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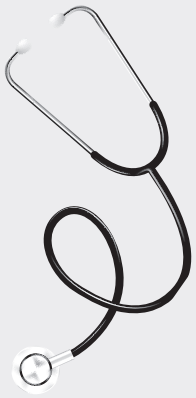

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Bionector TKO®

A COMPENDIUM OF CLINICAL REFERENCES

EVERY CATHETER, EVERY LINE – THINK TKO, EVERY TIME.

In the years since the technology was first developed for Bionector TKO, there have been many references about the benefits of the needle-free connector in IV therapy. With its unique design to prevent blood reflux, TKO reduces persistent withdrawal occlusions (PWO) and total thrombotic occlusion, delivering a number of benefits for patients, clinicians and healthcare providers.

A reduction in catheter occlusions, means patients require fewer clinical interventions to unblock or replace lines. This means less trauma for patients plus a greater likelihood they will receive their prescribed therapy on time.

A reduction in the time taken to replace or unblock lines, means that nurses and doctors are freed up for other clinical responsibilities.

Decreased usage of tissue plasminogen activator (tPA) and the elimination of heparin flushes in PICCs and CVCs results in reduced demand, and so lower costs, for solutions to dissolve blockages and flush out lines. There is also a corresponding fall in the nursing time required to complete these procedures and there are further cost benefits for healthcare providers.

This compendium lists many of the key clinical references citing the benefits of TKO technology from the US and UK. Plus, for additional reading, there is a further list of references comprising clinical papers published from 1998 onwards.

BJN British Journal of Nursing

WoCoVA World Congress Vascular Access

INS Infusion Nurses Society

Watch this short video

to see how Bionector TKO is making catheter occlusions a thing of the past

BIONECTOR TKO TRIALS WITH PERIPHERAL MIDLINES [1]

Evidence: **Clinical Evaluation** | *Line Type:* **Midlines** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- Concerns about high blockage rates and time spent (and associated costs of) trying to unblock and replace lines plus poor patient experience
- Trial A Bionector – 59% blockage rate, 9% line removal, 32% lines with no blockage problems
- Trial B – Bionector TKO – 6% blockage rate, 0.8% line removal, 93.2% lines with no blockage problems
- Time spent by ward staff and IV Team Nurse Specialist trying to unblock Midlines reduced from 44 to six hours
- Plus decrease in the risk of drugs not administered on time, or missed due to lack of IV access. Increased patient satisfaction and overall hospital experience
- Catheter occlusions were reduced by 89.8% and catheter removals were reduced by 83.3%

County Durham and Darlington NHS Foundation Trust IV Team, Presented at Vygon IV Week in France 2016

REDUCE CLINICAL TIME BY 86%

CATHETER OCCLUSIONS WERE REDUCED BY 89.8%

CATHETER REMOVALS WERE REDUCED BY 83.3%

MAXIMISING THE MIDLINE[2]

Evidence: **Clinical Evaluation** | *Line Type:* **Midlines** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- With TKO, the hospital could make use of Midline catheters for blood sampling, which meant they were able to cut down on the number of central line catheter days which, in turn, reduced the risk of central line-associated bloodstream infections (CLABSI)

Rodil Valentino RN, Vilma Farkas BSN, New York Methodist Hospital. Association of Vascular Access (AVA), Dallas, 2015

CUSTOMER TESTIMONIAL[3]

Evidence: **Clinical Evaluation** | *Line Type:* **Midlines** | *Clinical Specialty:* **Respiratory**

Key points and outcomes

- Bionector TKO is the device of choice for patients who require medium term IV antibiotics
- Before Bionector TKO failure rate of lines was around 30% (patients have lines in for around 14 days)
- After Bionector TKO the rate had reduced to between 2-3%

John Davison, Nurse Specialist – Complex Lung Disease at The Newcastle Upon Tyne Hospitals NHS Foundation Trust, 2013

REDUCTION IN FAILURE RATE OF LINES BY 90%

BI-DIRECTIONAL NEEDLELESS DEVICES TO PREVENT INTRALUMINAL OCCLUSION IN PERIPHERALLY INSERTED CENTRAL CATHETERS [4]

Evidence: Clinical Paper and Poster | *Line Type:* PICCs | *Clinical Specialty:* Hepatobiliary, Haematology & Oncology

