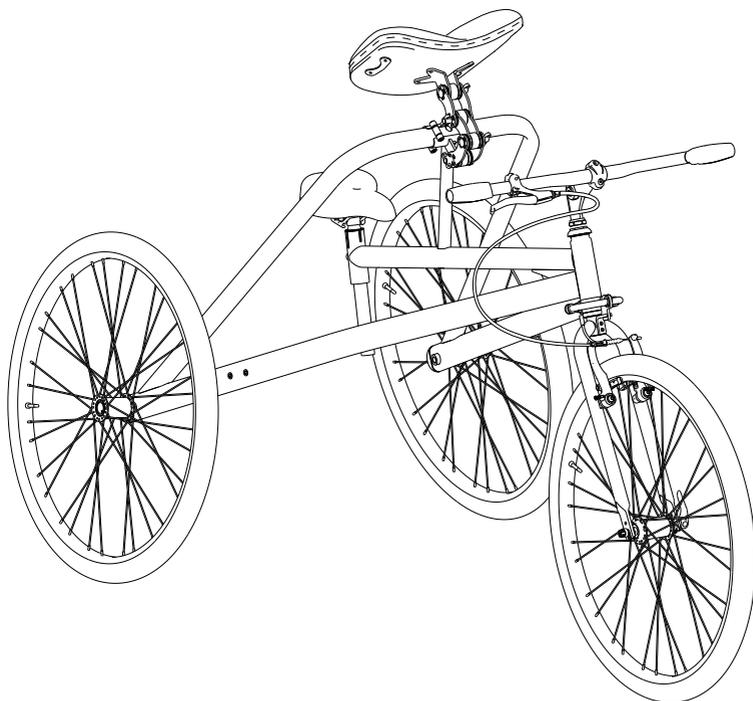


# Frame runner

ASSISTIVE DEVICE FOR RUNNING

ING-Cod 220810 - 19.02.25



USE AND MAINTENANCE HANDBOOK

# ORMESA®

• MADE IN ITALY SINCE 1980 •





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# 1. GENERAL INFORMATIONS

## 1.1 THANKS FOR CHOOSING THE MEDICAL DEVICE

**ORMESA s.r.l.** thanks you for your confidence in choosing **FRAME RUNNER**, a medical device designed and manufactured by **ORMESA Srl**, an ISO 13485 certified company.

**FRAME RUNNER** is an adaptable tricycle for children, teens and adults with motor and balance impairment of different degree.

ORMESA Frame Runner is a Medical Device classifiable to ISO 9999 with the code no. 12 27 22 **Running Bikes** (*sit-on vehicle with saddle and handlebars, propelled by pushing with the feet*) and to CND with the code Y122799 **Non-Motorized vehicles and means of transport - Others**.

**ORMESA s.r.l. recommends that you read this manual very carefully and thoroughly understand its contents.** It will help you familiarize yourself earlier and more effectively with **FRAME RUNNER**, but not only that, because you will find several practical tips on how to use it in the best and safest way and how to keep it in perfect working order at all times.

## 1.2 CONTACT DETAILS FOR ASSISTANCE

For configuration adjustment and modification, contact only the Health Care Professional who indicated/prescribed it; for technical adjustment, contact the professional who supplied it to you consistent with this manual or contact **ORMESA** directly at 0742 22927, by fax at 0742 22637; or by e-mail at [info@ormesa.com](mailto:info@ormesa.com).

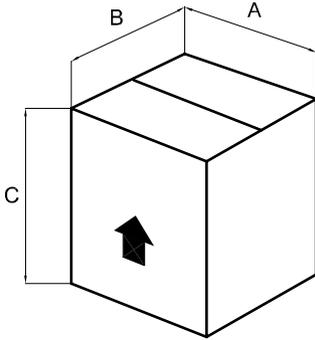
## 1.3 CONTACT DETAILS FOR INCIDENT OR NEAR INCIDENT

Contact [info@ormesa.com](mailto:info@ormesa.com) or the orthopaedic workshop that supplied the aid, to take the necessary actions in accordance with Regulation (EU) 745/2017, annex I, GSPR 23.4.z).



## 1.4 PACKAGING INFORMATION. UNPACKING INSTRUCTIONS AND SUPPLY COMPOSITION

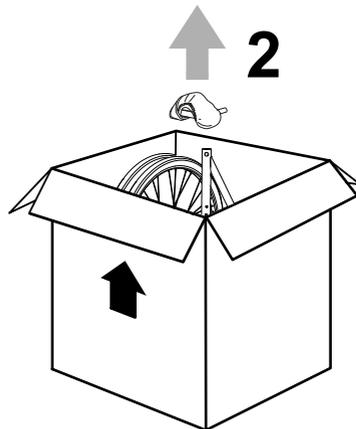
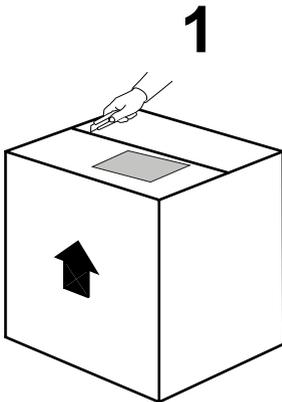
### PACKAGING INFORMATION



SIZE (in)	A cm (in)	B cm (in)	C cm (in)	VOLUME m <sup>3</sup> (in <sup>3</sup> )	WEIGHT kg (lbs)
M	75 (29,5")	65 (25,6")	110 (43,3")	0,53625 (32723")	26 (57,3 lb)
L	103 (40,5")	80 (31,5")	107 (42,1")	0,88168 (53803")	27 (59,5 lb)

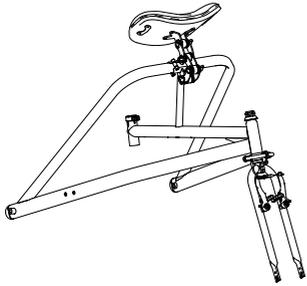
### HOW TO TAKE FRAME RUNNER OUT OF THE BOX

- 1) CUT WITHOUT EXERCISING TOO MUCH PRESSURE ON THE BLADE TO AVOID DAMAGING THE CONTENTS OF THE BOX.
- 2) TAKE THE ADDITIONAL COMPONENTS, THE WHEELS, THE SADDLE, THE HANDLE-BAR AND FINALLY THE FRAME OUT OF THE BOX.





# SUPPLY COMPOSITION



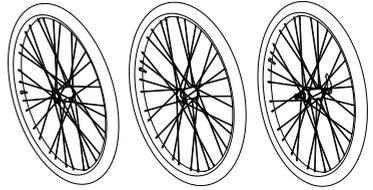
FRAME



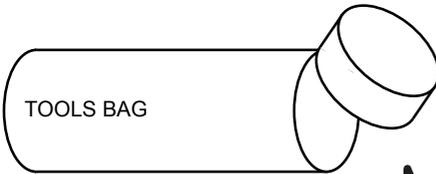
HANDLEBAR



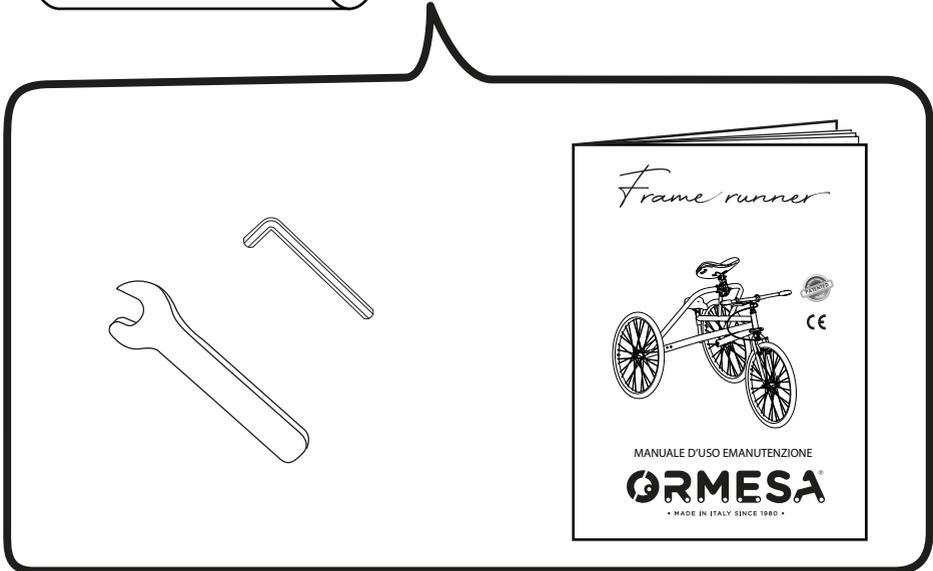
STANDARD SADDLE



WHEELS



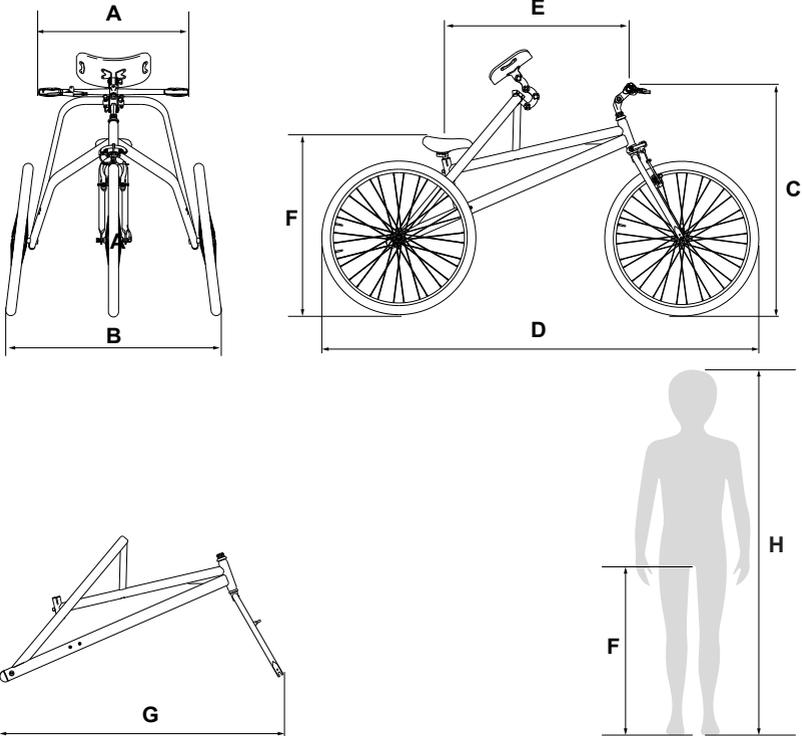
TOOLS BAG





## 1.5 MECHANICAL AND DIMENSIONAL CHARACTERISTICS

Measures in cm and inches, weight in kg and libbres



	A cm (in)	B cm (in)	C cm (in)	D <sup>1</sup> cm (in)	E cm (in)	F <sup>2</sup> cm (in)	G cm (in)	H cm (in)	Weight <sup>3</sup> kg. (lb)	Max load kg. (lb)
<b>M</b>	55 (21,6)	86 (33,8)	84-97 (33-38,1)	159 (62,6)	53-64 (20,8-25,1)	58-73 (22,8-28,7)	106 (41,7)	120-150 (47,2-59)	17 (37,4)	70 (154)
<b>L</b>	62 (24,4)	92 (36,2)	95-107 (37,4-42,1)	187 (73,6)	71-84 (27,9-33)	70-92 (27,5-36,2)	127 (50)	150-190 (59-74,8)	18 (39,7)	100 (220)

<sup>1</sup>Size M with 26" wheel  $D_{MAX}=164$  cm (64,5") - Size L with 26" wheel ,  $D_{MAX}=192$  cm (75,5")

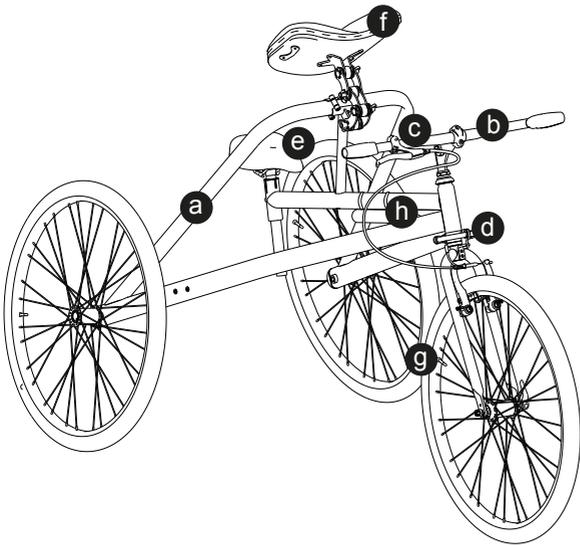
<sup>2</sup>With standard saddle. It is possible to further adjust the height position of the saddle ( $\pm 3$  cm - 1,18") by acting on the fixing clamp.

<sup>3</sup>Weights calculated without saddle abatement system.



## 1.6 PRODUCT PART LEGEND

- a) FRAME
- b) HANDLEBAR
- c) FRONT BRAKE
- d) STEERING LIMITER WITH SPRINGS
- e) ERGONOMIC SADDLE
- f) MULTI ADJUSTABLE TRUNK SUPPORT
- g) WHEELS
- h) TOOLS BAG
- i) SADDLE ABATEMENT SYSTEM (optional)





## 1.7 SYMBOLOGY USED IN THE MANUAL



Consult the use and maintenance handbook



Machine wash with neutral soap. Max. temperature 40°. Delicate cycle



European conformity mark.



Do not bleach



Warning: Consult the instructions for use for important precautionary information such as warnings and precautions that, for a number of reasons, cannot be displayed on the medical device in question.



Do not iron



Do not tumble dry

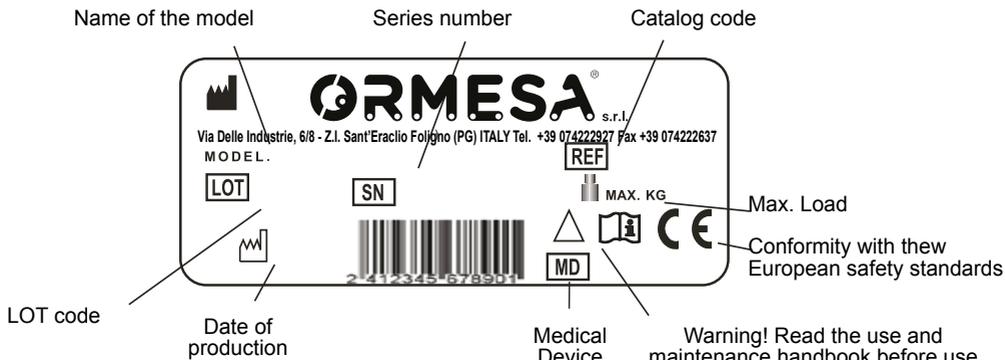


Do not disperse the product in the environment after use



Dry horizontally

## 1.8 IDENTIFICATION PLATE



**THE CE MARKING CERTIFIES FRAME RUNNER CONFORMS TO THE SAFETY REQUIREMENTS DEFINED WITH THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 APPLICABLE FOR MEDICAL DEVICE**



## 2. LEGAL AND REGULATORY REFERENCES

### 2.1 LEGAL REFERENCES

Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, repealing Council Directive 93/42/EEC, hereinafter also referred to as "Regulation (EU) 745/2017", or "RDM"

### 2.2 REGULATORY REFERENCES

#### HARMONIZED STANDARDS

UNI CEI EN ISO 13485	Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari. <i>Medical devices - Quality management systems - Requirements for regulatory purposes</i>
UNI CEI EN ISO 14971	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici <i>Medical devices - Application of risk management to medical devices</i>
UNI CEI EN ISO 15223-1	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali. <i>Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements</i>
UNI EN ISO 10993-3	Valutazione biologica dei dispositivi medici. <i>Biological evaluation of medical devices</i>

#### INTERNATIONAL STANDARDS

UNI CEI EN ISO 20417	Informazioni fornite dal fabbricante di dispositivi medici <i>Information provided by the medical device manufacturer</i>
UNI EN ISO 9999	Prodotti d'assistenza per persone con disabilità - Classificazione e terminologia <i>Assistance products for people with disabilities - Classification and terminology</i>
UNI EN 12182	Prodotti destinati all'assistenza di persone con disabilità - Requisiti generali e metodi di prova <i>Assistive products for persons with disability General requirements and test methods</i>
UNI EN ISO 21856	Ausili tecnici per disabili - Requisiti generali e metodi di prova <i>Assistive products - General requirements and test methods</i>
IEC 62366-1	Dispositivi medici Applicazione dell'ingegneria dell'usabilità ai dispositivi medici <i>Medical devices Application of usability engineering to medical devices</i>
IEC/TR 62366-2	Dispositivi medici - Guida all'applicazione dell'ingegneria dell'usabilità ai dispositivi medici . <i>Medical devices Guidance on the application of usability engineering to medical devices.</i>
UNI EN ISO 11199-1	Ausili alla deambulazione maneggiati da due braccia - Requisiti e metodi di prova - Strutture per deambulazione <i>Walking aids manipulated by both arms - Requirements and test methods - Part 1: Walking frames</i>



## 2.3 WARRANTY CONDITIONS

**ORMESA warrants the product for 2 years:** in case of problems, contact the supplier (health professional) where you purchased it. Always ask for original spare parts, otherwise the guarantee will decline.

ORMESA s.r.l. will not be liable for damage in the following cases:

- *use by an unsuitable person;*
- *incorrect assembly of parts or accessories;*
- *unauthorized modifications or service;*
- *use of other than original replacement parts and parts subject to wear (upholstery, wheels, etc);*
- *improper use (such as, transporting objects or loads larger or heavier than those ones shown in this use and maintenance handbook);*
- *damage caused by incorrect use and lack of regular maintenance, as shown in this user manual;*
- *exceptional events;*
- *failure to follow the instructions in this manual.*

**THE WARRANTY DOES NOT COVER WEAR PARTS, which are subject to wear and tear, such as the upholstery of the saddle, the grips, the removable upholstery of the additional components, the wheels and the brakes.**

## 3. SAFETY WARNINGS



### 3.1 MEDICAL DEVICE RISK CLASS ACCORDING TO ANNEX VIII OF REGULATION (EU) 745/2017

FRAME RUNNER belongs to Risk Class I (Non-Invasive Device)

### 3.2 GENERAL WARNINGS

- **BEFORE USING THE PRODUCT** because it has been written with the user's safety in mind and it will help the carer use the product safely and keep it in good working order. The Use and Maintenance Manual is an integral part of the product and must be carefully preserved for future reference.
- **THE USE AND MAINTENANCE HANDBOOK IS INTENDED FOR ALL USERS THE DEVICE: HEALTH PROFESSIONALS, CARERS (CARE GIVERS) PATIENTS;** It provides instructions for the correct use of the medical device.
- The manual reflects the technical state of the product at the time it was sold. **ORMESA S.R.L. RESERVES THE RIGHT TO MAKE ANY CHANGES TO THE PRODUCT OR MANUAL** suggested by experience, technical considerations or regulatory developments.
- **THE MEDICAL DEVICE MUST BE USED BY PEOPLE WHOSE BODY SIZE AND WEIGHT COMPLY WITH THE SPECIFICATIONS** in the § « MECHANICAL AND DIMENSIONAL CHARACTERISTICS », on pag. 6.



**FRAME RUNNER is a MECHANICAL MEDICAL DEVICE:**



**THE USER** has to perform **REGULAR MAINTENANCE** and **CLEANING** following the instructions shown in the “Maintenance” chapter on pages: from 55 to 60 and **HAVE THE PRODUCT INSPECTED AT THE INTERVALS INDICATED** to **VERIFY** that it is **WORKING PROPERLY** and in **GOOD CONDITION**, otherwise warranty will fail and **CE** marking will lapse.



