Temporary Myocardial Electrodes (TME)
In Theory and Practice

Summary of 25 Years of Experience

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Foreword

OSYPKA has developed and produced TMEs—Temporary Myocardial (Electrode) Leads—for over 25 years.

Today OSYPKA TMEs are offered in unipolar, bipolar and quadripolar models.

Over 1 million of OSYPKA TMEs have been implanted to date.

Our TMEs have proven themselves to be very effective and reliable in clinical use.

OSYPKA TME unit count 2004

All production takes place in Germany in Grenzach and Rheinfelden-Herten. This work has created and guarantees jobs for 25 employees.
The OSYPKA management and staff would like to offer a heartfelt thanks to all clinic and practice clients for their long-standing collaboration and support in the development of the TME range of products.

They have all had a major part in the success of these products.

We are counting on your continued support!

Thank you very much,

Sincerely

Dr. Peter Osypka
President / CEO
1 Introduction

Since 1975 it has been reported in medical journals that the regular application of temporary myocardial leads is a safe and reliable method for diagnosing and treating cardiac arrhythmias that manifest themselves postoperatively.

In a heart operation, where artificial circulation with cardioplegial myocardial protection is to be performed, in other words a situation where the heart’s performance is frequently even more limited, adequate heart rate is of primary importance.

The causes of this bradycardia may include:
- Hypothermia
- Myocardial perfusion with cardioplegial rupture
- Preoperative anti-arrhythmia therapy (beta-blockers, calcium antagonists, digitalis)
- Temporary, intraoperative ischemia
- Electrolyte imbalance
- Surgical mechanical causes

The heart's performance will show marked improvement when a relatively slow heart rate is elevated through the use of electronic pacing.

Patients who had postoperative sinus bradycardia achieved the following improvements through AV sequential pacing:
- Increase in cardiac output by approx. 25 %
- Suppression of ectopic ventricular activity
- Improved renal perfusion
- Improvement of peripheral supply (e.g. balancing out of the base deficit)
2 What are TMEs?

Temporary Myocardial Leads are used for temporary pacing of the heart in conjunction with an external pacemaker during and after open-heart surgery.

*Other terms used in the literature as designations for or abbreviations of temporary myocardial pacing leads (TMEs) are:*
- Temporary epimyocardial pacing leads (EME)
- Pacing leads
- Heartwires
- Myocardium leads, myocardial leads
- Epicardium leads, epicardial leads

A variety of fixation methods can be used for anchoring the heartwires to the heart.

When the pacing is terminated the heartwires can be detached from the heart by gently tugging on the external portion of the wire. Then the TME can be pulled out of the thorax and disposed of.
3 Use of TMEs

3.1 Indication
Temporary myocardial pacing leads are intended for temporary cardiac pacing and intracardial ECG monitoring during and after cardiac surgery. Heartwires are routinely used after open-heart surgery for the diagnosis and treatment of post-operative arrhythmias. Bradycardias or signal direction anomalies which arise in approx. 15% of the cases can be quickly and safely remedied with the help of a TME and an external pacemaker.

3.2 Contraindication
The use of temporary myocardial pacing leads is contraindicated if a permanent pacemaker has already been implanted. These myocardial leads should not be used for defibrillation.

3.3 Possible Complications
As with all other temporary or permanent myocardial or intracardial pacing systems, in rare cases the following problems may occur with the placement of heartwires:
- Pacing of skeletal muscles or nerves
- Infection
- Heartwire dislocation
- Contact or connection problems between TMEs and external pacemakers
- Rise in pacing threshold and undersensing
- Bleeding
- Arrhythmias caused by non-optimal pacing parameters

Experience shows that the rate of complications with OSYPKA TMEs is very low. No complications due to faulty devices have been reported to date (percentage of claims in 2004: 0%). Pacing of skeletal muscles or nerves can arise from pacing impulses which are set too high. OSYPKA TMEs react well to pacing thresholds, which is why a low pacing parameter may be chosen so undesired muscle or nerve stimulation is practically excluded.
Risk of infection is reduced by the smooth and evenly worked heartwire strand. The tissue can close snugly around the heartwire making penetration of microbes difficult.

Dislocation of the heartwire rarely occurs, since the various ways of anchoring OSYPKA heartwires hold them securely in place.

