VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

CleanPrint 10®, Core2Write®, and Core2Print®

Clean & Sterile Cleanroom Documentation Made Simple

Assure Sterility and Eliminate Fibers and Particulates from Cleanroom Documentation

The Writing Substrate

CLEANPRINT 10

The Custom Documentation

CORE 2 WRITE

The HEPA Filtered Printing System

CORE 2 PRINT

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What is the Industry Problem?

Items that shed fibers or particulates can wreak havoc on any aseptic GMP operation. Airborne fibers and particulates can come to reside on surfaces throughout the cleanroom including product contact surfaces. If this happens, such contaminants can then subsequently corrupt final product. Recent industry trends have shown an increase in the detection of such contaminants and have been documented in worldwide regulatory observations. Assuring product contact surfaces are free of these contaminants is the main concern for any firm. Contaminated sources may include bulk product tanks, tubing, assemblies, filling machine surfaces, stopper bowls, turntables, conveyers, personnel, open vials, and open syringes, etc. If such contaminants are found in post fill inspections or, in the worst case, the marketplace: the cost to a manufacturing firm is enormous.

GMP firms have a constant struggle with the task of reducing fibers, particulates, and microorganisms within classified areas. A main source of this problem is paper products used to document operations. Characteristically, paper products shed a high level of fibers and particulates. While many firms have attempted to institute electronic batch records, the need for writable documentation, in many venues, beyond the electronic scope, is ever present. Coupled with the particulate and shedding, this contamination problem has mandated that such paper products are rendered sterile prior to their entry of the controlled environment.

A second source of fibers and particulates is documentation systems used within manufacturing areas. Items such as paper, tags, logbooks, labels, notebooks, and batch formulas are currently printed on cellulose paper or fiber bonded and coated material. These materials shed fibers and harbor particulates that can corrupt environmental conditions. The concern for the reduction and hopeful elimination of such contaminants requires firms to conduct stringent evaluations of their systems and products deemed suitable for use in the controlled environments. The problem does not stop at the firm's manufacturing location and requires further supply chain evaluations.

How can the Core2Write®, Core2Print®, and CleanPrint 10® help?

Veltek Associates, Inc. (VAI®) is one of the leading companies in innovation that supplies the pharmaceutical, biotechnology, healthcare, and lab animal marketplace. Our newly patented product lines, **CleanPrint 10**, **Core2Write**, and **Core2Print,** address and solve problems surrounding particulate and fiber shedding in cleanroom documentation systems. Through the use of our patented **CleanPrint 10** synthetic substrate, we have provided the vehicle to assure documentation is printed via our **Core2Print** on a non-particulating, non-shedding plastic substrate with chemical resistant ink. The **Core2Print** is a patented cleanroom printing device that prints on **CleanPrint 10**, within a sealed HEPA filtered stainless steel, movable cabinet designed specifically for the aseptic core. The **Core2Write** product line is customized unique to each company by capturing internal document requirements of the firm, pre-printing the required documents (such as logbooks, tags, labels, and forms) on **CleanPrint 10**, and integrating our patented RFID and/or barcoding system, Core2Scan™. Quality and manufacturing includes quadruple bagging followed by validated sterilization via gamma irradiation, therefore, making these options extremely viable for aseptic operations. So where cleanroom documentation is required, VAI has an innovative solution.

What are CleanPrint 10, Core2Write, and Core2Print?

CleanPrint 10® is a patented synthetic substrate that is used as the base for all **Core2Write**® products and as the printing medium for the **Core2Print**®. **CleanPrint 10** is exceptionally durable and the adhesive bonds that comprise the material are as much as 10 times stronger than other synthetic substrates. **CleanPrint 10** is pliable, is resistant to abrasion, is resistant to chemicals, and is resistant to ink smearing. **CleanPrint 10** contains no cellulose and is extremely low in particle shedding. Each page is individually vacuumed and printed with a 10% screen of light blue so that end users can identify that **CleanPrint 10** is in use as opposed to regular paper. **CleanPrint 10** is far more advanced than other comparative products in the marketplace. It is packaged via VAI's patented ABCD Cleanroom Introduction System®, which quadruple bags each ream of paper for easy introduction to the aseptic core.*

* See page 5 for specifications and additional features.

Core2Write is a customized product specifically made for your organization. The patented technology provides the ability to print most any preprinted documentation requirements such as forms, logbooks, two-part tags, single tags, and labels. But **Core2Write** goes far beyond preprinting customized documentation. The system provides the ability to imbedded RFID in each item in order to provide tracking information via our Core2Scan™ System. It also provides the ability to number each **Core2Write** document type with a unique number and unique barcode. The system further assures that side stair stepping marks are incorporated into logbooks in order ascertain the removal of pages and that products are laminated to provide additional strength.*

* See page 15 for specifications and additional features.

Core2Print is a patent pending technology that revolutionizes the method for printing required, sterile, documentation within aseptic manufacturing environments (Grade A, B, C and D). The **Core2Print** unit is constructed of 316L stainless steel for durability and lexan windows for a clear view of the printer in operation. HEPA filtration at 99.997% in the cabinet is a mandatory feature. Therefore, positive pressure within the cabinet is equally filtered to the controlled environment. The contained printer emits no particulates and assures ink is dried and chemical resistant prior to exit from the unit. The CP10 printer, housed in the unit's cabinet, wirelessly prints onto VAI's **CleanPrint 10** synthetic writing substrate; the most durable in the industry. This assures remote printing to the core without concern for contamination.*

* See page 22 for specifications and additional features.

Document, Write, Identify, Label, and Print with Customized Sterile Supplies in Grade A/B

CLEANPRINT 10

O V E R V I E W

The **CleanPrint 10**® family of products

Product Overview

CleanPrint 10® is the base material used in the custom design of the **Core2Write®** products. It is also the printing medium used with the **Core2Print®** Cleanroom Printing System. **CleanPrint 10** is designed for ultraclean manufacturing environments and is void of any cellulose in its construction. The synthetic substrate is manufactured using patented technologies to assure strength, very low particulate generation, non-shedding characteristics, inability for ink to smear, chemical resistance, and the ability for lamination. The **CleanPrint 10** substrate combines the strength and dimensional stability of polyolefin with the absorbency of silica to form a unique microporous matrix. The result is a range of durability benefits not available from competing synthetic paper stocks.

