McKESSON

Monofil
ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE
INSTRUCTIONS FOR USE

DESCRIPTION
McKesson Monofil Suture (dyed and undyed) is a sterile synthetic absorbable monofilament suture composed of poly(glycolide-co-caprolactone). The empirical molecular formula of the polymer is $(C_2H_2O_2)_a$ $(C_6H_{10}O_2)_c$. Poly(glycolide-co-caprolactone) has non-pyrogenic properties. McKesson Monofil Suture is available either in undyed or dyed (D&C violet No. 2, Color Index No. 60725) form.

McKesson Monofil Suture is available in a range of gauge sizes and lengths and attached to standard stainless steel needles of varying types and sizes. McKesson Monofil 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. requirements for some suture sizes.

INDICATIONS
McKesson Monofil Suture is intended for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.

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

PERFORMANCE
McKesson Monofil Suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. McKesson Monofil Suture gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the copolymer degrades to adipic acid which are then absorbed and metabolized in the body. In dyed McKesson Monofil Suture, significant tensile strength i.e., 80%-60% of the original is retained for the first 7 days and 40%-30% of the original is retained for the first 14 days. In undyed McKesson Monofil Suture, significant tensile strength, i.e., 60%-50% of the original is retained for the first 7 days and 30%-20% of the original is retained for the first 14 days. There is a subsequent loss 28 days post implantation. Complete absorption of McKesson Monofil Suture usually takes place between 90 and 120 days.

CONTRAINDICATIONS
McKesson Monofil Suture (dyed and undyed) should not be used where extended approximation of tissues under stress is required. However, McKesson Monofil Suture undyed must not be used for abdominal or fascial tissue closure.

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 Monofil 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 Monofil 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 that 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. Skin sutures that must be in place for longer than 7 days may cause localized irritation and therefore should be snipped off or removed as indicated.

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 erythema and induration normally associated with the absorption process.

In handling McKesson Monofil 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 Monofil 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 Monofil Suture may contribute in enhancing an existing infection.

STERILITY
McKesson Monofil 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 Monofil Suture is available in U.S.P. sizes ranging from 6-0 to 2, undyed/dyed form, in plastic tray and pack sizes 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
	Sterilized using ethylene oxide
	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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