# aks-gelsit

Anti-decubitus gel seat cushion

# Instructions for use

Translation of the original instructions for use

Zertifiziertes QM System

aks®

DIN EN ISO 13485

"Certified quality management system for the development, production and distribution of equipment and accessories for patient positioning and patient transport"

MD CE

Date: 2022-03-03
Version 01

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## Version history

| Version | Date | Change |
|---|---|---|
| 01 | 2022-03-03 | Adaptations to Regulation (EU) 2017/745 |

# 1 Introduction

Dear customer,

Thank you for choosing an aks GmbH product. We appreciate your vote of confidence.

**Read the instructions for use in full before using the product for the first time and before each reuse, in order to avoid damage or risks due to misuse. The instructions contain important information and notes that are necessary for proper use of the product.**

**If you have queries, particularly regarding the safety instructions, please contact your authorised dealer. Do not use the product until all matters have been clarified. This is to prevent injuries and damage due to incorrect use.**

**Keep these instructions for use within reach of the user and include them with the product if it passes to another owner.**

We reserve the right to make changes and amendments. The text and illustrations may therefore not fully match the delivered product.

If you have any difficulty reading these instructions for use (e.g. due to the font size), you can always download the current version of these instructions for use as a PDF document from the aks website[1]. Open the PDF document and adjust the display on your screen according to your needs.

Using the product means a better quality of life for the patient and makes work easier for the user.

This product is not permitted for use in the **United States of America** or **Canada**. The distribution and use of the product in these countries, including any distribution or use by third parties, is prohibited by the manufacturer.

1 You can find the latest version of the instructions for use in the download area on the aks website.



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The **aks-gelsit anti-decubitus gel seat cushion** (hereinafter also referred to as the product/products) has been developed for decubitus prophylaxis and therapy.

Among other things, it distinguishes itself through the following features:

- PU full-gell cushion with good impact absorption for wheelchair users
- Proven pressure distribution for patients with residual mobility (partially mobile)
- Sturdy and long-lasting
- Supplied with inkoair® seat cushion cover fitted

The product is available in different sizes (see chapter **Scope of delivery**).

We hope the product fulfils your expectations and wish you every success in caring for your patients.

## 1.1 Explanation of the symbols used

For ease of reading, these instructions for use employ the following symbols to indicate important information:

| | |
|---|---|
|  | **Warning of danger**<br>Indicates safety instructions that must be observed under all circumstances in order to avoid an immediate danger to life and limb (risk of serious or fatal injury). |
|  | **Safety notice**<br>Indicates information concerning safe use of and safe work on the product. |
|  | **Information**<br>Indicates useful and important instructions and information. |

In these instructions for use, the following symbols, amongst others, are used to label medical devices:

| | |
|---|---|
|  | Observe instructions for use |
| LOT | Production batch number, batch |
| REF | Article number |
| SN | Serial number |
| SIZE | Dimensions of the product |

For more information on labelling, please refer to the chapter on **Product labelling**.

# 2 Intended use

The products are Class I medical devices according to Regulation (EU) 2017/745, Annex VIII.

The products are suitable for domestic use as well as for use in inpatient facilities.

See the rating plate or the chapter on **Technical data** for the permitted patient weight.

See the chapter on **Technical data** for the climatic conditions.

The products are suitable for reuse (see chapter on **Reuse**). Intended use further includes reading and observing these instructions for use as well as performing the inspections and maintenance tasks in accordance with the maintenance schedule (see the chapter on **Maintenance**).

## 2.1 Intended purpose

The intended purpose of the products is to be used as seating. They are to be placed on an appropriate seat (e.g. chair/wheelchair) (see chapter on **Commissioning**).

The products are used to prevent, treat and alleviate decubitus ulcers. They can be used for decubitus prophylaxis as well as for decubitus therapy. With regard to decubitus prophylaxis, the products are suitable only for patients with a low risk of decubitus.

**The products must only be used for decubitus prophylaxis and for therapy of decubitus ulcers up to and including Grade I (according to EPUAP).**

**Read and observe the instructions for use. Only use the products in accordance with the intended purpose as described. Any other use is prohibited.**

The products are intended for long-term use under normal conditions.

## 2.2 Indication

The products are intended for patients who, due to an illness, injury, disability or their age, have to sit for long periods of time.

## 2.3 Contraindication

**The products must not be used for patients who have a complete absence of stability when seated** (e.g. due to amputation)**.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

## 2.4 Side effects

Note that use of the products can result in a physiologically inappropriate seating situation (e.g. obstruction of motion when seated or feet are not able to touch the floor).

In case of a physiologically inappropriate seating situation, adequate measures must be taken to ensure a physiologically sound seating position.

# 3 Safety instructions

The safety instructions apply to all and any persons who perform work in any way with or on the product. Where a specific group is addressed, this does not exclude any other persons.

Read and observe the safety instructions. The safety instructions comprise text or a combination of a symbol with text. The symbols used are not substitutes for the text for the safety instructions. Read the text of the safety instructions and follow it precisely.

## 3.1 Explanation of the groups referred to

**The operator** is the person who is in possession of the medical device, i.e. any natural or legal entity whose employees operate/use the medical device. The operator does not necessarily need to be the proprietor of the medical device (e.g. medical supply store, authorised dealer, health insurer). The operator bears principal responsibility for the organisational measures and for ensuring compliance with national regulations.

The user must be trained in the safe handling of the medical devices described in these instructions for use (incl. accessories) prior to their first use and every reuse. **It is the duty of the operator (e.g. the responsible medical supply store/authorised dealer) to ensure that the user receives the proper training.**

If the medical device is to be used by relatives of the patient who are responsible for the patient's care[1], the operator must inform said relatives of the circumstances in which they should ask a health care professional for advice, e.g.:

- If they observe any health problems in the patient that are associated with the product.
- If they are unsure regarding a potential use of the product.

In Germany, the EU Medical Devices Adaptation Act (MPEUAnpG) applies, and in particular the Medical Devices Implementation Act (MPDG) and the Medical Devices Operator Ordinance (MPBetreibV) contained in Article 1. The corresponding national laws, regulations and requirements are applicable in other countries.

