Instruction for Use

INTRODUCTION

Biotex Non-Absorbable PTFE Suture is comprised of a single-arm, non-absorbable monofilament suture with a stainless-steel surgical needle connected to the suture. The suture is uncoated, undyed and sterile for single use only, composed of 100% high-density PTFE.

INDICATIONS

Biotex Non-Absorbable PTFE Suture is indicated for use in dental soft tissue approximation and/or ligation. The device is not indicated for use in cardiovascular, ophthalmic surgery, microsurgery or peripheral neural tissue.
Biotex is provided sterile as a single use device and the duration of use or contact with the body should be less than 30 days.

FEATURES

Biotex Non-Absorbable PTFE Suture meets all requirements established by the USP and Ph Eur for Non-absorbable surgical suture. There is no significant loss of tensile strength over time.

1. Thread (PTFE)
   - The high elasticity feature of PTFE allows easy knot security with less unsecured knot
   - The monofilament structure leaves no room for plague and protects from any possible bacterial infection which may interfere with the healing of the wounds.
2. Needle (304 Stainless Steel)
   - The uniquely slim, reverse cut needle produces a minimal entry size with the least possibility of peripheral tissue damage.
3. Package
   - The package prevents suture from tangling when pulling it out by using a needle holder.
   - It is easy to grasp the needle by simply pressing the transparent cover.
   - There are 10 individual packs of suture in one single packaged box.

CONTRAINDICATIONS

1. Application in cardiovascular, ophthalmic and peripheral neural tissue surgeries and microsurgery are prohibited.
2. Do not use in patients who suffer from mental and/or physical illness.

WARNINGS

1. If the suture is not removed within 30 days as indicated, it may be difficult to remove due to the adhesion between the suture and tissue.
2. Appropriate treatment should be given if any signs of active infection and/or potential infection are detected at the treatment site.
3. If allergic reaction or hypersensitivity to PTFE material at the treatment site is diagnosed, appropriate treatment should be provided to the patient.

PRECAUTIONS

1. Use for medical purposes only.
2. The device shall be used by medical professional who is well trained in surgical techniques.
3. Do not use suture if the needle is damaged or has been altered in any way.
4. Care should be taken to avoid any risk of contamination. Do not use if there is any possibility of suture contamination.
5. Broken needles or damaged threads may result in extended or additional surgery or retained foreign bodies.
6. Care should be taken when driving the needle while grasping it at the 1/3 to 1/2 point from the direction where the needle and thread are attached in order to avoid needle damage.
7. Practitioner must check with patients to see if they have any special conditions such as diabetes, which may require special care.
8. Select an appropriate length and thickness of suture for each patient.
9. Biotex Non-Absorbable PTFE Suture is designed for single use only. Reuse of this medical device bears the risk of patient cross-contamination.

SIDE EFFECTS

Below is the list of potential adverse events that are known to be associated with suture use.

1. Tissue dehiscence
2. Infection
3. Localized inflammatory reaction
4. Transitory local irritation

HOW TO OPERATE

1. Open the suture package.
2. Apply using appropriate needle holder.
3. Conduct surgical procedures on the wound or cut as indicated.
4. Once the knot is secured properly, the excess suture should be trimmed using surgical instruments.
5. Remove the sutures between 10 to 29 days after surgery.

STORAGE

1. Biotex Non-Absorbable PTFE Suture should be stored at the temperatures between 10~25℃ in a dry place.
2. Biotex Non-Absorbable PTFE Suture should be kept away from direct sunlight
3. Protect the package from any damage caused by the needle.

DISPOSAL

The used needle and suture must be disposed in an appropriate receptacle with the designated label on.

SYMBOLS GLOSSARY

	Do not reuse		Catalogue number
	Method of sterilization		Attention, see instruction for use
	Do not resterilize		Use by
	Manufacturer		CE mark and identification number of notified body
	EU Representative		Lot number
	Temperature limit		Do not use if package is damaged
	Keep away from sunlight	Rx Only	Prescription only

SIZES

No.	Model Name	Needle Length (mm)	Suture Length	Suture Diameter (USP)	EP / Metric	Circle	Needle Section	Tensile Strengths (kgf)
1	BT3019	19	18"/45cm	3-0	2	3/8	▽	≥ 0.96
2	BT4019	19	18"/45cm	4-0	1.5	3/8	▽	≥ 0.60
3	BT5019	19	18"/45cm	5-0	1	3/8	▽	≥ 0.42
4	BT3016	16	18"/45cm	3-0	2	3/8	▽	≥ 0.96
5	BT4016	16	18"/45cm	4-0	1.5	3/8	▽	≥ 0.60
6	BT5016	16	18"/45cm	5-0	1	3/8	▽	≥ 0.42
7	BT3013	13	18"/45cm	3-0	2	3/8	▽	≥ 0.96
8	BT4013	13	18"/45cm	4-0	1.5	3/8	▽	≥ 0.60
9	BT5013	13	18"/45cm	5-0	1	3/8	▽	≥ 0.42
10	BT301935	19	14"/35cm	3-0	2	3/8	▽	≥ 0.96
11	BT401935	19	14"/35cm	4-0	1.5	3/8	▽	≥ 0.60
12	BT501935	19	14"/35cm	5-0	1	3/8	▽	≥ 0.42
13	BT301635	16	14"/35cm	3-0	2	3/8	▽	≥ 0.96
14	BT401635	16	14"/35cm	4-0	1.5	3/8	▽	≥ 0.60
15	BT501635	16	14"/35cm	5-0	1	3/8	▽	≥ 0.42
16	BT301335	13	14"/35cm	3-0	2	3/8	▽	≥ 0.96
17	BT401335	13	14"/35cm	4-0	1.5	3/8	▽	≥ 0.60

18	BT501335	13	14"/35cm	5-0	1	3/8	▽	≥ 0.42
19	BTP3013	13	18"/45cm	3-0	2	1/2	⊙	≥ 0.96
20	BTP4013	13	18"/45cm	4-0	1.5	1/2	⊙	≥ 0.60
21	BTP301335	13	14"/35cm	3-0	2	1/2	⊙	≥ 0.96
22	BTP401335	13	14"/35cm	4-0	1.5	1/2	⊙	≥ 0.60
23	BTP4019	19	18"/45cm	4-0	1.5	1/2	⊙	≥ 0.60

Manufactured by:
Purgo Biologics Inc.
E-607, 700, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea, 13516

EU Authorized Representative:
REGEDENT AG
Zollikerstrasse 144
CH-8008 Zürich
Switzerland
Tel: +41 (0)44 700 37 77
Fax: +41 (0)44 700 47 97

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