zolid gen-x 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)

Zolid Gen-X

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

++494ZIRKON5F5

Medical device nomenclature description / text

The European Medical Device Nomenclature (EMDN) number is not yet available.

Class of device

IIa

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

2020

Authorized representative if applicable; name and the SRN

n/a

sNB'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

Zirconium-oxide blanks for permanent and partly removable dental prosthetics.

2.2 Indication(s) and target population(s)

_ Anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, abutments)
_ Anatomically reduced and fully anatomical (monolithic) three to multi-unit bridges with a maximum of three contiguous pontics in the anterior region and a maximum of two contiguous pontics in the posterior region
_ Cantilever frames and bridges with a maximum of one bridge pontic (maximum one free-end pontic and no further than the second premolar)

Indication limitation for Canada:
_ Single crowns
_ Front-tooth bridges
_ Posterior bridges with up to four units

Suitable for patients of all ages and gender.

2.3 Contraindications and/or limitations

_ Insufficient tooth-structure availability
_ Insufficient preparation
_ Insufficient oral hygiene
_ More than two connected bridge units in the posterior region, more than three connected intermediate units in the anterior region
_ Known incompatibilities with respect to the components
_ Heavily discoloured hard tooth structure
_ Provisional insertion

3 Product description

3.1 Product description

Operating principles and mode(s) of action

Zirconium-oxide blanks for permanent and partly removable dental prosthetics. The blanks are made of zirconium oxide(ZrO_2) for type II, class 5 dental applications in accordance with DIN EN ISO 6872. They are used for fabri-cation of permanent and partly removable prosthetic restorations (e.g., crowns and bridges, conical/telescopic crowns, superstructures, abutments, etc.) using CNC milling machines (e.g., Ceramill milling machines). After completion of the specified end-sintering, the material meets the requirements of DIN EN ISO 6872.

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

Product name	Blank type	Heights	Colour / Shades
Zolid Gen-X	d-shape (71)	14, 16, 20 mm	8 A-D Vita-Shades + Bleach
	disc shape (98)	12, 14, 16, 18, 20, 22, 25 mm	8 A-D Vita-Shades + Bleach

Tab. 1

Fig. 1 Example image of Zolid Gen-X Multilayer, blank type: d-shape (71)

Fig. 2 Example image of Zolid Gen-X Multilayer, blank type: disc shape (98)

Chemical description / material composition

Zolid Gen-X consist of yttrium-stabilized zirconia oxide.

Oxide	Concentration in wt. %	In contact with patient tissues? (Yes / No)
$ZrO_2 + HfO_2 + Y_2O_3$	≥ 99	yes
Y_2O_3	6.0 – 7.0	yes
HfO_2	≤ 5	yes
Al_2O3	≤ 0.5	yes
Other oxides	≤ 1	yes

Tab. 2

Technical data / physical properties

Concerning the physical properties, the relevant technical standard for Zolid Gen-X is "DIN EN ISO 6872 – Dentistry – Ceramic materials".

Property	Zolid Gen-X
3-point bending strength	1000±150 MPa
4-point bending strength	900±150 MPa
E-module	≥ 200 GPa
Thermal expansion coefficient (CTE) (25-500)	$10,4±0,5×10^{-6}$/K
Chemical solubility	100 µg/cm^2
Vickers hardness	1300±200 HV

Tab. 3

Single use product

The subject device is not intended for single use.

Method of sterilization

No sterilization required.

Information about constituents

Zolid Gen-X are zirconium-oxide blanks for permanent and partly removable dental prosthetics. As a permanent and/or partly removable prosthetic restoration, zirconium-oxide is in direct contact with the oral mucosa and hard tooth tis-sue. Therefore, the subject device must provide high biocompatibility in direct contact with the oral mucosa.

Generally, the use of zirconium-oxide in dental restorations has been a practice since 1998, wherefore the material properties are well known, including its good biocompatibility and chemical inertness. So far, no adverse events or general tissue reactions have been reported in scientific literature.

