# PRODUCT TECHNICAL DATASHEET

| ITEM REF: | 011-41229-01 | REVISION: | 06 |
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| **LEGAL MANUFACTURER** | **ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA |
| **IMPORTER** | **ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands |
| **EU AUTHORISED REPRESENTATIVE (EUAR)** | **Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany |
| **ASSEMBLY SITE** | **ICU Medical (Utah), Inc.,** 4455 Atherton Drive, Salt Lake City, UT 84123 |
| **CLASSIFICATION CODE** | **GMDN** Code: 34925 |
| **INTENDED USE** | Catheter, cardiac, balloon, thermal dilution. A flexible, balloon-tipped tube with a probe that monitors cardiac output by use of thermodilution techniques. It is used to measure cardiac output, right atrium, pulmonary artery and pulmonary capillary wedge pressures; continuously monitor pulmonary artery temperature and sample blood and administer drugs and solutions intravenously and measure cardiac output via the computers which interface with 14K ohm catheters. The device can also monitor an existing pacing device. |
| **ITEM DESCRIPTION** | TD Catheter, 7F, 4 Lumen, 110 cm, Heparin Coated |

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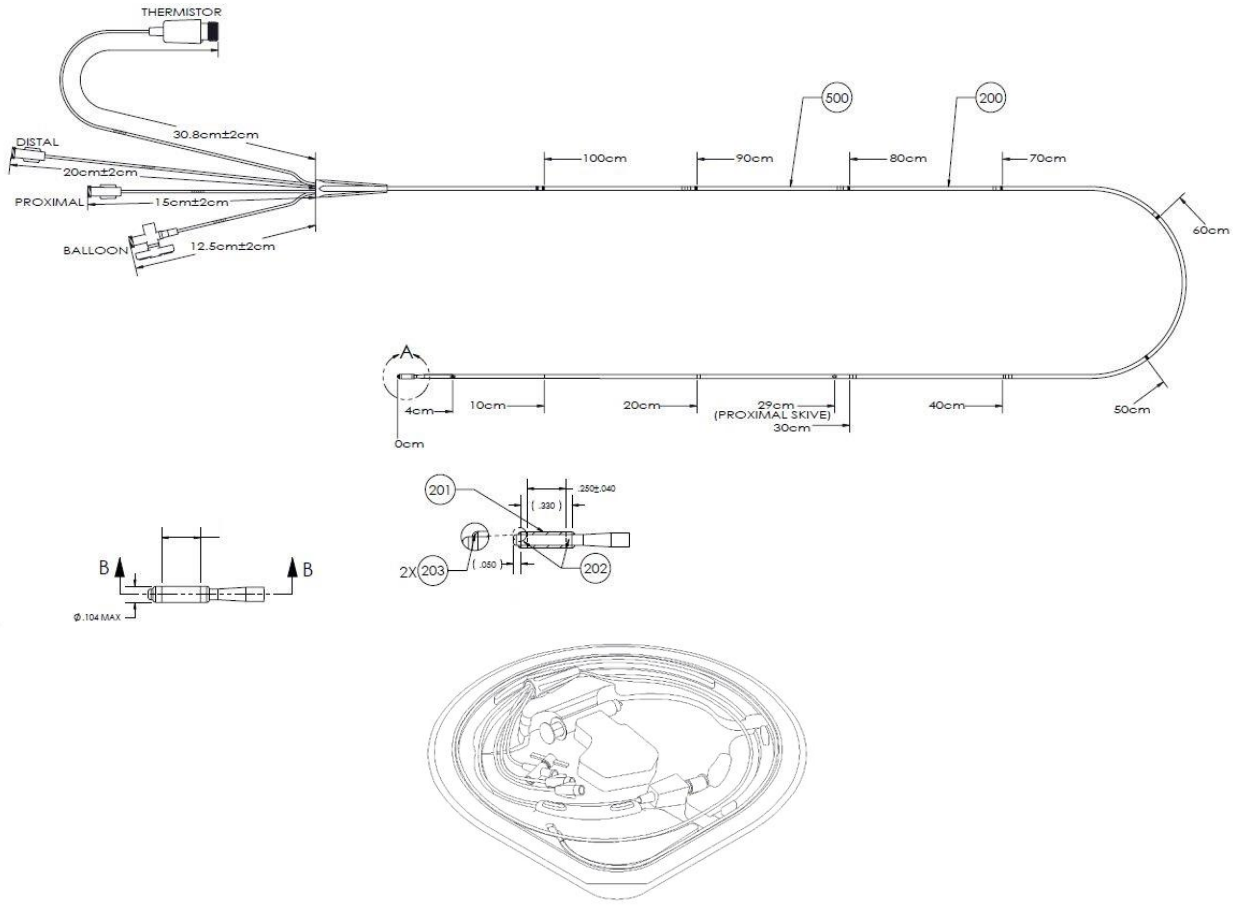
| **PRIMING VOLUME (ml)** | Distal: 0.99<br>Proximal: 1.08 | **LENGTH (cm)** | 110 | **WEIGHT (g)** | N/A | **CASE QTY** | 5 |



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| **ITEM SPECIFIC DATA** | | **Chemical Compatibility** | Lipids & Common Chemotherapeutics |
| | | **Luer Compatibility** | ISO 80369-7 Compliant. |
| | | **Sterilization and Shelf Life** | ETO; 18-Month Expiration |
| **LIST OF COMPONENTS** *(Contains Latex and DEHP)* | 200 | TD CATHETER, 7F, 4 LUMEN, 110 CM, SUB | PVC<br>INK<br>POLYURETHANE ADHESIVE<br>PVC/POLYURETHANE ALLOY<br>PCTG<br>ABS |
| | 201 | BALLOON, KILLIAN, OPTICATH | NR LATEX |
| | 500 | HEPARIN COATING | HEPARIN BENZALKONIUM |
| | - | 3CC SYRINGE STAKED | POLYPROPYLENE<br>POLYISOPRENE |
| **MATERIAL COMPLIANCE AND BIOCOMPATIBILITY** | Product has met the requirements of ISO 10993-1 and related standards for biocompatibility. | | |
| **PRECAUTIONS** | Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package. | | |
| **LABELS AND DIRECTIONS FOR USE** | Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual package and on the outside of the cardboard box. Each sales package contains a Direction for Use where applicable. | | |
| **PACKING AND PACKAGING** | The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging met the requirements of BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials. | | |
| **TRACEABILITY** | Lot number provides full traceability of all components and manufacturing processes. | | |
| **STORAGE** | Store in a dry and clean place. Product should be retained in packaging until ready for use. | | |
| **DISPOSAL** | The user must dispose of the device according to hospital disposal policy. | | |
| **PRODUCTION AND ENVIRONMENT CONTROLS** | • Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures.<br>• Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures.<br>• Production and release specific tests are performed according to quality procedures.<br>• Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures.<br>• Bioburden tests are performed on production samples to verify conformity of the microbial charge according to quality procedures. | | |
| | **Quality System complies to:** | ISO 13485:2016 | |

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| **QUALITY SYSTEM AND PRODUCT CERTIFICATION** | **Product Certification:** | The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended. |
| | **CE Certificate Number:** | 252.129 |
| | **Notified Body:** | NSAI National Standards Authority of Ireland. |
| | **MDD Device Classification:** | Class III |