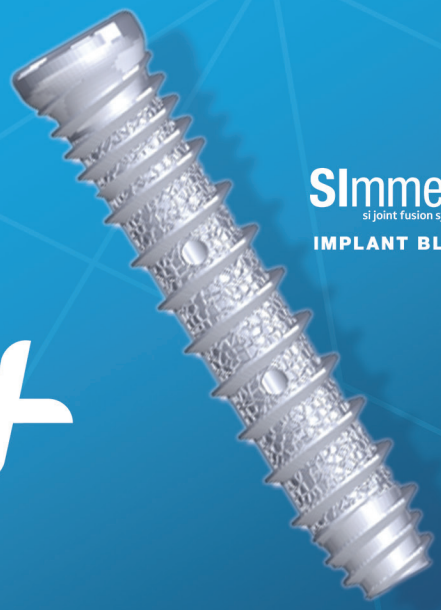


SImmetry®+

si joint fusion system

*Authentic **FUSION**, compelling **SAFETY** profile and **CLINICAL OUTCOMES***

***Relieving Pain**, Restoring Life.*

SImmetry®+
Surgical Technique Manual
Addendum

TENON MEDICAL®

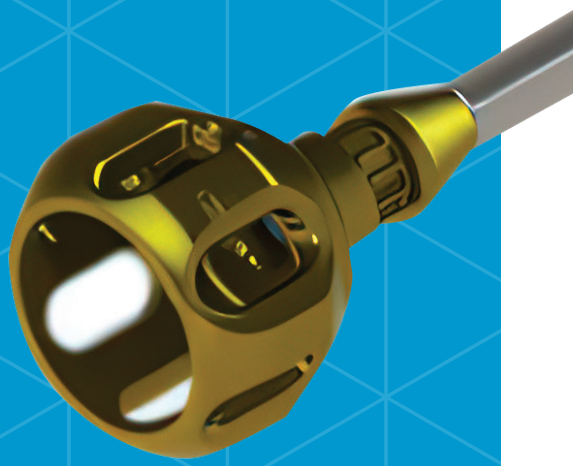
Tenon Medical, Inc.

SImmetry®+ Decorticator

Surgical Technique Manual Addendum

The Tenon Medical SImmetry+ Decorticator is an additional set of instruments to be used in conjunction with the Tenon Medical SImmetry+ instruments.

This addendum does not offer complete guidance for the SImmetry+ SI Joint Fusion System implantation; it only describes the detailed steps for the use of the SImmetry+ Decorticator. For complete guidance on surgical techniques, please refer to the Surgical Technique Manual STM003.



Introduction

Use of This Manual

This manual provides details specific to the SImmetry⁺ Decorticator. The Decorticator is designed to be used with the SImmetry⁺ SI Joint Fusion System.

Refer to the SImmetry⁺ SI Joint Fusion System Surgical Technique Manual STM003 and Instructions for Use IFU003 for full surgical procedure steps, information, warnings, precautions, and risks.

Refer to the SImmetry⁺ Instructions for Use, IFU003, for information on cleaning and sterilization.

GENERAL WARNINGS AND PRECAUTION:

With all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the SI Joint Fusion System. Please review the Instructions for Use provided with the SI Joint Fusion System for warnings, precautions, and risks.

Failure to properly follow all instructions may lead to injury and improper functioning of the system. Avoid exerting excessive force as breakage or damage may occur when an instrument is subjected to excessive or inappropriate loads and/or angles.

INDICATIONS FOR USE:

The SImmetry⁺ SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS

Customary general contraindications associated with elective surgery should be observed. These include, but are not limited to: pregnancy; sensitivity or allergy to titanium; metabolic bone disease; clotting disorders; current treatment with therapeutic agents that may have an effect on the surgical site, surrounding tissue, or normal healing responses (e.g., chemotherapy, radiation therapy, chronic steroid treatment, anticoagulant therapy, kidney dialysis); or other metabolic or physical disorders that interfere with bone growth, bone maintenance, or wound healing.

Certain degenerative diseases or underlying physiological conditions may alter the healing process or prevent fusion, such as uncontrolled diabetes, active systemic infection, infection localized to the site of the proposed implantation, rheumatoid arthritis, or osteoporosis.

The SImmetry⁺ Decorticator instrument, removes cartilage and decorticates opposing joint surfaces.

Drilling and Decortication

Refer to the SImmetry+ SI Joint Fusion System Manual STM003 for complete surgical procedure steps. The SImmetry+ Decorticator, starting after Step 2 for decortication from STM003.

DRILLING

Step 3

Insert Dilator 1 (Figure 1), take note of the length of the implant from the laser marking on the 3.2mm Trocar Pin (Figure 2).

