SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for HEALTH CARE PROFESSIONNALS
CEMSTOP®

Foreword

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor intended to provide diagnostic or therapeutic suggestions to intended users or patients

The following information is mainly intended to users (health care professionals such as surgeons). Following this information, there is a summary intended for patients.

1. Device Identification and general information

1.1. Device Trade Name(s): **CEMSTOP®**

The medical device has also the following private labels: CLEARCUT®, ESOBLOCK®, MECTAPLUG®, NEPTUN PLUG, QUIRURFIX®, B-PLUG®, CemP®, CPS Plug, Ic cement restrictor resorbable, TEKSTOP®.

1.2. Manufacturer name and address(es):

TEKNIMED S.A.S.		
Headquarters 8, rue du Corps Franc-Pommiès 65500 Vic en Bigorre France	*Production and facilities* 11-12, rue d'Apollo - ZI de Montredon 31240 L'Union France	*Distribution site (labelling)* ZI de la Herray 65500 Vic en Bigorre France

1.3. Manufacturer's SRN (Single Registration Number): FR-MF-000001224

1.4. Basic UDI-DI: 376017704B02CU

1.5. Medical device nomenclature description

CND nomenclature: P099002 – Orthopaedic cements, fitting and application devices and kits

1.6. Class of device: class III

1.7. Year when the first certificate (CE) was issued covering the device: 1998

The medical device has been introduced for the first time in the following countries:

Country	Year of introduction
Europe	1998
COLOMBIE	2017
EQUADOR	2017
MACEDOINE	2017
UKRAINE	2016
VIETNAM	2016
BRAZIL	2018
URUGUAY	2018
USA	2003

1.8. Authorised representative if applicable; name and SRN

N/A as the manufacturer is located in the UE

1.9. NB's name (the NB that will validate the SSCP) and single identification number BSI Netherlands (CE 2797)

2. Intended use of the device

2.1. Intended purpose

CEMSTOP ® cement restrictor is a diaphyseal plug intended to occlude the medullary cavity before the introduction of acrylic cement during hip arthroplasty surgeries.

2.2. Indication(s) and target population(s)

CEMSTOP® cement restrictor is indicated in cemented hip joint arthroplasties.
CEMSTOP® is to be used in patients for whom a cemented hip joint arthroplasty surgery is indicated.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section.
- Patients susceptible to allergic reactions to the CEMSTOP® components and its products of metabolism.
- As of today, no information concerning possible contraindications of CEMSTOP® on children, pregnant or breastfeeding women are published. Nevertheless, this population remains at risk for all complications related to a surgical procedure.

3. Device description

3.1. Description of the device

The CEMSTOP® cement restrictor is a flexible diaphyseal plug for orthopaedic use. It is designed to occlude the medullary cavity before the introduction of acrylic cement. It helps to prevent cement progression into the diaphysis and facilitates cement pressurization.



CEMSTOP® restrictors is designed with three rings seated on a truncated base. These three rings are 2mm oversized in order to ensure a good occlusion of the medullary cavity. A long inner canal facilitates secure insertion.

CEMSTOP® is a mixture of neutral compounds, gelatine, water, glycerol and methyl parahydroxybenzoate; the main component is porcine gelatine.

Chemical Composition	
Gelatin (porcine-based)	40 %
Glycerol	35 %
Water	25 %
Methyl Parahydroxybenzoate	2.5 ‰

CEMSTOP® is available in 6 different sizes: 8, 10, 12, 14, 16, 18 mm. Each size corresponds to the size of the medullary canal to occlude. A restrictor size 10 therefore effectively occludes a medullary cavity of diameter 10.
CEMSTOP® is supplied sterile. It is a single use product.

3.2. Reference to previous generation(s) or variants if such exist, and a description of the differences

CEMSTOP® isn't issued from any previous generation and has no variant.

3.3. Description of any accessories which are intended to be used in combination with the device

CEMSTOP® is intended to be used with the following instrumentation:
- CEMSTOP® bio-absorbable cement restrictor instrumentation – Reference: T067700 – Classification: Ir.

3.4. Description of any other device or products which are intended to be used in combination with the device

CEMSTOP® is designed to occlude the medullary canal during hip cemented arthroplasty. It is therefore intended to be used in combination with bone cement.

