



Value Life

IV Access
Closed Needle-free Devices



Bionector[®]

The neutral needle-free device

Global recommendation:

CDC 2011 guidelines suggest that needle-free devices address occlusion problems by incorporating neutral fluid displacement.⁽¹⁾

Bionector®

Exceeding global opinion leaders' recommendations

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

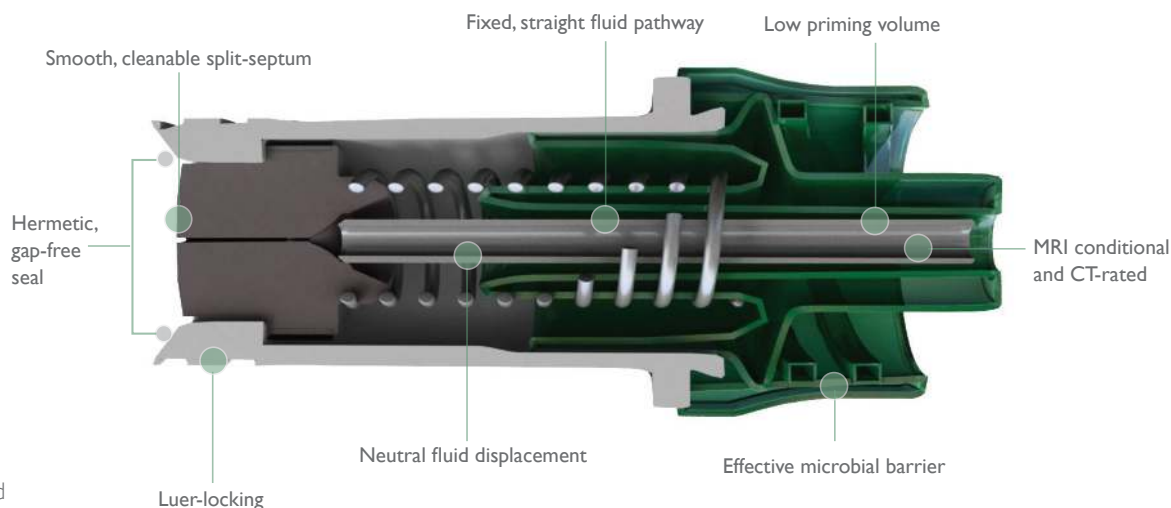
Backed up by a robust library of clinical studies Bionector is proven to be easy to clean and clear. Its smooth split-septum fits tightly into the device housing ensuring it is free from any gaps. The straight, fixed fluid pathway has been proven 'easy to clear', designed to provide the most direct and 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

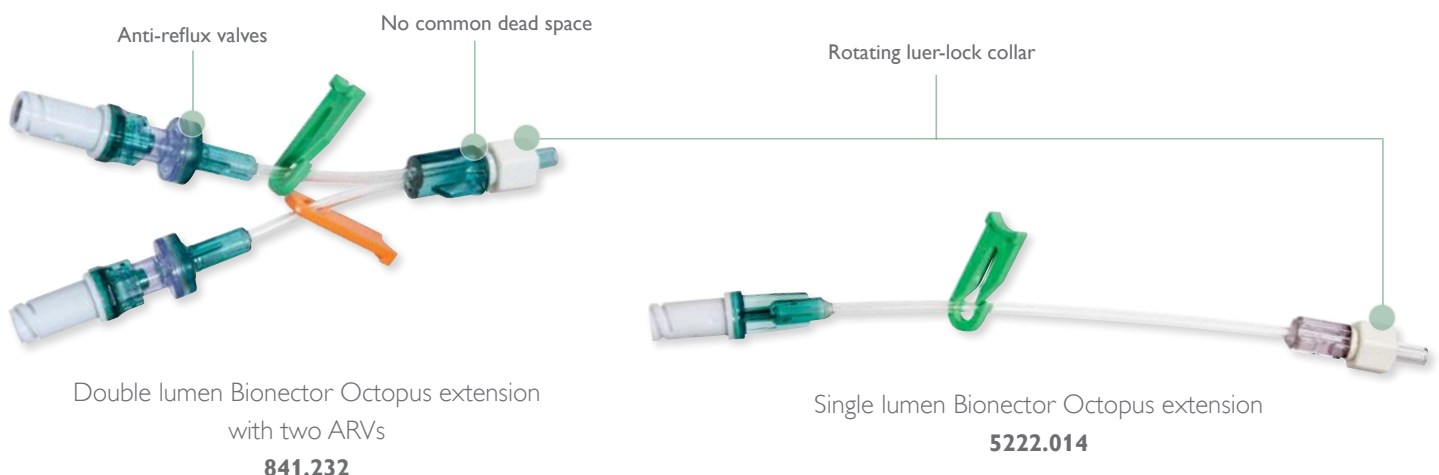
The Bionector Octopus range is produced with biocompatible PUR tubing to help prevent the risk of drug loss which can occur with PVC tubing.⁽⁸⁾ Central lines and syringe drivers do not contain PVC within the fluid pathway, with Bionector you can be assured you're not putting PVC into the patient's IV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



