

# ÓPPONENT®

*VívacSo srl*

ONE STEP BEYOND.

## **USER MANUAL**



Please read carefully the present document  
Pay attention to safety instructions



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# 1. Product description

**ÓPPONENT® is an AFO (Ankle-foot orthosis) for the treatment of foot drop and spasticity**

Materials:

- composite fibres structure (carbon fibres and kevlar®+vectran™)
- shoulder-spiral covering in PCM (Phase Change Material), laces in velcro.

Elements of the composite fibres structure (Fig. 1):

- shoulder **(1)**
- spiral **(2)**
- plantar (adaptable in size and profile) **(3)**

As part of the covering:

- covering of shoulder-spiral and related velcro **(4)**
- plantar covering and related velcro (optional) **(5)**
- plantar lace, adjustable, and related velcros **(6)**
- superior lace, adjustable, and related velcros **(7)**

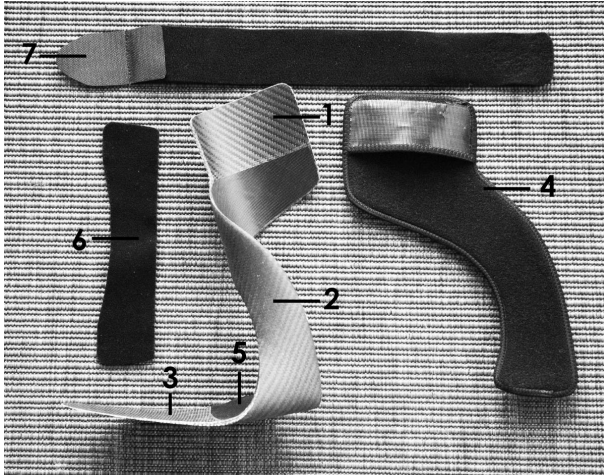


Figure 1: Product parts

### **1.1 Indications and advantages**

ÓPPONENT improves the gait in the presence of foot drop and spasticity (as in case of stroke, cerebral trauma, multiple sclerosis, spastic paraparesis, etcetera) or without spasticity (as in case peripheral nerves failure, muscle dystrophy, etcetera).

In case of foot deformity ÓPPONENT is recommended only when the physiological foot position can still be reached (reducible deformity).

ÓPPONENT helps the customer to gain a more physiological, dynamic and stable gait. During the terminal part of the stance phase of the step, the elastic force accumulated in bending the plantar is returned as a forward thrust. The heel has free contact with the shoe, making easy to wear the AFO and avoiding length differences between the lower limbs.

Moreover, the put on and put off operations can be made by the customer with one hand only.

### **1.2 Contraindications**

ÓPPONENT should not be used in case of:

- intolerance to used materials
- skin injuries of the leg and foot
- moderate to severe oedema
- non-reducible foot deformity

If a reducible foot deformity is present, the addition of a further correction plantar, between the plantar and the foot, can be necessary.

Consult your doctor in case of:

- skin lesions/diseases
- local inflammation
- lymphatic disturbances or swelling of soft tissues
- lower limbs circulatory impairments.

**⚠ WARNING**

**Risks due to inappropriate application.**

**The first adaptation and application of the orthosis must be done exclusively by professionals.** *The product is conceived exclusively for the use on a single user. In case the orthosis was used by other persons, the adapted parts and those in direct contact with the skin could cause functional and hygienic risks.*

*Laces fastened too tight can cause compression of nerves, vessels and skin.*

*Consult your doctor in case of local pain, swelling, reddening and altered function of the foot, with new features than before wearing the orthosis.*

### **1.3 Safety instructions**

**The first adaptation and application of the orthosis must be done exclusively by professionals.** The daily use duration must be prescribed by the doctor.

**⚠ WARNING**

**Risks for the user due to inappropriate modifications.**

*ÓPPONENT is made in composite fibres and is not thermoformable. It cannot be pierced without altering the structure's mechanical features (see 5, Responsibilities, below).*

**⚠ WARNING**

**Risks for the user due to inappropriate environmental conditions.**

*The product is not fireproof: it must not come into contact with flames or other heat sources.*

**⚠ WARNING**

**Risks of car accidents while driving wearing ÓPPONENT.**

*Always observe the laws related to the management of cars within the country and, for insurance reasons, make ascertain the competent authorities and make them confirm your capacity to drive while using ÓPPONENT.*

## 2. Size choice and first adaptation to the user

### 2.1 Size choice

**The size choice and first adaptation to the user must be done by professionals.** Choose the suited size (S-M-L) on the basis of both foot and shoe size.

### 2.2 Shoe choice

ÓPPONENT is suited to any kind but heeled shoes: open or close, summer or winter shoes, lace-ups or sandals.

