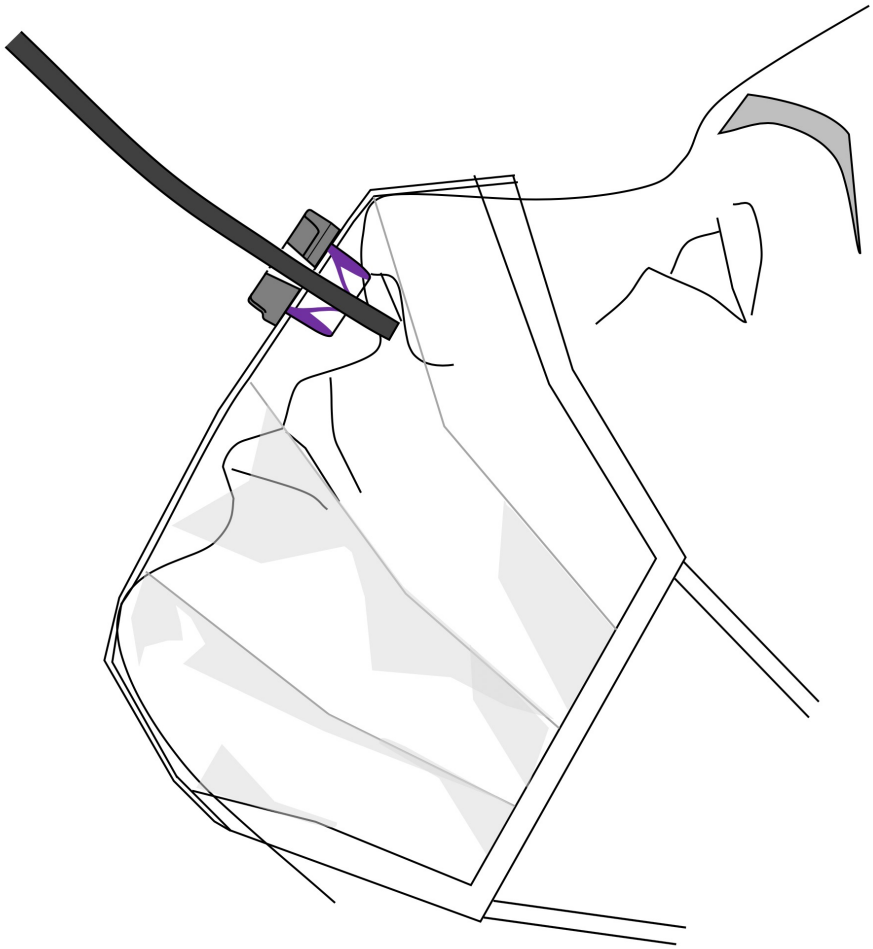
Safe Nasendoscopy Assisted Procedure

Product information

18 August 2020UK Patent Application No. 2005725.3



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Introduction

SNAP is a 'short-term' single use Class I Medical Device as described by Rule 5 of Annex IX of the 93/42 EEC Medical Device Directive. It provides a safe conduit for the passage of a nasal endoscope through a surgical mask.

On the 17th April 2020, Public Health England released updated guidance on the risks posed by Aerosol Generating Procedures (AGP)[1]. Within this they have stipulated that endoscopic examination via a nasendoscope with suction is considered an AGP. This has been backed by national societies such as ENT-UK, The British Laryngology Association (BLA) and the Royal College of Speech and Language Therapists (RCSLT). The appropriate 'High Level' Personal Protective Equipment (PPE) should be donned by the clinician to perform such an examination[2]. This includes earring an FFP3 Respirator, Fluid resistant gown, gloves and sealed goggles or a full face shield. Environments in which these procedures are performed on a regular basis are considered 'High Risk' clinical areas.

The severity of COVID-19 infection has been linked to increased viral load and exposure meaning that healthcare workers are particularly vulnerable to this virus[3]. In particular those performing investigations of the upper aero digestive tract are vulnerable to aerosol, promote and droplet exposure which could potentially transmit viral particles.

In order to restore general clinical practice ENT-UK have highlighted a number of steps to use a guidance in order to mitigate risks[4]. Evidence has been presented to support the use of a patient worn mask during nasendoscopy. In particular a mask fitted with a valved mechanism has demonstrated far superior efficiency in reducing particle production than either NOT wearing a mask or wearing a mask with a hole but into it[5].

