Bicon TRINIA
Summary of Safety and Clinical Performance for the Healthcare Professional

Document number: SSCP-003
Document revision: 05
Date issued: August 1, 2023

The 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 following information is intended for users/healthcare professionals.

The SSCP is not intended to replace the Instructions For Use 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.

1. Device identification and general information

1.1 Device trade name(s)
TRINIA Fiber Disks and Blocks

1.2 Manufacturer's name and address
Bicon, LLC
501 Arborway
Boston, MA 02130 USA

1.3 Manufacturer's single registration number (SRN)
US-MF-000002782

1.4 Basic UDI-DI
081311002TRI8S

1.5 Medical device nomenclature description / text
The European Medical Device Nomenclature (EMDN) and Classificazione Nazionale dei Dispositivi Medici (CND) code and descriptor for TRINIA is listed in Table 1.

Table 1 – Medical Device Nomenclature

EMDN / CND Code	Term	Definition
Q010206	Dental prostheses / Dental implant suprastructure, permanent	A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to help mimic preparations of natural teeth. It is used during dental implant restorative procedures and will provide the permanent intermediate fixture level between the dental implant and the final restoration (e.g., bridge, single tooth, overdenture). The device can be used for cement or screw retained restorations and typically includes abutments, abutment screws, and cylinders. It is available in a variety of shapes and designs (e.g., ball, bar) and is made of various materials [e.g., titanium (Ti), plastic, gold alloy].

1.6 Class of device
Class IIa

1.7 Year when the first (CE) was issued covering the device
2014

1.8 Authorized representative is applicable; name and the SRN
Bicon Europe, Ltd.
Unit 4 Ballycummin Village
Ballycummin, Limerick
Ireland
SRN: IE-AR-000002497

1.9 NB's name and the NB's single identification number
BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands
Notified Body number: 2797

2. Intended use of the device

2.1 Intended purpose
TRINIA is intended to be used by dental technicians and dentists for the fabrication of copings, substructures, removable dentures, or frameworks for permanent and transitional single crowns and bridgework in the anterior and posterior regions.

2.2 Indication(s) and target population(s)
TRINIA is indicated for use in the treatment of edentulism or partial edentulism through use as copings, substructures, removable dentures, or frameworks.

The intended population is edentulous or partially edentulous patients. The intended users of the devices are laboratory technicians and dentists who place the restoration.

2.3 Contraindications and/or limitations
TRINIA should not be used in patients with parafunctional habits, such as bruxism.

3. Device description

3.1 Description of the device
TRINIA fiber disks are milling blanks composed of a multi-directional interlacing of fiberglass and resin in several layers. TRINIA is intended to be used by dental technicians and dentists for the fabrication of copings, substructures, removable dentures, or frameworks for permanent and transitional single crowns and bridgework in the anterior and posterior regions. TRINIA is also intended to be used as a substructure that can be for cemented or uncemented restorations such as telescopic restorations.

Principle of Operation

TRINIA is a solid block composed of composite resin that can be fabricated into the appropriate design with the CAD/CAM dental restoration system. TRINIA can be modified to match the basic shade of the restored tooth or teeth. The TRINIA acts as a framework for dental teeth to be placed. The resulting restoration is placed on top of existing abutments and fixed into place.

Key Functional Elements

TRINIA is a solid block composed of composite resin that can be used with the CAD/CAM dental restoration system and modified to the desired framework shape. The key features of TRINIA are the shape, diameter or length, and thickness. The thickness will determine the maximum possible height of the restoration. The diameter or length will determine the maximum size of the restoration, though typically multiple restorations can be manufactured from a single unit.

The TRINIA configurations are summarized in Table 2.

Table 2 – Product Codes and Device Configurations

Catalog Number	Description	Color	Diameter / Length (mm)	Thickness (mm)
260-612-115	TRINIA Disc 98mm x 15mm Ivory	Ivory	98	15
260-612-125	TRINIA Disc 98mm x 25mm Ivory	Ivory	98	25
260-612-215	TRINIA Disc 98mm x 15mm Pink	Pink	98	15
260-612-225	TRINIA Disc 98mm x 25mm Pink	Pink	98	25
260-613-115	TRINIA Block 55 x 19 x 15mm Ivory	Ivory	55	15
260-614-115	TRINIA Block 40 x 19 x 15mm Ivory	Ivory	40	15
260-615-115	TRINIA D-Shape 89 x 71 x 15mm Ivory	Ivory	89	15
260-615-215	TRINIA D-Shape 89 x 71 x 15mm Pink	Pink	89	15

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

There are no previous generations of the device produced. The devices currently produced are the same design as produced previously.

