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tactee
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Magnetic Adaptor System

User Manual



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Instructions for Use

This instruction manual is for a magnetic adaptor system, in accordance with EEC Directive 93/42 and subsequent inclusions pursuant to Directive 2007/47/EC regarding Class 1 medical devices, and it is intended to be a guide for the application, regulation and correct use of the system. The conformity statement has therefore been issued by Tecnoway under its own liability, pursuant to Appendix VII of this directive. Manufactured using the Quality management system and certified per ISO 9001:2008 and ISO 13485 Standards.

General Information

Read the instructions carefully. The product should be fitted by a medical professional such as an occupational therapist, physical therapist, orthopedic technician or a medical doctor.

Patients with diabetes, circulatory problems or sensitive skin should consult their doctor before use. If the patient is allergic, check the material content under the point Material Composition.

Indications

The Tactee magnetic adaptor system has been designed to create a functional grip for patients with spinal cord injuries or neurological indications like CVA/Stroke, MS or tetraplegia or other disabilities where the functional grip is impaired or lost.

Precautions

- Both the knife and fork are sharp objects that can pose a risk of cut or stab wounds if used the wrong way. It is therefore important to assess each patient individually before you make the choice of the accessories.
- The adaptor contains three strong magnets that can affect sensitive electronics such as displays, electronics, metal objects or medical devices such as pacemakers. Be sure to include this risk assessment in your overall assessment of the patient.
- Patients with sensitive skin or poor circulation should be observed for edema or general swelling above or below the adaptor. Also check for pressure marks.

Precautions for Use

- This set of components may not be used for any purpose other than that for which it was designed.
- Do not allow children to use any of the components of this kit without adult supervision.
- Do not allow persons affected by psychological or cognitive disorders to use any elements of this kit alone, without the supervision of a responsible assistant.
- Contact a physician if the patient experiences any skin discomfort or any other sensitivity issue.
- Avoid the use of creams that may come into contact with any of the elements of the system during use.
- The correct use of the kit components requires correct maintenance of the same, and therefore they must be inspected periodically.
- Please pay attention to the cleanliness of Velcro® parts. To maintain their gripping properties, eliminate any threads, fuzz, etc. that may reduce the grip between the various components.
- Periodically clean all the components of the kit and maintain proper personal hygiene. If any part of the system presents anomalies, consult the orthopedic technician where the system was purchased.
- The components of this system are not fire-resistant, so do not use them near open flames.
- Do not use this system in the presence of strong electromagnetic fields.

Warnings

Read these instructions carefully before using any element included in this system. If you have any question, consult your treating physician, qualified paramedical personnel or the orthopedic technician from whom this system was purchased.

- First use and adjustment of the product must be performed by a physician, qualified paramedical personnel or an orthopedic technician, in order to ensure the effectiveness, tolerability and correct operation of the product.
- To obtain the correct functional effect, you must use the correct size of the product.
- The clasp system must be fitted and adjusted by the orthopedic personnel who sold this system, to fit the anatomy and pathology of the patient who will use the system.
- The components of this kit may not be modified without the supervision of qualified personnel for any reason.
- In the pressure support zone, the skin must not be broken or hyper-sensitive. If inflammation, irritation of the skin or other secondary issues occur, we recommend that you immediately contact your treating physician.
- The general instructions for use and the indications prescribed by the physician or by qualified paramedical personnel must be respected at all times.
- Every component of this kit is strictly for personal use. Do not reuse it on another patient. If the device is used by another person, parts in direct contact with the skin may cause hygienic as well as functional risks.
- Do not use this device if it is damaged or malfunctions. If the device is no longer able to be used, it must be replaced and disposed of.

⚠ Patients with a pacemaker are prohibited from using the device.

Features

The system presented in this instruction manual consists of a series of plastic and steel components that, when magnetically joined together, allow the user to carry out daily tasks, such as drinking, eating, writing, etc.

Basic Components of the Tactee System

- 1 grasping adaptor to be worn on the hand, comprising a flexible structure and soft straps to perfectly fit the patient's hand structure
- 1 bottle holder to connect to the grasping adaptor
- 1 fork to connect to the grasping adaptor
- 1 spoon to connect to the grasping adaptor
- 1 knife to connect to the grasping adaptor
- 1 universal adaptor to connect to the grasping adaptor
- 2 dorsal pads for the grasping adaptor

Note: The empty space in the case is intended for an additional grasping adaptor (optional) that may be purchased separately.



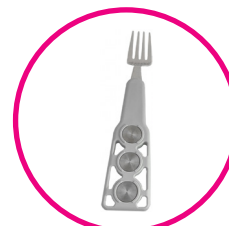
Storage Case



Grasping Adaptor



Bottle Holder



Fork



Spoon



Knife



Universal Adaptor



Dorsal Pads

Instructions

The Tactee system described in this instruction manual consists of a set of magnetic components that have been researched and developed for all persons who have a partial or complete functional grip deficit involving one or both hands due to orthopedic impairments, trauma or neurological issues.



