

Cube[®] and VenSure[®]

PRODUCT CATALOG



Simplify your patients'
journey to relief.

Cube[®] + VenSure[®]

With innovations such as Photo Registration – we offer surgeons the ability to provide an optimized patient experience, quickly and efficiently

We seek to expand our product offering and deepen our value proposition for physicians in the ENT market through the physician-focused approach of providing disruptive, innovative technologies. As we continue to grow, Fiagon will remain true to our founding principles, creating increasingly innovative methods of simplifying user experience for physician-focused navigation solutions.

Fiagon set out to reimagine how image guidance could support your procedures everyday– the routine and the complex. Today, Fiagon’s portfolio offers surgical solutions for offices, clinics and OR’s around the world, enabling your surgical excellence with easy-to-use, integrated navigation guidance.

Fiagon Values & Commitments

Provide consistent, reliable, and accurate navigation in your procedures:

- Sinus Application
- Otology Application

Optimize surgical navigation workflow by:

- Integrating navigation sensor and navigation unit into the existing operating theater
- Providing malleable instruments
- Enabling the use of rigid instrumentation compatible with the Fiagon PointerShell platform

Refer to PointerShell IFU for list of compatible instrumentation

Provide surgeons control over procedures by offering:

- Open platform
- Malleable instrumentation
- Versatile service support

Please be aware that this document does not replace an instruction for use.

Rx Only. Refer to product’s IFU for instructions and important safety information.

Please find the instructions for use of the devices found in this document at www.VenSureAndCube.com

Custom Navigation System Configuration

You can choose the custom configuration of your choice in nine steps.

Step 1 **System**

Step 2 **Patient Positioning**

Step 3 **Software Modules**

Step 4 **Software Add-ons**

Step 5 **Patient Registration**

Step 6 **Patient Localizers**

Step 7 **Instruments**

Navigated Pointers

Navigated Suction Tubes

Navigated Adapters

Balloon Sinus Dilation System

Step 8 **Accessories**

Step 9 **Service(s)**

The Next Dimension

VIRTUAL GUIDANCE PLATFORM



Step 1 Fiagon Cube Navigation System

The Cube 4D is equipped with the latest high-performance computing hardware including 4K monitor support and a VirtuLink for instruments connected directly near the operative site for improved surgical guidance. Fiagon’s VirtuLite provides the user with direct visual feedback.

E 01 1106 -HD/8

Cube 4D Navigation Unit

Includes:

E 01 1136 – VirtuLink

1



1

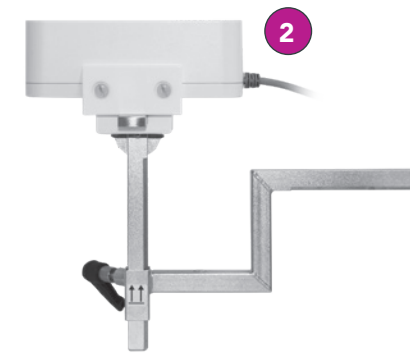
VirtuLink

- Can connect up to three instruments at once
- Compatible with Cube 4D Navigation Unit only



Step 2 Patient Positioning

PRODUCT	DESCRIPTION
E 01 1903 NA	<p>Navigation OR Headrest Kit</p> <p>Includes:</p> <p>E 01 1003 – Navigation Headrest Universal</p> <p>Compatible Adapters for OR tables (sold separately):</p> <p>E 01 1913 – Adapter for Maquet Table</p> <p>E 01 1914 – Adapter for Steris Table</p> <p>E 01 1915 – Adapter for Eschmann Table</p> <p>E 01 1916 – Adapter for OR Table Side Rails</p> <p>E 01 1917 – Adapter for Mizuho and Skytron Tables</p>
E 01 1003 NA	<p>Navigation OR Headrest FNS Kit</p> <p>Includes:</p> <p>E 01 1903 NA - Navigation OR Headrest Kit</p> <p>A 01 1000 - Fiagon Navigation Sensor</p>
E 01 1001	Navigation Headrest Flat
E 01 1002	Navigation Headrest Maquet
E 01 1905	Flexarm Adapter for Fiagon Navigation Sensor
E 01 1008	<p>Navigation Headrest Office</p> <p>Available adapters for Office Chairs (sold separately):</p> <p>E 01 1960 – Chair Adapter A</p> <p>E 01 1961 – Chair Adapter B</p> <p>E 01 1962 – Chair Adapter C</p> <p>E 01 1963 – Chair Adapter D</p> <p>E 01 1964 – Chair Adapter E</p> <p>E 01 1965 – Chair Adapter F</p>