**Qualified personnel** are persons who, through their training and practical activities, possess the required specialist knowledge and means to properly maintain [assemble, perform commissioning, maintain, inspect, repair, treat (clean/disinfect) and dispose of] the medical devices – defined in these instructions for use – (incl. accessories) and who are capable of performing and documenting the required tasks within the necessary scope.

1 Relatives who care for the patient do **not** usually possess formal health care training.



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In the context of these instructions for use, the word **user** refers to the person who uses (operates) the medical device (incl. accessories) on the patient. The user will be taught the skills and knowledge required to do this by means of proper training in the use of the product provided by the operator, in accordance with these instructions for use.

The user must be physically and mentally able to perform the following activities in relation to the medical devices (incl. accessories) described in these instructions for use:

- Use them in accordance with their intended purpose.
- Set them up in accordance with their intended purpose (e.g. carry out permissible adaptations/modifications in line with the intended use and the permissible combinations).
- In case of obvious damage: shut them down, mark them clearly as “Out of order” and inform the appropriate qualified personnel.

Users must be able to assess the patient’s clinical condition and to take specific action to protect the patient from danger. If relatives take over responsibility for the patient’s care, these relatives must be in a position to consult a health care professional when in doubt.

Prior to each use of the medical devices (incl. accessories) described in these instructions for use, the user must ensure that the products are in good condition and full working order, and observe the instructions for use.

In these instructions for use, the term **patient** is used to refer to a person who requires care due to their illness, injuries, disability or age.

For the sake of better legibility, only the male form (he/his) is used in the texts . The female form is of course always implicit in such use.

## 3.2 General safety instructions

**Training is required in the proper handling of the product (incl. accessories). The training must be documented in an appropriate form.** The training must be conducted on the product itself in accordance with the instructions for use, and must observe all the contents of said instructions for use.

**Please note the minimum and maximum permitted patient weight (see chapter on Technical data).** Undershooting or exceeding the permitted patient weight increases the risk of decubitus that is always present when the product is used. The product may only be used on adult patients. Failure to comply means that safe operation can no longer be guaranteed.

**Do not use a damaged or severely worn product/accessory.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

**In addition to the periodic checking by suitably qualified personnel, check that the product and its accessories** are in a safe state at regular intervals (see chapter on Maintenance, **section Maintenance schedule: Inspection by the user**). Do not continue to use the product (incl. accessories) if damage has occurred. If you have any doubts about the safety of the product or the accessories, do not use them. Mark the product/accessories clearly as “out of order” and inform your authorised dealer immediately.

**Observe the specifications regarding cleaning/disinfecting (**see the chapter on **Cleaning/disinfecting).**

**When cleaning/disinfecting the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be transported without any risk to third parties.**

**Keep the product (incl. accessories) away from direct sunlight. Protect the product from intense heat** (e.g. heating, stoves) **or open flames** (e.g. fireplace, cigarette ember, candle) **and other heat effects** (e.g. from electric blankets). It is not flame retardant. There is a risk of fire. This also applies when drying.

**Protect the product (incl. accessories) from pointed and sharp-edged objects and surfaces** (this also includes the claws and teeth of pets). There is a risk of damage.

Check the suitability of the product (incl. accessories) for the patient at regular intervals (e.g. in case of physical changes [amputation] or weight gain/loss). In doing so, take account of the special characteristics of the patient. Ensure that professional assessment in the form of a risk analysis is ensured, so that the correct size and version of the seat cushion are used for the patient. Match the functional characteristics of the aks seat cushion to the specific disabilities and functional limitations of the respective patient. Note that the patient’s feet must have sufficient contact with the ground or have contact with the footrests of the wheelchair. Potential contraindications must be observed here.

Use the product in line with its intended purpose only and always observe the instructions for use.

Explain any potential risks to the patient and brief them to ensure that their behaviour does not generate any additional risks. There is a higher risk for unsupervised persons sitting in a chair/wheelchair who are also mentally deranged or extremely fragile. Strictly comply with the safety instructions specified here in order to minimise the residual risk.

Prevent the patient from having direct skin contact with the seat cushion or seat cushion cover. Only use the product with a suitable cushion cover. Please note that no other overlays (e.g. fur) are to be used on the seat cushion (seat cushion cover).

Make sure that there is no foreign matter (e.g. food scraps) between the seat cushion cover and the patient.

Do not use the seat cushion on soft supports such as armchairs, sofas etc. Instead, use it only on firm and even support surfaces.

For hygiene reasons, always use the product for the same patient.

Use only original aks accessories/spare parts in order to avoid danger (see the chapter on **Accessories/combinations**).

If the mattress is not used for an extended period, observe the requirements for storage in the chapter **Storage**.

If you experience any serious incidents[2] involving the product (incl. accessories), please contact aks GmbH and the relevant national authorities without delay.

2 "Serious incident" means any incident involving the product (or its accessories) that directly or indirectly led, might have led or might lead to any of the following: (the death of a patient, user or other person, or the temporary or permanent serious deterioration of a patient's, user's or other person's state of health).

## 3.3 Safety instructions for the operator

**Prior to initial use and every reuse, train the user on the product itself (incl. accessories) on the basis of the instructions for use, explain the safety instructions, test the effectiveness of the training, and properly document said training. Make the user aware of the hazards that may arise in case of unintended use of the product (incl. accessories).**

Only allow suitable qualified personnel to perform the commissioning, maintenance, treatment (cleaning/disinfecting) and repair of the product (incl. accessories).

Make sure that the user is physically and mentally able to perform the following activities in relation to the medical device (incl. accessories) described in these instructions for use:

- Use them in accordance with their intended purpose.
- Set them up in accordance with their intended purpose (e.g. carry out permissible adaptations/modifications in line with the intended use and the permissible combinations).
- In case of obvious damage: shut them down, mark them clearly as “Out of order” and inform the appropriate qualified personnel.

Inform the user that, in addition to the periodic checking by suitable qualified personnel, the user themselves must check that the product and its accessories are in a safe state before each use (see chapter on Maintenance, section **Maintenance schedule: Inspection by the user**).

