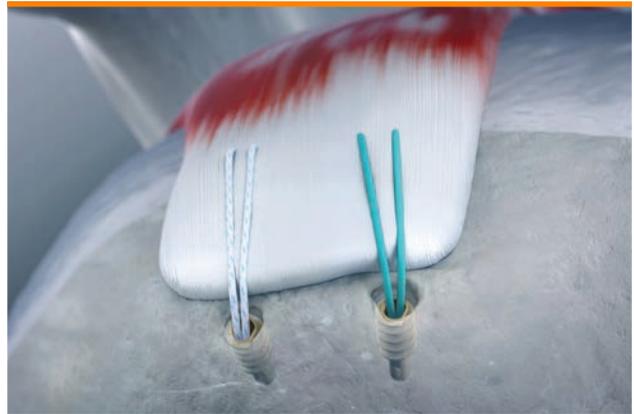




SPEEDSCREW[◇] system

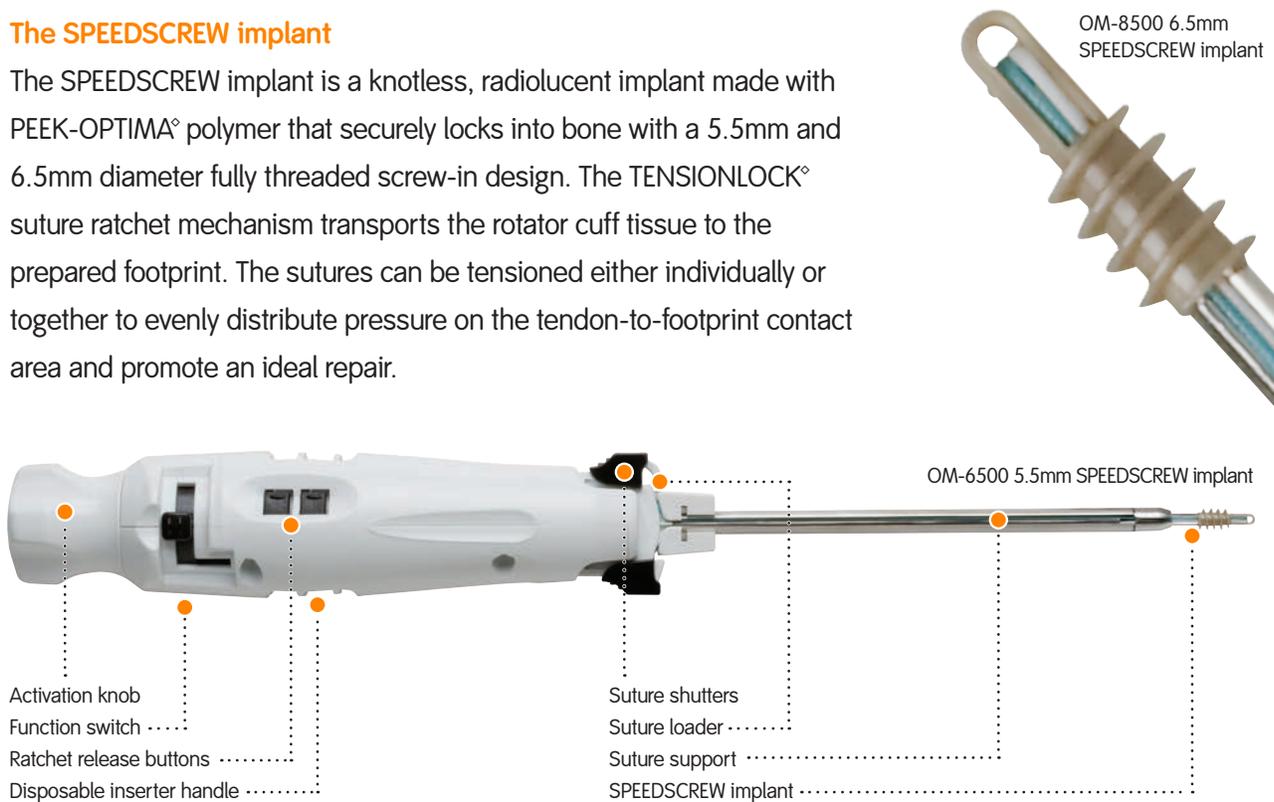
Fully threaded knotless implant system

The SPEEDSCREW system is specifically designed for rotator cuff repair surgery. The system enables the surgeon to restore the anatomic footprint of the rotator cuff with a secure knotless repair. The system consists of the SMARTSTITCH[◇] suturing device and the SPEEDSCREW implant with inserter handle; accessories include the punch tap, insertion guide and obturator.