With regard to Zolid Gen-X, outcomes of biocompatibility tests (cytotoxicity, organic extractables, inorganic leachables and radioactivity) according to DIN EN ISO 10993-1, -5, -12, -15 and -18 confirm the high biocompatibility of the product. Additionally, extensive biological tests including intracuntaneous reactivity, acute systemic toxicity and sensitization in scope of animal tests were performed for Ceramill ZI, the first zirconium-oxide material of Amann Girrbach launched in 2006, proofing the clinical safety for this product. Amann Girrbach's many years of experiences with the sales of zirconium-oxide blanks as well as continues post-market surveillance show that the zirconium-oxide blanks are biocompatible within their intended use. According to CLP-VO 1272/2008, no CMR substances are contained.

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

The previous generation of Zolid Gen-X is Ceramill Zolid HT+ preshade. Zolid Gen-X is multicoloured variant of the previous monocoloured product Ceramill HT+ preshade. It has been developed to improve the aesthetics of the Ceramill HT+ preshade. With the colour gradient of the Zolid Gen-X imitates the aesthetics of natural teeth without any decrease of the bending strength. Especially in monolithic application the Zolid Gen-X can provide good aesthetic results. As a further development Ceramill Zolid HT+ preshade, Zolid Gen-X contains the same raw materials, resulting in the same chemical, physical and biological properties.

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

Dental restorations from zirconium-oxide can be optically individualized by the application of (A) veneering materials, (B) colouring liquids and/or (C) stain and glaze materials.

(A) Veneering

For veneering using the layering technique, a suitable veneering ceramic has to be selected that is coordinated to the coefficient of thermal expansion (CTE) of the zirconia framework material. To name two examples, Creation ZI (Willy Geller) and Vita VM9 (Vita Zahnfabrik) are suitable veneering ceramics for zirconia. Alternatively, zirconia frameworks can be overpressed with veneering porcelain. Either way, the instructions for use of the zirconia material as well as of the selected veneering material has to be followed.

(B) Colouring liquids

For optical individualization and characterization, white zirconia materials can be coloured in the presintered state with colouring liquids using the dipping or brushing technique. Amann Girrbach offers two colouring liquids that are coordinated to the materials under evaluation (except of Ceramill® Zolid preshade and Ceramill® Zolid HT+ preshade), namely Ceramill® Liquid CL and Ceramill® Liquid "new formula". Please carefully follow the instructions for use.

(C) Stain and Glaze materials

After sintering, zirconia materials can be individualized with stain and glaze materials. For this, Amann Girrbach offers the Ceramill® Stain & Glaze Kit. Please carefully follow the instructions for use.

For Zolid Gen-X Multilayer

These blanks are available in 16 A-D Vita shades + 2 bleach colours. The integrated colour gradient gives the multilayer blanks a natural appearance immediately after sintering. The finalising takes place using glazing material, stains and/or veneer ceramics.

3.4.1 Cementation/Adhesive bonding

Restorations made from the products under evaluation can either be cemented using (a) traditional cements or adhesively bonded using (b) adhesive composite resin cements. The major criterion for the cementing/bonding material selection is the preparation design, which should be chosen according to the guidelines for all-ceramic preparations.

(a) Traditional cementation (using glass-ionomer cement or zinc phosphate cement)

For a traditional cementation using glass-ionomer cement (e.g. Ketac Cem, 3M or Vivaglass CEM, Ivoclar Vivadent), the prepared tooth should offer an adequate form of retention and resistance. Optional, zinc phosphate cements (e.g. Fuji PLUS, GC) can be used.

(b) Adhesive bonding (using conventional or self-adhesive composite resin cements)

For adhesive bonding, the zirconia restoration should be pre-treated by moderate airborne-particle abrasion (particle size ≤ 50 µm, maximum pressure of 1bar, 10 mm distance). Before adhesive bonding, the use of eugenol containing temporary cements should be avoided. For adhesive bonding, either conventional adhesive resin cement (e.g. Panavia 21, Kuraray or Multilink Automix, Ivoclar Vivadent) or self-adhesive resin cements (e.g. RelyX Unicem 2, 3M or SpeedCEM, Ivoclar Vivadent) can be used. Composite resin cements with additionally used adhesive systems based on dimethacrylate require separate conditioning of the zirconia with an adhesive system that contains phosphate (e.g. Clearfil Porcelain Activator, Kuraray or RelyX Ceramic Primer, 3M). If the conventional composite resin cement contains phosphate monomers like 10-methacrylayloxydecyl dihydrogen phosphate (MDP) no chemical pre-treatment of the zirconia surface is required. Please always follow the instructions for use of the products respectively.

