

TECHNICAL FILE

Impregnated surgical brush

901.00

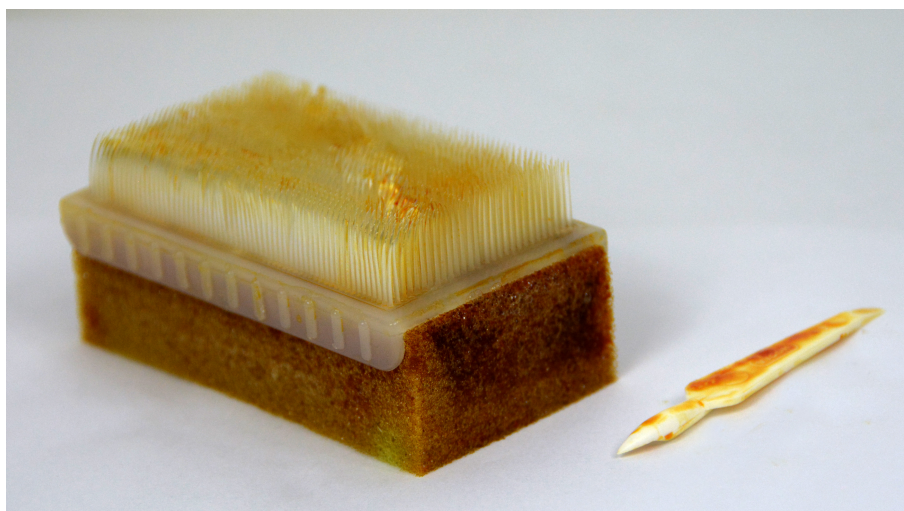
Dated : 06-01-2021

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 Povidone-iodine (finale concentration of pure iodine : 1.25 %).



2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	901.00	1 (Rigid blister)	25 (Carton box)	25 (Carton box)	200 (Case box)

Single unit packaging

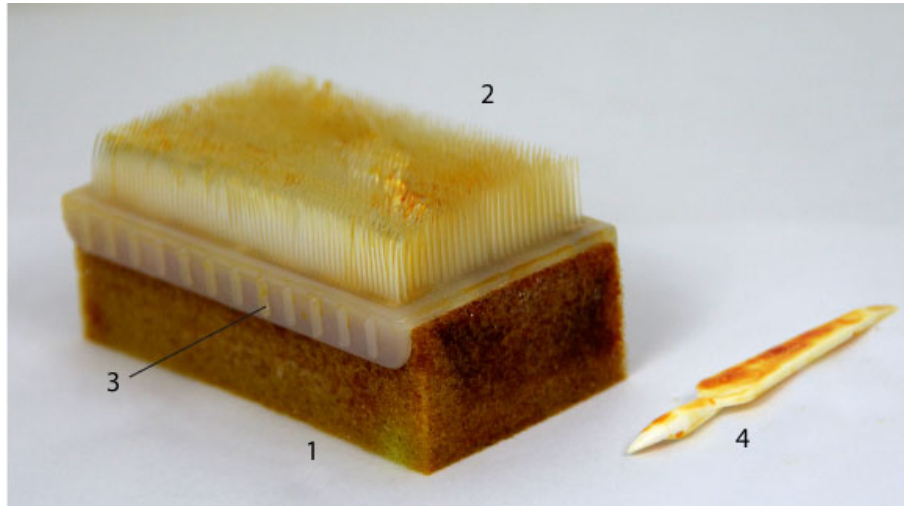


Box



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



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 :**
Surgical hand washing

3 Accessories

4 Sterilization process

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

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

6 Security of use

7 Instructions for use

- 7.1**

7.2	Indications : Surgical hand washing
7.3	
7.4	

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Additional information relating to the product

	* This product is not considered as a medical device.
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