User manual

Head protection

Starlight® Flex





Foreword

Dear Customer!

We would like to thank you for your trust extended to us and for purchasing our product.

The head protection Starlight® Flex distinguishes itself by its quality, security, easy operation and modern design.

For optimal use of this aid, we ask you and possible other users to carefully read this operating manual.

Please read through these instructions carefully before first use and handle equipment appropriately!



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2 Table of contents

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Safety instructions

3 Safety instructions

The head protection series Starlight® Flex is CE-marked and fulfils the requirements of the latest directive. It was developed in line with most recent findings. Production is subject to an on-going quality control.

Please read this user manual carefully before operating the head protection.

In case of loss, request a new copy or download directly from our download area on our homepage www.ato-form.com.

Please keep the user manual in a safe place, accessible to care and maintenance staff.

The user manual does not replace the experience of supervisory staff with the experience and knowledge of operators, which they gained from (for example) training courses.

In the event of specific or difficult applications, the user manual represents a guide to the most important handling.



Ensure all users of this aid understand its handling and the meaning of the symbols attached to the device.

Accidents can be prevented when technical instructions according to the EWG guidelines are followed.

Protective coverings, labels and warning notices may not be removed.

Regular monitoring at your specialist dealer (at least once a year) lengthens the life time of the head protection and gives you security.

Please also see section: maintenance and overhaul.



Safety instructions

3 Safety instructions

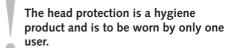
- Before mounting or using the head protection series Starlight® Flex carefully read all instructions of this user manual, as these have been drawn up for your safety and as a guideline for the correct use and maintenance of this product. This operating manual is an indispensable component of the delivery and should be stored carefully for further use.
- The operating manual is intended for retailers and users of the head protection series Starlight® Flex, (or their carers), it contains the required information to secure the correct use of the product, it cannot, however replace the necessary experience of the user or assistant in handling the device.
- The reseller has the duty to deliver the device ready for operation and to explain precisely the functions and technical data of the device, as well as provide the necessary support and briefing needed for a correct and efficient use of the device.
- The given instructions of the operating manual, refers to the point in time of the device being placed on the market.
 The manufacturer reserves the right to introduce any modifications which prove necessary to the device and associated operating manual, without being bound to change previous devices and associated operating manuals.
- Use of the rehabilitation aid and its accessories, must be administered under medical supervision.

- The head protection should be worn by only one user.
- Adjust the head protection correctly before use!
- ATO FORM head protection is equipped with an adjustable chin strap. Adjust the straps to ensure a good fit of the head protection, however not too tight. This also applies to the chin protection, which is accessorily available.
- Please ensure that the straps are firmly locked!
- The head protection is designed to absorb shocks and falls of the user. It is not a helmet that provides protection against falling objects.
- The ATO FORM head protection may only be used for the provided indication and must not be used for any other purposes (sports and alike)!
- The head protection should preferably be stored in the same place and close to the user, when not wearing the head protection. Ensure the head protection is always handy, so that it can be put on quickly and properly.
- The head protection series Starlight® Flex may only be operated by persons or their carers who have familiarized themselves with the standards and rules of the present operating manual.
- Do not use the rehab aid before ensuring a complete and correct fitting of the chin strap.



- Check all adjustable parts are locked, before every use of the aid.
- Please note the individual and overall safety relevant information when using several rehabilitation aids simultaneously.
- Do not use the aid, if parts of it are damaged or missing. Missing parts are only to be replaced with original spare parts.
- Do not carry out any interferences or measurements if you are unsure of their effects; for your own safety contact the nearest service centre or contact the dealer directly.
- In case of accidents or malfunctions, contact the dealer or manufacturer from whom you purchased the device.
- The manufacturer is not liable for damage to persons, objects or animals resulting from false usage of the equipment by the user or third parties, through incorrect mounting of parts and accessories, by neglect or poor maintenance, neglect, through unauthorized alterations and modifications, usage of non-original spare parts or accessories, through unpredictable and exceptional events resulting from non-compliance of the regulations in the presented operating manual.
- Any serious incidents occurring in connection with the product must be reported to the manufacturer (ATO FORM GmbH) and the competent authority of the country in which the user is resident.

