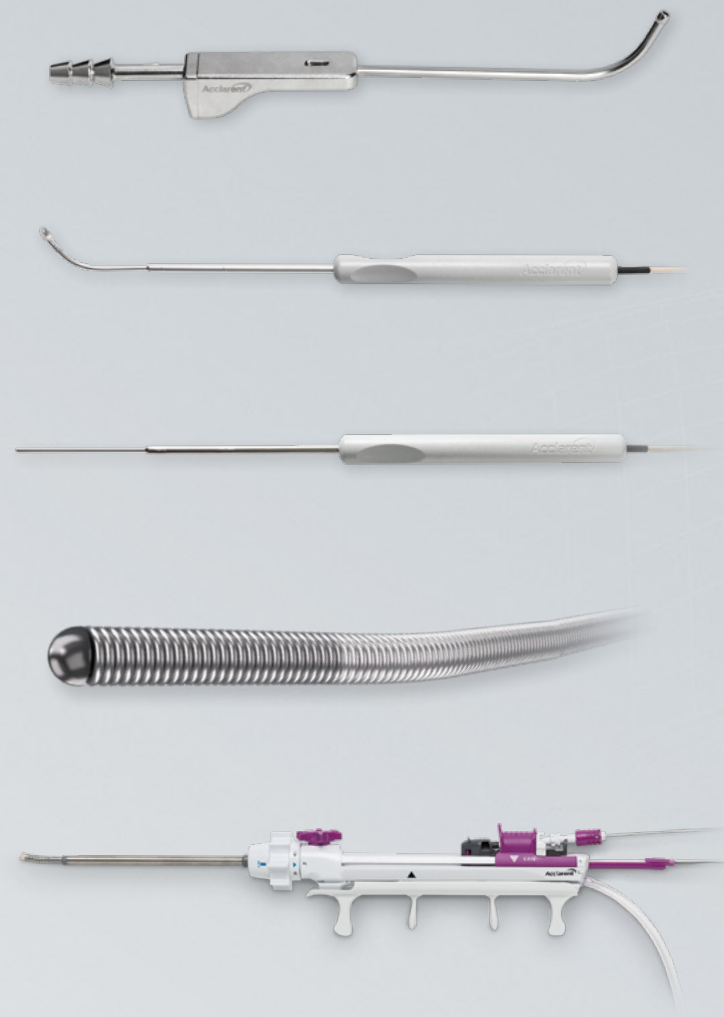




# TruDi® Navigation System and Navigation Instruments



Tap here  
to begin



## TruDi® Navigation System

TruDi® is an ENT Navigation System that strives to go beyond what's imaginable today.



### State-of-the-art engineering:

Emitter pad with 15 electromagnets

Large accuracy zone (6,400 cubic cm)

Micro-sensors embedded at distal-tip

Pre-calibrated instruments for plug-and-play



# TruDi® Navigation System

TruDi® is an ENT Navigation System that strives to go beyond what's imaginable today.



## SUBMILLIMETER ACCURACY<sup>1</sup>

For complete visibility from start to finish with real-time mapping.

**True Reassurance**



## REAL-TIME FEEDBACK<sup>2</sup>

To optimize procedures for a more complete case.

**True Navigation**



## CONSTANT ADVANCEMENTS

To redefine what's possible for you and your patients.

**True Innovation**

## Hardware components and accessories

Designed to deliver an efficient, user-friendly experience.



### Remote Touch Pad

Using the Remote Touch Pad, surgeons can access TruDi® Navigation System's features from up to 3 meters away.



### TruDi® Cart

The new, improved cart allows for safe and easy transport.

