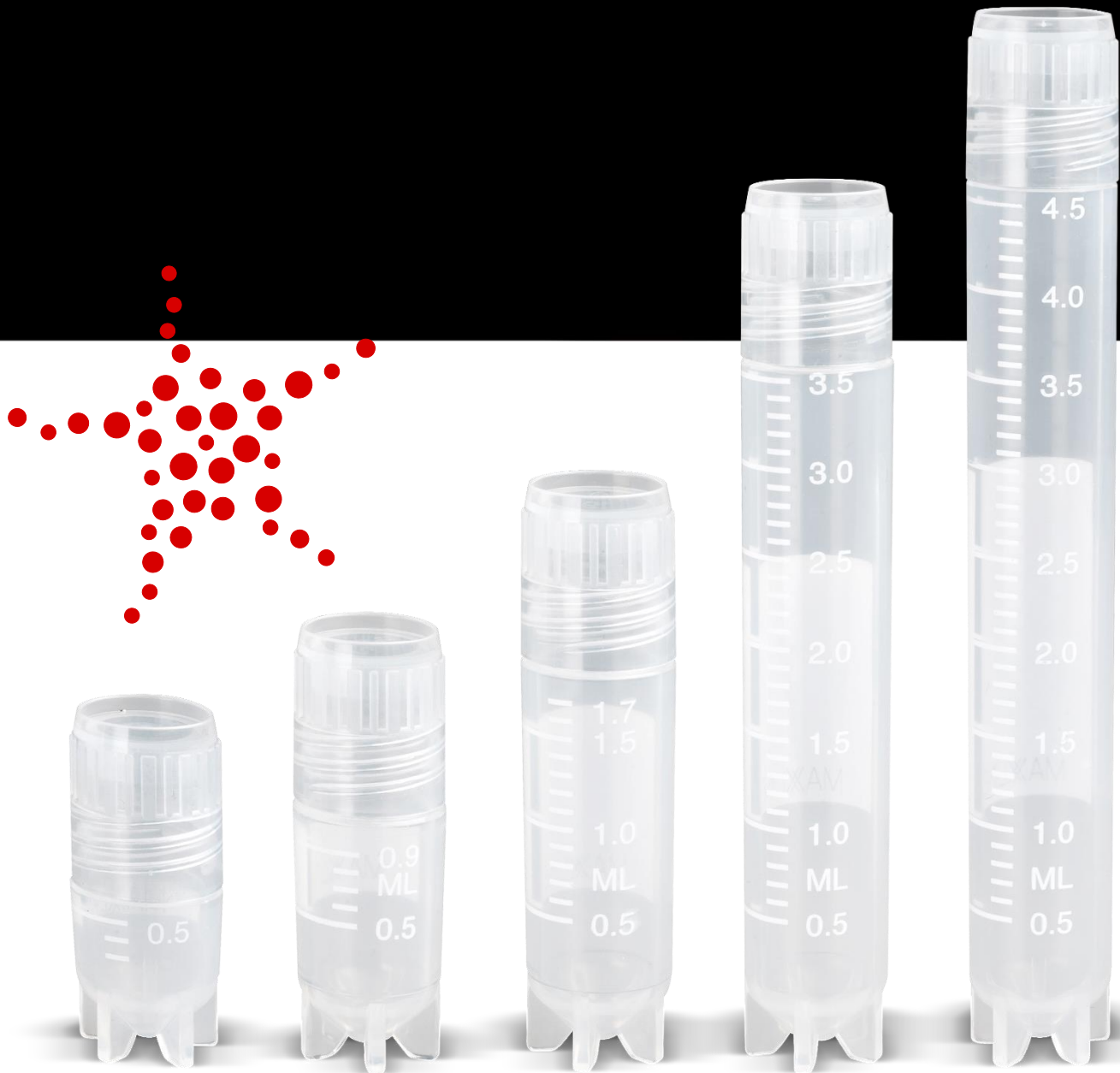


MAXXLINE Cryo Tubes™

DATASHEET



0,5 ml • 1,0 ml • 2,0 ml • 4,0 ml • 5,0 ml
External Thread

Our Product

Maxxline Cryo Tubes™ are developed for valuable samples and to provide users with safe and handy solutions for storing within cell banking, biobanks, pharma research and transportation of biological materials.

The Maxxline Cryo Tubes™ are one of the most complete lines of cryogenic vials available.

The unique StraightLine™ design minimize risk of contamination.

The tubes are self standing and available in 5 different sizes from 0,5 ml to 5,0 ml.

It's the only cryo tube with external thread and star foot that can be stored in standard 10 x 10 cryo boxes. This gives 23% additional storage capacity compared to conventional cryo solutions.

The cryo tubes are easy to recognize with the red line indicator. The red line indicate the maximum recommended filling for freezing in liquid nitrogen in the vapor phase at -196°C, which is your security for safe storage.

