

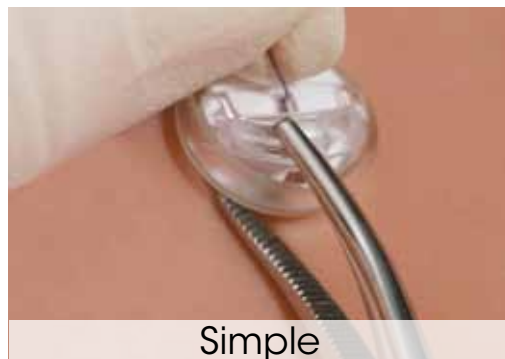


MIC Introducer Kits

Gastropexy made Safe, Simple and Effective



Safe



Simple



Effective

Gastropexy is a well known technique that has, until now, been hampered by the equipment available. The new Kimberly Clark MIC Introducer Kit, supplied by Vygon (UK) Ltd, addresses the problems of the past and provides a simple and safe procedure to allow primary placement of a MIC balloon gastrostomy or gastro jejunostomy device.

In addition to supplying everything needed for the gastropexy procedure in one kit, significant improvements have been made to each of the components. For the user, individual pre-loaded safety gastropexy needles with a simple locking mechanism start the procedure. This is followed by a single unit serial dilator and split sheath introducer over a guidewire. For the patient and carer, the locking mechanism for the gastropexy is soft, comfortable and discreet, and allows easy cleaning and care. The absorbable sutures ensure that the gastropexy adhesion is formed, before the locking discs detach after a few weeks. Gastropexy using the MIC Introducer Kit is ideally suited to radiologic or endoscopic placement of a MIC balloon-retained gastrostomy or gastro jejunostomy device.

