

## Swann-Morton sterile disposable scalpel



Blade number - Item number			
N°6 - Ref. 0516	N°9 - Ref. 0517	N°10 - Ref. 0501	N°10A - Ref. 0502
N°11 - Ref. 0503	N°11P - Réf. 0591	N°12 - Ref. 0504	N°14 - Ref. 0519
N°15 - Ref. 0505	N°15A - Ref. 0520	N°15C - Réf. 0521	N°15T - Ref. 0592
N°16 - Ref. 0522	N°18 - Ref. 0523	N°19 - Ref. 0524	N°20 - Ref. 0506
N°21 - Ref. 0507	N°22 - Ref. 0508	N°22A - Ref. 0509	N°23 - Ref. 0510
N°24 - Ref. 0511	N°25 - Ref. 0512	N°25A - Réf. 0515	N°26 - Réf. 0513
N°27 - Ref. 0514			
N°E11- Réf. 0525	N°12D- Réf. 0518		

Product	Sterile disposable scalpel with stainless steel fixed blade		
Sales unit	Box of 10 units		
Factory packaging	Transit box of 158 boxes (1580 units)		
Sterilization	Radiation from Cobalt 60 at a minimum of 25kGy operated by Swann-Morton Services Ltd, Owlerton Green, Sheffield S6 2BJ Great Britain.		
Material	Stainless steel blade SF100 – Surgical quality - Blade width of 0.394 mm - Compliant with BS EN ISO 7153-1:2016 <u>Steel composition</u> Carbon : 0,60% - 0,70%      Chrome : 12,0% - 13,5% Silicium : 0,50% max.      Sulphur : 0,025% max.      Manganese : 1,00% max. Phosphoru 0,03% max.      Nickel : 0,50% max. Molded handle : MIPS Polystyrene 427 D - face side graduated, back side CE marking		
Packaging composition	Box :	White laminate cardboard (550µ) – Product characteristics and visual clearly visible.	
	Individual :	Sterile molded tray with a holding pin - Transparent and thermoformable APET 250 ou DPET 250 microns. Cover film : laminated polymer of 12 microns on special low-density polyethylene peelable of 50 microns	
Safety	When the sealing of the package is broken, it whitens. The scalpel is presented in a flared tray, allowing a safety handling. Product delivered without protective guard according to the European Directive 2010/32/EU. Medical device reserved for medical staff		
Directive	Class IIa - Directive MDR 2017/745 - Certificate (EU) MDR 721051 R000 – Conformity EU - Declared at ANSM since 18 July 2013		
Standards	Materials standards : BS2982 - Standard BS EN ISO 7153-1:2016 « Surgical instruments – Steel materials Part 1 Stainless steel » - Notified Body BSI marking CE2797 - UKCA 0086 – GMDN 47569 - CLADIMED F52AA01. - Made in Great Britain : Blades manufactured and assembled by the factory Swann-MortonLtd at Sheffield ISO 13485:2016 - EU Authorised Representative : Emergo Europe		
Marking	Labelling : GS1 code compliant with the UDI registered under the number 503395500004 – QR code with Datamatrix format with indication of the item number, the lot number and the expiration date.		
Preservation	Clean and dry environment - between 0 and +40°C - Do not expose near a heat source.		
Expiration date	5 years from the date of sterilization, indicated on the packages		
Elimination	The product must be eliminated in a specific container and/or by cremation.		
Contact	Swann-Morton/Sinner - ZA du Verdalaï - 13790 Peynier - 04 42 29 08 08 - services@swann-morton-sinner.com		

# Product packaging

## Single use Disposable scalpel

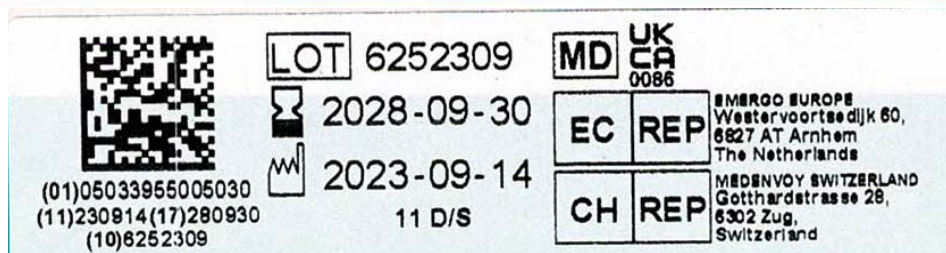
### 1-Product



### 2-Primary packaging : individual for each unit



### 3- Secondary packaging - box of 10 : unit of sales



# Reading of the markings on the unit packaging : Sterile Disposable Scalpel

REF 0503 = Item number

LOT **6152001**

615 = 3 sequential figures  
20 = Year of sterilization  
01 = Month of sterilization