It is preferable to make first adaptation wearing lace-ups shoes: the result will be likely appropriate to any other shoe.

### 2.3 First adaptation of ÓPPONENT to the user

#### 2.3.1 Plantar adaptation

Every ÓPPONENT size includes 3 shoe sizes:

- Large: 43, 44 and 45 (EU)
- Medium: 40, 41 and 42 (EU)
- Small: 39, 38 and 37 (EU)

Therefore the plantar dimension can exceed the foot size and should be conveniently cut, as indicated on the plantar edge (Fig. 2 e 3).

Smooth out possible cutting edges with appropriate abrasive paper.

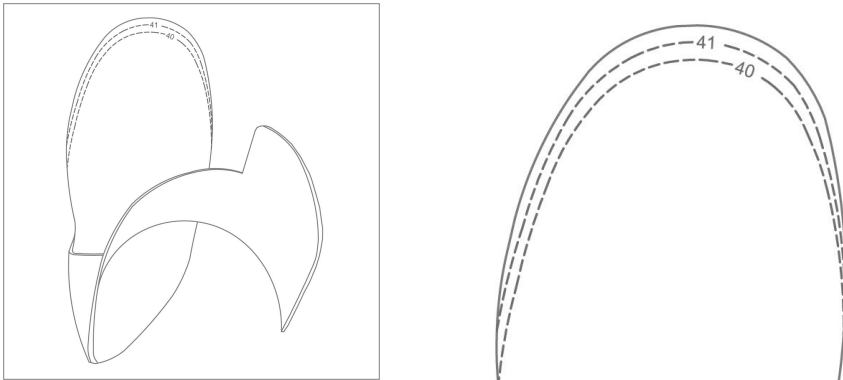


Figure 2 and 3: Cut indications reported on the plantar

**⚠ WARNING: An excessive plantar size could provoke painful conflicts between the spiral and your instep and between the plantar and your heel (see below, 2.4).**

If the user wears shoes with extractable insole, remove it and verify if this improves the comfort. However, if the insole is not extractable, this does not compromise the use of ÓPPONENT. If the user wears a corrective insole in the shoes, once adapted ÓPPONENT to her/him, verify if the said insole is still necessary. If it is so, place it between plantar and foot in order to reproduce the advantages for which it was initially applied.

### **2.3.2 Plantar (or anterior) lace positioning**

The plantar lace should be positioned so that the anterior edge is aligned with the roots of the fingers (Fig. 3).

Apply the 2 adhesive velcros on the inferior surface of the plantar in order to fix the anterior lace in the correct position (Fig. 4).



Figures 3 e 4: Plantar lace positioning and related velcros

Cut the soft part of the velcro fastening at the right length, and close the front strap so that it is well attached to the forefoot, yet not so much as to create discomfort.

### **2.3.3 Spiral adaptation**

Apply the 2 adhesive velcros to the internal surface of spiral: one at half height, the other to the bottom (Fig. 5). **Do not try to change velcros position, if they are already applied**



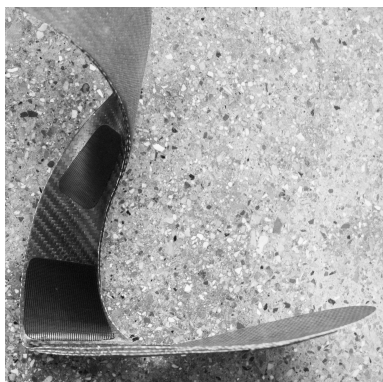


Figure 5: Velcros' application to the spiral

Apply the covering starting wearing the shoulder, then make it adhere to the spiral, so that it is correctly aligned.  
The orthosis is now ready to be worn (Fig. 6).

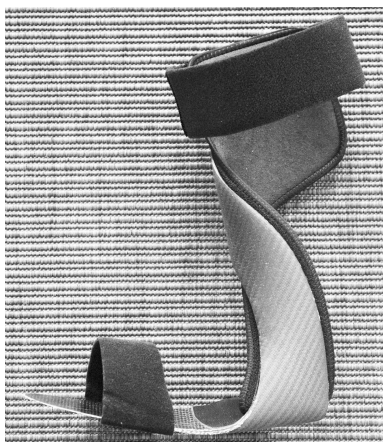


Figure 6: ÓPPONENT ready to use

## 2.4 First application and product regulation

How to wear ÓPPONENT:

- wear knee socks
- roll up your pants to the knee
- wear the orthosis on the foot, with the anterior lace already set
- push the foot until the anterior edge of the anterior lace is aligned to the roots of the fingers (Fig. 7).
- then fasten the superior lace. It has to embrace the calf passing through its posterior face, then coming to the front of the leg passing laterally, and finally reaching the internal side of the leg crossing its anterior face, where it will stick to the velcro applied to the shoulder (Fig. 8).
- put on the shoe



Figures 7 and 8: ÓPPONENT positioning

- roll down your pants (Figures 9 and 10).
- lace up your shoe.
- **Do not tightly fasten the superior lace. Its function is to maintain the correct relationship between the parts.**
- Fasten tighter the superior lace only in case of knee hyperextension: this will contrast the knee hyperextension pushing the leg to bend forward during the stance phase of step.

