Dentsply Sirona

Summary of Safety and Clinical Performance (SSCP)

Prime&Bond NT
Spectrum Bond

ENGLISH

Summary of safety and clinical performance

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

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

The following information is intended for users/healthcare professionals.

1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 Device trade name including any model number or version

Trade Name(s):	Prime&Bond NT Spectrum Bond ([1])

1.2 Manufacturer's name and address

Name:	Dentsply DeTrey GmbH
Address:	De-Trey-Str. 1
City / Postal Code:	78467 Konstanz
Country:	Germany

1.3 Manufacturer single registration number (SRN)

SRN No:	DE-MF-000005905

1.4 Basic UDI-DI

Basic UDI-DI:	++D010ADH01MC

1.5 Medical device nomenclature

Description:	Q01010104

1.6 Class of device

Risk class:	According to Annex VIII of Regulation (EU) 2017/745 of 5. April 2017 on medical devices, Prime&Bond NT is classified as a class IIa medical device (rule 19 and rule 8).

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

Year :	1998

1.8 Authorized representative if applicable; name and SRN

Authorized representative:	Not applicable

[1] Spectrum Bond is a second brand of Prime&Bond NT. The composition of both brands is identical. For this reason, only the main brand Prime&Bond NT will be mentioned in the following document.

Name:	Not applicable
SRN No:	Not applicable

1.9 Notified body (NB) involved in the conformity assessment of the device

Notified Body (NB):	TÜV SÜD Product Service GmbH
NB single identification number (SIN)	0123

2. INTENDED USE OF THE DEVICE

2.1 Intended purpose

Dental adhesive for tooth substrates and primer for restorative materials.

2.2 Indication(s) and target population(s)

Prime&Bond® NT adhesive (visible light cured):

- Direct, light cured composite and compomer restorations
- Indirect restorations; light cured, resin cemented veneers
- Composite, ceramic and amalgam repairs

Prime&Bond® NT adhesive mixed with Self Cure Activator (dual cure):

- Direct, dual cure or self cure composite restorations and core build-ups
- Indirect restorations; dual cured and self cured resin cemented inlays, onlays, crowns and bridge retainers
- Dual cured and self cured resin cemented endodontic post cementation

Besides the limitations given in chapter 2.3 (Contraindications) and chapter 4 (Risks and warnings), no restriction of the target population is defined.

2.3 Contraindications and/or limitations

- Prime&Bond® NT adhesive is contraindicated for use in patients with a known hypersensitivity to methacrylate resins (e.g., Diethyleneglycol dimethacrylate (DGDMA) or to any other component.

- Prime&Bond® NT adhesive is contraindicated for direct application to dental pulp tissue (direct pulp capping).

3. DEVICE DESCRIPTION

3.1 Description of the device

Description:

Prime&Bond® NT Nano-Technology Etch & Rinse Dental adhesive is a self-priming dental adhesive system designed to bond resin based materials to enamel and dentin as well as to metals and ceramic. Prime&Bond® NT adhesive combines primer and adhesive in a one-bottle material. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.

When mixed with Self Cure Activator, Prime&Bond® NT adhesive is designed to be used with Dentsply Sirona manufactured dual cure/self cure resin cements to bond all indirect restorations and Dentsply Sirona manufactured dual cured composite restoratives. When used with the Amalgam Bonding Accessory Kit[2], available separately, Prime&Bond® NT adhesive also adhesively bonds fresh amalgam to enamel and dentin.

[2]**Some products may not be available in all countries.**

Application:

Single Use	☐ Yes	☒ No

Information about Sterilization:

Sterile (Yes/No)	☐ Yes	☒ No
	Method of sterilization: ☐ EO Gas ☐ Radiation ☐ Steam or Dry Heat ☐ Aseptic Techniques	

Information about constituents:

Medicinal substance part of the device	☐ Yes Please list:	☒ No
Contains tissue / cells of human origin or their derivates	☐ Yes Please list:	☒ No
Contains tissue / cells of animal origin or their derivates	☐ Yes Please list:	☒ No
Device is intended to be absorbed or locally dispersed in the human body	☐ Yes	☒ No
Device contain CMR or endocrine substance	☒ Yes Please list:	☐ No

