DSI DENTAL
SOLUTIONS

Sterile Synthetic Absorbable Surgical Suture

DSI PGA RAPID Suture

INSTRUCTIONS FOR USE

DESCRIPTION

DSI PGA Rapid sutures are sterile, synthetic, absorbable, multifilament (braided), coated surgical sutures intended for soft tissue approximation.
The suture is composed of a copolymer of approximately 90% glycolide and 10% L-lactide (Polyglactin 910).
The coating consists of a glycolide-lactide copolymer and calcium stearate.
The coating improves handling characteristics, reduces tissue drag, and enhances knot tie-down performance.
DSI PGA Rapid sutures are supplied in violet colour to enhance visibility in the surgical field.
The sutures are available in a range of sizes and lengths and may be supplied with permanently attached hardened stainless steel needles of various types and sizes.
Full details of the product range are available in the product catalogue.

INDICATIONS: DSI PGA Rapid sutures are indicated for soft tissue approximation in dental implantology, general surgery, plastic surgery, ophthalmic surgery, gynecology and obstetrics (including episiotomy), pediatric surgery, gastrointestinal procedures, and orthopedic soft tissue procedures where short-term wound support is required.
Not indicated for use in cardiovascular or neurological tissues.

SELECTION: The suture should be selected and implanted based on the patient's condition, surgical experience, surgical technique, tissue type, wound characteristics, and the required duration of wound support.
Because of its rapid loss of tensile strength, DSI PGA Rapid is intended for procedures requiring short-term tissue support.

PERFORMANCE

DSI PGA Rapid sutures elicit a minimal initial inflammatory tissue reaction followed by ingrowth of fibrous connective tissue.

Progressive loss of tensile strength and absorption occur by hydrolysis. During this process, the copolymer degrades into glycolic acid and lactic acid, which are subsequently absorbed and metabolized by the body.

Tensile Strength Profile (in vivo):

- Approximately 50% of the initial tensile strength remains at 5 days post-implantation.
- Complete loss of tensile strength occurs by approximately 14 days.

Absorption Profile:

- Absorption begins with loss of tensile strength followed by loss of mass.
- Complete absorption occurs within approximately 40-45 days.

ADVERSE REACTIONS

Adverse reactions associated with the use of this device may include tissue separation or wound dehiscence, transient local irritation at the wound site, temporary inflammatory foreign body response, erythema and induration during absorption, suture extrusion, delayed absorption in tissues with poor blood supply, potentiation of infection, and calculus formation in urinary or biliary tracts following prolonged exposure to salt solutions.

As with all foreign bodies, the suture may aggravate an existing infection.

CONTRAINDICATIONS

Due to the rapid loss of tensile strength, DSI PGA Rapid should not be used where extended tissue approximation under stress is required or where wound support beyond approximately 7-10 days is necessary.

The use of this suture is contraindicated in patients with known sensitivities or allergies to glycolide, lactide, caprolactone (if present in coating), or calcium stearate.

WARNINGS

a. Healthcare professionals should be familiar with surgical procedures and techniques involving rapidly absorbable sutures before employing DSI PGA Rapid for wound closure.

b. Because of rapid strength loss, wound dehiscence may occur if used in tissues requiring prolonged support.

c. In sites subject to expansion, stretching, or distension, supplemental non-absorbable sutures should be considered.

d. As an absorbable suture, this device may act transiently as a foreign body.

e. Do not reuse, reprocess, or re-sterilize. Reuse may compromise structural integrity and increase the risk of contamination or cross-infection.

f. Do not use if the package is opened or damaged.

PRECAUTIONS

a. Follow accepted surgical practice for management of contaminated or infected wounds.

b. Skin sutures remaining in place longer than necessary may cause localized irritation and should be removed as clinically indicated.

c. Use caution in tissues with poor blood supply, as delayed absorption or extrusion may occur.

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

e. Avoid crushing or damaging the suture with surgical instruments.

f. Grasp the needle at a point one-third (1/3) to one-half (1/2) the distance from the attachment end to the tip.

g. Avoid grasping the needle tip, as this may impair penetration or cause fracture.

h. Do not reshape needles, as this may weaken them.

i. Exercise caution to avoid needle stick injuries. Dispose of needles in approved sharps containers.

STERILITY

DSI PGA Rapid sutures are sterilized by ethylene oxide. Sterility of unopened, undamaged packages is guaranteed. Do not re-sterilize. Do not use if the package is opened or damaged.

Discard opened, unused sutures.

STORAGE

Store at 5°C-25°C. Protect from moisture and direct heat.
Do not use after the expiry date. Failure to comply with storage conditions may affect performance characteristics and reduce shelf life.

DISPOSAL

Used sutures and needles contaminated with blood should be discarded in designated infectious waste containers. Unused expired products should be disposed of according to local regulations (e.g., incineration).

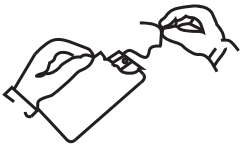
INSTRUCTIONS FOR USE

A. Technique for Opening the Overwrap

1. The scrub nurse should hold the sterile pack with the colour-coded top facing upward. The notch will be located at the top right.

2. Using sterilized gloved hands or sterilized forceps, pull the paper folder until the needle is visible. For non-needled sutures, remove the entire paper folder from the pack, open the folder, and retrieve the suture.

3. Using sterilized forceps, grasp the needle and gently pull to remove the suture from the folder.



B. Technique for Opening Peel-Open Pouches

1. Hold the pack upright and locate the peel indication mark.
2. Grasp the protruding edges of the aluminum foil and peel open carefully to expose the needle attached to the paper folder.
3. Using sterilized forceps, grasp the needle and remove the suture from the folder.

PACKAGING

Length: 75 cm
Needle: 3/8 circle, reverse cutting, atraumatic
Packaging unit: 12 sutures per box

Available sizes and needle configurations:

- 3/0 USP (EP 2.0), 19 mm needle **Ref: DS-PGRA30**
- 4/0 USP (EP 1.5), 19 mm needle **Ref: DS-PGRA40**
- 5/0 USP (EP 1.0), 19 mm needle **Ref: DS-PGRA50**
- 5/0 USP (EP 1.0), 13 mm needle **Ref: DS-PGRA50-N13**

Available sizes and configurations may vary by market. Refer to the product catalogue for the complete range.

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 damaged		Date of Manufacture

Failure to comply with the conditions of storage leads to changes in the working characteristics of the material and decreases its shelf life.
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.