

TECHNICAL FILE

Bulb syringe for irrigation and aspiration


451.00

Dated : 13-11-2023

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

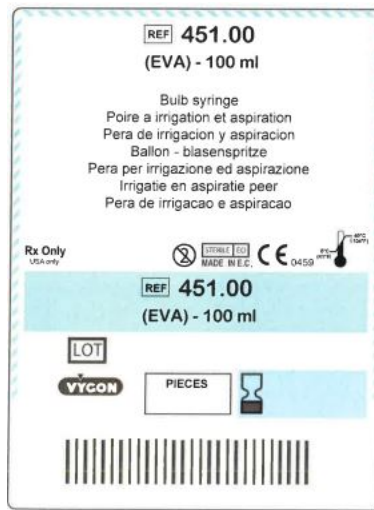
2 Information about the device or equipment

2.1					
2.2	Commercial name : Bulb syringe for irrigation and aspiration				
2.4	Medical Device Class : I Applicable regulation : 93/42/CEE in accordance with Appendix n° : Vs Notified body N° : 0459 Medical Device Manufacturer : Vygon				
2.5	Description of the device : The irrigation and suction bulb syringe, made of ethylene vinyl acetate (EVA), is graduated from 5 to 100mL in order to determine the quantity of solution to be injected and/or urine removed. It is provided with a polyethylene protective cap (plastic spigot 478.00). This accessory is intended to be connected to the proximal end of vesical catheters from size 10 to 24 Fr. It is not intended to remain in place. It is removed immediately after the procedure for which it was used.				
					
2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	451.00	1 (Rigid blister in APET)	30 (Carton box)	30 (Carton box)	30 (Case)

Single unit packaging



Box



2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Bulb syringe	1	EVA
Protector	2	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

<p>2.8</p>	<p>Indications : This device combined with a vesical catheter is used in case of: Urinary drainage: In case of incontinence or chronic urinary retention Preventive drainage: before, during or after surgery Bladder lavage Injection of contrast products to perform an examination of the bladder or urethra Urine sampling for analysis for diagnostic purposes</p>
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3 Accessories

4 Sterilization process

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

<p>5.1</p>	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
<p>5.2</p>	
<p>5.3</p>	<p>Duration of product validity : 60 months</p>

6 Security of use

7 Instructions for use

<p>7.1</p>	
<p>7.2</p>	<p>Indications : This device combined with a vesical catheter is used in case of: Urinary drainage: In case of incontinence or chronic urinary retention Preventive drainage: before, during or after surgery Bladder lavage Injection of contrast products to perform an examination of the bladder or urethra Urine sampling for analysis for diagnostic purposes</p>
<p>7.3</p>	<p>Precautions : Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
<p>7.4</p>	



Value Life

8 Additional information relating to the product