

Plaintiff’s Preliminary Infringement Claim Chart
New Amsterdam LLC v. Medtronic plc, et al.
Cause No.: 2:23-cv-421
U.S. Patent No. 6,916,483
Asserted Claims: 1, 2, 3, 4, and 16.

Plaintiff provides this Infringement Chart based upon its best reasonable evaluation of publicly available information as of the date of service hereof. Most, if not all, of the infringing functionality is proprietary to Defendant; thus, Plaintiff reserves its right to supplement these Contentions as necessary following full technical production on the part of Defendant and following full review of the relevant historical source code for the Accused Instrumentalities by Plaintiff’s experts to be designated in due course of this litigation.

As of the date of preparation of this Infringement Chart, which is being undertaken without the benefit of discovery, Plaintiff believes and alleges that each element is literally present in the Accused Instrumentalities. To the extent discovery reveals infringement occurs in manners or using systems different than those believed to be made, used, and sold by Defendant, Plaintiff intends to argue that such differences are nevertheless infringing under the Doctrine of Equivalents.

This Infringement Chart is applicable to methods practiced and/or implemented by or in connection with all iterations of the Accused Instrumentalities made, used, sold, and/or offered for sale, from and after the date falling prior to the date of filing of the Original Complaint in this litigation, and extending through the expiration of the ’483 Patent. Plaintiff contends, and hereupon alleges, that all such iterations, versions, and progressively more robust implementations of the Accused Instrumentalities during the period of infringement nevertheless infringe the Asserted Claims in substantially the same or identical manner as is set forth herein.

In preparing these Charts, and for the sake of completeness, Plaintiff has included the preambles for each Asserted Claim. In so doing, Plaintiff does not contend that such preambles are in any way limiting on any Asserted Claim.

For each element of these Charts, it is herein alleged to infringe literally, or in the alternative, under the doctrine of equivalents.

US6916483	Medtronic Sinuva
1. An implantable prosthetic device having a surface contour, and comprising a solid modular implantable drug delivery device within a shaped recess within the outer surface of an implantable prosthesis,	DISCOVERING RELIEF WITH SINUVA SINUVA is an option for the treatment of nasal polyps that’s been shown to provide effective relief, compared to daily steroid nasal spray[†] alone in a clinical trial with 300 patients.[‡] [†] Mometasone furoate nasal spray. https://www.sinuva.com/nasal-polyps-treatment/ 

-----**DOSAGE AND ADMINISTRATION**-----

- The SINUVA Sinus Implant is loaded into a Delivery System and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. (2.2)
- To be inserted by physicians trained in otolaryngology. (2.3)
- Repeat administration has not been studied. (2.4)

-----**DOSAGE FORM AND STRENGTH**-----

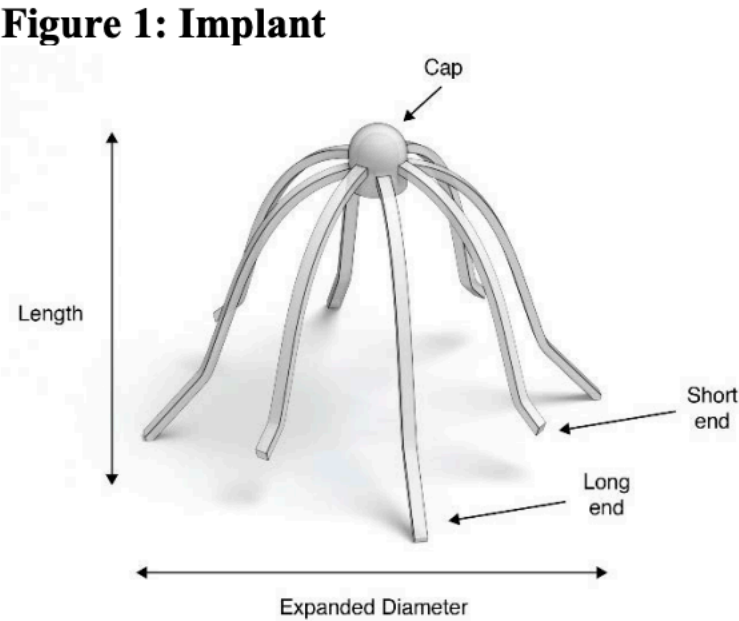
One SINUVA Sinus Implant system contains 1350 mcg of mometasone furoate and a sterile Delivery System. (3)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf

See Also:

<https://www.sinuva.com/wp-content/uploads/2021/02/SINUVA-Patient-Brochure-Print.pdf>

<https://www.sinuva.com/sinuva-patient-card.pdf>



said device being operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal, the device comprising:



SINUVA is a steroid-releasing (mometasone furoate) implant indicated for the treatment of nasal polyps, in patients ≥ 18 years of age who have had ethmoid sinus surgery.

SINUVA is not a surgery; it's a stent inserted into the ethmoid sinus cavity through the nasal opening during a routine office visit using local anesthesia and delivers anti-inflammatory medication right to the nasal polyps.

Download a brochure about SINUVA to help start a discussion with a doctor.

 **Download the Patient Brochure**

<https://www.sinuva.com/nasal-polyps-treatment/>

How SINUVA works

SINUVA targets the underlying sinus inflammation with a 2-in-1 design and 4 easy steps:

- 1 SINUVA is inserted into the sinus cavity through the nose during a routine office visit
- 2 Expands in the sinus
- 3 Delivers anti-inflammatory medicine directly to nasal polyps, not to the rest of your body*
- 4 SINUVA delivers anti-inflammatory medicine over the course of 90 days



<https://www.sinuva.com/wp-content/uploads/2021/03/SINUVA-Patient-Brochure-Print.pdf>

-----DOSAGE AND ADMINISTRATION-----

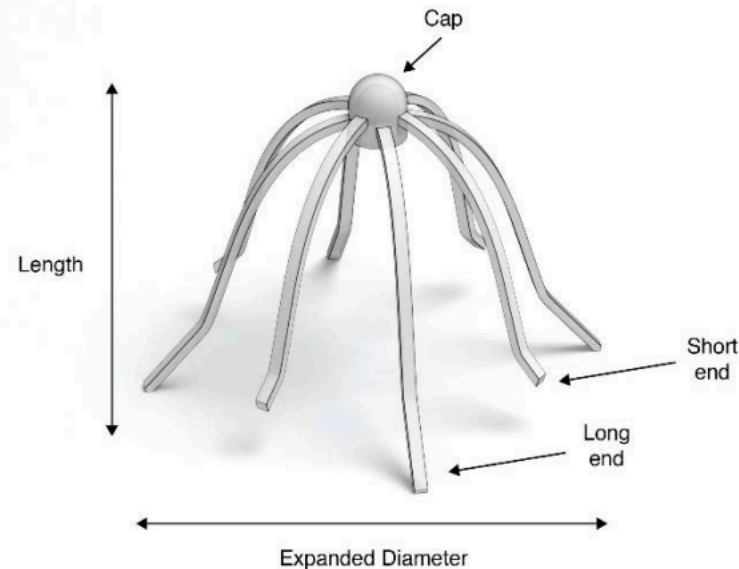
- The SINUVA Sinus Implant is loaded into a Delivery System and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. (2.2)
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https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf

Figure 1: Implant



(a) solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and

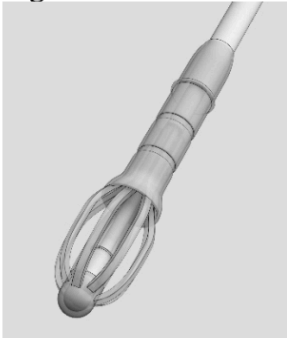
8. Apply a downward push on the Delivery System to ensure that the SINUVA Sinus Implant is secured in the Cup (Figure 10). This will also ensure the Implant is compressed to its smallest profile for insertion.

Figure 10



9. Retract the Delivery System from the Crimper. The SINUVA Sinus Implant should remain symmetrically loaded in the Cup of the Delivery System (Figure 11).

Figure 11



https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf

(b) a therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer over a predefined dosing period.