	- CAS 10287-53-3, Ethyl 4-dimethylaminobenzoate	
Device contains materials that could result in sensitization or an allergic reaction by the patient or user	☒ Yes Please list: - methacrylate	☐ No

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

Previous generation / variant	Description of differences to current generation/variant
There are no previous generations/variants of Prime&Bond NT	Not applicable

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

Accessories to the device	Description of accessory
Applicator tip	Application of dental material
ClixDish	Transient chairside storage of dental adhesives

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

Other devices and products intended to be used in combination with the device	
Dentsply Sirona Self Cure Activator	Self-Cure Activator (SCA) is for use with Prime&Bond active in conjunction with a dual-cure or self-cure resin cement such as Calibra, SmartCem2 or core.X flow. SCA is suitable for bonding of all indirect restorations including metal, porcelain and composite based crowns, inlays, onlays, veneers, bridge retainers and endodontic posts.

4. RISKS AND WARNINGS

4.1 Residual risks and undesirable effects

Side effects and other risks are limited and identical to those found with the available dental alternatives (see chapter 5.4)

Residual risk(s) / undesirable side effect(s)	Quantitative data	Data source
Pulpitis, post-operative pain or hypersensitivity	Very rare (< 0,01%) within 5 years.	☐ clinical study

		☒ systematic literature review ☐ reported incident
Secondary Caries	Very rare (< 0,01%) within 5 years.	☐ clinical study ☒ systematic literature review ☐ reported incident
Degradation and failure of restoration	Very rare (< 0,01%) within 5 years.	☐ clinical study ☒ systematic literature review ☒ reported incident
Debonding	Very rare (< 0,01%) within 5 years.	☐ clinical study ☒ systematic literature review ☐ reported incident
Allergic Reactions	Very rare (< 0,01%) within 5 years.	☐ clinical study ☐ systematic literature review ☒ reported incident
Acute oral inflammation	None reported within 5 years.	☐ clinical study ☐ systematic literature review ☐ reported incident

4.2 Warnings and precautions

Warnings

The material contains polymerizable (meth)acrylate monomers, which may be irritating to skin, eyes, and oral mucosa and may cause allergic contact dermatitis in susceptible persons.

This product contains Ethyl-4-dimethylaminobenzoate, which is classified as a CMR substance according to Regulation EC 1272/2008 on Classification, Labelling and Packaging of substances and mixtures. Based on a toxicological risk assessment, the presence of Ethyl-4-dimethylaminobenzoate does not pose a toxicological risk, if the product is used as intended.

- Avoid eye contact to prevent irritation and possible corneal damage. In case of contact with eyes, rinse with plenty of water and seek medical attention.
- Avoid skin contact to prevent irritation and possible allergic response. If contact with skin occurs, remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.

- Avoid contact with oral soft tissues/mucosa to prevent inflammation. If accidental contact occurs, remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.
- For full coverage vital crown preparations, condition remaining enamel only. Etching of full coverage dentin surfaces is not recommended to minimize the possibility of post-operative sensitivity.

Precautions

This product is intended to be used only as specifically outlined in these Directions for Use.

Any use of this product inconsistent with the Directions for Use is at the discretion and is the sole responsibility of the practitioner.