Creating a bespoke Medical Device for the specific purpose of safe nasendoscopy to reduce droplet spread will ensure a replicable a safely adopted process that can be adhered to a Standard Operating Protocol (SOP)

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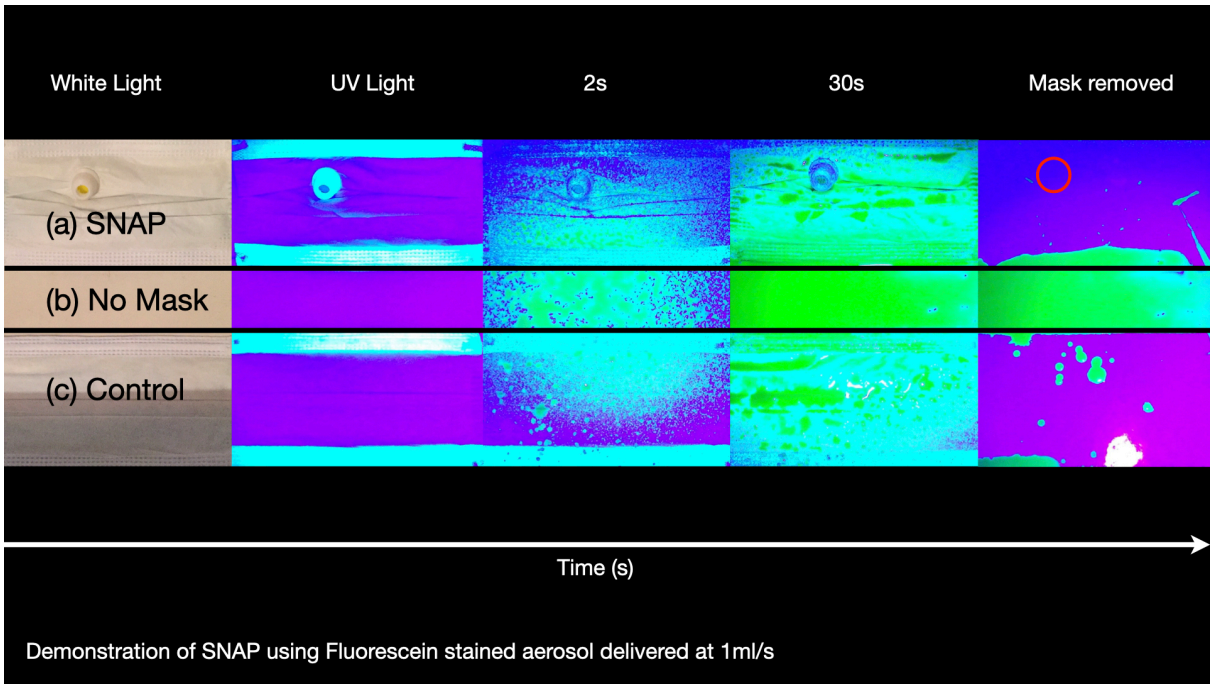
In Vitro testing

SNAP has been leak tested in-vitro using a surrogate fluorescein aerosol test. 3 conditions were analysed looking at any potential contamination when comparing a standard surgical mask, the same mask fitted with SNAPe-i and no mask. After 30 seconds of exposure at a rate of 1ml/s of fluorescein the results demonstrated no fluorescein leakage through the SNAPe-i device. There was no contamination through the mask with the SNAP fitted. The 'No mask' scenario lead to significant fluorescein radiance under ultra violet conditions.



In Vitro Aerosolised Fluorescein test results 1ml/s through a 50 micron point. From superior to inferior: (a)mask fitted with SNAP' vs (b)'no mask' vs (c)'mask with no SNAP' as positive control to demonstrate no leakage through the mask material. No visual difference seen and no leak though the SNAP valve (red circle)

