Endoplast ApS

Summary of safety and clinical performance

Appendix no. 11 to Medical Device File MDF-01

Classification Name	Dental composite resin (GMDN code: 35870, EMDN code: Q01010103)
Model name	Retroplast
Catalogue number	RP01
EU MDR Class	Class IIa, according to rule 8 in Annex VIII of the MDR

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1. Introduction

In order to meet the requirements of Article 32 of the MDR, a summary of safety and clinical performance has been prepared. This summary forms appendix no. 11 of the Medical Device File, MDF-01.

The summary of safety and clinical performance forms part of the documentation submitted to Intertek Medical Notified Body AB involved in the conformity assessment pursuant to Article 52 and has been validated by that body. Intertek Medical Botified Body AB will upload this summary to Eudamed, when the relevant module is available.

Endoplast ApS has mentioned in the instructions for use that the summary is available on their websites now that it has been validated by the Notified Body.

2. Requirements

The summary of safety and clinical performance shall include at least the following aspects:

a) the identification of the device and the manufacturer, including the Basic UDI-DI and the SRN,

b) the intended purpose of the device and any indications, contraindications and target populations,

c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device,

d) possible diagnostic or therapeutic alternatives,

e) reference to any harmonised standards and CS applied,

f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up,

g) suggested profile and training for users,

h) information on any residual risks and any undesirable effects, warnings and precautions.

The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2), which itself refers to article 4 of Regulation (EU)182/2011.

3. Summary

The summary is based on the paragraphs shown in section 2 for Requirements.

The manufacturer is Endoplast ApS, the product is Retroplast, the Basic UDI-DI from GS1 is 57000022403RETROPLAST4E and the SRN is DK-MF-000001268.

a) The intended use of Retroplast is to be used for retrograde endodontic sealing of tooth roots and to prevent outflow of bacteria from an infected root canal. The product can be used on all people having endodontic surgery.

b) Retroplast is a well-documented material for endodontic surgery. It is a two-component chemical polymerizing composite, and it is used with a dentin-bonding agent. It does not need a cavity, just a slightly hollowed root surface. It is a technique that is very suitable for difficult accessible molars, teeth with posts, tiny

roots, perforations, resorptions, hemi-sections and infractions.

There are no contraindications listed in the Instructions for Use.

Retroplast is biocompatible, it has radiopacity and it is thixotropic. It requires a good haemostasis. It is coloured red as it is important to have a colour, because the sealing is very thin. The technique does not require any special machines or equipment.

It is sold as a set comprising 2 x 1.5 g syringes. Each set can be used for approximately 25 operations.

There has been one change made to the formulation since it was introduced in 1984. In 1986, the silver for radiopacity bonds was replaced by Ytterbium trifluoride.

The target population for Retroplast is for use in patients who are having endodontic surgery.

The estimated number of sets to be sold is known by Endoplast ApS. This information is confidential.

c) There are a number of possible alternatives to Retroplast as retrograde root filling materials. In Europe, the alternative materials could be Mineral Trioxide Aggregate (MTA), Intermediate Restorative Material (IRM) or Super EBA in Europe. However, it should be noted that these materials need another surgical technique and do not cover all the indications of Retroplast. For the American product, an alternative is “Geristore”, which is also a resin composite as Retroplast. However, Geristore does not have the same “flowability” as Retroplast.

d) There is a common specification used for the manufacture of Retroplast. This is maintained by Endoplast ApS.

Retroplast meets the relevant applicable requirements of ISO 6876:2012 Dentistry – Root canal sealing materials and the following harmonized and non-harmonized Standards, EN ISO 14971:2019, EN ISO 13485:2016, ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14644-1:2015, EN ISO 14644-2:2015, IEC 62366-1:2015, EN ISO 10993-1:2020 and EN 10993-5:2009.

e) In the Clinical Evaluation Report, it has been demonstrated that Retroplast complies with the General Safety and Performance Requirements 1, 2, 3, 4, 5, 8 and 23 of the Medical Device Regulation.

Retroplast has an acceptable risk / benefit profile taking into consideration the

intended patient population and the benefits. Current state-of-the art medical practice continues to advocate the use of Retroplast in endodontic surgery. Current state of the art continues to support the established risk profile for endodontic surgery in consideration of the benefits to the patient currently.

The information provided to the user regarding appropriate and safe use of Retroplast contains adequate information regarding the intended purpose of the device. Clinically relevant information, such as precautions for the reduction of risks have been considered in the device labelling to give adequate information to the user regarding safe use of the device. The instructions for use are written for use by a dentist.

The residual risks associated with use of Retroplast are consistent with the known risks of any endodontic surgery, namely potential reaction to unpolymerized resins. These risks as inherent in endodontic surgery. As demonstrated in Retroplast risk management report, this risk has been reduced as low as possible.

Retroplast has a well-known safety and clinical performance profile. As demonstrated in the clinical investigations and literature, the effects and safety aspects of these device types are well-known and well-characterized. Retroplast is subject to appropriate post-market surveillance to monitor and ensure the established safety-profile of the devices is maintained. As the safety and performance profile of the device is well-known and there are no changes to the formulation or intended use, no Post Market Clinical Follow-up studies are required for Retroplast. A review has been made of clinical literature and this has found to show that there is a low risk in using Retroplast.

This Clinical Evaluation complies with the relevant General Safety and Performance Requirements and Annex XIV of the Medical Device Regulation 2017/745.

f) In principle, all qualified dentists are able to use Retroplast as the bonding technique is the same as used on most composite fillings in general dentistry with various composite materials. Improvement of the clinical outcome is dependent on the dentist’s surgical skills. Extra surgical training could be beneficial in order to increase the ability to perform the technique.

g) The residual risks associated with use of Retroplast are consistent with the known risks of any endodontic surgery. As demonstrated in the Retroplast risk management report, the risks have been reduced as far as possible.

In addition, in the Instruction for Use, there are warnings for storage of Retroplast

between 2 – 8 °C; the use of adrenaline on a certain type of patient and the disposal of Retroplast and the syringes must not be with household waste.

4. Conclusion

It is concluded that this summary meets the requirements of Article 32 of the Regulation (EU) 2017/745.