

TECHNICAL FILE

Bionector

896.01

prie 19 beadatinis kamštukas (uždara beadatin sistema, antiokliuzinis, atsparus lipidams, chemoterapiniams ir kt. medikamentams, be metalini komponent (pažym ta simboliu);

Dated: 23-04-2021

1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecouen, France	Fax : + 33 (0)1 34 29 19 34 E-mail : questions@vygon.com Website : www.vygon.com
1.3	Medical Device vigilance Representative : Laurent GUILLARDEAU	Tel : +33 (0)1 39 92 65 69 Fax : +33 (0)1 39 92 64 82 E-mail : quality@vygon.com

2 Information about the device or equipment

2.1	Generic name : Needle-free access device
2.2	Commercial name : Bionector
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon

2.5 Description of the device :

Bionector is a multi-purpose, closed, needle-free, small size I.V. connection device for blood sampling, intermittent injections or continuous infusions of fluids or drugs. Bionector has a very easily disinfectable membrane (disinfection must be carried out before and after use) which closes automatically when the infusion line or the syringe is disconnected. Bionector is resistant to lipid emulsions (lipid-resistant), most cytotoxic drugs and antiseptics. This simple to use device protects both health care workers (prevents needle-stick injury, no blood reflux) and patients (closed system: reduces risk of air embolism and blood loss).

Bionector features a male Luer-lock distal fitting which means that Bionector can be connected to all devices featuring a female Luer-lock hub (IV catheter, extension tubes, infusion devices for implantable ports, ramps, stopcocks...). The proximal end of Bionector is a female Luer-lock fitting and will accept any device featuring a male Luer or male Luer-lock fitting (syringe, infusion set ...).

Bionector is a needleless connector with reverse split-septum technology and neutral displacement of volume.

Bionector is approved for use with power injectors (CT-scan).

Maximum pressure resistance : 350 psi (24 bars).

To inject contrast medium products (Visiopaque 320 mg iodine/ml), the flow rate has been measured as such :

35 psi (2.4 bars) : > 5 ml/s

145 psi (10 bars) : > 10 ml/s

Bionector code 896.01 is supplied in rigid transparent non-touch applicator.

Bionector code 896.02 is supplied in a double packaging: rigid transparent non touch applicator + a soft blister pack.

Bionector code 896.03 is supplied in a soft blister pack.

Bionector code 896.038 is supplied in a soft blister pack and the male cone of the device is protected by a cap.

Clean in accordance with your hospital/department protocol. Bionector can be cleaned with most disinfecting agents (eg 70% alcohol). Avoid antiseptics containing both alcohol and hydrogen peroxide.



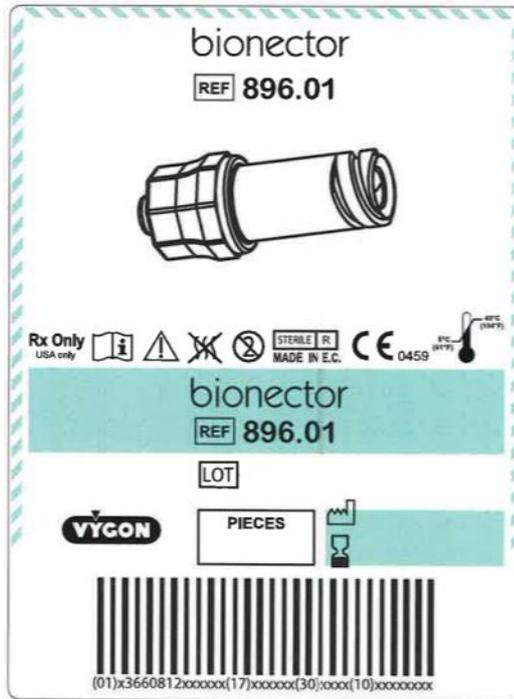
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
896.01	1 (Rigid protective non-touch applicator (PC))	50 (Carton box)	50 (Carton box)	1600 (Case box)