Quite simply, the right equipment for gastropexy for the first time

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MIC Introducer Kit

Gastropexy made **Safe, Simple & Effective**

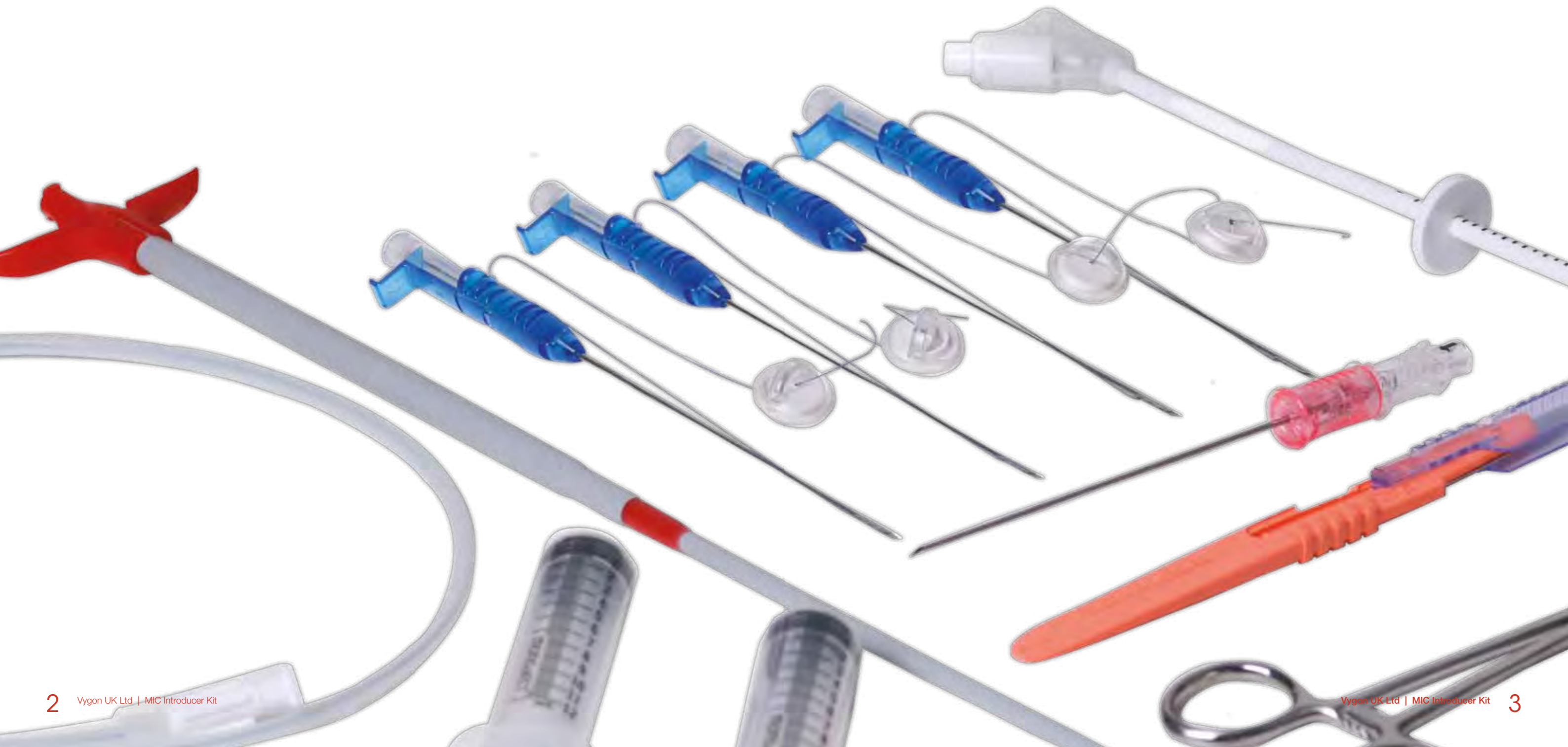
Features and Benefits

Primary Placement of a Balloon Device

With the MIC Introducer Kit you can safely place a balloon device during the initial placement procedure. Traditional gastrostomy placement techniques involve an initial procedure to place a PEG tube, which stays in place while the stoma forms, and is then replaced with a balloon device. The unique SAF-T-PEXY T-Fasteners secure the stoma and can safely remain in situ until the stoma has become properly established. This reduces the number of procedures, eliminating associated costs and minimising patient discomfort.

Convenient Procedure Pack

The MIC Introducer Kit includes all the components required to perform a gastropexy procedure, presented in a single sterile pack. This saves time, and gives you peace of mind that you have everything to hand at the start of the procedure, with only the balloon device to be added once the stoma site has been measured. Having all the required components in a single sterile pack also reduces the risk of cross-contamination associated with opening multiple packs, and reduces your ordering and stock holding costs.





Pre-Loaded SAF-T-PEXY Needles

The MIC Introducer Kit contains four individual introducer needles that are pre-loaded with SAF-T-PEXY T-Fasteners, reducing the time taken to perform the procedure.

Each introducer needle has a built-in safety mechanism that covers the needle tip once the T-Fastener has been deployed, reducing the risk of clinician or patient injury.

The use of individual needles reduces the risks of infection associated with crossing the peritoneal cavity repeatedly with the same needle at different sites.



Unique Locking Disc

The T-Fastener sutures feature unique locking discs that are quick to fix in place, leaving a securely held suture.

This design allows easy cleaning of the gastropexy site, which significantly reduces the risk of infection, and the smooth, rounded base offers a major improvement in patient comfort.

The locking discs then fall away once the suture has been absorbed.



SAF-T-PEXY T-Fastener

The SAF-T-PEXY T-Fastener sutures are designed to remain in situ for 2-3 weeks before being absorbed by the body once the gastropexy adhesion has fully developed.

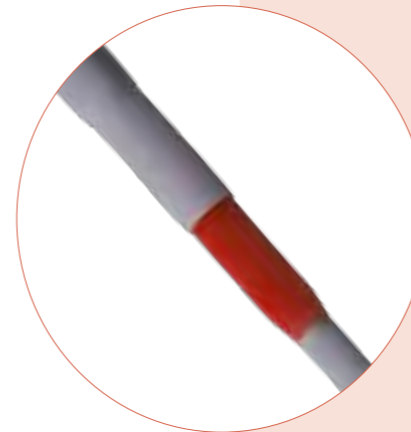
This makes gastropexy a more reliable technique, and improves patient comfort during stoma formation.