Make sure that the user possesses the skills and knowledge required to check the suitability of the product (incl. accessories), to assess the patient’s clinical condition, and to take specific action to protect the patient from danger.

If relatives take over responsibility for the patient’s care, check that these relatives are in a position to consult a health care professional when in doubt. Explain to the users when they should ask a health care professional for advice, e.g.:

- If they observe any health problems in the patient that are associated with the product/accessories.
- If they are unsure regarding a potential use of the product/accessories.

When using the product, comply with all the provisions of the EU Medical Devices Adaptation Act (MPEUAnpG), and in particular the Medical Devices Implementation Act (MPDG) contained in Article 1, and all additionally applicable legal regulations as well as with the applicable work health and safety regulations, accident prevention regulations and the general provisions concerning the handling of technical devices.

Note that this product is a medical device and the Medical Devices Operator Ordinance (MPBetreibV) are binding for the operator in Germany.

The corresponding national regulations apply in other countries. For use in countries other than Germany, observe the respective applicable national laws, regulations and provisions.

## 3.4 Safety instructions for the user

**Arrange for the operator (e.g. your responsible medical supply store/authorised dealer) to train you in the safe handling of the product (incl. accessories) using the product itself, in accordance with the instructions for use.**

**Only use the product (incl. accessories) if you have been instructed about its handling – including the safety instructions – and you have the corresponding expert knowledge to assess the suitability of the product (incl. accessories) for the patient. If in doubt, ask a health care professional for advice. If you have queries, particularly regarding the safety instructions, please contact the operator. Do not use the product (incl. accessories) until all matters have been clarified. This is to prevent injuries and damage due to incorrect use.**

When using the medical devices (incl. accessories) described in these instructions for use, ensure regularly that the products (incl. accessories) are in good condition and full working order (see chapter on Maintenance, section **Maintenance schedule: Inspection by the user**). Observe the instructions for use.

# 4 Scope of delivery

The product has already been inspected at the factory to ensure completeness and freedom from defects. Nevertheless, check the product immediately after receipt for possible transport damage.

After removing all individual parts, check the completeness of the scope of delivery using the delivery note. If not all the individual parts of the scope of delivery are present, contact your authorised dealer.

The product's scope of delivery includes:

- 1 x anti-decubitus gel seat cushion aks-gelsit
- 1 x inkoair® seat cushion cover
- 1 x instructions for use


**Fig. 4.01 – Scope of delivery**

The product is optionally available in the following dimensions:

| REF<br>**aks-gelsit** | SIZE<br>**W x D x H [cm]** |
|---|---|
| 04150 | 40 x 40 x 2.5 |
| 04151 | 42 x 45 x 2.5 |

All specifications regarding dimensions and weights are approximate specifications. The sizes of the seat cushions are affected by manufacturing tolerances; this means that deviations in the stated dimensions of up to 1 cm are possible.

