

Ascenda intrathecal catheter

The Ascenda® intrathecal catheter consists of a spinal segment and a pump segment with a sutureless pump connector designed for intrathecal baclofen therapy.



For use with the company's SynchroMed II programmable baclofen injection pump.

The SynchroMed II pump is implanted below the skin and the Ascenda Catheter snakes from the device to the intrathecal space that surrounds the spinal cord. By directly delivering the medication to the spinal cord, side effects from the baclofen can be substantially reduced.

- The Ascenda™ Catheter was approved by the U.S. Food and Drug Administration as an innovation to improve the durability and ease of medication delivery for both Medtronic Targeted Drug Delivery and Medtronic Intrathecal Baclofen (ITB) TherapySM.
- Ascenda is a key component of the implantable SynchroMed® II system, a battery-powered programmable pump that delivers medication through a catheter directly to the fluid surrounding the spinal cord for potential relief with less medication and fewer side effects than oral treatments.
- The unique combination of a robust polymer braided design, increased anchoring strength, and an enhanced, tactile catheter connection make the Ascenda Catheter the most robust and reliable catheter available.

Recall

Medtronic is removing specific lots of the Ascenda Intrathecal Catheters and Revision Kits, which are used with the implantable SynchroMed drug infusion pump. This recall is being conducted due to a single component of the catheter, the retainer ring, not meeting specification criteria. There is a possibility of unintentional disconnection of the catheter from the pump, or difficulty in disconnection. FDA Determined Cause 2 Nonconforming Material/Component Action. Medtronic sent an Urgent Medical Device Removal letter dated July 11, 2014, to all affected customers. The letter described the issue, identified affected product, provided patient management recommendations for patients implanted with an affected device, asked for Risk Management to quarantine unused inventory within the hospital, and to contact Medtronic Customer Service at 1-888-638-7627 to facilitate return of devices.

Case series

2016

In a [single center study](#) Motta et al investigated the [complications](#) occurring before and after the introduction of the new Ascenda [intrathecal catheter](#) (Medtronic Inc.) in [pediatric patients](#) treated with [intrathecal baclofen](#) therapy (ITB) for [spasticity](#) and/or [dystonia](#).

This was a [retrospective review](#) of 508 [children](#) who had received ITB, 416 with silicone catheters in the 13 years between September 1998 and September 2011 and 92 with [Ascenda intrathecal catheters](#) in the 3 years between September 2011 and August 2014. The authors evaluated major complications such as [infections](#), CSF [leaks](#) treated, and problems related to the catheter or pump, and they compared the 2 groups of patients who had received either a silicone catheter or an Ascenda catheter implant.

One hundred twenty patients in the silicone group (29%) and 1 patient in the Ascenda group (1.1%; $p < 0.001$) had a major complication. In the silicone group 23 patients (5.5%) were affected by CSF leakage and 75 patients (18%) experienced 82 catheter-related events, such as occlusion, dislodgment, disconnection, or breakage, which required catheter replacement. In the Ascenda group, only 1 patient (1.1%) was affected by CSF leakage.

To the authors' knowledge, this study is the first in the [literature](#) to compare the performance of the new Ascenda catheter, introduced in 2011, with the traditional [silicone catheter](#) for intrathecal drug infusion. In their analysis, the authors found that the Ascenda catheter can reduce major complications related to the catheter after ITB pump implantation. Further investigation is necessary to expand on and confirm their results ¹⁾.

Case reports

A 14-year-old boy diagnosed with a Neurodegeneration with brain iron accumulation type 1 (NBIA-1, presenting intractable progressive generalized [dystonia](#) leading to unresponsive status dystonicus (SD). The patient received a SynchroMed II (model 8637) programmable system pump (Medtronic®, Inc.) implant with an Ascenda intrathecal catheter for intrathecal morphine therapy (IMT). The initial dose of morphine was 1.0 mg/day. Overall, we observed no complications with IMT treatment and important improvement of the patient's motor function with stabilization of his incapacitating dystonia and his quality of life. On the Global Dystonia Severity Rating Scale, he presented 52% improvement, 30% improvement on the Unified Dystonia Rating Scale, and 38% improvement on the Fahn-Marsden Rating Scale after 10 months, when the dose was 1.7 mg/day. IMT should be considered as a potential palliative treatment in the management of intractable dystonia and SD secondary to NBIA-1 ²⁾.

¹⁾

Motta F, Antonello CE. Comparison between an Ascenda and a silicone catheter in intrathecal baclofen therapy in pediatric patients: analysis of complications. J Neurosurg Pediatr. 2016 Oct;18(4):493-498. PubMed PMID: 27341610.

²⁾

Lopez WO, Kluge Schroeder H, Santana Neville I, Jacobsen Teixeira M, Costa Barbosa D, Assumpção de Mônico B, Talamoni Fonoff E. Intrathecal morphine therapy in the management of status dystonicus in neurodegeneration brain iron accumulation type 1. Pediatr Neurosurg. 2015;50(2):94-8. doi: 10.1159/000370005. Epub 2015 Apr 17. PubMed PMID: 25896138.

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Last update: **2024/06/07 02:59**

