



Topic: SUTURE MATERIALS AND PIERCING NEEDLES

The objective: To study classification, assortment of suture material and piercing needles. To carry out inspection analysis using corresponding normative documentation and to evaluate quality of the goods.

Basic concepts and terms which should be acquired by students during their training and studying

Suture material, surgical needles, non-traumatic needles, ligature needles.

Questions for self-training

1. Application of suture materials.
2. Classification of suture materials.
3. Package for suture materials.
4. Technical requirements for suture materials.
5. Methods of sterilization for suture materials.
6. Packing, marking, storage, transportation of suture materials.
7. Application of surgical, non-traumatic, ligature needles.
8. Assortment of surgical needles.
9. Classification of surgical needles.
10. Non-traumatic needles, their classification and assortment.
11. Ligature needles, brackets.
12. Packing, marking, storage of surgical, non-traumatic, ligature needles.
13. Methods of sterilization for surgical, non-traumatic, ligature needles.
14. Acceptance procedures and quality evaluation of suture material and piercing needles.

Methodical maintenance of the class

1. Tests for control of student knowledge about topic of the lesson.
2. Reference documentation:



GOST 396-84 Silk surgical twisted unsterile suture.

GOST 26641-85 Non-traumatic needles.

GOST 25981-83. Surgical needles.

GOST 21643-82. Stapling suturing medical machines.

3. Assortment of suture materials and piercing needles:

Set of surgical needles.

Set of suture materials.

Non-traumatic needles in individual packing.

Catgut in ampoules.

Chromic catgut in ampoules.

Catgut in polymeric packing.

Catgut unsterile in skeins.

Silk in ampoules.

Blunt ligature needles.

Acute ligature needles.

Set of suture retention bridges.

Silk in skeins.



Task N 1

Carry out inspection analysis of the suture material arrived in a drugstore by main organoleptic (visual) quality parameters. Make a conclusion about opportunity of its acceptance.

Write down results of the analysis into table 1 by a sample below.

Working technique

For example, inspection analysis of «Silk surgical twisted unsterile suture» by its main organoleptic (visual) quality parameters is performed according to requirements of GOST 396-84 «Silk surgical twisted unsterile suture».

Table 1

Results of inspection analysis
silk surgical twisted unsterile suture (unpacked)
(name of the goods)

Name of parameter	Characteristics	
	according to requirements of RD	of the goods to be evaluated
Appearance	Surgical suture should be boiled and rinsed. Color of suture should be white with cream shade	Color of suture – white with cream shade
Inadmissible defects	The following defects in appearance are not admissible: slub, snarls, corkscrews, impurities, mossiness, films, slipping of threads on edges of a reel.	Defects are not revealed
Quantity of knots: -in a conic reel not more than -in unpacked reel, not more, than	10 4	There are 2 knots.
Packing	Surgical sutures in unpacked reels are stacked up into cardboard boxes 260x100x90 mm in size by the following quantity: 60 items – for conventional suture number 000; 54 items - for other conventional numbers. Boxes by 6 items are put into a pack. A pack is	Boxes by 6 items are put into a pack. The pack is wrapped up with packing paper, tied up with a band.



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	<p>wrapped with packing paper in accordance to GOST 8273-75, tied up with a cord or fiber band in accordance to GOST 17308-71.</p> <p>Surgical sutures in conic reels should be wrapped up with soft paper in accordance to GOST 1908-77 or with other paper providing safety of a reel. Reels are packed into cardboard boxes in accordance to GOST 13512-81 or GOST 13514-82 not more than 15 kg in weight; then tied up with a cord or fiber band.</p>	
Marking	<p>On a label attached to boxes there should be following information:</p> <ul style="list-style-type: none">- name of manufacturer and its trade mark;- name of a product;- conventional number and grade;- type of production unit and length of a string in one production unit;- quantity of production units in a box and a pack;- batch (lot) number;- manufacturing date;- designation of the standard;- warranty period of storage – 5 years.	<p>On a label the following information is printed:</p> <ul style="list-style-type: none">- the name of manufacturer and its trademark;- the name of a product;- conventional number and grade;- type of production unit and length of a string in one production unit;- quantity of production units in a box and a pack;- batch number;- manufacturing date 03.12.07;- designation of the standard – GOST 396-84;- warranty period of storage – 5 years.

