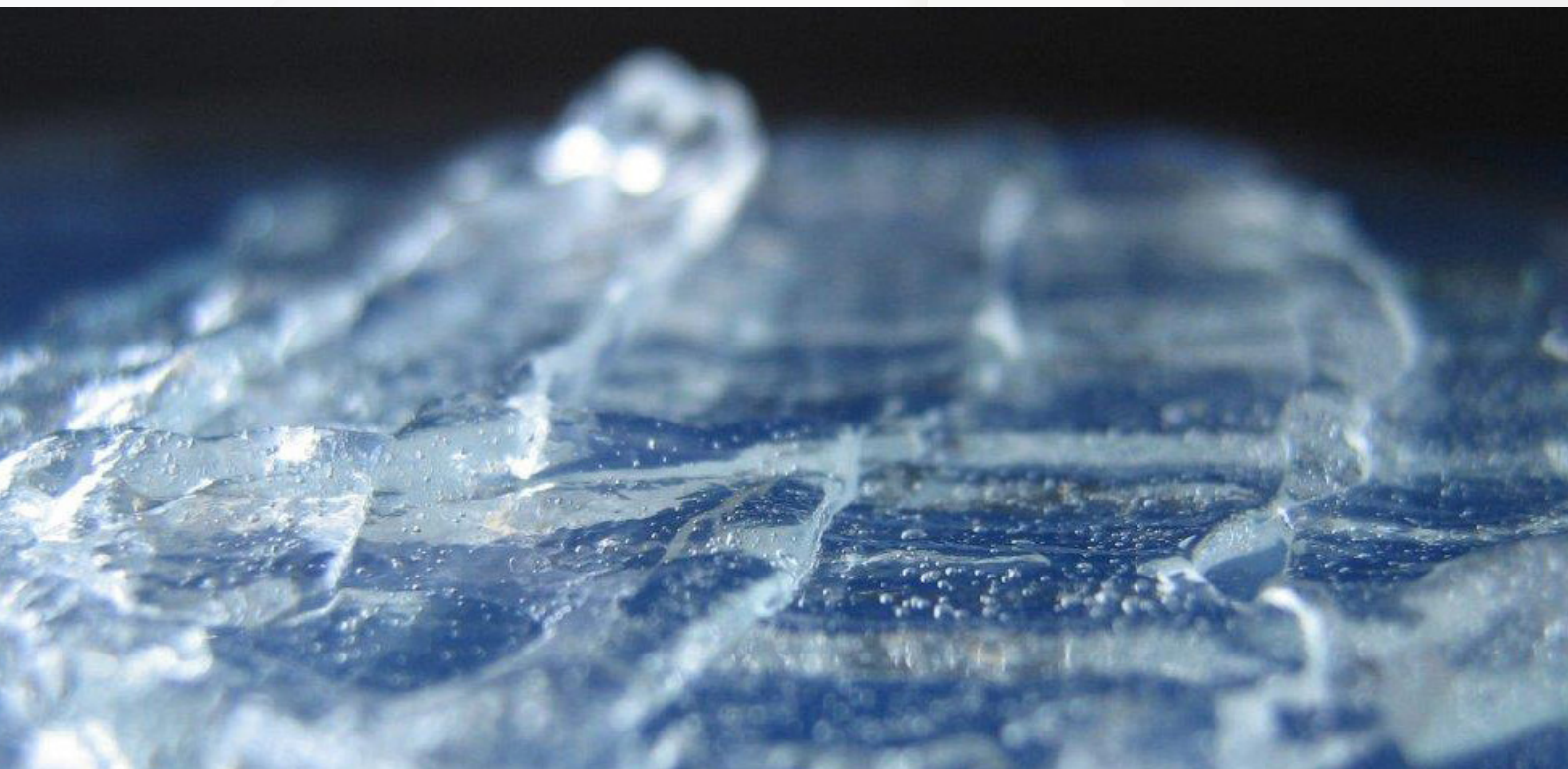


# DAC<sup>®</sup>

DEFENSIVE ANTIBACTERIAL COATING

NOVAGENIT



THE HYDROGEL BARRIER TO INFECTION

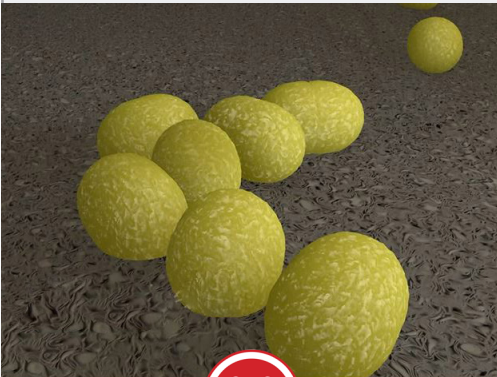
# THE MECHANISM OF INFECTION: THE RACE TO THE SURFACE

In case of contamination of the implant surface, colonisation by pathogens results in formation of a barrier known as **Biofilm**.