CleanPrint 10

Product Use

CleanPrint 10 is made for use in the **Core2Print** cleanroom printing system and is the best mechanism to assure the cleanest print and bonding available. The substrate, however, can also be used with a multitude of printers including laser, ink jet, ribbon, dot matrix, and toner. **CleanPrint 10** can be used for recording data and note taking in the aseptic core as opposed to writing on regular paper. Furthermore, it can be used for batch record retention, equipment manuals, and work instructions or procedures. **CleanPrint 10** is used as the basis to our **Core2Write** products.

CleanPrint 10 printing from the **Core2Print**

Writing on **CleanPrint 10** with a **Core2Write** Sharpie®: VAI-SHA-01

Features and Benefits

- *Durability and Strength:* **CleanPrint 10** is exceptionally durable and the adhesive bonds that comprise the material are as much as 10 times stronger than other synthetic substrates. Polyolefin provides **CleanPrint 10** substrate with the rigidity and reinforcing strength of plastic, while microporosity allows it to remain lightweight and flexible in a broad array of processing and service conditions.

- *Adhesion of Inks:* **CleanPrint 10** is pliable, is resistant to abrasion, is resistant to chemicals, and is resistant to most ink smearing (no smearing in the **Core2Print**). The synthetic material base includes a microporous structure for accepting, adhering, and drying ink immediately. The tiny holes in the **CleanPrint 10** substrate readily absorb inks and toners to ensure brilliant color reproduction and to lock-in printed text, graphics, and photos nearly instantaneously. The polyolefin base helps the material retain form when submerged in or exposed to water, enabling it to meet British Standard (BS) 5609 for immersion-labeling testing.
- *Ink and Toner Protection:* Inks and toners absorb into the microporous matrix of the **CleanPrint 10** substrate, thus, locking printed text and graphics into its surface and making them nearly indestructible.
- *Abrasion and Scuff Resistance:* **CleanPrint 10** assures printed text and graphics cannot be scratched or rubbed off the surface of the **CleanPrint 10** substrate without destroying the material itself. This print permanence results in tamper-evident/tamper-resistant performance without the need for laminates or protective coatings.
- *Water Resistance:* Polyolefin is hydrophobic, which causes the **CleanPrint 10** substrate to repel water. This enables the **CleanPrint 10** substrate to meet British Standard (BS) 5609 for immersion-labeling testing. This standard includes detailed durability criteria for print permanence, adhesive strength, and abrasion-resistance for water-exposed labels.
- *Chemical Resistance:* The **CleanPrint 10** substrate withstands exposure to a variety of chemicals and solvents; it can even be dry-cleaned. Most other synthetic papers require a coating to perform as well as the **CleanPrint 10** substrate does without enhancement. Results of chemical exposure testing are reported below. PPG Industries presents this data for guidance in the use of the **CleanPrint 10** substrate. Samples should be tested under actual or simulated use conditions to confirm the stability of the **CleanPrint 10** substrate in the proposed environment.
    - Inorganic acids generally have little effect on the dimensions and mechanical properties of **CleanPrint 10** substrate even at elevated temperatures (e.g., 122°F / 50°C). Certain organic acids can cause swelling of the polymer.
    - Strong oxidizing acids, e.g., concentrated nitric and fuming sulfuric acids will attack the polymer phase and lead to embrittlement and loss of properties of the **CleanPrint 10** substrate.
    - Hydrofluoric acid will dissolve the silica filler leading to shrinkage of product. A portion of the filler in the **CleanPrint 10** substrate grade is acid sensitive; therefore, these grades are not recommended for contact with acids.
    - Aqueous solutions of acidic or neutral salts generally do not affect the dimensions or physical properties of the **CleanPrint 10** substrate.
    - Bases with a pH less than approximately 8.5 have little effect on the dimensions of the **CleanPrint 10** substrate. Alkaline bases (e.g., sodium or potassium hydroxide) with a higher pH or elevated temperatures will attack the silica filler and lead to shrinkage as the silica is removed from the sheet. Elevated temperatures may also lead to dimensional changes with weaker bases.
    - Polar solvents, e.g., alcohols and esters, typically have little to no effect on the dimensions or physical properties of **CleanPrint 10** substrate. Some discoloration has been noted when highly colored impurities in such solvents are absorbed on the silica in **CleanPrint 10** substrate.

  - Chlorinated organic and aromatic solvents, generally the most aggressive organic solvents cause swelling of **CleanPrint 10** substrate and some loss of tensile properties.
- *Thermal Stability:* The **CleanPrint 10** substrate remains pliable in temperatures from -70°C/-94°F to 180°C/356°F, even during prolonged exposure or rapid temperature change. Unlike **CleanPrint 10**, other synthetics can become brittle or melt when exposed to elevated temperatures such as those generated by desktop laser printers.
- *Tear Resistance and Conformability:* The flexibility of **CleanPrint 10** enables it to resist tearing and to conform to pointed, rough, and uneven surfaces or fluid-filled bags.
- *Sterilization Compatible:* The **CleanPrint 10** substrate withstands various sanitization methods including steam cleaning and gamma irradiation.
- *Temperature Attributes:* **CleanPrint 10** is pliable in extremely cold temperatures (can be cryogenically frozen) and is able to survive in heat up to 180^0C (356^0F) even when exposed to rapid fluctuations in temperature that can cause other synthetic substrates to fail.
- *Lamination and Finish Friendly:* The **CleanPrint 10** substrate bonds with laminate films when either the adhesive or the laminate itself flows into its pores, thus enhancing the durability of the material. Due to the unyielding strength of the resulting mechanical bond, edge sealing is not required. The **CleanPrint 10** substrate is able to withstand punishing finish processes such as perforating, punching, folding, sewing, grommeting, foil stamping, and embossing without cracking.
- *No Cellulose:* **CleanPrint 10** contains no cellulose and is extremely low in particulates and shedding features.
- *Color:* **CleanPrint 10** is printed on one side with a 10% light blue screen to further trap possible contaminants and provide a mechanism for operators to know the correct paper is in use.
- *Ability to Write:* **CleanPrint 10** has excellent ability to write features that include writing while the substrate is wet.
- *ESD:* **CleanPrint 10** has low ESD potential for reduced risk of electrostatic damage.
- *Recycle:* To assure a "Green" Environment, the **CleanPrint 10** substrate recycles as a plastic. 
- *Thickness:* The **CleanPrint 10** substrate has a 10 mil/254 micron thickness.
- *Regulatory Compliance:* When used as intended, the **CleanPrint 10** Food-Grade substrate is fully compliant for single and repeated use applications under the U.S. Federal Food and Drug Administration (FDA) and all applicable U.S. food additive regulations as a food contact material. The substrate is fully compliant with all types of food and under all conditions of use. It is technologically suitable and is not limited by food type, amount of material used, or operating conditions.
- *Moisture Resistance:* British Standard BS 5609 is a specification for printed, pressure sensitive or self-adhesive coated labels for maritime use. Under the United Nations' Global Harmonization System (GHS) and the International Maritime Dangerous Goods (IMDG) code, chemical manufacturers transporting dangerous goods on international waters are required to meet BS 5609 specifications for labeling. This standard requires that labels are able to withstand a three-month salt-water submersion test. Labels that are BS 5609 compliant are proven to meet stringent tests for durability and are suitable for use in harsh environmental conditions. The **CleanPrint 10** substrate based labels were tested to demonstrate conformity to BS 5609.
- *Available Options:* Available sterile or non-sterile in standard 8.5''x11'' or A4 size.

