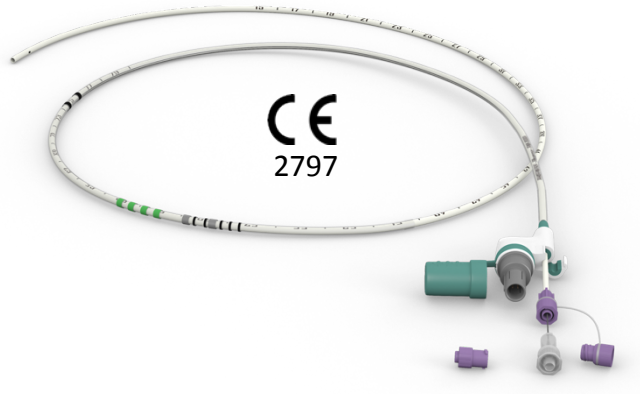
Phagenyx®
Treat dysphagia, restore control

PHAGENESIS®

Manufacturer - Phagenesis Limited, Enterprise House, Manchester Science Park, Manchester M15 6SE, UK



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PNX-1000 Catheter Instructions for Use

Version 3.0
2022-07-11

Intended Purpose

The Phagenyx PNX-1000 Catheter is part of the Phagenyx System. The intended purpose of the Phagenyx System is to restore swallow function using neurostimulation and to provide nutritional support for patients who require liquid feedings as a substitute for solid food.

Indications for use

Use in combination with the Phagenyx Base Station for the treatment of adult patients with neurogenic dysphagia.

Contraindications

- Do not attempt to insert in the presence of oral/pharyngeal anatomical abnormalities, oesophageal perforation, stricture or pouch. The PNX-1000 catheter should not be used in patients with severe heart failure or end stage COPD in whom there is a concern that a foreign body in the pharynx might impact on their respiratory status. Do not use if patient is pregnant. Do not use in children.

- For a full list of contraindications relating to the use of the PNX-1000 for neurostimulation, please refer to the Phagenyx System instructions for use.

Warnings

The catheter should only be used by a suitably trained healthcare professional.

Inspection of product and packaging - The catheter and accessories are sterilised by EO - do not use if packaging is damaged or unintentionally opened before use. The catheter should also be inspected prior to use - do not use if it is damaged. If there is any variation in the expected performance of the catheter do not continue to use it. Check the expiry date on the label - do not use if expiry date has passed.

Catheter properties and use - The catheter is single patient use. Reuse in another patient may lead to infection. It is not possible to re-sterilise the catheter. The catheter is not MRI compatible or defibrillation proof. It should only be used with the Phagenyx Base Station or a compatible enteral feeding set. Do not use anything other than water as a lubricant to facilitate catheter insertion. The feeding tube part is 8Fr with an internal diameter of 2.0mm - do not use with fibre rich feeds. The catheter must only be used for the delivery of liquid feeds and water. The catheter must not be used for the delivery of medication.

Patient factors and use - Any oropharyngeal infection, if present, should be treated and resolved before an attempt is made to insert the catheter. In common with all nasogastric feeding tubes, care must be taken to avoid misplacement of the tip of the tube into the airways and checks made for any movement of the catheter during or between feeds. It's important not to start feeding before confirming the end of the tube is in the patient stomach and not in the airways. In addition, the area around the nostrils should be checked regularly for any tissue irritation to avoid the development of pressure sores.

Reporting an event – As per the requirements of EU MDR 2017/745, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

Contents

The PNX-1000 comprises a two-part catheter, an enteral feeding adaptor and a Garment Clip.

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Transforming the lives of people with dysphagia using revolutionary treatments developed through a commitment to scientific and clinical excellence

Directions for insertion

Warning *– Local best practice for the insertion position confirmation and securing of fine bore nasogastric feeding tubes should be followed in conjunction with the guidance below. This guidance covers the insertion and correct positioning of the catheter in the patient for feeding purposes. For information on how to use the catheter in conjunction with the Phagenyx Base Station for treatment of dysphagia see the Instructions For Use supplied with the Phagenyx Base Station.*

1. Explain the insertion procedure to the patient and obtain consent.

2. Ensure the patient is sitting in a supported inclined position on a bed or chair. The head should not be tilted backwards nor the head and neck extended.

3. Wash and dry hands and put on a pair of latex and powder free non-sterile gloves.

4. Remove the catheter from the packaging ensuring the sleeve does not separate from the feeding tube part.

5. Place the electrical connector cap on the electrical connector.

6. The correct insertion distance should be measured using the catheter tubing by placing the distal tip of the feeding part of the catheter in line with the patient's nostril and then measuring the distance from this point to the earlobe and then to the xiphisternum using the printed guide on the NG tube (Figure 1).

7. Note and record the number on the printed guide on the feeding tube that corresponds to the location of the xiphisternum (X). In the example in Figure 2 the number is 57. It will vary from patient to patient.

