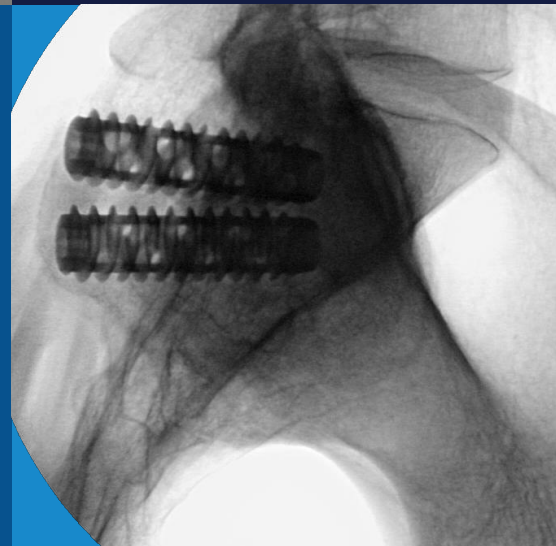


Rialto™
SI Fusion System

**FLUOROSCOPIC
IMAGING**



Medtronic

FLUOROSCOPIC FLOW

1 Sacral Outlet View (If Necessary)

Identify the superior aspect of the S1 foramen and inferior aspect of the S2 foramen.

Mark these lines across the posterior of the patient, above the posterior superior iliac spine (PSIS) which is the entry corridor.

Note:

This view is used when the surgeon is unable to palpate/identify the PSIS.

2 Lateral View

Place the PAK needle at the desired entry point.

Confirm the trajectory is directed at, or inferior to, the sacral promontory.

3 Posterior Oblique View (PO)

Identify the lateral wall of the PSIS.

Make the incision above the PSIS along the lateral wall.

Confirm the instruments have crossed the SI joint.

Once the joint is crossed, there is no need to continue to the anterior cortex of the sacral ala.

The step of the PAK needle shaft is 40mm (implants are 40mm, 50mm, and 60mm).

4 Sacral Inlet View

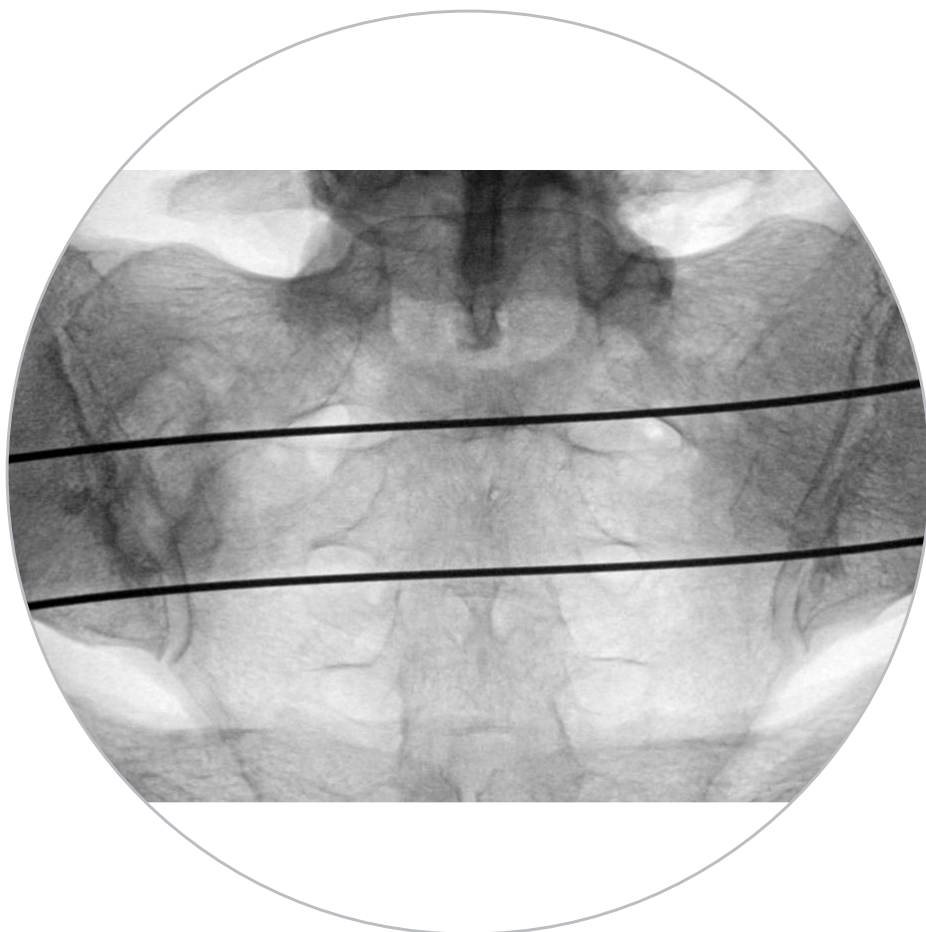
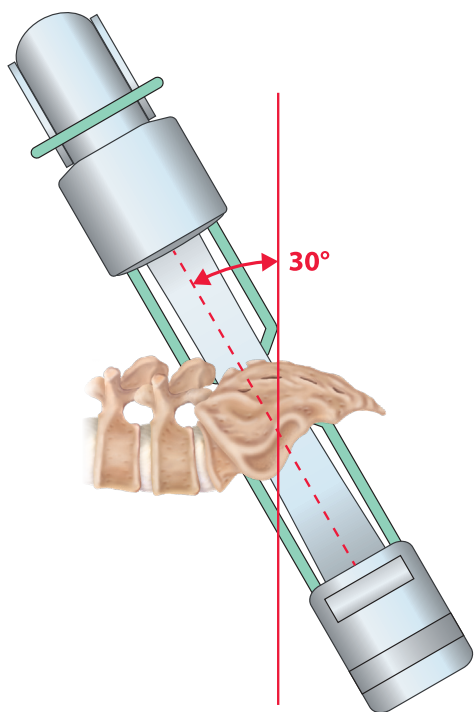
Confirm the instruments and implants have not violated the anterior wall.