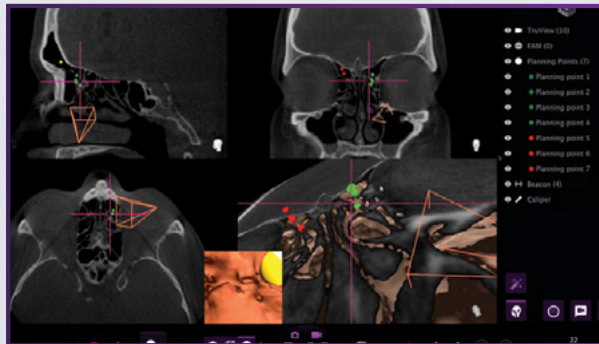
1. In the preclinical study, *Xoran (2020). Accuracy of Acclarent TruDi Surgical Navigation using MiniCAT 2020 and MiniCAT IQ In-Office CT White Paper*, a head phantom was used to assess TruDi's accuracy using images from the MiniCAT™ CT scanners. Target Registration Error (TRE) measurements were made by 3 testers who gathered 3 points per marker. The average of all TRE values measured was 0.34 mm.

2. ACCLARENT® ENT Navigation System Instructions for Use. UG-2000-00 02A 11.2018.



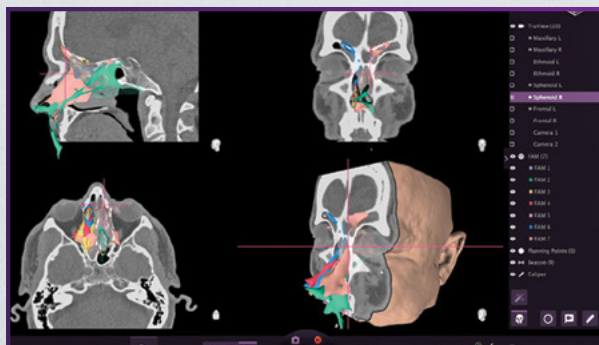
## Software Features

Innovative features that offer enhanced visualization and real-time feedback.



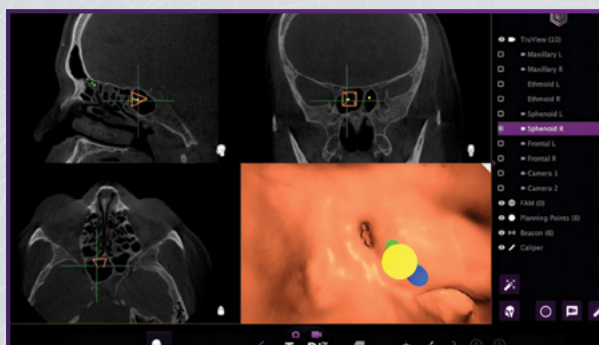
### Planning Points and Beacons

Assists in identifying drainage pathways, challenging anatomy and structural anomalies. Planning points also function as beacons, alerting the user when a navigated surgical device approaches the point.



### Fast Anatomical Mapping (FAM)

Real-time imaging software that documents surgical changes to the anatomy.



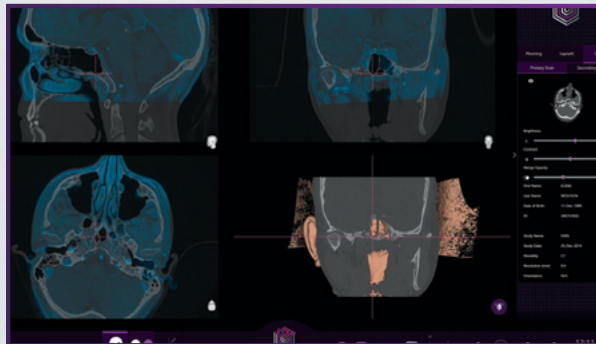
### TruView

Place an unlimited number of virtual cameras in areas of interest and see beyond the endoscope.



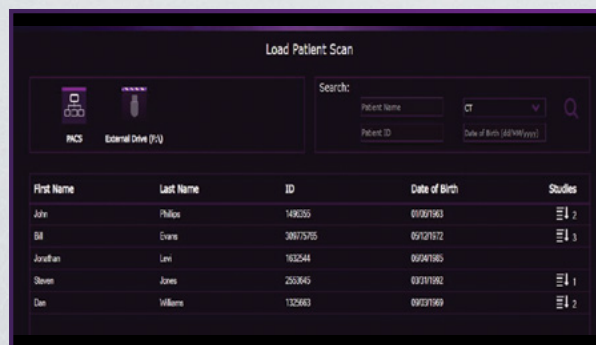
## Upgrade Kits

Proprietary software upgrade kits offer additional functionality.