Key points and outcomes

- Six-week audit of PICCs estimated occlusion rate to be 5% but it was felt this under-estimated the problem
- Three-month product evaluation led to a 12-month month evaluation of 180 PICCs. Total dwell time of 970 catheter days mean dwell of 53.9 days and a median dwell of 35 days
- Persistent withdrawal occlusion (PWO) rate fell to 1/1000 catheter days and intraluminal to 0.4/1000 catheter days
- TKO was introduced across the Trust from April 2013 onwards based on evaluation
- 2015-16 the PWO rate was 0.13/1000 catheter days and no known complete intraluminal occlusions

Jan Hitchcock, Lead Nurse Vascular Access, Infection Prevention and Control, Imperial College Healthcare NHS Trust, British Journal of Nursing, 2016, (IV Therapy Supplement) Vol, 25, No 19 2016

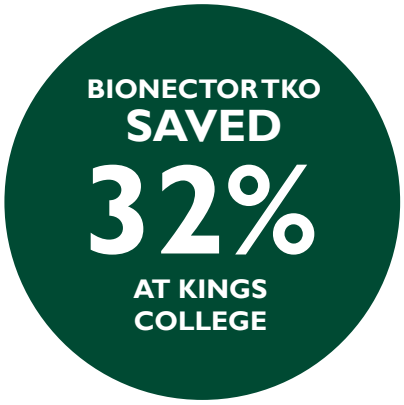
COST COMPARISON FOR TKO BUNG AUDIT [5]

Evidence: Audit | *Line Type:* PICCs | *Clinical Specialty:* General IV Access

Key points and outcomes

- Finchley Memorial Hospital and Lister Ward, Kings College Hospital
- Costs evaluated for incidences of blocked lines
- Comparison made for cost of bung, nursing time to sort blockage and Alteplase (tissue plasminogen activator tPA)
- TKO 32% saving at Kings College and 34% at Finchley Memorial Hospital

Finchley Memorial Hospital and Lister Ward, Kings College Hospital, London 2015



BIONECTOR TKO PRODUCT EVALUATION[6]

Evidence: **Clinical Evaluation** | *Line Type:* **PICCs** | *Clinical Specialty:* **Haematology, Oncology & OPAT**

Key points and outcomes

- Four-month study covered 70 patients
- 2133 dwell days, average 30.4 days, range 3-93 days
- Before study occlusion rate was 5%, during evaluation of TKO that fell to less than 1%

Jan Hitchcock MSc, PG Cert ITU, BN, NZRCpN, Lead Nurse Vascular Access, Infection Prevention and Control, Imperial College Healthcare NHS Trust, 2012

OCCLUSION RATE REDUCED BY 90%

BIONECTOR TKO[7]

Evidence: **Clinical Evaluation** | *Evidence:* **Clinical Evaluation** | *Clinical Specialty:* **Gastroenterology**

Key points and outcomes

- Previous occlusion rate of 74.6% based on 63 catheters inserted over a 3.5 month period in 20-bedded ward
- Six-week evaluation saw 26 catheters inserted (over 746 catheter days) and occlusion rate fell to just 7.7%
- Savings made on the use of Urokinase, plus nursing time reduced to administer the anti-clotting agent. Also less likelihood of drugs not being given on time or missed completely

OCCLUSION RATE REDUCED BY 89%

Aldwin Del Mundo BSN RN, Specialist Nurse Practitioner, Vascular Unit, Cambridge University Hospital NHS Foundation Trust 2011

QUANTITATIVE ASSESSMENT OF CATHETER REFLUX IN COMMERCIALLY AVAILABLE NEEDLELESS CONNECTORS[8]

Evidence: **Poster** | *Line Type:* **All lines** | *Line Type:* **All lines**

Key points and outcomes

- Focus on catheter occlusion and the causes of blood reflux
- Study determined the quantitative and experimental reflux of negative, positive, neutral and anti-reflux connectors
- Needleless IV connectors that contained pressure-activated valves provided the best performance in preventing reflux upon connection and disconnection
- Negative, positive and neutral displacement connectors show no correlation to their specific marketed classification and efficacy in the prevention of fluid reflux

Garrett Hull and Shram Sengupta, PhD, Department of Bioengineering, University of Missouri Columbia 2015

CENTRAL LINE IMPROVEMENTS PRESENTATION[10]

Evidence: **Presentation** | *Line Type:* **CVCs, PICCs, Multilumen & Introducers** | *Clinical Specialty:* **Critical Care**

Key points and outcomes

- Aim to decrease central line occlusions, eliminate unnecessary heparin and introduce best practice central line bundle
- PICC line occlusions for the standard NS/heparin flush was 4.46%. With TKO and saline only flush the rate fell to 1.26%
- PICCs, Multilumen, Introducers – occlusion rate 2.14% before TKO. Fell to 0.77%
- Heparin doses down from 1392 to 138

