Bionector Important Cautions and Warnings

The Bionector range of closed, needle-free access devices have been commercially available in the UK since 1994.

These instructions were updated in March 2010. By the time you read this there may have been changes to the Bionector or to our knowledge about its use in certain circumstances. If in doubt about any aspect of clinical use or if you wish to establish whether there is more up to date information then please contact us.

Bionector quick reference FAQs

The following quick reference guide should be read in conjunction with the full and complete instructions for use that accompany Bionector.

Q. How often do I need to replace Bionector?
A. *Every 7 days or 150 accesses, whichever comes first.*

Q. What is the flow rate of Bionector?
A. *Bionector can achieve flow rates of up to 170ml per minute [gravity feed ISO10555].*

Q. Can I give blood or blood products via Bionector?
A. *Yes, Bionector has an internal fluid pathway the size of a 16g grey cannula.*

Q. Can I infuse lipid or lipid products through Bionector?
A. *Yes, Bionector is made of a lipid and alcohol resistant material.*

Q. Is Bionector safe to use with MRI scanners?
A. *Yes, because MRI looks at very small anatomical segments there can be a very localised distortion. We suggest that the Bionector is moved away by a minimum of 10cm from the area to be scanned. The Bionector may drift towards the magnetic field, in this case you may wish to tape the extension down.*

Q. Is Bionector compatible with anti-cancer medication?
A. *Yes, Bionector has been tested with a range of commonly used anti-cancer medication (please see overleaf for details).*

Q. Can Bionector be used with pre-filled emergency syringes.
A. *Bionector is currently compatible with the Mini-Jet range of syringes, however the Aurum range of syringes is not compatible. Therefore, we recommend that when emergency medication needs to be given via a pre-filled syringe that in the case of a central venous catheter the Bionector is removed, or in the case of ported peripheral cannulae the top port of the cannula is used in line with hospital protocol.*

Q. Do I need to prime Bionector?
A. *In the case of the Octopus range of short extensions with Bionector, yes. Always read the full instructions for use that accompany the device. In the case of the individual Bionector, the priming volume is 0.020ml and thus negligible from a clinical viewpoint. However there may be specific occasions when you may wish to prime Bionector.*

These notes were updated to incorporate the following developments:

Frequency for replacing Bionector

We recommend that Bionector should be changed every 7 days or 150 accesses whichever comes first. The independent data that supports this claim has been reviewed and validated by the MHRA.

The Medicines Healthcare Regulatory Authority (MHRA) issued a hazard warning (MDA/2005/030 & MDA/2007/051) in relation to all needle-free devices sold in the UK. The MHRA stipulate that all needle-free devices sold in the UK must be accompanied by instructions for use that pertain to both the number of activations (accesses) and the length of time that the device can remain in situ (dwell time). Bionector fulfils both of the above stipulations.

First time users of the device are advised to check the compatibility of equipment used with Bionector in accordance with the instructions for use or with current product information.

Important: Although Bionector is validated for 150 accesses, please remember that your own clinical judgement and common sense are also factors in deciding whether a particular product is in good working order. The Bionector should be included in the regular checks of all of the patient's intravenous equipment.

Latex allergies *

The membrane of Bionector has been independently tested for latex allergenicity and confirmed as non-sensitising.

The membrane is made of dry rubber and the manufacturing process of dry rubber is completely different to the process used for making products such as surgical gloves. Dry rubber is processed at temperatures which destroy the natural proteins in latex and it is these natural proteins which are the cause of immediate hypersensitivity (type 1 reaction). The Bionector contains none of the processing agents associated with delayed hypersensitivity and the Bionector has been subjected to the most stringent testing to confirm that it is non-sensitising.

An information pack is available on latex allergies and the pack includes a complete copy of the independent laboratory report.

Magnetic Resonance Imaging (M.R.I)

Bionector has been in regular use in the U.K. since January 1994 and is used regularly in many M.R.I. units. We can confirm that we have never received any report that Bionector has caused either a clinical or a mechanical problem.

Bionector is invariably attached to an extension and because the magnetic scanner looks at very small anatomical segments it can cause very localised distortion. We suggest that the Bionector is moved away by a minimum of 10cm from the area to be scanned. The Bionector may drift toward the magnetic field, in this case you may wish to tape the extension down.

Cautions and warnings

We are constantly talking to users of the Bionector and these notes reflect our knowledge at the time of writing. We have chosen to include all known reports of problems with Bionector, even when we have not been able to show that any fault lies with the product.

1 Cracking of Bionector where the cause has not been identified

There have been reports of Bionector cracking when used with seemingly compatible luer fittings on I.V. equipment including syringes, giving sets and extension lines.

