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TECHNICAL DATA SUMMARY (TDS)

CORONARY CONTROL SYRINGES

1. DEVICE DESCRIPTION

The CCS is a three piece control syringe comprised of a clear polycarbonate barrel, silicone piston/tip, and ABS plunger. The syringes are available with either a: fixed male luer or a rotating male adapter connector with silicone O-Ring; palm pad, ring grip or wing grip; and locking ring or solid plunger. The ring grip and ring plunger provide single-handed control for filling and injecting. Merit's CCS syringes are available in size options of 6, 8, 10, 12 and 20 mL. Customization of Merit's control syringes (K06 series catalog numbers) include colored plungers and printed text (verbiage as well as ink color).

The CCS Smart Tip syringe is unique in that the tip is pressure-energized for reduced force and friction. The Smart Tip was designed to adjust its barrel control with any increase in injection pressure. When higher pressures are generated, the syringe tip expands itself against the inner walls of the syringe to maintain the injection seal. As injection pressure decreases, the syringe tip automatically lightens its contact with the syringe barrel walls to improve smoothness and feel. Merit's Smart TIP syringes are available in size options of 10, 12, and 20 ml.

The Inject8 Coronary Control Syringe is an 8 mL syringe similar to the standard CCS. The TIPInject8 syringe is unique in that the barrel inner diameter is small enough to achieve appropriate pressures during injections. The plunger design of the Inject8 syringes differs from the standard CCS syringe in that:

- CCSB series syringes have a palm pad style plunger instead of the locking ring plunger design of the standard CCS syringes.
- CCSW series syringes have a palm pad style plunger with an open "wing" style grip instead of the closed "ring" style grip.

The Inject10 syringe is the same syringe as the Inject8 with the exception that the barrel has a nominal fluid delivery capacity of 10 mL. In order to achieve the greater capacity, the barrel was lengthened. The Inject10 syringe has a two-ring barrel grip fitted with either a rotating adapter or a fixed male luer connector on the plunger. It also is available with a palm pad and wing grip.

2. INTENDED USE / INDICATION FOR USE

The Merit Coronary Control Syringe is intended to be used by a cardiologist or radiologist during angiographic or radiological procedures.

3. Contraindications

There are no contraindications or warnings for this product.

4. INSTRUCTIONS FOR USE

The Instructions for Use and product labelling for the product have been formatted in multiple languages.

5. Classification:

a. European Community:

The classifications take into consideration of all rules based on the component with the highest classification. For devices claiming conformity to the Essential Requirements of the MDR, the following classification rules are used:

The product is not an active device, and none of the special rules apply.

Subjects	Applied Rules	Justification
Non-invasive devices	☐ 1, ☒ 2, ☐ 3, ☐ 4	See table below.
Invasive devices	☐ 5, ☐ 6, ☐ 7, ☐ 8	Not an invasive device.
Active devices	☐ 9, ☐ 10, ☐ 11, ☐ 12	Not an active device.
Special rules	☐ 13, ☐ 14, ☐ 15, ☐ 16, ☐ 17, ☐ 18	None of the special rules apply.

Table 1: MDR Classification Rationale of Triboglide

Component	Rationale	Rule	Class
Syringe	Non-invasive devices intended for channeling liquids… for the purpose of eventual infusion, administration or introduction into the body	2	I – Sterile Measuring

b. United States Food and Drug Administration:

Class:	II
Product Code/CFR:	DXT / 21 CFR 870.1650
510(k) Reference:	K163084 – CCS, Inject8, Inject10 K875196 – SmartTip
Device Name:	Piston Syringe

c. Canada:

Class:	II (Rule 5)
License:	6072

d. GMDN and CND

GMDN Codes:	47017 - General-purpose syringe, Single Use 15286 – Angiographic syringe
CND Code:	A0201 - Single Use Syringes

6. DEVICE SPECIFICATIONS

SPECIFICATION NAME	DESCRIPTION
Capacity	6 mL, 8 mL, 10 mL, 12 mL, 20 mL
Plunger style	Ring plunger with ring grip Locking ring plunger Palm pad plunger with ring grip Palm pad plunger with wing grip
Luer Connections	Per ISO594-1/2 (or ISO 80369-7 testing currently underway)
Graduation Scale	Per ISO 7886-1

7. MATERIALS OF CONSTRUCTION

PRODUCT COMPONENT	MATERIAL
Barrel	Polycarbonate
Fixed Male Luer	Polycarbonate
Rotating Adapter Body	Polycarbonate
Plunger/Adapter	Acrylonitrile-Butadiene-Styrene (ABS)
Retainer Cap	Polyethylene
O-ring / tips / seals	Silicone rubber
Lubricant	Medical grade silicone fluid
Ink	Black or White U.V. Curable

PACKAGING COMPONENT	MATERIAL
Blister	Formed blister of 1073 Tyvek and EVA Trilayer film
Carton	Corrugate single wall

8. Packaging

Merit's syringes are packaged as sterile, single use devices. The barrier properties of the packaging assure that sterility is maintained. All units are packaged in a pre-formed blister tray and sealed with medical grade Tyvek™, or a Nylon pouch configuration. CCS syringes are packaged 25 units per carton, 4 cartons per shipper.

