IV THERAPY

Closed Needleless Connectors

bionector™

The Neutral Displacement, Split Septum, Needleless Connector

VYGON

Value Life

Why choose bionector™?

When deciding which needleless connector to choose for your hospital, it is important to ensure that your choice meets the current 'global standards' for these devices. The global opinion leaders make a number of recommendations in terms of the essential features you should demand when choosing a needleless connector.[1,2,3,4]

We have designed **bionector™** to meet these standards and furthermore, our clinical performance studies* provide the evidence to support our claim that **bionector™** meets these standards.

What do the global opinion leaders recommend?

- A needleless connector that is supported by microbial ingress testing data.[1]
- A split septum needleless connector is associated with a lower incidence of CRBSI compared to a mechanical valve needleless connector.[2,4]
- A needleless connector with a smooth external septum surface with few, if any, gaps, that can be more thoroughly disinfected.[3]
- A tight seal between the septum and the needleless connector housing to reduce or eliminate space for contamination to occur and biofilm to develop.[3]
- A needleless connector with a direct, that is, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for biofilm development.[3,4]
- A needleless connector with the most direct and least tortuous fluid pathway, with preferably no moving parts to reduce the potential risk of CRBSI.[3]
- A needleless connector with little or no dead space in the fluid pathway minimises the surfaces that infusates can contaminate and where biofilm can develop.[3]
- A needleless connector that does not require a specific clamping sequence.[3]
- A luer access mechanical valve needleless connector with little or no blood reflux.[3,4]

* Refer to the back page for more details.

VYGON

bionector™'s features and benefits

• Neutral Fluid Displacement [3,7]

This means that a specific post flushing clamping sequence is not essential as it is with positive and negative fluid displacement connectors.

• Low Priming Volume [3]

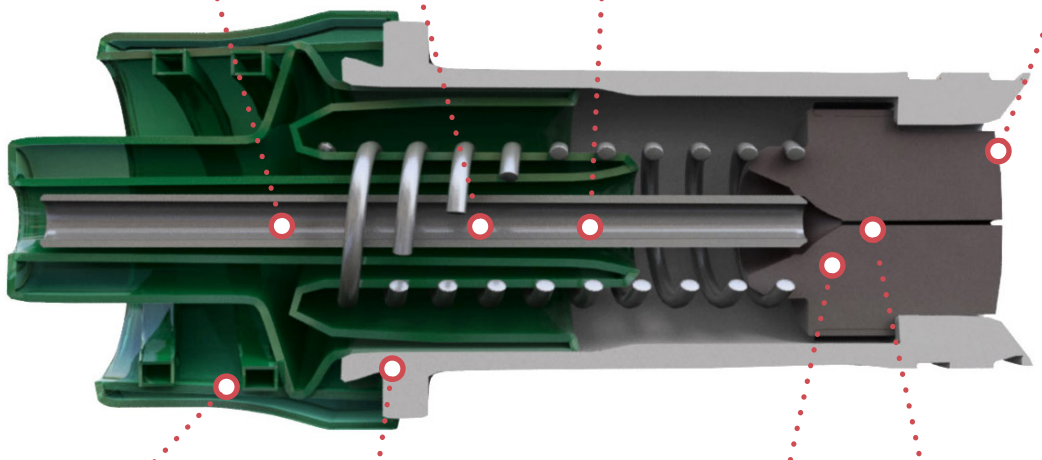
Suitable for clinical applications where very low priming volumes and dead space are required. Bionector has a priming volume of just 0.03ml.

• Direct Fluid Pathway [3,10]

Proven 'flushable' due to its straight fluid pathway. We can prove that macro and microscopic particles, for example blood, can be successfully flushed from the device.

• Cleanable Membrane [1,3,5]

Proven 'cleanable' using the latest disinfectants. Bionector has a smooth easy to swab membrane that fits very tightly into the device's housing.



• MRI Compatible [8]

Proven not to represent any risk to either patient or practitioner during an MRI of up to 3 Teslas.

• Effective Microbial Barrier [1,3,5,6]

Supported by numerous microbiological studies which conclude that microbial ingress does not occur.

• Split Septum Technology [2,3]

Split septum needleless connectors have demonstrated a lower incidence of CRBSI than other designs of connector.

• High Pressure Compatibility (CT-Rated) [9]

Approved for use with power injectors.

. Maximum pressure resistance: 350 psi

. Maximum flow rate: > 10 ml/s.

VYGON

References

1. 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.

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

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

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

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

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

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

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

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

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

A summary of our clinical performance studies are detailed in the '**bionector**™ Clinical Performance Studies brochure'. The full protocols and results are available in 'The **bionector**™ Electronic Handbook'. Please contact us directly or request copies directly from your local Sales Executive.

Technical specifications	
Latex-free	Yes
Maximum duration of use	7 days
Flow rate at gravity	105ml/min
Priming volume	0.03ml
MRI compatible	Yes
Blood compatible	Yes
Lipids resistant	Yes
Alcohol resistant	Yes
Chlorhexidine resistant	Yes

- Do not place a cap, plug or obturator of any sort on **bionector**™ other than a disinfecting cap.
- Do not use a needle to access **bionector**™.
- Remember to clean **bionector**™ prior to access.

CRITICAL CARE

For further information, please contact: questions@vygon.com

The specifications given in this brochure are for information only and are not, under any circumstances, of a contractual nature.

Vygon – 5, rue Adeline • 95440 ECOUEN • FRANCE
Reception: +33 (0)1.39.92.63.63 – Service clients France: +33 (0)1.39.92.63.81
Export customer service: +33 (0)1.39.92.64.15
Fax: +33 (0)1.39.92.64.44 • www.vygon.com

VYGON
www.vygon.com

DB BION 13 193 E - 01/19