ceramill® a-temp
ceramill® a-temp multilayer

EN Summary of Safety and Clinical Performance (SSCP)

Part 1 - SSCP intended for users / healthcare professionals

AMANNGIRRBACH

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1 Device identification and general information

Device trade name(s)

Ceramill A-Temp, Ceramill A-Temp ML

Manufacturer's name and address

Amann Girrbach AG
Herrschaftswiesen 1
6842 Koblach, Österreich

Manufacturer's single registration number (SRN)

AT-MF-000000252

Basic UDI-DI

++E494ATEMPML3Q

Medical device nomenclature description/text

Der Code der Europäischen Nomenklatur für Medizinprodukte (EMDN) ist noch nicht verfügbar.

Class of device

IIa

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

2019

Authorised representative if applicable; name and the SRN

n/a

NB's name (the NB that will validate the SSCP) and the NB's single identification number

TÜV SÜD Product Service GmbH, CE0123

2 Intended use of the device

2.1 Intended use

Ceramill A-Temp and Ceramill -Temp ML are ready to use, polymethyl methacrylate-based CAD/CAM blanks, for milling long-term temporary crowns and bridges and for verifying the fit on the plaster model/mouth before the final restoration is manufactured.

2.2 Indication(s) and target population(s)

_ Temporary anterior and posterior crowns with a wearing time of maximum one year
_ Temporary anterior and posterior bridges with a maximum of two connected pontics and a maximum wearing time of one year
_ Verifying the fir on the plaster model/mouth before the final restoration

Suitable for patients of all ages and gender.

2.3 Contraindications and/or limitations

_ Bridge constructions with more than two connected pontics
_ Use for definitive restorations
_ Known incompatibilities with the components
_ All indications that are not listed under “Indication”.

3 Product description

3.1 Product description

Operating principles and mode(s) of action

Ceramill A-Temp and Ceramill A-Temp ML are ready to use, polymethyl methacrylate-based CAD/CAM blanks, for long-term temporary crowns and bridges and for verifying the fit on the plaster model/motuh before the final restoration is manufactured. Ceramill A-Temp and Ceramill A-Temp ML are tooth-colored milling blanks, replacing lost tooth substance in permanent dentures in the form of temporary crowns and bridges in the anterior and posterior region. The maximum wearing period is one year.

Design characteristics, for example key functional elements and any materials or substances in contact with the patient's tissue

Produktname	Blank type	Heights	Shades(Vita Shade guide)
Ceramill A-Temp	d-shape (71)	14, 16, 20 mm	A1, A2, A3, A3.5, B2, C2
	disk shape (98)	14, 16, 20 mm	A1, A2, A3, A3.5, B2, C2
	block shape (B40 / B55)	15.5 mm	A1, A2, A3, A3.5, B2, C2
Ceramill A-Temp ML	d-shape (71)	14, 16, 20 mm	0/A1, A2/A3, B2/B3, C1/C2
	disc shape (98)	14, 16, 20 mm	0/A1, A2/A3, B2/B3, C1/C2

Tab. 1

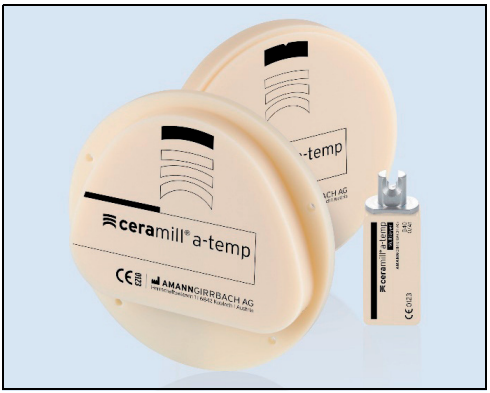

Fig. 1 *Exemplary pictures of the product line of Ceramill A-Temp: with d-shape (71) on the left, block shape on the right B40 and the disc-shape (98) in the back.*

Fig. 2 *Exemplary pictures of the product line of Ceramill A-Temp ML: with disc-shape (98) in the front and d-shape (71) in the back*

Chemical description / material composition

Ceramill A-Temp, Ceramill A-Temp ML consist mainly of pigmented PMMA. The pigments are responsible for adjusting the respective tooth color of the CAD/CAM blanks.

	Concentration in wt.%		In contact with patient
Component	**Ceramill A-Temp**	**Ceramill A-Temp ML**	**tissue? (Yes / No)**
Polymethylmethacrylate (PMMA)	> 98,83 Gew.-%	> 98,85 wt.-%	Yes
Methylmethacrylat (MMA)	< 1,0 Gew.-%	< 1,0 wt.-%	Yes
Colour pigments	< 0,17 Gew.-%	< 0,15 wt.-%	Yes

Tab. 2

Technical data / physical properties

Concerning the material's physical properties, the relevant technical standard for Ceramill A-Temp and Ceramill A-Temp ML is "DIN EN ISO 10477- Polymer-based crown and veneering materials".

Property	**Ceramill A-Temp**	**Ceramill A-Temp ML**
3-point bending strength	> 135 MPa	> 135 MPa
Density	1.19 g/cm^3	1.19 g/cm^3
Vickers hardness	24 HV0,2	24 HV0,2
Water absorption	< 25 µg/mm^3	< 25 µg/mm^3
Water solubility	< 6 g/mm^3	< 6 g/mm^3
Residual monomeric content	< 1 %	< 1 %
Fracture toughness	–	–

Tab. 3

Single use product

The subject device is not intended for single use.