Small ○	Medium ○○	Large ○○○
190mm - 220mm	210mm - 240mm	230mm - 270mm

Instructions for Technical Practitioner Only (first use)

Select the correct size. The grasping adaptor is available in three sizes, identified by the number of holes present in its structure.

⚠ The grasping element is offered in an ambidextrous version. Determine your size (see the size chart) and the correct side (right or left), and trim the belt extending over your fingers.

- 1.2 Put on and adjust the grasping adaptor on the patient's hand, placing it at the level of the palm. The curvilinear portion of this element must be supported against the medial edge of the palm (reference 2nd finger) with the portion that contains the magnets facing downward.
- 1.3 If the hand is particularly narrow (the dorsal portion of the grasping adaptor is separated from the back of the hand) or is particularly large (the dorsal portion of the grasping adaptor uncomfortably compresses the back of the hand), using a heat gun modify the structure of the original design so that the grasping adaptor fits comfortably against the back of the hand.
- 1.4 Once the grasping adaptor is customised to fit the patient's hand, apply one of the two provided pads. The hole in the upper part of the pad must be aligned with the triangular peg.
- 1.5 Adjust the length of the strap that crosses the palm using the adjustment clasp. Cut off any excess. Secure the strap by hooking the triangular hole on the corresponding tooth on the grasping adaptor.
- 1.6 Pass the extra strap around the thumb and hook it on the corresponding tooth on the grasping adaptor. Cut off any excess.
- 1.7 For greater comfort, and to better stabilise the grasping adaptor on the patient's hand, inspect and adjust the closure of both connections.

If the grasping adaptor must be used on both hands, repeat the steps for putting it on and fitting it that are specified above for the second grasping adaptor.

Patient Wear Instructions (after fitting)

- 2.1 Put the grasping adaptor on the hand and adjust it by placing it in the palm of the hand. The curvilinear portion of the adaptor must be supported against the medial edge of the palm (reference 2nd finger) with the part holding the magnets facing down.
- 2.2 Mount the strap that passes around the palm of the hand to the grasping adaptor by hooking the triangular hole on the corresponding tooth on the grasping adaptor. If necessary, adjust the length of the strap using the adjustment clasp.
- 2.3 Pass the extra strap around the thumb and hook it on the corresponding tooth on the grasping adaptor.
- 2.4 For greater comfort, and to better stabilise the grasping adaptor on the patient's hand, inspect and adjust the closure of both connections.

If the grasping adaptor must be used on both hands, repeat the steps for putting it on and fitting it that are specified above for the second grasping adaptor.

Coupling Action

For the coupling action of the various components to be stable and correct, be sure that the three magnets on the grasping adaptor line up with the three magnets on the coupled element. If the coupling of the various elements only mate one or two magnets, they may come apart during various activities.

Coupling of the grasping adaptor and the utensils (fork, spoon, knife)

- Place the grasping adaptor on the hand and secure the belts following the instructions above.
- Move the magnets on the lower part of the grasping adaptor near the desired utensil until it is firmly attached.

⚠ Ensure that the top of the connected utensil is always facing forward (e.g. knife with blade forward and down). If it is not, remove it and reattach the utensil correctly.

Coupling of the grasping adaptor and the universal adaptor

Before coupling the grasping adaptor to the universal adaptor, insert the item to be used in the adaptor (toothbrush, razor, pen, etc.).

Always ensure that the size of the item to be inserted is of dimensions that fit the opening in the adaptor.

Now move the grasping adaptor towards the universal adaptor, ensuring that the end of the item inserted in the adaptor is turned in the correct direction. If the item to be inserted is too large, it may damage the internal structure of the adaptor, making it unusable to hold other items firmly. If the item to be inserted is too thin, it may not be held firmly in the adaptor, thus adversely affecting the intended function and the safety of the patient.

⚠ If the item to be inserted is too large, it may damage the internal structure of the adaptor, making it unusable to hold other items firmly.
If the item to be inserted is too thin, it may not be held firmly in the adaptor, thus adversely affecting the intended function and the safety of the patient.

Coupling of the grasping adaptor and the bottle/glass adaptor

Before coupling the grasping adaptor to the bottle/glass adaptor, wrap the two Velcro® straps around the object to be used. Ensure that the two Velcro® straps are securely and firmly closed around the item. Now bring the grasping adaptor close to the bottle/glass adaptor.

Uncoupling the grasping adaptor and various elements

- Support the coupled element on a flat surface.
- Gradually and slightly turn the wrist clockwise or counterclockwise until the grasping adaptor gradually separates from the coupled element.
- If the item to be uncoupled must remain in a vertical position (e.g. a bottle), gently push or pull on the adaptor to be separated, until the two elements become detached from each other.

Material Composition

The adaptor is made from injection molded nylon and the straps are made from polyurethane. The cutlery is made from stainless steel and injection molded polycarbonate.

Cleaning

The adaptor can be washed daily using soap and water. It can also be disinfected using rubbing alcohol.

The various types of cutlery can be machine washed.

Note that the universal adaptor and the bottle adaptor should not be machine-washed; they should be wiped off using soap and water.

Notes

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