IV THERAPY

Closed Needleless Connectors

bionector™

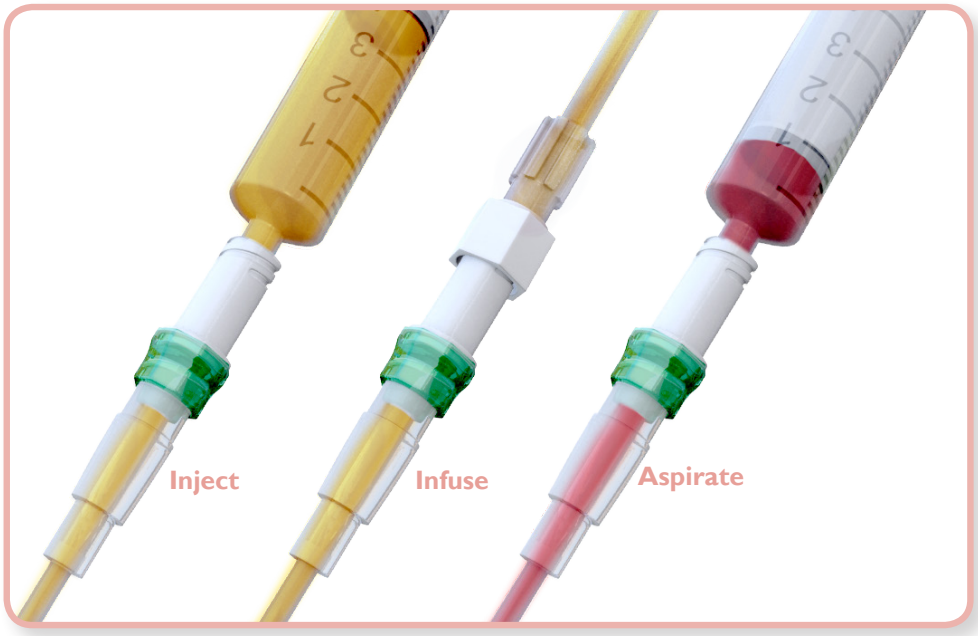
The Neutral Displacement Split Septum, Needleless Connector

VYGON

Value Life

What is **bionector**™ ?

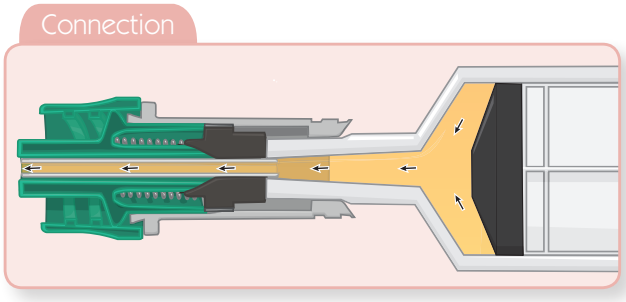
- **bionector**™ is a Neutral Displacement Needleless Connector for use with all I.V. equipment (e.g. syringes, giving sets, stopcocks, extension lines, vascular catheters and cannulae).

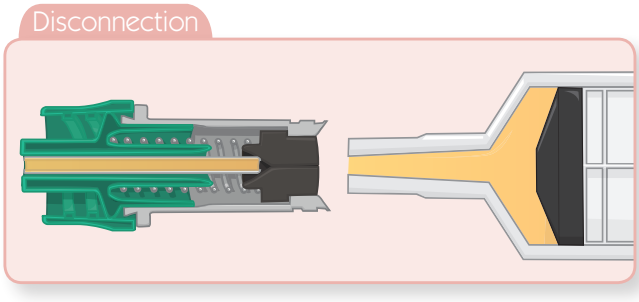


- When **bionector**™ is connected, you can infuse, inject, sample and change your I.V. tubing without opening the I.V. circuit to the atmosphere.

How does **bionector**™ work ?

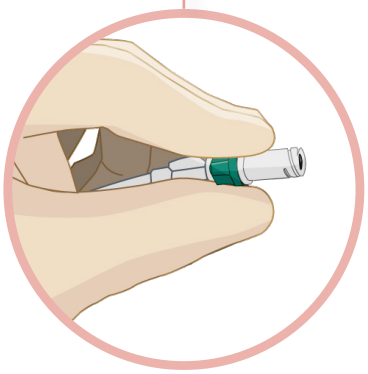
- **bionector**™'s protective split-septum opens the fluid pathway only when a male Luer has been inserted. When you disconnect the male Luer, the septum automatically seals the fluid pathway.