4 Risks and warnings

4.1 Residual risks and undesirable effects

_ If the material-specific minimum parameters are not observed: mechanical overloading (e.g. chipping of the veneering ceramics, fracture of the restoration, decementation)
_ Biological incompatibility

		Cumulative Data per Source				
Residual risks or side-effects (at least the ones included in the IFU)	**Available Data Sources**	**Number of Patient**	**Sales Number per defined Time Period**	**Estimated usage per defined Time Period**	**Time Period of the usage of the device**	**Quantification residual risk or side-effects in %**
Mechanical overloading (chipping of the veneering ceramics, fracture of the restoration, decementation)	[1]	18	n/a	20	58.7 months	0.0 % technical complications
	[2]	34	n/a	109	23.8 months	0.0 % technical complications
	[3]	261	n/a	556	60.70 months/ 59.20 months	0.5 % (chipping)
	[4]	49	n/a	100	36.5±6 months	1.9 % (extensive ceramic chipping)
	[5]	60	n/a	214	35.1±6,3 months	2.7 % (0.68 % chipping; 2.0 % loss of retention)
	[6]	88	n/a	303	7 years	3 % (total failures)
Biological incompatibility	[1-27]	1.414	n/a	2.670	23.8 8 months up to 10.3 years	0.0 %

Tab. 4

			Cumulative Data per Source			
Residual risks or side-effects (at least the ones included in the IFU)	**Available Data Sources**	**Number of Patient**	**Sales Number per defined Time Period**	**Estimated usage per defined Time Period**	**Time Period of the usage of the device**	**Quantification residual risk or side-effects in %**
			Signal Detection			
Mechanical overloading (chipping of the veneering ceramics, fracture of the restoration, decementation)	[7]	162	n/a	143	5 years	4.9 % (1.9 % chipping; 2.9 % loss of retention)
	[8]	22	n/a	153	2011 - 2016	4.97 % (2.4 % chipping; 0.5 % framework fracture; 1.9 % loss of retention)
	[9]	44	n/a	49	35±6 months	6.1 % (4.0 % chipping)
	[10]	24	n/a	48	4 years	6.25 % (chipping solely)
	[11]	68	n/a	323	79.7±12.2 months	8.7% (extensive chipping)
	[12]	65	n/a	147	41.5±31.8 months	7.5 % (4.8 %chipping; 2.7 % framework fracture)
	[13]	58	n/a	40	5 years	7.5% (unrestorable chipping)
	[14]	67	n/a	45	60 months	8.9 % (6.7 % chipping; 2.2 % framework fracture)
	[15]	28	n/a	33	62 months	9.1 % (chipping)
	[16]	21	n/a	21	2 years	9.1 % (chipping)
	[17]	37	n/a	40	50±2.4 months	10 % (minor chipping)
	[18]	14	n/a	43	85.4±54 months/91.7±50 months	10.3 % (loss of retention)

