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TYPE: INSTRUCTIONS FOR USE

ID: W-7.5.3-W1A

ADDENDUM to IFU W-7.5.3-W1
for MultiCROC® (aka CROC® Multiple Sample Biopsy Forceps) models.

IMPORTANT: READ AND FOLLOW ALL THE INSTRUCTIONS IN THE IFU BOOKLET W-7.5.3-W1 AND THE INSTRUCTIONS IN THIS ADDENDUM BEFORE USING THE MULTICROC® FORCEPS.

INTENDED USE

The CROC® Multiple Sample Biopsy Forceps (only model numbers starting with “MC”) have the capability to collect multiple biopsies in a single pass of the device through the channel of the endoscope (up to 5 tissue samples per single pass). Total number of biopsies collected will depend on tissue type and user’s preference.

CAUTIONS

- Do not attempt to pass the instrument when the scope is excessively articulated. Doing so will damage the endoscope
- MultiCROC® biopsy forceps jaws are designed to facilitate collection and storage of multiple biopsies. During each subsequent biopsy, tissues samples are pushed toward the back to fill-up the jaw’s elongated cups. Always monitor amount of samples stored inside the jaw’s cups and do not overload them. Overloading may result in crush artifacts and lost samples.

WARNING

- MultiCROC® biopsy forceps jaws have a smaller aperture, when opened, and a longer distal end than standard biopsy forceps. Do not apply excessive force to advance the forceps into the tissue. Applying excessive force may result in perforation of the biopsy site.
- The jaws are designed to travel about 1-2mm back during closing of the device. If necessary, compensate for this movement by gently forwarding the biopsy forceps toward the biopsy site. Make sure to apply a sufficient force to close the jaws completely. Maintain pressure to keep the jaws closed to retain the sample(s) until the next biopsy is taken.

USE

- To obtain subsequent samples, it is not necessary to withdraw the forceps from the endoscope. Up to five biopsy samples may be taken without withdrawing the forceps from the scope.
NOTE: When performing biopsy in confined spaces such as in the Esophagus, pull jaws closer to tip of endoscope to avoid potential obstruction to jaws during opening. The Jaws may not open fully unless a slight continuous pressure is applied to the handle prior to taking the sample.
NOTE: Do not drag open jaws loaded with harvested samples against the surrounding organ cavity and do not open or close the jaws rapidly. Doing so may result in a loss of tissue samples.
NOTE: If a device is to be reused on the same patient during the same procedure, be sure that all biopsy samples are removed prior to reuse. Failure to do so may result in a misdiagnosis.