Quality and Manufacturing

- Assembled in a controlled environment
- Sterile versions are terminally sterilized to a 10^{-6} Sterility Assurance Level and is completely validated for sterility and shelf life
- Lot sterility tested according to current USP Compendium
- Each ream of sterile **CleanPrint 10** is individually double bagged in easy tear bags and packaged into 2 liner bags using VAI's ABCD Cleanroom Introduction System®*
- Delivered with a lot specific Certificate of Conformance, Certificate of Irradiation, and Certificate of Sterility
- Reams are individually labeled with lot number and expiration
- Completely traceable from start to finish

CLP10-8.5x11-02

CleanPrint 10 – Synthetic Writing Substrate	
Certificate of Conformance	**Specifications**
Basis Weight (ave.):	5.12 oz/yd^2
Dimension (ave.):	10 mils
Whiteness Index:	92%
Brightness:	80%
Opacity:	96%
Shelf Life:	5 years

CLP10-8.5x11-01

Ordering Information

Order #	Description	Qty/Case
CLP10-8.5X11-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5"x11", White, Non-Sterile	500 Sheets/Cs
CLP10-8.5X11-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5"x11", White, Sterile	500 Sheets/Cs
CLP10-A4-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, A4, White, Non-Sterile	500 Sheets/Cs
CLP10-A4-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, A4, White, Sterile	500 Sheets/Cs

*For more information on our ABCD Cleanroom Introduction System, see page 18.

Material Specifications and Testing

Performance Characteristics		
Property	**Typical Value**	**Test Method**
Basis weight	172 g/m2	Basis Weight Determination
Caliper	10.0 mil/254 um	Basis Thickness Determination
Tensile Strength		
Machine direction 2	7.0 kg	Federal Standards No. 191A: Methods 5102
Cross direction	2.9 kg	Federal Standards No. 191A: Methods 5102
Tear Strength		
Machine direction	110 g	Elmendorf tear test
Cross direction	Tore to MD	Elmendorf tear test
Opacity	98%	TAPPI Test Method T-425
Surface Resistivity		
Average at 12% RH (Ohms/sheet)	7.87×10^{12}	Per EIA-531, between 1.0×10^{5} and 1.0×10^{12} Ohms/sheet is static dissipative
Average at 50% RH (Ohms/sheet)	5.32×10^{10}	Per EIA-531, between 1.0×10^{5} and 1.0×10^{12} Ohms/sheet is static dissipative

Performance Characteristics		
Property	**Typical Value**	**Test Method**
Particles (>0.5 µm)	0.31 million particles/m2	Adapted ASTM F311 - 08(2013)
Ions		
Sodium	200 ppm	Adapted ASTM D4191 - 08
Chloride	40 ppm	Adapted ASTM D512 - 12

Sub-Micron Particles Released by CleanPrint 10 Paper				
Among the Lowest of Typical Cleanroom Substrates				
Sample	**Number of Particles/ ft^3 1 sq. ft. Down Stream**			
	>0.3 micron	**>0.5 micron**	**<0.3 micron**	**<0.5 micron**
CleanPrint 10	120	88	11953	8760
Tyvek 1073	133	109	132293	10902
Xerox 4024 D 20#	55552	41863	5560000	4190000

Chemical Resistance of CleanPrint 10 Substrate at 70° F (21° C)					
Chemical	**Concentration**	**Contact**	**Effect on**		
Testing	**%**	**Time, Hr.**	**Strength**	**Color**	**Dimension**
Nitric Acid	10	100	None	None	---
Nitric Acid	70	10	Some	Some	---
Phosphoric Acid	10	10	None	None	---
Hydrochloric Acid	37	1000	None	Slight	---
Sulfuric Acid	10	1000	None	None	---
Sulfuric Acid	96	1000	None	Slight	---
Ammonium Hydroxide	28	1000	None	None	Shrinkage
Sodium Hydroxide	40	1000	Some	None	Shrinkage
Methyl Ethyl Ketone	100	1000	None	None	---
Toluene	100	1000	None	None	Slight Swelling
Glycerol	100	1000	Some	None	Swelling
Ethyl Acetate	100	1000	None	None	---
Tetrahydrofuran	100	1000	None	None	---
Xylene	100	1000	None	None	---