Tab. 4

		Cumulative Data per Source				
Residual risks or side-effects (at least the ones included in the IFU)	**Available Data Sources**	**Number of Patient**	**Sales Number per defined Time Period**	**Estimated usage per defined Time Period**	**Time Period of the usage of the device**	**Quantification residual risk or side-effects in %**
Mechanical overloading (chipping of the veneering ceramics, fracture of the restoration, decementation)	[19]	30	n/a	30	64.4±17.6 months	16.7 % (10.5 % chipping of veneering ceramic; 6.9% loss of retention)
	[20]	21	n/a	11	3 years	18 % (minor chipping resolved by polishing)
	[21]	44	n/a	53	10.3 years/ 10.0 years	18.9 % major chipping; framework fracture 4.6 %; loss of retention 22.7 %
	[22]	40	n/a	20	5 years	20 % (minor chipping)
	[23]	53	n/a	57	6.,3±1.9 years	28 % (10.5 % “small localized chipping”; 17.5% “extended chipping”)
	[25]	36	n/a	36	36 months	33.2 % (13.8 % minor chipping; 19.4 % major chipping)
	[24]	25	n/a	24	10 years	36 % (chipping)
	[26]	40	n/a	45	61.0±1.4 months	42.2 % (chipping)
	[27]	5	n/a	7	58.8±43.7 months	100 % chipping; 20 % loss of retention; 53.3 % framework fracture
Biological incompatibility	no signal detection for the risk of biological incompatibility					

Tab. 4

			Cumulative Data per Source			
Residual risks or side-effects (at least the ones included in the IFU)	**Available Data Sources**	**Number of Patient**	**Sales Number per defined Time Period**	**Estimated usage per defined Time Period**	**Time Period of the usage of the device**	**Quantification residual risk or side-effects in %**
Residual risks or side-effects	Mechanical overloading (chipping of the veneering ceramics, fracture of the restoration, decementation) → 0.02 % – 2 %					
Quantification in %	Biological incompatibility → 0.02 %– 2 %					
Justification (in case the cumulative data percentage differs significantly from the identified signal in a specific period of time)	_ Predominately, clinical data from scientific literature represents percentages of the risk of mechanical failure higher than the suspected incidence of 0.02 – 2% from the risk management of the subject device. The risk of mechanical failure considers either chipping of the veneering ceramic, total fracture of the restoration as well as decementation / loss of retention. Most of the data listed under "signal detection" present high percentages of chipping of the veneering ceramics, however, in many cases, chipping of the veneering ceramic can be resolved by intraoral polishing, while debonded restorations can often be recemented. When considering the survival rates of zirconia restorations presented in the scientific literature (predominantly > 94%), it is concluded that most restorations that suffered from chipping or debonding are still and clinical use and that chipping, and loss of retention rarely result in total failure of the restoration. _ Due to high aesthetics, the subject device is particularly suitable for monolithic use, wherefore no veneering is required. Further, if veneering is required, the CAD-controlled design of the restoration ensures an adopted, anatomically supported framework design that is suitable for veneering. Since these aspects contribute to lower the risk of mechanical overloading / failure, the quantification of the risk of mechanical overloading was defined to be <2%. _ So far, no incidence of biological incompatibility reactions has been observed caused by zirconia restorations. Nonetheless, the incidence of the residual risk of possible incompatibility reactions was defined to 0.02 – 2% for safety reasons.					

Tab. 4

4.2 Warnings and precautions

"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."

Possible health impairment from zirconium-oxide dust!

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

▷ Do not breathe dust/fume/gas/mist/vapours/spray.

▷ Avoid release to the environment.

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 Zolid Gen-X, 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

Not 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 permanent or removeable prosthetic restorations made from Y-TZP zirconium oxide 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 sections 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

As 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 tables:

Clinical claim	Data from literature	Justification
Excellent esthetic properties (natural colour gradient and translucency gradient)	[28]	proof of excellent aesthetics properties for Zolid Gen-X (case report)
	[1, 3, 5, 10, 14, 16, 26]	proof of excellent esthetic properties for devices of the same generic device group (Lava, 3M; Cercon Base, Degudent; Cercon ht, Degudent; IPS e.max ZirCAD, Ivoclar Vivadent; In-Cerami YZ, Vita Zahnfabrik)
Outstanding mechanical values (flexural strength over 1000 MPa for all indications)	[29–33]	In-vitro data on mechanical properties for devices of the same generic device group (Ceramill Zolid HT+ white, Ceramill ZI, Ceramill Zolid; all Amann Girrbach)
	[1–26]	(In-Ceram YZ, Vita Zahnfabrik; Cercon Base / Cercon ht, Degudent; Zenotec, Wieland Dental; IPS e.max ZirCAD, Ivoclar Vivadent; Ceramill Zolid, Amann Girrbach; Everst ZS, KaVo; Lava, 3M; Denzir, Decim; Zirite, Keramo; Procera, Nobel Biocare