Biofilm is an impervious polymeric matrix, able to make the bacterial colony resistant to antibiotic treatment and the patients immune system<sup>13;14;15;16</sup>.

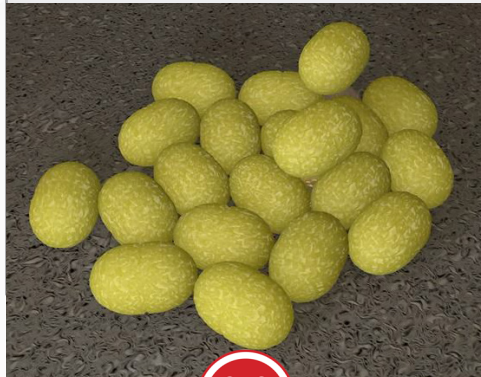
## THE INFECTION MECHANISM FOLLOWS THREE STAGES IN QUICK SUCCESSION

Immediately after surgery



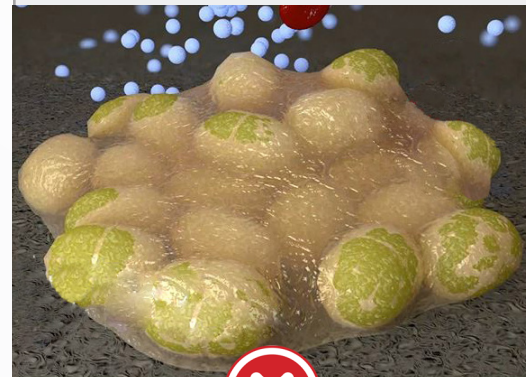
Pathogens begin to adhere to the prosthetic surface.

Few minutes after surgery



Pathogens start to multiply and irreversibly fix themselves to the implant.

Few hours after surgery



In the absence of a reaction of the organism, the bacterial colony starts biofilm production.

# DAC<sup>®</sup> HYDROGEL: THE BARRIER EFFECT

The application of **DAC<sup>®</sup>** disrupts the ability of pathogens to bind to the implant surface, inhibiting the initial stages of bacterial colonisation that would then result in biofilm formation.

**DAC<sup>®</sup>** forms a hydrogel that acts as a temporary barrier, providing an effective mechanism for prevention of bacterial infection.

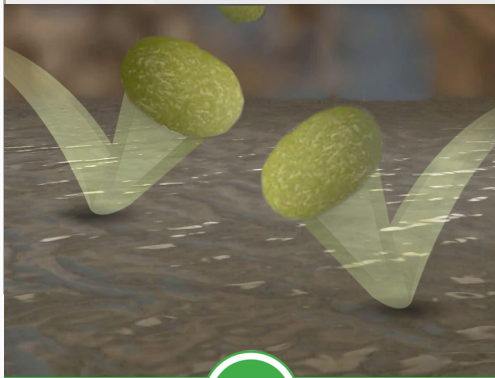
## THE DAC<sup>®</sup> HYDROGEL DEFENSIVE MECHANISM CAN BE ILLUSTRATED IN THREE STAGES:

### Immediately before surgery



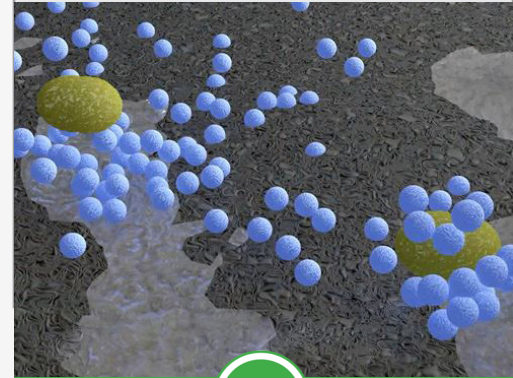
The implant surface is evenly coated with the **DAC<sup>®</sup>** hydrogel.

### Immediately after surgery



Bacterial adhesion and colonisation of the implant surface is interrupted by the **DAC<sup>®</sup>** hydrogel layer and by its hydrophilic properties.