### TruMerge™

Allows automatic merging between the CT scan and an MR scan. TruMerge™ lets you control the blending level between both scans while simultaneously navigating them using the navigated tools.



### TruPACS™

Connect to the facility's PACS server and easily load scans directly from the network using TruPACS™.



# Service Programs

An investment in TruDi® is an investment in your patients. Optimize that investment with our customer-focused, performance-driven service options.



Available terms
Annual preventative maintenance
Correct maintenance for manufacturing defects, including labor, parts and travel; exclusions apply
Technician response within 2 business days
System replacement guarantee within 2 business days
Phone support – Mon-Fri 7AM-8PM EST
Technician support on-site – Mon-Fri 7AM-5PM (local time)
Relocation(s) and re-installation(s) within 100 miles by certified technician
Software updates**
Software upgrades***
2 single units of new hardware****

BASIC	ELITE
1 or 2 years	3, 4, or 5 years
●	●
●	●
●	●
●	●
●	●
●	●
1*	2*
●	●
	●
	●

\* Number indicated in above table represents the total number of relocations and resulting re-installations allowed over the duration of the service agreement.  
\*\* Software updates are defined as any changes made to the system to keep it operational (i.e. bug fixes, ability to navigate new instruments).  
\*\*\* Software upgrades are defined as any software enhancements that provide new functionality (TruMerge, TruPACS).  
\*\*\*\* New hardware is defined as any new piece of hardware that is available for purchase (Cart, Remote Touch Pad).



## TruDi® Navigation Instruments

Enable the advanced functionality of TruDi® software features, including TruView, Planning Points, Beacon, and FAM.<sup>1</sup>



### TruDi® Suction

- Advanced visualization of tip location and orientation
- Simple plug-and-play solution with reliable accuracy



### TruDi® Curette

- A navigated, customizable dissection tool
- Indicated to dissect and remove bone, cartilage, and tissue



### TruDi® Probe

- Distal tip sensors enable plug-and-play solution
- Customizable to help reach targeted anatomy
- Strong enough to meet your clinical needs



### TruDi® NAVWIRE®

- Distal tip sensor for accurate, real-time visualization of the anatomical position of the wire<sup>2</sup>
- Flexible, safe, wire-based technology
- Increased compatibility with balloon dilation systems and reusable instruments<sup>3</sup>



### ACCLARENT PIVOT™ Navigation Balloon Dilation System

- 2-in-1 Balloon Dilation System: Indicated for both sinus and eustachian tube navigation and dilation
- The articulating and rotating guide catheter allows for a smooth transition from sinus to sinus
- The rigid guide tip can manipulate, separate, and divide tissue

1. ACCLARENT® ENT Navigation System Instructions for Use. UG-2000-00 02A 11.2018. 2. IFU005149 Rev E. ACCLARENT® NAVWIRE® Sinus Navigation Guidewire. 3. As compared to previous generation TruDi® NAVWIRE® Sinus Navigation Guidewire.

## Ordering information



Catalog code	Product name
ENS02B	<p>ACCLARENT® ENT Navigation System components include:</p> <p>(a) Emitter Pad, (b) Instrument Hub, (c) Navigation Console, (d) Workstation (Computer, Monitor and Mouse), (e) Power Supply, (f) Registration Probe (2 each), (g) Patient Tracker (2 each), (h) Instrument Adapter, (i) System Cart, (j) Clamp for Instrument Hub, (k) Cables for Power / Connectivity, (l) Instructions for Use, (m) Professional Installation, (n) Physician and Staff Training, (o) One-Year Warranty and (p) baseline software license.</p>