4. Risks and warnings

4.1. Residual risks and undesirable effects

No unacceptable residual risks have been identified during the risk analysis. No undesirable side-effects and no interactions with other agents have been recorded during the past 10 years, neither during PMCF conduction, nor during post-market surveillance, or in the literature analysis on similar products.
Any serious incident occurring in relation to the device CEMSTOP® must be reported without delay to TEKNIMED and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions

Read instructions for use carefully prior to use of CEMSTOP® device.
Ignoring the instructions for use may lead to potential undesirable effects.
For an optimum use of CEMSTOP®, it is essential to perform a thorough pre-operative review of the patient before the intervention in order to confirm the indication and plan the surgical technique.

Conservation

- It is strictly forbidden to re-sterilise the product. This product is supplied sterile unless package has been opened or damaged.
- This device is packaged and sterilised for single use only. Do not reuse, reprocess or resterilise. Reuse, reprocessing, or resterilisation may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury or illness. Also, reprocessing or resterilisation of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Before use, check the protective wrapping carefully to ensure that it has not been opened nor damaged in a way that could affect its sterility.
- Do not use this product after the expiration date printed on the package.

Use

- Examine the product visually to identify any defects such as crack or deformation. Do not implant products with defects.
- When removing the product from its wrapping, be sure to follow asepsis rules.
- if packaging is unintentionally opened before use or damaged, do not use the product.
- Special attention should be given to the choice of the size of the cement restrictor to avoid risks of cement flowing down or tearing of the cement restrictor.

4.3. Other relevant aspect of safety, including a summary of any field safety corrective action (FSCA) if applicable

In 2017, 1 labelling error required a field safety action (i.e. a batch recall): the date mentioned on the product and on the patients labels was the manufacturing date and not the expiry date. The product quality was not questioned in this issue. As first corrective action, the corresponding batch has been recalled. The devices have been relabelled with correct labels. As second preventive action, the label validation process has been reinforced with the addition of a third step of control to avoid any recurrence.

5. Summary of clinical evaluation and relevant information on post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

Non applicable. No devices are claimed equivalent.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Non applicable. No investigations have been conducted before the CE-marking.

5.3. Summary of clinical data from other sources, if applicable

Performance and safety of CEMSTOP® were evaluated through a PMCF study performed in 2018, in France.

Title: CEMSTOP® Outcomes Study - A Post-Market Clinical Follow-up

Identity of the device: CEMSTOP®

Intended use of the device in the study: occlusion of the medullary cavity before the introduction of acrylic cement during hip arthroplasty surgeries

Objectives of the study: The objective of this study was to confirm the clinical performance and safety of the biodegradable CEMSTOP® cement restrictor in a "real life" setting.

Indication: CEMSTOP ® cement restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during total hip arthroplasty.

Study design: The study was a non-controlled, observational post-market clinical follow-up. Clinical data were collected from patients' medical records from baseline visit and during 12 months post-surgery, according to the standard care of patient's visits.

Endpoints: *Clinical outcomes*: Pain, Quality of Life; *Radiological outcomes*: cement leakage, plug migration, stability of the prosthesis; *Safety*: Evaluation of complications, adverse events

Inclusion criteria: Patient 18 years of age or over, Patient having a surgical indication, Patient able to be followed according to the protocol, Patient consenting to the use of their clinical data

*Exclusion criteria***:** Patients allergic to the product components

Statistical Analysis: Statistics analyses will be descriptive as the study is an observational follow-up with no comparison. As required by statistical guideline for a small number of patients, data will be presented as follow: median (minimal value; maximal value), except for the variable Age: mean±SD.

Study Population and number of enrolled subjects: 30 patients were included in the study with a mean age of 74 ± 12 years old (Min 39 - Max 93). 15 patients were normal weight (BMI≤27), 7 overweight (27≤BMI≥30) and 8 obese (BMI≥30).

Perioperative outcomes: 30 patients beneficiated from a total (n=20), partial (n=9) or revision hip replacement (n=1). All prostheses were cemented: 26 with high viscosity and 4 with medium viscosity cement. During the surgery, no complication or adverse effect such as cement leakage or plug migration were reported.

Device usability: Investigators qualified the CEMSTOP® instrumentation as "Easy to use" and the use of the cement restrictor as "Easy", allowing an easy and safety insertion of the CEMSTOP® product.