Non-sterile syringe assemblies are packaged to facilitate incorporation into customized procedure packs which are provided to clinicians as sterile, single use devices. Product labeling of non-sterile devices clearly specifies the requirement for further processing (e.g. sterilization).

Certain bulk non-sterile syringe assemblies include labeling that specifies the validated sterilization parameters that repackers can use to leverage Merit's CE mark. These are triple poly-bagged and placed into cartons to protect the product and to reduce particulate contamination.

Figure 1: Syringe Line Multivac Packaging

9. Labeling

Figure 2: Unit Label – CCS Family

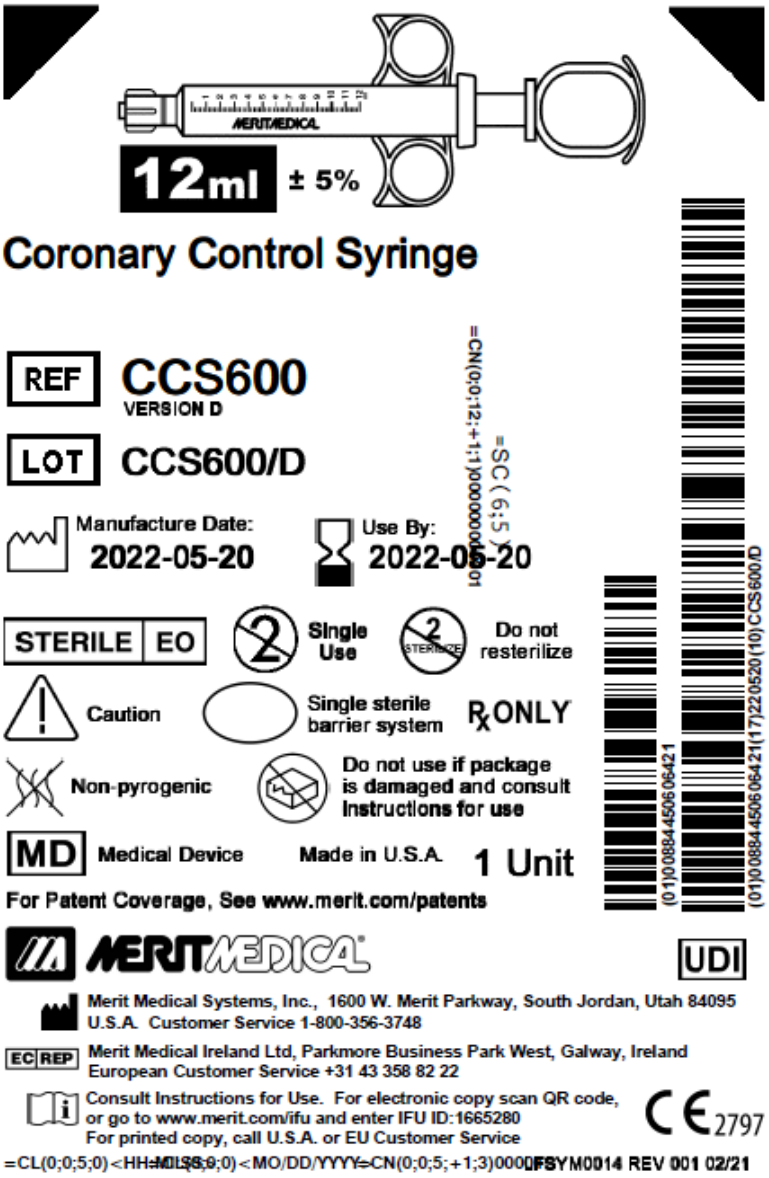


Figure 3: Carton Label – CCS Family

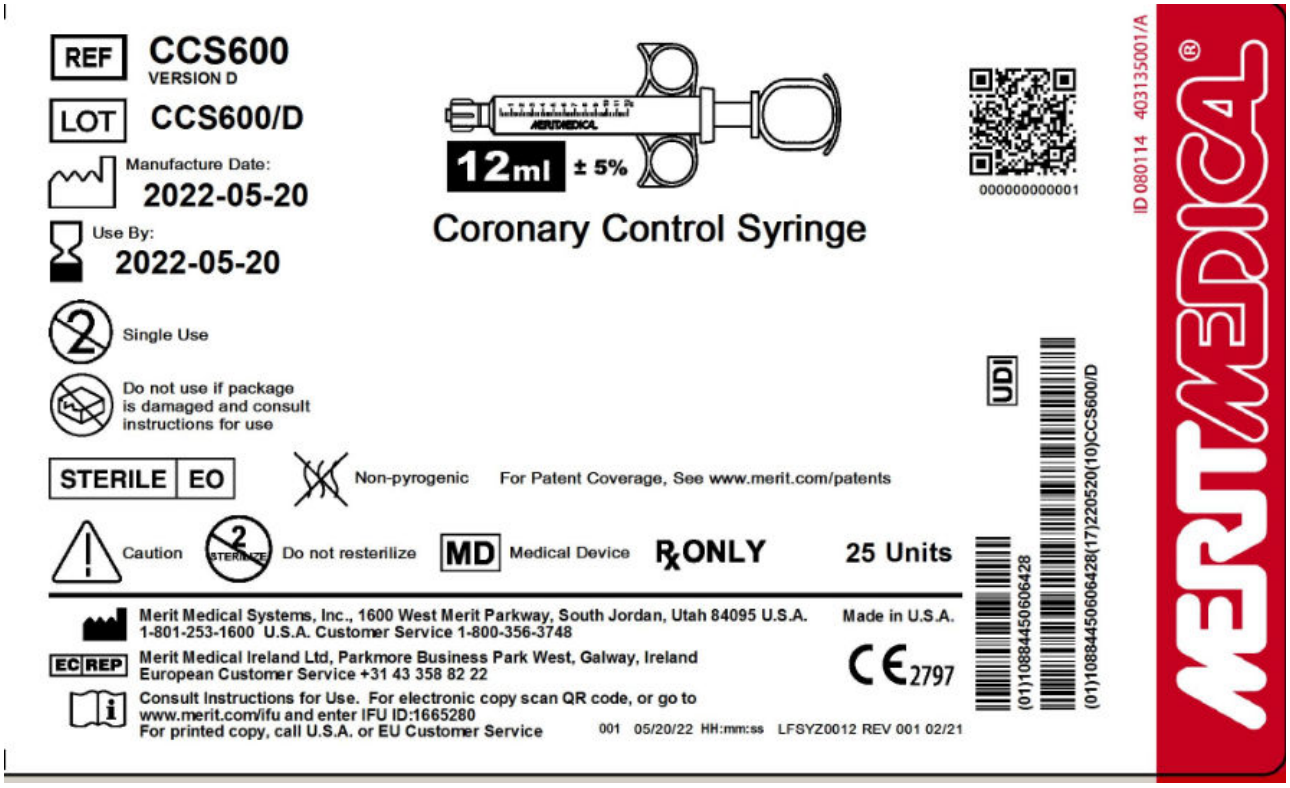
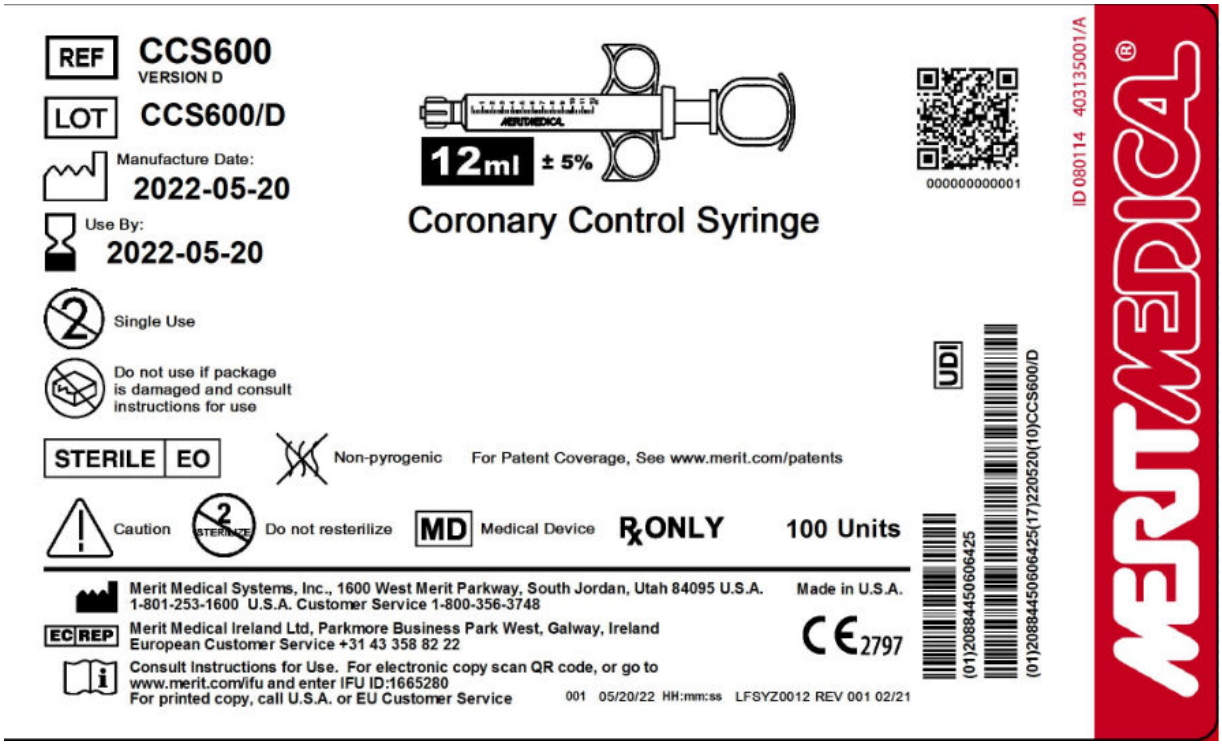


