



North America
United States
Health Care
Medical Supplies &
Devices

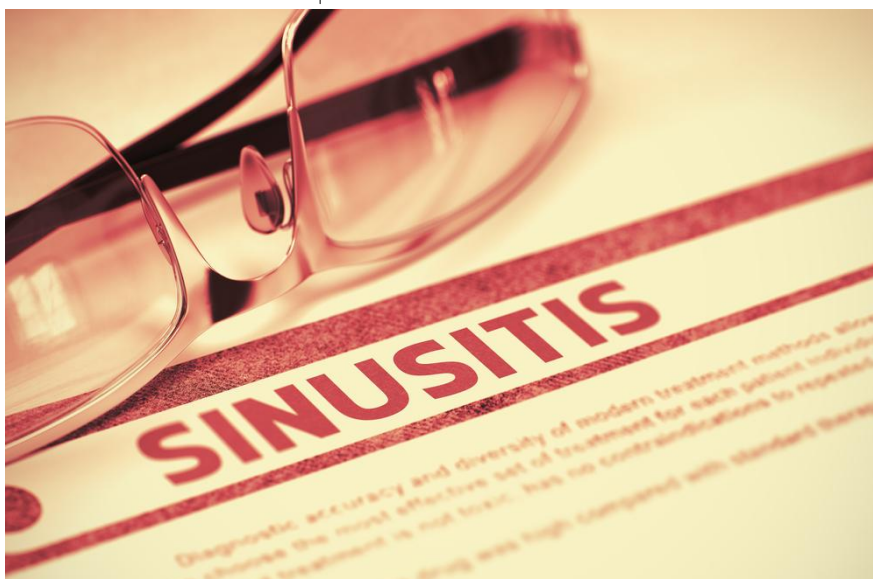
Industry
**Ear, Nose, and
Throat (ENT)**

Date
6 October 2016

Industry Update

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Follow Your Nose

Paradigm Shift in the Chronic Sinusitis Market

In 2015, we estimate there were 29M US adult chronic sinusitis patients, making it one of the most prevalent chronic conditions amongst US adults. The disease represents a significant cost burden to society, with substantial direct costs related to the management of the disease (we estimate \$4.3B-\$5.8B per annum), as well as indirect costs, as a result of lost productivity (we estimate \$10B). With its large societal burden and the healthcare system's shift away from 'fee for service', we view chronic sinusitis treatment in the midst of a paradigm shift with new treatment strategies, therapies and technologies that drive clinical outcomes, while reducing overall costs, emerging as winners.



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Key Themes to Drive Industry Shift

- **Minimally Invasive Treatment is Large and Underpenetrated:** Balloon sinus dilation (BSD) is a minimally invasive alternative to functional endoscopic sinus surgery (FESS). The procedure was introduced in 2005, but remains underpenetrated (we estimate 20% today). We view penetration increasing to 26% in 2021 lead primarily by continued economic and clinical data.
- **From the Operating Room to the Physician's Office:** We believe an increasing number of chronic sinusitis procedures will shift from the operating room to the physician's office setting moving forward. This shift provides benefits to all: patients, physicians, and payors.

DB Survey Supports View of Market Growth and Penetration

We conducted a survey of 30 US based, board certified otolaryngologists. We asked our survey respondents to comment on volume expectations, procedure settings, and market share trends. Our results indicate increased volume across procedure types, a move toward office based procedures, and further penetration of minimally invasive treatment options.

Opportunities for Technologies that Lower Costs and Improve Outcomes

New technologies that further enable minimally invasive procedures and the shift to physician's office based care are also garnering more attention. Medical supplies and devices companies have taken note with recent launches of more compact navigation systems, steroid eluting stents, and more compact surgical tools and technologies.

Initiate Coverage of the Two ENT Pureplays: ENTL at Buy and XENT at Hold

We are initiating coverage of two pure play ear, nose, and throat (ENT) medical supplies and devices companies. For Entellus (ENTL), we see upside from current levels as the company continues to enable the shift of procedures from the operating room to the physician's office and expands its product portfolio to become a "one stop shop" for in office ENT solutions. For Intersect ENT (XENT), we believe risk around execution and reimbursement offsets the company's differentiated product platform in the near term.

