PHAGENESIS

Phagenyx System Safety Information

Base Station

Contraindications and Cautions

While there are relatively few absolute contraindications to the use of Phagenyx System, the physical aspects of the Phagenyx PNX-1000 catheter should be considered in a similar clinical category to standard nasogastric feeding tubes. Therefore, Phagenyx treatment is generally contraindicated in circumstances where it is not possible to pass a standard NG tube, for example, nasal, oral or pharyngeal anatomical abnormalities that preclude passage of a feeding tube, history of oesophageal perforation, stricture or pouch.

1. The Phagenyx 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.

2. Phagenyx treatment is contraindicated in any patient with an implanted electrical device or any invasive device with active electrical components that cannot be safely removed for the duration of treatment.

3. The Phagenyx PNX-1000 catheter should not be left in place if a patient is to receive an MRI scan. Insertion of the catheter should either be delayed until such time as the MRI has been completed, or the catheter should be removed and disposed of and a new catheter inserted after the MRI is completed.

4. Phagenyx treatment should not be applied to pregnant women.

5. The Phagenyx System is for the treatment of neurogenic dysphagia in adults and should not be used in children.

6. The Phagenyx EPSB3 Base Station unit may not be operated within an enriched oxygen environment but the catheter part may be used within an enriched oxygen environment. Delivery of treatment is therefore allowed if the patient is receiving supplementary oxygen support via a nasal cannula.

7. If, prior to insertion of the Phagenyx PNX-1000 catheter, the patient presents with throat pain this should be investigated and the presence or absence of an infection confirmed. Any such infection should be treated and resolved prior to the insertion of the catheter.
8. The catheter is provided as a sterile single patient use device. The EPSB3 Base Station is not suitable for sterilization.

January 2026

9. Suitable personal protective equipment must be worn when inserting the catheter in patients to minimize the likelihood of infection. Follow local or national best practice guidelines in relation to catheter insertion for patients suspected of having transmissible infections such as COVID-19 or equivalent.

10. Any equipment in contact with the patient should be disinfected as per the instructions in this guide before being used with another patient.

Known Side Effects and Patient Management

A small number of rare side effects have been seen, either as a result of Phagenyx stimulation, or due to the physical presence of the treatment catheter. These are listed below together with the actions to be taken in the event that they occur.

1. Jaw chattering or facial/ear pain – These are rare events associated with active stimulation. If they occur, pause treatment and adjust the catheter further in to the patient by 1-2cm and retry treatment. If the chattering or pain persists consider stimulating at a lower current level. If this still does not resolve the issue discontinue treatment and remove the catheter.

2. Hypersalivation – Some patients produce excess saliva during treatment. This is not considered harmful. Suctioning to remove the saliva at the end of treatment may improve patient comfort.

3. Arytenoid oedema or pharyngeal abscess – In common with any indwelling catheter, the physical presence of the Phagenyx catheter may give rise to contact irritation over time. In rare cases this might give rise to an abscess. In the event the patient reports pain or discomfort that persists (>4hours) after the end of stimulation, the catheter should be removed on completion of the treatment regimen and replaced with a standard nasogastric feeding tube if enteral feeding is still required.

PHAGENESIS

PNX-1000 Catheter

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.

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 – 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 or country in which the user and/or patient is established.