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

There are no accessories that are provided with TRINIA.

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

TRINIA is used with CAD/CAM systems and modified to the desired framework shape. The CAD/CAM system determines the connection as there is only a specific way to connect following the instructions of the CAD/CAM milling machine.

4. Risks and warnings

4.1 Residual risks and undesirable effects

Per the clinical evaluation report, where the data was sourced from a systematic review of scientific literature on the actual TRINIA device, there have been no reported occurrences of harm after placement in the oral cavity from residual risks such as rejection of the material, an allergic reaction to the material, or fracture of the material, beyond replacing the restoration. All known and foreseeable hazards and associated risks have been identified and reduced as far as possible, and the residual risks are deemed acceptable.

4.2 Warnings and precautions

TRINIA is supplied in a ready state. This material should not be fired under any circumstances.
TRINIA should not be milled or used at temperatures above 150°C (302°F).
Do not contaminate TRINIA with oils or grease.
Do not exceed the mechanical tolerances of the device. TRINIA has a flexural strength of >300 MPa and a flexural modulus of elasticity of <20 GPa and requires an occlusal thickness of 2.0mm for bars. Failure to observe these parameters may compromise the results achieved with TRINIA.
If patients are known to be allergic to any of the ingredients, TRINIA restorations should not be used. The processing of TRINIA discs and blocks produced dust which may irritate the skin and eyes or cause other health issues. Refer to the Material Safety Data Sheet (available at www.bicon.com).
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established, if applicable.

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

There have not been any Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN) for TRINIA.

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

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

Current clinical data available is based on Bicon devices. No clinical data has been used from other devices other than to support the conclusion that TRINIA continues to be state-of-the-art in the industry for dental substructions or frameworks.

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

There were no specific clinical investigations performed on the device before CE-marking.

5.3 Summary of clinical data from other sources, if applicable

Clinical data exists from a variety of sources, including use in doctor offices or clinics and use recorded in clinical articles and surveys. The clinical data within the Clinical Evaluation Report utilizes data gathered from actual Bicon devices.

The clinical data gathered from these sources show high survival rates. There are some failures which is to be expected, especially events involving poorly designed restorations or overloading the restoration. The clinical data gathered suggested the benefits outweighed any

risks as final restorations were able to be constructed and the patient's chewing function restored with high survival rates.

From the literature review, TRINIA is used in the following selection of articles:

1. Marincola M, Morgan V, Perpetuini A, Lapucci S. Fixed full arch metal-free prosthesis on four SHORT implants. Implants 3_2012 p.28-31
2. Rolf Ewers, Mauro Marincola, Vincent Morgan, Paolo Perpetuini, Florian Wagner, Rudolf Seemann. Restoration of the Atrophic Maxilla with Four Narrow and Ultrashort Implants. International Journal of Clinical Oral and Maxillofacial Surgery. Vol. 4, No. 2, 2018, pp. 35-41. doi: 10.11648/j.ijcoms.20180402.11
3. Petroni, G., Passaretti, A., Marincola, M., Pompa, G., & Cicconetti, A. (2019). Alternative solution for mandible rehabilitation: fixed full arch prosthesis on short implant, a randomized cohort study. Journal of Osseointegration, 11, 477-484.
4. Wagner, F., Seemann, R., Marincola, M., & Ewers, R. (2018). Fiber-Reinforced Resin Fixed Prostheses on 4 Short Implants in Severely Atrophic Maxillas: 1-Year Results of a Prospective Cohort Study. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons, 76(6), 1194–1199. https://doi.org/10.1016/j.joms.2018.02.001DOI: 10.1016/j.joms.2018.02.001
5. Seemann, R., Wagner, F., Marincola, M., & Ewers, R. (2018). Fixed, Fiber-Reinforced Resin Bridges on 5.0-mm Implants in Severely Atrophic Mandibles: Up to 5 Years' Follow-Up of a Prospective Cohort Study. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons, 76(5), 956–962. https://doi.org/10.1016/j.joms.2017.11.043
6. Aiuto, R., Barbieri, C., Garcovich, D., Dioguardi, M., Redaelli, M., & De Micheli, L. (2020). Rehabilitation of Edentulous Jaws with Full-Arch Fixed Implant-Supported Prostheses: An Approach with Short and Ultrashort Implants and Metal-Free Materials. Case Reports in Dentistry, 2020.
7. Cheng, Y. C., Bergamo, E. T., Murcko, L., Hirayama, M., Perpetuini, P., Speratti, D., & Bonfante, E. A. (2022). Fiber-reinforced composite partial fixed dental prostheses supported by short or extra-short implants: A 10 year retrospective study. Clinical Implant Dentistry and Related Research.
8. Ewers, R., Perpetuini, P., Morgan, V. J., Marincola, M., Wu, R., & Seemann, R. (2017). TRINIA™—Metal-free restorations. Implants, 1, 2-7.
9. Hayashi, K., Shigeta, Y., Tsumita, M., Shigemoto, S., Ikawa, T., Ihara, K., ... & Ogawa, T. (2020). Dual-structured CAD/CAM restoration with fiber-reinforced composite resin for posterior fixed partial dentures. 日本デジタル歯科学会誌, 9(3), 183-186.

Table 3 and Table 4 below summarize the literature included for the evaluation of the safety and performance of TRINIA. For evaluation of performance, success was defined by the survivability of the restoration. For evaluation of safety, adverse events were summarized from the clinical literature data.

Other data from the implementation of the PMCF plan showed no changes in the likelihood of an undesirable side-effect, no significant increase in the frequency or severity of incidents, no trends, and no other findings including serious adverse events, rejection, or misuse.

Table 3 – Literature Summary Characteristics

Reference / Author (Year)	Study Design	No. of Patients	No. of TRINIA prostheses and/or Bicon Implants	Age Mean / Range (if known)	Intervention	Follow-up Range
1. Marincola (2011)	Case Report	1	1 TRINIA prosthesis 4 Bicon short implants	52 years old	Survival of fixed, full arch non-metallic TRINIA framework prosthesis on 4 short implants in compromised mandibular bone	3 months
2. Ewers (2018)	Prospective Cohort Study	18 (4 men; 12 women)	18 full arch TRINIA framework prosthesis, Bicon Integra-CP implants	55-80 years	TRINIA's survivability on 4 short implants in atrophic maxillas	2.1 ±0.9 years
3. Petroni (2019)	Randomized Cohort Study	10 (4 males; 6 females)	10 TRINIA fixed full arch prostheses 40 Bicon implants	61.1 years (42-80)	Survival of TRINIA and implants as fixed full arch mandibular prostheses set on 4 implants	6 months to 3 years
4. Wagner (2018)	Prospective Cohort Study	18 (12 women; 6 men)	18 TRINIA bridge prostheses 72 Bicon implants	67.1 years	Survival of TRINIA prosthetic rehabilitation in atrophic maxillas supported by four implants	6 months to 1 year
5. Seeman (2018)	Prospective Temporal Cohort Study	17 (14 women; 3 men)	17 TRINIA prostheses 64 implants	62.2 (40.7-73.9 years)	Survival of TRINIA as fixed, full-arch prostheses on ultra short implants in patients with severely atrophic mandibles	1.1-5.6 years
6. Aiuto (2020)	Case Report	1 male	7 Bicon implants with 2 TRINIA prostheses (1 upper and 1 lower fixed-denture base)	66 years old	TRINIA bars for the base of upper and lower implant supported full-arch fixed dentures	2 years
7. Cheng (2022)	Retrospective Review	96	121 TRINIA prostheses 261 Bicon implants	68.46 (40-93)	Survival of TRINIA fixed partial dental prostheses on implants	118 months
8. Ewers (2022)	Case Series	2 (1 female, 1 not reported)	1-10 unit TRINIA base fixed full-arch denture 1-12 unit TRINIA base fixed full-arch denture	59, 69 years old	Survival of TRINIA as fixed, full-arch prostheses on Bicon implants	39 months / 64 months
9. Hayashi (2020)	Case Report	1	1 TRINIA fixed partial denture	N/A	Survival of TRINA fixed partial denture and intraoral response	7 months after placement

