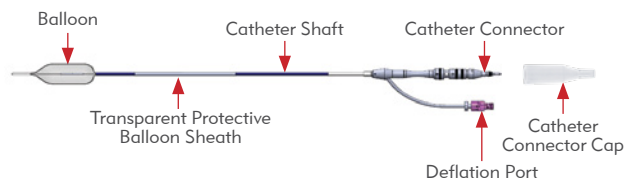


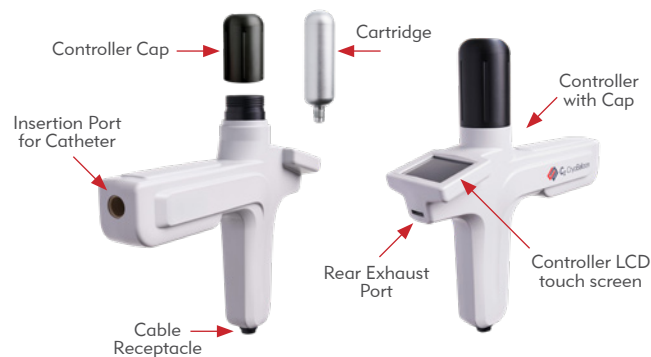
C₂ CryoBalloon® Ablation System Quick Reference Guide

System Components

C2 CryoBalloon® Focal Catheter



C2 CryoBalloon® Controller, Cartridge & Foot Pedal



System Preparation

1. Foot pedal power on and placement

- 1a Plug the Power Cable into the Foot Pedal Power Supply
- 1b Plug the Power Cable Plug into the mains power source
- 1c Position the Foot Pedal at the desired location



2. Controller power on

- 2a Plug the Interconnect Cable of the Foot Pedal into the Controller (align the arrow and dot). Turn clockwise to ensure tight connection
- 2b Lightly tug on the Interconnect Cable to ensure attachment
- 2c The Controller screen will turn on



3. NitroClip attachment (if being used)

- 3a Attach suction tubing to tapered end of NitroClip
- 3b Depress the NitroClip hinges and insert into the Controller rear exhaust port
- 3c Connect the other end of the vacuum tubing to suitable vacuum system. Set the vacuum to 431-584 mm Hg (17-23 in Hg)



4. Catheter Advancement through endoscope

- 4a Keep the clear connector cap on the distal end of the catheter during catheter advancement through the endoscope
- 4b Insert the Balloon with Introducer Sheath into the opened biopsy valve and advance Catheter until Balloon exits distal endoscope
- 4c Withdraw Sheath from the biopsy valve and slide proximally onto the Catheter shaft



5. Catheter attachment to Controller and dosimetry setting

- 5a Remove Catheter Connector Cap and set aside. Insert the Catheter Plug into the Controller Connection Port until a click is heard
- 5b Firmly tug on Catheter connector to ensure Catheter is locked to Controller
- 5c Confirm attachment by pressing the checkmark on Control LCD touch screen

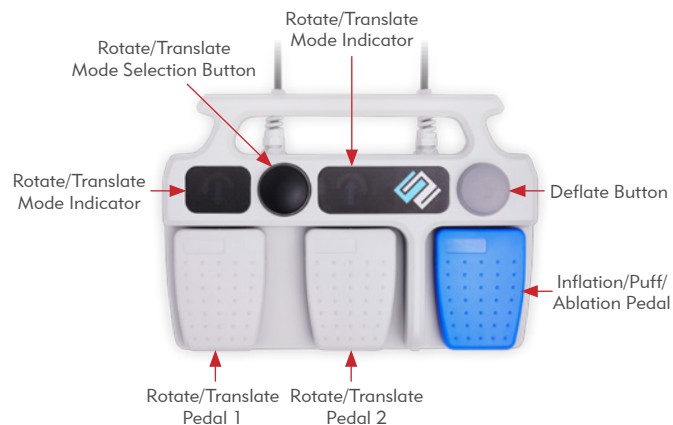


6. Cartridge Loading

- 6a Load Cartridge into Controller Cap, rotating it as it is being inserted
- 6b Insert Cap and Cartridge into the Controller
- 6c Screw the Cap clockwise until the Controller screen changes from red to green
- 6d Confirm dosimetry setting on Controller

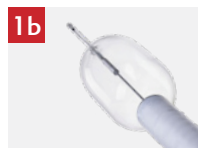


System Operation



1. Inflate balloon and establish good visibility

1a Once the endoscope is properly positioned within the body and the deflated balloon has exited the distal end of the endoscope, briefly press and release the blue inflation/puff/ablation pedal to inflate the balloon

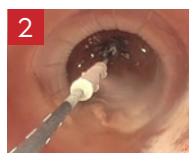


Balloon sits directly against therapeutic endoscope

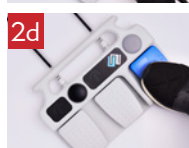
1b Adjust position of balloon relative to endoscope to gain visibility by pulling the Catheter proximally. The Catheter Balloon will rest against the endoscope lens. (The copper band on catheter will be pulled back into the endoscope)

2. Target desired treatment location and perform treatment

2a The Catheter Diffuser is aligned with white dots on Catheter Shaft. Perform a puff to momentarily freeze (turn white) the desired target area. If diffuser spray area is aligned with the diseased area, continue with treatment



2b Reposition diffuser to target new treatment area. Diffuser movement can be selected by pressing the mode selection button. The Diffuser can move translationally (up or down) or rotationally (clockwise or counterclockwise)



2c Move the Diffuser to the desired position by pressing the Rotate/Translate pedals

2d Once desired treatment location has been targeted, press and hold blue inflation/Puff/ablation pedal. The ablation will automatically stop when completed

3. Axial Balloon repositioning (if required)

3a Deflate the balloon by pressing the Deflate Button on the Foot Pedal



3b Reposition the catheter with the balloon in a deflated state. Advance or withdraw the endoscope to align with the next intended treatment site



3c Press the blue Ablation/Inflation/Puff Pedal to re-inflate the balloon

3d Repeat targeting and treatment (see Step 2)

4. Cartridge replacement (if required)

4a If prompted by the Controller to replace Cartridge, rotate the Controller Cap counterclockwise until Cap and Cartridge can be removed



4b Load new Cartridge into Cap and re-attach to the Controller

5. Catheter withdrawal and detachment from Controller

5a Depress and hold the Deflation Button on Foot Pedal while pulling the Catheter proximally into the endoscope to deflate the balloon and withdraw the Catheter out of the endoscope. Alternatively, use the deflation port and a syringe to deflate the Balloon



5b Once Catheter is out of the endoscope, touch the eject button on the LCD Touch Screen and follow the subsequent prompts



5c The controller will automatically eject the catheter partially from the device. Allow the motion to fully stop before attempting removal of the catheter. The catheter should disengage easily; **DO NOT APPLY FORCE OR PULL ON THE CATHETER**

5d Confirm detachment on the LCD Touch Screen