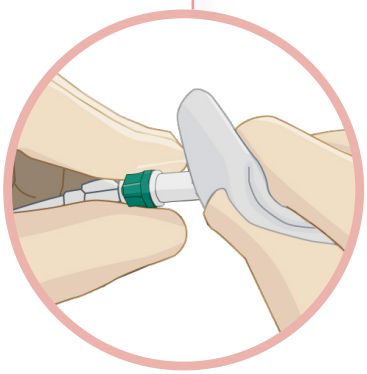


What are the benefits of bionector™ ?

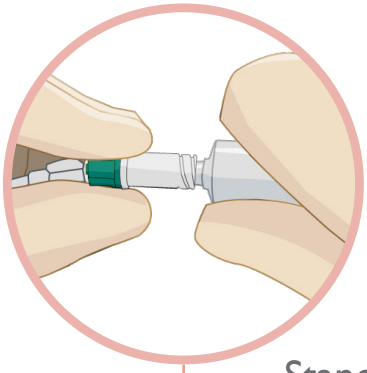
One piece only



Closed and cleanable

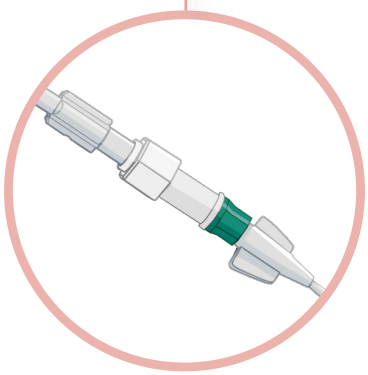


SAFE

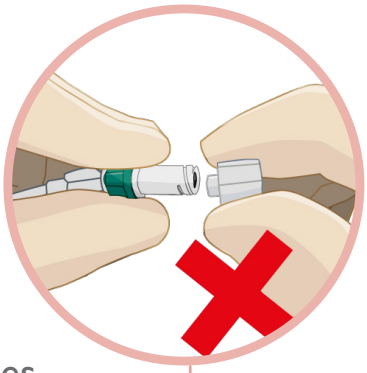


Standard IV fittings lockable

Cost-effective access



ECONOMIC



No caps or accessories

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.

Which features do the global opinion leaders suggest have the greatest impact on CRBSI and VAD occlusion ?

- 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.

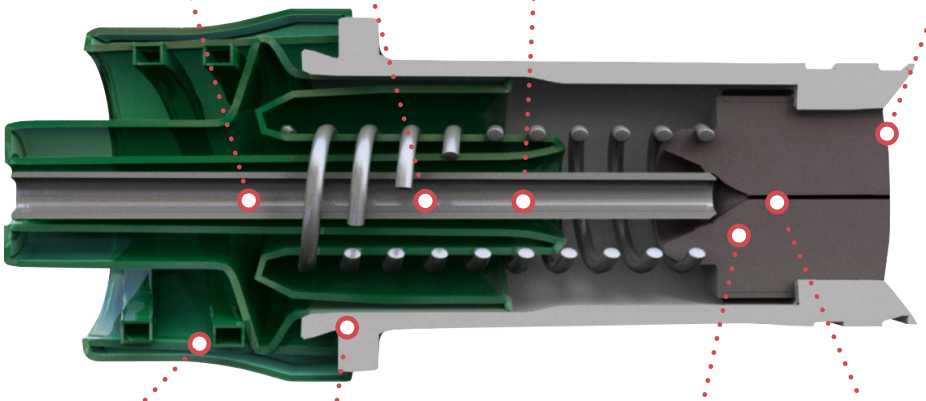
bionector™'s features and benefits

• 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.

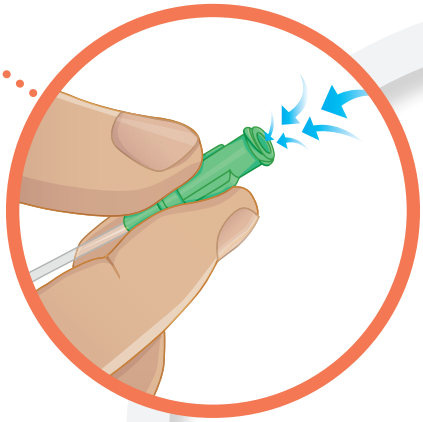
• Split Septum Technology [2,3]
Split septum needleless connectors have demonstrated a lower incidence of CRBSI than other designs of connector.