# 5 Product overview

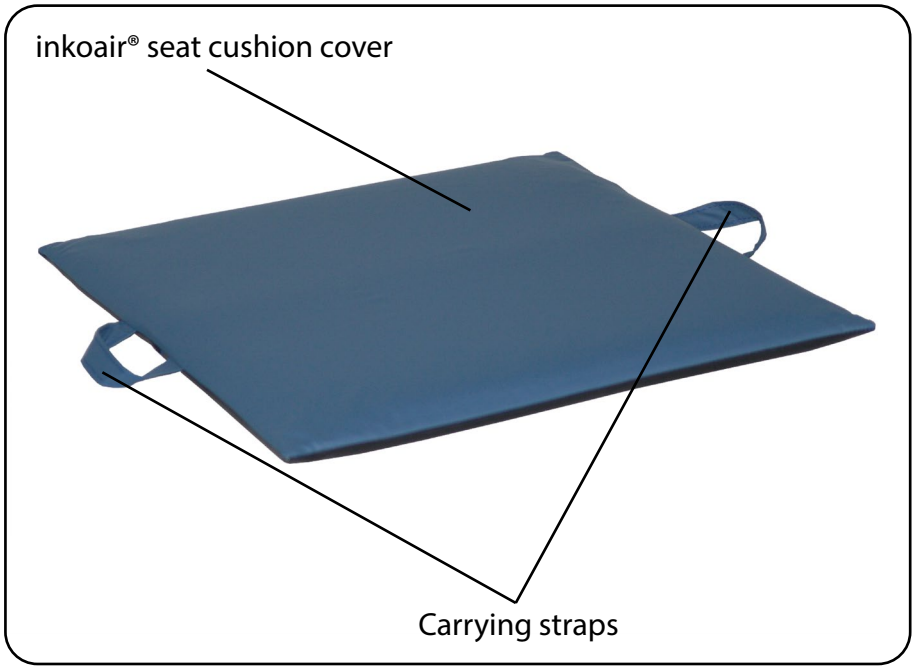


**Fig. 5.01 – Top**

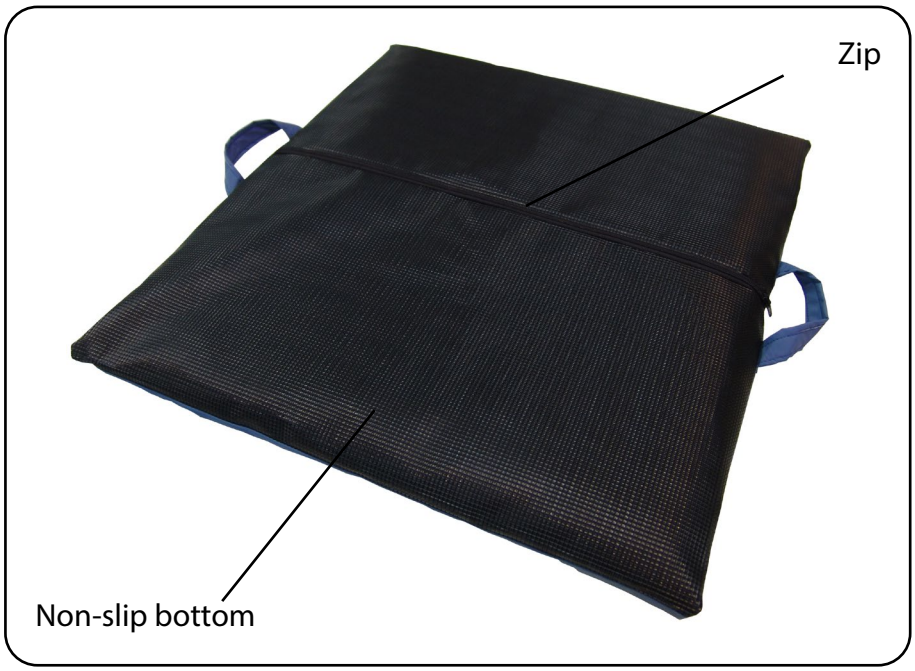


**Fig. 5.02 – Bottom**

The product is a PU full-gel cushion with a single-piece seating surface. It functions in accordance with the pressure-reducing support principle and reduces the support pressure and shear forces. It is used for decubitus prophylaxis and to support decubitus therapy in the area of the posterior.

In particular, it is suitable for wheelchair users and only for people who have residual mobility, i.e. who are able to carry out movements themselves. The seat cushion also reduces shear forces and absorbs impacts.

The aks-gelsit gel seat cushion consists of transparent polyurethane gel held in shape by a hard-wearing PU plastic film. The gel's flow characteristics make it malleable, so that it adjusts to the body contours of the buttocks area. It can adapt to changes of position. Due to the sitting patient's own movements or shifting weight, an alternating reduction of pressure takes place. This improves blood circulation in the tissue areas that currently have less pressure on them and the risk of decubitus development is reduced. In addition, the gel's flow characteristics reduce the shear forces.

The product is protected from soiling by the liquid-impermeable inkoair® seat cushion cover. The seat cushion cover is closed with a zip fastener and is removable. The underside of the cover has a non-slip coating (Fig. 5.02), which ensures that the seat cushion sits more securely on the seat (wheelchair, chair etc.).

The inkoair® seat cushion cover is a liquid-impermeable seat cushion protector, designed especially for patients with bladder and/or bowel incontinence.

Two carrying straps (Fig. 5.01) on the sides of the seat cushion cover make it easier to handle and transport the seat cushion.

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# 6 Commissioning

The product (incl. accessories) has been developed for use on a suitable seat (e.g. chair/wheelchair).

**Do not use a damaged or heavily worn product. Inspect the relevant product (incl. accessories) before and during set-up for damage and defects.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

**Ensure that the seat cushion cannot slip down from the seat.**

When using the product on a wheelchair, ensure that none of the wheelchair's functions are impaired and that no safety risks arise, such as restriction of tilting stability.

Note that the seating surface of the seat must not have any sharp edges and corners that could damage the seat cushion.

If you have established that the delivery is complete based on the **Scope of delivery** chapter in this manual and that the delivery is undamaged, proceed with the commissioning as follows:

1. Check whether the seat is suitable for use with the seat cushion. Note the safety instructions for the user (see chapter on Safety instructions, section **Safety instructions for the user**).

**You must train the user and make them aware of the hazards that may arise in case of improper use of the product, e.g.:**

- Damage to the product (incl. accessories) due to incorrect cleaning/disinfecting, including washing/drying at too high temperatures, using additional brighteners/ bleach (see chapter **Cleaning/disinfecting**)

2. Open the lid of the cardboard packaging. Remove the product, which is already covered with a seat cushion cover, from the packaging. Retain the packaging for future transport or storage of the product.
3. Leave the product to acclimatise for at least 30 minutes at room temperature.
4. Place the product with the non-slip underside against the seating surface of the seat (wheelchair, chair etc.). The side without the zip is the top side of the seat cushion/seat cushion cover.
5. The two carrying straps on the seat cushion cover must face towards the sides of the seat.
6. When positioning the product, ensure that the seat cushion is not compressed or folded and/ or that curvature arises.

## 6.1 Size selection

The product is available in different sizes (see chapter on **Scope of delivery**).

Ensure that the seating surface is stable and that the external dimensions of the seating surface are appropriate for the product.

Check that the seat cushion is suitable for the patient's specific circumstances. The seating surface of the seat cushion must be selected according to the size of the supporting surface. It must also be sufficiently sized for the posterior of the patient. If this is not the case, a seat cushion of different dimensions must be selected.

**If the seat cushion is too small, this will increase the risk of decubitus that is always present when the product is used.**

Your authorised dealer and aks GmbH are available to provide additional information. They help you to take account of the patient's individual requirements and characteristics when it comes to version and size selection.

## 6.2 Placement of the patient on the seat cushion

After all the preparations for use have been made (see chapter on **Commissioning**), the patient can be placed on the seat cushion.

**Ensure that the patient has sufficient stability when sitting if using the seat cushion. The feet of the patient must have sufficient contact with the ground or have contact with the footrests of the wheelchair.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

The patient must not sit through the cushion, i.e. the patient's posterior must not come into contact with the supporting surface of the seat under the seat cushion.

It is recommended that persons with acute illnesses do not sit for longer than two hours and that they should not sit again for an hour thereafter (c.f. expert standard "decubitus prophylaxis in care" (2nd Update 2017)).

### 6.3 Fitting the seat cushion cover to the product

The product is delivered fitted with a cover. However, it may be necessary to remove and then re-fit the cover for cleaning (see chapter **Cleaning/disinfecting**). To fit the cover, proceed as follows:

- The non-slip cover side is the bottom and must be placed on the bottom of the seat cushion (Fig. 5.02).
- You can identify the underside of the seat cushion because it has a transparent film. The gel is covered with a white film in the area of the seating surface.
- There is no need to distinguish between the front and back of the gel seat cushion during positioning.
- The seating surface of the cover is the side without a zip.
- Fit the seat cushion cover onto the seat cushion, taking care to prevent any creases. Make sure that the corners of the gel seat cushion are fitted into the corners of the seat cushion cover.
- The cover must be installed without any creases and without any compression of the seat cushion.
- Now proceed as described in point 3 in chapter **Commissioning**.