The conclusion: Inspection analysis has shown, that silk surgical twisted unsterile suture conforms the requirements of GOST 396-84 and can be accepted in drugstore.



Task N 2

In drugstore a batch of surgical needles has arrived. Decode designation of surgical needles. Write down results into working copybook.

Working technique

From the list of normative documentation we choose GOST 25981-83 Surgical needles where we can find necessary data for decoding (use Annexes 7.1, 7.5, 7.6).

For example: the code of a surgical needle is **OA 2-0,4x30**, which means:

- O** – straight;
- A** - with round edge;
- 2** - with continuous needle eye;
- 0,4** - diameter of wire, mm;
- 30** - length of unbent needle, mm.

Task N 3

In warehouse surgical needles have arrived. Carry out inspection analysis of the arrived goods and provide necessary conditions of their storage.

Write down results of your work into table 2.

Working technique

Inspection analysis of surgical needles is provided in conformity to requirements of GOST 25981-83 Surgical needles (use Annex 7.6).

Results should be written down in table 2 by the sample below.

Table 2

Results of inspection analysis of surgical needles

The name of surgical needles	Technical requirements		
	State of needle surface	State of piercing parts	Corrosion resistance
1	2	3	4

Marking of consumer package	Storage conditions (in accordance to GOST 15150-69)
5	6

The conclusion: _____



Task N 4

In a drugstore non-traumatic needles have arrived. Carry out inspection analysis of needles and make a conclusion about opportunity of their acceptance.

Write down results of your work into table 3.

Working technique

Inspection analysis is provided in conformity to requirements of GOST 26641-85 Non-traumatic needles. Technical requirements (use Annex 7.6).

Write down results into table 3.

Table 3

Results of the inspection analysis of non-traumatic needles

Name of non-traumatic needles	State of needle surface	State of piercing parts	Fastening of suture string
1	2	3	4

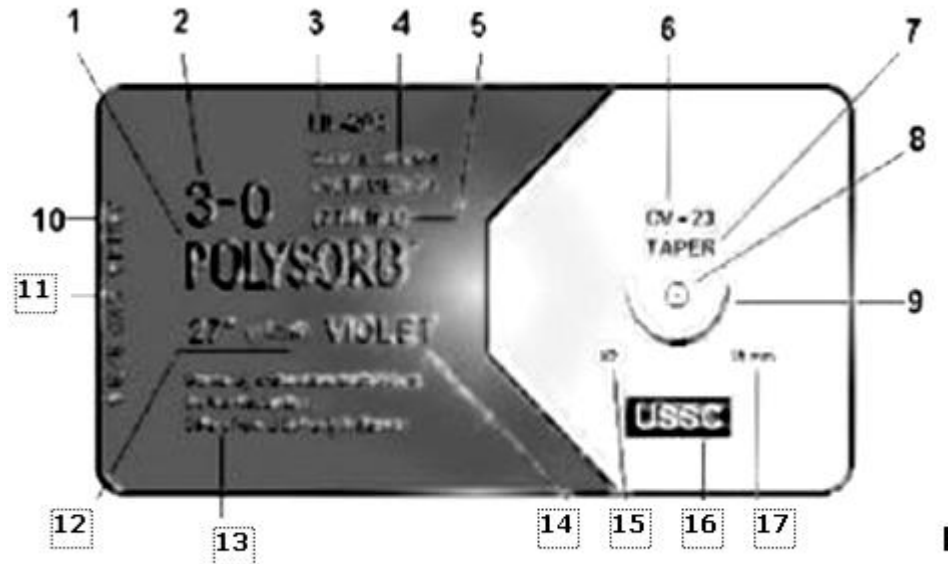
Continuation of table 3

Diameter of a needle near fastening of a string	Corrosion resistance	Marking of consumer package	Storage conditions
5	6	7	8

