DAC®

Defensive Antibacterial Coating

ADLER® ORTHO

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implant risk

Biofilms can form on implants in the first few post operative hours and can determine the ultimate outcome of the procedure.

Introducing foreign materials, like orthopaedic implants into the body carries the risk of infection due to possible biofilm formation. Biofilms are a particular concern because they resist antibiotics and host defense systems.

Despite advancements in orthopaedic devices and surgery, managing infection remains challenging. Infections invariably lead to prolonged treatment, unstable fixation, early revision, implant removal, functional loss, and sometimes amputation. These consequences strain hospitals financially and greatly impact patients' well-being.

Although global infection rates are low in the primary population, peri-prosthetic joint infection (PJI) and fracture-related infection (FRI) can occur more frequently in patients with increased risk factors. [1, 2]

While the factors contributing to implant infections may vary, focusing on prevention of biofilm formation can mitigate the environmental impact, resource burdens (such as bed space) and overall direct end costs. [3]

The impact on patients, their carers and families as well as the clinical team should not be underestimated.

bacteria mechanism

There are more bacteria cells than human cells in our bodies [4]. Bacteria typically exist freely in a planktonic state within the body. However, when they encounter an implant surface, they can attach and form communities. Within hours, these bacteria enhance their survival by encasing themselves in exopolysaccharides, forming a biofilm on the ***entire implant surface, including at the bone-implant interface.***

The formation of this biofilm can negatively impact the fixation and overall stability of the implant, potentially leading to the need for revision surgery. Once established, biofilms are notoriously resistant to removal, withstanding shear forces and antibiotic treatments, which makes eradication challenging.

race for the surface

The concept of “race for the surface,” highlights the competition between microbial adhesion and tissue integration on biomaterial implants. Typically, the crucial phase occurs within the first 72 hours. If tissue cells win, the implant is covered by tissue and remains resistant to bacterial colonization. If bacteria win, a biofilm forms, hampering tissue cell function and increasing infection risk.

biofilm stages

The biofilm formation process is integral to the five stages of infection: [5]

STAGE 1

Micro-organisms may gather on the implant surface and bone-implant interface.

STAGE 2

These gatherings evolve into communities and become enveloped in a matrix.

STAGE 3

The matrix layer shields the biofilm from antibiotics, shear forces, and host’s immune responses.

STAGE 4

Protected within the biofilm, these bacterial communities exhibit increasingly complex characteristics and three- dimensional structures.

STAGE 5

Attachment becomes irreversible, and the biofilm community releases new organisms back into the planktonic form, facilitating the spread of infection.

DAC® defensive antibacterial coating

Defensive Antibacterial Coating (DAC®) is a smart hydrogel with hydrophilic properties, which, when spread onto the implant surface, acts as a physical barrier to prevent biofilm formation, defending against potential post-surgical infections, and optimising patient outcomes.

DAC® is a powdered medical device comprised of two bioresorbable polymers, designed for use in orthopaedic surgeries. DAC® forms a temporary hydrogel that adheres seamlessly to implant surfaces. This innovative hydrogel serves as a prophylactic coating, which can be easily applied both before and after the implantation of orthopaedic devices.

HYALURONIC ACID (HA)

Hyaluronic acid (HA) is a naturally occurring substance found in the human body. Highly biocompatible, surfaces coated with HA show minimal bacterial biofilm growth, making it renowned for its exceptional moisture retention capabilities.

POLY-LACTIC ACID (PLA)

Poly-lactic acid (PLA) is a safe, biodegradable and bio-absorbable synthetic polymer obtained from renewable sources (corn or other cereals). It is commonly used in various applications, including medical devices. PLA decomposes into harmless byproducts in the environment, contributing to its eco-friendliness.

Surgeons may choose to load antibiotics to DAC®.

