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Volume I

SUTURES

Sterile Catgut in Distributor

(*Catgut, Sterile, in Distributor for Veterinary Use, Ph Eur monograph 0660*)

Ph Eur

DEFINITION

Sterile catgut in distributor for veterinary use consists of strands 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 strands 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.

The strand is presented in a distributor that allows the withdrawal and use of all or part of it in aseptic conditions. The design of the distributor is such that with suitable handling the sterility of the content is maintained even when part of the strand has been withdrawn. It may be stored dry or in a preserving liquid to which an antimicrobial preservative but not an antibiotic may be added.

TESTS

If stored in a preserving liquid, remove the strand from the distributor and measure promptly and in succession the length, diameter and breaking load. If stored in the dry state, immerse the strand 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 above.

Length

Measure the length without applying to the strand more tension than is necessary to keep it straight. The length is not less than 95 per cent of the length stated on the label. If the strand consists of several sections joined by knots, the length of each section is not less than 2.5 m.

Diameter

Carry out the test using 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 strand being tested. When making the measurements, lower the pressor foot slowly to avoid crushing the strand. Make not fewer than one measurement per 2 m of length. If the strand consists of several sections joined by knots, make not fewer than three measurements per section. In any case make not fewer than twelve measurements. Make the measurements at points evenly spaced along the strand or along each section. The strand is not subjected to more tension than is necessary to keep it straight during measurement. The average of the measurements carried out on the strand being tested and not less than two-thirds of the individual measurements are within the limits given in the column under A in Table 0660.-1 for the gauge number concerned. None of the measurements is outside the limits given in the columns under B in Table 0660.-1 for the gauge number concerned.

Table 0660.-1. – *Diameters and breaking loads*

Gauge number	Diameter (millimetres)				Breaking load (newtons)	
	A		B		C	D
	min.	max.	min.	max.		
1	0.100	0.149	0.085	0.175	1.8	0.4
1.5	0.150	0.199	0.125	0.225	3.8	0.7
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	38.4	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 strand held in the right hand over the other end held in the left hand, passing one end over the strand and through the loop so formed (see Figure 0660.-1) and pulling the knot tight.

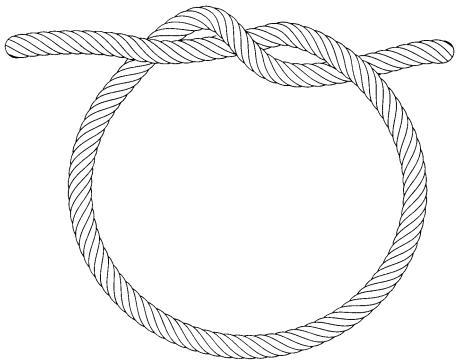

Figure 0660.-1. – *Simple knot*

Make not fewer than one measurement per 2 m of length. If the strand consists of several sections joined by knots, make not fewer than three measurements per section and, in any case, not fewer than one measurement per 2 m of length at points evenly spaced along the strand or along each section. Determine the breaking load using a suitable tensilometer. The apparatus has two clamps for holding the strand, one of which is mobile and is driven at a constant rate of 30 cm per minute. The clamps are designed so that the strand being tested can be attached without any possibility of slipping. At the beginning of the test the length of strand 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 strand. If the strand breaks in a clamp or within 1 cm of it, the result is discarded and the test repeated on another part of the strand. The average of all the results, excluding those legitimately discarded, is equal to or greater than the value in column C and no value is less than that given in column D in Table 0660.-1 for the gauge number concerned.

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).

Sterility (*2.6.1*)
It complies with the test for sterility as applied to catgut and other surgical sutures. Carry out the test on three sections, each 30 cm long, cut off respectively from the beginning, the centre and the end of the strand.

STORAGE
Store protected from light and heat.

LABELLING
The label states:
— the gauge number,
— the length in centimetres or in metres.

Ph Eur

Sterile Non-absorbable Strands in Distributor

(*Strands, Sterile Non-absorbable, in Distributor for Veterinary Use, Ph Eur monograph 0605*)

Ph Eur

DEFINITION
The statements in this monograph are intended to be read in conjunction with the individual monographs on sterile non-absorbable strands in distributor for veterinary use in the Pharmacopoeia. The requirements do not necessarily apply to sterile non-absorbable strands which are not the subject of such monographs.

Sterile non-absorbable strands in distributor for veterinary use are strands which, when introduced into a living organism, are not metabolised by that organism. Sterile non-absorbable strands vary in origin, which may be animal, vegetable or synthetic. They occur as cylindrical monofilaments or as multifilament strands. Multifilament strands consist of elementary fibres which are assembled by twisting, cabling or braiding. Such strands may be sheathed. Sterile non- absorbable strands may be treated to render them non-capillary, and they may be coloured with colouring matter or pigments authorised by the competent authority. The strands are sterilised.

