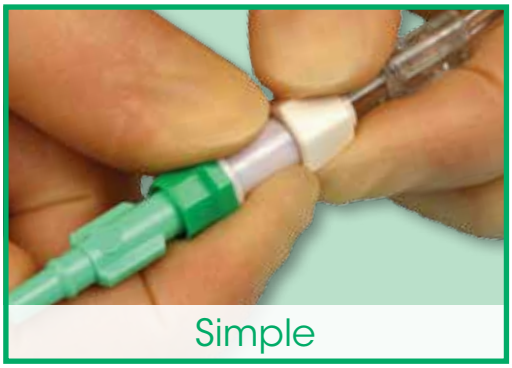
VYGON
Value Life

# Bionector

## The 7 Day/360 Access, Closed, Needle-Free, IV Access System

Safe



Simple

Economic

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# Bionector

## The 7 Day/360 Access, Closed, Needle-Free, IV Access System

Bionector was first commercially available in the UK in 1994. Vygon have since sold over 15 million units and we remain the market leader.

The concept of Bionector began with the need to reduce infection rates in vascular access devices. A number of articles have been published highlighting the connection between hub manipulation of central venous catheters and the increased incidence of catheter infection. The more times the female hub of a catheter is exposed to the atmosphere, the more likely the hub is to become colonised with bacteria.

Bionector works on the principle that providing closure to the catheter hub reduces the risk of infection. We first introduced Bionector to oncology, haematology and neonatal departments due to the problems they experience with catheter related infection and the impact that these infections have on their patient group.

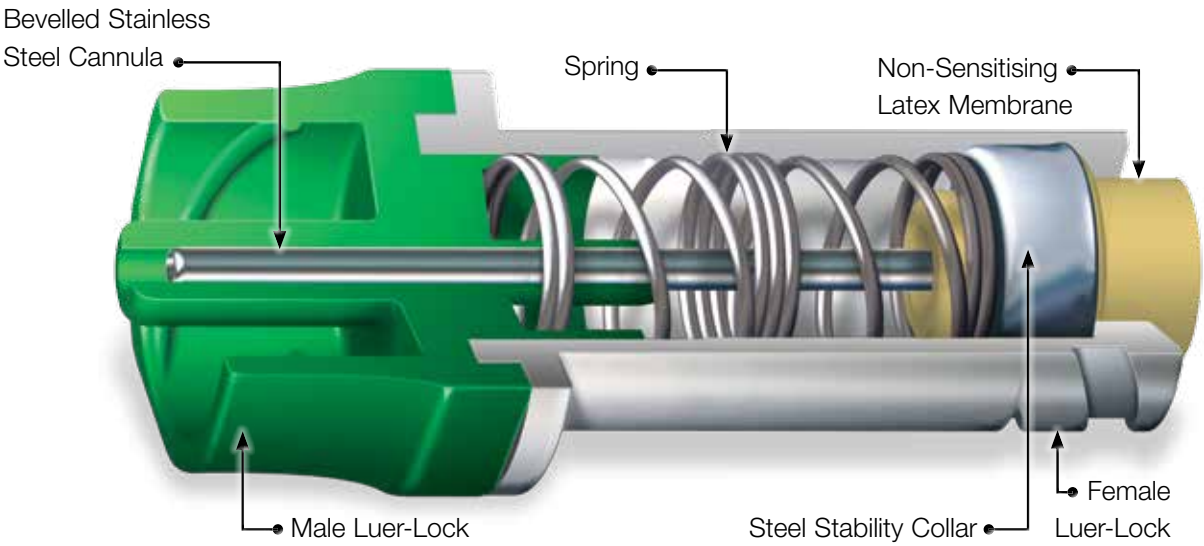
With the increased awareness of the risk of needle-stick injuries, Bionector has now taken on the dual role of eliminating access-associated needle-stick injuries and helping to reduce catheter/cannula related complications. The use of Bionector is simply seen by many clinicians as best clinical practice.

Bionector is now widely used within all specialities of medicine and can be found in almost any hospital department. The Bionector range of products has grown and developed as clinical demands have changed, Bionector can now be used on virtually any type of vascular access device. Some hospitals in the UK have adopted Bionector as their standard means of accessing all vascular access devices.

# How does Bionector work?

When Bionector is connected you can infuse, inject, sample and change your IV tubing without opening the IV circuit to the atmosphere.

Bionector's protective membrane automatically opens the fluid pathway only when a male luer has been fully inserted. When you disconnect the male luer, the protective membrane automatically seals the fluid pathway.