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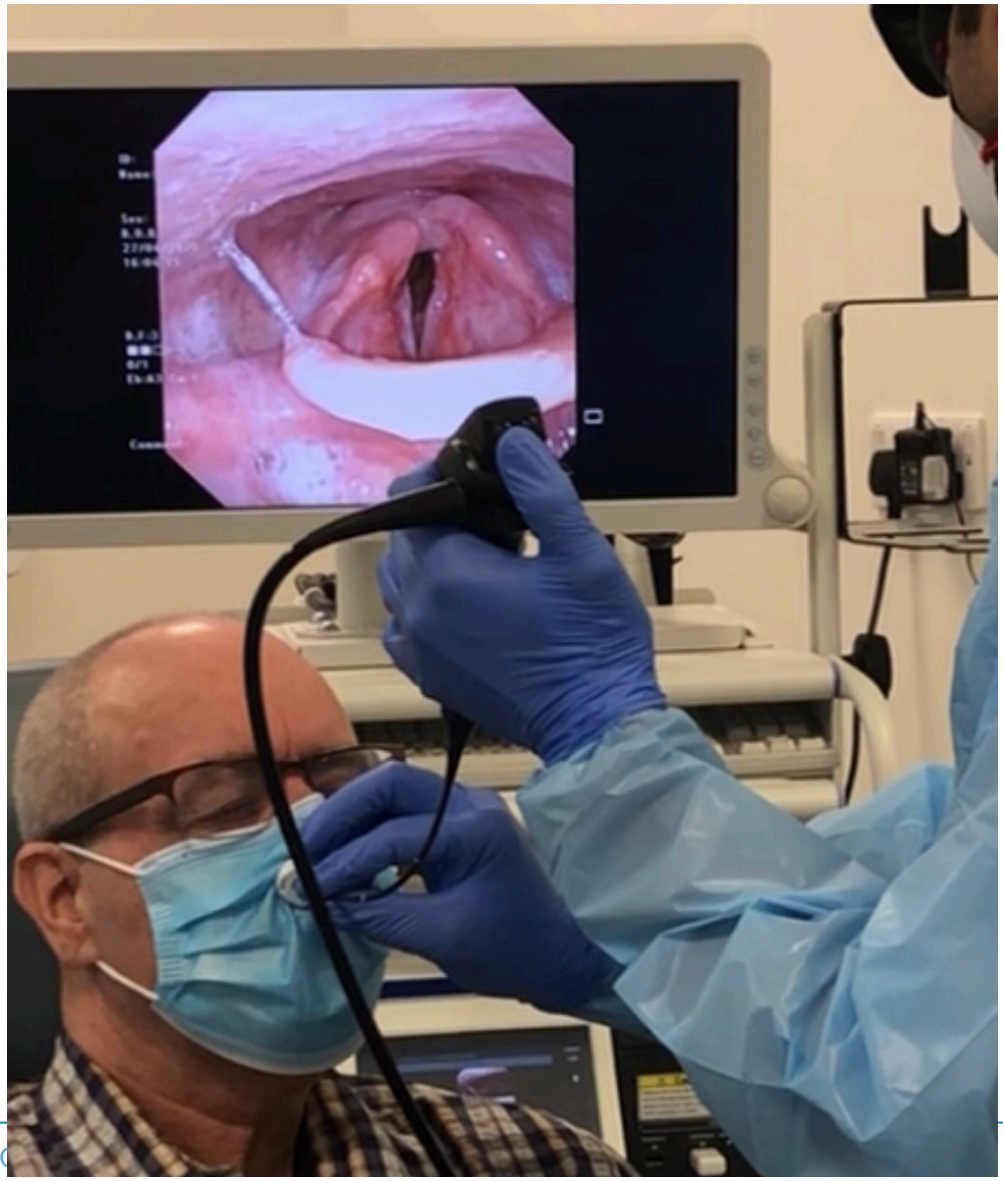
Clinical Evaluation of use

SNAP is currently undergoing close clinical evaluation during the COVID-19 pandemic. By following current guidance set out by ENT-UK, BLA, RCSLT and BAHNO, endoscopy continues to be performed for the selected assessment of only high risk patients. These examinations would normally take place without the added protection of the SNAP mask. The results of this evaluation are awaiting peer review and are currently available to view in pre print. The outcomes being assessed were;

- Ease of passage of the scope through the SNAP mask
- Success of performing the procedure
- Induction of an aerosol generating cough or sneeze
- Trauma caused during endoscopy or by the SNAP device
- Health of the performing endoscopist and supporting staff



Objective evaluation of safety

The fluid resistance property of the SNAP mask valve is being independently evaluated by Medical Engineering Technologies Ltd, Unit 16, Holmestone Road, Dover, Kent, C17 0UF, UK.

A specific protocol for testing SNAP (MET P1952) has been developed to simulate a nasal fluid challenge to a surgical mask fitted to the SNAP device by modifying an industry standard test method ATSM F1862/F1862M-17 (Testing protocol available on request).