Step 3 Software Modules

We offer surgeons around the globe – in various specialties – the ability to provide an optimized patient experience, quickly and efficiently.

Our physician-focused approach enables a versatile product offering for physicians in the ENT market. We increasingly create innovative methods of simplifying user experience for physician-focused navigation solutions. Fiagon offers solutions for various ENT procedures.

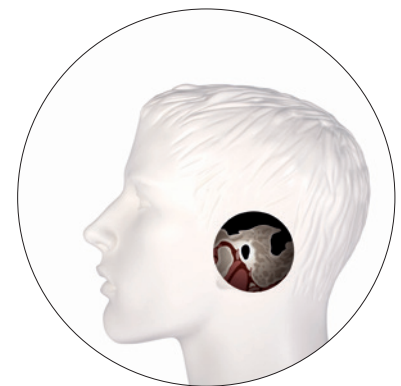
SINUS APPLICATION

PRODUCT	DESCRIPTION
E 01 4000	Sinus Navigation Software



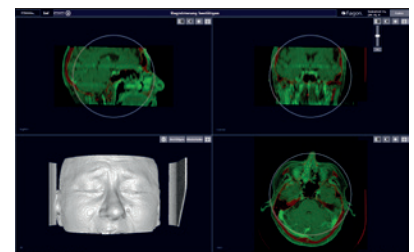
OTOLOGY APPLICATION

PRODUCT	DESCRIPTION
E 01 4001	Otology Navigation Software



Step 4 Software Add-Ons

PRODUCT	DESCRIPTION
E 01 4002	Fusion Navigation Software Automatic fusion of CT and MR images for sinus and otology surgeries



Step 5 Patient Registration

TACTILE REGISTRATION

PRODUCT	DESCRIPTION
E 01 2003	RegistrationPointer 1



1

RegistrationPointer

- Registration tool which features a ball tip for patient comfort and ease of use for the surgeon
- Not for surgical use
- Non-sterile

PHOTO REGISTRATION

PRODUCT	DESCRIPTION
E 01 1430	VirtuEye V2 2



2

VirtuEye V2

- Contact-free Photo Registration technology without touching the patient
- Non-sterile

Step 6 Patient Localizers

PRODUCT	DESCRIPTION
E 01 2202	<p>Localizer Adhesive Pad 1</p> <p>E 00 3001 – Adhesive Pads</p> <p>Used with Fiagon Standard Navigation System</p>
E 01 2202 C	<p>Localizer Adhesive Pad C-Type 1</p> <p>E 00 3001 – Adhesive Pads</p> <p>Used with Cube 4D Navigation Unit</p>



Localizer Adhesive Pad

- Used for patient reference, this localizer provides surgeons with an effortless, noninvasive alternative for fixation
- Fixed with the single use component Adhesive Pad (disposable)
- Non-sterile
- Reusable

Step 7 Navigated Pointers

All products starting with a “Flex” in their names are malleable and can be bent. Please check the IFU for further information.

PRODUCT	DESCRIPTION
E 01 2004	FlexPointer 1.5 1
E 01 3004	FlexPointer 1.5 Single Use 2

2

FlexPointer Single Use

- Eliminates time-consuming cleaning processes
- Ø 1.5 mm
- Tip tracked
- Single use
- Malleable
- Blunt



1

FlexPointer

- 1.5 mm
- Tip tracked
- 10 times reusable
- Malleable
- Blunt



Step 7 Navigated Suction Tubes

All products starting with a “Flex” in their names are malleable and can be bent. Please check the IFU for further information.

