

**Category**

Best Medical Technology

**Drug / Device Name**

Solo-Dex Fascile

**Compound/ Tech Name**

Fascile Continuous Peripheral Nerve Block

**Trade Name**

Solo-Dex Fascile

**Date of Approval**

2016-01-22

**Indications**

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit is intended for use in regional

anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator, or to be

seen by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous and/or intermittent

administration of local anesthetics or analgesics to the targeted nerve bundle in surgical procedures.

**Therapeutic Categories**

Orthopedics; Anesthesiology; Surgery; Acute Pain

**Background information and need for drug/device**

The Solo-Dex Fascile catheter range for continuous Peripheral Nerve Block (cPNB). This revolutionary device aims to manage acute pain pre-, intra-, and post-surgery, reducing reliance on opioids. Our mission is to set a new standard in post-surgical acute pain management through:

- Enhanced patient safety by minimizing anesthesia risks, particularly for seniors and for cognitive impairment.
- Improved recovery and discharge times as much as three hours.
- Effective home recovery with decreased opioid dependency by reducing or eliminating post operative opioids.
- Cost savings for healthcare providers/patients.
- Increased patient satisfaction through complete blockage of pain during recovery.
- Reduced infection risks for surgical staff

Solo-Dex operates in a \$4 billion acute pain management market. Our patented and FDA-approved products are also CE-marked, registered in Brazil, and Halal-certified, offering global reach.

## **History of the development of the drug/device**

In 2011, with the advent of ultrasound visualization enhancing the possibilities for continuous peripheral nerve block procedures, Dr. Sundar Rajendran and Dr. Dan Kopacz identified a significant need for improved techniques. The traditional methods of nerve block catheter placement, which relied on electrical stimulation and demanded sterile fields, numerous assistants, and complex setups, were resulting in surgical delays of 30 to 45 minutes.

Driven by their passion for regional anesthesia and commitment to advancing the field, the duo decided to innovate and streamline the process. They devised a method that positioned the catheter on the exterior of the needle, curved the catheter for stable placement, and employed a safe, modified needle tip. Over time, and with the clinical experience of over 7,000 patients, the Solo-Dex Fascile was conceived.

The Solo-Dex Fascile, which can be placed in under three minutes using ultrasound, provides up to five days of post-surgery relief, effectively bridging the gap from acute pain management to over-the-counter solutions. This efficient and user-friendly approach rekindled interest among physicians trained in regional nerve block placement, offering them a more effective means of managing patient pain.

In 2016, the Fascile device received both FDA approval and CE marking, validating its safety and efficacy. During the Covid-19 pandemic, the device proved instrumental in maintaining operational surgical suites, as patients did not need intubation for the administration of general anesthesia. By 2022, the device received Halal certification and was declared safe for use alongside MRI studies, eliminating the need for device removal during follow-up imaging.

Today, Solo-Dex continues to offer this groundbreaking innovation to countries across the globe, including the US, Brazil, India, Europe, and the Middle East, transforming the landscape of regional anesthesia and offering a new paradigm in pain management.

## **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition**

The Solo-Dex Fascile Continuous Peripheral Nerve Block device represents a significant innovation in the field of regional anesthesia and pain management, and its implications for future research and improvement of the human condition are profound.

### **Innovation**

The primary innovation of Solo-Dex lies in its unique design and the efficiency it introduces to the field of regional anesthesia. Traditional methods of nerve block catheter placement are time-consuming and complex, requiring multiple assistants and elaborate setups. In contrast, the Solo-Dex device simplifies this process significantly. The catheter is positioned on the outside of the needle, curved for stable placement, and used with a safe, modified needle tip. This design allows for quick, ultrasound-guided placements in under three minutes, a substantial reduction compared to traditional methods.

### **Implications for Future Research**

The success of Solo-Dex Fascile opens a new frontier in regional anesthesia and pain management

research. The device's proprietary features include rapid ultrasound-guided placement which can pave the way for more research into image-guided anesthetic procedures, making a more surgeries safer, quicker, and more efficient. Furthermore, the reduced need for general anesthesia with intubation could spur research into less invasive and more effective pain management techniques, all while reducing the potential risks and side effects associated with more traditional methods.

#### Improvement of the Human Condition

The Solo-Dex device markedly improves the human condition by enhancing perioperative patient comfort and recovery. By providing five days of post-surgery pain relief, it helps patients transition smoothly from acute pain management to over-the-counter pain solutions. This can lead to faster recoveries, improved patient satisfaction, and a reduction in the reliance on potent and addictive prescription painkillers, thereby helping to combat the global issue of opioid dependence.

Moreover, during situations like the Covid-19 pandemic, the Solo-Dex device proved essential in reducing the need for intubation for general anesthesia. This not only allowed surgical suites to remain operational but also decreased the risk of virus transmission to healthcare workers and other patients.

In summary, the Solo-Dex device is not only a technological innovation but also a beacon of progress for patient care, post-operative recovery, and the broader field of anesthesia. By pushing the boundaries of what's possible in regional anesthesia, it holds promise for a future where pain management is safer, more efficient, and more patient-centric.

#### **Please provide appropriate references (ie Pubmed links)**

Ilfeld BM. Continuous Peripheral Nerve Blocks: An Update of the Published Evidence and Comparison With Novel, Alternative Analgesic Modalities. *Anesth Analg*. 2017 Jan;124(1):308-335. doi: 10.1213/ANE.0000000000001581. PMID: 27749354.