The conclusion:

ANNEX 7

7.1. Marking on package of suture material



1. Trade name of suture material - Polysorb
2. Thickness of a suture in standard units (" in zeros ")
3. A code for an order
4. The description of suture material ("coated, bonding lactomer 9-1 ")
5. Thickness of a suture in metric system
6. Code of a needle
7. Type of a needle (in the given example - taper)
8. Conventional sign indicating type of a needle (in the given example - taper)
9. Full-scale image of a needle
10. Batch number of the given suture material
11. Expiry date (month and year)
12. Length of a suture in inches and in centimeters
13. Description of a suture : " Sterile synthetic absorbable suture. Do not sterilize.
Differs from USP system only by diameter "
14. Color of a suture : violet
15. Curve ("steepness"): in the given example - 1/2 of circle
16. The title of firm (USSC - Surgical Corporation the USA)
17. Length of unbent needle



7.2. Classification and assortment of suture materials

By Suture Configuration:

1. Monofilament sutures (less risk of infection) – are those constructed from one filament (nylon, polybutester and others)
2. Braided multifilament sutures (easier to handle and tie) – are those containing multiple fibers (nylon, polyester, stainless steel and silk)

By Suture degradation: Absorbable and Nonabsorbable Suture

ABSORBABLE SUTURE

Definition

Suture loses tensile strength in 60 days under skin

Indications

Buried Suture to reduce wound edge tension

Assortment of Absorbable Sutures

- A. Catgut Suture
- B. Treated Catgut Suture (Mild Chromic Gut)
- C. Polyglycolic Acid Suture (Dexon)
- D. Polylactic Acid Suture (Vicryl)
- E. Polydioxanone (PDS)
- F. Polyglyconate (Maxon)

Mild Chromic Gut

Catgut

I. Category

First natural Absorbable Suture

II. Indications

Use Vicryl or Dexon instead for Absorbable Suture

III. Catgut (rarely used now)



Derived from sheep intestinal intima
Poor tensile strength
Poor knot security
Quickly absorbed within 4-5 days
High tissue reactivity (absorbed by proteolysis)

IV. **Chromic acid treated catgut (Mild Chromic Gut)**

Tensile strength longer than with cat gut
Moderate tissue reactivity (absorbed by proteolysis)
Poor knot security

Dexon

Polyglycolic Acid Suture

I. **Category**

First synthetic Absorbable Suture (1970)

II. **Indications**

Subcutaneous and intraoral closure

III. **Absorption (Hydrolysis)**

Tensile and knot strength roughly equivalent to Vicryl
Day 7: 60% of tensile strength retained
Day 15: 20% of tensile strength
Day 28: 5% of tensile strength
Day 90 to 120: Suture completely absorbed

IV. **Preparations**

Monofilament

1. Stiff, and difficult to handle

Braided Dexon

2. Easier to handle

Dexon Plus (synthetic coat)

3. Eases knot tying and tissue passage



Vicryl

Polylactic Acid Suture

I. Indications

Subcutaneous and intraoral closure

II. Category

Second synthetic Absorbable Suture (1974)

Polymer

1. Lactide
2. Glycolide

Coating (assists with handling and tying)

3. Polyglactin 370
4. Calcium stearate

III. Absorption (Hydrolysis)

Tensile and knot strength roughly equivalent to Dexon

Day 28: 8% of tensile strength

Day 60 to 90: Suture completely absorbed

Much more rapid than Dexon

IV. Preparations

Undyed braided Suture

Violet-dyed braided Suture

1. May be seen under skin in some cases

NONABSORBABLE SUTURE

I. Nonabsorbable Sutures

- A. Silk Suture
- B. Nylon Suture (Ethilon, Dermalon)
- C. Polypropylene suture (Prolene, Surgilene)
- D. Braided Polyester Suture (Ethibond, Ethiflex, Dacron)
- E. Polybutester (Novafil)



