Cavity Access Set

DENTAL USE ONLY

ENDODONTIC ACCESS PREPARATION: DIRECTIONS FOR USE

1) INDICATION FOR USE
These products have to be used only in hospital environments, clinics or dental offices by qualified dental person.

Application field: A set of rotary cutting instruments utilized for initiating, progressively expanding and then finishing the endodontic access preparation. Complete access improves diagnostic, root canal treatment or retreatment success.

Objectives
The access cavity should be prepared so that, when present, all restorative materials and tooth structure, including the entire pulpal roof, are removed. The axial walls are extended laterally such that the orifice(s) are just within this outline pattern. Access objectives are confirmed when all the orifices can be visualized without moving the mouth mirror.

2) CONTRAINDICATIONS
Not known.

3) WARNINGS
• The instruments should not be totally immersed in 5 % sodium hypochlorite for a period exceeding 5 minutes;
• The instruments utilized should not be immersed for more than 15 minutes in a decontamination tray.

4) PRECAUTIONS
• Carefully review different horizontally angulated radiographs to observe the relationship between the clinical crown and the underlying roots. Try to visualize the size and depth of the pulp chamber and if stones are present;
• Auxiliary magnification and lighting devices, such as the dental operating microscope, promote safe, efficient and predictably successful treatment;
• Use new burs, and when appropriate, with a water spray to improve tactile control, decrease heat build-up and the potential for clinical mishaps;
• Use a fulcrum when cutting to avoid skipping and procedural accidents;
• The longer length carbide round burs may be used as side cutting instruments when there is narrow intra-occlusal space;
• Use the long tapered diamond bur (Cavity Access Set) or the Endo-Z (Cavity Access Z Set) to flatten, wippen and finish the internal axial walls. The abrasively coated rounded tip of the tapered diamond bur enables you to precisely finish the pulpal floor too;
• Use the X-Gates, with a brushing action on the withdrawal stroke, to intentionally relocate the canal away from furcal danger.
5) ADVERSE REACTIONS  
A lack of judgment, anatomical knowledge or clinical training or the improper use of any rotary cutting instrument may contribute to iatrogenic dentistry.

6) STEP BY STEP INSTRUCTIONS  
Predictably successful endodontic treatment starts with complete access. There is an old expression „start with the end in mind“. Visualize complete access and select the appropriate rotary instrument for each step-by-step procedure to improve diagnostic, treatment or retreatment success.

6.1) Rotary Instrument Selection  
Carefully inspect the tooth to be endodontically treated to determine if the crown is natural and intact, cariously involved or fabricated with a metal or tooth-colored restorative. The rotary instrument selected is based on the type of material to be removed.

6.2) Tooth Color Restorations  
Use the round bur diamond with a light brush-cutting action and water spray to progressively sand away and eliminate tooth-color restoratives.

6.3) Metal Restorations  
The working end of the Transmetal bur is used to initially cut a small window through metal. Optimally use the lateral side of this instrument to decrease heat, reduce vibration and improve efficient performance.

6.4) Removing Tooth Structure, Caries or Smaller Sized Restorations  
In general, use the long length, smaller-sized carbide round bur to access anterior and bicuspid teeth; whereas, use the long length, larger-sized carbide round bur to access molar teeth. These longer length burs serve to move the head of the handpiece further away from the occlusal table providing an improved line of sight. Use these burs with a light brush-cutting action to move progressively deeper into the clinical crown of a tooth, enter the pulp chamber, then remove all unsupported dentin overlying the pulpal roof.

6.5) Expanding the Access Preparation  
Select the tapered diamond or the Endo Z to expand the access cavity and finish the axial walls so they smoothly diverge from the pulpal floor to the occlusal cavo surface. Please note: the tapered diamond has a parabolic working end that enables you, at slower rpm, to precisely sand away and selectively remove dentin to uncover hidden grooves and orifices, whereas the endo-Z has a non working end that enables you to preserve the original pulpal floor morphology without perforation risks.
6.6) Flaring and Intentionally Relocating the Orifice

Use the X-Gates with a brush-cutting action, at 500-800 rpm, to flare and blend the orifice into the lateral axial walls. Importantly, the shaft of the X-Gates should be arced so the cutting flutes selectively cut dentin on the outstroke and to intentionally relocate the canal away from an external root concavity.

