

BD Medical

9450 South State Street
Sandy, Utah 84070 USA.

For information not listed here, see appropriate Buy Specification.

Title: BD Nexiva Dual Port IFU

Artwork Drawing Number: D16123

Single Unit Dimensions: 25" x 22" sheet folded to 5.5" x 5"

Print Colors: PMS 2755 Blue

Notes: Finished folded size is 5.5" x 5" with the BD Logo panel facing up.

Material: 40# White Offset

Revision History

Rev	Description of Changes	ECO No.
2	Material number 8008888 will be replaced by 8014368. Update File Version from D16123-1 (12-07) to D16123-2. Update labeling to meet the requirements found in the new Medical Device Directive (MDD) per PDN 09-3300-366. 1.) Remove Latex Symbol. 2.) Add Latex statement. 3.) Remove PVC Symbol. 4.) Add DEHP Free Statement. 5.) Add the Manufacture symbol in front of the Sandy address. 6.) Add the EC rep. symbol in front of the Temse Address. 7.) Update addresses from S-Drive 8.) Add the package damage symbol. Replaced country names with abbreviations, added title of Closed IV Catheter System before each instruction, and revised BD byline for consistency. The translations for Contrast Media and Max Flow Rate were moved to the front of the IFU.	ECO103156
3	With the addition of new translations from version 2, the dimensions need to be corrected from 24" x 22" to 24" x 19". Folding should go from 4.8 x 5.5 to 4.8 x 4.75.	ECO116328
4	Add "Indications Use" and "Device Description" sections. Add Rx ONLY statement. Add last line in Cautions section and Warnings section. Updated ISO symbols legend. Updated trademark by-line date. Updated address to RA S: drive. Updated SAP and document numbers. Changed page size to 25" x 22" and fold size to 5.5" x 5".	ECO151232