LENIO® *flex*

System for Sinus Ostia Dilation

Small balloon – great effect

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LENIO®*flex* -System for Sinus Ostia Dilation

Balloon System for Sinus Ostia Dilation

The Lenioflex Balloon System offers minimally invasive intervention for those patients with chronic rhinosinusitis who may no longer respond to or be treated effectively with medication.

The efficacy and establishment of balloon sinuplasty techniques has been proven by several U.S.studies over the past few years (as referenced at the bottom of this brochure).

The technique enables controlled expansion of the ostia to allow symptoms to be treated whilst preserving tissue. It is suitable for both primary and secondary treatment either as a single or multi-procedure approach (e.g. FESS).

Lenioflex catheters are suitable for treating ostia in the areas of

- Frontal sinuses
- Maxillary sinuses
- Sphenoid sinuses

The advantages for patients, as reported in the literature mainly include:

- Minimally invasive technique and preservation of mucous membrane
- Low risk of bleeding
- Minimal risk of failure
- Permanent improvement of symptoms
- Quick recovery

Procedure

1 Under endoscopy, a guide wire (Lenioguide) is inserted transnasally into the respective paranasal sinus with an angled cannula introducer (Leniointro).
(An optional illuminated guide wire is also available to show the sinus entrance via diaphanoscopy.)

2 Once the guide wire is correctly in-situ, the flexible balloon catheter (Leniocat) is then introduced in order to position the balloon within the ostium. Fluoroscopic control (C-arc) may also be used to verify correct placement of the balloon.

3 The balloon is then inflated to its designated diameter (5-7mm) using a high-pressure syringe (Leniоinflate). Typical pressures required are approximately 8-10 bar and should never exceed 12 bar.

4 Having left the balloon fully inflated for several seconds, the pressure is then released and the balloon is removed to enable the expanded ostium to be re-examined.

Treatment Steps

Ostia dilation remodels the bone structure of the excretory sinus ducts by permanently displacing adjacent paranasal sinus structures.

Before use, please refer to the operating instructions for possible contraindications and adverse factors.

LENIO®*flex* -Flexible and Highly Effective Technique

The Lenioflex components can be easily combined into a system that is simple and easy to use.

LENIO®*intro*

Tubes with a distal angle of 0-110° for targeted navigation of the balloon catheter into the respective ostium.

LENIO®*bridge*

A unique handle that locks components together and enables simple handling and navigation of the sinuscope.

LENIO®*cat*

Balloon catheters available in both traditional cylindrical shape and custom peanut shape (for particularly precise and stable placement) for expanding the respective ostia.

LENIO®*guide*

Guide wire in regular or light-compatible options for sinus cavity navigation and as an insertion aid for the balloon catheter. (Light version used to confirm correct placement by diaphanoscopy.)

LENIO®*inflate*

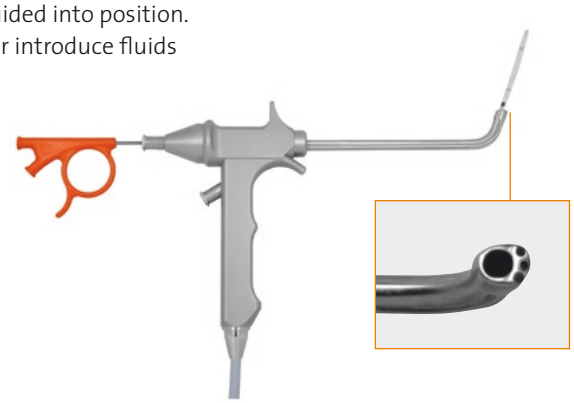
Precision high-pressure syringe for inflating the balloon, including manometer for precise pressure monitoring. Typical pressure range 8-10 bar, but no more than 12 bar.

Sinuview

Use the new Sinuview Optics for quick and precise placement of the balloon in the frontal ostium. The endoscope enhances navigation and enables the correct placement of the catheter under direct vision. The catheter is inserted through the optical working channel and easily guided into position. The additional suction/flushing channel makes it possible to remove secretions or introduce fluids to clean the distal end of the optic.