SNAP is fitted to a Surgical Mask to maintain adherence to BSI 14683-2019 standards. We do not advocate fitting SNAP to an N80,N95 or N99 Respirator as this will invalidate its filtration properties.

An Air monitoring test was carried out independently by Filtrex Global, Unit 17, Burnt Mill Industrial Estate, Harlow, CM20 2HS. The test was performed comparing nasendoscopy with and without a SNAP mask to ensure use of the mask does not exacerbate sneezing or coughing. This was objectively measured by assessing particle/m3 in a 42m3 ENT endoscopy room. The results demonstrate a reduction on particle production when the SNAP mask is worn during endoscopy. The overall particle values are extremely small reflecting on the clean clinical environment, use of FULL PPE and examination protocols and the use of a HEPA room filtration system. A considerable amount of particles are produced during the consultation itself as droplets are produced from talking[6].

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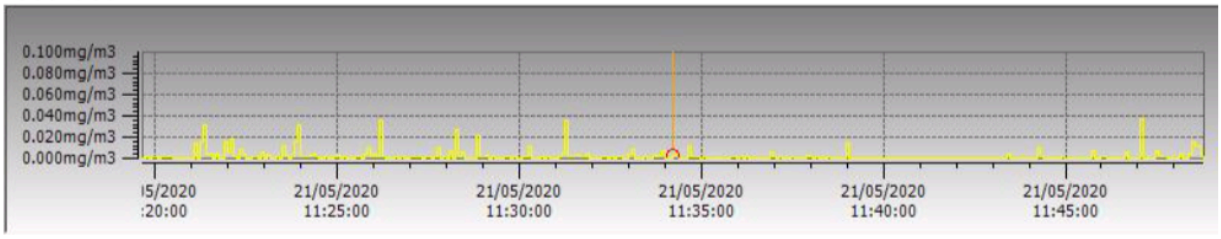
Location: Procedure room 4
Time: 12:58:00 – 13:10:00
Condition: Cleaned room – air cleaner had been running prior. Action in the room as follows:

11:20 - logger starts
11:28 - consultant and patient enter room
11:33 - attempting to use scope and going out to get another one
11:34 - start scope procedure with no mask
11:38 - procedure complete
11:38 – 11:42 - leave air cleaner running to clean room
11:43 – scope procedure with mask
11:45 - finish scoping with mask
11:47 - wipe down room
11:49 - turn off machine

Results: Consistent particle measuring although very low due to clean room. The readings can be seen to drop once the air cleaner is started and no particles were recorded.



Indication for use in Ear Nose and Throat Clinics

In a controlled clinical setting, a surgical mask worn by a patient and safely disposed of, can offer added protection to healthcare workers, particularly those in 'high risk' areas[5]. However, for nasendoscopy a surgical mask obstructs the view of the nasal cavity thus making the procedure impossible to perform. The endoscopist has no choice but to perform the procedure without placing any protective cover over the patients nose or mouth. Thus any aerosol generated through the regular coughing and sneezing during this examination is projected widely into the clinical environment This is currently the standard of care in the UK and across the world. In order to mitigate the risk ENT-UK have recommended limiting the number of nasendoscopy procedures performed. The negative effects from this are that cancers of the head and neck may be missed without a detailed examination. This will have impacts long after the current COVID-19 pandemic has passed.

There is currently no good evidence that surgical masks block aerosol generation. There is evidence that they reduce large droplet dispersion (the main source of viral transmission) as well as the distance dispersion of aerosol. Any perceived risk caused by handling of a potentially contaminated mask by the patient can be counter acted in a controlled clinical environment by

1. Using the mask for only a short period of time
2. Disposing the mask in a clinical waste bin
3. Washing hands or using an alcohol hand sanitiser following mask removal

The SNAP device facilitates the safe passage of a nasendoscopy through a surgical mask into the nasal cavity. Aerosolised droplets produced through coughing or sneezing during the procedure will be caught in the surgical mask. One withdrawn of the the endoscope, the one-way valve within the SNAP closes to maintain reduction in potential aerosol spread. It is a single use device which is disposed of once the surgical mask is doffed by the patient.

