

Summary of Safety and Clinical Performance

COPAL® G+C

- Patient Section -

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English

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2 Abbreviations / Explanations

ALBC	Antibiotic loaded bone cement
BCIS	Bone Cement Implantation Syndrome
BfArM	Federal Institute for Drugs and Medical Devices [Bundesinstitut für Arzneimittel und Medizinprodukte]
CE	Conformité Européenne
CER	Clinical Evaluation Report
CND	Classificazione Nazionale dei Dispositivi medici [National Classification of Medical Devices]
CPR	Cardiopulmonary Resuscitation
CS	Common Specifications as defined in the MDR
DIN	German standard [Deutsches Institut für Normung]
E141	chlorophyll-copper-complex (food colorant)
EMDN	European Medical Device Nomenclature
EN	European Standard [Europäische Norm]
EU	European Union
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
HME	Heraeus Medical GmbH
IFU	Instructions for Use
ISO	International Organization for Standardization
MDD	Medical Device Directive
MDR	Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and the amendments of 2017/745 (2020/561, 2023/607 and 2024/1860)
MRI	Magnetic resonance imaging
N/A	Not applicable
NB	Notified Body
PMCF	Post-Market Clinical Follow-Up
PMMA	poly (methyl methacrylate)
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Report
SOTA	State-of-the-Art
SpO ₂	Peripheral Oxygen Saturation
SRN	Single Registration Number for an economic operator
SSCP	Summary of Safety and Clinical Performance
TD	technical documentation
Swissmedic	Swiss Agency for Therapeutic Products
UDI-DI	Unique Device Identification - device identifier
URL	Uniform Resource Locator (internet address)

3 General Information

This document applies to implantable class IIb, and class III medical devices developed by Heraeus Medical GmbH and is established to comply with the Medical Device Regulation (MDR) 2017/745 (EU) of 5th April 2017, valid from May 2021.

The Summary of Safety and Clinical Performance (SSCP) is intended to provide a summary of clinical data pertinent to the safety and clinical performance of the medical device. The SSCP is an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the MDR objectives, to enhance transparency and provide adequate access to information.

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3.1 Relevant information for Users/Healthcare Professionals

Please refer to the English language version for healthcare professionals for the contents of this section.

3.2 Relevant Information for patients

The following chapters provide a summary of the safety and clinical performance of the device intended for patients.

This Summary of Safety and Clinical Performance (SSCP) provides public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below addresses patients or lay persons. The first part of the document shows a more extensive summary of safety and clinical performance prepared for healthcare professionals.

The SSCP does not provide general advice on the treatment of a medical condition. Please contact your doctor/surgeon in case you have questions about your medical condition or about the use of the device in your situation. This SSCP does not replace an Implant Card or the Instructions for Use (IFU) to provide information on the safe use of the device.

3.2.1 Background information

COPAL® G+C is a bone cement. It is based on a biologically safe material called poly (methyl methacrylate) (PMMA). This material has a long history of safe use in humans.

COPAL® G+C is used in adults such as elderly patients with degenerative joint disease. Osteoarthritis is an example for such a joint disease. Osteoarthritis is the most common form of arthritis and affects millions of people worldwide. It occurs when the protective cartilage that cushions the ends of the bones wears down over time. Patients with trauma after severe accidents with several fractures in a bone can also be considered for treatment with bone cements. The bone cement is used to anchor total or partial joint endoprostheses. It attaches endoprostheses firmly and stably to the bone. Endoprostheses are medical devices used to replace parts of the inside of your body. Hip, knee or shoulder joints can be replaced by an endoprostheses, for example.

Arthroplasty is a surgical procedure to restore the function of a joint. Primary arthroplasty refers to the first joint replacement. Revision arthroplasty refers to follow-up surgery on the same joint. In total joint replacement parts of a joint are removed and replaced by an implant, the endoprosthesis. In partial joint replacement artificial surfaces replace only the moveable surfaces of a joint. The healthy parts of the joint stay intact.

Your doctor/surgeon applies the bone cement during surgery. The instructions for use give directions.

Your doctor/surgeon takes care of the following aspects during your surgery:

- The bone cement is applied to your carefully cleaned, aspirated, and dried bone.
- Your prosthesis is put in place and held until the bone cement has set completely.
- During and immediately after the bone cement is applied, your doctor/surgeon will monitor your blood pressure, pulse, and breathing carefully. This ensures early detection and treatment of adverse events such as low blood pressure and cardiac arrest. Drops in blood pressure have occurred remotely and shortly after application of bone cement. However, consequences such as cardiac arrest are only reported in very few cases.

