NICE advice

CORTRAK 2 Enteral Access System for placing nasoenteral feeding tubes

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Summary

The CORTRAK 2 Enteral Access System (EAS) is designed to help guide the placement of nasoenteral feeding tubes and to help confirm that they are correctly placed. It uses an electromagnetic sensor to track the path of the feeding tube during the placement procedure. Relevant evidence was mainly from studies of CORTRAK EAS in placing post-pyloric tubes in ICU patient populations. The evidence shows that the time to placement, technical success and safety of CORTRAK EAS for post-pyloric tubes is similar to endoscopic placement; some outcomes were better when compared with blind placement, but CORTRAK EAS increased the time needed for post-pyloric tube placement in children. No evidence was found in relation to the use of CORTRAK EAS for guiding nasogastric tube placement.

The device costs £12,000 excluding VAT. Consumable costs per patient are £51 for a nasogastric tube and £103 for a post-pyloric tube, compared with prices of £7 and £70 for corresponding standard tubes. Confirmation of correct placement using conventional procedures will incur additional costs.

A patient safety alert issued by NHS England (2013) states that it is vital that healthcare

professionals use pH or X-ray testing to confirm correct placement of nasogastric tubes after initial insertion, even when using placement devices.

Product summary and likely place in therapy	Effectiveness and safety
• The CORTRAK 2 Enteral Access System (EAS) is used to aid the placement of nasoenteral feeding tubes passed through the nose into either the stomach (nasogastric), duodenum (nasoduodenal) or jejunum (nasojejunal). The latter 2 types are also known as post-pyloric placement. • CORTRAK 2 EAS would be used in place of, or in addition to, existing methods of tube placement in people of all ages who need nasoenteral feeding.	• The published evidence summarised in this briefing comes from 7 studies (n=667 patients; 681 placements) and includes 3 randomised controlled trials (RCTs). Only 1 of the studies was done in the UK and this was the only study of nasogastric tube placement. Most studies drew patients from an ICU setting. • Three RCTs and 3 prospective cohort studies provide evidence on the use of CORTRAK EAS for guiding post-pyloric or nasogastric tube placement and 1 prospective cohort study provides evidence on confirmation of post-pyloric tube placement. • One RCT (n=66) compared CORTRAK EAS with the standard endoscopic technique and found that post-pyloric (nasojejunal) feeding tube placement using CORTRAK was as fast, safe and successful as the endoscopic method in an adult ICU population. • A second RCT (n=49) compared CORTRAK EAS with blind post-pyloric tube placement and found that CORTRAK EAS increased the time needed for accurate placement in critically ill children. • A third RCT (n=37) compared CORTRAK EAS with blind placement of post-pyloric tubes and found that CORTRAK EAS was faster and more effective in and adults.

	• Two prospective cohort studies (1 in adults [n=101] and 1 in children [n=107]) compared CORTRAK EAS with blind post-pyloric tube placement and concluded that CORTRAK EAS was a safe and effective method of guiding post-pyloric tube placement. • One prospective cohort study in adults (n=113) compared CORTRAK EAS with existing methods such as pH and X-ray and concluded that CORTRAK EAS can accurately guide nasogastric tube placement. • One prospective cohort study of post-pyloric tube placement in children (n=18) and adults (n=176) compared CORTRAK EAS with X-ray and concluded that CORTRAK EAS can accurately confirm tube placement.

Technical and patient factors	Cost and resource use
• A Patient Safety Alert issued by NHS England in 2013 states that it is vital that healthcare professionals perform pH or X-ray testing to confirm correct placement of nasogastric tubes after initial insertion even when using placement devices. The alert was issued following reports of 2 deaths after enteral nutrition was unintentionally given into the respiratory tract through a misplaced nasogastric tube inserted with the aid of a placement device. • CORTRAK 2 EAS uses electromagnetic sensing technology to track and display the path of a feeding tube during placement. • The system consists of an LCD monitor unit, specific nasoenteral feeding tubes each containing a stylet with a transmitter, and a signal receiver unit. • CORTRAK 2 EAS is intended for use by trained operators in a secondary care setting. • The included studies used CORTRAK 2 EAS or the previous operationally identical version, CORTRAK EAS (collectively referred to as CORTRAK EAS in this briefing). • CORTRAK EAS must be used with proprietary CORTRAK feeding tubes.	• CORTRAK 2 EAS costs £12,000 excluding VAT. Consumable costs per patient are £51 for a nasogastric tube and £103 for a post-pyloric tube compared with prices of £7 and £70 for corresponding standard tubes. Confirmation of placement by conventional methods such as X-ray or pH testing will incur additional costs. • Two conference abstracts and 4 published articles considered the cost and resource consequences of using CORTRAK EAS. All studies analysed a small prospective or retrospective cohort. Three were based in the USA and 3 in the UK. • Four of the studies compared nasoenteral feeding using CORTRAK EAS with conventional bedside placement and provided some evidence of relative cost savings. • Two of the studies did not compare resource use. One estimated the overspend in a single ICU from the combined use of CORTRAK EAS and X-rays to confirm nasogastric tube placement. The other costed the system from the perspective of a single NHS trust and found it reduced the number of X-rays and endoscopic feeding tube placements needed, both of which could be associated with a cost reduction.

Introduction

Enteral feeding is the delivery of a nutritionally complete feed directly into the stomach or small intestine using a feeding tube. Tubes can be inserted through the abdominal wall (percutaneous) or through the nose (nasoenteral). Percutaneous feeding tubes are generally only considered if long-term feeding (4 weeks or more) is needed. Nasoenteral tubes, used for short-term feeding, can deliver feeds directly into the stomach (nasogastric [NG]), jejunum (nasojejunal [NJ]) or duodenum (nasoduodenal [ND]). The latter 2 types are also known as post-pyloric placement.

NG feeding is the most common method used, and an estimated 271,000 NG tubes are supplied to the NHS annually (Macmillan Cancer Support 2013; Great Ormond Street Hospital 2014, National Patient Safety Agency Quarterly Data Summary 2008). The actual number is likely to be higher than this estimate as multi-packs may have been considered as single tubes.

Inserting feeding tubes is a common clinical procedure with well-recognised risks. Incorrectly placed NG tubes are relatively common and if undetected can result in significant complications. Between September 2005 and March 2011, the National Patient Safety Agency in the UK recorded 21 deaths and 79 cases of harm relating to NG feeding tubes being placed into the lower bronchial tree rather than the digestive tract. All nasoenteral tube placements carry further risk of pneumothorax, nose bleeds, bronchopleural fistula, aspiration pneumonia and vocal cord injury (Metheny et al. 2007, Roberts et al. 2007). In addition, once placement has been confirmed, nasoenteral tubes are often secured to the nose or cheek with tape. If this tape is not secure, or the patient has an episode of vigorous movement or vomiting, there is a risk that the tube can migrate, for example from the jejunum into the stomach. Nasoenteral tube placement is therefore frequently reviewed (often on a daily basis), using the centimetre markings printed on the tubes, to ensure migration has not occurred. People at increased risk of incorrect placement or migration of nasoenteral tubes include those who are intubated or ventilated, and those with decreased levels of consciousness, vocal cord dysfunction or dysphagia (National Patient Safety Agency 2011, Roberts et al. 2007).

Improving the accuracy of nasoenteral feeding tube placement may lower the risk of complications associated with the procedure.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of

healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

CORTRAK 2 EAS was CE marked in September 2012 as a class I self-certified device. CORTRAK enteral feeding tubes are CE marked separately as class IIb devices (since November 2008). Both the system and the tubes are manufactured and distributed by CORPAK MedSystems (USA).

CORTRAK 2 EAS is regulated under the European Medical Device Directive (2007/47/EC).

Description

CORTRAK 2 EAS uses electromagnetic sensing technology to track and display the path of the feeding tube during a placement procedure. The CORTRAK 2 EAS unit must be used with device-specific CORTRAK enteral feeding tubes.

CORTRAK 2 EAS consists of 3 major parts:

- **A portable, battery powered monitor unit (width 31 cm, height 34 cm, depth 8 cm) with an LCD display and touchscreen interface** – This unit, which weighs 3.6 kg, contains the electronics and software for the system. The internal rechargeable battery will operate the device for approximately 2 hours (if in continuous use) when fully charged. Charging an empty battery to full capacity takes approximately 4 to 6 hours. The system can also be powered from the mains electricity supply.
- **A single-use polyurethane CORTRAK radiopaque tube and tip (for X-ray visualisation)** – Each tube is supplied with a pre-inserted, single patient-use braided stainless steel stylet with a small electromagnetic coil (transmitter) located at the tip. A cable connects the stylet to the monitor unit. The tube has water-activated C-19 lubricant on the tip and in the internal lumen, an anti-clog exit port and a Y-access port for irrigation, aspiration or feed, allowing a closed system to be maintained. Centimetre markings are printed on the tube to aid placement and check for migration during use. CORTRAK NG feeding tubes are 92 cm long and CORTRAK post-pyloric feeding tubes are either 109 cm or 140 cm long. The feeding tubes are available in 3 sizes: 8, 10 or 12 Fr (French scale: 1 Fr is 0.33 mm). The length and diameter chosen will depend on the patient; for example, smaller tubes are needed for children. A stylet storage bag is provided with each tube.