Method of sterilization

No sterilization required.

Information about constituents

Ceramill A-Temp, Ceramill A-Temp ML consist mainly of pigmented PMMA. The pigments are responsible for adjusting the respective tooth color of the CAD/CAM blanks.

As a temporary restoration, the subject device is in direct contact with the oral mucosa and hard tooth tissue and are subject to chewing forces. Therefore, the device must provide long-term stability in the patient's mouth up to 12 months and biocompatibility in direct contact with the oral environment in the patient's mouth.

ndeed, PMMA-based restorative materials are associated with the risk of incompatibility reactions based by residual monomer (methyl methacrylate, MMA). Scientific literature indicated the prevalence of contact allergy to MMA with 1% [1]. However, PMMA CAD/CAM blanks, such as the subject device were found to be most compatible with epithelial cells of the oral mucosa when compared to therapeutic alternatives such as conventional acrylic resin (powder/liquid) and modern composite resins [2]. This indicates, that industrially polymerized PMMA materials have an excellent biocompatibility [3, 4]. Due to the production technology, the residual monomer exposure of Ceramill A-Temp and Ceramill A-Temp ML is limited to the required normative threshold of < 1%. For this reason, no specific needs need to be defined in accordance to patients with special needs (pregnant women, children, immune comprised patients).

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

n/a

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

n/a

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

Following devices and products intended for veneering, relining and/or fixation of PMMA-based temporary materials might be used in combination with the subject device:

Veneering

Milled constructions made of Ceramill A-Temp and Ceramill A-Temp ML can be veneered with conventional veneering materials (e.g. light curing veneering composite “Signum” by Kulzer). In general, the following points must be observed when veneering Ceramill A-Temp and Ceramill A-Temp ML.

_ Prefer materials based on MMA.
_ Follow the manufacturer's instructions of the veneering-material.

When veneering with composite, the connection to Ceramill A-Temp and Ceramill A-Temp ML must always be made according to the instructions of the respective manufacturer.

Relining

Constructions made of Ceramill A-Temp / Ceramill A-Temp ML can be relined at any time with all commercially available cold-curing polymers based on MMA.

_ Condition the surface beforehand, preferably with a comparable bonding agent on the basis of MMA.
_ Follow the manufacturer's instructions of the relining-material supplier.

Fixation / luting materials

Suitable luting materials for Ceramill A-Temp and Ceramill A-Temp ML are provisional, eugenol-free cements/ luting materials.

_ Temporary cementation (e.g. “TempoCemNE” by DMG)

Provisional restorations that are intended to be applied for the maximum wearing period of 12 months can be bonded by adhesive cementation to increase the overall stability.

_ Permanent adhesive cementation (e.g. “Variolink Esthetic” by Ivoclar)

Generally, the fixation of Ceramill A-Temp and Ceramill A-Temp ML must always be made according to the instructions of the respective manufacturer.

4 Risks and warnings

4.1 Residual risks and undesirable effects

_ Incompatibility reactions caused by residual monomer content
_ Mechanical overstressing, if the material-specific minimum parameters are not observed

Residual risks or side- effects (at least the ones included in the IFU)	Available Data Sources	Number of Patient	Cumulative Data per Source: Sales Number per defined Time Period	Cumulative Data per Source: Estimated usage per defined Time Period	Cumulative Data per Source: Time Period of the usage of the device	Quantification residual risk or side-effects in %
reactions caused by residual monomer content	[1]	n/a	n/a	n/a	n/a	1 %
	additional supportive evidence					
	[5]	27	n/a	45	16 months	0 %
Mechanical over-stressing, if the material-specific minimum parameters are not observed	[5]	27	n/a	45	16 months	0.1 %
	additional supportive evidence					
	[6]	10	n/a	10	14 days	0 %

Tab. 4

4.2 Warnings and precautions

The following warnings and precautions have been provided in the IFU:

Health impairment due to dust from PMMA!

When processing constructions made of Ceramill A-Temp/A-Temp ML, dusts can develop that may lead to mechanical irritation of the eyes and respiratory tract.

▷ Always make sure that the extraction system for the milling machine and the workplace for individual reworking operates properly.

▷ When processing, wear personal protective equipment (dust protection mask, safety glasses/goggles, ...).

▷ Further safety-relevant information can be found in the safety data sheet.

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

There have been no field safety corrective actions associated with Ceramill A-Temp / Ceramill A-Temp ML, and no other relevant aspects of safety to be discussed.

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

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

No applicable. The conformity of the device was not assessed on the basis of equivalence.

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

Not applicable. There have been no clinical investigations conducted before CE-marking. The fabrication of temporary restorations made from acrylic resin (PMMA), as for the subject device, is defined as well-established technology according to Article 61(6b) of MDR, and the clinical evaluation was based on sufficient clinical data (see section 5.3). Therefore, no clinical investigation is required for the subject device.

5.3 Summary of clinical data from other sources, if applicable

Systematic literature review

A systematic literature review has been conducted to support the clinical claims as well as the identified general safety and performance requirements of the subject device. Published clinical data pertaining to devices of the same generic device group has been used to support the clinical safety and performance of the subject device.

