



## **INDICATIONS**

The Rotium™ Bioresorbable Wick is intended to be used in conjunction with suture anchors for the reattachment of tendon to bone in rotator cuff repairs.

## **PRODUCT DESCRIPTION**

The Rotium™ Bioresorbable Wick is an accessory to be used in conjunction with suture anchors for rotator cuff repair (see the Tables included at the end of this document). The wick is placed between the bone and the tendon and is designed to facilitate tendon-bone attachment. The wick is an electrospun, non-woven, microporous, microfiber matrix. The wick is made from two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA). The device is supplied gamma-sterilized. The device is single use only. The Rotium™ wick is provided as a 2 x 2cm sheet (FG-0007).

## **CONTRAINDICATIONS**

- The Rotium™ wick is not indicated for surgical procedures other than those listed in the INDICATIONS section.
- The Rotium™ wick is not indicated to be used without orthopedic suture anchors in surgical rotator cuff repair.
- The Rotium™ wick is not indicated for use in the presence of infection.
- The Rotium™ wick is not indicated for use in patient conditions including insufficient quantity and/or quality of bone or soft tissue.
- The Rotium™ wick is not indicated for use in patient conditions where insufficient blood supply or previous infections may hinder the healing process.
- The Rotium™ wick is not indicated for use in the presence of foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.
- The Rotium™ wick is not indicated for use in conditions which may limit the patient's ability or willingness to follow postoperative care instructions.
- The Rotium™ wick is not indicated to replace damaged tendon.
- The Rotium™ wick is not indicated to be placed over the rotator cuff tendon.

## **WARNINGS**

- The Rotium™ wick should only be used in the intended applications. Use of the device outside of the intended application may result in unforeseen adverse effects and complications.
- A surgeon should not begin clinical use of the device without reviewing the instructions for use.
- Additional precautions include those applicable to any surgical procedure. Careful attention must be devoted to avoiding all surgical hazards (but not limited to) infection, neurovascular damage, excessive tourniquet time, thermal/frictional trauma to cutaneous structures, improper implant position, an inappropriate implant deployment.
- Compatibility of the device has only been verified with size #2 sutures and tape-style sutures composed of UHMWPE.
- Do not place more than two holes in a single Rotium™ wick.

## **WARNINGS Cont.**

- Avoid any permanent crushing and deformation of the Rotium wick during entry and advancement through arthroscopic cannulas. Do not attempt to pass the device through arthroscopic cannulas of less than 6mm inner diameter.
- Sharp instruments or rough handling can result in damage to the Rotium wick
- The Rotium device should not remain folded over itself or rolled up when placement is complete

## **PRECAUTIONS**

- Do not trim the device.
- Proper placement of the implant is a critical determinant of successful outcomes with this device.
- Do not use the Rotium™ wick if the packaging is damaged or if the seal on the packaging is broken prior to use.
- The Rotium™ wick is supplied sterile. This packaging will serve as an effective barrier against contamination until the printed expiration date. Do not use after the expiration date.
- The Rotium™ wick is single use only. It should not be re-packaged or re-sterilized. Re-packaging or re-sterilization may result in damage to the device, device failure, reduced biocompatibility, and complications such as infection. Unused portions of the Rotium™ wick should be discarded.
- Do not use the Rotium™ wick if aseptic technique has not been followed throughout the handling of the device.

## **ADVERSE REACTIONS**

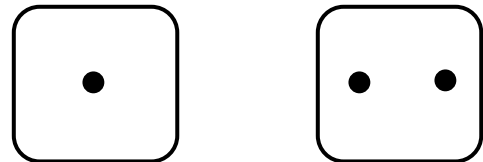
- Infections, both deep and superficial.
- Allergies and other reactions to device materials.

## **INSTRUCTIONS**

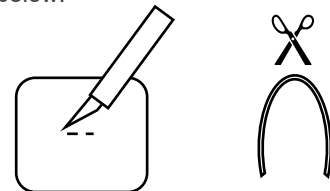
- See Tables 1, 2, 3, and 4 to verify compatibility with the Rotium™ bioresorbable wick.