24-Hour Solvent Resistance of CleanPrint 10 Substrate at 70° F (21° C)		
Solvent	**Effect On**	
Preferred Solvents	**Length**	**Thickness**
Methanol	None	None
2-Propanol	None	None
n-Butyl Alcohol	None	None
n-Propanol	None	None
Acetone	None	None
Ethyl Acetate	None	None
Methyl Ethyl Ketone (2-Butanone)	None	None
Hexane	None	None
Petroleum Ether	None	None
Tetrahydrofuran	None	None
Use Sparingly		
n-Hexyl Alcohol	None	Slight
Methylene Chloride	None	Slight
Mineral Spirits	Slight	None
Toluene	Slight	None
Xylene	Slight	None
Kerosene	Slight	None
Avoid if Possible		
Glycerol	Some	None
Isobutyl Acetate	None	Some

Electrostatic Dissipation (ESD) Testing:		
Surface Decay		
Surface	**Static Decay Time at 12% RH (Seconds)**	**Static Decay Time at 50% RH (Seconds)**
CleanPrint 10	Does not decay	0.05
PVC	Does not decay	Does not decay
PET	Does not decay	Does not decay
PC	Does not decay	Does not decay
Per MIL-STD-3010 specification, acceptable static decay materials should exhibit static decay time of ≤ 0.50 seconds when conditioned at 50% RH		

Electrostatic Dissipation (ESD) Testing:		
Surface Resistivity		
Substrate	**Average at 12% RH (Ohms/sheet)**	**Average at 50% RH (Ohms/sheet)**
CleanPrint 10	7.87×10^{12}	5.32×10^{10}
PVC	5.52×10^{13}	4.93×10^{13}
PET	$>1.0 \times 10^{15}$	7.97×10^{13}
PC	4.8×10^{14}	6.50×10^{13}
Per EIA-531, between 1.0×10^{5} and 1.0×10^{12} Ohms/sheet is static dissipative		

Environmental Details and Instructions:	
CleanPrint 10® and the Environment:	While the **CleanPrint 10** substrate is a recyclable plastic material and is not considered biodegradable, it contributes to environmental stewardship by enabling our customers to produce durable products that conserve resources. Additionally, **CleanPrint 10** grades are manufactured under strict corporate guidelines for environmental compliance and waste minimization.
CleanPrint 10 substrate and the environmental ecosystem:	**CleanPrint 10** does not contain any cellulose-based materials and does not contribute to forest harvesting. It is non-toxic and does not contain any ozone-depleting constituents.
Properly disposing of **CleanPrint 10** substrate:	The **CleanPrint 10** substrate can be safely disposed of in a landfill and will not leach into ground water. It can also be incinerated in an atmosphere of excess oxygen. When burned, **CleanPrint10** yields water, CO2, energy, and a clean ash due to its silica filler.
Recycling **CleanPrint 10** substrate:	The **CleanPrint 10** substrate is a highly filled polyolefin blend that is currently being recycled into general use bulk plastics such as plastic lumber, park benches, and industrial signs. It is classified as a 7 according to the voluntary container-coding system (7 = other resins or multi-resin polymers). Due to the high filler loading and the high molecular weight polymer matrix, **CleanPrint 10** substrate requires a high intensity mixer such as a twin screw extruder for recycling with HDPE.
CleanPrint 10 substrate is free of heavy metals:	VAI certifies that there is no lead, cadmium, mercury, or hexavalent chromium added intentionally to **CleanPrint 10**. VAI further certifies that the incidental total concentration of the above metals does not exceed 100 ppm, putting **CleanPrint 10** sheet in full compliance with the 1994 standards of the Coalition of Northeastern Governors' Model Toxic legislation (CONEG). **CleanPrint 10** substrate also complies with the current ASTM F963-86 standard Consumer Safety Specification on Toy Safety. VAI certifies that **CleanPrint 10** has no detectable quantities of either antimony or arsenic. Other metal analyses are available on request.
Toxicity:	It is non-toxic.
Ozone:	It contains no ozone-depleting constituents.
Composition:	It is 65% by weight inorganic filler (silica – derived from sand).
Cellulose:	It has no cellulose-based material content; does not contribute to forest harvesting.
Recycle Procedure:	Currently, it is recycled into general use bulk plastics such as plastic lumber, park benches, and industrial signs (a class 7 material).
Disposal in Landfill:	**CleanPrint 10** is safely disposed of in a landfill –will not leach into ground water. It incinerates in an atmosphere of excess oxygen to yield only water, CO2, energy, and a clean ash (from silica filler).
Compliance to CONEG:	It is fully compliant with 1994 standards of the Coalition of Northeastern Governors' Model Toxic legislation (CONEG) relative to heavy metal content.
Compliance to ASTM:	Fully compliant with current ASTM F963-86 standard, Consumer Safety Specification on Toy Safety – there are no detectable quantities of either antimony or arsenic.

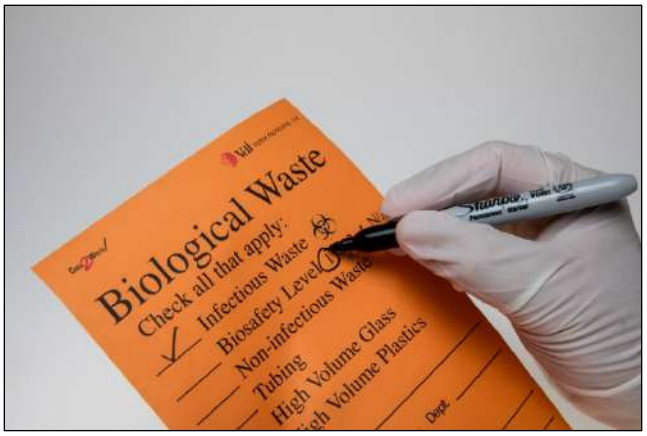
CORE 2 WRITE

O V E R V I E W

The **Core2Write**® family of products

Product Overview

Core2Write® is a patented technology that revolutionizes the method of cleanroom documentation by providing custom logbooks, one part or two-part identical tear off tags, labels and forms printed on VAI's cellulose free **CleanPrint 10**®. The **Core2Write** product line starts with a custom customer evaluation of what logbooks, forms, tags or labels are required. Once determined, such documents and artwork are digitally designed into the product required, printed, and RFID, QR coding and/or bar coding integrated. In addition, the **Core2Write** line offers gamma irradiated sterile sharpies and pens for use alongside the documentation materials.