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 microbiological 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!

- ✓ 7 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

Bionector® ordering information

Code	NHSSC	Description	Priming volume	Box
0896.01	FSW131	Bionector in non-touch applicator	0.02ml	50
0896.02	FSW132	Bionector in 'double wrap'	0.02ml	25
0896.03	FSW141	Bionector in 'soft pack'	0.02ml	50
0896.11	FSW164	Arterial Bionector in 'soft pack'	0.02ml	50
083801E	FSW584	Bionector TKO®	0.07ml	50

Bionector Octopus extension sets

↔ non-ARV
← ARV

Code	NHSSC	Description	Tubing length	Priming volume	Box
5222014	FSW311	Single lumen Bionector Octopus extension	10cm ↔	0.29ml	50
85222.01C	FSW384	Single lumen arterial Bionector Octopus extension	10cm ↔	0.28ml	50
0841264	FSW280	Double lumen Bionector Octopus extension	10cm ↔	2 x 0.34ml	50
0841232	FSW323	Double lumen Bionector Octopus extension with two ARVs	3cm ←	2 x 0.3ml	10
0841364	FSB390	Triple lumen Bionector Octopus extension	10cm ↔	3 x 0.34ml	10
0842312	FSW375	Triple lumen Bionector Octopus extension with three ARVs	6cm ←	3 x 0.44ml	10
0842.311	-	Triple lumen Bionector Octopus extension with two ARVs	6cm ← 6cm ↔	2 x 0.36ml 0.33ml	10
0842414	FSW489	Quad lumen Bionector Octopus extension with three ARVs	6cm ← 6cm ↔	3 x 0.36ml 0.25ml	10
0842514	FSW490	Quin lumen Bionector Octopus extension with four ARVs	6cm ← 6cm ↔	4 x 0.36ml 0.25ml	10

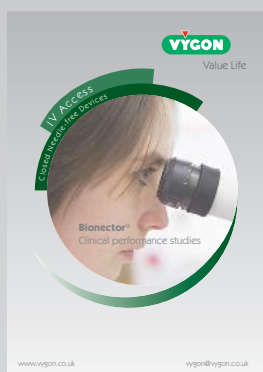
Bionector accessories

Code	NHSSC	Description	Tubing length	Priming volume	Box
7087620	FSW157	Vyclic three-way tap with one Bionector	-	0.26ml	50
0876.002	-	Vyclic three-way tap with two Bionector's	-	0.28ml	50
5141.01	FVK028	Vyclic three-way tap extension set with one Bionector	13.5cm	1.0ml	50
5141.011	-	Vyclic three-way tap extension set with two Bionector's	13.5cm	1.1ml	50
5141.10	FVK050	Vyclic three-way tap extension set with one Bionector	100cm	5.4ml	25
0822.111	FSB105	Readyset luer-lock T connector with Bionector	10cm	0.3ml	20
0822.611	FSB106	Readyset luer-slip T connector with Bionector	10cm	0.3ml	25

More Bionector products available on request

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.



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