Silk Suture

- I. **Category**
 - A. Natural Nonabsorbable Suture (braided)
- II. **Indications: Rarely used now**
 - A. Eye and lip skin surgery
 - B. Intraoral surgery
- III. **Advantages**
 - A. Best handling and tying of any Suture Material
- IV. **Disadvantages**
 - A. Least tensile strength of any Suture Material
 - B. High tissue reactivity (similar to Catgut Suture)
 - C. Increases risk of infection due to high capillarity

Nylon Suture

Ethilon Dermalon

- I. **Category**
 - A. Synthetic Nonabsorbable Suture (monofilament)
- II. **Advantages: Good choice for skin closure**
 - A. High tensile strength
 - B. Minimal tissue reactivity
 - C. Excellent elasticity
 - D. Low cost
- III. **Disadvantages**
 - A. High memory (requires 3 to 4 knot throws to hold)



1. Pliabilized ethilon in alcohol reduces memory

IV. Absorption (Hydrolyzes in skin at very slow rate)

- A. Year 1: 89% of tensile strength
- B. Year 2: 72% of tensile strength
- C. Year 11: 66% of tensile strength

Prolene
Polypropylene
suture

I. Category

- A. Synthetic Nonabsorbable Suture

II. Indications

- A. Subcuticular skin closure

III. Advantages

- A. High tensile strength (similar to Ethilon)
- B. Minimal tissue reactivity (similar to Ethilon)
- C. Slippery (allows for easy removal from tissues)

IV. Disadvantages

- A. Slippery (requires 4 knot throws to hold)
- B. High plasticity (loose after wound edema resolves)
- C. More expensive than Nylon Suture (Ethilon)
- D. More difficult to use than Nylon Suture



Braided Polyester Suture

Ethibond Ethiflex

Mersilene Dacron

I. Category

- A. Synthetic Nonabsorbable Suture

II. Advantages

- A. High tensile strength
- B. Low tissue reactivity
- C. Improved handling
- D. Improved knot security

III. Disadvantages

- A. High tissue drag (Ethibond and Mersilene)
 - 1. Ethibond has less drag due to coating
 - 2. Coating may crack after knot tied
- B. Higher cost than other Nonabsorbable Suture

Polybutester

Novafil

I. Category

- A. Synthetic Nonabsorbable Suture

II. Advantages

- A. High tensile strength
- B. Low tissue drag
- C. Marked elasticity
 - 1. Elongates 50% of length at 25% of knot-breaking load
 - 2. Stretches with wound edema
 - 3. Snug after edema resolves



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7.3. Suture Characteristics

A. Tensile Strength

1. Related to suture size (see below)
2. Related to weight required to break a suture

B. Knot strength

1. Force required for a knot to slip

C. Elasticity

1. Degree suture stretches and return to original length

D. Memory or suture stiffness

1. High memory: Suture stiff, difficult handling, unties

E. Tissue reactivity (inflammatory response to suture)

1. Reaction peaks in first 2 to 7 days

Suture types recommended for skin closure

A. Deep (dermal or buried) Absorbable Sutures

1. Polyglecaprone 25 (Monocryl)
2. Polydioxanone (PDS)
3. Polyglactin-910 (Vicryl)
4. Polyglycolic acid (Dexon)

B. Superficial, monofilament Nonabsorbable Sutures

1. Nylon (Ethilon)
2. Polypropylene (Prolene)

Suture Size (See suture types above)