Table 4 – Safety and Performance Summary

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
1. Marincola (2011)	Case Report	0	Not specified	0 of 1 devices (0%)	Good gingival response and no marginal bone loss around the implants.	No performance issues were noted. Patient's jawbone compromised. Limited follow-up period
2. Ewers (2018)	Prospective Cohort Study	2 implant failures but prostheses were able to survive on 3 implants	TRINIA – 100% after 2.1 years Implants: 97.2% after 1 year.	0 of 18 devices (0%)	Good outcomes of TRINA prostheses on implants in patients with extreme maxillary atrophy. 2 implant failures but prostheses were still able to be placed.	Limitation of small population and follow-up time
3. Petroni (2019)	Randomized Cohort Study	0 for TRINIA 2 for implants	TRINIA – 100% after 3 years Implants – 95%	0 of 10 devices (0%)	No significant marginal bone level variation; no significant clinical periodontal indices change.	Success measured by absence of symptoms, stability of marginal bone, functional integrity, and peri-implant mucosa response. No peri-implant inflammation noted.
4. Wagner (2018)	Prospective Cohort Study	0 for TRINIA 2 for implants	TRINIA – 100% Implants – 97.2% after 1 year	0 of 18 devices (0%)	Marginal bone levels were stable	Small study cohort. Limited follow-up period.
5. Seeman (2018)	Prospective Temporal Cohort Study	1 for TRINIA	TRINIA overall prosthetic survival rate of 94.1% Overall implant success rate was 98.5%	0 of 17 devices (0%)	Stable marginal bone levels reported 1 TRINIA bridge fracture	Results were in line with other study results of implant-fixed protheses on ultrashort implants and implants of conventional lengths. Patients lost in follow-ups.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
6. Aiuto (2020)	Case Report	0 for TRINIA 1 for implants	TRINIA – 100% after 2 years; Implants – 87.5% after 2 years	0 of 2 devices (0%)	1 – 4.5 x 5 mm implant removed for failure after 3 weeks due to lack of osseointegration before loading. 2-year radiographic follow-up showed the absence of signs of bone resorption around the implants, and absence of peri-implantitis. Success of 2 fiber reinforced composite (FRC) bars digitally designed for double full-arch fixed prostheses.	Single case report. The FRC (TRINIA) material, which may reduce the number of implants, has excellent aesthetic properties, low cost, biotolerability, and simplified/fast workflow. Short implants represent a valid alternative to bone regeneration techniques and can be a solution in cases of limited bone height. The advantages of composite materials over traditional metal-ceramic systems include improved aesthetics, excellent biomechanical behavior, and possibility of repair or modifying denture chairside.
7. Cheng (2022)	Retrospective Review	0	High survival probability and success rates were seen at 95.9% and 89.8%; 5 prostheses modified or recemented	0 of 121 devices (0%)	The average time between two radiographic measurements was 38.34±24.08 months, and the average rate of marginal bone loss change over time was -0.01±0.05mm/month. Stable peri-implant levels noted.	Three prostheses had to be recemented after becoming loose. Two prostheses were removed and modified and recemented to add pontics, no prosthetic issues.
8. Ewers (2022)	Case Series	0	100% survival at 64 months; 100% survival at 39 months	0 of 2 devices (0%)	The report also noted 100% survival of an additional 101 TRINIA bridges and prostheses placed observed over 64 months.	TRINIA noted for desirable flexural strength and modulus, CAD/CAM milling abilities, and is lightweight. Limited study population.
9. Hayashi (2020)	Case Report	0	100% survival after 7 months	0 of 1 devices (0%)	TRINIA used as substrate in fixed partial denture, no chipping or fracturing reported.	Noted for metallic restorative material alternative due to its flexural strength, aesthetics, and bio-tolerability

5.4 An overall summary of the clinical performance and safety

The complaint rate for Bicon TRINIA is very low which is indicative of the performance and safety of the device. The clinical literature has successful studies going out to 5 years and beyond. The overall survival of the material has been very good with use of TRINIA in the maxilla and mandible and in both posterior and anterior regions. Some studies have reported 100% survival rates at 1-year and 3-year timeframes. The benefit/risk ratios are acceptable for both overall and for individual products. The biocompatibility risk of the materials used in Bicon TRINIA was determined to be low due to published literature, testing, and use of recognized international standards, as well as clinical use.