## 7 First time use

Before using the product for the first time and every time it is reused, check that the product (incl. accessories) is in safe condition based on the maintenance information in the chapter on **Maintenance**. Before the product (incl. accessories) is reused, always clean and disinfect it in accordance with the instructions given in the chapter on **Cleaning/disinfecting**.

Observe the safety instructions (see chapter on **Safety instructions**).

# 8 Use

Before and during each use of the product, note the following information:

**If the product is to be used on a wheelchair, also read and observe the instructions for use for the wheelchair.**

Inspect the product (incl. accessories) regularly, especially after cleaning/disinfecting (see the chapter on Maintenance, section **Maintenance schedule: Inspection by the user**).

**Do not use a damaged or severely worn product.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

**Keep the product (incl. accessories) away from intense heat or open flame.** It is not flame retardant.

**Observe the specifications regarding cleaning/disinfecting** (see the chapter on **Cleaning/disinfecting).**

**Avoid placing the patient directly on existing wounds.**

**Note that the use of the product does not completely replace the need for regular repositioning of the patient.**

The product (incl. accessories) may only be used after careful consideration of the individual patient. The suitability of the product (incl. accessories) for the patient must be checked at regular intervals (e.g. in case of weight gain/loss). Consider the special requirements of the patient to ensure that a seat cushion in the right size and right version is always used for the patient in question. Match the functional characteristics of the aks seat cushion to the specific disabilities and functional limitations of the respective patient. Potential contraindications must be observed here.

Leaving a patient in a sitting position always involves a certain risk.

# 9 Accessories/combinations

**Only original aks accessory/spare parts may be used as accessories/spare parts because only these have been tested by aks GmbH and thus guarantee faultless and safe function.** Accessories/spare parts that have not been approved by aks GmbH can cause hazards.

| Accessories/spare parts | |
|---|---|
| REF<br>**inkoair®**<br>**seat cushion replacement covers** | SIZE<br>**(W x D x H) [cm]** |
| 41160 | 40 x 40 x 2.5 |
| 41161 | 42 x 45 x 2.5 |

Further accessories/spare parts available on request.

We reserve the right to make changes and amendments. As a result, the specifications for REF may vary. Latest REF available on request.

# 10 Cleaning/disinfecting

**Cleaning:** Achieving a state of cleanliness (visible). Removal of contamination to the extent required for the intended purpose of the product.

**Disinfection:** Reducing the number of or destroying microorganisms (not visible). Procedure designed to reduce the number of viable micro-organisms to a pre-defined acceptable level appropriate to the intended purpose of the product.

**When cleaning/disinfecting the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be transported without any risks to third parties.**

Note the difference between cleaning/disinfecting for use by "**the same patient**" and cleaning/disinfecting for "**reuse**". Note that, for reuse in particular, only disinfection methods that are performed according to a validated procedure[1] with the suitable process parameters are permitted.

## 10.1 General cleaning and disinfecting instructions

The product is suitable for reuse (see the chapter on **Reuse**). The product is manufactured subject to the highest quality standards. The following manufacturer information on cleaning/disinfecting must always be observed to ensure that the characteristics stated by the manufacturer do not change. This is the only way to guarantee that the product is safe and effective for its intended purpose.

All products are equipped with a rating plate (see chapter on **Product labelling**).

Please observe the relevant washing and care instructions on the rating plate for cleaning and disinfection. The table "Explanation of the care symbols" in the chapter **Product labelling** explains what these symbols mean. Failure to observe the care instructions, for example by washing/drying at too high temperatures, or using additional brighteners/bleach, will damage the product.

Both domestic and professional cleaning agents and disinfectants can be used to clean and disinfect the product. The following points must be observed:

**Never use**

- Abrasive agents or cleaning materials containing ammonium chloride
- Basic/alkaline cleaning agents
- Aggressive cleaning materials, e.g. solvents and hard brushes etc.

**If possible, use**

- Environmentally and dermatologically tested cleaning agents
- Alcohol-free and chlorine-free disinfectants and methods for wipe disinfection from the Robert-Koch Institut (RKI) list or the disinfectants list of the Verbund für Angewandte Hygiene e.V. (VAH)

1 E.g. in accordance with the requirements of the Robert Koch Institute (RKI) or another procedure that has been validated by the operator/treatment personnel.



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Observe the instructions and safety precautions from the manufacturers of the cleaning and disinfectant materials.

Clean and disinfect the product at regular intervals and whenever there is evident soiling and keep a proper log of the cleaning/disinfection.

In addition to regular maintenance, regular cleaning helps to identify loose and/or worn parts. This ensures trouble-free operation and extends the product's service life.

Wear gloves during cleaning/disinfection to prevent the cleaning agents/disinfectants from coming into direct contact with your skin.

Keep the surface disinfectants you use in sealed containers and note that these will need replacing at regular intervals in accordance with the manufacturer's specifications. We recommend using re-sealable pump dispensers to apply cleaning agents/disinfectants to cleaning cloths.

Make sure the room is ventilated sufficiently, or air it out thoroughly after wipe disinfection.

## 10.2 Cleaning by the user/operator

The (liquid-impermeable) inkoair® seat cushion cover can be cleaned by hand with a mild, alcohol-free cleaning agent and a cloth. The inkoair® seat cushion cover is removable and it can be washed in a washing machine using normal household washing agents. Observe the washing and care instructions on the rating plate (see the chapter on **Product labelling**) and choose the right settings / process parameters.

Note that washing at 60 °C with normal household washing agents is a type of cleaning that is only effective for the same patient. Note that, when the product is used by a different patient (=reuse), only disinfection methods that are performed according to a validated procedure with the suitable process parameters are permitted.

Clean the product at regular intervals and whenever there is evident soiling.

The uncovered seat cushion (gel) is suitable for manual cleaning with a damp cloth, when necessary.

Before refitting the inkoair® seat cushion cover (see the section **Fitting the seat cushion cover to the product** in the Commissioning chapter) both the seat cushion (gel) and the seat cushion cover must be completely dry. Otherwise, there is a risk of mould. Do not use any hot air (e.g. a hairdryer) for drying purposes.