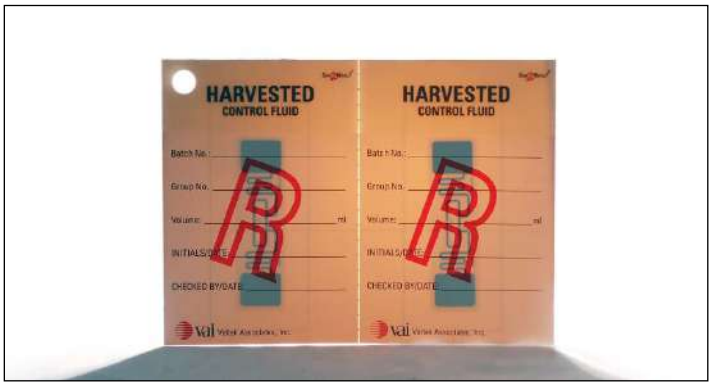


Writing on a **Core2Write** Label with a **Core2Write** Sharpie®: VAI-SHA-01

Two-Part Tags available in thousands of colors

Features and Benefits

- **Core2Write** products are fully customized to the facility's needs. Depending on these needs the following items can be customized: color, company name, logo, SOP Name & Number, Document Revision Number, RFID, bar coding, QR coding, lamination, specific entry requirements, quantity/case, transportation requirements, bagging, labeling, and sterility.
- **Core2Write** products are printed on VAI's **CleanPrint 10** synthetic writing substrate that is exceptionally durable and is extremely low in particle shedding. VAI's **CleanPrint 10** can be easily written on without the ink smearing of most pens in the marketplace (See VAI-PEN-01 for compatible pen ordering or VAI-SHA-01 for compatible sharpie ordering).
- **Core2Write** products can have RFID inlays embedded into the material so that assets, equipment & procedures can be tracked and found with a RFID reader up to 50 feet away. **Core2Write** products, via its RFID inlay capabilities, are compatible with VAI's Core2Scan end-to-end tracking system.
- **Core2Write** products can incorporate barcoding with a unique number per item.



RFID Embedded Two-Part Tag

- **Core2Write** products are available in thousands of colors. Print stock color and text colors are customized to meet facility requirements.
- **Core2Write** logbooks, tags, and labels can be individually numbered per item. This means in a case of logbooks, tags, and labels each item has a unique number on the cover and all pages.

Core2Write Custom Features

Specification	Logbooks	Tags	Labels	Forms
RFID Embedded	✓	✓	✓	✓
Barcoding/ QR Coding	✓	✓	✓	✓
Lamination (full or partial)	✓	✓		✓
Tear Apart/ Perforation		✓	✓	
Unique Numbering	✓	✓	✓	✓
Gamma Irradiated Sterile	✓	✓	✓	✓
Sterile Packaging	✓	✓	✓	✓
Hole Punch		✓	✓	
Page Numbering	✓			✓
Custom Printing	✓	✓	✓	✓
Custom Colors	✓	✓	✓	✓
Validation Packages	✓	✓	✓	✓
Side Stair Stepping Edge Separation	✓			
Thickness (single/double)		✓		

Product Use

The **Core2Write**® documentation materials are used to document GMP operations, label or tag GMP containers, and transfer cans/tanks/bottles in Grade A-D environments. With RFID inlay capability, **Core2Write** products can be used for traceability and documentation assurance via our Core2Scan System. What is Core2Scan? The Core2Scan system is an identification and tracking system that pairs RFID identification tags, scanners (middleware), and software tracking technology with a facility's equipment, products, and/or procedures.

VAI-TAG-01 for use with Core2Scan

Since **Core2Write** labels, tags, and logbooks are cellulose free and low in particulate shedding, operations can be assured additional particulates will not be introduced into the aseptic manufacturing core. **Core2Write** products help to reduce overall particulate counts and cross-contamination exposure in cleanrooms.

Quality and Manufacturing

Core2Write Logbook

- Processed in a controlled environment
- Bagging is custom; option of individual or bulk and double or triple bagging with all products available quadruple bagged via VAI's ABCD Cleanroom Introduction System®
- Sterile items are gamma irradiated at 10^{-6} sterility assurance level and have been completely validated for sterility and shelf life with either standard or custom validations available
- 5 year expiration dating
- Sterile products are lot sterility tested according to current USP compendium
- Lot and expiration labeling is custom; all individual bags, case liners, and boxes have the ability to be labeled with lot number, expiration, and irradiation indicator
- Completely lot traceable
- Sterile products delivered with lot specific documentation including a Certificate of Sterility and a Certificate of Irradiation

ABCD Cleanroom Introduction System®

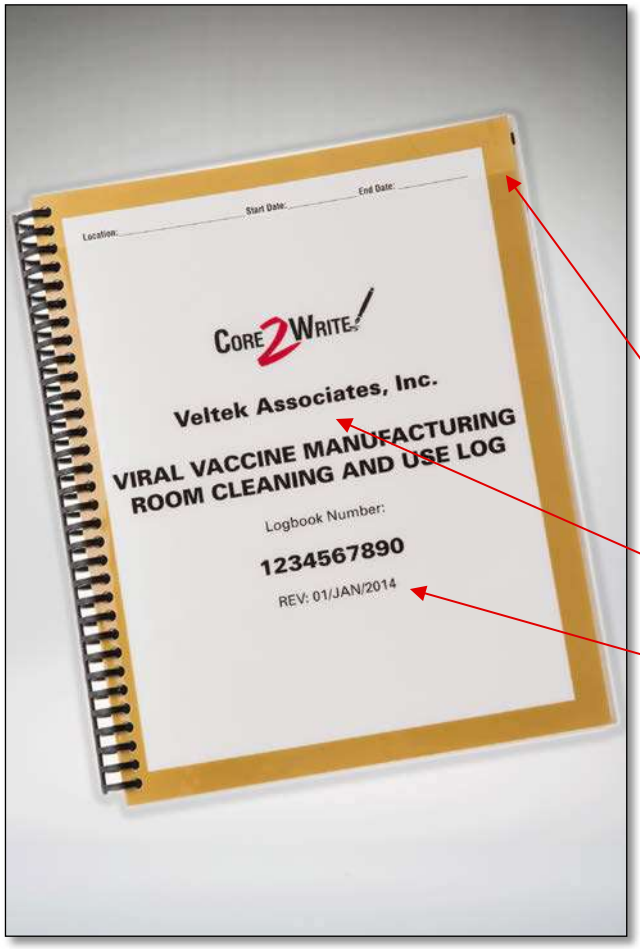
The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