From the Clinical Evaluation Report and PMCF data, patients are likely to see high survivorship of the TRINIA. The main goal of having a successful dental substructure or framework was achieved at 95% or greater with over five years of data with low undesirable side effects, and has led to benefits for the patient which included restored chewing ability.

Table 5 – Overall Performance for TRINIA

Performance Outcome	**Survivorship**		
	# of failures reported	**# of TRINIA**	**Cumulative Success Rate**
	1	190	189/190 (99.5%)

Table 6 – Overall Safety for TRINIA

Safety Outcome	**# of adverse events**	**# of TRINIA**	**Adverse Event Rate**
	0	190	0/190 (0%)

5.5 Ongoing or planned post-market clinical follow-up

Clinical evaluations will be performed to determine any new or previously unidentified risks that would cause a change in the benefit/risk ratio. In addition, the evaluations will review any changes to state-of-the-art. Surveys and literature reviews continue to be the post-market clinical follow-up method. There are currently no unanswered questions relating to the use of the device that need to be investigated. If there are any emerging risks, complications, or unexpected device failures these will feed into the risk analysis and be investigated.

6. Possible diagnostic or therapeutic alternatives

Alternatives to TRINIA is to use another material, such as a metals, ceramics, glass ceramics, or other resin composites, made by other manufacturers available on the market. Any of these devices can be used to perform the required function of acting as a dental substructure or framework. Below is a tabulated summary of alternatives.

Therapeutic Alternative	**Potential Composition**	**Benefit**	**Risk**
Metals	Cobalt-chromium alloys, titanium	Mechanically strong Easily machined	Heavy Lack of aesthetics Corrosion
Ceramics	Glass, polycrystalline fillers	High aesthetic properties	Fragile Decreased mechanical properties
Zirconia	Zirconium oxide	High toughness	Limited aesthetics Difficult to bond Risk of breakage

Therapeutic Alternative	Potential Composition	Benefit	Risk
Composites	PMMA	Fast to mill Less wear on burs Variety of uses	Low mechanical strength Temporary use due to faster wear

7. Suggested profile and training for users

Bicon offers training courses on how to fabricate Bicon restorations with TRINIA successfully. First-time users should attend the training to realize the benefit of short implants and their use with TRINIA. More experienced users can also benefit from hands-on training courses.

8. Reference to any harmonized standards and CS applied

Applied in full:

Standard	Title
EN 1641 (2009)	Dentistry – Medical devices for dentistry – Materials
EN 62366-1 (2015)	Medical devices: Part 1: Application of usability engineering to medical devices
EN ISO 10993-1 (2020)	Biological evaluation of medical devices. Evaluation and testing within a risk management process
EN ISO 13485 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 14971 (2019)	Medical devices. Application of risk management to medical devices
EN ISO 15223-1 (2021)	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 20417 (2021)	Medical devices – Information to be supplied by the manufacturer
ISO 14125 (1998)	Fibre-reinforced plastic composites – Determination of flexural properties
ISTA 3A (2019)	Packaged-Products for Parcel Delivery System Shipment
MDCG 2019-9 (2022)	Summary of safety and clinical performance – A guide for manufacturers and notified bodies
MDCG 2020-6 (2020)	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MEDDEV 2.7/1 (2016)	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.12-1 (2013)	Guidelines on a Medical Devices Vigilance System

9. Revision history

SSCP revision number	Date issued DD-MM-YYYY	Change description	Revision validated by the Notified Body
00	10-11-2020	Original issue	☐Yes ☒ No
01	16-04-2021	Added SRN numbers	☐Yes ☒ No
02	11-04-2022	Correct intended use; update standards.	☐Yes ☒ No
03	05-10-2022	Update standards.	☐Yes ☒ No
04	26-06-2023	Update to current CER.	☐Yes ☒ No
05	01-08-2023	Update indications for use to match required definition per MDR.	☒Yes Validation language: English ☐ No

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Bicon TRINIA®
Summary of Safety and Clinical Performance for the Patient

Document number: SSCP-003
Document revision: 05
Date issued: August 1, 2023

The 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 information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for health professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace the Instructions For Use to provide information on the safe use of the device.