Valuation and Risks

We value the two pure play ENT medical supplies and devices companies using a peer group enterprise value to sales metric. Upside risks include market expansion, increased sales force productivity, reimbursement wins, and product pipeline acceleration. Downside risks include increased competition, product failures and / or adverse events, market contraction, sales force disruptions, reimbursement losses, and additional capital raises.

Key Changes

Company	Target Price	Rating
ENTL.OQ	- to 26.00(USD)	NR to Buy
XENT.OQ	- to 17.00(USD)	NR to Hold

Source: Deutsche Bank

Top picks

Entellus Medical (ENTL.OQ),USD22.12	Buy
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Source: Deutsche Bank

Companies Featured

Entellus Medical (ENTL.OQ),USD22.12	Buy
Intersect ENT (XENT.OQ),USD16.60	Hold
Johnson & Johnson (JNJ.N),USD119.18	Buy
Medtronic (MDT.N),USD86.30	Buy
Olympus (7733.T),¥3,700	Buy
Smith & Nephew (SN.L),GBP1,265.00	Hold
Stryker (SYK.N),USD116.66	Buy

Source: Deutsche Bank

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Table Of Contents

Executive Summary	3
DB Otolaryngologist Survey	4
Chronic Sinusitis	5
Highly Prevalent Disease... ..	6
Significant Cost Burden to Society	6
The Treatment Continuum	7
Medical Therapy	8
Functional Endoscopic Sinus Surgery (FESS)	9
Balloon Sinus Dilation	10
From ‘Open’ to ‘Minimally Invasive’	11
Underpenetrated Market with Opportunity to Expand	11
Future Drug Eluting Stents Could Replace Revision Surgical Procedures	14
From the Operating Room to the Office	15
Company strategies are shifting	15
Current In-Office Penetration Varies, but Will Shift More in that Direction Over Time	15
Procedural Volume Should Continue to Increase	24
DB Survey Suggests Increasing Volume across Procedures.....	24
New Technologies to Drive Further Growth	32
Recreating the Surgical Suite in the Office via Image Guided Navigation	32
Steroid Eluting Intranasal Implants	35
Competitive Landscape	39
DB Survey Shows Surgical Market Shares Sticky	41
DB Survey Shows Acclarent Continues to Lead in Balloons	42
Reimbursement Dynamics	43
Sinus Surgery Reimbursement is Well Established.....	43
Proposed 2017 Medicare Changes Could Drive More Procedures in Office.....	44
Balloon Sinus Dilation: Reimbursement Generally Established.....	45
The Stock Opportunity	48
We View ENTL as Best Positioned.....	48
XENT: Shares Fairly Valued Given Near Term Risks	49



Executive Summary

In 2015, we estimate there were 29 million US adult chronic sinusitis patients, making it one of the most prevalent chronic conditions amongst US adults. The disease represents a significant cost burden to society, with substantial direct costs related to the management of the disease (we estimate \$4.3 - \$5.8 billion per annum), as well as indirect costs, as a result of lost productivity (we estimate \$10 billion).

With its large societal burden and the healthcare system's shift away from 'fee for service', we view chronic sinusitis treatment in the midst of a paradigm shift with new treatment strategies, therapies and technologies that drive clinical outcomes while reducing overall costs, emerging as winners.

Our industry thesis is driven by the following key themes:

Chronic Sinusitis is a Large and Costly Disease

The Centers for Disease Control (CDC) estimates that chronic sinusitis occurs in approximately 12% of the adult (18 years and older) population. In 2015, we estimate there were 29 million US adults with chronic sinusitis. The disease ranks as one of the top ten most costly healthcare conditions in the US with more than 12 million physician visits each year.

The Shift from "Open" to "Minimally Invasive" Treatment Should Aid Growth

The shift from "open" surgical procedures to minimally invasive surgical procedures, in our view, continues to accelerate across a number of medical supplies and devices subsectors, including ear, nose, and throat (ENT). While we estimate there is a total addressable adult patient population of approximately 630,000, we believe it is approximately 20% penetrated at present.

