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Indications for Use

The PerQdisc Nucleus Replacement System is intended for replacement of the nucleus pulposus to an intervertebral disc at one level (L1-L5) following single-level nuclectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD), with or without leg pain, with less than 3mm static spondylolisthesis (anterolisthesis or retrolisthesis) or less than 4mm dynamic spondylolisthesis. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The PerQdisc is implanted using a lateral surgical approach. Prior to receiving the PerQdisc, patients must have exhausted conservative (nonoperative) treatment for at least 6 months.

A comprehensive list of Inclusion and Exclusion Criteria can be found below.

Inclusion Criteria

1. Skeletally mature male or female subjects aged 22-70 (inclusive)
2. Subject has a primary diagnosis of single level discogenic back pain caused by degenerative disc disease (L1 to L5) identified via MRI.
3. Subject has an intact annulus (as determined by MRI) and endplates (as determined by MRI and X-ray) at the level to be treated.
4. Subject must have failed to respond to a minimum of 6 months of conservative treatment for their back pain (e.g., physical therapy, medications, injections, ablations, lifestyle changes, etc.).
5. Subject has a low back pain Visual Analog Scale (VAS) ≥40 mm (4 cm).
6. Subject has adequate disc height (≥6mm measured at the center of the disc) at the level to be treated. [*As measured by the investigator*]
7. Subject is psychosocially, mentally and physically able and willing to fully comply with this protocol including adhering to follow-up schedule and requirements and filling out forms.
8. Subject has read and understand the IRB approved informed consent document prior to signing and dating the document and before the initiation of any study-related procedures.
9. Subject is an appropriate candidate for the PerQdisc surgical approach [*as defined in the surgical technique guide*].

Exclusion Criteria

1. Subject has symptomatic degenerative disc disease at more than one lumbar level.
2. Subject has had a prior spinal fusion in the lumbar or thoracic intervertebral spaces.
3. Subject has had a prior SI-joint fusion.
4. Subject has a spinal cord stimulator.
5. Subject has had any prior lumbar spine surgery (instrumented or non-instrumented).
6. Subject has a significant disc herniation at the level to be treated. Significant is defined as a large, extruded herniation that creates a risk for expulsion.
7. Subject has congenital moderate or severe spinal stenosis or epidural lipomatosis.
8. Subject has spondylolisthesis (antero- or retrolisthesis) in static X-ray ≥3 mm [*measured via neutral lateral x-ray*].
9. Subject has ≥4 mm dynamic spondylolisthesis [*measured via flexion/extension x-rays*].
10. Subject has > 20 degree range of motion at the index level [*measured via flexion/extension x-rays*].
11. Subject has a history of any invasive malignancy (except non-melanoma skin cancer) unless treated with curative intent and there have been no clinical signs or symptoms of malignancy for at least 5 years (in particular, spinal tumors).
12. Subject has an active systemic infection or infection at the operative site.
13. Subject has evidence of symptomatic facet joint degeneration or disease where the investigator feels the facet is a major contributor to the subject's pain as diagnosed by injection and/or imaging.
14. Subject has a known allergy to silicone or barium sulfate.
15. Subject has been diagnosed with fibromyalgia, hepatitis, rheumatoid arthritis, lupus erythematosus, AIDs, ARC, HIV, or an autoimmune disease that affects the musculoskeletal system.
16. Subject has been diagnosed with Paget's disease, osteomalacia or any other metabolic bone disease.
17. Subject has current or recent history (defined ≤ 1 year prior to screening) of substance abuse (alcoholism and/or narcotic addiction) using standard medical definitions of DSM-5
18. Subject has morbid obesity defined as a body mass index (BMI) > 40.
19. Subject participated in an investigational drug or another medical device study within the last 30 days prior to surgery.
20. Subject has Osteoporosis, defined as a T-score ≤ -2.5.
    a. An existing DEXA is allowed if completed within 6 months of subject surgery.
    b. For all subjects without an existing DEXA, the SCORE/MORES will be utilized to screen if a DEXA scan is indicated. If SCORE/MORES value ≥ 6, then a DEXA scan is required.
21. Female subjects who are pregnant or are trying to become pregnant during the course of the trial.
22. Subject has diabetes mellitus (Type 1 or 2) requiring daily insulin management.
23. Subject belongs to a vulnerable population or has a condition such that his/her ability to provide informed consent, comply with follow-up requirements, or provide self-assessments is compromised (e.g. developmentally disabled, prisoner, chronic alcohol/ substance abuser).
24. Subject is currently receiving worker's compensation or is involved in any litigation for medical negligence, trauma, or worker's compensation.
25. Subject has lumbar scoliosis > 10 degrees at index level.
26. Subject has a large, rectangular or irregularly shaped Schmorl's node with an associated active inflammatory process (Modic I changes).
27. Subject has motion of < 3 degrees on pre-operative lateral flexion/extension radiographs at the index level.
28. Subject has opioid medication usage > 60 MME (morphine milligram equivalent)/day or change in opioid prescription within 60 days of surgery.
29. Subject has a preoperative VAS right or left leg pain score > the preoperative VAS Back score.
30. Subject has a history of vertebral fractures in the lumbar spine.
31. Subject has evidence of severe compression of cauda equina.
32. Subject is on chronic anticoagulation therapy due to a bleeding disorder and is unable to safely stop anticoagulants or has taken anticoagulants within 3 days prior to procedure.
33. Subject has low back pain (LBP) of non-spinal or unknown etiology.
34. Subject is unable to undergo X-ray, MRI, or other radiographic assessments, including discography.
35. Subject has a degenerative muscular or neurological condition that would interfere with evaluation of outcomes, including but not limited to spinal disease (not at index level), Parkinson's disease, amyotrophic lateral sclerosis (ALS), or multiple sclerosis.