To ensure a longer service life, avoid drying in a tumble dryer.

## 10.3 Disinfection by the user

Please note: it is important to clean the product thoroughly prior to disinfection! To perform manual wipe disinfection of the inkoair® seat cushion and the seat cushion (gel), use a listed disinfectant according to a listed process[2].

When using disinfectant, always observe the concentration (dosage) and exposure time specified by the manufacturer. Always use cold water (max. 30 °C) when diluting disinfectants.

## 10.4 Disinfection by the operator

Please note: it is important to clean the product thoroughly prior to disinfection! In addition to the wipe disinfection methods specified above, the following disinfection methods are also possible:

The inkoair® seat cushion cover can be cleaned and disinfected using validated mechanised processes. Observe the washing and care instructions on the rating plate (see the chapter on **Product labelling**) and choose the right settings / process parameters.

2 e.g. from the Robert-Koch Institut (RKI) list or the disinfectants list of the Verbund für Angewandte Hygiene e. V.(VAH) or another disinfectant/method that has been validated by the operator/treatment personnel.



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## 10.5 Approved disinfectants and disinfection methods

When using disinfectants and disinfection methods, always observe the corresponding information from the manufacturer, particularly the specifications regarding concentration (dosage) and exposure time. Always use cold water (max. 30°C) when diluting disinfectants.

The following disinfectants and disinfection methods have been tested and approved by aks GmbH.

### Wipe disinfection

| Component | Manufacturer of disinfectant | Designation / active ingredient | Effectiveness* (degree of disinfection) |
|---|---|---|---|
| Seat cushion (gel)<br>inkoair® seat cushion cover | Ecolab | Incidin™ Rapid[3] | A |

### Mechanised disinfection

| Component | Manufacturer of cleaning agent / disinfectant | Designation / active ingredient | Effectiveness* (degree of disinfection) |
|---|---|---|---|
| inkoair® seat cushion cover | Ecolab | Ozonit method:<br>Ecobrite Magic Emulsion (cleaning agent) + Ozonit super[4] (disinfectant) | AB |

* A: Suitable for killing vegetative bacteria, including mycobacteria and fungi including fungal spores

B: Suitable for inactivation of viruses

We recommend the certified treatment unit at aks pura GmbH for cleaning and disinfection of the product.

3 According to the Verbund für Angewandte Hygiene e. V. (VAH) - Active ingredient basis: Aldehyde(s), quaternary compound(s)

4 According to the Verbund für Angewandte Hygiene e.V. (VAH) - Active ingredient basis: peroxide compound(s)

## 11 Storage

The storage location should be as cool and dry as possible and not exceed normal room temperature. The climatic conditions are described in the chapter on **Technical data** and must be complied with.

Ensure damage and continual strain are ruled out during the storage period.

Do not place anything on the product that could damage it (e.g. pointed objects with sharp edges).

The maximum stacking height specified in the chapter on **Technical data** must not be exceeded.

For short-term storage in between use, the product should preferably be stored in ventilated cabinets.

With regard to long-term storage, the product should be stored in a cardboard box and in a clean, dry and unfolded state. Use the original packaging for storage to protect the product against dust and/or cover the product with foil or a sheet.

Keep the product away from direct sunlight, fire and heat sources (e.g. heating, stoves etc.).

## 12 Reuse

The products described in the instructions for use are suitable for reuse. Before reusing the product in question (e. g. in the event of a change of patient), make sure that it has been cleaned and disinfected as described in the chapter on **Cleaning/disinfecting** and serviced as described in the chapter on **Maintenance**, and that any defects or damage found has been repaired by the appropriate qualified personnel and/or the components in question replaced.

Observe the safety instructions (see chapter on **Safety instructions**).

# 13 Service life

If the product is used as intended, cleaned and disinfected as described in the chapter on **Cleaning/ disinfecting**, and maintenance work is carried out at regular intervals as defined in the maintenance schedule (see chapter on **Maintenance**), a service life/useful life of up to **five years** is possible.

**Do not use a damaged or severely worn product.** Failure to observe this requirement can increase the risk of decubitus that is always present.

**Do not carry out any repairs or modifications to the product.**

Please note the permitted patient weight (see chapter on **Technical data**). Exceeding the permitted patient weight not only reduces the service life/useful life of the product, it also increases the risk of decubitus that is always present when the product is used.

The product's service life/useful life is of course dependent on how it is used. Frequent transportation, cleaning and disinfection reduce the service life/useful life as do improper handling, improper storage and irregular maintenance.

If the products are treated properly and handled carefully, and they are cleaned/ disinfected as described in the chapter on **Cleaning/disinfecting**, they can also be used for longer.

The fact that aks GmbH specifies an expected service life/useful life for the products does not represent an additional guarantee.

## 14 Disposal

The products described in these instructions for use are made of metal and plastic parts (zip). It must be disposed of professionally and in accordance with the statutory requirements.

Sort the packaging materials according to the parts that are recyclable, and recycle these in accordance with the applicable environmental regulations. Properly dispose of the parts that are not recyclable in your country.

**When disposing of the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be disposed of without any risk to third parties.**

Contact your local disposal company. For disposal in countries other than Germany, observe the respective applicable national laws, regulations and provisions.

The product is compliant with Regulation (EU) 2020/171, known as the REACH Regulation of the European Parliament and of the Council from 6 February, 2020 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

## 15 Warranty

The products described in these instructions for use are distinguished by their long service life and high reliability. If a problem arises, inform your authorised dealer. The authorised dealer will assist you as quickly as possible.

We guarantee the faultless condition of our products in accordance with our sales and delivery conditions. In respect of material defects, we provide a manufacturer's warranty for **24 months** from the date of purchase (soiling and normal wear are not covered by the warranty).

Non-observance of the instructions for use, improper use, improperly carried out maintenance work, and technical modifications and additions (e.g. attachments) without the permission of aks GmbH render the warranty and general product liability void.