Postoperative performance outcomes: The median time to the follow-up visit (FU) was 2 months after surgery (Min 1 month, Max 5 months). *Clinical outcomes*: Before the surgery, pain was evaluated at a median level of 8/10 (Min 7; Max 9) and was decreased at a median level of 1/10 (Min 0; Max 2) at FU visit. Quality of life was evaluated by way of a questionnaire covering 4 domains: Mobility, Usual activities, Pain/discomfort and Anxiety/depression, with 4 modalities: 'Normal', 'Mild', 'Severe' or 'Disability'. A clear improvement was observed at FU with more than 90% of patients reporting a 'Normal' or 'Mild' quality of life after surgery versus 90% reporting a "severe" or "disability" condition before the surgery.

Radiological outcomes: The good integration of the femoral stem, observed with the X-Ray analysis, confirms the effectiveness of the CEMSTOP® to occlude the diaphysis to create a regular cement mantle: 100% of "good/excellent" cement mantle and 100% of "stable" prosthesis were reported.

Postoperative safety outcomes: After the surgery and up to the postoperative follow-up visit, no adverse event or complication related to the CEMSTOP®, such as allergy or local inflammatory response, were observed. No prothesis revision due to a failure of the CEMSTOP® was reported.

Other reported complications were: 1 Heparin-induced thrombocytopenia during hospitalisation, which generated a prolongation of hospitalisation up to 30 days without sequelae; 1 fracture due to a fall from bed during hospitalisation, which generated a prolongation of hospitalisation up to 34 days without sequelae; 1 fracture due to a fall in a patient suffering from Parkinson's disease was reported at 3 months post-surgery, and treated by immobilisation (no surgery). None of these adverse events were related to the CEMSTOP®.

To conclude, all these clinical data confirm the performance and safety of use of the CEMSTOP® cement restrictor.

5.4. An overall summary of the clinical performance and safety

CEMSTOP® biodegradable gelatine restrictor is a product issued from a very-well known technology which has been used in orthopaedic surgeries for many years. It allows successful cementations of the femoral stems during hip joint replacement surgeries, leading subsequently to clinical benefits for the patients such as pain alleviation and improvement in quality of life. Claims for performance and safety of CEMSTOP® have been verified and confirmed through Post-Market Clinical Follow-up (PMCF), and Clinical Evaluation:

Performance and safety claims	Reported rates for CEMSTOP® in PMS / PMCF
Easy handling and safe introduction in bone shaft	CEMSTOP® use = 100% "Easy" CEMSTOP® Instrumentation = 100% "Easy to use"
Efficient sealing of medullar cavity	100% "good/excellent" cement mantle 100% "stable" prosthesis
Safe occlusion to support cement pressurisation	0 case of plug migration 0 case of cement leakage
Easy revision due to solvability (no plug to remove)	0% loosening / 100% survival
Clinical benefits for the patients	Pain: Improvement of pain level by 7 points (on a scale of 10) after vs before surgery
	Quality of life: 90% of patients reporting an improved quality of life after vs before the surgery
Undesirable side-effects	None

The only residual risk for CEMSTOP® is the risk for allergy. No new or unexpected risks were identified during Post-Market Surveillance (PMS) or PMCF. Considering the clinical benefits on pain and quality of life, as documented in the PMCF, versus the low level of residual risks, the overall benefit-risk balance of CEMSTOP® can be considered acceptable for the patients.

5.5. On-going or planned post-market clinical follow-up

Teknimed is currently implementing and conducting a post-market clinical follow-up which will assess clinical, safety and usability outcomes for all the Teknimed Arthroplasty range products, including CEMSTOP®.

Title: Safety and Clinical Performance Assessment of Bone Cements and Cement Restrictor used in Arthroplasty (Ref. CA01-TK-ARTHRO)

Justification/Context: TEKNIMED has developed several bone cements and a cement restrictor currently used in arthroplasty procedures. With the increasing use of these procedures, there is a need for real-life long-term safety and efficacy data on these products.

This retro- and prospective study is performed to assess the safety and performance of TEKNIMED arthroplasty products in their current clinical use.

Objective: The objective is to collect immediate, medium and long-term data after arthroplasty surgery, on the related clinical functional and complications outcomes of market-approved TEKNIMED arthroplasty products (cements and cement restrictor) to assess their performance and safety in a real-world setting.

Study design: global, single arm, non-controlled, multi-center, ambispective observational study. Patients will be followed as per local standard medical practices of the center. Data will be collected pre-operatively, at surgery and at standard of care follow-up (FU) visits.