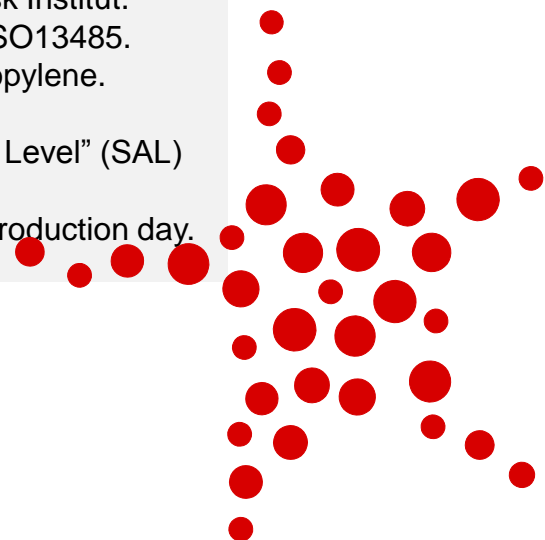
Maxxline Cryo Tubes™ are featured with single-handed quick seal closure. The super fast thread design allows tightening or removal with only half a turn, thus avoiding long-term injuries to the user.

We are proud to announce that our new product is designed and manufactured in Denmark.

Quality standards

Maxxline Cryo Tubes™ are subjected to extensive testing and certified:

- Quality test performed by Dansk Teknologisk Institut.
- 20-years-life-cycle-test performed by Dansk Teknologisk Institut.
- Manufactured according to ISO 9001, ISO14001 and ISO13485.
- Manufactured of FDA-approved, medical grade polypropylene.
- Manufactured in at clean room environment.
- Sterilized after ISO 11137-2:2013 - "Sterility Assurance Level" (SAL) by standard products 10^{-6} .
- Full VDMax25 validation test performed from the first production day.



Features

- ▶ **Designed and manufactured in Denmark.**
- ▶ The design of the Maxxline Cryo Tubes™ ensures optimization in all perspectives, such as storing and handling.
- ▶ The range offer 5 convenient sizes of tubes; 0,5 ml – 1,0 ml – 2,0 ml – 4,0 ml – 5,0 ml.
- ▶ The 0,5ml cryo tube fits in a 32 mm cryo box.
- ▶ The Unique design of tube and cap is the only cryo tube with external thread and star foot which can be stored in standard 10 x 10 cryo boxes. This gives 23% additional storage capacity compared to conventional cryo solutions.
- ▶ The unique StraightLine™ design minimize risk of contamination.
- ▶ The self standing cryo tube with star foot is compatible with common working stations on the market.
- ▶ Featured with single-handed quick seal closure. The super fast thread design allows tightening or removal with only half a turn, thus avoiding long-term injuries to the user.
- ▶ Special designed cap with lip seal feature ensures 100% leak proof seal.
- ▶ Made of specially formulated polypropylene. Cap and tube are both made of polypropylene and has the same coefficient of expansion, which further enhances the leak proof qualities at various temperatures.
- ▶ Graduated and with writing area for sample identification.
- ▶ Easy to recognize with the red line indicator. The red line indicate the maximum recommended filling (MaxFilling196™) for freezing in liquid nitrogen in the vapor phase at -196°C, which is your security for safe storage.
- ▶ Maxfilling indicator for freezing at -20°C (MaxFilling20™) and -80°C (MaxFilling80™), which is your security for safe storage.
- ▶ Turnable2Colored Inserts™ for Maxxline Cryo Tubes allowing easy recognition of the tubes.
- ▶ Packaged in resealable stand-up pouches that minimize the use of benchtop space.
- ▶ Optimized for vapor phase in liquid nitrogen storage.

Overview

Turnable2Colored Inserts™
Offered in 3 different color combinations. In total 6 colors.

Special designed cap
Lip seal feature. Ensures 100% leak proof seal.

Print
Graduated and white marking area for sample identification.

StraightLine™
The design minimize risk of contamination. Fits into 9x9 and 10x10 cryo boxes.

StarFoot™

External thread

Single-handed QuickSealClosure™
Super fast thread design allows tightening or removal with only half a turn.

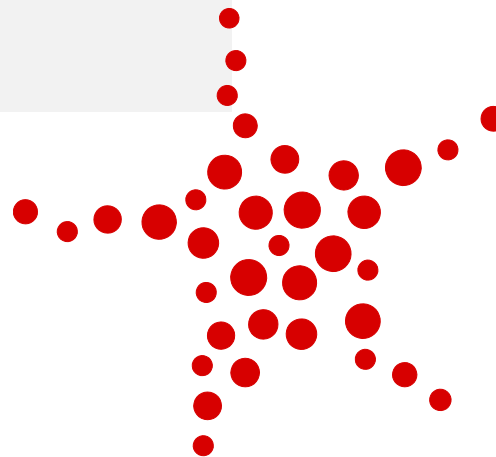
MaxFilling20™
Maximum recommended filling for freezing at -20°C.

MaxFilling80™
Maximum recommended filling for freezing at -80°C.

