Power Injection Guidelines

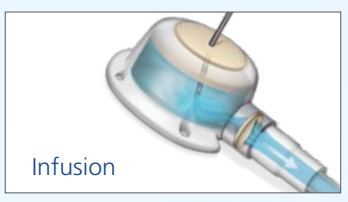
BioFlo Power Injectable Ports
with Endexo and PASV Valve Technology

INDICATIONS AND USAGE

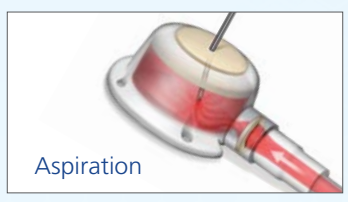
The BioFlo* Power Injectable Port with Endexo* and PASV* Valve Technology is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.

When used with a power injectable needle, the BioFlo Power Injectable Port with Endexo and PASV Valve Technology is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/sec with a 19G or 20G non-coring power injectable needle or 2 mL/sec with a 22G non-coring power injectable needle.

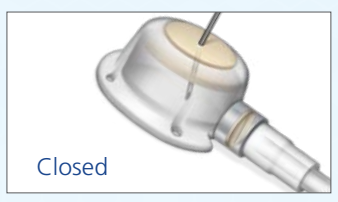
PASV Valve Technology is designed to:



Open with minimal pressure and automatically close after infusion



Open for sampling and automatically close to resist pressure fluctuations that may cause blood reflux

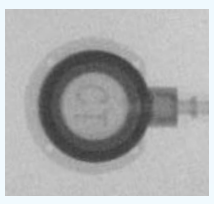


Remain closed during normal increases in central venous pressure to prevent blood reflux in the catheter tip

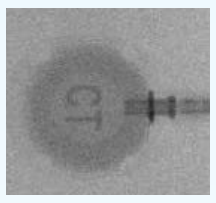
IDENTIFICATION

Always verify the patient has a BioFlo Power Injectable Port with Endexo and PASV Valve Technology by at least 2 means and ensure it is accessed with a non-coring power injectable infusion set.

BioFlo Power Injectable Ports with Endexo and PASV Valve Technology can be distinguished from traditional ports through the following means:



Titanium Port Body



Plastic Port Body

- Check patient's chart for BioFlo Power Injectable Port with Endexo and PASV Valve Technology patient record sticker or notation in the patient's chart.
- Via X-ray, CT scout, fluoroscopy or chest X-ray, visualize the letters "CT" on the port.
- Request confirmation from the patient by asking them to show you the patient identification card, reminder band or key ring card that they received when the port was implanted.

POWER INJECTION

1. Access the BioFlo Power Injectable Port with Endexo and PASV Valve Technology with a power injectable needle.
   WARNING: Failure to use a power injectable needle with the port for a power injection procedure may result in port system failure and patient injury may occur.
2. Attach a 10 mL or larger syringe filled with sterile normal saline.
3. Check for patency with the patient in the position that they will assume during the CECT procedure. Check blood return and vigorously flush the port with at least 10 mL of sterile normal saline for injection.
   WARNING: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure and patient injury may occur.
4. Detach syringe.
5. Warm contrast media to body temperature.
   WARNING: Failure to warm contrast media to body temperature prior to power injection may result in port system failure and patient injury may occur.
6. Attach the power injection device to the power injectable needle ensuring connection is secured. Check table below to confirm the maximum flow rate and maximum pressure setting.
7. Check Table 1 to confirm the maximum flow rate and maximum pressure setting.
8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
   WARNING: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately as patient injury may occur.
9. Inject warmed contrast, taking care not to exceed the flow rate limits.
10. Disconnect the power injection device.
11. Flush the BioFlo Power Injectable Port with Endexo and PASV Valve Technology with 10 mL of sterile normal saline.
12. Perform heparin lock procedure per institutional protocol. BioFlo Power Injectable Port with Endexo and PASV Valve Technology may be flushed and locked with either normal saline or heparinized saline per institutional protocol.

Table 1

Needle Size (G) Non-coring Power Injectable	Maximum Recommended Flow Setting (mLs)	Maximum Recommended Pressure Setting (psi)
19	5	300
20	5	300
22	2	300

WARNING: Do not exceed 300 psi pressure limit setting or the maximum recommended flow rate setting. Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement and patient injury may occur.

USE AND MAINTENANCE

It is recommended that institutional policies and procedures be followed for all aspects of port care, use and maintenance.

Use

- Only use non-coring needles to access the port septum.
- Do not use syringes smaller than 10 mL when accessing the port as system damage can occur. In case the port is occluded, excess pressure could damage either port septum or catheter.
- Prior to any treatment, check the correct position of the port chamber and inspect the incision site for any wound or infection symptoms.
- Sterile conditions must be prevailed for any puncture procedure. (Figure 1)
- For precise drug administration, please refer to the individual pharmaceutical instructions.
- Palpate the port and port septum then access the septum with the non-coring needle at a right angle. (Figure 2)
- If more than one drug is to be administered between the individual drug applications, flush per flushing protocol to prevent drug interactions.
- After implantation and any infusion, injection or bolus application, the port has to be flushed per flushing protocol to prevent later occlusion of the catheter. (Figure 3)

Figure 1

Figure 2

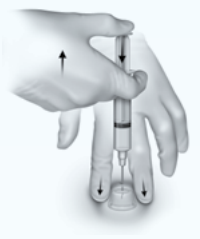


Figure 3

Maintenance

- Flush the BioFlo Power Injectable Port with Endexo and PASV Valve Technology with 10 mL of sterile normal saline or 5 mL heparinized saline using a 10 mL syringe or larger at least once every 4 weeks in order to maintain the patency of the system.
- BioFlo Power Injectable Port with Endexo and PASV Valve Technology may be flushed and locked with either normal saline or heparinized saline per institutional protocol.

BioFlo

Learn more at BioFloPort.com

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angiodynamics

BIOFLO POWER INJECTABLE PORTS WITH ENDEXO AND PASV VALVE TECHNOLOGY

CT (300 psi) MR (3T)

INTENDED USE/INDICATIONS FOR USE: The BioFlo Power Injectable Port with Endexo and PASV Valve Technology is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.

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CONTRAINDICATIONS: Inadequate body tissue to support device, bacteraemia, sepsis, known or suspected allergic response to materials, severe chronic obstructive lung disease exists, past irradiation of prospective insertion site, previous episodes of venous thrombosis or vascular surgical procedures at the postoperative placement site, local tissue factors will prevent proper device stabilization and/or access.

Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Possible Complications, Warnings and Precautions prior to using this product.

CAUTION: Federal Law (USA) restricts this device for sale by or on the order of a physician.