TECHNICAL DATA SUMMARY (TDS)

ZEONEX (COP)

1. DEVICE DESCRIPTION

The Zeonex (COP) syringe is similar in design and use to the Medallion syringe but made from a Cyclo-Olefin Polymer that acts as a moisture barrier. The COP material prevents leaching and allows for a longer shelf life when used in a pre-filled form.

The COP Syringes are standard 3 piece piston syringes constructed with clear barrels, color plungers, and a black piston seal. The barrel may be customized with black or white printed text. Available size options include 1, 10, and 20 mL.

The syringe barrels are constructed from a clear cyclo-olefin polymer with flat style finger grips and a fixed male Luer connector. The syringe barrels are marked for accurate, clear and easy reading, and are available in EO configuration. The COP (Zeonex) plungers are molded of Acrylonitrile-Butadiene-Styrene (ABS) and are fitted with a silicone rubber piston seal. Configurations are also available in polycarbonate plungers.

2. INTENDED USE / INDICATION FOR USE

The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body.

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 Zeonex (COP)

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:	FMF / 21 CFR 880.5860
510(k) Reference:	K182216 – 1 mL K142636 – 10 mL K152783 – 20 mL
Device Name:	Piston Syringe

c. Canada:

Not Licensed

d. GMDN and CND

GMDN Code:	47017 - General-purpose syringe, Single Use
CND Code:	A0201 - Single Use Syringes

6. DEVICE SPECIFICATIONS

SPECIFICATION NAME	DESCRIPTION
Capacity	1 mL, 10mL, and 20mL
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	Cyclo Olefin Polymer (COP)
Plunger	Acrylonitrile-Butadiene-Styrene (ABS); or Polycarbonate
O-ring / tips / seals	Silicone rubber
Ink	Black or White U.V. Curable
Lubricant	Medical grade silicone fluid

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. Zeonex (COP) syringes are packaged25 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).

Figure 1: Syringe Line Multivac Packaging

9. Labeling

Figure 2: Unit Label - Zeonex (COP)

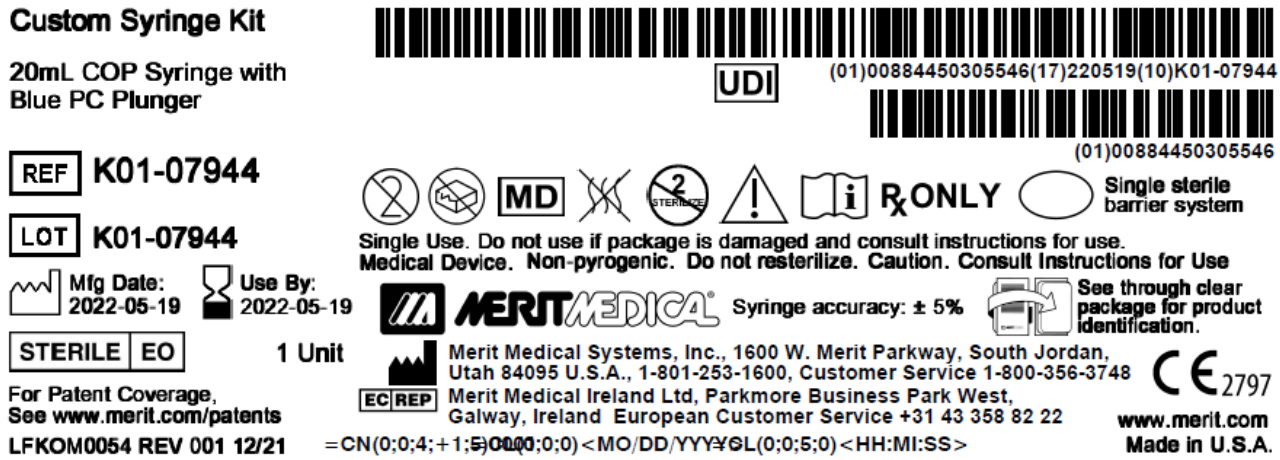


Figure 3: Carton Label - Zeonex (COP)