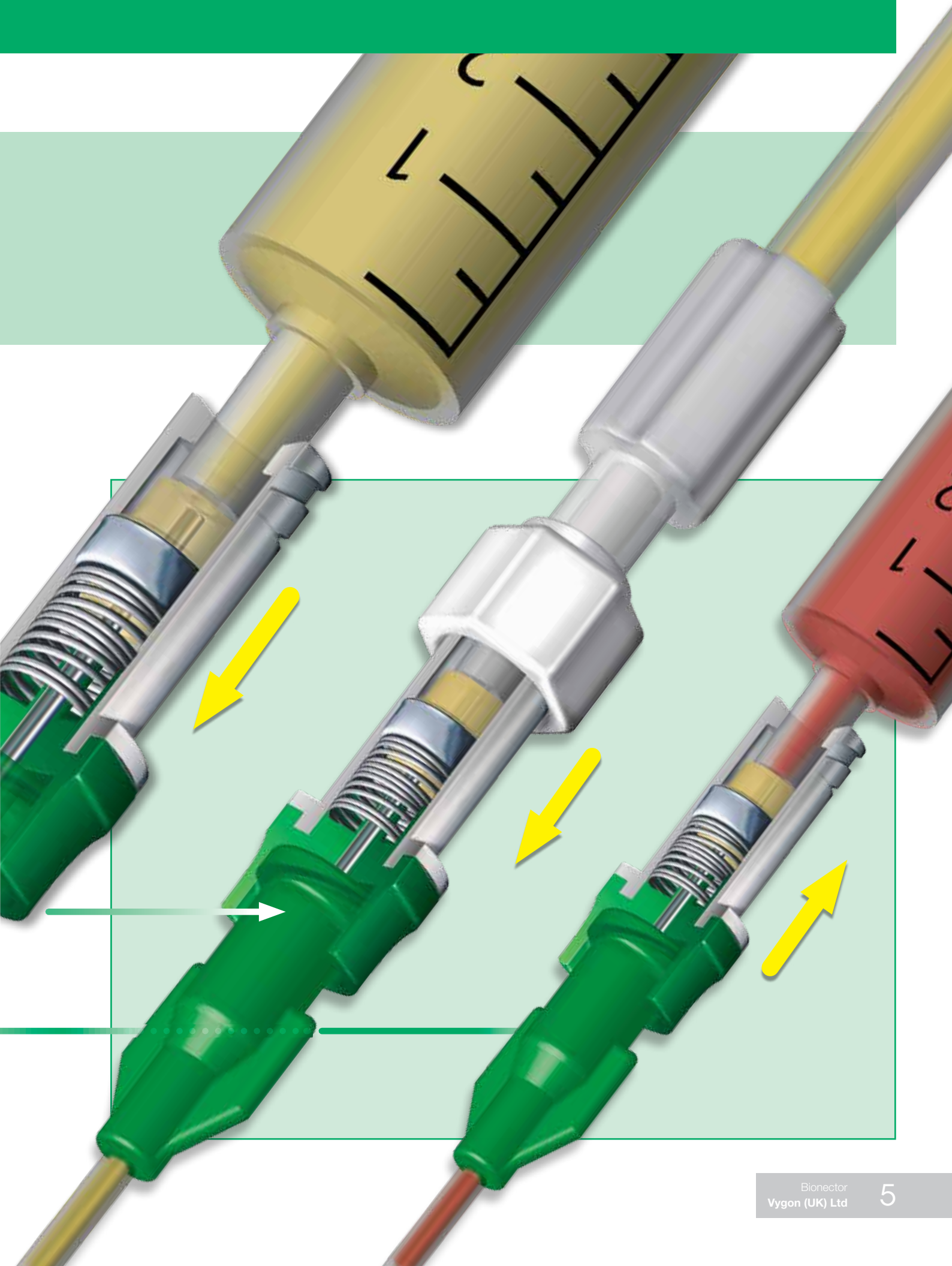



## ✓ Inject

## ✓ Infuse

## ✓ Sample

**For information on how to use Bionector, turn to pages 14-15.**

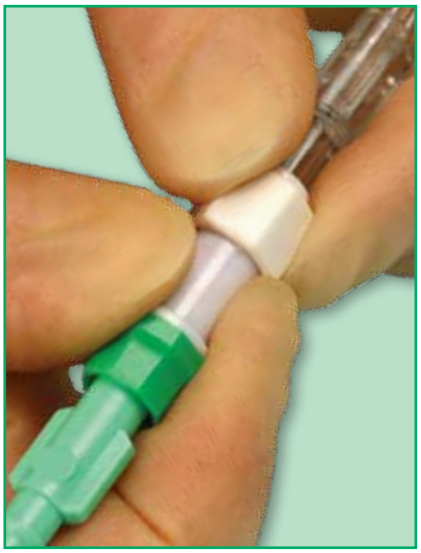


# What are the benefits of Bionector?

## Safe

- ✓ One piece only
- ✓ Closed and cleanable

- ✓ Standard IV fittings, lockable
- ✓ Infuse, inject, and sample



## Economic

- ✓ No caps or accessories
- ✓ Cost-effective access

# Bionector do's and don'ts

**Do** remember to clean the membrane before and after access and allow to dry.

**Do** use only luer-slip or luer-lock fittings.

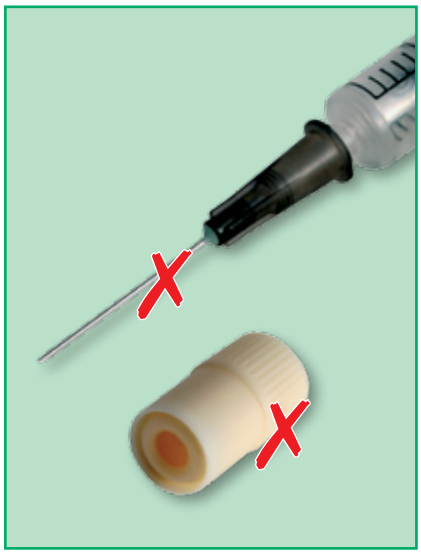
**Don't** cap Bionector. The membrane is the seal, no cap is necessary.

**Don't** use needles with Bionector.

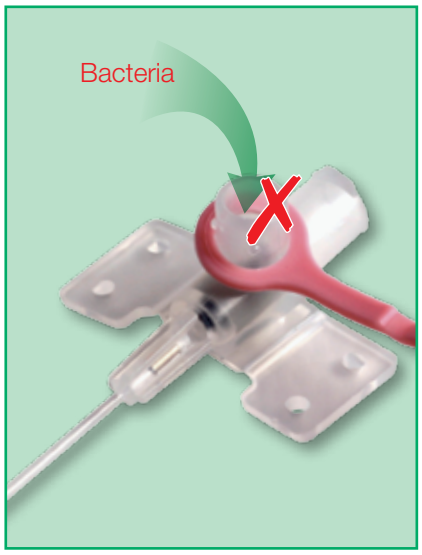
**Do** flush each lumen before and after use and prior to connection to a patient catheter or cannula.

