

## SURGERY

intraoral hyaluronic acid  
**HYAMIX 5**

### HYALURONIC ACID STERILE SOLUTION FOR DENTAL USE

#### Indications

##### Implant surgery

- as an adjuvant treatment in the regeneration of bone defects of the peri-implant alveolar ridge in association with bone substitutes and resorbable membranes.
- protection of the implant surface, implant site and sutures.

##### Treatment of peri-implantitis

as an adjuvant treatment in bone regeneration processes also in association with bone substitutes and with resorbable membranes.

##### Extractive surgery

as an adjuvant treatment in the bone regeneration of the alveolus and prevention of post-extraction alveolitis.

##### Treatment of peri-implant mucositis

#### Instruction for use

Aspirate the desired amount of solution from the vial with the sterile syringe.

##### Implant surgery

- as an adjuvant treatment for the regeneration of peri-implant bone defects, mix the product with the bone particles until a homogeneous mixture is obtained, remove the excess solution with a sterile gauze, then apply the product in the bone defect modeling it with a special sterile instrument.
- to protect the implant and the implant site, apply the film-forming solution bending the blunt needle to mimic a periodontal probe. Place the blunt needle tip near the base of the implant site and inject the product until the solution comes out of the upper margin. Pull the needle out of the site.

Apply few drops of the product on the implant immediately before insertion into the site and make sure that the entire surface is wet.

##### Treatment of peri-implantitis

mix the product with the bone particles until a homogeneous mixture is obtained, eliminate the excess solution with a sterile gauze, then apply the product in the bone defect modeling it with a special sterile instrument.

##### Extractive surgery

(in particular for delayed implant placement): mix the product with the bone particulate until a homogeneous mixture is obtained, eliminate the excess solution with a sterile gauze, then apply the product in the alveolus modeling it with a special sterile instrument.

##### Treatment of peri-implant mucositis

apply the solution by positioning the blunt tip of the needle in the peri-implant space and inject the product until the solution comes out of the gingival margin.

Dispose the syringe and the blunt needle after use.

  
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#### Composition

Sodium hyaluronate, monobasic potassium phosphate, dibasic sodium phosphate, water for injections.

#### Packaging Contents

- n.1 multi-dose bottle 5 ml sterile solution
- n.5 sterile disposable syringes 2,5 ml (Artsana CE 0373)

#### Warnings

- Medical Device for dentist use only
- Sterile product
- Multi-dose bottle for at least 5 applications
- Do not reuse the needles and syringe: throw them immediately after use
- Not for injection
- Keep away from heat sources and out of reach of children
- Do not use after the expiration date
- Store at a temperature not exceeding 25 ° C.
- The unused solution, if stored in the fridge at 4° temperature, maintains the efficacy for 5 weeks

Information status: April 2019



# Hyaluronic Acid (HA) in Intraoral Applications.

## Reference bibliography.

<sup>1</sup> Casale M. et al, Hyaluronic acid: Perspectives in dentistry. A systematic review. *Int'l J. of Immunopathology and Pharmacology*, DOI: [10.1177/0394632016652906](https://doi.org/10.1177/0394632016652906)

<sup>2</sup> T. Sasaki, C. Watanabe **Stimulation of Osteoinduction in Bone Wound Healing by High-Molecular Hyaluronic Acid in Bone.** *Bone Vol. 16. No.1 January 1995:9-15*

- Controlled experimental study in femoral bone defects

- In the test side treated with high molecular weight HA the new bone formation had already been induced at 4 days both on peri and endosteal surfaces of the cortical bone and at 1 week the medullary cavities were completely filled with new trabecular bone with an acceleration with respect to the control sides.

“The data suggest that high molecular weight HA works by effectively retaining osteoinductive growth factors in their environment by virtue of its physicochemical properties: it is able to accelerate new bone formation during bone wound healing by stimulating the differentiation of osteogenic cells”.

<sup>3</sup> Muzaffer et al, **The Effect of Hyaluronic Acid-supplemented Bone Graft in Bone Healing: Experimental Study in Rabbits.**

*Journal of Biomaterials Applications* DOI: [10.1177/0885328206051047](https://doi.org/10.1177/0885328206051047)

- Controlled experimental investigation in 30 tibial defects of 3 mm in diameter and depth. Test side: bone graft + HA- Control side: bone graft only.

- At 30 days: Test side: new thin bone formation. Control side: cavities filled only with fibrous tissue

- At 40 days: Test side: newly formed bone in all cavities. Control side: cavities filled with fibrous and cartilagen tissue.

“The bone healing values of the test group are significantly higher than the values of the control group at 30 and 40 days”.

<sup>4</sup> Shamma et al. **Evaluation of the effect of hyaluronic acid mixed with biphasic calcium phosphate on bone healing around dental implants (experimental study).**

*Alexandria Dental Journal. (2017) Vol.42 Pages:104-11 104*

- Split mouth experimental study in canine model.

- Test side: dental implants + calcium phosphate + high molecular weight HA (10: 1 ratio). Control side: dental implants + calcium phosphate.

- Complete biopsies of the implant performed at 2, 4 and 6 weeks. The new bone formation was more evident in the test group.

“Hyaluronic acid accelerates the onset of new bone formation when combined with a bone graft”.

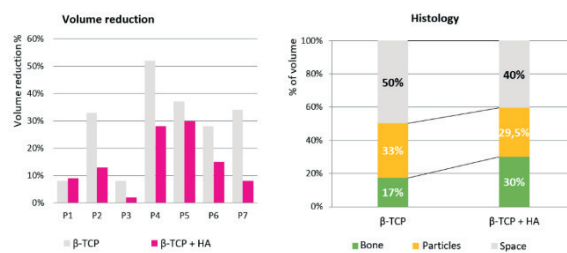
<sup>5</sup> Stiller M. et al. **Performance of  $\beta$ -tricalcium phosphate granules and putty, bone grafting materials after bilateral sinus floor augmentation in humans.**

*Doi.org./10.1016/j.biomaterials 2013.12.068*

- Controlled clinical study in bilateral sinus lift in 7 patients.

- Test side:  $\beta$ -TCP with hyaluronic acid- Control side:  $\beta$ -TCP.

- At six months: both histological and radiographic evaluation of the bone formation, volume stability and expression of osteogenic markers.



“TCP + HA demonstrated improved surgical handling properties, increased bone formation, higher Col, ALP, OC and BSP expression as well as a significantly lower reduction in graft volume”.

<sup>6</sup> Pirnazar P. et al. **Bacteriostatic effects of Hyaluronic acid.**

*J.Periodontol April 1999, Volume 70 Number 4*

<sup>7</sup> Asparuhova M. et al. **Activity of two hyaluronan preparations on primary human oral fibroblasts.**

*Journal of Periodontal Research* <https://doi.org/10.1111/jre.12602>