

USER'S INSTRUCTIONS SHAKLETON PTFE SUTURE THREAD

1.0 Device Identification and Destination of Use


IESS PTFE is a monofilament thread for surgical sutures, made 100% of Polytetrafluoroethylene (PTFE), a non-absorbable polymer. The suture is undyed and contains no additives. The IESS PTFE non-absorbable suture is indicated for approximation and/or ligation of the soft tissue in the oral cavity (including the securing of barrier membranes). Additionally, applications are possible also in plastic surgery, peripheral vascular surgery and general surgery.


2.0 Performance and known side effects


PTFE suture has been shown in clinical studies to elicit minimal tissue reaction and does not cause any known side effects. IESS PTFE suture is not absorbed, does not degrade in the presence of infections and is not subject to weakening by tissue enzymes.

3.0 Manipulation method and use

The use of the medical device is reserved exclusively to qualified personnel (surgeon or dentist): misuse of this suture, like any other suture, can result in serious injury or death of the patient. As with any suture, care should be taken to avoid damages during handling. Avoid crushing or crimpling the suture with surgical instruments. Avoid exposing the suture to sharp edges or sharp corners. In order to minimize needle damages, do not grasp or drive the needle from near the channel where the suture is attached. Surgeon's knots require standard surgical techniques, to be assessed according to the specific surgical circumstances and the surgeon's experience: when tying knots, tension should be applied by pulling each strand of the suture in opposite directions, applying equal force.

 **Attention: tension on the thread should not be applied by pulling on the needle itself, but by grasping the suture with the fingers or using surgical instruments**

 **The action of knot tensioning causes air in the suture to be forced out.**

 **Uneven tensioning of a well-formed square knot may result in an unsecured knot.**

The action on the thread must be implemented without tearing, which may cause the breaking of the suture or cause the separation of the needle. The correct tensioning of the thread according to the standard surgical knotting techniques, will produce a secure knot.

4.0 Storage instructions

IESS PTFE sutures should be kept at a temperature between +5° C and +40° C and at a relative humidity not exceeding 80%. Do not expose to aggressive airborne agents.


5.0 Warnings and Instructions

The safety and effectiveness of the suture in applications involving the peripheric nervous system, microsurgery and applications in ophthalmic surgeries have NOT been established. Furthermore:

- DO NOT attempt to resterilize or, in any case, reuse the suture thread as the device is exclusively a single use device. Misuse of this suture can result in severe dangers of infection or require additional invasive medical interventions by a specialist. Furthermore, an inadequate sterilization of the tool may implicate the deterioration of the resistance to the thread traction.
- DO NOT use the suture thread if the original packaging is compromised as, in such event, the sterilization of the Medical Device is not guaranteed.

6.0 Contraindications and limitations of use

SHAKLETON PTFE sutures are not non usable in the ophthalmic field, in the treatment of neural tissues and in microsurgery. Additionally, they are not intended for use in the sphere of invasive surgery which involves the nervous system and/or the central circulatory system.

 **The suture thread cannot remain inside the body for more than 30 consecutive days.**

7.0 Disposal

For the handling of the expired or exhausted Device, please comply with what provided by the national laws which regulate waste management and to the regulations of the local Governing Authority. In the absence of other indications, handle the medical device that needs to be disposed of, as hazardous hospital waste.

8.0 Key of the symbols used in labeling

-  CE marking
-  Manufacturer
-  Article Code
-  Manufacturing Lot Number
-  Attention (Generic risk)
-  Do not reuse
-  Sterilized with Ethylene Oxide