

Ordering Information

407-290-000 Discmonitor Unit (10/pkg)

407-295-000 Printer

Contraindications

The Discmonitor is not intended for patients who present the following clinical and radiological findings:

1. Radiological evidence of severe lateral recess stenosis, calcified disc herniations, severe degenerative facet disease, and ligamentum flavum hypertrophy.
2. Radiological evidence of free or extruded disc fragments within the spinal canal.
3. Clinical evidence of significant progressive neurological deficits and/or cauda equina syndrome.
4. The existence of other pathologies, such as fracture, tumor, pregnancy, sensitivity to contrast agent or other conditions that could place the patient at risk.

General anesthesia is contraindicated.

The Discmonitor is not intended for procedures that require pressures greater than 120 psi [827 kPa].

Special Notes

1. Only trained and experienced health care professionals should use this equipment. Before using any system component or any component compatible with this system, read and understand the instructions. Pay special attention to WARNING information. Become familiar with system components prior to use. Failure to comply may result in patient and/or operating room staff injury.
2. The health care provider performing any procedure is responsible for determining the appropriateness of this instrument and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.
3. Sterile only if package is unopened and undamaged. Single use only. DO NOT reuse or resterilize.
4. Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the Discmonitor. Install and place the Discmonitor into service according to the EMC information in this manual. Portable and mobile RF communications equipment can affect the function of the Discmonitor.
5. DO NOT use this equipment in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
6. Prior to use, operate components and inspect for damage. Do not use if damage is apparent.
7. Use only Stryker approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Stryker sales representative for a complete list of accessories. DO NOT modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
8. Follow current local regulations directing the handling and disposal of materials that may be a potential biohazard.

Caution

1. Read all instructions carefully prior to use.
2. U.S. Federal law restricts this device to sale by or on the order of a physician.
3. For single procedure use only, do not use on multiple patients.

For complete product information and instructions, please refer to the Discmonitor Instructions for Use.

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Endoscopy

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Patient Handling Equipment

EMS Equipment

The information presented in this brochure is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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Operative Technique Guide

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Discmonitor

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Intended Use

The Stryker Discmonitor is used to inject fluids into the intervertebral disc nucleus during discography procedures and monitor the pressure of that fluid.

Note: Physicians using the Discmonitor should have training and experience with fluoroscopy, discography, and other intradiscal therapies.



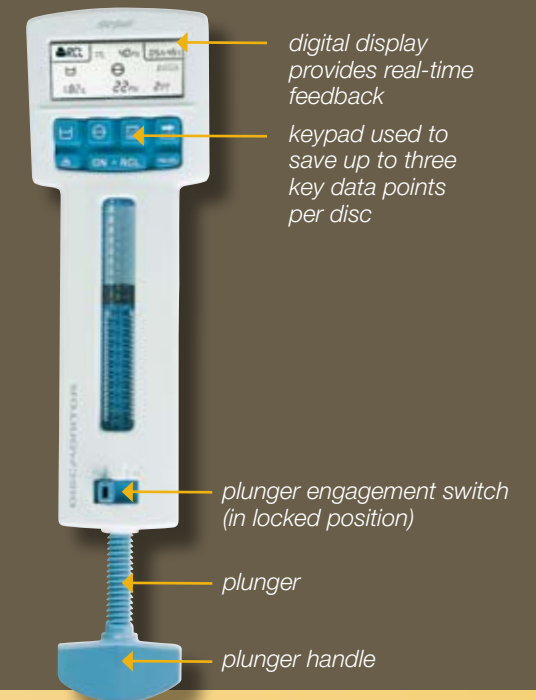
Above. AP view of discography needles in injected disc

Ideal Patient Selection

- Patients with unremitting spinal pain which has been unresponsive to all appropriate methods of conservative therapy
- Patients with suspected discogenic pain
- Uncertain diagnosis of the extent of internal disc disruption

Preparation

- Prepare the patient pre-operatively according to standard procedures
- Prior to opening the package, verify that packaging is not damaged in a way that could compromise sterility of the device
- Flush the introducer cannula with sterile saline
- Fill the reservoir with contrast dye by pulling back on the plunger handle
- To expel any air, hold the Discmonitor in a vertical position with the plunger handle pointing downward and push the handle upward
- Advance the plunger engagement switch to locked position (switch is in "unlocked" position when opened)



Surgical Technique

Step 1

Under fluoroscopic guidance, advance the introducer cannula and stylet into the disc.