**PRODUCT REPAIRS** other than the regular maintenance shown on pages from 55 to 60 of the manual must be **ONLY MADE** by a **SPECIALIZED SERVICE CENTER** in the maintenance of mechanical aids for disables, otherwise warranty will fail and **CE** marking will lapse.



Any **CHANGES** in the product **ARE NOT AUTHORIZED**, otherwise warranty and **CE** marking will be voided.



In case of **DOUBT** about the **SAFETY** of the product or **DAMAGE** to parts or components, you are urged to **IMMEDIATELY DISCONTINUE USE** and **CONTACT** the **HEALTH PROFESSIONAL WHO SUPPLIED IT**, or directly **ORMESA**.

### 3.3 SPECIFIC WARNINGS

- Being a medical device, the indication for use must be proposed by a **MEDICAL SPECIALIST**;
- provision can be made through the **PRESCRIPTION CHANNEL** or through **SPORTS ASSOCIATIONS SPECIALIZED IN ADAPTED SPORTS**; in either case the initial set-up and evaluation must be performed by a health professional licensed by the National Health System;
- **PROVIDER HAS THE OBLIGATION** to explain the functions, warnings, and maintenance contained in this manual, to perform the assembly and adjustment of the components, and to provide after-sales service on the product;
- in case of wet road pavement, moderate speed as it can affect braking distances;
- in case of use with low natural light use reflective clothing.

Before each use always be sure that:

- 1) **ALL THE ADJUSTABLE PARTS ARE WELL LOCKED**: the locking of the **HANDLEBAR** , of the **SADDLE** and of the **TRUNK SUPPORT** (see § 5.2, 5.3, 5.4).
- 2) the **BRAKES** are working, the wear and tear on the **WHEELS**.



The product must not be used without the constant presence of a qualified person or family member.



The product is intended for persons whose size and weight fall within the specifications in the “**TECHNICAL FEATURES**” on page 6 of this manual. Change to a larger product as the user grows.



**Attention!!** **FRAME RUNNER** is intended for individuals with good head control, a discreet trunk control and depth perception.



Add-ons 845 and 875 bind the user to the device, which prevents freedom of movement in the event of a fall. Evaluation and adjustment must be done by a Specialist.



When adjusting the height of the seat and handlebar tube **DO NOT EXCEED THE STOP SIGN** because in this case it is not possible to ensure sufficient clamping.



use of helmet is recommended

(Compliant with the EN 1078.)

### 3.4 REASONABLY FORESEEABLE MISUSE

- **DO NOT USE THE MEDICAL DEVICE WITH SUBJECTS WITH DIMENSIONS GREATER THAN** those indicated on pag. 6.
- **NEVER LEAVE THE USER ALONE** in the medical device.
- **DO NOT USE THE MEDICAL DEVICE ON ACCIDENTED GROUND NEAR STRONG SLOPES OR STAIRS.**
- **DO NOT PLACE THE MEDICAL DEVICE IN PARK ON SLOPING GROUND.**
- **DO NOT USE THE MEDICAL DEVICE TO CLIMB OR DESCEND STAIRS:** its structure was not designed for this purpose.
- **DO NOT LIFT THE MEDICAL DEVICE WHEN IT IS IN USE WITH THE SUBJECT.**
- **DO NOT ALLOW OTHER CHILDREN TO USE THE MEDICAL DEVICE, EVEN FOR PLAY.**
- **DO NOT ALLOW OTHERS TO CLIMB ON THE MEDICAL DEVICE IN ADDITION TO THE USER.**
- **DO NOT USE THE DEVICE IF THERE ARE DAMAGED OR MISSING PARTS.**
- **DO NOT ADJUST THE MEDICAL DEVICE WHEN THE USER IS SITTING ON IT**

### 3.5 CONTRAINDICATIONS AND SIDE EFFECTS

Frame runner is not indicated in circumstances of:

- **epileptic seizures that are not pharmacologically controlled;**
- **severe low vision;**
- **severe attentional, cognitive, perceptual or relational deficits;**
- **outcomes of recent functional surgery.**

### 3.6 OPERATING ENVIRONMENTAL CONDITIONS

**DO NOT PARK THE DEVICE FOR A LONG TIME UNDER THE SUN OR IN THE VICINITY OF HEAT SOURCES;** exposed surfaces may reach high surface temperatures and cause slight sunburn at points in direct contact with the user.

### 3.7 CONDITIONS OF TRANSPORT AND PACKAGING

- **THE MEDICAL DEVICE MUST BE STORED AND PACKED** using the Ormesa original packaging materials, unless the guaranteed will be voided.
- Once unpacked, **TRANSPORT** must be done by **ADEQUATELY ANCHORING IT** to the vehicle.
- **When travelling by plane, or in the car, DO NOT SUBJECT THE FRAME TO LOADS THAT, especially with road bumps, COULD DAMAGE ITS STRUCTURE .**
- **THE MEDICAL DEVICE MUST BE PARKED/STORES IN CLOSED AND DRY PLACES.**



- THE OPERATING ENVIRONMENT HAS NO PARTICULAR INFLUENCE ON THE PRODUCT UNLESS IT IS USED INCORRECTLY, SUCH AS BY LEAVING IT PARKED FOR A LONG TIME IN DIRECT SUNLIGHT OR EXPOSED TO BAD WEATHER SUCH AS RAIN, OR IN MARINE ENVIRONMENTS, WHERE THE SALT AIR COULD CORRODE THE PAINT AND SLIDING PARTS. IN THIS CASE, WE RECOMMEND CAREFULLY CLEANING AND DRYING THE FRAME FOLLOWING THE INSTRUCTIONS SHOWN IN THE “MAINTENANCE, CLEANING AND DISINFECTION” CHAPTER ON PAGES FROM 55 TO 60 AND THE WARNINGS ON PAGE 55.

### 3.8 PRE-INSTALLATION/INSTALLATION AND PUTTING INTO SERVICE

**FRAME RUNNER does not require installation.**

For putting into service (including the possible insertion of additional components) it **requires configuration and adjustment exclusively by a health professional licensed** by the National Health System.

## 4. DEVICE DESCRIPTION

### 4.1 INTENDED USE OF THE MEDICAL DEVICE

The Ormesa Frame Runner is intended for children/adults who need mobility and balance aids without which they would not be able to run, who are aware of the space around them.

It is suitable for people with severe motor and coordination difficulties who can use the Frame Runner as a therapeutic and recreational activity: its use improves fitness and strength as well as physical and emotional well-being.

Even those who have difficulty controlling their balance while walking can benefit from the use of the Frame Runner, thanks to the stability provided by the entire system.

### 4.2 MAINS COMPONENTS/AVAILABLE VERSIONS

The device is available in two sizes and different configurations depending on the components chosen by the health care professional.

- Configuration with a fixed saddle
- Configuration with saddle abatement system, to facilitate getting on and off the aid

For a list of components, their assembly/adjustment by a health professional, and functionality, see § 5.3 on page 20.

### 4.3 MEDICAL DEVICE DESCRIPTION

The Frame Runner is a three-wheeled medical device that enables children, teens and adults with mobility disabilities to exercise and run. The steel frame complete with the 3 wheels (two rear and one front) and spring-loaded steering limiter make it a stable and safe assistive device.

A fundamental aspect of the Frame Runner is the pursuit of performance in running, seeking to position the user/athlete in the most propulsive posture possible within the limits of his or her abilities.



The standard configuration, equipped with adjustable trunk support, front handlebar with steering limiter and return spring, and front brake with parking lock, can be enriched with some accessories useful for achieving and maintaining a propulsive posture.

A rear restraining strap can be added to the thoracic support. We can also insert, as an alternative to the standard saddle, the unicycle saddle, so as to have different possibilities of pelvis management. The handlebar grip can be optimized with the use of adjustable ergonomic handles and other accessories that make it easier to grip.

It is available in 2 different sizes, to be used by people between 120 cm and 190 cm tall. The frame is lightweight and, for ease of transport, the front wheel is removable with a "Quick Release" system, it is also possible to remove the two rear wheels with the appropriate wrench.

Another important aspect is the size of the wheels, which, in addition to the standard sizes, 24" for size M and 26" for size L, can be chosen in different sizes depending on the user's height and the needed set-up for the assistive device.

<b>Wheels dimensions: POSSIBLE CONFIGURATIONS</b>
<b>FRAME RUNNER size M</b> Standard with 3 wheels of 24"
Front wheel with dedicated fork 20" - Rear wheels 24"
Front wheel with dedicated fork 24" - Rear wheels 26"
<b>FRAME RUNNER size L</b> Standard with 3 wheels of 26"
Front wheel with dedicated fork 24" - Rear wheels 24"
Front wheel with dedicated fork 24" - Rear wheels 26"
Front wheel with dedicated fork 26" - Rear wheels 24"
Front wheel with dedicated fork 26" - Rear wheels 28"
Front wheel with dedicated fork 28" - Rear wheels 28"



## 5. OPERATING INSTRUCTIONS

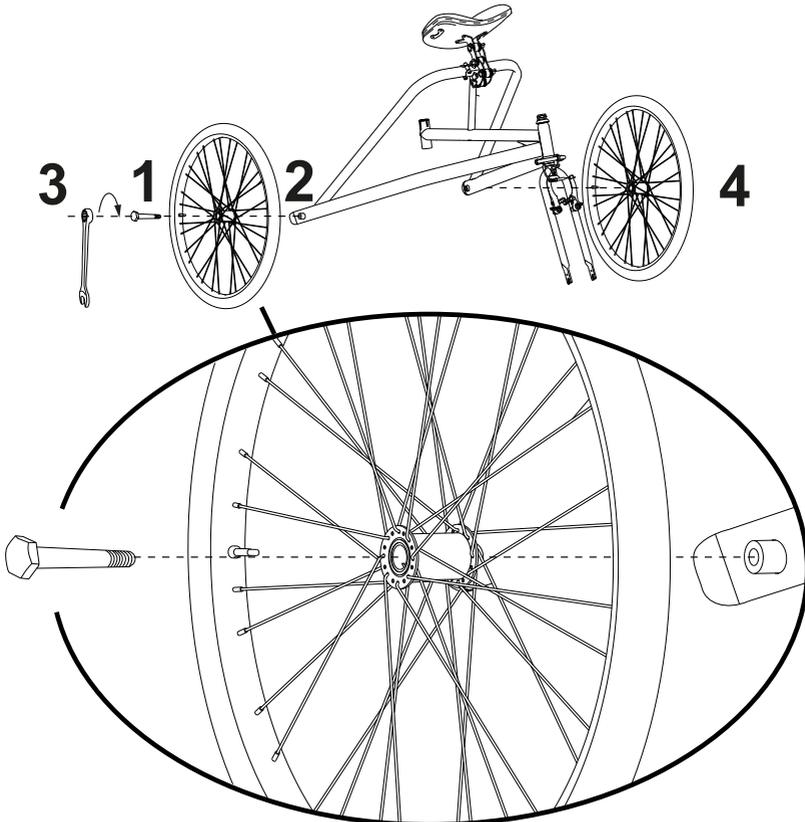
### 5.1 FIRST USE

The medical device **MUST BE CONFIGURED AND REGULATED BY A HEALTHCARE PROFESSIONAL**, who must also provide the family with explanations on proper use. The supplier shall explain the warnings and maintenance activity, in accordance with this manual (§ 5.3 and 5.4)

### 5.2 ASSEMBLY

#### BACK WHEELS ASSEMBLY

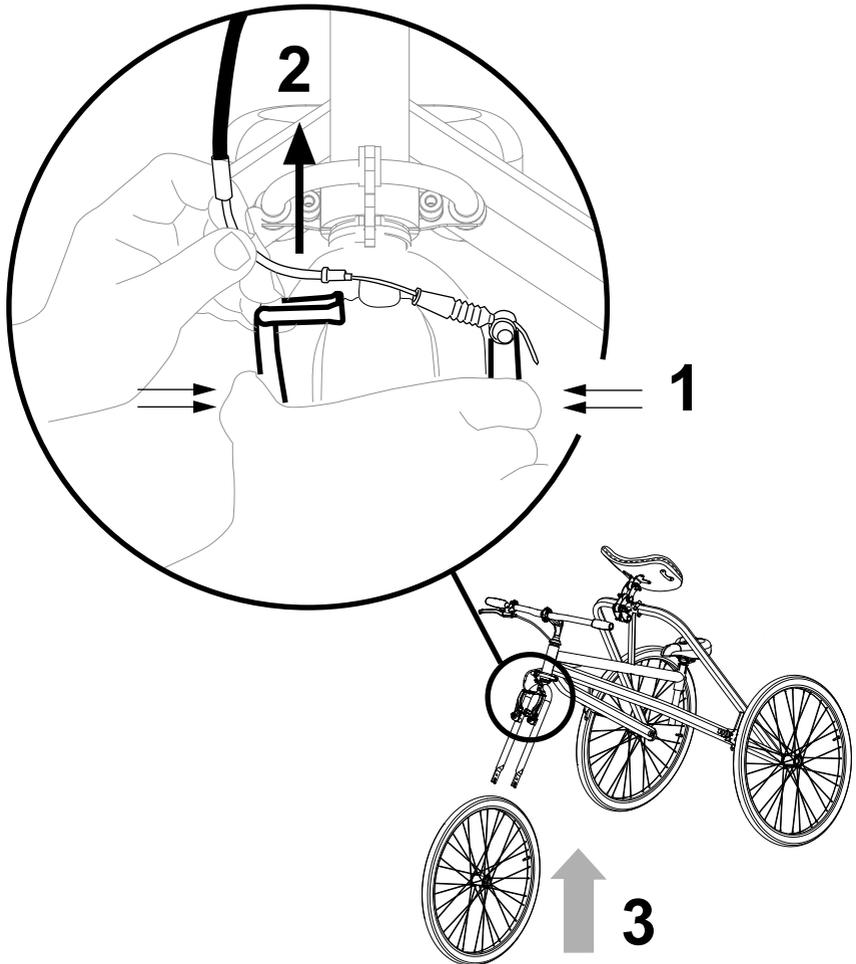
- 1) INSERT THE HEX SCREW INTO THE SEAT OF THE WHEEL HUB
- 2) INSERT THE PIN INTO ITS SEAT ON THE FRAME
- 3) SCREW WITH A 19 SOCKET WRENCH
- 4) REPEAT THE OPERATION ON THE OPPOSITE SIDE





## FRONT WHEEL ASSEMBLY

- 1) TIGHTEN THE TWO PARTS OF THE BRAKE
- 2) DISCONNECT THE TRANSMISSION CABLE FROM THE SEAT
- 3) THREAD THE WHEEL
- 4) TIGHTEN THE BOLT WITH ONE HAND
- 5) CLOSE THE LEVER
- 6) TIGHTEN THE TWO PARTS OF THE BRAKE
- 7) INSERT THE BRAKE CABLE INTO THE SEAT





