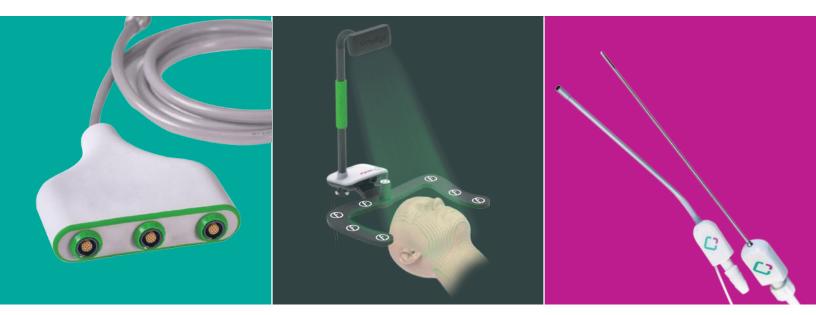




# Cube<sup>™</sup> and VenSure<sup>™</sup> PRODUCT CATALOG



Simplify your patients' journey to relief.



# Reimagining

# THE ROLE OF IMAGE GUIDANCE WITHIN SURGERY



# 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, Intersect ENT will remain true to our founding principles, creating increasingly innovative methods of simplifying user experience for physician-focused navigation solutions.

Intersect ENT set out to reimagine how image guidance could support your procedures everyday– the routine and the complex. Today, Intersect ENT'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.

# Intersect ENT 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 Intersect ENT 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 https://www.fiagon.com/us/company/instructions-for-use

# Equipped

# WITH THE CONFIGURATION OF YOUR CHOICE JUST IN A FEW STEPS



# 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 Guidewire

Navigated Adapters

**Balloon Sinus Dilation System** 

- Step 8 Accessories
- Step 9 Service(s)

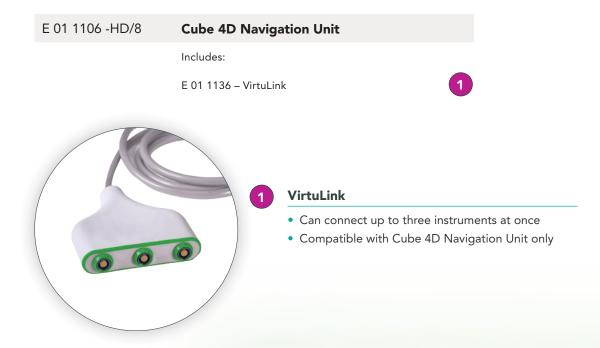
# The Next Dimension

# VIRTUAL GUIDANCE PLATFORM



# Step 1 Intersect ENT 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. Intersect ENT's VirtuLite provides the user with direct visual feedback.





Intersect ENT | Cube and VenSure Product Catalog | MPM-11944 Rev 4.0

# Step 2 Patient Positioning

| PRODUCT      | DESCRIPTION   |   |
|--------------|---|---|
| E 01 1903 NA | Navigation OR Headrest Kit                              | 1 |
|              | Includes:   |   |
|              | E 01 1003 – Navigation Headrest Universal               |   |
|              | Compatible Adapters for OR tables (sold separately):    |   |
|              | E 01 1913 – Adapter for Maquet Table                    |   |
|              | E 01 1914 – Adapter for Steris Table                    |   |
|              | E 01 1915 – Adapter for Eschmann Table                  |   |
|              | E 01 1916 – Adapter for OR Table Side Rails             |   |
|              | E 01 1917 – Adapter for Mizuho and Skytron Tables       |   |
| E 01 1003 NA | Navigation OR Headrest FNS Kit                          | 1 |
|              | Includes:   |   |
|              | E 01 1903 NA - Navigation OR Headrest Kit               |   |
|              | A 01 1000 - Fiagon Navigation Sensor                    |   |
| E 01 1001    | Navigation Headrest Flat                                | 2 |
| E 01 1002    | Navigation Headrest Maquet                              |   |
| E 01 1905    | Flexarm Adapter for Fiagon Navigation Sensor            |   |
| E 01 1008    | Navigation Headrest Office                              | 3 |
|              | Available adapters for Office Chairs (sold separately): |   |
|              | E 01 1960 – Chair Adapter A                             |   |
|              | E 01 1961 – Chair Adapter B                             |   |
|              | E 01 1962 – Chair Adapter C                             |   |
|              | E 01 1963 – Chair Adapter D                             |   |
|              | E 01 1964 – Chair Adapter E                             |   |
|              | E 01 1965 – Chair Adapter F                             |   |
|              |   |   |
|              |   |   |
|              |   |   |
|              |   |   |
|              |   |   |
|              |   |   |
|              |   |   |