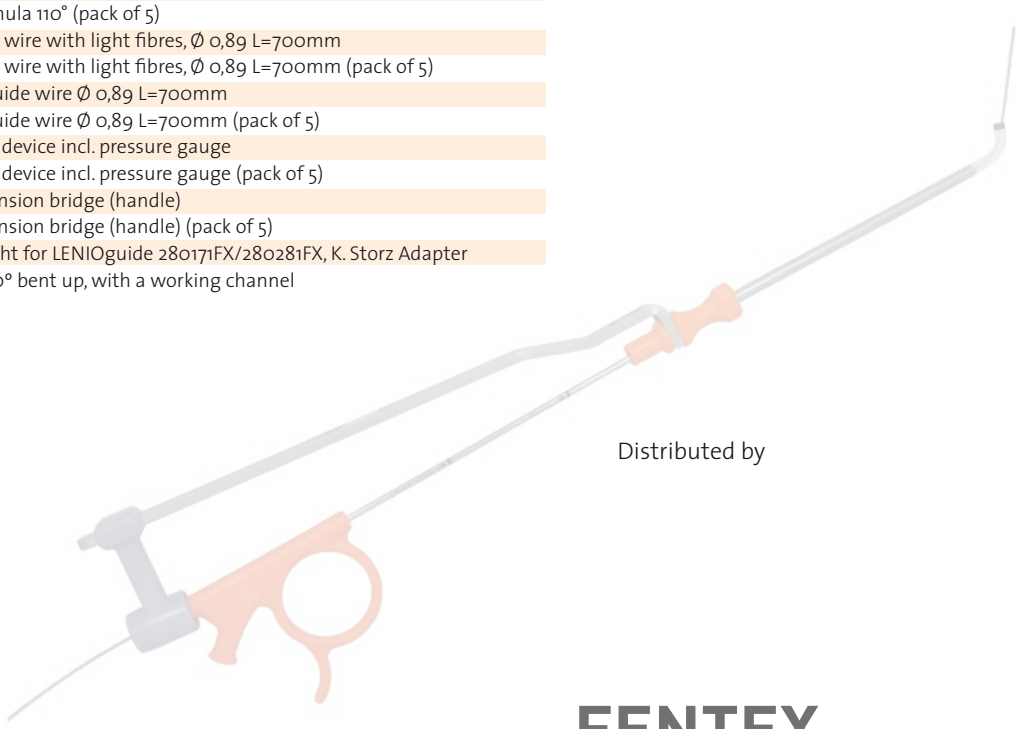
Other advantages include:

- 17,000 pixels fiber optics (vision)
- 2.3 mm working channel with distal angle of 70°
- Integrated light fibre and suction
- Steam autoclavable (134.4°C / 273°F)
- When using Sinuview Optics, the Leniointro and Leniobridge components are not required.



Order Information

Fentex Ref.	Sources:
280516FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 5mm x 16 mm
280521FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 5mm x 16 mm (pack of 5)
280616FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 6mm x 16 mm
280621FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 6mm x 16 mm (pack of 5)
280716FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 7mm x 16 mm
280721FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 7mm x 16 mm (pack of 5)
280524FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 5mm x 24 mm
280528FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 5mm x 24 mm (pack of 5)
280624FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 6mm x 24 mm
280628FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 6mm x 24 mm (pack of 5)
280724FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 7mm x 24 mm
280728FX	LENIOcat, Dilating-Balooncatheter, cyl. balloon Ø 7mm x 24 mm (pack of 5)
281724FX	LENIOcat, Dilating-Balooncatheter, fitted (waist) balloon Ø 7mm x 24 mm
281728FX	LENIOcat, Dilating-Balooncatheter, fitted (waist) balloon Ø 7mm x 24 mm (pack of 5)
280100FX	LENIOintro, guiding cannula 0°
280105FX	LENIOintro, guiding cannula 0° (pack of 5)
280130FX	LENIOintro, guiding cannula 30°
280135FX	LENIOintro, guiding cannula 30° (pack of 5)
280170FX	LENIOintro, guiding cannula 70°
280175FX	LENIOintro, guiding cannula 70° (pack of 5)
280190FX	LENIOintro, guiding cannula 90°
280195FX	LENIOintro, guiding cannula 90° (pack of 5)
280110FX	LENIOintro, guiding cannula 110°
280115FX	LENIOintro, guiding cannula 110° (pack of 5)
280271FX	LENIOguide, Light, guide wire with light fibres, Ø 0,89 L=700mm
280281FX	LENIOguide, Light, guide wire with light fibres, Ø 0,89 L=700mm (pack of 5)
280270FX	LENIOguide, standard guide wire Ø 0,89 L=700mm
280280FX	LENIOguide, standard guide wire Ø 0,89 L=700mm (pack of 5)
280350FX	LENIOinflation, inflation device incl. pressure gauge
280355FX	LENIOinflation, inflation device incl. pressure gauge (pack of 5)
280300FX	LENIObridge, guide extension bridge (handle)
280305FX	LENIObridge, guide extension bridge (handle) (pack of 5)
716800FX	Light Carrier 1.80 m lenght for LENIOguide 280171FX/280281FX, K. Storz Adapter
700880FX	SINUVIEW endoscope 70° bent up, with a working channel



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Literature:

Multicenter Registry of Balloon Catheter Sinusotomy Outcomes for 1,036 Patients
Howard L. Levine, MD; Anthony P. Sertich II, MD; Douglas R. Hoisington, DO; Raymond L. Weiss, MD; Jordan Pritikin, MD; for the PatiENT Registry Study Group
Ann Otol Rhinol Laryngol 2008;117:263-270.

CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)
Bolger et al. Otolaryngol Head Neck Surg. 2007 Jul;137(1):10-20

Long-term outcome analysis of ballon catheter sinusotomy: Two-year follow-up
Raymond L. Weiss, MD, Christoper A. Church, MD, Frederick A. Kuhn, MD, Howard L. Levine, MD, Michael J. Sillers, MD Wiston C. Vaughan, MD
Otolaryngology-Head and Neck Surgery (2008) 139, S38-46

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