Bicon Dental Implant and Abutment System
Summary of Safety and Clinical Performance for the Healthcare Professional

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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 (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.

1. Device identification and general information

1.1 Device trade name(s)

Implants	Abutments	
Integra-CP	Brevis	Sinus Lift
Integra-Ti	Fixed-Detachable	Stealth
Short Implants	Healing / Transitional / PEEK	Temporary
Max 2.5	Non-Shouldered	Universal
Narrow Implants	Overdenture	

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

System
081311002BDIASNP

Implants	Abutments
081311002ITi8X	081311002HPI6Q
081311002ICP64	081311002TAbut5L
	081311002PAbut48

1.5 Medical device nomenclature description / text

The European Medical Device Nomenclature (EMDN) and Classificazione Nazionale dei Dispositivi Medici (CND) code and descriptor for implants and abutments is listed in Table 1.

Table 1 – Medical Device Nomenclature

EMDN/CND Code	Term	Definition
P01020101	Dental implants	A sterile device made of alloplastic materials [e.g., titanium (Ti), stainless steel, ceramic] intended to be surgically implanted into alveolar and/or basal bone of the mandible or maxilla to provide support and a means of retention for a dental prosthesis (e.g., bridge, single-tooth, overdenture). It is a two-piece device composed of an anchorage component (implant body) in the form of a single, double, and/or triple contiguous cylinder(s) that is implanted into bone, and a retention component (implant abutment), typically attached to the anchorage component after implantation, that protrudes through gingival tissues to support the prosthesis.
P01020180	Dental implants - Accessories	A prefabricated device intended to provide a permanent intermediate fixture level between a dental implant and the final prosthesis/restoration (e.g., bridge, single tooth, overdenture). It includes one or more structural component(s) [e.g., abutment, ball, bar, bar overlay, coping, ring], and may be made of various materials [e.g., titanium (Ti), plastic, gold alloy]. It includes devices glued to prostheses and/or devices that can be replaced during cleaning cycles. An abutment screw(s) may be included, however the suprastructure does not represent the screw(s) in isolation. It may also be referred to as an abutment assembly or mesostructure.

1.6 Class of device

Class IIb

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

1998

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

Bicon implants and abutments are surgically placed by dentists in the jawbone to help restore the chewing function of patients who may be missing one or more teeth.

2.2 Indication(s) and target population(s)

The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.

The intended population is edentulous or partially edentulous patients. The intended users of the devices are dentists who ultimately place the implant surgically and perform the final restoration using the abutment.

2.3 Contraindications and/or limitations

Bicon implants should not be used in patients with contraindicated diseases such as blood dyscrasias, uncontrolled diabetes, hyperthyroidism, bruxism, oral infections or malignancies. Nor should Bicon implants be used in patients with contraindicated conditions such as myocardial infarction within the past year or insufficient surrounding bone to permit the use of an appropriately sized implant. The 3.0 x 6.0, 3.0 x 8.0, and the 3.5 x 8.0mm implants are not indicated for use as a single tooth replacement either splinted or unsplinted in the molar region. Implants should not be placed if there is insufficient alveolar bone width and height to surround the implants.

3. Device description

3.1 Description of the device

Bicon implants and abutments, made from surgical grade titanium alloy (Ti6Al4V), are surgically placed by dentists in the jawbone to help restore the chewing function of patients who may be missing one or more teeth. Healing abutments, such as the healing, transitional healing, or PEEK temporary abutments, can be used as a temporary abutment during the healing period. After the healing period, also known as the osseointegration process, the healing abutment will be replaced with the permanent titanium alloy abutment. This titanium alloy abutment is connected to the implant which will provide the support for a traditional dental prosthesis such as a crown or bridge. A denture may also be secured to the dental abutment. Bicon implants and abutments are single-use and sterilized by gamma irradiation.

Principle of Operation

The Bicon implant is placed below the crest of the bone and covered. This allows for the osseointegration process to occur, typically four to six months, where the bone cells or osteoblasts interact and integrate with the implant, especially between the fins or plateaus.

After the healing period, the Bicon abutment is attached to the implant by a 1.5˚ locking taper depending on the well/post size. The locking taper is a well-known engineering principle used for joining two pieces of like metal together. A locking taper consists of a tapered post that fits into a corresponding tapered well. When a light force is applied to the abutment, the post of the abutment and the well of the implant become one through an engineering process known as cold welding. Other applications that utilize a locking taper are orthopedic hip implants and the dental lathe.

Key Functional Elements

The Bicon Implant and Abutment System is a two-piece implant system comprised of an implant body and an abutment. The key features of the implant are the diameter, length, well size, and the fins or plateaus. Correspondingly, the key feature of the abutments are the diameter, length, and post size. The total length will determine the height of the restoration. The largest diameter that will fit appropriately in the space should be chosen.

The Bicon Dental Implant and Abutment configurations are summarized in Table 2.