DAC® difference

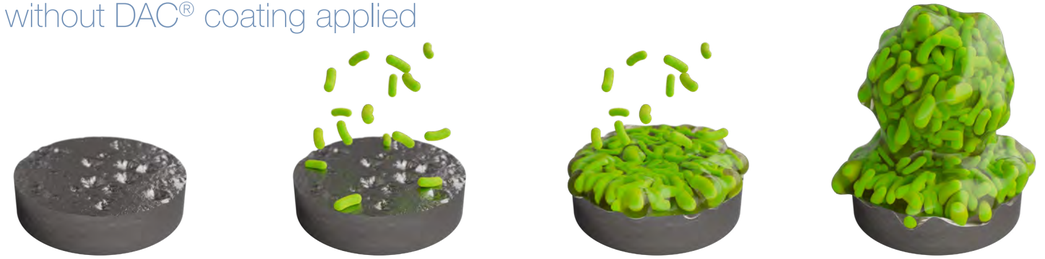
DAC® effectively prevents biofilm formation on the implant surface, including the bone-implant interface, during the critical first 72 hours, reducing infection risks in orthopaedic procedures. It allows surgeons to coat any implant with a hydrogel, preventing bacterial adhesion and enabling the direct application of antibiotics to the site.

DAC® consistently demonstrates effectiveness across various challenging surgical procedures, facilitating localized antibiotic release to target infection-prone areas.

Clinical assessments, such as those for periprosthetic joint infections in total hip revision arthroplasty [13], support its efficacy. Using antibiotic-loaded DAC® with cementless prostheses, alongside systemic prophylaxis, reduces early postoperative infections. Furthermore, a comprehensive review of clinical data [6] highlights DAC®'s efficacy, with notable success in high-risk vertebral surgeries.

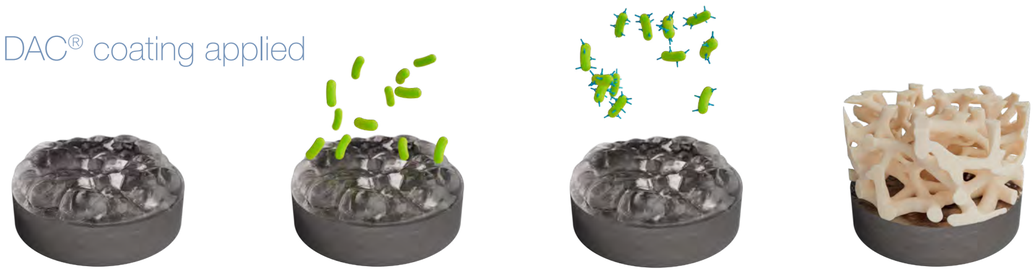
These findings underscore DAC®'s potential in enhancing infection control and improving surgical outcomes.

without DAC® coating applied



Implants are susceptible to pathogens adhering to their surface. In the absence of a response to the organism, bacterial colonies initiate biofilm production.

DAC® coating applied

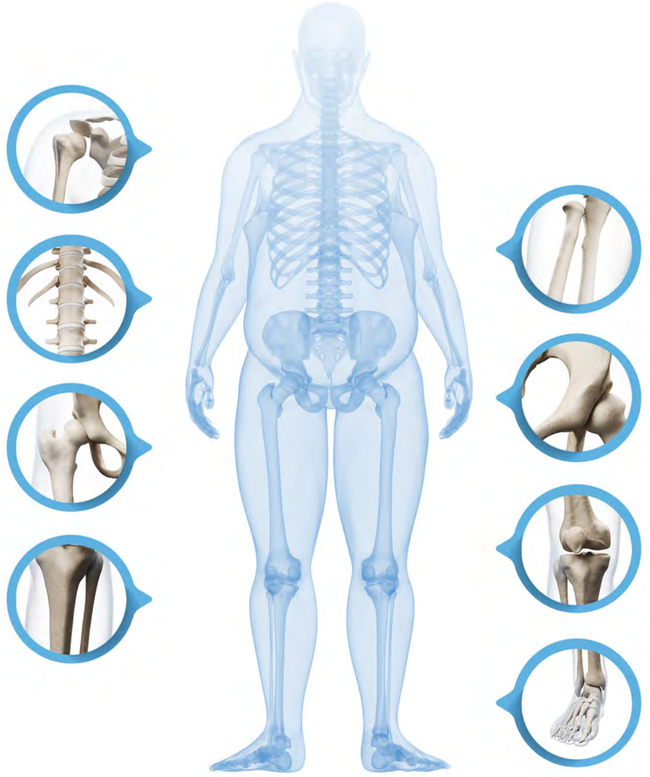


The DAC® hydrogel layer interrupts bacterial adhesion to the implant surface, due to its hydrophilic properties. The immune system and administered systemic antibiotics can effectively target planktonic micro-organisms.

relative risks

In any surgical setting, infection prevention is paramount, even among healthy individuals. While the relative risks in primary settings are generally low, they can quickly escalate with the presence of one or more risk factors. These factors, whether in primary, revision joint replacement, trauma, or oncology cases, increase the patient's susceptibility to infection.

