

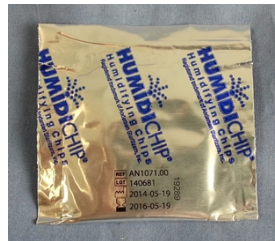
ANDERSEN STERILIZERS HUMIDICHIP AND HUMIDITUBE TECHNICAL DATA SHEET**DEVICE GENERAL DESCRIPTION AND CLASSIFICATION**

The AN1071 Humidichip is utilized within the EOGas 4 Sterilization system to maintain relative humidity in the sterilization bag during the sterilization cycle. Relative humidity in the sterilization bag is maintained above 35% and below 90% using the Humidichip. The Humidichip is a cellulose pad containing a solution of distilled water and proprietary antimicrobial solution hypochlorite as a preservative. Each Humidichip is individually packaged in a foil/plastic pouch, over packed with a foil shipping pouch with a resealable feature. During use, the Humidichip is placed inside the AN1072 Humiditube in the sterilization bag appropriate for the EOGas sterilization system. The Humiditube is placed in the sterilization bag with both open ends unobstructed by the product being sterilized. The HumidiTube ensures that both surfaces of the Humidichip are exposed within the sterilization bag, allowing for adequate evaporation to occur, thereby maintaining the relative humidity as the load temperature increase to 50°C.

The AN1071 is sold with the refill kits for the EOGas Sterilization system which is registered and classified as a Class II medical device in the US and Canada, and a Class IIb device in the UK and European Union.



Foil shipping pouch



Individual foil pouch

Open individual pouch
using tear open
notches on either side

Humidichip



HumidiTube

INDICATIONS FOR USE

Refer to Technical Data Sheets for Indications for Use for EOGas 3 and EOGas 4 sterilizer systems.

DIRECTIONS FOR USE

Items to be sterilized are prepared according to the Instructions for use found in the Refill Kit and in the EOGas Sterilizer User's Manual which are provided with purchase. The Humidichip and Humiditube also contain individual instructions for use which are provided with purchase.

APPLICATION OF USE

- To be used only in Andersen EOGas 3 and 4 sterilizer systems.
- Humidichip are sold in bulk and are also included in Refill kits as follows: AN1006.00, AN1005.00 and AN1004.16.
- Each Humidichip is single use.
- HumidiTube is reusable and sold separately as an AN1072.00.

SPECIFICATIONS

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AN Number	Dimensions	Other Specification
AN1071	1.75" X 1.75"	4.3 +/- 10% Solution
AN1072	3.23" long cylinder	Injection Molded in 2 pieces forming half a cylinder

RAW MATERIAL COMPOSITION

- AN1071:
 - Distilled water
 - Proprietary antimicrobial solution
 - Filter paper
- AN1072:
 - Polystyrene

MANUFACTURING AND DESIGN

- The EOGas 4® System is manufactured and designed under a full Quality Management System certified (certificate number 0085440) under MDSAP and registered by Intertek, an MDSAP recognized auditing organization as conforming the requirements of ISO 13485:2016 for the Canadian Medical Device Regulations – Part 1 – SOR 98/282 and the United States USFDA 21CFR 820, 21 CFR 803, 21 CFR 806, 21CFR 807. A Risk Management Program is fully adopted per ISO14971:2019.
- Andersen Sterilizers maintains EC Certification through a full Quality Assurance System certification number 4134704-02 under Directive 93/42/EEC on Medical Devices allowing for the use of CE 0413 marking.

TESTING AND INSPECTION

- Functional testing for presence of proprietary antimicrobial solution hypochlorite in solution
- Visual inspection of packaging for seal integrity and pouch printing alignment
- Visual inspection of labeling
- Net Solution Fill Weight verification
- Shelf-life testing through expiration date

PACKAGING AND LABELING

- Humidichip are packaged in a primary foil package and labeled with an ink jet printer, then packaged in a shipping pouch with a label. The shipping pouch is boxed and labeled with a lot number label. Examples of labels are included in this technical data sheet.
- HumidiTubes are packaged individually.

STORAGE CONDITIONS

- The AN1071 Humidichip should be stored at room temperature away from sunlight. Initial use of the product requires that the user remove the hermetic factory heat seal on the shipping pouch using the tear open notches provided. For subsequent use, to avoid possible loss of moisture, reseal the Ziplock feature of the outer shipping pouch.
- The AN1072 has no required storage conditions.

DISPOSAL

Used and unused Humidichip and Humiditube may be discarded in ordinary trash.

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SHELF LIFE

Humidichip may be used up to 3 years of the date of manufacture. HumidiTubes have no expiration date.