- Safety and effectiveness in pregnant or breastfeeding women have not been established.
- Devices marked “single use” on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- The bottles cannot be reprocessed. To prevent bottles from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the bottle is handled offside the dental unit with clean/disinfected gloves. During treatment clinicians with patient contact should not handle bottles.
- Contact with saliva and blood during placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- The Prime&Bond® NT adhesive bottles should be tightly closed immediately after use.
- Once Prime&Bond® NT adhesive is mixed with Self Cure Activator, apply immediately onto prepared surfaces.
- Proceed immediately once material is dispensed to avoid evaporation. Do not apply evaporated material.
- Use only in well ventilated areas. Avoid inhaling vapor.
- Flammable: Prime&Bond® NT adhesive and Self Cure Activator contain acetone. Keep away from sources of ignition. Take precautionary measures against static discharges.
- Interactions:
  - Eugenol- and hydrogen peroxide containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
  - Prime&Bond® NT adhesive is light cured material. Protect from ambient light.
  - If mineral-impregnated (e.g., ferric compounds) retraction cords and/or hemostatic solutions are used in conjunction with adhesive procedures, marginal seal may be adversely affected, allowing microleakage, subsurface staining and/or restoration failure. If gingival retraction is necessary, use of plain, non-impregnated cord is recommended.
  - The use of a dual cure adhesive system such as Prime&Bond® NT adhesive mixed with Self Cure Activator can shorten working time of a dual cure resin cement system. This effect should be investigated in the laboratory prior to clinical use.
  - Various in vitro data exist regarding use of light-cured-only adhesives such as Prime&Bond® NT adhesive without Self Cure Activator in conjunction with most dual cured or self cured resin restoratives or cements. Chemical/Product incompatibility may adversely affect product efficacy, leading to premature restoration failure.

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

There have been no Field Safety Corrective Actions (FSCA) with respect to product Prime&Bond NT since the first certificate (CE) was issued covering the device in 1998.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

5.1 Summary of clinical data related to equivalent device

Not applicable as equivalence is not claimed.

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

No clinical investigations of Prime&Bond NT were conducted before marking CE.

5.3 Summary of clinical data from other sources

Summary of reviewed literature (review period: January 2020 to May 2025) including 71 patients / 73 cases in total: Clinical acceptable ratings for the device under evaluation for survival rate of restorations and retention ranged from 75.0% to 100% and for marginal quality (marginal adaptation) 100%. Clinical acceptable ratings for the device under evaluation for secondary caries range from 95.2% to 100% and 100% for postoperative hypersensitivity/pain. The longest observation period was up to six years. Adverse events, not being hypersensitivity or related to the restoration or tooth/restoration interface were not reported in the reviewed literature.

All pertinent publications identified between January 2020 and May 2025 are listed hereinafter:

1. Koç-Vural, U.; Kerimova-Köse, L.; Kiremitci, A. Long-term clinical comparison of a resin-based composite and resin modified glass ionomer in the treatment of cervical caries lesions. Odontology. 2025. doi: 10.1007/s10266-024-00958-6
2. Dukić, W.; Majić, M.; Prica, N.; Oreški, I. Clinical Evaluation of Flowable Composite Materials in Permanent Molars Small Class I Restorations: 3-Year Double Blind Clinical Study. Materials (Basel). 2021. doi: 10.3390/ma14154283
3. Vinagre, A.; Ramos, J.; Marques, F.; Chambino, A.; Messias, A.; Mata, A. Randomized clinical trial of five adhesive systems in occlusal restorations: One-year results. Dent Mater J. 2020. doi: 10.4012/dmj.2019-011

Conducted PMCF studies are listed hereinafter:

1. Merte K. Clinical investigation of Dyract AP and Prime&Bond NT in Class V cavities. University of Leipzig (2004)

Study design	Prospective longitudinal randomized trial	
Follow-up duration	28 months	
Summary of methods	220 Prime&Bond NT/Dyract AP restorations were placed using four different application procedures. In two control groups, Prime&Bond 2.0 was used with either Spectrum TPH (N = 37) or Dyract AP (N = 47).	
Summary of results	The re-assessment rate is 65.2%. The overall clinical success rates vary between 68% and 83.3%. For the group including acid etch procedure, the success rate was 73.2%. Statistically relevant differences could be found neither between the adhesives nor between the restorative materials.	
	Marginal integrity	85% acceptable
	Marginal discoloration	99.5% acceptable
	Secondary caries	N = 1
	Immediate postoperative hypersensitivity	None
	Persistent or late arising hypersensitivity	N = 1
	Pulp vitality	100%
	Adverse events	None
	Survival rate	73.2%

2. Haller B. Clinical investigation of Prime&Bond NT in Class V cavities with Dyract AP and Spectrum TPH. University of Ulm (2002)

