INSTRUCTIONS FOR USE

Polyglycolic Acid Suture

Absorbable - Multifilament - Synthetic - Sterile

Description:

Polyglycolic Acid (PGA) is a sterile absorbable synthetic, multifilament suture composed of glycolic acid. The yarns are braided and coated with a blend of polycaprolate, copolymer of caprolactone and glycolide and calcium stearate. The PGA Suture is available dyed and undyed (natural) from sizes USP4-8/0.

PGA sutures fulfill all the requirements of USP and the European Pharmacopoeia for sterile, synthetic, absorbable sutures.

Indications:

PGA sutures are indicated for use in general surgery. It is suitable for the coating of soft tissue and for ligation and also for use in ophthalmic procedures but not for use in cardiovascular tissue and neural tissue.

Actions:

A slight tissue inflammation may occur when PGA Sutures are placed in tissue, which is characteristic of foreign body response, which is followed by gradual encapsulation by connective tissue. PGA sutures have a high initial tensile strength, which is retained for up to 28 days. After which absorption by hydrolysis begins, where the polymer degrades to glycolic acid, which is absorbed by the body between 60-90 days.

Contraindications:

The PGA sutures are absorbable and should not be used where long suture support is necessary.

Adverse Events / complications:

Wound dehiscence, enhanced bacterial infectivity, infection and transitory local irritation.

Warnings:

This product must not be re-sterilized. If the suture sachet is damaged, it should be discarded. The PGA Sutures should be stored in a dry room, not exposed to direct sunlight or extreme temperatures. As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

Sterile product. Sutures cannot be re-sterilized or reused. Do not use if the inner package is damaged, or there will be risk of fever, infection, etc. Reuse of the suture will cause the following situation during surgery: thread break, texture, dirt, connection of needle and thread break and for the patient more risks after surgery, like fever, infection thrombus, etc. In the case of partly used of suture, the remaining should not be used, otherwise there are risks for patient like fever, infection, thrombus etc.

Precautions:

When handling PGA sutures, it is necessary to handle the suture and needle with care, paying particular attention to the needle and avoiding damage being caused by the needle holders. The users should have sufficient knowledge and be familiar with absorbable surgical sutures and the particular decreasing tensile strength before handling sutures.

PGA is not suitable for elderly or debilitated patients or patients with retarded wound healing. Tissue with poor blood circulation may reject the suture material due to the delayed absorption.

Reactions:

Slight inflammatory tissue reactions may occur initially in the environment of the suture material. Prolonged contact of any suture with salt solutions, such as those in the urinary or biliary tracts, may cause calculus formation.

How supplied:

Polyglycolic Acid Sutures are available from USP4-8/0. They are available violet coloured and are supplied sterile, in a variety of lengths, non-needled or affixed to various needle types in one, two or three dozens per box.

Storage Conditions:

It is recommended that PGA sutures are stored below 25°C kept away from direct heat and moisture.

Carefully observe the expiry date.

Manufacturer:

Shandong Haidike Medical Products Co., Ltd.
Add: Tianfu Road, Dongcheng District, Shan County,
274300 Heze City, Shandong Province, China

Explanation of the Symbols on Packaging:

2	Do not re-use
STERILE R STERILE EO	Gamma irradiation Ethylene Oxide irradiation
	Consult instructions for use
	Do not use if package is damaged
	Expiration Date
	Manufactured Date
REF	Catalogue Number
LOT	Batch number
	Keep away from sunlight
	Keep dry
	Temperature Limitation
	Fragile: Handle with care
CE	CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

EC REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
Tel: +34 951 214 054
Email: info@cmcmedicaldevicec.com

Importer:

GRAPH GROUP Vitalii Lutskov
Add: Sikorskiego Av. 18/28, 02-758, Warsaw, Poland
Tel: +48 884 099 660
Email: info@graphgroup.pl
Web: www.graphgroup.pl

SRN: PL-IM-000044202 CE 2292 UDEM **Version No.: A/3**