

Instructions for Use (IFU) Microbrush Applicators

INTENDED USE:

Microbrush Applicators are single use medical devices that are intended for use in a dental environment. Applicators are utilized during various types of dental procedures for the application of a controlled amount of material in areas of difficult access within the oral cavity.

Microbrush (Ultrafine Size, Superfine Size, Fine Size and Regular Size)

The Microbrush takes the form of a plastic handle composed of proprietary combination of resins and colorants. Feature characteristics of the handle include a break-off portion for user preference, ribbed gripping portion for improved user grip, and a bending portion for access to tight spaces and enhanced ergonomics. The tip of the brush includes various sizes of non-absorbent nylon flocking adhered to a spherical tip to apply various dental products. The Microbrush may be used for applying and removing materials such as resins, cements, etchants, bonding agents, fluoride, hemostatic solutions and conditioners.









Microbrush Original (Superfine Size, Fine Size and Regular Size)

The Microbrush Original takes the same form as the Microbrush listed above. The only differentiation from the standard Microbrush is the handle does not include a break-off portion. The Microbrush Original may be used for applying and removing materials such as resins, cements, etchants, bonding agents, fluoride, hemostatic solutions and conditioners.



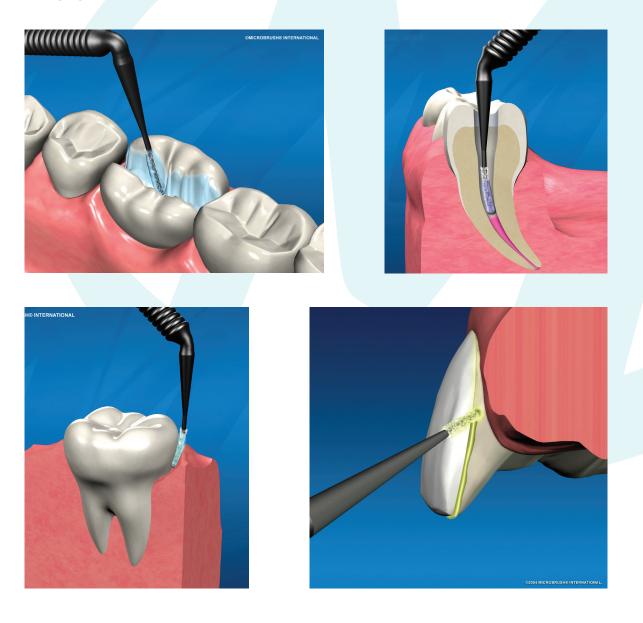






Microbrush X

The Microbrush X takes the same form as the Microbrush listed above. The only differentiation from the standard Microbrush is that the nylon fibers are adhered extending further down the length of the tip for extended reach applications. The Microbrush X is intended for use in bonding posts, inlay/onlay cementation, and perio/subgingival areas.

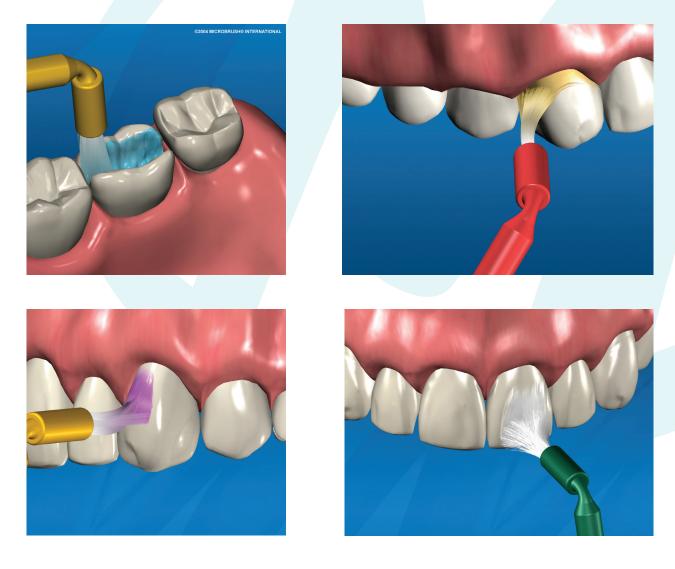




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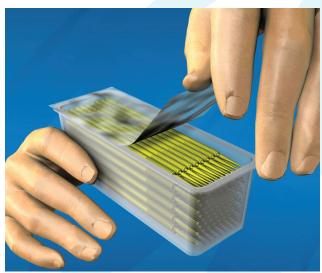
<u> UltraBrush (Bristle Brushes)</u>

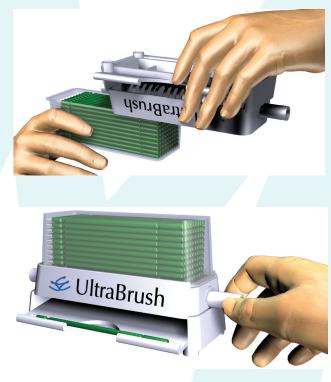
The UltraBrush is a plastic handled applicator composed of proprietary combination of resins and colorants. Feature characteristics of the handle include a break-off portion for user preference, a bending portion for access to tight spaces, and enhanced ergonomics. The tip of the brush is constructed with nylon bristles to apply dental products such as whitening agents, fluoride, etchants, bonding agents, sealants, desensitizers, and resins.





Dispenser The device is packaged in groups and dispensed individually from one sealed.







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Safe Disposal

There are no precautions to be taken against any special, unusual risk related to the disposal of the device. Disposal for local regulations could be done through the general dental waste. This device does not require any unusual storage conditions.

Caution

Microbrush Applicators are designed as a single-use product, should an Applicator be used more than once it is possible the performance of the device may deteriorate. More importantly, the reuse of an Applicator may result in the introduction of microbes into the body due to reuse of the Applicator which may have been contaminated during its first use, which can result in subsequent deterioration in the health of the patient.

This is a disposable product. Dispose of properly after one use. If a single-use product is reused, the device cleaning, decontamination, sterilization or lack thereof can result in cross-infection, alternations, and/or degradations of device material and mechanical function, and the absorption and leaching of cleaning agents or decontaminants.

Warnings and Precautions

This device can be used safely without special warnings or precautions, taking account of the training and knowledge of potential users.

Contraindications:

None.

MFP400 MPD PR400BL P0400TE WMRG100 0TD MFY400 MPX PR400GR PX100 WMRG100-S U2D MSF400 MRA400 PR400-KIT WMFP100 WMRPE100 U1R200 MUT400 PF400 PR400PE WMFP100-S WMRPE100-S U2R200		MSF400	MRA400	PR400-KIT	WMFP100	WMRPE100	U1R200
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