It is safe to have magnetic resonance tests (MRI) with COPAL® G+C bone cement. But the composition of the prosthesis you receive together with the bone cement may affect your ability to have magnetic resonance tests. You will receive an implant card for the bone cement that was used. Additionally, you will receive an implant card for the prosthesis. Please keep these documents and provide them in future examinations (e.g., X-ray, CT scan, MRI).

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3.2.2 Device identification and general information

3.2.2.1 Products (device trade names) covered by this document

- COPAL® G+C

3.2.2.2 Manufacturer name and address

Heraeus Medical GmbH
Philipp-Reis-Str. 8/13
61273 Wehrheim
Germany

3.2.2.3 Basic UDI-DI number of the concerned product

The unique device identification (UDI) consists of a series of numbers or numbers with letters. It allows the unmistakable identification of a specific medical device on the market. A UDI device identifier (UDI-DI) is specific to a device, connecting the product to the information on the EUDAMED database.

The following UDI-DI numbers are assigned to the different products:

Product	UDI-DI
COPAL® G+C	4260102130102010002B5

3.2.2.4 Year of first CE-mark

Before a medical device is introduced on the market in the European Union, it needs to show that the product fulfills the requirements. The so-called CE-certification documents the fulfilment, and the CE-mark is placed on the product. The legal requirements for medical devices have changed in May 2021. Then, the Medical Device Regulation (MDR) replaced the Medical Device Directive (MDD).

The following table contains the detailed information about the products. The table lists the year of the first CE-mark under MDR and under MDD.

Product	Year of first CE-mark under MDR	Year of first CE-mark prior to MDR
COPAL® G+C	2024	1998

3.2.3 Intended use of the device

3.2.3.1 Intended purpose

COPAL® G+C is a PMMA bone cement intended for stable anchoring of total or partial joint endoprostheses in living bone.

3.2.3.2 Indications and intended patient groups

COPAL® G+C is indicated for surgical treatment such as

- anchoring of endoprosthesis in primary and revision arthroplasty procedures of
 - hip
 - knee
 - ankle
 - shoulder
 - elbow

These treatments are typically conducted in adults, predominantly elderly patients with risk factors for periprosthetic joint infection and patients with trauma.

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3.2.3.3 Contraindications / advice against treatment

COPAL® G+C must not be used in the following cases:

- suspected or proven hypersensitivity to components of the bone cement including gentamicin, other aminoglycoside antibiotics, clindamycin, or lincomycin
- patients with renal impairment
- for permanent fixation purposes in the presence of an active or incompletely treated infection at the bone site caused by gentamicin and clindamycin non-sensitive strains
- spinal surgery
- during pregnancy or breast-feeding
- children

The safety of the bone cement in pregnant women or in children has not been established. Bone cement may adversely affect bone growth and fetal health.

3.2.3.4 Lifetime of the device

There is no general factor influencing the lifetime of COPAL® G+C. The actual lifetime of COPAL® G+C can be influenced by factors such as your medical situation and your lifestyle.

Removal of the implant is not necessary unless it is clinically required. Implant removal is in the discretion of the responsible surgeon based on your medical condition.

3.2.4 Device description

COPAL® G+C is a bone cement which is based on a biologically safe material called polymethylmethacrylate (PMMA) which has a long history of safe use in humans.

Composition

The cement consists of 2 main components, a powder and a liquid. The table below shows the composition of the components. Mixing of the components starts a chemical reaction. This so-called polymerization forms a soft dough. The dough becomes more and more solid over time. Your surgeon determines the right time for application of the dough to the bone. There it hardens completely. In addition, the cement contains two antibiotics (gentamicin and clindamycin). Your treating surgeon chose these antibiotics to prevent an infection.