36. Subject has, in the opinion of the investigator, a behavioral, cognitive, social or medical problem that may interfere with the assessment of the safety or effectiveness of the device.
37. In the opinion of the investigator, the subject has a major psychiatric disorder that may interfere with the assessment of the safety or effectiveness of the device.
38. Subject has myelopathy
39. Subject has primarily leg pain with associated nerve root compression, in the opinion of the investigator.
40. Subject has an annular defect greater than 6mm that extends from the interior of the disc to the outer margin of the annulus as evaluated on MRI.

PerQdisc Nucleus Replacement System: Device Description

The PerQdisc Nucleus Replacement System consists of 6 sterile, single use, disposable medical devices used to implant the PerQdisc Nucleus Replacement Device. The individual device descriptions and instructions for use can be found below in their respective section.

- Section A: PerQdisc Disc Access System (REF 9001)
- Section B: PerQdisc 20A Imaging Balloon (REF 9006)
- Section C: PerQdisc 50A Imaging Balloon (REF 9005)
- Section D: PerQdisc Implant Delivery Device (REF 9003)
- Section E: PerQdisc Implant Fill Device (REF 9007) / PerQdisc Dispenser Gun (REF 9008)

Additional Devices, Accessory Products and Reusable Instruments Required for PerQdisc Procedure

The following devices, accessories and reusable instruments are required for use with the PerQdisc Nucleus Replacement System.

Compatibility with other devices has not been established.

Refer to instructions for use provided with these devices for important use and safety information.

Required Accessory Products

Disposable Single Use Devices

- Pressure Inflation Device
- 3-way Stopcock and Flexible Line
- 60 mL VacLok syringe
- 6 mL syringe
- Lubricating Jelly
- Contrast media such as ISOVUE 300 or equivalent

Reusable Instruments

Rongeurs and Sterilization Container

- Sterilization container w/ Aspico Filter (PSM Medical Solutions REF 73-310-10-05)
- Sterilization Basket with Silicone Inserts for Endoscopic Instruments (PSM Medical Solutions REF 74-330-03)
- Rongeur Straight, Low Profile, 30cm (PSM Medical Solutions REF P-98-056-03)
- EndoRongeur overload protection, wl 330 mm, 2.5 mm, oval tip (Insight Spine GmbH SP8-330-1)
- EndoRongeur overload protection, wl 330 mm, 3.5 mm, oval tip (Insight Spine GmbH SP8-330-2)
- EndoRongeur overload protection, wl 330 mm, 2.5 mm, semi-flexible tip upwards (Insight Spine GmbH SP8-330-8)
- EndoRongeur Platinum Cup Powergrip, wl 330, 4.0 mm, Straight (Insight Spine GmbH SP8-330-P40)

Holding Arm and Container

- MedFix Rigid Arm, Single Medium 400mm Length Arm, L-Column w/Spacer QC (MedFix REF MF112-0150)
- MedFix Table Clamp for Rigid Arm, Rotatable (MedFix REF MF112-015)
- MedFix Instrument C-Clamp w/Square QC Fitting (MedFix REF MF112-0156)
- MedFix Vision Universal 1 Level Large Case (MedFixREF MFV-1000-INSERT)
- MedFix Vision Universal 1 Level Large Case Lid (MedFix REF MFV_1195-LID)

Risks

Possible, anticipated, procedure-related risks that are associated with any surgery include, but are not limited to the following:

Possible risks associated with <u>any</u> surgery include:

- Local incision risks:
  - Injury to blood vessels - Hematoma (collection of blood outside of a blood vessel)
  - Soft tissue and muscular damage
  - Edema (swelling)
  - Failure of the tissue to heal properly (e.g., hematoma [a pocket of blood caused by bleeding from a broken blood vessel]; seroma [buildup of clear body fluid in the tissue]; wound dehiscence [failure of the incision to completely heal which may allow it to reopen]) which may require drainage, aspiration (removing a substance using suction), debridement (surgery to clean foreign material and dead tissue out of a wound), or other treatment
  - Pain at the incision
- Local infection risks:
  - Superficial (shallow) infection
  - Abscess (swollen tissue containing pus)
  - Deep wound infection
- Systemic infection risks:
  - Pneumonia (lung infection)
  - Septicemia (blood poisoning)
- Systemic medical complication risks:
  - Atelectasis (collapsed lung)
  - Phlebitis (inflammation of the blood vessel in your leg)
  - Thrombosis (blood clot in the vessel)
  - Pulmonary embolism (blood clot in the lung)
  - Respiratory distress or depression (slow, shallow, or difficulty breathing)
  - Pulmonary edema (abnormal collection of fluid in the lungs)
  - Myocardial infarction (heart attack)
  - Stroke
  - Death
- Unexpected reactions:
  - Reactions to the drugs or anesthesia used before, during and after surgery
  - Reactions to imaging techniques used during and after surgery (e.g., x-ray, fluoroscopy).
  - Reactions to blood transfusions
- Inability to resume activities of daily living
- Surgery may not reduce the preoperative pain experienced

Possible anticipated, procedure-related risks associated with <u>any</u> lateral approach lumbar surgery include:

- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- Spinal instability
- Damage to nerves, blood vessels, and nearby tissues
- Injury to kidney, ureter, or bowel
- Impaired muscle or nerve function
- Degenerative changes to the spine
- Damage to bony structures during or after surgery
- Loss of proper spine curvature/height
- Postoperative muscle and tissue pain
- Inflammatory conditions affecting soft tissues or nervous structures