Contact or connection problems between the TME and an external pacemaker may practically be ruled out, since OSYPKA offers a wide variety of adapters, extension cables and equipment specifically calibrated for the heartwires and all commercially available pacemakers.

Increase in pacing threshold and undersensing also rarely occur with OSYPKA TMEs. Leads and tines are designed so that myocarditis is minimal. The configuration of the leads offers good sensing properties in the atrium as well.

Bleeding at the time of removal of the heartwire is minimal with the smooth transition between the strands, tines and anodes as well with the straightening out of the tines (TME..Z, TME..V, TME..Loop) or the upending of the tines with light pulling.

A suitable heartwire can be chosen from the large range of products (including unipolar, bipolar, and quadripolar heartwires, and various anchors) for each use and for each patient, which keeps complications and malfunctions to a minimum.
3.4 Precautionary measures and warnings

- Temporary myocardial leads may only be implanted by experienced, trained physicians.
- It is recommended that at the time of pacing with temporary myocardial leads there should be separate and continuous ECG monitoring of the patient since a clear increase in the pacing threshold and undersensing is possible.
- Pacing leads apply a direct low ohm current to the heart. As is known, small amounts of cut-off current (approx. 10 µA AC) are sufficient to cause the heart to fibrillate. Therefore, do not touch the bare connector with bare hands. Do not allow the connector to come in contact with surfaces which are conductive or wet. Unused connectors should always be protected with the attached protective cap.

All static electricity must be kept far away from the pacing system. Measurements may be carried out with CE-tested or UL approved equipment. Make sure that the equipment has a CE mark on it or is UL approved.

- Temporary myocardial leads may stay in the body for a maximum of 30 days. However, it is recommended that heartwires be removed after 10 days at the most in order to prevent infections and guarantee safe pacing. Patients who are not yet stabilized should subsequently be implanted with intracardial temporary leads and should, if necessary, receive a permanent pacemaker.
- Connection cables and leads are intended for single use only and should not be resterilized.
- Monitor the patient continuously. Keep a defibrillator available in case of emergency.
- Under no circumstances may any part of the heartwire be touched during defibrillation of the patient.

- Removal of the lead must take place with utmost care and be undertaken by an experienced physician.

- Patients with temporary myocardial leads should not be exposed to any large electrical or magnetic fields.

- Therefore, machines that work based on the principle of magnetic resonance imaging (MRI) may not be used for the purpose of diagnosis or treatment of these patients.

- Avoid damaging the leads through the use of electrocautery.
4 Construction and Properties of the TMEs

4.1 Features
The features of an ideal TME are:
- Biocompatibility
- Minimal pacing threshold
- Good fixation capacity – no dislocation
- Small dimensions
- Highly flexible supply wires
- Good sensing capacities
- Easy implantation in the heart, which makes it well tolerated
- Easy removal of the leads after use

Significance of the individual EKG-segments

P-wave: atrial activation
PQ-interval: Interval between the contraction of the atrium and the ventricle
Q-spike: Septum activation
QRS-complex: Activation of the left and right ventricles
T-wave: Repolarization of the ventricular cells

4.2 Construction of OSYPKA TMEs
OSYPKA TMEs consist of an insulated strand equipped with a myocardial needle and a thorax needle.
4.2 Construction of OSYPKA TMEs

4.2.1 Heartwires for Adults
An insulated stainless steel strand serves as lead supply.
The strands consist of 19 individual stainless wires.
The diameter of the bare strand is 0.2 mm.
A biocompatible polyethylene insulator is used for insulation.
The diameter of the insulated strand is 0.45 mm in total.

In the interest of better identification, the strands are offered in different colors: white and blue.
In the case of the quadripolar TMEs, the white one is chosen for use in pacing of the atrium and the blue one for ventricular pacing.
The tear resistance of the strand material is 750 Newton/mm², i.e., with the strand of 0.20 mm diameter used here, a weight of approximately 3 kg would cause the supply to tear (a heart weighs approx. 0.5 - 1 kg).

4.2.2 TMEs for Children
An insulated stainless steel strand serves as lead supply.
The strands consist of 8 individual stainless wires.
The diameter of the bare strand is 0.15 mm.
The diameter of the polyethylene insulated strand is 0.30 mm.
The tear resistance of the strand material is 700 Newton/mm²; i.e. with the strand of 0.15 mm diameter used here, a weight of approximately 1 kg would cause the supply to tear (a child’s heart weighs approx. 200 grams).
4.2.3 TME thorax needles for adults
The chest needle is made of a stainless steel cannula with lancet point tip.
The length of the chest needle, which is arched, is \( L = 80-90 \text{ mm} \) when straightened out.
The diameter of the chest needle is \( D = 1.0 \text{ mm} \).

