

TECHNICAL FILE

Thoracic trocar drain - 28 cm

636.28

Dated : 03-01-2022

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 : Thoracic trocar drain - 28 cm
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 : 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 / Containers

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



705624030



Value Life





VYGON
5 rue Adeline
95440 Ecoeu - FRANCE

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 / Thoraxdrän av typen troakar

Code ACL 7161858




Rx Only
USA only

STERILE EO
MADE IN E.C.



0459

Box



Technical features :

Code	Thoracic 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



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

2.8 Indications :
Thoracic / pleural drainage in case of pneumothorax, hemothorax, chylothorax, pyothorax...

3 Accessories

4 Sterilization process

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

5 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

6 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 product