COPAL® G+C contains:

Powder:		
PMMA copolymer	82 %	Polymer (powder component)
Zirconium dioxide	10 %	X-ray contrast medium (enabling visualization with X-ray, CT)
Benzoyl peroxide	1 %	Chemical component initiating the polymerization reaction
Gentamicin sulfate	4 %	Antibiotic
Clindamycin hydrochloride	3 %	Antibiotic
Liquid:		
Methyl methacrylate	98 %	Monomer (liquid component)
N, N-dimethyl-p-toluidine	2 %	Chemical component accelerating the polymerization reaction

The data is rounded

Other constituents:

- Powder: chlorophyll-copper-complex (E141) (Food colorant. Improving visibility of the bone cement in the surgical field)
- Liquid: chlorophyll-copper-complex (E141), hydroquinone (chemical component stabilizing the chemical reaction)

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Traces of histamine may be present in the bone cement. But no manufacturing residuals that could pose a risk to you have been found. Be aware that the composition table shows the constituents before mixture of the bone cement components. The methyl methacrylate is completely used up during setting and forms the hardened bone cement. COPAL® G+C bone cement is intended for single-use and is supplied sterile.

3.2.5 Risks and warnings

Contact your doctor/surgeon if you believe that you are experiencing side effects. This applies for side effects related to the device or its use, and also if you are concerned about risks. This document does not replace a consultation with your doctor/surgeon if needed.

Side effects are events that are known when using the device. They can be caused by the device.

Residual risks are risks which cannot be controlled by the device manufacturer. They are mostly related to the surgical procedure in general.

Adverse events are events that can occur in a clinical investigation. They have a negative impact mostly on the patient. No causal relationship with the device must be present.

Heraeus Medical GmbH has a risk management process according to harmonized risk management guidelines. It ensures that the benefits of using the medical device are greater than potential risks.

Side effects and residual risks of the device can occur with different frequencies. As an example, if a side effect occurs in less than 1% of cases (< 1%), the side effect will occur in less than 1 in 100 surgeries.

Side effects

Frequencies are taken from the literature, < 0.001% can include potential risks not reported in the literature so far.

Table 1 Frequencies of side effects

Frequency	Side effect
Immune System	
< 10%*	• hypersensitivity / allergic reaction and local reaction which may include inflammation, induration, reddening of skin, itching or pain
< 0.001%	• anaphylactic shock
Kidney and Urinary Tract	
< 10%*	• renal impairment
Musculoskeletal System	
< 0.001%	• tissue modification to bone
< 0.001%	• dissolution of bone
Skin and Subcutaneous Tissue	
< 0.001%	• rash
< 0.001%	• hives

*cases reported to Heraeus Medical GmbH showed frequencies lower than in literature

Residual risks

Residual risks listed below are procedure related risks which are beyond the control of the manufacturer because they are procedure or user related. Frequencies are taken from literature, < 0.001% can include potential risks not reported in literature so far.

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Table 2 Frequencies of residual risks

Frequency	Residual Risk
Vascular System, Heart, Respiratory System, Blood and Lymphatic System	
Bone Cement Implantation Syndrome (BCIS): Insertion of bone cement may produce a high medullary pressure that forces bone marrow constituents into the venous vascular system, resulting in fat and marrow emboli. To avoid BCIS, it is recommended that the implantation site is cleaned thoroughly with pulsatile, high pressure, high-volume lavage using an isotonic solution and dried before the bone cement is introduced. The bone cement should be applied retrogradely under sustained low pressure into the medullary canal. Subsequently, the prosthesis should be introduced slowly into the cemented medullary canal. In case of pulmonary or cardiovascular events, it is necessary to monitor blood volume and possibly increase it. In case of acute respiratory failure, anesthesiologic measures should be taken. In general, adverse reactions of BCIS might include low blood pressure / hypotension, hypoxia, bradycardia, tachycardia, pulmonary hypertension, thrombosis, embolism, pulmonary embolism, myocardial infarction, cerebrovascular accident, respiratory arrest, and cardiac arrest.	
> 10%*	BCIS grade 1 moderate hypoxia (SpO ₂ < 94 %) or hypotension [fall in systolic blood pressure > 20 %]
< 10%*	BCIS grade 2 severe hypoxia (SpO ₂ < 88 %) or hypotension [fall in systolic blood pressure > 40 %] or unexpected loss of consciousness.
< 1%*	BCIS grade 3 cardiovascular collapse, requiring CPR
Nervous System	
< 0.0001%	• numbness
Blood and Lymphatic System	
< 0.0001%	• hypovolemia
Musculoskeletal System	
< 10%*	• aseptic loosening
< 0.0001%	• unequal limb length
< 1%*	• loss of range of motion
< 0.0001%	• ambulation difficulties
Infection	
< 10%*	• Bacterial infection including cellulitis, and / or osteomyelitis
Generalized Disorders	
< 0.0001%	• inflammation
< 0.0001%	• swelling / edema
< 10%*	• fibrosis
< 0.0001%	• heat necrosis

* cases reported to Heraeus Medical GmbH presented with frequencies lower than in literature

Please contact your doctor/surgeon if you have any questions.

