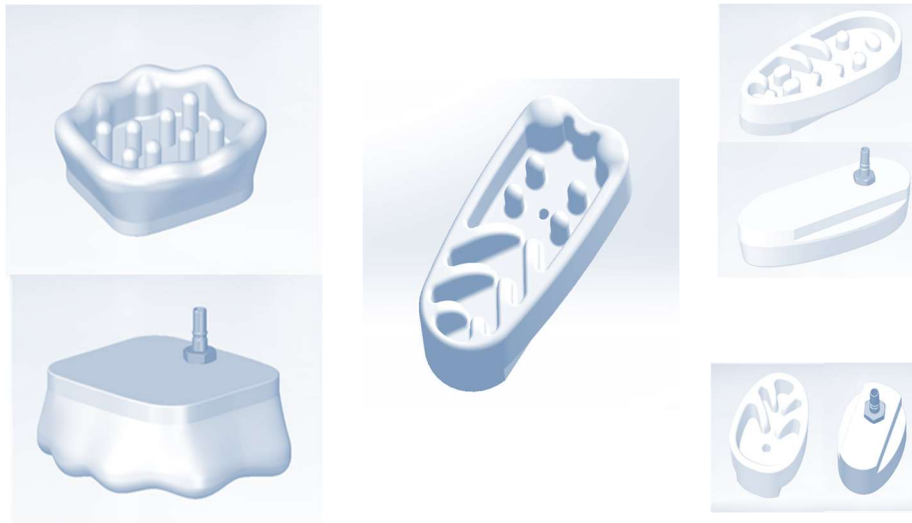




INSTRUCTIONS FOR USE

Application heads (TACs) for MyoRK equipment



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1. INTRODUCTION

With the idea of developing equipment allowing to work without penibility and with increased efficiency, RK INNOV has developed an electromedical massage equipment MyoRK. It comprises a vacuum pumping system allowing to perform a suction action with control of the applied suction pressure to the application heads. It is programable and operates automatically (hands- free) and also allows a manual use.

It is equipped with flexibles and application heads called TACs. These are the parts applied to the patient, which are connected to the flexibles themselves connected to the MyoRK equipment.

This notice is intended to introduce the TACs. It contains the instructions that must be followed to ensure the proper use with proper operation and maintenance in hygiene and safety conditions. It completes the User's manual of MyoRK equipment referenced "MRK Manual". Both documents need to be read before the first use, particularly the warnings and restrictions given in clause 3.

The first edition date of this document is *June 2021*, the revision date is indicated in the document reference at the top right of the page (date codified upside down YYMMDD).

Intended use

MyoRK equipment equipped with TACs is intended to the application of vacuum therapy to relieve musculoskeletal pain for the following indications:

- Muscle tension
- Back pain (including low back pain and neck pain) and joint pain
- Prevention and supporting pathologies of locomotor apparatus, such as tendinopathies ...
- Venolymphatic drainage.

with the main clinical benefits:





- Reduction of the myofascial and tendinous tensions (general relaxation)
- Reduction of the pain (Increase of the pressure pain threshold)
- Decrease of the osteoarticular pain and gain a better joint flexibility (increase of the range of motion)
- Quality of life improvement.

MyoRK equipment and TACs are intended for the health professionals use only, practitioners of manual therapies such as physicians, physiotherapists, osteopaths after a specific training provided by RK INNOV. TACs are placed under the responsibility of a person trained by RK INNOV and designated as the responsible user.

Description

The application heads are provided in a storage suitcase that includes up to 9 TACs (4 TACR, 2 TACL, 2 TACJP, 1 TACP) and this instructions for use.

The TACs of different sizes and ergonomic shapes are patented. They can be applied to different parts of the body and are interchangeable depending on the application. They are mentioned in the table below.

| Reference and designation | | Dimensions (cm) | Site use examples |
|---------------------------|---|---------------------------------|---|
| TACR Round head |  | 12.7 x 13.4 thickness 4.6 mm | Back, shoulders, belly, buttocks, thighs, ... |
| TACL Long head |  | 7.8 x 17 cm | Trapezius, back, psoas, thighs, gluteus medius, Fascia Lata Tensor (FLT), adductors, calves, arms, forearm... |
| TACJP Medium head |  | 7.4 x 16.1 | Forearm, anterior tibial, trapezius, ... |
| TACP Small head |  | 3.3 x 7.3 | Neck, forearm, wrist, palms, soles of the feet, located point as Achille's tendon ... |

Technical characteristics

- Rigid material
- Different shapes and sizes (see the above table)
- Made in France
- Warranty 2 years
- Expected lifetime of 5 years

Use performances

- 4 models that are ergonomic for comfortable applications and adapted to different anatomical segments
- Several TACs of large sizes allowing to work on large body surfaces and then to work quickly the whole body, the back as well as the front sides
- Quick and reliable connections to the flexibles
- Washable
- Storage in a suitcase








Safety

- Design for a safe application
 - Different shapes and sizes fitting to different anatomical areas
 - Wide edge and presence of pins allowing to reduce pressure on skin-contact surfaces and skin detachment
 - Smooth and washable surfaces for ease of decontamination
 - Biocompatible material to avoid any biological risks
- Use limited to dry cupping (non-invasive, without breaking the skin barrier)
- Use limited to the health professionals after a preliminary training

Vacuum therapy can be associated with PCPTtherapy (Profound Continuous Pressure) and then to provide a more effective and deep massage allowing to reinforce clinical benefits for the given indications (see page 3), to increase blood and lymphatic circulation, to decrease myofascial tensions including deep muscle and connective tissue and allowing muscle recovery and improvement of posture.