### **Preparation:**

- Prepare the wick implantation site using standard surgical technique.
- Always use aseptic techniques when handling the Rotium™ wick.
- Remove the device from its packaging and place it on a sterile surface.
- The Rotium™ Wick is supplied in a nested pouch configuration. The inner foil pouch is sterile, and may be placed on the sterile field.
- Make a small hole or incision in the device to allow for the suture passage.
  - For use with one anchor, the hole should be centered on the device face. For use with two anchors, holes should be placed no closer than 3mm from any edge of the device. Example hole placements are given below:



- A sharp blade, scissors, or suture passing device may be used to create the suture hole, some examples are illustrated below:



### **Application:**

- Pass the desired suture limbs through the hole produced in the Rotium™ wick.
- Advance the Rotium™ wick down the suture limbs until the device is in contact with the prepared bone surface.
  - **WARNING:** Avoid any permanent crushing and deformation of the Rotium™ wick during entry and advancement through arthroscopic cannulas. Do not attempt to pass the device through arthroscopic cannulas of less than 6mm inner diameter.
- If the device is not lying flat on the bone surface, gently use a blunt instrument (e.g. surgical probe or suture retriever) to manipulate the device.
  - **WARNING:** Sharp instruments or rough handling can result in damage to the Rotium™ wick.
  - **WARNING:** The Rotium™ device should not remain folded over itself or rolled up when placement is complete.
- When the device placement over the bone is complete, secure the device into place by securely fixing the rotator cuff down on top of the device.

### **STERILITY**

The Rotium™ bioresorbable wick is supplied gamma-sterilized.













### **STORAGE AND HANDLING**

Rotium™ must be stored in its original packaging, preferably in a cool and dry place (30°C max). Dispose of packaging and unused Rotium™ materials following normal waste disposal procedures.

### **CUSTOMER SUPPORT**

For product complaints and potential adverse events, please contact your local Sales Representative or Customer Support.

### **SYMBOLS**

	Lot Number
	Reference Number
	Manufacturer Information
	Date of Manufacture
	Maximum Storage Temperature
	Caution: US Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Do Not Re-sterilize
	Single Use Only
	Do Not Use if Package is Damaged or Crushed
	Use By Date
	Sterilized via irradiation
	Refer to Instructions for Use Before Use

Tables listing compatible suture anchors are provided in the electronic copy of this IFU. See:

<https://www.atreonortho.com/IFU>

**Table 1: Compatible Pre-loaded Suture Anchors**

Manufacturer	Product Name	Catalogue #	Anchor Material	Suture	Suture Size	Anchor Dimensions
Arthrex	SwiveLock C Suture Anchor	AR-2324PSLC-2	PEEK	UHMWPE	#2	4.75 mm x 22 mm
Arthrex	SwiveLock C Suture Anchor	AR-2323PSLC-2	PEEK	UHMWPE	#2	5.5 mm x 22 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PSF-45	PEEK	UHMWPE	#2	4.5 mm x 14 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PNF-45	PEEK	UHMWPE	#1	4.5 mm x 14 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PSF-475	PEEK	UHMWPE	#2	4.75 mm x 14 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PSF	PEEK	UHMWPE	#2	5.5 mm x 14.7 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PNF	PEEK	UHMWPE	#2	5.5 mm x 14.7 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PSF-3	PEEK	UHMWPE	#2	5.5 mm x 14.7 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1927PSF-65	PEEK	UHMWPE	#2	5.5 mm x 14.7 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1928SF-45	Titanium	UHMWPE	#2	4.5 mm x 14 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1928SF-2	Titanium	UHMWPE	#2	5.5 mm x 16.3 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1928SNF-2	Titanium	UHMWPE	#2	5.5 mm x 16.3 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1928SFT-2	Titanium	UHMWPE	#2	5.5 mm x 16.3 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1928SF-3	Titanium	UHMWPE	#2	5.5 mm x 16.3 mm
Arthrex	Corkscrew FT Suture Anchor	AR-1929SF-3	Titanium	UHMWPE	#2	5.5 mm x 16.3 mm
Arthrex	FiberTak® DR All-Suture Anchor	AR-3651	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® DR All-Suture Anchor	AR-3651T	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® DR All-Suture Anchor	AR-3651TT	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® All-Suture Anchor	AR-3600	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® All-Suture Anchor	AR-3600-2	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® All-Suture Anchor	AR-3603	UHMWPE	UHMWPE	#2	N/A
Arthrex	FiberTak® All-Suture Anchor	AR-3603-2	UHMWPE	UHMWPE	#2	N/A
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203981	PEEK-OPTIMA	UHMWPE	#2	4.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203982	PEEK-OPTIMA	UHMWPE	#2	4.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203983	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203984	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203378	PEEK-OPTIMA	UHMWPE	#2	4.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203379	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Smith and Nephew	HEALICOIL™ PK Suture Anchor	72203380	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Smith and Nephew	Q-FIX™ All-Suture Anchor	25-2800	UHMWPE	UHMWPE	#2	2.8mm
Smith and Nephew	SUTUREFIX All-Suture Anchor	72203852	UHMWPE	UHMWPE	#2	1.7mm
Smith and Nephew	SUTUREFIX All-Suture Anchor	72203853	UHMWPE	UHMWPE	#2	1.7mm
Smith and Nephew	SUTUREFIX All-Suture Anchor	72203854	UHMWPE	UHMWPE	#2	1.9mm
Smith and Nephew	Twinfix with Ultrabraid	72200755	Titanium	UHMWPE	#2	5.0mm
Smith and Nephew	Twinfix with Ultrabraid	72200759	Titanium	UHMWPE	#2	5.0mm
Smith and Nephew	Twinfix with Ultrabraid	7210708	Titanium	UHMWPE	#2	5.0mm
Stryker	ICONIX™ All Suture Anchor System	3910-500-512	Polyester	UHMWPE	#2	1.4mm
Stryker	ICONIX™ All Suture Anchor System	3910-500-522	Polyester	UHMWPE	#2	2.3mm
Stryker	ICONIX™ All Suture Anchor System	3910-500-532	Polyester	UHMWPE	#2	2.3mm
Stryker	ICONIX TT™ All Suture Anchor System	3910-500-322	Polyester	UHMWPE	#2	2.3mm
Stryker	ICONIX™ Self-Punching	3910-500-920	Polyester	UHMWPE	#2	2.3mm

**Table 1: Compatible Pre-loaded Suture Anchors**

Manufacturer	Product Name	Catalogue #	Anchor Material	Suture	Suture Size	Anchor Dimensions
Stryker	ICONIX™ Self-Punching	3910-500-922	Polyester	UHMWPE	#2	2.3mm
Stryker	ICONIX XBraid TT™ All Suture Anchor System	3910-500-322	Polyester	UHMWPE	2.0mm	2.3mm
Stryker	ICONIX XBraid TT™ All Suture Anchor System	3910-500-920	Polyester	UHMWPE	2.0mm	2.3mm
Stryker	PEEK Zip	3910-200-030	PEEK	Polyester or polyethylene	#2	5.5mm
Stryker	PEEK Zip	3910-200-070	PEEK	Polyester or polyethylene	#2	6.5mm
Wright	INSITE™ FT Anchor w/Needles	SMP000515	PEEK	UHMWPE	#2	5.5 mm x 16.5 mm
Wright	INSITE™ FT Anchor w/Needles	SMP000415	PEEK	UHMWPE	#2	4.5 mm x 16.5 mm
Wright	INSITE™ FT Anchor w/Needles	SMT000515	Titanium	UHMWPE	#2	5.5 mm x 16.5 mm
Wright	INSITE™ FT Anchor w/Needles	SMT000415	Titanium	UHMWPE	#2	4.5 mm x 16.5 mm
Zimmer Biomet	Quattro® X Suture Anchors	CM-9255	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Zimmer Biomet	Quattro® X3 Suture Anchors	CM-9255X3	PEEK-OPTIMA	UHMWPE	#2	5.5 mm
Zimmer Biomet	Quattro® X Suture Anchors	CM-9265	PEEK-OPTIMA	UHMWPE	#2	6.5 mm
Zimmer Biomet	SureLock® All-Suture Anchors	CM-9614	UHMWPE	UHMWPE	#2	1.4mm
Zimmer Biomet	SureLock® All-Suture Anchors	CM-9622F	UHMWPE	UHMWPE	#2	2.2mm
Zimmer Biomet	JuggerKnot® Soft Anchor	912029	Polyethylene	Polyethylene	#2	2.9mm
Zimmer Biomet	JuggerKnot® Soft Anchor	912529	Polyethylene	Polyethylene	#2	2.9mm