- Scarring or soft tissue damage – affecting muscle, nervous tissue, or skin (Perineural fibrosis)
- Musculoskeletal spasms (back or leg)
- Abdominal wall weakness
  - Herniation of bowel
  - Core muscle weakness
  - Deep incisional pain
- Injury to psoas muscle:
  - Injury to lumbar plexus (leg weakness, leg numbness, dysesthesias and related syndromes)
  - Injury to deep vessels (deep wound bleeding, excessive blood loss, deep vein thrombosis, vascular insufficiency and ischemia to limb or internal organs)
  - Autonomic nervous dysfunction (RSD, causalgia, bladder or erectile dysfunction)

Possible anticipated, procedure-related risks associated with <u>any</u> lumbar disc surgery include:

- Spinal instability
  - Spondylolisthesis acquisita (vertebral slippage)
  - Retrolisthesis
  - Spinal stenosis (narrowing of the spinal canal)
  - Spondylosis
  - Facet joint deterioration
  - Infection of the bone, or surrounding soft tissue
  - Degenerative changes in adjacent segment
  - Loss of disc height
  - Disc herniation
  - Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery
  - Loss of proper spine curvature/height
  - Osteolysis
- Surgery at incorrect level
- Neurological injury:
  - Cauda equina syndrome
    - Loss of bowel or bladder function
    - Incontinence (loss of bowel or bladder control)
  - Epidural bleeding, hematoma, or fibrosis
  - Perineural fibrosis
- Dural injury:
  - Meningitis
  - Dural tear, dural leak, and/or dural injury with or without cerebrospinal fluid (CSF) leakage
  - Arachnoiditis
  - Cerebrospinal fistula
  - Headache
- Risks to neurological structures including:
  - Compressive lumbar radiculopathy
    - Neurological deterioration
  - Injury to nerves or nerve roots associated with the spinal cord (resulting in pain, weakness, paralysis (partial or complete), paresthesia, altered reflexes, numbness, tingling, or other changes in sensation)
- Remote neurological complications:
  - Coordination abnormalities
  - Dysphasia
  - Gait disturbance
  - Otitis media
  - Tremors
  - Stroke

Possible risks associated with the <u>PerQdisc implant</u> include the following below. Based on the preliminary data collected on PerQdisc patients implanted outside of the United States the following risks are <u>potentially more likely to occur:</u>

- Fracture, wear, or breakdown of the PerQdisc device
- Implant subsidence (sinking) into the vertebral endplate(s) (top of vertebrae)
- Implant migration outside of the vertebral space but not subsiding (sinking) into the vertebral endplate(s) (top of vertebrae)
- Additional surgery to revise, remove or replace the implant.
- Improper placement of the PerQdisc device.
- Back pain due to altered spinal biomechanics (structure, function and motion)
- No pain relief or worsening of pre-operative symptoms.
- Expulsion of the PerQdisc from the spinal disc.

Additional potential PerQdisc risks include the following:

- Allergic or foreign body reaction to the implant materials
- Anatomical or technical difficulties at time of implantation
- Back pain due to altered spinal biomechanics (structure, function, and motion)
- Technical problems with bending or breakage of surgical instruments or device delivery system.
- Development of new radiculopathy (pinching of nerve root, can present as, weakness, numbness and tingling).
- Periprosthetic and periarticular calcification and/or spontaneous fusion (bone growth around the implant location)
- Intra-operative findings that preclude implantation of the PerQdisc device (meaning the PerQdisc cannot safely be implanted due to items such as your anatomy or spine structure)
- Loss of neurological function or interference with neural structures
- Improper placement of the PerQdisc device
- No pain relief or worsening of pre-operative symptoms
- Expulsion of the PerQdisc from the spinal disc
- Abnormal movement in the nucleus space

Warnings

- Do not use device if package is opened or damaged.
- Do not use a device that has been damaged. Use of damaged devices may result in complications. Before use, inspect the components to verify that no damage has occurred.
- Do not use devices after “Use By” date.
- Disc nucleus replacement procedures should only be performed in medical settings in which decompressive surgery is available.
- Device is sterilized with ethylene oxide.
- It is the responsibility of the physician to determine the appropriateness of this product and specific technique for each patient.
- Read and understand the instructions before using this product.
- Follow handling and preparation instructions carefully.
- The physician must complete company-sponsored training program prior to performing the PerQdisc Surgical Procedure on a patient. The physician should also attend a company-sponsored refresher training program if there is an extended period of time between PerQdisc procedures.
- Intended for use with devices in the PerQdisc System Kit (REF9013).
- Adhere strictly to good surgical principals and techniques.
- Deep wound infection is a serious postoperative complication and may require total removal of the implanted device. Deep wound infection may be latent and not manifest itself even for several years postoperatively.
- Use appropriate imaging techniques to verify correct instrument and device placement.
- The device is intended for single use only. Do not re-sterilize or reuse. Re-sterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-contamination and potential patient injury, illness or death.
- Avoid contacting imaging equipment with the procedure instruments/devices.

- Frequent use of fluoroscopy is necessary when placing devices and instruments inside the disc space to minimize the risk of damaging the annulus and/or endplates.
- Use extreme caution to avoid removing material from the dorsal margin of the disc space during the nuclectomy. Damage to the dorsal annulus could result in the need to convert to an alternative surgical treatment.
- The PerQdisc Disc Access System and rongeurs should remain parallel to the endplates at all times when placed inside the disc space. Damaging the endplates with any device could result in the need to convert to an alternative surgical treatment.
- Always use sequential dilation when accessing the disc space to position the access cannula.
- The 50A Imaging balloon must have a minimum volume of 1.5 mL in order proceed with the final implant.