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AN1071.16 – 14 count pouch label

↑ RESEAL ZIPLOCK AFTER EACH USE ↑**AN1071**
HUMIDICHIP®
Humidifying Chips**CONTENTS: 14 CHIPS (1.75 INCH)**
Designed for use with Andersen
Gas Sterilization Systems.Solution content: Sodium Hypochlorite 0.5%
as a preservative. 4.3 gm ± 10% / chip**Use Humidichips to ensure that humidification requirements for Ethylene Oxide Sterilization are met.****INSTRUCTIONS FOR USE:** One Humidichip should be placed in each **EOGas®** or Anprolene® sterilizing bag as follows:**PRECAUTIONS**

AN2948.16 Rev. 4

- Remove Humidichip from the tear open foil pouch. The Humidichip should feel damp, soft and flexible to the touch. If it feels dry and stiff, discard it.
- Place Humidichip inside an AN1072.00 Humiditube to maximize exposed evaporative surface area and then place inside sterilizing liner bag with items to be sterilized.
- **Do not reuse Humidichips. They are designed for single use only.**

Anprolene® EOGas® and Humidichip® are
registered trademarks of Andersen Sterilizers, Inc.

- Each individually foil pouched Humidichip weighs a minimum of 6.1 grams.
- Keep the Humidichip pouch securely sealed between uses at room temperature and away from direct sunlight.
- You may discard used Humidichips in ordinary trash.



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Distributor: Andersen Products, Inc. • Haw River, NC 27258 • USA



H.W. Andersen Products, Ltd. • Clacton-on-Sea • UK



H.W. Andersen S.A.R.L. • Lille • France

AN1071.01 – 25 count pouch label

↑ RESEAL ZIPLOCK AFTER EACH USE ↑**AN1071**
HUMIDICHIP®
Humidifying Chips**CONTENTS: 25 CHIPS (1.75 INCH)**
Designed for use with Andersen
Gas Sterilization Systems.Solution content: Sodium Hypochlorite 0.5%
as a preservative. 4.3 gm ± 10% / chip**Use Humidichips to ensure that humidification requirements for Ethylene Oxide Sterilization are met.****INSTRUCTIONS FOR USE:** One Humidichip should be placed in each **EOGas®** or Anprolene® sterilizing bag as follows:**PRECAUTIONS**

AN2948.00_Rev. 3

- Remove Humidichip from the tear open foil pouch. The Humidichip should feel damp, soft and flexible to the touch. If it feels dry and stiff, discard it.
- Place Humidichip inside an AN1072.00 Humiditube to maximize exposed evaporative surface area and then place inside sterilizing liner bag with items to be sterilized.
- **Do not reuse Humidichips. They are designed for single use only.**

Anprolene® EOGas® and Humidichip® are
registered trademarks of Andersen Sterilizers, Inc.

- Paper and cloth items are highly absorbant of water vapor. Use two Humidichips in any load that is comprised of large volumes of paper or cotton cloth.
- Keep the Humidichip pouch securely sealed between uses and away from direct sunlight.
- You may discard used Humidichips in ordinary trash.



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ANDERSEN STERILIZERS HUMIDICHIP AND HUMIDITUBE TECHNICAL DATA SHEET

AN1071.00 Lot Label

REF

AN1071.00



USE BEFORE DATE: 9999-99-99



MANUFACTURE DATE: 9999-99-99

LOT

999999



Andersen Sterilizers Inc. Haw River NC, 27258 USA

MSPLAN1071.00 Rev. 0

AN1071.16 Lot Label

REF

AN1071.16



USE BEFORE DATE: 9999-99-99



MANUFACTURE DATE: 9999-99-99

LOT

999999



Andersen Sterilizers Inc. Haw River NC, 27258 USA

MSPLAN1071.16 Rev. 0

AN1071.01 Lot Label

REF

AN1071.01



USE BEFORE DATE: 9999-99-99



MANUFACTURE DATE: 9999-99-99

LOT

999999



Andersen Sterilizers Inc. Haw River NC, 27258 USA

MSPLAN1071.01 Rev. 0

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AN1072 Label

AN 1072**HUMIDITUBE****Humidifying Tubes**

Help assure Humidification Requirements for
Ethylene Oxide Sterilization in
Andersen Gas Sterilization Systems

INSTRUCTIONS FOR USE:

- You may reuse **HUMIDITUBES**
They are designed for multiple use
- Place one Humidichip® Humidifying Chip in a Humiditube
- Place one Humiditube in each sterilization liner bag
- Ensure that both ends of the Humiditube remain open and unblocked by product to allow complete evaporation of the Humidichip

For more information contact us at the numbers below or visit our website at www.sterility.com

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AN4859.00_Rev 0

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Lot Label AN1072

REF

AN1072.00

MANUFACTURE DATE: 2020-##-##

LOT

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MCPL 1072.00 Rev 0

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Revision History

ECN Number	Revision	Effective Date	Reason for Change
2021078	0	2021-11-16	Updated to include data requested by international customers. Created as controlled documents under revision control in document management system.

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Signatures:

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