DyeVert™ Power XT Contrast Reduction System
INSTRUCTIONS FOR USE

DEVICE DESCRIPTION
The Osprey Medical DyeVert™ Power XT Contrast Reduction (DyeVert Power XT) System is compatible with power injectors used in angiographic procedures using contrast media and provides fluid pathway resistance modulation such that excess contrast volume (i.e. contrast for diagnostic or therapeutic purposes that is without clinical benefit) is minimized in the patient's vasculature and total contrast media dosage reduction occurs; while maintaining adequate image quality. Age, diabetes, moderate and severe chronic kidney disease (CKD, renal insufficiency) and heart failure on presentation are leading factors when considering renal protection measures such as contrast minimization tools and processes.

The DyeVert Power XT is a disposable, single-use sterile device consisting of a diversion line and two catheter size-dependent Diversion Valves. The device is positioned between the power injector's most proximal connector and the angiographic catheter via the DyeVert Power XT Stopcock. Each of the Diversion Valves responds to the contrast injection pressure and modulates the amount of contrast diverted. The diverted contrast is collected in the Contrast Collection Bag.

The DyeVert Power XT has been designed for use with Luer fittings demonstrated to comply with ISO 594 "Conical fittings with a 6% luer taper for syringes, needles and certain other medical equipment". Use of catheters and power injectors beyond those listed below have not been substantiated.

Diagnostic	Guide	Guide w/Rx
4F	-	-
5F	5F	-
6F	-	6F
-	-	7F

POWER INJECTOR COMPATIBILITY
The DyeVert Power XT has been designed for use with any power injector capable of injecting at an injection flow rate $\geq$ 3 mL/s.

MODEL NUMBER

Model Number	Contrast Viscosity Range at 20 C
HV-POWER-A-EU	8.8 to 26.6 cps (mPa*s)

APPLIED PARTS
DyeVert Power XT Module and Contrast Collection Bag

INTENDED USE
The DyeVert™ Power XT Contrast Reduction System is intended to reduce the amount of contrast media administered to the patient during angiographic procedures using automated injections of contrast media.

Clinical evidence has demonstrated that contrast media can be toxic to the kidneys, leading to contrast induced nephropathy (CIN).

CONTRAINDICATIONS
The DyeVert Power XT System is not intended to be used during manual contrast injections.

WARNINGS
For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocess or re-sterilization may create a risk of patient infection which could lead to injury, illness or death.

The DyeVert Power XT System is to be used with power injector flowrates set to a minimum of 3mL/s.

Do not use if product packaging appears compromised or damaged.

Not for use with catheters not listed in the IFU or contrast media outside of the viscosity range listed in the IFU.

Bypass the DyeVert Power XT System for Aortograms, LV grams and other structural images.

Refer to the contrast media Labeling for dosage recommendations, warnings, contraindications, detail of reported adverse event types and detailed directions for use associated with contrast administration.

Refer to the applicable power injector instruction manual for system warnings, contraindications and directions for use.

If delivering drugs through the power injector stopcock, bypass DyeVert Power XT to ensure full dosage is delivered.

PRECAUTIONS
In the event the device malfunctions or changes in performance that is not expected, discontinue use immediately and report experience to Osprey Medical representative. If the incident is considered reportable (e.g. serious) by the regulating authority, please ensure the incident is also reported to the qualifying regulatory authority.

Using the DyeVert Power XT off-label may result in undesired affects such as poor imaging or lack of contrast reduction.

The DyeVert Power XT is designed to be used with non-diluted, room temperature (non-warmed) contrast media only.

As with any tubing used to inject contrast media into a patient, care should be taken to ensure all air has been removed from the lines, prior to injection, to avoid air embolization.

Use only light tapping, if necessary, to remove air while priming the DyeVert Power XT. Do not use tools such as hemostats or other instruments.

Be cautious to not over-tighten luer connections when connecting the DyeVert Power XT Stopcock.

If using saline flush function of the power injector, bypass DyeVert Power XT.

The graduations on the Contrast Collection Bag are approximate and are not intended for estimating diversion volume measurement. In addition to contrast, the Contrast Collection Bag may contain saline, blood or other fluids.

POTENTIAL ADVERSE EVENTS
Possible adverse effects include but are not limited to: air embolism and infection.

HOW SUPPLIED
The DyeVert Power XT is disposable and is supplied sterile. DyeVert Power XT has been sterilized with ethylene oxide (EO).

STORAGE
Store the DyeVert Power XT Disposable Kit between -15°C and +38°C (5°F and 100°F).