1.0 Device identification and general information

Device trade name:	TRINIA®
Manufacturer information:	Name: Bicon, LLC Address: 501 Arborway Boston, MA 02130 USA
Basic UDI-DI:	081311002TRI8S
Year Device was first CE-Marked	2014

2.0 Intended use of the device

Intended purpose:	To help provide a structure for the teeth.
Indications:	TRINIA is used by dental technicians and dentists for making the structures that help with tooth replacement.
Intended patient groups:	Patients with missing teeth or who are in need of tooth replacement.
Contraindications:	TRINIA is not for patients who have habits that wear teeth such as teeth grinding.

3.0 Device description

TRINIA is made of glass fiber and resin. TRINIA provides a structure on which the teeth are placed. TRINIA can be used as the structure for single crowns, bridges, or dentures.

3.1 Materials/Substances in contact with patient tissues

TRINIA, made of glass fiber and resin, is placed in the mouth on top of the dental abutments. TRINIA is covered by other material on which the teeth are bonded. There are no medicinal substances.

3.2 Operating principle

TRINIA is milled into the shape designed by the dental lab for each patient. The resulting structure is worked on some more by the lab with the teeth which can then be placed in the patient's mouth on dental abutments.

3.3 Accessories

None needed.

4.0 Risks and warnings

Contact your doctor if you have any problems or if you are concerned about risks. This document is not intended to replace a consultation with your doctor if needed. Risks and side effects include rejection of the material, allergic reaction, or fracture.

Residual risks and undesirable effects

- Rejection of the material
- Allergic reaction
- Fracture

Warnings and precautions

Consult with your doctor on what to do before and after placement. Inform your doctor without delay if any allergies and/or adverse reactions occur. Caution should be taken if you have any medical conditions that may prevent use. Inform your health care provider if you have any of the contraindications or conditions listed in Section 2.0.

There have not been any Field Safety Corrective Actions (FSCA), Field Safety Notices (FSN), or recalls for TRINIA.

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

TRINIA has been used for more than eight years in Europe and worldwide. Each year data is reviewed to ensure TRINIA is safely performing. The review also looks for any new risks or side effects. The following table summarizes the data from the clinical evaluation of the device. The clinical evidence is based on studies where TRINIA was the device used in treatment.

Device Used	Safety and Performance analysis	Potential adverse effect(s)
TRINIA	There were no reported rejections of TRINIA. There was a 0.5% reported fracture rate in 190 TRINIA units.	• Rejection of the material • Allergic reaction • Fracture

6.0 Possible diagnostic or therapeutic alternatives

You should contact your doctor if you want to learn more about different treatments.

Alternatives to TRINIA is to use another material on the market. Examples include metals, ceramics, or other resin composites.

- Metals – Cobalt-chromium alloys, titanium
- Ceramics – Glass, polycrystalline fillers
- Zirconia – Zirconium oxide
- Composites – PMMA

7.0 Suggested training for users

Only trained doctors or laboratory technicians may use the product.

8.0 Model numbers covered by this document

Catalog Number	Description	Color	Diameter / Length (mm)	Thickness (mm)
260-612-115	TRINIA Disc 98mm x 15mm Ivory	Ivory	98	15
260-612-125	TRINIA Disc 98mm x 25mm Ivory	Ivory	98	25
260-612-215	TRINIA Disc 98mm x 15mm Pink	Pink	98	15
260-612-225	TRINIA Disc 98mm x 25mm Pink	Pink	98	25
260-613-115	TRINIA Block 55 x 19 x 15mm Ivory	Ivory	55	15
260-614-115	TRINIA Block 40 x 19 x 15mm Ivory	Ivory	40	15
260-615-115	TRINIA D-Shape 89 x 71 x 15mm Ivory	Ivory	89	15
260-615-215	TRINIA D-Shape 89 x 71 x 15mm Pink	Pink	89	15