Made for GDT Implants
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INSTRUCTION FOR USE

GDT PTFE SUTURE

DESCRIPTION

The GDT PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% polytetrafluoroethylene (PTFE) polymer. The suture is undyed and contains no additives.

IMPORTANT: Read this entire leaflet prior to use and follow all instructions carefully.

ACTIONS

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The GDT PTFE Suture is not absorbed or subject to weakening by tissue enzymes and does not degrade in the presence of infection.

INDICATIONS

The non-absorbable GDT PTFE suture is intended for use in the approximation and ligation of soft tissue in the oral cavity (including fixation of barrier membranes). The device should NOT be used in neurological and cardiovascular surgeries. The device is NOT indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

CONTRAINDICATIONS

This device is contraindicated for use in cardiovascular and neurological surgeries, ophthalmic surgery, microsurgery, and peripheral neural tissue.

WARNINGS

- The safety and effectiveness of this suture in peripheral neural, microsurgical and ophthalmic applications has not been established.
- The device is for single use only. Re-using may lead to infection.
- Do not re-sterilize. Re-sterilizing may lead to infection and loss of tensile strength.
- The device is surgically invasive and should NOT stay in the body for more than 30 days.

PRECAUTIONS

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges. In order to minimize needle damage, do not grasp or drive the needle from near the channel where the suture is attached.

Knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.

When lying knots with the GDT PTFE Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. Caution: this tension should not be applied by pulling on the needle itself but is applied by grasping the suture with the fingers or surgical instruments. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion, which could break the suture or cause separation of the suture from the

needle. Uneven tensioning of a well-formed square knot may result in an unsecure knot. When the GDT PTFE Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

STERILITY

The GDT PTFE Suture is supplied STERILE. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the "Use By" (expiration) date printed on the box. Do not resterilize.

The GDT PTFE Suture is designed for single use only; do not reuse device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.

ADVERSE REACTIONS

Possible adverse reactions associated with the use of any suture include, but are not limited to, tissue dehiscence, infection, localized inflammatory reaction, and transitory local irritation. Broken needles or damaged thread may result in extended or additional surgery or retained foreign bodies.

DOSAGE AND ADMINISTRATION

Use as required per surgical procedure.

STORAGE

Store at room temperature (under 25°C), away from moisture and direct heat.

Keep out of reach of children.

HOW SUPPLIED

GDT PTFE Sutures are available as sterile strands in a variety of sizes and lengths with attached needles.

SYMBOLS

	Consult instructions for use		Caution, consult accompanying documents
REF	Catalogue number	LOT	Batch code
	Manufacturer		Date of Manufacture
	Temperature limit		Use by
	Keep dry		Keep away from sunlight
	Do Not Reuse		Do Not Re-sterilize
	Do Not Use if Package is Damaged		Reverse Cutting Needle
STERILE EO	Sterilized by ethylene oxide		Prescription only

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.