Box size: 2.25 x 5
Overall size: 18 x 21.5
Folds to: 2.25 x 4.3

COVIDIEN

Flexon™

Multifilament Temporary Cardiac Pacing Lead

1300378

EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
Flexon™ multifilament temporary cardiac pacing lead is a stainless steel twisted, multistrand wire coated with orange, white or clear FEP poly (tetrafluoroethylene-co-hexafluoropropylene).

INDICATIONS
Flexon™ temporary cardiac pacing lead is indicated for use in temporary atrial and ventricular pacing and sensing during and after cardiac surgery.

ACTIONS
Flexon™ temporary cardiac pacing lead elicits minimal acute inflammatory reaction in tissues and is not absorbed.

CONTRAINDICATIONS
1. When permanent pacing or monitoring is required, the use of Flexon™ temporary cardiac pacing lead is contraindicated.
2. The use of this product is contraindicated in patients with known sensitivities or allergies to its components.
3. The particular medical condition and anatomy of the patient may dictate the lead system and implantation procedure to be used.

WARNINGS
1. Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused pacing wire. Store at room temperature. Avoid prolonged exposure to elevated temperatures.
2. An implanted lead constitutes a direct, low resistance current pathway to the myocardium. During pacing lead insertion and testing, use only battery powered equipment or line powered devices designed to protect against possible fibrillation that may be caused by alternating currents. Line powered equipment in the patient's vicinity must be properly grounded. Pacing lead connector(s) must be insulated from leakage currents from either line or battery powered equipment. Avoid unintentional contact between the pacing lead(s), including the extension cable, and any equipment or conductive surface.
3. To avoid unintentional contact with equipment or conductive surfaces when not in use, cover the pacing lead connector(s) with the supplied plastic sleeves and secure them to the patient.
4. Users should be familiar with surgical procedures and techniques involving temporary pacing before employing Flexon™ temporary cardiac pacing lead as the risk of complications may vary.
5. Extreme care must be taken during placement and removal of the lead in order to minimize the risk of tissue trauma and/or bleeding.
6. Acceptable surgical practice must be followed with respect to the management of contaminated or infected wounds.

PRECAUTIONS
1. It is recommended that defibrillation equipment be readily available during the lead insertion and removal.
2. In handling this temporary pacing lead material, care should be taken to avoid disruption of the Flexon™ temporary cardiac pacing lead coating or damage to the conductive wire from handling or manipulation.
3. The lead must be cut perpendicularly, utilizing an appropriate surgical wire cutter, to avoid fraying or brooming.
4. Dispose of contaminated pacer lead and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.
5. The lead should be connected only to an IEC compliant external pacing device or extension cable.

ADVERSE REACTIONS
1. Adverse effects which may be associated with the use of this product include: allergic response in patients with known sensitivities to stainless steel; infected wounds; minimal acute inflammatory tissue reaction; transitory local irritation; and electrical burn.
2. As with any other lead, the possibility exists of dislodgement, lead fracture, threshold elevation and sensing inconsistency. Other potential complications include, but are not limited to, myocardial irritability, septicemia and myocardial infections, myocardial bleeding and damage, especially on removal of the lead(s).

INSTRUCTIONS FOR USE
NOTE: DO NOT DISCARD THE PLASTIC SLEEVES INCLUDED IN THE PACKAGE. These will be used to cover the pacing lead connectors when not in use.
1. After implantation, the needle shafts are to be cut at an appropriate length to serve as connectors to the pacing equipment.
2. Cut the needles at the score line on the needle shaft to form the pacing lead connector(s). If the shaft is not scored, cut the needle shaft to leave a remaining length of 2.0cm connected to the pacing lead.
NOTE: After cutting the needles to form the connectors, slide the plastic sleeves over the cut needles and back onto the pacing lead. The plastic sleeves should be used to cover the needle shafts as in Step 3 (below).
3. When not connected to the pacing equipment, the cut needle (pacing lead connector) should be covered with the supplied plastic sleeve. The connector should be centered in the sleeve to ensure that the connector is completely covered.