These problems have also been reported with other manufacturer's devices (Anaesthesia, September 1994 Problems with the Interlink System).

Since these reports of cracking all occurred with products having standard luer connections which should be compatible with one another, it would seem prudent to prevent any mechanical stress on these connections. It is strongly recommended that undue force is not used to connect or disconnect luer fittings to the Bionector.

In the case of luer lock fittings it is important not to overtighten them and it is important not to use objects such as forceps to tighten or untighten fittings.

Follow the instructions for use on making a quarter turn of the syringe as it is introduced into the Bionector to give a good connection. Do not force the syringe into the Bionector and do not lever it or flex it while it is in position.

2 Damage to the membrane of Bionector when used with certain male luer fittings

Technically, the Bionector is compatible with all luer fittings that conform to ISO 594, parts 1 and 2, but to work effectively the Bionector needs to be used with a male luer fitting which has an internal diameter of not less than 1.7mm.

If this measurement is not respected then damage can occur to the membrane.

There may be other products which we have not come across which also have a male luer nozzle with an internal diameter of less than 1.7mm. If users are in any doubt about the suitability of a product for use with Bionector then we advise that the product should not be used until it has been established whether it has an internal diameter equal or greater than 1.7mm and Vygon are happy to check this for users if samples are made available to us.

Important: If the membrane of the Bionector is being damaged because of connection with the male fitting of another manufacturer's product, then you will need to decide whether you stop using the Bionector or whether you stop using the other manufacturer's product.

Naturally, we hope that the advantages and benefits of the Bionector will encourage you to keep the Bionector and find an alternative to the other product. Please contact us if you would like advice on alternatives to the product in question.

3 Damage to the membrane from non-concentric internal diameters

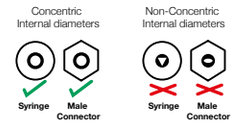
N.B. This does not refer to eccentric nozzles, only to a non-concentric internal diameter.

It is important that the Bionector should only be used with male luer nozzle fittings having a concentric internal diameter.

Use with a non-concentric internal diameter could result in damage to the membrane of the Bionector.

If users are in any doubt about the suitability of a particular product for use with Bionector then we advise that it should not be used until this matter has been verified.

Vygon will be pleased to confirm the suitability of a product for use with Bionector if samples are made available.



4 Blood products

The Bionector contains a stainless steel tube which is the approximate equivalent to a 16 gauge needle.

It is therefore suitable for the infusion of blood and blood products which your hospital would normally infuse through a 16 gauge needle, cannula or catheter.

Other than using a conventional syringe and needle, there are two other methods of blood sampling popular in the UK. They are the Sarstedt Monovette and Becton Dickinson (Vacutainer) systems. We confirm that the following adaptors are compatible with Bionector:

Sarstedt ref: 14.1205.100

5 Priming volumes

The priming volume of the Bionector is: 0.020ml.
Although this dead space is negligible from a clinical viewpoint there may be specific occasions where you wish to prime the Bionector prior to use.

The non-touch applicator makes it impossible to prime a Bionector effectively while the applicator is in place.
The recommendations are therefore to either use a female luer accessory to remove the Bionector aseptically from the applicator and then to prime it (e.g. a female/female adaptor, Vygon code 0892.00) or to use a soft-packed Bionector (0896.03) which has no non-touch applicator and which allows the Bionector to be handled prior to connection to a female luer.

* Does not apply to the latex-free Bionector range of products, which contain a polyisoprene membrane.

Re-use of this device may change its mechanical or biological features and may cause device failure, allergic recations or bacterial infections.

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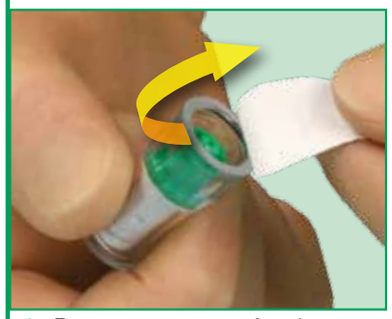
Bionector Directions for Use

PERFORMANCE
- Equivalent Gauge Size: 16G needle
- Priming Volume: 0.020ml
- Pressure Tested up to 50bar
- Back pressure tested to 1bar

Applying Bionector



1. Remove tamper-proof seal.

2. Securely lock the **Bionector** onto female luer of the device or extension line.

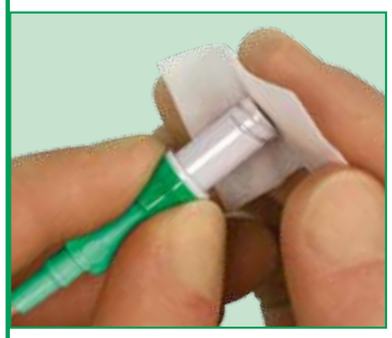
3. Remove the applicator by flexing it downwards and then upwards.