Primary endpoint: Prosthesis survival defined as time from implantation to revision surgery due to a cement defect.

Performance endpoints: Evaluation of pain, quality of life, and patients' satisfaction; radiological evaluation of the cement mantle, plug migration, and cement leakage.

Safety endpoints: Adverse events will be documented during the study and categorized as whether they are serious and whether they are related to the TEKNIMED orthopedic product.

Statistical Analysis: Statistics analyses will primarily be descriptive as no hypotheses are enunciated to be demonstrated. Each outcome will be reported for each product separately, however, some products may be grouped and summarized

if the products are related and if needed (e.g.: cement + injection system). There are no intentions to compare or test data across products unless requested for a publication or other clinical evidence need. Should this later case occur, analytical analyses would be performed. According to the multiplicity of the explored parameters, the results of the statistical tests will have to be considered only as an exploratory basis. Kaplan-Meier survivorship analyses will be performed for several endpoints such as implant revision or aseptic loosening.

6. Possible diagnostic or therapeutic alternatives

Cement restrictors are designed to occlude the medullary cavity before the introduction of acrylic cement during hip cemented arthroplasty. Their main objective is to prohibit the passage of cement to bone cavity during the surgery. They are also responsible to regulate the pressure during the insertion of the bone cement. This property reduces the manifestation of fat embolism and cardiovascular problems during arthroplasty, preventing hypotension, and improves cement penetration, shear strength and clinical outcome.

The medullary canal can be occluded by bone, bioabsorbable plugs, cement plugs or polyethylene restrictors.

When the bone is of too poor quality, uncemented prothesis can be indicated to avoid the temperature elevation intrinsic to the acrylic cement polymerisation. In these cases, cement restrictors are no longer needed.

7. Suggested profile and training for users

Implantation of TEKNIMED products should only be performed in an adapted environment and by qualified operators having a sound knowledge and full mastery in preparation techniques specific to TEKNIMED products. Preparation techniques may be acquired from the distributors qualified by TEKNIMED. The operator is responsible for any complications or harmful consequences which might result from an erroneous indication or operative technique, an improper use of the equipment and/or a failure to comply with the safety rules provided in the instructions for use. Neither TEKNIMED as manufacturer nor the authorized TEKNIMED representative can be held responsible for these complications.

8. Reference to any harmonized standards and CS applied

Standard reference	Standard revision	Standard title	Applicability
> General standards			
EN ISO 13485	2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes	Fully whenever applicable
EN ISO 14630	2013	Non-active surgical implants -- General requirements	Fully whenever applicable
EN ISO 14971	2012	Medical devices -- Application of risk management to medical devices	Fully whenever applicable
EN ISO 14155	2011	Clinical investigation of medical devices for human subjects — Good clinical practice	Fully whenever applicable
EN 62366	2015	Medical devices – Application of usability engineering to medical devices	Fully whenever applicable
> Product standards			
EN ISO 22442-1	2016	Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management	Fully whenever applicable
EN ISO 22442-2	2016	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	Fully whenever applicable

EN ISO 22442-3	2007	Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents	Partial (except §5.4 regarding TSE*)

* Pigs are not naturally susceptible to infection via oral route. Therefore, they are not TSE relevant animal species with the meaning of the chapter 5.2.8 of the European Pharmacopoeia as explained in the supplier statement 'BSE status of porcine skin'.

> Biocompatibility standards

ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Fully whenever applicable
EN ISO 10993-2	2006	Biological evaluation of medical devices — Part 2: Animal welfare requirements	Fully whenever applicable
EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Fully whenever applicable
EN ISO 10993-9	2019	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products	Fully whenever applicable
EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Fully whenever applicable
EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Fully whenever applicable
EN ISO 10993-12	2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	Fully whenever applicable
EN ISO 10993-17	2009	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	Fully whenever applicable
ISO 10993-18	2020	Biological evaluation of medical devices — Part 18: Chemical characterization of materials	Fully whenever applicable

> Labelling and packaging standards

NF EN ISO 14698-1	2004	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods	Fully whenever applicable
NF EN 868-7	2017	Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods	Fully whenever applicable
EN ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1	Fully whenever applicable
EN ISO 11607-2	2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1	Fully whenever applicable
ISO/DIS 15223 -1	2020	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	Fully whenever applicable
ISO/DIS 20417	2019	Medical devices — Information to be provided by the manufacturer	Fully whenever applicable
EN 1041	2008	Information supplied by the manufacturer of medical devices	Fully whenever applicable
EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 1: requirements for terminally sterilized medical devices	Fully whenever applicable
ISO 2206	1987	Packaging -- Complete, filled transport packages -- Identification of parts when testing	Fully whenever applicable
ASTM D 4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems	Fully whenever applicable

