

TECHNICAL FILE

PICC Grip-Lok

5804.10

Dated : 19-10-2018

12.

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 : PICC Grip-Lok
2.4	Medical Device Class : I Applicable EU Directive : 93/42/CEE in accordance with Appendix n° : V Notified body N° : 0459 Medical Device Manufacturer : VYGON
2.5	Description of the device : Fixation device for adult and paediatric PICC catheters (peripherally inserted central catheters). Grip-Lok ensures an efficient catheter fixation to prevent accidental removal of the catheter or catheter migration. Grip-Lok is a latex-free device supplied sterile in a peel-pack. Code 5804.04 : Grip-Lok for adult PICC catheter fixation - Dimensions : 9 cm x 3.5 cm Code 5804.08 : Grip-Lok for paediatric PICC catheter fixation - Dimensions : 4.2 cm x 1.8 cm Code 5804.09 : Grip-Lok for various type of PICC catheters fixation - Dimensions : 9 cm x 3.4 cm Code 5804.10 : Grip-Lok for Maxflo PICC catheter fixation Grip Lok is available in others models to allow the fixation of feeding tubes, drains and others tubes. See corresponding techical files : 5804.11, 5804.12, 5804.13, 5804.14, 5804.15, 5804.16, 5804.17 and 5804.21.



2.6 Packaging / Containers


Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
5804.10	1 (Peel-pack)	50 (Carton box)	50 (Carton box)	500 (Case box)

Single unit packaging

REF 5804.10	MaxFlo PICC fixation Fixation de cathéter MaxFlo PICC MaxFlo PICC fijación MaxFlo PICC Fixierung Fissaggio per MaxFlo PICC MaxFlo PICC Katheterbevestigingshulpmiddel Fixação de PICC MaxFlo MaxFlo PICC-fixering	Grip-Lok®	
     	LOT 12345678 2020-08-05	Rx Only USA Only STERILE R	Value Life 
Manufactured by:  VYGON 5 rue Adeline 95440 Écouen France		STERILE R	Grip-Lok is a registered trademark of TIDI Products, LLC PATENT# 8,500,698

Box

REF 5804.10



(01)33660812086449(17)200825(30)50(10)12345678

MaxFlo PICC fixation
 Fixation de cathéter MaxFlo PICC
 MaxFlo PICC fijación
 MaxFlo PICC Fixierung
 Fissaggio per MaxFlo PICC
 MaxFlo PICC Katheterbevestigingsmiddel
 Fixação de PICC MaxFlo
 MaxFlo PICC – fixering

Grip--Lok is a registered trademark of TIDI Products, LLC
 Manufactured by:
VYCON
 5 rue Adelin, 95440 Écouen France

VYCON
 Value Life
 Grip-Lok®

5°C (41°F) 40°C (104°F)

STERILE R
 Rx Only USA Only
 LOT 12345678
 2020-08-25
 PIECES 50
 CE 0459

2.7 Composition of the device and Accessories : 5804.10

COMPONENTS	MARKER	MATERIALS
Base for adhesive	1	PU + Polyester
Adhesive	1	Acrylic
Velcro	2	PP



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 :

Fixation device for PICC catheters

3 Accessories

4 Sterilization process

	Sterile Medical Device : YES Sterilization made for the device : Radiosterilization
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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	Special precautions : Please refer to the IFU in the packaging.
5.3	Duration of product validity : 60 months

6 Security of use

	Technical security : Please refer to the IFU in the packaging.
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7 Instructions for use

7.1	Instructions : Please refer to the IFU in the packaging.
7.2	Indications : Fixation device for PICC catheters
7.3	Precautions : Please refer to the IFU in the packaging.
7.4	Contra indications : Please refer to the IFU in the packaging.

8 Additional information relating to the product