Precautions

- Markings on the PerQdisc Disc Access System are for reference only and are not intended to replace the use of fluoroscopic imaging.
- Store devices in original container until time of use.
- Do not use this product if you have not been properly trained in its use.
- Physicians using the device should be familiar with the physiology and pathology of the selected anatomy and have adequate training in the performance of the surgical technique.
- Access to the lumbar spinal disc requires specific knowledge of the dimensions for the site of insertion to the disc as assessed by MRI, Fluoroscopy, CT or other imaging methods.
- Never use electric power (or any other alternative power sources) in conjunction with the PerQdisc Nucleus Replacement System. Manual control only.
- Applying excessive leverage to surgical instrument and devices may result in damage.
- Use recommended accessories of proven chemical compatibility with the PerQdisc devices and contrast agents.
- Only use devices in the PerQdisc Nucleus Replacement System provided by SST or as specified by SST.
- Always use fluoroscopic guidance while filling PerQdisc Imaging balloons and PerQdisc Implant.
- Never add other substances or foreign bodies to the silicone resin or modify the ratios between the liquid components.

CAUTION- Investigation device. Limited by Federal (or United States) law to investigational use

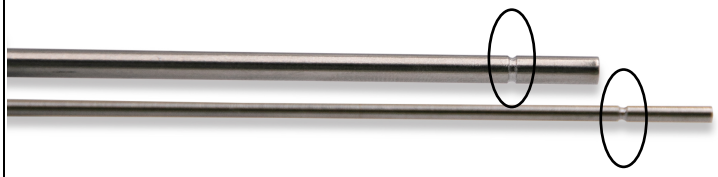
A: PerQdisc Disc Access System (REF 9001)

The PerQdisc Nucleus Replacement System is designed to support a lateral surgical approach to the L1-L5 lumbar spinal disc nucleus.

The Disc Access System (Figures 1 & 2) is a part of the PerQdisc Nucleus Replacement System. The Disc Access System contains sterile, single-use, disposable devices, consisting of four sequential dilators and an Access Cannula. The components are shown in Figures 1 and 2 below. The PerQdisc Disc Access System is intended to achieve controlled dilation of the annular access site and facilitate the use of rongeurs for a nuclectomy.

Figure 1. Dilator Set

1. 2.05 mm outside diameter solid dilator
2. 3.5 mm outside diameter dilator
3. 4.9 mm outside diameter dilator
4. 6.17 mm outside diameter dilator



Dilator notch (1cm from proximal end)

Figure 2. Access Cannula

Recommended Procedure

Note: Perform steps below under fluoroscopic guidance as applicable. The markings on the PerQdisc Disc Access System are for reference only and are not intended to replace the use of fluoroscopic imaging.

Pre-Preparation

Check Packaging – Ensure components are intact; undamaged

Check preparation accessories and ensure they are specifically compatible with the product.

Access cannula must be properly positioned prior to performing the nuclectomy, and positioning of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device placement.

Gaining Access to the Nucleus Pulposus using the PerQdisc Disc Access System

1. Achieve access to the disc margin using a Use a lateral surgical approach.
2. After gaining access to the disc, place the tip of the 2.05 mm solid dilator on the midpoint of the craniocaudal dimension of the annulus.
3. Use fluoroscopy to ensure good position.
   - Good position is achieved when the access starts at the midpoint of the craniocaudal dimension of the disc margin, parallel to the endplates and with a trajectory that will facilitate a sufficient nuclectomy.
4. Pierce the annulus by advancing the solid dilator (Figure 1) 1.0 cm through the annulus and confirm position with fluoroscopy. The first mark on the distal tip of the dilator is approximately 1.0cm. Advance the dilator midway across the disc space on lateral fluoroscopy. When viewed under fluoroscopy, the dilator should be centered in both AP and lateral dimensions simultaneously.
   - Gentle rotation of the dilator is typically all that is needed for advancement. However, occasionally a mallet may be desired to place the dilators.
   - Use an Insertion Tool, if necessary, to protect the dilators when using a mallet.
5. Place the 3.5 mm OD dilator over the solid dilator.

- Each dilator will be advanced until the 1 cm notch (Figure 1) is visible on the proximal end of the previous dilator.
- Repeat this step sequentially until the largest dilator (6.17mm OD) is in place.

6. The Access Cannula must be placed into position prior to performing the nuclectomy. Insert the Access Cannula over the largest dilator in order to maintain annular access and to facilitate re-entry of instruments into the nucleus. The Access Cannula will remain lodged within the annulus until the procedure is completed.
   - The Access Cannula is advanced until the tip of the cannula is in line with the medial boundary of the ipsilateral pedicle.
   - Once the Access Cannula is positioned, all dilators may be removed leaving the Access Cannula in position.
7. Perform a nuclectomy as described in the Surgical Technique Manual

Warning
- Frequent use of fluoroscopy is necessary when placing devices, and instruments inside the disc space to minimize the risk of damaging the annulus and/or endplates.
- The PerQdisc Disc Access System and rongeurs should remain parallel to the endplates at all times when placed inside the disc space. Damaging the endplates with any device could result in the need to convert to an alternative surgical treatment.
- Do NOT advance dilators past midline of the disc space.

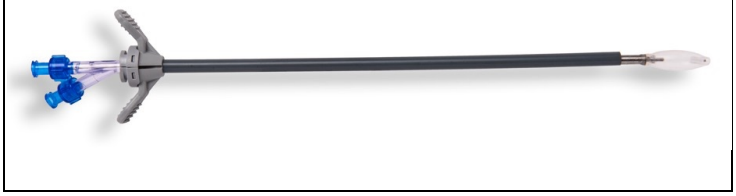
Caution
- Positioning and deployment of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device must be done through the Access Cannula
- Markings on the PerQdisc Disc Access System are for reference only and are not intended to replace the use of fluoroscopic imaging.

Note
- Intradiscal pressure can create force, pushing the dilators out. Be sure the dilator in place has not backed out prior to advancing the next dilator. If this occurs, the Insertion tool may be helpful in advancing dilators 3 & 4.