The Shift from the "OR" to the "Physician's Office" Should Increase

With physicians and healthcare systems beginning to take a closer look at the cost of patient care, an increasing number of otolaryngologists have begun to shift their uncomplicated chronic sinusitis procedures from the hospital operating room to the physician's office.

We view this shift as having a host of benefits for the physician as he or she is paid more, for the healthcare system as it costs less, and for the patient who can enjoy an outpatient procedure in the comfort of his or her physician's office. As patients become more involved in their healthcare decision making, we anticipate patient preference may also drive demand in the future.

New Technologies Enabling these Shifts Should See Growth

We believe new technologies that further enable the physician to recreate its operating room surgical suite in the physician's office will garner increased attention. These technologies include: navigation, steroid eluting stents, and photodynamic therapy. In addition, we continue to believe products that provide both clinical, as well as economic data should also garner high demand in the future.



DB Otolaryngologist Survey

We conducted a survey of 30 US based, board certified otolaryngologists. We asked our survey respondents to comment on volume expectations, procedure settings, and market share trends. Our results indicate increased volume across procedure types (functional endoscopic sinus surgery (FESS), hybrid, and balloon sinus dilation), a move toward office based procedures, and further penetration of minimally invasive treatment options, such as balloon sinus dilation.

Figure 1: Summary of Findings

Topic	Findings
Expected volume trends	Our survey showed an overall weighted average increase in volume across procedure types: <ul style="list-style-type: none"> ■ Functional endoscopic sinus surgery (FESS): +7% in 2016 and +9% in 2017 ■ Hybrid: +18% in 2016 and +7% in 2017 ■ Standalone balloon sinus dilation: +11% in 2016 and +6% in 2017
Current procedure setting	Our survey revealed that practice setting varies by procedure type with the majority of functional endoscopic sinus surgery (FESS), hybrid, and revision procedures performed in the operating room and standalone balloon sinus dilation procedures almost evenly split between the operating room and physician's office.
Expected procedure setting	In 2017, our survey estimates an overall shift from the operating room to the physician's office across procedure types. Further, we asked our respondents to comment on the percent of their hybrid and standalone balloon sinus dilation procedures they believe are conducive to the physician's office. <ul style="list-style-type: none"> ■ The majority of our respondents indicated less than 25% of hybrid procedures are conducive to the physician's office. ■ The majority of our respondents indicated more than 50% of standalone balloon sinus dilation procedures are conducive to the physician's office.
Image guidance (all procedures)	Our survey showed that use of image guidance systems vary by procedure type and practice setting with standalone balloon sinus dilation rarely being performed with image guidance.
Image guidance (in office)	Our survey showed limited use of image guidance systems in the physician's office, with respondents primarily citing cost as a limiting factor.
Oral steroid use	Our survey concluded that physicians prescribe oral steroids more than 50%, on average, in revision procedures and less than 50% on average in other procedures, such as functional endoscopic sinus surgery (FESS), hybrid, and standalone balloon sinus dilation procedures.
Market share – surgical tools and instruments	Our survey showed that Medtronic, with its large presence in the hospital operating room, is the clear leader in the surgical tools and instruments segment of the ENT market.
Market share – balloon sinus dilation	Our survey concluded that despite market share losses in recent years, Acclarent (J&J) continues to lead the balloon sinus dilation market, with Entellus, Medtronic, and Smith & Nephew behind.
Steroid eluting intranasal stents	Our survey showed that most of the physicians use the technology due to better patient outcomes, while most of the physicians who do not use the technology cited cost and "other" which included unclear advantage, familiarity and outpatient setting.

Source: Deutsche Bank 2016 Otolaryngologist Survey



Chronic Sinusitis

Sinuses are air filled pockets that are housed within the bones of the face. There are four pairs of sinuses, with one of each pair located on either the right or left side of the face.

