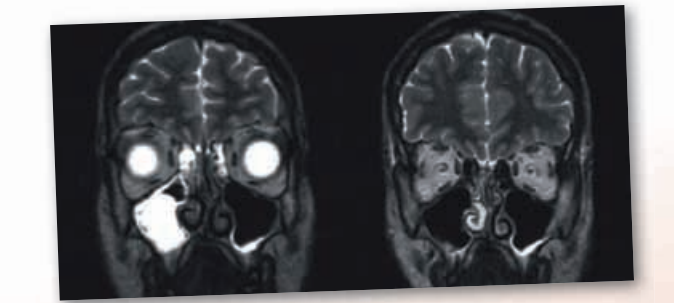


Treatment with the PARI SINUS takes just 5 minutes (if possible, treat the left and right nostril for about 2.5 minutes each).



## Results of previous studies:

### 1) Case Study: Patient with chronic sinusitis<sup>3</sup>



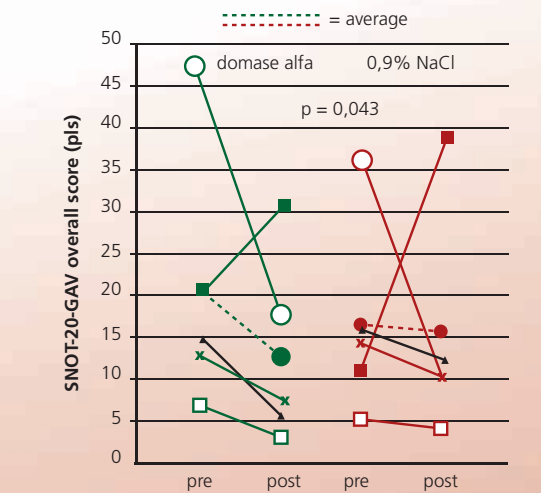
**Fig. 3:** A patient with persistent, chronic sinusitis (image on left) had already been scheduled to undergo surgery. After a three-month course of steroids (budesonide solution 1x daily for three months) administered using the PARI SINUS, the planned operation could be cancelled (image on right).<sup>3</sup>

### 3) Sinonasal inhalation of tobramycin (gernebcin) in CF<sup>6</sup>

	Tobramycin group	Control group
Reduction of P.a. in the nasal lavage	50%	0%

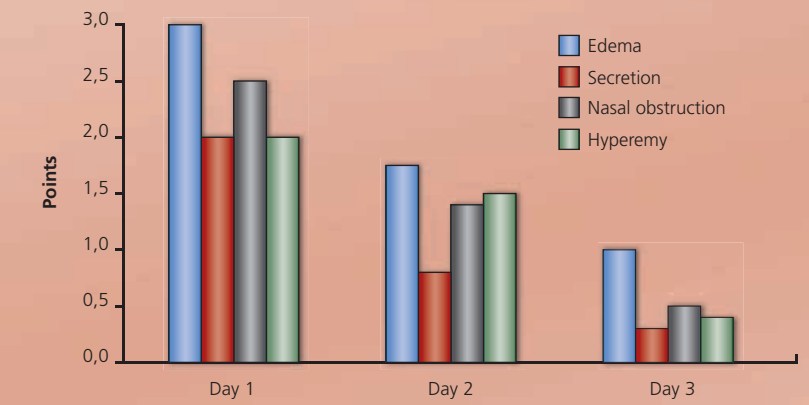
Table: Sinonasal inhalation with pulsed aerosol is a promising method for reducing colonisation by P.a. (*Pseudomonas aeruginosa*) in the upper respiratory tract. 9 patients (6 were treated with tobramycin and 3 with 0.9% NaCl). 80 mg tobramycin (gernebcin, 2 ml, 4 min for each nostril) or NaCl 0.9% were inhaled once a day for 28 days using the PARI SINUS. A reduction of P.a. in the nasal lavage was demonstrated for 50% of the patients in the tobramycin group.

### 2) Sinonasal inhalation of dornase alfa by CF patients<sup>5</sup>



**Fig. 4:** Effect of sinonasal inhalations with dornase alfa and NaCl 0.9% on the general SNOT-20 score. A marked reduction is shown in the scores for dornase alfa compared with 0.9% NaCl;  $p = 0.043$ . In this case, results from the first day of inhalation were compared with results from the last day. Def SNOT: sinonasal outcome test, a special test in which patients evaluate their own sinonasal disorders in terms of 20 predefined subject areas.

### 4) Sinonasal inhalation by children with allergic rhinosinusitis<sup>7</sup>



**Fig. 5:** Patients (n= 15) suffering from allergic rhinosinusitis were treated for one week with budesonide suspension (0.125–0.25 mg), oxymetazoline 0.05% (2 drops) dissolved in 0.9% isotonic sodium chloride solution, ambroxol (1 ml; 15 mg). Treatment with the PARI SINUS significantly alleviates the symptoms, particularly nasal congestion and rhinorrhoea.