Reporting of side effects, residual risks, or adverse events

If you experience any of these side effects or residual risks, or if you notice any adverse events not listed in this document, contact your doctor/surgeon immediately. You can also contact Heraeus Medical GmbH directly using the following email- address: hm.vigilance.medical@heraeus.com

Warnings and precautions

COPAL® G+C bone cement contains gentamicin and clindamycin, two antibiotics. It is most unlikely that this bone cement causes gentamicin or clindamycin overdosage because the gentamicin and clindamycin it carries mostly stays in the area where the cement is applied. It only leads to low and short-lived levels of antibiotics in the rest of the body.

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Gentamicin can potentially cause side effects in patients with impaired renal function, patients who are at risk of developing renal failure, or in patients who simultaneously receive drugs which affect the kidneys. In these cases, your doctor/surgeon may advise to monitor your blood levels of the antibiotic, electrolytes, or renal function.

Clindamycin can potentially enhance the effect of muscle relaxants.

Other relevant aspects of safety

In 2017, Heraeus Medical GmbH officially informed users on the proper handling of the bone cement packaging. It had received complaints on issues regarding the opening of the bags. Slight delays in operating times had happened.

Heraeus Medical GmbH updated the instructions for use and included a new picture to illustrate the proper handling. Information on this Field Safety Notice can also be found in the national safety databases of BfArM, Swissmedic, and MHRA.

3.2.6 Summary of clinical evaluation and Post-Market Clinical Follow-Up

COPAL® G+C has been on the market since 1998. It is considered as state-of-the-art in the field of stable anchoring of joint endoprostheses.

The manufacturer performs the analysis of any clinical data regularly. Sources can be endoprostheses registries and scientific publications, for example. These activities are called Post-Market Clinical Follow-Up measures. They allow the continuous proof of the benefit/risk ratio of the medical device. Registries are databases which collect long-term results after application of products in patients. These databases can be initiated by governmental authorities, medical societies, or manufacturers. In most cases they collect data from hospitals or private practices on a regional or national level.

The following clinical benefits and outcome parameter relate to the use of the bone cements:

- Stable fixation of the endoprosthesis with a low risk of revision surgery. This is evaluated on the basis of long-term data from regional or national registries.
- Improvement of impaired body function with a high patient satisfaction. This is evaluated on the basis of quality-of-life data from registries.
- Relief of symptoms related to the surgical procedure with high patient success. This is evaluated on the basis of quality-of-life data from registries.
- Application of bone cements in combination with an antibiotic with a low risk of reinfection. This is evaluated on the basis of revisions that are caused by infections, compared to the overall number of revisions (based on data from registries).
- Local use of an antibiotic within the bone cement can result in a low risk for side effects compared to oral or intravenous administration of the antibiotic. This is evaluated on the basis of complaints reported to manufacturer, evaluation of databases and data regarding the development of the medical device.

The above-mentioned clinical benefits and clinical outcome parameters are important to decide on the benefit/risk ratio of COPAL® G+C. The manufacturer evaluates the achievement of these clinical benefits.

The analysis revealed that COPAL® G+C performed as expected in all aspects of the above-listed outcome parameters:

- Stable fixation was analyzed by two aspects: the rate at which operations needed to be repeated (revision rate) and the rate at which endoprostheses loosened over time (aseptic loosening). Both rates were in a range comparable with the current state-of-the-art. For example, the revision rate of COPAL® G+C was reported to be 2.2% for primary hip and 2.5% for primary knee, which is comparable to benchmark standards (range for hip: 1.1% - 3.2%; range for knee: 1.4% - 4.3%).