4.2.4 TME thorax needles for children
The chest needle is made of a stainless steel cannula with a lancet point tip.
The length of the chest needle, which is arched, is \( L = 60 \text{ mm} \) when straightened out.
The diameter of the chest needle is \( D = 0.7 \text{ mm} \).

4.2.5 TME heart needles for adults
The heart needle is composed of a stainless steel cannula with a lancet point tip.
The needle length is \( L = 15-17 \text{ mm} \) and is arched.
The diameter of the needle is \( D = 0.46 \text{ mm} \).

4.2.6 TME heart needles for children
The heart needle is composed of a stainless steel cannula with lancet point tip.
The needle length is \( L = 15-17 \text{ mm} \) and is arched.
The diameter of the needle is \( D = 0.4 \text{ mm} \).
4.2.7 Electrode distance in leads

**Lead capsule:**
A stainless steel capsule is formed at the site of contact between the lead and the bare strand. The surface of the capsule is 10 mm².
A piece of the bare stainless steel strand may serve as an additional electrode, in order to carry out fixations in different configurations (see Chapter 8).

**Electrode distance:**
As experience has shown, the distance between the two pacing leads is proven to be optimal at approximately 2-3 mm for good pacing threshold, similar to the implantation of permanent pacemakers.
Please see Section 8 TME Fixation, for different fixation options.

4.2.8 Length of the TMEs
OSYPKA TMEs come in the two standard lengths of 60 cm and 220 cm (220 cm preferred for quadripolar use).
For pacing using the 60 cm long TME, an extension cable has been designed (VHC cable). The bipolar model of this type is OSYPKA’s most widely produced temporary myocardial lead to date.
5 Electrical Pacing of the Heart with OSYPKA TMEs

5.1 Physiological pacing of the heart
Physiological pacing of the heart is understood to be the optimization of cardiac function by preserving or re-establishing atrioventricular coordination. That means that not only must the ventricles be paced, but also the atria.

5.2 What does “Electrical pacing of the heart” mean?
The activation of cardiac muscle fibers with “electricity” has been well known for many years. Electricity is understood to be the action of various electrically charged particles (electrons, ions).
The accumulation of different charges builds voltage potential, between which an electrical field spreads. It is known that between a normal membrane of the cardiac muscle there is a charge differential that is called resting potential or resting voltage. If the resting potential of a cell is influenced by an external electrical field, for example a pacemaker impulse, it will be “activated” (depolarized) after a critical (threshold-) value (pacing threshold) is exceeded.
The voltage measured at the moment of cell pacing is called action tension or action potential. This phenomenon is called electrostimulation.
Electrophysiologically, the cardiac muscle is characterized by the need to stimulate only a few cells in order to provoke activation of the entire ventricular muscle through a cascade effect.
The same applies to the atrium. The atrium and ventricle are electrically separate, which means that the pacing can only occur over special conduction paths. This property makes it possible for electrostimulation to be used routinely as a therapeutic procedure.

5.3 Pacing threshold and its course
A requirement for electrostimulation is therefore the effective activation of cardiac cells. The smallest amount of electrical energy necessary for the reliable activation of the cells is called the **pacing threshold**.
A distinction is made between the acute pacing threshold – the pacing threshold which is measured at the time of implantation – and the chronic pacing threshold which appears after several days.
The pacing threshold is measured by adapting the frequency of the pacemaker to the patient’s own frequency (by 1 ms impulse length).
Then the amplitude of the pacing impulse is raised until the heart “catches on”, i.e., it exhibits the same frequency as the pacemaker.
Now the amplitude of the pacemaker is slowly reduced till the heart goes back to its own rhythm.
This operation should be repeated several times.

The impulse level that is now stimulating the heart in order for it to assimilate the pacemaker frequency is called **acute pacing threshold**.

Over the following days the pacing threshold rises and after two to three weeks reaches a new, stable value, which is called **chronic pacing threshold**.