ISTA 3A	2008	Packaged Products for parcel Delivery System shipment 70Kg (150IB) or less	Fully whenever applicable
ASTM D 4332	2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Fully whenever applicable
ASTM D 5276	2019	Standard Test Method for Drop Test of Loaded Containers by Free Fall	Fully whenever applicable
ASTM D 642	2015	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads 1	Fully whenever applicable
ASTM D 999	2015	Standard Test Methods for Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM D 6653 / D6653M	2013	Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method	Fully whenever applicable
ASTM D 4728	2017	Standard Test Method for Random Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM D 6344	2004	Standard Test Method for Concentrated Impacts to Transport Packages	Fully whenever applicable
ASTM F 1929	2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Fully whenever applicable
ASTM F 88	2015	Standard test method for seal strength of flexible barrier materials	Fully whenever applicable

> Microbiology standards

NF EN ISO 11737-1	2018	Sterilization of medical devices — Microbiological methods - Part 1: Determination of a population of microorganisms on products	Fully whenever applicable
NF EN ISO 11737-2	2019	Sterilization of medical devices — Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Fully whenever applicable
NF EN ISO 11138-1	2017	Sterilization of health care products — Biological indicators - Part 1: General requirements	Fully whenever applicable

> Sterilisation standards

EN ISO 11137-1	2015 / A2:2019	Sterilization of health care products — Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Fully whenever applicable
EN ISO 11137-2	2015	Sterilization of health care products — Radiation - Part 2: Establishing the sterilization dose	Fully whenever applicable
EN ISO 11137-3	2017	Sterilization of health care products — Radiation - Part 3: Guidance on dosimetry aspects	Fully whenever applicable

9. Revision history

Revision	Date issued	Revision validated by the Notified Body
1.6	18 OCT 2021	☒ Yes, validation language: English ☐ No

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS - English Version
CEMSTOP®

Version 1.6, dated 18OCT2021, validated by BSI (English version)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and general information

1.1. Device Trade Name: **CEMSTOP®**

The medical device has also the following private labels: CLEARCUT®, ESOBLOCK®, MECTAPLUG®, NEPTUN PLUG, QUIRURFIX®, B-PLUG®, CemP®, CPS Plug, Ic cement restrictor resorbable, TEKSTOP®.

1.2. Manufacturer name and address(es):

TEKNIMED S.A.S.		
Headquarters 8, rue du Corps Franc-Pommiès 65500 Vic en Bigorre France	*Production and facilities* 11-12, rue d'Apollo - ZI de Montredon 31240 L'Union France	*Distribution site (labelling)* ZI de la Herray 65500 Vic en Bigorre France

1.3. Basic UDI-DI: 376017704B02CU

1.4. Year when the device was first CE-marked: 1998

2. Intended use of the device

2.1. Intended purpose

CEMSTOP ® cement restrictor is a small plug intended to occlude the inner cavity of the femur before the introduction of bone cement during a total hip joint replacement surgery.

2.2. Indication(s) and intended patient groups

CEMSTOP® is indicated in cemented hip joint replacement surgery.
CEMSTOP® is to be used in patients for whom a cemented hip joint replacement surgery is indicated.

2.3. Contraindications

- Use in other surgeries than those listed in the INDICATIONS section.
- Patients susceptible to allergic reactions to the CEMSTOP® components and its products of metabolism.
- As of today, no information concerning possible contraindications of CEMSTOP® on children, pregnant or breastfeeding women have been identified. Nevertheless, this population remains at risk for all complications related to a surgical procedure.

3. Device description

CEMSTOP® is a flexible small plug for use in orthopaedic surgery. It is designed to occlude the inner cavity of the femur before the introduction of the bone cement. It helps to prevent cement progression into the inner cavity and facilitates cement pressurization to ensure a good prosthesis fixation.
CEMSTOP® is designed with three rings seated on a truncated base. These three rings are 2mm oversized in order to ensure a good occlusion of the medullary cavity. A long inner canal facilitates its secure insertion.



