

OSTEOFAST 1

CE IVD *In vitro* diagnostic medical device

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

Light blue fixative and decalcifying solution for bone and hard tissue in histology

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30799PROCYU		
EMDN code	W01030799		
REF Catalog number	Volume	UDI-DI number	
OF1-OT-1L	1000 mL	0385888821173	
OF1-OT-2.5L	2500 mL	03858890005684	



Intended use and test principle

It is necessary to conduct decalcification of bones and other hard tissue for the purpose of microscopic analysis of the sample during regular histological processing. OsteoFast 1 is solution that fixates (thanks to formaldehyde content) and decalcifies the sample with inorganic acids. The length of time needed for demineralization (decalcification) depends on the size and density of the treated sample. Bone and hard tissue decalcification requires inorganic or organic acids, or chelating reagents. OsteoFast 1 consists of inorganic hydrochloric acid. It rapidly removes calcium, that way softens the tissue and makes it ready for further processing. Test samples are bone and hard tissue (teeth) and keratinized tissue (filiform warts, nails). OsteoFast 1's light blue color distinguishes the product from other BioGnost's products for decalcification (light yellow OsteoFast 2 and colorless OsteoSens) as well as other fixatives and solutions used in histological laboratories. Do NOT use OsteoFast 1 on delicate tissues, such as the iliac crest punctate. For this type of tissue, use OsteoSens.

Product description

- **OSTEOFAST 1** – Light blue fixative and decalcifying solution for bone and hard tissue in histology. Contains formaldehyde and hydrochloric acid

Decalcification procedure

Preparing the sample for decalcification

- Immerse entire tissue sample into OsteoFast 1

Bone, teeth, hard tissue

The length of time needed for decalcification and amount of used OsteoFast 1 depends on the size, type and density of the treated sample. 1 x 1 x 0.3 cm dimensions bone (such as the femur) should be calcified for 6-8 hours.

Note: Decalcification of teeth and other hard tissues must be controlled in order to appropriately define the end of the process.

Mildly calcified tissue

Mildly calcified tissue, such as blood vessels, should be calcified for 30-60 min.

Keratinized tissue

Keratinized tissue, such as nails and filiform warts, require mild decalcification by immersing the fitted section into OsteoFast 1 for 15-60 min. Cross section must be oriented down. The block then must be rinsed with tap water and cut in a usual manner. The cross section is 5 µm thick.

The end of decalcification process

The end of the process is determined by using the needle to puncture the part that is not important for further diagnostic procedure.

Incomplete decalcification

Incomplete decalcification of the fitted sample can be supplemented by immersing the surface of the section into the container filled with OsteoFast 1 for 15-20 min. Rinse with tap water afterward.

Result

Decalcified tissue is cartilaginous, similar to rubber. Further treatment is conducted with further histological procedures

Note

If the process of decalcification lasts for too long, it can lead to destruction of morphological structure of tissue and in turn negatively influence the consequent nucleus staining. Immunohistological methods cannot be applied after decalcification using OsteoFast 1 because tissue antigens are no longer detectable. If immunohistological methods are necessary for the diagnosis, you should use OsteoSens (EDTA-based decalcifying solution that does not damage the tissue antigens).

Usability

30 ml of OsteoFast 1 (enough to cover the entire section) is sufficient for 2 uses. The solution must be clear and uncontaminated

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the decalcifying procedure described in this Instruction for use may cause differences in staining results. Immunohistochemical methods can not be conducted on histological samples treated with OsteoFast 1.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining, mounting of the slides, and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards.

If a serious incident occurs during use of this product 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, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

Storage, 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 expiration date is printed on the product label.

References

- Carson, F. L., Hladik, C. (2009): Histotechnology: A Self-Instructional Text, 3rd ed., Chicago: ASCP Press.
- Kieman, J.A. (2008): Histological and histochemical methods: Theory and Practice, 4th ed., Bloxham, Scion Publishing Ltd.
- 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:	
	<p>H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May irritate the respiratory system. H341 Suspected of causing genetic defects. H350 May cause cancer. H370 Causes damage to organs (eyes).</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): remove immediately all contaminated clothing. Rinse skin with water (shower). P305+P351+P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing. P308+P311 IF exposed or concerned: call POISON CENTER/doctor. P501 Dispose of contents/container according to local regulations.</p>

OF1-IFU_ENV7, 25.02.2026. IŠP

 Manufacturer	 Batch code	 Consult instructions for use	 <i>In vitro</i> diagnostic medical device
 Date of manufacture	 Catalogue number	 Caution	 European conformity
 Use-by date	 Temperature limit	 Contains hazardous substances	 Unique device identifier

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Version	Description / reason for change	Date
7	Revised acc. to Regulation (EU) 2017/746 - IVDR	25.02.2026.