Ordering Information

Order #	Description	Qty/Case
C2WR-00*	Custom Labels, Tags, Logbooks, & Forms, RFID, Barcode, QR Coding Available, Custom Packaging, Sterile or Non-Sterile	Custom
VAI-PEN-01	Core2Write, Pen, Blue Ink, 1.0mm Tip, 10/bag, 10 bags/cs, Triple Bagged, Sterile	100
VAI-SHA-01	Core2Write, Sharpie Marker, Permanent Black Ink, Fine Tip, Individually Bagged, 1/bag, 5 bags/pack, 20 packs/case, Sterile	100
VAI-TAG-01	Core2Write, RFID Tag, White, Laminated, Compatible with Core2Scan, Non-Sterile	500
VAI-TAG-GAMMA-01	Core2Write, RFID Tag, Gamma Irradiation Sterilizable, White, Laminated, Compatible with Core2Scan, 25/bag, 20 bags/cs, Sterile	500

** Due to the customization nature of the product, all available options and packaging will need to be decided with your firm during the ordering process. Custom VAI part numbers that are specific to your firm will be created for reordering purposes. No standard products are available.*

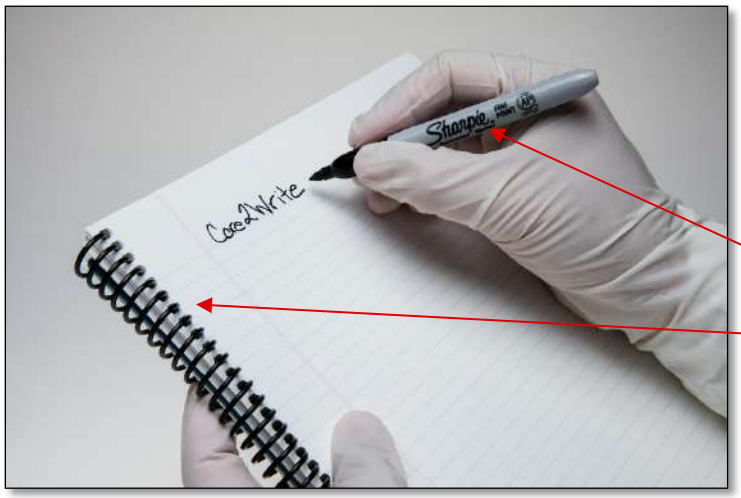
Core2Write® Logbook Features



- Each logbook in the case has a unique sequential number located on every page

- Rounded Corners to eliminate bending
- Laminated hard front and back cover with easy write areas
- Custom firm's procedure & logo printed on the logbook including REV date, SOP#, & procedure name
- Each page contains page number, REV date, SOP#, procedure name, and logbook number
- RFID imbedding capable for easy tracking
- Custom number of pages per book: 10, 20, 40 etc.

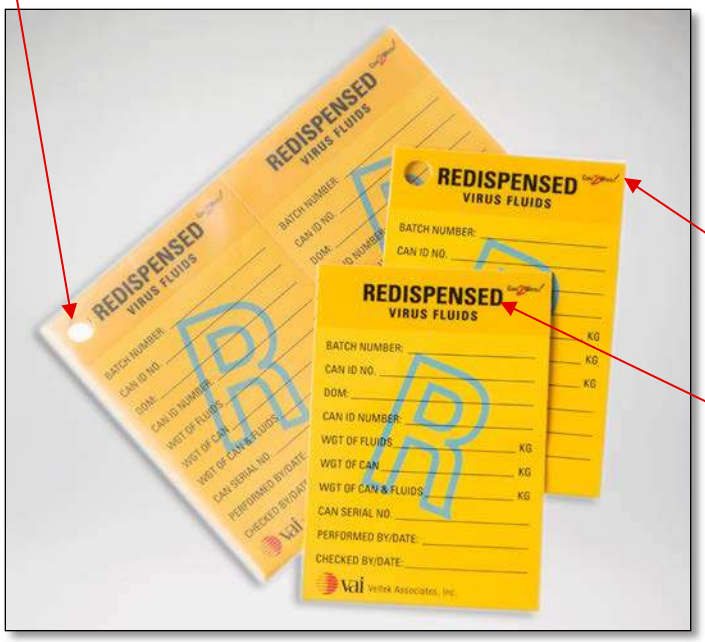
- Printed on VAI's **CleanPrint 10** synthetic writing substrate that is cellulose free
- Available in thousands of colors and color schemes to assure distinguishing between books



- Side stair stepping so ripped out pages can be ascertained
- Compatible with VAI's sterile **Core2Write** Pens and Sharpies; easily written on without ink smearing
- Non-shedding plastic spiral binding for easy lay flat opening
- Bar coding and QR coding of each book is available