BOLT

LEVER

4

5

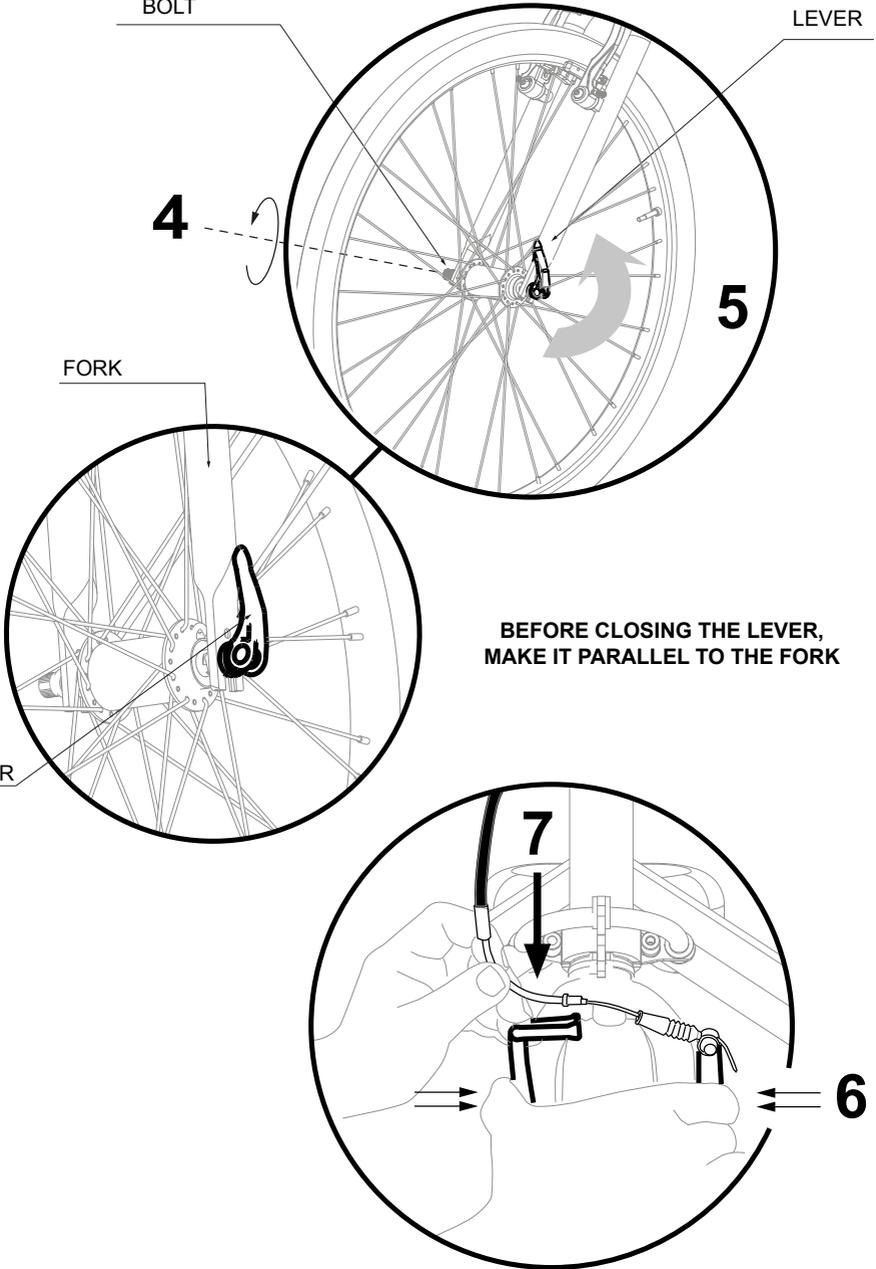
FORK

**BEFORE CLOSING THE LEVER, MAKE IT PARALLEL TO THE FORK**

LEVER

7

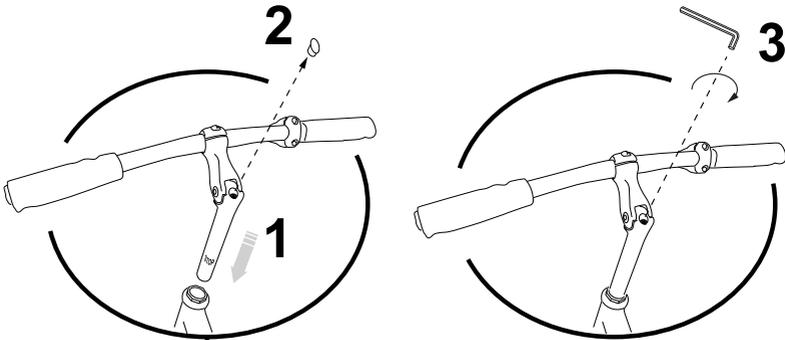
6



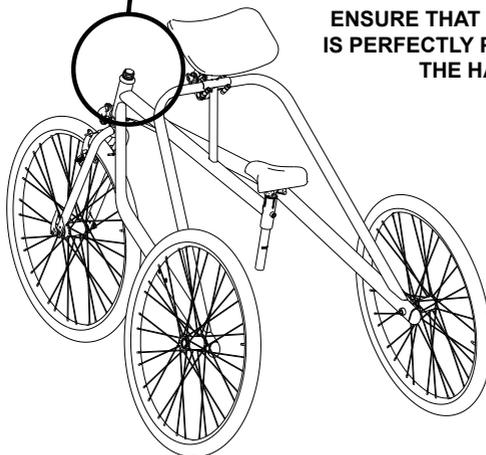


## HANDLEBAR ASSEMBLY

- 1) INSERT THE HANDLEBAR
- 2) REMOVE THE CAP
- 3) TIGHTEN THE SCREW



**ENSURE THAT THE FRONT WHEEL  
IS PERFECTLY PERPENDICULAR TO  
THE HANDLEBAR**

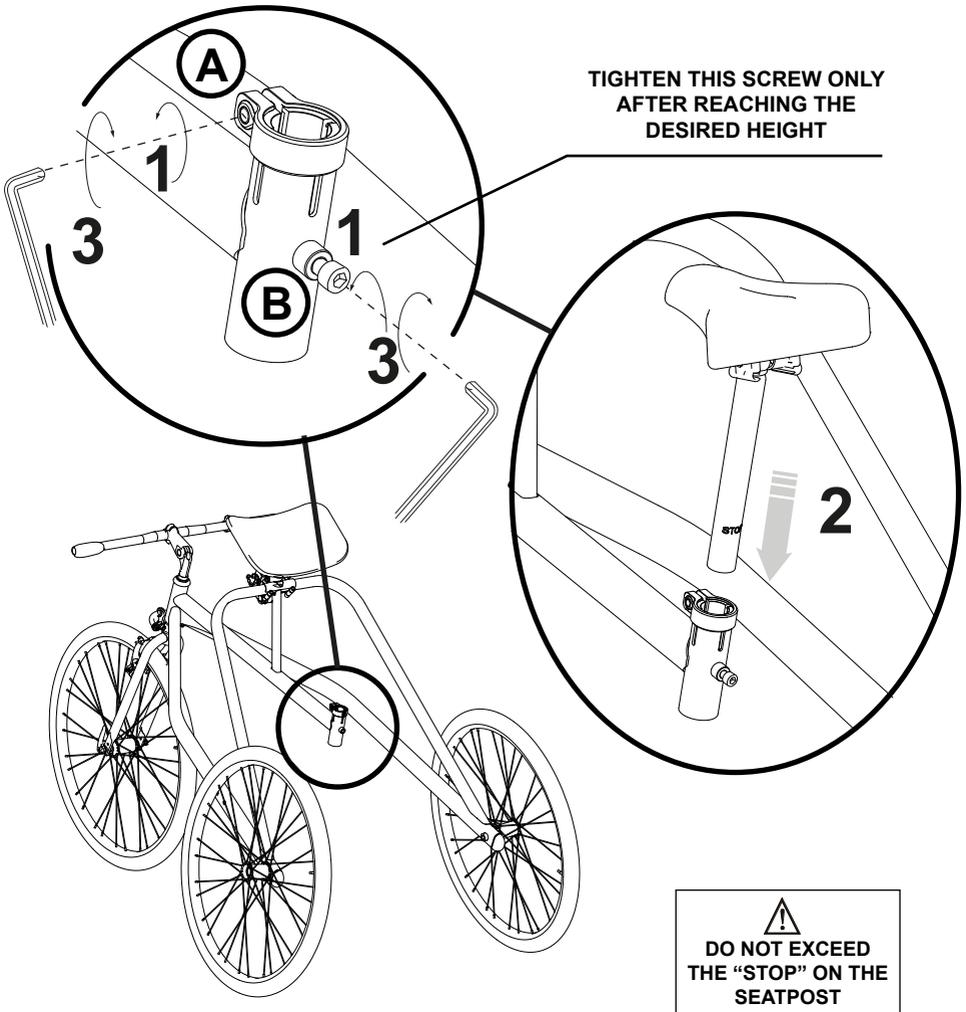


**TIGHTEN THE TUBE ONLY AFTER DEFINING THE HEIGHT**



## SADDLE ASSEMBLY

- 1) LOOSEN THE SCREWS
- 2) INSERT THE SADDLE AND RAISE IT TO THE DESIRED HEIGHT
- 3) TIGHTEN SCREW A (TIGHTEN SCREW B ONLY AFTER REACHING THE DESIRED HEIGHT)





### 5.3 CONFIGURATION OF THE MEDICAL DEVICE by the health professional or by a licensed sports technician consistent with the clinical assessment of the medical specialist

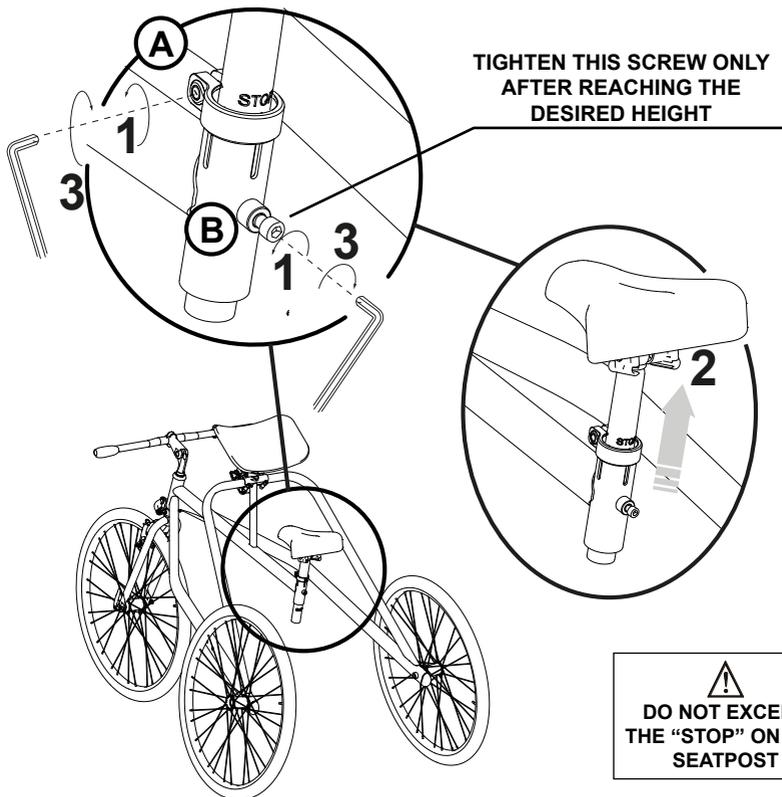
#### SADDLE and HANDLEBAR ADJUSTMENT

CAN BE CARRIED OUT BY THE FAMILY OR THE CARE GIVER AT THE DIRECTION OF THE HEALTH PROFESSIONAL.

#### SADDLE ADJUSTMENT

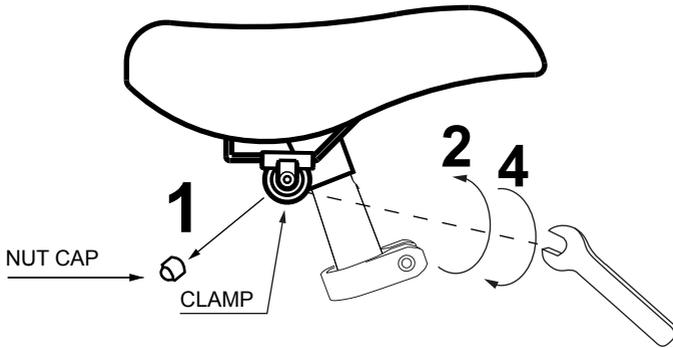
##### A. WIDE SADDLE HEIGHT ADJUSTMENT

- 1) LOOSEN THE SCREWS
- 2) BRING THE SADDLE TO THE DESIRED HEIGHT
- 3) TIGHTEN SCREW A (TIGHTEN SCREW B ONLY AFTER REACHING THE DESIRED HEIGHT)

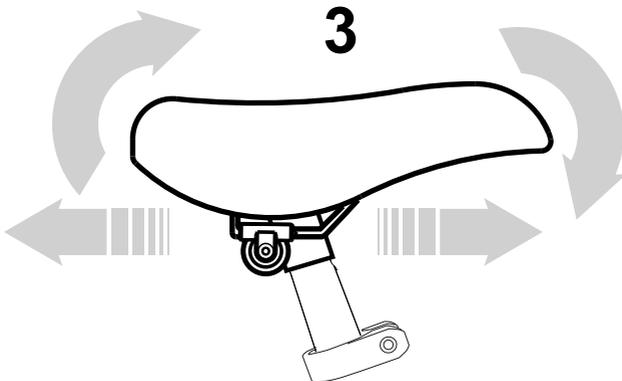




## B. SADDLE: TILT AND FORWARD-BACKWARD DIRECTION ADJUSTMENT



- 1) REMOVE THE NUT CAP
- 2) LOOSEN THE BOLT TIGHTENING CLAMP
- 3) ADJUST THE SADDLE
- 4) TIGHTEN THE BOLT AND REPLACE THE NUT CAP

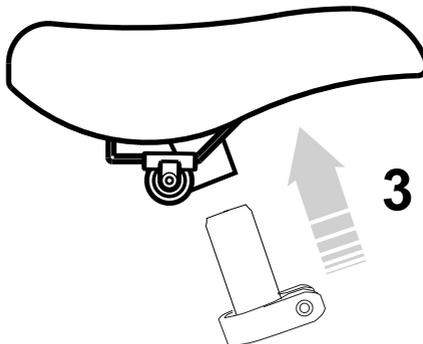
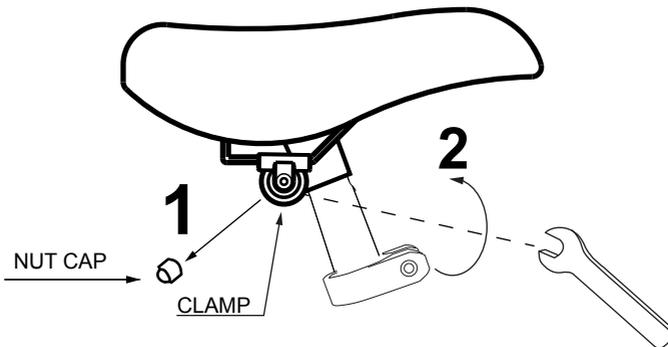


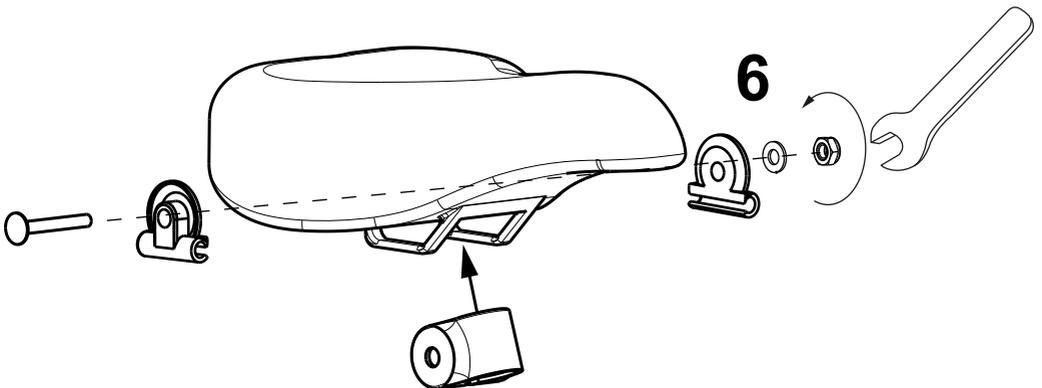
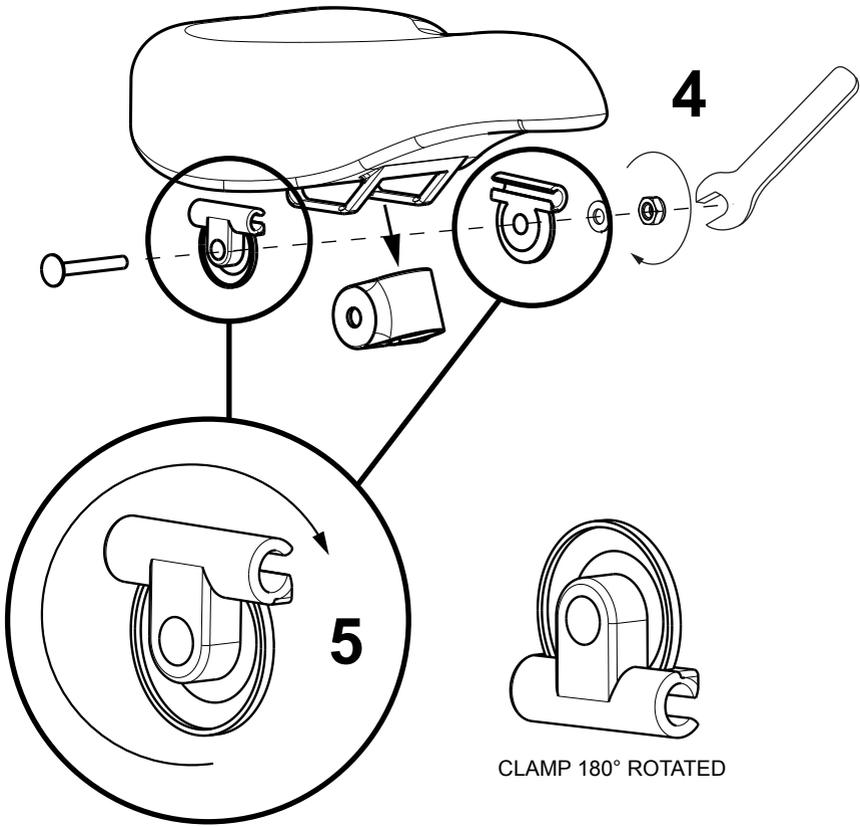


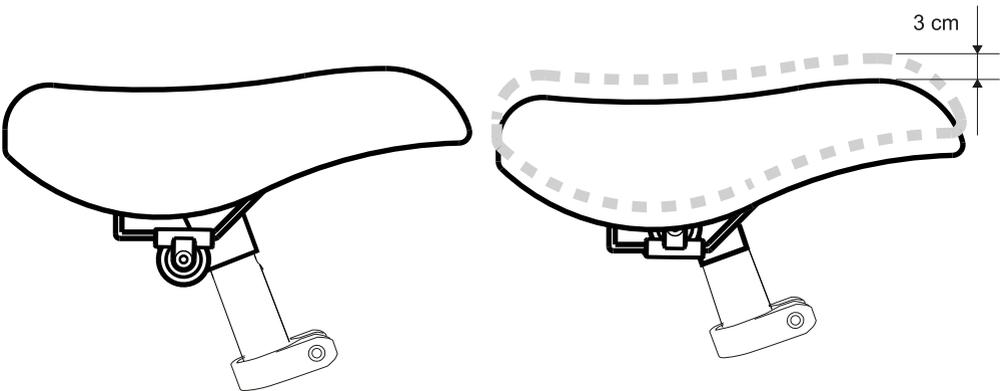
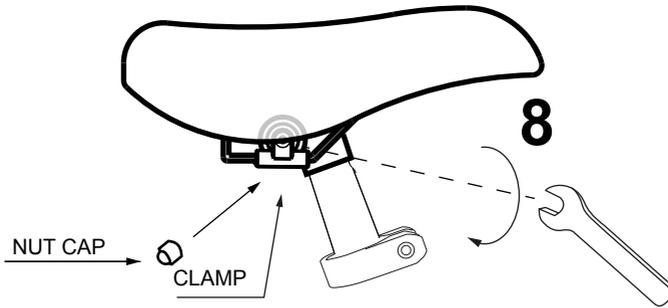
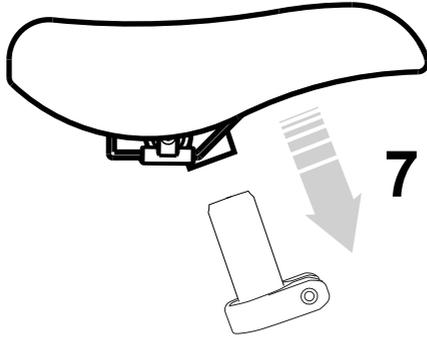
IT IS POSSIBLE TO DECREASE THE HEIGHT OF THE SADDLE BY A FURTHER 3 CM BY FOLLOWING THE PROCEDURE DESCRIBED BELOW:

### C. SMALL SADDLE HEIGHT ADJUSTMENT

- 1) REMOVE THE NUT CAP
- 2) LOOSEN BOLT TIGHTENING CLAMP
- 3) REMOVE THE SADDLE BY THE SEATPOST
- 4) REMOVE THE SCREW, NUT AND WASHER TO REMOVE THE CLAMP
- 5) TURN THE CLAMPS AROUND 180°
- 6) MOUNT THE CLAMPS ON THE SADDLE ATTACHMENT AND SCREW THE NUT WITHOUT TIGHTENING
- 7) INSERT THE SADDLE IN THE SEATPOST
- 8) TIGHTEN THE NUT AND PUT THE CAP





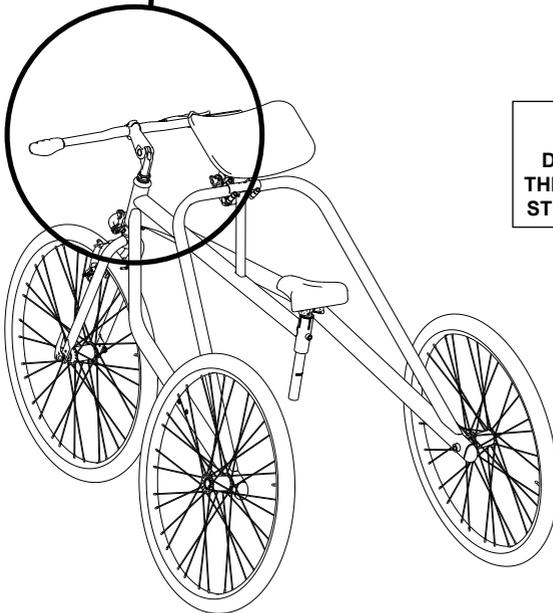
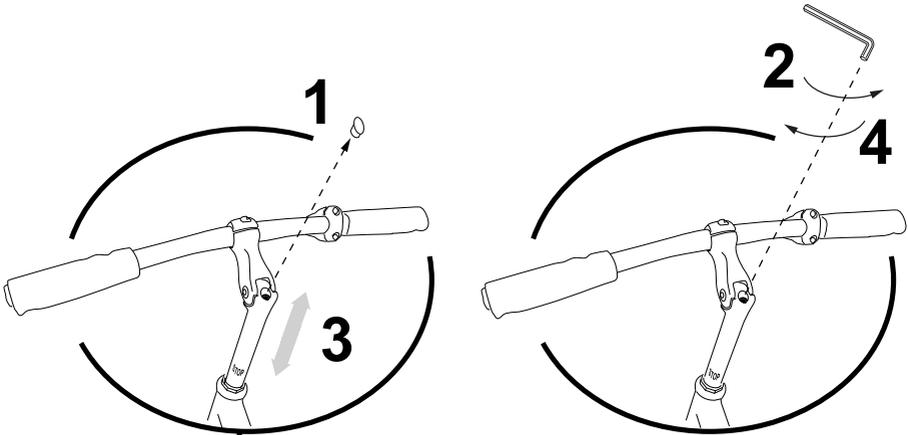