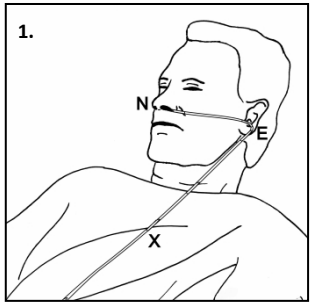
8. Slide the outer sleeve along the feeding tube until the X number is located between the two black bands that form the nasal positioning guide (Figure 3).

9. Close the tube clamp on the S-connector to fix the sleeve to the feeding tube (Figure 4).

10. Identify the preferred nostril for insertion ensuring that it is clear from any obstructions or debris. The end of the NG part of the catheter should be lubricated with water and inserted into the chosen nostril. Insertion should be continued gently, feeding the catheter along the floor of the nose to the nasopharynx. Do not use any lubricant other than water.

Warning *- If significant resistance is felt withdraw the tube and insert again in a different direction or if possible via the other nostril. If at any point in the insertion process the patient presents with respiratory distress or sudden onset ear pain the catheter should be withdrawn immediately and only inserted again if such a response is not seen. Some patient discomfort is to be expected during insertion.*

1.



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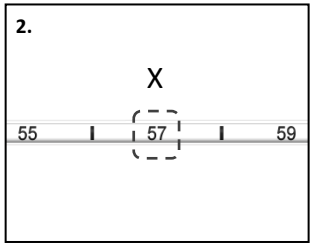

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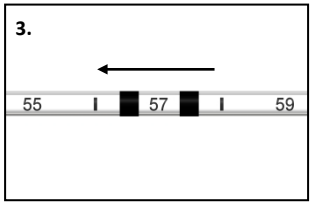

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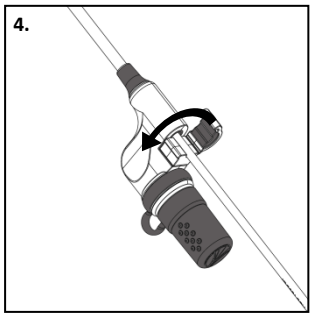
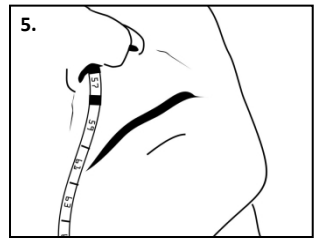


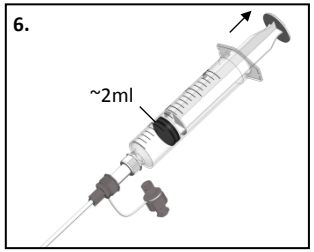
11. As the tube passes into the nasopharynx, ask the patient to attempt a swallowing action. The patient should not be given liquid to swallow. Continue to insert the tube at this time through the pharynx and oesophagus into the stomach with a gentle pressure until the first part of the nasal guide is located at the entrance to the nostrils and the X number is still visible (Figure 5). Please be aware that this may take more than one attempt and ease of insertion varies from patient to patient. Tape loosely to secure the catheter.

5.



12. Connect a 20mL ENFit syringe to the clear connector on the feeding tube part and use it to slowly withdraw approximately 2ml of stomach aspirate (Figure 6). If an aspirate cannot be obtained and it is safe to do so, position the patient on their left side and wait 5 minutes before trying again. Check the pH of the aspirate by placing it on the pH paper and using the labelled recess in the tray provided. A pH of 5.5 or less is indicative that the end of the tube is in the stomach. If it is not possible to obtain an aspirate, or the pH of the aspirate is more than 5.5, then an X-ray should be carried out to ensure the end of the catheter is not located in the airways.

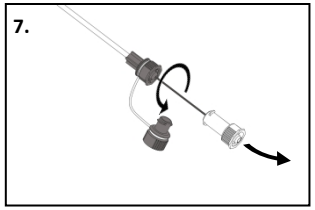
6.



Warning *- Do not flush the feeding tube or use it for delivery of nutrition unless confirmation that the end of the tube is in the stomach has been obtained.*

13. Flush the feeding tube with 10ml of water. Unscrew and withdraw the guidewire and dispose of it in clinical waste (Figure 7). Take care that the catheter remains in the patient.

7.



Securing the catheter

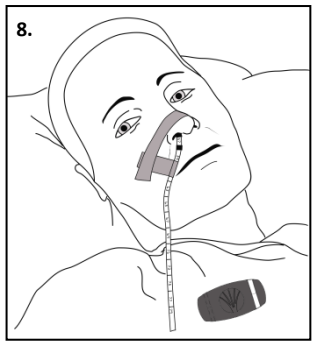
1. Secure the catheter using a suitable medical tape over the nose and around the catheter as shown (Figure 8). Do not cover the nasal guide. Inspect the area around the entrance to the nostrils regularly for localised tissue irritation or damage. If such irritation is seen adjust the fixation of the catheter to move contact points between the catheter and the patient.