Figure 4: Shipper Label – CCS Family



10. Compliance with Relevant Regulations and Technical Standards

EU:
Medical Device Regulation (MDR) of the European Union (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices). The applicable Certificate is MDR 716389.

US:
The product is legally marketed according to the requirements of the United States Food and Drug Administration in compliance with the premarket notification 510(k) process. The 510(k) clearance letters are K163084 and K875196

CAN:
The product is legally marketed in Canada as a class II device per license 6072.
The qualification activities that were performed for the product were based on the below applicable standards:

DOCUMENT	TITLE
Horizontal (General) Standards	
Council Directive 93/42/EEC	Medical Device Directive of the European Union
Regulation (EU) 2017/745	Medical Device Regulation (MDR) of the European Union (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices)
ISO 13485	Quality Systems – Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes
MEDDEV 2.1/5 (June 1998)	Medical Devices: Guidance Document: Medical Devices with a Measurement Function
ISO 14971	Medical devices — Application of risk management to medical devices
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11135-1	Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-1	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ASTM D4169	Standard practice for performance testing of shipping containers and systems
ASTM F1980	Standard guide for accelerated aging of sterile barrier systems for medical devices
ASTM F2475	Standard Guide for Biocompatibility of Medical Device Packaging Materials
ASTM F 2096	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
ASTM F 1929	Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration
ASTM F88/F88M	Standard Test Method for Seal Strength of Flexible Barrier Materials.

DOCUMENT	TITLE
BS EN 980	Symbols for use in the labeling of medical devices
BS EN 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
USP	United States Pharmacopeias
EN 556-1	Sterilization of medical devices – Requirements for medical devices to be labeled "sterile"
AAMI TIR 28	Product Adoption and process equivalency for ethylene oxide sterilization
ANSI/AAMI ST72:2011	Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Product Specific Standards	
ISO 7886-1	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 594-1	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
ISO 594-2	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
ISO 80369-7	Small bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

11. Storage and handling

Store under general warehouse conditions.

12. Biocompatibility

The Product meets ISO 10993-1 and the FDA guidance document: Use of International Standards ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process."

13. SHELF LIFE

The Products are labelled for a 5-year shelf life.
Non-sterile units are labeled for 5-year shelf life.

14. STERILIZATION DETAILS

Merit Medical Systems, Inc. utilizes Ethylene Oxide (EO) sterilization for the CCS Syringes. The sterilization cycle is validated according to European International Standard ISO 11135-1. These products meet ISO 10993-7 requirements for ethylene oxide sterilization residuals.

Merit also offers the option to Gamma sterilize some of the products described in this Technical Data Summary. The Gamma radiation process is validated using the Method VD_{max}^{25} – Substantiation of 25 kGy as the sterilization dose procedure from ISO 11137-2. Dose Audits are performed quarterly according to ISO 11137-2.

15. MATERIAL COMPLIANCE

EU REACH: To the best of our knowledge based on information currently available from our raw material suppliers as well as an assessment of the general material properties, the product does not contain substances listed on the ECHA Candidate List of Substances of Very High Concern (SVHC).

CMR and Endocrine-Disrupting Substances: An assessment of the raw materials used to manufacture the product in this summary with respect to carcinogenic, mutagenic or toxic to reproductive ('CMR') compounds, of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272|2008 of the European Parliament and of the Council, or substances having endocrine-disrupting properties was completed. No CMR compounds or substances having endocrine-disrupting properties are contained in the products that are the subject of this Technical Data Summary.

16. MANUFACTURING CONDITIONS / QUALITY CONTROL

Merit Medical Systems, Inc. manufactures the products in this summary in accordance with the United States Food and Drug Administration (FDA) Quality System Regulations, 21 CFR Part 820 *Quality Systems Regulations*.

Merit Medical Systems facilities used to manufacture the product in this summary are also certified to ISO 13485 Quality Management System.