Made For GDT Implants
Yltzhak Ben Zvi 9/64
Beer Sheva, Israel
Tel: +972.54.77.90.282
info@gdt-implants.com
www.gdentalt.com

ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE

GDT PGA SUTURE

INSTRUCTIONS FOR USE

DESCRIPTION

GDT PGA suture is a synthetic coated, braided absorbable sterile surgical suture composed of a homo polymer of glycolide (100%). Violet is dyed and coated with a unique combination of polycaprolactone and calcium stearate.
Available in abroad range of sutures sizes and lengths, attached to hardened stainless steel needles.
The needles are attached permanently to the suture. Entire detail of the product range is contained in the catalogue.

INDICATIONS

PGA sutures are indicated for use in general, soft tissue including use in ophthalmic. But not for use in cardio vascular & neurological tissues.

SELECTION

The sutures should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE

GDT PGA suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. Progressive loss of tensile strength occurs as the suture gets absorbed by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized in the body. Absorption begins with loss
of tensile strength followed by loss of mass. All of the original tensile strength is lost between four and five weeks post implantation. GDT PGA suture elicits a minimal tissue reaction and in growth of fibrous connective tissue. Absorption of bio absorbable suture occurs by hydrolysis: beginning with loss of tensile strength with loss of mass.
GDT PGA retains 70% of its tensile strength by the end of the second week and it's progressively absorbed between 60 and 90 days. Absorption pattern for suture when tested on rats:

- Approx 96.1 % of the tensile strength at 7 days.
- Approx 83.3 % of tensile strength at 14 days.
- Approx 53.8 % tensile strength after 21 days.
- Approx 19.95 % tensile strength after 28 days.

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include transitory local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, PGA suture may enhance an existing infection.

CONTRAINDICATIONS

PGA suture, being absorbable, should not be used where extended approximation of tissues under stress is required. If there is any localized inflammation, itching or any sort of allergy of a particular patient then the usage of this product should be stopped and medical advice should be taken immediately. The use of this suture is contraindicated in patients with known sensitivities or allergies to polyglycolic acid, calcium stearate and polycaprolactone.

WARNINGS:

a. Surgeons should be familiar with surgical procedures and techniques involving absorbable sutures before employing PGA suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

b. This suture many be inappropriate in patients suffering from conditions which may delay wound healing e.g., patient that are elder, malnourished or depilated. As this is an absorbable suture, the use of supplemental non-absorbable suture should be considered by the surgeon in the close of the abdomen, chest, joints or other sites subjects to expansion or requiring additional support.

c. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.

d. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

e. Contamination of the device may lead to injury, illness of the patient.

PRECAUTIONS

a. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

b. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

c. Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

d. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.

e. When handling this or any other suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

f. Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area, one third (1/3) to one half (1/2) of the distance from the attachment end to the point.

g. Grasping in the point area could impair the penetration performance and cause fracture of the needle.

h. Grasping at the butt or attachment end could cause bending or breakage.

i. Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.

j. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use.

STERILITY

Sutures are sterilized by ethylene oxide. The sterility of undamaged, unopened packs is guaranteed. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

STORAGE

Recommended storage condition 5°C-25°C, away from moisture and direct heat. Do not use after the expiry date.

DISPOSAL

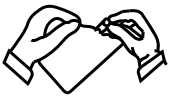
Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

INSTRUCTIONS FOR USE

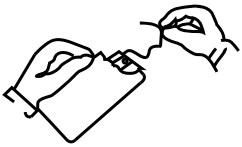
A. Technique for opening the over wrap

1. The scrub nurse should hold the sterile pack in their left hand with the color-coded top facing her. The notch will be located at the top right.

2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needled suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.



3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.



B. Technique for opening the peel open pouches containing sutures.

1. Hold the pack in an upright manner and see the peel logo.
2. Hold the protruded portions of the aluminum foils and peel open to see the needle fixed on the paper folder.
3. With the help of sterilized forceps pull the needle to remove the suture from the folder.

PACKAGING

2/0 USP (metric EP 3.0)	**Ref: PA30**
3/0 USP (metric EP 2.0)	**Ref: PA40**
4/0 USP (metric EP 1.5)	**Ref: PA50**

SYMBOLS

	Consult instructions for use		Do not resterilize
	Caution, consult accompanying documents		Do not re-use/ for single use only
	Temperature limit		Manufacturer
	Keep away from sunlight	REF	Catalogue number
	Keep dry	LOT	Batch code
STERILE OE	Sterilized by ethylene oxide		Use by
	Do not use if package is damage		Date of Manufacture

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.
The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product.
Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.