PRODUCT	DESCRIPTION
E 01 2104	FlexTube 3 mm 1
E 01 2106	FlexTube 4 mm 1
E 01 3104	FlexTube 3 Single Use 2
E 01 2107	PointerTube Keat 3
E 01 2108	PointerTube Kennedy 4



FlexTube

- Suction featuring Fiagon’s direct navigation
- Ø 3 mm suction
- Ø 4 mm suction
- Outlet in the handle for variable suction capacity
- Tip tracked
- 10 times reusable
- Malleable



FlexTube 3 Single Use

- Maintain optimal hygiene requirements
- Tip tracked
- Single Use
- Malleable



PointerTube Keat

- Ø 3 mm suction
- With olive tip
- Tip tracked
- 10 times reusable
- 75° angle
- Rigid



PointerTube Kennedy

- Ø 4 mm suction
- Outlet in the handle for variable suction capacity
- With olive tip
- Tip tracked
- 10 times reusable
- Straight
- Rigid

Step 7 Navigated Adapters

PRODUCT	DESCRIPTION
E 01 2904	PointerShell Universal 1
E 01 2902	PointerShell 3 mm
E 01 2900	PointerShell 4 mm 2
E 01 2901	PointerShell 5 mm



1
PointerShell Universal

The inspiringly unique PointerShell Universal allows you to navigate straight surgical instruments such as a shaver. It simply clamps around your instrument of choice, providing navigation after a quick calibration.

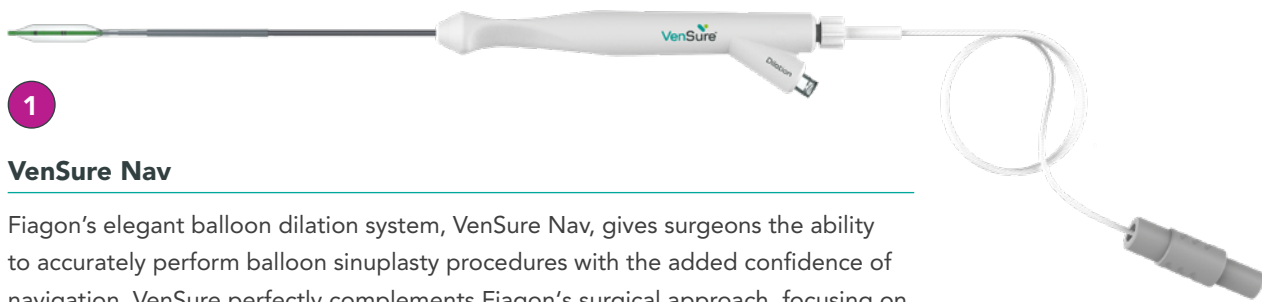
- Open platform technology with smart sensor tracking
- Compatible with commonly available suctions, debridors, ostium seekers, and curettes with a diameter from 2.5 to 5 mm¹
- 10 times reusable

¹Refer to Instructions for Use - PointerShell for compatible debrider systems

2
PointerShell 4 mm

Step 7 Balloon Sinus Dilation System - Vensure

PRODUCT	DESCRIPTION	
E 01 3526	VenSure	1
E 01 3536	VenSure Light	1
E 01 3546	VenSure Nav	2



1

VenSure Nav

Fiagon’s elegant balloon dilation system, VenSure Nav, gives surgeons the ability to accurately perform balloon sinuplasty procedures with the added confidence of navigation. VenSure perfectly complements Fiagon’s surgical approach, focusing on simplicity and ease of use.

- 1.63 mm Tip Diameter
- 6 mm x 18 mm Balloon
- VenSure - Non-Navigated
- VenSure Nav - Navigated



2

VenSure Light

Fiagon’s balloon sinus dilation system now includes a light confirmation option called VenSure Light ensure position of the device through subcutaneous transillumination.