- **A receiver unit** – This tracks the electromagnetic signal from the transmitting stylet throughout the placement procedure. The receiver unit is attached by a cable to the monitor unit, which then provides a graphical display of the feeding tube tip location relative to the receiver unit and track.

An optional printer is available for printing adhesive labels to attach to patient records, detailing the anterior view of the tube track along with patient and operator details.

In practice, CORTRAK 2 EAS can be operated in 2 modes: accounts mode and anonymous mode. There is also an administrative mode which allows access to additional system features not needed during placements.

- In accounts mode each operator is assigned a unique account consisting of a login name and a password which must be used to perform or review placements. The monitor unit can save video files to an external USB flash drive. These files may subsequently be reviewed on a computer for reference and training purposes.
- In anonymous mode no operator login is needed. The entire placement video is temporarily held in the monitor unit's memory for immediate review or critique, but is not recorded.

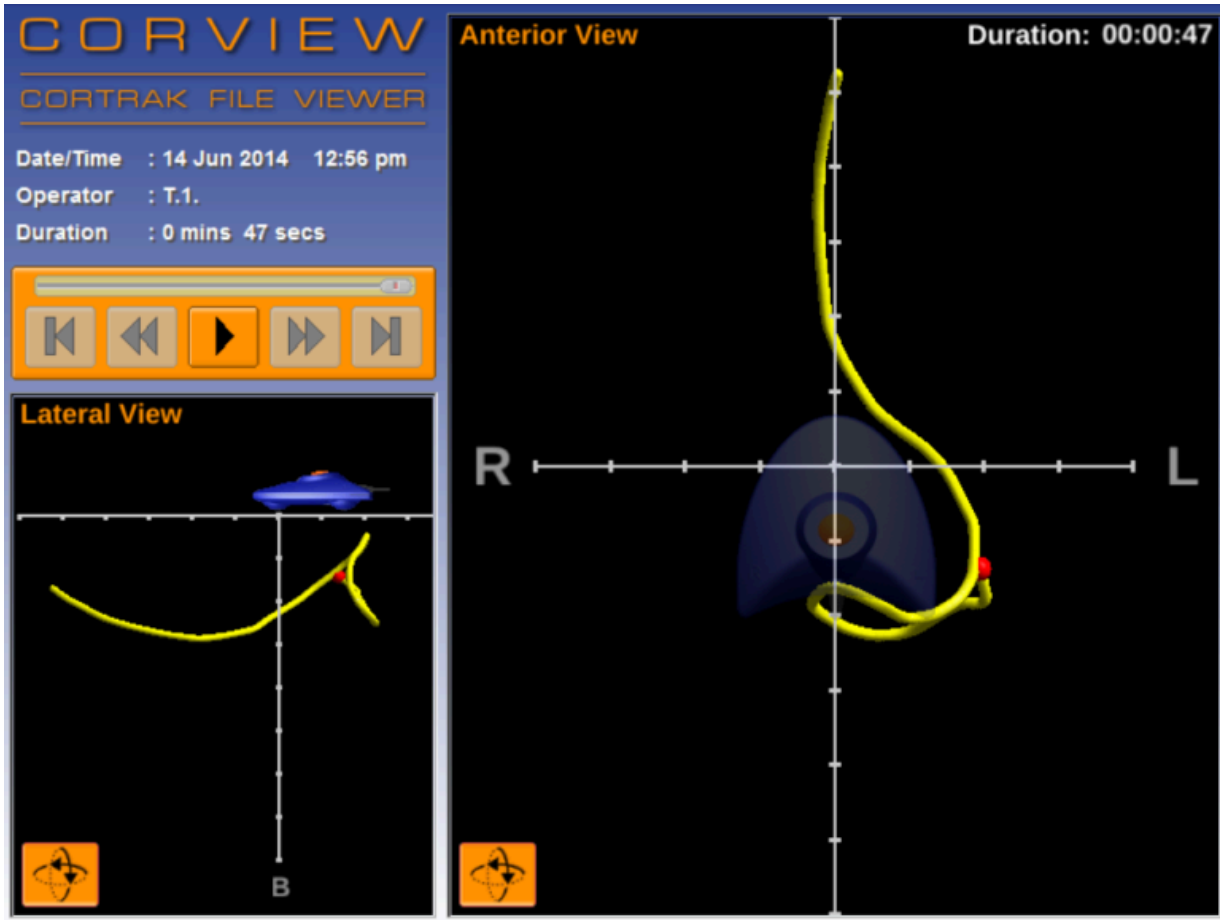
CORTRAK 2 EAS is used as follows:

- After the person is positioned in accordance with hospital protocol (usually in a semi-upright position) for tube placement, the front of the receiver unit is placed over the xiphoid process (the anatomical landmark for the oesophageal/gastric junction on the lower sternum). The receiver unit, which does not need to be placed directly on the skin, is held in place either by a second staff member or by a stabiliser, which is a weighted accessory available from the manufacturer. The receiver unit is attached by a cable to the monitor unit.
- The distal end of the stylet (which is pre-inserted into and spans the length of the feeding tube) is connected to the monitor using a short interconnecting cable.
- The feeding tube (containing the stylet) is inserted via the nostril into the stomach or small intestine.
- The monitor unit displays a real-time graphical representation of the tube tip path and tip location relative to the receiver unit (not an image of the actual feeding tube position). The track of the tube is shown on the computer monitor with 3D views, obtained from a combination of the 'anterior view' (frontal plane), the 'depth cross-section view' (transverse plane) and the 'lateral view' (sagittal plane) simultaneously (figure 1).

- If the position of the stylet tip is outside the range of the receiver unit (approximately 30 cm), the monitor unit displays 'Out of range'.
- When placement is complete, the stylet is disconnected (the stylet cable should remain connected to the monitor unit). The stylet is then removed from the feeding tube, leaving the feeding tube in situ.
- The stylet can be re-used if placement needs to be confirmed again in the same patient. If re-use is intended, the stylet should be cleansed in warm water or 70% isopropyl alcohol and retained in the stylet storage bag provided (or similar aerated container). The bag should be labelled with the patient's details to ensure single-patient use.
- To re-use the stylet, the stylet must be re-connected to the monitor unit cable. The tip of the stylet can then be inserted into the centre of the feeding tube and down the length of the tube.

Although the manufacturer indicates that CORTRAK 2 EAS may be used to confirm tube placement instead of X-ray imaging, the instructions for use state that users should ultimately confirm the position according to facility protocol, which may include X-ray or endoscopy depending on tube type.

Figure 1: The CORTRAK 2 EAS monitor unit display during tube insertion (receiver unit shown in blue)



CORTRAK 2 EAS is operationally identical to the predecessor system, CORTRAK EAS. All CORTRAK EAS devices have been upgraded to CORTRAK 2 EAS.

Setting and intended use

CORTRAK 2 EAS is intended to guide appropriately qualified operators (medical or nursing staff trained in tube placement and use of the CORTRAK system) in the correct placement of CORTRAK enteral feeding tubes into the stomach or small intestine. The manufacturer states that CORTRAK 2 EAS can also be used for periodic re-confirmation of the placement, or repositioning, of indwelling CORTRAK feeding tubes. This may be useful in situations where the tube may have moved after routine (per hospital protocol) placement checks.

The device is not intended to be used as a training aid for staff learning to place nasoenteral feeding tubes. CORTRAK 2 EAS should not be used in people with implanted medical devices that may be affected by electromagnetic fields. Precautions should be taken with burns patients in identifying the xiphoid process by palpation and placing the receiver unit on the chest.

Healthcare professionals must be trained to use the device according to the instructions for use; CORPAK MedSystems offers a training programme.

CORTRAK 2 EAS is intended to be used in the secondary care setting and is currently being used in a number of NHS hospitals.

Current NHS options

The NICE guideline on nutrition support for adults recommends that enteral tube feeding should be considered in people who are malnourished or at risk of malnutrition and have:

- inadequate or unsafe oral intake (including both food and drink)
- a functional, accessible gastrointestinal tract.

