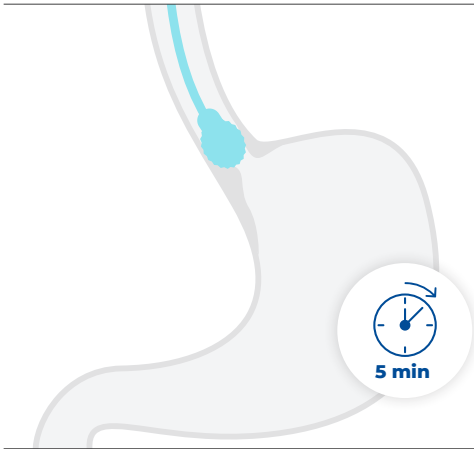


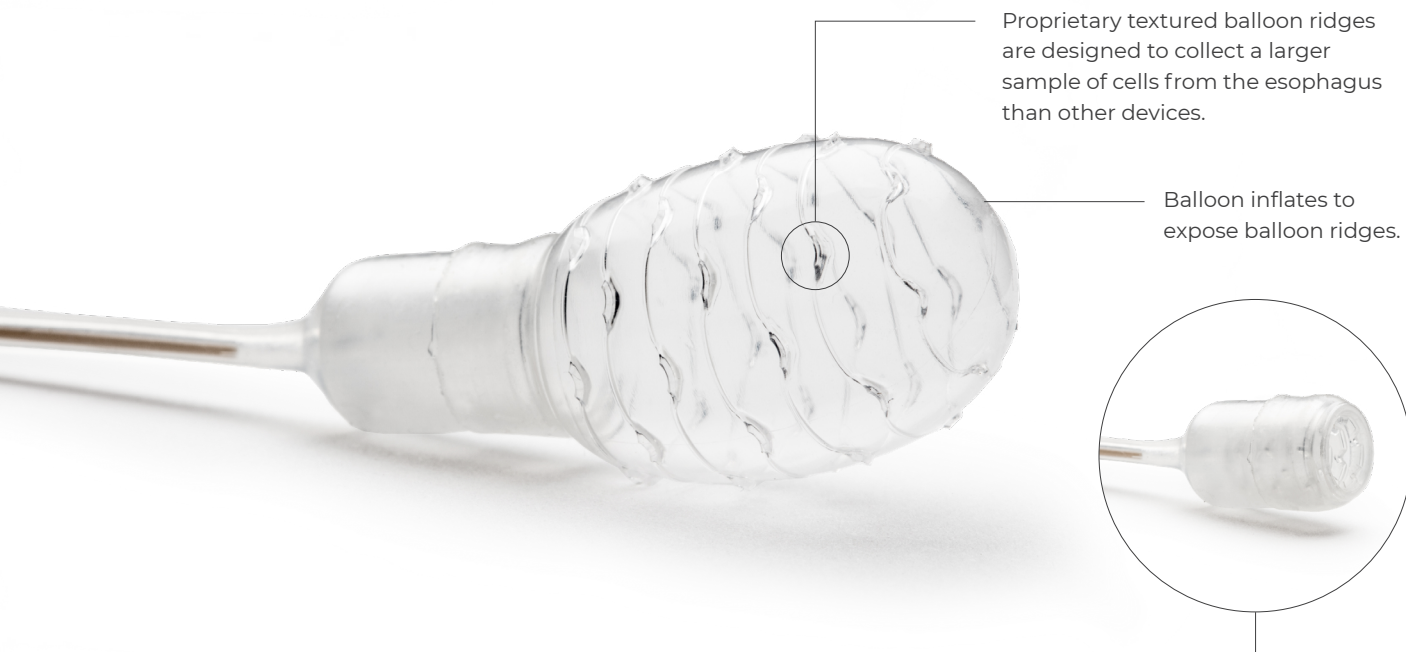
EsoCheck

cell collection device



A non-invasive five-minute office-based procedure to collect cells from the esophagus.