### Few days after surgery



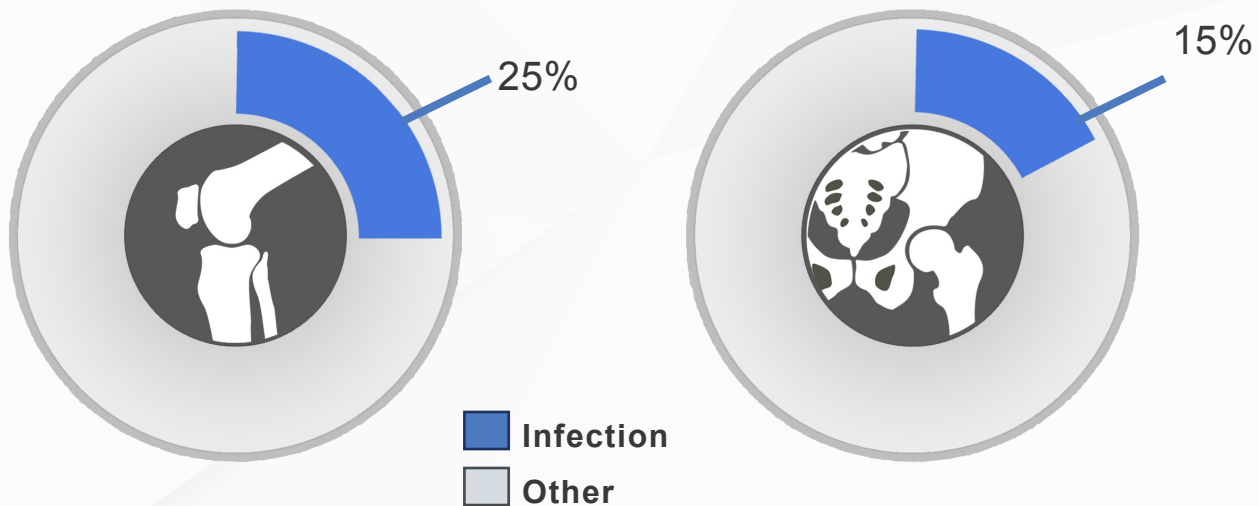
Bacteria left on the implant surface or on the hydrogel are identified and attacked by the immune system.

# THE BURDEN OF INFECTION

Infection is the principal cause for failure of primary total knee implants and a significant cause of failure of primary total hip replacement<sup>1;2;3;4</sup>, with a rate varying between 0.5% and 4%<sup>5;6;7</sup>.

Infection accounts for respectively 25% and 15% of all TKA and THA revisions.

## REASONS FOR REVISIONS



### Intraoperative bacterial contamination

In spite of modern aseptic procedures, the risk of peri-operative bacterial contamination cannot be completely eliminated. One study demonstrated how 63% of surgical fields show evidence of bacterial contamination<sup>12</sup>.

### Factors contributing to raised infection risk:<sup>19</sup>

- Autoimmune diseases e.g. Rheumatoid Arthritis<sup>8</sup>
- Diabetes<sup>9</sup>
- Obesity<sup>10</sup>
- Immunosuppression<sup>11</sup>

# ANTI-BACTERIAL BIO-ABSORBABLE COATING

**DAC®** is a kit for the preparation of a bio-absorbable hydrogel containing hyaluronic acid and polylactid acid, with the following indications:

- Uncemented orthopaedic prostheses
- Osteo-synthesis devices for Traumatology
- Mega-prostheses for Oncology



Experimental studies demonstrated that, as a complement to its barrier effect, the hydrogel powder could be hydrated with a solution of water for injectable preparations containing a final concentration between 2% and 5% of Vancomycin or Gentamycin. *In vitro, in vivo*, as well as clinical studies demonstrated how these antibiotics are compatible with **DAC®**, with no negative effect on the hydrogel. Optional antibiotic usage (they are not included in the **DAC®** procedure kit) did not result in any adverse effect in the clinical studies to date. The decision to add antibiotics is the decision and responsibility of the operating surgeon.

The hydrogel it is completely absorbed within 72 hours from its application, and therefore it has no adverse effect on osseointegration or the bone healing process<sup>17</sup>.

# DAC® KIT PREPARATION AND APPLICATION

THE PROCEDURE DESCRIBED BELOW MUST BE PERFORMED WITHIN A STERILE FIELD.

Before starting product preparation, ensure the availability of sterile water and syringe needles for injectable preparation.

NOTE: Saline solutions not to be used.



Open the blister containing the empty graduated syringe and draw a suitable quantity of water for injectable preparation. Remove the needle and replace it with the luer-lock connector.

Open the syringe containing the **DAC®** powder. Slightly retract the syringe piston and gently tap the syringe to loosen the powder, making reconstitution easier. The backstop (extension flange) may be attached to the syringe for easier handling if required.