- Clean the head protection series Starlight® Flex accordance with the instructions given in the chapter "cleaning".
- Please ensure before use the product is cleaned according to the cleaning instructions and if indicated also disinfected.





The head protection should not be used by children when climbing or doing other activities where there is a risk of strangulation/hanging if the child becomes entangled with the head protection.

We constantly develop new aids and improve existing products. We are happy to receive your suggestions of every description.



Warranty and product liability

4 Warranty and product liability

ATO FORM grants the required by law warranty of your country against defects in workmanship and materials.

The warranty would be adversely affected if the customer's responsibility of servicing and/or daily maintenance is not carried out according to the guidelines and intervals prescribed by the supplier and/ or stated in the manual.

For further information, we refer to the ATO FORM homepage/download www. ato-form.com.

The warranty can only be sustained if the ATO FORM product is in use in the same country where it was purchased and if the product can be identified by the serial number. The warranty does not cover accidental damage, including damage caused by misuse or neglect.

The manufacturer's obligations transfer then to the person carrying out the modifications.

The warranty does not extend to nondurable parts, which are subject to normal wear and tear and need periodic replacement.

6 CE-sign and position

The CE-Label with details of the serial number, the manufacturer and the washing instructions is sewn into the inner lining of the head protection.

The warranty is null and void if non-original ATO FORM parts/accessories are used, or if the product is repaired or altered by anyone other than an authorized ATO FORM representative or by trained personnel officially recognized by ATO FORM for repair and maintenance of ATO FORM products.

ATO FORM reserves the right to inspect the product being claimed for and the relevant documentation before agreeing to the warranty claim and to decide upon whether to replace or repair the defective product. It is the customer's responsibility to return the item being claimed for under warranty to the address of purchase.

The warranty is given by ATO FORM or, subsequently, an ATO FORM dealer.





Indications and prophylaxis
Purpose of use

6 Indications and prophylaxis

- Safety during independent movements and activities, for cerebral paretics, epileptics and others at risk of falling.
- Protection against increased injury potential in autoaggressive patients.
- Protection against head injuries in the case of uncontrolled falling movements or movement sequences.
- Protection against fall hazards with increased potential of injury.
- Models with the top closed offers patients special protection, who for example have part of their skull cap missing.

The only contraindications to be mentioned here are possible skin intolerances to the materials used.

We use selected materials for the processing of the head protection models that meet the highest quality standards.

7 Purpose of use

The shape of the head can change due to illness, growth or surgery - for a variety of reasons.

Thanks to its innovative design, the Starlight® Flex can be adjusted in many places and can thus be ideally adapted to the user's individual requirements.

You can rightly expect us - Europe's largest manufacturer of medical head protection - to consistently dispense with potentially dangerous metal parts, screws or the like that could cause head injuries to the user in the event of a fall, without compromising wearing comfort, multi-adjustability or the required protective effect!

The device must be prescribed by a medical specialist, who has tested beforehand and determined if the Starlight® Flex is suitable for the individual therapeutic goal of the patient. Furthermore, the medical specialist has determined the aid to be suitable according to measurements, weight and willingness of the patient to use the aid.

The aid is delivered via an authorised technician in compliance with the requirements of the country where it is being used and in strict accordance with the information and instructions in this manual for adjustments of the aid according to the measurements of the user. Only compliance of the regulations and instructions can lead to positive ergonomically effects.

We wish you every success when using the head protection Starlight® Flex.