 **2025-01**

2025 = Year of expiration  
01 = Month of expiration  
(expiration delay = 5 years)

**3** = Number of the machine for producing

**015** = Number of the day of production  
over the year of sterilization

**11** = Blade number

Brand = Swann-Morton


Address of the manufacturer

CE = ICE marking  
2797 = CE number

Product designation



 Single use

 "Do not use if the seal is open or damaged"

**STERILE R** Product sterilized by irradiation

## Products classification and codes

Factory code	REF ARTICLE	DESIGNATION	Class	Medical Devices	CE Marking	UKCA Marking	GMDN CODE	CLADIMED CODE	CUSTOMS NOMENCLATURE	UDI CODE	UNIT OF USE UDI	Basic UDI DI
0516	U6	STANDARD DISPOSABLE SCALPEL N°6	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005160	05063043005161	50339550STERILEDISPS89
0517	U9	STANDARD DISPOSABLE SCALPEL N°9	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005177	05063043005178	50339550STERILEDISPS89
0501	U10	STANDARD DISPOSABLE SCALPEL N°10	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005016	05063043005017	50339550STERILEDISPS89
0502	U10A	STANDARD DISPOSABLE SCALPEL N°10A	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005023	05063043005024	50339550STERILEDISPS89
0503	U11	STANDARD DISPOSABLE SCALPEL N°11	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005030	05063043005031	50339550STERILEDISPS89
0591	U11P	STANDARD DISPOSABLE SCALPEL N°11P	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005917	05063043005918	50339550STERILEDISPS89
0504	U12	STANDARD DISPOSABLE SCALPEL N°12	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005047	05063043005048	50339550STERILEDISPS89
0519	U14	STANDARD DISPOSABLE SCALPEL N°14	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005191	05063043005192	50339550STERILEDISPS89
0505	U15	STANDARD DISPOSABLE SCALPEL N°15	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005054	05063043005055	50339550STERILEDISPS89
0520	U15A	STANDARD DISPOSABLE SCALPEL N°15A	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005207	05063043005208	50339550STERILEDISPS89
0521	U15C	STANDARD DISPOSABLE SCALPEL N°15C	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005214	05063043005215	50339550STERILEDISPS89
0592	U15T	STANDARD DISPOSABLE SCALPEL N°15T	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005924	05063043005925	50339550STERILEDISPS89
0522	U16	STANDARD DISPOSABLE SCALPEL N°16	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005221	05063043005222	50339550STERILEDISPS89
0523	U18	STANDARD DISPOSABLE SCALPEL N°18	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005238	05063043005239	50339550STERILEDISPS89
0524	U19	STANDARD DISPOSABLE SCALPEL N°19	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005245	05063043005246	50339550STERILEDISPS89
0506	U20	STANDARD DISPOSABLE SCALPEL N°20	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005061	05063043005062	50339550STERILEDISPS89
0507	U21	STANDARD DISPOSABLE SCALPEL N°21	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005078	05063043005079	50339550STERILEDISPS89
0508	U22	STANDARD DISPOSABLE SCALPEL N°22	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005085	05063043005086	50339550STERILEDISPS89
0509	U22A	STANDARD DISPOSABLE SCALPEL N°22A	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005092	05063043005093	50339550STERILEDISPS89
0510	U23	STANDARD DISPOSABLE SCALPEL N°23	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005108	05063043005109	50339550STERILEDISPS89
0511	U24	STANDARD DISPOSABLE SCALPEL N°24	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005115	05063043005116	50339550STERILEDISPS89
0512	U25	STANDARD DISPOSABLE SCALPEL N°25	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005122	05063043005123	50339550STERILEDISPS89
0515	U25A	STANDARD DISPOSABLE SCALPEL N°25A	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005153	05063043005154	50339550STERILEDISPS89
0513	U26	STANDARD DISPOSABLE SCALPEL N°26	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005139	05063043005130	50339550STERILEDISPS89
0514	U27	STANDARD DISPOSABLE SCALPEL N°27	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005146	05063043005147	50339550STERILEDISPS89
0525	U11E	STANDARD DISPOSABLE SCALPEL N°E11	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005252	05063043005253	50339550STERILEDISPS89
0518	U12D	STANDARD DISPOSABLE SCALPEL N°12D	Ila	DM	2797	0086	47569	F52AA01	90189084	5033955005184	05063043005185	50339550STERILEDISPS89