2. MEANING OF SYMBOLS AND LABELS

TACs application heads are accessories of the MyoRK equipment which is a class IIa medical device. In accordance with the regulation, they bear the **CE** marking. A marking appears on the top of each TAC, the complete marking is affixed on the primary packaged and recalled in the TAC suitcase. The used symbols are:

| | |
|---|---|
|  | Name and address of the Manufacturer |
|  | Manufacturer's product name |
|  | Manufacturer's catalogue reference |
|  | Manufacturer's serial number |
|  | Unique Device Identifier |
|  | Medical device put on the market in accordance with the European regulation (EU) 2017/745 |
|  | Obligation to read instructions before first use. |

3. CAUTIONS AND WARNINGS



Please, follow recommendations from training and read all safety information, contraindications, precautions, and warnings prior to use the TACs. The responsible user of the MyoRK equipment is responsible of the TACs and their use complying with instructions. Failure to follow these instructions could cause tissue damage, injury or pain to the patient. RK INNOV will not responsible in case of misuse of the TACs.

Do not use or store TACs in the following environments:

- Near any source of dust, biological and / or chemical pollutants or contaminates.

Do not use in the following cases:

- Without preliminary training provided by RK INNOV
- With another equipment (use of TACs is exclusively for MyoRK equipment)
- In case of doubt about the surface state of the TACs
- Without health check-up of patient, identification of areas of pain and fragility (sensitivity)
- In case of doubt or medical treatment in progress, pain or tingling during the session, stop immediately and search for the causes, ask the advice of the attending physician.

Do not apply TACs on face, throat, navel, folds (abdomen, buttock), chest, sexual organs.

Contraindications:

- Generalized cancer, systemic infectious pathologies
- Acute infectious, tumor and neurological diseases
- Locally, at the level
 - injured, infected, cancerous areas
 - acne, cutaneous herpes, wart, suspicious mole...
 - hematoma, erythema, dermatosis
 - deep varicose veins and for 2 months after vein surgery
 - recent trauma, fracture, ...

Use with caution for patients:

- Children (only soft pulsating programs, see MRK Manual)
- Pregnant women (no treatment on the abdominal and lumbar areas)
- Elder and/or fragile people (only soft pulsating programs)
- Suffering from vascular pathology, in particular thrombo-embolics and coagulation disorders or anticoagulant treatment in progress after advice of the attending physician
- Suffering from acute osteoporosis, osteoarticular fragility and other heavy pathology, neurodegenerative, autoimmune, ...
- Locally, at the level of areas of vascular nodes, varicose vein, edema, ...

For the application of the TACs, take the following precautions:

- Apply only on healthy skin, clean and dry
- In case of skin desquamation (after sun exposure for example), ask patient to do an exfoliation before coming so as not to clog the filters of the flexibles
- Ask the patient to remove the jewelry from the treated areas, hair up
- Use only clean and dry TACs
- Before a session, always perform a pre-test to assess the pressure pain threshold of the patient
- Use "Soft" programs in pulsed mode for the first session(s), children, elder and/or fragile people
- Do not apply more than 45 min / 10 min in pulsed / continuous mode
- After each patient, clean and disinfect TACs according to the procedure given in § 5
- Always keep the TACs in a clean and dry place protected from dust and contaminants.

4. OPERATING USE

The technical handling is very simple but read fully and carefully the User's manual of MyoRK equipment (MRK Manual) before use, mainly concerning the human interface (control keyboard, potentiometers and TAC control buttons).

Before the 1st use of TACs and after each storage, clean and disinfect the TACs according to § 5.

Prepare the patient's installation

- Prepare the massage table, put a cover (except during COVID risk periods for which the working table shall be cleaned and disinfected after each patient according the clause 5)
- Put a suitable cushion for the head and a suitable cushion for under the ankles or knees when lying down
- Place an examination sheet (single use)
- Let the patient settle down (on the belly or on the back depending on the area to be treated) and place cushions according to the good massage practices
- Provide the suitable information (see additional information in annex)

Prepare the application

- Start the MyoRK equipment and ensure that the 2 potentiometers are on the graduation 1 (see MRK Manual)
- Connect TAC to the flexible of the direct line
- In the case of fibromyalgia and fragile patients, do this test with TACP.
- Evaluate the pain threshold by placing the TAC on parts of the body to be treated
- Adjust the vacuum pressure to the pain threshold by placing the TAC on body areas to be treated
- Adjust the vacuum pressure according to the pain threshold with the safety potentiometer and lock it
- Select programs fitting to the patient's pain threshold and the pathology
- Connect TACs to the flexibles and for each, check the effective connection by traction

- Position the TAC, check the correct adhesion with the minimum holding pressure
- Press OK to start the program
- Press the top button (function "ON") for vacuuming
- if necessary, press the bottom button (release function) to shift TAC during session or remove it at the end of the session
- If necessary, repeat the unlock/lock the safety potentiometer for a new vacuum pressure according to the evolution of pain of the patient.

