**Hunt Developments (UK) Ltd.**
Units 15-18 Holmbush Industrial Estate, Midhurst, West Sussex, GU29 9HX, England
**T** +44 (0) 1730 813020 **F** +44 (0) 1730 815083 **E** info@huntdevelopments.co.uk **W** www.huntdevelopments.co.uk

HUNT

# Nasosorption™ FX·i Price List

*Hunt Ref # HMD 798-34 HMD 874-9, February 2018*

Thank you for your interest in our current range of **Nasosorption™ FX·i devices.**

## Description:

Nasosorption™ FX·i is a non-sterile single-use device consisting of a synthetic absorptive matrix (SAM) strip attached to an applicator handle for the ease of nasal sampling. Nasosorption™ FX·i is supplied housed in a cryo-transport tube for protection.

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## General Requirements:

These medical devices are C.E. marked, Class 1 Single-Use Non-Sterile Medical Devices, manufactured in accordance with a quality system audited against the requirements of ISO 13485 (Medical Devices). The devices are gamma irradiated for bioburden control. These devices are currently manufactured for distribution which is limited to a number of selected organisations and are not for distribution outside of the supplied organisations. Please see our full Terms and Conditions on page 3.

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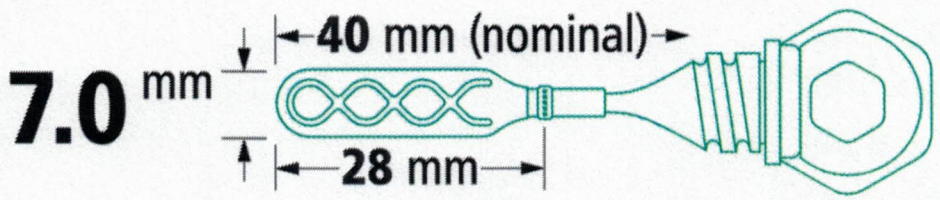
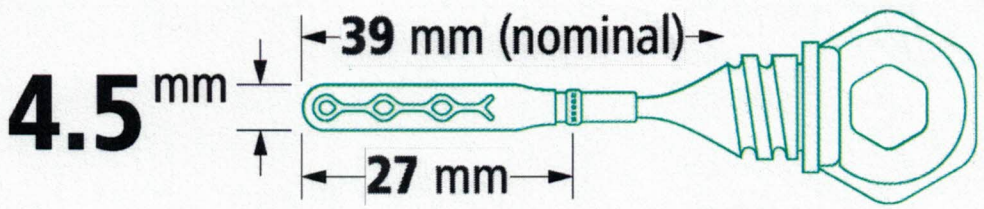
## Nasosorption™ FX·i device size range (device drawings not to scale):

**NSFL-FXI-11** *(HMD 798-34)* Nasosorption™ FX·i, working length 40mm, swab size 7 x 28mm long, 2 year shelf life. Imperial college have used this size of device for adults.




**NSFL-FXI-13** *(HMD 874-9)* Nasosorption™ FX·i, working length 39mm, swab size 4.5mm x 27mm long, 2 year shelf life. Imperial college have used this this size of device for children.



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Nasosorption™ FX·i Instructions for Use:

NASOsorption® FX·i

**Hunt Developments (UK) Ltd**
Units 15-18
Holmbush Industrial Estate
Midhurst, West Sussex
GU29 9HX
UNITED KINGDOM

+44 (0) 1730 813020
**www.nasosorption.com**

General contact
**info@huntdevelopments.co.uk**
Complaint reporting
**complaints@huntdevelopments.co.uk**