2. Attach the Garment Clip to the patient clothing on the same side as the nostril used for insertion and in the location near the clavicle shown in Figure 8.

3. Insert the sleeve tubing into the white recess in the Garment Clip leaving approximately 8cm between the clip and the S-connector (Figure 9).

Warning *- Take care when using the safety pin on the Garment clip to avoid patient injury.*

8.



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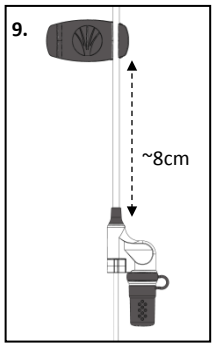
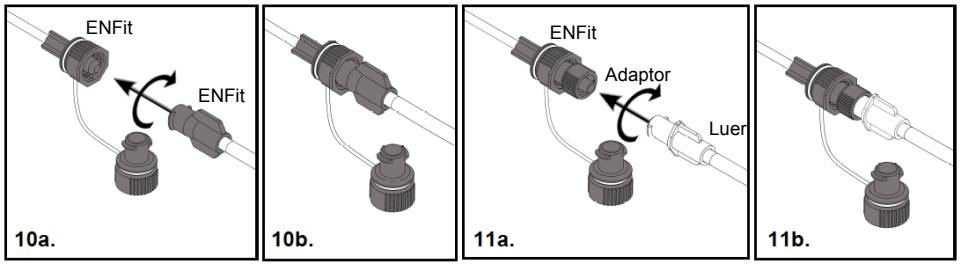


Connection to other devices

There are two connection points on the catheter: one for feeding, which is only to be connected to a compatible enteral feeding set, and one for electrical stimulation, which is only to be connected to the Phagenyx Base Station via the treatment cable provided.

For feeding - The enteral feeding connector should be connected to an ENFit compatible enteral feeding set (Figure 10a and 10b) or, via the enteral feeding adaptor supplied, to an enteral feeding set with a luer connector as shown below (Figure 11a and 11b). Ensure the connection is firm but do not over tighten. If using the adaptor, take care to retain it when the feeding set is changed.



***Warning** - Check that the correct number is located within the nasal guide between feeds to show that the catheter has not moved. If movement is seen, readjust the position of the feeding tube to the correct position and reconfirm of stomach placement using pH measurement or X-ray before feeding is re-started. Unless otherwise directed follow local best practice with respect to use of NG tubes for feeding.*

For electrical stimulation - The electrical connector on the sleeve should only be connected to the treatment cable connector of the Phagenyx Base Station. Do not connect to any other devices. When not in use the connector should be covered by the cap supplied. For information on how to connect the catheter to the Phagenyx Base Station and for the use of the catheter in the treatment of dysphagia see the Instructions For Use supplied with the Phagenyx Base Station.

Directions for maintenance and disposal

Irrigation - The catheter must be irrigated with 20ml of water between each administration of feeding formula. High pressure should not be applied when irrigating the catheter as this may result in damage to the catheter and risk harming the patient.

Cleaning - During the period when the catheter is in place, the parts of the catheter external to the patient may be cleaned if required using a cloth or gauze dampened with water. No other cleaning agents should be used. Care should be taken not to introduce any liquid into the electrical connector on the catheter.

Disposal - To remove the catheter carefully detach any tape from the patient ensuring discomfort is minimised and damage to skin avoided. Gently withdraw via the nose using a continuous steady movement. The entire catheter should be disposed of in clinical waste. Do not attempt to re-use or re-sterilize.

Expected Clinical Benefits

The pharyngeal electrical stimulation used in Phagenyx has been shown to reduce penetration and aspiration, improve secretion management, increase spontaneous swallowing, reverse pharyngeal desensitization and improve nutritional status. Clinical benefit is seen in the majority of patients treated but specific benefits will vary from patient to patient.

Storage and Disposal

Store the catheters in a dry place and do not expose to direct sunlight. Store and use between 10°C and 30°C, between 45% and 85% relative humidity non-condensing and between 50kPa and 106kPa atmospheric pressure. Dispose of in clinical waste. Care should be taken when disposing of the Garment Clip as it contains a pin which has the potential to cause injury.

Explanation of symbols used on the PNX-1000 labels

Symbol	Description	Symbol	Description
LOT	Batch code	EC REP	EU Authorised Representative
	Use by date		Single sterile barrier system
STERILE EO	Sterilized using EO	MD	Medical Device
	Do not re-use	UDI	Unique Device Identifier
	Do not re-sterilize	GB	Date of Manufacture Country of Manufacture
	Do not use if package is damaged		Refer to instructions for use
	Keep away from sunlight	REF	Catalogue number
	Keep dry		Manufacturer
	Temperature limits		Type BF applied part
%	Humidity limits		Device must not be disposed of in general or domestic waste

PNX-1000 en v3.0 IFU (DOC-2066) Ver. 3

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