**Acute pacing thresholds are between approx. 0.6 to 0.9 Volts.**

**Chronic pacing thresholds are between approx. 0.8 to 1.8 Volts.**

5.4 The pacing threshold is dependent on several factors
5.4.1 Impulse interval
TME measurements have shown that the pacing threshold of an impulse interval of less than 1 ms increases rapidly.

**Therefore, an impulse length of 1.0 ms should always be chosen in external pacemakers for safety reasons.**

**Note:** The impulse interval should be lengthened in case of problems with overly high pacing threshold.

*The output pulse of the pacemaker*
5.4.2 Lead shape
Typical electrical fields are built up between the two electrodes which can influence the pacing threshold depending on lead placement and shape of the two TME electrodes.

5.4.3 Site of lead placement
It is important that the leads are not placed in fatty tissue on the heart. Fatty tissue cannot be stimulated electrically!
Tissue that is damaged because of myocardial infarction is also unsuitable for the placement of pacing leads!
Good pacing thresholds for ventricular pacing can be found in the area of the tip of the right ventricle.
Good pacing thresholds for atrial pacing can be found in the right atrium near the opening of the superior vena cava.

**Warning:** Occasionally there are atria that cannot be stimulated (“atrial quiescence”), Waldo et. al, Circulation, 46:690-697, 1972

5.4.4 Electrode distance
As has already been noted in section 4.2.7, the distance between the electrodes greatly influences the quality of pacing.
Optimal pacing conditions are present when the electrodes are placed close together (2 -3 mm) in the myocardium.

**Note:** An electrode swap (swap supply wires) should be carried out on the external pacemaker in order to determine the lowest pacing threshold.

5.4.5 Risk of injury
Cardiac tissue cells can be destroyed and / or damaged when the leads are fixated in the heart muscle (insertion of the heart needle), i.e. the cells’ potassium-sodium balance will be disrupted. This is called injury potential, and contributes to a temporary increase in the pacing threshold.

**Note:** After fixation of the leads, 2-3 minutes should elapse before pacing threshold measurements so that the injury potential can dissipate and the acute pacing threshold can be accurately measured.
5.4.6 Mechanical pacing or irritation

Mechanical irritation of the lead may cause further injury potentials and lead to an increase in the pacing threshold. These can be so great that they can cause an exit block.

Exit block is the condition in cardiac pacing where the heart contraction cannot be triggered, even with higher energy output from the pacemaker (amplitude, impulse length). Therefore, it is important to make sure that the TME sits unstressed in the chest and is fixed at the site where it exits the thorax. This way it can easily follow the heart’s movement without irritation from external mechanical factors.
6 External Pace OSYPKA 203 H Pacemaker for Support of the Hemodynamics of the Heart

The Pace 203 H has proven itself to be an ideal dual chamber external pacemaker (CE, FDA approval). All commonly required pacing means are available for intra- and post-operative pacing of the heart. Therefore, the Pace 203 H is best suited for the temporary support of hemodynamics after cardiac surgery. The pacing parameters are easy to adjust to the next value range by simply turning the appropriate knobs. The plastic casing protects against accidental splashes of liquids.

The **Pace 203 H distinguishes itself through the following features:**

- Easy to use and reliable
- Pacing is maintained for a minimum of 30 seconds at the time of battery change
- A retrievable and modifiable standard program is available for each mode of operation
- In an emergency situation an emergency program can be retrieved by pushing a button
- A locking button protects against the unintentional change of the programmed parameter
- A LCD display shows all programmed parameters, changes, and error messages
- Pacing and the sensing function are depicted on an LED display
- Disruptions and shorts are signaled by a lead monitoring system
- Necessary battery changes are signaled optically and acoustically
7 Placement of TMEs on the Heart

7.1 TME placement in the atrium
Placement usually takes place in the right atrium.

**Important:** Leads must not be placed in fatty tissue!

**Caution:** The atrium has very thin walls in certain places.

7.2 TME placement in the ventricle
Placement usually takes place in the right ventricle near the tip of the heart.

**Important:** Leads must not be placed in fatty tissue!
7.3 Bi-ventricular pacing/resynchronization
The pacing of both ventricles of the heart is called resynchronization. The pacing of both ventricles after a heart operation improves the ejection fraction in particular and, as a result, heart function. Bi-ventricular pacing is carried out simply using two bipolar TMEs or one quadripolar TME. The connection to the external pacemaker is made using an adapter that is suitable for the Pace 203 H external pacemaker and was developed specifically for bi-ventricular pacing by OSYPKA.