**Do** remember to clamp off any secondary infusion when delivering a bolus of medication through other port.

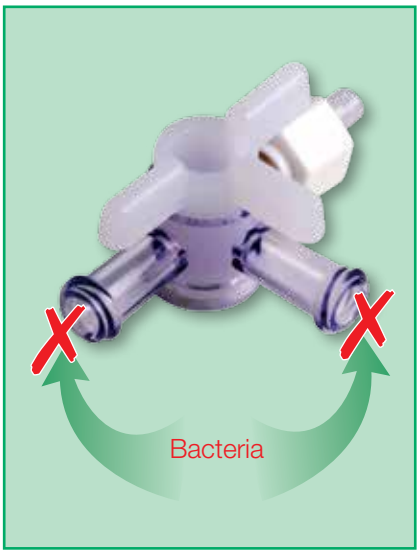
# What are the problems associated with current vascular access device management?



✗ The use of an injection membrane to access a vascular access device (VAD) can result in a needle-stick injury. The RCN suggests that innovative products are available that can reduce the risk of sharps injury[1]. Furthermore, the RCN highlights a safety device, for example a needle-free system, as the preferred method of accessing an injection access site[2].

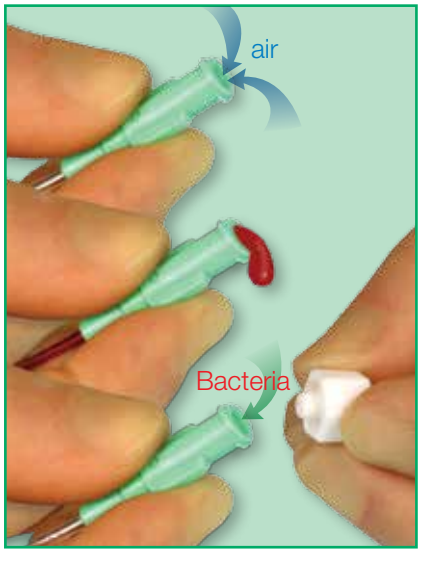



✗ In vitro studies suggest that cannula injection port bacterial colonisation rates can be as high as 55%[3].




✗ The use of three-way taps to facilitate the administration of more than one infusion is common. However, numerous research articles recommend against their use. In vitro studies suggest that the female ports of a three-way tap have a similar bacterial colonisation rate to that of a cannula injection port[4].

The bulky nature of a three-way tap can increase insertion site manipulation[5] thus increasing the risk of mechanical phlebitis and therefore premature cannula failure.



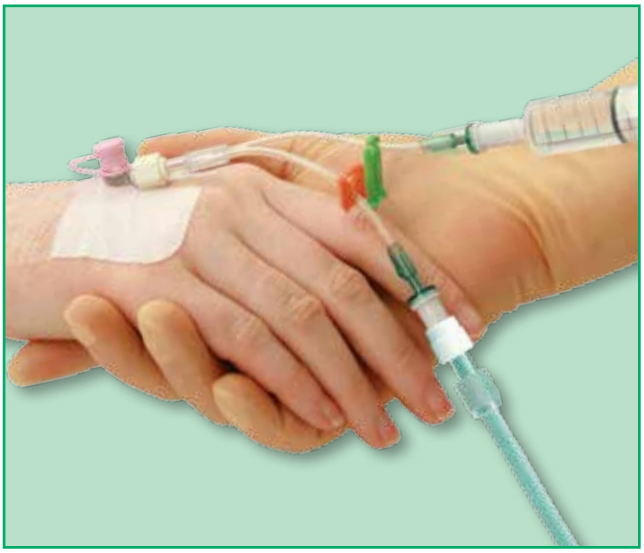

✗ Opening a VAD to the atmosphere can allow air to enter the catheter, thus increasing the risk of air embolus.[9]

✗ Opening the female hub of a VAD can allow reflux of the patient's blood, thus increasing the risk of cross infection associated with blood spillage.[9]

✗ The act of repeatedly opening and closing the female hub of a vascular access device increases the risk of bacterial colonisation of the hub surface.[7,8]

**How can Bionector be used clinically?**
Turn the page opposite to reveal our solutions to your problems.

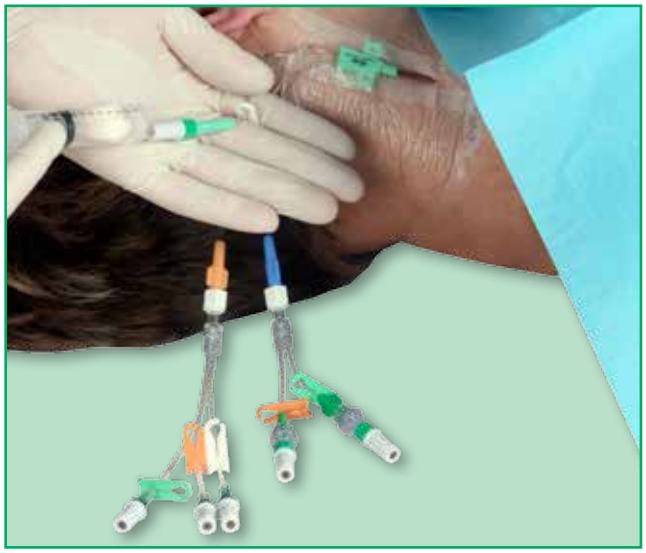
# How does Bionector provide the solutions?



