CE 0197

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OSYPKA

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Deutsch **OSYPKA Temporäre Myokardiale Elektroden (TME)**

English **OSYPKA Temporary Myocardial Electrodes (TME)**

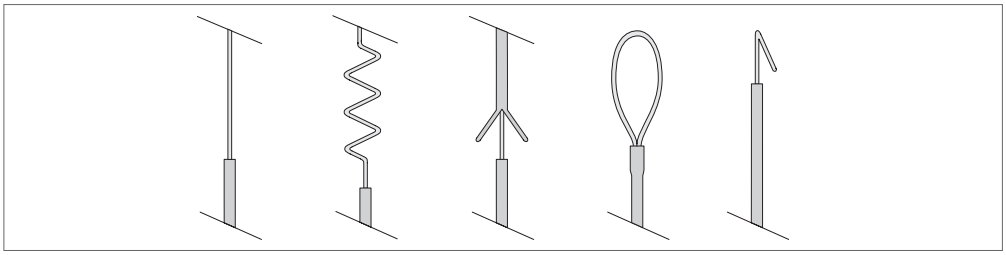
Français **OSYPKA Électrodes Myocardiques Temporaires (TME)**

Italiano **OSYPKA Elettrodi cardiaci temporanei (TME)**

Español **OSYPKA Electrodos miocárdicos temporales (TME)**

OSYPKA TME

Version: 2014-11-06



TME...S TME...Z TME...T TME...L TME...V

Deutsch English Français Italiano Español

Symbole • Symbols • Symboles • Simboli • Símbolos

	• Hersteller • Manufacturer • Fabricant • Fabbricante • Fabricante	STERILE EO	• Sterilisation mit Ethylenoxid • Sterilization with ethylene oxide • stérilisation à l'oxyde d'éthylène • Sterilizzazione con ossido di etilene • Esterilizado con óxido de etileno
	• Nur zum Einmalgebrauch • For one-time usage only • A usage unique • Monouso • De usar sólo una vez		• Gebrauchsanweisung beachten • Consult Instructions for Use • Consulter les instructions d'utilisation • Consultare le istruzioni per l'uso • Consulte las instrucciones de uso
LOT	• Chargen-Bezeichnung • Batch name • Désignation des charges • Lotto, designazione • Descripción de la carga	REF	• Bestellnummer • Order number • Référence de commande • Numero d'ordine • Número de referencia
	• Verwendbar bis • To be used before • Utiliser avant • Utilizzabile fino a • Utilizar antes		• Inhalt beschädigter Packung nicht verwenden • Do not use if package damaged • Ne pas utiliser si l'emballage est endommagé • Non utilizzare se la confezione è danneggiata • No usar si el paquete está dañado
	• Temperaturbegrenzung • Temperature limitation • Limites de température • Limiti di temperatura • Límite de temperatura	STERILIZE	• Nicht erneut sterilisieren • Do not sterilise anew • Ne pas stériliser à nouveau • Non sterilizzare di nuovo • No esterilizar de nuevo
	• Trocken aufbewahren • Keep dry • Conserver au sec • Mantenere secco • Mantener seco		• Vor Sonnenlicht geschützt aufbewahren • Keep away from Sunlight • Ne pas exposer aux rayons solaires • Evitare l'esposizione alla luce del sole • Evitar la exposición a los rayos solares
	• Hier öffnen • Open here • Ouvrir ici • Aprire qui • Abrir aquí		

TM10141106B_EN_TME-mit-Confix

General notes

Caution: Please read these instructions carefully before using the product.

1. Inspection before use

The product, packaging and any accessories must be inspected for damage and malfunction before use. The product must not be used if any damage or malfunction is encountered. If the instructions for use are no longer available you can request replacement instructions from OSYPKA AG. The instructions for use may only be disposed of after all products in the product unit have been used.

2. Use and handling

Caution: Use of the product in sterile conditions.

The product may only be used in a medical treatment facility that has been specifically set up for the appropriate application and by trained staff. The product may only be used if its safe application can be guaranteed. It is the doctor's responsibility to select the medically appropriate procedure and method. The operating instructions are intended purely as general information on handling the product. The product must not be modified in any way.