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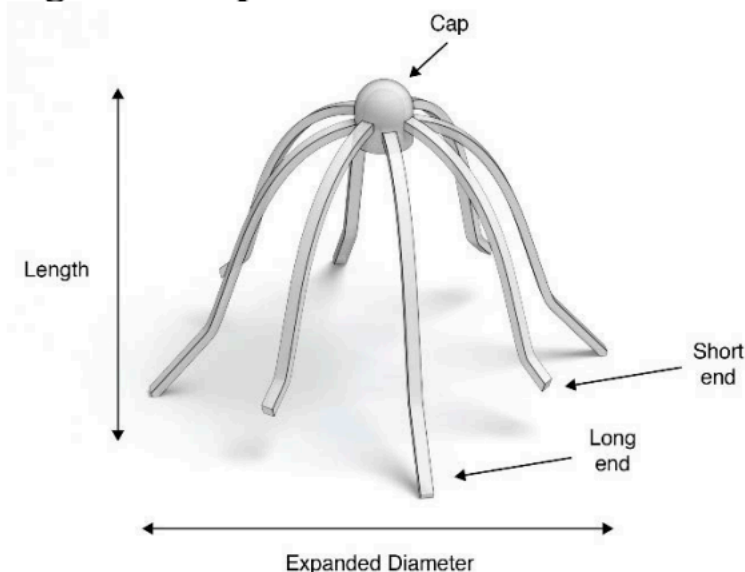
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2. The device of claim 1 wherein when said solid module comprising a biodegradable polymer is received within the shaped recess of the implantable prosthesis, the contour of the outer surface of the prosthesis is not substantially altered.

Comment: On information and belief, when the solid module comprising a biodegradable polymer is received in the shaped recess of the implantable prosthesis, the contour of the outer surface of the prosthesis is not substantially altered as can be seen in the figures.

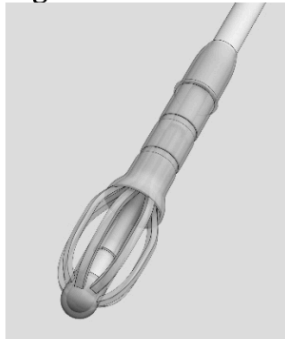
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Figure 10

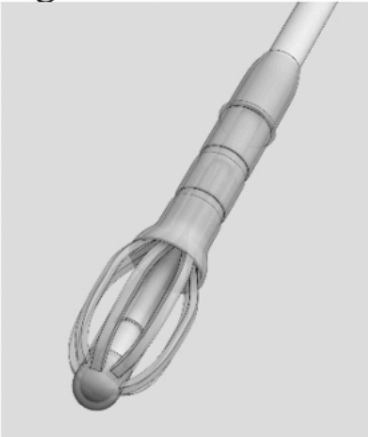


9. Retract the Delivery System from the Crimper. The SINUVA Sinus Implant should remain symmetrically loaded in the Cup of the Delivery System (Figure 11).

Figure 11

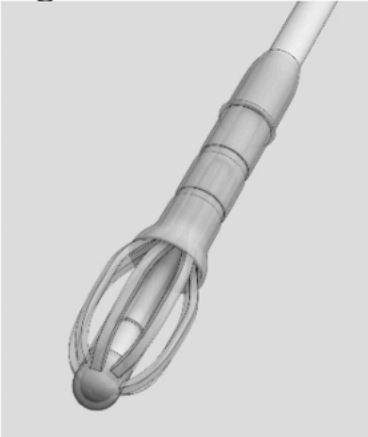


https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf

3. The device of claim 1 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.	Comment: On information and belief, the solid module comprising a biodegradable polymer is affixed to the prosthesis. 9. Retract the Delivery System from the Crimper. The SINUVA Sinus Implant should remain symmetrically loaded in the Cup of the Delivery System (Figure 11). Figure 11  https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf
4. The device of claim 2 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.	Comment: On information and belief, the solid module comprising a biodegradable polymer is affixed to the prosthesis.

9. Retract the Delivery System from the Crimper. The SINUVA Sinus Implant should remain symmetrically loaded in the Cup of the Delivery System ([Figure 11](#)).

Figure 11



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16. The implantable prosthetic device of claim 1, wherein the solid module is shaped like a tapered conical plug.

DISCOVERING RELIEF
WITH SINUVA

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