



GIJaw™
Single-Use
Biopsy Forceps

Instructions for use.
Read carefully prior to use.

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

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Diversatek Healthcare GIJaw™ Single-Use Biopsy Forceps
Instructions for Use.
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INTENDED USE

The GIJaw™ Single-Use Biopsy Forceps is used to obtain tissue samples within the gastrointestinal tract during endoscopic procedures for pathological analysis.

<u>Part Number</u>	<u>Description</u>
1190-01	2.3 mm cup, serrated, needle, 230 cm
1190-02	2.3 mm cup, serrated, no needle, 230 cm
1190-03	2.3 mm cup, serrated, needle, 180 cm
1190-10	1.8 mm cup, smooth, no needle, 160 cm

CONTRAINDICATIONS

Including (but not limited to) coagulopathy.

WARNINGS AND PRECAUTIONS

1. Do not use if the package is damaged.
2. Do not use expired product.
3. Read the IFU carefully prior to use.
4. Prior to use, examine the device for any damage or malfunction such as bent components or inability to open and close the jaws. Do not use if damaged.
5. During use, gently advance the forceps to the biopsy site through the endoscope channel. If resistance is encountered during advancing, do not apply force to avoid damage to the endoscope.
6. This device is intended for single-use only. Do not re-use, reprocess, or re-sterilize single-use products. After use, dispose of according to local and institutional guidelines.
7. This product must be used by a trained physician.
8. Remove the protective cap prior to use.

INSTRUCTIONS FOR USE

1. Observe the biopsy site through the endoscope and select suitable product for use.
2. Close the forceps cups by pulling the handle towards the thumb loop and insert into the endoscope biopsy channel.
3. Slowly advance the forceps until it is endoscopically visualized exiting the scope.
4. Advance the forceps to the biopsy site, open the cups, and advance onto tissue sample.
5. Pull the handle towards the thumb loop to close the cups around the tissue.
6. **Caution:** If the forceps fail to close, remove endoscope and biopsy forceps together from the patient, then manually close the cups and withdraw biopsy forceps from endoscope.
7. Maintain force on the handle to keep cups closed and gently withdraw forceps from endoscope.
8. Prepare specimen for examination according to local and institutional guidelines.

POTENTIAL COMPLICATIONS

Those associated with gastrointestinal endoscopy include, but are not limited to: mucosal tearing, swelling, bleeding, perforation, and infection.

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DESCRIPTION OF SYMBOLS USED ON LABELS



Manufactured for



Use-by date
(YYYY-MM-DD)



Lot Number



Part number



Sterilized using ethylene oxide



Temperature limit



Humidity limitation



Atmospheric pressure limitation



Keep dry



Do not use if package is damaged



Keep away from sunlight



Do not re-use



Consult instructions for use



Not made with natural rubber latex