


sippa



EN Instructions for Use

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 Germany
Made in Germany

1 Important notes








Read through the whole of this instruction manual. Keep this document for future reference. If these instructions are not properly followed, the possibility of injuries or damage to the product cannot be ruled out.

1.1 Information about these instructions for use

The contents of these instructions for use are intended for healthcare professionals and home users. Healthcare professionals are persons conversant with the hygiene requirements in clinics and medical practices and also include specialist dealers, pharmacists, medical assistants, speech therapists, doctors, nurses, carers, etc.



1.2 Explanation of symbols

The product/packing carries the following symbols:



	Follow the instructions for use.
	This symbol indicates the manufacturer of the medical product.
	The product meets the fundamental requirements according to the provisions of the European Medical Products Regulations 2017/745 EU.
	This symbol indicates the date of manufacture of the medical product.
	This symbol indicates the date beyond which the medical product should no longer be used.
	The medical product should not be used if the packaging is damaged.
	The medical product must not be filled with liquids hotter than 100°C.



1.3 Information on safety guidance

Safety-related information or warnings are identified as follows in this instruction manual:

 NOTE	The heading NOTE identifies general precautions that should be followed when handling the product in order to prevent product damage or faults.
 CAUTION	The heading CAUTION identifies hazards which could potentially result in injuries or impairment of use if precautions are not taken.

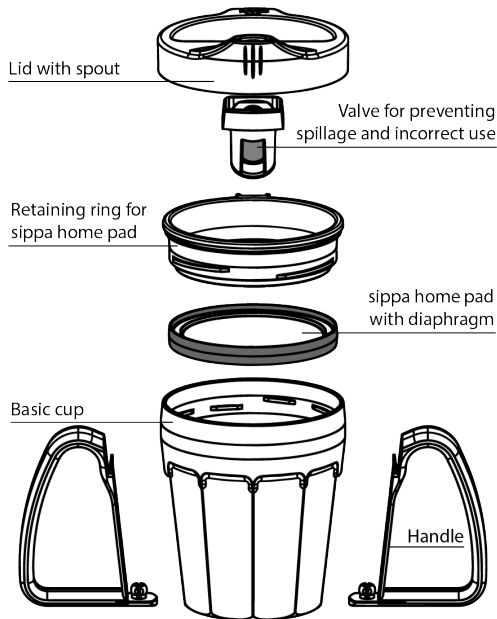
1.4 General safety guidance

 CAUTION	If the sippa home drinking aid is used without the pad and retaining ring components, it is not being used as intended.
 CAUTION	All individual components must be cleaned daily. To do so, follow the instructions given in Section 4, Cleaning and disinfection. Make sure that all individual components are always adequately dried after cleaning and disinfection. Healthcare professionals must observe the general rules for hospital hygiene and infection prevention.

 <p>NOTE</p>	<p>iuvas medical GmbH accepts no liability for damage arising from the use of the sippa home with accessories made by other manufacturers.</p>
 <p>CAUTION</p>	<p>Small parts contained may pose a risk of choking if swallowed. Keep small parts out of the reach of children.</p>

2 Product description

2.1 Specifications supplied



The specifications vary according to the set supplied. The specifications of your set are shown in the table below.

Article number	Components included
4260551630309	Cup, retaining ring, pad, lid
4260551630316	Cup, retaining ring, pad, lid, handle, valve
4260551630408 4260551630903	Pad
4260551630507	Handle, valve
4260551630606	Cup
4260551630705	Lid
4260551631108	Handle
4260551631207	Valve
4260551631009	Retaining ring

The specifications supplied also include an instruction manual.

Please immediately check that the product supplied is complete and undamaged on delivery. If the item is damaged or incomplete, please immediately inform the dealer from whom you have purchased the **sippa home**.



2.2 Intended purpose

The medical product **sippa home** is intended as a drinking aid for persons who have dysphagia and/or a risk of pulmonary aspiration. Because the liquid level remains constant, users can drink with their head tilted forwards and their chin lowered towards their chest. Having your head in that position makes drinking safer and reduces the risk of pulmonary aspiration.




The **sippa home** can be used for persons with difficulty swallowing, dysphagia, drinking difficulties and/or restricted mobility of the head, neck or arms.

