

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

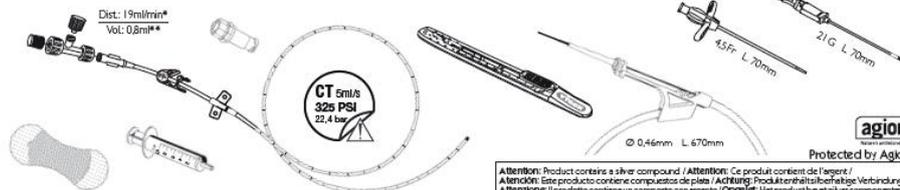
CT-PICC
(XRO / ORX / RXC)

REF. / Art.-Nr. / Code **8394.414**

1 lumen catheter-set / Cathéter, 1 lumière /
Catheterset 1 lumen / 1-lumiges Katheter-Set /
Set Catetere a 1 / 1-lumen catheter-set /
Conjunto de cateter de 1 lumen / 1lumen kateter kit

SIZE / Taille / Tamaño / Größe / Misura /
Grootte / Tamanho / Storlek

Length / Longueur / Longitud / Länge /
Lunghzza / Lengte / Comprimento / Längd



Attention: Product contains a silver compound / Attention: Ce produit contient de l'argent /
Atención: Este producto contiene compuestos de plata / Achtung: Produkt enthält silberhaltige Verbindung /
Attenzione: Il prodotto contiene un composto con argento / Opgelet: Het product bevat zilver componenten /
Atenção: O produto contém um composto de prata / OBS: Produtoen inneholder en silverforing

* Flow Rate: Débit, Flujo, Riserata, Flusso, Flow Dobbels, Flöskastighet (0,1 bar) ** Priming Volume, Volume mort, Volumen muerto, Totraumvolumen, Volume di riempimento, Dosis rullmål, Volume de preenchimento, Fyllningsvolum
Pack contents may vary / Représentation non contractuelle / Représentazione non contrattuale / Abbildungen nicht verbindlich / Représentazione non contrattuale / Niet-bindende afbeelding / O conteúdo da embalagem pode variar / Põrpuhtingimused ei ole garantiid
VYRON GmbH & Co. KG Prager Ring 100 Tel.: +49(241)9130-0 info@vyron.de 4219190036 / Stand 2017-01 CE 0481 Made in Germany

1L - 4Fr - 55cm
maxfloexpert
CT-PICC
VYRON

Box

maxfloexpert
REF 8394.414
CT-PICC 4Fr 1L 55cm

1 lumen catheter set (Interventional PICC)/Cathéter,
1 lumière (PICC interventionnelle)/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

Rx Only  **STERILE EO**  **CE 0481**

maxfloexpert
REF 8394.414
LOT 111116GA

10  2019-12-31



(01)53660812076062 (17)191231 (30)10 (10)111116GA

Technical features :

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

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>Indications : 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

	<p>Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide</p>
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5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	
5.3	<p>Duration of product validity : 36 months</p>

6 Security of use

7 Instructions for use

7.1	
7.2	<p>Indications : 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>Precautions : 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