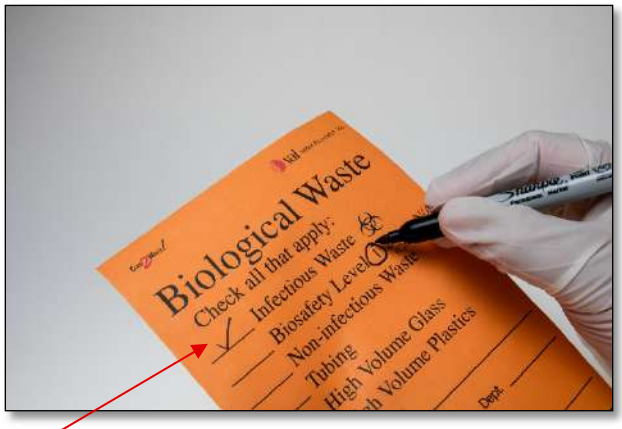
Core2Write® Tags Features

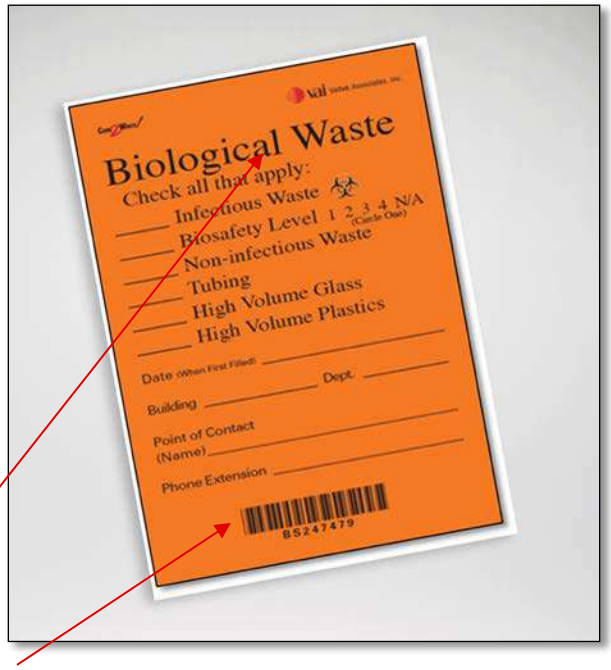
- Printed on VAI's **CleanPrint 10** synthetic writing substrate that is cellulose free
- Compatible with VAI's sterile **Core2Write** Pens and Sharpies; easily written on without ink smearing
- Optional hole punching in place of choice



- Easy tear perforations that will not shed
- Two-Ply bonding for strength – additional lamination available
- RFID imbedding capable for easy tracking
- Bar coding & QR coding of each tag is available
- Custom firm's procedure & logo printed on the tag including REV date, SOP#, & procedure name
- Each tag in the case can have a unique sequential number
- Available in thousands of colors and color schemes to assure distinguishing between tags

Core2Write Label Available Features





- Compatible with VAI's sterile **Core2Write** Pens and Sharpies; easily written on without ink smearing
- Custom firm's procedure & logo printed on the label including REV date, SOP#, & procedure name
- Easy peel, non-shedding, sticky label back
- Available in rolls, sheets, and cut labels in any size
- Crack and peel label available
- Excellent adhesion

- Bar coding and QR coding of each label is available
- RFID imbedding capable for easy tracking
- Printed on VAI's **CleanPrint 10** synthetic writing substrate that is cellulose free

Core2Write® RFID Key Tag Features

- Printed on VAI's **CleanPrint 10** synthetic writing substrate that is cellulose free
- Can be attached to any asset via hole punch
- Laminated for enhanced durability
- RFID inlay
- Gamma Irradiation resistant and sterilizable inlay available
- Available as an Ultra High Frequency RFID
- RFID can be read up to 50 feet away
- QR coded for optional QR code scanning

VAI-TAG-01

Core2Write Sharpie®

- Black ink & permanent, fine tip
- Individually double bagged
- Quadrupled bagged via the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Gamma irradiated sterile at 10^{-6} SAL
- Lot sterility tested according to current USP Compendium
- Compatible with all **Core2Write** products
- **CleanPrint 10** is easily written on without ink smearing

VAI-SHA-01

Core2Write Pens

- Retractable ball point
- Blue ink, medium point; 1.0 mm Tip
- Triple bagged at 10 per bag
- Bagged via the ABCD Cleanroom Introduction System®
- All bags individually labeled with lot number and expiration
- Gamma irradiated sterile at 10^{-6} SAL
- Lot sterility tested according to current USP Compendium
- Compatible with all **Core2Write** products
- **CleanPrint 10** is easily written on without ink smearing

VAI-PEN-01

OVERVIEW

The **Core2Print**® and its compatibility with **CleanPrint 10**®

Product Overview

Core2Print®, a patent pending technology, revolutionizes the method for printing required sterile documentation within aseptic manufacturing environments. The **Core2Print** unit is constructed of 316L stainless steel for durability and lexan windows for a clear view of the printer in operation.

Core2Print printing onto **CleanPrint 10**

HEPA filtration at 99.997% in the cabinet is a mandatory feature. Therefore, positive pressure within the cabinet is equally filtered to the controlled environment. The CP10 printer, housed in the cabinet, wirelessly prints onto VAI's pre-sterilized, cellulose free, **CleanPrint 10** synthetic writing substrate: the most durable in the industry.

Product Use

The **Core2Print** has been designed to provide the capability to print clean, low particulate, and sterile documents within the aseptic manufacturing environment. Due to the many features of the **Core2Print** unit and the CP10 printer, the cleanroom stays clean throughout documentation efforts. The mandatory HEPA filter, housed within the **Core2Print** unit, continuously makes the cleanroom cleaner while preventing contamination from exiting.

Features and Benefits

- Unit is chemical resistant and can be completely disinfected with VAI's sterile chemicals
- HEPA filtered with a sealed cabinet so contamination exiting to the controlled environment is reduced
- Utilizes the CP10 printer that is capable of printing without releasing particles into the controlled environment.
- CP10 printer uses patented Memjet® technology
- Has wireless capabilities so documentation required in the controlled areas can be signaled to print in the core from the exterior
- CP10 printer is a sheet fed, high speed, and digital quality printer that can print up to 12 inches/second (~60 pages per minute)
- CP10 printer has a high quality resolution, up to 1600x1600 dpi
- Prints on **CleanPrint 10** with chemical resistant and permanent ink
- Made for Grades A, B, C, & D