A. General



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1. Superficial facial lesions: 6-0 nylon
2. Other superficial skin lesions
 - a. Low skin tension areas: 5-0 nylon
 - b. Higher skin tension areas: 4-0 nylon
- B. Annotation for suture size indications below
 1. Skin: Superficial monofilament Nonabsorbable Suture
 2. Deep: Dermal Absorbable Sutures
- C. Size 0: Largest suture
- D. Size 2-0
- E. Size 3-0
 1. Skin: Foot
 2. Deep: Chest, Abdomen, Back
- F. Size 4-0
 1. Skin: Scalp, Chest, Abdomen, Foot, Extremity
 2. Deep: Scalp, Extremity, Foot
- G. Size 5-0
 1. Skin: Scalp, Brow, Oral, Chest, Abdomen, Hand, Penis
 2. Deep: Brow, Nose, Lip, Face, Hand
- H. Size 6-0
 1. Skin: Ear, Lid, Brow, Nose, Lip, Face, Penis
- I. Size 7-0: Smallest Suture
 1. Skin: Eyelid, Lip, Face

Suture indications by location (see suture types above)

- A. Scalp, Torso (chest, back, abdomen), Extremities
 - i. Superficial Nonabsorbable Suture: 4-0 or 5-0



- ii. Deep Absorbable Suture: 3-O or 4-O
- B. Face, Eyebrow, Nose, Lip
 - i. Superficial Nonabsorbable Suture: 6-O
 - ii. Deep Absorbable Suture: 5-O
- C. Ear, Eyelid
 - i. Superficial Nonabsorbable Suture: 6-O
- D. Hand
 - i. Superficial Nonabsorbable Suture: 5-O
 - ii. Deep Absorbable Suture: 5-O
- E. Foot or sole
 - i. Superficial Nonabsorbable Suture: 3-O or 4-O
 - ii. Deep Absorbable Suture: 4-O

Suture removal timing

- I. Scalp: 6-8 days
- II. Face, Eyelid, Eyebrow, Nose, Lip: 3-5 days
 - A. Follow with papertape or steristrips
- III. Ear: 10-14 days
- IV. Chest and abdomen: 8-10 days
- V. Back: 12-14 days
- VI. Extremities: 12-14 days
- VII. Hand: 10-14 days
- VIII. Foot and sole: 12-14 days
- IX. Penis: 8-10 days
- X. Condition delaying wound healing: 14 to 21 days



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- A. Chronic Corticosteroid use
- B. Diabetes Mellitus



7.4. Storage of suture materials

The shelf-life period of suture filaments is specified on their individual packing with prefix EXP. or EXP. DATE. As a rule, for nonabsorbable filaments it takes 5 years, for absorbable ones – 3 years.

Suture of all types should be stored at room temperature. It's especially critical for synthetic absorbable filaments which change their native properties and lose durability under warming higher than 30°C or cooling lower than 0°C.

It is inadmissible to store filaments in open individual packages more than 24 hours. Besides reasons of aseptics, it is necessary to take into account, that synthetic resolving filaments absorb atmospheric moisture and become spoiled. For the same reasons they can't be sterilized in liquid mediums and formalin chambers. It is allowed to store suture filaments in closed individual foil package without external wrap within formalin chambers.