- Ergonomic device housing for seamless advancement of the fiber
- 20 mm atraumatic LED light fiber advancement
- 5 mm advancement markers on the housing of the device to ensure precision advancement
- Thoughtful weight distribution through a symmetric, cylindrical design



VenSure Inflation Device

Tactile and audible confirmation helps ensure consistent and accurate dilation

- Ergonomic, sleek design for one-handed operation
- One-Click™ mechanism locks-in
- 12 atm to ensure a full dilation
- Comes integrated with all balloon variations

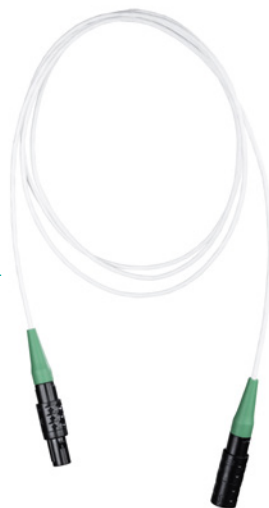
Step 8 Accessories

PRODUCT	DESCRIPTION
A 01 1000	Fiagon Navigation Sensor
A 00 1200	Extension Cable Instrument 1
A 00 1201	Extension Cable Localizer
A 01 1203	Double Instrument Support (Y-Cable)
E 01 1136	VirtuLink
A 00 9101	PC Mouse
A 00 9102	Service Keyboard
A 21 9200	Power Cable US
A 01 9201	Power Cable Hospital Grade
A 00 9201	DVI Monitor Cable
A 00 9203	VGA Monitor Cable
A 00 9204	Monitor Control Cable
A 00 9207	HDMI Monitor Cable
A 00 9208	Composite-Video Cable
A 00 9210	HDMI-HDMI Cable

1

Extension Cable Instrument

- With a 2 m extension cable for your localizer or your instruments you can set up your operation theatre according to your needs



Step 9 Service(s)

PRODUCT	DESCRIPTION
	Installation & Support
	E 01 5401 – System Installation including In-service
	E 01 5411 – Surgery Support Day
	E 01 5021 – Network Connection & Installation
	E 01 5421 – PACS Integration by Fiagon
	E 01 5007 – Service Software Update
	E 01 5011 – Onsite Maintenance Visit
	Maintenance
	E 01 5000 – Maintenance by Fiagon
	includes:
	E 01 5500 – Safety Check
	E 01 5510 – EM Inspection
	Service Contract - Please check local availability
	E 02 1000 – Service Contract Standard
	E 02 3000 – Service Contract Deluxe
	System Repair
	E 01 5701 – System Diagnostic (System repair varies)
	Loaner Product
	E 01 5601 – Loaner Navigation Unit per Week (E 01 5602 additionally needed)
	E 01 5602 – Navigation Unit Preparation and Configuration
	E 01 5603 – Loaner Headrest or Navigation Sensor per Week
	Demo Material
	E 00 9301 – Phantom Head Demo ENT
	A 00 9902 – Fiagon Transport Case “Head Rest”
	A 00 9906 - Fiagon Cube 4D Transport Case

ENT Portfolio

SYSTEMS

Navigation	E 01 1106 -HD/8	Cube 4D Navigation Unit
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SOFTWARE

Software	E 01 4000	Sinus Navigation Software
Software	E 01 4001	Otology Navigation Software
Software	E 01 4002	Fusion Navigation Software

INSTRUMENTS

Instruments	E 01 2003	RegistrationPointer
Instruments	E 01 2202	Localizer Adhesive Pad
Instruments	E 01 2202 C	Localizer Adhesive Pad C-Type
Instruments	E 01 2002	FlexPointer
Instruments	E 01 2004	FlexPointer 1.5 mm
Instruments	E 01 3004	FlexPointer 1.5 Single Use
Instruments	E 01 2300	FinePointer
Instruments	E 01 2104	FlexTube 3 mm
Instruments	E 01 2106	FlexTube 4 mm
Instruments	E 01 3104	FlexTube 3 Single Use
Instruments	E 01 2107	PointerTube Keat
Instruments	E 01 2108	PointerTube Kennedy
Instruments	E 01 2904	PointerShell Universal
Instruments	E 01 2902	PointerShell 3mm
Instruments	E 01 2900	PointerShell 4mm
Instruments	E 01 2901	PointerShell 5mm
Instruments	E 01 3913	GuideWire 0.6 Single Use
Instruments	E 01 3526	VenSure
Instruments	E 01 3536	VenSure Light
Instruments	E 01 3546	VenSure Nav