The true value of DAC® becomes particularly evident in cases involving higher-risk patients, complex surgeries, or when additional factors need consideration. In these scenarios, the benefits of DAC® can significantly outweigh its costs, especially given the increasing prevalence of such cases. [14]

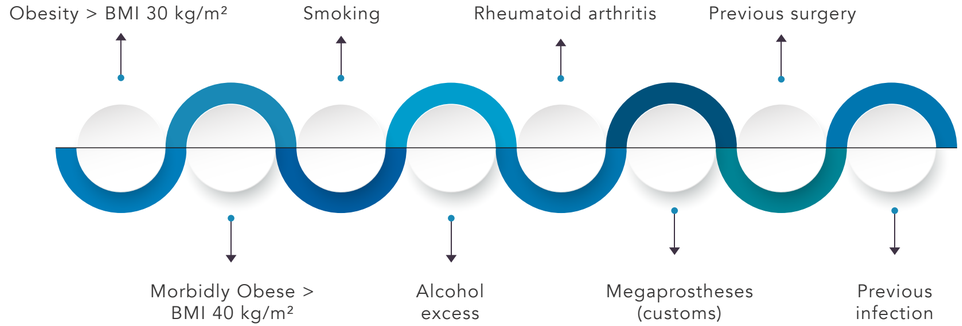


other factors:

An observational cohort study in the UK analysed 623,253 primary hip procedures, focusing on revisions due to periprosthetic joint infections (PJI). Data from the National Joint Registry, linked to Hospital Episode Statistics, identified several risk factors for PJI after primary hip replacement:

- Elevated BMI
- Comorbidities such as diabetes
- Previous septic arthritis or infection
- Previous femoral neck fracture

These factors are associated with an increased risk of PJI, highlighting the need for targeted infection control measures in these patient groups. [15]



Furthermore, a large-scale analysis [16] involving over 2 million patients identified higher BMI, particularly obesity (BMI above 30 kg/m²), as a significant risk factor for both deep and superficial infections. Morbidly obese individuals (BMI over 40 kg/m²) exhibited an even higher susceptibility. Additional risk factors included:

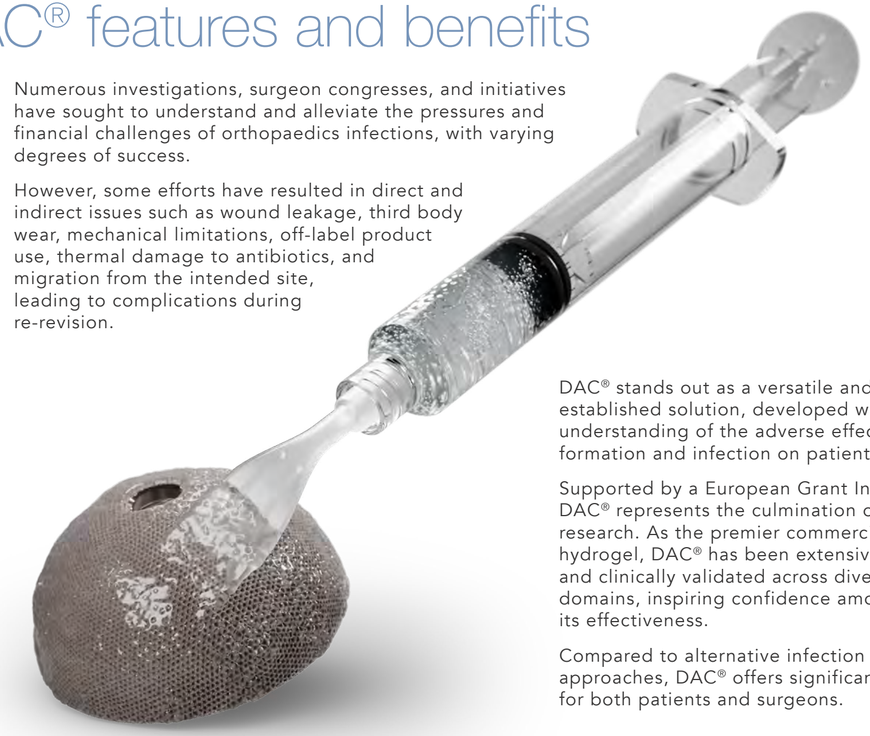
- High ASA grade
- Trauma site surgery
- Certain ethnic groups
- Comorbidities
- Previous infections
- Multiple site operations
- Use of mega-prostheses
- Smoking