Remove the cap from the syringe containing the **DAC®** powder and connect it to the syringe containing the water.



4

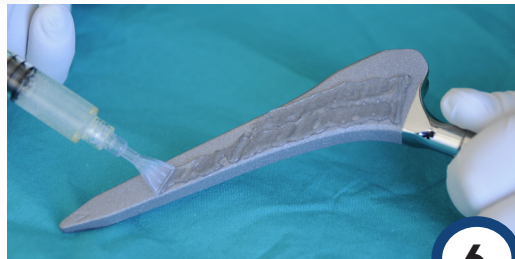
Hold the two syringes near vertically; with the syringe containing the **DAC**<sup>®</sup> powder inferiorly. Retract the piston of the latter while at the same time pressing on the syringe with water. Transfer the gel several times from one syringe to the other until a homogenous gel is formed. Leave the gel loaded syringe to rest for 5-10 minutes before use. Finally, disconnect the empty syringe and connector.

## **DAC**<sup>®</sup> HYDROGEL APPLICATION

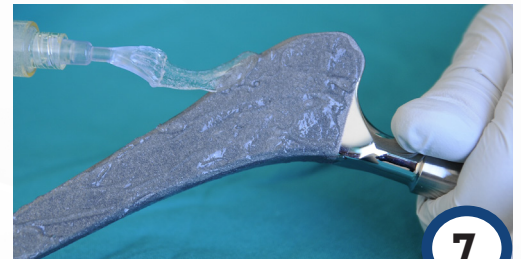
The gel can be spread on the implant surface directly from the syringe, or by using a spreader attachment on the syringe to coat wider surfaces.



5



6



7

## **DAC**<sup>®</sup> IN VIVO AND IN VITRO STUDIES <sup>17,18,19,20, 21,22</sup>

**DAC**<sup>®</sup> safety has been demonstrated by executing:

- All the *in vivo* and *in vitro* bio-compatibility tests required by the ISO 10993-1 standard;
- *In vitro* degradation studies according to ISO 10993-9, ISO 10993-13, ISO 13781;
- Osseointegration *in vivo* studies;
- Clinical studies performed according to ISO 14155 employing the hydrogel in combination with some commonly available antibiotics.

The barrier effect against bacterial adhesion provided by the **DAC**<sup>®</sup> hydrogel has been tested with a series of *in vitro* studies demonstrating that:

- **DAC**<sup>®</sup> forms an homogeneous adhesive layer on the implant surfaces;
- **DAC**<sup>®</sup> interferes with the bacterial adhesion on the implant surfaces;
- **DAC**<sup>®</sup> can dislocate those bacteria possibly present on implant surfaces;
- **DAC**<sup>®</sup> inhibits biofilm formation.



A range of DAC® kit sizes are available offering different quantities of hydrogel according to requirements

DAC® KIT code	Composition	Note
DAC001800	Single Kit composed by 1 sterile DAC® syringe containing 180mg of dry powder; 1 complete DAC® sterile components set (connector; back-stop; spreader), 1 empty 5ml graduated syringe.	To prepare 3 ml DAC® Hydrogel.
DAC003000	Single Kit composed by 1 sterile DAC® syringe containing 300 mg of dry powder; 1 complete DAC® sterile components set (connector; back-stop; spreader), 1 empty 10ml graduated syringe.	To prepare 5 ml DAC® Hydrogel.
DAC003002	Double Kit composed by 2 sterile DAC® syringe containing 300mg of dry powder; 2 complete DAC® sterile components sets (connector; back-stop; spreader), 2 empty 10 ml graduated syringe.	To prepare 10 ml DAC® Hydrogel.
DAC003003	Triple Kit composed by 3 sterile DAC® syringe containing 300mg of dry powder; 3 complete DAC® sterile components sets (connector; back-stop; spreader), 3 empty 10 ml graduated syringe.	To prepare 15 ml DAC® Hydrogel.

The DAC® Kit is a Class III sterile disposable medical device, according to the attached IX of the European Directive 93/42 CEE. Syringe and accessories are double blister packed for use in an Operating Room sterile field.

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Manufactured and distributed in Italy by:  
**NOVAGENIT srl** Viale Trento 115/117 - 38017 Mezzolombardo (TN) Italia Tel. +39 0461 1916500 Fax +39 0461 1916591 - e-mail info@novagenit.com [www.novagenit.com](http://www.novagenit.com)



United Kingdom - **ADLER ORTHO UK**  
 Unit A2, Beech House - Oaklands Office Park  
 Hooton - Cheshire - CH66 7NZ - United Kingdom

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