Introducer cannula and stylet introduced into disc

Step 2

Once the cannula is placed, remove stylet and connect 3-way valve to cannula.

Step 3

Press the **On/Recall** button to turn Discmonitor on.

Step 4

Under live fluoro, inject contrast dye by rotating plunger clockwise.

Step 5

At the first hint of contrast in the disc, press the **Volume Reset** button and **Pressure Reset** button to save opening pressure.

Step 6

Continue slowly turning the plunger handle to inject additional contrast dye and increase disc pressure.

Step 7

Push the save button as required.

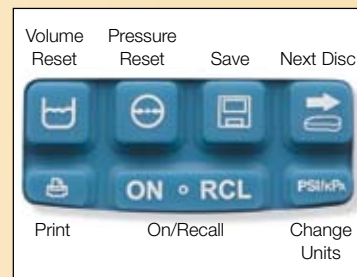
Note: Maximum allowed is three times per disc.

Step 8

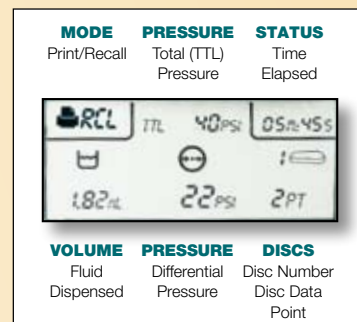
When the first disc is complete, disconnect from introducer cannula, reconnect to next cannula and press **Next Disc** button.

Step 9

Repeat steps 1-8 as required.



Button pad is used to save up to three key data points per disc, up to six disc levels



Digital display provides real-time feedback

Retrieving Data

USING RECALL MODE

Step 1

Push the **On/Recall** button momentarily to view the first saved point data on the display.

Step 2

Continue to push **On/Recall** button to sequentially view the data of each individual disc. You may hold down the **On/Recall** button to quickly cycle through all the disc data sequentially.

Note: Disc data will be shown starting with the last disc, followed by the second to the last disc, etc.

first saved point

second saved point

third saved point

opening pressure

maximum pressure*

maximum volume*

*automatically recorded

Pts	Time (mls)	TTL Press. (PSI)	Diff. Press. (PSI)	Volume (mL)
1	00:20	20	5	1.25
2	00:45	40	22	1.82
3	01:05	80	64	2.05
P \emptyset	00:10	15	00	.30
P max	01:40	88	78	2.15
V min	01:40	88	78	2.15

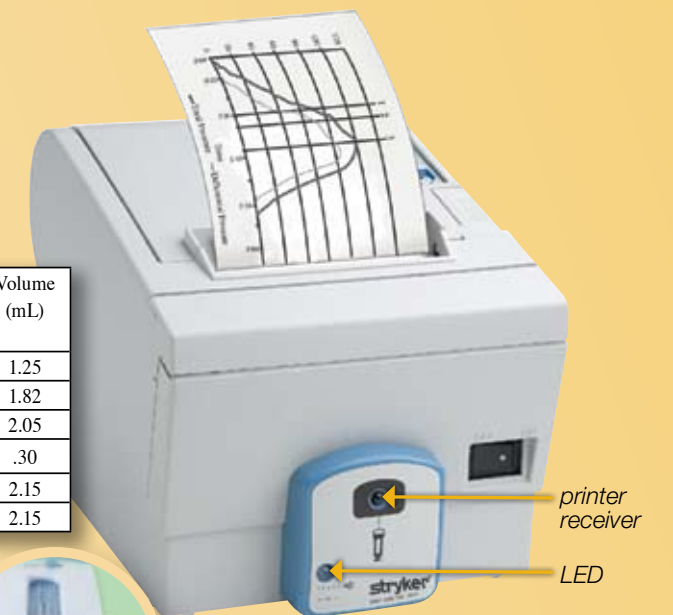
USING PRINTER (sold separately)

Step 1

Point the Discmonitor transmitter at the IR printer receiver (6 to 8 inches away).

Step 2

Press and hold the **Print** button until the LED light stops flashing.



wireless IR data transmitter

Wirelessly prints out comprehensive reports in tabular followed by graphic formats.

* For complete instructions please refer to the Discmonitor Instructions for Use 407-290-705 Rev. D