Single Serial Dilator

The new single serial dilator features all dilation stages in a single device, you simply feed each dilator stage over the previous one until the stoma site is correctly sized.

This saves you time during the procedure, and removes the need to re-thread each dilator stage over a guidewire, reducing the risk of infection.

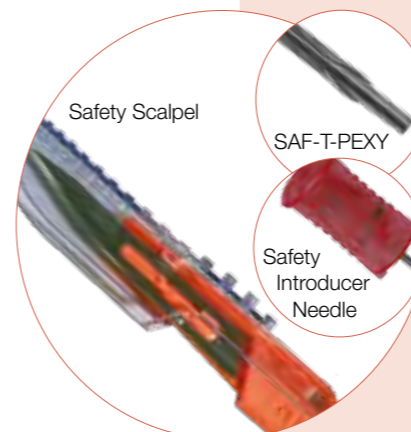


Made to Measure

When placing a MIC-KEY button gastrostomy or transgastric jejunostomy device you need to measure the stoma length during dilation.

The serial dilator features a red-coloured stage to indicate that the stoma is large enough to accept the measuring device.

The dilator is simply removed once the red stage has been inserted, then replaced after stoma measurement so dilation can continue.



Sharps Safety

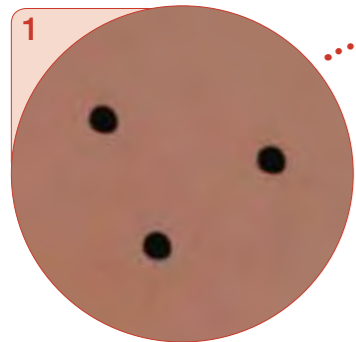
Sharps safety is an important concern for all, and this has been incorporated as standard into the MIC Introducer Kit.

All needles have built-in safety mechanisms, and a safety scalpel is included to reduce the risk of injury.

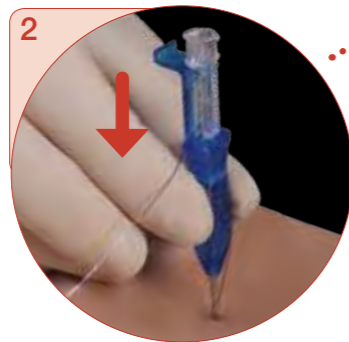
MIC Introducer Kit

Gastropexy made **Safe, Simple & Effective**

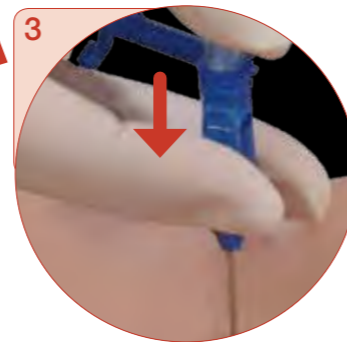
Suggested Procedure



1 Mark the insertion site with introducer points in a triangle at 2cm away from the stoma site. Infiltrate with local anaesthetic.



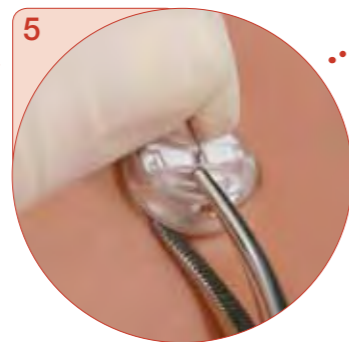
2 Prime the SAF-T-PEXY introducers with sterile water and insert at the points marked.



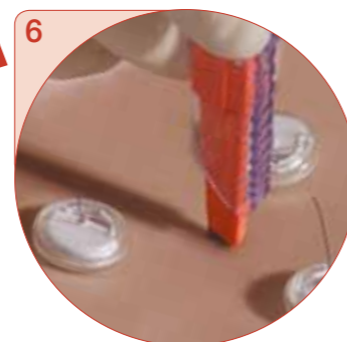
3 Pull back the blue clip and push the clear hub down to eject the T-Fastener.



