

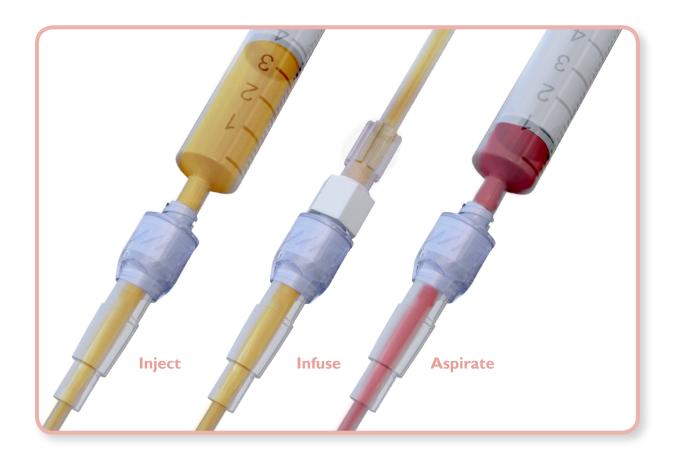
vadsite[®]

The Transparent, Split Septum, Needleless Connector



What is vadsite?

- vadsite is a Neutral Displacement Needleless Connector for use with all I.V. equipment (e.g.: syringes, giving sets, stopcocks, extension lines, catheter and cannulae).
- vadsite first became commercially available in 1994. As part of our ongoing programme of product development, Vygon has upgraded vadsite to ensure its specification and clinical performance continues to lead in terms of improved patient outcomes



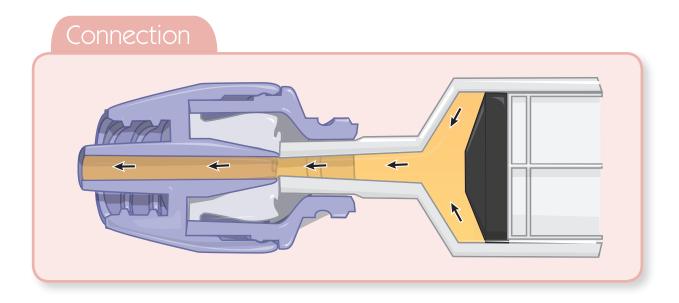
• When vadsite is connected you can infuse, inject, sample and change your I.V. tubing without opening the I.V. circuit to the atmosphere.

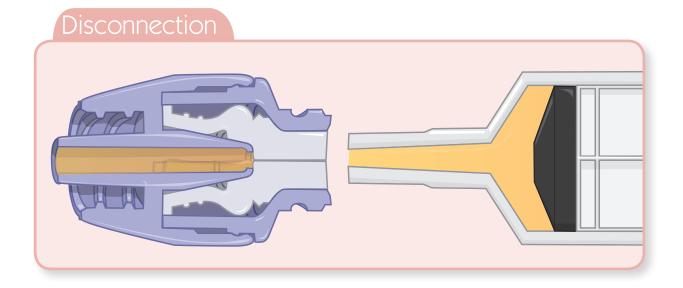




vadsite®

• vadsite's protective split-septum opens the fluid pathway only when a male Luer has been fully inserted. When you disconnect the male Luer the septum automatically seals the fluid pathway.







Why choose vadsite?

Vadsite is a closed, needleless connector for use with all I.V. equipment for example: vascular access devices, syringes, giving sets, stopcocks, extension lines, catheters and cannulae.

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 Vadsite to meet these standards and furthermore, our clinical performance studies* provide the evidence to support our claim that Vadsite 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 clamping sequence. Or, alternatively, use only one needleless connector type that requires a specific clamp-disconnection sequence (e.g., all negative pressure, all positive pressure or all neutral pressure) throughout the healthcare facility or system and insure that all Healthcare Workers understand and are well trained in this clamp-disconnection sequence.⁽³⁾
 - A transparent needleless connector is preferable to one that is opaque. (3)

^{*} Refer to the back page for more details.





vad**site**'s features and benefits

vadsite®

• Transparent (3,8)

Vadsite has a transparent housing and transparent silicone membrane that allows the health worker to see the fluid pathway and confirm complete flushing.

• Low Priming Volume (3)

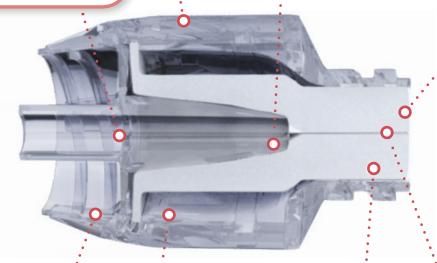
Suitable for clinical applications where very low priming volumes and dead space are required. Vadsite has a priming volume of just 0.07ml.

• Direct Fluid Pathway (3)

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 (1,3,6)

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



• Effective Microbial Barrier (1,2,3,4,5,6

Vadsite is supported by numerous microbiological studies which conclude that microbial ingress does not occur.

Universal Male Luer Compatibility

Any ISO standard male Luer can be connected to Vadsite including those with a very small internal diameter.

• High Pressure Compatibility (CT-Rated)⁽⁷⁾

Vadsite is approved for use with power injectors.

- Maximum pressure resistance: 350 psi
- Maximum flow rate: > 10 mL/s

• Split SeptumTechnology (2,3)

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

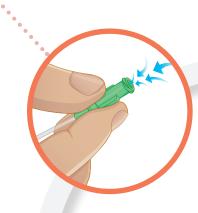




Unplanned Complications of IV Therapy

Air embolus:

Opening the female hub of a VAD can allow fatal volumes of air to be entrained.



• Infection:

Repeated exposure of the female hub of a vascular access device (VAD) to the atmosphere can increase the risk of bacterial colonization and catheter related bloodstream infection (CRBSI).





• Needle-Stick injury:

The use of injection membranes to access a the healthcare worker.



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Premature Vascular Access Device failure:

CRBSI and catheter occlusion are the main causes of VAD failure and extend treatment





• Time inefficacy:
Avoidable CRBSI and catheter occlusion increase the amount of time healthcare workers are absent from the bedside and extend treatment time.

VAD can result in a needle-stick injury to





- 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. Evaluation of Vadsite Microbial Integrity, CARSO Laboratoire Santé, Lyon, April 2009.
- 6. Evaluation of Disinfection Procedures, CARSO Laboratoire Santé, Lyon, February 2011.
- 7. CT Pressure Testing, Laboratoire Central d'Essais, Report RE12210, Vygon SA France, August 2012.
- 8. 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 'vad**site**® Clinical Performance Studies brochure'. The full protocols and results are available in 'The vad**site**® Electronic Handbook'. Please contact us directly or request copies directly from your local Sales Executive.

Technical specifications	
Maximum number of activations	360
Flow rate at gravity	170mL/min
High pressure flow rate	> 10 mL/s
Priming volume	0.07 mL
MRI compatible	Yes
Blood compatible	Yes
Lipids resistant	Yes
Latex-free	Yes
Alcohol resistant	Yes
Chlorhexidine resistant	Yes

- Do not put a cap, plug or obturator of any sort on Vadsite other than a disinfecting cap.
- Do not use a needle with Vadsite.
- Remember to clean Vadsite 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.

