

01/2008:90004

demonstrate that individual production batches of sterile catgut are suitable for wound closure according to usual surgical techniques.

INTRODUCTION

The following monographs apply to sutures for human use: Catgut, sterile (0317), Sutures, sterile non-absorbable (0324), Sutures, sterile synthetic absorbable braided (0667) and Sutures, sterile synthetic absorbable monofilament (0666). They cover performance characteristics of sutures and may include methods of identification. Sutures are medical devices as defined in Directive 93/42/EEC.

These monographs can be applied to show compliance with essential requirements as defined in Article 3 of Directive 93/42/EEC covering the following:

Physical performance characteristics: diameter, breaking load, needle attachment, packaging, sterility, information supplied by the manufacturer (see Section 13 of Annex 1 of Directive 93/42/EEC), labelling.

To show compliance with other essential requirements, the application of appropriate harmonised standards as defined in Article 5 of Directive 93/42/EEC may be considered.

01/2008:0317

CATGUT, STERILE

Chorda resorbilis sterilis

DEFINITION

Sterile catgut consists of sutures prepared from collagen taken from the intestinal membranes of mammals. After cleaning, the membranes are split longitudinally into strips of varying width, which, when assembled in small numbers, according to the diameter required, are twisted under tension, dried, polished, selected and sterilised. The sutures may be treated with chemical substances such as chromium salts to prolong absorption and glycerol to make them supple, provided such substances do not reduce tissue acceptability.

Appropriate harmonised standards may be considered when assessing compliance with respect to origin and processing of raw materials and with respect to biocompatibility.

Sterile catgut is a surgical wound-closure device. Being an absorbable suture it serves to approximate tissue during the healing period and is subsequently metabolised by proteolytic activity.

PRODUCTION

Production complies with relevant regulations on the use of animal tissues in medical devices notably concerning the risk of transmission of animal spongiform encephalopathy agents.

Appropriate harmonised standards may apply with respect to appropriate validated methods of sterilisation, environmental control during manufacturing, labelling and packaging.

It is essential for the effectiveness and the performance characteristics during use and during the functional lifetime of catgut that the following physical properties are specified: consistent diameter, sufficient initial strength and firm needle attachment.

The requirements outlined below have been established, taking into account stresses which occur during normal conditions of use. These requirements can be used to

TESTS

If stored in a preserving liquid, remove the sutures from the sachet and measure promptly and in succession the length, diameter and breaking load. If stored in the dry state, immerse the sutures in alcohol R or a 90 per cent V/V solution of 2-propanol R for 24 h and proceed with the measurements as indicated below.

Length. Measure the length without applying to the suture more tension than is necessary to keep it straight. The length of each suture is not less than 90 per cent of the length stated on the label and does not exceed 350 cm.

Diameter. Carry out the test on 5 sutures. Use a suitable instrument capable of measuring with an accuracy of at least 0.002 mm and having a circular pressor foot 10 mm to 15 mm in diameter. The pressor foot and the moving parts attached to it are weighted so as to apply a total load of 100 ± 10 g to the suture being tested. When making the measurement, lower the pressor foot slowly to avoid crushing the suture. Measure the diameter at intervals of 30 cm over the whole length of the suture. For a suture less than 90 cm in length, measure at 3 points approximately evenly spaced along the suture. The suture is not subjected to more tension than is necessary to keep it straight during measurement. The average of the measurements carried out on the sutures being tested and not less than two-thirds of the measurements taken on each suture are within the limits given in the columns under A in Table 0317-1 for the gauge number concerned. None of the measurements is outside the limits given in the columns under B in Table 0317-1 for the gauge number concerned.

Table 0317-1.— *Diameters and Breaking Loads*

Gauge number	Diameter (millimetres)				Breaking load (newtons)	
	A		B		C	D
	min.	max.	min.	max.		
0.1	0.010	0.019	0.005	0.025	-	-
0.2	0.020	0.029	0.015	0.035	-	-
0.3	0.030	0.039	0.025	0.045	0.20	0.05
0.4	0.040	0.049	0.035	0.060	0.30	0.10
0.5	0.050	0.069	0.045	0.085	0.40	0.20
0.7	0.070	0.099	0.060	0.125	0.70	0.30
1	0.100	0.149	0.085	0.175	1.8	0.40
1.5	0.150	0.199	0.125	0.225	3.8	0.70
2	0.200	0.249	0.175	0.275	7.5	1.8
2.5	0.250	0.299	0.225	0.325	10	3.8
3	0.300	0.349	0.275	0.375	12.5	7.5
3.5	0.350	0.399	0.325	0.450	20	10
4	0.400	0.499	0.375	0.550	27.5	12.5
5	0.500	0.599	0.450	0.650	38.0	20.0
6	0.600	0.699	0.550	0.750	45.0	27.5
7	0.700	0.799	0.650	0.850	60.0	38.0
8	0.800	0.899	0.750	0.950	70.0	45.0