1

SACRAL OUTLET VIEW

The C-arm is angled 30 degrees cephalic from standard AP. The angle will vary by patient, but should be perpendicular to the sacral inclination. An acceptable radiograph will identify the S1 foramen. This view can be used to determine the initial starting point cephalic to caudal.

C-ARM FOR
SACRAL OUTLET
VIEW

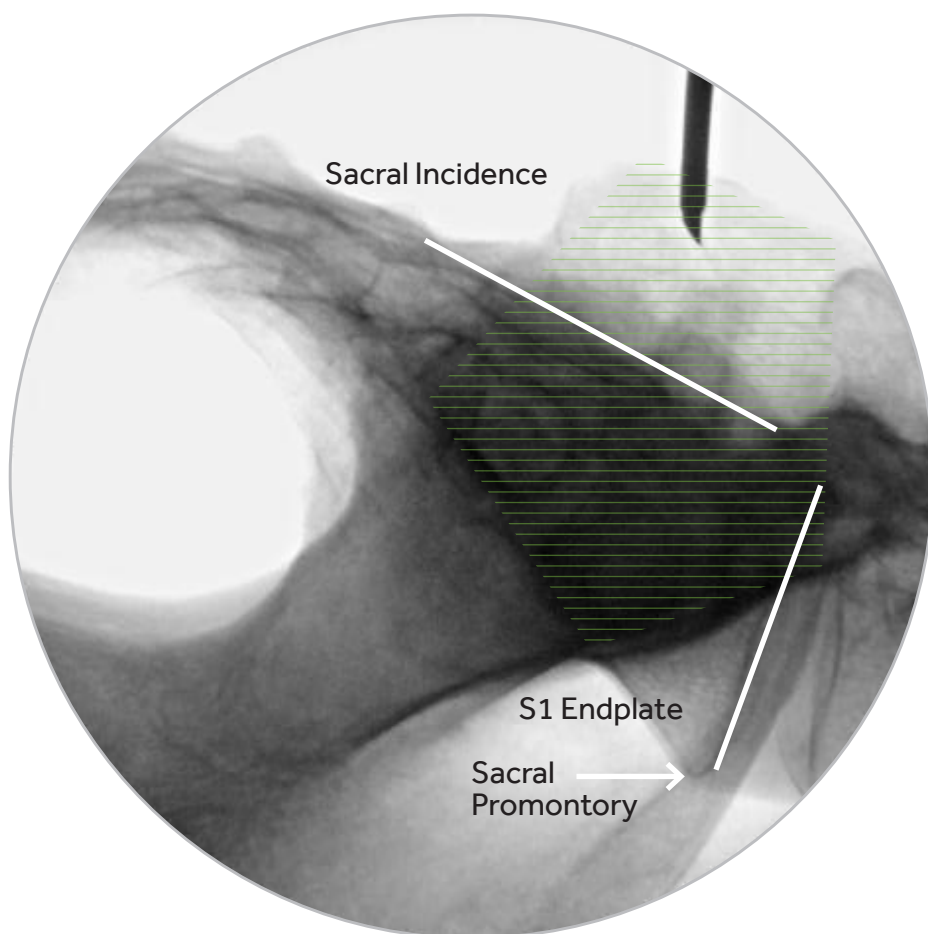
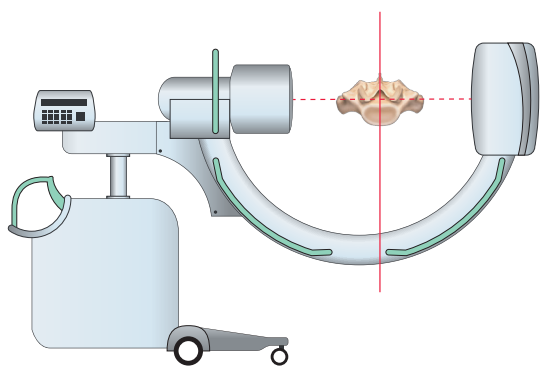


