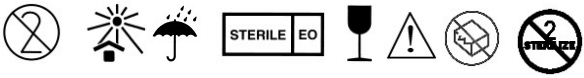
Algerbrush Burrs

ALT I021 Issue 11/0123



Intended Use	Used with an Algerbrush Machine to grind out rust rings left from metallic foreign bodies that have penetrated the cornea. The Algerbrush Burrs are connected to the Algerbrush Handpiece by the use of an Accessory called a Chuck. The Alger brushburrs make contact with rust rings in the cornea and slowly grinds them out.
Indication(s)	Rusty ferrous corneal foreign bodies embedded in the cornea
Sterility	The sterile devices are supplied sterile and single use and are not designed to be reprocessed or reused. Reprocessing may alter the structure and surface of the device and affect the performance and safety in use causing possible harm to the patient. Incorrect handling and reprocessing will also increase the risk of cross contamination and infection.
Intended Patient Group(s)	Patients with rusty ferrous corneal foreign bodies. Burrs contain nickel, do not use on patients with known allergic sensitivity to this metal as this may cause hypersensitivity.
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel. A new sterile burr should be used for every patient. Only suitably qualified personnel who have been trained on the Algerbrush Machine should use these devices in a low distraction environment. Examination by slit lamp should confirm that the corneal foreign body is superficial with no sign of penetration. If penetration is suspected, appropriate investigation and treatment should be instigated. Advance the drill obliquely to the anaesthetized eye so that the side of the burr works on the cornea until all the rust stain has been removed. If the rust ring does not come off easily, use an antibiotic ointment (if deemed appropriate) and let the epithelium heal over. After three days, the cornea will soften then try again. Advise patient that they will have a new abrasion which may cause soreness, they will need to restart the topical antibiotic. If the injury is in the pupillary aperture, it may produce glare or a slight decrease in vision. Care should be taken with deep centrally placed rust rings in line with the visual axis. In these cases, over-zealous debridement which breaches the sub-epithelial Bowman's layer can lead to permanent scarring and visual loss.
Clinical Benefits & Performance Characteristics	During metal working procedures such as welding, sanding, or grinding, it is possible that a welding spark / piece of metal can be ejected from the machine into the patient's cornea. If this occurs, it is essential that all traces of the foreign body and resulting rust are removed. The Algerbrush has been specially designed to remove rust spots from a patient's cornea. Motor will stop rotating if too much pressure is applied. The gentle slow rotation rate provides easy control. The high quality, cold-chisel-edges of the carbide steel on the Algerbrush Burrs provide a good clean surgical area and help to speed up the healing process. Operates with a normal AA battery and low amperage motor means longer battery life. Repairable.

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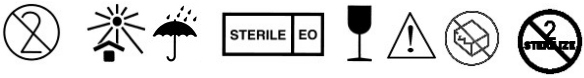

Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water.
Contraindications	Burrs contain nickel, do not use on patients with known allergic sensitivity to this metal as this may cause hypersensitivity.
Warnings and Precautions	• Only for use on Algerbrush rust ring remover machine, Altomed ref: A4955. • Burrs contain nickel, do not use on patients with known allergic sensitivity to this metal as this may cause hypersensitivity. • Burrs are delicate devices and must be handled with care. Do not drop or bang against hard surfaces as this may damage the tip. • The Chuck and Burr are held on by friction, if too much pressure is applied the Burr will stop rotating. • Point Burr away from body and hands when removing to prevent accidental stabbing injury. • Carefully follow the instructions for use supplied with your Algerbrush Machine. If you have lost the instructions for use, please contact Altomed for a replacement. Select either the Standard or Large burr depending upon the size of the rust ring. • Check the Peel Pouch to make sure it has not been damaged in any way, e.g., check for wet patches, splits and tears etc. If the Peel Pouch is damaged do not use the Burr. • All Burrs are inspected before supply however it is recommended to inspect the Burr before use to ensure no physical damage has occurred after packing e.g., check for chips, loose metal fragments, staining and any other damage to the tip etc. • Use hospital approved (PPE) glasses to prevent cross contamination or unwanted debris coming into contact with your, or the patient's eyes. Use approved (PPE) medical gloves at all times when handling the burr.
Residual Risks & Undesirable Side-Effects	Whilst undesirable side effects are possible, (i.e. corneal damage and scarring) these relate to the surgeons skill and the anatomy of the patient. This cannot be designed out.
Additional Safety Information	To Remove a Burr: 1. Remove the Chuck and Burr from the Housing - Grasp the base of the Chuck with your fingers and pull it away from the Housing. If the Chuck cannot be pulled off by hand, slip a small flat bladed screwdriver (or similar) between the Chuck base and the top of the base unit. Very GENTLY twist in order to pry off the Chuck. 2. Remove the Burr - Hold the base of the Chuck and pull the Burr straight out from the lumen.

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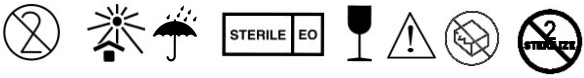
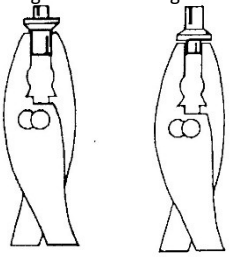


	3. If stuck, use a pair of old Artery Forceps (or similar) and grasping the shaft of the Burr, pull straight out from the lumen. To Install a Burr: 1. Ensure the old Burr has been removed and the Chuck is separated from the Base Housing. 2. Remove the Sterile Burr from its packing, inspect as described above in Before Use, and push into the longer lumen of the chuck 3. Ensure the Burr is snug in the bottom of the lumen, if necessary, use a pair of Artery Forceps or similar. 4. Switch on the machine and then gently push the new Burr and Chuck assembly onto the motor shaft. The shaft will stop rotating when pressure is applied. You should feel some resistance, if not see On-Site Repairs below. **5.** The lip of the Chuck should be close to, but not touching the Housing. Ensure that the Chuck is secure, rotates freely and is on straight, i.e., not out of alignment. **On-site Repairs** If the Burr and/or Chuck are too loose, tighten the Chuck with a small pair of stainless-steel pliers as follows: If Burr is loose: Gently pinch base of Chuck Burr Lumen (see Fig. 1) If Chuck is loose on the Motor Shaft, gently pinch the other side of the Chuck. the Motor Shaft Lumen (see Fig 2). Return any faulty Algerbrush Machines to Altomed for repair. Fig 1 Fig 2 
Disposal Considerations	After use, used Burrs must be disposed of immediately in a Yellow Sharps Bin to avoid the risk of accidental re-use. It is not recommended to reprocess these devices due to their size and delicate nature and the increased risks of cross contamination and physical damage to the device causing patient harm. Reuse may result in decreased cutting efficiency,

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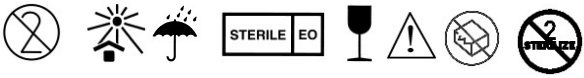

	device failure, patient discomfort, tissue necrosis, cross contamination, and infection.
In the event of an incident or defective device	If any serious incident has occurred in relation to the device, the user and/or patient should be report it to the manufacturer at the contact details below, and the competent authority of the Member State in which the user and/or patient is established (refer to https://ec.europa.eu/health/md_sector/contact_en)

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