Warnings / general information / precautionary measures must always be observed even if a differing procedure is chosen for medical reasons! Failure to observe these can result in complications and malfunction!

3. Sterilisation and storage

The products are sterilised with ethylene oxide. Provided the sterilised product is stored correctly, it may be used up until expiry date (use before date) indicated on the package.

Store the sterile product in its original packaging in a cool, dry place away from light at between 10°C and 25°C.

Caution: Not autoclavable. Single use only. Do not re-sterilise used product. Re-use brings the risk of infection and the possibility of malfunction!

4. Disposal

The product may be contaminated after use. For this reason please observe your hospital's regulations regarding disposal. Any pointed or sharp objects such as needles, hypodermic needles or scalpels that were part of the product must be disposed of safely and separately in order to prevent injury and infection.

5. Liability limitation

Medical products from OSYPKA AG are manufactured from high-quality materials using managed and proven production processes. Quality is continuously monitored during manufacture and prior to delivery. Should you nevertheless encounter a functionally impaired or inoperative product, please return it once the defect occurs indicting the nature of the defect and impairment. We will then inspect the returned product immediately. In the event of a justified complaint we will provide a replacement free of charge.

Product damage that results from improper storage, handling, use for which the product is not intended, unauthorised modification to the product or prohibited re-use and re-sterilisation is excluded from warranty. The warranty will become void if the product is interfered with or modified by persons who have not been authorised to do so in writing by the manufacturer.

Product-specific instructions

1. Product description

OSYPKA temporary myocardial electrodes (TMEs) are used for the temporary stimulation of the heart in combination with an external cardiac pacemaker (OSYPKA PACE 101H, OSYPKA PACE 203 H, OSYPKA PACE 300) during and after heart surgery procedures. OSYPKA TMEs are supplied in unipolar, bipolar and multipolar versions. Bipolar OSYPKA TMEs are also available as bifurcated models. The strand wires for the quadripolar OSYPKA TME models are coloured white and blue in order to ensure that a distinction is made between atrial and ventricular positioning. There are two options for connection to an external cardiac pacemaker: a TME with Confix or adapter. The pre-assembled Confix connectors can be connected direct to an extension lead or to the cardiac pacemaker after the thorax needle has been cut off.

The different methods for attaching the TME to the heart for the different versions are described in section 3 (Handling).

2. Indication

OSYPKA TMEs are intended for temporary cardiac stimulation during and after heart surgery procedures.

3. Handling

As a safety precaution, have an additional TME available as a replacement.

Caution: The needles must be handled with care and must not be bent any further.

Caution: The TMEs create a direct, low-resistance current path to the patient's heart. For this reason do not touch the adapters / Confix with your bare hands. Do not allow the adapters / Confix to come into contact with electrically conductive or moist surfaces. All static electricity sources must be kept away from the stimulation system.

Caution: It is important that the electrodes are not placed in fatty cardiac tissue or in tissue that is damaged, e. g. due to previous myocardial infarction.

Caution: At least one electric pole for each chamber that should be stimulated must be placed on or embedded into the myocardium.

Note: It is important to avoid any damage to the plastic protective tube.

3.1 Unpacking OSYPKA TMEs

After the outer sterile bag has been torn open, the inner sterile bag must be carefully transferred to the sterile working environment. The holding plate is removed after the inner sterile bag has been opened. Then carefully detach the cardiac needle from the plate, unwind the OSYPKA TME and detach the thorax needle as a final step.

3.2 Positioning and attaching OSYPKA TME..Z models

Fasten the distal end of the OSYPKA TME..Z using the smaller, curved cardiac needle at the desired location of the heart in the myocardium (atrium, ventricle). Fastening is largely achieved as a result of the zigzag arrangement of the OSYPKA TME..Z (figs. 1a, 1b).

Do not use an additional ligature to fasten the zigzag anchoring attachment. Position the bipolar version in such a way that the hull is on and not in the myocardium (fig. 1b).

Cut off the distal end of the OSYPKA TME..Z including the cardiac needle.

