



THE UNIVERSITY OF IOWA

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.

Device Description

SurgiWings is a forceps-based support attachment for use during operations. 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. This device has been shown to increase steadiness of manipulations and augment hand relaxation during use of forceps in a study involving surgeons and surgical trainees¹.

The device consists of “Thumb” and “Fingers” units that are positioned on the forceps shafts based on user’s preference. While optimally both units are used on the forceps simultaneously, the Fingers or Thumb unit may be used alone based on user preference.

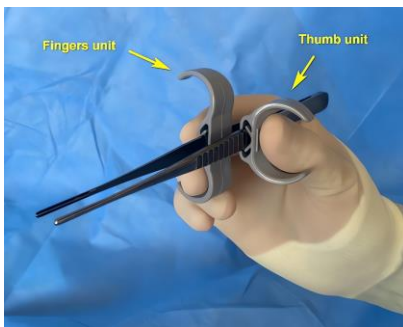


Figure 1. SurgiWings in use.

Sizes:

SurgiWings are manufactured in medium (gray color) and small (white color) sizes. Medium (gray) SurgiWings are recommended for users with gloves

larger than size 6.5 and small (white) SurgiWings are recommended for users with glove size smaller than 6.5. Final size selection is up to an individual user.

Compatible forceps types:

SurgiWings were designed as an ergonomic attachment for commonly used forceps such as DeBakey, Resano, or similar instruments. SurgiWings work with forceps with a minimum handle width of 11.8 mm and minimum thickness of 2.8 mm. It is recommended that users test SurgiWings on the forceps of their preference to confirm acceptable fit and function prior to use. Some wider handles will require a certain force for advancement through the slots. SurgiWings are made of a high-quality polypropylene and will tolerate moderate expansion.

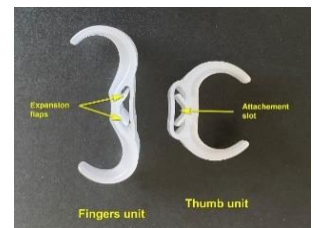


Figure 2. SurgiWings and their labeled components.

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 clean.

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).

Indications for Use

SurgiWings are recommended for users who perform long and arduous procedures and users with unfavorable hand conditions. SurgiWings are meant to aid and enhance function but are not a replacement for proper training and technique.

Contraindications

- No contraindications

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 Figure 2 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

Adverse Events

Patient Population

In a study involving 21 surgeons and surgical trainees, no adverse effect on speed and accuracy of peg board performance was observed¹.

Observed Adverse Events

Zero adverse events have been observed using the SurgiWings.

Adverse Event Reporting

Any adverse event involving the SurgiWings should be reported to Iowa MADE customer service. To contact, call (319) 384-3425 or email iowa-made@uiowa.edu

Directions for Use

1. Ensure device arrives packaged properly and the device functions as intended.
2. 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 users with glove size larger than 6.5 should use the medium size (gray).

3. Insert the SurgiWings into the forceps through the attachment slot. Make sure the SurgiWings face outward, as shown in Figure 3. “Thumb” unit is naturally positioned closer to the forceps hinge while 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 largely depends on the individual preferences of the user.

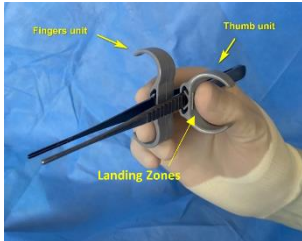


Figure 3. SurgiWings in use.



Figure 4. Landing zones of SurgiWings.

The exact position of fingers on the SurgiWings is determined by the user per individual preference and may depend on the length of the forceps used. Generally, it is suggested to place fingertips on the landing zones of the Thumb and Fingers units (as pictured in Figure 3 and Figure 4). On the Fingers unit, users can choose the position of the index finger either on the upper wing or on top of the attachment slot based on the preferred way of holding forceps in an everyday practice.

4. Proceed as usual with normal operating procedures using SurgiWings as a support attachment for the fingers, as seen in Figures 5, 6, and 7.



Figure 5. View of each finger on the landing zone of the Thumb and Finger units.



Figure 6. Side view of each finger on landing zones.



Figure 7. Side view of SurgiWings position on forceps.

5. 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

attachment slot that has been used will accommodate replacement forceps with the 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. This is pictured in Figure 8.



Figure 8. Use of forceps to tighten expansion flaps.

Instrument Cleaning and Sterilization

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 sterile saline solution.

Reference:

1. Arshava EV et al. “Surgical Wings”: Forceps-Based Device Improves Surgeon Hand Ergonomics. Presented at the American College of Surgeons Clinical Congress, San Diego, October 2022.



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 THE UNIVERSITY OF IOWA



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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