Figure 1
Insert Dilator 1

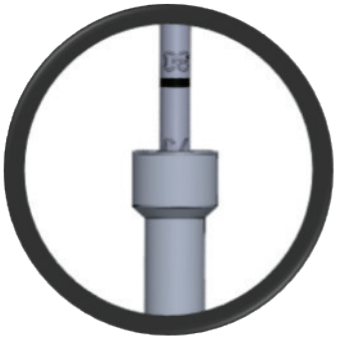


Figure 2
Note the length of the implant from the laser marking

3.2mm Trocar Pin

Dilator 1

Figure 3
Working Cannula

Insert Working Cannula over Dilator 1 and the 3.2mm Trocar Pin and through the soft tissue until contacting bone (Figure 3).

Drilling and Decortication *(cont.)*

Remove the Dilator 1. Place the 9mm Drill (Figure 4) drill over the 3.2mm Trocar Pin. Drill through the ilium and stop at the joint. Continue drilling under fluoroscopy until the drill has just pierced the lateral cortex of the sacrum. Confirm the final placement with an Outlet Oblique view (Figure 5).

Do not remove the 9mm Drill.

Figure 4
9mm Drill

CAUTION:

Confirm with fluoroscopy that the 3.2mm Trocar Pin does not advance while drilling.

Place the Impactor (Figure 6) over the Working Cannula and 9mm Drill.

Impact the Working Cannula so that the distal edge is secure in bone but not protruding into the SI joint. Remove the 3.2mm Guide Pin (Figure 7).

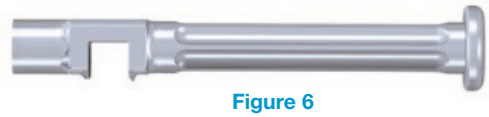


Figure 6
Impactor

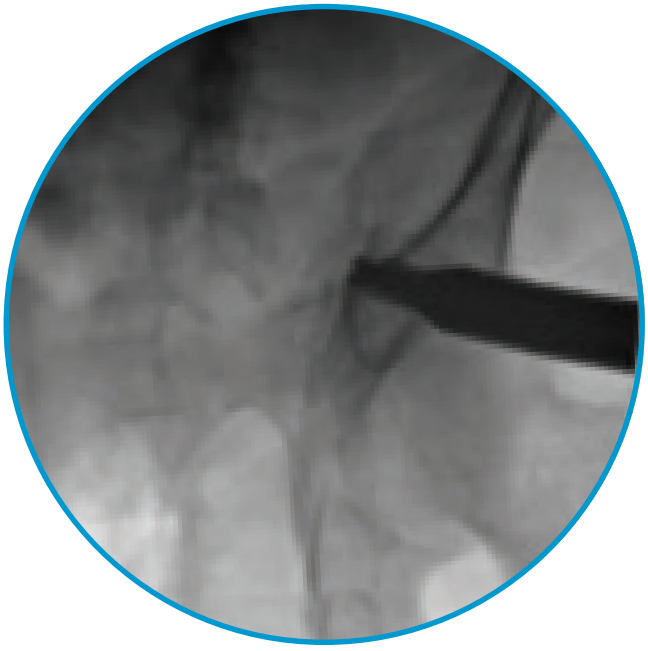


Figure 5
Confirm final placement with an Outlet Oblique view

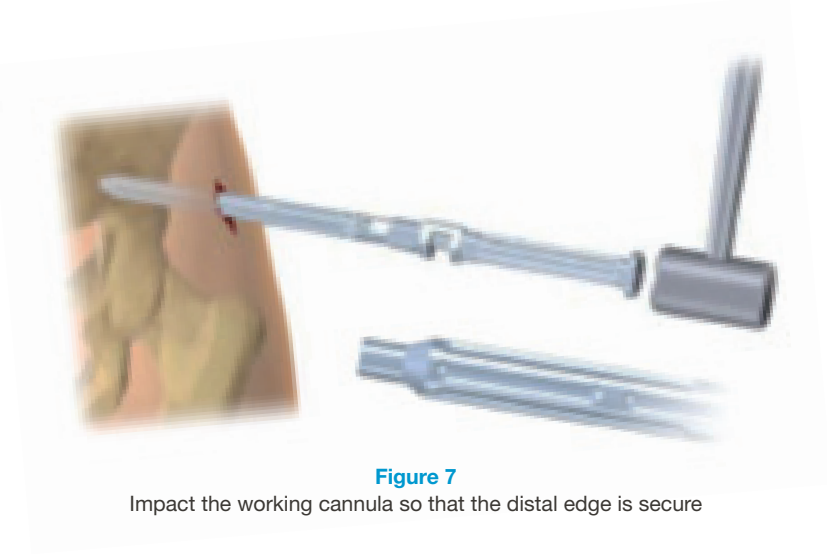


Figure 7
Impact the working cannula so that the distal edge is secure

Drilling and Decortication *(cont.)*

Remove the 9mm Drill from the Working Cannula leaving the 3.2mm Trocar Pin in place.