The results are summarized in the following table:

Clinical claim	Data for supporting evidence from literature	Justification
Acrylic for long-term temporary restoration with a wearing period of up to 12 months	[5, 7]	Data on products of the same generic device group (Vita CAD-Temp, Vita Zahnfabrik; Telio CAD Ivoclar Vivadent) confirm that temporaries from PMMA-based CAD/CAM blanks are suitable for long-term use of at least one year presenting survival rates of 90.4%.
Temporary anterior and posterior crowns	[5, 7]	Data on products of the same generic device group (Vita CAD-Temp, Vita Zahnfabrik; Telio CAD Ivoclar Vivadent) considered clinical use of temporaries from PMMA-based CAD/CAM blanks in anterior and posterior crowns and revealed safe and sound performance.
Temporary anterior and posterior bridges with a maximum of 2 intermediate units	[5, 8–13]	Data on products of same generic device group (Vita CAD-Temp, Vita Zahnfabrik; Telio CAD, Ivoclar Vivadent; Ceramill Temp, Amann Girrbach; Cercon base PMMA, Degudent) considered clinical use of temporaries from PMMA-based CAD/CAM blanks in anterior and posterior bridges including bridges with a maximum of 2 intermediate units and revealed safe and sound performance.
Can be fabricated fully anatomical.	[5.7]	Data on products of the same generic device group (Vita CAD-Temp, Vita Zahnfabrik; Telio CAD Ivoclar Vivadent) considered fully anatomical application of temporaries from PMMA-based CAD/CAM blanks and revealed safe and sound performance.

Tab. 5

Clinical claim	Data for supporting evidence from literature	Justification
Can be veneered with conventional crown and bridge resin.	[5]	Data on products of the same generic device group (Vita CAD-Temp, Vita Zahnfabrik) considered partially veneered application of temporaries from PMMA-based CAD/CAM blanks and revealed safe and sound performance.
Highest aesthetics due to perfectly matched VITA A-D shades for the Zolid DNA generation.	[14]	Data on product of the same generic device group (Ceramill Temp, Amann Girrbach) confirmed that industrially fabricated PMMA-based CAD/CAM blanks have favorable aesthetical properties (low color change and low marginal gap).

Tab. 5

General safety and performance requirement	Reference for supporting evidence
Mechanical stability in the patient's mouth > 30 days	[7, 5, 15–17]
Biocompatibility in direct contact with the oral mucosa and hard tooth tissue in the patient's mouth	[7, 5, 18–21, 8–13, 22, 23]

Tab. 6

The scientific literature search was initially performed in January and June 2018. Since the products under evaluation were only introduced to the market beginning of 2019, the literature search was based on similar products of the same generic device group, namely PMMA CAD/CAM-Disc (Polident), Telio CAD (Ivoclar Vivadent), Vita CADTemp (Vita Zahnfabrik), Cercon base PMMA (DeguDent), Zenotec Pro Fix (Wieland Dental) and Vipi block (Vipi Industria / Madespa). Literature data on the similar product PMMA CAD/CAM-Disc by PoliDent was particularly of interest because PoliDent is the supplier of the subject device and has extensive experience with PMMA CAD/CAM-Disc in the market for approximately 10 years.

Based on the evaluation of the state of the art, the subject device was considered well-established technology. The analysis of the current literature revealed fourteen in-vitro laboratory studies that address risks and side-effects associated with devices of the same generic device group. The risks/side-effects include mechanical failure due to insufficient mechanical strength and incompatibility reactions due to residual monomer content. The evaluated data consistently showed that industrially polymerized PMMA CAD/CAM blanks have enhanced mechanical and biological properties when compared to therapeutic alternatives (conventional acrylic resin or composite resin) because of the fabrication technology under ideal and controlled industrial conditions.

The literature review performed in 2018 (pre-market) showed two main limitations in terms of the quality of the data:

_ First, only in-vitro studies were included in the scope of the clinical evaluation, since no clinical data was available. This limitation did not weaken the quality of the clinical evaluation report at that stage, since the evaluated in-vitro studies critically examined possible impacts affecting the clinical safety and performance of industrially polymerized PMMA CAD/CAM blanks indicated for temporary restorations. Most experimental studies tested clinical relevant factors in form of thermocycling or chewing simulation which enhanced the informative value of the results in a clinical context. Even though, the subject device being well-established technology has well-known performance in clinical application, clinical data was missing.

_ The second limitation was based on the fact, that the initial scientific review was performed before the products under evaluation were introduced to the market (pre-market literature review). Thus, the clinical evaluation was only based on data for products of the same generic device group. To cover these two major limitations and to follow up on the clinical safety and performance of the subject device, a prematurely update of the scientific literature review was performed in scope of the deficiency report in June 2020, annulling the initially calculated review for 2022. The prematurely post-market scientific literature update appraised ten relevant references. In detail, four in vitro studies representing clinical relevant results for similar products, three case reports, two clinical studies, and one review/meta-analysis on patient-reported outcome were included.

