

Instructions For Use (IFU)

MICROBRUSH APPLICATORS

Manufacturing Facility:

Microbrush International
1376 Cheyenne Ave.
Grafton, WI 53024
United States
Tel: 866-866-8698
www.microbrush.com

Intended Use:

Microbrush Applicators Device Description

Microbrush Applicators are single use, non-sterile Class I medical devices that are intended for use in a dental environment by dental professionals. Microbrush Applicators are utilized during dental procedures for the application of a controlled amount of material in areas of difficult access within the oral cavity. Due to its nature Microbrush Applicators are considered invasive but not implantable and they are not intended for use in combination with other devices or equipment. These devices do not have contraindications when used as directed. The applicators enable the dental professional to utilize and control the applicators by applying pressure by hand without risk of injury in connection with their physical features, including volume/ pressure ratio, dimensional and where appropriate ergonomic features. These devices do not need calibration or installation and do not need additional consumables. After its use the device can be disposed in normal dental operatory waste.

The device is manufactured and packaged under controlled conditions. Microbrush applicators do not contain medicinal substances, tissues, cells or any materials of human, animal or biological origin; The device has no substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), The device has no substances having endocrine-disrupting; they are constructed of a proprietary combination of polymers, fillers, colorants and process aids, epoxy adhesive, filament fibers and do not contain substances that could cause combustion, flammability or explosions.

The device is not composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action.

The device is packaged in a plastic case which is sealed with a 5 year shelf life. Kraft paper is used as a fill once it's being placed into a card board shipper box. These devices are non-sterile; therefore the label does not state to sterilize before use and between uses.

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.

Risk Statement

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.

Caution

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.

Languages

English, French, Italian German, Dutch and Spanish

Warnings and Precautions

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

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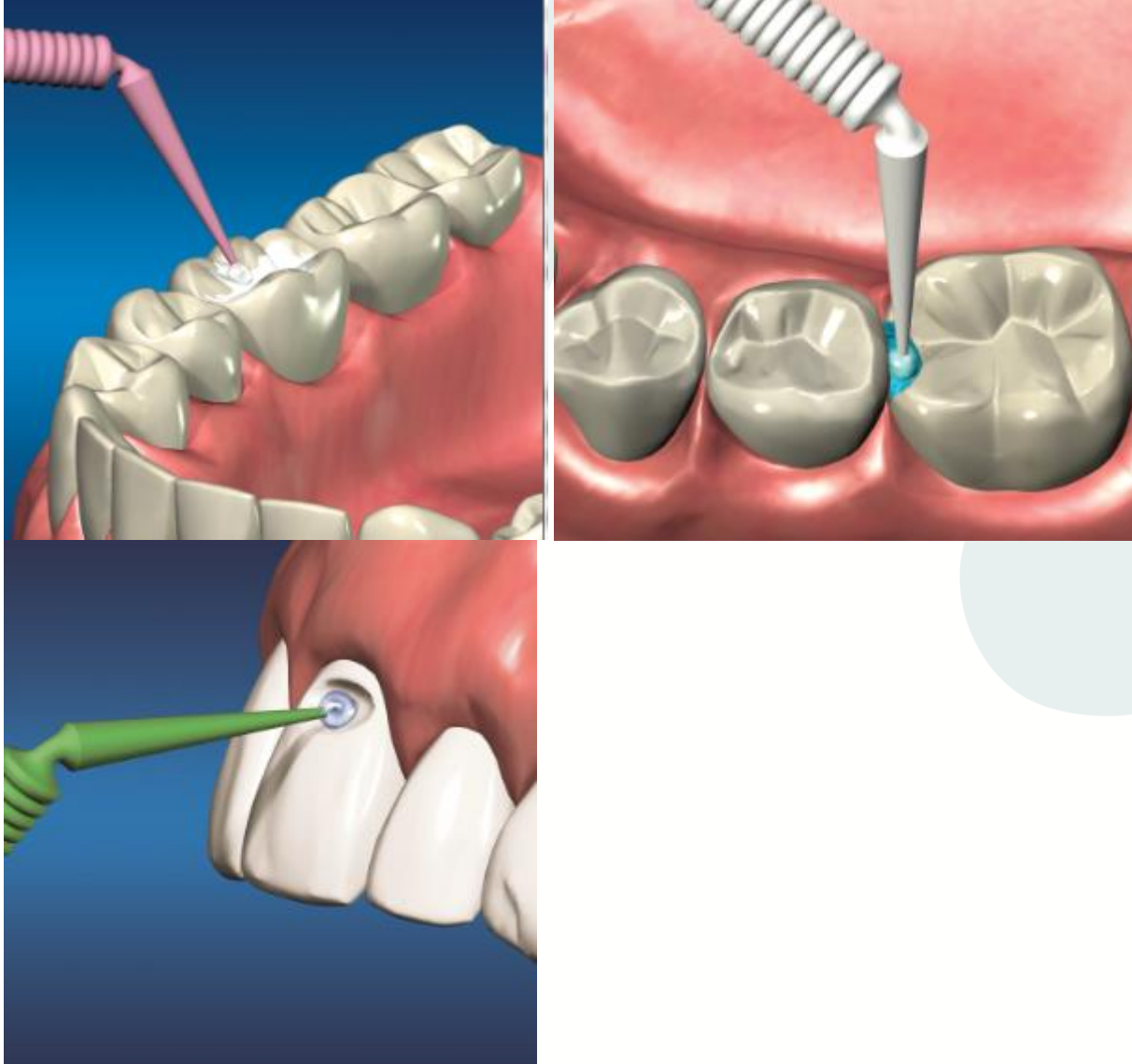
The IFU is available upon request and it is also available electronically in the following websites:

www.microbrush.com

www.microbrush.eu

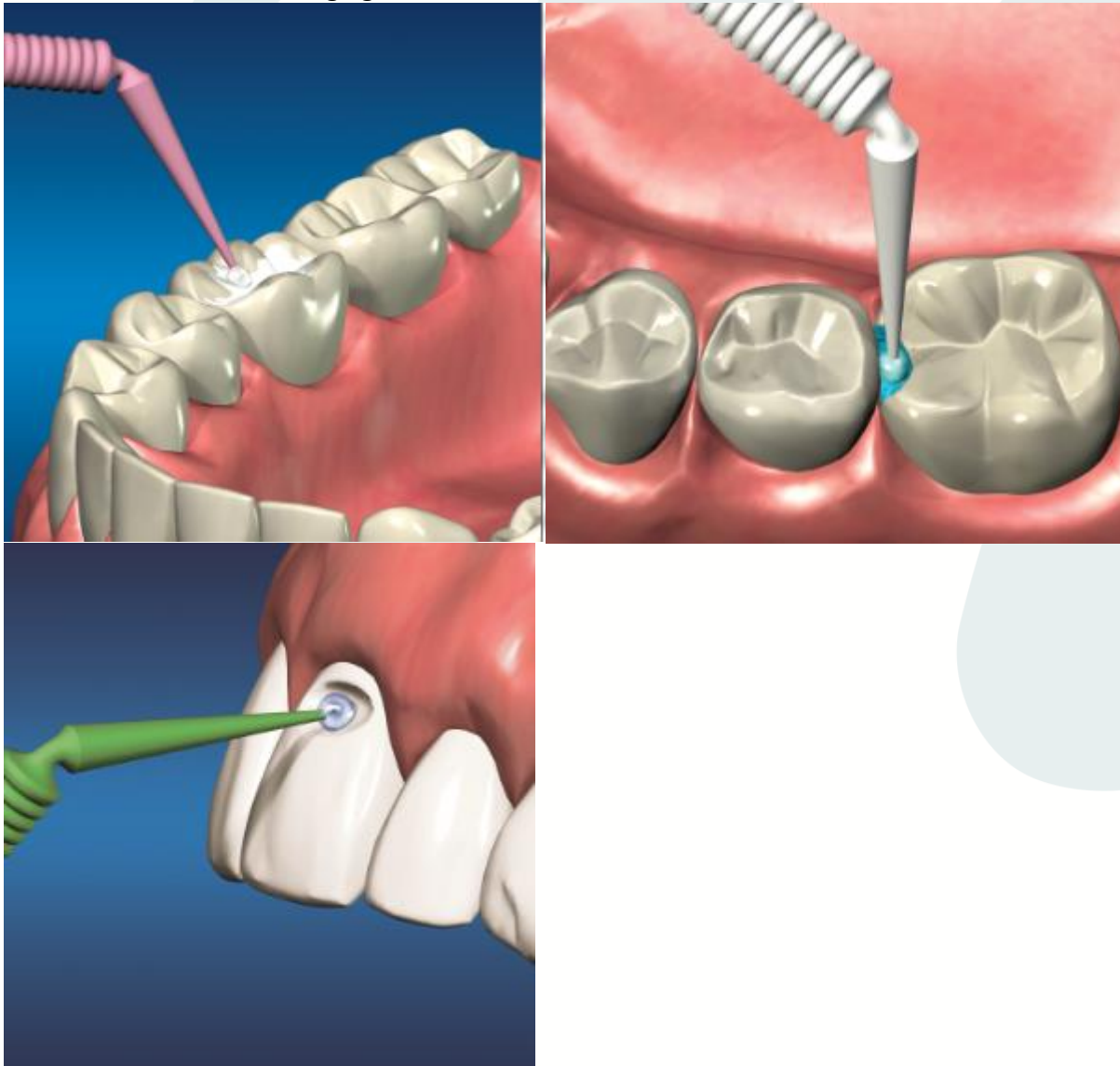
Microbrush (Ultrafine Size, Superfine Size, Fine Size and Regular Size)