These factors collectively increase the risk of infections, emphasizing the importance of tailored infection control strategies in orthopaedic surgery.

DAC® features and benefits

Numerous investigations, surgeon congresses, and initiatives have sought to understand and alleviate the pressures and financial challenges of orthopaedics infections, with varying degrees of success.

However, some efforts have resulted in direct and indirect issues such as wound leakage, third body wear, mechanical limitations, off-label product use, thermal damage to antibiotics, and migration from the intended site, leading to complications during re-revision.



DAC® stands out as a versatile and well-established solution, developed with a deep understanding of the adverse effects of biofilm formation and infection on patient outcomes.

Supported by a European Grant Initiative, DAC® represents the culmination of extensive research. As the premier commercially available hydrogel, DAC® has been extensively published and clinically validated across diverse anatomical domains, inspiring confidence among clinicians in its effectiveness.

Compared to alternative infection prevention approaches, DAC® offers significant advantages for both patients and surgeons.

- Indicated for prevention of infection
- Clinically proven
- Articulating joints
- Can be used with trauma plates and nailing
- Cemented and cementless devices
- Easy to mix
- Simple to apply
- Can be used with antibiotics
- Active for 72 hours
- Suitable for trauma, revision, oncology implants

DAC® prophylactic infection prevention

DAC® has proven its capacity to improve overall outcomes and healthcare economics with substantial clinical evidence spanning the past decade. Its impact is particularly notable in reducing infection-related costs, which can soar for revision cases. This cost reduction can be achieved through DAC®'s effectiveness, demonstrating efficacy even at critical interfaces like the bone implant, in articulating joint replacements and with cementless implants in long bones.

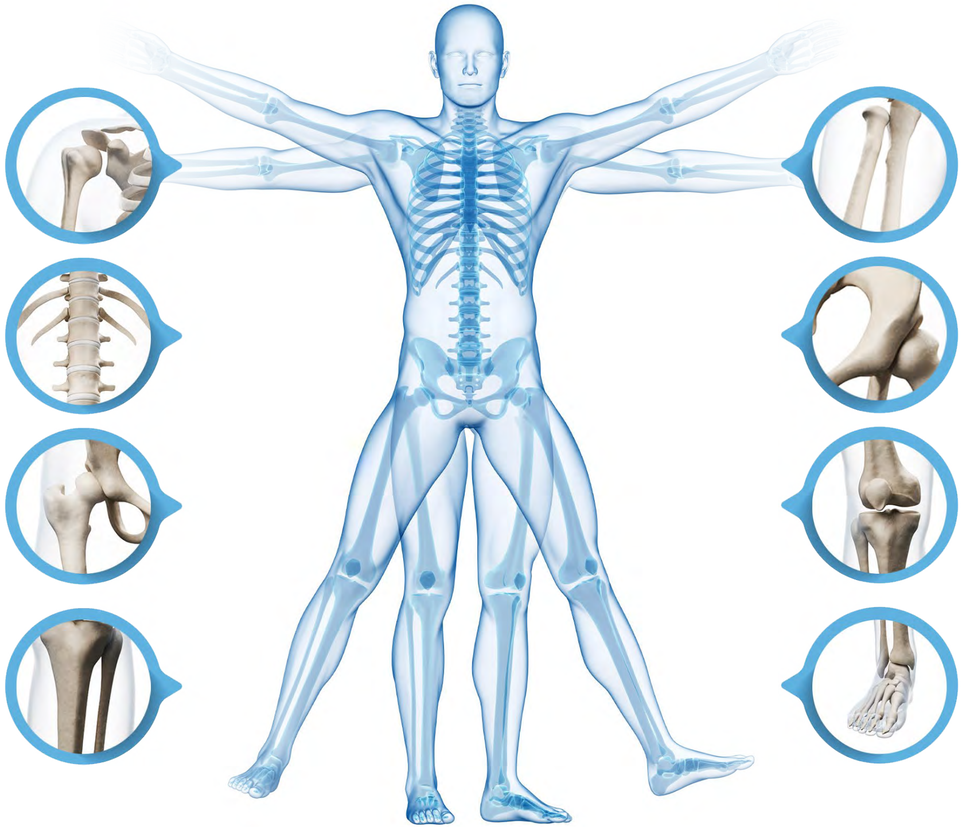
DAC® presents a reliable infection prevention strategy across a spectrum of surgical scenarios, including trauma, revision, elective, and oncology procedures. Surgeons rely on DAC® with confidence, as its safety and efficacy have been clearly demonstrated through post market surveillance.