## HANDLEBAR ADJUSTMENT

### A. HEIGHT ADJUSTMENT

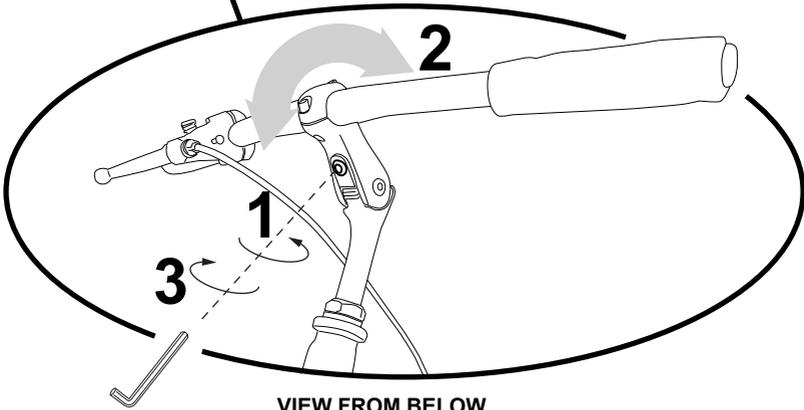
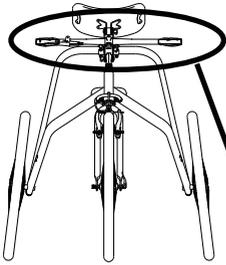
- 1) REMOVE THE CAP
- 2) LOOSEN THE SCREW
- 3) MOVE THE HANDLEBAR TO THE DESIRED HEIGHT
- 4) TIGHTEN THE SCREW



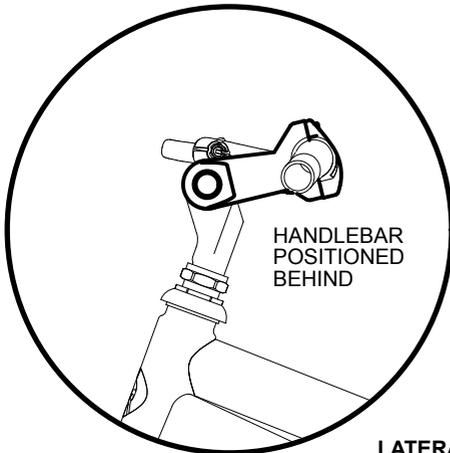
  
DO NOT EXCEED  
THE "STOP" ON THE  
STEERING COLUMN



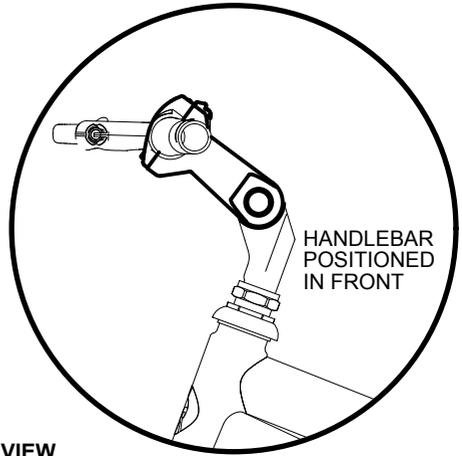
## B. FORWARD-BACKWARD POSITION ADJUSTMENT



VIEW FROM BELOW



HANDLEBAR  
POSITIONED  
BEHIND

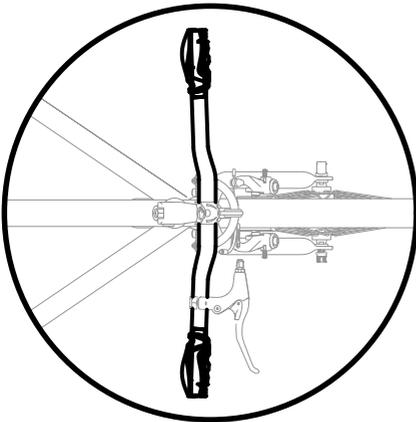
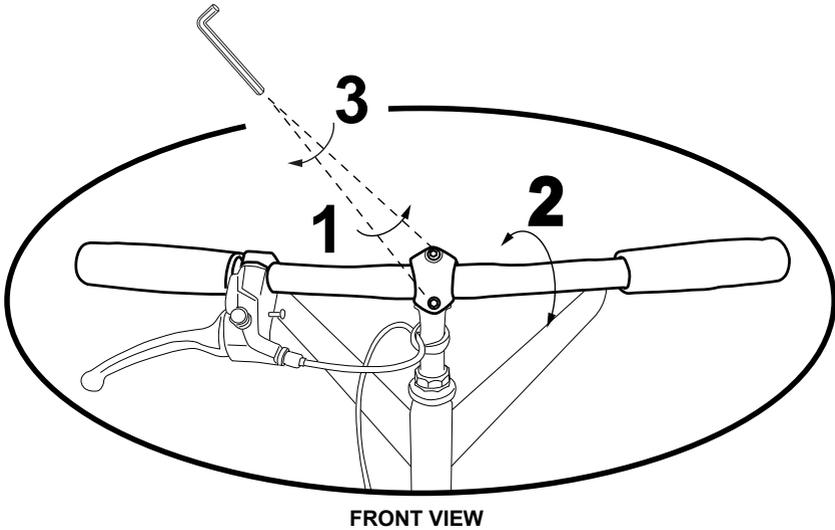


HANDLEBAR  
POSITIONED  
IN FRONT

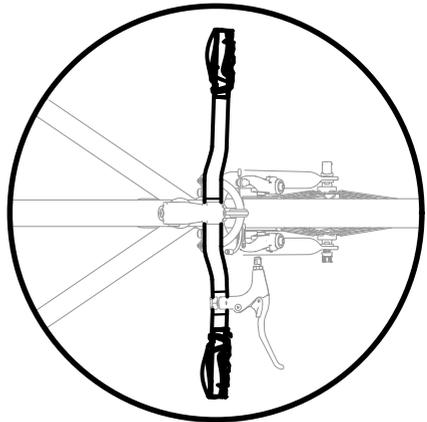
LATERAL VIEW



## C. ROTATION ADJUSTMENT



**HANDLEBAR  
TURNED BEHIND**



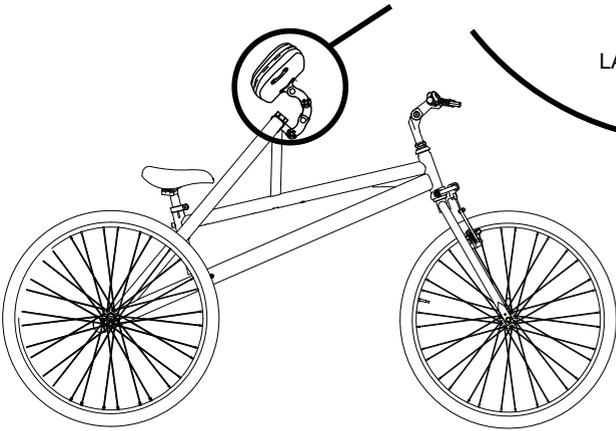
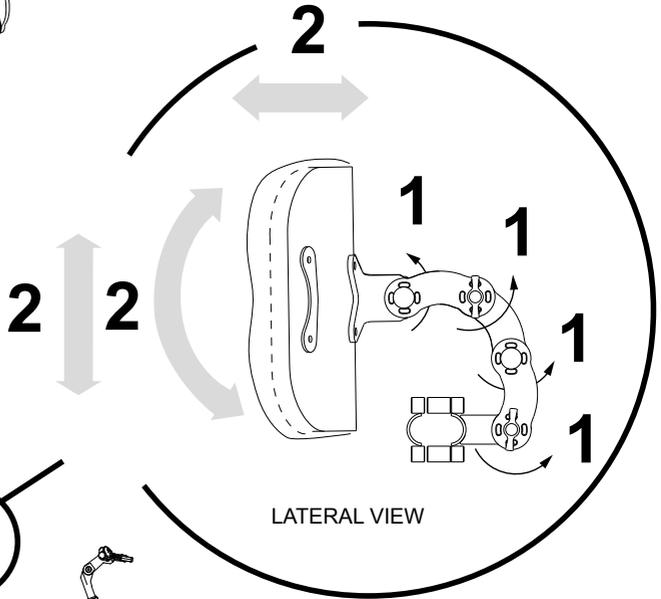
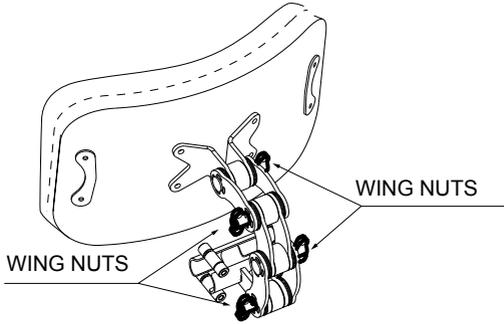
**HANDLEBAR TURNED  
TO THE FRONT**

**VIEW FROM ABOVE**



## TRUNK SUPPORT ADJUSTMENT

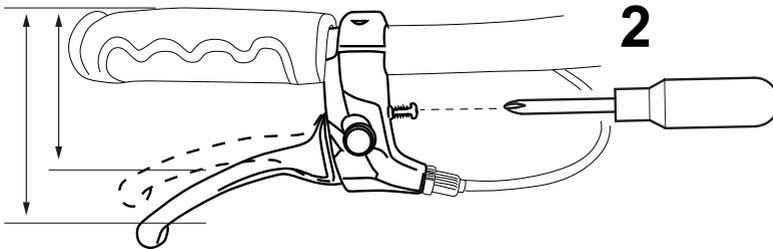
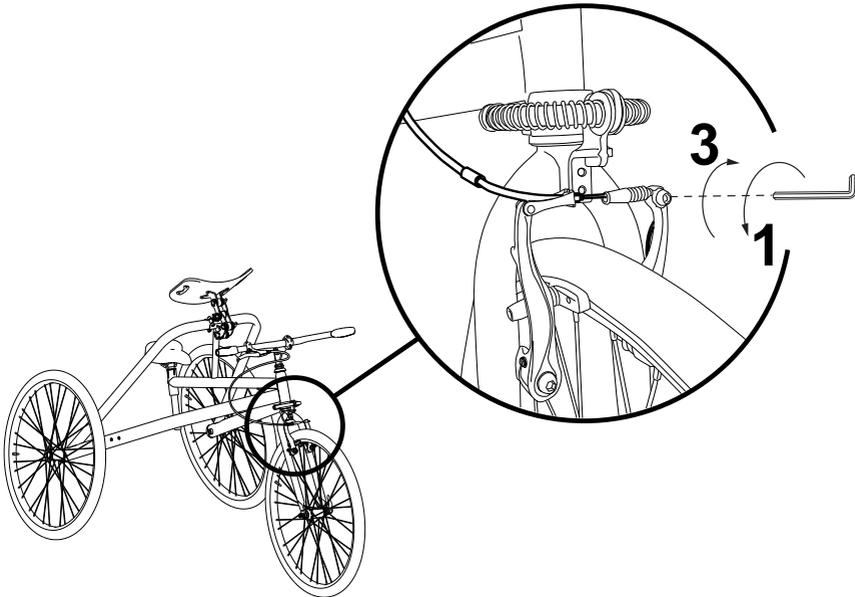
- 1) LOOSEN THE WING NUTS
- 2) ADJUST THE TRUNK SUPPORT AND TIGHTEN THE WING NUTS





## ADJUSTMENT OF THE BRAKE LEVER POSITION

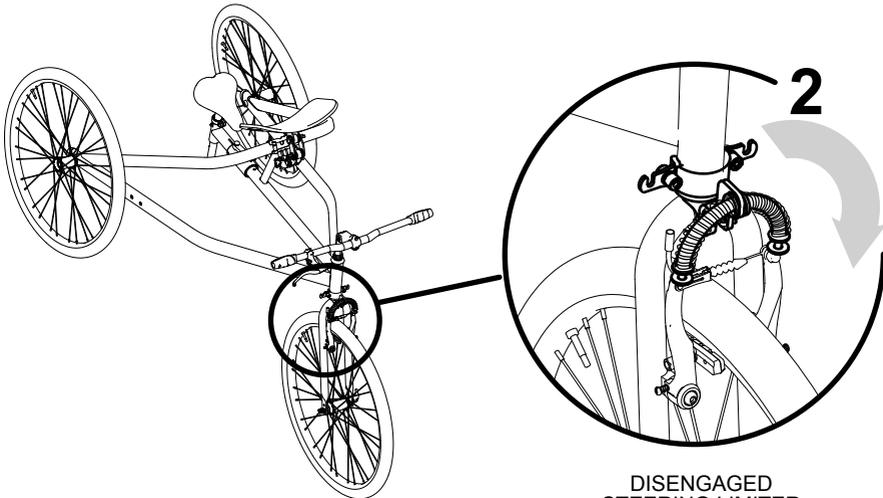
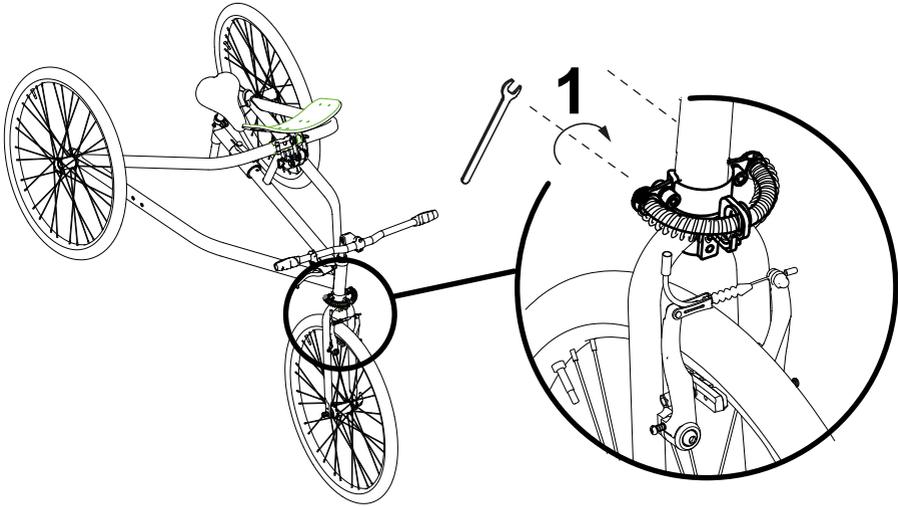
- 1) LOOSEN THE CABLE SCREW, BEFORE ADJUSTING THE LEVER ON THE HANDLEBAR
- 2) TIGHTEN UNTIL THE LEVER IS AT THE DESIRED OPENING
- 3) TIGHTEN THE CABLE SCREW, ADJUSTING THE BRAKE





## DISENGAGE STEERING LIMITER WITH SPRINGS

- 1) LOOSEN THE TWO BOLTS LOCATED BEHIND THE SPRINGS
- 2) DISENGAGE THE STERLING LIMITER CHECKING THAT THE BOLTS ARE LOCKED

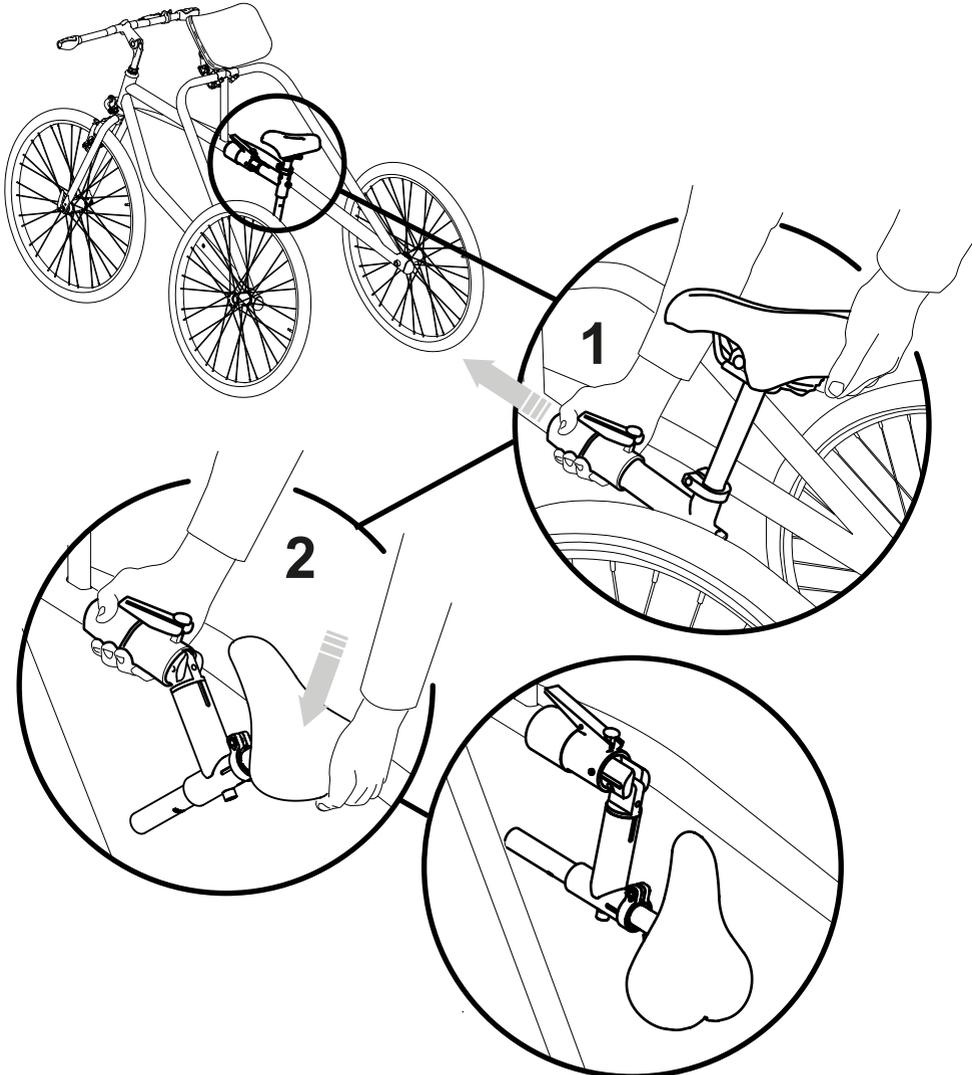


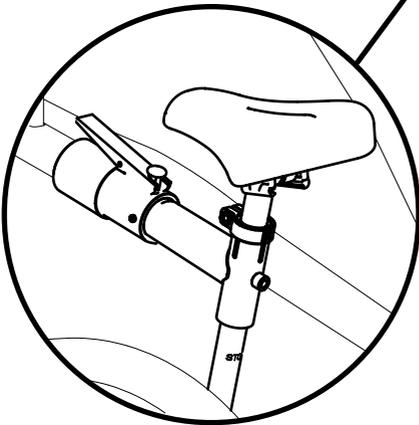
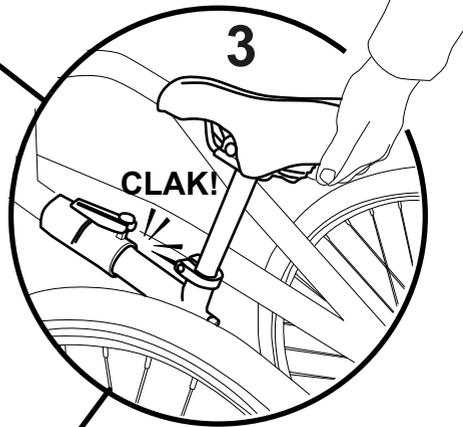
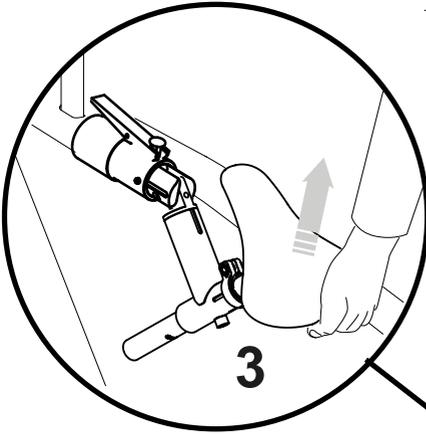
DISENGAGED  
STEERING LIMITER



## SADDLE ABATEMENT SYSTEM - OPERATION

- 1) SUPPORTING THE SADDLE WITH ONE HAND, PRESS THE LEVER AND MOVE THE SLEEVE IN THE DIRECTION INDICATED BY THE ARROW
- 2) GUIDE THE SADDLE DOWNWARDS AND RELEASE THE LEVER
- 3) TO RETURN THE SADDLE IN ITS INITIAL POSITION, GUIDE IT UP UNTIL YOU HEAR A "CLAK". IT WARNS THE SUCCESSFUL ENGAGEMENT. NO NEED TO PRESS THE LEVER ON THE SLEEVE.