7.5. Classification and Assortment of Surgical Needles

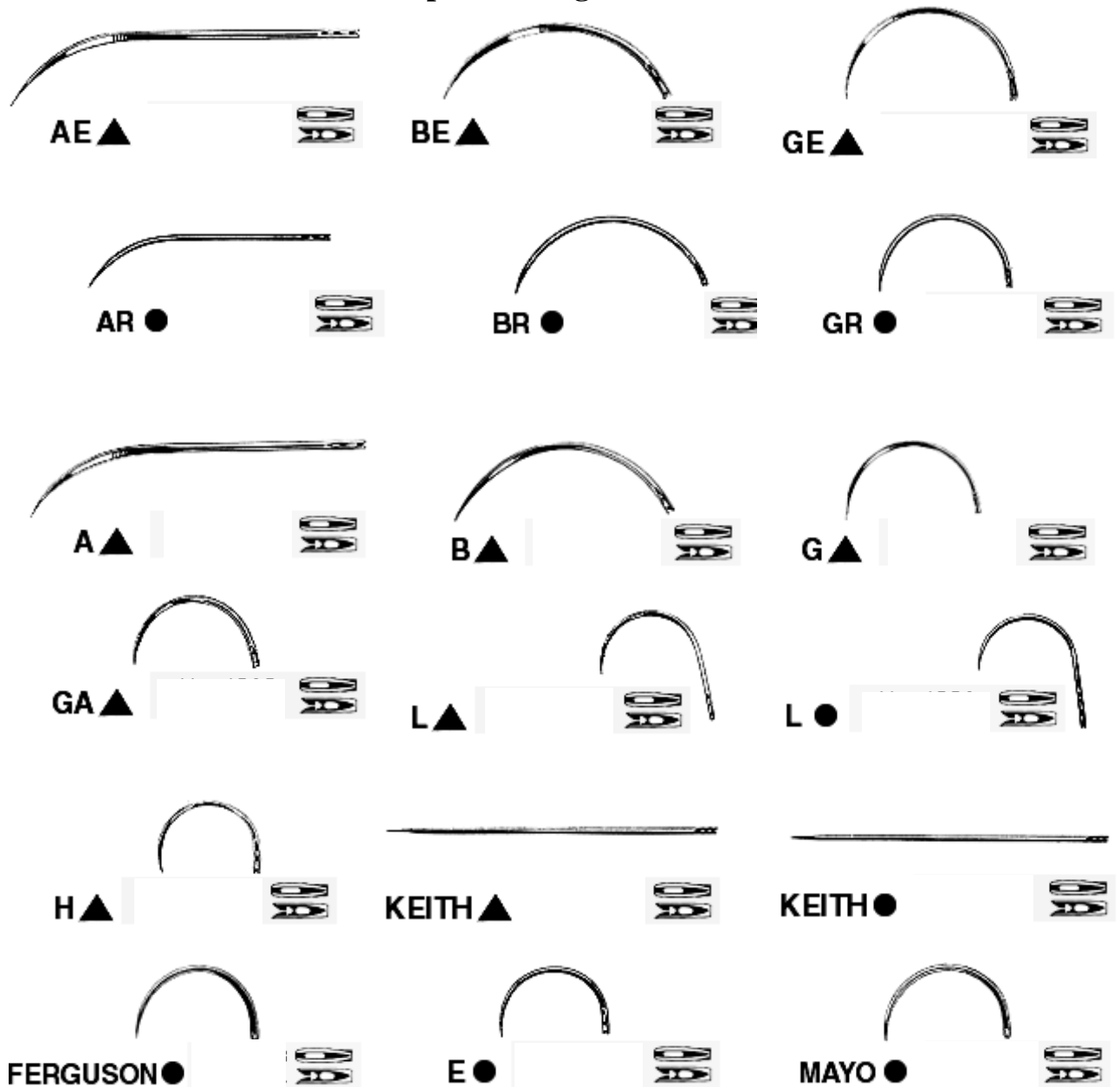
According to curvature

1. Straight needle
2. Curved 2/8 of circle
3. Curved 3/8 of circle (preferred needle in most cases)
4. Curved 4/8 of circle
5. Curved 5/8 of circle

According to needle tip

1. Tapered (used in vascular sutures)
2. Conventional cutting needle
3. Reverse cutting needle (preferred in most cases)

Examples of Surgical Needles



7.6. General information

Piercing needles

Piercing needles include surgical, non-traumatic and ligature ones.

Surgical needles are intended for sewing organism tissues together during surgical operations and anatomic autopsy. By purpose they are divided into surgical dermal needles, needles of general purpose (thick and thin), ophthalmic ones, cutting, intestinal (bent, straight with plain- oval part), vascular (bent and straight), for a liver.

Surgical needles have three basic parts: eye, body and edge.