Beyond infection prevention, DAC® completely disaggregates and does not hinder implant osseointegration, and ensures implant adherence, rendering it suitable for comprehensive coating of entire devices.

Notably, DAC® is specifically designed for infection prevention, distinguishing it from other strategies. This specialisation further enhances its effectiveness in safeguarding patient health and minimising the burden of post-operative infections.

DAC® is effective in various surgical scenarios, including:

- Trauma
- Elective procedures
- Oncology surgeries
- Cemented or cementless procedures
- Megaprostheses
- DAIR cases
- Nailing & Plates
- Articulating joint replacements
- Prevention of fracture-related infections in both primary and revision surgeries



mixing DAC®

1

Before use, de-compact the powder as necessary by carefully and slightly retracting the syringe plunger position and digitally flicking or tapping the syringe until the powder is loosened and moving freely.

2

Connect the backstop to the DAC® powder syringe. Ensure the BD is pointing up towards the plunger.

3

Draw up 5ml of sterile water (or 5ml of antibiotic solution).

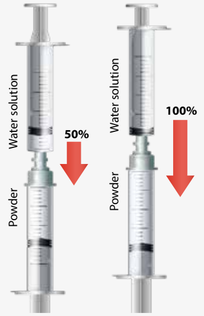
4

With the syringe in an upright vertical position and plunger towards table, unscrew the cap from the DAC® syringe. Screw on the luer-lock connector.

5

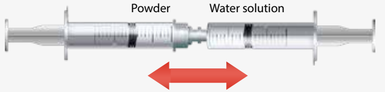
Connect the solution syringe and place the fluid in the top and powder at the bottom.

6



Press 50% of the solution firmly and quickly into the DAC® powder. Press the remaining 50% of fluid slowly into the powder maintaining a vertical position of the syringe throughout this motion.

7



Place the syringe into a horizontal position and move the solution part way between the two for the first few passes. Once the mix starts to take place then fully depress each syringe until a homogenous mix is achieved.

8

Mix is complete once all powder is dissolved. Ensure the hydrogel is transferred completely into one syringe. Disconnect syringes.

Screw on the applicator and leave for 5 to 10 minutes minimum before application.

Once DAC® is prepared it is safe to rest for up to 6 hours before use.

9

The implant surface is coated with DAC® preventing bacterial adhesion and colonisation of the implant.

any implant DAC®

DAC® should be kept cool and stored in a fridge between 2°C and 8°C to ensure it is easier to mix and the HA is stable.

Unmixed DAC® should not be used if the ambient temperature has reached 25°C since the HA can become unstable.

Surgical Procedure:

Mix DAC® at the very start of any procedure before the skin incision. This ensures the mix is ready when required and once mixed into a stable compound the temperature is no longer of concern.

In any event DAC® should be mixed 15 minutes before it is to be applied to an implant.

Once mixed and hydrated DAC® can safely be used for up to 6 hours.

To prepare the DAC® :

DAC® Kit
Sterile water
Small sterile pot

Antibiotic if required
Syringe needle to draw up antibiotic

laboratory studies

Laboratory studies have demonstrated high rate of infection eradication following cementless one-stage revision hip arthroplasty using antibacterial hydrogel coating [17].
The DAC® coating layer remains attached to the device in the case of a cementless stem [18] and DAC® does not impact the bony ingrowth of cementless implants.
Moreover, the product can be applied between the implant bone interface safely.

