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Technical Data Sheet

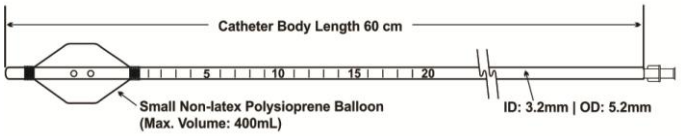
CR1B - Reusable PVC Expulsion Catheter

PRODUCT DESCRIPTION and INTENDED USE:

The CR1B Anorectal Balloon Expulsion Catheter is a specific Reusable PVC Manometric Catheter model which isolates the anorectal balloon function of an anorectal manometric catheter. The Anorectal Balloon Expulsion Catheter is used to evaluate the muscular contractions of the rectum.

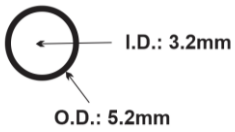
Lifetime of product: 5 years or 50 uses (whichever occurs first)

Time period for each use: 30 minutes inside the gastrointestinal system

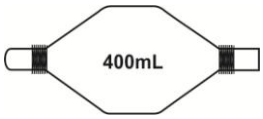


DEVICE COMPONENTS:

Single Lumen Tubing:



Non-Latex Polyisoprene Balloon (max volume: 400mL)



LIST OF MATERIALS IN PRODUCT:

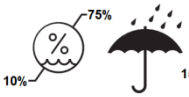
- PVC tubing
- PVC Luer
- Silk Sutures
- Loctite UV Glue (#3972)
- Polyisoprene Balloon

OTHER DEVICES/ACCESSORIES

- Syringe (not included)
- Stopcock (not included)

APPLICABLE STANDARDS:

Standard/CS/Document Name	Description
MDR (EU) 2017/745	European Medical Device Regulations
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016/A11:2021 EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019/A11:2021 EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1:General requirements
EN ISO 10993-1:2020 ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10: Tests for skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
EN ISO 20695:2020	Enteral feeding systems - Design and testing
ISO 17664-1:2021	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
MDCG 2020-13	Clinical evaluation assessment Report Template
MDCG 2020-5	Clinical Evaluation on Equivalence A guide for manufacturers and notified bodies
MEDDEV 2.12-1 rev 8, January 2013	Guidelines on a Medical Device Vigilance System.
MEDDEV 2.7/1: rev. 4, June 2016	Clinical evaluation: A guide for manufacturers and notified bodies.
MEDDEV 2.12/2 rev. 2 January 2012	Post market clinical follow-up studies; A guide for manufacturers and notified bodies
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
MDCG 2019-9 - Rev.1	Summary of safety and clinical performance A guide for manufacturers and notified bodies
EN ISO/IEC 17050-1:2010	Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements
EN IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
EN ISO 80369-3:2016/A1:2022 EN ISO 80369-3:2016	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications - Amendment 1
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice

CE 2862        Made In Canada