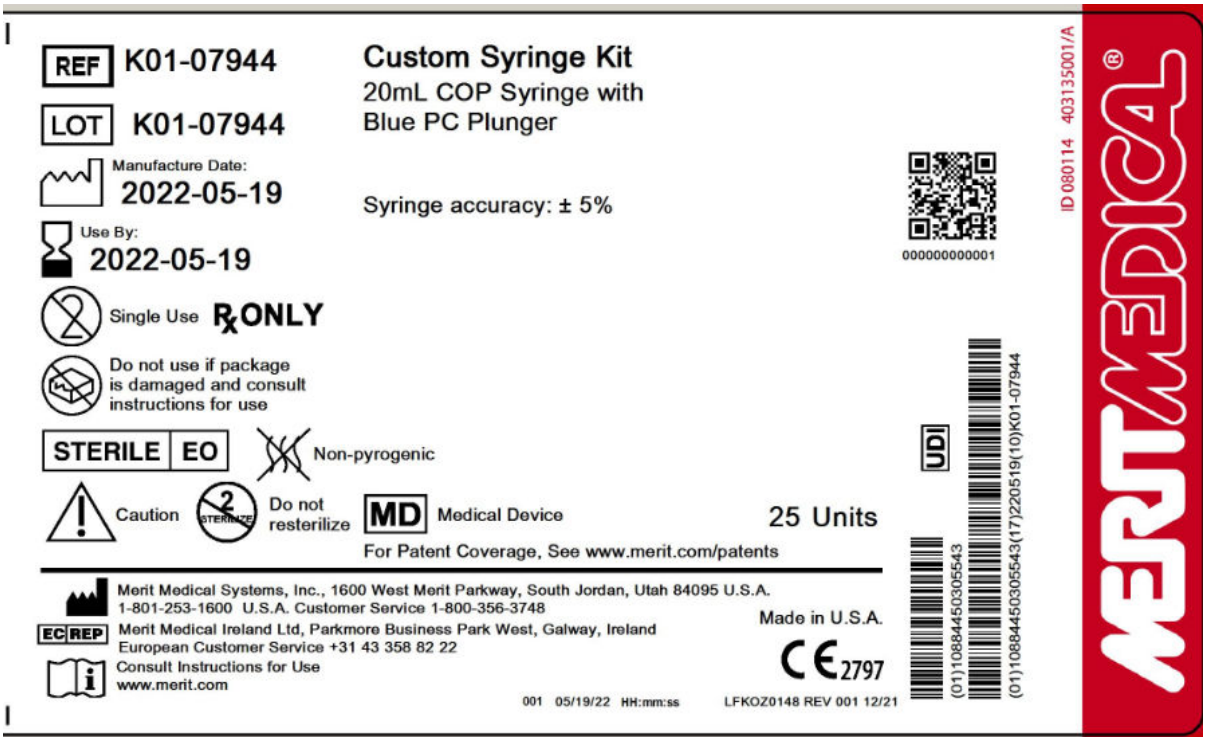
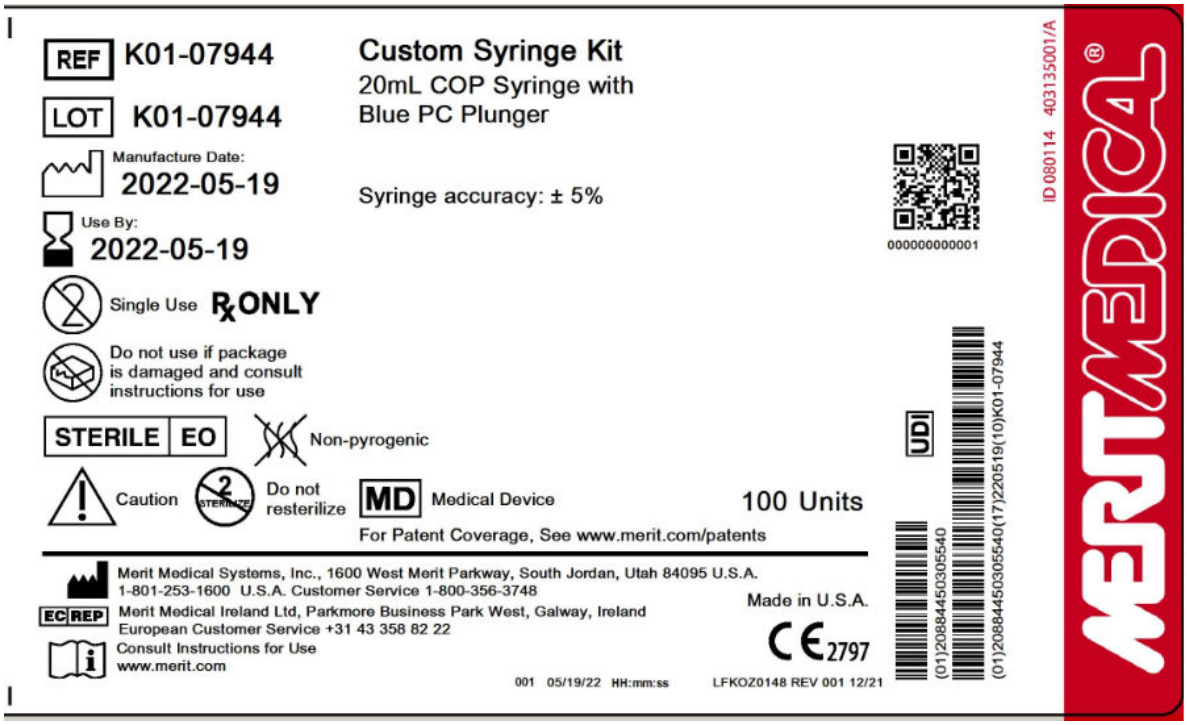


Figure 4: Shipper Label - Zeonex (COP)



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: K182216 (1 mL), K142636 (10 mL), K152783 (20 mL).

CAN:
This product is not licensed in Canada

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
EN/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 11135-1	Sterilization of health care products -- Ethylene oxide -- 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.
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

DOCUMENT	TITLE
EN 556-1	Sterilization of medical devices – Requirements for terminally-sterilized medical devices to be labeled "Sterile"
USP	United States Pharmacopeias
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 Zeonex (COP) Syringe. 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.

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.