Study design	Prospective longitudinal randomized trial	
Follow-up duration	18 months	
Summary of methods	125 Prime&Bond NT restorations were placed in 56 patients in three different application procedures (no-etch, NRC, phosphoric acid) and/or in combination with two different restorative materials.	
Summary of results	The reassessment rate was 78.4%. The retention rates vary between 56.1% and 71.4%, with an overall retention success of 65.9%. For the group including acid etch procedure (but no mechanical pre-treatment of lesions), the success rate was 70.0%. Microleakage at charlie level was not seen. The author concludes that in his study the specified success criteria (less than 10% failures) were not met. Haller strongly recommends a mechanical pre-treatment/preparation of lesions.	
	Marginal adaptation	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	Not reported
	Persistent or late arising hypersensitivity	None
	Pulp vitality	100%
	Adverse events	Not reported
	Survival rate	70%

3. Peters M. Clinical investigation of Prime&Bond NT for Class V Dyract AP and Spectrum TPH restorations. University of Michigan (1999)

Study design	Prospective longitudinal randomized trial	
Follow-up duration	18 months	
Summary of methods	105 Prime&Bond NT restorations were placed in 60 patients in three different application procedures (no-etch, NRC, phosphoric acid) and/or in combination with two different restorative materials.	
Summary of results	The re-assessment rate is 94.3%. The overall clinical success rates after 18 months vary between 71% and 91.7%. For the group including acid etch procedure, the success rate was highest with 91.7%. The restorations in situ showed excellent clinical performance according to the evaluation criteria. Hypersensitivity to air and mechanical stimuli was at a level close to zero. No side effects or adverse sensitivity reactions were reported at any interval of the study. The investigator concludes that the study results support the safety and effectiveness of Prime&Bond NT when used after a conventional phosphoric acid total-etch procedure. The study does not support the use of NRC as an alternative to phosphoric acid etching. The original sensitivity of the root surfaces was fairly high and the sensitivity after 18 months was close to zero, even in the debonded sites. The adhesive system used functioned well as a desensitizing agent for exposed root surfaces.	
	Marginal adaptation	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	N=2
	Persistent or late arising hypersensitivity	None
	Adverse events	N=2
	Survival rate	91.7%

4. Peters M. Clinical investigation of Prime&Bond NT for Class V restorations at the University of Michigan (2003)

Study design	Prospective longitudinal randomized trial	
Follow-up duration	18 months	
Summary of methods	114 Prime&Bond NT restorations were placed in 60 patients in three different application procedures (no-etch, NRC, phosphoric acid) and/or in combination with two different restorative materials. The study at hand represents the second cohort of an earlier project (see 3.), using a slightly modified clinical procedure with regard to the first study as to increase the level of clinical success: the surfaces of lesions were roughened with a bur and a two-coat application mode was used.	
Summary of results	The re-assessment rate is 96.5%. The clinical success rates after 18 months vary between 94.4% and 97.4%. For the group including acid etch procedure, the success rate was highest with 97.4%. Microleakage at Charlie level was not seen in this study. After 18 months the sensitivity to air and mechanical stimuli was zero, even at the dislodged sites. The adhesive procedure applied at time of placement of the restorations still provided sufficient seal and protection to the sensitive root dentin. The investigator concludes, that “the restorations in situ are of superior quality and showed excellent clinical performance according to USPHS evaluation criteria.” The non-sensitive and caries-free debonded sites suggest that the adhesive system functions as a desensitizing agent for exposed root surfaces. With regard to the proceeding trial, Prof. Peters states that the results of the study “support the current clinical practice to roughen the dentin and bevel the enamel prior to bonding, in order to optimize the micro-mechanical retention and subsequently the success rate of the restorations.”	
	Marginal adaptation	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	None
	Persistent or late arising hypersensitivity	None
	Adverse events	None
	Survival rate	97.4%

5. Toh CG. Clinical investigation of a compomer in the restoration of Class I and II cavities in permanent posterior teeth at the University of Malaya (2001)