The prematurely post-market scientific literature update confirmed the conclusion from the initial literature search stating that industrially polymerized PMMA CAD/CAM blanks showed improved biocompatibility compared to therapeutic alternatives. The literature update revealed that PMMA CAD/CAM-Discs (PoliDent) showed superior mechanical properties when compared to therapeutic alternatives. The mechanical strength is safety-relevant in clinical application. For two similar products, the clinical performance under sound clinical conditions was proven up to at least 1 year. The survival rate and the complication rate of 3- to 4-unit restorations were estimated to 90.4% and 88.3% respectively for an observation time of 16 months.

The safety and performance of temporary PMMA-based CAD/CAM materials can be confirmed for products of the same generic device group over the device lifetime when used as intended. Neither previously unknown side-effects nor emergent risks could be identified from literature. Based on the technology being well-established, the overall findings from literature are considered supportive to prove the clinical safety and performance of the subject device.

Complaints and vigilance data

Amann Girrbach conducts complaint management according to the internal complaint process. Quality reports are created and reviewed monthly by the management team. There is annual review of risk management analysis within the scope of the post-market monitoring. Complaint data from device of the same generic device groups (PoliDent CAD/CAM-Disc) with extensive experience on the market has been summarized as well.

So far, neither mechanical failure of the subject device nor incompatibility reactions caused by the subject device was detected in clinical application; neither by Amann Girrbach nor by the supplier of the subject device (PoliDent), who offers a material of the same generic device group for more than 10 years.

Since market launch of the subject device in 2019, no safety issues related to the patient's or user's health (e.g. intolerance reactions) have been registered. The latest evaluation of complaint management in March 2021 revealed a total of two complaints that have been recorded within the observation period from 05/2020 to 02/20201, resulting in a complaints rate of 0.016% regarding the sold number of items (7'489) or rather 0.0013% regarding the estimated number of fabricated single units (149'780). In comparison, the previous observation period from 07/2019 to 04/2020 revealed a complaint rate of 0.19% with respect to the sold number of items (1'039) and 0.005% with respect to the number of fabricated single units (37'480). Within both observation periods, none of the complaints was clinically relevant, but referred to either color or processing issues.

The device of the same generic device group, namely PMMA CAD/CAM-Discs by PoliDent, has been launched in 2010. Since then approx. 68'000 PMMA CAD/CAM-Discs have been sold. The complaint is 0.007%, whereof none of the received complaints represented a complication to the patient in form of adverse events or incompatibility reactions. Since PoliDent is the supplier of the subject device, the extensive experience and post-market surveillance outcomes of PMMA CAD/CAM discs are supportive to confirm the clinical safety of the subject device.

Data derive from PMCF activities (PMCF)

A first customer survey was carried out in April 2020. The survey was performed as a general method to confirm the evaluation of the complaint management and to confirm the safety and performance of the device under evaluation over the device lifetime, to identify previously unknown side-effects or emergent risks as well as possible systematic misuse or off-label use, to monitor the identified side-effects and contraindications, and to ensure the continued acceptability of the benefit-risk-ratio.

The rational of the activity was to detect early any unexpected problems experienced by users and patients, to analyse the occurrence of problems, to initiate corrective and preventive actions, and to compare and review the medical device risk management file.

The customer survey addressed customers (dental laboratories) in the German market and was carried out via phone calls through the direct sales department. The survey covered seven questions regarding the clinical use of the materials under evaluation, namely type of indications, estimated numbers of restorations produced in 2019, negative feedback/complications for restorations used in patients; in case of negative feedback/complications, the affected types of restorations and the types of complications. In total, N=12 participants joined the customer survey for Ceramill A-Temp / A-Temp ML.

Based on the customer survey, approx. 1700 dental units were fabricated from Ceramill A-Temp / A-Temp ML. More than 50% of the users indicated that Ceramill A-Temp / A-Temp ML are used to fabricate either crowns, short-span bridges or other indications (e.g. long-term provisional restorations). Approx. 33% of the user fabricate multi-unit (long-span) bridges. Irrespective of the indication, no negative feedback has been received for restorations from Ceramill A-Temp or A-Temp ML used in patients. With respect to the total number of fabricated restorations (1700 provisional restorations for Ceramill A-Temp / A-Temp ML), it can be concluded that the products under evaluation show reliable clinical performance when processed by experienced personnel (dental technicians, dentists) and when used as intended. This outcome is in accordance with the evaluation of the complaint management. The limitation regarding the limited number of participants of the survey is relativized by the high number of fabricated restorations which increases the quality of the data obtained.

Even though the number of respondents in the customer survey is limited, the data are considered as valuable because of the high number of fabricated single dental units in 2019. It is assumed that the total number of fabricated single dental units corresponds to at least 400 treated patients, whereof no one was reported with intolerance reactions caused by the subject device.

A second customer survey was initiated in October 2020 and performed until February 2021. The survey was splint in two parts: The first part was a customer survey via call-centre which was done in October 2020 after reduction of wearing period and included two questions:

1. What is the maximum wearing period you let Ceramill A-Temp stay in the patient's mouth if you are using the material for long-term temporary restorations?
   Please give your reply in months.
2. Did any problems with clinical relevance / in clinical application occur during the device's lifetime? (Open-ended response)

This activity was initiated to confirm the safety of the medical device over the device lifetime which is 12 months. N=80 customers participated in the survey. The average using period for Ceramill A-Temp used as long-term temporary restoration material was 9.3 months. 89% of the participants were using the material within a maximum wearing period of 12 months, while 11% were even reporting a long-term use of more than 12 months. None of the participants reported any problems during clinical application. The results were all positive, which also confirms the outcomes of in-vitro testing. As a result, it can be concluded, that the material performs safe as intended over the device lifetime.

