OsteoRemedies®
ADVANCED MEDICAL TECHNOLOGIES

Surgeon Information

BioBrush™ Powered Debridement Device

CAUTION: U.S. Federal Law restricts this product to sale by or on the order of a physician or hospital.

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INSTRUCTIONS FOR USE

Description

The BioBrush is intended for the debridement of the surface of implants, necrotic soft tissues, and bone in surgically invasive wounds. The brushes are intended for use in any applicable patient anatomy and may be used in the presence of infection. The bristles are composed of nylon and fixed with epoxy to a metal shaft intended to be used with a powered rotary handpiece. A plastic (Delrin) handle that freely rotates is affixed to the metal shaft. The BioBrush is packaged as a large rigid brush. The product is individually packed and sterilized via ethylene oxide (EO) sterilization. BioBrush is intended for SINGLE USE ONLY. The BioBrush must not be re-sterilized once the packaging has been opened or reprocessed after initial use. The products are sterile unless the packaging has been opened or damaged.

Intended Use

The BioBrush is intended for the debridement of the surface of implants, necrotic soft tissues, and bone in surgically invasive wounds. The brushes are intended for use in any applicable patient anatomy and may be used in the presence of infection. The brushes are intended to be powered by a compatible surgical rotary handpiece.

Contraindications

The BioBrush is not designed or sold for any use except as indicated. The device should not be used on a rotary handpiece setting other than “REAM”.

Warnings

The entire device is sterilized by EO. Contents of this package are STERILE unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded. Device is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the device.

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Precautions

- Do not use device with Zimmer X Series™ Power System Standard Reamer Attachment.
- Do not leave device in wound.
- Do not use in more than one surgical wound.
- Do not use this product in patients with a known intolerance or allergy to one or more of the device components/materials.
- Do not modify device geometry.
- Do not use in proximity to blood vessels, nerves and other vital structures.
- Device has been tested for continuous use up to 3 minutes, not to supersede manufacturer’s guidance on rotary hand-piece IFU.
- Excessive or incorrect use may result in bristle shedding.
- It may not be possible in every situation to fully debride all desired surfaces.
- Use on fistulae with unclear connections must be performed with particular caution
- Avoid exerting excessive pressure on the wound as this could cause the patient pain, entanglement of vessels, implant damage, or soft tissue damage.
- Nylon bristles are radiolucent.
- Ensure user’s hand does not contact rotating parts. The user should only contact handle during use.
- Do not use on sutures or intact skin.
- Do not apply excessive force to brush.
- Do not use on sharp edges/surfaces.
- Do not force into tight spaces.

Potential Adverse Reactions

In very rare cases, allergy or skin irritation may develop.
Note: Device is not made with Latex.

Surgical Technique

Surgical Prep

NOTE: All procedures should be performed in the Operative Room under aseptic conditions. Refer to the rotary handpiece (large bone) manufacturer’s IFU manual for system sterility and setup. Select the corresponding manufacturer’s adjustable keyed chuck that accommodates up to a ¼ inch (6.4mm) shaft for use in ***Step 1.*** Use sterile technique to open the Tyvek® POUCH and provide the devices into the sterile field.

1. Select the desired size brush for insertion into the rotary handpiece’s keyed chuck. Insert until fully seated. Tighten the adjustable keyed chuck using a chuck key and verify the device is firmly in place and in-line with drill axis.

2. Turn the rotary handpiece to REAM setting,
- **a.** Check security of attachment with drill before use on patient by spinning brush inside sterile field.

3. Debride by applying the rotating brush brush head to the wound, soft tissue, bone, or implant as shown in Figure 1.
- **a.** If necessary, the brushes can be disposed of and replaced with a new set of brushes.

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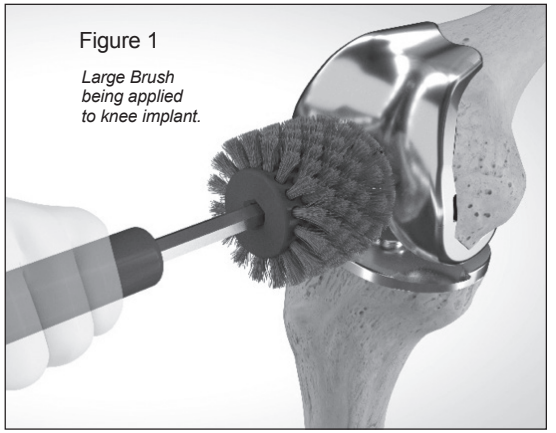


Figure 1

Large Brush being applied to knee implant.

Note: When debriding hard-to-reach areas, visualize the brush at all times to ensure you can anticipate the location where the brush is being placed. Start the brush rotation before applying to the area for debridement.

4. Repeat ***Step 3*** as necessary until thorough debridement is achieved. Following use, dispose of brush and packaging in accordance with local biomedical waste regulations.
- **a.** DO NOT REUSE

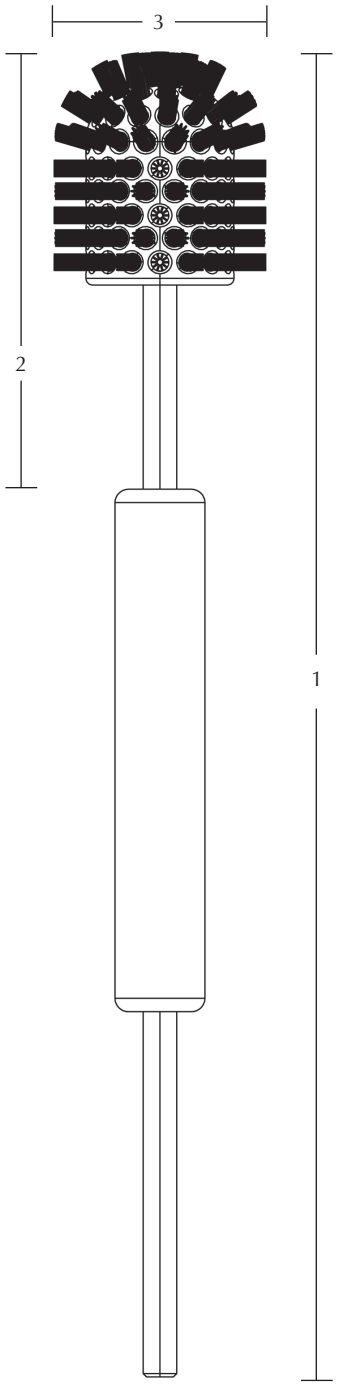
STORAGE CONDITIONS

Optimum storage conditions:
- 15-30 °C (59 - 86 °F)
- In a secure and dry environment

SHELF-LIFE / DISPOSAL

The expiration date is printed on the label. DO NOT USE AFTER EXPIRATION DATE. Disposal of the unused device should be in accordance with local waste regulations. No special disposal is necessary. DO NOT REUSE.

4



Qty. 1

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Description		Powered Debridement Device
Catalog #		DDBK02
(mm)	1	252
	2	84
	3	42

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Manufactured By:

OsteoRemedies®
ADVANCED MEDICAL TECHNOLOGIES

6800 Poplar Avenue | Suite 120 | Memphis, TN 38138
901.453.3141 | info@OsteoRemedies.com | OsteoRemedies.com