VYGON

Value Life

IV Access

Closed Needle-free Devices

Vadsite®

The benefits are clear

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Global recommendation:
A needle-free device with a direct, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for biofilm development.[1,2]

Vadsite®

Vadsite®

The clear, split-septum needle-free solution

Vadsite is the first clear, split-septum needle-free device in the UK to combine a fixed, straight fluid pathway with glass syringe compatibility.

Vadsite has been designed to meet global opinion leader's recommendations for reducing CRBSIs with a fixed, straight fluid pathway which offers improved blood clearing and a low priming volume.

Its patented ergonomic design reinforces best practice for non-touch technique and offers improved handling functionality for connection and disconnection of male luers.

Compatible with glass syringes

Vadsite is designed to work with all types of pre-filled glass syringes while remaining incompatible with the use of non-IV luer devices, such as oral syringes.

Reduce infections

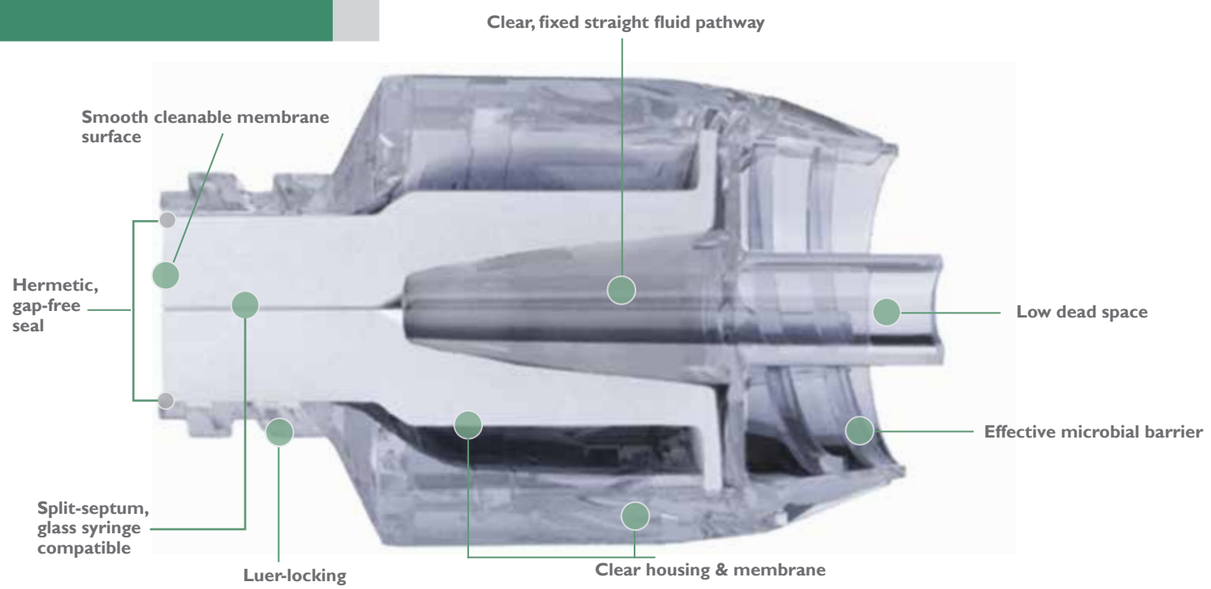
Vadsite is proven to be easy to clean with a smooth split-septum that fits tightly into the device housing ensuring it is free from any gaps. The straight, fixed fluid pathway has been designed to provide the most direct and least tortuous route, with no moving parts (such as mechanical valves), which reduces the surface area available for biofilm formation.

Clear benefits

Vadsite has a transparent housing and a translucent silicone split-septum. This enables you to visually assess the fluid pathway when priming and flushing the device.

Ergonomically designed

The UK has embraced the concept of aseptic practice to help reduce the contamination of devices and subsequently decrease the risk of CRBSIs. Vadsite has been designed to help promote best practice and improve the ability of the caregiver to effectively handle the device without touching the split-septum and other key parts.



Vadsite Octopus extension sets

To support the **MHRA Alert MDA/2010/073** Vygon has produced 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 Vadsite Octopus range is produced with biocompatible PUR tubing to help prevent the risk of drug loss which can occur with PVC tubing.[3]

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.