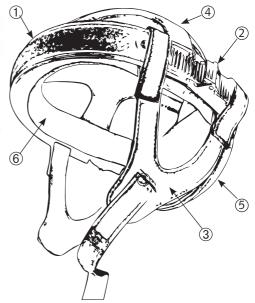


Product overview

8 Product overview

8.1 Basic model

- 1. Outer ring, adjustable to the head circumference
- 2. Ratchet closure for adjustment
- 3. Ear straps, padded, adjustable in length and inclination
- 4. Upper side, anatomically shaped, adjustable
- 5. Back head plate with Velcro tab for top attachment.
- 6. Padding-Inlet, soft, flexible, firmly connected to the back head plate and the rear outer ring





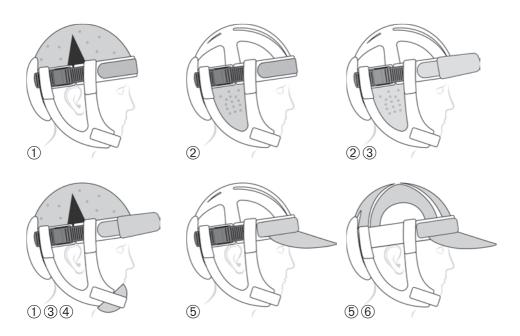
Product overview

8.2 Accessories / options

The Starlight® Flex is with following options available:

- 1. Closed top
- 2. Ear protection
- 3. Forehead protection
- 4. Chin protection
- 5. Sunshild
- 6. Alternative upper side, head circumference adjustable with velcro
- 7. Different fasteners (without image)

For a complete overview of our extensive range of accessories for the Starlight® Flex see item 11.2 Types and accessories on page 18.





Initial operation

9 Initial operation

The reseller is to unpack the unit, ensure that the components and accessories listed in the scope of delivery are all present and undamaged, and give the buyer the initial instructions on use of the aid. Above all the reseller should read through the complete present user manual carefully, in order to then explain it to the customer in detail.

This way, with help of the reseller, the user as well as the attendant must become familiar with the correct operation of the aid.

Once the demonstration has been completed, the reseller must ensure the user and/or the assistant have fully understood the basic functions of the equipment. This is the only way to prevent the user from dangerous situations.

The above mentioned requirements must be observed for first use and also for reuse.

The seller must give instruction for use, as well as explain the basic functions of the device according to MPG (medical products law) to qualified staff.



10 Assembly and adjustments

10.1 Basic model

The Starlight® Flex head protection is designed in such a way that it can be adjusted to the individual dimensions of the user at different points.

The following basic adjustment options are available:

- Length of the ear straps
- Inclination of the ear straps
- Head circumference
- Upper side

The head protection is stabilised and held in its shape by the connection of the outer ring with the padding-inlet.

To adjust your head protection, the padding-inlet must be loosen in the front area of the outer ring first for all adjustment options.

Setting the length of the ear straps and the ear cut-out

To adjust the length of the ear straps (3), detach them from the Velcro connection with the outer ring (1). Stagger the ear straps according to the required length according following steps.

- 1. First fix the position of the straps at the inner side of the outer ring and...
- 2. and then fix this position on the outside with the Velcro.

Inclination

You can adjust the inclination of the head protection or the ear straps via the ear straps as described above by only adjusting the straps slightly at the front or back.

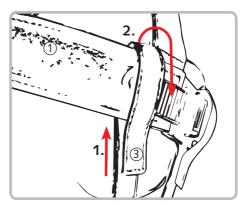


Fig. 2: Picture shows setting with standard ear straps



Adjusting the head circumference on the outer ring

You have the option of adjusting the head protection to a range of approx. 4 cm on each side by means of the ratchet closure.

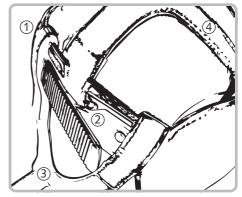


Fig. 3

Do not adjust the head circumference too tightly, after completing the settings the head circumference can be adjusted slightly using the ratchet closure.

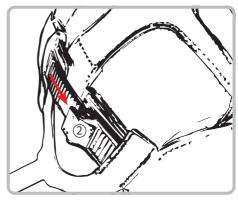


Fig. 4

After completing all adjustments, fix the padding-inlet to stabilise the settings as described on page 17.



