

## TECHNICAL FILE

Maxflo Expert PICC (with stylet and guidewire of 67 cm)

8394.414

Dated : 26-11-2018

10.

### 1 Administrative information relating to the company

1.1	<b>Name :</b> Vygon SA	
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> Maxflo Expert PICC (with stylet and guidewire of 67 cm)
2.4	<b>Medical Device Class :</b> III <b>Applicable EU Directive :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II.4 <b>Notified body N° :</b> 0481 <b>Medical Device Manufacturer :</b> Vygon

## 2.5 Description of the device :

The Maxflo is a radiopaque peripherally inserted central catheter designed for medium and long-term therapy which can also be used for CT-rated injections of contrast media. Pressure resistance 325 psi / 22.4 bar.

Maxflo Expert is made of biostable polyurethane which allows a long-term use of the catheter (several months if necessary). It is supplied with a stylet to facilitate its insertion.

Maxflo is a PICC cathéter type (PICC : peripherally inserted central catheter) in polyurethane.

Other features of the product:

- Length of catheter 55 cm
- Radiopaque
- Antimicrobial (Antimicrobial agent : Agion technology made of silver ions)
- Centimetric graduations and numerical markings
- 1, 2 or 3 lumen
- Stylet
- Introducer Micro-Seldinger type with safety puncture needle (21G)

Maxflo Expert can be used for parenteral nutrition, chemotherapy, antibiotherapy, pain treatment, administration of drugs etc... and is suitable for use with power injectors (CT scan).

Maxflo Expert is supplied in a rigid blister pack (double packaging) containing:

- 1 antimicrobial catheter, winged hub and integral extension tube (length 9 cm) with Roberts clamp with a printed inlay with on one side "maximum flow rate" and on the other side "325 psi"
- 1 stylet to make the catheter more rigid and thus facilitate its insertion
- 1 "T" proximal connector. The lateral port of the T connector allows the injection of saline solution (with a syringe) to lubricate the stylet and facilitate its sliding on removal or to inject saline solution in case of venous spasm, to open the path
- 1 echogenic puncture needle of small diameter 21G with safety features to avoid the risk of needle-stick injury
- 1 Nitinol guidewire with golden tungsten flexible tip and guide advancer, Ø 0.46 mm, length 67 cm
- 1 peel-away Desilet length 7 cm MST type (Micro-Seldinger Technique)
- 1 safety scalpel
- 1 Bionector (2 Bionector for double lumen Maxflo, 3 Bionector for triple lumen Maxflo)
- 1 syringe 10 ml
- 1 tape measure
- 1 Grip-Lok stabilization device (available in sterile individual packaging code 5804.10)

Other types of kits are available :

- Maxflo " Nurse kit" with a guidewire of 50 cm : see technical file code 8394.105/14/15/16/206/25/36.
- Maxflo "Radiology kit - Over the wire" with a guidewire of 137 cm, without stylet, see technical file code 8394.505/506/514/515/525/526/536.



## 2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
8394.414	1 (Double packaging : peel-pack + rigid blister)	10 (Carton box )	10 (Carton box )	10 (Carton box )

## Single unit packaging

maxfloexpert

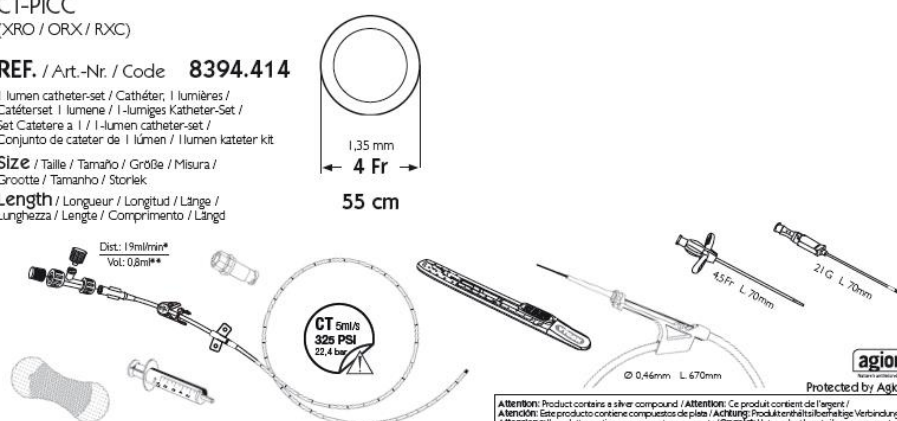
CT-PICC  
(XRO / ORX / RXC)

REF. / Art.-Nr. / Code 8394.414

l lumen catheter-set / Cathéter; l lumières /  
Catéterset l lumene / l-lumiges Katheter-Set /  
Set Catetere a l / l-lumen catheter-set /  
Conjunto de cateter de l lúmen / l lumen kateter kit

**Size** / Taille / Tamaño / Größe / Misura /  
Grootte / Tamanho / Storlek

**Length** / Longueur / Longitud / Länge /  
Lunghezza / Lengte / Comprimento / Längd



\* Flow Rate, Débit, Flujo, Flussrate, Flusso, Flow Débito, Rôdestardtshet (0,1 bar)

\*\* Primite Volume, Volume mort, Volumen muerto, Totumvolumen, Volume di riempimento, Dode ruimte, Volume de preenchimento, Pílnipivolum.

