



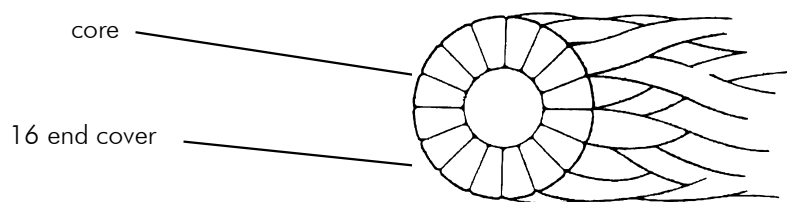
PRODUCT

Pearsalls Silk Sutures have been developed over many years to achieve the greatest tensile strength whilst maintaining a consistent diameter within the limits of the European or US Pharmacopoeia.

By application of the most modern textile processing techniques Pearsalls convert a traditional natural filament into a suture material for modern surgery. Black silk can be supplied dyed with the traditional Sulphol black, meeting European Pharmacopoeia requirements. Alternatively it is available dyed Logwood black, complying with the US and European Pharmacopoeia standards. It is also available in a natural Ivory colour.

CONSTRUCTION

Individual filaments of the highest quality Chinese silk are specially treated to give good handling properties. The filaments are then twisted together and braided. The braid is made up of the core of twisted silk around which a cover is plaited from 8, 12 or 16 silk threads. Special processes are then applied to ensure regularity of diameter, surface smoothness and the best extension for good knotting characteristics.



PHYSICAL PROPERTIES

EP Metric Size	USP Size	Standard Diameter (mm)	Tensile Strength		Extension at Break (Note 3) %	Sales Unit (m/reel)
			Standard Knot Pull (Note 1) (kg)	Pearsalls Average Knot Pull (Note 2) (kg)		
0.5	7/0	.050-.069	0.14	0.17	8.01	1000
0.7	6/0	.050-.069	0.25	0.37	9.23	1000
1	5/0	.100-.149	0.50	0.63	7.77	3000
1.5	4/0	.150-.199	0.75	1.10	8.00	3000
2	3/0	.200-.249	1.20	1.55	10.24	3000
2.5	-	.250-.299	1.40	1.94	10.39	2000
3	2/0	.300-.349	1.80	2.62	12.42	2000
3.5	1/0	.350-.399	2.70	3.80	10.63	1000
4	1	.400-.499	3.40	4.93	13.15	1000
5	2	.500-.599	4.40	7.05	13.48	500
6	3+4	.600-.699	6.10	8.41	16.21	500
7	5	.700-.799	7.70	12.23	17.30	250
8	6	.800-.899	9.10	13.56	17.45	250

NOTES

1. Standard knot pull tensile strength is as stated in the latest editions of European Pharmacopoeia and US Pharmacopoeia.
2. for non-absorbable sutures Class 1 – plus 25% for non-sterile sutures.
3. Pearsalls knot pull test is made with a simple knot.
4. Extension is the elongation of the material at break or rupture in a straight pull test expressed as a percentage of the original length.



MATERIALS

Silk Colours	Protein fibre from filaments spun by the silkworm – Bombyx Mori L. Sulphol Black. Logwood Black Natural Ivory
Dyestuffs	Black CI 53185 Sulphol Black 1 (EP Vol III) Formulae (Empirical only) – $C_{24}H_{16}N_6O_8S_7$. Logwood Black CI 75290. Natural Tinctorial Wood Extract obtained from Haematoxylon Campechianum. Conforms to US Code of Federal Regulations 21 CFR 73.1410.
Finishes	Wax – 100% Pure Beeswax BP. Silicone – Nusil Med 2174 Silicone Elastomer. Uncoated

SUPPLY PACKAGES

On large reels containing up to 3,000 metres. On small reels for hospital use with 22m or 90m and supplied in boxes of 10 reels.

COATINGS

Silicone and Wax coatings are available from stock in Taunton. Uncoated sutures are made to special order.

BATCH NUMBERING

All reels are marked with a batch number which identifies the date of production, materials used and details of Quality Control tests. Records of dispatches of each batch are maintained so that recall of individual batches can be effected in accordance with Good Manufacturing Practice.

QUALITY

Pearsalls Ltd quality system conforms to ISO 9001 2000. We are audited twice a year to ensure that we continue to meet the highest standards that can be achieved. Our notified body is SGS Yarsley. Certificates of conformity which show the test results obtained by Quality our Control Department are supplied with every batch or lot in a shipment.

GOOD MANUFACTURING PRACTISE

Pearsalls Sutures have introduced FDA Good Manufacturing Practice into all aspects of production and quality control. These procedures include the maintenance of detailed batch records, control of processes and procedure, staff training and a controlled production environment.

U.S. FOOD AND DRUG ADMINISTRATION (F.D.A.)

Pearsalls sutures are registered with the United States Food and Drug Administration as a manufacturer of non-sterile suture materials. Registration No. 8010203-6B

INTERNATIONAL STANDARDS

The products of Pearsalls sutures are designed and inspected to comply with the latest editions of the European Pharmacopoeia and United States Pharmacopoeia.



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