<b>Table 2: Compatible Orthopedic Anchors</b>				
<b>Manufacturer</b>	<b>Product Name</b>	<b>Material</b>	<b>Catalogue #</b>	<b>Dimensions</b>
Arthrex	Corkscrew Suture Anchor	Titanium	AR-1902SF	5 mm x 15.5 mm
Arthrex	Corkscrew Suture Anchor	Titanium	AR-1920SF	5 mm x 15.5 mm
Arthrex	Corkscrew Suture Anchor	Titanium	AR-1920NSF	5 mm x 15.5 mm
Arthrex	Corkscrew Suture Anchor	Titanium	AR-1925SF	6.5 mm x 15.5 mm
Arthrex	SwiveLock C Suture Anchor	PEEK	AR-2324PSLC	4.75 mm x 19.1 mm
Arthrex	SwiveLock C Suture Anchor	PEEK	AR-2323PSLC	5.5 mm x 19.1 mm
Arthrex	SwiveLock SP Suture Anchor	PEEK	AR-2324PSLM	4.75 mm x 24.5 mm
Arthrex	SwiveLock SP Suture Anchor	PEEK	AR-2323PLSM	5.5 mm x 24.5 mm
Arthrex	SwiveLock SP Suture Anchor	Titanium	AR-2324SLM	4.75 mm x 24.5 mm
Arthrex	SwiveLock SP Suture Anchor	Titanium	AR-2323SLM	5.5 mm x 24.5 mm
Arthrex	PEEK-SwiveLock Suture Anchor	PEEK	AR-2323PSL	5.5 mm x 20 mm
Arthrex	PushLock Suture Anchor	PEEK	AR-1922PS	4.5 mm x 24 mm
Arthrex	PushLock Suture Anchor	PEEK	AR-1922PSM	4.5 mm x 28 mm, Self-Punching*
Depuy	Healix Advance™ Knotless	PEEK	222333	4.75mm
Depuy	Healix Advance™ Knotless	PEEK	222334	5.5mm
Depuy	Healix Advance™ Knotless	PEEK	222335	6.5mm
Smith and Nephew	Magnum 2 Knotless Fixation Device	Stainless Steel	OM-1502	2.8mm
Smith and Nephew	Magnum X Knotless Fixation Device	Stainless Steel	OM-1503	2.8mm
Smith and Nephew	Speedscrew Threaded Knotless Anchor	PEEK	OM-6500	5.5mm
Smith and Nephew	Speedscrew Threaded Knotless Anchor	PEEK	OM-8500	6.5mm
Stryker	CinchLock SS	PEEK	CATO2462	2.4mm
Stryker	CinchLock Flex	PEEK	CATO2643	2.4mm