\* How fast, Loose, Fast, Huzza, Huzza, How Loose, Hossanahgah (all car)      \* Pruning, Volume, Volume more, Volume many, Volume a, Volume, Loose Volume, Volume so, Pruning Volume, Volume many

Symbole/Symbole ISO 31000 / ISO 1582





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4C19190006 / Stand 2017-01

CE0481 Made in Germany

1L - 4Fr - 55cm

maxfloexpert  
CTPICC

<div> <div>Box</div> <div>maxfloexpert</div> <div>REF 8394.414</div> <div>CT-PICC 4Fr 1L 55cm</div> <div> 1 lumen catheter set (Interventional PICC)/Cathéter,  1 lumières (PICC interventionnel)/Catéterset 1 lumene (PICC  intervencionista)/1-lumiges Katheter-Set (interventioneller  PICC)/Set Catetere a 1 (PICC intervencionista)/1-lumen  katheter-set (Interventionele PICC)/Conjunto de cateter de  1 lumen (PICC intervenção)/1lumen kateter kit  (Interventionell PICC)  Guidewire/Guide/Guia/Führungsdraht/Guida/Voerdraad/  Guia/Ledare: 670mm </div> <div> Rx Only  <div>STERILE EO  CE 0481</div> </div> <div>maxfloexpert</div> <div>REF 8394.414</div> <div>LOT 111116GA</div> <div>10  2019-12-31</div> <div>   (01) 53660812076062 (17) 191231 (30) 10 (10) 111116GA </div> </div>																																															
<div>Technical features :</div> <table> <tr> <th>Code</th><th colspan="9">Catheter</th><th colspan="2">Guidewire</th></tr> <tr> <th></th><th>Lumen -</th><th>Ø Fr</th><th>Ext. Ø mm</th><th>Length cm</th><th>Flow rate ml/min</th><th>Prim. vol. ml</th><th>Max. flow rate ml/s</th><th>Max. pressure bar</th><th>Proximal end -</th><th>Ø mm</th><th>Length cm</th></tr> <tr> <td>8394.414</td><td>1</td><td>4</td><td>1.35</td><td>55</td><td>19</td><td>0.8</td><td>5</td><td>22.4</td><td>Tapered</td><td>0.46</td><td>67</td></tr> </table>												Code	Catheter									Guidewire			Lumen -	Ø Fr	Ext. Ø mm	Length cm	Flow rate ml/min	Prim. vol. ml	Max. flow rate ml/s	Max. pressure bar	Proximal end -	Ø mm	Length cm	8394.414	1	4	1.35	55	19	0.8	5	22.4	Tapered	0.46	67
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**2.7 Composition of the device and Accessories : 8394.414**

COMPONENTS	MARKER	MATERIALS
Hub / stylet	1	POM / Stainless steel
Proximal T connector	2	PC
Hub	3	PA
Extension tube	4	PU
Clamp	5	PC
Fixation wings	6	PU
Catheter	7	PU
Guidewire / guide advancer	8	PP / PE / Nitinol
Bionector	9	Stain. steel/PC/polyisoprene
Cap	10	PP
Grip-Lok	11	PU / Polyester / acrylix / PP
Safety scalpel	12	Stainless steel / ABS/ PP
Syringe	13	PP/SI
Puncture needle	14	MABS/Stainless steel/PES/PE
Desilet	15	PP/PTFE/PE



**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

Pyrogen-free

2.8	<p><b>Indications :</b> Medium and long-term IV therapy at home or in the hospital (parenteral nutrition, chemotherapy, antibiotherapy, pain treatment ...).</p> <p>CT-rated injection of contrast media.</p>
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### 3 Accessories

### 4 Sterilization process

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

### 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> 36 months</p>

### 6 Security of use

### 7 Instructions for use

7.1	
7.2	<p><b>Indications :</b> Medium and long-term IV therapy at home or in the hospital (parenteral nutrition, chemotherapy, antibiotherapy, pain treatment ...).</p> <p>CT-rated injection of contrast media.</p>
7.3	<p><b>Precautions :</b> Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
7.4	

### 8 Additional information relating to the product