

OSTEOFAST 2



IVD In vitro diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - Class A device

Light yellow decalcifying solution for bone and hard tissue in histology

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30799PROCYYU		
EMDN code	W01030799		
REF	Catalog number	Volume	UDI-DI number
	OF2-OT-1L	1000 mL	03858888821401
	OF2-OT-2.5L	2500 mL	03858890007855



Intended use and test principle

Bone and other hard tissue decalcification is required for microscopic analysis of the test sample in routine histological processing procedures. The time required for demineralization (decalcification) depends on the size and density of the treated test specimen. Decalcification of bone and hard tissue requires the use of inorganic, organic acids or chelating agents. Organic formic acid is an integral part of OsteoFast 2, in the presence of which calcium is removed, making the tissue softened and ready for further processing. Samples for testing are bones and hard tissue (teeth) and keratinized tissue (pointed warts, nails). The light yellow colour of OsteoFast 2 makes it easier to distinguish it from other BioGnost decalcification products (light blue OsteoFast 1 and colourless OsteoSens), as well as other fixatives and solvents used in histological laboratories.

Product description

- **OSTEOFAST 2** - Light yellow decalcifying agent for bone and hard tissue in histology. Contains formic acid

Decalcification procedure

Preparation of the sample for decalcification

- The tissue sample to be decalcified **must** be fixed beforehand
- Immerse the tissue sample with its entire surface in OsteoFast 2

Determining the end of decalcification

The completion of decalcification is determined by piercing the needle of that part of the tissue that is not relevant for further diagnostic procedure.

Incomplete decalcification

Incomplete decalcification of the embedded sample can be done by immersing the sample cross-sectional area in a container with OsteoFast 2 followed by rinsing with tap water.

Result

Decalcified tissue is cartilaginous, like rubber. Further treatment of the sample is carried out by usual histological procedures

Usability

30 ml of OsteoFast 2, which is approximately enough to cover the entire volume of tissue, can be used 2 times while keeping the solution clear and uncontaminated.

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instruction for use may cause differences in staining results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, decalcification and histological processing of samples and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards.

If a serious incident occurs during use or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label, instructions for use and in the safety data sheet, which is available on request.

Storage, transport, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The production date and expiration date are printed on the product label.

References

1. Carson, FL, Hladik, C. (2009): Histotechnology: A Self-Instructional Text, 3rd ed., Chicago: ASCP Press.
2. Kiernan, JA (2008): Histological and Histochemical Methods, Theory and Practice, 4th ed., Banbury: Scion Publishing Ltd.

3. Callis, G., Sterchi, D. (1998): Decalcification of bone: literature review and practical study of various decalcifying agents, methods and their effects on bone histology. J. Histotechnol. 21:49-58.

Warnings and precautions regarding the materials contained in the product:		
	H314	Causes severe skin burns and eye damage.
	H318	Causes serious eye damage.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P303+P361+P353	IF ON SKIN (or hair): immediately take off all contaminated clothing. Rinse skin with water [or shower].
	P305+P351+P338	IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to. Continue rinsing.

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	Manufacturer	 LOT	Batch code		Consult instructions for use		European conformity
	Date of manufacture	 REF	Catalogue number		Caution	 UDI	Unique device identifier
	Use-by date		Temperature limit		In vitro diagnostic medical device		

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Version	Description / reason for change	Date
7	Revised acc. to Regulation (EU) 2017/746 – IVDR and Commission Delegated Regulation (EU) 2024/2564	17.07.2026.