

Instructions for Use

These instructions are valid for:



- Nunc™ Universal Tube, 2 mL internally-threaded
- Nalgene™ Cryogenic Tube, 2 mL externally-threaded
- Nalgene™ Cryogenic Tube, 5 mL externally-threaded



- 374512
- 5000-0020
- 5000-0050

GTIN

- 10850016058574
- 10850016058598
- 10850016058604

GMDN

- 47775

Intended Use

| | |
|------------------------------------|--|
| Intended Purpose/Use | These polypropylene tubes are specimen receptacles and are intended for use in cryogenic storage and inter-laboratory ground transportation of human specimens containing biological materials and cells subjected to <i>in vitro</i> diagnostic (IVD) examination. The tubes can be used to store samples down to the vapor phase of liquid nitrogen temperatures. The tubes are disposable and for single use only. Intended for laboratory and healthcare professional use. |
| Indications for Use | To be used when a healthcare professional has ordered <i>in vitro</i> diagnostic testing be performed on patient specimens. |
| Intended User Group | Healthcare and laboratory professionals. |
| Use Environment | Hospitals, clinical collection sites and clinical laboratories. |
| Intended Patient Population | Patients with a medical or clinical condition that requires <i>in vitro</i> diagnostic investigation, diagnosis, and possible medical treatment. |
| Contraindications | No known contraindications have been identified. |

Instructions for Use

1. Fill the tubes to no more than 90% total capacity.
2. Ensure that the threads of tube and cap are dry before closing.
3. Tighten the cap.
4. Specific instructions for use of these tubes in cold storage must be defined and implemented by the end user according to the type of sample stored as well as the downstream application.
5. If used with liquid nitrogen (LN₂), only place these cryogenic tubes in the vapor phase of the LN₂.

Conditions of Use (without Specimen)

| Nunc™ Universal™ Tubes and Nalgene™ Cryogenic Tubes | |
|---|---|
| Transportation Conditions | Ambient temperature (-30°C to 60°C or -22°F to 140°F) |
| Suggested Storage Conditions | Room temperature (20°C to 25°C or 68°F to 77°F) |

Limitation of Use

The Nunc™ Universal Tubes and Nalgene™ Cryogenic Tubes are only intended for use in cryogenic storage and inter-laboratory ground transportation of human specimens containing biological materials and cells subjected to in vitro diagnostic (IVD) examination.

Technical Information

Disposal of the device must be handled according to local regulations.

This medical device complies with IVDR (EU) 2017/746.

Declaration of Conformity is available from the manufacturer and/or EU Representative.



Warnings and Precautions

To ensure correct usage, familiarise yourself with the following warnings before using the device.

1. Warning: For use in vapor phase of liquid nitrogen only. Submersion can lead to hazardous situation.
2. Overfilling can lead to caps bursting during sample expansion, which can lead to leakage and contamination.
3. For single use only.
4. Nunc™ Universal Tube, 2 mL internally-threaded have a two year shelf life. Nalgene™ Cryogenic Tube, 2 mL and 5 mL externally-threaded have a five-year shelf life. Do not use after expiry date.
5. This device is supplied sterile via irradiation sterilization method. Do not use the product if the product packaging is unsealed or damaged.
6. Fluid path is sterile and non-pyrogenic while cap is intact. Discard any tube that arrives with cap missing or askew.
7. If samples are being shipped by methods other than ground, shipping on dry ice to prevent leakage is recommended.
8. Dispose of used tubes in appropriate biohazard collection container.
9. Report any serious incident that occurred in relation to these devices to the manufacturer and EU competent authority.
10. Use of Nunc™ CryoFlex Tubing (Catalog# 343958) can offer additional safe handling protection.

Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

Quality Assurance Release Specifications

5000-0020, 5000-0050

| TEST | RELEASE LIMIT(S) |
|--|---|
| Pyrogen (endotoxin) | < 0.5 EU/mL |
| Irradiation Certificate of Processing Review | 19.0 - 28.0 kGy |
| DNase | 8 x 10 ⁻⁷ Kunitz units/μL |
| RNase | 1.9 x 10 ⁻¹⁰ Kunitz units/μL |

374512

| TEST | RELEASE LIMIT(S) |
|--|---|
| Pyrogen (endotoxin) | < 0.5 EU/mL |
| Irradiation Certificate of Processing Review | 19.0 - 40.0 kGy |
| DNase | 8 x 10 ⁻⁷ Kunitz units/μL |
| RNase | 1.9 x 10 ⁻¹⁰ Kunitz units/μL |

Pack Label

thermo scientific

Nunc™ Universal™ Tube, 2 mL
internally-threaded

2.0 mL 48 tubes per bag

REF 374512

UDI  (01) 1 0850016 05857 4
(11) 240611
(17) 290610
(10) 999999999
(240) 374512

LOT 999999999 2029-06-10

IVD  **STERILE R**

EC REP Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000
Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800

