Watson Flex

RETRACTOR SYSTEM

Biophyx Surgical, Inc.

To find out more about the Watson Surgical Retractor System, or to place an order, contact:

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INSTRUCTIONS FOR USE
MODEL WFRSSQ170

R_x Only

DEVICE DESCRIPTION / INTENDED USE

The Watson Flex Retractor System is a single-use retractor that provides unparalleled access and visualization across a wide range of surgical applications. It is comprised of a self-retaining Retractor Frame with an Adhesive Stability Membrane and uses compatible Elastic Stays, such as those utilized with the Cooper Lonestar systems. The Elastic Stays (not included) are single-use, disposable devices that are used to adapt the Retractor Frame to the patient's anatomy. The flexible design of the system allows for adjustment and repositioning of the Watson Flex Retractor System during surgical procedures and provides optimal exposure of the surgical site.

INDICATIONS FOR USE

The Watson Flex Retractor System is indicated for use to provide incision retraction and to aid in visualization during surgical procedures.

INTENDED USERS

The Retractor system is used by healthcare professionals, nurses, or technicians in a professional environment such as a hospital, clinic, or doctor's office. Patients are selected based on their surgical needs and the need of the medical healthcare professionals for incision retraction and to aid in visualization during surgical procedures.

PATIENT POPULATION

The Watson Flex Retractor System is intended to be used by healthcare professionals on human patients. The patient population includes patients undergoing surgical procedures in a professional environment such as a hospital, clinic, or doctor's office. The system is used during general operations to retract tissue in the surgical wound site. There is no restriction on age or gender.

WARNINGS

• For single use only. Do not reuse, reprocess, or re-sterilize the device. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

• Do not use if the sterile barrier on the packaging is damaged.

• Do not use if the device has been opened or damaged.

• Do not use past the expiration date.

• Federal Law (USA) restricts this device to sale by or on the order of a trained physician.

• Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices. PLEASE NOTE: If a serious incident is suspected from using the Watson Flex Retractor System, report the details of the incident to Biophyx Surgical via email to Info@BiophyxSurgical.com and to the local Health Authority in your country. A serious incident is one that may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

CAUTION

• To avoid damage to the device, avoid bending the device to a radius smaller than 40mm.

DIRECTIONS FOR USE

1. Ensure that the area to which the retractor will be applied is free and clear of surgical instruments, bodily fluids, or other contaminants that may interfere with the adhesive contact.
2. Remove the Stability Membrane's release liner starting by pulling the 'Solid 1'. Invert and place over the surgical site, aligning the open area within the frame with the center of the incision. Continue removing the sides of the release liner by pulling the 'Hollow 1' and firmly apply the Stability Membrane to the operative site.
3. Connect Elastic Stays to the retractor to establish the desired tissue retraction.
4. As dissection progresses, the position of Elastic Stays can be advanced into deeper tissue. Add or reposition Elastic Stays to desired angle for needed retraction.
5. To remove or replace the device intraoperatively, remove the release liner by pulling the 'Solid 2' and gently peel the release layer away from the stability membrane. If the surface of the stability membrane is contaminated with fluids, wipe clear with surgical sponge. Apply a new retractor following steps 1-2, above.