



**Virgin Silk for MICROSUTURES (Barraquer Silk)**

**METHYLENE BLUE, LOGWOOD BLACK, NATURAL WHITE**

**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 Logwood black, complying with the US Pharmacopoeia standards. It can also be dyed Methylene blue or supplied in Natural white.

**CONSTRUCTION**

Individual filaments of the highest quality Chinese silk are specially treated to facilitate processing. The filaments are delicately processed and dyed leaving for the most part intact the sericin or natural gum with which the silk worm coats the silk filament. This coating protects the delicate filament during processing and in use.

**PHYSICAL PROPERTIES**

EP Metric Size	USP Size	Standard Diameter (mm)	USP Minimum Class II	Tensile Strength		Extension at Break (Note 3) %	Sales Unit (m/reel)
				Standard Knot Pull (Note 1) (Kg) OR Knot Pull	Pearsalls Average Straight Pull (Note 2) (Kg)		
0.2	10/0	.020-.290	0.018		.050	11.5	50x4
0.3	9/0	.030-.039	0.036		.060	14.0	50x4
0.4	8/0	.040-.049	0.050	.070	.090	15.6	50x4

**NOTES**

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

**OR**

The tensile strength is measured by straight pull, except for 8/0, which is knot pull – see fourth supplement USP 28.

Virgin Silk Sutures are classified as Class II Non-absorbable suture as they are composed of coated natural fibres where the coating significantly affects the thickness but does not contribute to the strength.

**METHYLENE BLUE**

The Methylene Blue dyed silk is used in ophthalmic surgery. The dye fades after insertion and is physiologically absorbed by the tissues.

**LOGWOOD BLACK**

Logwood Black silk provides an excellent visual contrast and the materials conform to the United States Food and Drug Administration regulations for surgical sutures.

**NATURAL WHITE**

Natural silk is used where an uncoloured suture is required.



## MATERIALS

**Silk** Protein Fibre filaments spun by the silkworm Bombyx Mori L  
China National Silk Corporation

**Dyestuffs** **Methylene Blue** Cl. 52015

**Logwood Black**– Natural tinctorial wood extract from Haematoxylon Campechianum. Blower oxidised conforming to US Code of Federal Regulations Title 21, 73.1410. Logwood extract. Colour Index No. 75290

## SUPPLY PACKAGES

On reels of 50 metres each in a box of 4 reels.

## 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 our Quality Control Department are supplied with every batch or lot in a system.

## 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 both the European Pharmacopoeia and United States Pharmacopoeia.



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