Tab. 5

General safety and performance requirement	Reference for supporting evidence
Long-term mechanical stability in the patient's moth	[29–46] → pre-clinical tests / In-vitro data on Zolid Gen-X and devices of the same generic device group [28] → case report on Zolid Gen-X [1–26] → In-vivo data on devices of the same generic device group
Biocompatibility in direct contact with the oral mucosa and hard tooth tissue in the patient's mouth	[47–73] → pre-clinical tests / In-vitro data on Zolid Gen-X and devices of the same generic device group [28] → case report on Zolid Gen-X [2, 3, 6, 9, 10, 14, 25, 74] → In-vivo data on devices of the same generic device group

Tab. 6

The included literature covered clinical data with a minimum follow-up time of two years up to a maximum follow-up time of 13 years. The level of evidence of the included data ranged between Ib and IV and was mostly rated as high or medium. The clinical data covers all relevant indications that type II, class 5 ceramic materials are indicated for, namely single crowns, 3- or multi-unit bridges, copings and abutment. All long-term results consistently prove comparable clinical performance between all-ceramic restorations and the metal-ceramic restorations concerning survival, aesthetics, functional and biological outcomes.

For monolithic zirconia restorations, the short-term survival rates range between 98.5 % and 99.6 %, while those for zirconia-based restorations ranged between 44.9 % to 100 % over a follow-up time of 5 to 7 years. The majority of the mid-term survival rates was higher than 94.7 %. The long-term survival rates refer to follow-up periods of 10 years or even more and ranged between 12.1 % and 100%. Only few data indicated insufficient or unacceptable clinical performance due to high failure and complication rates, that might to some extent, be related to special indications such as cantilever- or inlay-retained zirconia-based restorations or to the failure of restorations supported by endodontically treated teeth.

The most frequently reported technical complications were either chipping of the veneering ceramic, debonding / loss of retention of the restoration or fracture of the zirconia framework on a rare basis. All complications relate to the residual risk of mechanical failure and are in accordance to those identified within the state of the art evolution. The most frequent problem being chipping of the veneering ceramic can be avoided by applying zirconia as monolithic restoration. Since the monolithic application of zirconia was only introduced with newer class 5 zirconia materials (Ceramill ZOLID HT+) scientific literature on the clinical performance and safety of monolithic zirconia restorations is scarce. With respect to the risk of biological incompatibility reactions, no events have been reported. Some data reported biological complications related to the abutment teeth, but outcomes concerning gingival index, plaque index, marginal index, plaque accumulation, peri-implant soft tissue and pocket depth were found to be excellent throughout the evaluated literature. Thus, the biocompatibility of zirconia is proven and neither previously unknown side-effects nor emergent risks could be identified in the scope of the scientific literature review.

Complaints and vigilance data

Amann Girrbach conducts complain 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 post-market monitoring.

The latest PMS meeting took place in March 2021. The evaluation period was 05/2020 to 03/2021 and included all variants of the products under evaluation in worldwide distribution. According to the summary of the latest update, a total number of 134'405 units of zirconium-oxide (including Ceramill ZI, Ceramill Zolid, Ceramill Zolid preshade, Ceramill Zolid HT+, Ceramill Zolid HT+ preshade and Zolid Gen-X) were sold (compared with 142'659 in 2019/2020). The number of sold units is equal to a total number of approximately 2'688'100 produced dental units (compared with 3'566'475 in 2019/2020). Overall, 36 complaints were received within the evaluation period (compared with 37 in 2019/2020) resulting in a complaint rate of 0.027 % (compared with 0.025 % in 2019/2020). In relation to the total number of possible manufactured dental units, the complaint rate is calculated to 0.004% being addressed as very low (compared to 0.001 % in 2019/2020).