**Peripheral Cannula-Care**

**Single and double Octopus with Bionector help reduce the common problems associated with the use of short peripheral ported IV cannulae.**

- ✓ Eliminates the risk of access-associated needle-stick injury.[1,2]
- ✓ Reduces the risk of cannula displacement.[5]
- ✓ Negates the need to use the cannula injection port.[3]
- ✓ Eliminates the need to use a three-way tap to run two simultaneous compatible solutions.[4]
- ✓ The Bionector membrane has a 0% bacterial colonisation rate following disinfection with alcohol.[6]
- ✓ Drug-compatible PUR tubing material.



**Acute Central Venous Catheter Care**

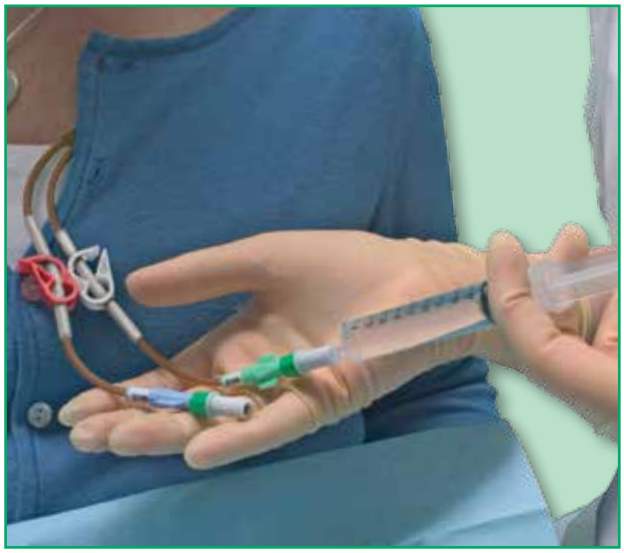
**Single Bionector and Octopus with Bionector help reduce the common problems associated with the complex intravenous management of the critically ill patient.**

- ✓ Provides closed, needle-free access for 7 days or 360 accesses, during syringe bolus dose administration and IV tubing change, thus reducing the risk of bacterial colonisation of the female hub of the catheter.[7,8]
- ✓ Eliminates the need to use a three-way tap to run two or more simultaneous compatible solutions.[4]
- ✓ The Bionector membrane has a 0% bacterial colonisation rate following disinfection with alcohol.[6]
- ✓ Eliminates the risk of blood spillage.[9]
- ✓ Eliminates the risk of air embolus.[9]
- ✓ Eliminates the risk of access associated needle-stick injury.[1,2]
- ✓ Drug compatible PUR tubing material.

**Paediatric & Neonatal Central Venous Catheter Care**

**The management of drug and fluid administration in paediatrics and neonates has always been complicated.**

- ✓ Provides closed, needle-free access for 7 days or 360 accesses, during syringe bolus dose administration and IV tubing change, thus reducing the risk of bacterial colonisation of the female hub of the catheter.[7,8]
- ✓ Eliminates the need to use a three-way tap to run two or more simultaneous compatible solutions.[4]
- ✓ The Bionector membrane has a 0% bacterial colonisation rate following disinfection with alcohol.[6]
- ✓ Eliminates the risk of access associated needle stick injury.[1,2]
- ✓ 96 hour (green) 0.22 micron filters reduce the risk of bacterial contamination, retain endotoxins and protect against particulate matter.[10,11,12]
- ✓ 24 hour (blue) 1.2 micron filters offer patient protection during infusions of nutrient lipid emulsions.[13]
- ✓ Eliminates the risk of blood spillage.[9]
- ✓ Eliminates the risk of air embolus.[9]
- ✓ Drug compatible PUR tubing material.



**Long-Term Central Venous Catheter Care**

**Long-Term Silicone Cuffed Catheters and Peripherally Inserted Central Catheters need careful management to ensure low complication rates throughout the duration of therapy.**

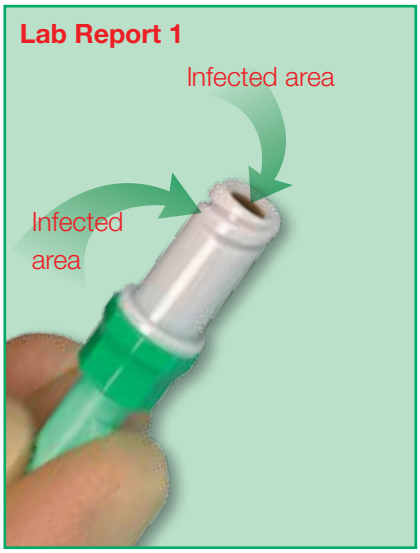
- ✓ Provides closed, needle-free access for 7 days or 360 accesses, during syringe bolus dose administration and IV tubing change, thus reducing the risk of bacterial colonisation of the female hub of the catheter.[7,8]
- ✓ The Bionector membrane has a 0% bacterial colonisation rate following disinfection with alcohol.[6]
- ✓ Eliminates the risk of blood spillage.[9]
- ✓ Eliminates the risk of air embolus.[9]
- ✓ Eliminates the need to use a three-way tap to run two or more simultaneous compatible solutions.[4]

# Microbiological studies

**Once the Bionector is in place, can it be cleaned/disinfected effectively?**

Laboratory Report 1 demonstrates that the Bionector can be deliberately contaminated, disinfected with customary cleaning agents and then used to infuse a sterile solution without any contamination of the fluid.