They are presented in a suitable distributor that allows the withdrawal and use of all or part of the strand in aseptic conditions. The design of the distributor is such that with suitable handling the sterility of the content is maintained even when part of the strand has been removed. They may be stored dry or in a preserving liquid to which an antimicrobial preservative but not an antibiotic may be added.

TESTS
Remove the strand from the distributor and measure promptly and in succession the length, diameter and minimum breaking load.

Length
Measure the length in the condition in which the strand is presented and without applying more tension than is necessary to keep it straight. The length of the strand is not less than 95 per cent of the length stated on the label.

Diameter
Unless otherwise prescribed, measure the diameter by the following method using the strand in the condition in which it is presented. 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 strand being tested. When making the measurements, lower the pressor foot slowly to avoid crushing the strand. Make not fewer than one measurement per 2 m of length and in any case not fewer than 12 measurements at points evenly spaced along the strand. During the measurement submit monofilament strands to a tension not greater than that required to keep them straight. Submit multifilament strands to a tension not greater than one-fifth of the minimum breaking load shown in column C of Table 0605.-1 appropriate to the gauge number and type of material concerned or 10 N whichever is less. For multifilament strands of gauge number above 1.5 make two measurements at each point, the second measurement being made after rotating the strand through 90°. The diameter of that point is the average of the two measurements. The average of the measurements carried out on the strand being tested and not less than two-thirds of the individual measurements are within the limits given in the columns under A in Table 0605.-1 for the gauge number concerned. None of the measurements is outside the limits given in the columns under B in Table 0605.-1 for the gauge number concerned.

Table 0605.-1. – *Diameters and minimum breaking loads*

Gauge number	Diameter (millimetres)				Minimum breaking load (newtons)			
	A		B		Linen thread		All other non-absorbable strands	
	min.	max.	min.	max.	C	D	C	D
0.5	0.050	0.069	0.045	0.085	-	-	1.0	0.35
0.7	0.070	0.099	0.060	0.125	1.0	0.3	1.5	0.60
1	0.100	0.149	0.085	0.175	2.5	0.6	3.0	1.0
1.5	0.150	0.199	0.125	0.225	5.0	1.0	5.0	1.5
2	0.200	0.249	0.175	0.275	8.0	2.5	9.0	3.0
2.5	0.250	0.299	0.225	0.325	9.0	5.0	13.0	5.0
3	0.300	0.349	0.275	0.375	11.0	8.0	15.0	9.0
3.5	0.350	0.399	0.325	0.450	15.0	9.0	22.0	13.0
4	0.400	0.499	0.375	0.550	18.0	11.0	27.0	15.0
5	0.500	0.599	0.450	0.650	26.0	15.0	35.0	22.0
6	0.600	0.699	0.550	0.750	37.0	18.0	50.0	27.0
7	0.700	0.799	0.650	0.850	50.0	26.0	62.0	35.0
8	0.800	0.899	0.750	0.950	65.0	37.0	73.0	50.0

Minimum breaking load
Unless otherwise prescribed, determine the minimum breaking load by the following method using the strand in the condition in which it is presented. The minimum breaking load is determined over a simple knot formed by

placing one end of a strand held in the right hand over the other end held in the left hand, passing one end over the strand and through the loop so formed (see Figure 0605.-1) and pulling the knot tight.

Make not fewer than one measurement per 2 m of length at points evenly spaced along the strand. Determine the breaking load using a suitable tensilometer. The apparatus has two clamps for holding the strand, one of which is mobile and is driven at a constant rate of 30 cm per minute. The clamps are designed so that the strand being tested can be attached with-out any possibility of slipping. At the beginning of the test the length of strand 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 strand. If the strand breaks in a clamp or within 1 cm of it, the result is discarded and the test repeated on another part of the strand. The average of all the results, excluding those legitimately dis-carded, is equal to or greater than the value in column C and no value is less than that given in column D in Table 0605.-1 for the gauge number and type of material concerned.

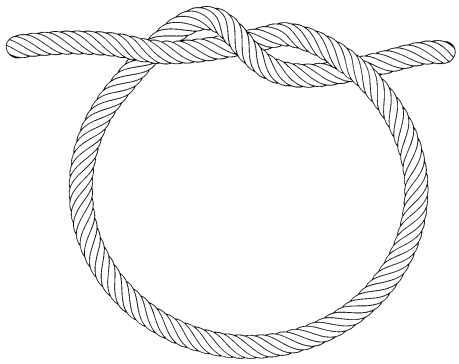

Figure 0605.-1. – *Simple knot*

Sterility (*2.6.1*)
They comply with the test for sterility as applied to catgut and other surgical sutures. Carry out the test on three sections each 30 cm long, cut off respectively from the beginning, the centre and the end of the strand.

