

CLOSURE SYSTEMS FOR STANDARD VIALS



ARaymondlife* proposes an innovative range of closure systems for pharmaceutical vials. RayDyLyo offers an all plastic solution, an alternative to aluminum caps.

ADVANTAGES

-))) Eliminates the crimping operation for liquid fill and lyo products
-))) Stopper pre-assembled in the RayDyLyo cap
-))) Vial closure by simple vertical pressure, manual or automatic
-))) Capping and closing in the lyophilizer (class A guarantee)
-))) Reduces the risk of the stoppers adhering to the lyophilizer plates
-))) Reduces « pop-off » effect



RayDyLyo CTO Ø 13, 20, 32 mm

- CTO version (Central Tear-Off)
- Suitable for **injectables** under liquids and freeze-dried forms
- **Specific development** on request for non ISO vials



RayDyLyo TTO⁽²⁾ Ø 20 mm

- TTO version (Total Tear-Off)
- **Easy access to the stopper** after cap removal and body part dismantling
- Usable for **mixing and reconstituting products**



SIMPLIFIED PROCESS

2 steps in 1



Traditional cap
2 steps

RayDyLyo cap
1 step only

CUSTOMIZATION



- **Wide color range** available for the cap
- **Labelling possibility** on body part

ERGONOMICS

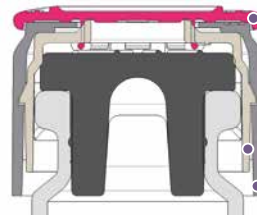
- **Easy cap removal**
- **Less risk of damaging gloves**

(1) Detailed information on demand.
(2) In progress, available soon.

	COMPATIBILITY					STERILIZATION		
	Vials ISO 8362-1	Vials ISO 8536-1	Lyo Stopper ISO 8362-5	Serum Stopper ISO 8362-2	Serum Stopper ISO 8536-2	Gamma Sterilization	Autoclave Sterilization	Process Lyophilization
CTO 13	✓		✓	✓		✓	✓	✓
CTO 20	✓		✓	✓		✓	✓	✓
CTO 32		✓			✓	✓	✓	

ADDITIONAL SERVICES

- Delivered with or without stopper
- Sterilization gamma or autoclave
- Packaging options in PE bag or Tyvek
- Possible delivery in standard or customized nests



SPECIFIC RAW MATERIALS

(Medical grades USP Class VI)

- Cap Polypropylene (PP)
- Cage Polycarbonate (PC)
- Body Polybutylene Terephthalate (PBT)

VALIDATIONS ON VIALS 2R, 4R, 6R, 8R⁽³⁾

Description	Reference number
Standard guide for accelerated aging of sterile barrier systems for medical devices	ASTM F 1980-07
Sterilization of health care products — Moist air Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 17665-1:2006
Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11137-1:2006
Sterilization of health care products — Radiation Part 2: Establishing the sterilization dose	ISO 11137-2:2012
Elastomeric parts for parenterals and for devices for pharmaceuticals use Part 3: Determination of released-particle count	ISO 8871-3:2003
Injection containers and accessories Part 2: Closures for injection vials	ISO 8362-2:2008
Injection containers and accessories Part 5: Freeze drying closures for injection vials	ISO 8362-5:2008
Infusion equipment for medical use Part 2: Closures for infusion bottles	ISO 8536-2:2003
Rubber closures for containers for aqueous parenteral preparations, for powders, and for freeze-dried powders	EP 3.2.9:2008 (Edition 7)

(3) Detailed validation plan of CTO 20 is available on demand.

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ISO 15378



ISO 9001

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