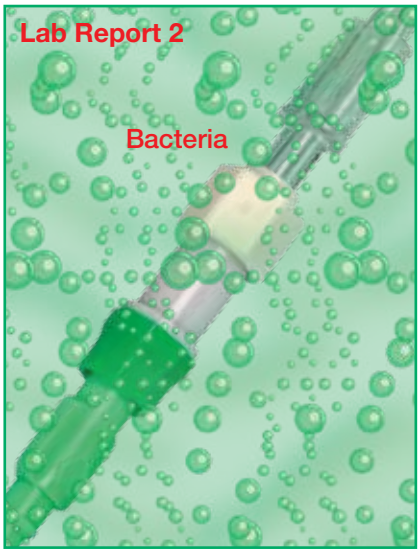
*Laboratory Report : Laboratoires EVIC-CEBA, November 1993.*




**Can bacteria enter the line via the connections between catheter and Bionector and between giving set and Bionector?**

Laboratory Report 2 shows that a Bionector can be used to join two lines filled with sterile fluid and that the assembly can be immersed in a broth of bacteria for 8 days and no contamination will be transmitted to the sterile fluid.

*Laboratory Report : Laboratoires EVIC-CEBA, December 1993.*



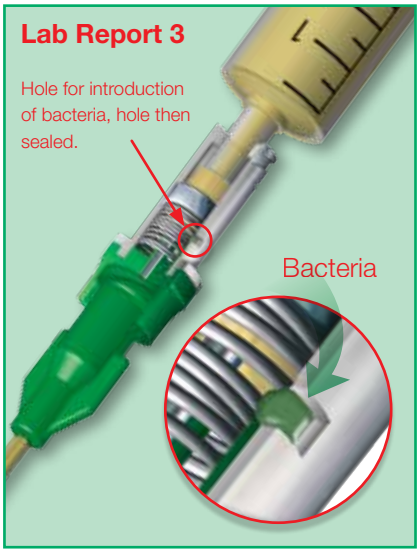

**Can Vygon prove that the Bionector is genuinely a closed IV system?**

Laboratory Report 3 shows that even when bacteria are deliberately introduced inside the housing of Bionector, there is no transmission of contamination from inside the housing to the sterile fluid inside the closed fluid pathway.

This test was done in two parts. The first simulates a Bionector being used for intermittent access. The second, a Bionector being used for an infusion.

*Laboratory Report : Dept of Microbiology, Laboratoires Pharmaceutiques Vygon, February 1994.*

**Reminder: Bionector has a unique, non-touch applicator to prevent touch-contamination of either the Bionector or the female luer connector. All the benefits of a closed IV system are lost if there is accidental contamination at the moment of connecting Bionector to the catheter.**



# Latex allergy study / MRI study

**Can Bionector be used in cases of latex allergy?**

Yes, Bionector contains a “dry rubber” (latex) membrane. However, the proteins that cause latex allergies are destroyed during the production process, which means that the latex used in Bionector is classed as non-sensitising. (Studies conducted have confirmed this and are included in the Bionector Handbook).

**Test summary:** A commonly used test was performed to determine the allergenicity of the rubber membrane used in Bionector. The objective was to evaluate the potential to elicit contact dermal allergenicity of extracts prepared with the natural rubber membrane for Bionector batch CH0689802.

**Methodology:**
**Phase 1 – Induction phase:** During this phase the first contact between living organism and allergen initiates the allergic process. On day 1, one intracutaneous injection of the extract liquid of the test article, with FREUND’S complete adjuvant and on day 8, and intracutaneous injection of the extract.

**Phase 2 – Rest period:** During this phase, cellular transformations occur, 2½ weeks without any treatment.

**Phase 3 – Challenge:** Contact between living organism and allergenic material, eliciting contact dermal allergenicity. When hypersensitivity is reached, a new contact between animal and material, in any area, elicits dermatitis. On day 25, the extract of the substance to be tested was injected by intracutaneous route in an area never treated. Challenge sites were read 24 and 48 hours after injection. Each site was graded for erythema and oedema in accordance with a table of test reactions.

**Conclusion:** The natural rubber membrane in Bionector, batch CH0689802, meets the requirements of a maximisation test, adapted from ISO 10993-10 1995 (E) and ASTM 720-81 standards, using two inductions and a challenge by intracutaneous route; the product, tested on extracts prepared at 37°C for 72 hours, ratio 3cm$^2$/ml with 0.9% sodium chloride solution was not sensitising. Sensitisation response: grade 0.

**Is Bionector suitable for use with MRI scanners?**

Yes, Bionector may be scanned safely and will not present any risk to the patient or clinical personnel under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.

MR image quality may be compromised if the area of interest is within a 10cm proximity to the device.

Bionector is classified as MR Conditional based on testing and definitions contained in The Magnetic Resonance task group of the American Society for Testing and Materials (ASTM) International: ASTM F2503-05.

Bionector has been tested in accordance with ASTM F2303-05 in an MRI environment of 3 Tesla or less.

A summary of the findings are as follows:

**1.** No magnetic attraction (no movement)
**2.** 0.5°C temperature rise
**3.** Image distortion at and immediately surrounding the device.

# Emergency syringe use

**Can Bionector be used with pre-filled emergency syringes?**

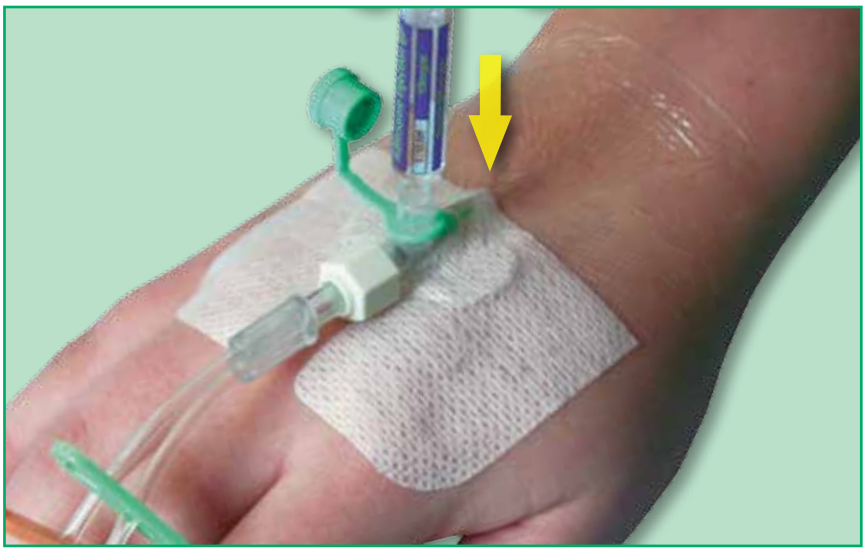
We have tested Bionector's compatibility with a number of pre-filled emergency syringes available in the UK. Currently only the Celltech Minijet is compatible. For all other brands, or where there is uncertainty, users should follow these instructions:

Where a pre-filled syringe is being used with any type of vascular access device which has a Bionector attached, the Bionector should be removed to avoid any confusion in terms of possible pre-filled emergency syringe incompatibility.

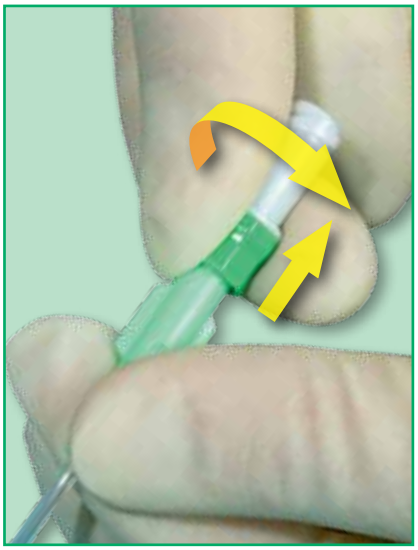
For more information regarding the Bionector-compatible Minijet range of pre-filled emergency syringes please contact:

Celltech Pharmaceuticals Ltd, 208 Bath Road, Slough, Berks SL1 3WE
Customer Services No: 0800 953 0183

In the case of a ported peripheral cannula, we recommend that the pre-filled syringe should be attached directly via the injection port.



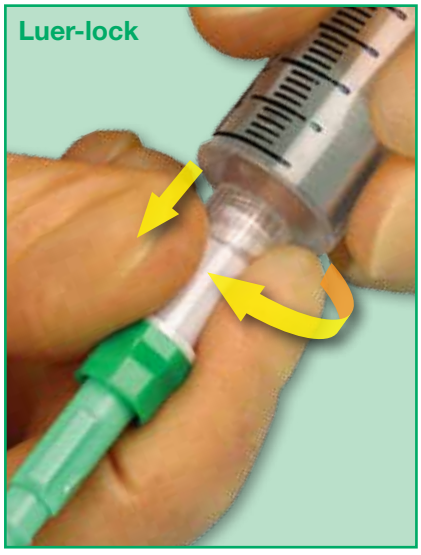
In the case of a central venous catheter, the Bionector should simply be removed from the pigtail and the pre-filled syringe attached directly to the female hub/luer.

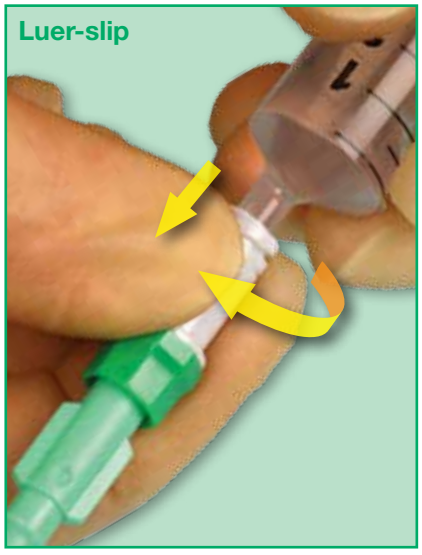


# Bionector directions for use








**How do I apply Bionector?**

1. Remove tamper-proof seal.
2. Securely lock the Bionector onto female luer of the device or extension line.
3. Remove the applicator by flexing it downwards and then upwards.
4. Withdraw the applicator to leave the Bionector in place.

**How often do I need to replace Bionector?**

Replace Bionector after 7 days or 360 accesses, whichever comes first.

**How do I use Bionector with syringes and IV fittings?**

When using a luer-lock fitting, connect normally to Bionector. You will find that making a luer-lock simply needs a little more pressure than traditional luer fittings.

When using a luer-slip fitting, e.g. a non-locking syringe, you will find that a quarter turn of the syringe as it is pushed firmly in will help provide a secure fit.

**How do I disinfect Bionector?**

**Disinfect the Bionector before and after use.**

Allow a minimum of 30 seconds for the disinfection agent to dry before use. This will allow effective disinfection and provide a dry connection onto the Bionector.

Clean in accordance with your hospital/department protocol.

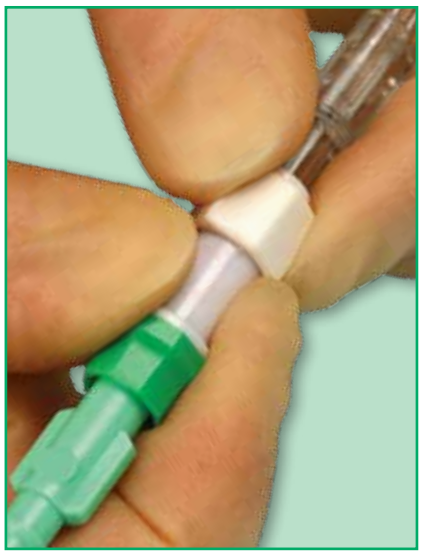
Bionector can be cleaned with most disinfecting agents including isopropyl alcohol, iodinated alcohol, ethyl-alcohol 70%, Hibiscrub, Hibitane, Betadine®, 2% Chlorhexidine gluconate in 70% isopropyl alcohol, or ChloraPrep®. Do not enclose or wrap Bionector in materials or containers impregnated with disinfectants.