According to the British Society of Gastroenterologists guidelines for enteral feeding in adult hospital patients (Stroud et al. 2003), enteral tubes should be placed by experienced medical or nursing staff. NG tubes can be placed without the aid of an endoscope to visualise the digestive system. This is known as 'blind' placement. For post-pyloric tubes (and complex NG tube placements), endoscopic visualisation may be used before either blind placement or placement under fluoroscopic guidance (using fluoroscopy after administering a contrast medium to guide tube placement in real time).

The NICE guideline on nutrition support for adults recommends that the position of all NG tubes should be confirmed after placement and before each use by aspirating the feeding tube and testing the aspirate for acidity using pH paper. Aspirates at pH 5.5 or below indicate placement in the stomach. X-ray may also be used if necessary. For post-pyloric tube placements a confirmatory X-ray should always be done unless the tubes were placed under fluoroscopic guidance.

NHS England issued a Patient Safety Alert in 2013, following reports of 2 deaths after enteral nutrition was unintentionally given into the respiratory tract through a misplaced nasogastric tube inserted with the aid of a placement device. Two similar moderate harm incidents had been reported previously. The placement device used was not stated. The alert states that it is vital that healthcare professionals perform pH or X-ray testing to confirm correct placement of nasogastric tubes after initial insertion even when using placement devices (NHS England 2013). The need for robust systems for supporting staff to deliver safety-critical placement checks of nasogastric tube has been emphasised in a 2016 Patient Safety Alert directed at trust boards (NHS England 2016).

NICE is not aware of any other CE-marked devices that have a similar function to the CORTRAK

2 EAS.

Costs and use of the technology

The capital components of the CORTRAK 2 EAS system (monitor unit, receiver unit and stylet connecting cable) cost £12,000 excluding VAT. This price also includes a CORTRAK 2 EAS accessory kit (with USB flash drive, stabiliser and levelling device), a replacement battery, a replacement receiver unit, a CORTRAK printer, a charger and a stand for the device. The prices of the consumables, per-procedure and excluding VAT, are:

- £51 for a NG tube (92 cm long)
- £103 for a post-pyloric tube (109 cm or 140 cm long).

The lifespan of the system is 5 years. October and Hardart (2009) estimated an average treatment session time of 1.7 hours (102 minutes) for post-pyloric tube placement (the time between taking a post-pyloric tube from stock to confirmation of placement). Taylor et al. (2010) suggested a median time of 17 minutes for post-pyloric placement. Windle et al. (2010) estimated 6 minutes as the mean time of placement, using a sample that included both NG and post-pyloric tubes. The latter 2 estimates, however, do not include setup time or the time to confirmation of tube placement. If it is assumed that 5 tubes can be placed in a day and 1200 tubes placed in a year (240 annual working days), and that CORTRAK 2 EAS use is split equally between NG and post-pyloric tube insertions using a standard annuity method with a discount rate of 3.5%, the estimated average treatment cost per tube placement is £79.

CORTRAK 2 EAS must be used with CORTRAK 2 EAS enteral feeding tubes. The cost of conventional polyurethane (non-CORTRAK) tubes for short-term placement range from as low as £3 (NG, 8 Fr and 10 Fr) to £9 (post-pyloric, 8 Fr) each (NHS supply chain 2015). The routine nature of nasoenteral feeding tube placement means that no information is included in published NHS reference costs. Instead, GP or self-referral plain film X-ray costs are reported to be £30 (Department of Health 2014; code DAPF). Windle (2010) reports a £66 (inflation-adjusted) unit cost for bedside chest X-rays to confirm tube placement, but this is not a national average and only represents the experience of 2 sites in the Mid Yorkshire Hospitals NHS Trust. Market prices suggest the cost of pH-graded paper strips (pH 0–6) is around £9.14 per 100 strips (NHS supply chain, 2015).

Post-pyloric tubes are generally placed using endoscopy. Tubes more suited for long-term placement and use with an endoscope cost around £70 (NHS supply chain, 2015). There is no nationally representative unit cost information available for endoscopically inserting post-pyloric

tubes. As an alternative, Windle (2010) notes that the cost of this procedure for a single NHS trust is reported to be approximately £700.

The manufacturer instructions state that users should ultimately confirm the position according to facility protocol. In this case, many of the costs mentioned above (pH strips or X-ray), as well as the usual NHS (labour and facility) costs will still be incurred. Therefore, the difference in cost per treatment session will be the per treatment cost calculated above (£79), minus the cost of a conventional polyurethane tube that is displaced because a CORTRAK 2 EAS specific tube is being used. This gives an additional cost of around £70 to £76 per treatment when CORTRAK 2 EAS is used.

Training is needed to use the system. The manufacturer provides classroom and clinical training at no cost.

No other practical difficulties have been identified in using or adopting the technology.

Likely place in therapy

CORTRAK 2 EAS is used as an adjunctive technology to aid in the blind placement of nasoenteral feeding tubes, or in place of (where used) endoscopic tube placement.

Although the manufacturer indicates that CORTRAK 2 EAS can be used to confirm the placement of nasoenteral tubes and may replace imaging, it states that users should ultimately confirm position according to facility protocol. In standard UK practice, this is aspiration and testing the aspirate using pH paper (and X-ray if necessary) for NG tubes. Initial post-pyloric tube placement is confirmed with an abdominal X-ray, unless placed under fluoroscopic guidance.

Specialist commentator comments

Two specialist commentators highlighted that CORTRAK feeding tubes are considerably more expensive than standard feeding tubes with pH or X-ray confirmation of placement. One commentator noted that procedural costs for the CORTRAK 2 EAS will vary depending on the location in which the device is used and the experience of the operator. The commentator added that using the same CORTRAK 2 EAS in different wards at the same hospital may also affect overall costs, because of the resource use associated with transporting the equipment, implementing appropriate infection control measures, and repairing any damage caused by repeated movement. However, they also stated that there may be additional costs if CORTRAK 2 EAS were used on a single ward, such as those associated with storage space. Finally, the commentator noted that

because the system is only compatible with CORTRAK feeding tubes, the impact of an increase in the price of these feeding tubes could be substantial. They suggested, therefore, it would be worthwhile performing a sensitivity analysis to demonstrate the extent to which any financial benefit derived from the system would be affected by an increase in the price of CORTRAK feeding tubes.

One commentator expressed concern at the availability of the anonymous mode, noting that there would be no audit trail from procedures where this mode is used. Another commentator noted that CORTRAK 2 EAS is more likely to benefit trainee clinicians than clinicians experienced in placing feeding tubes.

One commentator surmised that CORTRAK 2 EAS is not necessarily quicker, more reliable in preventing misplacement, or cheaper than standard methods of feeding tube insertion. They added that the exception appears to be cases where its use allows endoscopic feeding tube placement (and the associated cost and unpleasantness) to be avoided, although it was stressed that there are comparatively few of these cases. A second commentator stated that NG tubes are rarely placed with an endoscope. One commentator noted that in a subset of endoscopic tube placements, the endoscopy may be needed for other diagnostic purposes. In these cases, part of the endoscopic cost at the time of feeding tube placement should be attributed to the diagnostic effort.

Two commentators agreed that the benefits of using CORTRAK 2 EAS in addition to facility protocol (pH paper and X-ray) for confirming feeding tube placement are unclear. One commentator noted, however, that if CORTRAK 2 EAS were to reliably replace the need for X-ray tube placement confirmation, then potentially worthwhile savings would arise. According to the commentator, avoiding X-rays could reduce the time between insertion of tube and starting feeding, as well as save the time of nurses and other staff members who may need to accompany patients to X-ray. Another specialist added that although the device may be associated with a reduction in the number of X-rays, these slots are likely to be utilised by other services and, therefore, may not result in meaningful cost savings for a hospital. They added that it is important to note that X-ray costs differ substantially between trusts.

Finally, one commentator stated that from their personal experience, they were unsure how an electromagnetic probe system would be able to demonstrate the location of a feeding tube to the same degree of accuracy as air contrast on plain X-ray, which confirms location almost beyond doubt.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

CORTRAK 2 EAS may particularly benefit people with chronic diseases of the nervous system (such as cerebral palsy or multiple sclerosis), which may result in swallowing disorders. Multiple sclerosis is a progressive disease and people with multiple sclerosis are considered to have a disability from the point of diagnosis.

CORTRAK 2 EAS is contraindicated for people with implanted medical devices that may be affected by electromagnetic fields. Certain chronic diseases, such as heart disease, may be treated with implanted medical devices. Chronic disease is treated as a disability if it has a substantial and long-term adverse effect on a person's ability to carry out normal day-to-day activities.

Disability is a protected characteristic defined in the Equality Act 2010.

Patient and carer perspective

The Patients on Intravenous and Naso-gastric Nutrition Treatment (PINNT) support group made the following comments on the device.

Despite guidelines stating that NG tube placement is to be confirmed by aspiration and pH confirmation, many hospitals still use X-ray imaging for confirmation. This can be very distressing for patients because there is usually a long delay between tube placement and X-ray imaging confirmation.