Depending on design features they are divided:



◆ by curvature degree (from straight to strongly curved):

- 0 - straight needle;
- 1 - straight needle with bent end;
- 2 - needle bent on 2/8 circles;
- 3 - needle bent on 3/8 circles;
- 4 - needle bent on 4/8 circles;
- 5 - needle bent on 5/8 circles;

◆ by type of section and edge:

- A - with round edge (piercing);
- B - with three-edged (triangle section) edge (piercing & cutting);

◆ by kind of needle's eye:

- 1 - with cut eye (springing eye);
- 2 - with non-cut eye (non-springing eye);

Depending on design features and sizes each needle has its own symbols.
For example: surgical needle OA 2-0,4x30 GOST 25981-83 (a surgical needle, straight with round edge, non-springing eye, wire diameter is 0,4 mm and unbent length of a needle is 30 mm).

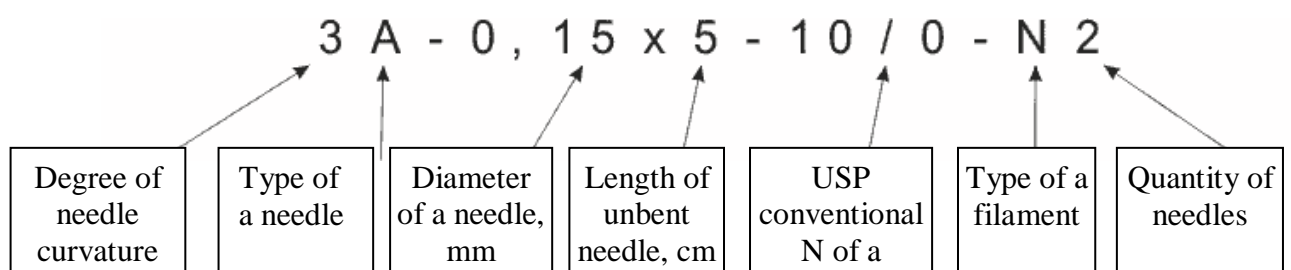
Needles are produced of carbonaceous steel wire.

Needles are sterilized by hot-air method at temperature 180°C during 45 minutes.

Non-traumatic needles– piercing needles with tightly fixed suture material, intended for sewing tissues of an organism during surgical operations, especially in heart, blood vessels, eyes, during cosmetic operations, in urinology and other fields of surgery where application of usual surgical needle causes additional traumas.

Non-traumatic needle is steel wire of direct or bent shape which has sharp end and the opposite one is a tube which holds end of filament (ligature) tightly pressed inside. Diameter of a needle is maximally close to thickness of a filament. Needles are produced of high-strength corrosion-proof steel.

The order of symbols in international coding of non-traumatic needles:





The table of correspondence of conventional filament numbers (USP) to metric sizes by European scale (E.P.)

USP (conventional number)	10/0	9/0	8/0	7/0	6/0	5/0
Eur. Ph (metric size)	0.2	0.3	0.4	0.5	0.7	1.0

By shape piercing needles are distinguished as:

round;

three-edged (cutting - with front and back-side edge),

piercing with cutting end (often applied to pierce connective tissues);

spatula-type;

blunt (for sewing of parenchymatous tissues).

Depending on way of assembly the goods are divided into single- and double-needed.

Many firms produce “pop-off” or “control release” needles which become broken away from a filament after sharp strength applied to needle axis.

Ligature needles for general surgery (fig. 1) are intended to conduct a suture material (ligature) under blood vessels and channels. There are right and left blunt needles for connection of bone fracture fragments with a wire of three numbers with bending radius of working part 14, 17 and 20 mm; for ophthalmology – blunt needles for lacrimal canal, 1 mm wide; acute ones – for sewing palatine handles № 1 (Kulikovsky’s) and № 2 with double flexure.

Ligature needles are produced of stainless steel.