We reserve the right to make technical changes for the purpose of improvement. For the product designation and information for clear identification (e.g. SN, LOT), refer to the rating plate (see chapter on **Product labelling**).

## 16 Declaration of conformity

The products described in these instructions for use comply with all the applicable requirements of Regulation (EU) 2017/745 on Medical Devices (MDR). During development of the products, the applicable parts of the following standards were taken into account:

- EN ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

The full Declaration of Conformity is available on request.



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# 17 Maintenance

## 17.1 General maintenance instructions

The service life of the products (incl. accessories) described in these instructions for use is of course dependent on the type of use.

In order to ensure safe operation, the product in question must be visually inspected at regular intervals by appropriate qualified personnel, every time the product is returned to use and after every repair, in accordance with the maintenance schedule.

If the product is not regularly and properly serviced, safe use is no longer guaranteed. Wear, damage as well as loosening of connecting elements can therefore not be detected.

If any checks indicate defects/damage, do not use the product any longer. Mark the product clearly as “out of order” and inform your authorised dealer immediately.

Do not carry out any repairs or modifications on the product that would alter the product characteristics. If this instruction is not observed, safe care can no longer be guaranteed and there is an increased risk of decubitus. In addition, any warranty claims and product liability are excluded.

Maintenance may only be carried out on the seat cushion when it is not being sat on.

Only original aks spare parts and aks accessory parts that are approved for this product may be used (see chapter on **Accessories/combinations**). Otherwise, any warranty claims and product liability are excluded. You must not make any technical modifications and additions without permission from aks GmbH.

In Germany, the EU Medical Devices Adaptation Act (MPEUAnpG) applies, including the Medical Devices Implementation Act (MPDG) and the Medical Devices Operator Ordinance (MPBetreibV). The corresponding national laws, regulations and requirements are applicable in other countries.

The maintenance schedule must be used as test specifications for the products (incl. accessories) described in these instructions for use, and this must be properly documented.

Perform all tests under normal indoor ambient conditions (humidity and temperature). Perform all the tests on the same product and document your results. The following information must be provided as a bare minimum:

- Name and address of testing company
- Name of tester
- Test date
- Information on the product, incl.: Type, size, date of manufacture/production, serial/LOT number, catalogue umber where applicable
- Permitted patient weight
- Name and address of the manufacturer
- Test results
- Indication of next test date

## 17.2 Maintenance schedule: Inspection by the operator

Perform maintenance on the product (incl. accessories) at regular intervals[1], every time it is returned to use and after every repair.

Article 7 of the MPBetreibV specifies the following:
*"Maintenance measures refer to inspections and **maintenance tasks** that are necessary in order to continuously ensure safe and proper operation of medical devices. The maintenance measures shall be performed taking the **manufacturer's instructions** into consideration (…)."*

| **Application area** | |
|---|---|
| ☐ Private household ☐ In-patient facility ☐ _____ | |
| Client: _____ | First time use (YYYY/MM) _____/_____ |
| Last inspected on: _____ | by: _____ |
| Inspection prior to initial commissioning conducted on: _____ | by: _____ |

| Model | Cover | Dimensions W x D (cm) | UDI-DI | |
|---|---|---|---|---|
| aks-gelsit | inkoair® | 40 x 40 | 04251818702082 | ☐ |
| | | 42 x 45 | 04251818702099 | ☐ |

1 Article 11 of the MPBetreibV specifies the following for technical safety inspections for the medical devices specified in Annex 1 of the MPBetreibV:

"*The owner shall schedule inspection intervals accordingly to ensure that the defects that are to be expected on the basis of past experience can be identified in good time.*"

Technical safety inspections do not apply to the products described in these instructions for use. The wording specifies the owner's responsibility.



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The following maintenance schedule provides help for this inspection:

| Inspection of the anti-decubitus seat cushion – inspection points* | OK | NOK | n/a |
|---|---|---|---|
| **Check of the basic requirements** | | | |
| Appropriate and safe use (see chapter Intended use, section **Intended purpose**) | | | |
| Permitted combinations of seat cushions and seat cushion covers (see chapter **Accessories/combinations**) | | | |
| Instructions for use available, legible and accessible to user | | | |
| No unauthorised interventions, modifications or improper handling | | | |
| **Inspection of the seat cushion (gel)** – The seat cushion cover must be removed | | | |
| Labelling is present and legible (including product designation, CE-marking etc.) (see chapter on **Product labelling**) | | | |
| No deformation, formation of depressions | | | |
| No damage (e.g. tears, cuts) | | | |
| No soiling of the gel and the surrounding film | | | |
| Seating surface is undamaged (no cracks, holes, hardening etc.) | | | |
| No wear, no worn/abraded areas | | | |
| Rating plate present, undamaged, legible and firmly adhered to the film | | | |
| **Inspection of the seat cushion cover** | | | |
| Inner labelling of the seat cushion cover present, attached and legible (see chapter on **Product labelling**) | | | |
| No damage (e.g. tears, holes, cuts, separating seams, scorch marks) | | | |
| No soiling | | | |
| No wear, no worn/abraded areas | | | |
| Zip fastener functional and complete (slider, slider grip) | | | |
| Both carrying straps present, undamaged and fastened | | | |
| **Overall assessment: Anti-decubitus seat cushion** | | | |
| aks anti-decubitus seat cushion and accessories are in order: ☐ YES ☐ NO | | | |
| Remark: | | | |

| Test date | Company | Inspector | Signature |
|---|---|---|---|
| | | | |

| Data for anti-decubitus seat cushion | | | | | |
|---|---|---|---|---|---|
| Product | Type | Dimensions W x D (cm) | SN / LOT | Date of manufacture (YYYY/MM) | Next maintenance/ inspection |
| Seat cushion (gel) | | | | | |
| Seat cushion cover | | | | | |

We recommend the aks pura GmbH certified treatment unit for periodic monitoring, cleaning and disinfection of the product.