7) DISINFECTION, CLEANING AND STERILIZATION

Reprocessing procedure for dental instruments.

I - FOREWORD

For hygiene and sanitary safety purposes, all instruments must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent ones.

Instruments which are marked as “sterile” do not require any specific treatment before the first use, but have to follow this procedure for all subsequent use if not labelled as “single use”.

II - AREA OF APPLICATION

Disinfection and sterilisation before each use (except for the first use of sterile instruments) and reprocessing procedures concerning:

DESINFECTION AND STERILIZATION

A. Device

A1. Instruments

Cutting instruments, (hand and engine driven) such as:
- Endodontic instruments (files, broaches, reamers, enlargers, endodontic burs, ultrasonic inserts);
- Rotary cutting instruments (Diamond burs, tungsten carbide burs, stainless steel drills, carbon steel burs).

Root canal filling instruments (Pluggers, spreaders, compactors).

Hand instruments, clamps and Rubber Dam accessories.

A2. Accessories

Supports, kits, instrument organisers and other accessories.

DESINFECTION ONLY

B. Filling material and calcinable plastic posts

Only chemical disinfection (no sterilisation), Gutta percha, Obturators, Uniclip and Mooser Calcinable plastic posts.
PRESENT PROCEDURE NOT APPLICABLE

C. Exclusion

• Equipment such as Motors, Apex locators and other devices with reprocessing procedures included in the individual Direction for Use.
• MTA, Glyde, TopSeal, Paper Points, Rubber Dam.

III - GENERAL RECOMMENDATION

1) Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer. For all metal instruments, it is recommended to use anticorrosion disinfecting and cleaning agents.

2) For your own safety, please wear personal protective equipment (gloves, glasses, mask).

3) The user is responsible for the sterilization or disinfection of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterilization.

4) It is safest for the practitioner to use our instruments only once. Should our instruments be reused, we recommend to always carefully inspect them before use: the appearance of defects such as cracks, deformations (bent, unwound), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.

In any case, we recommend not to exceed the following maximum number of uses for our root canal shaping instruments:

<table>
<thead>
<tr>
<th>Type of canal</th>
<th>Stainless Steel instruments with a diameter ≤ISO 015</th>
<th>Stainless Steel instruments with a diameter &gt;ISO 015</th>
<th>NiTi instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely curved (&gt;30°) or S-shaped canals</td>
<td>1 canal max.</td>
<td>2 canals max.</td>
<td>2 canals max.</td>
</tr>
<tr>
<td>Moderately curved canals (10° to 30°)</td>
<td>1 canal max.</td>
<td>4 canals max.</td>
<td>4 canals max.</td>
</tr>
<tr>
<td>Slightly curved (&lt;10°) or straight canals</td>
<td>1 canal max.</td>
<td>8 canals max.</td>
<td>8 canals max.</td>
</tr>
</tbody>
</table>

5) Single use marked devices are not approved for re-use.

6) The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

7) Tungsten carbide burs, plastic supports, hand instruments and NiTi instruments are degraded by Hydrogen Peroxide (H₂O₂) solution.

8) Only the active part of the NiTi Instruments should be immersed in a NaOCl solution at NOT more than 5%.

9) Do not use acid (pH < 6) or alkaline (pH > 8) solutions with aluminium devices. These types of devices are degraded in presence of caustic soda solutions with mercury salt.