Vygon (UK) Ltd

What do global opinion leaders **recommend?**

✓ A needle-free device that is supported by microbial ingress testing data.[4]

✓ A split-septum needle-free device is associated with a lower incidence of CRBSI compared to a mechanical valve needle-free connector.[2,5]

✓ A needle-free device with a smooth external septum surface with few, if any gaps, that can be more thoroughly disinfected.[1]

✓ 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.[1]

✓ A needle-free device with a direct, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for potential biofilm development.[1,2]

✓ 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.[1]

✓ 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.[1]

✓ 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.[1]

✓ A transparent needle-free device is preferable to one that is opaque.[1]

Vadsite meets these recommendations and more!

✓ Vadsite is designed to work with all types of glass syringes.

✓ Vadsite is CT-rated and approved for use with power injectors.

- Maximum pressure resistance: 350 PSI
- Maximum flow rate: > 10 ml/s.

✓ Vadsite Octopus is produced with PUR tubing to prevent drug loss.[3]

✓ Vadsite Octopus has no common dead space preventing the mixing of incompatible drugs.

Vadsite® ordering information

Vadsite

Code	NHSSC	Description	Priming volume	Box
0898.03	FSW597	Vadsite in soft blister pack	0.07 ml	25
0898.038	FSW661	Vadsite with protector on the male luer in soft blister pack	0.07 ml	25
0898.11	FSW662	Arterial Vadsite in soft blister pack	0.07 ml	50

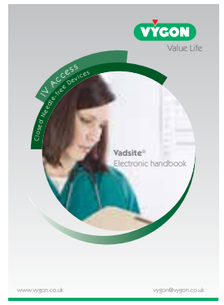
Vadsite Octopus extension sets

Code	NHSSC	Description	Tubing length	Priming volume	Box
5224.01	FSW598	Single lumen Vadsite Octopus extension	10 cm	0.29 ml	50
5224.012	-	Single lumen Arterial Vadsite Octopus extension	10 cm	0.29 ml	50
6841.21	FSW599	Double lumen Vadsite Octopus extension	8 cm 8 cm	0.34 ml 0.34 ml	50
6841.212	FSW601	Double lumen Vadsite Octopus extension with ARVs	8 cm 8 cm	0.43ml 0.43ml	50
6841.31	FSW663	Triple lumen Vadsite Octopus extension	8 cm 8 cm 8 cm	0.31 ml 0.31 ml 0.31 ml	50
6841.313	FSW664	Triple lumen Vadsite Octopus extension with ARVs	8 cm 8 cm 8 cm	0.44 ml 0.44 ml 0.44 ml	50

Vadsite's clinical performance studies are available on request

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

Vadsite Clinical Performance Studies
Key clinical studies and results.
0002.VADSTUDIES



Vadsite Electronic Handbook
All clinical studies and data.
PS283 - Electronic Handbook

Technical Specification

Recommendation	Vadsite's Performance
Glass syringe compatible	Yes
Split-septum (lower rate of CRBSI vs mechanical valve systems)	Yes (clinical performance study four)
Mechanical valve	No (no moving parts within fluid pathway)
Maximum number of accesses	360
Straight fluid pathway (open end to end)	Yes (reduces surface area for biofilm formation)
Fixed fluid pathway	Yes (prevents pathway contortion, easy to flush)
Duration of dwell time	7 days (clinical performance study one)
Membrane cleaning study (maximum of 30 seconds to dry)	Yes (clinical performance study two)
Blood clearing study (maximum of 5ml flush)	Yes (clinical performance study three)
Microbial ingress data (minimum period for life of product)	Yes - 8 days (clinical performance study one)
Flow rate (1m/H_2O ISO10555-1:2013)	170ml/min
Displacement	(0.03)ml
Priming volume	0.07ml
DEHP-free	Yes
Tubing material	Polyurethane (resists drug loss vs. PVC)
Cytotoxic drug compatible	Yes – Highly resistant polymer
Latex-free	Yes
MRI compatible	Yes
CT-rated for high pressure infusions	Yes to 350 PSI and 10ml per second
Back pressure tested	2 bar
Alcohol resistant	Yes – Highly resistant polymer
Lipid Resistant	Yes – Highly resistant polymer

References

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

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

3. 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.

4. 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.

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

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

For further information, please contact: vygon@vygon.co.uk

The specifications shown in this leaflet are for information only and are not, under any circumstances, of a contractual nature. This document is intended for use in the UK only.

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