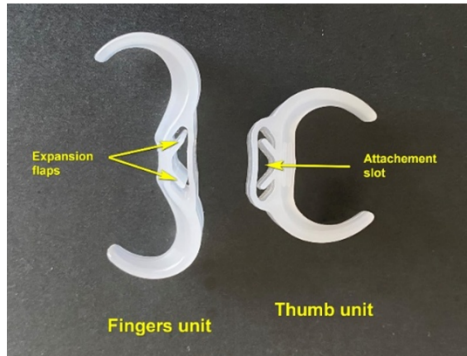


SurgiWings

Instructions for Use

IMPORTANT

- This product is intended to be used by a professional with appropriate training and experience.
- This device is not intended to be used in sterile procedures.
- Do not attempt to use the SurgiWings before completely reading and understanding the information contained in this Instructions for Use.



Intended Use: As a support device, SurgiWings are intended to increase stability of manipulations and ease of forceps use and decrease hand fatigue and discomfort such as cramps and pain.

Contents of Packaging

- Thumb Unit
- Finger Unit
- Instructions for use

How Supplied: Devices are packaged in sets that contain 1 Finger unit and 1 Thumb unit. Units are provided clean and non-sterile.

Storage: Devices should be stored at room temperature: 22° C to 26° C (72° F to 78° F). Device storage temperature must not exceed 70° C (158° F).

Warnings ⚠

- Do not use in sterile procedures. If device is used in a sterile setting, it may lead to surgical site infection.

Precautions

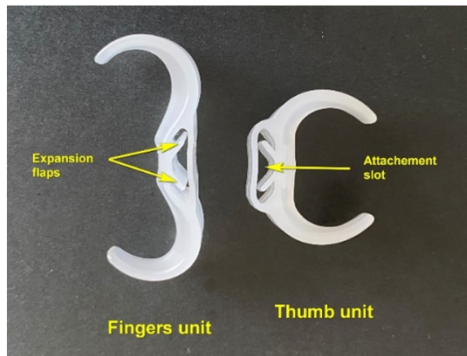
- If there are any variations between these Instructions for Use and your facility's policies, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with device.
- SurgiWings should only be used with flat handle or rounded surgical forceps (i.e., DeBakey, Resano) with minimum handle width of 11.8 mm and minimum thickness of 2.8 mm.
- The SurgiWings are disposable and intended for single use only.
- It is recommended that the thumb unit be closer to the forceps' hinge than the finger unit.
- It is recommended that the thumb and finger units do not overlap, as this may hinder the pinching ability of the forceps.
- If the forceps are too wide, the SurgiWings cannot properly slide up the forceps.
- Having the SurgiWings too close to the ends of the forceps decreases the working length of the forceps.
- Prior to use, inspect device to ensure it fits snug on the compatible forceps and that there is no physical damage to the device. Refer to the figure shown to view proper physical condition of device.
- User shall test the fit and function of the SurgiWings prior to first use to become familiar with their position and use.
- Do not use SurgiWings if it has physical damage.
- Do not use SurgiWings if package is open or damaged.
- Avoid bending or twisting, as it may damage the device.
- Do not re-process.
- Do not attempt to sterilize

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SurgiWings Instructions for Use

Directions for Use

1. Determine the correct size of SurgiWings to use based on glove size. Users with glove size 6.5 or smaller should use the small size (white), and surgeons with glove size larger than 6.5 should use the medium size (gray).
2. Insert the SurgiWings into the forceps through the attachment slot. SurgiWings should face outward. The "Thumb" unit is naturally positioned closer to the forceps hinge, and the "Fingers" unit is placed closer towards the tips. Units have a symmetrical shape and can be interchangeably used in right and left hands without needing to reposition the units. Ensure that the units do not overlap. Final location of the units on the forceps depends on preferences of surgeon.
3. Proceed as usual with normal operating procedures using SurgiWings as a support attachment for the fingers.
4. We recommend using SurgiWings on a single pair of forceps for the entire operation. However, it is possible to place SurgiWings onto another set of forceps during a single case if necessary. The used attachment slot will accommodate replacement forceps with same or thicker handles that were used previously. Although not recommended, if they are transferred from wider to thinner forceps, tightening the expansion flaps is necessary. Per user's discretion insert closed ends of forceps or scissors to push expansion flaps towards each other.



Note: SurgiWings are for single use and not intended for repeat use between different cases. To clean for use during the same case, rinse in a saline solution.

For a more detailed Instructions for Use:



Or visit: iowamade.org/instructions-for-use

MADE, The University of Iowa
25 South Grand Ave
Iowa City, IA 52242
(319) 384-3425

For product ordering or reporting of adverse events, please call (319) 384-3425, email iowa-made@uiowa.edu, or visit iowamade.org

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