Table 2 – Product Device Configurations

Product	**Description**	**Dimensions**
Implants		
Integra-Ti Integra-CP	Well	2.0mm, 2.5mm, 3.0mm
	Diameter	3.0 – 6.0mm
	Length	5.0 – 11.0mm
Abutments		
Brevis	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	4.0mm
	Total Height	8.0 – 13.0mm
	Catalog Height	2.0 – 6.0mm
Fixed-Detachable / Universal	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	4.0mm
	Total Height	8.0 – 12.5mm
	Catalog Height	3.0 – 7.0mm
Healing / Transitional / PEEK	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	4.0 – 7.5mm
	Total Height	7.0 – 9.0mm
	Catalog Height	4.5 – 6.5mm
Overdenture	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	3.5mm
	Total Height	6.0 – 10.5mm
	Catalog Height	1.0 – 5.0mm
Non-Shouldered	Post	2.0mm, 2.5mm, 3.0mm

Product	Description	Dimensions
	Diameter	4.0 – 7.5mm
	Total Height	12.0 – 18.5mm
	Catalog Height	6.5 – 12.0mm
Sinus Lift	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	5.0 – 7.0mm
	Total Height	5.0 – 6.0mm
	Catalog Height	2.5mm
Stealth	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	3.5 – 6.5mm
	Total Height	8.5 – 15.0mm
	Catalog Height	1.5 – 6.0mm
Temporary	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	3.2 – 7.5mm
	Total Height	5.0 – 11.0mm
	Catalog Height	4.5 – 6.5mm
Universal	Post	2.0mm, 2.5mm, 3.0mm
	Diameter	4.0 – 7.5mm
	Total Height	9.5 – 15.3mm
	Catalog Series/Profile	4 Series / LP – 7 Series / TP

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. Abutments made today fit into implants made 20 years ago and implants made today fit into abutments made 20 years ago.

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

The Bicon Dental System also includes a variety of Class I accessories which are sold non-sterile to assist the doctors with the surgical placement and restorative phase of implant treatment. These accessories are placed on the implant or the abutment either by the dentist or by laboratory technicians for the purpose of accurate positioning of dental implant analogs. These include items such as impression sleeves, impression posts, abutment copings, waxing sleeves, scan posts, and prosthetic components. The end user is not required to use any of these additional parts and may elect to use their own.

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

There are no other products to be used in combination with the device except with the accessories described in Section 3.3.

4. Risks and warnings

4.1 Residual risks and undesirable effects

One hundred percent implant success cannot be guaranteed. Failure to observe the limitations of use may result in failure. Reuse of single-use devices increases risk of rejection, infection, and disease transmission. Factors such as infection, disease, inadequate bone quality and/or quantity, and patient behavior such as smoking or poor oral hygiene can result in osseointegration failures following surgery or initial osseointegration.

Possible typical complications following the insertion of dental implants include pain, swelling, bleeding, dehiscence, delayed healing, paresthesia, edema, hematoma, infection, inflammation, and generalized allergenic reaction. More persistent symptoms include chronic pain in connection with implants, permanent paresthesia, nerve damage, loss of bone, infection, and fracture of the implant or prosthesis.

The probability of experiencing these residual risks depends on many factors, including patient health, surgery planning, etc. and can increase significantly if instructions are not followed. The typical side effects, such as pain, swelling, bleeding, and temporary inflammation are probable while more persistent symptoms are rare. In one of the scientific studies[22] in the clinical evaluation report, there was a 7.2% chance of exhibiting peri-implant mucositis or an inflammatory lesion after five years. Patients with a history of periodontal disease have their chances of failure increase; this study[22] had the probability of occurrence at 4% over a five-year period. 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

Implant surgery is a highly specialized and complex procedure. Special training is required in established techniques of oral implantology. Implant courses and seminars are strongly recommended before surgery is attempted. Improper technique can result in implant failure and substantial loss of surrounding bone. Bicon implants should not be used in sites or situations other than those specifically indicated. To do so may result in failure of the implant with the concomitant destruction of supportive bone. Bicon implants are intended to be used only with the specially designed bone drills supplied by Bicon. When using Bicon implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to the implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If these implants show mobility or show greater than 50% bone loss, the implant should be evaluated for possible removal. The 3.0mm diameter implant is designed to be used with straight abutments only. Concerning MR safety, due to the large variety of MRI scanners available on the market, Bicon cannot make any predictions regarding the safety or behavior of our implants and components in any specific MRI system. The risk assessment concluded that this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Panoramic radiographs should be used to determine if adequate bone is present at the proposed implant site as well as to locate established critical anatomical features such as the

mandibular canals, mental foramina, maxillary sinuses and adjacent teeth. Palpation and direct visual inspection of the prospective implant site are also necessary to determine the anatomy of available bone. A thorough clinical evaluation is imperative. Proper patient motivation is essential, if the procedure is to be successful.

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), Field Safety Notices (FSN), or recalls for any Bicon implant or abutment.