2

LATERAL VIEW

An acceptable radiograph will demonstrate posterior and anterior walls of the sacrum. This view can be used to determine the orientation of the S1 endplate, the approximate sacral incidence, and the sacral promontory. The trajectory in this plane should be directed at, or inferior to, the sacral promontory.

C-ARM FOR LATERAL VIEW



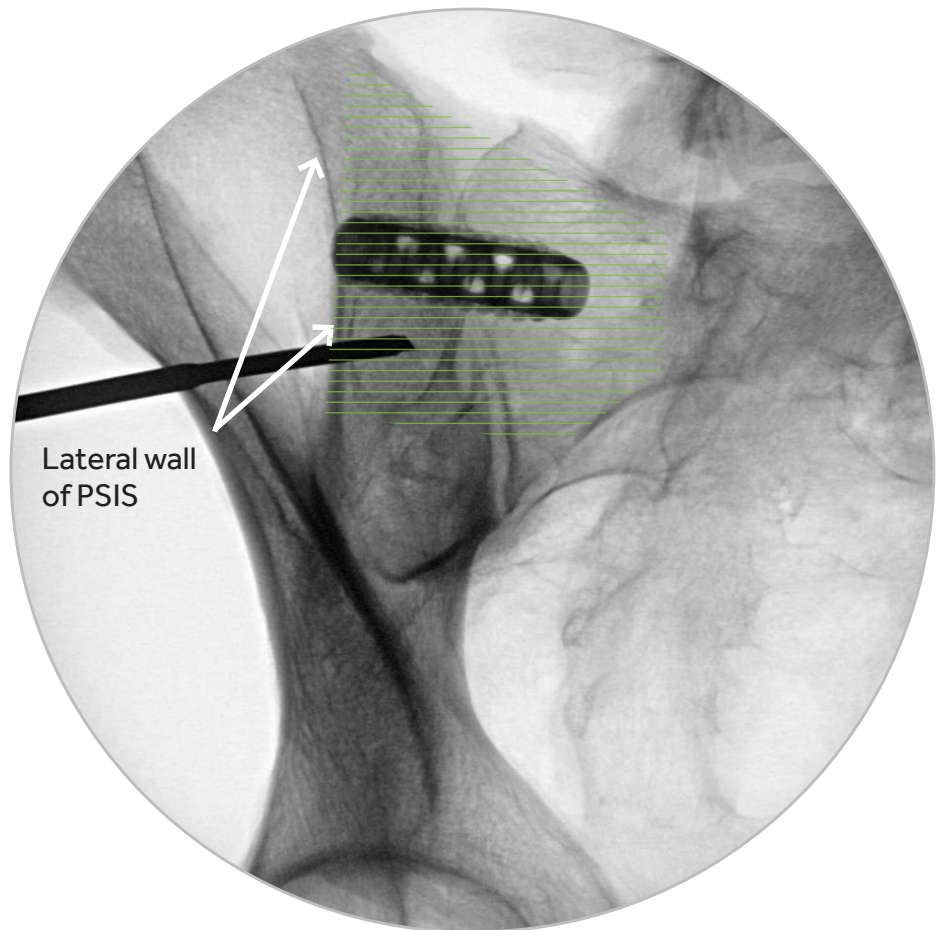
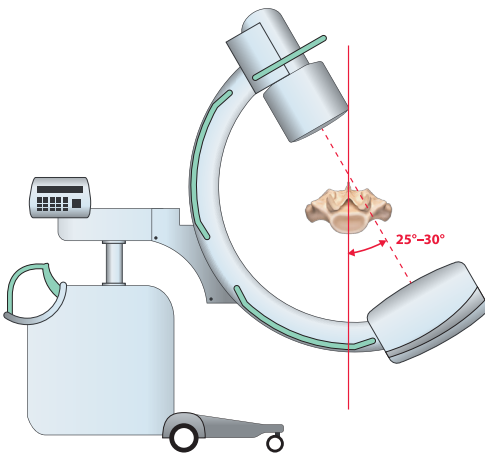
Placement Corridor