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- Impaired body function was evaluated through questionnaires. In these, patients have reported on how much they are impacted in their daily activities. In all cases, COPAL® G+C was comparable to current state-of-the-art.
- Relief of symptoms was evaluated through questionnaires. In these, patients have reported on how much better their joint was after the surgery. In all cases, COPAL® G+C was comparable to current state-of-the-art.
- The number of re-operations because of an infection at the site of surgery was comparable to the current state-of-the-art in patients who underwent their first operation with COPAL® G+C and for revision surgeries. Exceptions were the numbers of re-operations because of an infection for first-time elbow procedures and for revision shoulder procedures, where the rates were higher than expected. It should be noted that many doctors use COPAL® G+C for operation mainly in patients with many other health issues. Because of this, their risk of infection is generally higher. As there are not many bone cements with two antibiotics like COPAL® G+C, also bone cements with only one antibiotic are considered for the state-of-the-art. But patients receiving a bone cement with only one antibiotic are typically of better health.
- COPAL® G+C bone cement contains antibiotics that can also be given directly into the veins. From this it is known that too high amounts can cause severe side effects. In a clinical study, it was measured how high up the blood concentrations of antibiotics released from the bone cement would go after an operation with COPAL® G+C. The result was that the values remained far below the levels which can lead to severe side effects.

Additionally, the scientific literature for COPAL® G+C was thoroughly evaluated. Eighteen clinical studies were identified and analyzed. It can be concluded that overall, the data show favorable clinical results for COPAL® G+C.

In conclusion, the success rates of the clinical benefits were comparable to or better than the current state-of-the-art.

Therefore, the manufacturer confirms that the benefits outweigh the risks for the indications of COPAL® G+C:

- anchoring of endoprosthesis in primary and revision arthroplasty procedures of
 - hip
 - knee
 - ankle
 - shoulder
 - elbow

The following activities are planned to ensure safety and performance of COPAL® G+C:

- Device Registry Analysis, to monitor the safety and performance of COPAL® G+C
- Screening of Scientific Literature, to monitor the safety and performance of COPAL® G+C
- Authority Databases (adverse events and recalls), to monitor the safety of COPAL® G+C

The same activities are performed for similar products to detect potential safety or performance issues early. The results will be summarized in reports. These activities will be conducted on an annual basis in connection with the continuous updates of the clinical evaluations.

3.2.7 Possible diagnostic or therapeutic alternatives

General information

Contact your doctor/surgeon when you consider alternative treatments. Depending on your individual situation, two treatment approaches are possible. On the one hand conservative treatment such as physiotherapy or pain medication without a surgery is possible. On the other hand, surgical treatment such as joint surgery like hip replacement surgery could be reasonable. Choice of treatment depends on your specific condition and your doctor's opinion.

Joint surgery

If possible, your doctor/surgeon will try to treat defective joints by other means. If all other treatment options fail, a reconstructive joint surgery may be necessary. This means that the complete joint or only parts of the joint are

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replaced by an endoprosthesis. Joint surgeries and endoprosthesis revision operation as well as the use of PMMA bone cements are very well-established procedures in joint replacement surgery.

PMMA is widely and successfully used for the fixation of various endoprostheses since decades. At present, PMMA is still the most commonly used fixation material in primary joint surgeries. Uncemented procedures have also been used in primary joint surgeries. However, current data do not allow to determine if cementless or cemented procedures generally perform better in joint surgeries. The advantage of the cemented procedures using PMMA is the long-term experience with this material. Also, the majority of orthopedic surgeons is familiar with the use of PMMA. Furthermore, bone cement can apply local antibiotics. This allows for infection prevention in patients at risk for infection. In addition, bone cements generally spread the force of movement evenly into the bone. Especially in patients with poor bone substance this is an advantage. Your doctor/surgeon will decide on the procedure that fits to your specific clinical condition best.

There is no other treatment option than a surgery in patients with suspected or confirmed infection of the implanted device (so-called prosthetic joint infections). Such a revision surgery can be either a one-stage or a two-stage surgery. A so-called one-stage surgery takes place in a single surgical step. The surgeon removes the infected prosthesis and bone cement, cleans the surgical site thoroughly, and places a new prosthesis. A so-called two-stage approach consists of two separate surgeries. During the first surgery, the surgeon removes the infected prosthesis and bone cement, cleans the surgical site thoroughly, and places a provisional spacer. This ensures proper treatment of the infection. The spacer also provides a limited range of motion during the time until the second operation. After the infection is cured, the second surgery takes place. The surgeon removes the provisional spacer and places a new permanent prosthesis. The attending surgeon will choose the appropriate surgical approach according to the patient's situation.

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