The second part was a more detailed customer survey which was embedded on the Amann Girrbach website in December 2020. This activity was initiated to confirm the evaluation of the complaint management and to confirm the safety and performance of the device under evaluation over the device lifetime, to identify previously unknown side-effects or emergent risks as well as possible systematic misuse or off-label use, to monitor the identified side-effects and contraindications, and to ensure the continued acceptability of the positive benefit-risk-ratio. The rationale of the activity was to detect early any unexpected problems experienced by users and patients, to analyse the occurrence of problems, to initiate corrective and preventive actions, and to compare and review the medical device risk management file.

The customer survey was created with the help of the software "Survey Monkey". The link to the survey was embed on the manufacturer's website and send out via customer newsletter in December 2020 proactively asking customers for feedback on the safety and performance of the subject device. The customer survey was created in accordance to the requirements of the MDR.

Annex XIV Part B 6.1. The proposed questions were chosen to confirm the requirements defined in the MDR Annex XVI Part B 6.1 being:

(a) confirming the safety and performance of the device throughout its expected lifetime,
(b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,
(c) identifying and analysing emergent risks on the basis of factual evidence,
(d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and
(e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the identified purpose is correct

Overall, 35 participants participated in the survey and provided feedback on the clinical safety and performance of temporary restorations from the subject device that were fabricated and used in patients within the reporting

year 2020. The total number of fabricated single units in 2020 was 9'248. The participants indicated that the subject devices are predominately used for the fabrication of short-span bridges (Ceramill A-Temp: 68.75%; Ceramill A-Temp ML: 59.38%), while the fabrication of multi-unit bridges and crowns is less frequent (Ceramill A-Temp: <18.75%; Ceramill A-Temp ML: <25%). The wearing period resulted in a mean of 5,4±4,8 months, while overall no complaints were reported (complaint rate: 0.00%). Thus, possible systematic misuse or off-label use of the devices is excluded, while the identified purpose is verified as correct. The results of the proactive customer survey are in great agreement with the current outcomes of the complaint management (complaint rate: 0.0013%), wherefore the safety and performance of the subject devices is confirmed throughout the expected lifetime of max. 12 months. According to the complaint rate of 0.00% obtained in scope of the customer survey, no previously unknown side-effects have been identified, while the monitoring of the identified side-effects and contraindications was completely unobtrusively. Based on factual evidence, no emergent risks were identified that require further analysis. Concluding, the continued acceptability of the positive benefit-risk profile of the subject devices referred to in Section 1 and 9 of Annex I of MDR is ensured. This finding is supported by the outcome that the majority of the respondents indicated that the subject devices perform at least about the same, but rather better when compared to relevant therapeutic alternatives.

5.4 An overall summary of the clinical performance and safety

The clinical benefits for patients with relevant and specified clinical outcome measures, and the success rate for achieving the outcome measures

Temporary restorations made from the subject device offer the benefit of protecting the pulp and the dentine of the prepared tooth, restoring function and aesthetics, maintaining and/or stabilizing the bite situation, promoting gingival health and finally enabling the patient and the clinician to evaluate the form, function and aesthetics before the final restoration is inserted.

Literature states that temporary restorations from PMMA CAD/CAM materials successfully fulfill all these benefits [7] as was measured by patient satisfaction. Further, the evaluation of literature revealed that industrially polymerized PMMA CAD/CAM blanks, such as the subject devices, are especially suited for the fabrication of long-term temporary restorations [5, 7] as well as multi-unit restorations [5, 8–13]. This finding is justified by improved mechanical strength [9, 13, 24–28] and good biocompatibility due to the reduced residual monomer [2, 27, 29] when compared to therapeutic alternative materials. The same is supported by the state of the art evaluation.

The manufacturer has the following clinical claims for the subject device:
_ Acrylic for long-term temporary restoration with a wearing period of up to 12 months.
_ Temporary anterior and posterior crowns
_ Temporary anterior and posterior bridges with a maximum of 2 intermediate units
_ Can be fabricated fully anatomical
_ Can be veneered with conventional crown and bridge resin.
_ Highest aesthetics due to perfectly matched VITA A-D shades for the Zolid DNA generation.

The compliance to the general safety and performance requirements being long-term stability in the patient's mouth as well as biocompatibility in direct contact with the oral mucosa and hard tooth tissue in the patient's mouth can be confirmed for the subject device Ceramill A-Temp / A-Temp ML. All acceptance criteria defined in the applied standards (EN ISO 10993-1, -5, -12, -15, -18; DIN EN ISO 20795-2; DIN EN ISO 10477) were passed. Further, the subject device shows no abnormalities in clinical application, wherefore the benefit-risk profile is accepted, and all risk mitigation measures as well as clinical claims foreseen by the manufacturer are considered adequate.