Once correctly worn, it will be difficult to note ÓPPONENT under either elegant or casual pants.



Figures 9 and 10: Correctly positioned, ÓPPONENT becomes hardly visible

**N.B.:** In order to get the best benefits, ÓPPONENT must be fit properly. In particular:

1 - Check that the rear edge of the plantar is in front of the heel area so that the latter can freely rest on the shoe, avoiding any conflict with the plantar (Fig. 11-12).



Figure 11: **WRONG** position



Figure 12: **RIGHT** position

- 2 – Check that in the “rest” position a free space, even minimal, is maintained between spiral and tibia. The direct contact is unnecessary and could facilitate conflicts with the instep and decrease the comfort (Figures 13 and 14).



**Figure 13: WRONG position**



**Figure 14: RIGHT position**

After the initial set up made by the orthopaedic professional, the whole operation can be done by the user with one hand only.

To remove the orthosis, untie the shoe, remove it, then unfasten the superior lace and remove the orthosis.

### **3. Restrictions**

The product is designed and tested for the use by a single user only.

The daily use duration depends by your physician prescriptions.

ÓPPONENT was not tested for use in extreme meteorological conditions.

#### **⚠ WARNING**

#### ***Risk of lesions due to inappropriate use.***

*The orthosis was tested and is guaranteed exclusively for standing, sitting, lying posture and gait. The user should be informed of risks that may occur in different situations. For instance, a jump could provoke an excessive structure bending, and subsequent rupture of the latter.*

## 4. Care and disposal

### Cleaning and care

- Composite fibres structure: clean it with a wet rag.
- Covering and laces: washing machine 30°C/60°F. Use a common detergent for delicate tissues. Carefully rinse and air dry.

#### WARNING

#### **Damage from improper cleaning.**

*Detergent residue can irritate the skin and damage the covering and laces material. ÓPPONENT should never get in touch with fat- and acid-containing product, ointment and lotions. This could limit its duration and functionality.*

In case of loss, wear or deterioration of removable parts, your orthopaedic workshop can substitute them.

### Disposal

The product should be discarded in accordance with national requirements and according to the rules about environmental protection.

## 5. Responsibilities

The warranty is valid only if the product is used for its intended purpose, in the reported conditions, and if the first adaptation is performed by the orthopaedic technician. The manufacturer recommends to follow the instructions provided.

#### WARNING

#### **Operating problems.**

*Should problems arise (such as an unusual orthosis' movement or wear of a particular structural component), immediately discontinue use and contact your doctor. The guarantee does not apply in case of customization beyond that specified in this manual, and it is therefore strongly discouraged.*

**⚠ WARNING**

**Damage due to inappropriate modifications.**

*Inappropriate modifications of the product, that is, outside of those recommended in this booklet, or not previously agreed with the producer (see below contact details and references) and such as to modify the characteristics certified at the time of sale, release the producer from any legal liability about the damage caused by the product to the customer.*

## **6. EC product conformity**

ÓPPONENT complies with the requirements indicated in the EEC directive 93/42 concerning medical devices. The classification criteria for medical products in accordance with Annex IX of the directive, allows to classify the product under the 'I'. The declaration of conformity was therefore issued by VívacSo Srl, with sole responsibility, in accordance with Annex VII of the Directive.

## **7. Solutions to most common problems**

### **1. Ópponent aches in your plantar heel area**

- 1.1. Ópponent plantar's posterior edge has likely to be moved forward
  - 1.1.1. Ask your technician to cut the anterior plantar edge adapting it to your foot size (if he hasn't done it already)
  - 1.1.2. Ask the technician to slide the arch support forward and move the foot back an inch, and then secure the stability of the new position with the forefoot lace.
  - 1.1.3. Place the foam pad slightly leaning from the posterior plantar edge.
  - 1.1.4. Repeat operations if the improvement is present but your heel still aches
  - 1.1.5. write to customer service if the problem persists

### **2. Ópponent aches in your tibia (anterior calf) or instep area**

- 2.1. Superior lace is likely too tight, and at rest position a finger cannot easily pass between Ópponent and tibia: loosen the superior lace. Its function is only to maintain parts in correct reciprocal position.
- 2.2. write to customer service if the problem persists

### **3. Forefoot aches in the shoe while using Ópponent**

- 3.1. There is likely a crease of the forefoot lace or of your socks that is calling for your attention

**ÓPPONENT®**

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