Extractable colour
Strands that are dyed and intended to remain so during use comply with the test for extractable colour. Place 0.25 g of the strand to be examined in a conical flask, add 25.0 ml of *water R* and cover the mouth of the flask with a short-stemmed funnel. Boil for 15 min, cool and adjust to the original volume with *water R*. Depending on the colour of the strand, prepare the appropriate reference solution as described in Table 0605.-2 using the primary colour solutions (*2.2.2*).

Table 0605.-2. – *Colour reference solutions*

Colour of strand	Composition of reference solution (parts by volume)			
	Red primary solution	Yellow primary solution	Blue primary solution	Water
Yellow - brown	0.2	1.2	–	8.6
Pink - red	1.0	–	–	9.0
Green - blue	–	–	2.0	8.0
Violet	1.6	–	8.4	–

The test solution is not more intensely coloured than the appropriate reference solution.

STORAGE
Store protected from light and heat.

LABELLING
The label states:
— the gauge number,
— the length in centimetres or in metres,
— where appropriate, that the strand is coloured and intended to remain so during use.

Ph Eur

Sterile Linen Thread in Distributor

(*Linen Thread, Sterile, in Distributor for Veterinary Use, Ph Eur monograph 0608*)

Ph Eur

DEFINITION
Sterile linen thread in distributor for veterinary use consists of the pericyclic fibres of the stem of *Linum usitatissimum* L. The elementary fibres, 2.5 cm to 5 cm long, are assembled in bundles 30 cm to 80 cm long and spun into continuous lengths of suitable diameter. The thread may be creamy-white or may be coloured with colouring matter authorised by the competent authority. The thread is sterilised.

IDENTIFICATION
A. Dissect the end of a thread, using a needle or fine tweezers, to isolate a few individual fibres. Examined under a microscope, the fibres are seen to be 12 µm to 31 µm wide and, along the greater part of their length, have thick walls, sometimes marked with fine longitudinal striations, and a narrow lumen. The fibres gradually narrow to a long, fine point. Sometimes there are unilateral swellings with transverse lines.

B. Impregnate isolated fibres with *iodinated zinc chloride solution R*. The fibres are coloured violet-blue.

TESTS
It complies with the tests prescribed in the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

If stored in a dry state, expose to an atmosphere with a relative humidity of 65 ± 5 per cent at 20 ± 2 °C for 4 h immediately before measuring the diameter and for the determination of minimum breaking load immerse in water R at room temperature for 30 min immediately before carrying out the test.

STORAGE
See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

LABELLING
See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

Ph Eur

Sterile Poly(ethylene terephthalate) Suture in Distributor

(*Poly(ethylene terephthalate) Suture, Sterile, in Distributor for Veterinary Use, Ph Eur monograph 0607*)

Ph Eur

DEFINITION

Sterile poly(ethylene terephthalate) suture in distributor for veterinary use is obtained by drawing poly(ethylene terephthalate) through a suitable die. The suture is prepared by braiding very fine filaments in suitable numbers, depending on the gauge required. It may be whitish in colour, or may be coloured with authorised colouring matter or pigments authorised by the competent authority. The suture is sterilised.

CHARACTERS

It is practically insoluble in most of the usual organic solvents, but is attacked by strong alkaline solutions. It is incompatible with phenols.

IDENTIFICATION

A. It dissolves with difficulty when heated in *dimethylformamide R* and in *dichlorobenzene R*.

B. To about 50 mg add 10 ml of *hydrochloric acid R1*. The material remains intact even after immersion for 6 h.

TESTS

It complies with the tests prescribed in the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

STORAGE

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

LABELLING

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

Ph Eur

Sterile Polyamide 6 Suture in Distributor

(*Polyamide 6 Suture, Sterile, in Distributor for Veterinary Use, Ph Eur monograph 0609*)

NOTE The name Nylon 6 as a synonym for Polyamide 6 may be used freely in many countries, including Great Britain and Northern Ireland, but exclusive proprietary rights in this name are claimed in certain other countries.

Ph Eur

DEFINITION

Sterile polyamide 6 suture in distributor for veterinary use is obtained by drawing through a suitable die a synthetic plastic material formed by the polymerisation of ε-caprolactam. It consists of smooth, cylindrical monofilaments or braided filaments, or lightly twisted strands sheathed with the same material. It may be coloured with colouring matter authorised by the competent authority. The suture is sterilised.