**Is Bionector MHRA verified?**

The MHRA stipulates that there needs to be clear instructions for use concerning the intended duration of use and number of activations, backed up by clinical evidence. This is also supported by the RCN IV Therapy Forum, Standards for Infusion Therapy, November 2005, section 4.6, (injection site access). Our instructions for use relating to the frequency of change and the number of accesses are based on independent microbiological testing and verified clinical data. Our technical support data has been reviewed and verified by the MHRA.

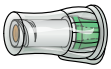

**Important note on connecting or disconnecting:**

Always grip the Bionector firmly in one hand before using the other hand to connect or disconnect a luer fitting.

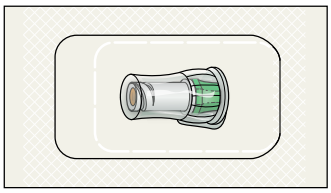


# The Bionector range

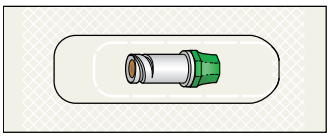
**1.** Bionector in Non-Touch Applicator **0896.01**



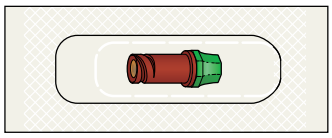
**2.** Bionector in 'Double-Wrap' **0896.02**



**3.** Bionector in 'Soft Pack' **0896.03**

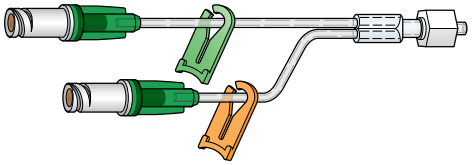


**4.** Arterial Bionector in 'Soft Pack' **0896.11**

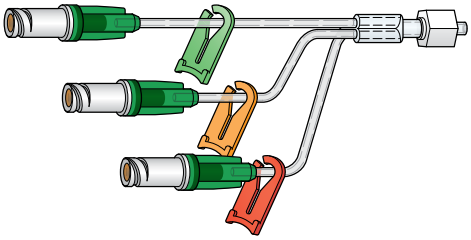


**5.** Integrated Bionector Flexible Extension with Clamp **5222.014**

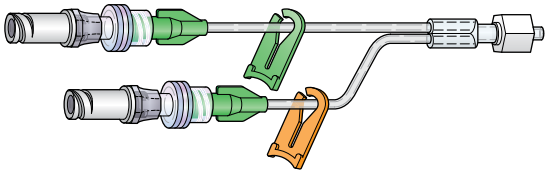
**6.** Octopus Double Equal Lumen with 2 Integrated Bionectors and Clamps **0841.264**



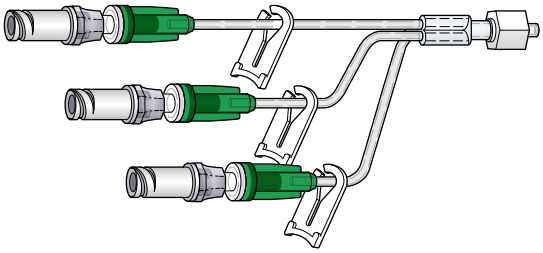
**7.** Octopus Triple Lumen with 3 Integrated Bionectors **0841.364**



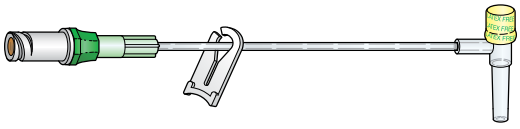
**8.** Octopus Double Lumen with 2 Non-Return Valves and Bionectors **0841.232**



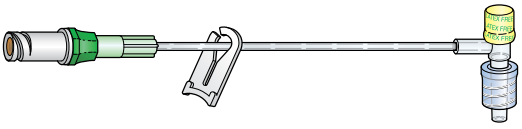
**9.** Triple-lumen Octopus with Bionectors and Anti-Reflux Valves **0842.312**



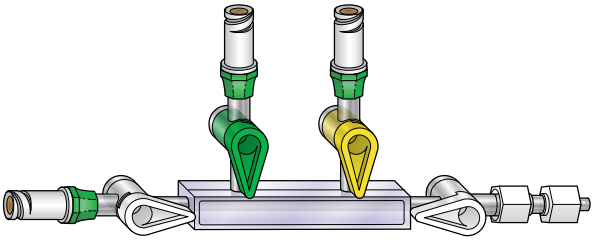
**10.** 'T' Connector Luer-Slip with Bionector (Low Profile) **0822.611**



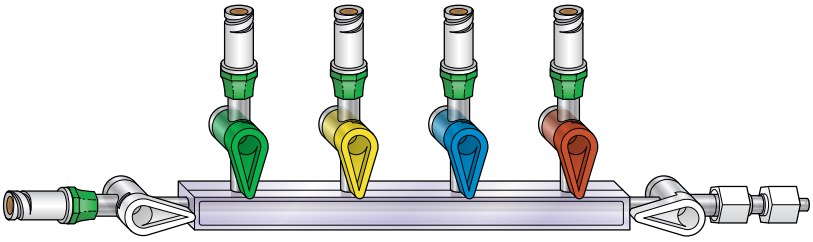
**11.** 'T' Connector Luer-Lock with Bionector **0822.111**



