



Pre-Stabilised Braided Polyester SUTURES

GREEN AND WHITE

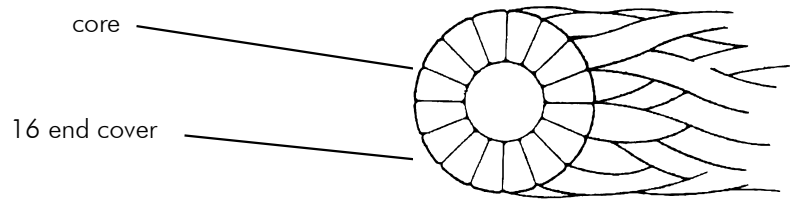
PRODUCT

By using the latest development in pre-stabilised polyester, Pearsalls Polyester braid is now more regular and consistent as there is less shrinkage during the production processes. The braid has more plaits per metre so the surface is smoother.

Pearsalls pre-stabilised polyester braids are dyed with D. & C. Green No. 6 dyestuff so they now fully conform to the U.S. Food and Drug Administration requirements as well as U.S. and European Pharmacopoeia. It is also available in Natural White.

CONSTRUCTION

Filaments of pre-stabilised or pre-set polyester are precision braided around a central core. The braid is then dyed and special processes applied to ensure regularity of diameter, and the best extension for good knotting characteristics. The wax, silicone or Filodell is then applied throughout the length of the braid, which improves the smoothness and gives a non-capillary effect.



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)		
0.7	6/0	.070-.099	0.25	0.64		
1	5/0	.100-.149	0.50	0.70	20.0	3,000
1.5	4/0	.150-.199	0.75	1.30	12.6	3,000
2	3/0	.200-.249	1.20	1.40	19.0	3,000
2.5	-	.250-.299	1.40	2.00	19.0	2,000
3	2/0	.300-.349	1.80	2.70	18.0	2,000
3.5	1/0	.350-.399	2.70	3.50	18.8	1,000
4	1	.400-.499	3.40	4.30	22.9	1,000
5	2	.500-.599	4.40	6.50	22.0	500
6	3	.600-.699	6.10	8.20	25.2	500

NOTES

1. Standard knot pull tensile strength is as stated in the latest editions of the 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.

MATERIALS

- Polyester** High tenacity filaments of Polyethylene Terephthalate.
Pre-stabilised
- Dyestuffs** D. & C. Green No. 6 C.I. 61565
- Finishes** Wax – 100% Pure Beeswax BP.
Silicone – Nusil Med 2174 Silicone Elastomer
Filodel – Dispersion of Ethyl Cellulose.
Teflon
Uncoated



COLOURS

Green (D. & C. No. 6); Natural White.

SUPPLY PACKAGES

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

FINISHES

Silicone and Wax finishes are available from stock in Taunton. Filodel Teflon and 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 despatches 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 Yardsley. Certificates of Conformity which show the test results obtained by our Quality Control Department are supplied with every batch or lot in a shipment.

GOOD MANUFACTURING PRACTICE

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 is 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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