The low complaint rate confirms that the products under evaluation categorized as type II, class 5 ceramic materials are suitable for the fabrication of dental restorations. The products are established on the market for more than 12 years. The continuous monitoring of the complaint rate shows comparably low complaint rates for the past years (2017/2018: 0.02 %; 2018/2019: 0.019 %). This proves the reliably high quality of the products under evaluation and confirms the successful and smooth launch of new product variants of the products under evaluation (launch of Ceramill ZOLID HT+ in 2017, Zolid Gen-X in 2020). Further the high sales figures demonstrate the high acceptance of the products on the market.

It is to summarize that no new product risks have arisen from the evaluation of customer complaints. Thus, no revision of the risk management files was necessary. The comparison of the feedback from the market with the existing risk management contacts showed that all reported complaints are within the scope of the acceptable risk (<1/50; <2 %). None of the complaints represented an increased risk for either patients, users or third parties. The products can be classified as clinically safe and the performance of the products under evaluation is proven when used as intended. No previously unknown side-effects and no emergent risks could be identified within the evaluation of customer complaints. Thus, the continued acceptability of the benefit-risk-ratio is given.

Data derive from PMCF activities

A proactive customer survey was initiated in December 2020 and performed until spring 2021.

The activity was initiated to confirm the evaluation of the complaint management and to confirm the safety and performance the device under evaluation, 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 XIV Part B, 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 of the device, with a view to verifying that the identified purpose is correct.

Overall, 88 participants participated in the survey and provided feedback on the clinical safety and performance of dental restorations fabricated from the subject devices and used in patients within the reporting year 2020. The total number of fabricated single dental units was 100'010 with a reported complaint rate of 0.21 %.

All subject devices were predominately used for the fabrication of single crowns (8.33 – 47.37 %), short-span (50.51 – 58.33 %) or multi-unit bridges (5.26 – 48.28). Only occasionally, abutments (<8.70; except for Ceramill ZI: 28.21 %) or other indications such as telescopic crowns (<6.52 %) are fabricated from the subject devices. Thus, the subject devices are used as intended and the intended purpose is verified as correct. No possible systematic misuse or off-label use was identified.

The reported complaints referred to short-span bridges and/or crowns fabricated from Ceramill ZI, Ceramilll Zolid HT+ or Ceramill Zolid HT+ preshade and involved either cracks, fractures, chipping or debonding of the restoration. At no time, the patient's health was affected by the complication. No complaints were reported for Ceramill Zolid, Ceramill Zolid preshade or Zolid genx. All observed complications were in accordance to the residual risk of mechanical failure / overload identified and indicated in the risk management analysis. No complaints have been reported with respect to the risk of biological intolerance reactions. The complaint rate of 0.21% shows that the reported complaints relating to the residual risk of mechanical failure / overload were less than the as critically defined incidence (<2 %; 1/50). Therefore, no additional risk mitigation measures are required. Since in addition, no previously unknown side-effects or emergent risks have been identified based on factual evidence, the safety and performance of the subject devices is confirmed.

The continued acceptability of the benefit-risk ratio referred to Section 1 and 9 of Annex I is ensured by the low complaint rates as well as by the evaluation of the survey participants that shows that the subject devices perform at least about the same, but rather better, when compared to 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

Permanent and partly removable dental prosthetic from zirconium-oxide offer the benefit of restoring the missing tooth and gingiva structures and therefore to restore functions and aesthetics.

Following clinical claims apply for Zolid Gen-X:
_ excellent aesthetic properties (natural colour gradient and translucency gradient)
_ Outstanding mechanical values (flexural strength over 1000 MPa for all indication)
The compliance to the general safety and performance requirements, being long-term stability in the patient´s mouth for all types of indications as well as biocompatibility in direct contact with the oral mucosa and the hard tooth tissue, can be confirmed for Zolid Gen-X. All acceptance criteria defined in the applied standards (DIN EN ISO 10993-1, -5, -12, -18, DIN EN ISO 7405 and DIN EN ISO 6872) were passed. For devices of the same generic device group as Zolid Gen-X, survival rates were predominantly reported to be > 94% when applied as framework or as monolithic restoration for observation times ranging from 2 to 10 years. Only few data reported insufficient performance which might be related to specific indications. Therefore, currently available data confirm the sound clinical performance and the positive benefit-risk ratio of Zolid Gen-X and prove that all associated risks have been minimized as far as possible.