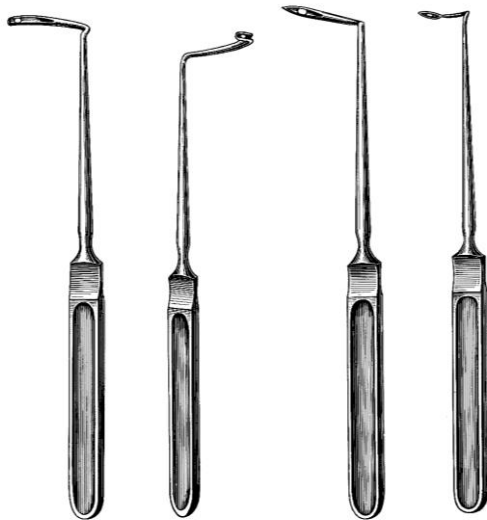


Fig. 1. Ligature needles.

Clips and brackets for sewing and ligation. For ligation of brain vessels silver clips are used. To apply clips there is special tool kit including three types of forcepses – direct and bent horizontally and vertically, together with clip bearing plate preliminary composed before surgery operation.

For skin closure Michel's brackets are applied (fig. 2). They are removed after wound healing. For ligation of umbilical cord special brackets are applied.

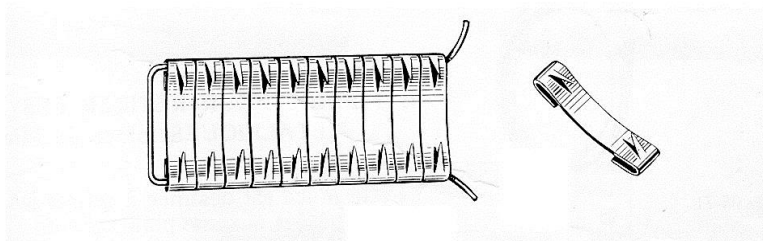


Fig. 2. Michel's brackets.

Technical requirements for surgical needles:

- 1) piercing parts should be sharp;
- 2) a needle should be straight, even and smooth by all length;
- 3) needles should be resilient (should not have residual deformation);
- 4) needle's eye should be unbroken, without jags, acute edges which can damage or tear suture material;
- 5) stirrups of springing needle eye should be resilient and tightly hold suture material;
- 6) needles should withstand disinfection, presterilizing processing and



sterilization;

7) needles should be corrosion-proof.

Packing, marking, transportation and storage

Packing. Surgical needles should be packed into consumer, group and shipping containers. Non-traumatic sterile needles with suture material are packed into individual consumer package. Sterilization is provided by gaseous method. Term of sterility – 2 years. Non-sterile suture materials in reels and surgical, non-traumatic needles are packed into cardboard boxes. For group package it's also possible to use cardboard boxes or packs wrapped with packing paper, tied with twine or band of synthetic fibers. Cardboard or wooden boxes are used as shipping containers.

Marking. Onto consumer and group package an inscription or label should be rendered indicating the following:

- name of an enterprise - manufacturer and its trademark;
- name of a product;
- symbols, numbers and brands;
- type of production units and length of a string;
- quantity of production units;
- batch (lot) number;
- manufacturing date;
- designation of the standard.

Each box is provided with two labels (one is put inside, and the second one is stuck onto outside surface) indicating:

- name of enterprise - manufacturer and its trademark;
- name of a product;
- symbol;
- quantity;
- information about passing through quality checking department;
- manufacturing date;



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- designation of the standard.

Onto shipping containers handling instructions "Avoid damp", "Fragile" (for sterile products, packed into ampoules) are printed.

Transportation. Suture materials and surgical needles are shipped by different types of transport in covered vehicles.

Storage. Suture materials and surgical needles should be stored in package within aired premises under conditions preventing their pollution, mechanical damages and effect of solar beams. It is necessary to place them on racks and shelves providing distance from a floor not less than 20 cm, avoiding contact with walls and heating devices. Air temperature in premises should vary 5 to 20°C, relative humidity- not more than 70 %.