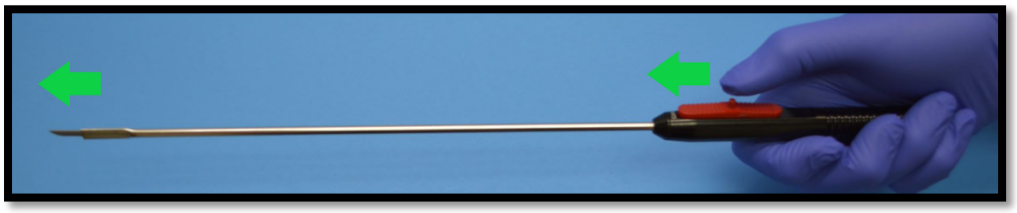
**Instructions for Use: Mainstream Medical Devices Retractable Surgical Knife**

This single use instrument is intended for use in surgical procedures.

**Description**:

The retractable surgical knife consists of a stainless-steel blade attached to a handle made of aluminum. The knife is retractable using a plastic trigger on the handle. When ready to use, extend the knife by pressing down on the trigger and sliding the actuator forward. The knife will lock in the extended position. When ready to dispose, retract the knife by again pressing down on the trigger and sliding the actuator back. When locked in the retracted position, the knife can be disposed in a non-sharps bio-hazard trash container. Do not reuse this product.



**Intended Use**:

Mainstream Medical Devices Retractable Surgical Knives are manually operated devices intended for use during surgical procedures. If there is any doubt or uncertainty concerning the proper use of this instrument, please contact Mainstream Medical Devices for instructions. The knife is intended for manually cutting tissues and bone during surgical procedures.

**General Warnings, Cautions and Precautions:**

The methods of use are to be determined by the user's experience and training in surgical procedures.

During use, avoid putting excessive force or strain on the blade in order to help prevent breakage. Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting.

Keep in mind that surgical knives are sharp instruments. Take proper precautions in handling the Knife so as not to injure yourself or others before, during, or after use.

This instrument should be treated as any precision instrument. To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used.

Knives marketed and sold by Mainstream Medical Devices are Single Use Devices and are not intended to be re-used, re-sterilized or re-packaged.

**Disposal**:

Once the device has been used, retract the knife and dispose in a non-sharps biohazard container. Do not reuse the knife.

**Hazards and Risks related to Re-use of a Single Use Device:**

Material:

Autoclave Self-Destruct™: The Mainstream Medical Devices Retractable Surgical Knife has an added safety feature that will self-destruct at autoclave temperatures, resulting in a product that will not function. Do not attempt to autoclave and/or reuse these knives. The internal mechanisms and the endcap on the handle will deform if it is put in an autoclave. The device will seize and loose functionality. If the endcap is deformed or missing before use, this is a visual queue the device has been autoclave and is not to be used.

Biological:

Cross-patient infection may occur as a result of the following residuals: biofilms, biological material, pathogens, prions, etc. remaining on a device after initial use.

Pyrogen reactions: Devices can be contaminated with endotoxins that can cause pyrogenic reactions if re-used.

Re-use of a single-use device is prohibited. Hazards and risks associated with re-using this product are not limited to the above referenced examples and should be considered when using this product.

Intact end cap (ok to use)

Self-destructed end cap (do not use)

**Packaging**:

Mainstream Medical Devices Retractable Surgical Knives are supplied as sterile. Sterile instruments will be clearly labeled as such on the package label. The sterility of instruments supplied sterile can only be assured if the packaging is intact. Packages for sterile components should be intact upon receipt. All instruments should be carefully checked for signs of damage, prior to use. Damaged packages or products should not be used and should be returned to Mainstream Medical Devices. Only sterile instruments should be used in surgery.

**Examination**:

Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, trigger, cleanliness, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of deformation, excessive wear, damage, or that are incomplete or otherwise non-functional.

If the endcap on the handle is missing or deformed, do not use the knife.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

**Further Information**:

In case of complaint, or for supplementary information, please contact Mainstream Medical Devices.

**Product Complaint**:

Any Health Care Professionals (e.g., customer users of Mainstream Medical Devices), who have any complaint or who have experienced dissatisfaction in the product's quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or Mainstream Medical Devices. Further, if any instrument "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor or Mainstream Medical Devices should be notified immediately. If any Mainstream Medical Devices product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor or Mainstream Medical Devices should be notified as soon as possible by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint.

**Contact**:

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