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 only on Bicon implants and abutments. No clinical data has been used from other devices other than to support the conclusion that Bicon implants and abutments continue to remain state-of-the-art in the industry for tooth root replacement.

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 as part of the development of devices before the initial CE-marking in 1998.

5.3 Summary of clinical data from other sources, if applicable

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

The clinical data gathered from these sources show high survival rates and a low volume of complications. There are some failures which are to be expected, especially events involving lack of osseointegration or overloading of the restoration as these involve factors outside of Bicon's control. The clinical data gathered suggested the benefits outweighed any risks as final restorations were able to be placed and patients' chewing function was restored with high survival rates.

From the literature review, Bicon implants and abutments were used in the following selection of articles:

1. Urdaneta, Rainier A., et al. "The survival of ultrashort locking-taper implants." International Journal of Oral and Maxillofacial Implants 27.3 (2012): 644.
2. Lee, Eui-Hee, et al. "Effects of installation depth on survival of an hydroxyapatite-coated Bicon implant for single-tooth restoration." *Journal of Oral and Maxillofacial Surgery* 68.6 (2010): 1345-1352.
3. Akeredolu, Patricia A., et al. "Implant restoration of partially edentulous ridges: A review of 121 Nigerian patients." *Implant Dentistry* 19.1 (2010): 65-72.
4. Susarla, Srinivas M., Sung-Kiang Chuang, and Thomas B. Dodson. "Delayed versus immediate loading of implants: survival analysis and risk factors for dental implant failure." Journal of Oral and Maxillofacial Surgery 66.2 (2008): 251-255.

5. Erakat, Mohammed S., et al. "Immediate Loading of Splinted Locking-Taper Implants: 1-Year Survival Estimates and Risk Factors for Failure." International Journal of Oral & Maxillofacial Implants 23.1 (2008).
6. Gentile, Michael A., Sung-Kiang Chuang, and Thomas B. Dodson. "Survival estimates and risk factors for failure with 6 x 5.7-mm implants." *International Journal of Oral & Maxillofacial Implants* 20.6 (2005).
7. Vehemente, Valerie A., et al. "Risk factors affecting dental implant survival." Journal of Oral Implantology 28.2 (2002): 74-81.
8. Muftu, A. L. I., and Robert J. Chapman. "Replacing posterior teeth with freestanding implants: four-year prosthodontic results of a prospective study." The Journal of the American Dental Association 129.8 (1998): 1097-1102.
9. Chapman, Robert J., and William Grippo. "The locking taper attachment for implant abutments: use and reliability." Implant dentistry 5.4 (1996): 257-261.
10. May MC, Andrews PN, Daher S, Reebye UN. Prospective cohort study of dental implant success rate in patients with AIDS. Int J Implant Dent. 2016 Dec;2(1):20. doi: 10.1186/s40729-016-0053-3. Epub 2016 Sep 28.
11. Markose, Joji, et al. "Clinical outcomes of ultrashort sloping shoulder implant design: A survival analysis." Clinical Implant Dentistry and Related Research 20.4 (2018): 646-652.
12. Lombardo, Giorgio, et al. "Single-crown, short and ultra-short implants, in association with simultaneous internal sinus lift in the atrophic posterior maxilla: A three-year retrospective study." Materials 13.9 (2020): 2208.
13. Lombardo, Giorgio, et al. "Survival of short and ultra-short locking-taper implants supporting single crowns in the posterior mandible: a 3-year retrospective study." Journal of Oral Implantology 46.4 (2020): 396-406.
14. Petroni, G., et al. "Alternative solution for mandible rehabilitation: fixed full arch prosthesis on short implant, a randomized cohort study." Journal of Osseointegration 11.3 (2019): 477-484.
15. Gaxho, Ledia, et al. "High crown to implant ratio as stress factor in short implants therapy." Balkan Journal of Dental Medicine 20.2 (2016): 94-98.
16. Akbulut, Nihat, et al. "Comparison of Survival Rates of Short Versus Long Dental Implants: A Retrospective Study." Turkiye Klinikleri Journal of Dental Sciences 25.1 (2019).
17. Lombardo, Giorgio, et al. "Assessment of peri-implant soft tissues conditions around short and ultra-short implant-supported single crowns: a 3-year retrospective study on periodontally healthy patients and patients with a history of periodontal disease." International Journal of Environmental Research and Public Health 17.24 (2020): 9354.
18. Geng, Wei. "Prosthetic complications of fixed dental prostheses supported by locking-taper implants: a retrospective study with a mean follow-up of 5 years." BMC oral health 21.1 (2021): 1-8.
19. Stanbouly, Dani, Rami Stanbouly, Alexander Y. Z. Li, & Sung-Kiang Chuang. "Design and the future of locking-taper screwless and cementless dental implants: a narrative review." Frontiers of Oral and Maxillofacial Medicine (2022)
20. Xia, Xun, Zhen-Yu Wei, and Hong-Wu Wei. "Displacement of the full body of a dental implant into the sinus space without membrane perforation and subsequent osseointegration: a case report." Journal of International Medical Research 49.12 (2021): 03000605211060674.
21. Lombardo, Giorgio, et al. "Short and ultra-short (< 6-mm) locking-taper implants supporting single crowns in posterior areas (part II): A 5-year retrospective study on