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

The intended use of the subject device is the fabrication of permanent fixed and partly removable dental prosthetics for patients of any age and any gender with a diseased or defective chewing apparatus. The benefit of perma-nent fixed or removeable prosthetic dentures fabricated from zirconia is the replacement of tooth and gingiva structures in the patients' mouth which in turns restores aesthetics and function of the chewing apparatus. In
comparison to metal-ceramic restorations that have been the "gold standard" for dental prosthetic restorations for many years, the benefit of zirconia restorations lies in the toothlike colour and thus improved aesthetics. Several clinical studies reported high patient's satisfaction for zirconia restorations [1, 3, 10, 12, 19, 23–26] and confirm similar clinical performance when compared to metal-ceramic restorations [4, 13, 14, 17, 21, 22]. Especially the aesthetic outcomes were rates as excellent with mainly no discrepancy in colour and translucency in comparison to the neighboring dentition [1, 3, 5, 10, 12, 14, 20, 23]. The patient satisfaction and the colour outcomes were used as measurable outcome to confirm that the clinical benefits being the restoration of function and aesthetic providing full masticatory function to the patient is fulfilled. Even though some studies showed that zirconia-based restorations tend to have more technical complications due to chipping of the veneering ceramic [21, 17, 22, 13], others proved that this complication can be solved by the application of monolithic zirconia restorations [2, 5]. The benefit of monolithic zirconia restorations does not solely lie within the avoidance of technical complications, such as chipping, but also consists of an acceptable wear of natural enamel opposed to the zirconia restoration when compared to veneered restorations [75]. This observation is caused by the homogenous surface as well as decreased surface roughness that is comparable to glazed surfaces [76]. The clinical data held

by the manufacturer including evaluation of complaints, outcomes of proactive customer surveys as well as esthetic and functional results presented an individual case report [28] support the positive benefit/risk profile of the subject device. Overall, there are no uncertainties or unanswered questions identified for the subject device within the present clinical evaluation. The analyzed data show that the benefit-risk profile of the subject device is compatible for each aspects of the intended use with a high level of protection of health and safety for the patient.

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 Zolid Gen-X 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. The incidence of all observed complications was less than the as critically defined probability of occurrence (< 2 %).

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 the relevant parts of the technical documentation and do not trigger a need for preventive and/or corrective measures. Zolid Gen-X shows reliable performance in clinical practice when used as intended.

6 Possible diagnostic or therapeutic alternatives

The possible alternatives to Zolid Gen-X for the fabrication of permanent and partly removable prosthetic restorations include:

- Precious or base-metal alloys (e.g. gold alloys, CoCrMo, NiCrMo)
- Glass-ceramics (e.g. feldspathic/silica-based glass ceramic, leucite-reinforced glass ceramic and lithium (di)silicate glass ceramic)
- Titanium and titanium alloys (for abutments)

Metal-ceramic restorations either based on precious or non-precious metal (such as gold or cobalt-chromium) finally veneered with porcelain are known to be the gold standard for dental prostheses such as single crowns and multi-unit fixed dental prosthetics. Today, metal-ceramic restorations have been used for more than

