

TECHNICAL FILE
Impregnated surgical brush
902.00

Dated : 06-01-2021

1 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
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 : 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 %).
	

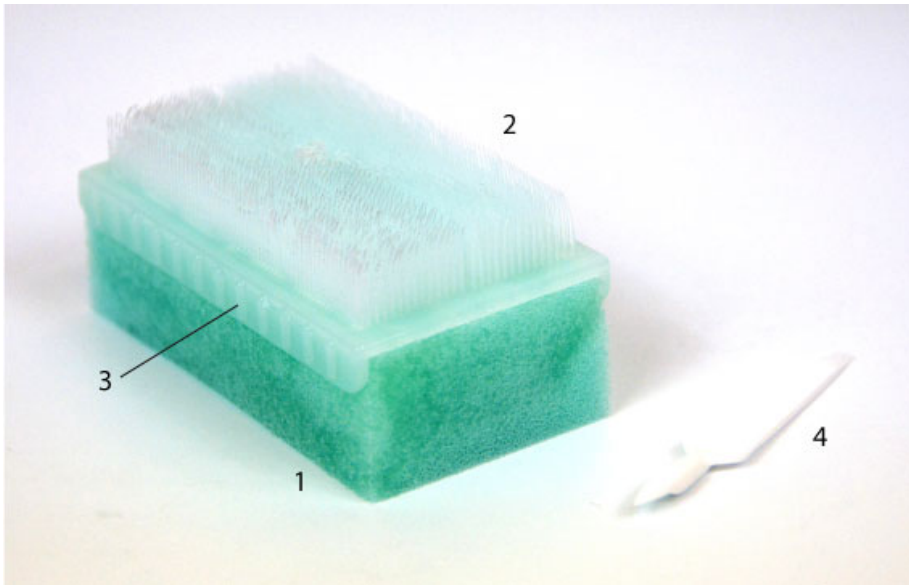
2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	902.00	1 (Rigid blister)	25 (Carton box)	25 (Carton box)	200 (Case box)

Single unit packaging



Box



2.7	Composition of the device and Accessories :		
	COMPONENTS	MARKER	MATERIALS
	Sponge	1	PU
	Bristles	2	PE
	Body of brush	3	PE
	Nail cleaner	4	PC
 <p>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</p>			
2.8	Indications : Impregnated surgical brush		

3 Accessories

4 Sterilization process

	Sterile Medical Device : NO Sterilization made for the device : Non sterile
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5 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

7 Instructions for use

7.1	
7.2	Indications : Impregnated surgical brush
7.3	
7.4	

8 Additional information relating to the product

	* This product is not considered as a medical device.
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