MAGPIX® Drive Fluid PLUS
Product Information Sheet (IVD)

Document Revision History

Effective Date	Revision	Section	Description of Change
05/2022	B	Intended Purpose	Added Intended Purpose statement
05/2022	B	Procedure- Note	Added link to website for translations
05/2022	B	Symbols Glossary	Updated Manufacturer symbol description Updated footnote
05/2022	B	Back Cover	Added European Union Statement Updated revision and date
05/2022	B	Legal page	Updated copyright date to include 2022 Updated trademark statement
05/2023	C	Symbols Glossary	Added UK CA and Importer symbol
05/2023	C	Back Cover	Updated EC Rep information

Summary

Use MAGPIX® Drive Fluid PLUS (40-50020) as the delivery and flush medium to carry the sample to the optics component of the MAGPIX based instruments.

Intended Purpose

The MAGPIX® Drive Fluid PLUS is an in vitro diagnostic accessory to the MAGPIX System intended to serve as the delivery medium used to transport sample to the optics component of the MAGPIX Instrument.

For Laboratory Professional Use Only. This is not an automated medical device.

Safety Precautions

Avoid contact with skin and eyes. A Safety Data Sheet (SDS) is available upon request.

Ingredients

MAGPIX® Drive Fluid PLUS contains sodium and potassium salts and an antimicrobial cocktail in water.

Storage

Store at 15°C to 30°C.

Limitations

You must follow these product information sheet instructions. Reliability of results cannot be guaranteed if you deviate from these instructions. When stored at 15°C to 30°C, the product should perform as expected up to the expiration date stated on the container label.

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Disposal

MAGPIX® Drive Fluid PLUS contains sodium azide (less than 0.025%) as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Refer to local guidelines and regulations for proper disposal of unused and used Drive Fluid PLUS.

Procedure

1. Open the carton of drive fluid. Open the MAGPIX® instrument fluid compartment and remove the empty drive fluid bottle and dispose of properly.
2. Slide the new drive fluid bottle part in, then firmly grip the seal tab while holding the bottle and remove the foil seal.
3. Extend the drive fluid tubing from the fluid compartment and carefully insert the plug in the drive fluid bottle opening ensuring the tubing is pointing straight down into the bottle indention.
4. Slide the drive fluid bottle in place inside the compartment. The bottle should fit into the indents of the tray. Check that the waste container is empty.
5. Prime the unit per the user manual's instructions.
   NOTE: Product Information Sheets are available in other languages upon request. Contact Luminex Technical Support for information or access on website at *https://www.luminexcorp.com/documents/.* Then, using the Search feature, search for the desired product information sheet.

Refer to the user manual for proper use of the MAGPIX® Drive Fluid PLUS as applicable.

Symbols Glossary

5.1.5* 	Batch Code. Indicates the *manufacturer's batch code* so that the batch or lot can be identified.	5.1.1* 	Manufacturer. Indicates the medical device manufacturer.	5.3.7* 	Temperature Limit. Indicates the temperature limits to which the medical device can be safely exposed.
5.1.4* 	Use-by date. Indicates the date after which the medical device is not to be used.	5.4.3* 	Consult instructions for use or consult electronic instructions for use. Indicates the need for the user to consult the instructions for use.	5.1.6* 	Catalogue Number. Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.5.5* 	Contains Sufficient for <n> Tests. Indicates the total number of tests that can be performed with the medial device.	5.5.1* 	*In vitro* diagnostic medical device. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	† 	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only).

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# CE	Conformite Europeenne (EU CE Marking of Conformity). CE conformity marking.	5.1.2* EC REP	Authorized representative in the European Community/European Union. Indicates the Authorized representative in the European Community/European Union.	2 UKCA	UK Conformity Assessed
5.1.8*	Importer				

* ANSI/AAMI/ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
# Council Directive Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
† 21 CFR 809 (FDA Code of Federal Regulations).
2: *Medical Devices Regulations 2002* (UK MDR 2002)

For EU only: Please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to Luminex Technical Support and the competent authority of the EU Member State in which the user and/or patient is established.

Rx Only

IVD For *In Vitro* Diagnostic Use.

89-60000-00-173 Rev C
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Product No: 40-50020
Quantity: 4 x 700 mL
To order more product:
Email:
orders@luminexcorp.com
Fax: 512-219-0544

CE

EC REP
DiaSorin Italia S.p.A.
Via Crescentino snc
13040 Saluggia (VC)
Italy

UKCA
DiaSorin Italia S.p.A.
UK Branch
Central Road
Dartford Kent DA1 5LR
UK

Technical Support
Telephone:
512-381-4397
North America Toll Free:
1-877-785-2323
International Toll Free:
+ 800-2939-4959
Email:
support@luminexcorp.com
www.luminexcorp.com

Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727
U.S.A.

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