## 5.4 ADJUSTMENT AND CONFIGURATION OF THE ADDITIONAL COMPONENTS BY THE HEALTH PROFESSIONAL

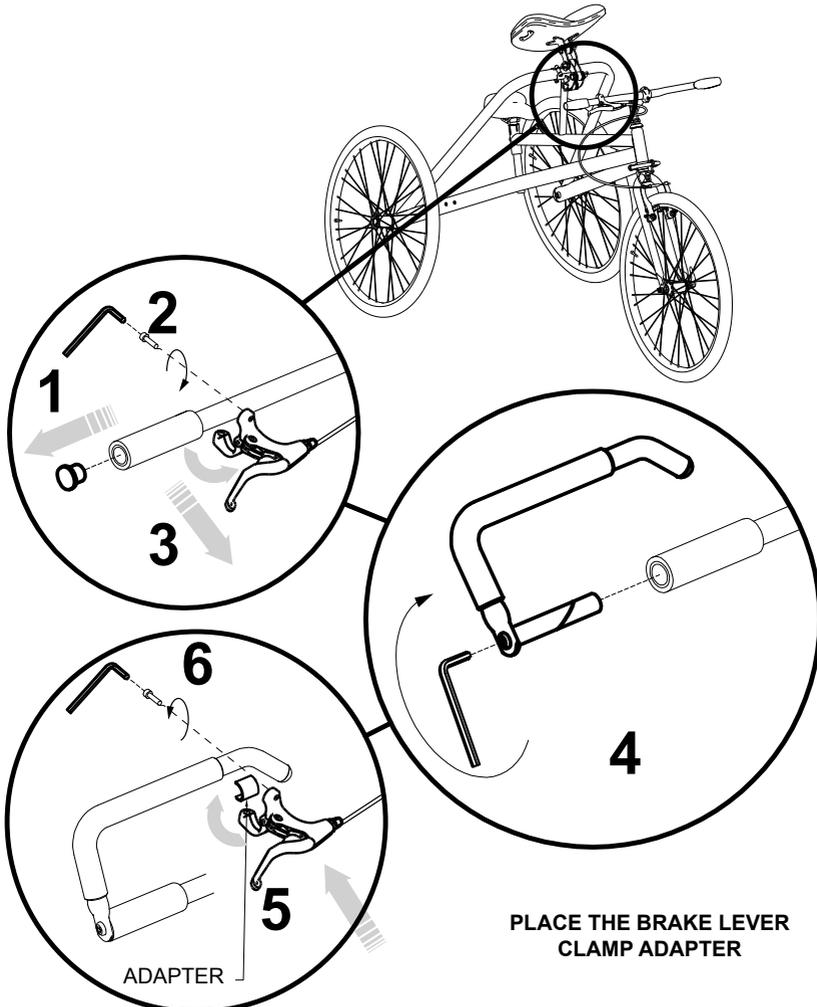
*Assembly of the add-on component must be carried out by a specialised technician.*

### ADJUSTABLE, ERGONOMIC HANDLES 880

#### A. MOUNTING

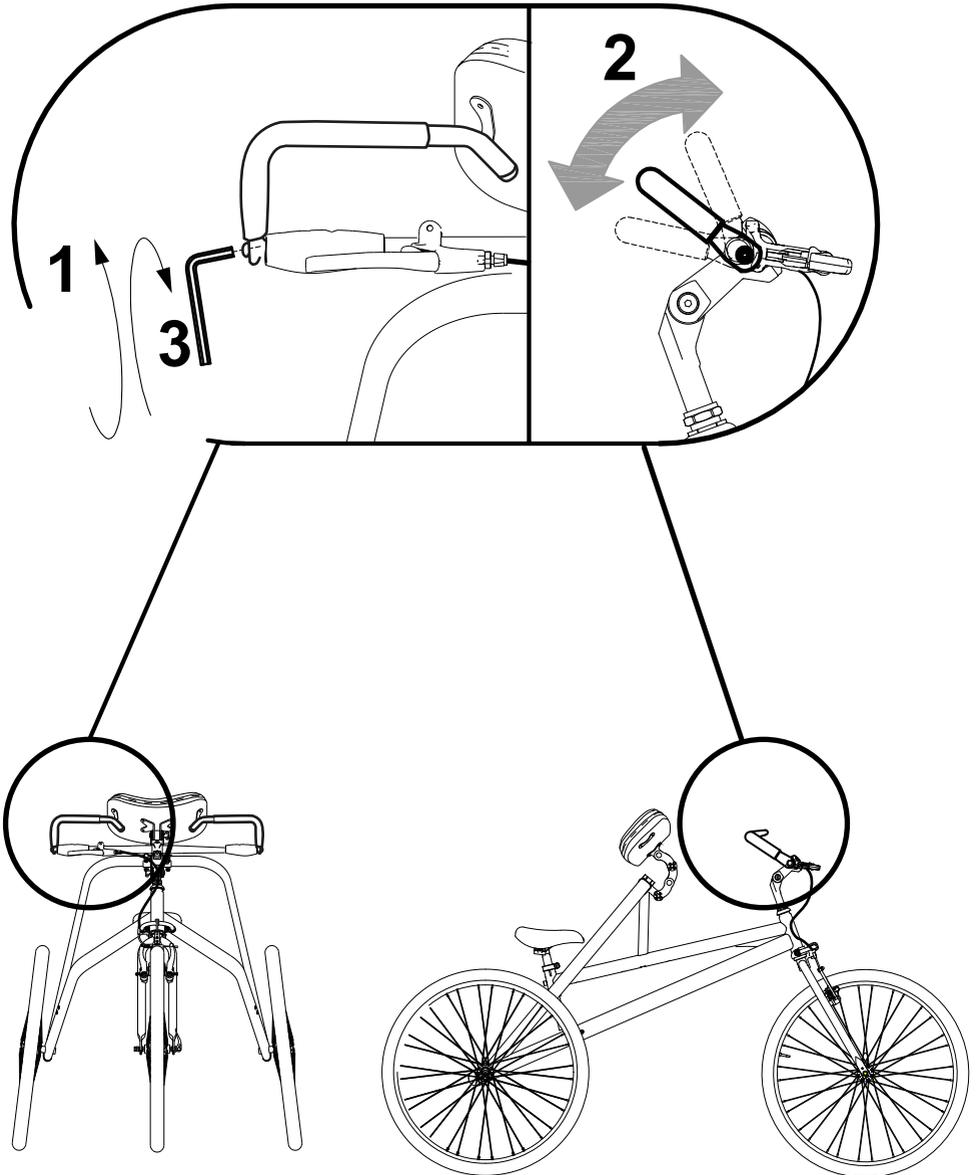
They have the function and purpose of offering the user a grip closer to the body and more grip points than the standard handlebar. Useful for those users who have difficulty extending their elbows completely. They can be adjusted in height/inclination to accommodate various positions in space.

They can be adjusted asymmetrically or independently, to accommodate any need for important asymmetry between the two upper limbs.





## B. ADJUSTMENT





*Assembly of the add-on component must be carried out by a specialised technician.*

## WRIST RETAINER WITH SUPPORT AND MULTI-ADJUSTABLE GLOVE INDEPENDENTLY 875

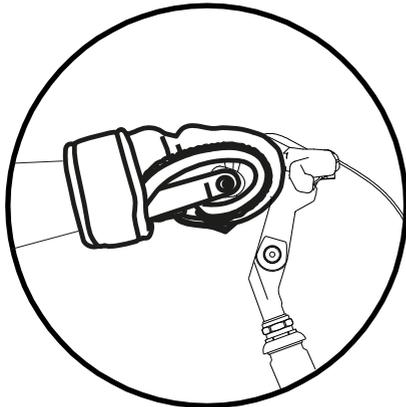
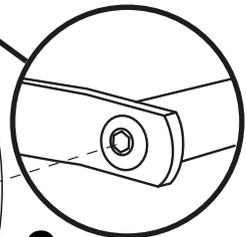
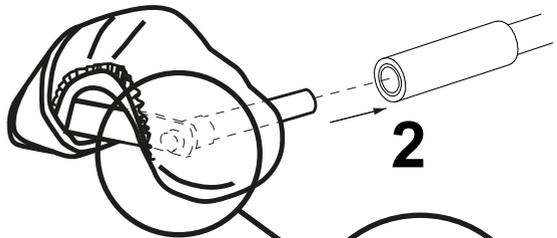
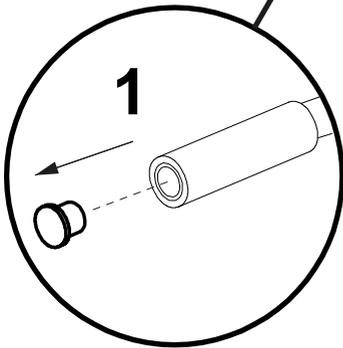
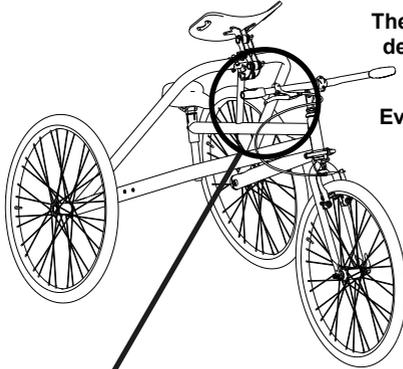
Make a binding to the handlebar in case of an ineffective grip.

### A. MOUNTING



The component binds the user to the device, and it prevents freedom of movement in the event of fall.

Evaluation and adjustment must be done by a Specialist





*Assembly of the add-on component must be carried out by a specialised technician.*

## FOREARM SUPPORT 845

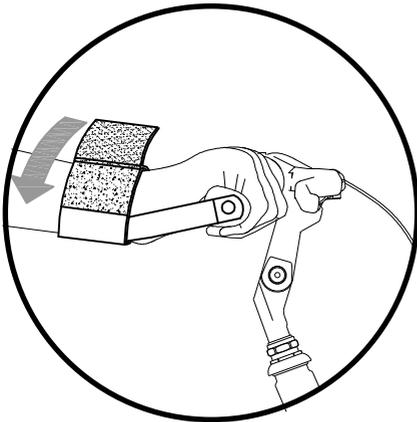
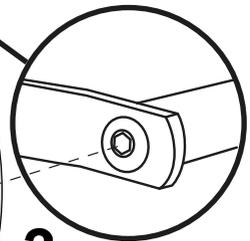
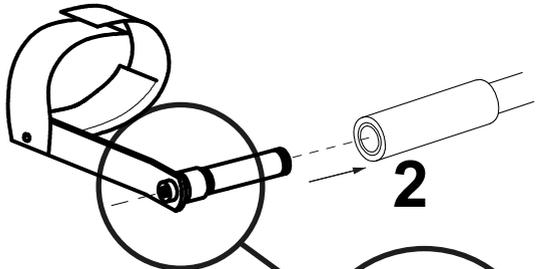
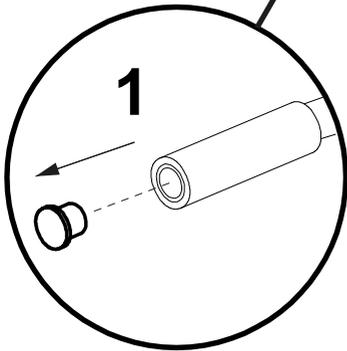
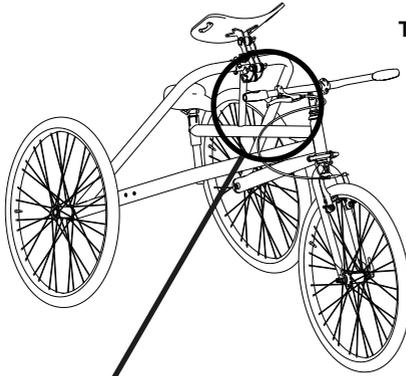
It supports the forearm; suitable for users without any grip holding.

### A. MOUNTING



The component binds the user to the device, and it prevents freedom of movement in the event of fall.

Evaluation and adjustment must be done by a Specialist





*Assembly of the add-on component must be carried out by a specialised technician.*

## TRUNK SUPPORT WIDE STRAP, WIDTH ADJUSTABLE MOD. 102

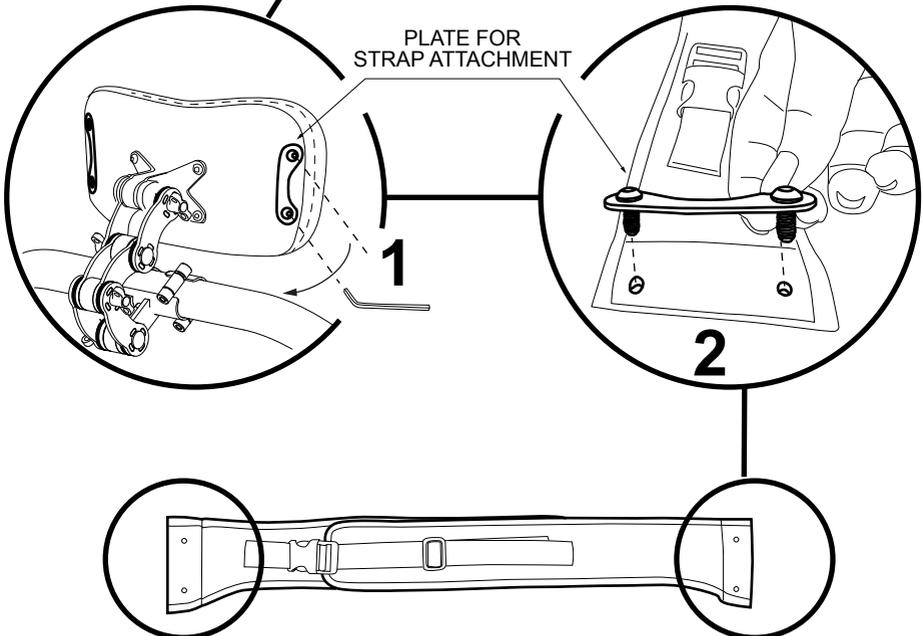
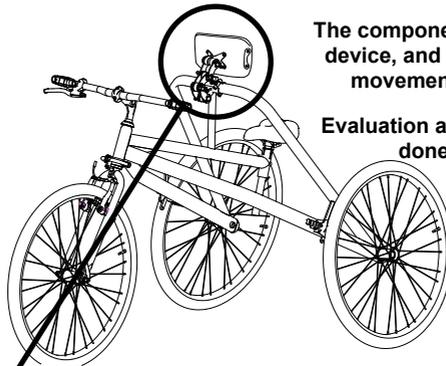
### A. MOUNTING

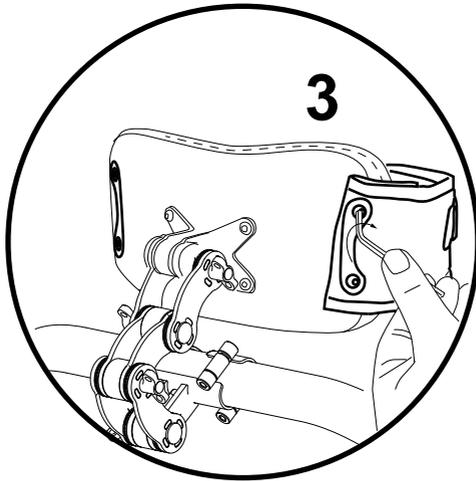
- 1) REMOVE THE PLATE FROM BEHIND THE TRUNK SUPPORT
- 2) REPLACE IT AT THE END OF THE STRAP
- 3) REPLACE THE PLATE ON THE TRUNK SUPPORT AND REPEAT THE OPERATION BY THE OTHER SIDE.



The component binds the user to the device, and it prevents freedom of movement in the event of fall.

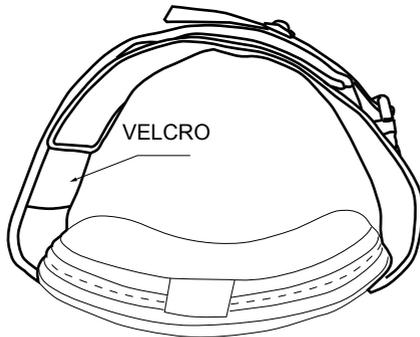
Evaluation and adjustment must be done by a Specialist



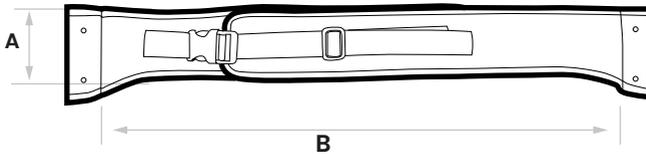


## B. ADJUSTMENT

ADJUSTABLE IN CIRCUMFERENCE BY VELCRO



VIEW FROM ABOVE



	A	B
M	8 cm (3,15 In)	45-59 cm (17,7-23,2 In)
L	8 cm (3,15 In)	63,5-84 cm (25-33 In)



*Assembly of the add-on component must be carried out by a specialised technician.*

## MONOCYCLE SADDLE 876

Adjustable in height, inclination and antero-posterior direction

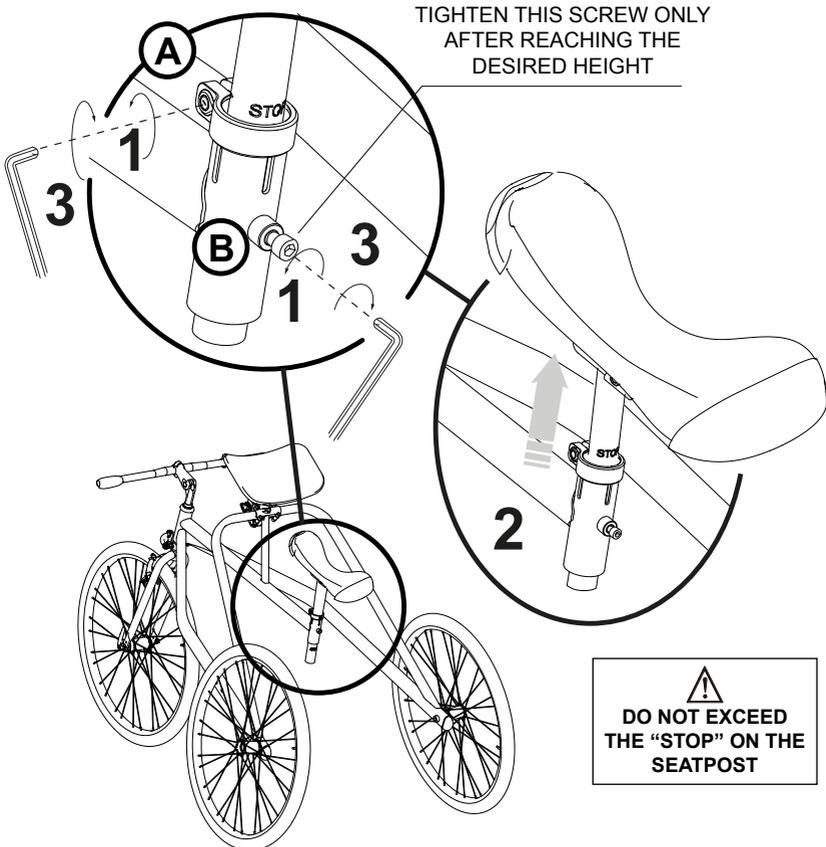
### A. MOUNTING

follow the standard saddle assembly instructions

### MONOCYCLE SADDLE ADJUSTMENT

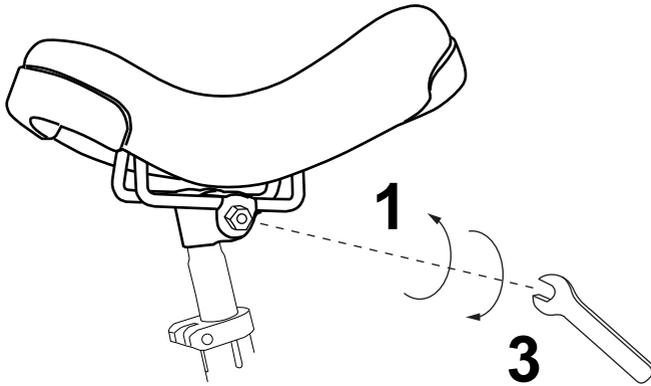
#### A. LARGE SADDLE HEIGHT ADJUSTMENT

- 1) LOOSEN THE SCREWS
- 2) BRING THE SADDLE TO THE DESIRED HEIGHT
- 3) TIGHTEN THE SCREW A (TIGHTEN THE B SCREW ONLY AFTER REACHING THE DESIRED HEIGHT)