Study design	Prospective longitudinal randomized controlled trial	
Follow-up duration	12 months	
Summary of methods	In this prospective longitudinal randomized controlled trial, 23 patients received 77 Class I and II, placed with NRC in combination with 2 different restorative materials (compomer Dyract AP and composite Spectrum TPH).	
Summary of results	The reassessment rate was 100%. Only one restoration failure was counted (at charlie level). The author concludes that “the clinical results indicate that NRC and Prime&Bond NT can be used for restoring posterior teeth with good clinical response at 1 year.”	
	Marginal integrity	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	Not reported
	Persistent or late arising hypersensitivity	N=1 was bravo
	Adverse events	Not reported
	Survival rate	98.7%

6. Lo CM, Lou Y. Field monitoring study of Dyract AP in combination with NRC and Prime&Bond NT for Class I and II restorations in posterior permanent teeth at the University of Hong Kong (2000)

Study design	Prospective longitudinal trial
Follow-up duration	24 months

Summary of methods	In this prospective longitudinal trial, 91 restorations were placed in 39 patients making use of Prime&Bond NT in combination with NRC and Dyract AP compomer.	
Summary of results	The reassessment rate was 83.5%. The overall success rate is 93.4%. During the 2-year observation period, no adverse effects and symptoms of pulpal problem related to the Dyract AP restorative system were found. The authors conclude that "the 2-year findings of this study showed that the clinical performance […] was satisfactory."	
	Marginal integrity	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	N=3
	Immediate postoperative hypersensitivity	N=3
	Persistent or late arising hypersensitivity	None
	Adverse events	None
	Survival rate	93.4%

7. Jedynakiewicz N. Clinical investigation of Dyract flow for Class I and II restorations at the University of Liverpool (2001)

Study design	Prospective longitudinal trial	
Follow-up duration	36 months	
Summary of methods	In this prospective longitudinal trial, 55 Prime&Bond NT / Dyract flow restorations were placed. The cavities were conditioned with NRC prior to the application of the adhesive.	
Summary of results	Only 1 restoration had to be replaced (root-filling because of pulpal symptoms). Beyond, neither Bravo nor Charlie ratings were given for any evaluated criteria. The Kaplan-Meyer probability of survival for these restorations at 3 years is 0.97. The author concludes that the restorative system used "has been demonstrated to be a satisfactory treatment option for the restoration of minimal invasive, but load bearing Class I and II cavities in permanent teeth over a period of 3 years."	
	Marginal integrity	100% excellent
	Marginal discoloration	100% excellent
	Secondary caries	None
	Immediate postoperative hypersensitivity	None
	Persistent or late arising hypersensitivity	N=1 resulting in root-filling
	Adverse events	Not reported
	Survival rate	97%

8. Chew CL, Mok BYY. Clinical investigation of Dyract AP / Prime&Bond NT and NRC or Conditioner 36 for Class IV restorations at the University of Singapore (2001)

Study design	Prospective longitudinal controlled trial	
Follow-up duration	12 months	
Summary of methods	In this prospective longitudinal controlled trial, two groups of Prime&Bond NT/ Dyract AP restorations, used with NRC or DeTrey Conditioner 36 were compared.	
Summary of results	The reassessment rate was 100%. The retention rate was 91% (NRC) and 100% (DeTrey Conditioner 36), with an overall survival rate of 88% (NRC) and 96% (DeTrey Conditioner 36). Bravo type marginal discoloration occurred slightly more frequent for the NRC group. Microleakage at Charlie level was not seen in this study. None of the patients experienced post-operative sensitivity at any recall. The investigators conclude that the clinical performance of both restorative systems for Class IV restorations and for diastema closure was acceptable.	
	Marginal adaptation	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	None
	Persistent or late arising hypersensitivity	None

	Adverse events	Not reported
	Survival rate	92%

9. Moscuardó AP. Field monitoring study on the fissure sealant Dyract Seal in combination with Prime&Bond NT at the University of Valencia (2000)