ACCESSORIES

Accessories	E 01 1136	VirtuLink
Accessories	A 01 1000	Fiagon Navigation Sensor
Accessories	E 01 1903 NA	Navigation OR Headrest Kit
Accessories	E 01 1003 NA	Navigation OR Headrest FNS Kit
Accessories	E 01 1913	Adapters for Maquet Tables
Accessories	E 01 1914	Adapters for Steris Tables
Accessories	E 01 1915	Adapters for Eschmann Tables
Accessories	E 01 1916	Adapters for Side Rails
Accessories	E 01 1917	Adapters for Mizuho/Skytron Tables
Accessories	E 01 1001	Navigation Headrest Flat
Accessories	E 01 1002	Navigation Headrest Maquet
Accessories	E 01 1905	Flexarm Adapter for Navigation Sensor
Accessories	E 01 1008	Navigation Headrest Office
Accessories	E 01 1960	Chair Adapter A
Accessories	E 01 1961	Chair Adapter B
Accessories	E 01 1962	Chair Adapter C
Accessories	E 01 1963	Chair Adapter D
Accessories	E 01 1964	Chair Adapter E
Accessories	E 01 1965	Chair Adapter F
Accessories	E 01 1430	VirtuEye V2
Accessories	E 00 3001	Adhesive Pads (Pack of 10)
Accessories	A 00 1200	Extension Cable Instrument
Accessories	A 00 1201	Extension Cable Localizer
Accessories	A 01 1203	Double Instrument Support (Y-Cable)

ACCESSORIES

Accessories	A 00 9101	PC Mouse
Accessories	A 00 9102	Service Keyboard
Accessories	A 21 9200	Power Cable US
Accessories	A 01 9201	Power Cable Hospital Grade
Accessories	A 00 9201	DVI Monitor Cable
Accessories	A 00 9203	VGA Monitor Cable
Accessories	A 00 9204	Monitor Control Cable
Accessories	A 00 9207	HDMI Monitor Cable
Accessories	A 00 9208	Composite-Video Cable
Accessories	A 00 9210	HDMI-HDMI Cable

SERVICE(S)

Service(s)	E 01 5401	System Installation including In-service
Service(s)	E 01 5411	Surgery Support Day
Service(s)	E 01 5021	Network Connection & Installation
Service(s)	E 01 5421	PACS Integration by Fiagon
Service(s)	E 01 5007	Service Software Update
Service(s)	E 01 5011	Onsite Maintenance Visit
Service(s)	E 01 5000	Maintenance by Fiagon includes Safety Check (E 01 5500) and EM Inspection (E 01 5510)
Service(s)	E 02 1000	Service Contract Standard
Service(s)	E 02 3000	Service Contract Deluxe
Service(s)	E 01 5701	System Diagnostics (System repairs varies)
Service(s)	E 01 5601	Loaner Navigation Unit per Week (E 01 5602 additional needed)
Service(s)	E 01 5602	Navigation Unit Preparation and Configuration
Service(s)	E 01 5603	Loaner Headrest or Navigation Sensor per Week
Service(s)	E 00 9301	Phantom Head Demo ENT
Service(s)	A 00 9902	Fiagon Transport Case "Head Rest"
Service(s)	A 00 9906	Fiagon Cube 4D Transport Case

Partnership with Fiagon

Contact a consultant in your region or our team directly to set up an evaluation of our technology.

North America

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Reimagining

THE ROLE OF IMAGE GUIDANCE WITHIN SURGERY

[For more information, visit VensureAndCube.com](https://VensureAndCube.com)