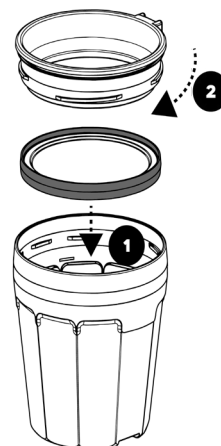
3 Use

Using the **sippa home** with the **pad** increases safety during the process of drinking. With the aid of the patented sip-pa-mechanism, the user's head position does not need to be altered while drinking.

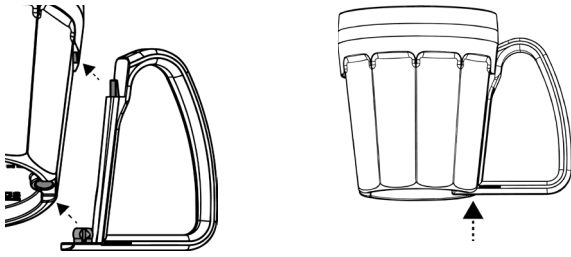
 <p>NOTE</p>	<p>Risk of damage: Note the sensitivity of the pad. Do not use any sharp objects when assembling or using the product.</p>
 <p>NOTE</p>	<p>Risk of damage: Stirring with an object may damage the pad. Please stir the drink in a different receptacle.</p>

3.1 Assembling the sippa home drinking aid

 <p>NOTE</p>	<p>There are various versions of the sippa home drinking aid that can be used.</p>
 <p>CAUTION</p>	<p>Risk of contamination: Make sure you observe the rules of hygiene when assembling and using the product.</p>
 <p>NOTE</p>	<p>Risk of damage: Always check all individual parts before use. Replace any parts that are broken, misshapen or show significant discoloration. Parts that have passed their use-by date must not be used. Damaged individual parts and incorrect assembly may impair function and, therefore, use of the product.</p>



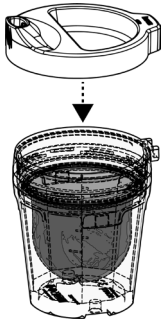
Place the **pad** in the **cup**, screw the **retaining ring** securely in place with a twist.



Handles can be attached to the sides of the **cup** as required. Simultaneously, slide the tab at the top and the button at the bottom into the fixings provided until they snap into place.



To fit the **valve**, turn the **lid** over and insert the **valve** into the recess provided. Press firmly until the retaining tabs snap into place on the right and left with a click.



Fit the **lid** on the **cup**.

If the **sippa home** is used without the **pad**, the **retaining ring** is not required.

3.2 Filling the sippa home drinking aid with pad

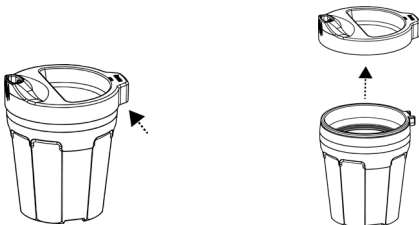


NOTE

Risk of incorrect use:

When using the **sippa home** with the **pad**, note that the **retaining ring** must be securely in place when filling.

Take off the **lid**.



NOTE

Risk of overfilling:

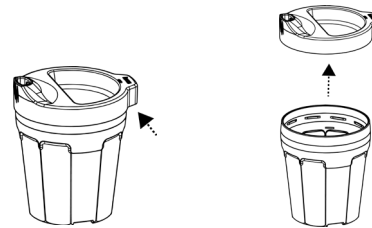
When first using the **pad**, fill the **sippa home** very slowly with tap water in order to pre-expand the diaphragm. Then empty the **sippa home** again. After that, you can fill the **sippa home** normally.

Pour the liquid onto the **pad** and the **pad** will expand accordingly. You can check on the expansion through the side viewing windows in the **cup**.



3.2.1 Filling the sippa home drinking aid without pad

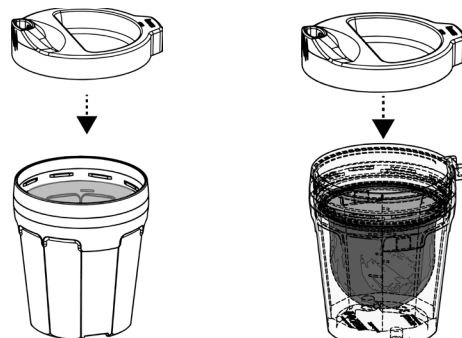
Take off the **lid**.



Pour liquid into the **cup**.







If a means of preventing spillage is required, the **lid** must be fitted.