periodontally healthy patients and patients with a history of periodontitis." Clinical Implant Dentistry and Related Research 24.4 (2022): 455-467.
22. Lombardo, Giorgio, et al. "Survival rates of ultra-short (< 6 mm) compared with short locking-taper implants supporting single crowns in posterior areas: a 5-year retrospective study." Clinical Implant Dentistry and Related Research 23.6 (2021): 904-919.
23. Ewers, Rolf, et al. "Severely atrophic mandibles restored with fiber-reinforced composite prostheses supported by 5.0-mm ultra-short implants present high survival rates up to eight years." Journal of Oral and Maxillofacial Surgery 80.1 (2022): 81-92.

Table 3 and Table 4 below summarize the literature included for the evaluation of the safety and performance of Bicon implants and abutments. For evaluation of performance, success was defined as the survivorship. 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 main findings including serious adverse events, rejection, or misuse.

Table 3 – Literature Summary Characteristics

Reference / Author (Year)	Study Design	No. of Patients	No. of Bicon Implants	Age Mean / Range (if known)	Intervention	Implant Staging	Follow-up Range
1. Urdaneta (2012)	Retrospective Cohort Study	291	410	58.9 ± 12 years	Bicon Integra-CP implants with lengths ranging from 5mm (ultrashort) to 8mm (short) and overdenture abutments.	Two-stage	Up to 30 months
2. Lee (2010)	Retrospective Cohort Study	305	613	51.3 years	308 HA-coated implants 305 TPS-coated implants	Two-stage	1 to 5 years
3. Akeredolu (2010)	Retrospective Cohort Study	121	227	15-74 years	Bicon dental implants	Immediate (10) Two-stage (111)	1 to 6 years
4. Susarla (2008)	Retrospective Cohort Study	855	2,826	53.1 years / 14.9-92.5 years	Bicon dental implants ranging in diameter from 3-6mm, lengths from 6-14mm, coated (HA, TPS), uncoated, and well size from 2-3mm.	Immediate and Two-stage	Up to 13 years
5. Erakat (2008)	Retrospective Cohort Study	209	477	54.5 years / 15-91 years	Bicon dental implants	Immediate	0 to 25.3 months
6. Gentile (2005)	Retrospective Cohort Study	35	172	55.8 ± 11.1 years	Bicon dental implants 6 x 5.7mm and Bicon healing abutments	Two-stage (60.2%) Immediate (20.4%)	<5 years
7. Vehemente (2002)	Retrospective Cohort Study	677	2,349	53.5 years 16.9-92.5 years	Bicon dental implants	Immediate and Two-stage	0 to 85.6 months
8. Muftu (1998)	Prospective Cohort Study	168	432	Not specified	Bicon dental implants	Two-stage	4 years
9. Chapman (1996)	Retrospective Cohort Study	Not Specified	1,757	Not Specified	Bicon Locking taper implant abutment systems and Bicon Non-Shouldered abutments	Two-stage	4 to 7 years
10. May (2016)	Prospective Cohort	16	33	36.19 years	Bicon implants	Not reported	5 years
11. Markose (2018)	Retrospective Cohort Study	375	744	30-50+	Bicon short implants (6mm or less)	Immediate and Two-stage	28 months
12. Lombardo (2020)	Retrospective Study	31	51	53.59 ± 10.48 years (34-75)	Bicon implants (5mm, 6mm, 8mm length, 4mm, 4.5mm, 5mm, 6mm diameter) Bicon sinus lift abutments	Two-stage	36 months

Reference / Author (Year)	Study Design	No. of Patients	No. of Bicon Implants	Age Mean / Range (if known)	Intervention	Implant Staging	Follow-up Range
13. Lombardo (2020)	Retrospective Study	98	201	45.05-70.77 years at follow-up	Bicon implants (5mm, 6mm, 8mm length, 4mm, 4.5mm, 5mm, 6mm diameter)	Two-stage	36 months
14. Petroni (2019)	Randomized Cohort Study	10	40	61.1 (42-80) years	Bicon short 4x5mm implants with fiber reinforced composite (FRC) fixed prosthesis and healing abutments	Not reported	36 months
15. Gaxho (2016)	Cohort Study	33	66	47.87±14.97 years	Bicon implants (5mm length, 4mm diameter)	Immediate, Two-stage	24 months
16. Akbulut (2019)	Retrospective Cohort Study	137	548	44.4 years (19-67)	Bicon Integra-CP implants (6mm, 11mm length, 3mm, 3.5mm, 4mm, 4.5mm, 5mm diameter) and Bicon non-shouldered abutments	Two-stage	25.18 months
17. Lombardo (2020)	Retrospective Review	140	326	18-90	Bicon 8.0, 6.0, and 5.0 mm locking-taper implant supporting a single crown and healing abutments	Immediate/ 2-stage	3 years
18. Geng (2021)	Retrospective Review	392	541 Bicon implants/ 434 locking taper implants	43.07	Bicon implants, 1.5 locking tapers with internal cone	Not reported	1, 5, and 10 year follow ups
19. Stanbouly (2022)	Retrospective Review of 4 studies using Bicon implants	642 patients // 291 patients // 206 patients // 81 patients	1,494 short and ultra-short locking taper implants // 410 IAC locking taper short/ultra-short implants // 235 HA coated IAC implants // 326 IAC implants	N/A	Design of Bicon locking-taper screwless and cementless implants	Not Reported	10 years // 42 months // N/A // 70.7 months