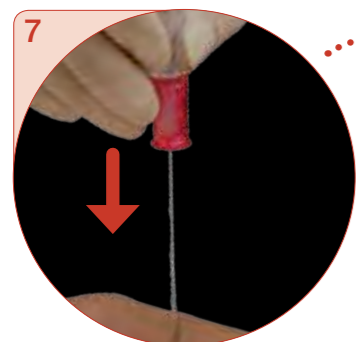
4 Slide the locking disc to the skin but do not lock. Secure sutures with a haemostat until all are introduced.



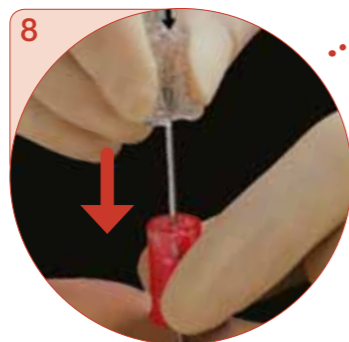
5 Pull the sutures up until resistance is felt (the T-Fasteners will be against the stomach wall) then slide locking discs down to skin level, lock in position with an audible click and cut sutures to length.



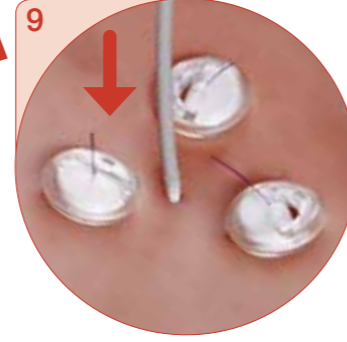
6 Anaesthetise the stoma site, make an incision using the safety scalpel through the abdominal wall.



7 Insert the 18G safety introducer needle at the stoma site, then insert the guidewire.



8 Remove the introducer needle, sliding the pink section down to cover the needle tip as you withdraw. For TJ placement, the seeking catheter may be used to facilitate placement.



9 Apply a water-soluble lubricant. Thread the serial dilator over the guidewire then insert the smallest dilator stage into the stoma, twisting as you advance into the stoma.



10 Gradually insert the next dilator stages, using a clockwise/counter clockwise twisting motion, stopping after the red stage when you need to use a measuring device.



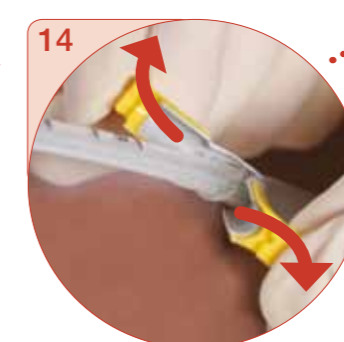
11 **Optional** when measurement is required, remove the dilator, apply lubricant to the tip of the measuring device and insert over wire. Take measurement from above disc.



12 Once the measurement is taken, re-insert the serial dilator and continue the dilation up to the largest stage (peelable sheath).



13 Twist the hub to release the dilator from the peelable sheath. Lubricate the exterior of the sheath and advance into the stomach, then remove the dilator.



14 Inspect the gastrostomy balloon then ensure it is fully deflated. Lubricate the tip, then insert the tube into the peelable sheath and begin to peel apart.



15 Advance the feeding tube as you peel and remove the sheath. Once the sheath is fully removed, make sure that the feeding tube is fully inserted and inflate the balloon with the correct amount of water.



16 Keep the site clean, and observe for any signs of irritation or leakage. Do not rotate the gastrostomy.

Important

The sutures will be absorbed in approximately 3 weeks, at which point the locking discs will fall away.

Do not rotate the feeding tube during the first two weeks after placement.

Only use water-soluble lubricants.

For full procedure please refer to instructions for use.