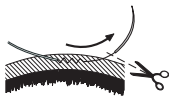


Fig. 1a: TME..Z, unipolar or bifurcated

Fig. 1b: TME..Z, bipolar

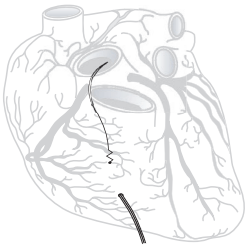


Fig. 1c: TME..Z in heart

3.3 Positioning and attaching OSYPKA TME..T models

Fasten the distal end of the OSYPKA TME..T using the smaller, curved cardiac needle at the desired location of the heart in the myocardium (atrium, ventricle).

Fastening is largely achieved as a result of the anchors splaying and catching (figs. 2a, 2b).

You splay the anchors by drawing the OSYPKA TME..T through the cardiac muscle until the anchor fully emerges from the myocardium.

Subsequently carefully draw the OSYPKA TME..T back until the distal sections of the anchors just protrude from the myocardium. The anchors will splay open in this process. Then draw the OSYPKA TME..T again forwards slightly so that the anchors do not exert any pressure on the myocardium.

Do not use an additional ligature to fasten the anchoring attachment.

Position the bipolar version in such a way that the hull is on and not in the myocardium (fig. 2b).

Cut the distal end off leaving a clearance of at least 10 mm to the anchor.

(The 10 mm residual section and a narrow connecting bridge between the anchor and the proximal end ensure that the anchor does not shear off and remain in the heart when the OSYPKA TME..T is removed.)

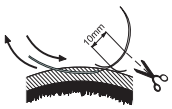


Fig. 2a: TME..T, unipolar or bifurcated

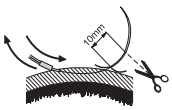


Fig. 2b: TME..T, bipolar

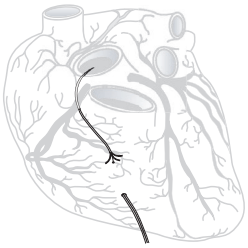


Fig. 2c: TME..T, in heart

3.4 Positioning and attaching OSYPKA TME..V models

Catch the V-end of the OSYPKA TME..V in the purse-string suture. You may also set a U-stitch suture at any desired location in the myocardium and fasten the V-attachment of the OSYPKA TME..V to it (see examples in figs. 3a, 3b).

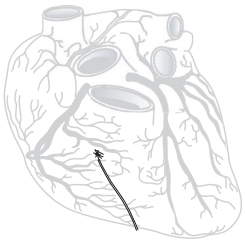


Fig. 3a: TME..V in heart

Fig. 3b: TME..V

3.5 Positioning and attaching OSYPKA TME..L models

The OSYPKA TME..L is fastened by means of a ligature with a surgical thread (fig. 4a). The suture should not be set too tightly in order to allow the OSYPKA TME..L to be removed with a gentle pull after use. The OSYPKA TME..L is removed as shown in fig. 4b.

Caution: Do not draw the suture through the loop in order to avoid injury during removal (fig. 4c).

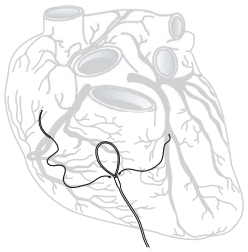


Fig.4a: TME..L in heart

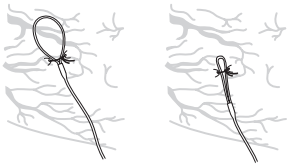


Fig. 4b: TME..L Removal

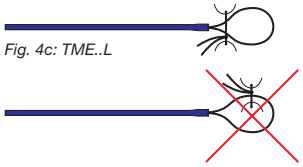


Fig. 4c: TME..L

3.6 Positioning and attaching OSYPKA TME..S models

Fasten the distal end of the OSYPKA TME..S (baby TME) using the smaller, curved cardiac needle at the desired location of the heart in the myocardium (atrium, ventricle).

Note: Depending on the surgeon's personal experience, the OSYPKA TME..S can be anchored on or in the cardiac muscle in various ways with or without suture material (e.g. the exposed strand wires can be bent slightly with a scalpel after the cardiac needle is cut off).