Section B: PerQdisc 20A Imaging Balloon (REF 9006)

The PerQdisc 20A Imaging Balloon (Figure 3) is a part of the PerQdisc Nucleus Replacement System. The 20A Imaging Balloon contains a sterile, single-use, disposable device as shown in Figure 3 below. The PerQdisc 20A Imaging Balloon is the first balloon introduced and is used to assess and evaluate the extent of the nuclectomy, as well as determine annular and endplate integrity. The PerQdisc 20A Imaging Balloon can be distinguished by the two blue ports at the proximal end of the device.

Figure 3. 20A Imaging Balloon



Recommended Procedure

Note: Perform steps below under fluoroscopic guidance as applicable. The filling process should be done, while visualizing the dorsal annulus, under lateral fluoroscopic view (or variant).

Pre-Preparation

Check Packaging – Ensure components are intact; undamaged.

Check preparation accessories and ensure they are specifically compatible with the product.

Use accessories of proven chemical compatibility with the Imaging Balloon components and contrast agents

Disc access and disc space preparation are to be completed ONLY with instruments provided by SST or as specified by SST

The Access Cannula must be properly positioned prior to performing the nuclectomy, and positioning of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device placement.

Preparation/Priming of 20A Imaging Balloon

Step 1: Fill 6 mL syringe with 6 mL of contrast.
Step 2: Attach 6 mL syringe to straight port of 3-way Stopcock and Flexible Line, and turn stopcock switch off to side port.
Step 3: Attach 3-way Stopcock and Flexible Line to angled port of the 20A Imaging Balloon.
Step 4: Depress plunger on the 6 mL syringe until contrast flows from the straight port of the 20A Imaging Balloon.
Step 5: Attach properly prepared Pressure Inflation Device to the straight port of the 20A Imaging Balloon. Ensure the Pressure Inflation Device has a volume of at least 7 mL of Isovue 300 (or equivalent).

Sheathing Process for 20A Imaging Balloon

Step 1: Apply lubricating jelly to the joint where the PerQdisc Imaging Balloon attaches to the stylet.
Step 2: Massage balloon to force contrast back into 6 mL syringe (Make sure stopcock switch is turned off to the side port).
Step 3: Gently pinch, stretch and twist balloon.
Step 4: Advance Delivery Sheath completely over the length of the 20A Imaging Balloon.
- Turn Stopcock switch off to the Imaging Balloon.
- Detach 6 mL syringe and discard contrast.
- Re-attach 6 mL syringe to the straight port of the stopcock.

Nuclectomy Assessment

Step 1: Insert the 20A Imaging Balloon through the Access Cannula, and advance the device until touching the contralateral annular margin of the disc. Verify device position using fluoroscopy.
Step 2: Secure the device into position with the holding arm.
Step 3: Unsheath the balloon by withdrawing the gray Delivery Sheath.
Step 4: Deliver contrast media from the Inflation Device to the 20A Imaging Balloon.
- Under fluoroscopic guidance, confirm filling of the Imaging Balloon with contrast media.
- Inflate the 20A Imaging Balloon to an initial pressure of 30 psi and assess the extent of the nuclectomy. (If the nuclectomy is sufficient proceed to the Annulus and Endplate Assessment)
- If the nuclectomy is not adequate, aspirate the balloon by turning the switch on the stopcock off to the side port and gently pull a vacuum with the 6 mL syringe. When the balloon is empty, turn the stopcock switch back off to the Imaging Balloon. Be sure to note the volume of contrast removed.

Step 5: To perform additional nuclectomy disconnect the Imaging Balloon from holding arm and withdraw the Imaging Balloon by grasping the delivery sheath and gently withdraw the device from the Access Cannula.
- With the device removed, perform additional nuclectomy.
- For repeated assessment with the 20A Imaging Balloon, first deliver the contrast from the 6 mL syringe by turning the stopcock switch off to the side port and depress the plunger on the 6 mL syringe, then turn the stopcock off to the Imaging Balloon. Observe the pressure before filling from the inflation device.
- Repeat steps 1-5 above as needed to achieve sufficient nuclectomy.

Step 6: Once the nuclectomy assessment is complete and satisfactory, leave the 20A balloon in place and proceed to Annulus and Endplate Assessment.

Annulus and Endplate Assessment

Step 1: Continue to fill the 20A Imaging Balloon to a pressure of 45 psi and use fluoroscopy to confirm annular and endplate integrity prior to implantation. Do NOT perform this step more than once.
Step 2: Withdraw the contrast from the balloon by turning the switch on the stopcock off to the side port and gently pull a vacuum with the 6 mL syringe. Be sure to note the volume of contrast removed.
Step 3: Disconnect PerQdisc 20A Imaging Balloon from holding arm and withdraw the Imaging Balloon by grasping the delivery sheath and gently withdraw the device from the Access Cannula.
- The Access Cannula remains in position throughout the procedure.
- Prepare for the trial implant with the PerQdisc 50A Imaging Balloon

WARNING
- If significant dorsal defects are observed stop the fill and consider an alternative treatment.
- If a significant endplate defect is observed, consider and alternative treatment.

Do not proceed if:
- Protrusion of the 20A Imaging Balloon up to or beyond the outer vertebral margin.
- Patient had a violated endplate as determined by Imaging Balloons during fluoroscopy.

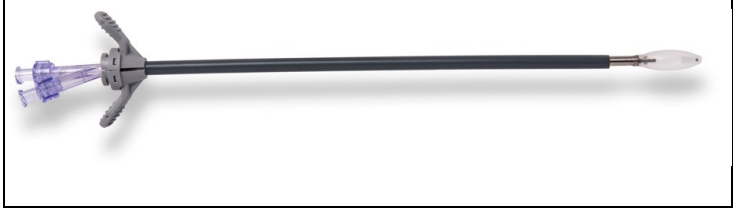
CAUTION
- Use appropriate imaging techniques to verify correct instrument and device placement.
- Use fluoroscopy to ensure the delivery sheath is completely withdrawn the entire length of the Imaging Balloon.
- Make sure the balloons are positioned completely inside the disc cavity.