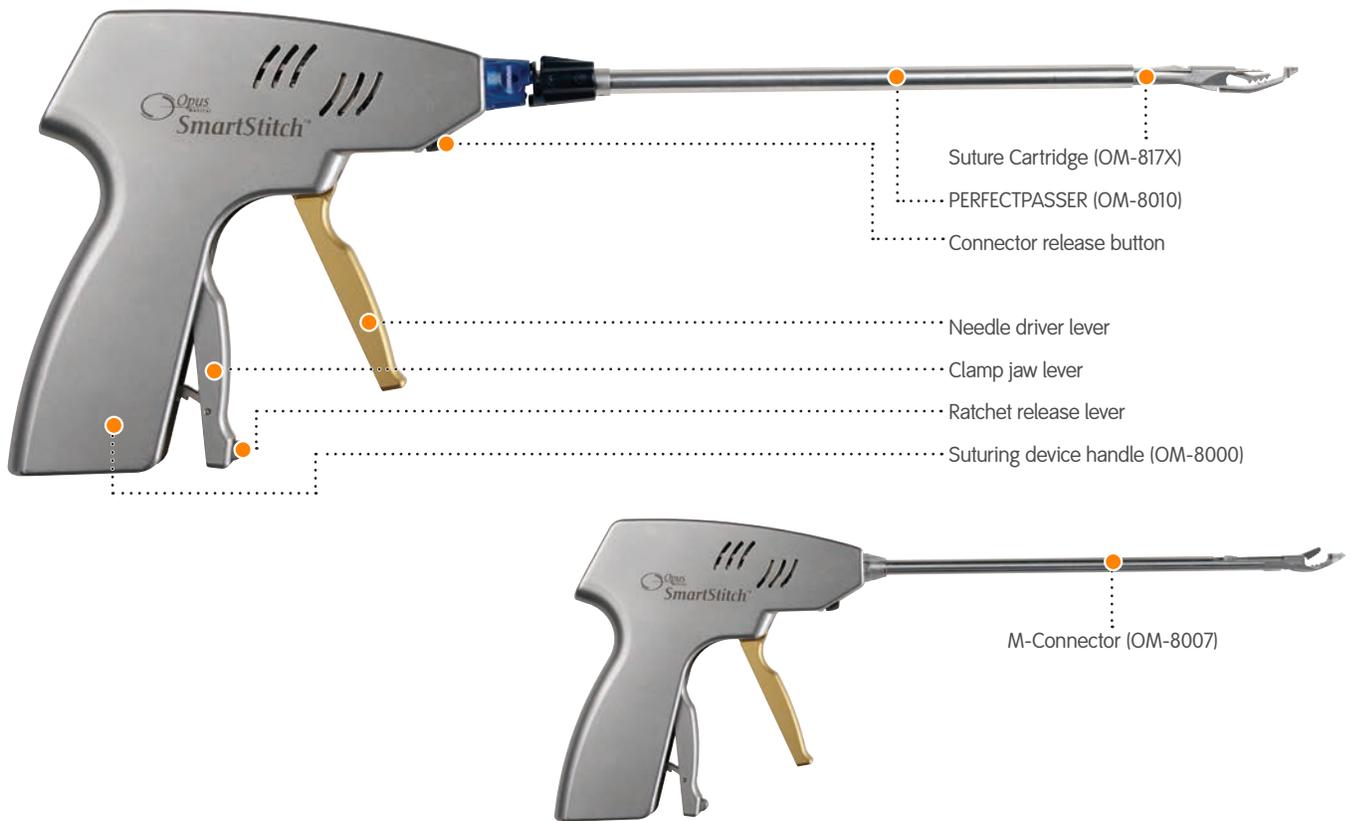
The SPEEDSCREW implant

The SPEEDSCREW implant is a knotless, radiolucent implant made with PEEK-OPTIMA[◇] polymer that securely locks into bone with a 5.5mm and 6.5mm diameter fully threaded screw-in design. The TENSIONLOCK[◇] suture ratchet mechanism transports the rotator cuff tissue to the prepared footprint. The sutures can be tensioned either individually or together to evenly distribute pressure on the tendon-to-footprint contact area and promote an ideal repair.



The SMARTSTITCH® system

The SMARTSTITCH system is an integrated grasper and suturing mechanism that allows the surgeon to grasp the cuff tissue and quickly place an Incline Mattress, or side-to-side stitch. The SMARTSTITCH system consists of a reusable SMARTSTITCH handle and a single use PERFECTPASSER® or M-Connector insert. In addition, the MAGNUMWIRE® suture used with the SPEEDSCREW® implant is a strong #2 braided polyethylene suture available in multiple colors to facilitate suture management.



