

Steel Burs Instructions for Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by a dental professional only.

IDENTIFICATION

Non-sterile, Single-Use Carbon Steel burs are rotary grinding instruments used to work hard tissues/teeth and create cavities in dentine. The part connecting to the contra-angle is manufactured in accordance with the current ISO 1797 (diameter of the counter angle connecting stem: $\varnothing 2.35$ 0/-0.16mm).



Product Name	Perfection Plus Steel Burs
Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK
Company Phone No.	+44 (0) 2380 866 677

PRODUCT CODE - REF

001/9000 Round RA ½ Pk 6	
001/9001 Round RA 1 Pk 6	001/9101 Round RA 1 Pk 25
001/9002 Round RA 2 Pk 6	001/9102 Round RA 2 Pk 25
001/9003 Round RA 3 Pk 6	001/9103 Round RA 3 Pk 25
001/9004 Round RA 4 Pk 6	001/9104 Round RA 4 Pk 25
001/9005 Round RA 5 Pk 6	001/9105 Round RA 5 Pk 25
001/9006 Round RA 6 Pk 6	001/9106 Round RA 6 Pk 25
001/9007 Round RA 7 Pk 6	001/9107 Round RA 7 Pk 25
001/9008 Round RA 8 Pk 6	001/9108 Round RA 8 Pk 25
001/9009 Round RA 9 Pk 6	001/9109 Round RA 9 Pk 25

CONTRA INDICATIONS FOR USE

- Strict Medical Contra-indication: Heart disease at high risk of infectious endocarditis if the pulp is necrotic.
- Relative medical contra-indication: cardiopathy at high risk if infective endocarditis if the tooth is live and cardiopathy at lower risk in all cases.
- The burrs are made of steel; do not use in case of known allergic sensitivity of the patient.
- Tooth without functional failure, cannot be restored in a sustainable way.
- Tooth with insufficient periodontal support.

PRECAUTIONS

- Check burs are in good working order prior to use, there is no damage, deformation, rust or scratches.
- It is essential to follow the cleaning disinfecting and sterilizing stages before use in accordance with the ISO 17664 standard.
- Only to be used by a trained dental professional in a clinical setting.

INSTRUCTIONS FOR USE

- The burs are single use and are supplied non-sterile. It is essential to follow the cleaning disinfecting and sterilising stages before use in accordance with the ISO 17664 standard.
- Remove damaged or poorly performing products.
- The responsibility for the sterilisation of products prior to first use lies with the user.
- For your safety we recommend the use of PPE (Personal Protective Equipment) for example eye protection and gloves.
- Only use disinfectants with proven efficiency (EU labelling, FDA Approved etc.).
- Connect to a contra angle hand piece. Select the most suitable speed and torque.

Sterilization Cleaning Protocol

- If you notice any marks or dirt, start by cleaning the instrument with a wipe or a nylon brush.
- Do not use chlorine based or acid-based cleaning agents, or disinfectants (beware using tap water that is too heavily chlorinated) and avoid any product containing aldehyde, because of the ability of this product to bind proteins.
- Only use disinfectants with proven efficiency (EU labelling, FDA Approved etc.) for example Instrument Forte+ from Helvemed SA.
- Clean, disinfect, rinse and dry the burs using a washer disinfector. (Ensure compliance according to the current EN ISO 15833-1 and follow the manufacturers instruction manual).
- After drying, place the burs in pouches for sterilisation. (Ensure compliance with the current EN ISO 11607-1 standard) such as Protect+ Self Steal Sterilisation Pouches 002/5000.
- Steam sterilise according to the prion program (134°C for 18 minutes) in an autoclave. (Ensure compliance according to the current standard BS EN 13060 + A1 and follow the manufacturers instruction manual especially regarding upkeep and maintenance).
- When sterilizing multiple burs during a single autoclave cycle, be sure not to exceed its maximum load. Avoid sterilizing devices of different materials in the load.



WARNING!

Use with care to avoid any needle stick injury.
Single Use



Caution



Should a serious incident in relation to the product occur, it should be reported to the manufacturer and the competent authority.

STORAGE

It is best to store instruments in their original packaging before use in a clean dry place and apply the “first in/first out” management method. Once sterilised, keep in a cool, clean, dry place.



Dispose of in accordance with current regulations, following the protocol for cross-infection control.

Batch code/Expiry Date

Expected lifetime of a single-use carbon steel bur is estimated at 3 years from the date of manufacture.



Perfection Plus Ltd
6 Westwood Court
Brunel Road
Hampshire
SO40 3WX, UK
www.perfectionplus.com



Perfection Plus EU Ltd
The Black Church
St Mary's Place.
Dublin, Ireland,
D07 P4AX
Regulatory@perfectionplus.com



Advena Ltd
Tower Business
Centre
2nd Floor Tower
Street
Swatar, Malta