Study design	Prospective longitudinal controlled trial	
Follow-up duration	24 months	
Summary of methods	Two fissure sealants (Dyract Seal and Delton) applied with Prime&Bond NT and NRC or DeTrey Conditioner 36 phosphoric acid were compared. In total, 94 sealings in 39 patients were observed up to 24 months. The sealants were placed according to a strict clinical protocol.	
Summary of results	The investigator considered both fissure sealants to be safe for use. At the time of recall, Dyract Seal was as secure as the Delton sealant, although the clinical performance of the Delton sealant applied with Prime&Bond NT on phosphoric-acid etched enamel was slightly better. No adverse reactions of the used materials have been reported.	
	Marginal adaptation	81.8% acceptable
	Marginal discoloration	100% excellent
	Secondary caries	N=1 was bravo
	Adverse events	None
	Survival rate	Not reported

10. Peters M. Clinical investigation of Dyract flow for minimally invasive Class I restorations in permanent teeth at the University of Michigan (2000)

Study design	Longitudinal partially randomized trial	
Follow-up duration	24 months	
Summary of methods	The clinical performance of Class I restorations and fissure sealants in a caries-prone population was investigated. Permanent teeth with occlusal carious lesions indicated for operative intervention were treated using air abrasion technology for preparation of cavities and adjacent fissures. After caries removal the teeth were restored and sealed. The adhesive treatment consisted of surface treatment with the non-rinse conditioner NRC, application of the bonding agent Prime&Bond NT, and restoration with the flowable compomer Dyract flow. A group of 62 subjects received 89 restorations.	
Summary of results	The clinical performance of a total of 63 restorations (71% recalled) after two years of intra-oral service was shown to be successful. The margins of some restorations showed a local deterioration, which could easily have been improved by re-finishing. The results support good clinical performance of the flowable compomer, with minimal loss of sealant retention of 6%, microleakage of 13% and slight local deterioration of the margins in 21%. Only one study tooth (2%) developed recurrent caries. This case was the only one that showed a slightly increased sensitivity over 2 years.	
	Marginal integrity	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	N=1
	Immediate postoperative hypersensitivity	None
	Persistent or late arising hypersensitivity	N=1
	Adverse events	Not reported
	Survival rate	Not reported

11. Barnes D. Clinical evaluation of Calibra cement for indirect posterior restorations: 2-year results. University of Maryland (2010)

Study design	Prospective longitudinal trial
Follow-up duration	24 months

Summary of methods	Thirty-three indirect composite inlays were adhesively placed in 26 patients using Calibra as the composite cement and Prime&Bond NT with Self-Cure Activator as the adhesive agent. Cemented restorations were evaluated for retention, anatomic form, marginal integrity, color match, marginal discoloration, recurrent caries, restoration integrity, proximal contact, sensitivity, gingival index and plaque index.	
Summary of results	After two years, 25 restorations were available for evaluation. Two restorations had small fractures that were repaired and did not require replacement. All other clinical parameters were within clinically acceptable limits. The investigator stated the cementing and adhesive agents were performing as expected.	
	Marginal integrity	100% acceptable
	Marginal discoloration	100% acceptable
	Secondary caries	None
	Immediate postoperative hypersensitivity	N=2 partial fractures
	Persistent or late arising hypersensitivity	None
	Adverse events	Not reported
	Survival rate	Not reported

Device registries on Prime&Bond NT have not yet been sponsored.

5.4 An overall summary of the clinical performance and safety

For each intended performance such as suitable handling properties, retention, marginal quality, and survival rate of restorations there is sufficient clinical evidence from the clinical data analyzed in chapter 5.3 and the clinical evaluation report of Prime&Bond NT. In summary, the clinical evaluation results show that Prime&Bond NT provided at least clinically acceptable results regarding parameters for evaluating the performance and safety. No gaps, uncertainties and unanswered questions or assumptions were identified. The clinical data also show a low incidence and severity of adverse events, which are acceptable in the light of the significant benefits of Prime&Bond NT. It should also be noted that in most cases the underlying cause for the adverse events remain unclear.