DAC® demonstrates remarkable efficacy in numerous indications including cemented and cementless arthroplasty, including those implants which are already in situ during revision surgery. Do not use DAC® on an infected area not surgically cleaned.

Recommended techniques include:

For cementless devices: Coat all areas within bone or interfacing with bone. Complete any pulse lavage stages. Coat any remaining areas outside the bone. For these products the ingrowth has been shown to be unaffected. The hydrogel remains on the device during insertion due to its adhesive properties.

For cemented devices: Cement the devices into place, perform final pulse lavage, and coat all visible areas.

For products requiring assembly: Fully assemble any morse tapers before coating the device. Under no circumstances should the hydrogel be applied to the inside of a hip head.

Trauma plates: Coat the backside of the plate, affix to the bone, perform pulse lavage, and coat the remainder of the device.

The coating should be uniformly and consistently applied in a thin layer to ensure comprehensive implant protection.

Care should be taken in application of DAC® for operations involving the spine, which should only be applied to coat vertebral stabilisation devices, including screws, rods and cages.

(Please refer to DAC® IFU for further information.)

DAC® and antibiotics

DAC003000

Single Kit comprises:

- 1 sterile DAC® syringe containing 300 mg of dry powder
- 1 complete set of sterile DAC® components (connector, back-stop, spreader)
- 1 empty 10ml graduated syringe Designed to prepare 5 ml of DAC® Hydrogel when reconstituted.

DAC003002

Double Kit comprises:

- 2 sterile DAC® syringes containing 300 mg of dry powder each
- 2 complete sets of sterile DAC® components (connector, back-stop, spreader)
- 2 empty 10 ml graduated syringes Intended to prepare 10 ml of DAC® Hydrogel when reconstituted.

Storage:
DAC® products should be stored in a refrigerator at temperatures between 2°C and 8°C.
Do not freeze. Refer to the full Instructions for Use (IFU) for comprehensive instructions.

Clinical Usage:
DAC® has been utilised effectively in clinical settings both with and without antibiotics.

The following chart serves as a guide for surgeons who opt to use DAC® in combination with antibiotics, in regions where regulatory clearance permits.

Guide	DAC®	DAC® Powder	Vancomycin	Sterile water	Draw up Total	Resultant antibiotics per DAC®
Primary / trauma plate	DAC003000 - 5 ml	300 mg	1 g	20 ml	5 ml	250 mg / 5 ml DAC®
Primary / trauma plate	DAC003000 - 5 ml	300 mg	500 mg	10 ml	5 ml	250 mg / 5 ml DAC®
Revision / trauma nail	DAC03002 - 10 ml	600 mg	1 g	20 ml	10 ml	500 mg / 10 ml DAC®
Revision / trauma nail	DAC03002 - 10 ml	600 mg	500 mg	10 ml	10 ml	500 mg / 10 ml DAC®
For megaprosthes / larger implants additional DAC® may be required						

Antibiotic to be used	Antibiotic quantity	Ampoules (as applicable)	DAC® quantity	Volume of sterile water	Draw up volume	Total Antibiotics / volume
Vancomycin	1 g	-	300 mg - 1 syringe	20 ml	5 ml per syringe	250 mg / 5 ml DAC®
Vancomycin	500 mg	-	300 mg - 1 syringe	10 ml	5 ml per syringe	250 mg / 5 ml DAC®
Vancomycin	1 g	-	600 mg - 2 syringes	20 ml	5 ml per syringe = 10ml total	500 mg / 10 ml DAC®
Vancomycin	500 mg	-	600 mg - 2 syringes	10 ml	5 ml per syringe = 10ml total	500 mg / 10 ml DAC®
Gentamycin	80 mg/ 2 ml	2	300 mg - 1 syringe	1 ml	5 ml per syringe	160 mg/ 5 ml DAC®
Gentamycin	80 mg/ 2 ml	5	600 mg - 2 syringes	-	5 ml per syringe	200 mg / 5 ml DAC®
If the surgeon considers using other antibiotics if appropriate, then the final concentration should be not less than 2% and not more than 5%.						
Antibiotics are not supplied - please adhere to local regulations.						
Surgeons under their own responsibility can hydrate the product with antibiotic solution. The above serves as a reference only, based on published clinical data.						

DAC® evidence and references

evidence

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DAC_EN_19.06.2024 - V1

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