CRITICAL CARE

bionector®

The neutral needle-free device

VYGON

Value Life

Bionector®
EXCEEDING GLOBAL OPINION LEADERS' RECOMMENDATIONS

GLOBAL RECOMMENDATION:

CDC 2011 GUIDELINES SUGGEST THAT NEEDLE-FREE DEVICES ADDRESS OCCLUSION PROBLEMS BY INCORPORATING NEUTRAL FLUID DISPLACEMENT.[1]

Bionector is the only neutral displacement needle-free device in the UK to combine a split-septum with a fixed straight, fluid pathway.

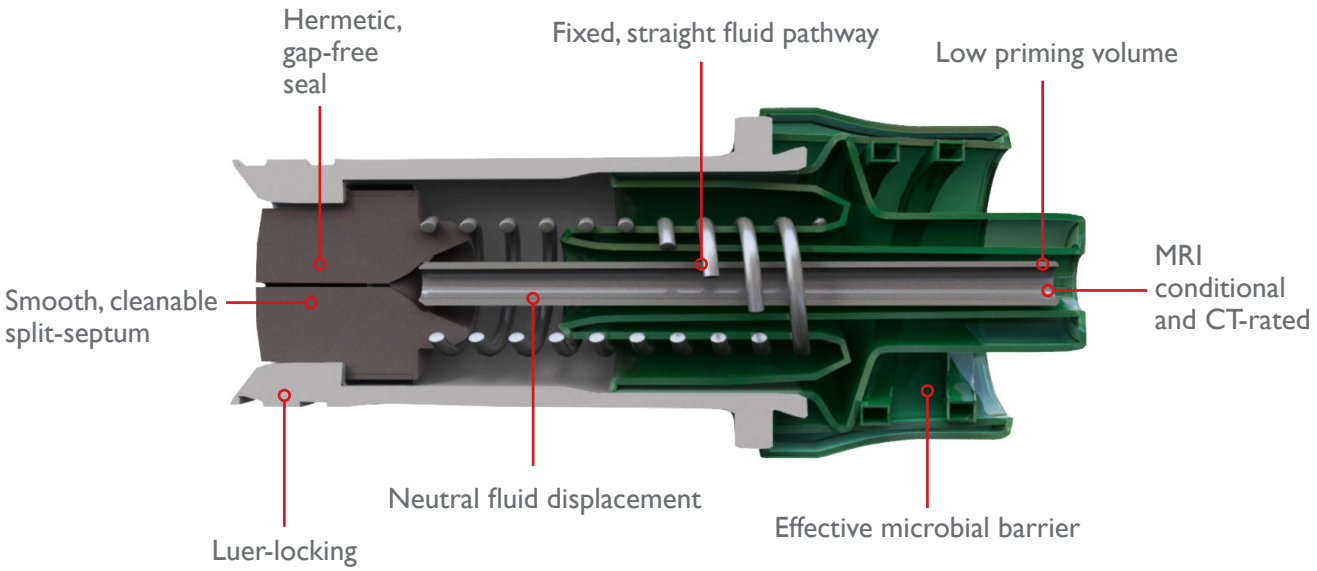
Bionector is an established market-leading needle-free device which meets the full range of global opinion leaders' recommendations for reducing CRBSIs. It has been proven to provide an effective barrier against microbial ingress and help standardise practice by combining a fixed, straight fluid pathway with innovative neutral displacement technology. [2,3,4]

Neutral displacement
Bionector leads the way with a neutral fluid displacement. This means a specific post-flushing clamping sequence is not required, which in turn helps prevent blood reflux and reduce catheter occlusions. [3]

Clinically proven
Backed up by a robust library of clinical studies Bionector is proven to be easy to clean and clear. Its smooth split-septum fits tightly into the device housing ensuring it is free from any gaps. The straight, fixed fluid pathway has been proven 'easy to clear', designed to provide the most direct and least tortuous route with no moving parts (such as mechanical valves), which reduces the surface area available for biofilm formation. [2,4,5]

MRI conditional and CT-rated
Bionector is proven not to represent any risk to either patients or practitioners during an MRI of up to three Teslas. CT-rated for use with power injectors Bionector has a maximum pressure resistance of 350psi and a maximum flow rate of 10ml/s. [6,7]

Low deadspace
Bionector's straight fluid pathway is proven 'flushable' for macro and microscopic particles such as blood. This is due to a minimal deadspace of just 0.018ml allowing for a low flushing volume (5ml) to clear the device. [3,4]



Bionector Octopus extension sets

To support the **MHRA Alert MDA/2010/073,** Vygon offers a wide range of multi-lumen extension sets with integrated anti-reflux valves (ARVs). These prevent the inadvertent backtracking and subsequent risk of drug overdose when running multiple infusions at different rates.

