

Appellation

1. Item Name

1) Item Name: Other Non-absorbable Suture Thread

Product Name: SOONI(순이)



2) Classification No.: B02020.14

3) Grade: 3rd Grade

2. Model Name

1) Model Name: ANGS 01 and other 45 Models

Shape and Structure - Operating Principle

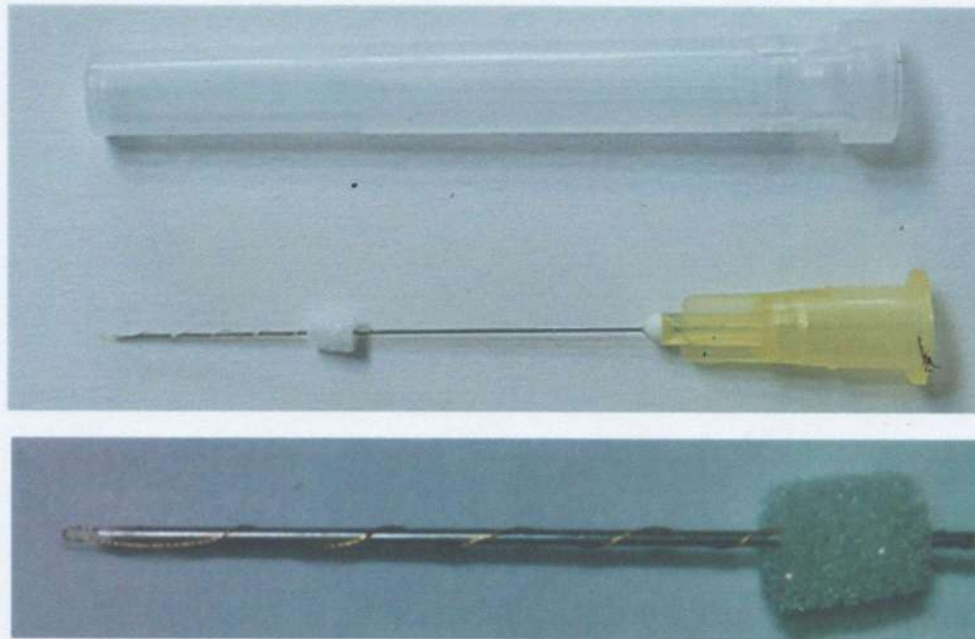
This product consists of non-absorbable gold thread (99.99% pure gold) and a sterile injection needle. It is used on the human body for treatment purposes, not for the injection of drugs or other substances.

Shape and Sturcture - Appearance

1. Picture of the Appearance



(1) GK TYPE

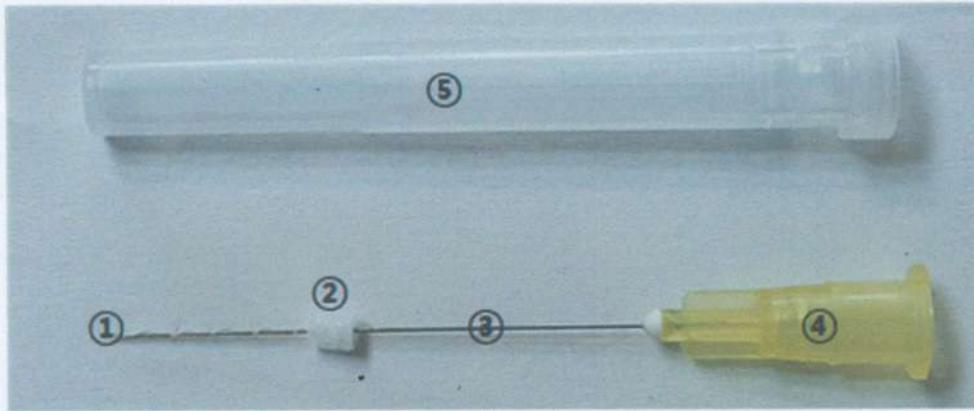


: Insert part of the suture thread into the needle tube, wrap the outside of the needle tube around with the remaining part of the suture thread, and secure it with a sponge.

