

## TECHNICAL FILE

PICC Grip-Lok

5804.10

Dated : 19-10-2018

12.

### 1 Administrative information relating to the company

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

### 2 Information about the device or equipment

|     |   |
|-----|---|
| 2.1 |   |
| 2.2 | <b>Commercial name :</b> PICC Grip-Lok  |
| 2.4 | <b>Medical Device Class :</b> I<br><b>Applicable EU Directive :</b> 93/42/CEE<br><b>in accordance with Appendix n° :</b> V<br><b>Notified body N° :</b> 0459<br><b>Medical Device Manufacturer :</b> VYGON  |
| 2.5 | <b>Description of the device :</b><br>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.<br>Grip-Lok is a latex-free device supplied sterile in a peel-pack.<br><br>Code 5804.04 : Grip-Lok for adult PICC catheter fixation - Dimensions : 9 cm x 3.5 cm<br>Code 5804.08 : Grip-Lok for paediatric PICC catheter fixation - Dimensions : 4.2 cm x 1.8 cm<br>Code 5804.09 : Grip-Lok for various type of PICC catheters fixation - Dimensions : 9 cm x 3.4 cm<br>Code 5804.10 : Grip-Lok for Maxflo PICC catheter fixation<br><br>Grip Lok is available in others models to allow the fixation of feeding tubes, drains and others tubes. See corresponding technical 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** **Grip-Lok®** **VYCON**  
Value Life

MaxFlo PICC fixation **LOT** 12345678

Fixation de cathéter MaxFlo PICC **2020-08-05**

MaxFlo PICC fijación

MaxFlo PICC Fixierung

Fissaggio per MaxFlo PICC

MaxFlo PICC Katheterbevestigingshulpmiddel

Fixação de PICC MaxFlo

MaxFlo PICC-fixering

**Rx Only**  
USA Only

**STERILE R**

**CE 0459**

**5°C (41°F)** **40°C (104°F)**

Grip-Lok is a registered trademark of TIDI Products, LLC  
PATENT# 6,500,698

Manufactured by:  
**VYCON 5 rue Adeline 95440 Écouen France**

**Box**

**REF 5804.10**

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

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Manufactured by:  
**VYGON**  
 5 rue Adelin... 95448 Écouen France



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

STERILE R

Rx Only  
USA Only

LOT 12345678

2020-08-25

PIECES 50

CE 0459

5°C (41°F) 40°C (104°F)

**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

|  |   |
|--|---|
|  | <p><b>Sterile Medical Device :</b> YES<br/> <b>Sterilization made for the device :</b> Radiosterilization</p> |
|--|---|

## 5 Conditions of conservation and storage

|     |  |
|-----|--|
| 5.1 | <p><b>Normal conservation and storage conditions :</b><br/>         Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p> |
| 5.2 | <p><b>Special precautions :</b><br/>         Please refer to the IFU in the packaging.</p>   |
| 5.3 | <p><b>Duration of product validity :</b> 60 months</p>   |

## 6 Security of use

|  |   |
|--|---|
|  | <p><b>Technical security :</b><br/>         Please refer to the IFU in the packaging.</p> |
|--|---|

## 7 Instructions for use

|     |   |
|-----|---|
| 7.1 | <p><b>Instructions :</b><br/>         Please refer to the IFU in the packaging.</p>       |
| 7.2 | <p><b>Indications :</b><br/>         Fixation device for PICC catheters</p>               |
| 7.3 | <p><b>Precautions :</b><br/>         Please refer to the IFU in the packaging.</p>        |
| 7.4 | <p><b>Contra indications :</b><br/>         Please refer to the IFU in the packaging.</p> |

## 8 Additional information relating to the product