The use of aspirate confirmation can be problematic for some people with low output in the stomach, for whom obtaining a positive aspirate can be a challenge. People with low stomach output would still have to undergo X-ray confirmation.

The nasal cavity can become very sensitive due to tube placement, irrespective of the care used during placement, so any delay in removing the guide wire causes additional discomfort and distress to the patient.

It is important to acknowledge that for many people tube placement is a distressing and upsetting procedure and therefore anything that can minimise the level of discomfort and anxiety that accompanies it is of benefit.

Placement of tubes in certain population can be particularly challenging, particularly people with learning difficulties or special needs. The necessity for quick placement and confirmation is vital for the person and their carer as repeated attempts will lead to further anxiety and distress.

For many people the use of CORTRAK 2 EAS when placing nasoenteral tubes will be of great benefit.

Evidence review

There are 2 versions of CORTRAK EAS (the original, predecessor version, referred to as CORTRAK 1 EAS for differentiation, and CORTRAK 2 EAS) included in the evidence. Because both versions work in the same way, studies which used either version were included in this briefing (referred to collectively as CORTRAK EAS unless explicitly stated otherwise).

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. There were 68 adverse events identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE) from 2007 to present. Fourteen events were device malfunctions and did not result in patient harm. Forty-one events involved incorrect tube placement which caused patient harm including pneumothorax and, in 5 cases, death.

Clinical evidence

A literature search revealed 48 journal articles that reported on CORTRAK EAS (1 or 2). Studies were included if they investigated the efficacy (successful tube placement, time to placement, the

proportion of patients needing imaging to confirm placement/resource utilisation, accuracy for confirming tube placement) and safety of the device. Retrospective studies and studies with fewer than 30 patients were excluded. Consequently, 7 studies (3 randomised controlled trials and 4 prospective cohort studies) have been included in this briefing.

Evidence on guiding post-pyloric placement in place of existing insertion methods

Holzinger et al. (2011) was a single-centre randomised controlled trial set in Austria (NCT00500851). The aim of the study was to compare the success rate of NJ feeding tube placement using CORTRAK 1 EAS with that of the endoscopic technique. Patients (n=66) were adults (55±18 years old) in intensive care (ICU) who did not tolerate NG feeding. The primary outcome was successful placement of the NJ feeding tube. Secondary outcomes included placement times, rates of nose bleeds, ICU survival and hospital survival. Neither the difference in placement success rates nor the difference in placement time between CORTRAK 1 EAS and the endoscopic technique were significant. However, CORTRAK 1 EAS resulted in correct placement at the first attempt more often than the endoscopic method (relative risk 2.44, 95% confidence interval [CI] 1.24 to 4.78, p=0.009). Comparisons between the rates of nose bleeds, ICU survival and hospital survival showed no statistically significant differences between the 2 groups. The authors concluded that using CORTRAK 1 EAS to place NJ feeding tubes in an ICU adult population is as fast, safe, and successful as using the endoscopic technique.

Gray et al. (2007) was a single-centre, prospective, observational study set in the USA. Its main aim was to evaluate the safety (absence of serious adverse events such as lung intubation) of CORTRAK 1 EAS in post-pyloric feeding tube placement compared to blind placement. Patients (n=101) were adults in ICU who needed post-pyloric feeding tubes. Secondary outcomes included a comparison of the rate of accurate placement (as confirmed by X-ray), number of X-rays needed to confirm placement, time from clinician request to start of enteral feeding (reported as 2 separate outcomes: time from clinician request to tube placement and time from placement to initiation of enteral feeding). For the primary outcome, no complications or adverse events were reported in the intervention or control groups. In terms of secondary outcomes, the difference in the success rate of feeding tube placement between the CORTRAK 1 EAS and blind placement groups was not statistically significant but the CORTRAK 1 EAS group needed 50% fewer abdominal X-rays to confirm feeding tube placement (p=0.0001). The time between clinician request and start of feeding was 66% lower in the CORTRAK 1 EAS group than in the blind placement group (p=0.0032). The time between clinician request and actual post-pyloric placement was 48% lower in the CORTRAK 1 EAS group than in the control group (p=0.0059); however, the median time between tube placement and initiation of feeding was 4.5 hours in the control group and 4 hours in

the study group (not statistically significant). The authors concluded that using CORTRAK 1 EAS for post-pyloric feeding tube placement avoided serious adverse events and resulted in fewer X-rays and more timely initiation of enteral feedings compared with the blind placement technique.

October and Hardart (2009) was a single-centre prospective cohort trial with serial control groups set in the US. The aim of the study was to evaluate the effectiveness of post-pyloric feeding tube placement using CORTRAK 1 EAS compared with blind placement. Patients (n=107; 1 month to 25 years old) were recruited from a paediatric ICU. The primary outcome of the study was the success rate of post-pyloric tube placement as determined by abdominal X-ray. The secondary outcomes included the median time to successful placement (as confirmed by the radiologist review of the abdominal X-ray) and the total number of abdominal X-rays conducted. The study found that the difference in the success rate between the CORTRAK 1 EAS group and the blind placement group was significant (82.0% versus 39.0%, $p<0.0001$) as was the median time to successful placement (including confirmation; 1.7 versus 21.0 hours, $p<0.0001$). The unusually long 'time to successful placement' shown for blind placement is due to the definition of this outcome in the paper and the fact that blind placement procedure might require repeated placement attempts and X-rays to confirm successful placement. Significantly fewer abdominal X-rays ($p<0.0001$) were needed in the CORTRAK group than in the blind placement group. The authors concluded that CORTRAK 1 EAS is a safe and effective technique for post-pyloric feeding tube placement.

Kline et al. (2011) was a single-centre randomised clinical trial set in the USA. The aim of the study was to compare the time to successful post-pyloric feeding tube placement using CORTRAK 1 EAS with that of blind placement. Patients (n=49) were children (neonates to 17 years old) in a paediatric ICU needing feeding tube placement. The primary outcome of the study was the time to successful placement. The secondary outcome was success rate as confirmed by X-ray. The time to successful placement was significantly longer in the CORTRAK 1 EAS group than in the blind placement group (hazard ratio 2.1; 95% CI 1.4 to 4.1, $p<0.03$). The difference between the success rates with CORTRAK 1 EAS and the blind placement technique was not statistically significant ($p=0.49$). The authors concluded that CORTRAK 1 EAS does not shorten the time needed by experienced practitioners to place post-pyloric feeding tubes in children.

Viana et al. (2011) was a single-centre randomised controlled trial set in Brazil. The aim of the study was to evaluate the success rate of post-pyloric feeding tube placement using CORTRAK 1 EAS with that of blind placement. Patients (n=37) were adults (67.3±14.2 years) in a general ICU of a tertiary hospital. The secondary outcome was time to successful placement. The difference in success rates between CORTRAK 1 EAS and blind placement was significant ($p<0.001$), and CORTRAK 1 EAS took significantly less time than blind placement ($p<0.001$). The authors concluded that CORTRAK 1 EAS was a faster and more effective method of placing post-pyloric

feeding tubes than blind placement.

Evidence on confirming post-pyloric placement in place of existing methods

Powers et al. (2011) was a multicentre, prospective cohort study set in the USA. The aim of this study was to compare the accuracy of CORTRAK 1 EAS with abdominal X-rays for confirmation of placement of post-pyloric feeding tubes at the bedside. Patients (n=194) included children and adults (12 days to 102 years old) needing feeding tube placement and were recruited from tertiary referral centres including an ICU, a general adult ward and a general paediatric ward. The primary outcome was agreement between the CORTRAK 1 EAS signal reading and X-ray image on potentially 3 separate occasions: directly following CORTRAK 1 EAS-guided placement, after contrast was injected through the feeding tube and during a final radiographic reading by an independent radiographer. Secondary outcomes included successful placement in the small intestine, percentage of placements where real-time tracing using CORTRAK 1 EAS showed airway placement and the process was halted, median time for feeding tube placement using CORTRAK 1 EAS, and safety. The percentage of agreement between CORTRAK 1 EAS interpretation and the X-rays was 86.9% for the first X-ray, 97.4% for the second X-ray and 99.5% for the third X-ray. During the study, 191 feeding tubes (98.4%) were successfully placed in the small intestine at the bedside. In 7.5% of cases, the tube's advancement was stopped after CORTRAK 1 EAS tracing on the screen demonstrated placement in the airway. Median time for feeding tube placement using CORTRAK 1 EAS was 12 minutes (range 1 to 52 minutes). No complications associated with the use of CORTRAK 1 EAS were identified. The authors concluded that CORTRAK 1 EAS can accurately confirm placement of post-pyloric tubes when compared with abdominal X-rays and that CORTRAK 1 EAS appears to be safe to use.

