Disposable Arthroscopic Shaver Blades, Burrs, PowerPick™, PoweRasp™, NanoResection™ and ShaverDrill™ Devices

DFU-0215-EO Revision 1 CE 2797 **2023-01**

Important Product Information

Symbols glossary can be found at www.arthrex.com/symbolsglossary.

A. DEVICE DESCRIPTION

Arthrex disposable arthroscopic shaver blades, burrs, PowerPick, PoweRasp, NanoResection and ShaverDrill devices (collectively “devices”) are rotary or reciprocating cutting devices for use in arthroscopic surgical applications for the resection of soft tissue and bone. With the exception of PowerPick and ShaverDrill devices, resected tissue is removed from the surgical site by suction through the inner lumen of the device. The PowerPick and ShaverDrill devices are used to drill into osseous tissue.

These devices are made of surgical stainless steel and are available with a variety of cutting window and burr configurations, as well as straight, curved, FlushCut™, ClearCut™, PowerPick, PoweRasp, NanoResection, and ShaverDrill device styles.

B. INDICATIONS

These devices are indicated for resection of soft and osseous tissues in both large and small articular cavities during arthroscopic procedures.

C. CONTRAINDICATIONS

1. Use in a surgical procedure for a patient where an arthroscopic procedure is contraindicated for any reason.
2. Insufficient quantity or quality of bone.
3. Blood supply limitations and previous infections, which may retard healing.

4. Any active infection or blood supply limitations.
5. Do not use for surgeries other than those indicated.

D. ADVERSE EFFECTS

1. Additional damage to tissue from excessive force during use.
2. Infections, both deep and superficial.

E. ⚠ WARNINGS

1. ⚠ Caution: Federal law restricts this device to sale by or on the order of a physician.
2. ⚠ This device is intended to be used by a trained medical professional.
3. Do not re-sterilize this device.

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4. A device labeled as a single-use device must never be reused. Reuse may pose health and/or safety risks to the patient that can include, but are not limited to cross-infection, breakage resulting in irretrievable fragments, compromised mechanical performance due to wear, lack of or no function, no guarantee of proper cleaning or sterilization of the device.
5. Failure to use this device in accordance with the directions for use below may result in device failure, render the device unsuitable for its intended use, or compromise the procedure.
6. Detailed instructions on the use and limitations of this device should be given to the patient.
7. Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment, should be safely disposed of in accordance with the institution's policy.
8. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

F. PRECAUTIONS

1. Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or contact your Arthrex representative for an onsite demonstration.

2. Surgeons must apply their professional judgment when determining the appropriately sized device based on the specific indication, preferred surgical technique, and patient history.
3. Reuse may result in patient infection and/or device malfunction.
4. Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
5. Arthrex disposable arthroscopic devices are packaged as a set. They must be used as supplied. Do not interchange any device components except when using hoodless sheaths with their respective size burr.
6. Do not allow the rotating portion of any device to touch any metallic object, such as a cannula or arthroscope, during use. Damage to both devices is likely. Damage to the device can range from a slight distortion or dulling of the blade/burr edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If there are cracks, fractures or dulling, or if there is any other reason to suspect a blade is damaged, replace it immediately.
7. Excessive "side-loading" on the device during use does not improve cutting performance and in extreme cases will cause irreversible damage to the device.
8. Excessive “loading” on the PoweRasp device will disengage the cam mechanism and stall the cutting effectiveness.
9. Irreversible damage to all devices will result if they are run without the flow of irrigation (dry).
10. Running the device without the flow of irrigation (dry) will cause the device to excessively heat and may cause a thermal burn.
11. All Arthrex disposable arthroscopic devices are preassembled, packaged sterile, and ready for use. Irreversible damage will result from any attempt to disassemble curved blades, FlushCut burrs, ClearCut burrs, PowerPick, and PoweRasp devices.
12. If disassembly of straight devices is required to remove a clog, care must be taken to prevent damage to the Teflon tubing on the inner tube during re-assembly.
13. A thrust washer on straight burrs can be dislodged if disassembly is required to remove a clog, the thrust washer must be snapped onto the inner hub prior to re-assembly in order to prevent damage during use.
14. Forcing the hood of any burrs, including FlushCut burrs and ClearCut burrs into anatomically tight spaces can cause the burr tip to collide with the hood and render the device inoperable.

15. PowerPick device tips can bind in bone and render the device inoperable if the device is stopped while inserted in bone and/or if the angle of the rotating tip is changed while drilling. Make sure handpiece is off while changing device tip position.
16. After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
17. The cutting surface of the disposable is sharp and my cause injury.

G. PACKAGING AND LABELING

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service at +1 800 934-4404 if the package has been opened, altered or damaged.

H. STERILIZATION

This device is provided sterile. Check the package labeling for more information. This device should never be re-sterilized under any conditions.

I. STORAGE CONDITIONS

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

J. INFORMATION

1. **In CE Accepting Countries:** Procedures carried out using these devices may be used on the general population.
2. **In CE Accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.
3. **In CE Accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

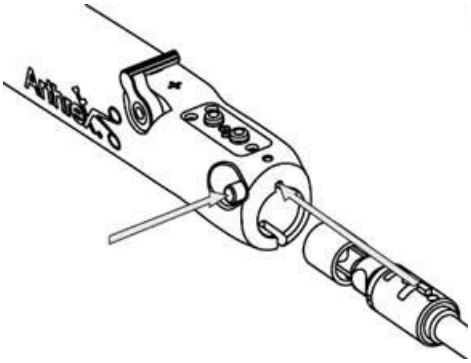
K. DIRECTIONS FOR USE

To remove a disposable arthroscopic blade from its sterile package, peel TYVEK™ seal off device tray and proceed with instructions below.

I. Device Insertion and Removal

For use with hand-controlled and non-hand-controlled handpieces:

1. To insert a disposable device, insert the device into the handpiece so that the plastic tab mates with the handpiece slot. The tab should be pushed in proximally as far as possible for a positive lock.



2. To remove a device, depress the button on the handpiece using a thumb or fingertip. This will disengage the device from the hand piece.
3. If the device does not lock in place; remove the device, rotate the inner hub slightly to align the hub with the output of the motor and reinsert in the handpiece for a positive lock.

Note: Refer to the DFU-0154-XX for detailed Instructions for Use regarding handpieces.

L. WARRANTY

This product is warranted to be free from defects in material and workmanship.

M. CONTACT INFORMATION

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the health authority where the incident occurred.

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