McKESSON

# Pediex
# ABSORBABLE POLY(P-DIOXANONE) SURGICAL SUTURE

## INSTRUCTIONS FOR USE

**DESCRIPTION**
McKesson Pediex Suture is a sterile synthetic absorbable monofilament suture composed of Poly(p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Poly(p-dioxanone) polymer has non-pyrogenic properties.

McKesson Pediex Suture is available in undyed or dyed (D&C Violet No. 2, Color Index number: 60725) form.

McKesson Pediex Suture is available in a range of gauge sizes and lengths, attached to standard stainless steel needles of varying types and sizes.

McKesson Pediex Suture complies with the "Absorbable Surgical Suture" requirements as per the United States Pharmacopeia (U.S.P.) and "Sterile Synthetic Absorbable Monofilament Strands" requirements as per the European Pharmacopeia (E.P.). However, it may be slightly oversized in diameter compared to U.S.P. requirement for some suture sizes.

**INDICATIONS**
McKesson Pediex Suture is indicated for use in soft tissue approximation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

**SELECTION CRITERIA**
The selection of suture for implantation depends upon patient condition, surgical technique, wound size, tissue characteristics, and surgeon's preference.

**PERFORMANCE**
McKesson Pediex Suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. McKesson Pediex Suture gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the copolymer degrades to monomeric acid (2-hydroxyethoxyacetic acid) which is then absorbed and metabolized in the body. Significant tensile strength (i.e., 70% of the original) is retained for the first 14 days and 50%-60% of the original is retained for the first 28 days. There is subsequently minimal absorption until about the 90th post-implantation day and complete absorption usually takes place between 180-220 days.

**CONTRAINDICATIONS**
These sutures being absorbable, should neither be used where prolonged (beyond 42 days) approximation of tissues under stress is required nor in conjunction with prosthetic devices, for example heart valve or synthetic grafts.

**WARNINGS**
Surgeons should consider the in vivo performance (under 'PERFORMANCE' section) and should be familiar with surgical procedures and techniques involving absorbable sutures before employing McKesson Pediex Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

In surgery of the urinary or biliary tracts, care should be taken to avoid prolonged contact of McKesson Pediex Suture with salt solutions, to prevent calculus formation. This suture may be inappropriate in patients suffering from conditions which may delay wound healing e.g., patients who are elderly, malnourished, or debilitated. As this is an absorbable suture, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the abdomen, chest, joints, or other sites subject to expansion or requiring additional support.

**PRECAUTIONS**
Acceptable surgical practice should be followed for the management of contaminated or infected wounds. Conjunctival, cuticular, and vaginal epithelium sutures which remain in place longer than 10 days may cause localized irritation and should be snipped off or removed. In some cases, particularly orthopedic procedures, immobilization of joints by external support may be employed at surgeon's discretion.
In tissue with poor blood supply, care should be taken while using absorbable suture as suture extrusion and delayed absorption may occur. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process.

In handling McKesson Pediex Suture or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping due to the application of surgical instruments such as forceps or needle holders. Adequate knot security requires the acceptable surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.

Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the sharp point. Grasping in the sharp point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause needle-suture detachment, bending, or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

Users should exercise caution while handling surgical needles to avoid inadvertent needlestick injury. Discard the used needles appropriately.

**ADVERSE REACTIONS**
Adverse reactions associated with the use of McKesson Pediex Suture include transient local irritation at the wound site, transient inflammatory foreign body response, erythema, and induration during the absorption process of subcuticular sutures. Like all foreign bodies, McKesson Pediex Suture may contribute in enhancing an existing infection.

**STERILITY**
McKesson Pediex Suture is sterilized by ethylene oxide (EtO) as indicated on the package. Do not resterilize. Do not use if package is opened or damaged. Discard opened remaining unused sutures.

**STORAGE**
Recommended storage conditions: Below 77°F (25°C), away from moisture and direct heat. Do not use after expiration date.

**HOW SUPPLIED**
McKesson Pediex Suture is available in a variety of U.S.P. sizes, undyed/dyed form, in plastic tray and pack size of 12 and 36.

**CAUTION**
Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

**SYMBOLS USED ON LABELING**

| | |
|---|---|
|  | Do not reuse |
|  | Date of manufacture |
|  | Use by |
| STERILE EO | Sterilized using ethylene oxide |
| LOT | Batch code |
|  | Consult instructions for use |
|  | Do not resterilize |
|  | Upper limit of temperature |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Do not use if package is damaged |
| MR | The suture is "MR Safe" only after needle is removed |

Questions? Call 1-800-777-4908

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