50 years and are often recommended because of their reliability and strength. Due to its high strength, metal-ceramic is indicated for anatomically reduced or fully anatomical single crowns as well as multi-unit fixed dental prosthetics in the anterior and posterior region (DIN EN ISO 22674). Clinical data show a 5-year survival rate of 96.6% for metal ceramic crowns [77]. However, the dark metal framework and opaque oxides make it difficult to emulate the aesthetics of a natural tooth. As dentistry has evolved, the demand for metal-free materials with increased translucency that mimic the natural dentition has arisen. This has led to the development of several different ceramics that are aesthetically pleasing, colour stable, wear resistant, biocompatible as well as chemically resistant. Next to the oxide ceramic zirconia, there are several glass ceramic materials available on the market. The glass ceramics include feldspathic/silica-based glass ceramic, leucite-reinforced glass ceramic and lithium (di)silicate glass ceramic [77]. While the range of indication for feldspathic/silica-based glass ceramics is limited to monolithic single unit restorations in the anterior and/or posterior region, the range of indication for lithium(di)silicate ceramic includes all kind of single-tooth and implant restorations to anterior and posterior 3-unit fixed dental prostheses. Therefore, lithium-disilicate ceramics are a serious treatment option to single unit and short-span zirconia restorations. Overall, clinical data revealed 5-year survival rates for glass ceramics ranging from 94.6 % and 96.6 % [77].

Even though glass ceramics provide high aesthetics due to the crystalline character, their main drawback is the limitation in mechanical strength that in turn limits their range of indication to short-span bridges when compared to zirconia.

In implant prosthetics, titanium and titanium alloys (specifically Ti-6AL-4V) have been the material of choice to fabricate stock (prefabricated) as well as customized abutments to retain or support dental prosthesis. It was reported that titanium custom abutments show comparable, if not better, clinical outcomes when compared with conventional titanium abutments [78]. However, the undesirable shine-through effect of the underlying metal abutment in thin soft tissue phenotype compromising the peri-implant mucosa shade has motivated the search for alternative materials such as zirconia for the fabrication of customized CAD/CAM abutments. The advantage here is that zirconia abutments demonstrate less effect on optical outcomes of peri-implant mucosal tissue when compared with titanium abutments [78]. In case of soft tissue recession, no titanium or rather its grayish appearance is exposed [79].

7 Suggested profile and training for users

Users of Zolid Gen-X 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 book online via our homepage but are not mandatory. For the subject devices e.g., the following training can be helpful: all CAD-CAM trainings (basic, advanced), Zolid DNA (basic, variations), Material management zirconium dioxide, All-on-X – highly aesthetic / implant restoration with gingiva design.

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

Harmonised standards to apply, if applicable

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

DIN EN ISO 6872:2019	Dentistry – Ceramic materials
EN ISO 6872:2015 + A1:2018	
ISO 6872:2015 + Amd.1:2018	
DIN EN ISO 9693:2020	Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems
EN ISO 9693:2019	
ISO 96932019	

Tab. 8

(We meet the standard DIN EN ISO 6872 for the mentioned points for type 2, class 5 ceramics, Therefore, the tests for uniformity and the glass transition temperature are not performed since these are not required for zirconia materials).

☐ 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
DIN EN 16412010	Dentistry - Medical devices for dentistry - Materials
EN 1641:2009	
DIN EN ISO 13485:2016	Medical devices quality management systems
ISO 134852016	
DIN EN ISO 14971:2020	Medical devices – Application of risk management to medical devices
EN ISO 14971:2019	

Tab. 9

ISO 149712019	
DIN EN ISO 15223 12017	Symbols for use in the labeling of medical devices
EN ISO 15223-1:2016	
ISO 15223-1:2016	
DIN EN 10412013	Information supplied by the manufacturer of medical devices
EN 1041:2008+A1:2013	
DIN EN 623662017	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 10993 12021	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 52009	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 122012	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 152009	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 182009	Biological evaluation of medical devices Part 18: Chemical characterization of materials
DIN EN ISO 10993 182021	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 74052018	

Tab. 9

DIN EN ISO 10993 102014	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-10:2013	
ISO 10993-10:2010	
DIN EN ISO 10993 112018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-11:2018	
ISO 10993-11:2017	
DIN EN ISO 14705:202104	
EN ISO 14705:2021	Fine ceramics (advanced ceramics, advanced technical ceramics) - Test method for hardness of monolithic ceramics at room temperature
ISO 147052016	
DIN EN ISO 843 12008	Advanced technical ceramics – Mechanical properties of monolithic ceramics at room temperature – Part 1: Determination of flexural strength
EN 843-1:2006	
ASTM E1876 - 15	Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio by Impulse Excitation of Vibration

Tab. 9

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