Drug loss prevention

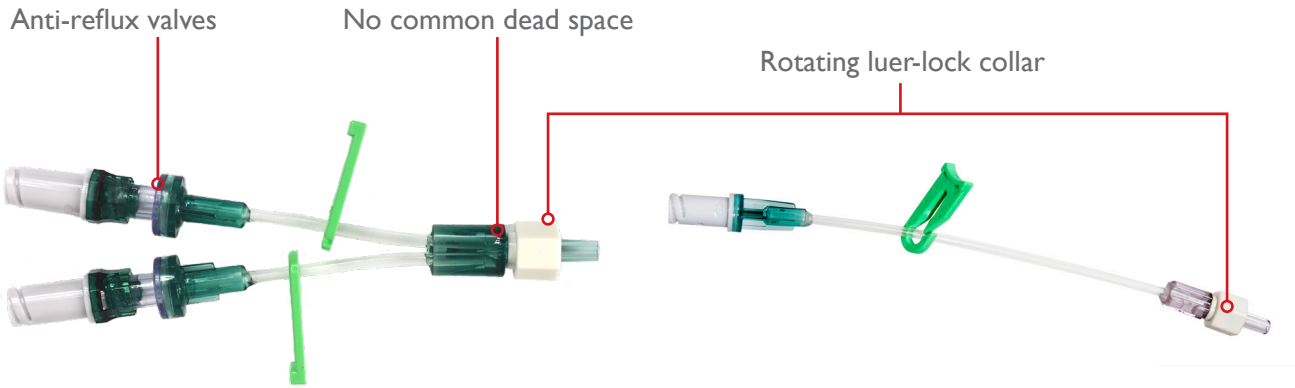
The Bionector Octopus range is produced with biocompatible PUR tubing to help prevent the risk of drug loss which can occur with PVC tubing.(8) Central lines and syringe drivers do not contain PVC within the fluid pathway, with Bionector you can be assured you're not putting PVC into the patient's IV circuit. Issues with PVC drug interactions are supported by Bionector's drug compatibility studies (Study Six).

No common dead space

Multi-lumen Octopus extension sets maintain separate fluid pathways right up to the catheter hub, preventing the mixing of incompatible drugs within the extension set.

Reduced catheter manipulation

The range is equipped with a freely rotating male luer-locking collar to enable easier connection to the IV catheter's female luer, helping reduce mechanical phlebitis and associated complications.



Double lumen Bionector Octopus extension with two ARVs
000841232

Single lumen Bionector Octopus extension

005222014

Global opinion leaders' recommendations

and how Bionector® meets them.

A needle-free device with little or no blood reflux. [9,10]
✔ Neutral fluid displacement of just 0.004ml (Study Two)

A needle-free device that is supported by microbial ingress testing data. [11]
✔ Supported by microbiogical studies showing microbial ingress does not occur (Study One) [2]

A split-septum needle-free device is associated with a lower incidence of CRBSI compared to a mechanical valve needle-free connector. [1,10]
✔ Cleanable split-septum supported by split-septum studies (Study Five) [5]

A needle-free device with a smooth external septum surface with few, if any gaps, that can be more thoroughly disinfected.[9]
✔ Smooth septum supported by a membrane cleaning studies (Study Three) [5]

A tight seal between the septum and the needle-free device housing to reduce or eliminate space for contamination to occur and potential biofilm to develop. [9]
✔ Gap-free, tight hermetic seal between the membrane and housing [2,5]

A needle-free device with a direct, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for potential biofilm development.[9,10]
✔ Straight, fixed fluid pathway (open end-to-end) [4]

A needle-free device with the most direct and least tortuous fluid pathway, with preferably no moving parts to reduce the potential risk of CRBSIs.[9]
✔ No moving parts or mechanical valves within the pathway [4]

A needle-free device with little or no dead space in the fluid pathway minimises the surfaces that infusates can contaminate and where biofilm can develop.[9]
✔ Low deadspace (0.018ml) supported by blood clearing studies (Study Four) [4]

A needle-free device that does not require a clamping sequence. Alternatively, use only one needle-free device type that requires a specific clamp-disconnection sequence (e.g. all negative pressure, all positive pressure or all neutral pressure) throughout the healthcare facility and ensure that all healthcare workers understand and are well trained in this clamp-disconnection sequence.[9]
✔ Does not require a specific clamping sequence

Bionector meets these recommendations and more!