Evidence on guiding nasogastric placement in place of existing methods

Taylor et al. (2014) carried out a single-centre, prospective study set in the UK. Although the stated aim of this study was to determine the success rate of CORTRAK EAS in confirming NG feeding tube placement compared with pH testing or X-ray, the study provides evidence on guiding NG feeding tube placement. The study included 113 adults (median age 53 years) in ICU who needed a new or replacement NG tube. A total of 127 tube placements using the CORTRAK EAS were included in the analysis. Overall, CORTRAK EAS guided placement and confirmation of placement (with aspiration of fluid with a pH≤5.0, or X-ray) took a median of 6.4 minutes (interquartile range 4 to 10.4). In 7% of patients, the CORTRAK EAS trace deviated significantly to the left or right, suggesting placement in the left or right main bronchus. All tubes were withdrawn without

complication, demonstrating that CORTRAK EAS enabled users to view the path of the feeding tube in real time which enabled them to avoid incorrect tube placement before trauma occurred. There were no reported tube misplacements.

Evidence on confirming nasogastric placement in place of existing methods

No relevant evidence was identified.

Recent and ongoing studies

Two ongoing studies on CORTRAK EAS were identified in the Netherlands Trial Register (NTR) and 1 was notified by the manufacturer.

- CORRECT trial (NTR4286): a parallel group randomised controlled trial which aims to compare the success rate of duodenal feeding tube placement using the CORTRAK EAS with the endoscopic technique. Patients had achalasia or dysphagia and needed a duodenal feeding tube. The trial had a planned starting date in December 2013 and its planned closing date was September 2014. The current trial status is unknown.
- CORE trial (NTR4420): a parallel-group, multicentre, non-inferiority randomised controlled trial which aims to evaluate the effectiveness of nasoenteral feeding placement with CORTRAK EAS compared with endoscopic placement. Participants were surgical patients admitted to gastrointestinal wards in 5 hospitals requiring nasoenteral feeding. The trial had a planned starting date in October 2013 and its planned closing date was March 2015. Data collection has been completed.

Costs and resource consequences

The British Association for Parenteral and Enteral Nutrition estimates that as of 2011, between 28% and 34% of those admitted to hospital in the UK were at medium or high risk of malnutrition. NG feeding is the most common method used, and an estimated 271,000 NG tubes are supplied to the NHS annually (Macmillan Cancer Support 2013; Great Ormond Street Hospital 2014, National Patient Safety Agency Quarterly Data Summary 2008). This indicates the potential use of the CORTRAK EAS for placing NG tubes in the NHS.

According to the manufacturer, the device is being used at 34 NHS centres and 1 private centre in the UK. In addition, the device is being used at 6 centres in Ireland.

If CORTRAK 2 EAS were adopted, there would be no need to change the way current services are organised or delivered. No other additional facilities or technologies are needed alongside the technology.

The systematic review identified 2 conference abstracts and 4 published studies that provide some evidence concerning resource consequences. All 6 are non-randomised with sample sizes below 100 patients. These studies provide some evidence of cost savings for the NHS based on savings in staff time and potential reduction in need for X-ray confirmation, endoscopic tube placement and intra-hospital transports. All costs were adjusted for inflation and, where relevant, converted to pounds sterling.

Three studies based in the US compared resource use between nasoenteral feeding using CORTRAK EAS and conventional blind bedside placement (sometimes including prokinetic medication). Brown (2012) suggested a relative cost savings for CORTRAK EAS system of around £94 per placement; Gray (2007) suggested cost savings of £115 per placement and October (2009) suggested savings of £41 per placement.

The Taylor (2010) study was based at Frenchay Hospital in Bristol and compared feeding with CORTRAK 1 EAS with NG feeding plus prokinetics. They report cost savings equivalent to £143 per patient (originally reported in US dollars).

Windle (2010) used medical, dietetic and nursing records for 2 sites in the Mid Yorkshire NHS Trust to provide a trust perspective costing estimate for CORTRAK 1 EAS. They estimate a cost of £122 per tube insertion attempt, inclusive of a wide range of resource use.

An abstract by Sharma (2013) describes the experience of a single UK ICU. They report that 2 inadvertent lung placements confirmed by CORTRAK EAS led to mistrust of the device and an increase in X-ray-led confirmation. This unnecessary use of X-rays and radiographer time while using the CORTRAK EAS created an average overspend of £86 per patient.

Strengths and limitations of the evidence

Two studies included in this briefing are randomised controlled trials and 4 are prospective cohort studies. Taylor et al. (2014) was the only study conducted in the UK and so these results may be more relevant to the NHS. It was also the only study of the use of CORTRAK EAS in NG tube placement. Although the authors concluded that CORTRAK EAS may be considered a standalone method of confirming NG tube position, this may be misleading because the study did not actually observe or confirm any tube misplacements.

All but 1 of the studies (Power et al. 2011) recruited patients from ICUs. However, according to the manufacturer, CORTRAK EAS can be used in other settings including acute assessment units and outpatient settings. This focus on critically ill populations introduces a significant source of bias. Many of the ICU patients are mechanically ventilated, sedated and having antihypotensive agents. These factors increase the risk of tube misplacement and also increase the likelihood that enteral tube placement will be needed.

The 2 randomised controlled trials (Holzinger et al. 2011 and Kline et al. 2011) and 1 prospective cohort study (October and Hardart 2009) had sample size calculations for their primary outcome of success rate and time needed for accurate placement. The third randomised controlled trial by Viana et al. (2011) was stopped early due to a lack of device supplies, but according to the authors the study was shown to have sufficient statistical power to confirm the study hypothesis. Gray et al. (2007) performed retrospective sample size calculations and stated that a larger sample size would have strengthened the power of their study. A small sample size reduces the probability of detecting a difference between groups where such a difference exists (type II error), and will also increase the likelihood that a statistically significant finding is actually a false positive. The 2 remaining prospective studies (Powers et al. 2011; Taylor et al. 2014) did not report sample size calculations. Due to the relative low frequency of harm associated with any tube insertion method and the rarity of direct harm in existing placement checks, it is unclear whether studies had enough power to compare the safety of CORTRAK EAS with comparator methods.

Most studies used appropriate comparators although it should be noted that comparators vary among countries and clinical settings. In the UK the gold standard for the placement of post-pyloric feeding tubes is the endoscopic technique, which has success rates above 90% (Byrne and Fang 2006; Wiggins and DeLegge 2006); endoscopy was the comparator in the Holzinger et al. (2011) study. However, Gray et al. (2007), October and Hardart (2009), Kline et al. (2011) and Viana et al. (2011) used blind placement as a comparator noting that this was the conventional technique for post-pyloric tube placement (Viana et al. 2011; October and Hardart 2009), the hospitals' standard clinical practice (Kline et al. 2011) or what is traditionally advocated (Gray et al. 2007). X-rays and pH measurement are standard methods for confirmation of the tube's position and were used in studies where confirmation was necessary (Gray et al. 2007; Powers et al. 2011; October and Hardart 2009; Taylor et al. 2014).

Four studies with evidence on CORTRAK-EAS used the same tube type for both the intervention and comparator groups. Only 1 study (Holzinger et al. 2011) used a different type of tube for the endoscopic placement control group (a 150 cm double lumen jejunal tube [Freka Trelumina, manufactured by Fresenius Kabi]) which may have biased the results. The operators could not be blinded to the intervention and control groups in any of the randomised controlled trials. Although

this may introduce performance bias, this limitation is common in studies involving medical devices.

In medical device procedures, another source of potential bias is the training provided to use the device and the resulting proficiency with the procedure. Holzinger et al. (2011) stated that endoscopy was done by experienced gastroenterologists, whereas the CORTRAK EAS-guided procedure was done by a single ICU staff member with limited experience (only 3 CORTRAK EAS-guided tube placements) before study initiation. Kline et al (2011) reported that all 3 practitioners placing the post-pyloric feeding tubes had experience of blind placement, and although they had received training in using the CORTRAK EAS they each had the opportunity to place only 1 electromagnetically guided post-pyloric tube before the start of the study. Gray et al. (2007) reported that blind tube placements were done by experienced clinical personnel who had also been trained in using CORTRAK EAS by both an outside expert and a manufacturer representative. October and Hardart (2009) was the only study to report an extensive training phase during which the group of CORTRAK EAS operators was trained in the use of the device over a 2-week period followed by a 6-week practice period. Powers et al. stated that tubes were placed by an investigator experienced in the use of CORTRAK EAS and that X-rays were read and verified by 2 radiologists. Taylor et al. (2014) did not report whether operators had undergone prior training or their level of experience.

