PRODUCT SPECIFICATION

Device subcategory: Carbide Rotary Dental Burs (non-sterile)

Document Approvers

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Document Revision History

Revision	Date	Changed By	Change Description
A0	05/Feb/2021	AJ	*First issuance of this document*
A1	04/JUN/2021	AJ	Revised for reference to FRM-71

1. Introduction

This document is intended as the top-level specification for Prima Dental carbide rotary dental burs (non-sterile) to be used for the purposes of design, development, specification product related requirements and regulatory compliance purposes.

It shall be maintained throughout the lifetime of the product including the required post-market surveillance (PMS) period after the device(s) ceases to be placed on the market.

All documentation including the instructions for use and all product labelling will be written in the English language only. Prima Dental Manufacturing will translate documentation on request.

2. Classification

Prima Dental Manufacturing dental burs have been classified as Class IIa devices in accordance with Annex IX of the Medical Device Directive 93/42/EEC according to Rule 6. All requirements of the Essential Requirements (Annex I of the MDD 93/42/EEC) have been fulfilled – See TP RA 002.

3. Intended Purpose

Dental burs are rotary cutting devices and are intended to be used to cut and shape tooth and bone within the mouth. Similarly, they are also designed to cut and/or remove materials, including enamel, dentine, amalgam, composite, glass ionomer cements, adhesives, polymer/ceramic veneers and precious/non-precious metals commonly used within dental and orthodontic procedures. These devices are supplied non-sterile for sterilisation before use and for use in combination with a rotary dental handpiece.

4. Benefit(s) of the Device

Through the user of dental burs in necessary dental/orthodontic procedures patients can have hardware implanted, hardware removed, carious teeth removed and broken teeth repaired. These are just some of the most common applications of dental bur usage but all result in alleviating or eradicating pain and discomfort associated with all aforementioned indications related to malocclusions.

In those requiring endodontic surgery for small fractures, canal damage, calcium deposits or damaged roots the use of surgical bur enables the patient to have their pain irradicated. Pain related to the root of the tooth can be extremely severe and therefore, the treatment through the use of the bur enables the pain to be alleviated. Similarly, those requiring traumatology owing injuries to the teeth, gums, jawbone or tooth loss the treatment through the use of a surgical bur enables pain to be eased.

Implantology surgery enabled through the use of surgical burs provides patients who through other conditions such as trauma have lost teeth to have an alternative implanted. The implants provide patients with an aesthetically pleasing result and also functional one. Tooth implants have metal screw like posts which means they are strong and as a result can endure daily life. Implantology surgery may also include the use of anchorage devices being fixated to the jaw bone – these help in orthodontic treatment of malocclusions and can help speed up the results obtained therefore, helping alleviate patients of any discomfort and yield aesthetically pleasing results within a shorter time interval.

In addition to the physical benefits to the patients identified, there is a health economic benefit associated with these devices. Burs within the scope of this risk management file are reusable devices – this means that rather than a new device being used for each procedure/patient, the devices are cleaned and resterilised prior to the next use. With patients in the UK paying for private healthcare or in countries where dental care costs are kept low to make it affordable the cost associated with reprocessing a device is much lower than when compared with a single use device. The initial cost of purchasing the product and the increased sharps waste disposal have are at the expense of the dentist. Additional costing will then be integrated into patient costs making dental care more expensive – this will deter patients from having necessary dental treatments as it is simply not affordable.

5. Description of Device

Dental burs are non-sterile reusable surgical instruments for use within the oral cavity. These are for transient use. Bur rotary cutting instruments are made from 3 sections – the head, neck and shank. All Prima Dental burs are derived from tungsten carbide, with some being brazed to a stainless-steel shank (the head is always tungsten carbide). All burs are brazed from the neck to the shank using a nickel compound, and gold finishing burs also have an additional nickel-plating layer followed by a gold-plated layer to achieve the final product. Dental burs manufactured by Prima Dental do not contain any medicinal products, tissues of animal origin nor do they contain human blood nor any of its derivatives.

FRM-71 Carbide Bur Specification and Manufacturing Information identifies all devices defined within the scope of this technical file and their intended application. Further detail including their dimensional specification and bur head shape can be seen in the device description – see TP RA 001.

