

## TECHNICAL FILE

PICC Grip-Lok

5804.08

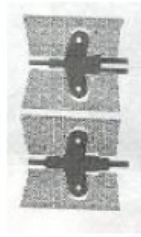
Dated : 05-04-2016

### 1 Administrative information relating to the company

1.1	<b>Name :</b> Vygon	
1.2	<b>Address :</b> 5 rue Adeline - 95440 Ecouen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
1.3	<b>Medical Device vigilance Representative :</b> Laurent GUILLARDEAU	<b>Tel :</b> +33 (0)1 39 92 65 69 <b>Fax :</b> +33 (0)1 39 92 64 82 <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 <b>Applicable EU Directive :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> V <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> VYGON
2.5	<b>Description of the device :</b> 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 3.8 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 technical files : 5804.11, 5804.12, 5804.13, 5804.14, 5804.15, 5804.16, 5804.17 and 5804.21.



Code 5804.04



Code 5804.08



Code 5804.09




Code 5804.10

**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
5804.08	1 (Peel-pack)	20 (Carton box)	20 (Carton box)	480 (Case)



**Single unit packaging**



**REF 5804.08**




(01)53660812077502(17)200831(30)480(10)12345678

**Paediatric PICC fixation device**  
**Système de fixation de cathéter PICC pédiatrique**  
**Dispositivo de fijación para PICC pediátrico**  
**Fixierpflaster für pädiatrische Katheter**  
**Dispositivo di fissaggio per PICC pediatrico**  
**Pediatrische katheter fixatie systeem**  
**Dispositivo de fixação de catéter PICC pediátrico**  
**Fästsystem för pediatrik PICC kateter**

**STERILE R**  

  **Rx Only**  
USA Only

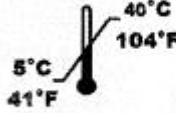
**LOT 12345678**


 **2020-08-31**

**Grip-Lok** is a registered trademark of TIDI Products, LLC

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

**VYCON**  
 Value Life  
**Grip-Lok®**

  
 5°C / 41°F to 40°C / 104°F

**PIECES 24 X 20**  **E0459**


**Box**

**REF 5804.08**

Paediatric PICC fixation device  
Système de fixation de cathéter PICC pédiatrique  
Dispositivo de fijación para PICC pediátrico  
Fixierplaster für pädiatrische Katheter  
Dispositivo di fissaggio per PICC pediatrico  
Pediatriische katheter fixatie systeem  
Dispositivo de fixação de catéter PICC pediátrico  
Fastsystem för pediatriisk PICC kateter

Grip-Lok is a registered trademark of TIDI Products, LLC

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



(01)33660812677502(17)200825(30)20(10)12345678

STERILE R

APPLY HERE

LOT: 12345678

2020-08-25

5°C (41°F) 40°C (104°F)

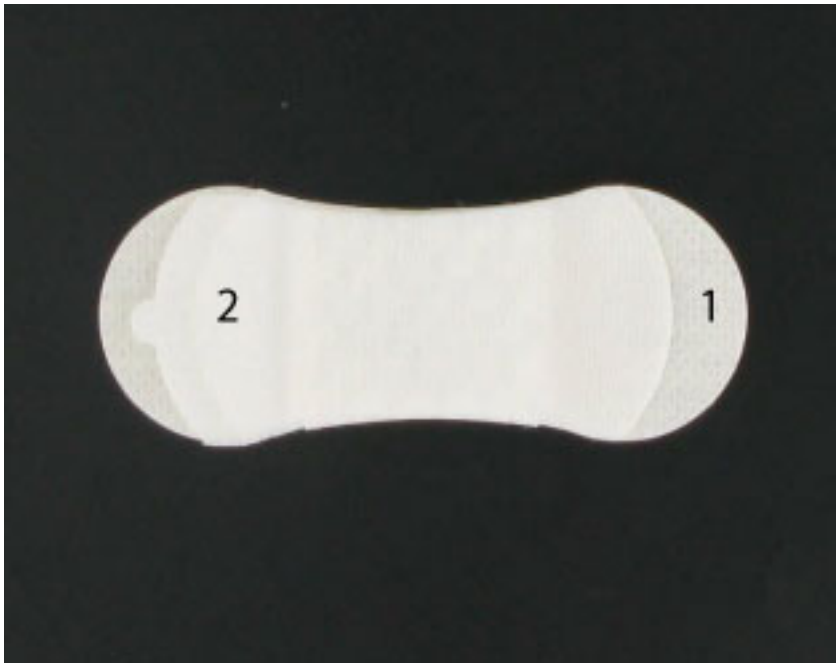
PIECES 20

CE 0459

Rx Only USA Only

**2.7 Composition of the device and Accessories : 5804.08**

COMPONENTS	MARKER	MATERIALS
Skin adhesive	1	PU + Polyester



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

#### 6 Security of use

#### 7 Instructions for use

7.1	
7.2	<p><b>Indications</b> :          Fixation device for PICC catheters</p>
7.3	
7.4	

#### 8 Additional information relating to the product