7.4 Bi-atrial pacing
The pacing of both atria after a heart operation has been shown to prevent the occurrence of atrial fibrillation.

**Caution:**
The wall thickness of the left atrium is minimal, so bleeding may occur later at the time of lead removal.

Bilateral pacing can be carried out simply with two bipolar TMEs or one quadripolar TME. The connection to the external pacemaker is made using an adapter that is suitable for the Pace 203 H external pacemaker, and was developed specifically for bi-atrial pacing by OSYPKA.
8 TME Fixation

A fixation (zigzag, tines, V-hook, loop) anchors the lead securely in the myocardium (exception: TME..AT: heartwires without myocardial needle and fixation for atraumatic use).

Fixation of the TME in the heart has to fulfill two criteria: it must be stable enough to guarantee reliable heart pacing during the entire pacing period, and it must also not be too securely anchored in the heart so that it can be removed without injury and without external visual control of the removal.

Ultimately, the fixations that are used in the operating room depend on the experience and preference of the operating team.

8.1 Zigzag model (TME..Z)

TME..Z distinguishes itself through the following features:

- Variable fixation rigidity
- Choice of the pacing surface size
- Cathode in the myocardium
  (good pacing and sensing properties)

The zigzag-shaped lead is formed out of a bare strand. Although at first the zigzags are very compact, they stretch out intentionally when pulled into the heart muscle.

The zigzag shape that results is sufficient for anchoring the lead in the heart.

Be very sure that with bipolar leads both electrodes are completely implanted in the myocardium, which means that they are no longer visible.
8.2 Plastic tines model (TME..T)
TME..T distinguishes itself through the following features:
- Secure fixation
- Defined lead surface
- Cathode in the myocardium
  (good pacing and sensing properties)

The shape of the tines collar was adapted from those found in permanent pacing leads.
They are shaped out of the same material as the strand insulation (polyethylene).
The lead surface – specifically the remaining surface of the bare strand under the tines – suffices for excellent pacing.
A requirement for that is that this surface is located in the heart muscle.

The anchoring is essentially achieved by spreading the tines. This is done by pulling the heartwire in until the tines are once again visible, and then by pulling the heartwire back a bit.
Cut off the excess wire including the heart needle.

*Warning:* *The excess wire should be cut at least 10 mm away from the tines.*

8.3 Loop model (TME..Loop)
TME..Loop distinguishes itself through the following features:
- Atraumatic fixation through attachment with surgical sutures
- Particularly suitable for atrial pacing

The elliptically shaped curve of the loop lead serves as an anchor in addition to being the lead surface.
The lead is attached to the epicardium with a ligature. The size of the ligature loop determines the tugging force necessary in order to remove the lead.

Note: The threads of ligature should never be pulled through the loop, since in that case a risk-free removal of the lead from the exterior is not possible.

**8.4 V-shape model (TME..V)**

TME..V distinguishes itself through the following features:
- Atraumatic fixation through attachment with surgical sutures
- Particularly suitable for atrial pacing

The V-shaped heartwire is an epicardial lead, which is fixed to the surface of the heart by ligature at the V-curve. Removal of the lead is achieved with light pulling, when the V-shaped strand straightens out and can be pulled out of the loop of the ligature.

**8.5 Atraumatic model (TME..AT)**

TME..AT distinguishes itself through the following features:
- Atraumatic fixation, no perforation of the myocardium
- For particularly unstable hearts (low fatty tissue requirement)

The atraumatic lead has two electrodes which lie one behind the other, each of which is linked to an electrode strand and is placed under the heart for pacing. This fixes the lead at the same time. Careful attention needs to be paid to the fact that the leads should not rest on or in fatty tissue since pacing cannot take place there.
8.6 Straight model (unipolar)

Straight unipolar wires are the oldest form of heartwire and are anchored in different ways either on or in the heart muscle depending on the personal experience of the surgeon (for example: after cutting the heart needle, the bare strand is bent to suit).

For pacing two unipolar heartwires are necessary!
9 Removal (Explantation) of TMEs

Procedure:
Before a TME is removed from a patient, the fixation method used during the operation should be checked.