Collect and save the bone from 9mm Drill flute for later grafting (Figure 8).

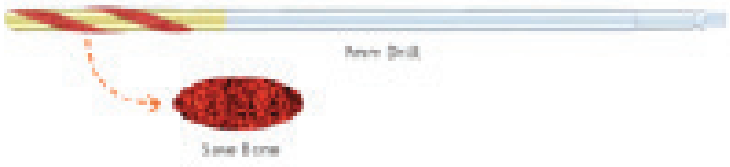


Figure 8
Collect and save bone from 9mm Drill flute

DECORTICATION

Assemble the Decorticator Knob, Blade and body on the back table (Figure 9).

Ensure that the Decorticator blade is aligned with the Decorticator Body. The Knob will make an audible "**click**'" when the cutting element is fully seated into the Decorticator Body.

Orient blade pointing up as shown (Figure 10).

Figure 9
Assemble Decorticator Knob, Blade, and Body

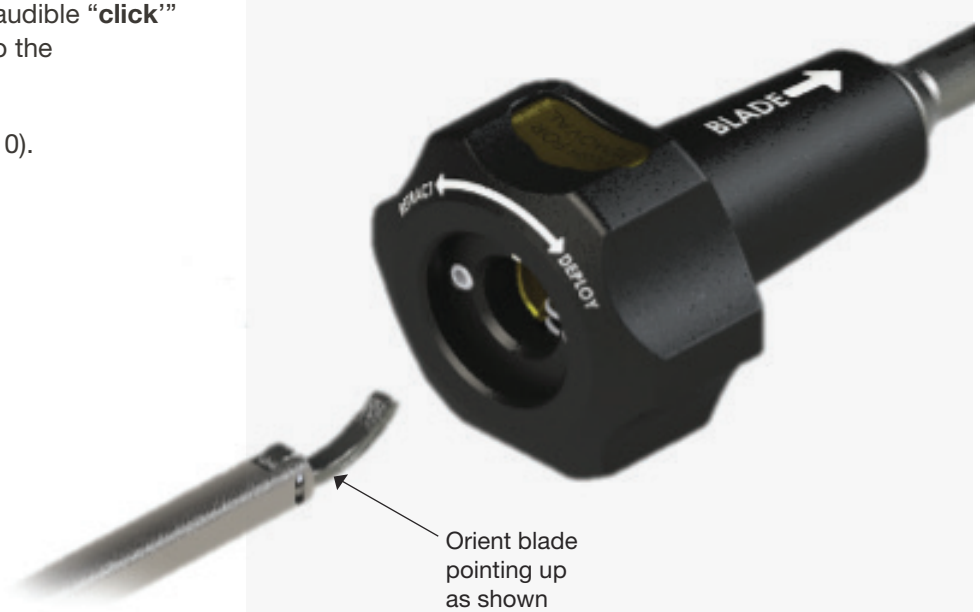


Figure 10
Orient blade pointing up as shown

Drilling and Decortication *(cont.)*

To deploy the cutting element, rotate the proximal Decorticator Shaft knob clockwise by 2 clicks. To decortcate, begin by rotating the proximal handle of the Decorticator Working Cannula (either direction) two or more complete rotations or until resistance drops (Figure 11). Two audible click of the Decorticator Shaft knob is equal to approximately 1mm of deployment of the cutting element. Repeat the deployment and decortication steps while confirming progress with fluoroscopic imaging to ensure proper cutter deployment and that the cutting element is within the margins of the sacroiliac joint and not destroying the cortex of the lateral sacral wall or the medial ilial wall (Figure 12).

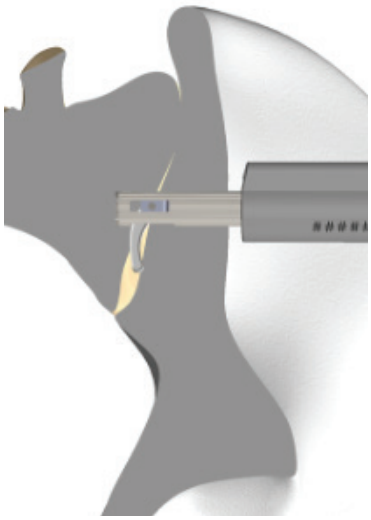


Figure 11
Decortication of the si joint

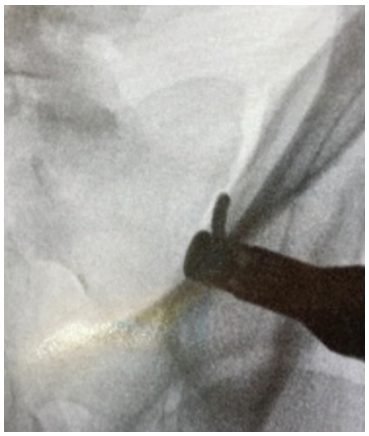


Figure 12
Confirming decortication with fluoroscopic imaging

1. **Rotate the Handle the opposite direction and continue in that direction.**
2. **Retract the Knob counterclockwise, click-by-click, until full Handle rotations can resume.**

The Decorticator is fully deployed when the Knob reaches the Stop Position.

