

**Technical Data Sheet**

**Swann-Morton Sterile Safety Scalpel Retracting Guard**



N° / Reference - No.3 fitment	
3601	No.10 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3603	No.11 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3605	No.15 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3626	STITCH CUTTER STERILE SAFETY SCALPEL (RETRACTING GUARD)
3691	No.11P STERILE SAFETY SCALPEL (RETRACTING GUARD)

N° / Reference - No.4 fitment	
3606	No.20 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3607	No.21 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3608	No.22 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3610	No.23 STERILE SAFETY SCALPEL (RETRACTING GUARD)
3611	No.24 STERILE SAFETY SCALPEL (RETRACTING GUARD)

Product Example Shown	No.10 Sterile Safety Scalpel (Retracting Guard)
Sales Unit	Unit of 10
Factory packaging	Unit of 10
Sterilization	Sterile product by Ethylene Oxide
Material	Sheath = Durastar - Copolyester Handle = High Impact Polystyrene Blade = Stainless Steel in accordance with BS EN ISO 7153-1
Packaging composition	Packaged in DXS100 coextruded film and grid lacquer paper - boxed into 10's
Compatibility	N/A

Maintenance	SINGLE USE PRODUCT
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Directive	Class IIa
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CE 2797 Mark and UKCA 0086 Mark will be present on the packaging where applicable - Product manufactured by Swann-Morton Ltd - Authorised EU representative: Emergo Europe

Standards	BS EN ISO 10993-1	Biological evaluation of medical devices
	BS EN ISO 11135	Sterilization of Healthcare products – Ethylene Oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices
	BS EN ISO 7153-1	Surgical instruments – Metallic materials – Specification for stainless steel
	BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling & information to be supplied
	BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
	BS EN ISO 11607-1	Packaging of terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems & packaging systems
	BS EN ISO 11607-2	Packaging of terminally sterilized medical devices. Part 2: Validation requirements for forming sealing & assembly processes
	BS EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
	BS EN ISO 14971	Medical devices – Application of risk management to medical devices

Marking	<p>Labelling: GS1 code conformed to the UDI in 2017 registered under the number 503395500004</p> <p>Unit Packet displays a batch number and expiry date.</p> <p>Outer carton labelled with a Data matrix format with reference, batch number, expiry date and manufacturing date.</p>
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Conservation	Clean and dry environment
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Expiration	5 years from the date of manufacture, indicated on the packaging
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Disposal	The product must be disposed of in a suitable container and/or by incineration.
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1: Product Image



2: Primary packaging - Individual Packed Product Label



3: Secondary packaging - Packed Product Artwork



**Classification and Product Codes**

Code	Product Description	UOM	Device Class	Marking CE	Marking UKCA	GTIN13 CODE GS1 Issuing Agency (EAN Barcode)	Packed Product Dimensions			Approximate Product Weight in KGS
							WIDTH (mm)	HEIGHT (mm)	DEPTH (mm)	
3601	No. 10 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036010	210	55	43	0.099
3603	No.11 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036034	210	55	43	0.097
3605	No. 15 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036058	210	55	43	0.097
3691	No. 11P STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036911	210	55	43	0.097
3626	STITCH CUTTER STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA	05033955036263	210	55	43	0.098
3606	No. 20 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036065	210	55	43	0.106
3607	No. 21 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036072	210	55	43	0.111
3608	No. 22 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036089	210	55	43	0.115
3610	No. 23 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036102	210	55	43	0.110
3611	No. 24 STERILE SAFETY SCALPEL (RETRACTING GUARD)	Box of 10	Class IIa	CE 2797	UKCA 0086	05033955036119	210	55	43	0.112