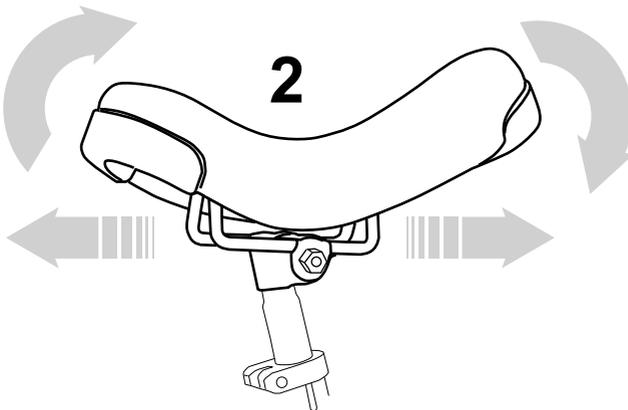




## B. SADDLE: TILT AND FORWARD-BACKWARD DIRECTION ADJUSTMENT



- 1) LOOSEN THE BOLT TIGHTENING CLAMP
- 2) ADJUST THE SADDLE
- 3) TIGHTEN THE BOLT AND REPLACE THE NUT CAP

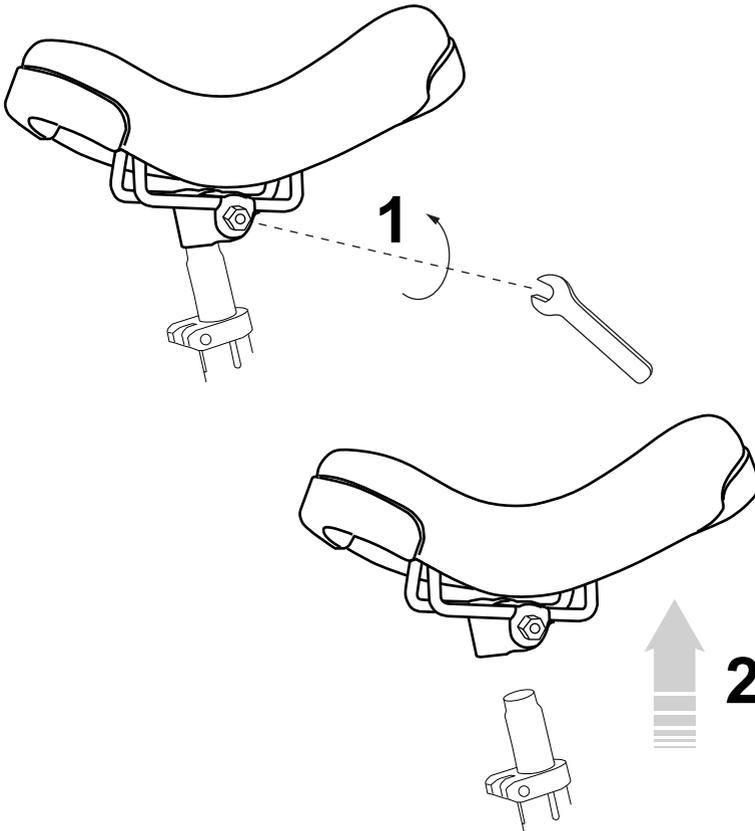


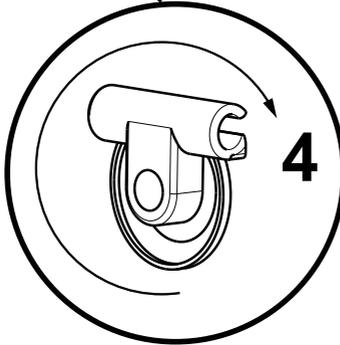
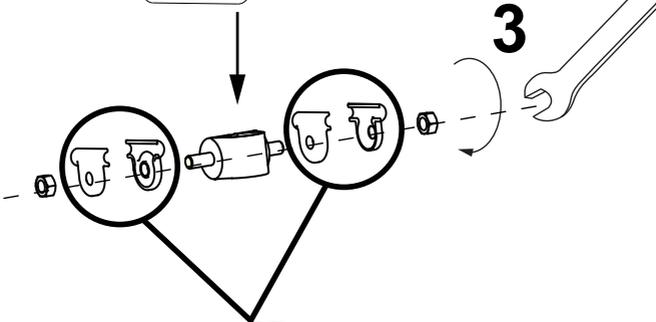
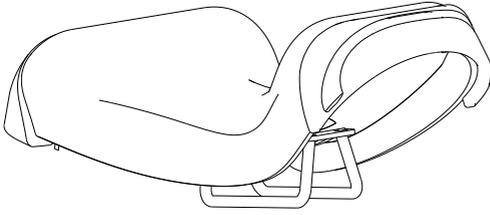


IT IS POSSIBLE TO DECREASE THE HEIGHT OF THE SADDLE BY A FURTHER 3 CM BY FOLLOWING THE PROCEDURE BELOW:

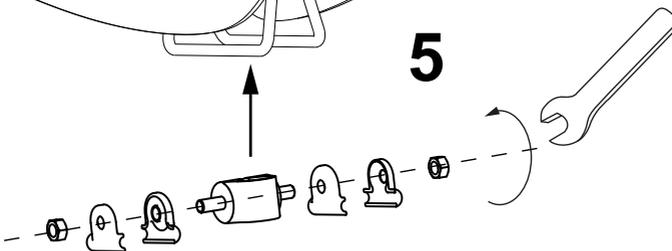
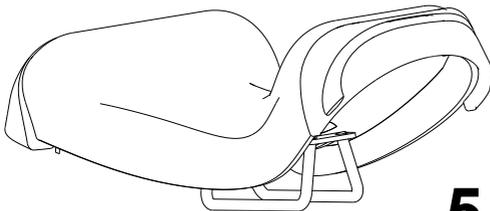
### C. SMALL SADDLE HEIGHT ADJUSTMENT

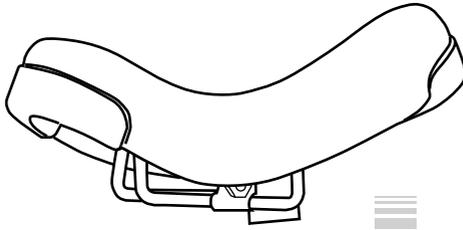
- 1) LOOSEN THE BOLT THAT TIGHTENS THE CLAMP
- 2) REMOVE THE SADDLE FROM THE SEAT POST
- 3) REMOVE THE NUT TO REMOVE THE CLAMPS
- 4) ROTATE THE CLAMPS 180°
- 5) FIT THE CLAMPS ON THE SADDLE ATTACHMENT AND SCREW THE NUT LOOSELY
- 6) INSERT THE SADDLE INTO THE SEAT POST
- 7) TIGHTEN THE NUT



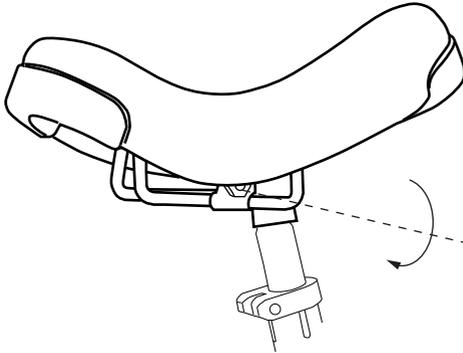


CLAMP 180° ROTATED

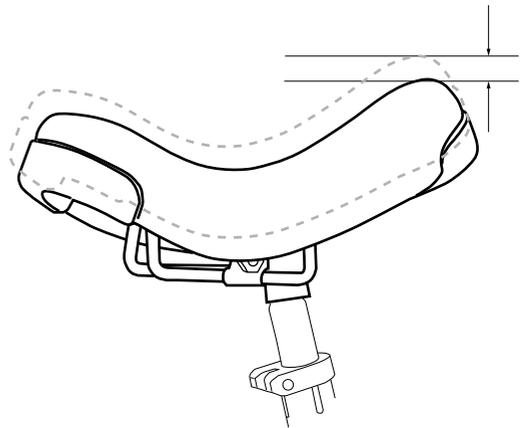
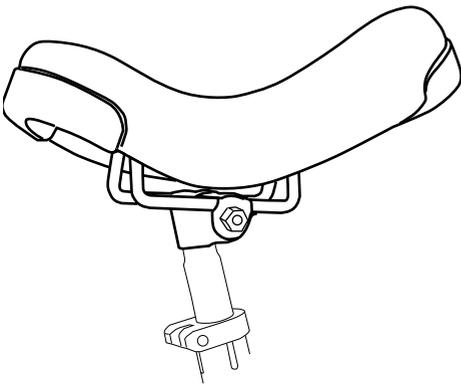




**6**



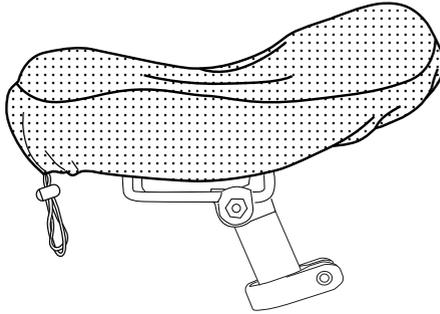
**7**





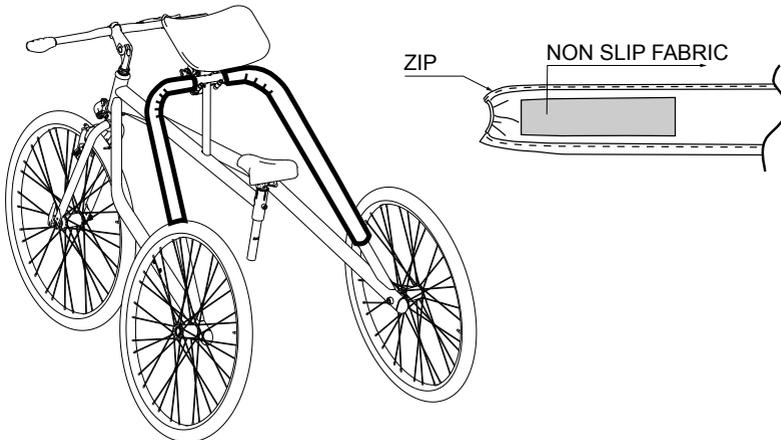
*Assembly of the add-on component must be carried out by a specialised technician.*

## MONOCYCLE SADDLE PADDING MOD. 103



## FRAME SIDE PADDINGS MOD. 104

With non-slip fabric inside, they hook up by zip

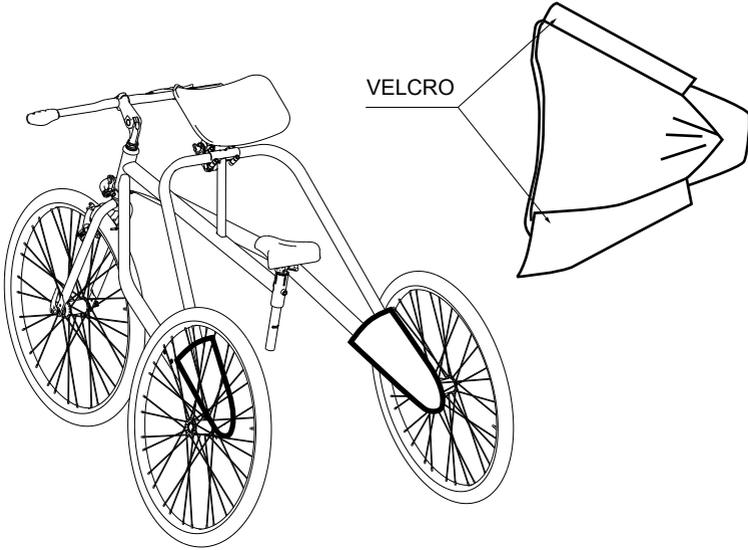




*Assembly of the add-on component must be carried out by a specialised technician.*

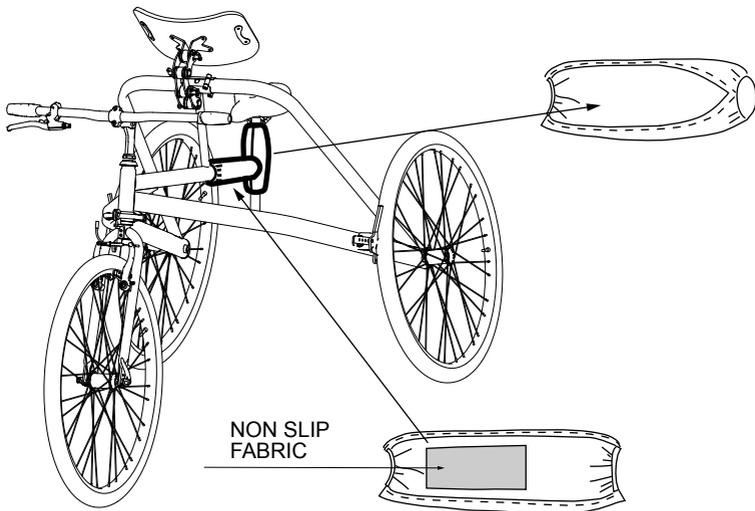
## FRAME REAR PADDINGS MOD. 105

They hook up by velcro



## UNDER SADDLE PADDINGS MOD. 106

With non-slip fabric inside, they hook up by zip



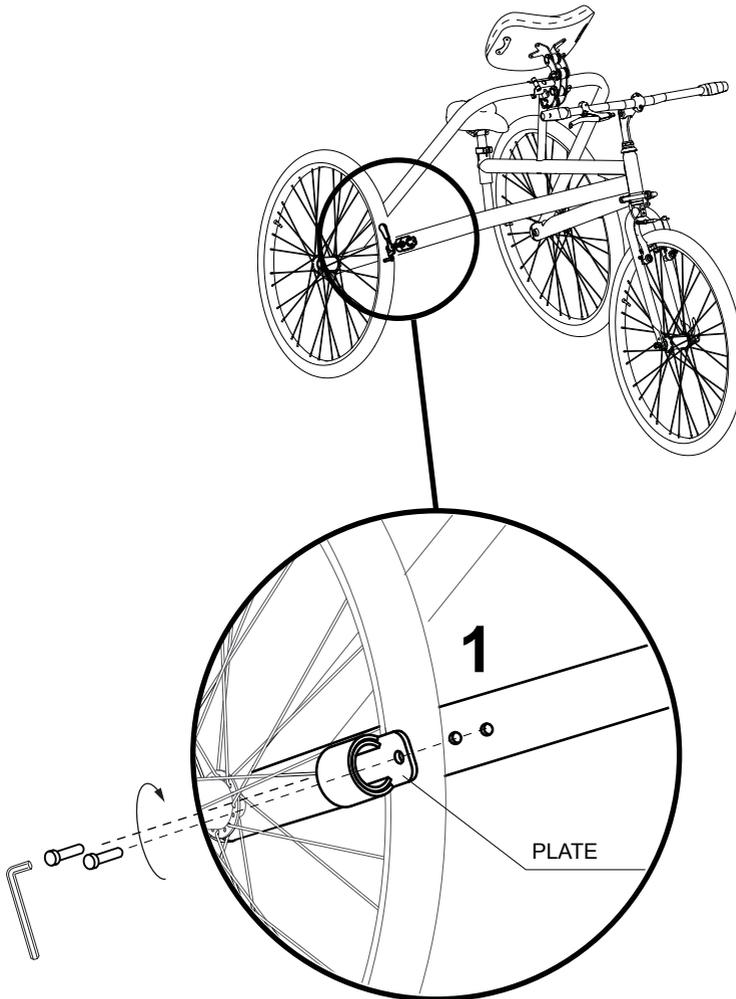


*Assembly of the add-on component must be carried out by a specialised technician.*

## **PARKING BRAKES 107**

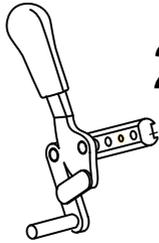
### **A. MOUNTING**

- 1) **MOUNT THE PLATE ON THE FRAME WITH THE APPROPRIATE SCREWS**
- 2) **INSERT THE BRAKE BLOCK INTO THE CLAMP**
- 3) **PLACE IT IN THE PLATE**
- 4) **TIGHTEN THE CLAMP SCREWS AND REPEAT THE OPERATION FROM THE OPPOSITE SIDE**

