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®

The clear, split-septum needle-free solution

Vadsite is the only 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 leaders' 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 currently marketed pre-filled glass syringes while remaining incompatible with the use of non-IV luer devices, such as oral syringes.

Reduces infections

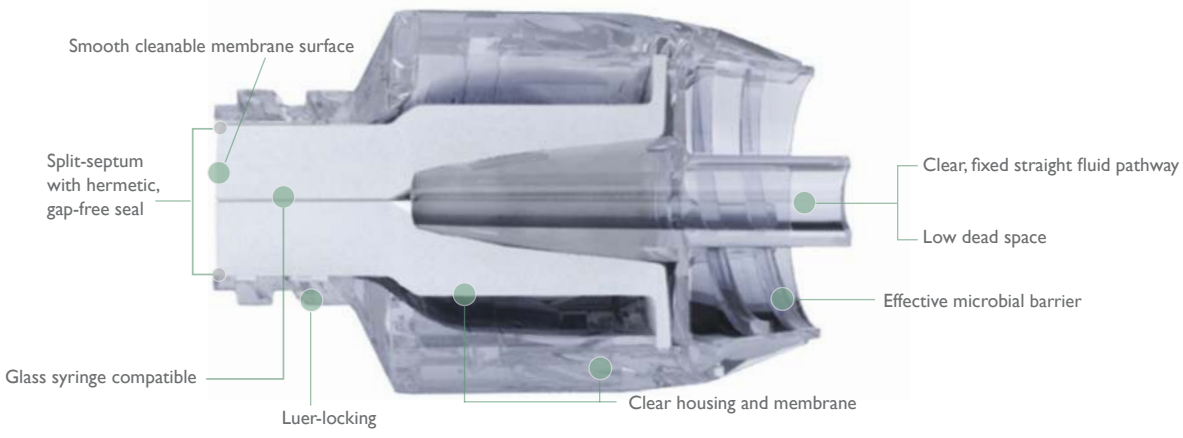
Vadsite is proven to be easy to clean with a smooth split-septum that fits tightly into the device housing ensuring it is free from any gaps. The straight, fixed fluid pathway has been designed to provide the most direct and least tortuous route, with no moving parts (such as mechanical valves), which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

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

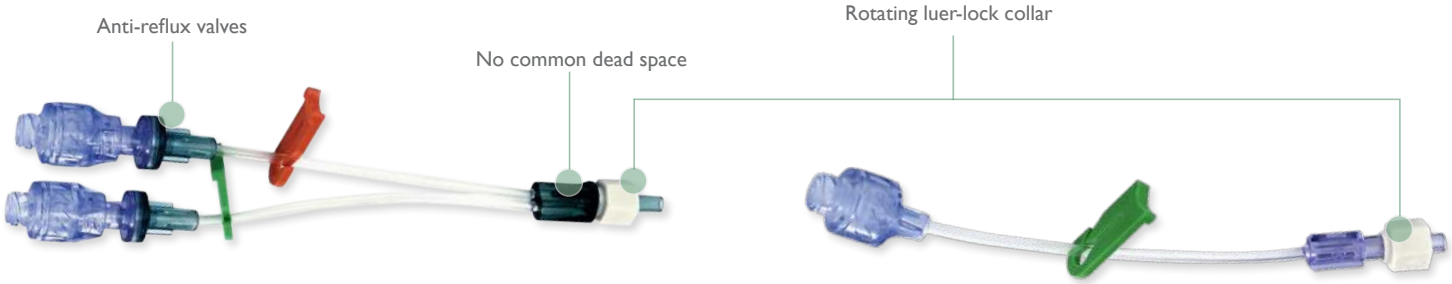
The Vadsite Octopus range is produced with biocompatible PUR tubing to help prevent the risk of drug loss which can occur with PVC tubing.[3] Central lines and PE syringe drivers do not contain PVC within the fluid pathway, with Vadsite you can be assured you're not putting PVC into the patient's IV circuit. Issues with PVC drug interactions are supported by Vadsite's drug compatibility studies (Study Five).

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.



Double lumen Vadsite Octopus extension with two ARVs
6841.212

Single lumen Vadsite Octopus extension
5224.01

Global opinion leaders' recommendations and how Vadsite® meets them.