<Magnified picture of our non-absorbable suture thread>



2. Explanation of the Appearance

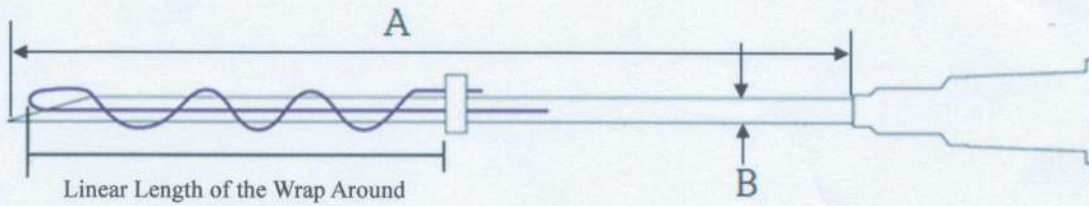


No.	Name	Functions
①	Suture (Thread)	The suture, made of four twisted strands of non-absorbable gold material , is inserted into the skin tissue.
②	Sponge	The needle tube and the suture are fixed with this.
③	Needle Tube	The needle is used to insert the non-absorbable suture thread into the body.
④	Needle Handle	The needle tube is inserted into its hole and fixed to facilitate the attachment of the needle and it serves as a handle during the treatment.
⑤	Protection Cover	The cover protects the needle tip and the suture.

Shape and Sturcture - Appearance

1) GK Type

No.	Model Name	Sterile Needle		Non-absorbable Suture Thread				
		Outside Diameter of Needle Tube (mm)	Length of Needle Tube (mm)	Diameter (mm)		Number of Strands	Linear Length of the Wrap Around	Total Length (mm) (95% or More of the Length below)
				Diameter of One Strand (Standard: USP)	Diameter of Twisted Strands			
1	ANGK 01	31G (0.254~0.267)	13 (+1.5/-2.5)	0.020~0.029 (10-0)	0.020~0.039	4		15
2	ANGK 07		25 (+1.5/-2.5)					30
3	ANGK 09	30G (0.298~0.320)	38 (+1.5/-2.5)	0.020~0.029 (10-0)	0.020~0.039	4		40
4	ANGK 10		38 (+1.5/-2.5)					50



O Material or Ingredients and Amount (Medical Products)

No.	Part Name	Name of Material or Ingredient	Specs	Content	Skin Contact	Note	
1	Suture Thread	GOLD	Company Spec 1	100%	Yes	Skin Tissue	
2	Sponge	Ethylene-vinyl Acetate Copolymer	Company Spec 2	100%	No		
3	Sterile Needle	Needle Tube	304 Stainless Steel	KS D3698	100%	Yes	Skin Tissue
		Lubricant	Polydimethylsiloxane	EP	100%	Yes	Skin Tissue
		Handle	Polypropylene	Company Spec 3	100%	No	
		Protection Cover	Polypropylene	Company Spec 3	100%	No	
		Adhesive	Poly(Bisphenol A-co-epichlorohydrin), glycidyl end-capped	Company Spec 4	100%	No	

Company Spec 1 GOLD

- Product Name: Gold Wire(4N)
- Manufacturer: HEESUNG METAL LTD.
- Material Name and Content

Chemical Name	CAS No.	EINECS No.	Content (%)
Gold	7440-57-5	231-165-9	≥99.99%

- Physical State: Solid at 20 °C
- Appearance: Wire (Not power)
- Hydrogen Ion Concentration (pH): 6.5~7.5 at 20 °C
- Flash Point: Not flammable below 110 °C (Rapid Equilibrium Method)
- Ignition Point: Does not spontaneously ignite below 300 °C
- Water Solubility: Insoluble at 20 °C
- Specific Gravity: 19.32 at 20 °C
- Melting Point: 1,065 °C (Gold)
- Boiling Point: 2,700 °C (Gold)

