CYTOPLAST
PTFE Suture

Cytoplast® PTFE Suture
INSTRUCTIONS FOR USE

Description:
Cytoplast® PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% high-density polytetrafluoroethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The suture is undyed and contains no additives. Cytoplast® PTFE Suture meets all USP requirements.

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

Indications:
The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Contraindications:
There are no known contraindications.

Warnings:
The safety and effectiveness of this suture in ophthalmic, microsurgical, and peripheral neural applications has not been established.

Tissue invasion of Cytoplast® PTFE Suture can result in attachment of the suture to the tissue it penetrates in long-term use. Such attachment may make removal of the suture difficult.

The device is for single use only. Do not resterilize.

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 tying knots with the Cytoplast® 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 Cytoplast® PTFE Suture is properly tensioned and formed. standard surgical knotting techniques will produce a secure knot.

Sterility:
Cytoplast® PTFE Suture is supplied STERILE unless the integrity of the package has been compromised. The device is for single use only. Do not resterilize.

Adverse Reactions:
None reported.

Dosages and Administration:
Use as required per surgical procedure.

How Supplied:
Cytoplast® PTFE Suture is available as sterile strands in a variety of sizes and lengths with permanently attached needles.

Caution:
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

LABELING SYMBOLS
Symbols may be used on package labeling for easy identification.

	Use By
	Do Not Reuse
	Attention, see instructions for use
STERILE EO	Method of Sterilization Using Ethylene Oxide
LOT	Lot Number
REF	Catalog Number
	Manufacturer
EC REP	Authorized Representative in the European Community

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