Diane Dorsch, RN, Critical Care, Welsley Medical Center, USA 2009

PICC AND MIDLINE CATHETER OCCLUSION RATES: A PROSPECTIVE STUDY COMPARING THE INTERLINK SPLIT SEPTUM DEVICE VERSUS NEXUS TKO SPLIT SEPTUM PRESSURE ACTIVATED ANTI-REFLUX VALVE[9]

Evidence: **Clinical Paper and Poster** | *Line Type:* **CVCs and PICCs** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- Prospective study with retrospective data were used to compare the anti-reflux valve in the TKO with the current Interlink Split Septum device
- Focus on occlusions and specifically thrombosis
- Use of tissue plasminogen activator (tPA) treatments use to unblock lines fell by 89%
- Also heparin flush was not used so less catheter exchanges, further savings achieved

Sarah Mitch, RN, CRNI & Brent Brandmeyer, RN, BSN, (Research Medical Center Poster) 2010

USE OF TPA TO UNBLOCK LINES FELL BY 89%

OCCLUSION REDUCTION AND HEPARIN ELIMINATION TRIAL USING AN ANTIREFLUX DEVICE ON PERIPHERAL AND CENTRAL VENOUS CATHETERS[11]

Evidence: **Clinical Paper and Poster** | *Line Type:* **CVCs and PICCs** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- Three-month trial to determine if TKO would help to reduce occlusions and heparin flushes could be eliminated
- Occlusion rate in PICCs fell from 30% to 12.5%
- Little change in occlusion rate in PICCs but there was a fall in phlebitis rates from 10% to 4%
- Other anticipated outcomes include improved patient satisfaction, lower costs, decreased nursing time devoted to IVs and improved patient safety due to elimination of heparin flushes and lower phlebitis rates

THE RATE OF PICC OCCLUSION WAS REDUCED BY OVER 50%

Lisa M. Jasinsky, BSN, RN and Julie Wurster, MSN, RN, OhioHealth, Columbus, Ohio. The Art and Science of Infusion Nursing Vol 32, Number 1 January/February 2009

REVOLUTIONARY CHANGE IN IV THERAPY UTILIZING THE LIFESHIELD TKO-5 ANTI-REFLUX DEVICE[12]

Evidence: **White Paper and Poster** | *Line Type:* **PICCs and Midlines** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- Year long study to gather data comparing Baxter Interlink valve versus the LifeShield TKO-5 device
- Interlink – 7.59% lines became blocked. TKO 0.77% became blocked
- Cost for flushing lines (heparin only, no nursing time accounted for) Interlink $18,798.12 versus $3,446.40 for TKO
- Additional benefits for TKO = less risk of infection (CLABSI), better patient safety and satisfaction and clinicians happier with less intervention

Sarah Mitch, RN, CRNI 2008

CLINICAL AND ECONOMIC BENEFITS OF TKO[13]

Evidence: **Letter** | *Line Type:* **PICCs & CVCs** | *Clinical Specialty:* **General IV Access**

Key points and outcomes

- Fall in occlusion rate by 90%
- Complete elimination of heparin to flush PICCs and central line catheters
- Reduced accesses into the IV catheter reduces the possibility of infection
- Cost for heparin to flush lines dropped 80% (saving over $15,000)

Sarah Mitch, Vascular Access Nurse, Research Medical Center, USA

FAQs

1. **What is the flow rate of the Bionector TKO during a CT-Scan procedure?**
   At 24 Bar/350 Psi, the flow rate of the Bionector TKO during a CT-Scan is 11.6 ml/s.

2. **What are the performances of Bionector TKO?**
   Like Bionector, Bionector TKO is a closed-system bidirectional valve, with neutral fluid displacement, which prevents any fluid displacement at the distal end of the catheter during disconnection. Thanks to the TKO valve and its sensitivity to opening/closing pressures, Bionector TKO has another special feature: it provides an 'anti-reflux' function at the distal end of the catheter, preventing any risk of catheter occlusion due to a pressure differential during infusion.
   • During infusion: The TKO valve prevents any backflow of blood. If counter-pressure occurs during the infusion (e.g. coughing), the TKO valve closes automatically. It reopens as soon as the infusion pressure exceeds the back pressure.
   • At the end of the infusion: The TKO valve closes before the air supply (approximately 10 cm before the Bionector TKO valve).
   • Between two infusions: The TKO valve ensures a closed system, providing a leak-proof circuit and reducing the risk of contamination. Bionector TKO is the preferred valve at the proximal end of long-duration catheters that are likely to occlude over time, or for catheters with a small internal diameter (e.g. neonatal catheters), which can also lead to occlusions. Finally, the use of the Bionector TKO is also recommended for patients who may generate pressures higher than the administration pressure (during coughing, sneezing, heavy breathing, vomiting, movement, etc.).