MAINTENANCE and REPAIR
Maintenance is not required.

DISPOSAL
Discard the DyeVert™ Power XT according to hospital procedures. The contrast in the Contrast Collection Bag should not be reused.

OPERATING CONDITIONS
The system is intended to be used in a standard hospital Cath lab environment.

MASS of DEVICE

DyeVert Power XT Module	61g
Contrast Collection Bag	37g (update)

PHYSICIAN TRAINING INFORMATION
Qualified physicians should be knowledgeable of Cath lab procedures, techniques and contrast media usage.

No additional special skills or training is required to operate the system, but physicians should be thoroughly familiar with the DyeVert Power XT Contrast Reduction System supporting material including all product labeling. Physicians may contact Osprey Medical to request training.

DIRECTIONS FOR USE

A. Assemble and Prime

1) Prime power injector as directed in the applicable Manual.
2) Introduce DyeVert Power XT and the Contrast Collection Bag into the sterile field per normal procedure.
3) Attach the female luer of DyeVert Power XT stopcock to the male luer at the end of the power injector line. (See Figure 1)

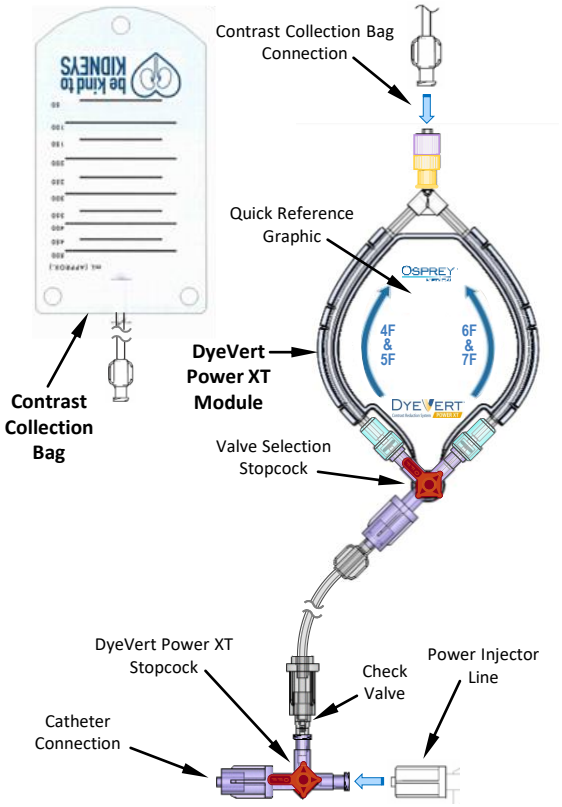

Figure 1 – Device Assembly and Components

4) Ensure DyeVert Power XT stopcock is oriented OFF towards the Catheter Connection and ON to the *Valve Selection Stopcock*. (See Figure 1)
5) Using the power injector, inject saline or contrast through the DyeVert Power XT system until all air is removed from the line and fluid exits the distal end of the DyeVert Power XT. **NOTE: since this will prime only one side of the DyeVert Power XT diversion line, continue with steps 6-7 to prime the opposite side before use.**
6) Turn the *Valve Selection Stopcock* to the other valve position. (See Figure 2)

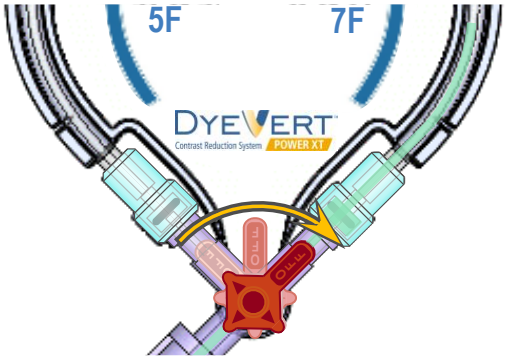

Figure 2 – Opposite Side Diversion Path Priming

7) Using the power injector, inject saline or contrast through the DyeVert Power XT until all air is removed from the line and fluid exits the distal end of the DyeVert Power XT.
8) Attach Contrast Collection Bag to the luer fitting located at the distal end of the DyeVert Power XT. (See Figure 1)

9) Turn the DyeVert Power XT Stopcock OFF toward the *Valve Selection Stopcock*. (See Figure 3)

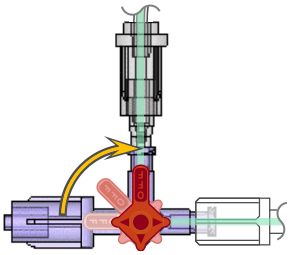

Figure 3 – DyeVert Power XT Stopcock OFF

10) Catheters and/or extension lines should be attached to the male rotating luer on the DyeVert Power XT stopcock. Flush and prime catheters and lines per normal operating procedure.