Reference / Author (Year)	Study Design	No. of Patients	No. of Bicon Implants	Age Mean / Range (if known)	Intervention	Implant Staging	Follow-up Range
20. Xia (2021)	Case Report	1	3 Bicon short implants and sinus-lift abutments	50 years	Sinus floor elevation with immediate implant placement and sinus lift abutment	Immediate	6 months after prosthesis loaded
21. Lombardo (2022)	Retrospective Study	142 patients (65 men and 77 women)	333 short/ultra short Bicon Integra-CP implants, healing, non-shouldered / shouldered abutments	54 (18-90)	Study reviewing short and ultra-short locking-taper implants supporting crowns in posterior areas on patients with and without periodontitis	Not Reported	5 years
22. Lombardo (2021)	Retrospective Review	142 patients (65 men and 77 women)	333 locking-taper short and ultra-short implants, healing, non-shouldered / shouldered abutments	54 (18-90)	Severely atrophic mandibles restored with FRC prosthesis using 5.0mm ultra-short implants	Not Reported	5 years
23. Ewers (2022)	Prospective Cohort Study	18 patients (4 men/14 women)	72 ultrashort 4 x 5mm Integra-CP implants with Universal or fixed-detachable abutments (4 implants per patient)	61.22 years (40-77)	Severely atrophic mandibles restored with FRC prosthesis using Bicon 5.0mm ultra-short implants and Universal and Fixed-Detachable abutments	Not Reported	< 8 years