3

POSTERIOR OBLIQUE VIEW

The oblique views are taken with the C-arm positioned at 25- 30 degree angle to the AP plane. An acceptable radiograph will demonstrate a closely collimated, centered SI joint with the anterior and posterior joint margins superimposed. The LPO demonstrates the right SI joint as the side up, and the RPO demonstrates the left SI joint side up. This view can show the lateral aspect of the PSIS. This will be the site of the incision.

C-ARM FOR
RIGHT PELVIC OBLIQUE/
LEFT PELVIC OBLIQUE VIEW



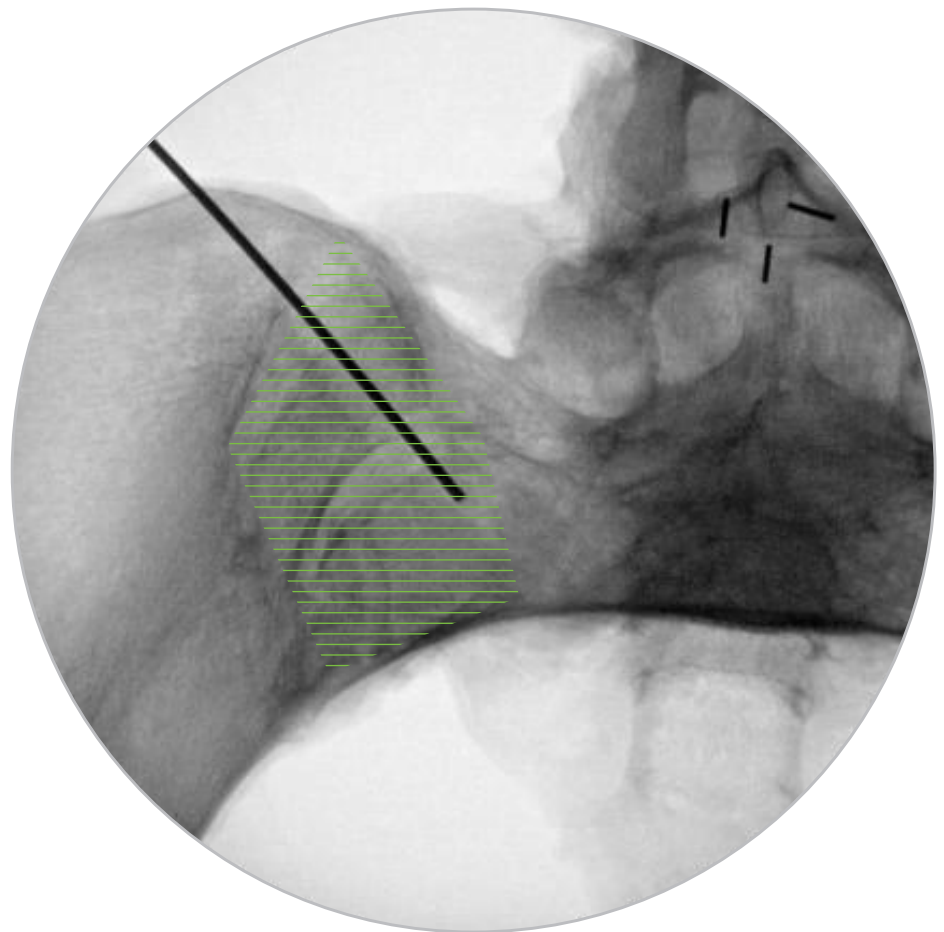
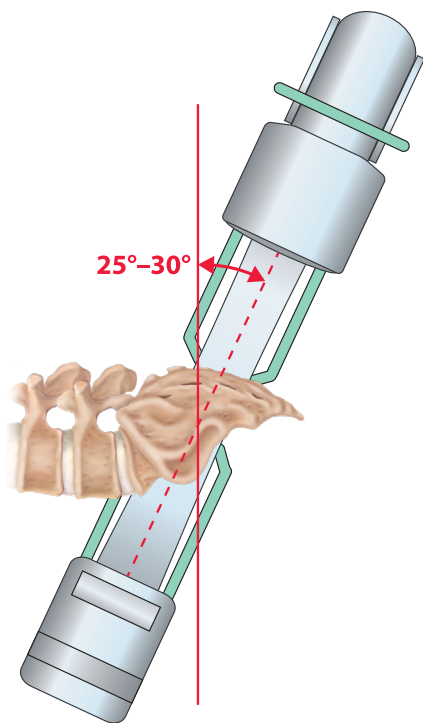
 Placement Corridor