### Hardware components and accessories

Catalog code	Product name
EE-0849-65N	Remote Touch Pad
TruDiCart	TruDi® Cart

### Software upgrade kits

Catalog code	Product name
KT-2000-023	TruMerge™ Upgrade Kit
KT-2000-022	TruPACS™ Upgrade Kit

### Service programs

Catalog code	Product name
BASIC1	Basic 1-Year Service Plan
BASIC2	Basic 2-Year Service Plan
ELITE3	Elite 3-Year Service Plan
ELITE4	Elite 4-Year Service Plan
ELITE5	Elite 5-Year Service Plan



Ordering information



TruDi® Navigated Instruments

Catalog code	Product name	Size	Packaging unit
TDNS000Z	TruDi® Suction - 0 Degree Tip Angle	6 FR	1-pack
TDNS070Z	TruDi® Suction - 70 Degree Tip Angle	6 FR	1-pack
TDNS090Z	TruDi® Suction - 90 Degree Tip Angle	6 FR	1-pack
TDNC001	TruDi® Cable	n/a	5-pack
TDP0005	TruDi® Probe - 0 Degree Tip Angle	5"	5-pack
TDP0705	TruDi® Probe - 70 Degree Tip Angle	5"	5-pack
TDNW001Z	TruDi® NAVWIRE® Sinus Navigation Guidewire	n/a	1-pack
TDNW001	TruDi® NAVWIRE® Sinus Navigation Guidewire	n/a	5-pack
TDC0005	TruDi® Curette - 0 Degree Tip Angle	5"	5-pack
PVT0616N	ACCLARENT PIVOT™ Navigation Balloon Dilation System	6 x 16 mm	5-pack

Important Safety Information:

ACCLARENT® TruDi® Curette is intended for use with the TruDi® Navigation System by or under the direction of a physician who is trained in the use of Acclarent Technology. TruDi® Curette is intended for use with the TruDi® Navigation System to manipulate, dissect and/or remove tissue, cartilage and bone during surgical procedures in ENT and ENT skull base surgery. A thorough understanding of the technical principles, clinical application, and risk associated with the use of ENT and ENT Skull Base procedures is necessary before using this device.

ACCLARENT® TruDi® Probe is intended for use with the TruDi® Navigation System by or under the direction of a physician who is trained in the use of Acclarent Technology. The TruDi® Probe is intended for use with the TruDi® Navigation System to locate anatomical structures during surgical procedures in ENT and ENT skull base surgery. A thorough understanding of the technical principles, clinical application, and risk associated with the use of ENT and ENT Skull Base procedures is necessary before using this device.

The ACCLARENT PIVOT™ is intended to dilate the cartilaginous Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older. It is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities, or maxillary sinus in children aged 17 and under, for diagnostic and therapeutic procedures; irrigate from within a target sinus, or within the maxillary sinus for children aged 17 and under; suction throughout therapeutic procedures, and to facilitate diagnostic procedures.

The ACCLARENT PIVOT™ with the navigation guidewire may be utilized in conjunction with the TruDi® Navigation System, to help direct access to nasal and paranasal spaces, and to confirm placement in the targeted anatomy. The ACCLARENT PIVOT™ may be utilized in conjunction with the TruDi® NAVWIRE® Sinus Navigation Guidewire to confirm placement of the balloon in the Eustachian tube. The ACCLARENT PIVOT™ with the illumination guidewire may be utilized to illuminate within and provide transcutaneous illumination across nasal and sinus structures. A thorough understanding of the technical principles, clinical application, and risks associated with the use of ENT and ENT Skull Base procedures is necessary before using this device.

TruDi® NAV Suction Instruments are intended for use with the TruDi® Navigation System during surgical procedures in ENT medicine and skull base surgery to provide navigation of the instruments to the targeted anatomy, and evacuation of gases, liquids, and fragments.

Acclarent Navigation Technology is intended for use by or under the direction of a physician. Devices guided by the Acclarent Navigation Technology have described risks including the potential for unintended injury to the orbits or CNS as a consequence of inaccurate navigation. Prior to use, it is important to read the Instructions for Use and to understand the registration process and the contraindications, warnings and precautions described for the system.