The Punch Tap

The Punch Tap was specifically engineered for use with the SPEEDSCREW implant and is easily inserted through a skin incision at a dead man's angle. Simply break the cortex with the punch and screw in the tap to create the bone hole for the deployment of the SPEEDSCREW implant.



Creating Punch Tap holes for the SPEEDSCREW[®] implant

The bone hole sites are planned by applying traction on the suture limbs. The cuff footprint is prepared by removing all soft tissue and creating a smooth bone surface.

Procedure

- 1 **Optional:** Insert the SPEEDSCREW Insertion Guide (OM-9610) with Blunt Nosed Obturator (OM-9650) through the skin incision with the insertion guide handle oriented 180° from the sutures. Remove the Blunt Nosed Obturator from the insertion guide. Using a suture retriever, shuttle one pair of sutures into the working portal.
- 2 Using the appropriate punch tap, ensure that the vertical laser line on the punch tap aligns with the edge of the tendon. Drive the tip into bone and rotate the tap until the black distal (horizontal) depth marker advances to reach the cortical surface of the bone site. If using the insertion guide, the black (proximal) horizontal depth marker on the punch tap should be flush with the top of the insertion guide when the insertion guide is against the surface of the bone.

NOTE: Make sure the suture is held taut and away while inserting the punch tap and implant.

- 3 Once the hole is made, remove the punch tap by unscrewing it from the bone.

NOTE: Do not load the suture into the device prior to inserting the implant into bone. If placing more than one implant, assure bone holes are at least 7mm apart.

Deploying the SPEEDSCREW[®] implant

- 1 Establish axial alignment of the implant to the tapped hole. Screw the implant into bone until the stepped edge of the inserter handle is flush with the cortical surface of the bone. Optionally, if the insertion guide is used and is held to the surface of the bone, screw the implant into bone until the depth marker on the shaft of the inserter aligns with the top of the insertion guide. Once the SPEEDSCREW implant is fully inserted, the open slot on the suture support shaft is aligned with the edge of the tendon.



If implant extraction is indicated at this point, turn the inserter handle counterclockwise to remove the implant. If the implant has detached from the inserter handle, use the Anchor Extraction Tool (OM-9630). Remove the inserter handle, engage the extraction tool and turn counterclockwise to remove the implant.

NOTE: Only use the Anchor Extraction Tool (OM-9630) if the implant is detached from the inserter handle and prior to suture lock deployment.

NOTE: Use care to properly align the implant and inserter handle with the bone hole during implant insertion. Do not lever the inserter handle prior to, during or after insertion as damage to the implant or incomplete insertion may result. Do not deploy a bent or damaged implant.

WARNING: Incomplete insertion or poor bone quality may result in implant pullout.

Note: Ensure that the suture does not wrap around the inserter while screwing the implant into bone by holding the suture taught and away from the implant.

2 Once fully inserted, the open slot on the suture support shaft should be aligned with the edge of the tendon. While supporting the inserter handle, thread the two free legs of suture from the tendon through each of the suture eyelets, in the direction of the arrows, ensuring that less than 2cm of suture leg extends from the end of the suture eyelets. Close the black suture shutters.



NOTE: Do not cross suture limbs inferior to the inserter shaft prior to inserting into suture eyelet.

NOTE: Loading the suture from the side opposite the open slot on the suture support shaft will result in a non-functional device.

3 Push the black function switch down and forward to unlock the activation knob. Rotate the activation knob to pull the suture limbs through the implant.

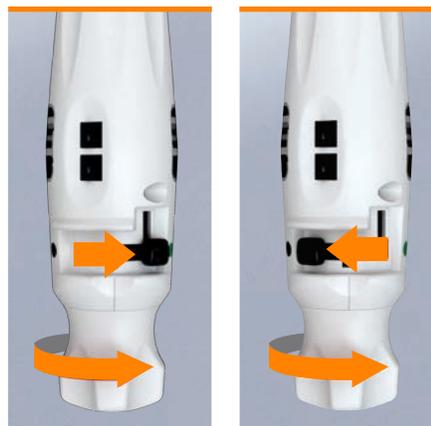


NOTE: Leave the function switch in the middle position until the MAGNUMWIRE[®] suture is seen around the suture reels.

4 Set the desired suture tension by rotating the activation knob. In order to assure adequate suture tension between tendon and bone, abduct/adduct the patient's appendage.