Benefit-risk assessment for the various indications including the acceptability of the benefit-risk ratio

The intended use of the subject device is the milling of long-term temporary crowns and bridges for patients of any age with a diseased or defective chewing apparatus. The general benefits of a temporary restoration to the patient are the evaluation of form, function and aesthetics of a dental restoration before insertion of the final restoration, the protection of the pulp and dentine, the restoration of functions and aesthetics, the maintenance and stabilization of the bite situation as well as the promotion of gingival health. Literature states that temporary restorations from PMMA CAD/CAM materials successfully fulfill all these benefits [7]. Further, the evaluation of literature revealed that industrially polymerized PMMA CAD/CAM blanks, such as the subject devices, are especially suited for the fabrication of long-term temporary restorations [7, 5] as well as multi-unit restorations [5,8–13]. This finding is justified by improved mechanical strength [9, 13, 24–28] and good biocompatibility due to the reduced residual monomer [2, 27, 29] when compared to therapeutic alternative materials. The same is supported by the state of the art evaluation.

The evaluation of the state-of-the-art shows, that intolerance reactions caused by residual monomer are often discussed in scientific literature. However, no intolerance reactions or undesirable side effects are reported in scientific literature for temporary restorations made from PMMA CAD/CAM materials. Instead, the materials were found to be positive for the maintenance of periodontal tissue health, avoiding irritation or tissue hypersensitivity in the oral mucosa. Nonetheless, a note on possible undesirable side effects was included in the instructions for use of the subject device to make the user aware when treating sensitive patients.

Literature proves that industrially polymerized PMMA CAD/CAM blanks are characterized by a reduced content of residual monomer as well as improved mechanical strength when compared to therapeutic alternatives such as conventional acrylic resins and composite resins. This finding is in accordance to the pre-clinical tests performed by the manufacturer of the subject device. The characteristics of biocompatibility and mechanical properties precisely address the risks that have been associated with PMMA-based temporaries for many years.

To further minimize the risks of incompatibility reactions and mechanical failure, appropriate notes and information have been included in the instruction for use by the manufacture indicating the chemical composition, design parameters and undesirable side effects for instance. Risk mitigation methods are considered effective and risks are reduced as far as possible. No clinically relevant complaints have been registered for the subject device since the beginning of 2019, which supports the safety of the device in post market. The observed probability of occurrence for incompatibility reactions and mechanical failure is less than the expected probability, therefore no additional mitigation measures are required.

Post market clinical follow up has been planned to confirm the expected probability of occurrence and severity levels for identified risks. The survey is aimed to obtain data regarding clinical safety and performance of the subject device, monitor the identified side-effects and contraindications, identifying and analyzing emergent risks as well as possible systematic misuse or off-label use of the device and to ensure the continued acceptability of the benefit-risk ratio.

Based on the above conclusions of the clinical evaluation and the positive benefit-risk profile established, the subject device Ceramill A-Temp / A-Temp ML is considered safe and effective when used as intended.

5.5 Ongoing or planned post-market clinical follow-up (PMCF)

Summary of the latest approved PMCF plan for the device

The currently valid PMCF planned includes four general PMCF activities, namely the scientific literature review, the evaluation of customer complaints and two proactive customer surveys. The next update of the scientific literature review is scheduled for 2024 according to the calculation of the review period, while the next planned evaluation of customer complaints as well as the next round of proactive customer survey is scheduled for spring 2022, provided that no unexpected events occur, and the subject devices performs as intended.

If any emerging risks, complications or unexpected device failures have been detected, and how these will be followed up

All performed PMCF activities show great agreement in the outcomes of the clinical safety and performance of the subject devices over the expected device lifetime when used as intended. Since no previously unknown side-effects, anomalies or emergent risks could be identified, the positive benefit risk ratio is ensured. The monitoring of the identified side-effects and contraindications revealed no discrepancies to the risk analysis or clinical evaluation report. Therefore, all risk mitigation measures and clinical claims foreseen by the manufacturer seem adequate. Further, neither possible systematic misuse nor off-label use could be identified. The overall results do not affect relevant parts of the technical documentation and do not trigger a need for preventive and/or corrective measures. The subject devices Ceramill A-Temp and Ceramill A-Temp ML show reliable safety and performance in clinical service when used as intended.

6 Possible diagnostic or therapeutic alternatives

The possible alternatives to Ceramill A-Temp and Ceramill A-Temp ML (PMMA based CAD-CAM blanks) for temporary restorations include:

- Conventional polymethylmethacrylate (PMMA) and polyethylmethacrylate (PEMA) materials. PEMA and PMMA are both typical acrylic resins.
- Composite resins, either based on bis-acryl such as bisphenol A-glycidyl methacrylate (bis-GMA) or rubberized urethane resins.

Both acrylic resins and composite resins represent the state of the art for temporary restorations. In general, newer bis-acryl materials are associated with improved physical and chemical properties. Rubberized urethane based composite resins (urethane dimethacrylate resin, UDMA) even show an increased strength when compared to a traditional bis-acryl. Despite of the increased strength, composite resin materials are known to be brittle and break relative easily when placed in areas of increased stress. Therefore, composite resins are the preferred material for the fabrication of single-unit provisional restorations while evidence has shown that acrylic resin temporary materials (PMMA, PEMA) are generally better suited for more complex cases, multi-unit, multi-pontic clinical situations, that require long-term durability.