In the October and Hardart (2009) study there was a large difference in the time to successful placement between CORTRAK and the blind placement technique (1.7 hours compared with 21 hours respectively). Time to successful placement was defined as the time between the operator removing the tube from stock to the confirmatory abdominal X-ray being done. In the case of CORTRAK placements, the shorter time is partly attributable to the real-time imaging that the technology can afford and the fact that the operator would be able to make appropriate adjustments before obtaining the confirmatory abdominal X-ray. The blind placement technique, on the other hand, does not allow for real-time assessment of tube placement and thus might require repeated attempts and multiple X-rays before the final confirmatory X-ray can be taken. This could account for the large difference in 'time to successful placement' outcome.

Lastly, the manufacturer funded the time and equipment for the Taylor et al. (2014) study and the lead author had served on a CORPAK MedSystems consultation committee in 2007. This had the potential for introducing bias in the reporting of outcomes.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Nutrition support for adults (2006) NICE guideline CG32

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Appendix

Contents

Data tables

Table 1 Overview of the Holzinger et al. (2011) trial

Study component	Description
Objectives/ hypotheses	To compare the success rate of NJ feeding tube placement using CORTRAK 1 EAS with that of the endoscopic technique in critically ill patients.
Study design	Single centre randomised controlled trial
Setting	Two ICUs at a university hospital in Austria; May 2007- February 2009 No follow up period was reported.

Inclusion/ exclusion criteria	Inclusion: • >18 years of age • intubated, mechanically ventilated, • intolerance of intragastric enteral nutrition. Exclusion: • contraindication for enteral nutrition or upper gastrointestinal endoscopy • previous upper gastrointestinal surgery • signs of active upper gastrointestinal bleeding • severe nasopharyngeal injuries or stenosis.
Primary outcomes	Primary outcome: • The success rate of correct NJ tube placement after 24 hours Secondary outcomes: • Success rate • Placement time (mins) • Nose bleeding events • Number of tube placement • Time in right location (days) • Intensive care unit survival • Hospital survival
Statistical methods	The study aimed to detect a difference in success probability of 30% given a baseline probability of nearly 100% at a power of 80% and a significance level of 5%. For the comparison of the "number of attempts" a chi-square test was used. Multiple linear regression was used to adjust the continuous variables for reflux.

Patients included	In total 66 critically ill adults who were unable to tolerate intragastric nutrition were recruited. CORTRAK 1 EAS (study group): n=44, age=55±18 years; 64% male, 35% female. Admission reason: 9% septic shock, 18% heart failure, 21% acute lung injury/ adult respiratory distress syndrome, 41% burn injury, 11% others. Endoscopic technique using a 150 cm double lumen jejunal tube (Freka Trelumina, manufactured by Fresenius Kabi; control group): n=22, age=56±15 years; 82% male, 18% female. Admission reason: 9% septic shock, 23% heart failure, 27% acute lung injury/ adult respiratory distress syndrome, 36% burn injury, 5% others.
Results	Correct NJ tube placement was achieved in 21 of 22 patients using the endoscopic technique (control group) and in 40 of 44 patients using CORTRAK (intervention group) (p=0.571). The placement times were not significantly different between the two groups (p=0.23). CORTRAK resulted in the correct nasojejunal position more often at the first attempt (p=0.009). Nose bleeding occurred equally in both groups (p=0.99). None of the nose bleeding events needed intervention or transfusion. There was no significant difference between groups in the amount of time the tubes stayed in the correct location (mean difference -1.32 days, CI -2.09 to +1.21). Neither ICU survival (p=0.72) nor hospital survival p=0.84) were different between the groups.
Conclusions	Correct NJ feeding tube placement using the CORTRAK system was as fast, safe, and successful as the endoscopic method in a comparative ICU patient population.
Abbreviations: CI, confidence interval; NJ, nasojejunal; n, number of patients; RR, relative risk.	

Table 2 Summary of results from the Holzinger et al. (2011) trial

	CORTRAK 1 EAS	Endoscopic technique	Analysis

Randomised	n=44	n=22	
Efficacy	n=44	n=22	
Primary outcome: successful implantation of the tube	91.0% (40/44)	95.0% (21/22)	RR: 0.95, 95% CI 0.80 to 1.12 p=0.57
Selected secondary outcomes:			
Placement time mean and range (minutes)	11 (6-19)	15 (10-21)	mean difference -1.26 minutes, 95% CI -1.88 to +1.17, p=0.23
Number of attempts	1.18±0.54	1.82±0.79	1.18±0.54, p<0.0001
Nose bleeding	18.0% (8/44)	18.0% (4/22)	RR 1.00, 95% CI 0.01 to 140.69, p=0.99
Time left in right location mean and range (days)	9 (4.5-16.5)	13 (9-20)	p=0.27
ICU survival	72.0%(32/44)	68.0%(15/22)	RR 1.07, 95% CI 0.75 to 1.51, p=0.72
Hospital survival	61.0%(27/44)	59.0%(13/22)	RR 1.04, 95%CI 0.73 to 1.48, p=0.84
Safety	n=44	n=22	
Patients reporting serious adverse events	0% (0/44)	0.0% (0/22)	
Abbreviations: CI, confidence interval; ICU, intensive care unit; n, number of patients; RR, relative risk.			

Table 3 Overview of the Gray et al. (2007) study

Study component	Description
Objectives/ hypotheses	To evaluate the safety of CORTRAK 1 EAS for placing feeding tubes compared with blind placement.
Study design	Single centre prospective observational study

Setting	ICU (USA) Control group recruitment: February 2004 to May 2005 Study group recruitment: August 2005 to March 2006 No follow up period was reported.
Inclusion/ exclusion criteria	Inclusion: • ICU patients who needed post-pyloric feeding tubes Exclusion: • implantable devices: automatic internal cardiac defibrillator (AICD), cardiac or gastric pacemaker • head trauma involving sinuses or nares • severe bleeding/clotting disorders such as disseminated intravascular coagulation (DIC).
Primary outcomes	Primary outcome: • safety/complications related to post-pyloric tube placement Secondary outcomes: • success rate of accurate placement into the small intestine • number of X-rays needed to confirm placement • basic cost of post-pyloric tube placement • time from clinician request to placement • time from placement to initiation of enteral feeding.

Statistical methods	Statistical analysis was performed using the Wilcoxon signed rank test to compare: • number of abdominal X-rays needed to confirm placement. • basic cost of post-pyloric tube placement • time from clinician request to placement • time from placement to feeding The post-pyloric tube placement success rate was analysed using chi-squared and Fisher's exact test.
Patients included	A total of 101 adults were recruited from ICU. CORTRAK 1 EAS (intervention group): n=81 (mean age: 55.9 years, 31% female, 69% male). Admission reason: 5% cardiovascular surgery, 10% gastrointestinal, 12% haematology/oncology, 14% sepsis/organ failure, 18% neurology/trauma, 18% organ transplant, 23% respiratory failure. Blind placement (control group): n=20 (mean age: 53.8 years, 60% female, 40% male). Admission reason: 5% neurology/trauma, 10% haematology/oncology, 20% organ transplant, 25% respiratory failure, 40% sepsis/organ failure.

Results	Primary outcome: No complications or adverse events were reported in the intervention or the control groups. Secondary outcomes: • Successful placement of the post-pyloric tubes into the small intestine was 78% in the CORTRAK group vs 63% in the blind placement group (not significant). • Median number of X-rays was 1 in the CORTRAK group vs 2 in the control group (p=0.0001). • The total time between clinician request for post-pyloric tube placement and initiation of feeding was 66% lower in the CORTRAK group versus the control group (median time of 7.75 hours versus 22.25 hours, p=0.0032). • Median time between tube placement and initiation of enteral feeding was 4.0 hours in the CORTRAK group and 4.5 hours in the control group (not significant). • The time between clinician request (for tube placement) and actual tube placement was 2.5 hours for CORTRAK) versus 4.75 hours (controls) (p=0.0059).
Conclusions	No adverse events occurred during post-pyloric tube placement in the intervention or control group. The use of CORTRAK resulted in fewer X-rays for confirmation of placement and more timely initiation of enteral feeding compared with blind placement.
Abbreviations: DIC, disseminated intravascular coagulation; GERD, gastroesophageal reflux disease; INR, international normalized ratio; ICU, intensive care unit; n, number of patients; PT, prothrombin time; PTT, partial thromboplastin time; USA, United States of America.	