6. Principles of Operation

The principles of operation of Prima Dental burs is to produce a cutting action by rotary motion. The devices are designed for use in combination with a dental rotary handpiece. They are connected by a specific shank type to a specific handpiece. The bur pattern selected will be chosen to cut a specific material in a specific application. The following table gives guidance:

Application	Bur Type	Material	Head Size (mm)	Speed (RPM)
Cavity Preparation	Standard	Enamel/Dentine	010 to 023	< 450,000
Removal of Fillings	Standard	Amalgam/Composite	010 to 018	60,000 to 120,000
Excavation	Standard	Enamel/Dentine/Bone	010 to 023	< 2,000
Finishing Margins	Finishing	Enamel	010 to 016	10,000 to 20,000
Finishing Restorations	Finishing	Amalgam	012 to 023	18,000 to 30,000
Finishing Restorations	Finishing	Composite	012 to 023	10,000 to 20,000
Finishing Restorations	Finishing	Glass Ionomer	012 to 023	10,000 to 20,000
Cutting Bone	Standard	Bone	018 to 027	500 to 3,000
Crown & Bridge Finishing	Finishing	C&B Polymer	010 to 016	40,000 to 80,000
Crown & Bridge Metal Finishing	Standard	Metals	018 to 027	< 30,000
Prosthetic Polymer Trimming	Standard	Polymer	018 to 027	< 20,000

7. GMDN Code

The GMDN code for reusable carbide rotary dental burs is 16668, the description of which is: ‘a rotary cutting device made of high-grade steel, the working end of which is made from or coated with tungsten carbide and which is designed to fit into a dental hand piece that provides the rotation allowing the user to cut hard structures in the mouth e.g., teeth/bone. It can also be used to cut hard metals, plastics and similar materials.’

8. Accessories

Prima Dental Manufacturing does not supply any accessories for use with these devices.

9. Intended User

The intended users for these devices are limited to Dentists, Orthodontists, Oral surgeons and Dental technicians. In some instances, dental hygienists or students of dentistry may use these devices. No users outside the field of Dentistry have been identified.

10. Conditions and environment of use

10.1. Transportation

Dental burs can be transported in both wet and dry conditions, however it is recommended that they are transported dry as any prolonged exposure to moisture may result in corrosion of the device. When transporting the devices suitable protection must be used in order to prevent damage to the device. Transport validation has been conducted in order to validate the recommended transit conditions (VLP 006 A0, VLR 001 A0).

10.2. Storage

The burs should be stored in the sterilisation container (instrument tray, bur stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents from water. Storage should be in dry, clean conditions at ambient temperature.

11. Handling and ergonomics

No risks related to ergonomics have been identified – see usability (RP RA 001).
With respect to handling, a warning is provided in the instructions for use regarding the removal of the burs from their sterilisation pouch/blister pack. The warning reads as follows: 'When removing the burs from a sterilisation pouch/blister pack, always use the peel tab mechanism. Never use the burs to pierce the packaging as this may have an adverse effect on the bur through undue stress and may result in premature failure of the device.'

12. Risks

Risks will be identified within an ISO 14971 risk assessment procedure; risks must be acceptable when weighed against the benefits to the patient.

13. Warnings and Precautions

The following warnings precautions are amongst the information provided to the end user from the manufacturer in order to ensure that the end user is provided with all information relevant to intended use, clinical safety and performance:

- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal.
- Suitable PPE including gloves and eye protection should be worn when re-processing these devices.
- During use eye protection shall be worn to protect against ejected particles.
- During use surgical masks shall be worn to avoid inhalation of dust and/or dust generated.
- Never exceed the maximum speeds as indicated by the manufacturer as it may result in generation of excessive heat.
- Do not apply excessive pressure on the bur during use as this can cause excessive heat generation and/or may cause the bur to fail.
- Beware of moving parts and the risk of laceration and entrapment type injuries.
- Ensure the bur is fully seated and gripped into the collet of the handpiece prior to use.
- Prior to use inspect the bur for broken and or damaged flute and discard any defective burs.
- Proper irrigation is required while using the device. Inadequate irrigation may generate excessive heat and cause patient discomfort, necrosis or patient burns.
- Ensure handpiece(s) is in good working condition prior to conducting the procedure. Failure to use a properly maintained handpiece can lead to procedural delays, injury to the user and injury to the patient through aspiration, swallowing or damage to the preparation site due to the vibration.
- Clean and sterilize the burs before initial use and thereafter in accordance with the instructions provided herein.
- During use ensure that the bur is moved continuously to avoid excessive heat generation caused by friction.
- Never force a bur into a handpiece as this could damage both the bur and handpiece collet.
- These devices have only been validated for steam sterilisation by autoclave. Use of any other method could result in premature failure of the device.

- Any re-processing method deviation from that defined within this IFU is not validated.
- Delays between the use of and the reprocessing of a used bur, must be kept to under 1 hour so as to reduce the likelihood of contaminants drying and making cleaning more difficult.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used with these burs.
- Do not use a bur for any application other than its intended use.

14. State of the Art

State-of-the-art devices are those that meet the safety and performance requirements as set out in the harmonised standards EN ISO 3823-1:1999 'Dental rotary instruments. Burs. Steel and carbide burs' and EN ISO 3823-2:2003+A1:2008 'Dentistry. Rotary bur instruments. Finishing burs' and deliver the desired cutting or polishing performance to the teeth or tooth restoration.

