

TECHNICAL FILE

Impregnated surgical brush 902.00

Dated: 06-01-2021

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	
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Information about the device or equipment

2.1 Commercial name: Impregnated surgical brush
2.4 Medical Device Class: NA*
2.5 Description of the device: Impregnated surgical brush supplied with nail cleaner. The sponge is impregnated with a disinfectant obtained from a concentrated solution of Chlorhexidine gluconate (finale concentration of chlorhexidine: 4 %).





2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	902.00	1 (Rigid blister)	25 (Carton box)	25 (Carton box)	200 (Case box)
			Single unit packagin	18	
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			REF 902.00 LOT XXXXXXXX PIECES	XXX XX XX XXX XX XX	



2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Sponge	1	PU
Brisltes	2	PE
Body of brush	3	PE
Nail cleaner	4	PC



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:

Impregnated surgical brush

3 Accessories

4 Sterilization process

Sterile Medical Device: NO

Sterilization made for the device: Non sterile

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



5.3 Duration of product validity: 24 months	
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- 6 Security of use
- Instructions for use

7.1	
7.2	Indications: Impregnated surgical brush
7.3	
7.4	

8 Additional information relating to the product

 $\ensuremath{^{*}}$ This product is not considered as a medical device.