Table 4 Overview of the October and Hardart (2009) study

Study component	Description
Objectives/ hypotheses	To evaluate the clinical and cost effectiveness of CORTRAK 1 EAS for bedside post-pyloric tube placement in comparison with standard blind placement.
Study design	Prospective cohort trial with serial control groups

Setting	Paediatric ICU at a tertiary care children's hospital (USA); from September 2005 to April 2006 No follow up period was reported.
Inclusion/ exclusion criteria	Inclusion: • children in ICU who underwent post-pyloric tube placement between 7am and 7pm. Exclusion: • weight <5 kilograms • post-pyloric tube placement between 7pm and 7am • presence of an internal cardiac pacemaker or defibrillator device, or external cardiac pacing during post-pyloric tube placement.
Primary outcomes	Primary outcome: success rate of tube placement as determined by abdominal X-ray. • success overall Secondary outcomes: • correct location of the tube • number of abdominal X-rays needed to confirm tube placement, • time to success placement (hours) • complications, • number of tubes used, • prokinetic drug use.

Statistical methods	Categorical variables were assessed by chi-square or Fisher's exact test. Continuous variables were analysed using unpaired Student's t test for parametric data and the Wilcoxon signed rank test for nonparametric data. Ordinal variables were analysed with the Cochran-Armitage Test. Two logistic regression models were performed; 1 with a response variable of successful outcome and 1 with successful placement dichotomized to <24 hours or >24 hours. Multivariate regression analyses were used to adjust for more than one variable. Cumulative-event curves were estimated using the Kaplan-Meier method and the treatment groups were compared using the log-rank test. All statistical tests were two-sided with a significance level of 0.05.
Patients included	A total of 107 children in ICU were recruited. CORTRAK 1 EAS (intervention group): n=50, age (months): median (range), 31 (1-211); 48% male, 52% female. Admission reason: 24% cardiac (medical and surgical); 16% neuromuscular disease; 50% respiratory failure; 10% sepsis; 0% trauma. Blind placement (control group): n=57; age (months): median (range), 39 (2-296); 61% male, 39% female. Admission reason: 38.6% cardiac (medical and surgical); 12.3% neuromuscular disease; 35.1% respiratory failure; 8.8% sepsis; 5.3% trauma.

Results	CORTRAK 1 EAS vs blind placement technique: Success rate (% patients): 82.0% vs 39.0% (p<0.0001) Placement success in <24 hours (% patients): 78.0% versus 21.1% (p<0.0001) Median time to successful placement including confirmation (range): 1.7 hours (0.2-130 hours) versus 21.0 hours (1-477 hours) (p<0.0001). Significantly fewer abdominal X-rays were needed in the CORTRAK 1 EAS group (mean, SE) (1.3±0.6) than in the controls (mean, SE) (2.4±1.4) (p<0.0001). There was no difference in location (duodenum) of successful post-pyloric tube placements between the 2 groups. CORTRAK 1 EAS was the only predictor of successful placement (odds ratio 8.4; 95% CI 2.6 –27.8) and early successful placement (success within 24 hours) (odds ratio 13.3; 95% CI 5.3–33.5) by univariate analysis. No difference was detected in the time to initiation of feeding between the 2 groups. There were no acute complications during the trial period in either group.
Conclusions	CORTRAK 1 EAS is an effective system for bedside post-pyloric tube placement in critically ill children.
Abbreviations: CI, confidence interval; n, number of patients; ICU, intensive care unit; SE, standard error.	

Table 5 Overview of the Kline et al. (2011) trial

Study component	Description
Objectives/ hypotheses	To determine whether CORTRAK 1 EAS shortens the time needed to achieve accurate placement of post-pyloric feeding tubes in critically ill children when compared with the standard blind placement technique.
Study design	Single centre randomised controlled trial
Setting	Paediatric ICU (USA) No follow-up period was reported

Inclusion/ exclusion criteria	Inclusion: • neonates to less than 18 years of age • request for placement of a post-pyloric feeding tube. Exclusion: • presence of a permanent or temporary pacemaker • presence of a gastrostomy or jejunostomy tube • gastrointestinal surgery in the preceding 90 days • recent gastrointestinal haemorrhage • cardiac surgery in the preceding 2 weeks.
Primary outcomes	Primary outcome: • Time needed for accurate placement of a post-pyloric feeding tube. Secondary outcome: • The placement success rate, as confirmed by X-rays.
Statistical methods	A Kaplan-Meier curve was used to examine differences in time to placement between the 2 groups and to estimate median time to placement, with Cox proportional hazards modelling used to determine significance. Differences in the rate of successful placement between groups were tested by using Fisher's exact test. Associations of time to placement with confounding factors were examined by using Cox proportional hazards modelling, again adjusting for clustering by practitioner by using robust standard errors. Differences between the 2 methods were compared by using a chi-squared test for nominal variables and a t-test for continuous variables. The level of significance used was 0.05.

Patients included	In total 49 children were recruited. CORTRAK 1 EAS (intervention group): n=22; age (mean±SD): 1.9±3.0 years; 32% male, 68% female. Blind placement (control group): n=27; age (mean±SD): 2.1±4.2 years; 63% male, 37% female.
Results	Primary outcome: • Time to placement was significantly longer in the CORTRAK group than in the control group ((9.5 vs 5.0 minutes; HR=2.10, 95% CI 1.10 to 4.10; p=0.03). Secondary outcome(s): • The success rate, as confirmed by X-rays, was 92% in the control group and 100% in the intervention group (p=0.49). • No adverse events were noted during tube placement in either the intervention or control group.
Conclusions	The use of CORTRAK 1 EAS does not benefit experienced practitioners in correctly placing post-pyloric feeding tubes in critically ill children when compared to the use of other routinely used techniques such as the blind placement technique.
Abbreviations: CI, confidence interval; n, number of patients; ICU, intensive care unit; HR, hazard ratio; SD, standard deviation.	

Table 6 Overview of the Viana et al. (2011) study

Study component	Description
Objectives/ hypotheses	The aim was to evaluate the success rate of post-pyloric feeding tube placement using CORTRAK 1 EAS compared to the conventional placement method (blind placement).
Study design	Single centre randomised controlled trial

Setting	General ICU of a tertiary hospital (Brazil) September 2008-December 2008 No follow up period was reported.
Inclusion/ exclusion criteria	Inclusion: • >18 years of age and at least one of the following criteria: Exclusion: — active gastrointestinal bleeding — history of oesophageal or gastric varices — severe thrombocytopenia (<50,000) — recent oesophageal or stomach surgery — pharyngeal or laryngeal obstruction — psychomotor agitation — contraindications for >30° angle of the head of the bed, head or face trauma — requirement for non-invasive mechanic ventilation.
Primary outcomes	Primary outcome: • the success rate of post-pyloric placement (as verified by pH aspirations and X-ray) Secondary outcomes: • time required to perform the entire procedure

Statistical methods	For continuous, normally distributed variables the Student's t-test was used. The Mann-Whitney U test was used for non-normally distributed continuous variables. For nominal variables, the Fisher exact test was used, with confidence intervals based on a normal approximation of a binomial distribution. Values of $p<0.05$ were considered significant.
Patients included	In total 37 adults were recruited. CORTRAK 1 EAS (study group): n=18, age=65.8±11.3 years; 44.4% male, 55.6% female. Admission reason: clinical patients 38.9%, elective surgery 38.9%, emergency surgery 22.2%, invasive mechanical ventilation 92.3%, use of vasopressors 29.4%, use of gastric protectors 50.0%, fluid form digestive tube 47.2% aspiration, tube replacement required 5.4%. Blind placement (control group): n=19, age=68.7±16.7 years; 47.4% male, 52.6% female. Admission reason: clinical patients 52.6%, elective surgery 21.1%, emergency surgery 26.3%, invasive mechanical ventilation 88.2%, use of vasopressors 47.4%, use of gastric protectors 55.6%, fluid from digestive aspiration 36.8%, tube replacement required 5.3%.
Results	Primary outcome: • The CORTRAK 1 EAS group achieved more post-pyloric placement than the control group ($p<0.001$) • Secondary outcomes: • Time required to perform the entire procedure was shorter in the CORTRAK1 EAS than in the control group ($p<0.001$).
Conclusions	The CORTRAK method was quicker and provided better placement accuracy than the blind placement technique.
Abbreviations: EAS, enteral access system; ICU, intensive care unit; n, number of patients.	

Table 7 Overview of the Powers et al. (2011) study

Study component	Description
Objectives/ hypotheses	To compare the accuracy of CORTRAK 1 EAS versus abdominal X-ray for confirmation of bedside placement of post-pyloric feeding tubes.
Study design	Multicentre prospective cohort study
Setting	The study was carried out in 3 tertiary referral centres in the USA. No follow up period was reported.
Inclusion/ exclusion criteria	Inclusion: • any inpatient with a request for post-pyloric feeding tube placement Exclusion: • subjects who were unable to have bedside placement because of gastric bypass surgery, hiatal hernia, or bleeding complications. • pregnancy • hyperthyroidism • contraindications to the use of barium.
Primary outcomes	Primary outcome: • Accuracy of post-pyloric tube placement (% of agreement between CORTRAK 1 EAS interpretation and abdominal X-ray). Secondary outcomes: • Success rate of post-pyloric feeding tube placement. • Percent where inadvertent airway placement was avoided. • Median time for feeding tube placement using CORTRAK 1 EAS.

