



US

INSTRUCTIONS FOR USE

Premier® Uni-Punch®

Seamless Disposable Biopsy Punch



Intended Use:

To remove a small section of dermal tissue including deep layers (epidermis, dermis and superficial fat) with a minimum of damage to the surrounding tissue.

Device Description:

Premier's Uni-Punch has a circular, hollow blade attached at the working end of the pencil-like handle. The ribbed handle provides firm, secure grip during tissue extraction. The instrument is available in eight (8) different sizes to meet clinical sample requirements. The Uni-Punch is provided sterile. Method of sterilization is ETO (Ethylene oxide).

Contraindications:

Do not use Premier Uni-Punch under the following conditions -

- Visible evidence of damage or debris on handle or circular blade.
- Reuse on different patient.
- Invasive cancer that is visible on examination.
- Bleeding disorders and anti-coagulative medication use.

PRECAUTIONS:

- Intended for single patient use only. Do NOT reuse.
- Device is sterilized, prior to packaging.
- Do not use if the package is damaged/broken, prior to use.
- Discard device, if any cracks/fractures are noticed on the handle.
- Medical professionals and assistants should always wear appropriate personal protective equipment (PPE) when performing skin biopsy procedure.
- Do not apply excessive pressure, as this could generate slight pain.
- Prescription device, Rx only.

WARNINGS:

- Device sterility cannot be guaranteed, if package is broken/damaged prior to use.
- Extra care should be taken while handling the device from coming in to contact with contamination.
- Minimal bleeding may be noted after the procedure.

ADVERSE EVENTS:

- Soreness or tenderness at the treatment site.
- Permanent scarring

 Manufacturer:
Premier® Medical Products Company
1710 Romano Drive,
Plymouth Meeting, PA 19462 U.S.A.
888-670-6100 • 610-239-6000
premiermedicalco.com



premiermedicalco.com/promise

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Contents and Setup:

Blade size (mm)	Item number	
	Box of 25	Box of 50
1.5	9033509	Not available
2.0	9033502	9033512
2.5	9033511	9033521
3.0	9033503	9033513
3.5	9033510	9033520
4.0	9033504	9033514
5.0	9033505	9033515
6.0	9033506	9033516
8.0	9033508	9033518
Assorted	9033525	Not available

Materials:

Component	Material
Circular Blade	ASTM 300 series Stainless Steel
Handle Shaft	polyethylene

Directions for Use:

1. Based on the patient's anatomy, test specifications and clinical preference, select the appropriate sized Uni-Punch.
2. Firmly press the sterile biopsy punch into the anesthetized site from which a specimen is desired. While continuing to exert pressure, twist the punch first clockwise and then counter clockwise to the appropriate depth of subcutaneous tissue.
3. It is most likely that the separated dermal tissue will need to be lifted with a pair of forceps after removing the punch. Scissors may be needed to cut beneath the sample to complete the excision.
4. The tissue lodged inside the cone can be extricated directly or by pushing through the hollow handle with a sterile instrument.

Storage:

- Device should be stored in a dry moisture-free area.
- Device storage and handling temperature should not exceed (37.7° C) 100° F.

Shelf Life:





Premier Uni-Punch have an indefinite shelf life.

Disposal:

Dispose the device as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

For Further Information:

Please visit premiermedicalco.com

Symbols	Symbol Meaning
	Manufacturer
	Batch number
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Sterile
	Do not reuse.