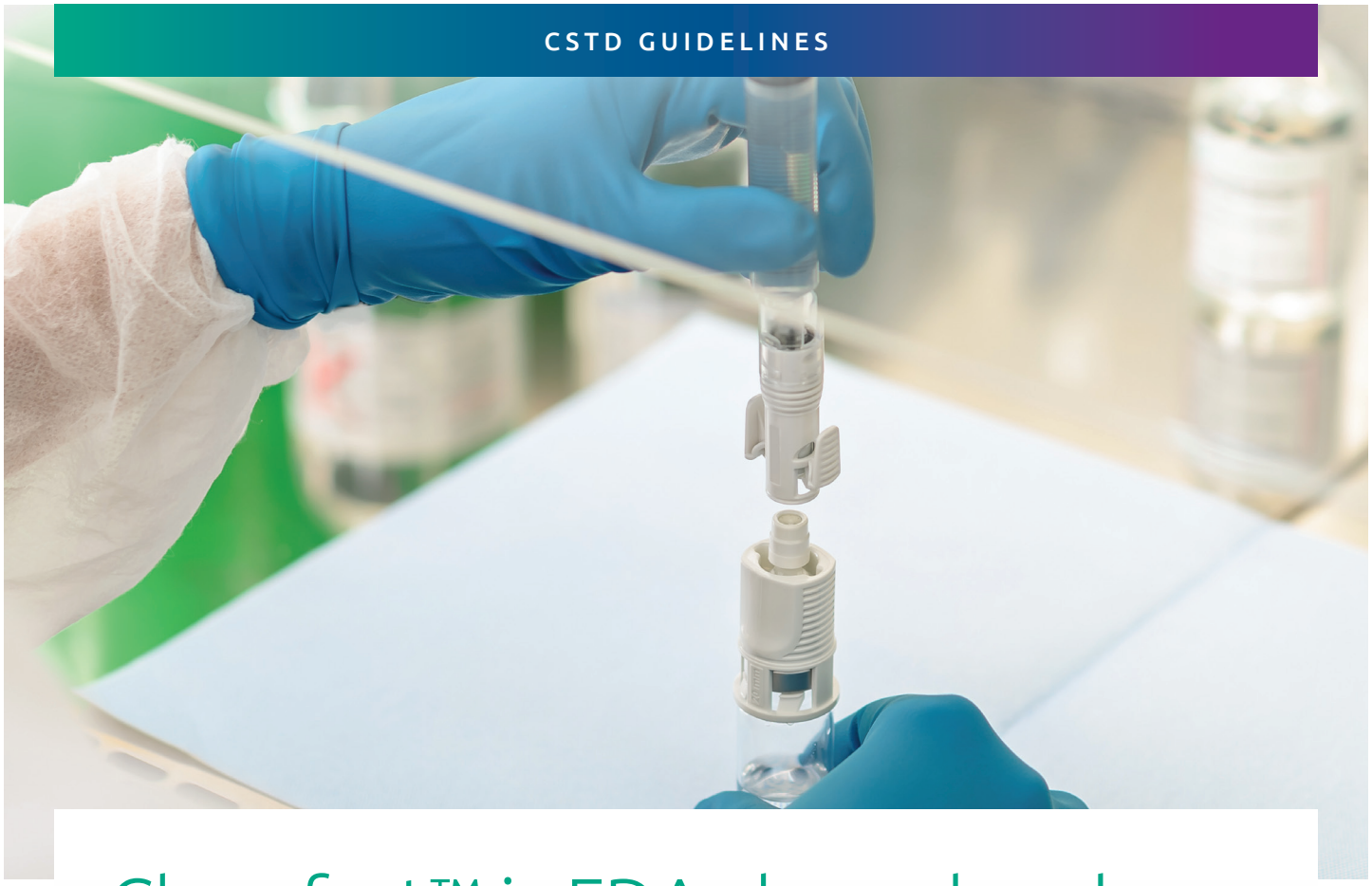
Chemfort™
Keeps you safe. Simply click

CSTD GUIDELINES



Chemfort™ is FDA cleared under ONB product code

Chemfort™ is a leading closed system transfer device (CSTD), designed to meet the highest safety standards when handling hazardous drugs

Chemfort™ is intended for the preparation, compounding and administration of antineoplastic and other hazardous drugs, keeping pharmacists, nurses and other health care workers safe.

Chemfort™ introduces new design and raw material upgrades, delivering a new level of efficiency, performance and ease of use, and has no known incompatibilities to hazardous drugs substances.

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices and others.

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What does ONB clearance mean?

It means that the FDA has found that Chemfort™ meets the standard for closed system transfer devices.

What is unique about Chemfort™ compared to other ONB devices?

Chemfort™ has the patented air cleaning Toxi-Guard® technology, which prevents airborne contaminants from entering the drug vial, as well as the escape of hazardous drug vapors, aerosols or droplets to the environment.

The Toxi-Guard® technology enables automatic equalization of pressure within the drug vial as diluent is added or drug is withdrawn, and retains sterility of the drug vials even after multiple uses.

What is the significance of the FDA ONB Product Code?

Prior to establishment of the ONB product code, Closed System Drug Transfer Devices such as Chemfort™ were evaluated by the FDA under the General Hospital Devices Branch (GHDB).
The ONB product code established a new standard for the industry that is specific for Closed System Drug Transfer Devices.
The ONB code is a part of the regulation description for Intravascular Administration sets, but it is specific for CSTDs.
ONB clearance is attained following presentation of data and tests which verify that the device prevents the escape of fluids, droplets or aerosoles and in parallel prevents entry of microbial and airborne contaminants.

How does the FDA define the ONB Product Code?[1]

In 2012, the U.S. Food and Drug Administration (FDA) began issuing 510(k) clearances under the product code ONB. All devices that are FDA cleared under the ONB code are considered as CSTDs **regardless** of their technology (air-cleaning or physical barrier).

Device
Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

Regulation Description
Intravascular Administration Set

Definition
Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare settings

Physical State
According to the FDA definition, the device should include multiple parts to enable a closed connection starting from the vial, through the syringe and ending in an IV set or transfer bag. It states that the Vial Adaptor should have piercing spikes, contain a Luer-Lock connector, fitted with an elastomeric membrane for a sealed connection. A needle-free access port and a side-pressure equalizing protector unit are optional.

Indications for Use

Chemfort™ is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol, or liquid form during preparation, reconstitution, compounding and administration, minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.

Chemfort™ prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.

1. FDA site: https://www.fda.gov/default.htm