Company Spec 2 Ethylene-vinyl Acetate Copolymer

- Product Name: Hanwha Total Ethylene Vinyl Acetate Copolymer E153F
- Chemical Name: Ethylene-vinyl Acetate Copolymer
- CAS NO.: 24937-78-8
- Manufacturer: Hanwha TotalEnergies Petrochemical Co., Ltd.
- Melting Point: 40~110 °C
- Specific Gravity: 0.920~0.960
- Auto-ignition Temperature: >350 °C
- Decomposition Temperature: 340 °C
- Molecular Weight: >1,000

Company Spec 3 polypropylene

- Product Name: TOPLENE J800S
- Chemical Name: Polypropylene
- CAS NO.: 9003-07-0
- Manufacturer: Hyosung Corporation
- Melting/Freezing Point: 130~170 °C
- Solubility in Water: Insoluble
- Specific Gravity: 0.88~0.92Kg/L (at 20 °C)
- Appearance (Color/State): Opaque colorless to yellow solid
- Odor: Odorless
- Molecular Weight: >10,000
- Molecular Formula: [CH₂-CHCH₃]_m

**Company Spec 4 Poly(Bisphenol A-co-epichlorohydrin), glycidyl end-capped**

- Product Name (Model): Polymer Resin (FD-15L)
- Manufacturer: SEGO ENG
- Composition and Content:

Name of Material	CAS NO.	Content (%)
Poly(Bisphenol A-co-epichlorohydrin), glycidyl end-capped	25036-25-3	85 - 90
Reactor	Complex	5 - 10
Additives	mixture	0 - 5

- Appearance: White or grayish-white high-viscosity liquid
- Odor: Odorless
- pH: 6 - 8
- Viscosity (25 °C): 8,000 - 40,000cps (25 °C)
- Specific Gravity: 1.1 - 1.4 (Water=1)
- Flash Point: 250 °C

Manufacture Method

A. Manufacture Method

Follow the manufacture method of the original manufacturer.

B. Sterilization Method

- ① Sterilization Method: E. O. GAS Sterilization (In accordance with ISO 11135)



Purpose of Use

This product consists of a sterile needle and a non-absorbable suture (99.99% gold thread). It is used for therapeutic purposes on the human body and not for the injection of drugs or other substances.

Performance

A. Performance of the End Product

- Appearance: It is the same as in 'Shape and Structure - Appearance'. There are no foreign substances, scratches, or damages on the product.



B. Performance of non-absorbable suture

- Total length: 95% or more of the indicated value in 'Shape and Structure - Dimensions'.
- Diameter: Complies with the allowable range in <Table 1>, when tested according to the non-absorbable suture section of the medical device standards.
- Diameter after Braiding: Complies with the allowable range in <Table 1>, when tested according to the non-absorbable suture section of the medical device standards.

<Table 1>

USP Size	Range of Average Diameter (mm)		Range of Average Diameter after Braiding (mm)	
	Minimum	Maximum	Minimum	Maximum
10-0	0.020	0.029	0.020	0.039
9-0	0.030	0.039	0.030	0.059
8-0	0.040	0.049	0.040	0.079

C. Performance of Sterile Needle

- Interior and exterior: Suitable, when tested according to the sterile hypodermic needles section of the medical device standards.
- Dimensions: Meets the specified dimensions, when tested according to the sterile hypodermic needles section of the medical device standards.
- Elasticity: The needle tube returns to its original position, when tested according to the sterile hypodermic needles section of the medical device standards.
- Flexural strength: The needle tube does not break, when tested according to the sterile hypodermic needles section of the medical device standards.
- Unplugging: The needle tube does not detach from the needle handle, when tested according to the sterile hypodermic needles section of the medical device standards.
- Elution test: Suitable, when tested according to the sterile hypodermic needles section of the medical device standards.

How to Use

A. Preparations before use

- 1) Check the model according to the dimensions.
- 2) Check if the expiration date has passed and ensure there are no damages to the package.
- 3) Familiarize yourself with how to use the product.