Table 4 – Safety and Performance Summary

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
1. Urdaneta (2013)	Retrospective Cohort Study	9	Over 30 months: Cumulative: 97.5% Ultrashort: 97.6% Short: 95.2%	9 out of 410 devices (2.2%)	NA	Failures occurred in posterior areas. Implant removal necessary not related to implant length.
2. Lee (2010)	Retrospective Cohort Study	42	Not definitively stated; Failures dependent on depth of installation and length of implant.	42 out of 613 devices (6.9%)	Failures potentially caused by loss of osseointegration	20 failures were TPS-coated implants.
3. Akeredolu (2010)	Retrospective Cohort Study	9	6-year success was 96%.	9 out of 227 devices (4%)	Two implants had crowns dislodged and had to be recemented	Two of the failures were repeated and remain functional. Smoking noted to impair wound healing.
4. Susarla (2008)	Retrospective Cohort Study	Not specified	Kaplan-Meier 1-Year Survival Estimates: Delayed: 95.5% Immediate: 90.3%	None specified out of 2,826 devices (N/A)	NA	Study did not look at loss to follow-up. Data only comes from one center.
5. Erakat (2008)	Retrospective Cohort Study	Not specified	Kaplan-Meier 1-Year Survival Estimates: 90.3%	None specified out of 477 devices (N/A)	NA	Study shows that placement of implants in fresh sockets reduced risk of failure.
6. Gentile (2005)	Retrospective Cohort Study	12	1-Year Survival Rates: 6x5.7mm: 92.2% Non-6x5.7mm: 95.2%	12 out of 172 devices (7%)	NA	Survival rates of 6x5.7mm vs. non-6x5.7mm not clinically significant. Medically compromising disease, staging, and use of reconstructive procedures.
7. Vehemente (2002)	Retrospective Cohort Study	Not specified	1-Year Survival: 95.2% 5-Year Survival: 90.2%	None specified out of 2,349 devices (N/A)	NA	Study limited number of implants to one per patient. The overall survival may be different.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
8. Muftu (1998)	Prospective Cohort Study	28, some were successfully reimplanted	4-Year Survival: Maxilla: 90.0% Mandible: 96.8%	28 out of 432 devices (6.5%)	Abutment loosening, abutment fracture, porcelain or crown failure	The locking-taper implant-abutment connection mechanism appears to reduce abutment fracture and loosening considerably. The safety of the patient was not in question.
9. Chapman (1996)	Retrospective Cohort Study	9	Fracture: 0.05% Loosening: 1.7%	9 out of 1,757 devices (0.5%)	NA	A locking taper connection has fewer problems when compared with screws which have a 16% complication rate over a 6-year period.
10. May (2016)	Prospective Cohort	3 (9.1%) early failures	Approximately 90% at 5 years of follow up	3 out of 33 devices (9.1%)	This study used Bicon implants. The study found a slightly higher failure rate of 10 % in patients with AIDS, compared to widely accepted failure rates in healthy patients at 5–7 %.	This study indicated that there was no significant difference in failure rate comparing AIDS patients to healthy patients. Failures could also be associated with patients' immunocompromised state.
11. Markose (2018)	Retrospective Cohort Study	14 failures: Age 30–40 years; 4 failures 40–50 years 8 failures > 50 years; 2 failures	Cumulative survival rate was 97% after 28 months	14 out of 744 devices (1.9%)	Short implants with sloping shoulder design and plateau-type roots saw superior survival rates compared with regular implants. The bone condition was also witnessed to be statistically significantly superior. Statistically significant in type and condition. Age was not a factor in overall survival. More failures were seen in immediate loading versus delayed.	The survival analysis pointed to very positive benefits for using Bicon. There were good survival rates with bone condition improvement over time. The fin design offers at least 30% more surface area than a screw implant of the same dimensions and allows for callus formation of mature Haversian bone between the fins of the implant. Bone quality and time of placement seemed to be major factors in failure.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
12. Lombardo (2020)	Retrospective Study	2	3-Year Survival: 96.08% 5mm Survival: 100% 6mm Survival: 91.3% 8mm Survival: 100%	2 out of 51 devices (3.9%)	Implant survival was high and bone levels remained stable. Patient level of satisfaction reportedly increased over time.	Short implants provide stable bone levels even while having a high crown-to-implant (CIR) ratio. History of periodontitis in one patient, one patient was a tobacco user.
13. Lombardo (2020)	Retrospective Study	5 failures after functional loading (late failures	The overall survival was 97.51% at 36 months; with 98.59% for the 8.0-mm implants, 97.56% for the 6.0-mm implants, and 95.83% for the 5.0-mm implants	5 out of 201 devices (2.5%)	No statistically significant differences were found among the groups regarding implant survival (P = .73), mean crestal bone loss (P =.31), or mean apical shift of the "first bone-to-implant contact point" position (P = .36).	Short and ultra-short single-crown locking-taper implants have been demonstrated to be a successful treatment option in the atrophic posterior mandible, survival rates similar to standard implants. Implant length was not a factor in implant survival. All failures were due to excessive bone loss in patients with a history of periodontal disease. Screwless, locking-taper design showing advantages in mechanical stability, no micromovements or micro gaps, leading to minimal bone resorption.
14. Petroni (2019)		2	Overall: 95%	2 out of 40 devices (5%)	Probing depth average was 1.6mm, indicating good peri-implant health.	The two implants were replaced and integrated.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
15. Gaxho (2016)	Cohort Study	2, 1 was successfully restored.	After 2 years there were only 2 failures, one was restored, and the other was not attempted to be restored.	2 out of 66 devices (3%)	The clinical significance of this finding is that locking-taper screwless implants maybe restored with single tooth restorations when the clinical crown length is almost twice as longer than the clinical implant length, or 3.7 times the crown-to-root ratio of the natural tooth, or when the clinical crown length is up to 3.2 times the clinical implant length.	One implant was in a smoker, was able to restore. Other failure was not restored.