4

SACRAL INLET VIEW

The sacral inlet view is taken with the C-arm typically positioned at a 25-30 degree angle caudally to the AP plane. An acceptable radiograph will demonstrate the complete, circular pelvic ring. Anatomically, this plane will be parallel to the anterior sacrum and thus the actual angle of the C-arm may vary. This view is critical in confirming depth and avoiding violation of the anterior pelvic rim.

C-ARM FOR
INLET VIEW

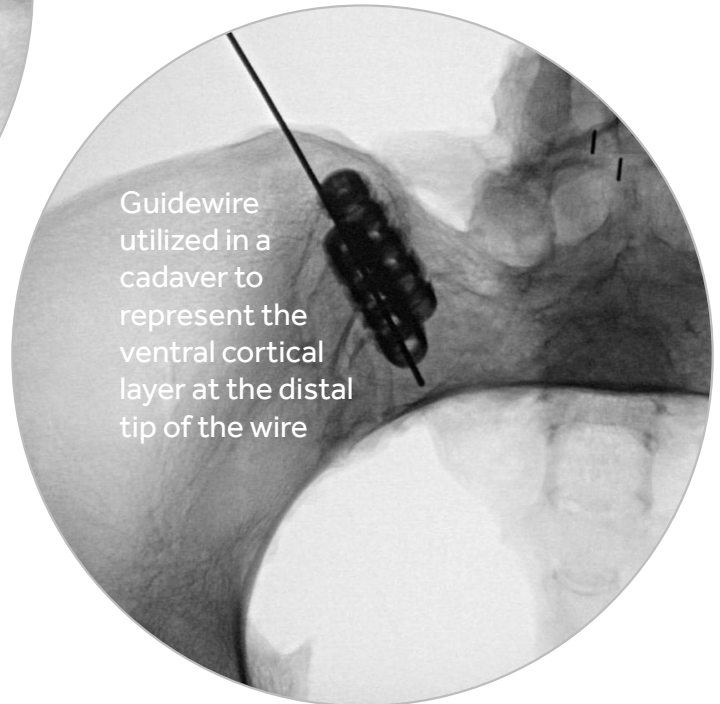
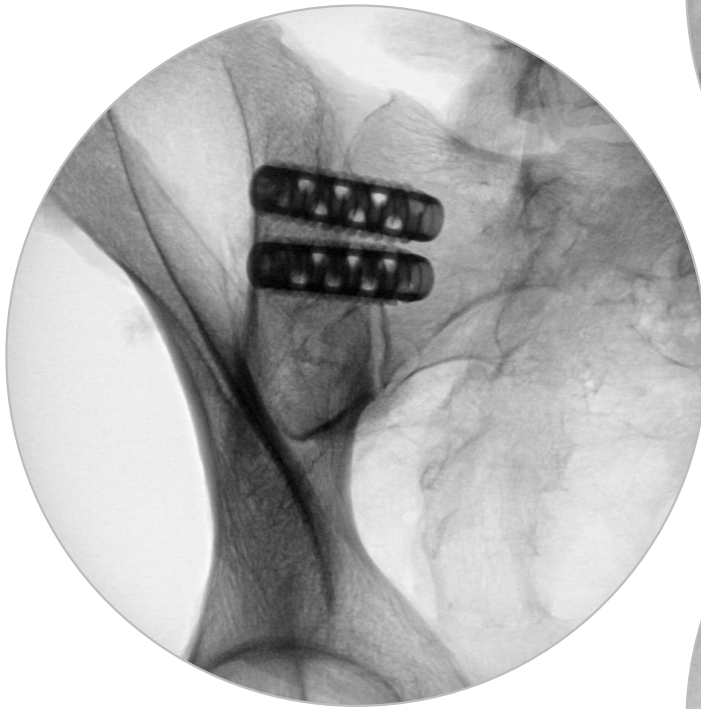


