

CapsoCam Plus Physician's Instructions for Remote (At-Home) Video Ingestion Administration of Capsule Under Medical Supervision via Video During COVID-19 Public Health Emergency

Supplement to "IFU-2796 Capsocam Plus Instructions For Use"

The below instructions pertain to remote administration of the CapsoCam Plus under medical supervision via video during the COVID-19 public health emergency. These instructions are provided as a supplement to the Instructions for Use (IFU-2796) for the CapsoCam Plus and discuss only the instructions that are specific to remote administration of the capsule. As such, the below instructions do not represent the complete labeling for the CapsoCam Plus. Please review IFU-2796 before reviewing this labeling supplement.

Preparation for Use

1. Determine if patient is at increased risk for choking and/or capsule aspiration by remotely administering the **FRM-6286-Patient Risk Assessment Questionnaire** to the patient. If the patient is at increased risk for choking and/or capsule aspiration, do not proceed with remote administration of the capsule.
2. Obtain informed consent from patient according to your facility's policy.
3. Inspect the foil seal. Do not provide capsule to patient if any break in the foil seal or in the foil

itself is observed. For more information, refer to the *CapsoCam Plus Instructions for Use*.

4. Package the **Patient Labeling (ADV-6288)**, CapsoCam capsule endoscope, the CapsoRetrieve capsule retrieval kit, and a glove (you can use any type of disposable glove you have available) for handling the capsule together in the same package. Mail the package to the patient by using your facility's preferred shipping method. Do not mail items if the patient has provided a foreign mailing address.
5. Schedule video call for capsule ingestion.

NOTE:

- **The remote administration of the capsule should be directly visualized by a trained healthcare professional.**
- **Prior to the patient swallowing the CapsoCam Plus, the accompanying adult should be provided a reference for first aid for choking (e.g. https://www.redcross.org/content/dam/redcross/atg/PDF_s/ConsciousChokingPoster_EN.pdf).**

Directions for Use

When you are ready to start the video call, please send an email or text invitation to the patient with a link to initiate the video call.

1. Verify that the patient has received a CapsoCam Plus capsule endoscope, CapsoRetrieve capsule retrieval kit and glove, without any damage to the package or its contents.
2. Verify that there have been no changes in the patient's medical condition and no changes to the patient's answers on the **FRM-6286-Patient Risk Assessment Questionnaire** that would disqualify the patient for remote administration of the capsule.
3. Verify that there is an adult present next to patient during the video call and that this adult is capable and agrees to assist and follow your instructions in event the patient has trouble swallowing the capsule. Verify that the adult has a car available standing by in the event that immediate visit to an urgent care facility is required.

- Instruct the patient to inspect the foil seal. Do not proceed with the ingestion if any break in the foil seal or in the foil itself is observed. For more information, refer to the *CapsoCam Plus Instructions for Use*.
- Instruct the patient to open the capsule package by peeling back the foil cover.
- Instruct the patient to put on the provided glove and remove the plastic lid covering the capsule.
- Instruct the patient to carefully grasp the capsule and pull it out and away from the package without pulling the magnet from the package. Ask them to be careful not to drop the capsule on the floor.
- Instruct the patient to hold the capsule in front of the camera so you can ensure it has been activated. For more information, refer to the *CapsoCam Plus Instructions for Use*.
- Instruct the patient to ingest the capsule with 0.5 liters (~16 fluid ounces) of water. If the patient attempts to swallow the capsule but is unsuccessful, they may attempt to swallow it a second time. If the second attempt is unsuccessful, do not proceed with remote administration of the capsule.
- Once the patient confirms they have ingested the capsule without any issues, you will need to observe the patient for 5 minutes and ask them to take a 1-2 minute walk to ensure there are no breathing difficulties or distress. Ask them to be sure to report to you any breathing difficulties.
- During or after the 5-minute observation period, educate the patient on how to use the retrieval kit. See *CapsoRetrieve Instructions For Use* for more information.

In the event of suspected capsule aspiration, call 911 or immediately instruct the accompanying adult to:

- Get the patient to stand up.
- Position oneself behind the patient.
- Lean the patient forward and give five blows to the patient's back with the heel of their hand.
- Place their arms around the patient's waist.

5. Make a fist and place it just above the patient's navel, thumb side in.
6. Grab their fist with their other hand and push it inward and upward on the patient at the same time.
7. Perform five of these abdominal thrusts.
8. Repeat steps 2-7 (alternating back blow and abdomen thrust) until the capsule is expelled and the patient can breathe or cough on their own.
9. If capsule expulsion is unsuccessful, immediately call 911.

18805 Cox Avenue, Suite 250, Saratoga, CA 95070 • p: 408-624-1488 • info@capsovision.com

The CapsoCam Plus video capsule system is intended for the visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel. © 2020 CapsoVision, Inc. All rights reserved. 05-28-2020