10) The washer-disinfector is not recommended for devices made of aluminium, tungsten carbide or carbon steel.
### IV - STEP-BY-STEP PROCEDURE

#### A. Devices

**A3. Contra Angle**

<table>
<thead>
<tr>
<th>Operation</th>
<th>Operating mode</th>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Disassembling</td>
<td>- Disassemble the device, if required.</td>
<td>- Silicone stops have to be removed.</td>
</tr>
</tbody>
</table>
| 2. Pre-Disinfection      | - Soak all instruments immediately after use in a detergent and disinfecting solution combined with proteolytic enzyme if possible. | - Follow instructions and observe concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on instruments).  
- The disinfecting solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor.  
- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the instruments (See general recommendations).  
- For visible impurities observed on instruments a pre-cleaning is recommended by brushing them manually with soft material. |
| 3. Rinsing               | - Abundant rinsing (at least 1 min).                                           | - Use quality water in accordance with local regulations.  
- If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the cleaning. |
| 4a Automated Cleaning with washer-disinfector | - Place the devices in a kit, support or container to avoid any contact between instruments or posts.  
- Put them in the washer-disinfector (Ao value > 3000 or, at least 5 min at 90 °C). | - Discard any instruments with large obvious defects (broken, bent).  
- Avoid any contact between instruments or posts when placing in the washer disinfecter use kits, supports or container.  
- Follow instructions and observe concentrations given by the manufacturer (see also general recommendations).  
- Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly. |
| 4b Manual Cleaning and assisted by an ultrasonic device | - Place the devices in a kit, support or container to avoid any contact between instruments.  
- Immerse in the disinfecting solution with cleaning properties, assisted by an ultrasonic device if suitable. | - No visible impurities should be observed on the instruments.  
- Discard any instruments with large obvious defects (broken, bent, and twisted).  
- Follow instructions and observe concentrations and time given by the manufacturer (see also general recommendations).  
- The disinfecting solution should be aldehyde free and without di- or triethanolamines as corrosion inhibitor. |
| 5. Rinsing               | - Abundant rinsing (at least 1 min).                                           | - Use quality water in accordance with local regulations.  
- If a disinfecting solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the autoclaving.  
- Dry on a single use non-weaved cloth, or with a drying machine or filtered compressed air. |
| 6. Inspection            | - Inspect devices and sort out those with defects.  
- Assemble the devices (stops). | - Dirty instruments must be cleaned and disinfected again.  
- Discard instruments which show any defect as described in the General Recommendation above.  
- Protect carbon steel bur with corrosion inhibitor before packaging.  
- For Contra Angle : lubricate the device with an adequate spray before packaging. |
7. Packaging - Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilisation pouches”. - Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607.

8. Sterilization - Steam sterilisation at: 134 °C / 273°F during 18 min. - The instruments, posts and the plastic supports must be sterilized according to the packaging labelling. - Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Use a validated sterilisation procedure according ISO 17665. - Respect the maintenance procedure of the autoclave device given by the manufacturer. - Use only this recommended sterilization procedure. - Control the efficiency (packaging integrity, no humidity, colour change of sterilisation indicators, physico-chemical integrators, digital records of cycles parameters). - Traceability of procedure records.

9. Storage - Keep devices in sterilization packaging in a dry and clean environment. - Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and validity period).

B. Filling material and calcinable plastic posts

<table>
<thead>
<tr>
<th>Operation</th>
<th>Operating mode</th>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Disinfection</td>
<td>- Immerse the obturation devices in NaOCl (2.5 % at least) during 5 min. at ambient temperature.</td>
<td>- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material. (See general recommendation).</td>
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</table>

Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>EN</th>
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<tbody>
<tr>
<td>🔄 xxxx-xxxx min⁻¹</td>
<td>Recommended rotation speed</td>
</tr>
<tr>
<td>⚠</td>
<td>See directions for use</td>
</tr>
<tr>
<td>🔄 BrowserRouter</td>
<td>Opened packages are not replaced</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch number</td>
</tr>
<tr>
<td>Can not be sold separately</td>
<td></td>
</tr>
<tr>
<td>Diamond</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td></td>
</tr>
<tr>
<td>Symbols</td>
<td>EN</td>
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<tr>
<td>---------</td>
<td>----</td>
</tr>
<tr>
<td>SSSt</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>WC</td>
<td>Tungsten carbide</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>135°C</td>
<td>Autoclavable at the specified temperature</td>
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