5 To independently tension the suture limbs, move the function switch towards the black or green dot and turn the activation knob. The left snare corresponds to the black dot and the right snare to the green dot.

NOTE: If suture tension needs to be released, push the corresponding ratchet release button.



6 To activate suture lock, move the function switch to the right then press down and forward. Deploy the suture lock by turning the activation knob approximately 3 turns until it stops.

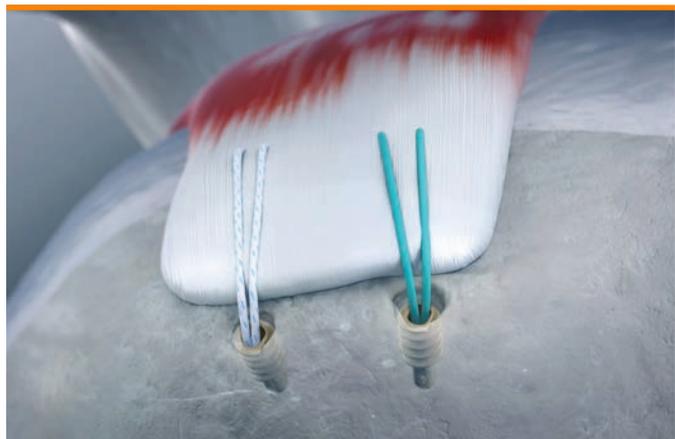
NOTE: Ensure activation knob is turned until it stops or detachment of implant from inserter handle may not be complete.



7 Remove the inserter handle and ensure adequate suture tension between tendon and bone. Trim the remaining loose suture tails at the bone hole.

NOTE: Do not over tension the suture.

Repeat the sequence if additional implants are needed to complete the rotator cuff repair.



Ordering information

SPEEDSCREW® implants

Reference #	Description
OM-6500	5.5MM SPEEDSCREW IMPLANT
OM-8500	6.5MM SPEEDSCREW IMPLANT
OM-9610	SPEEDSCREW INSERTION GUIDE
OM-9615	SPEEDSCREW OBTURATOR/INSERTION GUIDE SET
OM-9630	ANCHOR EXTRACTION TOOL
OM-9650	SPEEDSCREW OBTURATOR
OM-9061	5.5MM SPEEDSCREW PROCEDURE SET WITH M-CONNECTOR MAGNUMWIRE®
OM-9066	5.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (WHITE) SUTURE CARTRIDGE
OM-9067	5.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (BLUE COBRAID) SUTURE CARTRIDGE
OM-9068	5.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (BLACK COBRAID) SUTURE CARTRIDGE
OM-9081	6.5MM SPEEDSCREW PROCEDURE SET WITH M-CONNECTOR MAGNUMWIRE
OM-9086	6.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (WHITE) SUTURE CARTRIDGE
OM-9087	6.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (BLUE COBRAID) SUTURE CARTRIDGE
OM-9088	6.5MM SPEEDSCREW PLUS M-CONNECTOR MAGNUMWIRE (BLACK COBRAID) SUTURE CARTRIDGE
OM-9161	5.5MM SPEEDSCREW PROCEDURE SET WITH PERFECTPASSER® AGNUMWIRE
OM-9166	5.5MM SPEEDSCREW PLUS PERFECTPASSER MAGNUMWIRE (WHITE) SUTURE CARTRIDGE
OM-9167	5.5MM SPEEDSCREW PLUS PERFECTPASSER MAGNUMWIRE (BLUE COBRAID) SUTURE CARTRIDGE
OM-9168	5.5MM SPEEDSCREW PLUS PERFECTPASSER MAGNUMWIRE (BLACK COBRAID) SUTURE CARTRIDGE
OM-9181	6.5MM SPEEDSCREW PROCEDURE SET WITH PERFECTPASSERAGNUMWIRE
OM-9186	6.5MM SPEEDSCREW PLUS PERFECTPASSER MAGNUMWIRE (WHITE) SUTURE CARTRIDGE
OM-9187	6.5MM SPEEDSCREW PLUS PERFECTPASSER MAGNUMWIRE (BLUE COBRAID) SUTURE CARTRIDGE
OM-9620	5.5MM PUNCH TAP
OM-9820	6.5MM PUNCH TAP

ArthroCare Corporation

7000 West William Cannon Drive
Austin, TX 78735
USA

www.smith-nephew.com

Order Entry: 1-800-343-5717
Order Entry Fax: 1-888-994-2782

© 2015 Smith & Nephew, Inc.

®Trademark of Smith & Nephew. Reg. US Pat. & TM Office.

P/N A1079 Rev. H 01/15