

HELPIE® Flexible biteblock, tongue cone and suction

INSTRUCTIONS FOR USE

Thank you for choosing **HELPIE**.

We hope this treatment tool will be a real helper in your valuable work.

Please read these instructions carefully before use. These instructions only apply to the **HELPIE** treatment device, which is a single use product intended to be used in dental procedures by dental professionals and should only be used for the treatment of humans. The client should not be left unattended with the treatment device in their mouth at any time. If the treatment device is used for any other purpose or in violation of these instructions, the manufacturer is not liable for any resulting damage.

The **HELPIE** biteblock, tongue cone and suction is a one-piece, factory-clean and disposable care product. Due to human anatomy and to ensure comfort, there are separate pieces for the right and left sides of the mouth. The treatment device helps to keep the patients mouth open, preventing the mouth from closing during the operation, keeping the tongue out of the operating area, while sucking fluids (saliva, blood, etc.) from the mouth.

HELPIE is easy to use:



1. Start by pushing and twisting **HELPIE**'s own suction adaptor hose (within the package) into the front hole of **HELPIE**'s suction hole.

2. Continue by pushing and twisting the other end of the adaptor-hose into the saliva-suction apparatus. The adaptor-hose is suitable for general saliva-adaptors. Turn the saliva suction-apparatus on and **HELPIe** is now ready for use.



3. Ask your patient to open their mouth wide open once or twice, so that the jaw muscles can stretch a bit. This helps placing **HELPIe** in the patient's mouth. **HELPIe** should be placed on the opposite side of the mouth versus the intended operating area to ensure the work area is exposed.

4. When placing the **HELPIe** in to the patients mouth; the bite-block should be placed between the upper and lower teeth as far back in the mouth as possible, yet so that the patient still finds the placement comfortable.

The tongue usually settles on its own in the tongue cone when placed. If necessary, the client can be asked to raise their tongue when placing the **HELPIe** in their mouth. The patient can also place the **HELPIe** themselves to ensure the most comfortable fit and avoid the activation of any potential gag-reflex.



5. **HELPIe** guarantees a good working space, keeps the tongue away from the operating area and sucks liquid from the mouth keeping the molarteeth dry during the operation.

As the surface of the **HELPIe** is slightly curved, it is possible to adjust it when the customer is in a sitting, semi-sitting or lying position. The adjustment can be done by tilting the **HELPIe** up or down slightly to allow optimal suction for different situations. The position of the suction tube in the mouth can be changed by moving the **HELPIe** between the teeth in the lateral direction towards the pharynx. This procedure may be necessary if the client has larger thoraces or a narrower lower jaw.



Size Selection:

Select the size according to the opening size of the patient's mouth so that the HELPie biteblock is smaller than the patient's maximum opening. **THE MOUTH MUST NOT REMAIN OPENED TO THE MAXIMUM!**

Other notes

Check that the product packaging and bags are un-damaged before opening them. If they are damaged, do not use the product or dispose of the packaging, contact the seller or the manufacturer immediately. Retrieve the LOT number from the label of the package (important for traceability) and wait for instructions from the seller or manufacturer to resolve the issue.

In the event of any possible accident using **HELPie**, inform the seller or the manufacturer immediately. Do not dispose of the product or the packaging. Retrieve the LOT number from the label of the package (important for traceability) and wait for instructions from the seller or manufacturer to resolve the issue.

Storage:

Store **HELPie** at normal room temperature away from the sun.
Do not use this product after the date of expiry stamped on the packaging.
Disposal: The product and the packaging bag should be incinerated.

Specifications:

HELPie is a CE marked product. It meets the requirements of Council Directive EU 2017/745 on medical devices and the laws issued pursuant to the Directive (including Act 719/2021 on healthcare devices and supplies as an MD1 product.)

The material used in the manufacture of the product is plastic approved for the food and healthcare industry and is manufactured in accordance with ISO 9001: 2015, ISO 14001: 2015 and 13485: 2016.

Manufacturer:



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