B. How to operate and use

- 1) Determine the length of the needle, considering the treatment location.
- 2) Disinfect the affected area to be treated.
- 3) Insert the needle tube until the end of the suture is fully inserted into the epidermis of the affected area.
- 4) Remove the needle and place a bandage over the needle hole.

C. Storage and management after use

- 1) Dispose of the product even if it has not been used after opening.
- 2) Do not reuse this product as it is a single-use product.



Precautions for Use

A. Warnings

- 1) This product should be used by a qualified medical professional who has completed specialized training for the use of the product.
- 2) Do not re-sterilize this product. Dispose of any unused or expired products after opening.
- 3) Do not use this product for cosmetic or plastic surgery purposes, such as facial tissue fixation threads.

B. Precautions on the age, gender, or health condition of the patient, considering the characteristics of the medical device

- 1) Use with caution if there is inflammation on the treatment area or if there is a risk of other infections.
- 2) Do not use on patients with severely declined immune systems.
- 3) Do not use on patients with any medical conditions that prevent proper use of this product.

C. Precautions for adverse reactions and side effects due to improper use of the medical device

- 1) In case of infection at the wound or transient inflammatory reactions such as erythema or induration of the epidermis, seek medical advice and follow the doctor's prescription and guidance.

D. General Precautions

- 1) Users must fully understand the usage instructions before use.
- 2) Do not use and dispose of the product if the individual packaging is damaged.
- 3) Check the expiration date before use and do not use products that have expired.
- 4) This product is a single-use sterile medical device and should not be reused or re-sterilized under any circumstances.

E. Precautions in Application

- 1) Be cautious of needle stick injuries as they can transmit blood-borne pathogens.
- 2) Dispose of used needles safely in a designated disposal box.

Storage Method

A) Storage Method

Avoid direct sunlight and humid places; Store at room temperature.

B) Packaging Method and Packaging Material

- ① Packaging Method: Primary packaging followed by secondary packaging in an aluminum pouch.
- ② Packaging Material:
 - Primary packaging: Polyethylene Terephthalate film + Sterile paper = Pack
 - Secondary packaging: Aluminum (AL) pouch



Packaging Unit

Company's packaging unit

Period of Use

Three(3) years from the date of manufacture

Test Standards

A. Safety Tests

- 1) Non-absorbable Sutures
 - Comply with the "Common Standards for Biological Safety of Medical Devices."
- 2) Sterile Injection Needles
 - Comply with the "Standards for Medical Devices" under 'Sterile Injection Needles.'
- 3) End Products
 - Comply with the "Common Standards for Biological Safety of Medical Devices."



B. Performance Tests

1) Tests as a Whole

NO.	Test Area	Standards	Test Method
1	Exterior	Should be identical to the 'Shape and Structure - Appearance', free from foreign substances, scratches, or damage, etc.	Observe with the naked eye.

2) Tests for Non-absorbable Sutures

NO.	Test Area	Standards	Test Method
1	Exterior	There should be no defects such as wounds, peeling, twisting, or scratches that could hinder usage.	Observe with the naked eye.
2	Total Length	The length should be at least 95% of the indicated length.	Measure the length of the suture by placing it in a straight line on a flat surface without applying tension.
3	Diameter	The average diameter of 10 strands of sutures should be within the allowed range specified in the diameter standard table (Table 1).	Test according to the non-absorbable suture section of the Standards for Medical Devices.
4	Diameter after Braiding	The average diameter of 10 strands of sutures should be within the allowed range specified in the diameter standard table (Table 1).	Test according to the non-absorbable suture section of the Standards for Medical Devices.

Standard Table <Table 1>

USP Size	Range of Average Diameter		Range of Average Diameter after Braiding	
	Min.	Max.	Min.	Max.
10-0	0.020	0.029	0.020	0.039
9-0	0.030	0.039	0.030	0.059
8-0	0.040	0.049	0.040	0.079

3) Tests for Sterile Injection Needles

- Comply with the "Standards for Medical Devices" under 'Sterile Injection Needles.'