

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.
- The cold biopsy forceps must be used without electrosurgical unit.

INTENDED USE

- Horizons Disposable Cold Biopsy Forceps is intended to be used in the flexible endoscope for, 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.

CONTRAINDICATIONS

1. General medical condition that would not allow tolerance to endoscopy and/or other manipulation required.
2. Patients demonstrating resistance.
3. The device may not be used for applications other than for which it is intended.

4. The device must not be passed through an incompatible endoscope.
5. The device must not be re-sterilized and reused.
6. The device is not intended to be implanted

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.
4. 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
5. 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.
6. Continue to apply gentle pressure on the handle as the forceps are withdrawn from the channel.
7. Remove and prepare the tissue specimen according to standard technique for histologic evaluation.

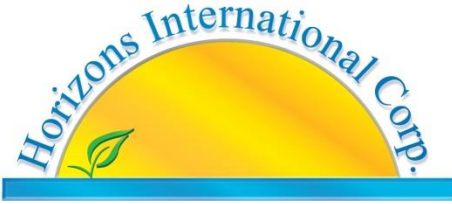
Any serious incident that has occurred in relation to the device must be notified to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Accessing Electronic Versions of IFU - Step-by-Step Guide

1. Start by opening a web browser on your device and enter the official website URL for Horizons Corp:
<https://www.horizonscorp.com>.
2. Once the website loads, you will be directed to the main page, which features various tabs and options. Look for the tab labeled "Products."
3. Click on the "Products" tab to access a dropdown menu that categorizes different product options. Within this tab, you can choose the specific product category that aligns with your requirements. Alternatively, you can enter the following URL <https://www.horizonscorp.com/products> which will take you directly in the product pages
4. Within your chosen product category, you will find a list of individual devices or models. Select the specific device that corresponds to your needs.
5. After selecting the device, the main page will load with comprehensive information about the chosen product. At this point, you will have multiple options to explore, including "Specifications," "IFU," "Brochure," or "Video."
6. To access the Instructions for Use (IFU), click on the "IFU" option. This will lead you to a section where the latest revision of the readable IFU is presented in an electronic format
7. In the IFU section, you will have the opportunity to view and read the most recent version of the IFU directly on the webpage. Additionally, if you prefer, you can choose to download a PDF copy of the IFU for offline reference.

8. If you are interested in accessing previous revisions of the IFU, you can find these versions within the same IFU section. Look for the category labeled "Previous Versions."

By following these steps, you will be able to access and utilize electronic versions of the Instructions for Use (IFU) for Horizons Corp products. Remember to make use of the IFU to ensure the proper and safe use of the products as intended.



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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