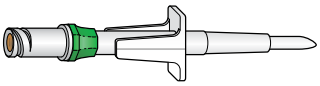
**12.** Bionector Ramp with 2 Lateral Ports and 3 Bionectors **080873.92M**



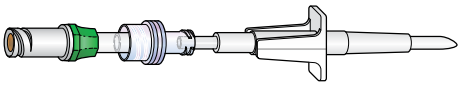
**13.** Bionector Ramp with 4 Lateral Ports and 5 Bionectors **080873.94M**



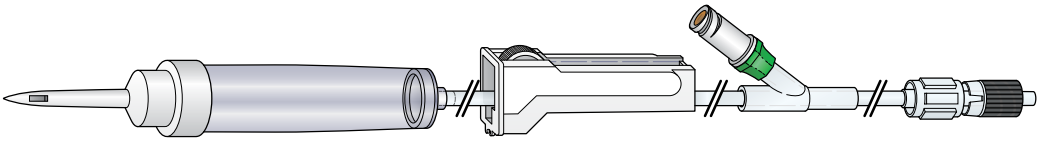
**14.** Bionector and Spike **0856.01**



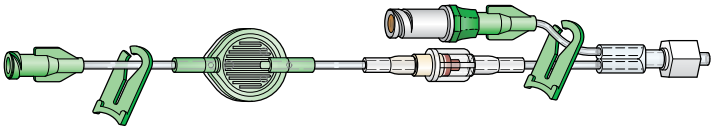
**15.** Bionector and Spike with Non-Return Valve **0856.11**



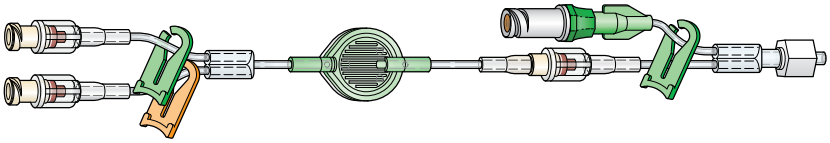
**16.** Single IV Giving Set with Bionector **5274.11**



**17.** Bionector Ready-Set 'Feed'* **0836.201**



**18.** Bionector Ready-Set 'Unite'* **0836.205**



* The filters in the Ready-Sets range are not suitable for blood or blood products. Do not attempt to administer lipids or lipid carried medications through a 0.22 micron (green) filter. Filter performance data available on request.

# Ordering information

| | Product Description | Vygon Code | NHSSC Code | Priming Volume (ml) | Length (mm) | Ext - Int Diameter (mm) | Flow Rate (ml/min) | Unit of issue |
|---|---|---|---|---|---|---|---|---|
| 1. | Bionector in Non-Touch Applicator | 0896.01 | FSW131 | 0.018 | | | 170 | 50 |
| 2. | Bionector in 'Double Wrap' | 0896.02 | FSW132 | 0.018 | | | 170 | 25 |
| 3. | Bionector in 'Soft Pack' | 0896.03 | FSW141 | 0.018 | | | 170 | 50 |
| 4. | Arterial Bionector in 'Soft Wrap' | 0896.11 | FSW164 | 0.018 | | | 170 | 50 |
| 5. | Integrated Flexible Extension with Clamp | 5222.014 | FSW311 | 0.4 | 100 | 2.5 - 1.5 | 80 | 50 |
| 6. | Octopus Double Equal Lumen With 2 Integrated Bionectors with Clamps | 0841.264 | FSW280 | 0.3<br>0.3 | 100<br>100 | 2.5 - 1.5<br>2.5 - 1.5 | 100<br>100 | 10 |
| 7. | Octopus Triple Lumen with 3 Integrated Bionectors | 0841.364 | FSB390 | 0.3<br>0.3<br>0.3 | 100<br>100<br>100 | 2.5 - 1.5<br>2.5 - 1.5<br>2.5 - 1.5 | 100<br>100<br>100 | 10 |
| 8. | Octopus Double Lumen with 2 Non-Return Valves and Bionectors | 0841.232 | FSW323 | 0.4<br>0.4 | 300<br>300 | 2.5 - 1.5<br>2.5 - 1.5 | 120<br>120 | 10 |
| 9. | Triple-lumen Octopus with Bionectors and Anti-Reflux Valves | 0842.312 | FSW375 | 0.4<br>0.4<br>0.4 | 100<br>100<br>100 | 2.5 - 1.5<br>2.5 - 1.5<br>2.5 - 1.5 | 110<br>110<br>110 | 10 |
| 10. | 'T' Connector with Bionector Luer-Slip (Low Profile) | 0822.611 | FSB106 | 0.3 | 100 | 2.4 - 1.3 | 60 | 20 |
| 11. | 'T' Connector with Bionector Luer-Lock | 0822.111 | FSB105 | 0.3 | 100 | 2.4 - 1.3 | 60 | 20 |
| 12. | Bionector Ramp with 2 Lateral Ports and 3 Bionectors | 080873.92M | FVK123 | 1.2 | | | | 25 |
| 13. | Bionector Ramp with 4 Lateral Ports and 5 Bionectors | 080873.94M | FVK125 | 2.1 | | | | 15 |
| 14. | Bionector and Spike | 0856.01 | FSB730 | | | | | 25 |
| 15. | Bionector and Spike with Non-Return Valve | 0856.11 | FSB729 | | | | | 25 |
| 16. | Single IV Giving Set with Bionector | 5274.11 | FSB350 | | 2500 | 4.0 - 3.0 | 170 | 25 |
| 17. | Bionector Ready-Set 'Feed'* | 0836.201 | FTC224 | 0.9 | | | | |
| 18. | Bionector Ready-Set 'Unite'* | 0836.205 | FTC225 | 0.9 | | | | |

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# Ordering information

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0002.BIONECTOR Content correct as of 12/2012