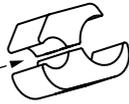




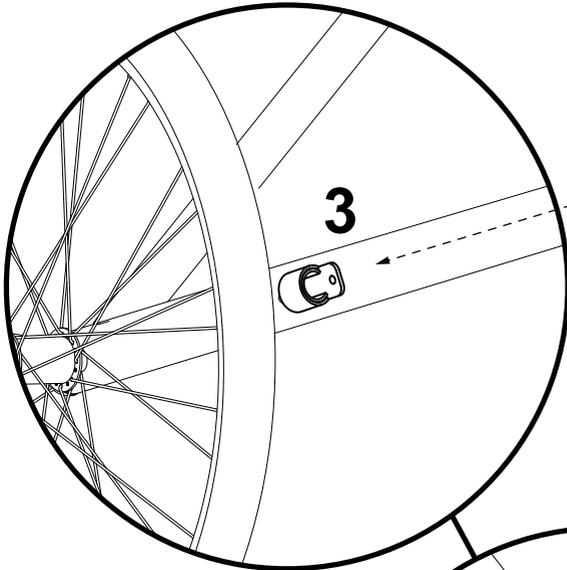
BRAKE  
BLOCK



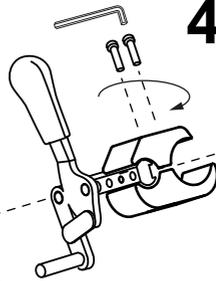
2



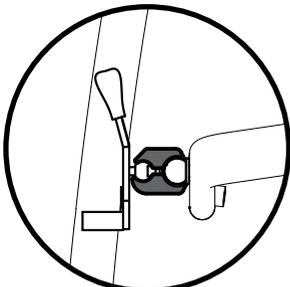
CLAMP



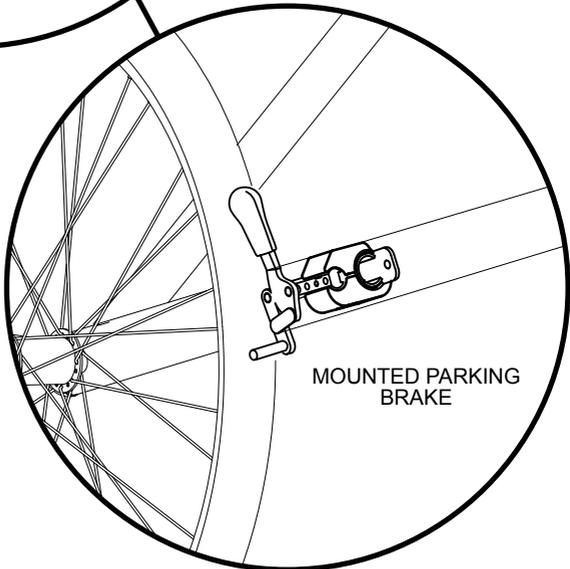
3



4



FRONT VIEW

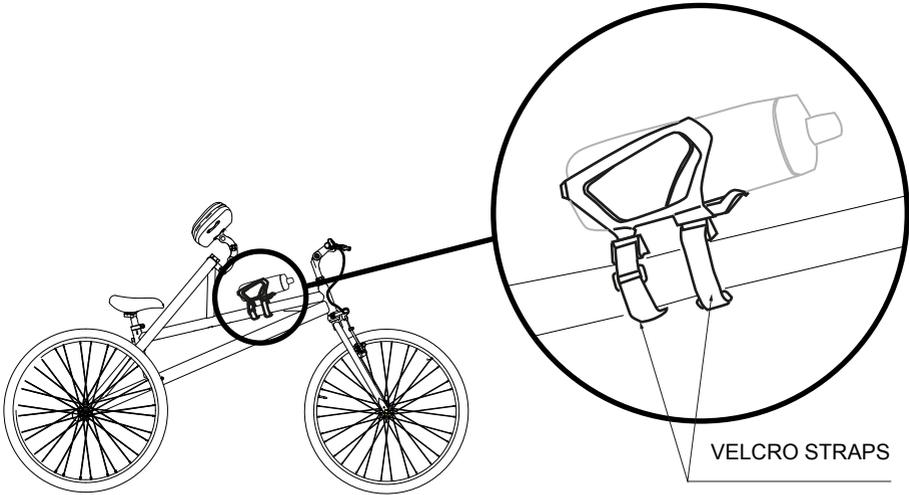


MOUNTED PARKING  
BRAKE



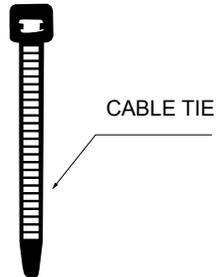
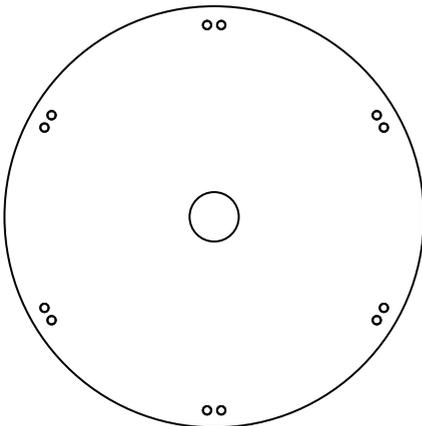
*Assembly of the add-on component must be carried out by a specialised technician.*

## BOTTLE HOLDER 110



## TRANSPARENT REAR WHEELS SPOKE PROTECTORS 111

Assembled with cable ties inside rear wheels.

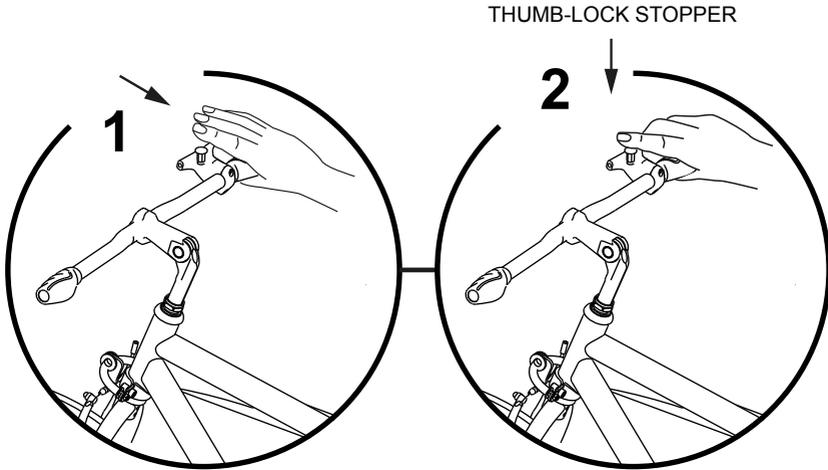




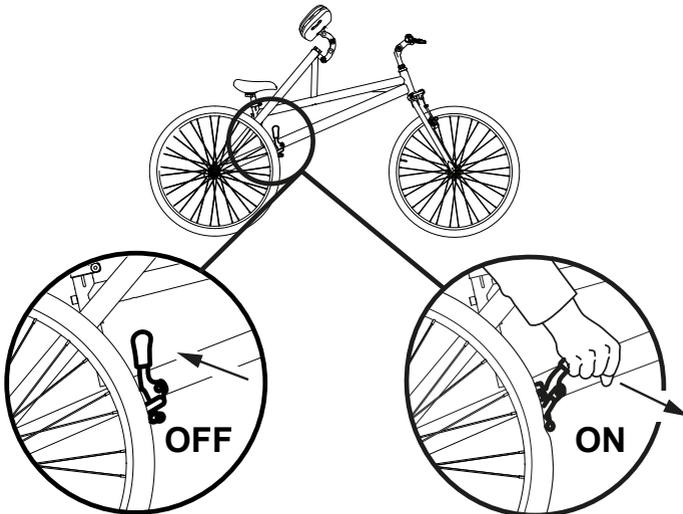
## 5.5 INSTRUCTIONS FOR DAILY USE by the family, care giver or user

### PARKING BRAKE

- 1) PULL THE BRAKE LEVER
- 2) PRESSING THE THUMB-LOCK STOPPER AND HOLD IT DOWN, RELEASE THE LEVER



### PARKING BRAKES (ADDITIONAL COMPONENT 107)

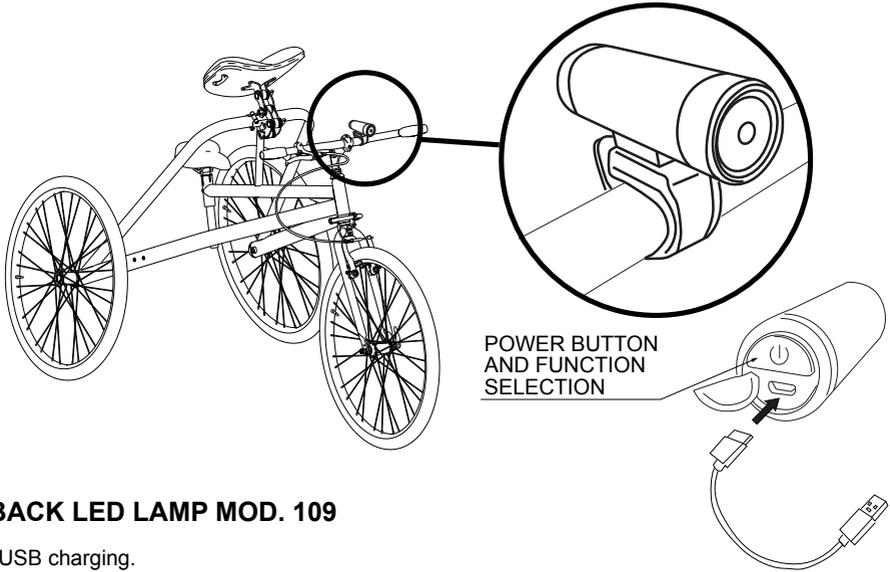




## FRONT LED LAMP MOD. 108

With USB charging.

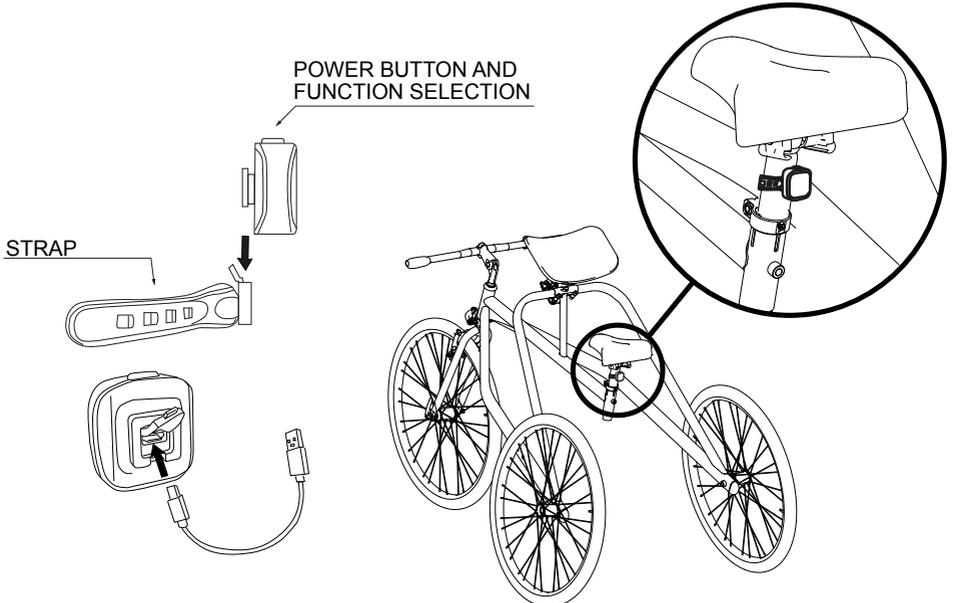
5 different light modes. With battery status indicator and usb



## BACK LED LAMP MOD. 109

With USB charging.

5 different light modes. With battery status indicator and usb

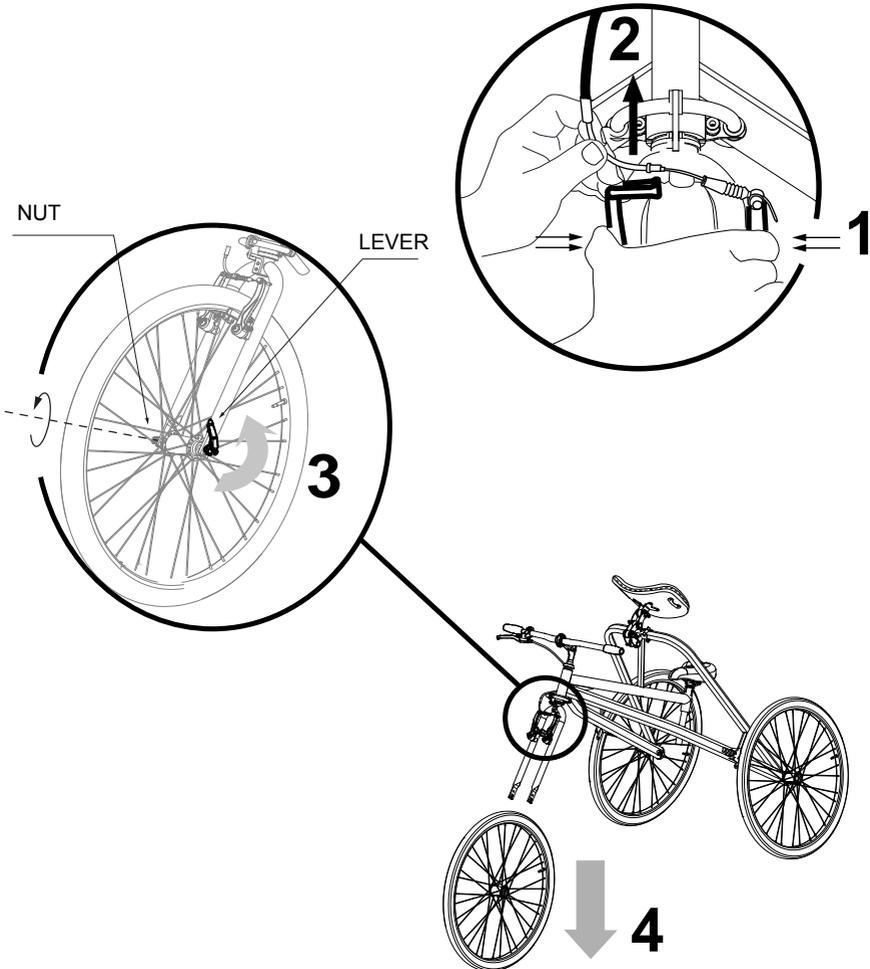




## DISASSEMBLY FOR TRANSPORT

### FRONT WHEEL DISASSEMBLY

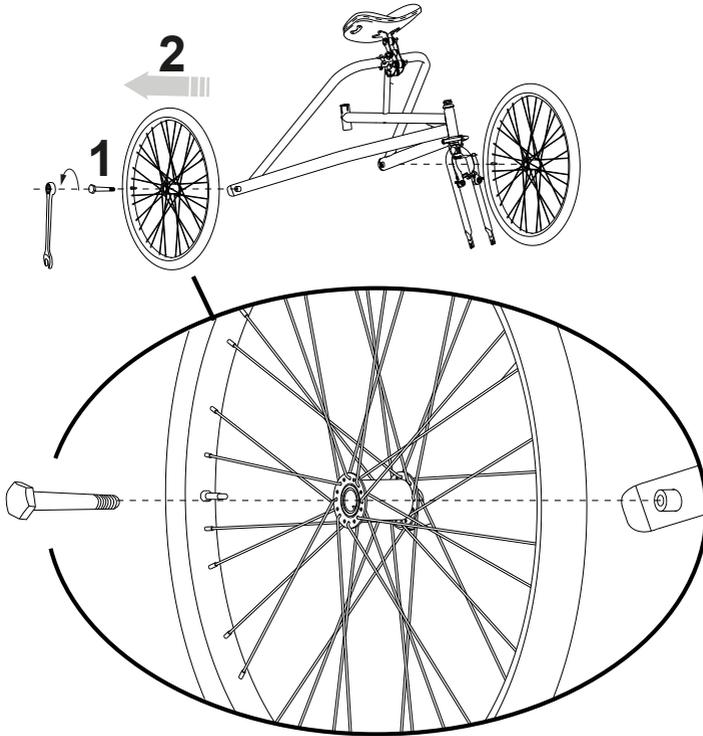
- 1) TIGHTEN THE TWO PARTS OF THE BRAKE SO THAT
- 2) REMOVE THE TRANSMISSION CABLE FROM THE SEATS
- 3) LOOSEN THE LEVER AND THE NUT AT THE SAME TIME
- 4) REMOVE THE WHEEL





## BACK WHEELS DISASSEMBLY

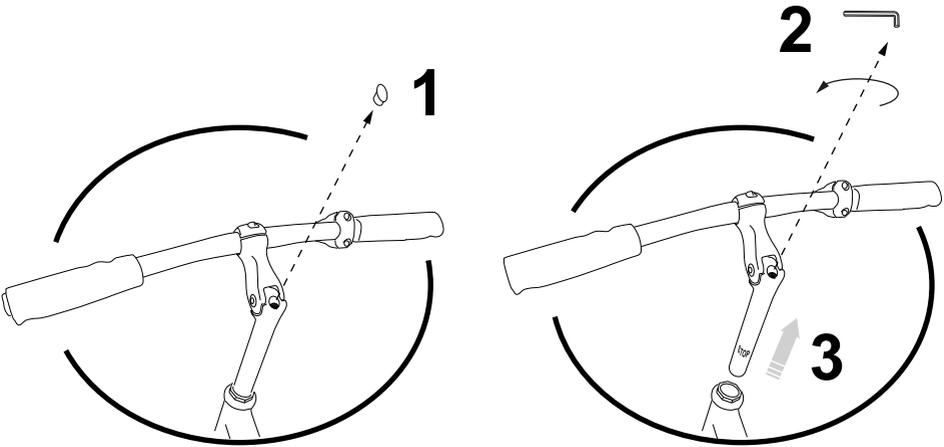
- 1) UNSCREW THE HEXAGONAL SCREW
- 2) REMOVE THE WHEELS





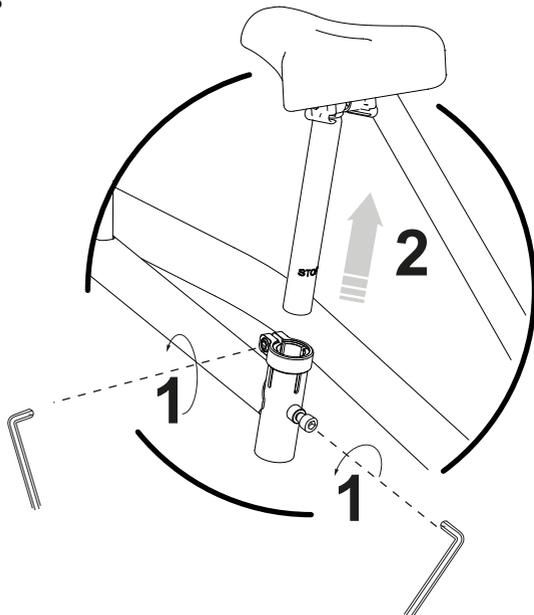
## HANDLEBAR DISASSEMBLY

- 1) REMOVE THE CAP
- 2) LOOSEN THE SCREW
- 3) REMOVE THE HANDLEBAR AND PUT THE CAP BACK



## SADDLE DISASSEMBLY

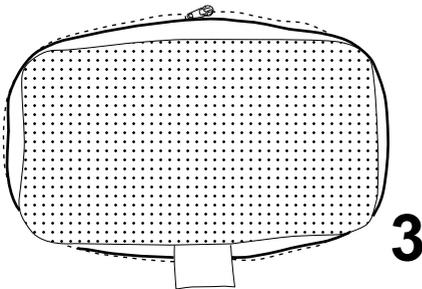
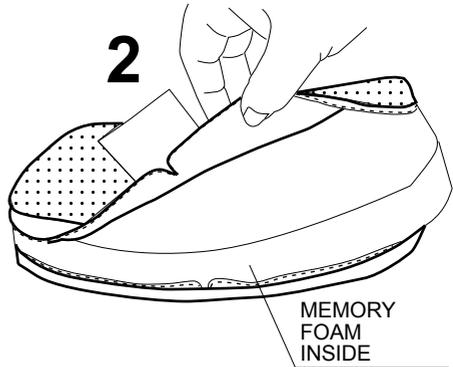
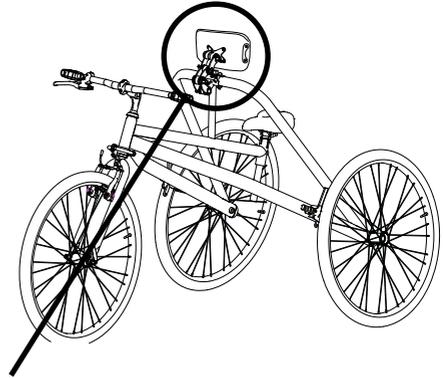
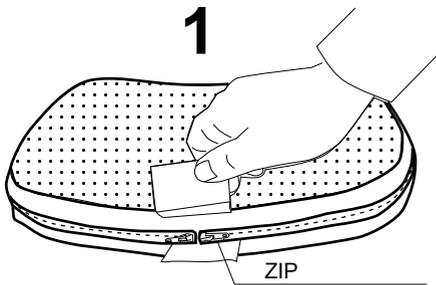
- 1) LOOSEN THE SCREWS
- 2) REMOVE THE SADDLE





## REMOVE THE UPHOLSTERY FROM TRUNK SUPPORT

- 1) OPEN THE CLOTH TAB
- 2) OPEN THE ZIP USING THE SPECIFIC ZIP
- 3) SLIDE OFF THE FRONT OF THE UPHOLSTERY FOR WASHING.





