>> TECHNICAL NOTE

BioFlo Port
with Endexo* Technology

Plastic Port with
PASV* Valve Technology

The BioFlo Port has demonstrated to be compatible with the following classes of chemotherapy drugs:

Reactive Class	Chemotherapy Drug
Alkylating Agents	Nitrogen mustards: (Chlorambucil, Chlormethine, Cyclophosphamide, Ifosfamide, Melphalan). Nitrosoureas: (Carmustine, Fotemustine, Lomustine, Streptozocin). Platinum: (Carboplatin, Cisplatin, Oxaliplatin, BBR3464). Busulfan, Dacarbazine, Mechlorethamine, Procarbazine, Temozolomide, ThioTEPA, Uramustine
Antimetabolites	Folic acid: (Methotrexate, Pemetrexed, Raltitrexed). Purine: (Cladribine, Clofarabine, Fludarabine, Mercaptopurine, Thioguanine). Pyrimidine: (Capecitabine). Cytarabine, Fluorouracil, Gemcitabine
Plant alkaloids	Taxman: (Docetaxel, Paclitaxel). Vinca: (Vinblastine, Vincristine, Vindesine, and Vinorelbine) Podophyllum: (Etoposide, Teniposide).
Antitumor antibiotics	Anthracycline family: (Daunorubicin, Doxorubicin, Epirubicin, Idarubicin, Mitoxantrone, Valrubicin). Bleomycin, Hydroxyurea, Mitomycin
Topoisomerase inhibitors	Topotecan, Irinotecan.
Monoclonal antibodies / Molecular targeted Therapies	Alemtuzumab, Bevacizumab, Cetuximab, Gemtuzumab, Panitumumab, Rituximab, Tositumomab, Trastuzumab
Other (administered IV only)	Amsacrine, Arsenic trioxide, Asparaginase, Bortezomib, Denileukin diftitox, Pentostatin

Extensive compatibility testing was performed on the following chemotherapy drugs and common agents:

Drug Name/ Chemical Name	Functionality / Mechanism of Reaction	Typical Dosage/ Concentration	Typical Dosage Duration	Preparation
Doxorubicin (Adriamycin*)	Chemotherapy: Radical based chemical attack; cleaves DNA	30-75 mg/m2 2mg/mL	over 30 minutes	Use 0.9% saline to dilute to desired concentration
Vancomycin (Vancocin*)	Antibiotic – Given for serious or severe infections; irritant to veins	1.0 g IV	every 12 hours	Dilute in 200 mL of normal saline solution.
Saline	Control; N/A	0.9% solution	n/a	Ready to infuse bags

Extensive compatibility testing was performed on the following chemotherapy drugs and common agents:

Drug Name/ Chemical Name	Static Exposure Concentration	Clinical Dosage	Clinical Duration of Infusion
Saline	0.9% solution ready to infuse bags	0.9% solution	Varies
Fluorouracil (Adrucil* or equivalent generic)	50 mg/mL solution as purchased	400 mg/m2 bolus, then 1,200 mg/m2 days 1 and 2 over 44 hours, repeats every 2 weeks.	Each cycle of 44 hours over average of seven cycles.
Docetaxel (Taxotere* or equivalent generic)	0.74 mg/mL in 0.9% normal saline.	60-100 mg/m2 per cycle	Over 60 minutes per cycle
Bevacizumab (Avastin* or equivalent generic)	25 mg/mL solution as purchased	10 mg/kg every 2 weeks	Over 30-90 minutes (1st infusion of 90 minutes, 2nd over 60 minutes and rest 30 minutes).
Asparaginase (Elspar* or equivalent generic)	10 mL vials with 10,000 IU of Asparaginase per vial	6,000 IU/m2 three times a week.	Over 30 minutes
Morphine	2 mg / 2 mL	2-10 mg / 70 kg of body weight.	Delivered over 4-5 minutes
tPA Anteplase (Activase* or equivalent generic)	2 mg / 2 mL	As needed	Dwell in catheter 150 minutes, up to 2 cycles
Heparin	100 units/mL	As purchased	12-24 hour catheter lock
Ionic Contrast Agent / Hexabrix*	As purchased solution	Not to exceed 200 mL	Minimum product labeled injection rate of 5 mL/sec, 200 mL infusation duration of 40 sec.

IMPORTANT RISK INFORMATION

BIOFLO PORTS WITH ENDEXO TECHNOLOGY

INTENDED USE/INDICATIONS FOR USE: The BioFlo Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the BioFlo Port 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 19 G or 20 G non-coring power injectable needle or 2 mL/sec with a 22 G non-coring power injectable needle.

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.

angiodynamics

USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 or 518-798-1215 > fax: 518-798-1360
International > Haaksbergweg 75 (Margriettoren), 1101 BR, Amsterdam Z-O > The Netherlands
tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

www.angiodynamics.com

Manufacturer:
Navilyst Medical, Inc.,
26 Forest Street, Marlborough, MA 01752