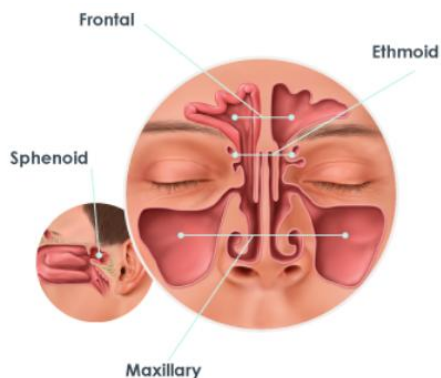
The **ethmoid sinuses** are located between the eyes and serve as a passageway to all the other sinuses. The ethmoid sinuses are currently the only sinuses that are unable to be treated via standalone balloon sinus dilation, however, they can be treated via traditional sinus surgery and every sinus surgery typically begins with an ethmoidectomy.

The **maxillary sinuses** are located on the cheekbone. These sinuses are the largest of the four sinuses and the most commonly treated.

The **frontal sinuses** are located above the eyes and just behind the eyebrow.

The **sphenoid sinuses** lie below the base of the brain and at the posterior end of the nose. As one might expect, the sphenoid sinuses are the most difficult to treat given their proximity to the brain.

Figure 2: Overview of the Sinuses



Source: Image Courtesy of Entellus Medical

Sinusitis occurs when the sinus cavities are unable to properly drain mucus, which results in an inflammation of the sinus cavity. The disease is primarily classified into three types: acute, recurrent, and chronic.

- **Acute sinusitis** lasts less than four weeks and is often caused by excess or thick mucus. In general, acute sinusitis is treated with medical management.
- **Recurrent acute sinusitis** is characterized by more than four episodes of acute sinusitis per year.
- **Chronic sinusitis** is the most severe form of sinusitis and lasts more than 12 weeks per year. Otolaryngologists further classify their chronic sinusitis patients into those with nasal polyps and those without nasal polyps.



In addition, there are a number of additional sinus conditions, including:

- **Barosinusitis** is a swelling or inflammation of the lining of one or more of the sinuses due to a change in air pressure.
- **Sinogenic Headache (also known as Sinus Headache)** is persistent or recurring headaches as a result of mucosal contact points within the nasal cavity.

Highly Prevalent Disease...

In Adults..

Chronic sinusitis is one of the most prevalent chronic conditions amongst adults in the US. The prevalence rates vary within the literature from approximately 5% - 15% of the adult population. The Centers for Disease Control (CDC) estimates that chronic sinusitis occurs in approximately 12% of the US adult (18 years and older) population. In 2015, we estimate there were approximately 29 million adult chronic sinusitis patients in the US.

... As Well as Pediatrics

In 2015, we estimate there were approximately 6 million pediatric chronic sinusitis patients in the US. While some clinicians believe pediatric chronic sinusitis patients should be left untreated, clinical studies have shown that pediatric patients with chronic sinusitis have a significantly reduced quality of life as compared to selected other diseases.

Significant Cost Burden to Society

Chronic sinusitis represents a significant economic burden to society, with substantial direct, as well as indirect costs.

Direct costs: Medication and Surgery are Costly Solutions

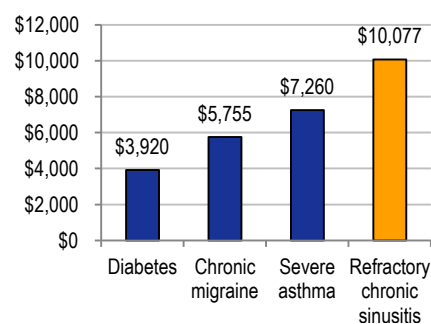
In 2015, we estimate there were more than 12 million individual physician's office visits related to chronic sinusitis in the US. Using data from the National Health Interview Survey (1997 – 2006), we estimate 66% of physician's visits were to the primary care physician (PCP), 23% of physician's visits were to the otolaryngologist, and 11% of physician's visits were to other facilities, including emergency room and hospital outpatient departments. The survey also suggested that more than 50% of patients spent \$500 or more per year on health care.

As a result, it is estimated that direct costs for the management of chronic sinusitis range between \$4.3 - \$5.8 billion per annum, with 30% of those costs used to treat pediatric patients, or those less than 12 years of age.

Indirect Costs

Chronic sinusitis also includes a host of indirect costs such as absenteeism, presenteeism, short and long term disability, and workman's compensation. A study published in 2014 concluded that productivity costs for chronic sinusitis were higher than other chronic conditions, including severe asthma, chronic migraine, and diabetes.