If using different liquids one after the other, rinse out the **pad** under running water after each use. Remove excess water through the spout and fill the **sippa home** as described.

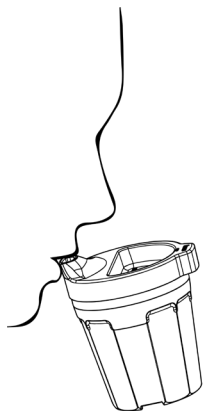
3.3 Drinking

 CAUTION	<p>General note:</p> <p>The sippa home enables safe ingestion of fluids because of the chin-down position required. That compensatory method is employed to prevent and reduce pulmonary aspiration. However, the method does not offer hundred-percent protection against pulmonary aspiration. Therefore, you should pay close attention to any signs of pulmonary aspiration.</p>
 CAUTION	<p>Risk with hot drinks:</p> <p>Because of the air cushion between the diaphragm and the inside wall of the cup, it is possible for the actual temperature of the liquid to be misjudged.</p>
 NOTE	<p>General note:</p> <p>The valve prevents the liquid running out if the cup tips over. Furthermore, the valve prevents the fluid from coming out if the user's head is tilted too far.</p>
 NOTE	<p>Risk of damage:</p> <p>Do not use a straw as an additional aid. Inserting a straw may result in damage to the diaphragm.</p>

Drinking with pad:

- o All individual parts must be firmly attached.
- o Adopt an upright and stable sitting position.
- o Move your chin towards your chest.
- o Drink the liquid in that position. You do not need to change the position of your head.
- o You can use the sippa home with or without the **lid**. The same applies to the **valve**.

Drinking method 1
(With **lid**)




Drinking method 2
(Without **lid**)




4 Preparation

4.1 General details

 CAUTION	<p>Risk of contamination:</p> <p>Preparation of the sippa home must be performed using suitable validated methods such that the success of the method is verifiable and the safety and health of the user is not endangered.</p> <p>Pay attention to the manufacturer's instructions regarding cleaning agents and disinfectants. The instructions for preparation meet the requirements of ISO 17664: 2018-04.</p> <p>The effectiveness of the preparation method has been validated by an independent laboratory that is certified to ISO 17025.</p>
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4.2 Limits of preparation

 NOTE	<p>Risk of damage:</p> <p>Do not expose the sippa home to temperatures higher than 100°C.</p>
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4.3 Preparations for cleaning

- o Remove the **lid** from the **cup**.
- o If the **valve** is fitted in the **lid**, remove it. To do this, bend the retaining tabs outwards.
- o Release the **retaining ring** with a twist.
- o Remove the **pad** from the **cup**.
- o If the **handles** are fitted, remove them.

4.4 Cleaning and disinfection

 NOTE	<p>When choosing cleaning agents and disinfectants, pay attention to compatibility with the material used as otherwise the possibility of damage to the sippa home cannot be ruled out.</p>
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4.4.1 Machine preparation

Equipment:

- o Standard dishwasher with 70°C programme
- o Cleaning agent comparable with validated method (see Validation)

For instructions on reprocessing in professional applications, please contact: contact@iuvas.de

Carrying out machine preparation:

- o Place product components in the dishwasher in a way that they can be optimally cleaned.
- o Position the pad firmly and securely in a basket where it is protected against sharp objects.
- o Select a suitable washing programme and cleaning agent.

Validation:

The process is validated if using the following:


- o Bosch brand dishwasher SPS24CW00E, Program Intensive 70°
- o Somat classic dishwashing tabs

Visual inspection:

Always check product components for damage after cleaning/disinfection and replace where necessary.

Replacing the **pad** after 10 days is recommended.

4.5 Storage

 NOTE	Risk of damage: Keep all parts of the product in a dry and dust-free location where they are protected against contamination.
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5 Miscellaneous

5.1 Technical data

Material	Components
Polypropylen	Lid, retaining ring, handles
Silicone	Pad
PBT	Pad
SMMA	Cup, valve
Stainless Steel	Valve

5.2 Disposal

The **sippa home** components and accessories can be disposed of as normal household waste provided the local regulations in the country of use do not specify otherwise.

5.3 Contact

For information of any kind about the product, if any faults occur or if you have any questions about handling the product, please contact the iuvas Service Centre:

Tel: +49 (0) 89 215 460 332

E-mail: contact@iuvas.de