The advantage of the industrially polymerized PMMA CAD/CAM blanks is that they are fabricated under optimum polymerization conditions with no interference from water, giving adequate time for post-polymerization processes and relaxation phenomena. This means that the provisional restorations fabricated from PMMA CAD/CAM blanks have lower values of residual monomer, minimal porosity and superior mechanical properties in comparison to those fabricated by conventional direct techniques from the moment the restoration is put in place. In addition, PMMA CAD/CAM blanks allow an easier fabrication of provisional restorations since some come off the challenges associated with conventional techniques such as polymerization shrinkage, impression errors, mixing errors and overall clean-up.

Irrespective of the form (conventional or as CAD/CAM blank), the acrylic resin PMMA is classified as longest used dental material still in use today, and the most frequently and intensively used resin in daily dental practice. It is well accepted and has long been and continues to be used for the fabrication of temporary restorations in modern dentistry. Even though there have been documented side effects in literature that have resulted from the use of PMMA, it was stated that it has far outweighed its negative characteristics and that without the development of PMMA, modern medicine and dentistry would have difficulty in providing the quality and dental care it does today.

7 Suggested profile and training for users

The intended users of the Ceramill A-Temp and Ceramill A-Temp ML blanks are dental technicians and dentists. The users are therefore professionally trained and qualified in handling medical devices or the patients.

If the intended user requires more information that goes beyond the IFU, trainings adapted to the specific product or the specific manufacturing process or individual trainings can be booked online via homepage (*www.amanngirrbach.com*); however, these trainings are not mandatory.

For Ceramill A-Temp and Ceramill A-Temp ML, for example, the following training can be helpful: CAD-CAM trainings (basic, advanced).

8 Reference to any harmonized standards and CS applied

Common specification(s) to comply with, if applicable

☐ not applicable ☐ not available ☑ applied in full ☐ applied in part

MDCG 2019	Summary of safety and clinical performance

Tab. 7

Relevant standards and regulations applied, if applicable

☐ not applicable ☐ not available ☑ applied in full ☐ applied in part

Reg. EU 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the council on medical devices
MEDDEV 2.7/1 Revision 4	Clinical Evaluation – A Guidance for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
Medical devices act	Austrian Federal Law on Medical Devices Version 2010 German Medical Devices Act Version 2010
MPDG	Gesetz zur Durchführung unionsrechtlicher Vorschriften betreffend Medizinprodukte (Medizinprodukterecht-Durchführungsges.) 2020
DIN EN 1641:2010	Dentistry - Medical devices for dentistry - Materials
EN 1641:2009	
DIN EN ISO 13485:2016	Medical devices quality management systems
ISO 13485:2016	
DIN EN ISO 14971:2020	Medical devices – Application of risk management to medical devices
EN ISO 14971:2019	
ISO 14971:2019	
DIN EN ISO 15223-1:2017	Symbols for use in the labeling of medical devices
EN ISO 15223-1:2016	
ISO 15223-1:2016	
DIN EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 1041:2008+A1:2013	
DIN EN 62366:2017	Medical devices – Part 1: Application of usability engineering to medical devices
EN 62366-1:2015 + AC:2015	
IEC 62366-1:2015 + COR1:2016	
DIN EN ISO 20795-2:2013	Dentistry – Base polymers; Part 2: Orthodontic base polymers
EN ISO 20795-2:2013	

Tab. 8

ISO 20795-2:2013	
DIN EN ISO 10993-1:2021	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-1:2020	
ISO 10993-1:2018	
DIN EN ISO 10993-5:2009	Biological evaluation of medical devices; Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-5:2009	
ISO 10993-5:2009	
DIN EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-12:2012	
ISO 10993-12:2021	
DIN EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
EN ISO 10993-15:2009	
ISO 10993-15:2019	
DIN EN ISO 10993-18:2021	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-18:2020	
ISO 10993-18:2020	
DIN EN ISO 7405:2019	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 7405:2018	
ISO 7405:2018	
DIN EN ISO 10477:2021	Dentistry - Polymer-based crown and veneering materials
EN ISO 10477:2020	
ISO 10477:2020	

Tab. 8

References

[1] Syed M, Chopra R, Sachdev V. Allergic Reactions to Dental Materials-A Systematic Review. J Clin Diagn Res 2015;9:ZE04-9. https://doi.org/10.7860/JCDR/2015/15640.6589.

[2] Souza IR, Pansani TN, Basso FG, Hebling J, Souza Costa CA de. Cytotoxicity of acrylic resin-based materials used to fabricate interim crowns. J Prosthet Dent 2020. https://doi.org/10.1016/j.prosdent.2020.01.030.

[3] Carvalho FR, Lentini-Oliveira DA, Prado LBF, Prado GF, Carvalho LBC. Oral appliances and functional orthopaedic appliances for obstructive sleep apnoea in children. Cochrane Database of Systematic Reviews 2016.

[4] Lee J-H, Jun S-K, Moon H-J, Lee H-H. Cytotoxicity and proinflammatory cytokine expression induced by interim resin materials in primary cultured human dental pulp cells. J Prosthet Dent 2017;118:524–34. https://doi.org/10.1016/j.prosdent.2016.11.014.