Adjusting the height of the top

The height of the top (4) can be adjusted by max. 1 cm at the front, back and sides.

To do this, loosen the Velcro fasteners inside the outer ring (2) at the front and/or sides and move them accordingly.

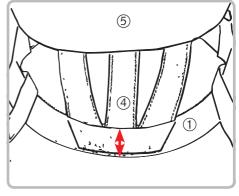


Fig. 5: Front side inner

To adjust the height of the top in the rear area, open the Velcro connection (6) on the back of the head (5) and replace the top (4) according to the desired settings.

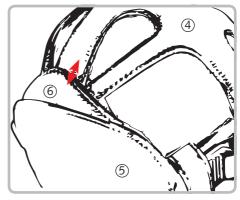


Fig. 6: Back side with back head plate (5) and Velcro connection (6) to the top side (4)

After completing all adjustments, fix the padding-inlet to stabilise the settings as described on page 17.



Re-inserting the padding-inlet

The padding-inlet is made of slightly stretchable or mouldable material and can be adjusted very well to the circumference of the head.

After completing all adjustments, fix the padding-inlet (6) back into the outer ring (1).

Make sure that the inlet is fixed evenly and centrally in the outer ring.

To do this, it is advisable to first fix the inlet in the front centre as shown in the illustration and then press it on evenly at the sides.

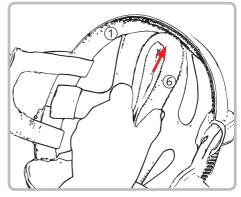


Fig. 7: Inserting the padding-inlet

Note!

The settings on your head protection are stabilised by the connection of the padding-inlet to the outer ring. Check that the padding-inlet sits at the correct height of the outer ring all round and is securely fastened.

10.2 Accessories / options

The illustrations in chapter 10.1 show the settings on the basic model. All optionally available models are set identically as described in chapter 10.1.

When using the forehead protection or the sunshield, make sure that they are firmly attached in the centre of the forehead.

For a complete overview of our extensive range of accessories for the Starlight® Flex see item 11.2 Types and accessories on page 18.

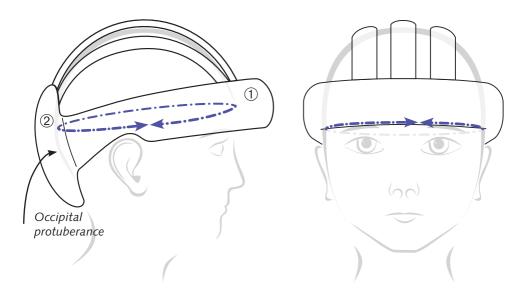


The correct fit of the head protection

10.3 The correct fit of the head protection

The head protection should fit the head without tension or gaps.

The head protection is in the correct position when the head protection ring (1) (see illustration) sits exactly above the eyebrows and the back of the head (the occipital protuberance) is well covered by the rear plate (2).





Types and Accessories

11 Types and accessories

11.1 Basic model

Article number Model

5582-... Basic model, ear strap padded

5589-... Closed top

5584-... With ear protection

5591-... Closed top, with ear protection

Fasteners

Standard Velcro fastener (Standard)

5182-02 Fixlock fastener

5182-02-SV Fixlock fastener with safety lock

5182-02 Thorn buckle

5182-03 Magnetic fastener (incl. key) 5182-06 Strengthened thorn buckle

11.2 Accessories / options

5555-01 Chin protection

5556-01 Fored protection, with velcro

5557-01 Sunshild, with velcro

The most up-to-date overview of our extensive range of accessories for head protection and their description as well as much more useful information can be found on our homepage www.ato-form.com.

For special problems, or if it seems the accessories you require are not demonstrated nor described, please contact us. We may already have the right solution for you.