Equivalent devices are those that meet the state-of-the-art characteristics and

a) Used for the same intended purpose namely cut or polish teeth or tooth restoration
b) Same/similar technical specification
c) Same/similar biological contacting materials

15. Intended Performance

The intended performance of the dental burs is to meet their defined application – see table 2.

Bur Type	Application
Operative	Effective evacuation and removal and/or shaping of carious dentine
Orthodontic	For de-bonding of adhesive materials and interproximal spacing
Metal Cutting	Ideal for rapid reduction of all dental materials including amalgam, precious/non-precious metals and tooth structure
Gold Finishing	For finishing and shaping all dental materials including composite, ceramics, amalgam and enamel
Oral Surgery	A comprehensive collection of surgical burs covering a range of applications including endodontic surgery, implantology and traumatology

Table 1. Application of Bur Type

16. Lifetime, storage and transport conditions

The devices do not have a specified life time; the device is reusable and as such, the lifetime of the device is dependent on the user. The device should continue to meet the intended performance and clinical safety defined where the warnings, precautions and all other information provided by the manufacturer is adhered to. Storage and transport in accordance with §10 should further sustain the lifetime of the device.

17. Design and Development

The device has been designed in accordance with EN ISO 13485:2016 and the Medical Device Directive 93/42/EEC. Design and development activities have also been conducted in accordance with EN ISO 14971:2019 to ensure that all risks have been adequately considered through the design and development phases.

18. Manufacture

The device has been manufactured in accordance with EN ISO 13485:2016 in order to ensure that the suppliers of raw materials and all manufacturing processes are adequately controlled in order to ensure the device is of high quality and meets the device intended performance.

19. Packaging

Blister Packs
White corrugated cardboard box containing 20 blister packs. Each pack contains 5 or 10 individual blisters in a row.

Clinic Packs
Transparent plastic box containing one plastic polygrip bag of 50 or 100 pieces.

Bulk Packs
White cardboard box containing one 2.25" x 3" plastic polygrip bag of 50 or 100 pieces.

Non-Sterile Pouch Strips
White cardboard box containing one folded or rolled strip of single piece PET plastic pouches

Devices are not directly marked, the labelling on the packaging is supplied in human readable form.

20. Chemical and physical properties of materials

Material	Composition	Physical
H10F	10% Cobalt 90% Tungsten Carbide	High toughness Extra fine grain cemented carbide alloy
EF10	10% Cobalt 90% Tungsten Carbide	Hard metal Cemented tungsten carbide product with cobalt binder
Steel	C 0.30 S 0.025 P 0.030 Si 0.40 Mn 0.50 Cr 13.20	1.4028 corrosion and heat resistant martensitic stainless steel
Brazing	Braze tech Shim Ag 49 Cu 16 Zn 23 Mn 7.5 Ni 4.5 Braze tech paste h285	Is a low melting silver based brazing alloy with excellent flow characteristics For brazing
Nikel plating	Nickel Sulphamate 65%	Plating agent and metal surface treating agent
Gold plating	Auruna Gold solution CAP 50 Auruna 311 Replenisher solution	Electroplating solution

Table 3. Chemical and physical properties

21. Product Leakage

There are no product leakage properties applicable to these devices

22. Infection and Microbial contamination

The device is supplied in a non-sterile condition with the intention of being sterilised by the end user. From the manufacturer they are supplied chemically clean in order to reduce the risk associated with contamination.

Cleaning validation (SN 29485 - SN 29488.1) has been conducted in order to verify that the reprocessing procedure defined within the instructions for use adequately removes contaminants to an acceptable level.

23. Material compatibility

The devices within this technical file are made from tungsten carbide; there are no known risks linked to their use in conjunction with other materials, substances and gases with which they may come into contact during manufacture and normal conditions of use.

Furthermore, a biological compatibility evaluation has been conducted to ensure the materials themselves are safe for use in compatibility with patients. Nickel is a compound used for both brazing and plating of these devices and it is acknowledged that this is a known allergen/sensitising agent as such, adequate warnings and precautions have been disclosed within the instructions for use.

24. Disposal

Burs as a cutting instrument regardless of their contamination status should be disposed of as sharps waste. All sharps waste is incinerated and therefore the contamination status is not applicable. In all instances, local guidelines regarding the disposal of medical devices should be adhered to.

25. Instructions for use

The instructions for use is as per Instructions for use_Carbide Rotary Dental Burs (non-sterile).

26. For avoidance of doubt

The following shall not apply to this device:

- Emission of radiation
- Energy source
- Electronics or software
- Measuring features or graduated scale
- Sterile
- Incorporation of biological substances
- Pressurisation or large volumes or weights
- Materials or processes during use liable to cause fire or explosion
- Does not contain substances which are dangerous, taking account of their nature, quantity or form.

Furthermore, this device does not contain any human or animal tissues or their derivatives nor does it contain any substance considered to be medicinal.