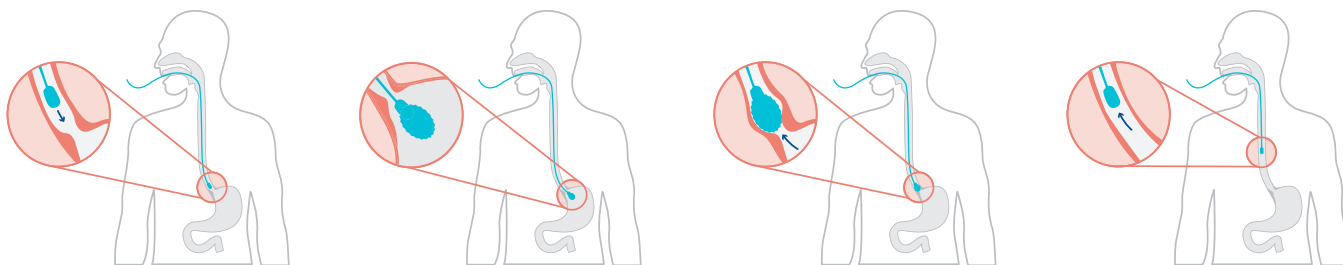
EsoCheck is a cell collection device that is designed to collect cells of a targeted region of the esophagus without the need for endoscopy. The sampled cells can then be subjected to any commercially available diagnostic test.



Collect+Protect™ Technology

protects the collected sample from dilution or contamination during device retrieval.

The Esocheck cell collection device consists of a capsule containing a small balloon with a textured surface to enhance cell collection.



1 Swallow



The patient swallows a capsule, which is attached to a thin catheter, until the capsule reaches the stomach.

2 Inflate



The balloon is inflated to expose the ridges and then withdrawn allowing them swab the targeted area of the esophagus, collecting cells on the balloon's surface.

3 Collect

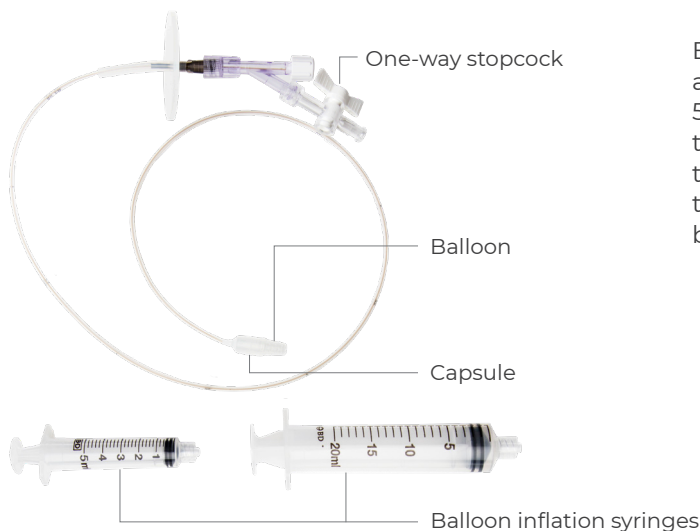


Collect+Protect™ technology pulls the collected cells into the capsule where they are protected from dilution and contamination during device retrieval.

4 Protect



The balloon covered with sampled cells, are placed in a preservation solution for transport to a diagnostic testing facility.



EsoCheck is provided in a kit with the balloon and capsule attached to a 68 cm catheter with 5 cm markings to indicate to the operator when the capsule is in the stomach and when the targeted region of the esophagus has been traversed by sampling balloon, as well as two balloon inflation syringes.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

READ INSTRUCTIONS PRIOR TO USING THIS PRODUCT

WARNING:

- Contents supplied STERILE using an ethylene oxide gas (EO) process. Do not use if sterile pouch barrier is damaged. Report damage to Manufacturer or Principal Investigator.
- Do not use if Package Labeling and Directions for Use are incomplete or not legible
- Store packages in a dry environment and at room temperature
- For single use only. Do not reuse, clean or reprocess or re-sterilize as this may compromise the device ability to perform as intended. Reuse could lead to patient injury or death. Reuse could cause cross contamination and transmission of infectious disease from one patient to another.
- The used device and packaging must be disposed of following hospital and local government procedure.