WARNING: TO AVOID UNINTENTIONAL CONTACT WITH EQUIPMENT OR CONDUCTIVE SURFACES WHEN NOT IN USE, COVER THE PACING LEAD CONNECTOR(S) WITH THE SUPPLIED PLASTIC SLEEVES AND SECURE THEM TO THE PATIENT. A MINIMUM OF 5MM OF THE SLEEVE SHOULD EXTEND PAST AND COVER THE DISTAL END OF THE CONNECTOR(S). THE SLEEVE SHOULD BE SECURELY TAPED TO THE LEAD PRIOR TO SECURING IT TO THE PATIENT.

HOW SUPPLIED
Flexon™ temporary cardiac pacing lead is available coated with orange, white or clear FEP in sizes 3-0 (2 Metric) through 0 (3.5 Metric).
Flexon™ temporary cardiac pacing lead is supplied sterile and affixed to various types of needles, including Breakaway™ needles. They are available in box quantities of one or three dozen.

FR
Electrode pour stimulateur cardiaque multifilament provisoire

DE
Temporäre Multifilament-Herzstimulationsleitung

IT
Elettrocatetere multifilamento di stimolazione cardiaca temporanea

ES
Derivación reguladora cardiaca temporal multifilamento

PT
Eletrodo multifilamentoso para estimulação cardíaca temporária

NL
Tijdelijke multifilament pacingelektrode

SV
Temporär pacingelektrod

DA
Multifilament temporær pacemakerelektrode

FI
Monisäikeinen, tilapäinen sydämentahdistusjohdin

EL
Πολύκλωνο καλώδιο προσωρινής καρδιακής βηματοδότησης

PL
Wielofilamentowa elektroda tymczasowe elektrostymulacji serca

TR
Multifilament Geçici Kardiyak Pacing Kablosu

RU
Многонитевый временный электрод кардиостимуляции

CS
Multifilamentní dočasný srdeční stimulující svod

HU
Többszálas ideiglenes kardiális pacemakervezeték

SK
Multifilamentný dočasný srdcový stimulačný zvod

NO
Midlertidig multifilament-pacemakerledning for hjerte

SL
Multifilamentni odvod za začasno spodbujanje srca

ZH
多纤维心脏临时起搏引线

ZH-T
複絲暫時性心臟調節導線

KO
다섬유 임시 심박 전극선

BG
Многонишков проводник за временна сърдечна стимулация

RO
Electrod multifilament pentru stimulare cardiacă temporară

ET
Multifilamentne ajutine südame stimuleerimiselektrood

LV
Daudzdzīslu pagaidu kardiostimulatora elektrods

HR
Multifilamentni privremeni kardiološki elektrodni kateter

SR
Multifilamentna elektroda za privremenu elektrostimulaciju srca

LT
Daugiagijis laikinasis kardiostimuliacijos elektrodas

Do not use if package is opened or damaged.
Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.
Bei geöffneter oder beschädigter Verpackung nicht verwenden.
Non utilizzare se la confezione è aperta o danneggiata.
No usar el dispositivo si la envoltura está abierta o dañada.
Não utilizar se a embalagem estiver aberta ou danificada.
Niet gebruiken als de verpakking beschadigd of geopend is.
Får ej användas om förpackningen är öppnad eller skadad.
Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.
Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.
Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.
Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.
Ambalaj açılmış ya da zarar görmüşse kullanmayın.
Не используйте изделие, если упаковка вскрыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.
Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült.
Nepoužívajte, ak je obal otvorený alebo poškodený.
Skal ikke brukes hvis emballasjen er åpnet eller skadet.
Ne uporabljajte, če je embalaža odprta ali poškodovana.
如果包装已打开或破损，请勿使用。
如果包裝已開啟或損毀，則請勿使用。
포장이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오.
Не използвайте, ако опаковката е отворена или повредена.
A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat.
Ärge kasutage, kui pakend on avatud või kahjustatud.
Nelietot, ja iepakojums ir atvērts vai bojāts.
Ne koristite ako je pakiranje otvoreno ili oštećeno.
Ne koristiti ako je pakovanje otvoreno ili oštećeno.
Nenaudokite, jei pakuotė atidaryta arba pažeista.

Syneture™

STERILE EO

Rx ONLY

Caution, consult accompanying documents

Upper temperature limit 130°F 54°C

CE 0123

© 2011 Covidien.
Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
www.covidien.com
10/04 - 4