CEMSTOP® is made of a mixture of neutral compounds: gelatine (40%), glycerol (35%) and water (25%). Methyl-para-hydroxy-benzoate is added as a conservative agent (0.25%). It contains no medicinal substance. It is naturally resorbed by the organism within a time lag of 1 to 15 days.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. Remaining risks and undesirable effects

No undesirable side-effects and no interactions with other agents have been recorded during the past 10 years for CEMSTOP®.
Any serious incident occurring in relation to the device CEMSTOP® must be reported without delay to TEKNIMED and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions

No warning and precautions are applicable for patients as this device is intended to be used only by healthcare professionals.

4.3. Summary of any field safety corrective action (FSCA) if applicable

In 2017, 1 labelling error on the packing boxes required a field safety action (i.e. a batch recall): the date mentioned on the product and on the patient labels was the manufacturing date and not the expiry date. The product quality was not questioned in this issue. As first corrective action, the corresponding batch has been recalled. The devices' boxes have been relabelled with correct labels. As second preventive action, a third step of control has been added to the Teknimed packing process to avoid any recurrence.

5. Summary of clinical evaluation and post-market clinical follow-up

5.1. Clinical background

CEMSTOP® is a product issued from a very-well known technology which has been used in orthopaedic surgeries for many years. Cement plugs are main helpers in cemented joint replacement surgery. They are placed inside the bone inner cavity, about 1 cm below the anticipated end of the prosthesis. Their objective is to prohibit the passage of cement in the below bone cavity. Cement plugs are also responsible to regulate the pressure of the cement during insertion of the prosthesis.

5.2. Clinical evidence for CE marking

CEMSTOP® was first CE marked and placed on the market in 1998. At that time, the clinical evidence was based on the equivalence of CEMSTOP® with another cement restrictor already placed on the market. More recently, Teknimed performed a clinical study to verify and confirm the performance and safety claimed for CEMSTOP®.

30 patients who beneficiated from a hip joint replacement involving the use of a CEMSTOP®, were included in this study (mean age was 74 ± 12 years old). 2 months after the surgery, all patients reported a clear alleviation of their pain and a clear improvement of their quality of life as compared to their preoperative condition. During the surgery and the follow-up period, no complications or incidents related to CEMSTOP® were observed: no cement leakage in the inner cavity, no migration of the plug, no allergy to components and no local inflammatory response. The good position of the femoral prosthesis was confirmed by X-Ray imaging. These clinical outcomes confirmed the clinical efficacy and safety of use of CEMSTOP®.

5.3 Safety

Teknimed is continuously conducting Post-Market Surveillance and Clinical Follow-up to document and evaluate the benefits and risks of using CEMSTOP®. Technical benefits for surgeons are: easy handling and safe introduction in the bone cavity, efficient sealing of the bone cavity, safe occlusion to support cement pressurisation. These technical benefits allow a good fixation of the prosthesis, resulting in clinical benefits for the patients: pain alleviation and improvement in quality of life. Regarding risks, the only identified one is the risk of allergy to one of CEMSTOP® component. No other risks were identified during many years of post-market surveillance. Patients who are at risks of allergy to glycerine or glycerol should discuss this with their surgeon.

Considering the clinical benefits on pain and quality of life, versus the low associated level of risks, the overall benefit-risk balance of using CEMSTOP® for patients is considered acceptable.

To corroborate safety and performance claims for this product, Teknimed is currently conducting a new Post-Market Clinical Follow-up (PMCF) on CEMSTOP®, as used in a real-life setting.

6. Possible diagnostic or therapeutic alternatives

Cement plugs are designed to occlude the inner cavity before the introduction of bone cement during cemented arthroplasty. Their main objective is to prohibit the passage of cement to bone cavity during the surgery. The inner canal of the bone can be occluded by bone, bioabsorbable plugs, cement plugs or polyethylene restrictors. When the bone is of too poor quality, uncemented prothesis can be indicated to avoid the temperature elevation due to the bone cementation. In these cases, cement plugs are no longer needed.

7. Suggested profile and training for users

Implantation of TEKNIMED products should only be performed in an adapted environment and by healthcare qualified operators having a sound knowledge and full mastery in orthopaedic surgery. The operator is responsible for any complications or harmful consequences which might result from an erroneous indication or operative technique, an improper use of the equipment and/or a failure to comply with the safety rules provided in the Instructions For Use. Neither TEKNIMED as manufacturer nor the authorized TEKNIMED representative can be held responsible for these complications.