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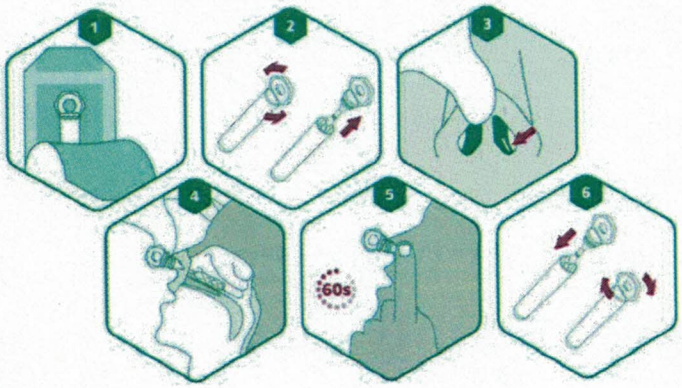
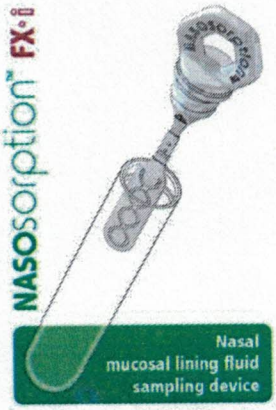
NSTL-FXI-IF10 rev 3




## Nasosorption™ FX·i

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### Important

Please read before use.

Do not use the device if the packaging is opened, damaged or expired, or if there is physical contamination or discolouration of the device.

### Description

NASOSORPTION™ FX·i is a non-sterile, single-use device consisting of a synthetic absorptive matrix (SAM) strip attached to an applicator handle for ease of nasal sampling.

NASOSORPTION™ FX·i is available in 3.0 mm, 4.5 mm and 7.0 mm widths.

NASOSORPTION™ FX·i is supplied housed in a cryo-transport tube for protection.

### Intended Use

NASOSORPTION™ FX·i is intended to be inserted into the patient's nasal cavity by a trained healthcare professional. A sample of mucosal lining fluid is taken from the lowest nasal turbinate (inferior turbinate) as shown in figure 4.

Intended for use in a single nostril of a single patient.

NASOSORPTION™ FX·i is inserted into the nasal cavity for a period of 60±2 seconds in order to obtain a sample.

### Contraindications

Not intended for infant use.

### Warnings & Precautions

Select a NASOSORPTION™ FX·i device of a size appropriate to the patient. Do not insert SAM beyond the nasal cavity into the nasopharynx.

Do not sterilise before use.

Before applying NASOSORPTION™ FX·i to the nose, in all cases the anterior nasal cavity should be carefully examined by appropriately trained clinical staff using a light source, and a speculum where appropriate.

Nasal sensitivity may cause involuntary head movement, e.g. sneezing.

Caution should be employed in conditions where there is any risk of NASOSORPTION™ FX·i causing damage to the epithelial surface:

- local anatomical defects of the nasal and sinus passages: congenital malformations, septal defects, previous surgery
- nasal polyps and other luminal lesions
- nasal mucosal ulceration, including Wegener's granulomatosis (granulomatosis with polyangiitis, GPA) and Churg-Strauss syndrome
- nasal bleeding (epistaxis)
- local nasal vascular and/or capillary defects
- systemic bleeding disorders including coagulation defects (inherited or acquired), platelet insufficiency and thrombocytopaenia
- severe allergic rhinitis, chronic rhinosinusitis
- herpes simplex and herpes zoster (shingles), staphylococcal and streptococcal infection
- malignant lesions

### Instructions for Use

1. Nasal examination should be performed as described in the Warnings & Precautions section above. With washed and gloved hands, peel open the foil pack and remove the NASOSORPTION™ FX·i device. Examine the device for signs of damage. If damage is found, do not use the device; contact the manufacturer. Keep the applicator housed in the tube until use to reduce the risk of contamination.
2. Unscrew the applicator using the handle and remove the applicator from the tube, avoiding contact with the absorbent end.
3. With one hand, hold the patient's head and push back the tip of the nose with the thumb to provide a clear line of sight. With the aid of a light source, carefully insert the NASOSORPTION™ FX·i device into the nostril and gently locate the absorbent strip flat against the surface of the inferior turbinate.
4. Figure 4 shows the correct position of the strip against the inferior turbinate.
5. Hold the device in place by asking the patient to press a finger against the side of the nostril for 60 seconds.
6. Release the finger before removing the applicator from the nasal cavity. Return the device to the tube and screw it back in.

### Preservation of Sample

The sample should be refrigerated immediately but stored between -60° and -80°C as soon as practically possible.

### Storage

Keep out of direct sunlight.

Until use, the device should be stored in its original packaging between 5°C and 25°C.

**Revised October 2016**

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