# 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. Intersect ENT offers solutions for various ENT procedures.

### SINUS APPLICATION

| PRODUCT   | DESCRIPTION               |
|-----------|---------------------------|
| E 01 4000 | Sinus Navigation Software |



#### OTOLOGY APPLICATION

| PRODUCT   | DESCRIPTION                        |
|-----------|------------------------------------|
| E 01 4001 | <b>Otology Navigation Software</b> |

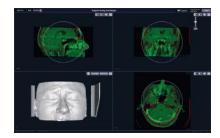


## Step 4 Software Add-Ons

#### 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 PHOTO REGISTRATION PRODUCT DESCRIPTION PRODUCT DESCRIPTION E 01 2003 RegistrationPointer 1 E 01 1420 VirtuEye V1 2





#### VirtuEye V1

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

#### RegistrationPointer

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

# Step 6 Patient Localizers

| DESCRIPTION                                 |  |
|---|--|
| Localizer Adhesive Pad                      | 1  |
| E 00 3001 – Adhesive Pads                   |  |
| Used with Fiagon Standard Navigation System |  |
| Localizer Adhesive Pad C-Type               | 1  |
| E 00 3001 – Adhesive Pads                   |  |
| Used with Cube 4D Navigation Unit           |  |
|   | Localizer Adhesive PadE 00 3001 – Adhesive PadsUsed with Fiagon Standard Navigation SystemLocalizer Adhesive Pad C-TypeE 00 3001 – Adhesive Pads |



#### 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 2002 | FlexPointer                | 1 |
| E 01 2004 | FlexPointer 1.5            | 1 |
| E 01 3004 | FlexPointer 1.5 Single Use | 2 |
| E 01 2300 | FinePointer                | 3 |

# 3

#### FinePointer

- Ø 1.5 mm
- Tip tracked
- 10 times reusable
- Rigid
- Sharp

## 2

#### FlexPointer Single Use

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

いの語言

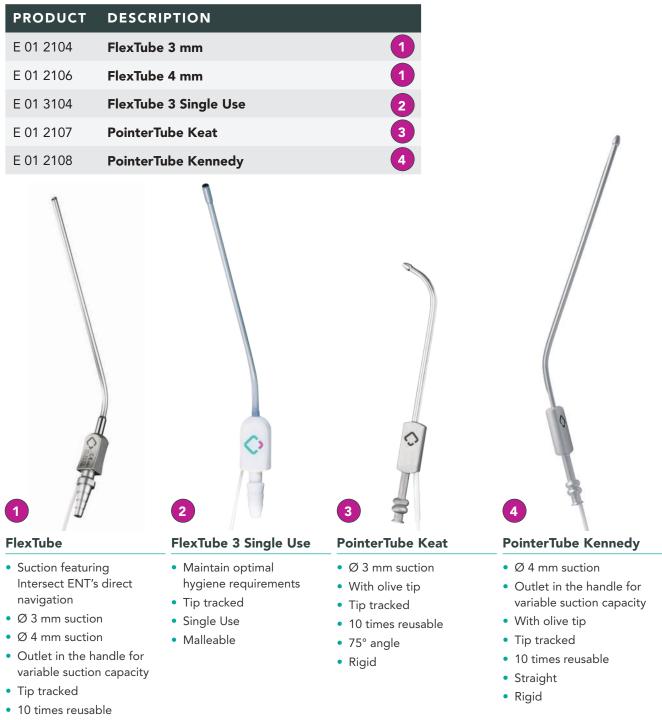
## 1

#### FlexPointer

- Ø 2.8 mm and 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.