Ending the session

- For each TAC, press the bottom button (release function) to release the TAC (air entry) and remove it slowly
- disconnect TAC from the flexible and place it in a tray or case intended to receive the TACs to be cleaned
- Store the flexibles (see MRK Manual)
- Ask the patient to sit slowly (see additional information in annex)
- Guide him to prevent him from moving towards the equipment
- Clean the cushions and table using the disinfectant solution (spray) and well dry before preparing the table for the next patient
- Clean TACs according to the procedure given in § 5
- Always keep TACs in a dry, clean and dust-protected place.

5. CLEANING AND DISINFECTION

- Provide a cleaning station with at least one tank for used TACs and one tank for cleaned and disinfected TACs
- Recommended cleaning and disinfecting product: solution SURFANIOS PREMIUM diluted to 0,3 % in water (25 ml in 8 L of water) or other solution for medical use intended for the disinfection of medical equipment
⚠ Except diluted alcohol, do not use organic solvents.
- Before the first use, after a long storage and after each patient, put the TACs in the tank provided for cleaning
- If possible, soak for 30 min
- Use a soft and appropriate brush with protective gloves
- Rinse well with running water and let drain
- Let the TACs (on the face) to dry on a clean absorbent surface
- Replace them on the MyoRK tray for a new use or store according to § 6.

6. STORAGE

At the end of the day after TAC cleaning, disinfection and drying according to the § 5, store them in a storage bin (clean and closed) or in the MyoRK drawer (optional).

In case of long-term storage or transport, use the storage suitcase provided by RK INNOV after placed each TAC in a food-grade plastic bag for a single use and with recommended minimum thickness of 40 µm.

In any case, store TAC in a proper and secure location under the responsibility of the responsible user of the MyoRK equipment, far away from pollutants, contaminates.

7. MAINTENANCE

Service control

Do a daily visual examination to check :

- cleanliness of the flexible ends at the level of the TAC connections
- integrity of the TACs (good surface state, no sticky surface, absence of roughness ...).
- In case of loss of integrity (rough surface, ...), contact RK INNOV.

After Sales Service

For any problem of usage, doubt, difficulty, replacing TACs or suggestion of improvement, thank you to note the serial number of your equipment and to contact RK INNOV SAS to contact@rkinnov.fr

In case of return of the TACs, clean them carefully as indicated in § 5.

Warranty

TACs are guaranteed 2 years from the date of delivery against any defect of manufacture and operation, resulting from a defect in material, workmanship or design. The RKINNOV guarantee does not cover damage caused as a result of:

- an intervention on a TAC that led to a design or surface coating change
- inappropriate use that does not comply with the instructions presented in this manual (lack of maintenance, overuse, etc.)
- an abnormal wear
- a case of force majeure (accident, ...)

Under the warranty and subject to the submission of a copy of the invoice, RKINNOV will repair or replace the defective components. This warranty covers labor and shipping costs after repair.

For disposal

After the last use, clean, disinfect and dry TACs according to 5 and discard them in accordance with local regulations in force.

ANNEXE - ADDITIONAL INFORMATION

A.1 - Undesirable effects and adverse events

Adverse events comprise those from any massaging techniques:

- dizziness at the end of the session due to the extended lying position on the front side
- headache from the draining effect leading to a mobilization of toxins.

Adverse events, that may be experienced mainly after the first sessions, are of mild to moderate severity, resolving within 2 days. They include:

- muscle weakness, curvatures
- occasional increase in pain
- ecchymoses leaving skin marks.

Strong ecchymosis with skin marks may last up to 5 days without any side effects but requiring to avoid exposure to the sun on the following days. In exceptional cases (patients with fragile vessels and/or application of an excessive vacuum pressure and/or duration), application can lead to bruise or hematoma.

A.2 Information to be given to the patients

The extended lying position on the front side with general relaxation can cause possible dizziness at the end of the session. To avoid any inconvenience, it is recommended to the patient to bend their legs to the side, slowly straighten up to the sitting position, sit and wait about 1 min before getting up.

Relaxation gives a feeling of lightness up to muscle weakness. Curvature and feeling tired may be experienced after the first sessions. It is recommended to avoid physical exertion for the next 24 to 48 h and follow the specific recommendations.

Like any cutaneous mobilization technique, the session provides a drainage effect. It is recommended to drink thoroughly after the session to promote and compensate the urinary elimination of toxins and waste.

The suction effect can leave skin marks (ecchymosis) that may last a few days without any side effects but requiring to avoid exposure to the sun on the following days.