CHARACTERS

It is practically insoluble in the usual organic solvents; it is not attacked by dilute alkaline solutions (for example a 100 g/l solution of sodium hydroxide) but is attacked by dilute mineral acids (for example 20 g/l sulphuric acid), by hot glacial acetic acid and by 70 per cent *m/m* formic acid.

IDENTIFICATION

A. Heat about 50 mg with 0.5 ml of *hydrochloric acid R1* in a sealed glass tube at 110 °C for 18 h and allow to stand for 6 h. No crystals appear.

B. To about 50 mg add 10 ml of *hydrochloric acid R1*. The material disintegrates in the cold and dissolves completely within a few minutes.

C. It dissolves in a 70 per cent *m/m* solution of *anhydrous formic acid R*.

TESTS

It complies with the tests prescribed in the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)* and with the following test:

Monomer and oligomers

In a continuous-extraction apparatus, treat 1.00 g with 30 ml of *methanol R* at a rate of at least three extractions per hour for 7 h. Evaporate the extract to dryness, dry the residue at 110 °C for 10 min, allow to cool in a desiccator and weigh. The residue weighs not more than 20 mg (2 per cent).

STORAGE

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

LABELLING

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

The label states whether the suture is braided, monofilament or sheathed.

Ph Eur

Sterile Polyamide 6/6 Suture in Distributor

(*Polyamide 6/6 Suture, Sterile, in Distributor for Veterinary Use, Ph Eur monograph 0610*)

NOTE The name Nylon 6/6 as a synonym for Polyamide 6/6 may be used freely in many countries including Great Britain and Northern Ireland, but exclusive proprietary rights in this name are claimed in certain other countries.

Ph Eur

DEFINITION

Sterile polyamide 6/6 suture in distributor for veterinary use is obtained by drawing through a suitable die a synthetic plastic material formed by the polycondensation of hexamethylene-diamine and adipic acid. It consists of smooth, cylindrical monofilaments or braided filaments, or lightly twisted strands sheathed with the same material. It may be coloured with authorised colouring matter or pigments authorised by the competent authority. The suture is sterilised.

CHARACTERS

It is practically insoluble in the usual organic solvents; it is not attacked by dilute alkaline solutions (for example a 100 g/l solution of sodium hydroxide) but is attacked by dilute mineral acids (for example 20 g/l sulphuric acid), by hot glacial acetic acid and by 80 per cent *m/m* formic acid.

IDENTIFICATION

A. In contact with a flame it melts and burns, forming a hard globule of residue and gives off a characteristic odour resembling that of celery.

B. Place about 50 mg in an ignition tube held vertically and heat gently until thick fumes are evolved. When the fumes fill the tube, withdraw it from the flame and insert a strip of *nitrobenzaldehyde paper R*. A violet-brown colour slowly appears on the paper and fades slowly in air; it disappears immediately on washing with *dilute sulphuric acid R*.

C. To about 50 mg add 10 ml of *hydrochloric acid R1*. The material disintegrates in the cold and dissolves within a few minutes.

D. It does not dissolve in a 70 per cent *m/m* solution of *anhydrous formic acid R* but dissolves in an 80 per cent *m/m* solution of *anhydrous formic acid R*.

TESTS

It complies with the tests prescribed in the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

STORAGE

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

LABELLING

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

The label states whether the suture is braided, monofilament or sheathed.

Ph Eur

Sterile Braided Silk Suture in Distributor

(*Silk Suture, Sterile, Braided, in Distributor for Veterinary Use, Ph Eur monograph 0606*)

Ph Eur

DEFINITION

Sterile braided silk suture in distributor for veterinary use is obtained by braiding a variable number of threads, according to the diameter required, of degummed silk obtained from the cocoons of the silkworm *Bombyx mori* L. It may be coloured with colouring matter authorised by the competent authority. The suture is sterilised.

IDENTIFICATION

A. Dissect the end of a strand, using a needle or fine tweezers, to isolate a few individual fibres. The fibres are sometimes marked with very fine longitudinal striations parallel to the axis of the strand. Examined under a microscope, a cross-section is more or less triangular or semi-circular, with rounded edges and without a lumen.

B. Impregnate isolated fibres with *iodinated potassium iodide solution R*. The fibres are coloured pale yellow.

TESTS

It complies with the tests prescribed in the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

STORAGE

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

LABELLING

See the monograph on *Strands, sterile non-absorbable, in distributor for veterinary use (0605)*.

Ph Eur