NOTE
- It is imperative to ensure the filling process for all devices is performed under fluoroscopic guidance, paying close attention to ensure that there is no expansion dorsally into the central spinal canal.

Section C: PerQdisc 50A Imaging Balloon (REF 9005)

The PerQdisc 50A Imaging Balloon (Figure 4) is a part of the PerQdisc Nucleus Replacement System. The 50A Imaging Balloon contains a sterile, single-use, disposable device as shown in Figure 4 below. The 50A Imaging Balloon is the second balloon introduced and is the same stiffness as the PerQdisc Implant Delivery Device, thus allowing this balloon to serve as a trial implant to estimate the volume, shape, and distribution of the final implant. The PerQdisc 50A Imaging Balloon can be distinguished by the two purple ports at the proximal end of the device.

Figure 4. 50A Imaging Balloon



Recommended Procedure

Note: Perform steps below under fluoroscopic guidance as applicable. The filling process should be done, while visualizing the dorsal annulus, under lateral fluoroscopic view (or variant).

Pre-Preparation

Check Packaging – Ensure components are intact; undamaged.

Check preparation accessories and ensure they are specifically compatible with the product.

Use accessories of proven chemical compatibility with the Imaging Balloon components and contrast agents

Disc access and disc space preparation are to be completed ONLY with instruments provided by SST or as specified by SST

The Access Cannula must be properly positioned prior to performing the nuclectomy, and positioning of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device placement.

Preparation/Priming of 50A Imaging Balloon

Step 1: Fill 6 mL syringe with 6 mL of contrast.
Step 2: Attach 6 mL syringe to straight port of 3-way Stopcock and Flexible Line, and turn Stopcock switch off to side port.
Step 3: Attach 3-way Stopcock and Flexible Line to angled port of the 50A Imaging Balloon.
Step 4: Depress plunger on the 6 mL syringe until contrast flows from the straight port of the 50A Imaging Balloon.
Step 5: Attach properly prepared Pressure Inflation Device to the straight port of the 50A Imaging Balloon. Ensure the Pressure Inflation Device has a volume of at least 7 mL of Isovue 300 (or equivalent).

Sheathing Process for 50A Imaging Balloon

Step 1: Apply lubricating jelly to the joint where the PerQdisc Imaging Balloon attaches to the stylet
Step 2: Massage balloon to force contrast back into 6 mL syringe (make sure stopcock switch is turned off to the side port).
Step 3: Gently pinch, stretch and twist balloon.
Step 4: Advance Delivery Sheath completely over the length of the 50A Imaging Balloon.
- Turn Stopcock switch off to the Imaging Balloon.
- Detach 6 mL syringe and discard contrast.
- Re-attach 6 mL syringe to the straight port of the stopcock.

Steps for 50A Imaging Balloon/Trial Implant

Step 1: Insert the 50A Imaging Balloon through the Access Cannula, and advance the device until touching the contralateral annular margin of the disc. Verify device position using fluoroscopy.
Step 2: Secure the device into position with the holding arm
Step 3: Unsheath the balloon by first withdrawing the gray delivery sheath.
Step 4: Deliver contrast media from the Pressure Inflation Device to the 50A Imaging Balloon under fluoroscopic guidance.
- Confirm filling of the 50A Imaging Balloon with contrast media.
- Inflate the 50A Imaging Balloon to an initial pressure of 30 psi to assess conformity and volume. This pressure may be increased as needed to conform to the nuclectomy, based on fluoroscopic imaging. Do not exceed a maximum fill pressure of 60 psi
- Verify the Imaging Balloon is centrally located with a robust dorsal annular margin. If the 50A Imaging Balloon extends past the posterior margin of the vertebral body, the PerQdisc cannot be implanted.
- Verify the balloon is not flowing into any defects in the endplate.

Step 5: Withdraw the contrast from the 50 A Imaging Balloon by turning the switch on the stopcock off to the side port and gently pull a vacuum with the 6 mL syringe.
- Be sure to note the volume of contrast removed.
- Volume measurement must be at least 1.5 mL in order to implant.

Step 6: Disconnect PerQdisc 50A Imaging Balloon from holding arm and withdraw the Imaging Balloon by grasping the delivery sheath and gently withdraw the device from the Access Cannula.
- The Access Cannula remains in position throughout the procedure.
- Prepare for the PerQdisc Implant Delivery Device deployment.

WARNING
- The 50A Imaging Balloon must have a minimum volume of 1.5 mL in order to proceed with the final implant.
- Do Not exceed a maximum fill pressure of 60 psi

NOTE
- It is imperative to ensure the filling process for all devices is performed under fluoroscopic guidance, paying close attention to ensure that there is no expansion dorsally into the central spinal canal.

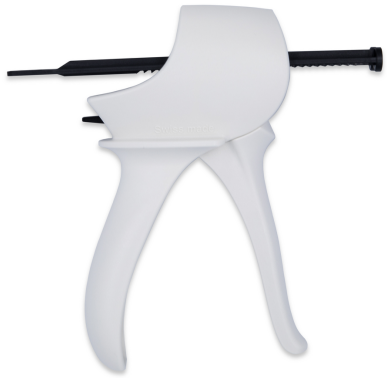
Section D: PerQdisc Implant Fill Device (REF 9007) and PerQdisc Dispenser Gun (REF 9008)

The PerQdisc Implant Fill Device (figure 6 and 7) and the PerQdisc Dispenser Gun (Figure 8) are part of the PerQdisc Nucleus Replacement System. The Implant Fill Device and Dispenser gun are sterile, single-use, disposable devices that include the following components as shown in Figures 6 and 7 below. The device consists of a Dual Cartridge Syringe, with Pistons and Cap filled with Part A and B Silicone, in addition to a mixing tip. When inserted into the PerQdisc Dispenser Gun (Figure 8), the silicone polymer can be manually injected into the PerQdisc Implant Delivery Device. The PerQdisc Dispenser Gun is a manually activated dispenser for the delivery of volumetric ratios of material while preventing cross-contamination and curing of the material in the outlet/inlet area.