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

✓ **Supported by eight day microbial ingress data (Study One)[5]**

A split-septum needle-free device is associated with a lower incidence of CRBSI compared to a mechanical valve needle-free connector.[2,6]

✓ **Cleanable split-septum supported by split-septum studies (Study Four)[7]**

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

✓ **Smooth septum supported by membrane cleaning studies (Study Two)[7]**

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]

✓ **Gap-free, tight hermetic seal between the membrane and housing[7]**

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]

✓ **Clear straight, fixed fluid pathway (open end-to-end)[8]**

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]

✓ **No moving parts or mechanical valves within the pathway**

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]

✓ **Low deadspace (0.07ml) supported by blood clearing studies (Study Three)[8]**

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]

✓ **One device for all clinical areas helping standardise practice**

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

✓ **Clear housing and membrane[8]**

Vadsite meets these recommendations and more!

- ✓ Glass syringe compatible
- ✓ (0.03)ml fluid displacement
- ✓ 7 Day / 360 accesses
- ✓ 170ml/min flow rate (1m/H_2O ISO10555-1:2013)
- ✓ Does not require priming
- ✓ DEHP-free
- ✓ PUR tubing material
- ✓ Cytotoxic drug compatible
- ✓ Latex-free split-septum
- ✓ MRI compatible
- ✓ CT-rated to 350psi and 10ml per second (bung only)
- ✓ Back pressure tested to 2 bar
- ✓ Alcohol resistant polymer
- ✓ Lipid resistant polymer
- ✓ Blood and blood product compatible

Vadsite® ordering information

Vadsite

Code	NHSSC	Description	Priming volume	Box
0898.03	FSW684	Vadsite in soft blister pack	0.07 ml	100
0898038	FSW689	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	100

Vadsite Octopus extension sets

Code	NHSSC	Description	Tubing length	Priming volume	Box
5224.01	FSW686	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
684121	FSW687	Double lumen Vadsite Octopus extension	8 cm	2 x 0.34 ml	50
6841211	FSB1497	Double lumen Vadsite Octopus with one ARV	8 cm	With ARVs 2 x 0.43 ml Without ARVs 2 x 0.34 ml	50
6841212	FSW688	Double lumen Vadsite Octopus extension with ARVs	8 cm	2 x 0.43ml	50
684131	FSW663	Triple lumen Vadsite Octopus extension	8 cm	3 x 0.31 ml	50
6841313	FSW664	Triple lumen Vadsite Octopus extension with ARVs	8 cm	3 x 0.44 ml	50
06841.41	-	Quad lumen Vadsite Octopus extension	8 cm	4 x 0.2 ml	10
06841.414	-	Quad lumen Vadsite Octopus extension with four ARVs	8 cm	4 x 0.3 ml	10

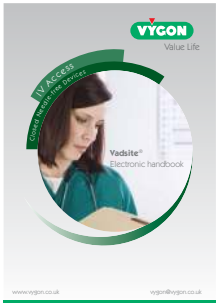
Vadsite accessories

Code	NHSSC	Description	Box
856115	FSB1496	Vadsite spike with ARV	25
856015	FSB1495	Vadsite spike	25
082131	FSB1493	Vial access cap with Vadsite - 14mm	50
082132	FSB1492	Vial access cap with Vadsite - 20mm	50
70876205	FVK191	Three-way tap with one Vadsite	50
0876005	FVK206	Three-way tap with two Vadsite	100
5141015	FVK190	Three-way tap with 13.5 cm extension and one Vadsite	50
822115	FSB1494	Luer-lock T piece with Vadsite	20
0822.615	-	Luer-slip T piece with Vadsite	20

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 local Vygon representative to request more information.

Vadsite Clinical Performance Studies
Key clinical studies and results.
Code: AJ02.VADSTUDIES



Vadsite Electronic Handbook
All clinical studies and data.
Code: PS283

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. Evaluation of Vadsite Microbial Integrity, CARSO Laboratoire Santé, Lyon, April 2009.
6. Centre for Disease Control, 'Guidelines for the Prevention of Intravascular Catheter-Related Infections', Needleless Intravascular Catheter Systems, page 19, No.6. 2011.
7. Evaluation of Disinfection Procedures, CARSO Laboratoire Santé, Lyon, February 2011.
8. Blood Clearing Analysis, 5ml Flush GLP Report, report 201301574 Rev 01, Nelson Laboratories, USA, 15th April 2013.

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

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

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