(*)

| | | |
|---|---|---|
| OK | in order | The condition or the function complies with the requirements |
| NOK | not in order | The condition or the function does not comply with the requirements. The defect has to be rectified by a repair or replacement |
| n/a | not applicable | Property/component not present, e.g. aks-3D air seat cushion cover |

## 17.3 Maintenance schedule: Inspection by the user

In addition to inspection by suitable qualified personnel, the user must check at regular intervals that the product is in a safe state. Do not use the product if you are concerned about the safety of using it. Contact your authorised dealer immediately.

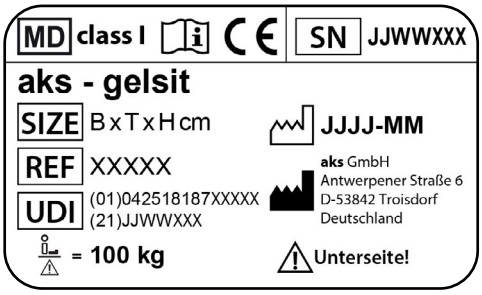
The following maintenance schedule provides help for this inspection:

| **Inspection of the anti-decubitus seat cushion / seat cushion cover – inspection points** |
|---|
| No deformation, formation of depressions |
| No damage (e.g. tears, holes, cuts, separating seams, scorch marks) |
| No soiling of the seat cushion cover |
| No wear, no worn/abraded areas |
| Zip fastener of the seat cushion cover functional and complete (slider, slider grip) |
| Both carrying straps on the seat cushion cover present, undamaged and fastened |

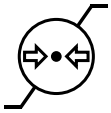
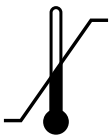
If any of these checks indicate defects/damage, the product/accessories must no longer be used. Mark the product clearly as “out of order” and inform your authorised dealer immediately.

**Do not use a damaged or heavily worn product.** Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

# 18 Product labelling

| Product labelling | |
|---|---|
|  | **Rating plate**<br>seat cushion<br>imprint (bottom) |
|  | **Rating plate**<br>inkoair® seat cushion cover<br>label (inside) |

| Explanation of the symbols | |
|---|---|
| CE | CE marking – this product satisfies the applicable requirements of the Regulation (EU) 2017/745 on Medical Devices (MDR) and other legal requirements of the European Union regarding affixing the relevant marking. |
| SIZE | Dimensions of the product |
| MD | Medical device as per Regulation (EU) 2017/745 on medical devices |
| **Class I** | Class I according to Annex VIII of Regulation (EU) 2017/745 on medical devices |
| UDI | Unique Device Identifier (UDI) – refers to a sequence of numeric or alphanumeric characters that allows unambiguous identification of specific products on the market |
| = kg | Permitted patient weight |

| Explanation of the symbols | EN ISO 15223-1 |
|---|---|
|  | Observe instructions for use |
|  | Attention |
|  | Manufacturer |
|  | Date of manufacture |
| LOT | Production batch number, batch |
| REF | Article number |
| SN | Serial number |
|  | Air pressure, limit |
|  | Humidity, limit |
|  | Temperature, limit |

| Explanation of the symbols | EN ISO 15223-1 |
|---|---|
|  | Keep dry/store in a dry place |
|  | Protect against heat/sunlight |

| Explanation of the symbols | IEC 60417 |
|---|---|
|  | Stacking limit by quantity |

| Explanation of the care symbols | EN ISO 3758 |
|---|---|
|  | Coloured wash (normal washing cycle)<br>Washing temperature 60 °C, normal process |
|  | Do not bleach<br>Use bleach-free detergents |
|  | Do not dry in a tumble dryer |
|  | Dry with reduced thermal load<br>Dry at low heat setting (maximum approx. 60 °C) |
|  | Do not iron |
|  | Do not dry clean |

# 19 Technical data

| **General information on the product** | | | |
|---|---|---|---|
| Classification | Class I medical device according to Regulation (EU) 2017/745, Appendix VIII | | |
| Basic UDI DI | 425181871**261011E8** | | |
| Permitted patient weight [kg] | 40–100 | | |
| Climatic conditions | Ambient temperature [°C] | Use | 15–38 |
| | | Transport/storage | 0–38 |
| | Humidity [%] | | 30–75 |
| | Air pressure [hPa] | | 800–1060 |
| | | | Normally composed atmospheric air |
| Storage in cardboard box | Max. stacking height [pcs] | | 7 |
| **Seat cushion** | **W x D x H** | | **Weight [kg]** |
| SIZE [cm] | 40 x 40 x 2.5<br>42 x 45 x 2.5 | | 3.9<br>4.8 |
| Material | PU gel, foil: PU | | |
| **inkoair® seat cushion cover** | | | |
| Material | Top side: 63% polyurethane, 37% polyester<br>Underside: 83% PVC, 15% PES, 2% PU (coated and non-slip) | | |

All specifications regarding dimensions and weights are approximate specifications. The sizes of the seat cushions are affected by manufacturing tolerances; this means that deviations in the stated dimensions of up to 1 cm are possible.

The product fulfils the requirements of the REACH Regulation, among other requirements.

All parts and data are subject to constant further development and can thus be different from the information shown in this document.

Notes:

Notes:

Enter the data for your product here:

**Type:**

- ☐ aks-variosit 8
- ☐ aks-variosit 10
- ☐ aks-variosit memo 8
- ☐ aks-variosit memo 10
- ☐ aks-therasit 8
- ☐ aks-therasit 10
- ☐ aks-maxisit
- ☐ aks-multisit
- ☐ aks-gelsit

**Seat cushion cover:**

- ☐ inkoair®
- ☐ aks-3D air

**SIZE** **[cm]**

- ☐ 35 x 35
- ☐ 35 x 40
- ☐ 40 x 40
- ☐ 40 x 45
- ☐ 42 x 42
- ☐ 42 x 45
- ☐ 45 x 45
- ☐ 50 x 40
- ☐ 50 x 45
- ☐ 50 x 50
- ☐ 55 x 40
- ☐ 55 x 45
- ☐ 55 x 50

**SN** _____

Year _____ Month _____

**First time use:** Year _____ Month _____

**Authorised dealer:**

Name _____

Street _____

Postcode/town _____

Telephone number _____

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Translation of the original instructions for use: z4200132_GA_Decu_gelsit_220303_Rev01_DE