4. Withdraw the applicator to leave the **Bionector** in place.

Disinfecting Bionector

Disinfect the Bionector before and after use.

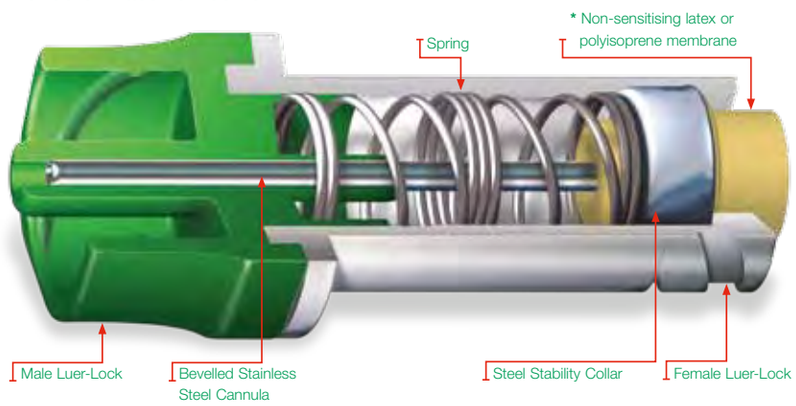
Allow a minimum of 30 seconds for the disinfection agent to dry before use. This will allow effective disinfection and provide a dry connection onto the **Bionector**.



Clean in accordance with your hospital/ department protocol.

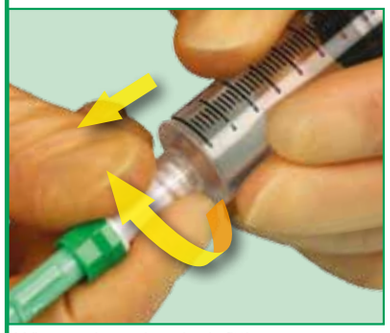
Bionector can be cleaned with most disinfecting agents including isopropol alcohol, iodinated alcohol, ethyl-alcohol 70%, Hibiscrub, Hibitane, Betadine®, 2% Chlorhexidine gluconate in 70% isopropyl alcohol, or Chloraprep®.
Do not enclose or wrap Bionector in materials or containers impregnated with disinfectants.

Bionector Passive Position

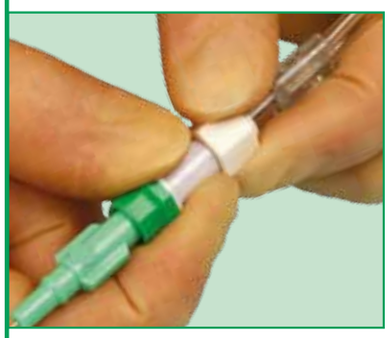


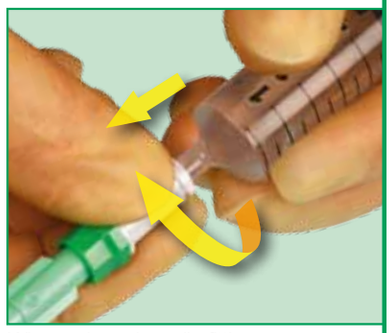
REPLACE BIONECTOR AFTER 7 DAYS OR 150 ACCESSES, WHICHEVER COMES FIRST *(SEE NOTES ON REVERSE)*.

Using Bionector with I.V. 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.

Important note on connecting/ disconnecting.
Always grip the **Bionector** firmly in one hand before using the other hand to connect or disconnect a luer fitting.

Applications

Bionector is a 7 day, or 150 accesses, closed, needle-free I.V. access system for use with all I.V. equipment e.g. syringes, giving sets, administration sets, stopcocks, extension lines, catheters and cannulae (see notes on reverse).

For use in all normal I.V. systems for:

✓**Infusions** ✓**Injections** ✓**Sampling** ✓**T.P.N.** ✓**Chemotherapy**

Bionector is lipid-compatible.

Bionector is non-sensitising in cases of latex allergy (See notes on reverse). *

Please Remember

DO NOT USE ANY NEEDLE WITH A BIONECTOR

DO NOT PUT A CAP, PLUG OR OBTURATOR OF ANY SORT ON BIONECTOR

When **Bionector** is used on the port of a ramp or a stopcock, it is recommended that the port should be in a closed position when not in use.

In the event of damage to the membrane of the **Bionector** please check the male fitting of the product being connected onto the **Bionector** (see notes on reverse).

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