

## DAC® HYDROGEL - FREQUENTLY ASKED QUESTIONS

- Q.** Does DAC® interfere with osseointegration and bone healing processes?
- A.** The DAC® Hydrogel immediately after implantation is degraded and metabolized by certain enzymes such as Hyaluronidase and Esterase. The gel, therefore completely reabsorbs within 72 hours after implantation, without any detectable interference on bone healing or implant osseointegration.

### References.

- *Hyaluronic Acid-based Hydrogel Coating Does Not Affect Bone Apposition at the Implant Surface in a Rabbit Model.* W. Boot and Others - Clin. Orthop. Relat. Res. 2017 Mar 16  
<https://www.ncbi.nlm.nih.gov/pubmed/28303535>
- *Efficacy of antibacterial-loaded coating in an in vivo model of acutely highly contaminated implant.* Gianluca Giavaresi and others – International Orthopaedics (SICOT) (2014) 38; 1505-1512  
<https://www.ncbi.nlm.nih.gov/pubmed/24363076>
- *Fast-resorbable antibiotic-loaded hydrogel coating to reduce post-surgical infection after internal osteosynthesis: a multicenter randomized controlled trial.* K. Malizos and Others - J Orthop Traumatol. 2017 Jun;18(2):159-169.  
<https://www.ncbi.nlm.nih.gov/pubmed/28155060>
- *Does an Antibiotic-Loaded Hydrogel Coating Reduce Early Post-Surgical Infection After Joint Arthroplasty?* C.L. Romanò and Others - J Bone Jt Infect. 2016 Jul 19;1:34-41  
<https://www.ncbi.nlm.nih.gov/pubmed/28529851>

- Q.** How much DAC® hydrogel remains on the implant surface after press-fit implantation?
- A.** The DAC® Hydrogel is able to withstand press-fit implantation adhering on the implant surface. In case of a hip stem press-fit implanted inside a femoral canal 80% of the DAC® hydrogel remains attached to the implant, while the remaining 20% adheres to the surrounding bone.

### References.

- *Does Implant Coating with Antibacterial-loaded Hydrogel Reduces Bacterial Colonization and Biofilm formation in Vitro?* – Lorenzo Drago and Others – Clin. Orthop. Relat. Res. 2014 Nov;472(11):3311-2  
<https://www.ncbi.nlm.nih.gov/pubmed/24622801>

**Q.** Can Saline solution be employed to hydrate the DAC<sup>®</sup> Hydrogel?

**A.** The DAC<sup>®</sup> Hydrogel must be hydrated only with sterile water for injections. The use of saline solution reduces the hydrogel viscosity.

**Q.** How far in advance can the gel be prepared before surgery?

**A.** The DAC<sup>®</sup> hydrogel can be hydrated and prepared up to 4 hours before surgery. Once hydrated It is recommended to keep the hydrogel at rest for 5 to 10 minutes before its application.

**Q.** Would the DAC<sup>®</sup> Hydrogel contained in one pack be enough to coat a primary implant?

**A.** A DAC<sup>®</sup> syringe would allow for 5ml hydrogel formation. That amount has been tested to be sufficient to coat the surface of a primary cementless THA or TKA.

**Q.** Can the DAC<sup>®</sup> hydrogel be used in conjunction with cemented implants?

**A.** DAC<sup>®</sup> has been designed to act as a physical temporary barrier to prevent bacterial colonization of the implant surface. Therefore, it cannot be used when bone cement is already covering the prosthesis. The DAC<sup>®</sup> Hydrogel can be applied in case of hybrid prosthesis (i.e.: Cemented TKA with press-fit femoral and/or tibial stem extensions) on those implant surfaces that are in direct contact with bone.

**Q.** Should the DAC<sup>®</sup> Hydrogel be always hydrated with water mixed with an antimicrobial/anti-biofilm agent?

**A.** The DAC<sup>®</sup> Hydrogel is a CE Marked medical device approved to act as a physical barrier against bacterial colonization of the implant surface without addition of bioactive substances. The Hydrogel can be safely mixed with a bioactive agent that could act as a complement to the Gel primary function. The decision to hydrate the DAC<sup>®</sup> powder using a water solution including a bioactive agent has to be taken at the Surgeon discretion, in the best interest of the Patient under treatment.

**Q.** Can DAC<sup>®</sup> be spread also on those implant surfaces that are not in direct contact with bone?

**A.** The DAC<sup>®</sup> Hydrogel can be applied on every part of the implant surface. For instance, it might be advisable to spread the gel in between the metal shell and the liner in case of modular acetabular components or in between the metal tray and the poly insert in case of TKA.

**Q.** Is there any contraindication In case some DAC<sup>®</sup> hydrogel will get in contact with the surrounding soft tissues during its application?

**A.** No adverse effects were observed in case the DAC<sup>®</sup> hydrogel was in contact with surrounding soft tissues; therefore, there are no contraindications in this case.