Figure 6. Dual Cartridge Syringe, with Pistons and Cap filled with Part A and B Silicone

Figure 7. Mixing Tip

Figure 8. PerQdisc Dispenser Gun



Recommended Procedure

Pre-Preparation

Check Packaging – Ensure components are intact; undamaged.

Check preparation accessories and ensure they are specifically compatible with the product.

Use accessories of proven chemical compatibility with the Imaging Balloon components and contrast agents

Disc access and disc space preparation are to be completed ONLY with instruments provided by SST or as specified by SST.

The Access Cannula must be properly positioned prior to performing the nuclectomy, and positioning of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device placement.

Preparation of the PerQdisc Dispenser Gun & PerQdisc Implant Fill Device

Step 1: Insert cartridge of the PerQdisc Implant Fill Device (with the notch facing up) into the PerQdisc Dispenser Gun.
Step 2: Advance plunger on the PerQdisc Dispenser Gun until flush against the pistons on the syringe barrel of the PerQdisc Implant Fill Device.
Step 3: Remove cap from the PerQdisc Implant Fill Device.
Step 4: Very gently depress trigger on the PerQdisc Dispenser Gun to verify polymer flow from both syringe barrels.
Step 5: When the PerQdisc Implant Delivery device is properly positioned and the surgeon is ready to begin the implant fill, attach the mixing tip to the PerQdisc Implant Fill Device
Step 6: Present device to surgeon

Caution:

- To prevent pre-mixing of the polymer, do not attach mixing tip until immediately prior to handing off to the surgeon.
- Do not attach PerQdisc Dispenser Gun and PerQdisc Implant Fill Device until the Implant Delivery Device is in properly positioned in the disc space.

Section E: PerQdisc Implant Delivery Device (REF 9003)

The PerQdisc Implant Delivery Device (Figure 5) is a part of the PerQdisc Nucleus Replacement System. The Disc Access System contains sterile, single-use, disposable device as shown in Figure 5 below. The PerQdisc device consists of a shaped silicone membrane assembly with two separate, inflatable chambers. The PerQdisc Implant Delivery Device can be distinguished by the yellow angled port, and purple straight port.

Figure 5. Implant Delivery Device

Recommended Procedure

Note: Perform steps below under fluoroscopic guidance as applicable. The filling process should be done, while visualizing the dorsal annulus, under lateral fluoroscopic view (or variant).

Pre-Preparation

Check Packaging – Ensure components are intact; undamaged.

Check preparation accessories and ensure they are specifically compatible with the product.

Use accessories of proven chemical compatibility with the Imaging Balloon components and contrast agents

Disc access and disc space preparation are to be completed ONLY with instruments provided by SST or as specified by SST.

The Access Cannula must be properly positioned prior to performing the nuclectomy, and positioning of the PerQdisc Imaging Balloons or PerQdisc Implant Delivery Device placement.

Preparation of the PerQdisc Implant Delivery Device

Step 1: Fill 6 mL syringe with 3 mL of contrast.
Step 2: Attach 6 mL syringe to straight port of the Implant Delivery Device.
Step 3: Orient the device correctly (balloon tip pointed towards the ground) and fill inner chamber w/ 0.5 mL of contrast, visually inspect that contrast is flowing into inner chamber.
Step 4: Aspirate inner chamber by pulling a vacuum with the 6 mL syringe, then repeat filling and evacuation of contrast 3 three times, leaving inner chamber full (0.5 ml) on the last cycle.
Step 5: Detach 6 mL syringe leaving a visible “meniscus” on the tip of the port.
Step 6: Attach a primed Inflation Device to straight port of the Implant Delivery Device. Ensure the Pressure Inflation Device has a volume of 3 mL of Isovue 300 (or equivalent).
Step 7: Inject an additional 0.25 mL of contrast from Inflation device.
Step 8: Verify pressure transduction by observing the pressure gauge on the Inflation device while gently squeezing the inner chamber from the distal tip.

Sheathing Process for the PerQdisc Implant Delivery Device

Step 1: Unlock Pressure Inflation Device.
Step 2: Apply lubricating jelly to the joint where the PerQdisc Implant Balloon attaches to the stylet.
Step 3: Fold balloon along longitudinal axis.
Step 4: Advance the delivery sheath the entire length of balloon, gently massaging inner chamber to allow contrast to return to Pressure Inflation Device, enabling the sheath to pass over the balloon.
Step 5: Once the delivery sheath has been advanced the entire length of the balloon lock Inflation Device.
Step 6: Attach a 3-way Stopcock and Flexible Line to angled port to the PerQdisc Implant Delivery Device, making sure that the Stopcock switch is turned off to the side port.
Step 7: The PerQdisc Implant Fill Device will be attached to the straight port of this 3-way Stopcock when the surgeon is ready to begin the PerQdisc Implant fill.
Step 8: Check to confirm Pressure Inflation device is LOCKED.
Step 9: The sheathed PerQdisc Implant Delivery Device is ready to be presented to the surgeon.