In summary treatment with adhesive techniques with devices as Prime&Bond NT have the following therapeutic effects and benefits to the patient:

- Anatomical and functional tooth restorations being highly esthetically and nearly invisibly.
- Operative procedures primarily involving minimally invasive or minimum intervention omitting preparation of retention elements.
- Maintenance and repair rather than replacing entire restorations.

Side effects and other risks are limited and identical to those found with the available dental alternatives:

- Pulpitis resulting in post-operative pain, hypersensitivity or loss of vitality
- Degradation and failure of restoration due to marginal breakdown or debonding,
- Marginal discoloration,
- Oral / perioral inflammatory changes,
- Secondary caries,
- Allergic reactions

In summary, the benefit/risk profile of Prime&Bond NT is compatible with a high level of protection of health and safety according to current knowledge with adhesive treatments, and according to available dental alternatives such as restorative or prosthodontic treatment with non-adhesive materials. Side effects and residual risks are limited and identical to those found with the available dental alternatives (cf. chapter 6).

5.5 Ongoing or planned post-market clinical follow-up

Data from the long-term and broad experience in the field of Prime&Bond NT, as well as the very rare incidence of serious and clinically relevant complaints indicate a high safety of the device and a high satisfaction of users. From

the data evaluated there are no indications of residual risks and uncertainties. Rare complications and safety under widespread use are continuously monitored by complaint management. PMCF activities on Prime&Bond NT include the following elements:

1. Evaluation of Adverse Events History (when adverse events are reported)
2. Update on clinical data from the literature (when Technical Documentation is updated)

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Treatment with Prime&Bond NT has the following advantages in comparison with alternative materials/treatments:

Alternative materials/treatments	Advantages of Prime&Bond NT treatment
Restorative treatment with non-adhesive materials such as amalgam	• Saving tooth structure • Mercury-free
Prosthodontic treatment such as cemented crowns	• Saving tooth structure • Cost-effective treatment
Restorative treatment with a self-etch adhesive	• Enhanced bond strength to enamel

Treatment with Prime&Bond NT has the following disadvantages in comparison with alternative materials/treatments:

Alternative materials/treatments	Disadvantages of Prime&Bond NT treatment
Restorative treatment with non-adhesive materials such as amalgam	• Possible allergic reaction to methacrylate • Higher placement complexity and technique sensitivity
Prosthodontic treatment such as cemented crowns	• Possible allergic reaction to methacrylate
Restorative treatment with a self-etch adhesive	• Longer procedure due to separate etching

7. SUGGESTED PROFILE AND TRAINING FOR USERS

This device is for dental use / professional use only. The general knowledge needed for the use of this medical device can be considered as part of the professional education. Additional training is not required.

8. REFERENCE TO ANY HARMONIZED STANDARDS AND CS APPLIED

- EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- DIN EN 1641:2010-02 Zahnheilkunde – Medizinprodukte für die Zahnheilkunde – Werkstoffe (EN 1641:2009 Dentistry – Medical devices for dentistry – Materials)
- DIN EN ISO 7405:2019-03 Zahnheilkunde – Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten (ISO 7405:2018, korrigierte Fassung 2018-12 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry)
- DIN EN ISO 10993-1:2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 14971:2019+A11:2021 Medical devices - Application of risk management to medical devices (ISO 14971:2019)
- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- IEC 62366-1 2020 + AMD1 - Medical devices – Part 1: Application of usability engineering to medical device

9. REVISION HISTORY

SSCP REVISION NUMBER	DATE ISSUED	CHANGE DESCRIPTION	REVISION VALIDATED BY THE NOTIFIED BODY
01	15/01/2024	First release	☐ Yes Validation Language: - ☒ No Explanation: -
02	29/04/2024	Correction in chapter 4.1	☐ Yes Validation Language: - ☒ No Explanation: -
03	08.09.2025	General update based on revision of product CER (1240-CER-009-V06), PMCF (1240-PMCFR-009-2025 V01) and IFU (1240-Master IFU-064 V07)	☐ Yes Validation Language: - ☒ No Explanation: -
04	See cover page	Corrections based on TÜV Süd validation project number: 713344624. English Master SSCP validated by TÜV	☒ Yes Validation Language: English ☐ No Explanation: -