

A brief report on the
**Electron Beam Sterilization of 3.15 lakh devices of BD Venflon Pro I.V. Cannula at ARPF,
RRCAT, Indore**

RRCAT received an order for electron beam sterilization of 640 cartons (2.4 ton – individual devices 3.15 lakhs – cost of product ~ Rs 36 lakhs) of Venflon™ Pro I.V. Cannula at ARPF (Fig.-1) from M/s Becton Dickinson India Pvt. Ltd., Bawal, Rewari, Haryana. The devices were received on 1st Oct. 2022. The product belongs to Risk Class-B, is made of polypropylene and used for blood/fluid transfusion. M/s Becton Dickinson (BD), is one of the largest global medical technology companies in the world engaged in manufacturing of medical devices.

All process operations were carried out as per SOPs under the Quality Management System (QMS) for regulated medical devices as per ISO 11137, Medical Device Rules-2017, GOI (Sch.-IV and Sch.-V) and ISO 13485. RRCAT successfully achieved the high quality levels required, at par with international standards, for electron beam sterilization of this product and was audited through in-depth audit by third party agencies and the quality control division of M/s Becton Dickinson.

After successful inventory QC checks as per ARPF QMS requirements, the complete consignment was divided into 20 batches (32 cartons in each batch) and the traceability of each carton inside the facility was established by unique bar-code system. The non-irradiated and irradiated cartons have been stored in different, designated storage areas, Fig. - 2 (a & b) and identified using irreversible radiation indicator (turned red after irradiation from yellow before irradiation), Fig.-3 (a & b). The linac was operated at 9.3 MeV, 6 kW beam power and the complete consignment has been irradiated within **three working days** (effective irradiation time 22 hr.). Fig. - 4 shows the critical process parameter during irradiation. The average minimum dose and maximum dose delivered to the cartons were, 29.5 kGy and 52.0 kGy which is within the specified range of M/s BD (range of 25 to 55 kGy). Performance Qualification (PQ) for the product was done earlier this year at ARPF.

Since this is a significant event, a formal function is proposed to flag off the dispatch of the processed material on 20th October 2022.



REF 393234

BD Venflon™ Pro IV Cannula

0218

Manufacturing Site & Consumer Complaint Address: Becton Dickinson India Pvt. Ltd., Plot No.1, Sector-3, IMT Bawal, Rewari, Haryana-123501, INDIA. M.L. MFG/MD/2019/000034

Sterilization by: Becton Dickinson India Pvt. Ltd at Raja Ramanna Centre for Advanced Technology, Department of Atomic Energy, Government of India, Agricultural Radiation Processing Facility, Devi Ahilyabai Holkar Fruit and Vegetable Mandi complex, Indore, Madhya Pradesh, India, under Loan License no. MFG/MD/2022/000080

Becton Dickinson Infusion Therapy AB, Florettgatan 29C, PO Box 631, SE-251 06 Helsingborg, Sweden

MRP Rs. (Incl. of all taxes) per unit See Overprint.

20G

BD Vialon™ Catheter Material

1.1 x 32mm

BD Luer-Lok™

67 mL/min

STERILE R Made in India

500 units



(17)250800(10)2253580(30)500



(01)50382903932349

MRP Rs. 281.00 2022-09-01 2025-08-31 LOT 2253580

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Consumer Complaint Cell: 01-124-2282582 Email: CS@bd.com

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Fig.-1: BD IV cannula Venflon™



Fig.-2 (a): Non-irradiated BD cartons stored in non-irradiated product storage area of ARPF



Fig.-2 (b): Irradiated BD cartons stored in ready to dispatch product storage area of ARPF

Agricultural Radiation Processing Facility, Indore
A CDSCO FDA, ISO 9001:2015 and ISO 13485:2016 Certified Facility

ARPF-10-2022-0007-008-0003-0029-30

Customer : Becton Dickinson India Pvt. Ltd. (BD)
 Registratoin Number : ARPF-REG-0007
 Order Number : ARPF-ORDER-0003
 Date of Irradiation : 06-10-2022
 Purpose of Irradiation : Sterilization

CONENTS OF THIS PACKAGE HAVE BEEN IRRADIATED WITH ELECTRON BEAM AT ARPF, INDORE

Fig.-3 (a): Non-irradiated carton barcode

Agricultural Radiation Processing Facility, Indore
A CDSCO FDA, ISO 9001:2015 and ISO 13485:2016 Certified Facility

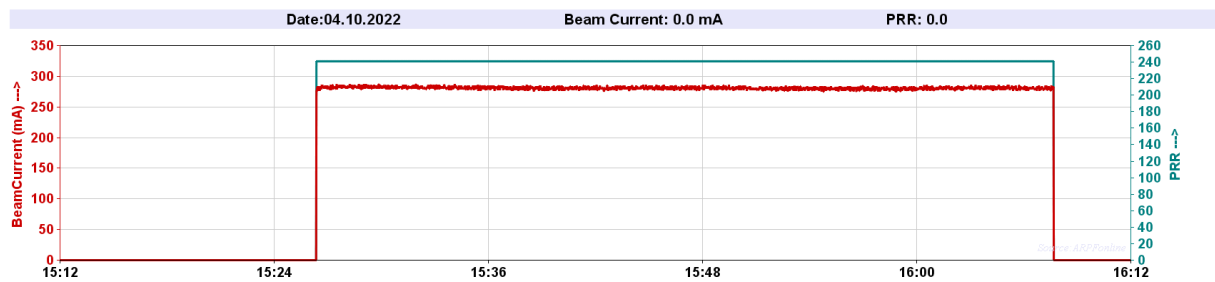
ARPF-10-2022-0007-008-0003-0029-30

Customer : Becton Dickinson India Pvt. Ltd. (BD)
 Registratoin Number : ARPF-REG-0007
 Order Number : ARPF-ORDER-0003
 Date of Irradiation : 06-10-2022
 Purpose of Irradiation : Sterilization

CONENTS OF THIS PACKAGE HAVE BEEN IRRADIATED WITH ELECTRON BEAM AT ARPF, INDORE

Fig.-3 (b): Irradiated carton barcode

ARPF Linac-2 Beam Information



04-Oct-2022 15:31:11 Critical Parameter Display ARPF-RPID-MD-022 CLOSE

Interlock OK

Product Name/ID	Target Dose (KGy)	Nominal Energy (MeV)	Power (KW)
IV Cannula	25.0	9.30	6.00

Parameter	Beam Current (mA)	PRR (Hz)	Kly HV (KV)	Scan Time (ms)	Scan Min Curr (A)	Scan Max Curr (A)	Conveyor Speed (mtr/min)
Online Value	280.25	241	113.66	399.64	-3.99	4.03	2.46

Beam Current (mA) PRR (Hz) Kly HV (KV) Scan Time (ms) Conv Speed (m/min) Scan Current (A)

Fig.-4: Beam parameter of Linac while irradiation and critical parameter display