16. Akbulut (2019)	Retrospective Cohort Study	13; before prosthetic treatment during healing phase	Survival rate of short implants was 97.6% with 25.18 months of follow up; 535 were functional	13 out of 548 devices (2.4%)	Short implants have similar survival rate as long Most failures in type III bone and in older population, no failures in Type I bone	More failures occurred in older population suggesting age may have been a factor. Bone quality may have been a factor in failure.
17. Lombardo (2020)	Retrospective Review	1 early failure, 7 failures after functional loading	Survival according to lengths were 97.79% for 8 mm implants, 97.37% for 6 mm implants, and 97.37% for 5 mm implants. According to arch-groups, 97.38% of the implants in the posterior mandible and 97.78% in the posterior maxilla survived.	8 out of 326 (2.5%)	Overall implant survival after 3 years of follow-up was 97.55%, 98.08% and 96.61% for PP and NPP ($p = 0.46$). Maintenance procedures before implant placement and during the follow-up time with adequate compliance of patients in homecare, mainly contributed to our stable results, both for PP and NPP.	This study, although with short-term outcomes, found that Bicon short and ultra-short locking-taper implants can be successfully placed and restored with single crowns in the atrophic posterior jaws in patients with and without periodontal disease, as well as the benefits of screw-less locking taper implant-abutment connections. No association was found between survival and failure groups, and any of the covariates considered.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
18. Geng (2021)	Retrospective Review	3, after prosthetic loading due to periimplantitis	3 failures out of 541 implants	3 out of 541 devices (0.6%)	The overall 5-year cumulative complication-free rate was 83.34%, with most common complication being chipping. No significant differences were observed in the gender, age, location, or prosthesis-type groups. The long-term clinical effect of locking-taper implant is stable, and implant success rate can meet clinical needs. The bone tissue level around the implant can maintain long-term stability.	After a 5-year follow-up with Bicon locking taper implants, very high success and retention rates were found along with few complications, and minimal marginal bone loss at implant sites. Bicon's locking taper design was also found to be more successful than screw-type implants by reducing the microgap at the abutment-implant connection site. Implant failures were all due to peri-implantitis.
19. Stanbouly (2022)	Retrospective Review of 4 studies using Bicon implants	N/A, number not specified but main cause of failures seen were intrinsic to the patient citing poor bone quality and quantity.	10-year cumulative implant survival rate of was an impressive 98.7%, and the 10-year complication free survival rate was 88.6%	None specified out of 2,465 devices (N/A)	The locking taper implant with frictional seal helps eliminate potential for microleakage and counters screw-retained implant systems. Short implants suited for patients with reduced bone levels and those that cannot undergo complex surgeries. Survival rates of short implants are comparable to conventional implants on grafted or pristine bone. The distance between the first implant plateau and root surface of adjacent tooth did not influence failure of plateau root-form implants. No significant correlation between tooth-implant proximity and changes in peri-implant bone levels surrounding plateau root-form implants existed. Placing a plateau implant in close proximity to an adjacent tooth does not cause detectable damage to the root surface or to the crestal bone on the adjacent tooth.	Failures mainly due to poor bone quality/quantity, failure of osseointegration or resorption. Secondary failures from poor clinical handling, poor implant design, or the complexity of the case. Bone volumes compromised by patient conditions like smoking, age, and periodontitis.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
20. Xia (2021)	Case Report	1 failure, 1 implant became displaced during second-stage surgery	100%, implant that became displaced was replaced and was successful at follow-up	1 out of 3 devices (33.3%)	Long-term outcomes suggest that short and ultra-short locking-taper implants can be successfully restored with single crowns in the posterior area of the maxilla and mandible. Case suggests that OSFE with simultaneous implant placement is feasible for severely atrophic maxillary sinus floor, but carries a risk of displacement	The main cause of implant displacement appeared to be inadequate residual bone height and insufficient support of the bone or bone graft material around the implant. Patient healthy with no history of drug misuse or systemic disease but smoked up to 20 cigarettes/day.
21. Lombardo (2022)	Retrospective Study	1 early failure; 9 overall failures at 60-month follow-up Peri-implantitis revealed cause in 6 of 9 failures (66.7%).	Implant-based survival after 5 years of follow-up was 95.77% for PP and 96.67% for NPP ($p = 0.77$). Overall implant success was 92.16% and 97.41%, respectively, for PP and NPP.	10 out of 333 devices (3%)	Regarding crestal bone level variations, average crestal bone loss was statistically different ($p = 0.04$) among PP (0.74 mm) and NPP (0.61 mm). 5 years after loading, among 320 survived implants, 19 (5.94%) presented peri-implantitis, 3 (2.59%) and 16 (7.84%) in NPP and PP.	Under strict maintenance programs, 5-year outcomes suggest short and ultra-short locking-taper implants can be successfully restored with single crowns in the posterior jaws in patients with and without a history of periodontal disease.
22. Lombardo (2021)	Retrospective Review	1 early failure; 12 implants were lost and removed after functional loading.	Implant-based survival after 5 years of follow-up was 96.10%: 96.85%, 95.65%, and 95.60% for 8.0-, 6.0-, and 5.0-mm length implants, respectively ($p = 0.82$).	13 out of 333 devices (3.9%)	The overall implant-based survival at 60-month follow-up was 96.10%. After 60 months, a peri-implantitis prevalence of 5.94% was reported, with an overall implant success of 94.06%: 95.93%, 92.73%, and 93.10% for 8.8, 6.0, and 5.0mm length implants, (p=55) Outcomes show stable crestal bone levels over time, with no statistically significant differences between survival and success with short and ultra-short implants.	A statistically significant difference was found for Crestal Bone Level (CBL) regarding history of periodontal disease and for bone to implant contact arch. Long-term outcomes suggest that short/ultra-short locking-taper implants can be successfully restored with single crowns in the posterior area of the maxilla and mandible.

