SSCP

	Prepared by	Reviewed by	Approved by
Name			
Signature			
Date			

Revision date	Revision No.	Reason for revision	Remark
2024.05.24	0	Initial establishment	

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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 Gutta Percha Points. The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor it is intended to provide diagnostic or therapeutic suggestions to intended users or patients. The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1 Device trade name: Gutta Percha Points

1.2 Manufacturer

Name: ACEONEDENT KOREA IND. CO.

Address:

103-606, Bucheon Techno-Park, 22, Samjak-ro, Ojeong-gu, Bucheon-si, Gyeonggi-do, Korea

Single registration number (SRN): KR-MF-000020812

1.3 Basic UDI-DI : 88001712

1.4 Medical device nomenclature description / text

EMDN Code: Q01010401

Text: Paper and gutta-percha tips, matrices and wedges for dentistry

1.5 Class of device

Class lla, Rule 8 in Annex VIII, Regulation (EU) 2017/745

1.6 Year when the first certificate (CE) was issued covering the device

1999. NOV. 29

1.7 Authorised representative

Name: JaviTech e.K

Address: Sachsenhausener Str. 16,

65824 Schwalbach a. Ts., Germany

Single identification number (SRN) : DE-AR-000005875

1.8 Notified Body (when the NB validate the SSCP)

Name: SGS BELGIUM NV

Address: Noorderlaan 87 BE-2030 Antwerpen Belgium

NB single identification number: 1639

2. Intended use of the device

2.1 Intended purpose

Dental root canal treatment & filling device used to plug and seal nerve ducts in denal cavities.

2.2 Indications and target populations

Dental root canal treatment & filling device used to plug and seal nerve ducts in denal cavities.

Patient Population: All age group

2.3 Contraindications

Do not reuse

3. Device description

3.1 Description of the device

GUTTA PERCHA POINT is being used as a filling material of the cleaned root canals of tooth.

It's not known to cause significant health problems.

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

Gutta percha point and the similar devices are all made of same materials which are gutta- percha, zinc oxide, barium sulfate and coloring agents. They all have same intended use and type of tissue contact. GUTTA PERCHA POINT is manufactured in accordance with ISO6877 and ADA.

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

No accessories

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

Can be used with sealer together.

4. Risks and warnings

4.1 Residual risks and undesirable effects

It's not known to cause significant health problems.

Follow the instructions of your dentist.

4.2 Warnings and precautions

1) Do not reuse.

2) Store in cool place.

3) Follow the instructions of your dentist.

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

No data available

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

PMCF will not be required for products for which the medium/long-term clinical performance and safety is already known from previous use of the device.

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

Gutta Percha Points and all of equivalent devices were shown to be equivalent in term of clinical, technical and biological aspects. In terms of equivalent device, a report was made in Manufacturer and User Facility Device Experience related to adverse events and other medical device reports within USA, EU, Canada, Korea.

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

Not applicable

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

Gutta Percha Points had neither side-effects nor adverse events reported.

5.4. An overall summary of the clinical performance and safety

Though negative effect of patient infection such as bacteria, viruses, and etc during filling root canal is undeniable, traditionally Gutta percha Point is the most widely used because its usage as a filling material is effective. Gutta percha Point product features thermoplasticity, good biocompatibility and no harmful effect. Also, it meets the standards 'ISO6877:2006 Root-canal obturating points and ADA (ANSI/ADA Specification no. 57 for Endodontic Filling Materials) and EN ISO10993-1:2009/Biological Evaluation and Biocompatibility Testing of Medical Device' and the probability of occurrence of harm was decreased noticeably. Furthermore, There was no side effect that has occurred since manufacturing and selling the product. Therefore, we judged that the benefit of the product exceeds its risk.

5.5. Ongoing or planned post-market clinical follow-up

None

6. Possible diagnostic or therapeutic alternatives

Not applicable

7. Suggested profile and training for users

Dentist

8. Reference to any harmonised standards and CS applied

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 6877:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2021, EN ISO 10993-18:2020, EN ISO TR 24971:2020 ,EN ISO 15223-1:2021, Meddev 2.7.1(Rev.4), Meddev 2.12.1(Rev.8), Meddev 2.12.2(Rev.2), (EU) 2021/2226