Placement Corridor

5

PLACEMENT CONFIRMATION

Confirmation of final placement should be examined in three views (lateral, sacral inlet, sacral outlet). If it is determined the guidewire has advanced, stop and verify instrumentation in all three views.



Guidewire
utilized in a
cadaver to
represent the
ventral cortical
layer at the distal
tip of the wire

SUMMARY OF IMPORTANT PRODUCT INFORMATION FOR THE RIALTO SI FUSION SYSTEM

PURPOSE

This device is a fusion device intended for stabilization use and to promote bone fusion of the sacroiliac joint. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations. This device is manufactured from medical grade titanium alloy and is provided non-sterile.

DESCRIPTION

The RIALTO™ SI Fusion System consists of cannulated devices of various widths and lengths used to provide temporary stabilization when fusion of the sacroiliac joint is desired. Autograft and/or allograft may be placed in conjunction with the RIALTO™ SI Fusion System. This device may be implanted via a minimally invasive approach.

No warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use titanium or titanium alloy implants with stainless steel in the same construct.

INDICATIONS

The RIALTO™ SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS

The RIALTO™ SI Fusion System is contraindicated for patients with the following conditions:

- Deformities.
- Tumor resection.
- Infection local to the operative site and/or signs of local inflammation.
- Failed previous fusion.
- Suspected or documented allergy or intolerance to the component materials.

POTENTIAL ADVERSE EVENTS

The following are specific potential adverse events which should be understood by the surgeon and explained to the patient. These do not include all adverse events, which can occur with any surgical procedure, but are important factors to consider which are specific to metallic internal stabilization devices. Potential adverse events specific to this device are:

- Post-operative infection, wound necrosis or wound dehiscence.
- Pain, discomfort, or abnormal sensations caused by the presence of the implant.
- Metal sensitivity, or allergic reaction to a foreign body, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Migration, loosening, or fracture of the implant.
- Decrease in bone density due to stress shielding.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING(S)

A successful result is not always achieved in every surgical case.

Patients who are pregnant or who are planning to become pregnant should not utilize this procedure.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Patients with previous surgery at the treated area may have different clinical outcomes compared to those without a previous surgery.

Proper patient selection and compliance will affect the results.

An implanted device should never be re-used unless otherwise specified. Implants which have come in contact with the patient are designed for single patient use only. Do not reuse, reprocess, or re-sterilize used implants. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death. Unused implants that have not been in contact with the patient or the patient's blood may be re-sterilized and used in subsequent procedures.

PRECAUTION(S)

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

FOR US AUDIENCES ONLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Please contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert for current indications, warnings, precautions and other important medical information.

NOTES

NOTES

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[medtronic.com](http://www.medtronic.com)



Consult instructions for use at this
website www.medtronic.com/manuals.

Note: Manuals can be viewed using a
current version of any major internet
browser. For best results, use Adobe
Acrobat® Reader with the browser.

Please see the package insert for the
complete list of indications, warnings,
precautions, and other important
medical information.

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