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
23. Ewers (2022)	Prospective Cohort Study	2 implants were not loaded due to non-osseointegration and sensorial disturbances/ 1 implant failure just before loading (placed in area previously treated for mandible fracture.	Implant survival rate was 97.2% %. The cumulative survival rate of prostheses was 100% after the mean observation period of 55 months, and survival rate after the 96-month follow-up was 75%, where a framework fractured after 84 months in function.	3 out of 72 devices (4.2%)	Fixed fiber-reinforced composite full-arch prostheses retained by 4 ultrashort implants showed stable bone levels and high implant/prostheses survival rates up to 8 years. Subcrestally placed implants saw 0.21 mm gain in average marginal bone level. In contrast, implants placed epicrestally demonstrated a statistically significant reduction, 0.5 mm, in marginal bone levels comparing values obtained at loading start (1.97 mm, CI, §0.58/ SD, 0.73 mm) and at the last follow-up (1.33 mm, CI, §0.58/ SD: 1.70 mm) (P = .005).	In this study, mean marginal bone level values remained stable in most patients are comparable with those of implants of standard lengths. Marginal bone level change over time was significantly influenced by the insertion depth (vertical implant position).

5.4 An overall summary of the clinical performance and safety

The complaint rate for the Bicon Implant System is very low which is indicative of the performance and safety of the device. The clinical literature has successful studies exceeding 10 years. If the locking taper design did not function as intended, bacteria would be able to invade an implant and potentially cause bone loss, creating implant mobility and ultimately causing failure. Uncoated and coated (HA) implants have shown high survival rates in the literature. Different sizes are not significantly different from one another in terms of survival rates as per the literature. Abutments, either straight or angled, have also shown high survival rates. The benefit/risk ratios are acceptable for the implant and abutment system overall and additionally as individual products. The biocompatibility risk of the materials used in the Bicon Implant System was determined to be low as seen from published literature and recognized international standards, as well as decades of actual clinical use.

From the Clinical Evaluation Report and PMCF data, patients have been able to receive dental implants, though performance would perceivably be improved if patients did not have a history of periimplantitis or were not tobacco users. The main goal of having a dental implant successfully osseointegrated has been achieved at 90% or greater with over five years of data in many of the clinical literature articles, with one article (4. Susarla (2008)), further noting a 96% survival over six years. Correspondingly, the failure rate would be less than 10%. There are no specific clinical claims in the IFU; patients should be able to receive a dental prosthesis after the procedure. From the clinical data in the CER, implants were placed and restored typically within 6 months.

The clinical benefits of the device for the patient continue to outweigh the risks, and as seen in the CER, Bicon implants and abutments are still considered state-of-the-art with an acceptable benefit-risk ratio. This is seen in comparison with the alternative treatments noted in the state-of-the-art analysis which used comparable procedures that produced similar survival and complication rates.

Table 5 – Overall Performance for Bicon Implants and Abutments

Performance Outcome	**Survivorship**		
	# of failures reported	**# of Bicon Implants and Abutments**	**Cumulative Success Rate**
	188	6,902	6714/6902 (97.3%)

Table 6 – Overall Safety for Bicon Implants and Abutments

Safety Outcome	**# of adverse events**	**# of Bicon Implants and Abutments**	**Adverse Event Rate**
	188	6,902	188/6902 (2.7%)

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. Per the latest approved PMCF plan, 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

There are several dental implants and abutments available on the market today and made from the same materials or from other materials. Additionally, there are alternative treatments to dental implants for tooth restorations such as bridges or partial dentures. A patient or health care provider may also elect to not to treat an edentulous or partially edentulous condition with any restoration. However, the risk of no treatment may lead to bone resorption over time and contribute to bone structure becoming weaker which may eventually lead to atrophy of the jaw. This in turn may limit restoration options in the future if a patient ultimately decides to undergo treatment.

7. Suggested profile and training for users

Bicon implants and abutments are intended for dental professional use only with knowledge of oral and/or maxillofacial dentistry and surgery. Bicon offers training courses on how to place Bicon implants successfully and has an array of restorative options for learning. First-time users should attend the training to realize the benefit of short implants. More experienced users can also benefit from hands-on training courses.

8. Reference to any harmonized standards and CS applied

The following harmonized standards and guidance documents were applied or considered during the clinical evaluation, including input processes such as design and development and output processes such as PMCF plans and reports, of Bicon implants and abutments. Harmonized standards relevant to other processes, such as the quality management (EN ISO 13485:2016) and risk management (EN ISO 14971:2019) systems, are addressed in the GSPR document (GSPR-001v03). EN ISO 14155:2020 has not been applied or considered during the clinical evaluation, as no clinical investigations have been undertaken to assess the safety or performance of Bicon implants or abutments. All standards have been applied in full unless otherwise noted below:

Standard	Title
ASTM F136 (2021)	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
EN 1642 (2011)	Dentistry. Medical devices for dentistry. Dental implants
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 11137-1 (2015)	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1 (2020)	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

Standard	Title
EN ISO 11607-2 (2020)	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1 (2018)	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 13485 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 14630 (2012)	Non-active surgical implants – General requirements
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
ISTA 3A (2018)	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 (Healthcare Professional SSCP)

SSCP revision number	Date issued DD-MM-YYYY	Change description	Revision validated by the Notified Body
00	23-02-2021	Original issue	☐Yes ☒ No
01	15-04-2021	Added SRN numbers	☐Yes ☒ No
02	05-10-2022	Update standards	☐Yes ☒ No
03	01-03-2023	Update to align with CER	☐Yes ☒ No
04	04-17-2023	SSCP for healthcare professional; Add System Basic UDI-DI; Expand device description; Align further with CER.	☒Yes Validation language: English ☐ No