Technical details

12 Technical details

| Starlight® Flex | | Size S | Size M | Size L | Size XL | | |
|---|----------------|--|----------------|----------------|----------------|--|--|
| Forehead protection (without accessory) | | approx. 23 cm | | | | | |
| Head circumference | (cm) | 48 – 52 | 52 – 56 | 56 – 60 | 60 – 63 | | |
| Filling | High-tech foam | | | | | | |
| Outer material | | Cowhide vegetable tanned, particularly free from PCP, azodye, formaldehyde and chromium (VI) compounds | | | | | |
| Lining Roughened calf leather, skin friendly, breathable heat and moisture regulating | | | | | | | |
| Outer material (Inlet) | | Spacer fabric | | | | | |
| Filling (Inlet) | | High-tech foam | | | | | |
| Product weight Basic model | g | approx. 340 | approx. 360 | approx. 380 | approx. 400 | | |

Technical changes reserved!

Construction

The head protection is made of genuine leather. Thorn buckles are nickel-free. The rivets are made of high-quality stainless steel. High-quality, shock-absorbing foams are used for all padding. The entire construction of the Starlight® Flex is based on the latest and most modern production strategies for allergen-free products with the best climate conditions.



Cleaning and disinfection Maintenance and overhaul

13 Cleaning and disinfection

Cleaning the textiles:

These may be cleaned using mild soap on a damp cloth or sponge.

Cleaning the leather:

ATO FORM leather head protection is to be cleaned with a leather cleaning agent! Hereby please follow given instructions.

Warning!

Strong solvents may contain substances, which can damage the head protection and thereby lead to an impairment of its protective effect.

Do not expose the head protection to high temperatures.

When using the cleaning agents, the manufacturer's instructions for use must be followed.

Disinfection:

We generally advise against disinfection, as this can damage the leather. If it is nevertheless necessary, only use a disinfectant suitable for natural leather.

If disinfecting is necessary, use household disinfectants and consider the following indications:

The assistant must wear suitable protective clothing (for example gloves) in order to avoid infections.

When using disinfecting agents always follow the instructions of the manufacturer.

14 Maintenance and overhaul

If any repair work is required on the Starlight®, please contact your specialist dealer or the ATO FORM service on tel.: +49 6093 944-0.

The head protection should only be used if in a faultless condition!

Immediately contact your specialist dealer in case of any defects!



Operating life and Re-use Faults, repairs, spare parts

15 Operating life and Re-use

Operating life

The product must be treated with care and diligence, to obtain optimum protection. Ensure a precise fit.

One or more of the following criteria can influence the service life or make a new acquisition necessary:

- The fit changes, for example through growth, changes in head form etc.
- Exceptional strain to the head protection, utilisation
- Frequency of wear, frequency of falls

- · Care degree
- Hygienic conditions of the head protection, influenced by (for example) medication and clinical picture

Re-use

A re-use of the head protection series Starlight® is excluded.

17 Faults, repairs, spare parts

Only original accessories and original spare parts may be used. Non-compliance with these instructions and repairs carried out or modifications made to the head protection or its parts by unauthorized persons, voids any warranties.

In these cases, any product liability granted by the manufacturer (ATO FORM GmbH, Zur Lauterhecke 34, 63877 Sailauf, Germany) is voided in advance.

For all questions about spare parts and accessories contact your specialist dealer or the ATO FORM-Service +49 6093 944-0.

18 Storage

Keep this operating manual in a safe place after reading, where you ore care and maintenance personnel can access it.



In environmental protection matters:
All packaging parts are re-useable. The cardboard packaging is to be recycled as waste paper. We therefore use paper as filler material. Possible used plastic film of the packaging are made out of PE and are therefore low in pollutant and can either be recycled or burnt.



Complete Range:

- Head and body protection
- Walking aids
- Gait trainer
- Standing aids
- Seating aids
- Hoists
- Customized solutions

Thank you for your interest in our products. For questions please contact ATO FORM GmbH or your specialist dealer.

Your ATO FORM Team



ATO FORM GmbH

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www.ato-form.com

Your specialist dealer