

INDICATIONS FOR USE

MAT-101-4000

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SmartShot[®]
MARROW ACCESS DEVICE

Marrow Access Technologies SmartShot[®] Marrow Access Device is a single-use disposable tool for stimulating marrow for the treatment of small localized articular cartilage defects of the knee, shoulder, hip, ankle, wrist or elbow.

PATIENT POPULATION

The patient population most likely to benefit from the Marrow Access Technologies SmartShot instrument is the same as that targeted for any bone marrow stimulation technique.

FACTORS	BETTER RESULTS WITH:
Age	<40 years
Duration of Symptoms	<12 Months
Lesion Size	Up to 2x2cm
Lesion Depth	<5mm
Body Mass Index	<30kg/m ²
Preoperative activity level - Tegner score	>4 (Better with higher preoperative activity levels)
Mechanical Alignment	Normal
Joint Anatomy	Normal
Joint Stability	Ligamentously stable with adequate muscle strength

WARNINGS AND PRECAUTIONS

THE SURGEON SHALL BE THOROUGHLY FAMILIAR WITH THE INSTRUMENTS AND MICROFRACTURE SURGICAL TECHNIQUE PRIOR TO PERFORMING THE PROCEDURE.

ALWAYS USE THE LEVER TO RETRACT WIRE.

APPLY FIRM PRESSURE WITH BOTH HANDS BEFORE FIRING.

DO NOT OVERTORQUE DEVICE WHILE CANNULA IS PLACED IN THE JOINT SPACE.

POSSIBLE ADVERSE EFFECTS

Complications reported with microfracture surgery include general surgical complications (infection,

blood clot, incisional irritation). Complications specific to the microfracture technique are poor tissue differentiation or repair, and osteophyte formation.

STERILIZATION

The Marrow Access Technologies SmartShot Marrow Access Instrument is provided STERILE, SINGLE USE via exposure to ethylene oxide.

Do not resterilize or reuse SmartShot. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device.

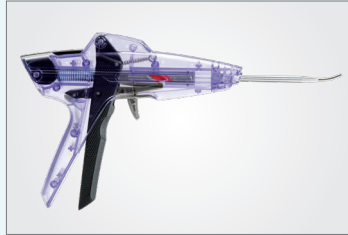
Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.

HOW TO USE THE SMARTSHOT MARROW ACCESS INSTRUMENT:

Treatment using the Marrow Access Technologies SmartShot Marrow Access Instruments will typically be accomplished as part of an arthroscopic or minimal access surgical procedure. No specific or unique surgical incisions are required. The SmartShot Marrow Access Instrument is packaged on a tray in a sterile barrier bag.



1 Unarmed. The instrument is first armed by squeezing the black handle, the wire will retract into the distal tip.



2 After arming, position the distal tip of the instrument at the target site.

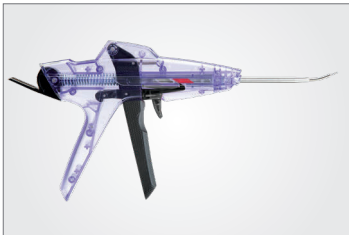


3 Apply firm pressure and fire the instrument by pulling the small trigger, penetrating the wire into the bone.

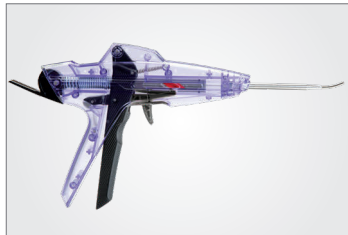


4 The instrument is then repositioned to create additional penetration sites.

DISPOSAL



1 Dry-fire the device safely away from the patient, then release cam to de-charge the spring.



2 Pull black lever to retract wire into the tube.



3 Dispose the device according to the facility's standard procedures for handling biohazard waste materials.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

STORAGE

Store in a cool, dry area.

STERILE EO

Sterile



Do Not Reuse



See Instructions for Use



Use by Date



Single Sterile Barrier System



Don't Get Wet



Store at This Temperature Range

Rx ONLY

Prescription Only



Do Not Use if Package is Damaged



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