PerQdisc Implant Delivery Device Fill Process

Step 1: Insert the PerQdisc Implant Delivery Device through the Access Cannula, and advance the device until touching the contralateral annular margin of the disc. Verify device location using fluoroscopy.
Step 2: Secure the device into position with the holding arm.
Step 3: Unsheath the balloon by withdrawing the grey Delivery Sheath. At this time the Access Cannula can be withdrawn.
Step 4: Under fluoroscopic guidance, deliver 0.25 mL of contrast media from the Pressure Inflation Device to the inner chamber of the PerQdisc Implant Delivery Device. The pressure gauge should register approximately 10 psi.
Step 5: Using fluoroscopy to visualize the PerQdisc inner chamber, to verify the implant is centered within the disc space and is not contacting the endplates.
Step 6: Attach the PerQdisc Implant Fill Device and mixing tip to the stopcock connected to the yellow angled port of the Implant Delivery Device. Make sure the stopcock switch is turned off to the side port, so the silicone is able to flow freely. Fill the PerQdisc implant to an initial pressure of 40 psi (the initial stopping point to assess conformity and volume) by squeezing the trigger mechanism on the PerQdisc Dispenser Gun which will inject the silicone polymer into the outer chamber of the implant. This pressure may be increased as needed to conform to the nuclectomy based on fluoroscopic imaging. Do not exceed a maximum fill pressure of 60 psi
- If it is determined that the implant needs to be removed **within the first 3 minutes** of the curing process, the silicone polymer remains fluid and the implant may still be removed by aspirating the inner chamber and then very gently withdrawing the PerQdisc Implant Delivery Device assembly.
- If removal of the PerQdisc Implant is necessary and it is recognized **after the first 3 minutes** of filling, it is recommended to wait 15 minutes until complete curing has occurred. Once the device is fully cured, forceps and rongeurs can be used to pull and cut the device in order to pass the device segments through the annulotomy.

Step 7: Once the implant is filled to the appropriate pressure, allow the silicone polymer to cure for 15 minutes.
Step 8: Following the 15-minute polymer cure, withdraw the contrast from the inner chamber by unlocking the Inflation Device and aspirating the solution.
Step 9: Disconnect the implant from the PerQdisc Implant Delivery Device stylet by grasping the colored ports on the device and rotating 360° which breaks the bond between the implant and the stylet.
Step 10: Withdraw the delivery system/PerQdisc Implant Delivery Device assembly and Access Cannula.
Step 11: Acquire final imaging.
Step 12: Perform a standard multi-layer closure.

Warning

- Anatomical variations may require advancing the PerQdisc Implant Delivery Device further into the enucleated cavity after the balloon has been unsheathed. If this is required, inflate the inner chamber to 10 psi and then carefully advance the device into position.
- Failure to position the PerQdisc completely inside the annular margin could lead to deploying into the annular access.
- Failure to properly prime the inner chamber and/or the Pressure Inflation Device can lead to inaccurate pressure measurement.
- If at any point in time during the filling process, the pressure reading drop or stops rising confirm that the inner chamber is visible. If not, gently add additional contrast, but do not exceed a maximum fill pressure of 60 psi.

Caution

- Frequent fluoroscopic use is needed to verify that the device is expanding as intended, and that there is no disruption or leak of the silicone.
- Closely monitor the pressure gauge on the Pressure Inflation device throughout the entire filling process.

Note

- Perform steps above under fluoroscopic guidance as applicable. The filling process should be done, while visualizing the dorsal annulus, using fluoroscopic control.
- Prior to filling the implant, use fluoroscopy to confirm the implant is not kinked or folded. The radiopaque markers at the distal and proximal implant edges in conjunction with the inner chamber can help in this process.

Symbols Glossary

Symbol	Meaning	Standard Reference
	Biological risks	ISO 15223-1:2021/A1:2025 Clause 5.4.1
	Catalogue number	ISO 15223-1:2021/A1:2025 Clause 5.1.6
	Caution, see Instructions For Use	ISO 15223-1:2021/A1:2025 Clause 5.4.4
	Contents of package	Not applicable
	Part Number	Not applicable
	Do not re-use	ISO 15223-1:2021/A1:2025 Clause 5.4.2
	Do not resterilize	ISO 15223-1:2021/A1:2025 Clause 5.2.6
	Do not use if package is damaged	ISO 15223-1:2021/A1:2025 Clause 5.2.8
	Lot number	ISO 15223-1:2021/A1:2025 Clause 5.1.5
	Manufacturer	ISO 15223-1:2021/A1:2025 Clause 5.1.1
	Nonpyrogenic	ISO 15223-1:2021/A1:2025 Clause 5.6.3
	Prescription only - device restricted to use by or on the order of a physician	USA 21 CFR 801.109
	Sterilized using ethylene oxide	ISO 15223-1:2021/A1:2025 Clause 5.2.3
	Use-by date	ISO 15223-1:2021/A1:2025 Clause 5.1.4
	MR Conditional	ASTM F2503

STORAGE AND HANDLING

There are no special storage or handling conditions required for the PerQdisc device. There is no need for controlled temperature or humidity and no additional light protection is needed for the PerQdisc device.

DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and national laws and regulations.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Spinal Stabilization Technologies, LTD warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the control of Spinal Stabilization Technologies, LTD directly affect the device and the results obtained from its use.

The obligation of Spinal Stabilization Technologies, LTD under this warranty is limited to the repair or replacement of this device and Spinal Stabilization Technologies, LTD shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Spinal Stabilization Technologies, LTD neither assumes, nor authorizes any other person to assume for it, any other or additional liability, or responsibility in connection with this device. Spinal Stabilization Technologies, LTD assumes no liability with respect to devices reused or reprocessed, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such device.

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For further product information please contact Customer Service: www.sstspine.com.

MRI Label for Instructions of Use

MRI Safety Information

A patient with the PerQdisc Nucleus Replacement System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	PerQdisc Nucleus Replacement System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	No restriction on transmit-receive coils
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 2 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.