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Instructions for use

Step 1
Check the packet is sealed. Ensure all three parts are available. These include the outer channel (grey), inner speculum (purple) and trocar (white)

Step 2
2 SNAP devices should be used to offer greater stability for the endoscopic procedure. These are spaced apart to match the patients features. The SNAPs should be located in the upper 1cms of a surgical mask on either side of the midline

Step 3
Place the inner speculum on the patient facing side of the mask in a location corresponding to the outer channel. The rounded end is for positioning inside the alar region of the patients nasal cavity.

Step 4
Snap the two parts together with the mask in between. The device should be securely locked onto the surgical mask.

Step 5
Place the trocar through the outer channel (from the clinician facing side of the mask) to perforate the surgical mask. This will check the SNAP is assembled correctly. Then twist the trocar 3 turns to ensure a good opening. Check no mask material is loose. Dispose the trocar in a sharps bin

Step 6
Place the surgical mask on the patient and locate the inner speculum rounded part in each of their nostrils till it feels comfortable.

Step 7
Perform the nasendoscopy as per the SNAP instructional video with THREAD, LIFT and SCOPE.

Step 8
Upon withdrawal of the scope ensure the SNAP is held in place on the nose to precent inadvertent removal of the surgical mask.

Step 9
Ask the patient to remove their own mask and dispose safely.

Step 10
Patient washes hands or hand sanitises and replaces with a fresh mask

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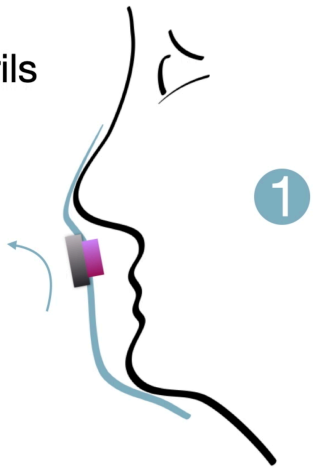
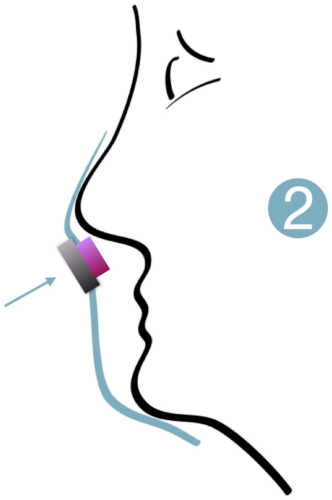
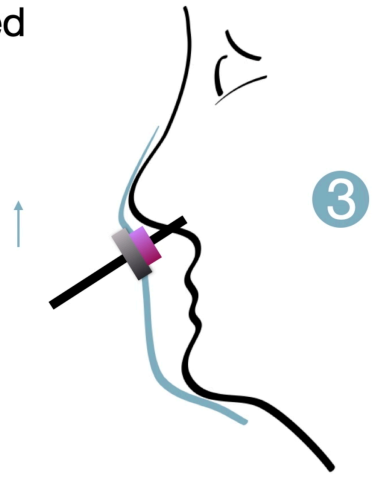
Adjust the snap to align with the nostrils



Thread the scope looking directly at the SNAP not the video monitor



Lift the threaded scope



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Endoscope SNAP compatibility listings by manufacturer

Brand	Model	Max diameter	Type	Compatible
Olympus	ENF V2	3.4mm	Digital	Y
Olympus	ENF V3	2.9mm	Digital	Y
Olympus	ENF VQ	3.9mm	Digital	N
Olympus	ENF VH	3.9mm	Digital	N
Olympus	GP	3.6mm	Fibre	Y
Olympus	GP2	3.5mm	Fibre	Y
Olympus	P4	3.6mm	Fibre	Y
Storz	Single Use Scope	3.5mm	Digital	Y
Storz	CMOS Rhino-Laryngoscope	2.9mm	Digital	Y
Storz	CCD Rhino-laryngoscope	3.7mm	Digital	Y
Storz	Rhino-fibrescope	3.5mm	Fibre	Y
Storz	Rhino-fibrescope	2.5mm	Fibre	Y
AMBU	Rhino-laryngo Slim	3.5mm	Digital	Y
Xion	EVNE	4.0mm	Digital	Y
Xion	EFN	3.4mm	Fibre	Y
Xion	EFN Slim	2.8mm	Digital	Y
Xion	EVNC	3.4mm	Digital	Y
Xion	XNHD	3.6mm	Digital	Y
Xion	XNP	2.7mm	Digital	Y
Xion	XNS	3.5mm	Digital	Y
Pentax	VNL9 CP	3.3mm	Digital	Y

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