B. System Operation

1) DyeVert Valve Selection

a. Based on the catheter size being used for the procedure and consistent with the fluid flow shown in Figure 1, orient the *Valve Selection Stopcock* to the corresponding “4F & 5F” or “6F & 7F” position. (See Figure 4)

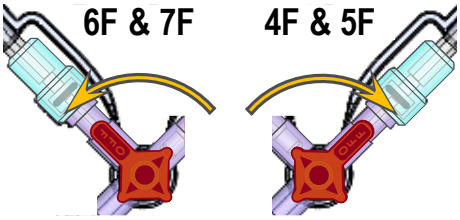

Figure 4 – DyeVert Valve Selection Stopcock

Note: If catheter size changes during the case – reorient Valve Selection Stopcock as appropriate.

2) Contrast Injections

a. To save contrast during a contrast injection, orient the DyeVert Power XT Stopcock such that it is ON to both the *Valve Selection Stopcock* and the catheter. (See Figure 5)

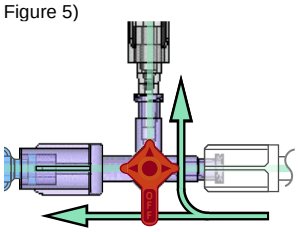

Figure 5 – Contrast Injection (Savings ON)

b. Inject contrast per normal operating procedure.

3) Saline Flushing

a. If flushing with saline, turn DyeVert Power XT Stopcock OFF to the *Valve Selection Stopcock*. (See Figure 6)

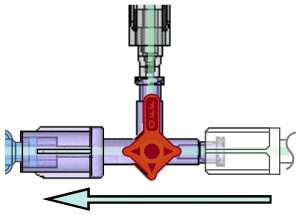

Figure 6 – Saline Flush (Savings OFF)

b. To allow contrast saving to resume, orient the DyeVert Power XT Stopcock such that it is ON to both the *Valve Selection Stopcock* and the catheter. (See Figure 7)

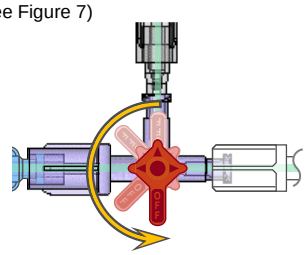

Figure 7 – Resume Savings

4) System Bypass

a. To bypass the DyeVert Power XT System (i.e. no diversion) orient the DyeVert Power XT Stopcock to OFF to the *Valve Selection Stopcock* (see Figure 8). The Power XT System should be bypassed for the following instances: saline flush of catheters or drug delivery.

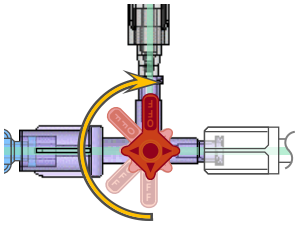

Figure 8 – System Bypass (Savings OFF)

b. To allow contrast saving to resume, orient the DyeVert Power XT Stopcock such that it is ON to both the *Valve Selection Stopcock* and the catheter. (See Figure 7)

5) Contrast Accounting Estimation

a. At the end of the case, to estimate the total volume of contrast that was delivered to the patient (i.e. Estimated Patient Contrast Volume), subtract the Estimated Diverted Contrast Volume (collected in the Contrast Collection Bag) from the power injector Contrast Volume stated on the power injector display screen.

Estimated Patient Contrast Volume = [Contrast Volume injected by power injector as shown in injector display minus estimated Diverted Contrast Volume contained in the Contrast Collection Bag]

Note: contrast accounting estimation may be inaccurate due to other fluids, such as saline being in the Contrast Collection Bag.

Packaging Symbol Definitions					
	Expiration Date YYYY-MM. Use by last day of month (MM).		Manufacturer	STERILE EO	Sterilized by ethylene oxide
	Consult electronic Instructions for Use		Keep Dry	REF	Model number
	Single Use	CE	European Conformity	LOT	Lot Number
RxOnly	Prescription Only		Do Not Use if Package is Damaged	EC REP	European Community Authorized Representative
MD	Medical Device		Consult instructions for use for important information	SBS	Identification of Sterile Barrier
MR	MR Unsafe		Power XT Module		Temperature Limit
			WEEE Directive	RoHS Compliant	Restriction of Hazardous Substances

CE 2797

EC REP

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