Single unit packaging



Box

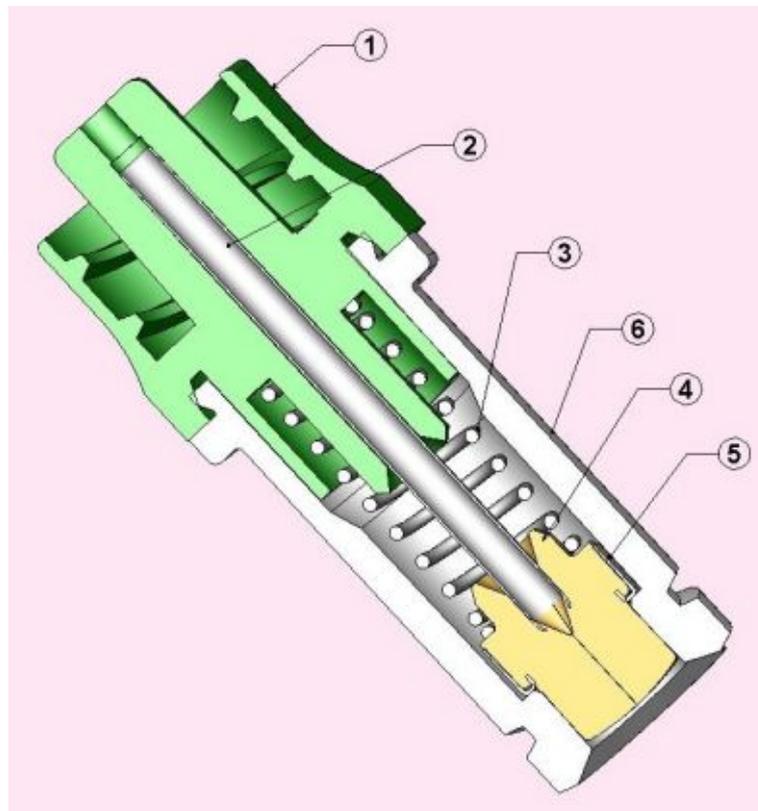


Technical features :

Code	Bionector					
	Flow rate ml/min	Priming volume ml	Number of accesses -	Max. duration of use -	Length mm	Diameter mm
896.01	105	0.03	360	7 days	25.7	10

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Male Luer-lock	1	PC
Tube	2	Stainless steel
Spring	3	Stainless steel
Membrane	4	Polyisoprene
Ring	5	Stainless steel
Body of Bionector	6	PC
Cap (code 896.038)		PE



For components which are likely to come into contact with the patient and/or administered products, additional points :

- Latex-free
- DEHP-free
- Does not contain any products of animal or biological origin
- Pyrogen-free

2.8 Indications :

Needle-free connector for I.V infusions. Bionector is connected directly to IV catheters or to IV extension tubes, stopcocks, ramps of stopcocks etc. It allows blood samplings, intermittent injections or continuous infusions of fluids or drugs maintaining constantly a closed IV system.

4 Sterilization process

	<p>Sterile Medical Device : YES Sterilization made for the device : Radiosterilization</p>
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5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	<p>Special precautions : Please refer to the IFU in the packaging.</p>
5.3	<p>Duration of product validity : 36 months</p>

6 Security of use

	<p>Technical security : Duration of use: 7 days or 360 connections whatever comes first. Please refer to the IFU in the packaging.</p>
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7 Instructions for use

7.1	<p>Instructions : Please refer to the IFU in the packaging.</p>
7.2	<p>Indications : Needle-free connector for I.V infusions. Bionector is connected directly to IV catheters or to IV extension tubes, stopcocks, ramps of stopcocks etc. It allows blood samplings, intermittent injections or continuous infusions of fluids or drugs maintaining constantly a closed IV system.</p>
7.3	<p>Precautions : Please refer to the IFU in the packaging. Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
7.4	

8 Additional information relating to the product