



# Impella® Updates\*

September, 2015

## 5% Dextrose with Heparin as Default Impella® Purge Solution

### WHAT'S NEW?

Abiomed recommends using 5% dextrose (D5) solution as the default purge fluid for the Impella® Catheter, even when transferring patients to the ICU. When using D5, the purge cassette used with the Automated Impella® Controller may no longer need to be changed daily, depending on hospital policy.

### BACKGROUND

Purge solution flows through the Impella® Catheter in the opposite direction of the patient's blood being drawn into the catheter during support. The purge solution creates a pressure barrier that prevents blood from entering the Impella® motor. The dextrose concentration determines the viscosity and flow rate of the purge fluid. Lower dextrose concentrations are less viscous and flow more quickly with less pressure through the purge system. Higher (more viscous) concentrations result in a slower purge rate and greater pressure barrier.

To date, Abiomed has recommended using a solution of 20% dextrose (D20, also called 20% glucose) with 50 IU/mL of heparin as the default purge fluid for all Impella® Catheters. Heparin in the purge solution provides additional anticoagulation protection. In the event that blood migrates into the motor, the heparin will help maintain the patency of the purge pathway.

A range of dextrose solutions, from 5% dextrose (D5) to 40% dextrose (D40) have been evaluated and qualified. Typically when an Impella® case is started, 5% dextrose is used as the purge solution since it is readily available in most clinical settings. If the physician determines that the patient should be transferred to the intensive care unit for longer-term care, the D5 purge solution is often replaced with a 20% solution of dextrose (D20) as recommended in the Impella® Instructions for Use (IFU) manuals. This purge solution change, however, is no longer necessary unless it is determined that the Impella® Catheter requires a higher concentration of dextrose to achieve the recommended 300 mmHg of purge pressure.

Many hospitals require that the Impella® purge cassette be replaced daily when using D20 purge solution. When using a purge solution of 5% dextrose, the purge cassette can be used for 5 days or longer, depending on hospital policy.

### PUTTING IT INTO PRACTICE

Abiomed has validated several concentrations of dextrose for use as the purge solution in the Automated Impella® Controller. It is important to understand the implications of using D5 purge solution rather than D20 on purge flow rate, the time required for purge fluid and purge cassette changes, and heparin infusion rate.

Implications of D5 on purge cassette durability. Abiomed recommends using its purge cassettes for up to 5 days with the Automated Impella® Controller using a purge solution of 5% dextrose. Since the purge cassette is qualified with D5, using D5 won't change the purge cassette durability.

## 5% Dextrose with Heparin as Default Impella® Purge Solution

### Implications of D5 on Impella® Catheter durability.

There has been no indication that D5 affects the durability of the Impella® Catheter either positively or negatively. Specific tests using D5 with the Impella CP® as the representative Impella® Catheter yielded similar run time durability as D20.

### Implications of D5 on purge flow rate.

D5, being less viscous than D20, will flow through the Impella® purge system more quickly. Purge flow rates increase by approximately 30% to 40% with D5 compared to purge flow rates with D20.

### Implications of D5 on time required to change purge fluid and purge cassette.

Higher purge flow rates through the purge system will reduce the amount of time the purge pressure can be maintained during purge fluid and purge cassette changes. All Impella® Catheters have a purge pressure reservoir—an expandable chamber on the clear sidearm attached to the purge cassette tubing—that temporarily supplies the purge system with purge fluid during purge fluid and purge cassette changes. When this pressure reservoir is filled with lower viscosity D5, it can maintain adequate purge pressure for a shorter duration of time. Experimentally, Abiomed has determined that this duration is 30% to 40% shorter when using D5 compared with D20. However, tests have shown that the typical Impella® Catheter operating with a purge solution of D5 can maintain purge pressure above 300 mmHg for 90 seconds or longer; an adequate duration of time for changing the purge fluid bag or purge cassette. It is possible, however, that a particular Impella® Catheter may not be able to maintain this pressure for 90 seconds.

### Implications of D5 on heparin infusion.

A purge solution of D5 increases flow rate by 40% compared to D20. As a result, patients receive a higher infusion volume over the duration of support. Because the purge fluid—whether D5 or D20—contains 50 IU/mL of heparin, the patient will also receive a higher rate of infusion of heparin. Clinicians should monitor and assess heparin concentration in the purge fluid on a case by case basis depending on the patient's tolerance to heparin and purge volume.

## SUMMARY

Abiomed has qualified 5% dextrose (D5) purge solution and it has been shown to perform as well as D20 purge solution with the Impella® Catheter. There is no indication that D5 purge solution adversely affects the purge cassette or Impella® Catheter and using D5 enables clinicians to replace the purge cassette less frequently.