## 6. CLEANING AND DISINFECTION

Cleaning operations (and those of disinfection before reuse of the device with a new user) should be carried out regularly with the procedures and timelines outlined in § 6.3 by the family or care giver.

### 6.1 INFORMATION

**SANIFICATION** is the complex of cleaning and / or disinfection procedures and operations

The **CLEANING** is a physical and mechanical process (i.e., rubbing) with which a large part of potential pathogenic microorganisms (bacteria, fungus, or virus), further to the visible dirt, is removed from the surface.

The combination of mechanical action with other factors such as the use of detergents (chemical action), temperature and duration can efficiently and sufficiently reduce the microbial load of the product.

**DISINFECTION**, after cleaning and cleansing, further reduces the number of microorganisms on a surface and it eliminates pathogenic microorganisms, ie bacteria causing disease and viruses.

Products that on the label bear the authorization / registration Number of the Ministry of Health or other competent authority of an EU member State. are “disinfectants”. Each disinfection action must always be preceded by a cleaning and cleansing operation, since dirt reduces the activity of the disinfectant. **DRYING** is essential because microbial growth can occur in the residual aqueous film.

**CHEMICAL PRODUCTS WITH VIRUCIDAL-GERMICIDAL-FUNGICIDAL EFFICACY** are available on the market for hospital equipment. These products are effective in cold conditions, and they are able to perform the cleaning (elimination of dirt) and disinfection (elimination of pathogenic microorganisms, i.e. bacteria due to disease and viruses) in a single operation.

Removable **UPHOLSTERIES** of trunk support and of the additional components 875, 102, 103, 104, 105, 106 are washable respecting the symbols on the label. Washing is an extraordinary sanitation measure Replace the **REMOVABLE UPHOLSTERY and the PADDING** when worn / difficult to sanitize.

**FRAME and LOAD-BEARING UPHOLSTERY** not removable, is washable according to the instructions in paragraphs 6.3.1 and 6.3.2

### 6.2 WARNINGS

**Read the TECHNICAL SHEET of the chemical product** to verify that it is suited to be used on chrome plated/varnished surfaces and on plastic components in PVC, PA, PP and to test on a small surface to ensure that it does not damage the medical device.

**For an effective operation, it is important to RESPECT THE POSOLOGY and TIMES OF ACTION indicated on the product LABEL.**

On **COVERS** avoid prolonged contact with acidic or basic solvents and cleaners; Do not use abrasive processes or products that may damage the product.

**Use the PPE** (gloves, FFP mask, visor, etc...) required on the product LABELP



**The operations of sanitization must be performed without the user inside the device. Do not use compressed air**, which can cause aerosol and contamination of possible virus and bacteria in the environment and on his own person



During the Covid-19 epidemic, the contaminated PPE (gloves, gowns, glasses, masks, caps, etc...) must be **thrown away in the general waste bin**, unless otherwise indications by the belonging municipality

## 6.3 PROCEDURE

Activities	Cadence	Description
<b>6.3.1 FRAME and UPHOLSTERY CLEANING and CLEANSING</b>	<b>daily or weekly</b> based on intensity of use and biological risk (patient with particular sweating, salivation; pandemic or endemic emergency period eg Covid-19)  <b>Before disinfection</b>	Soak a sponge or a clean disposable cloth (colorless and non-abrasive) with neutral detergent previously diluted in warm water (max. 40°). It is advisable to let the detergent act for a few minutes. Rub upholstery, frame, additional components and finally wheels. If necessary rub the surface with brushes having only soft bristles. Remove any traces of product by wiping with a clean damp sponge or cloth. Dry with a clean soft cloth. Proceed with any disinfection
<b>6.3.2 DISINFECTION</b>	<b>Before Re-using the product with a new user</b>	Spray a virucidal / germicidal / fungicidal chemical product for hospital equipment that is effective cold on a clean disposable cloth. Rub the upholstery, the frame and the clean accessories (6.3.1) finally the wheels, until complete evaporation
<b>6.3.3 REMOVABLE UPHOLSTERY WASHING</b>	<b>Based on use</b>	The REMOVABLE UPHOLSTERY are washable respecting the indications given in the washing labels (see page 8 for the description of the symbols ). For an ANTIVIRAL DISINFECTANT action, a SPECIFIC CHEMICAL PRODUCT can be added to the normal washing cycle; washing at a high temperature (60 ° C) is possible as long as occasionally, as the upholstery may wear out.
<b>6.3.4 SANIFICATION WITH PER- CARBONATE</b>	<b>Based on use</b>	The percarbonate is a natural product of mineral origin that is commercially available; when dissolved in water, it releases active oxygen already at 30 ° with disinfectant, antibiotic and antibacterial action. <b>For a sanitizing action during the cleaning of the frame and the washing of the harness and removable upholsteries, you can add 1 teaspoon of percarbonate &gt; 30% to the detergent:</b> - In the washing machine: add 1 teaspoon of percarbonate in the drum together with the detergent. - By hand/ for the frame cleaning: dissolve 1 teaspoon of percarbonate in the bowl together with the detergent, proceed with the washing, and cleansing. <b>WARNING!</b> <b>When washing / cleaning the fabric it is recommended not to mix sodium percarbonate with acids (for example: Vinegar, Lemon), as it could create chemical reactions that could damage it.</b>



## 7. ORDINARY AND EXTRAORDINARY MAINTENANCE

The execution of all maintenance operations is necessary to maintain the correct functionality and safety of the medical device.

If in doubt about the safety or damage of the product, cease use and contact the orthopedic workshop that supplied the product, or ORMESA.

### 7.1 ORDINARY MAINTENANCE OPERATIONS (monthly)

Frame Runner is a mechanical device and as such must be kept in efficiency to maintain a high level of performance. This is possible with regular maintenance, including cleaning, lubrication and inspection. Routine periodic checks and maintenance should be carried out by a person with good technical competence; otherwise contact the health professional who provided it, or company specializing in maintenance.



**Maintenance and replacement of parts or additional components must be carried out without the user sitting in the tricycle.**



**Intensify all checks in marine environments, clean more often, anoint the parts exposed to salt corrosion (such as chrome, bolts and screws).**



**Regular lubrication reduces friction between moving parts, preventing breakage or seizing and delays rust formation.**

PART	DESCRIPTION / INTERVENTION	MODE
TYRES	<ul style="list-style-type: none"><li>• Check the pressure. Maximum and minimum pressure values are shown on the tyre side.</li><li>• Check the state of wear.</li></ul> In case of wear contact your Health Professional who provided it or distributor, for replacement with an original component.	Pressure gauge/ functional/ visual test
RIMS	<ul style="list-style-type: none"><li>• Check the spokes tension and aegulate if necessary.</li><li>• Check the rims for any side and upper impacts.</li></ul> In case of damage contact your Health Professional who provided it or distributor, for replacement with an original component.	functional/visual test
BRAKES	<ul style="list-style-type: none"><li>• Check the braking system.</li></ul> In case of poor braking check the manual lever, the operating cable, the brake lever and the brake pads. In case of damage contact your Health Professional who provided it or distributor, for replacement with an original component.	functional/visual test



PART	DESCRIPTION / INTERVENTION	MODE
BOLTS/ SCREWS	<ul style="list-style-type: none"> <li>• Check the tightening of all bolts and screws. Tighten them if loose. recommended Tightening torque: Back wheels: 65 Nm – 85 Nm Handlebar: 10Nm Handle stem: 22 Nm</li> </ul>	Tools
HANDLE- BAR	<ul style="list-style-type: none"> <li>• Check the state of the handlebar and of the stem of the handlebar. In case of damage contact your Health Professional who provided it or distributor, for replacement with an original component.</li> </ul>	Visual Test
ADJUSTING MECHA- NISMS	<ul style="list-style-type: none"> <li>• Check the smooth operation of the MOVING PARTS and keep them clean from dust and dirt in order to avoid friction that could compromise correct functioning.</li> <li>• Check the tightness of the adjustment mechanism. If unsuccessful, discontinue use and contact the health professional who provided it, for replacement with an original component. In case you have encountered an inefficiency in TIGHTENING of the HANDLEBAR, of the SADDLE or of the ADJUSTMENT LOCKING LEVER, discontinue use and contact the Health Professional who provided it.</li> </ul>	Functional/visual test
FRONT and BACK LIGHT	<ul style="list-style-type: none"> <li>• Check the operation of the front (108) and back light (109) when available. Recharges the batteries of the front light and of the back light if not working.</li> </ul>	Visual test
PRODUCT INTEGRITY	<ul style="list-style-type: none"> <li>• Check the presence of all parts and components described in the manual.</li> <li>• Check the absence of oxidized parts, the uniformity of the painting on support elements or frame tightening.</li> <li>• Check the state of th anterior fork and of the frame. If unsuccessful, contact your health professional who provided it, for replacement with an original component.</li> </ul>	Visual/tools

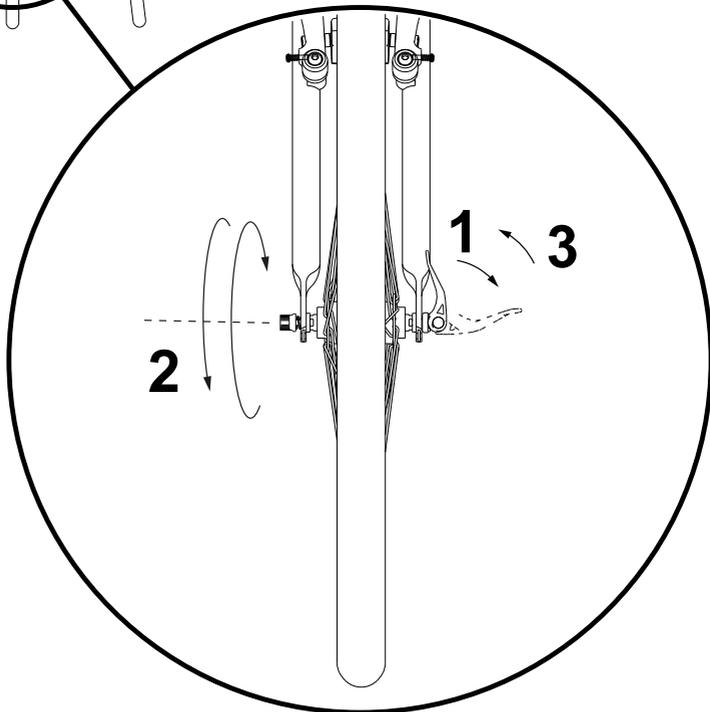
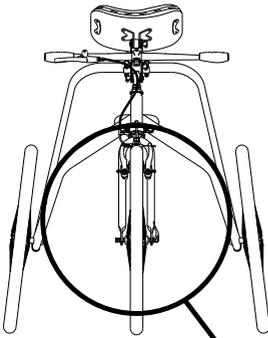


## BRAKE LEVER ADJUSTMENT

SEE PAG. 29

### FRONT WHEEL QUICK RELEASE LEVER ADJUSTMENT

- 1) OPEN THE LEVER
- 2) TIGHTEN OR LOOSEN THE NUT TO ADJUST THE CLAMPING FORCE
- 3) CLOSE THE LEVER





## 7.2 PREVENTIVE MAINTENANCE OPERATIONS (biennial)

The Manufacturer recommends a **COMPLETE REVIEW** of the product, in order to verify it according to the specific use and to maintain the initial performances for all its lifetime.

This activity can be carried out by the health professional who supplied the product or by an **SERVICE CENTER**, specialized in the maintenance of mechanical aids for people with disabilities and includes:

The general verification of the product, the integrity of the components and the locking of the mechanical parts, the smoothness of the moving parts

- 1) Performance verifications
- 2) The possible interventions aimed to restore the correct functionality
- 3) Mechanical control (in case of mechanical repairs)
- 4) Sanitization

The person who performed the maintenance is required to issue **A REPORT WITH THE EVIDENCE OF THE INTERVENTIONS (VERIFICATIONS, REPAIRS, CONTROLS, SANITIZATIONS)**

## 7.3 SPARE PARTS AND CONSUMER PRODUCTS

If you require service or spare parts, contact only the health professional who supplied the product.

## 7.4 EXTRAORDINARY OR CORRECTIVE MAINTENANCE OPERATIONS

**EXTRAORDINARY MAINTENANCE** are all operations done on the product other than regular or preventive maintenance (mentioned above).

Extraordinary maintenance must be carried out by the health professional who supplied the product or by another subject indicated by the Manufacturer or the Distributor of the **ORMESA** products in the country of destination.

The interventions must be performed with **ORIGINAL REPLACEMENTS PARTS** of the manufacturer

Modifications of the product **ARE NOT ALLOWED**, except for those of possible configurations provided on the brochure

For each maintenance work, the following must be performed:

- 1) The general verification of the product, the integrity of the components and the locking of the mechanical parts, the smoothness of the moving parts
- 2) Performance verifications
- 3) Mechanical control (in case of mechanical repairs)
- 4) Sanitization

**THE MANUFACTURER** or the **AUTHORIZED PARTY** must issue **A REPORT WITH EVIDENCE OF THE INTERVENTIONS (CHECKS, REPAIRS, TESTS, SANITATION) CARRIED OUT**



## 8. LIFE SPAN AND CONDITIONS FOR REUSE

**Granted that Ormesa products should be selected, evaluated and ordered for the needs of an individual user, reuse is however possible with the respect of the following conditions.**

Based on the experience of other similar sold models, on technological progress, on the guarantees of the Quality Management System certificated in 1998 according to ISO 13485, there is adequate confidence that the average **lifespan of FRAME RUNNER is about 5 years, on condition that it is used according to the directions given in the user manual**

Only when the conditions for storage and transport of chapter HOW TO STORE AND TRANSPORT THE MEDICAL DEVICE" are followed, the periods in which the product is stored at the health professional, should not be considered in that time period

**Factors unrelated to the product such as the development of the user, its diseases, the use and the surrounding environment can make significantly lower the duration of life of the product; on the contrary, if the indications on the use and maintenance are properly observed, the reliability of the product can extend well beyond the lifetime average above.**

**Prior to recycling or reassignment an already used Ormesa product, it is required that:**

- 1) **a doctor or therapist verifies that the medical device is appropriate and adequate to meet the dimensional, functional and postural needs of the new user, and if all its components are suitable / appropriate for him. You should also consider that the CE -marking and the manufacturer's responsibility for safety requirements for the product remain only if the original product still has not changed and only original accessories or spare parts have been applied**
- 2) **qualified technical personnel of a company specialized in the maintenance of technical aids for disabled people performs a detailed technical inspection to verify its condition and wear, the absence of any damage and failure of all components / adjustments, the presence of the user's manual, of the label with the date and serial number. A copy of the manual and maintenance may be always requested to the retailer that supplied the product or directly to Ormesa**
- 3) **The product has been thoroughly cleaned and disinfected following the directions given in the "MAINTENANCE, CLEANING AND DISINFECTION" Chapter**

We recommend to keep written records on all inspections performed on the product before any assignment to the new user.



**In case of doubt about the safety of the product or damage to parts or components, you are urged to immediately discontinue use and contact the Health Professional who supplied you with the product; the Distributor or the Manufacturer are at your disposal for any further doubt or assistance.**



## **9. END-OF-LIFE MANAGEMENT OF THE MEDICAL DEVICE**

### **9.1 USER OBLIGATIONS**

Comply with applicable local regulations and do not dispose of old products in normal household waste but separately in appropriate collection places.

Proper disposal of the product helps to avoid possible negative environmental and human health consequences. A benefit to the environment for the benefit of all.

### **9.2 END-OF-LIFE DISPOSAL**

The steel frame can be delivered to licensed recyclers.

Wheels and upholstery are composite components, therefore non-hazardous special waste to be sent to the 'ecological island' in your city.



# 10. MANUFACTURER'S DECLARATION

## 10.1 FACSIMILE EU DECLARATION

	<b>DICHIARAZIONE DI CONFORMITÀ "UE" PER DISPOSITIVI MEDICI EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES</b>	Rev. <b>0</b>
		Date <b>04/10/2024</b>

**Nome Fabbricante:** ORMESA s.r.l.  
*Manufacturer's Name:*  
**Indirizzo Fabbricante:** Via delle Industrie n. 6 | 06034 Foligno (PG) – ITALY  
*Manufacturer's Address:*  
**Certificazioni Fabbricante** UNI EN ISO 13485  
*(Manufacturer Certifications)* Dispositivi medici – Sistemi di gestione per la qualità. Requisiti per scopi regolamentari  
*Medical devices – Quality management systems. Requirements for regulatory purposes*  
**SRN (Numero di**  
**Registrazione Unico):** IT-MF-000034824  
*(Single Registration*  
*Number):*

**ORMESA srl dichiara sulla sua responsabilità che il Dispositivo Medico**  
*Ormesa srl declares on its own responsibility that the Medical Device*

**UDI-DI di base** 805404040FRAMERUNNERN4  
*Basic UDI-DI:*  
**Nome del Dispositivo:** FRAME RUNNER  
*Name of the Device:*  
**Codice del Dispositivo:** Vedi Allegato 1 da pagina 2 a pagina 3  
*Product code:* *See Attachment from page 2 to page 3*  
**Destinazione d'uso:** Il Frame Runner Ormesa è destinato a ragazzi/adulti che hanno bisogno di ausili per la  
*Intended purpose:* mobilità e l'equilibrio senza i quali non potrebbero correre, che abbiano cognizione dello spazio che li circonda.  
È adatto a persone con gravi difficoltà motorie e di coordinazione che possono utilizzare il Frame Runner come attività terapeutica e ricreativa: il suo utilizzo migliora la forma fisica e la forza e il benessere fisico e emotivo.  
Anche coloro che hanno difficoltà nel controllo dell'equilibrio durante il cammino, possono giovare dell'uso del Frame Runner, grazie alla stabilità offerta da tutto il sistema. Il dispositivo deve essere prescritto da un medico specialista, configurato e regolato da un professionista sanitario abilitato dal SSN.  
*The Ormesa Frame Runner is intended for children/adults who need mobility and balance aids without which they would not be able to run, who are aware of the space around them.*  
*It is suitable for people with severe motor and coordination difficulties who can use the Frame Runner as a therapeutic and recreational activity: its use improves fitness and strength as well as physical and emotional well-being. Even those who have difficulty controlling their balance while walking can benefit from the use of the Frame Runner, thanks to the stability provided by the entire system.*  
*The device must be prescribed by a specialistic doctor and must be configured and adjusted by a rehabilitation professional according to the laws in the user's place of residence.*

**Classificazione di Rischio:** Classe: / Class: I  
*Risk Classification:*

**soddisfa le prescrizioni del Regolamento (UE) MDR 2017/745 relativo ai i dispositivi medici**  
*Is compliant with the requirements of the Regulation (EU) 2017/745 on medical devices.*

**Specifiche comuni utilizzate:** Non disponibili  
*Common Specification applies:* *Not available*  
**Norme utilizzate** Vedi Allegato 2 da pagina 4 a pagina 4  
*Standards applied:* *See Attachment from page 4 to page 4*

**Valutazione della Conformità:** Dichiarazione di Conformità "UE" in accordo con Allegato II & III del Regolamento  
*Conformity Assessment Route:* (UE) 2017/745  
*EU conformity declaration according to Annex II & III of the Regulation (EU) 2017/745*

Foligno, 04/10/2024 Firma / *Signature:* Chiara Menichini (Legale Rappresentante)





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Health professional

*As Manufacturer, ORMESA srl reserves the right to make any modifications it deems appropriate to the data in this user and maintenance manual.*

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