• High Pressure Compatibility (CT-Rated) [9]
Approved for use with power injectors.
. Maximum pressure resistance: 350 psi
. Maximum flow rate: > 10 ml/s.

What are the unplanned complications of IV Therapy and how does **bionector**™ reduce the risk?

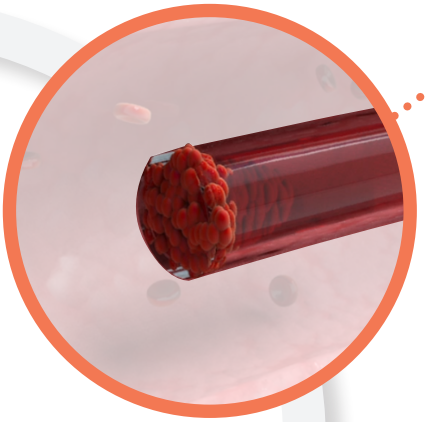
• **Air embolus**[11]
Opening the female hub of a Vascular Access Device (VAD) can allow fatal volumes of air to be entrained.

bionector™ **automatically closes once a syringe or fluid administration set is removed thus eliminating the risk of air embolus.**



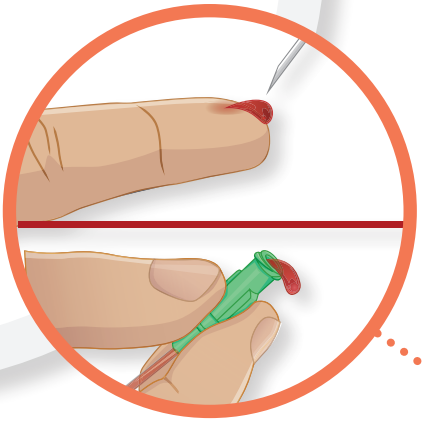
• **Infection**[11,16,17]
Repeated exposure of the female hub of a VAD to the atmosphere can increase the risk of bacterial colonization and catheter related bloodstream infection (CRBSI).

bionector™ **provides an easy to clean barrier to the patient's vascular access device, thus reducing the risk of CRBSI.**



• **Catheter Occlusion**[13,14,15,18]
Blood reflux into the distal tip of a VAD when disconnecting a male Luer device such as a medication syringe or IV administration set can result in catheter occlusion.

bionector™ is a neutral pressure needleless connector which means that there is no blood aspirated into the tip of the catheter when a syringe or fluid administration set is removed.



• **Needle-Stick injury and blood exposure** [11,12]
The use of injection membranes to access a VAD can result in a needle-stick injury to the healthcare worker. Also, opening the female hub of vascular access device can allow reflux of the patient's blood.

bionector™ eliminates both catheter access associated needle-stick injury and care-giver blood exposure.

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 Sytems 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.

11) Risks of Using Intravenous Administration Sets with Non-Self-Sealing Injection Sites. ECRI Institute's Medical Device Safety Reports. Health Devices. Dec, Vol 24, No 12, pp.515. 1995.

12) Good Practice in Infection Control (Managing Sharps). RCN Working Well Initiative. Vol. 4. 2004.

13) Complications Associated with Venous Access Devices: Part Two. Hamilton H. Nurs. Stand. 20:59-65. 2006.

14) The Efficacy and Safety of Blood Sampling through Peripherally Inserted Central Catheter Devices in Children. Knue M, Doellman D, Rabin K, Jacobs. BR. J Infus Nurs. 28: 30-35. 2005.

15) Predisposing Factors, Prevention, and Management of Central Venous Catheter Occlusions. Krzywda EA. J Intraven Nurs. 22 (6) (suppl): S11-S17. 1999.

16) A conservative Procedure for the Diagnosis of Catheter Related Infections. Cercenado E. Ena J, Redriguez-Creixems M, Romero I, Bouza E. Arh Intern. Med. Vol 150, pp. 1417-1420. 1990.

17) Central Venous Catheter-Related Infections in Critically Ill Patients. Diener J.R., Coutinho M.S., Zoccoli C.M. Rev Assoc Med Brad; Vol. 42, pp. 205-214. 1996.

18) The Effects of Needleless Connectors on Catheter-Related Thrombotic Occlusions. Imad F. Btaich, Debra S. Kovacevich, Nabil Khalidi, Lorelei F. Papke. The Art and Science of Infusion Nursing, Infusion Nurses Society. Volume 34, No.2. Mars / Avril 2011.

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

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.

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