MIC Introducer Kit

Gastropexy made **Safe, Simple & Effective**

MIC-KEY G and TJ Introducer Kit

MIC-KEY Low-Profile Gastrostomy Introducer Kit

Complete kit for primary placement of a MIC-KEY gastrostomy button.
(MIC120 and MIC2120 ranges)



For use with



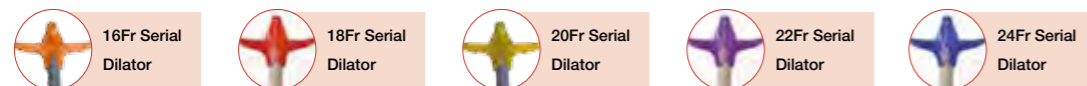
MIC-KEY Gastrostomy Button supplied separately

Product Code	Product Description	For use with	Box/Case Quantity
MIC98430	MIC-KEY G - 12Fr Introducer Kit <i>Includes 16Fr Dilator</i>	MIC-KEY 12Fr Low-profile Gastrostomy Feeding Tube*	1 Kit/Case
MIC98431	MIC-KEY G - 14Fr Introducer Kit <i>Includes 18Fr Dilator</i>	MIC-KEY 14Fr Low-profile Gastrostomy Feeding Tube*	1 Kit/Case
MIC98432	MIC-KEY G - 16Fr Introducer Kit <i>Includes 20Fr Dilator</i>	MIC-KEY 16Fr Low-profile Gastrostomy Feeding Tube*	1 Kit/Case
MIC98433	MIC-KEY G - 18Fr Introducer Kit <i>Includes 22Fr Dilator</i>	MIC-KEY 18Fr Low-profile Gastrostomy Feeding Tube**	1 Kit/Case
MIC98434	MIC-KEY G - 20Fr Introducer Kit <i>Includes 24Fr Dilator</i>	MIC-KEY 20Fr Low-profile Gastrostomy Feeding Tube*	1 Kit/Case

* Tube not included

Kit Contents

- 4 x SAF-T-PEXY T-Fasteners
- 1 x Haemostat
- 1 x 18G safety introducer needle
- 1 x 0.35" J-tip guidewire
- 1 x N° 11 safety scalpel
- 1 x Serial dilator
- 1 x Over-the-wire stoma measuring device
- 2 x 12ml syringes



MIC-KEY Low-Profile Transgastric-Jejunal Double Lumen Introducer Kit

Complete kit for primary placement of a MIC-KEY transgastric jejunal button.
(MIC270 range)



For use with



MIC-KEY TJ Button supplied separately

Product Code	Product Description	For use with	Box/Case Quantity
MIC98437	MIC-KEY TJ - 16Fr Introducer Kit <i>Includes 20Fr Dilator</i>	MIC-KEY 16Fr Low-profile Transgastric Jejunal Feeding Tube*	1 Kit/Case
MIC98438	MIC-KEY TJ - 18Fr Introducer Kit <i>Includes 22Fr Dilator</i>	MIC-KEY 18Fr Low-profile Transgastric Jejunal Feeding Tube*	1 Kit/Case

* Tube not included

Kit Contents

- 4 x SAF-T-PEXY T-Fasteners
- 1 x Haemostat
- 1 x 18G safety introducer needle
- 1 x 5Fr seeking catheter, compatible with a 0.38" guidewire
- 1 x N° 11 safety scalpel
- 1 x Serial dilator
- 1 x Over-the-wire stoma measuring device
- 2 x 12ml syringes



MIC Introducer Kit

Gastropexy made **Safe, Simple & Effective**

MIC G and TJ Introducer Kits

MIC Gastrostomy Introducer Kit

Complete kit for primary placement of a MIC gastrostomy tube.
(MIC100, MIC110 and 2371 range)

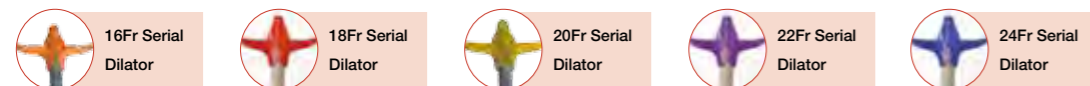


Product Code	Product Description	For use with	Box/Case Quantity
MIC98420	MIC G - 12Fr Introducer Kit <i>Includes 16Fr Dilator</i>	MIC-KEY 12Fr Gastrostomy Feeding Tube*	1 Kit/Case
MIC98421	MIC G - 14Fr Introducer Kit <i>Includes 18Fr Dilator</i>	MIC-KEY 14Fr Gastrostomy Feeding Tube*	1 Kit/Case
MIC98422	MIC G - 16Fr Introducer Kit <i>Includes 20Fr Dilator</i>	MIC-KEY 16Fr Gastrostomy Feeding Tube*	1 Kit/Case
MIC98423	MIC G - 18Fr Introducer Kit <i>Includes 22Fr Dilator</i>	MIC-KEY 18Fr Gastrostomy Feeding Tube*	1 Kit/Case
MIC98424	MIC G - 20Fr Introducer Kit <i>Includes 24Fr Dilator</i>	MIC-KEY 20Fr Gastrostomy Feeding Tube*	1 Kit/Case