Minimum breaking load. The minimum breaking load is determined over a simple knot formed by placing one end of a suture held in the right hand over the other end held in

the left hand, passing one end over the suture and through the loop so formed (see Figure 0317-1) and pulling the knot tight. Carry out the test on 5 sutures. Submit sutures of length greater than 75 cm to 2 measurements and shorter sutures to one measurement. Determine the breaking load using a suitable tensiometer. The apparatus has 2 clamps for holding the suture, one of which is mobile and is driven at a constant rate of 30 cm/min. The clamps are designed so that the suture being tested can be attached without any possibility of slipping. At the beginning of the test the length of suture between the clamps is 12.5 cm to 20 cm and the knot is midway between the clamps. Set the mobile clamp in motion and note the force required to break the suture. If the suture breaks in a clamp or within 1 cm of it, the result is discarded and the test repeated on another suture. The average of all the results, excluding those legitimately discarded, is equal to or greater than the value given in column C in Table 0317-1 and no individual result is less than that given in column D for the gauge number concerned.

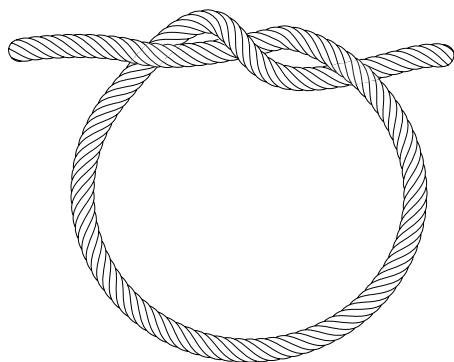


Figure 0317-1. – Simple knot

Soluble chromium compounds. Place 0.25 g in a conical flask containing 1 ml of *water R* per 10 mg of catgut. Stopper the flask, allow to stand at 37 ± 0.5 °C for 24 h, cool and decant the liquid. Transfer 5 ml to a small test tube and add 2 ml of a 10 g/l solution of *diphenylcarbazide R* in *alcohol R* and 2 ml of *dilute sulphuric acid R*. The solution is not more intensely coloured than a standard prepared at the same time using 5 ml of a solution containing 2.83 µg of *potassium dichromate R* per millilitre, 2 ml of *dilute sulphuric acid R* and 2 ml of a 10 g/l solution of *diphenylcarbazide R* in *alcohol R* (1 ppm of Cr).

Needle attachment. If the catgut is supplied with an eyeless needle attached that is not stated to be detachable, it complies with the test for needle attachment. Carry out the test on 5 sutures. Use a suitable tensiometer, such as that described for the determination of the minimum breaking load. Fix the needle and suture (without knot) in the clamps of the apparatus in such a way that the swaged part of the needle is completely free of the clamp and in line with the direction of pull on the suture. Set the mobile clamp in motion and note the force required to break the suture or to detach it from the needle. The average of the 5 determinations and all individual values are not less than the respective values given in Table 0317-2 for the gauge number concerned. If not more than one individual value fails to meet the individual requirement, repeat the test on

an additional 10 sutures. The catgut complies with the test if none of these 10 values is less than the individual value in Table 0317-2 for the gauge number concerned.

Table 0317-2. – Minimum Strengths of Needle Attachment

Gauge number	Mean value (newtons)	Individual values (newtons)
0.5	0.50	0.25
0.7	0.80	0.40
1	1.7	0.80
1.5	2.3	1.1
2	4.5	2.3
2.5	5.6	2.8
3	6.8	3.4
3.5	11.0	4.5
4	15.0	4.5
5	18.0	6.0

STORAGE (PACKAGING)

Sterile catgut sutures are presented in individual sachets that maintain sterility and allow the withdrawal and use of the sutures in aseptic conditions. Sterile catgut may be stored dry or in a preserving liquid to which an antimicrobial agent but not an antibiotic may be added.

Sutures in their individual sachets (primary packaging) are kept in a protective cover (box) which maintains the physical and mechanical properties until the time of use.

The application of appropriate harmonised standards for packaging of medical devices shall be considered.

LABELLING

Reference may be made to the appropriate harmonised standards for labelling of medical devices.

The details strictly necessary for the user to identify the product properly are indicated on or in each sachet (primary packaging) and on the protective cover (box) and include at least:

- gauge number,
- length in centimetres or metres,
- if appropriate, that the needle is detachable,
- name of the product,
- intended use (surgical suture, absorbable).

01/2008:0324

SUTURES, STERILE NON-ABSORBABLE

Fila non resorbilia sterilia

DEFINITION

Sterile non-absorbable sutures are sutures which, when introduced into a living organism, are not metabolised by that organism. Sterile non-absorbable sutures vary in origin, which may be animal, vegetable, metallic or synthetic. They occur as cylindrical monofilaments or as multifilament sutures consisting of elementary fibres which are assembled by twisting, cabling or braiding; they may be sheathed; they may be treated to render them non-capillary, and they may be coloured.