

# INSTRUCTION FOR USE DISPOSABLE COLD BIOPSY FORCEPS

## DEVICE DESCRIPTION

- The Horizons International Corp. Biopsy Forceps (Cold) are a single use, sterile, disposable, endoscopic instrument primarily designed for endoscopic use within a body cavity via an endoscope retrieve tissue and cell samples.
- The cold biopsy forceps must be used without electro-surgical unit.

## INTENDED USE

- Horizons Disposable Cold Biopsy Forceps is intended to be used in the flexible endoscope for Transendoscopic, dissecting and grasping tissue for biopsy.

## WARNINGS

- Training and understanding with endoscopic /Cold Biopsy Forceps is essential before performing biopsy.
- A physician who has adequate experience and training should only perform endoscopy.
- Please read these instructions carefully, failure to follow these instructions may lead to serious medical consequences.
- This device is for single use only. Device should be stored at room temperature 20°-25°C (68°-77 °F). Do not reuse, reprocess or re-sterilize. Reuse, re-processing 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 also create a risk of contamination of the device and/or cause patient infection or cross-infection including, but not limited to, transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury illness or death of patient.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and hospital, administrative and/or local government laws and regulations.



## PRECAUTIONS

- The device is ETO sterile. Do not use this device if there is any evidence of damage to the sterile package.
- Do not use this device for any purpose other than the stated intended use.
- Verify the expiration date on the package label of sterile devices prior to using the product. If the expiration date has lapsed, do not use or re-sterilize the device.

## INSTRUCTIONS FOR USE

1. Select the forceps compatible with the biopsy channel of the endoscope.
2. Open the sterile pouch. Remove and inspect forceps for obvious damage. Uncoil the forceps and actuate the handle several times to be sure the biopsy cups open and close properly. Should there be evidence of damage, or if the unit is not functioning properly, DO NOT USE THIS PRODUCT.
3. After endoscopic visualization of the area for biopsy, place thumb in loop of forceps handle, rest middle and index finger (placing gentle pressure) on the handle's spool edge.
3. With gentle pressure on the handle to keep the cups closed, insert the forceps through the biopsy channel of the endoscope using short strokes until the cups are visualized exiting the endoscope.
4. Maneuver the forceps towards the targeted site. Open the cups by activating the handle. Advance the opened forceps over the targeted site and close the forceps. Use only enough pressure to bite the tissue. Over-exertion could cause forceps to become misaligned or to fail.
5. Continue to apply gentle pressure on the handle as the forceps are withdrawn from the channel.
6. Remove and prepare the tissue specimen according to standard technique for histologic evaluation.




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

















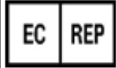




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EC REP

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 San José, San Pedro

Symbol	Description	Symbol	Description
	Contry of manufacture		Translation
	Date of manufacture		Do not use if package is damaged
	Use by date		Do not re-use
	Batch Code		Consult instructions for use
	Catalogue number		Important cautionary information
	Sterilized using ethylene oxide		Do not re-sterilize
	Caution Federal (USA) law restricts this device to sale by or on the order of a physician		Latex Free
	Keep Away from Sunlight		Keep Dry
	Type BF applied part		Medical Device
	Importer		Authorized Representative
	Unique device identifier		Sterile Barrier