<b>Table 3: Compatible Orthopedic Suture</b>				
<b>Manufacturer</b>	<b>Product Name</b>	<b>Material</b>	<b>Catalogue #</b>	<b>Dimensions</b>
Arthrex	FiberTape Suture	UHMWPE	AR-7237	36 inch (blue) tape with each end tapered to #2 FiberWire suture, 54 inches
Arthrex	FiberTape Suture	UHMWPE	AR-7237-7	7 inch (blue) tape with each end tapered to #2 FiberWire suture, 30 inches
Arthrex	FiberTape Suture	UHMWPE	AR-7237-7B	7 inches (blue), each end tapered to #2 FiberWire suture, collagen coated
Arthrex	FiberTape Suture	UHMWPE	AR-7237-7T	7 inch (white/black) tape with each end tapered to #2 TigerWire® suture, 30 inches
Arthrex	FiberTape Suture	UHMWPE	AR-7237-17N	17 inches (blue), each end tapered to #2 FiberWire suture w/tapered Needle, 26.5 mm 1/2 circle
Depuy	Permatape	Polyethylene	223169	2.5mm Blue Braided Flat
Depuy	Permatape	Polyethylene	223170	2.5mm White/Blue Braided Flat
Smith and Nephew	ULTRATAPE Suture	UHMWPE	72203896	#2 Blue
Smith and Nephew	ULTRATAPE Suture	UHMWPE	72203897	#2 Cobraid Blue
Teleflex Medical (Marketed by Stryker)	Force Fiber®	UHMWPE	3910-900-021	#2 Blue Co-Braid 38" Strand
Stryker	XBraid TT	UHMWPE	3910-900-018	2.0mm Blue Co-Braid 39" Strand
Wright	Force Fiber	UHMWPE	SMK100101	#2 36" White/Blue
Wright	Force Fiber	UHMWPE	SMK100201	#2 36" White/Black
Wright	Force Fiber	UHMWPE	SMK100401	#2 36" Blue
Wright	Force Fiber	UHMWPE	SMS100101	#2 36" White/Black K-Point
Wright	Force Fiber	UHMWPE	SMS100201	#2 36" White/Blue K-Point
Zimmer Biomet	MaxBraid PE	Polyethylene	900284	#2 Blue
Zimmer Biomet	MaxBraid PE	Polyethylene	900333	#2 White
Zimmer Biomet	MaxBraid PE	Polyethylene	900334	#2 Blue
Zimmer Biomet	MaxBraid PE	Polyethylene	900335	#2 Blue

**Table 4: Compatible Tools**

<b>Manufacturer</b>	<b>Product Name</b>	<b>Catalogue #</b>
Arthrex	FiberWire Grasper w/NR Handle	AR-13975NR
Arthrex	FastPass Scorpion™ SL Suture Passer	AR-13999MF
Arthrex	SCORPION-multifire Suture Passer	AR-13997MF
Arthrex	FastPass Scorpion	AR-13997SF
Arthrex	Scorpion Suture Passer	AR-13990
Arthrex	Humpback Scorpion	AR-13993
Arthrex	Suture Retriever, 3.4mm, straight	AR-12540
Arthrex	Suture Retriever, 3.4mm, 15deg up	AR-12550
Arthrex	Suture Retriever, 3.4mm, 45deg right	AR-12580
Arthrex	Suture Retriever, 3.4mm, 45deg left	AR-12590
Arthrex	KingFisher Retriever/ Grasper w/SR Handle	AR-13970SR
Arthrex	KingFisher Retriever/ Grasper w/NR Handle	AR-13970NR
Arthrex	KingFisher Retriever/ Grasper w/WishBone™ Handle	AR-13970W
Smith and Nephew	FIRSTPASSTM ST Suture Passer, Self-Capture	22-4038
Smith and Nephew	FIRSTPASSTM ST Suture Passer, Standard	22-4039
Smith and Nephew	TRUEPASS Suture Passer, Self-Capture	72203791
Smith and Nephew	TRUEPASS Suture Passer, Standard	72203792