

TECHNICAL FILE

Thoracic trocar drain - 28 cm

636.28

Dated : 03-01-2022

1		Administrative information relating to the company		
	1.1	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 : Thoracic trocar drain - 28 cm	
2.4	Medical Device Class : Ila 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 : The thoracic trocar drain code 636 is made of: - a transparent PVC drain with radiopaque line - length 28cm, 2 lateral eyes and markings at 5, 10 and 15 cm from the tip, - a stainless steel trocar with handle, - a fixation disc, - a protector present at the distal end of the drain, to withdraw before starting the procedure. 14Fr (code 636.14), 18Fr (code 636.18), 20Fr (code 636.20), 24Fr (code 636.24), 28Fr (code 636.28) and 30Fr (code 636.30). 	

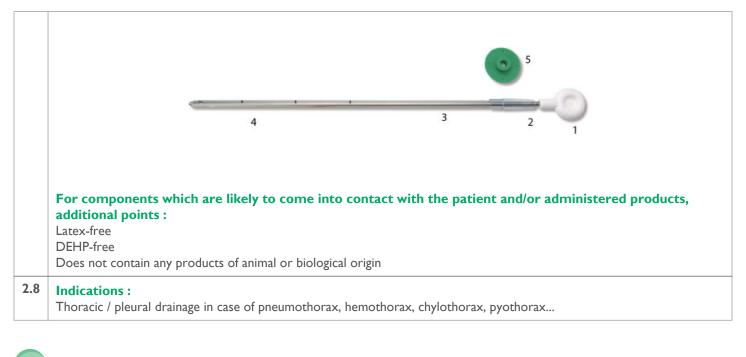


2.6	Packaging / Contai					
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case	
	636.28	1 (Dble pack: internal PE bag + peelpack)	10 (Carton box)	10 (Carton box)	90 (Case)	
	Single unit packaging					
	735624020	Vigeon Value Life	Drenaje trocar torácio Drenaggio trequarti to Dreno trocarte torácio	Ø 9.0mm - 28Fr - L.28cm Of drain / Drain trocart thoracique co / Thoracale trocart drain oracico / Thoraxdrainage - Trokark co / Thoraxdrän av typen troakar	Code ACL 7161858	



		Вох		
		REF 636.28 Ø 9.0mm - 28Fr - L.28cm ORX / XRO / RXC - PVC Thoracic trocar and drain Drain trocart thoracique Drenaje trocar torácico Thoracale trocart drain Drenaggio trequarti toracico Thoraxdrainage - Trokarkatheter Dreno trocarte torácico Thoraxdrain av typen troakar		
		REF 636.28 Ø 9.0mm - 28Fr - L.28cm LOT XXXXXXXX VYCON PIECES W XXXX X VYCON PIECES W XXXX X (01)x3660812xxxxx(17)xxxxxx(30)xxxx(10)xxxxxxxx)		
	Technical features :			
	Code Thoracic		racic drain	
		Length cm	Diameter Fr	
	636.28	28	28	
2.7	Composition of the device and Accessories :			
	COMPONENTS	MARKER	MATERIALS	
	Handle	1	ABS	
	Proximal connector	2	MABS	
	Trocar	3	Stainless steel	
	Drain	4	PVC	
	Distal protector		PVC	
	Fixation collar	6	SEBS	





Accessories

Sterilization process

Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide

Conditions of conservation and storage

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

Security of use

Technical security : Technical safety: EN 1617

7	Instructions for use
7.1	
7.2	Indications : Thoracic / Pleural Drainage



7.3	Precautions :		
	Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.		
7.4			

8 Additional information relating to the pr	roduct
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