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.



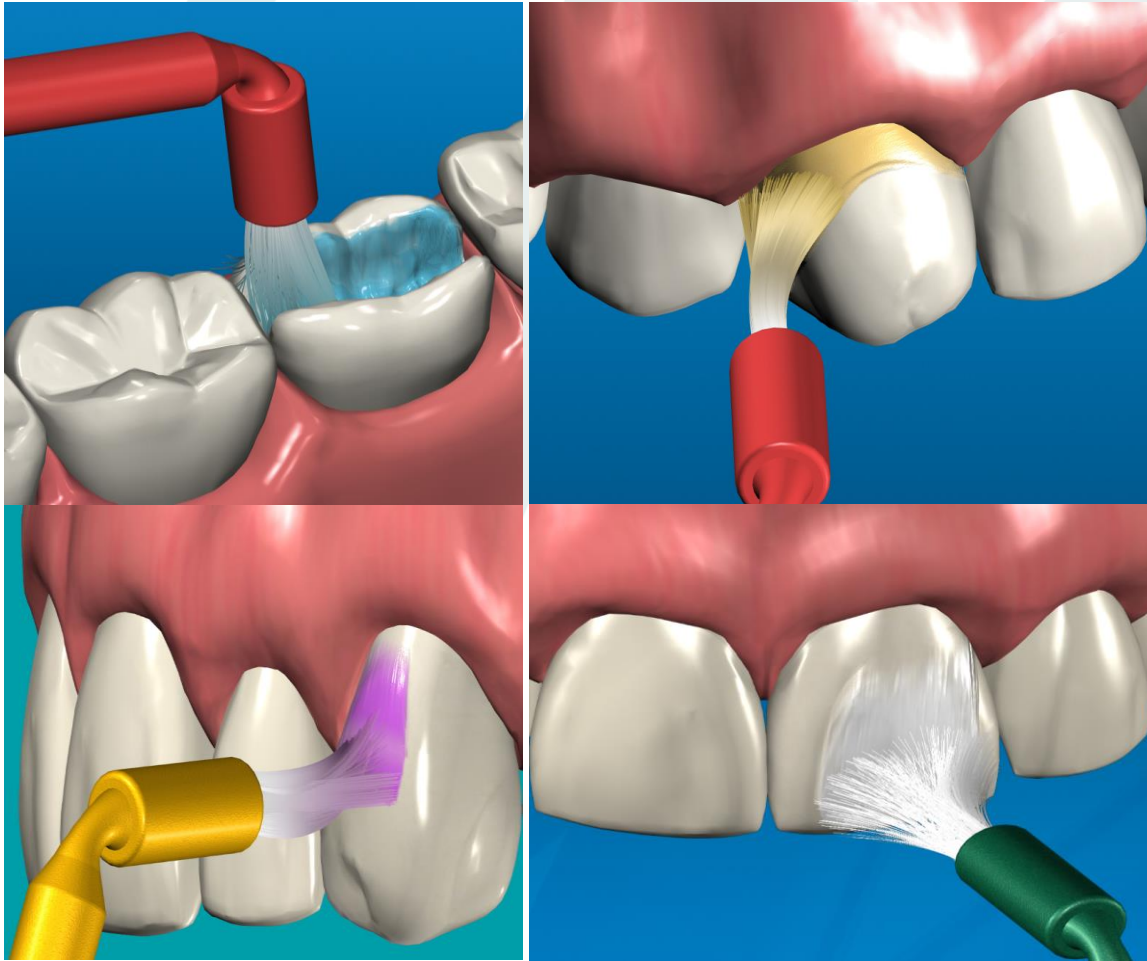
Microbrush X

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.



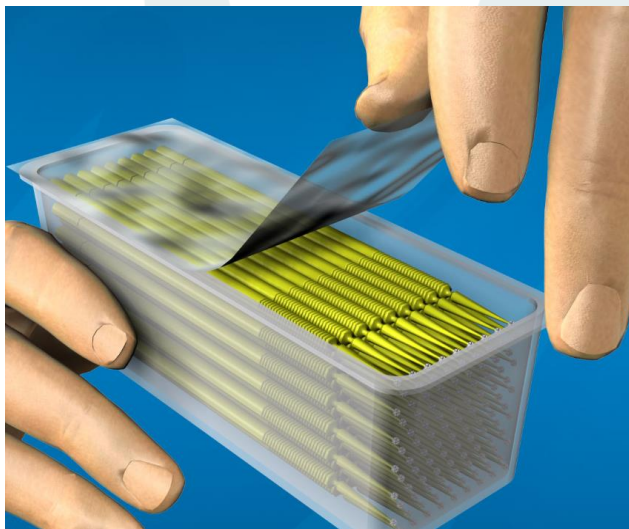