3. **Does Bionector TKO prevent backflow at the distal end of the catheter during infusion?**
   Yes, the Bionector TKO valve closes automatically when the back pressure is greater than the administration pressure. E.g. when the patient coughs.

4. **Is Bionector TKO considered to be a non-return valve?**
   No, Bionector TKO is not a non-return (unidirectional) valve. It is a bi-directional valve with an 'anti-reflux' function at the distal end of the catheter, thanks to the TKO valve, which has specific opening/closing characteristics.

   The TKO valve closes when strong back-pressure is generated (generally by the patient, during coughing, sneezing, movement, etc.), thereby limiting the risk of blood reflux at the distal end of the catheter and preventing catheter occlusion. The TKO valve closes to prevent blood reflux at the distal end of the catheter. It reopens as soon as the infusion pressure is higher. However, the TKO valve is in no way a non-return valve.

5. **What can cause blood reflux on an infusion line not fitted with a Bionector TKO?**
   During an infusion without the Bionector TKO, the circuit is free. Therefore, blood reflux can occur at the distal end of the catheter, particularly in the following situations:

   Physiological changes
   • Generation of higher pressure by the patient (coughing, sneezing, breathing, vomiting, etc.)

   Mechanical changes
   • Low flow from the vein guard
   • Infusion bag exhaustion
   • Syringe plunger rebound
   • Connection and disconnection of the syringe

6. How does Bionector TKO work?

The TKO valve is built into the Bionector TKO. It is sensitive to changes in infusion line pressure:
Forward direction (in the direction of administration): When the infusion pressure drops or if the infusion is stopped (e.g. when the infusion bag runs out), the TKO valve closes.

Reverse direction (in the opposite direction to the administration direction): When the patient generates a pressure greater than the administration pressure, the TKO valve also closes.

The sensitivity and reaction of the TKO valve to pressure differences - both in the direction of administration and in the opposite direction - prevents blood from flowing back to the distal end of the catheter, thereby avoiding any risk of occlusion.

7. What is the opening pressure of the TKO valve?

The TKO valve has a special opening pressure. Its opening pressure in the forward direction (direction of administration) is different from its opening pressure in the reverse direction (direction of sampling).

Forward direction: if the administration force is greater than 20 mbar (20.4 cm of water), the valve opens, allowing the infusate to flow towards the patient.

Reverse direction: Its opening pressure in the opposite direction to the administration direction is a higher pressure of 200 mbar (204 cm of water), a value well above the maximum venous pressure, which is 28 (28.5 cm of water) mbar.

ORDERING CODE

Product Codes					Description	Box Quantity
Vygon	NHSSC	Welsh Stores	NDC	PALS		
083801E	FSW584	FSN0345	183128	FVU000317	Bionector TKO® needle-free device	50
005222838	FSW788	N/A	N/A	N/A	Self-Administration Set (SAS) 27cm + Bionector® TKO	25

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OUR COMMITMENT TO THE ENVIRONMENT

2021 was a landmark year as Vygon UK achieved carbon neutrality in accordance with the guidance set out in PAS 2060, with certification renewed in 2022 as year-on year emission reductions were achieved and the residual emissions were offset with the purchase of high-quality Verified Carbon Standard (VCS) emission reduction projects. Vygon are in the process of expanding its emissions reporting to include Scope 3 emissions, this will involve a baseline year reset and result in reporting higher emissions than in previous years and therefore, unable to purchase carbon credits. Following the baseline year and emission targets reset, our focus will be to regain Carbon Neutral status.

We are delighted to announce that Vygon UK has successfully undergone the NHS Evergreen Sustainable Supplier Assessment, attaining level 2 status. This is key to supporting us to understand how we align to the NHS's long term sustainability priorities and the pathway to progress.

We're proud to be a Planet Mark Certified Business, marking a vital first step on our journey to net zero. We annually measured our carbon emissions with Planet Mark, as we cannot manage what we do not measure. Vygon UK are committed to a 5% annual reduction in Scope 1 and 2 emissions. We look forward to sharing our progress through Planet Mark's Net Zero Certification Programme.

These accomplishments underscore our unwavering dedication to sustainable practices and reinforces our role as a responsible contributor to the healthcare system.

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