3.7 Drawing through the thorax

Insert the thorax needle through the thorax and draw the TME out until no great tension occurs and there are no hindrances to fastening. The OSYPKA TME can be fastened once more on the surface of the thorax.

Note: OSYPKA TMEs must be strain-relieved in order to ensure safe operation.

3.8 Handling OSYPKA TMEs with Confix

Cut off the proximal residual section (thorax needle and wire) of the OSYPKA TME direct after the proximal end of the Confix (see fig. 5).

Confix connectors can be connected direct to the relevant extension leads or to the external cardiac pacemaker. There is no need to adapt the plug connector.

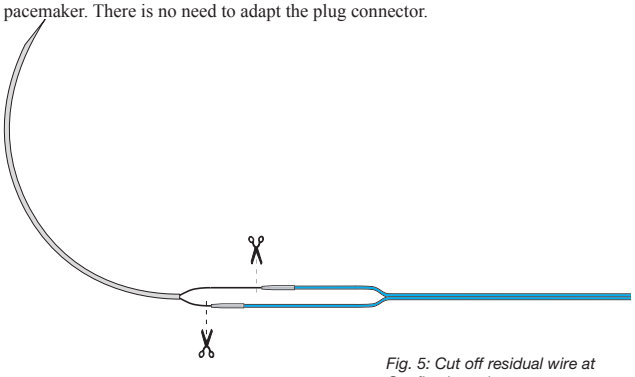


Fig. 5: Cut off residual wire at Confix pin end

If the TME is not connected to an external cardiac pacemaker or extension lead immediately, slip the protective caps (Confix holders) over the Confix connector (fig. 3). This protects the Confix from being touched.

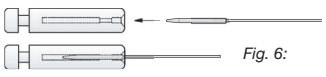


Fig. 6:

3.9 Handling OSYPKA TME adapters (2 mm pin adapters)

TME adapters can be used for all OSYPKA TME models without Confix connectors.

Use one adapter for each strand wire (1 adapter for unipolar OSYPKA TME models, 2 adapters for bipolar OSYPKA TME models and 4 adapters for quadripolar OSYPKA TME models). Cut off the thorax needle by cutting through the exposed strand wired at a distance of 1.5 cm from the insulation. Then insert the individual strand wires through the hole of the adapter pin (fig. 7a).

Caution: Make sure you only touch the OSYPKA TME and the adapter pin with gloves.

Pull the plastic adapter hulls over the adapter pin (fig. 7b). The plastic adapter hulls must completely cover the strand wires.

If the TME is not connected to an external cardiac pacemaker or extension lead immediately, slip the protective adapter cap over the blank adapter pin (figs. 7c, 7d). This protects the adapter from being touched.

Twisting the protective tube fastens it firmly to the connector.

Caution: OSYPKA TME adapters can only be used for OSYPKA TME electrodes without a Confix pin.

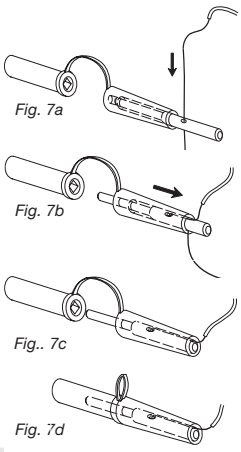


Fig. 7a

Fig. 7b

Fig.. 7c

Fig. 7d

Fig. 7: Method for adapting connectors

3.10 Connecting the TME to an external cardiac pacemaker

Connect the proximal end of the OSYPKA TME direct, or with the use of an OSYPKA extension lead (e.g. D2-SP, D2P-SP), to an external OSYPKA cardiac pacemaker.

Please follow the instructions for use of the external cardiac pacemaker and of the extension lead.

Caution: OSYPKA TMEs may only be used with external OSYPKA cardiac pacemakers (such as PACE 101H, PACE 203H, PACE 300) and the corresponding OSYPKA connecting leads. The instructions for use of the products concerned must in all cases be followed.

Caution: OSYPKA TMEs may not be connected to the external cardiac pacemaker with exposed strand wires – without adapter or without Confix – under any circumstance. (Stimulation or sensation loss may occur if only the exposed strand wire is connected.)