CE 2797

Assembled/Packed in USA  8-1030-201 0324 **00088**
www.thermofisher.com

Case Label

thermo scientific

Nunc™ Universal™ Tube, 2 mL
internally-threaded

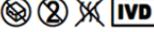
2 mL 480 / CS 48 tubes per bag

REF 374512

UDI  (01) 1 0850016 05857 4
(11) 210916
(17) 260915
(10) 0000000
(240) 374512

LOT 000000000

2026-09-15 **STERILE R**

IVD 

CH REP Thermo Fisher Scientific Inc. (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland +41 61 716 77 00

EC REP Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000
Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 www.thermofisher.com

CE 2797

Case: 00004  01234 8-1030-210

Made in USA

thermo scientific

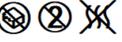
Nalgene™ Cryogenic Tube, 2 mL
externally-threaded

2.0 mL 25 tubes per bag

REF 5000-0020

UDI  (01) 1 0850016 05859 8
(11) 240611
(17) 290610
(10) 999999999
(240) 5000-0020

LOT 999999999 2029-06-10

IVD  **STERILE R**

EC REP Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000
Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800

CE 2797

made in USA  8-1030-201 0324 **00088**
www.thermofisher.com

thermo scientific

Nalgene™ Cryogenic Tube, 2 mL
externally-threaded

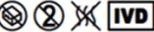
2 mL 500 / CS 25 tubes per bag

REF 5000-0020

UDI  (01) 3 0850016 05859 2
(11) 210916
(17) 260915
(10) 0000000
(240) 5000-0020

LOT 000000000

2026-09-15 **STERILE R**

IVD 

CH REP Thermo Fisher Scientific Inc. (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland +41 61 716 77 00

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Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 www.thermofisher.com

CE 2797

Case: 00004  01234 8-1030-210

Made in USA

thermoscientific****

Nalgene™ Cryogenic Tube, 5 mL externally-threaded

5.0 mL 10 tubes per bag

REF 5000-0050

UDI  (01) 1 0850016 05860 4
(11) 240514
(17) 290513
(10) 999999999
(240) 5000-0020

LOT 999999999  2029-05-13

IVD  **STERILE R**

EC REP Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800

made in USA  8-1030-201 0324 **00088**
www.thermofisher.com

thermoscientific****

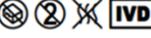
Nalgene™ Cryogenic Tube, 5 mL externally-threaded

5 mL 500 / CS 10 tubes per bag

REF 5000-0050

UDI   (01) 3 0850016 05860 8
(11) 210916
(17) 260915
(10) 0000000
(240) 5000-0050

LOT 000000000  2026-09-15 **STERILE R**

IVD  **STERILE R**

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Case: 00004  01234 8-1030-210

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Made in USA

Symbols Glossary in accordance with ISO 15223-1:2021 and other references

| Symbol | Title of Symbol | Description of Symbol | Reference Number |
|---|---|--|------------------|
|  | Manufacturer | Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. | 5.1.1 |
| EC REP | Authorized representative in the European Community | Indicates the authorized representative in the European Community. | 5.1.2 |
|  | Date of Manufacture | Indicates the date the medical device was manufactured. | 5.1.3 |
|  | Use-by date | Indicates the date after which the medical device is not to be used. | 5.1.4 |
| LOT | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. | 5.1.5 |
| REF | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. | 5.1.6 |
| STERILE R | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. | 5.2.4 |
|  | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened. | 5.2.8 |
|  | Single <i>sterile</i> barrier system | Indicates a single barrier system. | 5.2.11 |
|  | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed. | 5.3.7 |
|  | Do not re-use | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. | 5.4.2 |

| | | | |
|---|---|---|---------------|
|  | Consult instructions for use | Indicates the need for the user to consult the instructions for use. | 5.4.3 |
|  | Caution | Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions | 5.4.4 |
|  | <i>In vitro</i> diagnostic medical device | Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device | 5.5.1 |
|  | Non-pyrogenic | Indicates a medical device that is non-pyrogenic. | 5.6.3 |
|  | Unique Device Identifier | Indicates a carrier that contains Unique Device Identifier information. | 5.7.10 |
|  | European Conformity Mark | Indicates European technical conformity. | (EU) 2017/746 |
|  | Authorized representative in Switzerland | Indicates the authorized representative in Switzerland. | IvDO |

Contact Information

Legal Manufacturer

Nalge Nunc International Corporation,
a part of Thermo Fisher Scientific Inc.
75 Panorama Creek Drive
Rochester, New York 14625 USA
Phone: +1 585 586 8800
www.thermofisher.com

EU Representative

Nunc A/S,
a part of Thermo Fisher Scientific Inc.
Kamstrupvej 90
DK-4000 Roskilde, Denmark
Phone: +45 4631 2000
www.thermofisher.com

Swiss Representative

Thermo Fisher Scientific (Schweiz) AG
Neuhofstrasse 11, 4153
Reinach (BL) Switzerland
+41 61 716 77 00
www.thermofisher.com

This is revision D01 of this IFU. This revision updated the following information:

- Updated the pack label images.