• Malleable

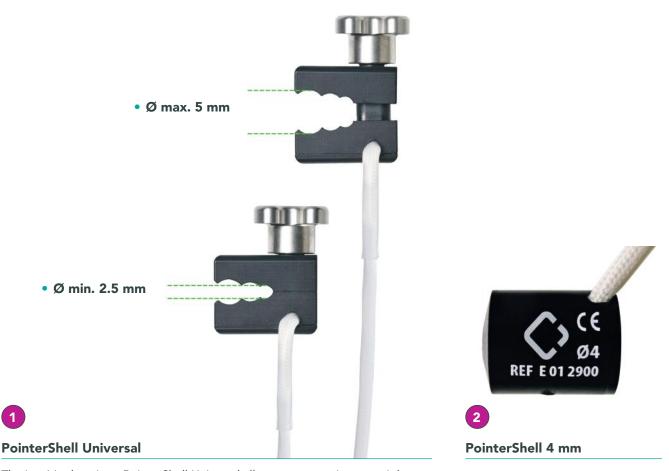
# Step 7 Guidewire



• Single Use

# 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      |   |



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, debriders, ostium seekers, and curettes with a diameter from 2.5 to 5 mm<sup>1</sup>
- 10 times reusable

<sup>1</sup>Refer to Instructions for Use - PointerShell for compatible debrider systems

# Step 7 Balloon Sinus Dilation System - Vensure

| PRODUCT    | DESCRIPTION                 |   |
|------------|-----------------------------|---|
| E 01 3506  | VenSure                     | 1 |
| E 01 3516  | VenSure Nav                 | 1 |
| E 01 3591S | Disposable Inflation Device |   |



Intersect ENT'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 Intersect ENT'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

# Step 8 Accessories

| PRODUCT   | DESCRIPTION                         |
|-----------|-------------------------------------|
| A 01 1000 | Fiagon Navigation Sensor            |
| A 00 1200 | Extension Cable Instrument          |
| 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                     |



#### **Extension Cable Instrument**

1

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# 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 Intersect ENT
- E 01 5007 Service Software Update
- E 01 5011 Onsite Maintenance Visit

#### Maintenance

E 01 5000 - Maintenance by Intersect ENT

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 Intersect ENT Transport Case "Head Rest"
- A 00 9906 Intersect ENT Cube 4D Transport Case

# **ENT** Portfolio

#### **SYSTEMS**

| Navigation  | E 01 1106 -HD/8 | Cube 4D Navigation Unit       |
|-------------|-----------------|-------------------------------|
| SOFTWAR     | E               |                               |
| Software    | E 01 4000       | Sinus Navigation Software     |
| Software    | E 01 4001       | Otology Navigation Software   |
| Software    | E 01 4002       | Fusion Navigation Software    |
| INSTRUME    | NTS             |                               |
| Instruments | E 01 2003       | RegistrationPointer           |
| nstruments  | E 01 2202       | Localizer Adhesive Pad        |
| nstruments  | E 01 2202 C     | Localizer Adhesive Pad C-Type |
| nstruments  | E 01 2002       | FlexPointer                   |
| nstruments  | E 01 2004       | FlexPointer 1.5 mm            |
| nstruments  | E 01 3004       | FlexPointer 1.5 Single Use    |
| nstruments  | E 01 2300       | FinePointer                   |
| nstruments  | E 01 2104       | FlexTube 3 mm                 |
| nstruments  | E 01 2106       | FlexTube 4 mm                 |
| nstruments  | E 01 3104       | FlexTube 3 Single Use         |
| Instruments | E 01 2107       | PointerTube Keat              |
| nstruments  | E 01 2108       | PointerTube Kennedy           |
| nstruments  | E 01 2904       | PointerShell Universal        |
| nstruments  | E 01 2902       | PointerShell 3mm              |
| nstruments  | E 01 2900       | PointerShell 4mm              |
| nstruments  | E 01 2901       | PointerShell 5mm              |
| nstruments  | E 01 3913       | GuideWire 0.6 Single Use      |
| Instruments | E 01 3506       | VenSure                       |
| Instruments | E 01 3516       | VenSure Nav                   |
| Instruments | E 01 3591S      | Disposable Inflation Device   |

#### 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 1420    | VirtuEye V1                           |
| 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   |
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| 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 Intersect ENT                              |
| Service(s)  | E 01 5007 | Service Software Update  |
| Service(s)  | E 01 5011 | Onsite Maintenance Visit                                       |
| Service(s)  | E 01 5000 | Maintenance by Intersect ENT 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 | Intersect ENT Transport Case "Head Rest"                       |
| Service(s)  | A 00 9906 | Intersect ENT Cube 4D Transport Case                           |
|             |           |  |

# Partnership with Intersect ENT

Contact a consultant in your region or our team directly to set up a trial.

#### **North America**

Intersect ENT 1555 Adams Drive Menlo Park, CA 94025 USA

#### Sales

Tel: +1 (866) 531-6004 Email: customerservice@intersectent.com

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 https://www.fiagon.com/us/company/instructions-for-use

# Simplify your patients' journey to relief.





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