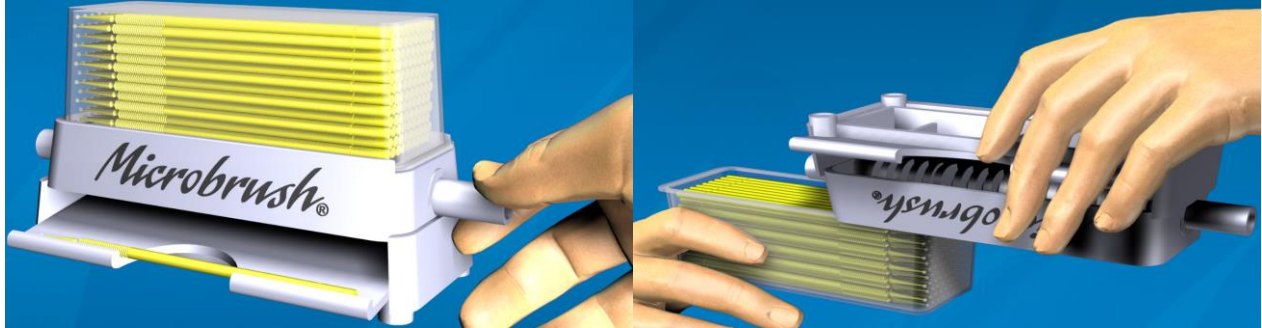
UltraBrush (Bristle Brushes)

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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Made in USA



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