CAUTION:

Extending the Cutting Element outside the joint margins may damage surrounding anatomical structures. It is suggested to take an Inlet View to confirm that there is not an anterior breach of the cutting element.

NOTE:

If an obstruction is met during the decortication step, attempt the following until full rotations can resume.

The Decorticator is fully deployed when the Knob reaches the Stop Position.

Drilling and Decortication *(cont.)*

The Decorticator is fully deployed when you cannot rotate the Decorticator Knob and the extension indication line is at the end of the window (Figure 13).

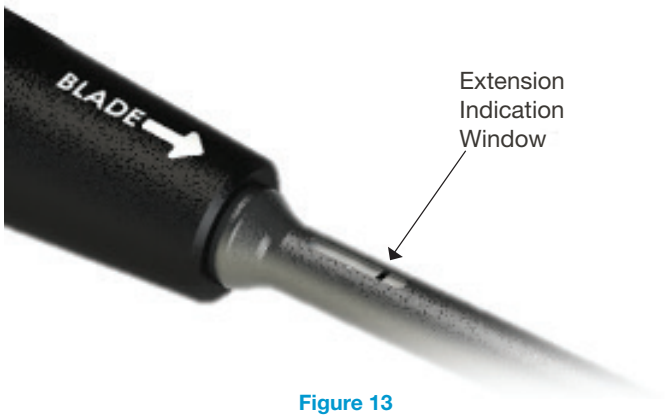


Figure 13
Extension indication window

Remove the Decorticator Cutting Blade from the Decorticator Body by pushing the Gold Button "Push for Removal (Figure 14).

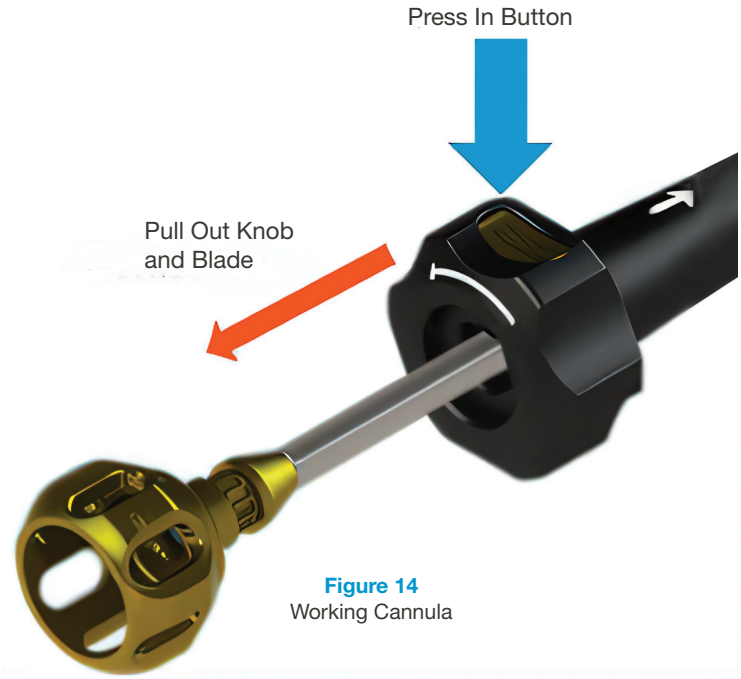


Figure 14
Working Cannula

Remove Decorticator Body from Working Cannula. Reinsert the 3.2mm Guide Pin. Place final dilator and handle over the 3.2mm Guide Pin and Working Cannula.

Final dilator and handle goes over the 3.2mm Guide Pin and Working Cannula.

Remove Working Cannula from Final by hand, Kocher or heavy needle holder. Do not use the Impactor to remove the Working Cannula from the Final Dilator.

Refer to grafting, implant assembly & insertion steps in STM003 to complete the surgical procedure.

CLEANING AND STERILIZATION

All components of the SImmetry+ Decorticator are provided **NON-STERILE** and must be cleaned and sterilized prior to use. Please review the **Instructions For Use** IFU003 for cleaning and sterilization instructions. The surgical instruments and accessories are manufactured from stainless steel.

Instrument Guide

The SImmetry+ Decorticator consists of three components and an accessory tool.

PART NUMBER	DESCRIPTION DEVICE	DEVICE
142-000001	Decorticator Blade	
142-000002	Decorticator Knob	
142-0000043	Decorticator Body	
SV01-0475	Working Cannula	

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