Statistical methods	Accurate placement using the CORTRAK 1 EAS and abdominal X-rays were compared using percentage of agreement. All variables were assessed to determine any possible correlations between gender, diagnosis, duration of placement, and investigator as predictors of proper placement or complications.
Patients included	A total of 194 people were recruited (including 18 children). Age: Mean for all patients (range): 55 years (12 days-102 years) 60% male, 40% female Admission reason: 50.2% medical, 25.4% neurological, 13.2% trauma, 11.2% surgery, Admitting service: 78.4% ICU, 12.4% non-ICU, 9.2% paediatric.

Results	Primary outcome: • Percentage agreement between CORTRAK 1 EAS interpretation and: — 1st abdominal X-ray: 86.9 — 2nd abdominal X-ray: 97.4 — Independent X-ray: 99.5 Secondary outcomes: • Successful placement at the bedside: 191 post-pyloric feeding tubes (98.4%) • Avoidance of inadvertent airway placement (based on detection with CORTRAK 1 EAS): 7.5% of patients, • Median time for feeding tube placement using CORTRAK 1 EAS in minutes (range): 12 (1–52) (1 outlier of 122 minutes). • No complications associated with the use of CORTRAK 1 EAS were identified. Paediatric subset data results: • Median time for post-pyloric feeding tube placement (min, range): 20 (1–45). • Correlation between CORTRAK 1 EAS interpretation and the first X-ray: 99.4% and 100% (before and after injection of water-soluble contrast respectively) • Avoidance of inadvertent airway placement: 22%. • No complications were encountered during placement.
Conclusions	Findings indicate that the use of CORTRAK 1 EAS can accurately confirm placement of post-pyloric tubes at the bedside when compared to X-ray. CORTRAK 1 EAS can be used safely at the bedside to facilitate placement of feeding tubes.
Abbreviations: ICU, intensive care unit.	

Table 8 Overview of the Taylor et al. (2014) study

Study component	Description
Objectives/ hypotheses	To determine accuracy of the CORTRAK EAS in guiding NG feeding tube location when compared with pH and, in cases where results were inconclusive, X-rays.
Study design	Prospective, single centre study
Setting	ICU (UK) No follow up period was reported.
Inclusion/ exclusion criteria	Inclusion: • ICU adults requiring a new or replacement nasogastric tube. Exclusion: • No exclusion criteria were provided
Primary outcomes	Primary outcome: • Success rate of nasogastric tube placement as determined by pH and X-ray Secondary outcome: • Time to confirmation of placement
Statistical methods	Agreement between CORTRAK EAS NG tube placement with the other methods was tested using Cohen's kappa coefficient.
Patients included	A total of 113 adults were recruited from ICU (with a total of 127 tube placements). Age: median (IQR); 53 (36, 66) Weight: median (IQR); 80 kg (68, 90) Height: median (IQR) 174 cm (166, 180) 66% male, 34% female Admission reason: 30% medical, 12% neurosurgery, 14% surgery (general), 44% trauma.

Results	Primary outcome: Success rate: of 127 placements, 125 of 127 placements (98%) were confirmed as correctly NG. Secondary outcomes: CORTRAK EAS placement and confirmation of placement took a median of 6.4 minutes (IQR: 4, 10.4) and was completed in the late morning (median 11:30: 11:00, 12:24) during the 8:00–12:00 no feeding 'rest' period, whereas X-ray, when needed, was completed later (median 14:00: 13:00, 15:00). Confirmation of position was immediate for CORTRAK and pH but X-ray delayed feeding and medicines by 2 hours.
Conclusions	The use of CORTRAK EAS results in quick and successful placement of most NG tubes.
Abbreviations: CI, confidence interval; ICU, intensive care unit; IQR, interquartile range; NG, nasogastric; n, number of patients.	

Table 9 Summary of the economic studies

Author (year)	Country	Intervention and comparator	Total patients (total SP; total AP)	Costs included	Original costs	Adjusted costs (PPP ER, inflation)
Brown (2012)	USA	CORTRAK EAS, conventional blind placement	77 (83; 152)	Tubes, X-rays, intra-hospital transports and staff time	$132 cost saving per episode	£94 cost saving per episode
Gray (2007)	USA	CORTRAK 1 EAS, conventional blind placement	101 (75; 100)	Confirmatory X-rays	$150 cost saving per placement	£115 cost saving per placement

October (2009)	USA	CORTRAK 1 EAS, conventional blind placement	107 (126 SP)	Confirmatory abdominal radiographs	$56 cost saving per placement	£41 cost saving per placement
Sharma (2013)	UK	CORTRAK EAS only	41(48 AP)	Confirmatory X-rays	£83 X-ray related waste per patient	£86 X-ray related waste per patient
Taylor (2010)	UK	CORTRAK 1 EAS, nasogastric tube plus prokinetics	76 (69 SP)	Tubes, prokinetic agents and staff costs	$193 cost saving per treatment course	£143 cost saving per treatment course
Windle (2010)	UK	CORTRAK 1 EAS only	36 (27; 39)	Human resources, consumables like enteral feeding tubes and X-ray films and Nasal-bridle kits	£111 cost per tube insertion attempt with CORTRAK	£122 cost per tube insertion attempt with CORTRAK
Abbreviations: AP, attempted placement; ER, exchange rate; PPP, purchasing power parity; SP, successful placement						

Search strategy and evidence selection

Search strategy

For the clinical evidence

Embase 1980 to 2015 Week 35, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 18 September 2015.

1. CORTRAK.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

2. corpak.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

3. viasys.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

4. electrom*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

5. feeding tub*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

6. enteral feed*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, tn, dm, mf, dv, kw]

7. 5 or 6

8. 4 and 7

9. 2 or 3

10. 4 and 9

11. 1 or 8 or 10

12. remove duplicates from 11

For the health economics evidence

Embase 1974 to 2015 September 29, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Searched on 30 September 2015

1. CORTRAK.mp.

2. corpak.mp.

3. viasys.mp.

4. electrom*.mp.

5. feeding tub*.mp.

6. enteral feed*.mp.

7. 5 or 6

8. 4 and 7

9. 2 or 3

10. 4 and 9

11. 1 or 8 or 10

12. remove duplicates from 11

13. cost$.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

14. economic$.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

15. 13 or 14

16. 12 and 15

Cochrane Database of Systematic Reviews: Issue 9 of 12, September 2015, Database of Abstracts of Reviews of Effect: Issue 2 of 4, April 2015, Cochrane Central Register of Controlled Trials: Issue 8 of 12, August 2015, Cochrane Methodology Register: Issue 3 of 4, July 2012, Health Technology Assessment Database: Issue 3 of 4, July 2015, NHS Economic Evaluation Database: Issue 2 of 4, April 2015

#1 CORTRAK (Word variations have been searched)

#2 corpak

#3 viasys

#4 electrom*

#5 feeding tub*

#6 enteral feed*

#7 #5 or #6

#8 #4 and #7

#9 #2 or #3

#10 #4 and #9

#11 #1 or #8 or #10

#12 $cost

#13 $economic

#14 #12 or #13

#15 #11 and #14

Evidence selection

For the clinical evidence

- Total number of publications reviewed: 48
- Total number of publications considered relevant: 20
- Total number of publications selected for inclusion in this briefing: 7

For the health economics evidence

Total abstracts: 53

Duplicates: 2

Abstracts reviewed: 51

Full papers reviewed: 10

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/abstracts, animal studies, non-English language studies, not using the CORTRAK

Studies for review: 6

Update information

December 2016: Republished with revisions to the evidence; for further information please contact nice@nice.org.uk.

September 2016: Withdrawn after external query.

June 2016: Reference to a patient safety alert was added and changes were made to the cost of comparator tubes. Evidence from studies into guiding the placement of nasogastric and post-pyloric tubes have now been presented separately from studies confirming the placement.

March 2016: Withdrawn after external query.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The Interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Tracy Earley, Consultant Nurse - Nutrition, Lancashire Teaching Hospitals NHS Foundation Trust
- Dr Timothy Heymann, Consultant Physician and Gastroenterologist, Kingston Hospital NHS Foundation Trust
- Zillah Leach, Clinical Nurse Specialist - Nutrition Support, University Hospital Southampton NHS Foundation Trust

Declarations of interest

Zillah Leach was involved in a study comparing NG and NJ tube placement in stroke patients – CORTRAK EAS was used to place the NJ tubes. In addition, she collaborated with CORPAK MedSystems to produce a training video and app.

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