MonoPlus®

Description
MonoPlus® is a sterile synthetic absorbable monofilament surgical suture made from the homopolymer poly-pdioxanone. MonoPlus® is coloured violet with the dyestuff D&C violet No. 2. MonoPlus® fulfils all the requirements of the European and the United States Pharmacopoeia for sterile synthetic absorbable monofilament sutures except for minor variations in suture diameter.

Indications
MonoPlus® sutures are intended for use in general soft tissue approximation and/or ligation, especially in cases where an extended wound support of more than 4 weeks is desirable. MonoPlus® can also be used in pediatric cardiovascular surgery. Not to be used in adult cardiovascular tissue, microsurgery and neural tissue.

Mode of action
When MonoPlus® suture is used, there is a mild inflammatory reaction, which is typical for an endogenous reaction to a foreign body. MonoPlus® degrades in the body by means of hydrolysis to 2-hydroxyethoxyacetic acid, which is subsequently absorbed and eliminated by the body. After implantation, the hydrolytic process leads to a successive decrease of tensile strength and finally to a complete mass degradation. After implantation for approximately 28 days, MonoPlus® suture still retains 50 to 70% of its original knot-pull tensile strength depending on the monofilament's size. The mass absorption of MonoPlus® is essentially completed after 180 to 210 days.

Contra-indications
Usage of MonoPlus® is contra-indicated for approximation of tissue under tension and for the suturing of synthetic implants like vascular grafts or cardiac valves.

Warning note
MonoPlus® must not be re-sterilized. Open, unusued or damaged packs should be discarded. MonoPlus® suture material should be stored at room temperature. Do not expose to extreme temperatures for a prolonged period of time. Do not use MonoPlus® after expiry date. The user should be familiar with surgical suturing techniques, when using MonoPlus®. The user must take into consideration that the risk of wound dehiscence may vary depending upon the site of application and the type of suture material used. As with all other suture materials, prolonged contact with salt solutions, such as urine and bile can lead to lithiasis. Consideration should be taken in the use of MonoPlus® in low vascularized tissue as a delayed absorption may occur. Usage of MonoPlus® may not be advised in case of patients suffering from diseases or conditions which delay the wound healing process. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. As MonoPlus® is an absorbable suture material, the surgeon should consider the use of supplemental non-absorbable sutures in the closure of the sites which may undergo expansion, stretching or distension, or which may require additional support.

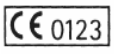
Note/precautionary measures
Great care must be taken when working with MonoPlus® in order to avoid damage as a result of crushing or snapping, due to the use of surgical instruments such as tweezers and needle holders. The user should be familiar with surgical suturing techniques, before employing MonoPlus® suture materials. As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.
To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should be careful when handling surgical needles to avoid inadvertent needle sticks. Discard needles in "sharps" containers.

Adverse reactions
Adverse effect associated with this device include wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritations, when skin sutures are left in place for more than 7 days, calculi formation when prolonged contact with salt solutions such as urine and bile occur, enhanced bacterial infectivity, minimal acute inflammatory reaction and pain, edema and erythema at the wound site. Hardening of tissues may not always be avoided during absorption of subcuticular sutures and existing infections may also occasionally be enhanced. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

How supplied
MonoPlus® sutures are available in USP 2 to 7/0 (metric 5 to 0,5). The sutures are supplied sterile, in pre-cut lengths, ligating reels or as loop, non-needled or attached to needles, with permanent or removable (take-off) needle attachment techniques. The boxes contain 1, 2 or 3 dozens of sutures.

Caution
Federal (USA) law restricts this device to sale or use by or on the order of a physician.

Symbols used on labeling

	Do not reuse
	Use by: Year + Month
	Sterile unless package is opened or damaged. Method of Sterilization - Ethylene oxide
	CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.
	Batch number
	See instructions for use
REF	Cat. No.

CUSTOMER SERVICE
For further information regarding MonoPlus® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissueseal.com

Distributed by:

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