- ✔ Day / 360 accesses
- ✔ 105ml/min flow rate (1m/H2O ISO10555-1:2013)
- ✔ Does not require priming
- ✔ DEHP-free
- ✔ PUR tubing material
- ✔ Cytotoxic drug compatible
- ✔ Latex-free split-septum
- ✔ MRI conditional
- ✔ CT-rated to 350psi and 10ml per second
- ✔ Back pressure tested to 2 bar
- ✔ Alcohol resistant polymer
- ✔ Lipid resistant polymer
- ✔ Blood and blood product compatible

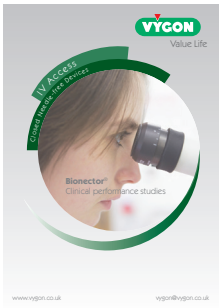
Code	NHSSC	Description	Priming volume	Box
00089601	FSW131	Bionector in non-touch applicator	0.02ml	50
00089602	FSW132	Bionector in 'double wrap'	0.02ml	25
00089603	FSW141	Bionector in 'soft pack'	0.02ml	50
00089611	FSW164	Arterial Bionector in 'soft pack'	0.02ml	50
00083801 E	FSW584	Bionector TKO®	0.07ml	50

Code	NHSSC	Description	Tubing length		Priming volume	Box
005222014	FSW311	Single lumen Bionector Octopus extension	10cm	⟷	0.29ml	50
08522201C	FSW384	Single lumen arterial Bionector Octopus extension	10cm	⟷	0.28ml	50
000841264	FSW280	Double lumen Bionector Octopus extension	10cm	⟷	2 x 0.34ml	50
000841232	FSW323	Double lumen Bionector Octopus extension with two ARVs	3cm	⟵	2 x 0.3ml	10
000841364	FSB390	Triple lumen Bionector Octopus extension	10cm	⟷	3 x 0.34ml	10
000842312	FSW375	Triple lumen Bionector Octopus extension with three ARVs	6cm	⟵	3 x 0.44ml	10
000842311	-	Triple lumen Bionector Octopus extension with two ARVs	6cm 6cm	⟵ ⟷	2 x 0.36ml 0.33ml	10
000842414	FSW489	Quad lumen Bionector Octopus extension with three ARVs	6cm 6cm	⟵ ⟷	3 x 0.36ml 0.25ml	10
000842514	FSW490	Quin lumen Bionector Octopus extension with four ARVs	6cm 6cm	⟵ ⟷	4 x 0.36ml 0.25ml	10

Code	NHSSC	Description	Tubing length	Priming volume	Box
07087620	FSW157	Vyclic three-way tap with one Bionector	-	0.26ml	50
000876002	-	Vyclic three-way tap with two Bionectors	-	0.28ml	50
00514101	FVK028	Vyclic three-way tap extension set with one Bionector	13.5cm	1.0ml	50
00514110	FVK050	Vyclic three-way tap extension set with one Bionector	100cm	5.4ml	25

Bionector® clinical performance studies are available on request

Bionector is supported by an extensive library of clinical studies and technical data.
Speak to your Vygon representative to request more information.



Bionector Clinical Performance Studies
Key clinical studies and results.
Code: DXJB0100003

Bionector Electronic Handbook
All clinical studies and data.
Code: PS290

References

1. Centre for Disease Control, 'Guidelines for the Prevention of Intravascular Catheter-Related Infections', Needleless Intravascular Catheter Systems, page 19, No.6. 2011.

2. An Evaluation of Bionector Microbial Integrity, report 65-07, The Health Protection Agency UK, 28th November 2007.

3. Bionector Fluid Displacement Test, report 200700807, Rev 01, Nelson Laboratories USA, 19th April 2007.

4. Blood Clearing Analysis, 5ml Flush GLP Report, report 201301574 Rev 01, Nelson Laboratories, USA, 15th April 2013.

5. Efficacy of the Valve Systems of Needle-Free Closed Connectors, report 67-08, The Health Protection Agency UK, 21st May 2009.

6. CT Pressure Testing, Laboratoire Central d'Essai, Essai No. RE12176, Vygon SA France, 14th May 2012.

7. Bionector MRI Safety Testing, Shellock R & D Services Inc. USA, 4th March 2013.

8. Smith JC et al, Uptake of drugs by catheters: the influence of the drug molecule on sorption by polyurethane catheters. 1996; Biomaterials, 17, (15): 1469-1472.

9. William R. Jarvis, MD, 'Choosing the Best Design for Intravenous Needleless Connectors to Prevent Bloodstream Infections'. Infection Control Today, July 28th, 2010.

10. The Infusion Nurses Society, Infusion Nurses Standards of Practice; page S32, section 27, Practice Criteria A & B, 2011.

11. Food and Drug Administration Agency (FDA), 'Guidance for Industry and FDA staff ': Pre-market notification submissions, Microbial Ingress Testing, section 8, page 9, July 11th 2008.

The full protocols and results are available in 'The Bionector® Electronic Handbook'. Please request copies directly from your local Sales Executive.

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.

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

DISCOVER OUR JOURNEY
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07/2024 - DXJB0100001 V00586 v1

FOR FURTHER INFORMATION, PLEASE CONTACT: **info@vygon.co.uk**

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