**Bipolar TME 60 cm:**
Disconnect the external pacemaker and carefully and slowly pull the strand out.

**TME multipolar with PE protective tube:**
Disconnect the external pacemaker.
The PE protective tube should be located on the outside of the chest cavity during implantation.

*Warning: Do not pull all of the electrodes out at the same time! Carefully pull the wires out one at a time!*

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PE-tube

Wires can be carefully pulled out one at a time!
10 Models and Variants

The following TME models are regularly produced by OSYPKA:

<table>
<thead>
<tr>
<th>Model</th>
<th>Number of Electrodes</th>
<th>Number of TMEs needed</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>TME1 – Unipolar</td>
<td>1</td>
<td>2 (1) 4</td>
<td>Atrium (AAI) or ventricle (VVI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dual chamber (DDD)</td>
</tr>
<tr>
<td>TME2 – Bipolar</td>
<td>2</td>
<td>1 2</td>
<td>Atrium (AAI) or ventricle (VVI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dual chamber (DDD)</td>
</tr>
<tr>
<td>TME2 – Bipolar Bifurcated</td>
<td>2 x 1</td>
<td>1 2</td>
<td>Atrium (AAI) or ventricle (VVI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dual chamber (DDD)</td>
</tr>
<tr>
<td>TME4 – Double Bipolar</td>
<td>2 x 2</td>
<td>1 1 1</td>
<td>Dual chamber (DDD) Bi-atrial Bi-ventricular</td>
</tr>
<tr>
<td>TME4 – Quadripolar</td>
<td>4 x 1</td>
<td>1</td>
<td>Dual chamber (DDD)</td>
</tr>
</tbody>
</table>

10.1 TME1 – unipolar 60 cm length

The unipolar model was the original model used at the inception of open-heart surgery. The leads are made from stainless steel strand for a conductor, which ends in an electrode. Other companies offer a unipolar lead with a straight, bare strand; OSYPKA on the other hand, has five different fixation options.

Two leads (cathode and anode) are necessary in order to pace the heart. Unipolar leads are only rarely used in Germany and some other countries because of their comparatively poorer pacing properties.
10.2 TME2 – bipolar 60 cm or 220 cm lengths
The bipolar lead is composed of two wires that are kept apart from each other and that end in two electrodes. This way only one integrated twin wire lead is necessary. The bipolar TME was developed by OSYPKA 25 years ago and today it is the most used lead in Germany. The variability of the fixation allows users to implement whichever model is preferred. The leads are available in white or blue.

Advantages:
- Only one supply wire per heart chamber and therefore less trauma to the cardiac tissue
- Defined short distance between anode and cathode (2.5 mm) and therefore excellent pacing properties
- The overall length of 220 cm makes an extension cable unnecessary

10.3 TME4 – 4 x unipolar 220 cm length
This lead has four unipolar leads placed together in the same casing (polyethylene tube). That enables the selective fixation on the atrium and the ventricle.

The lead is advantageously used on hearts for which it is difficult to enable fat-free bipolar lead placement because of added fatty tissue. The identification for atrium and ventricle is done by using different colors (white/blue) for the wires. The overall length of 220 cm makes an extension cable unnecessary.
10.4 TME4 – double bipolar 220 cm length
This lead has two bipolar leads placed together in the same tubing (polyethylene tube).
This makes it possible to simply and reliably pace the atrium and ventricle.
The identification for atrium and ventricle is done with different colors (white/blue) for the wires.

Advantages:
- Only one wire per heart chamber, thus less trauma to cardiac tissue
- Free choice of fixation in the atrium and ventricle
- Defined, short distance between anode and cathode (2.5 mm) and therefore excellent pacing properties
- The overall length of 220 cm makes an extension cable unnecessary

10.5 TMK – TME for children
TMK child leads are available in unipolar and bipolar models.
They are distinguished by their miniaturized size.

Unipolar:
The supply wires are made of a thin insulated stainless steel strand and have a diameter of 0.2 mm –including the insulation.
Two unipolar leads are necessary for pacing.
The active lead, which is anchored in the heart muscle, has a diameter of 0.15 mm.

Bipolar:
The wires of the bipolar model is made of two thin, insulated, parallel stainless steel strands, each 0.20 mm, which are attached to a twin supply wire.
The active lead, which is anchored in the heart muscle, has a diameter of only 0.15 mm.
One bipolar lead is necessary for pacing.
10.6 MP – Temporary pacing with a permanent lead

Another possibility for temporary pacing is with a permanent myocardial lead (MP) that is implanted as a prophylactic measure in the myocardium during a heart operation.