* Tube not included

Kit Contents

- 4 x SAF-T-PEXY T-Fasteners
- 1 x Haemostat
- 1 x 18G safety introducer needle
- 1 x 0.35" J-tip guidewire
- 1 x N° 11 safety scalpel
- 1 x Serial dilator
- 1 x 12ml syringe



MIC Transgastric-Jejunal Double Lumen Introducer Kit

Complete kit for primary placement of a MIC transgastric jejunal tube.
(MIC650 range)



Product Code	Product Description	For use with	Box/Case Quantity
MIC98435	MIC TJ - 16Fr Introducer Kit <i>Includes 20Fr Dilator</i>	MIC 16Fr Transgastric Jejunal Feeding Tube*	1 Kit/Case
MIC98436	MIC TJ - 18Fr Introducer Kit <i>Includes 22Fr Dilator</i>	MIC 18Fr Transgastric Jejunal Feeding Tube*	1 Kit/Case

* Tube not included

Kit Contents

- 4 x SAF-T-PEXY T-Fasteners
- 1 x Haemostat
- 1 x 18G safety introducer needle
- 1 x 5Fr seeking catheter, compatible with a 0.38" guidewire
- 1 x N° 11 safety scalpel
- 1 x Serial dilator
- 1 x 12ml syringe



Training and Support

Vygon puts customer service first in everything we do. In order to help you meet "Best Practice" requirements, we offer a number of support services as standard. These services include:

- In-service product training which can be tailored to match your local policies and protocols.
- Patient information leaflets that can be customised to reflect your local practice.
- Access to our Technical Support Department, which handles technical enquiries about products, procedural advice and regulatory device issues.
- Customised posters reflecting your NHS Trust's policies and protocols to promote current practice guidelines.
- Local workshops for specific requirements, with guest speakers, to reinforce the message to your teams.

Gastrostomy Study Days

Vygon also organises a number of gastrostomy study days around the country. These are funded by an educational grant, with all proceeds from the small registration fee going to our nominated charity PINNT. Delegates spend the day hearing guest speakers from the field of gastrostomy placement and care, and take part in hands-on workshops. The study days provide an ideal forum for group discussion of local practices, and an opportunity to make contacts in your local area.



From Our Post-Insertion Care Guide

Care of the Site

You will notice your gastrostomy tube on your stomach in the middle of two, three or four small discs.

These discs lock in place a suture that secures your stomach to the inside of your abdomen. After 2-3 weeks these suture locks will have done their job and will start to fall off.

If the suture lock does not fall off in the suggested time, your doctor or nurse may cut the suture.

Inspect the stoma and suture lock sites daily and assess for any signs of infection. Notify your doctor or nurse of any of the following;

- **Redness**
- **Irritation**
- **Oedema (bruising)**
- **Swelling**
- **Tenderness**
- **Warmth**
- **Rash**
- **Purulent or gastrointestinal discharge**

Assess for any signs of pain, pressure or discomfort.

It is important to keep the stoma site and suture lock sites clean.

Routine care should include cleaning the skin around the stoma and suture lock sites with warm water and mild soap followed by thorough rinsing and drying. A cotton bud is ideal for cleaning under the suture lock.



MIC Introducer Kit Care Guide Leaflet
Available to order, code: PS165

CAUTIONS

The suture locks (discs) may pose a choking hazard. Ensure that children do not attempt to swallow the discs.

DO NOT rotate the suture locks, this may weaken the suture and cause early detachment.

DO NOT rotate the gastrostomy tube for the first two weeks after placement. Do not rotate a gastro-jejunal tube at any time.

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