MaxFilling196™
Red line indicate the maximum recommended filling for freezing in liquid nitrogen in the vapor phase at -196°C.

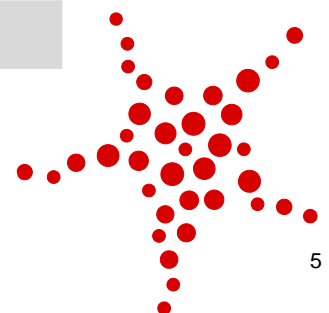
Do not use cryo tubes for storage in the liquid phase but in the vapor-phase above the level of the liquid phase nitrogen.
Always use appropriate safety equipment and handle according to following steps:

- 1) Freeze to -20°C and keep for two hours.
- 2) Freeze to -80°C and keep for two hours.
- 3) Freeze to -196°C.



Product basic

	0,5 ml	1,0 ml	2,0 ml	4,0 ml	5,0 ml
Catalog no.	MLC05	MLC1	MLC2	MLC4	MLC5
Product line	Maxxline Cryo Tubes TM				
Length (mm)	28,6	36,1	47,6	73,3	88,5
Diameter outer (mm)	12,08	12,08	12,08	12,08	12,08
Calibrated max indicator Vapor LN2 (to -196C)	0,4	0,8	1,3	3,3	4,3
Max indicator -20°	0,5	0,9	1,7	3,5	4,5
Max indicator -80°	0,4	0,9	1,5	3,5	4,5
Material	Polypropylene				
Closure	Lip seal				
Quick seal	Half turn				
Writing area	√	√	√	√	√
Anti-rotation lid	√	√	√	√	√
External thread	√	√	√	√	√
Anti-rotation bottom	Star Foot				
Style	Self Standing				
Bottom shape	Conical				
Sterility SAL 10-6	√	√	√	√	√
RNase -/DNase free	√	√	√	√	√
Type	Bio banking and cell culture cryogenic				
Autoclavable	√	√	√	√	√
RCF (g)	17.000				
CE certified	CE				



Quality standards

PRODUCTION

Almeco Streightline Cryo tubes are designed and manufactured in Denmark. All produced of raw materials, compliant to applicable regulations and standards.

Almeco products are manufactured in a clean room environment. Hygienic production is ensured by a sealed of area. Visitors are not allowed in the production area without permission.

QUALITY MANAGEMENT SYSTEM

Production GMP oriented

Certified ISO 9001:2008

Fulfills the criteria of medical devices according to European Directive 93/42/ECC

BIOLOGICAL SAFETY

Polypropylene (PP)

Non-cytotoxic according to ISO 10993-5, USP 312008 test

Free of stripping agents, softeners and heavy metals

Free of detectable DNA/RNA and ATP

Free of detectable DNase/Rnase

Does not contain substances of animal origin and is therefore free of TSE/BSE

Free of detectable endotoxins (pyrogens).

Product is sterilized, process is validated according to ISO 11137-2:2013

Sterility Assurance Level (SAL) 10^{-6}

Product intended for single use only

QUALITY CONTROL

Quality test performed and approved by Dansk Technological Institute.

All products are subject to visual and measurement control, passing through the production line, and visually inspected before packing.

Quantity electronic counted and controlled by check weighing

Leakage test for each batch

Lot number printed on each product pouch and case label

COMPONENT MATERIAL

Colorings are free from heavy metals

Packaging materials are free from heavy metals

DISPATCH CONTROL

Products are dispatched only when all criteria of our quality assurance system is fulfilled.

STORAGE AND WAREHOUSING

Expiration time (EXP) 5 years from date of sterilization

Storage recommendation relative humidity max.: 50-60% . Temperature: 10-30°C (50-86°F).

Do not expose to direct sunlight

CERTIFICATIONS/COMPLIANCE

CE Marked for storage of in vitro diagnostic samples.

Meets all the provisions on in vitro diagnostic medical devices 98/79/EC – Directive DS EN14254 + DS EN14820

The star

Our five star standards

Raw material

Raw material passes a rigorous and documented access.

Production

Clean room production is regular documented by quality controls based on ISO9001.

Maintenance

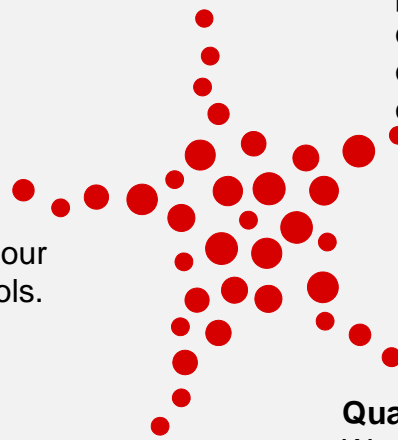
Our technical department provides daily examinations on our machines and tools.

Dispatch control

Our internal quality department perform random examinations of the quality and quantity before final release.

Quality control

We conduct quality control and daily freezing tests on each manufactured lot no. This is documented in reports and by picture material.





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