Note: After connecting the OSYPKA TME and when the thorax is still open, please check the position of the attachment, the sensation and stimulus threshold. This process can be used for dual-chamber or bi-ventricular stimulation to determine whether atrial or ventricular OSYPKA TMEs were also connected to the appropriate channels of the pacemaker. If necessary change the channels.

If it is not possible to successfully generate the stimulation or sensation, connect the OSYPKA TME with the reverse polarity to the external cardiac pacemaker. Use a new OSYPKA TME if stimulation is subsequently still not possible.

3.11 Care when not in use

If the patient does not require any more cardiac stimulation for a temporary period, the OSYPKA TMEs can be disconnected from the external cardiac pacemaker. The connections must be protected from contact by attaching the protective caps.

Caution: Make sure you only touch the adapters or Confix of the OSYPKA TMEs with gloves. The electrostatic potential between the user and the patient should be equalised before handling the external cardiac pacemaker or the OSYPKA TMEs, for example by touching the patient at a point away from the OSYPKA TMEs.

3.12 Removing OSYPKA TMEs

When the patient no longer requires any further cardiac stimulation, remove the OSYPKA TMEs by pulling carefully on the ends of the TME. TMEs must not be cut off at the thorax.

Caution: OSYPKA TMEs must be removed after 7 days at the latest. Complications may arise if the TMEs are in situ for more than 7 days.

Caution: Please note the following approach to removing multipolar OSYPKA TME models in order to avoid irritation during removal: Gently pull each individual strand wire a few centimetres out in order to release the attachment to the cardiac muscle. The OSYPKA TME can then be drawn out completely.

4. Patients

TME: unrestricted

5. Warnings

- OSYPKA TMEs create a direct, low-resistance current path to the patient's heart. Slight residual currents are known to stimulate the heart and in some cases may cause cardiac fibrillation. Never touch the adapters / Confix with your bare hands or allow them to come into contact with electrically conductive or moist surfaces. Static electricity sources must be kept away from the stimulation system. Great care must also be taken to ensure that the operating table as well as any electrical equipment used (e.g. x-ray devices) are sufficiently and centrally earthed.
- Please follow the relevant instructions for use when connecting and using external devices.
- The product is not suitable for defibrillation.
- Monitor the patient continuously. Keep a defibrillator available for emergencies.
- When defibrillating the patient, OSYPKA TMEs, including parts of them, must not be touched.
- Perform intracardiac ECG measurements only with an ECG device equipped with insulated floating input since there is the danger of ventricular fibrillation.
- Patients with OSYPKA TMEs may not be exposed to significant electrical or magnetic fields.

Caution: The product may not be used during MRT examinations. Please contact our product management team for more information.

WARNING: If devices are used in the direct vicinity of the patient that operate on mains electricity, it is vital to act in accordance with the instructions for electro-medical devices in order to prevent current leakage to the heart.

6. Precautionary measures

- OSYPKA TMEs may only be implanted by experienced, trained medical staff.
- Continuous, separate ECG monitoring of the patient is recommended when stimulating via OSYPKA TMEs since a significant increase in the stimulus threshold and a loss of sensation are possible.
- OSYPKA TMEs may remain in the body for a maximum of 7 days only.
- Removal of OSYPKA TMEs must be effected with great care and should only be performed by an experienced doctor.
- Avoid damaging OSYPKA TMEs through the use of HF surgical equipment.

7. Contraindications

The use of OSYPKA TMEs is contraindicated when a permanent cardiac pacemaker has already been implanted. OSYPKA TMEs may not be used for defibrillation or cardioversion.

8. Possible complications/side-effects

The following problems occasionally occur in connection with OSYPKA TMEs:

- Cardiac arrhythmias, pneumothorax or hematoma during the operation
- Skeletal muscle and nerve stimulation
- Infections
- Perforation through the electrode
- Dislocation
- Contact problems between OSYPKA TMEs and external cardiac pacemakers
- Significantly increased stimulus threshold
- Loss of sensation
- Bleeding
- Cardiac tamponade
- Death