[5] Huettig F, Prutscher A, Goldammer C, Kreutzer CA, Weber H. First clinical experiences with CAD/CAM-fabricated PMMA-based fixed dental prostheses as long-term temporaries. Clin Oral Investig 2016;20:161–8. https://doi.org/10.1007/s00784-015-1475-7.

[6] Sari T, Usumez A, Strasser T, Şahinbas A, Rosentritt M. Temporary materials: comparison of in vivo and in vitro performance. Clin Oral Investig 2020. https://doi.org/10.1007/s00784-020-03278-5.

[7] Edelhoff D, Beuer F, Schweiger J, Brix O, Stimmelmayr M, Guth J-F. CAD/CAM-generated high-density polymer restorations for the pretreatment of complex cases: a case report. Quintessence Int 2012;43:457–67.

[8] Rosentritt M, Raab P, Hahnel S, Stockle M, Preis V. In-vitro performance of CAD/CAM-fabricated implant-supported temporary crowns. Clin Oral Investig 2017;21:2581–7. https://doi.org/10.1007/s00784-017-2057-7.

[9] Digholkar S, Madhav VNV, Palaskar J. Evaluation of the flexural strength and microhardness of provisional crown and bridge materials fabricated by different methods. J Indian Prosthodont Soc 2016;16:328–34. https://doi.org/10.4103/0972-4052.191288.

[10] Rayyan MM, Aboushelib M, Sayed NM, Ibrahim A, Jimbo R. Comparison of interim restorations fabricated by CAD/CAM with those fabricated manually. J Prosthet Dent 2015;114:414–9. https://doi.org/10.1016/j.prosdent.2015.03.007.

[11] Penate L, Basilio J, Roig M, Mercade M. Comparative study of interim materials for direct fixed dental prostheses and their fabrication with CAD/CAM technique. J Prosthet Dent 2015;114:248–53. https://doi.org/10.1016/j.prosdent.2014.12.023.

[12] Yao J, Li J, Wang Y, Huang H. Comparison of the flexural strength and marginal accuracy of traditional and CAD/CAM interim materials before and after thermal cycling. J Prosthet Dent 2014;112:649–57. https://doi.org/10.1016/j.prosdent.2014.01.012.

[13] Alt V, Hannig M, Wostmann B, Balkenhol M. Fracture strength of temporary fixed partial dentures: CAD/CAM versus directly fabricated restorations. Dent Mater 2011;27:339–47. https://doi.org/10.1016/j.dental.2010.11.012.

[14] Elagra MI, Rayyan MR, Alhomaidhi MM, Alanaziy AA, Alnefaie MO. Color stability and marginal integrity of interim crowns: An in vitro study. Eur J Dent 2017;11:330–4. https://doi.org/10.4103/ejd.ejd_66_17.

[15] Amann Girrbach R&D. 20180731 Test report water absorption and solubility Ceramill A-Temp A3,5; 2018.

[16] Amann Girrbach R&D. 20180724 Test report bending strength Ceramill A-Temp A3,5; 2018.

[17] Amann Girrbach R&D. 20190213 Test report wearing period Ceramill A-Temp A-Splint; 2019.

[18] Nordic Institute of Dental Materials (NIOM). Test report residual monomer Ceramill A-Splint; 2018.

[19] Medical Device Services. Test report cytotoxicity Ceramill A-Temp; 2018.

[20] Medical Device Services. Test report chemical analysis inorganic leachables Ceramill A-Temp; 2018.

[21] Medical Device Services. Test report chemical analysis organic leachables extractables Ceramill A-Temp; 2018.

[22] Medical Device Services. Certificate biological safety Ceramill A-Temp; 2018.

[23] Medical Device Services. Biological safety Ceramill A-Temp; 2018.

[24] Arslan M, Murat S, Alp G, Zaimoglu A. Evaluation of flexural strength and surface properties of prepolymerized CAD/CAM PMMA-based polymers used for digital 3D complete dentures. Int J Comput Dent 2018;21:31–40.

[25] Prpić V, Schauperl Z, Ćatić A, Dulčić N, Čimić S. Comparison of Mechanical Properties of 3D-Printed, CAD/CAM, and Conventional Denture Base Materials. J Prosthodont 2020. https://doi.org/10.1111/jopr.13175.

[26] Alp G, Murat S, Yilmaz B. Comparison of Flexural Strength of Different CAD/CAM PMMA-Based Polymers. J Prosthodont 2018. https://doi.org/10.1111/jopr.12755.

[27] Ayman A-D. The residual monomer content and mechanical properties of CAD\CAM resins used in the fabrication of complete dentures as compared to heat cured resins. Electron Physician 2017;9:4766–72. https://doi.org/10.19082/4766.

[28] Stawarczyk B, Ender A, Trottmann A, Özcan M, Fischer J, Hämmerle CHF. Load-bearing capacity of CAD/CAM milled polymeric three-unit fixed dental prostheses. Effect of aging regimens. Clin Oral Investig 2012;16:1669–77. https://doi.org/10.1007/s00784-011-0670-4.

[29] Steinmassl P-A, Wiedemair V, Huck C, Klaunzer F, Steinmassl O, Grunert I et al. Do CAD/CAM dentures really release less monomer than conventional dentures? Clin Oral Investig 2017;21:1697–705. https://doi.org/10.1007/s00784-016-1961-6.

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