Core2Print CP10 Printer

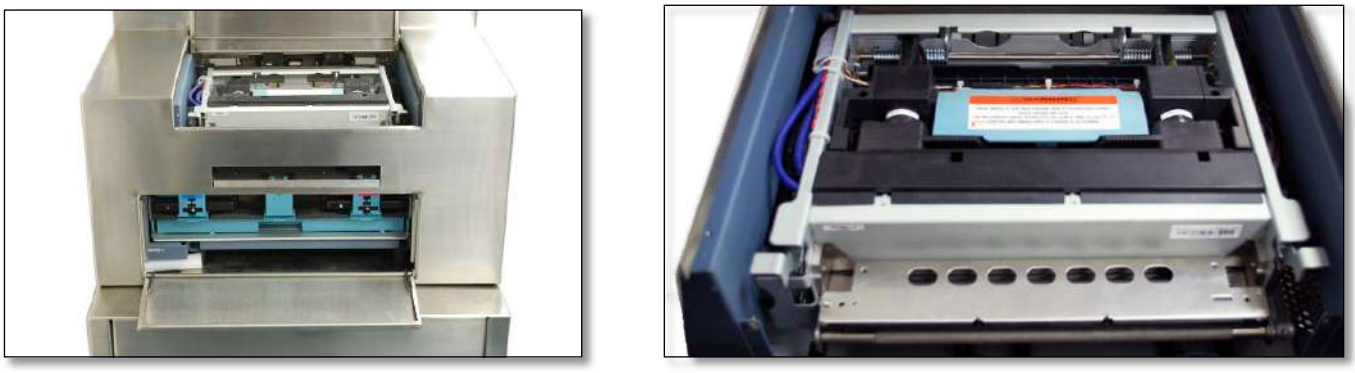
Quality and Manufacturing

- Constructed of epoxy coated 316L Stainless Steel that is chemical resistant
- CP10 printer is completely housed within the Stainless Steel **Core2Print** Unit and is accessible via a lift handle
- Side windows constructed of lexan for a clear view of the printer in use
- Standard buttons and lights are programmed into unit to indicate print status and warnings
- USB port, network port, main power switch, and power receptacle located on the outside of the unit
- White swivel caster wheels and push handle for easy transportation and maneuvering
- CP10 compatible ink is double bagged sterile
- **CleanPrint 10** compatible paper is double bagged sterile
- **CleanPrint 10 is** sheet fed into the CP10 inside the cabinet with adjustable paper guides
- Delivered as a complete unit

Complete **Core2Print** Unit

What is Memjet Technology?

Memjet technology is a page-wide printing format where the print head does not need to move. There are 70,400 print nozzles in each print head. The ink is water-based dye, therefore, allowing for an extremely small droplet size (1 picoliter). The combination between the page-wide format and droplet size enables CMYK process color printing to print at 1600 dpi resolution at speeds ranging to 30 feet to 60 feet per minute. Due to the ink's chemistry, the ink dries instantly, even at top speed. Substrates, which includes VAI's **CleanPrint 10**, must be receptive to water based dye ink.



Core2Print CP10 Printer

Printer Specifications

Feature	Specification
Size:	20" W x 24" L x 17-1/4" H (50.8 cm x 61 cm x 44.0 cm)
Weight:	75 lbs. (34 kg)
Electrical:	110 VAC, 50/60 Hz (220-240 VAC, 50/60 Hz available)
Interface:	CP10 enables wireless printing or use of a network (Ethernet) or USB cable
Media Size:	Minimum: 3" x 4.2" (76 mm x 107 mm), maximum: 9.5" x 17" (241 mm x 431 mm)
Cabinet Construction:	Epoxy coated steel/stainless
Patents:	Over 3,000 worldwide patents
Print Area:	8.5" x 17" (215 mm x 431 mm)
Width of Media:	CP10 printer can print **CleanPrint 10**® sheets from 3”-8” wide
Media Size:	Full bleed
Media Thickness:	Minimum: 0.004" (0.102 mm), Maximum: 0.020" (0.5 mm)
Media Area:	Sheet fed **CleanPrint 10** substrate and **CleanPrint 10** sheet fed labels in varying sizes Minimum: 0.004" (0.102 mm) Maximum: 0.020" (0.5 mm)
Print Speed:	12 inches per second (~60 pages per minute); 8X faster than printers in the market
Print Quality:	Digital quality process printing
Colors:	Rich colors at full-bleed, excels in printing readable small fonts and sharp barcodes
Print Quality:	High quality resolution process printing up to 1600 x 1600 dpi
Print Type:	Capable of printing full digital color at the same cost as monochrome
Print Mechanism:	Uses Memjet technology
Print Head:	5 color Waterflow print head (dramatically reduces particulates)
Nozzles/Head:	70,400 nozzles/print head to provide 900,000,000 drops of ink/second
Ink:	Water based dye chemically resistant permanent ink
Ink Cartridge:	Memjet®; changed in seconds with double bagged sterile ink cartridges
Ink Dry Time Period:	0.19 seconds
Counter:	Digital display for number of pieces run/job
Trays/Guides:	Intake and exit trays with adjustable guides
Buttons/Warning Lights:	Print status lights/buttons
Printing Orientation:	Portrait/landscape/labels color in one pass
Software:	CP10: print monitor software, label design software, and support software
Storage Temperature Range:	Long term: 14° F to 86° F (-10° C to 30° C) Short term: -11° F to 140° F (-25° C to 60° C) NOTE: Cumulative storage duration above 86° F (30° C) must not exceed 72 hours
Humidity Range:	5% to 95% relative humidity, non-condensing
Atmospheric Pressure Range:	70 kPa to 106 kPa (70 Kilopascals = 10.15264166 Psi and 106 Kilopascals = 15.374000228 Psi)
Electrostatic Discharge:	8kV air discharges or 4kV contact discharges, tested in accordance with IEC 61000-4-2
Sterile Media Expiration:	24 months

Ordering Information

Order #	Description	Qty
C2P-00	Core2Print, HEPA Filtered Printing System, Complete Unit, 316L Stainless Steel	1 Unit

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Product Validations – custom or standard
- Sample lot specific documentation packages
- Operators Manuals
- Additional product specifications

VAI's Cleanroom Documentation Systems – Via VAI's Disposable Products Manufacturing Division and Environmental Control Manufacturing Division, VAI has developed an innovative way to address and solve questions surrounding particulate and fiber shedding from cleanroom documentation. VAI's complete cleanroom documentation line includes: **CleanPrint 10** a synthetic writing substrate, **Core2Write** customized documentation, and **Core2Print** a cleanroom printing system. In addition to cleanroom documentation, VAI offers: sterile chemicals, process cleaners, saturated & dry wipes, sterile garments, cleaning equipment, viable environmental monitoring, cleanroom cart transfer systems, and consulting, training, and laboratory services. To learn more visit: www.sterile.com or call 610-644-8335.

Patents: www.sterile.com/patents