Often, permanent myocardial leads are implanted after heart operation so if a pacemaker is eventually indicated, the permanent leads can be readily used. This prophylactic procedure is typically used for small hearts, i.e. in children.

OSYPKA has developed a specific adapter to allow the leads to be used as temporary leads as well. The adapter fulfills two criteria:

First, it protects the plug of the permanent myocardial lead. Second, it makes connection to an external pacemaker possible by means of flexible electrical wires.

After successful pacing, the wires are "pulled" as with TMEs, whereby the adapter, which remains in the chest cavity, closes itself off hermetically, still containing the myocardial lead’s plug.

10.7 Color coding

**Identification:**

- Ventricle: white wire
- Atrium: blue wire

**Note:**

_Cathode and anode are not coded. The respectively lowest pacing threshold for each can be established by swapping the connections on the external pacemaker._
11 Adapting to External Pacemakers

11.1 Adapting with Confix
Confix-plug prongs have a diameter of 1.0 mm, are made of gold-plated brass and are attached directly behind the thorax needle to the heartwire.

They are arranged in sequence (one behind the other) so that the opening in the thorax can be kept as small as possible when the wires are being pulled through.

After the thorax needle is cut, the Confix plugs can be attached either directly to the pacemaker or with an extension cable (e.g. VHC cable).

11.2 Adapting by adapter
With the patented OSYPKA adapters, heartwires can easily be connected without requiring tools on the operating table with the standard 2 mm plug prongs.

The procedure is as follows:
- Cut the thorax needle
- Plug the strands in the transverse opening of the adapter pin
- Push the pins into the plastic part of the adapter
- Push the protective cap onto the pin

The leads adapted in this manner can be attached either directly to an external pacemaker or with an extension cable.
12 Accessories / Aids / Notes

12.1 VHC extension cable
The VHC cable was developed to extend the 60 cm long TME with a Confix plug. It is 250 cm long and has two standard 2 mm plugs with protective caps on one of its ends. Cable colors are red and black. A security device is attached to the side where the Confix plug is attached, to prevent accidental detachment of the plug by the patient.

12.2 Extension cable D2-SP
The D2-SP cable is a universal extension cable for the attachment of the collets, which permits the attachment and fixation of plugs with diameters between 0.8 mm and 2.0 mm. It is 250 cm long and has on the other end two standard 2 mm plugs with protective caps. The cable colors are red and black.
12.3 Patient bags as storage bags

In cases where the TME is sometimes not connected to an external pacemaker after an operation, it is wrapped up and secured to the patient using tape. OSYPKA has developed a plastic bag with a zip closure for this purpose, which can be taped to the patient (similar to an ECG lead), avoiding contamination of the lead. The unused lead wires can thus be temporarily and neatly stored in this bag.

13 TME Packaging

13.1 Winding spool

The leads are always delivered on a winding spool for better handling during the operation.

13.2 Double packaging

OSYPKA TMEs are shipped in double packaging (2 sterile bags) in order to guarantee the unambiguous and secure transfer from unsterile to sterile during the operation. The unsterile person opens the outer packaging and offers the contents to the sterile person. The sterile person then removes the second sterile pack from the outer packaging.
14 EN Symbols *
Certain standardized indications and instructions have been put into use recently. They were established internationally through the European standard EN 980 and are also used in the USA.

*EN = European Norm

Examples:

- **Manufacturing date**
- **Use before**
- **Non reusable**
- **Serial number**
- **Lot number**
- **Catalogue number**
- **Sterilization: Ethylene Oxide Gas**
- **See accompanying documents**

15 Sterilization
OSYPKA TMEs are sterilized with 6% ethylene oxide gas (EO) at a temperature of approx. 40°C. The duration of guaranteed sterility (use before date) is noted on the packaging and equals 5 years.

Resterilization
To optimize patient’s safety TMEs are made for single use. Resterilization is therefore not recommended. The expenses for controls and documentation for resterilization greatly exceed the costs for purchasing a new product.
Appendix

We are always grateful to hear your questions and comments!
Please contact directly, by e-mail, telephone or in writing:

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Please visit us on the web at www.osypka.de.

Thank you very much!
References