Figure 3: Annual Productivity Costs



Source: Slide Presentation – American Rhinology Society (ARS) Annual Meeting 2016, Deutsche Bank

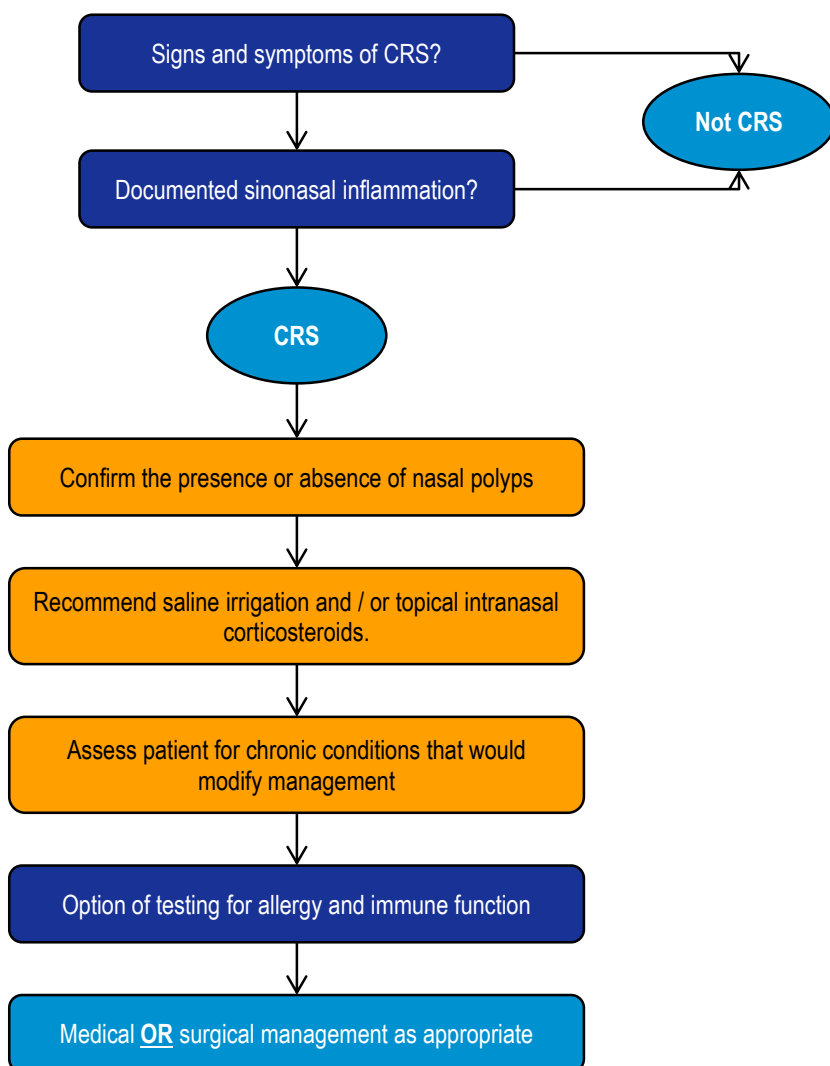


The Treatment Continuum

We believe chronic sinusitis patients progress slowly through the treatment continuum. When symptoms first present, patients often seek care from their primary care physician or PCP. These physicians typically prescribe or recommend over the counter (OTC) medications, such as decongestants, nasal and systemic steroids, mucolytics, and irrigation.

As symptoms persist and possibly worsen, patients are often referred to more specialized physicians, such as otolaryngologists and / or allergists, who then are able to diagnose chronic sinusitis via endoscopic imaging.

Figure 4: Treatment Algorithm, Adult Chronic Sinusitis



Source: American Academy of Otolaryngology (AAO), Deutsche Bank



Medical Therapy

Patients that seek medical help from otolaryngologists, often progress to more aggressive treatment options, though medical therapy continues to be the first line therapy. Often, patients are prescribed more aggressive medication treatment options, such as additional antibiotics, oral steroids, intra-nasal steroid sprays, and / or saline irrigations. We estimate antibiotic use related to chronic sinusitis is \$150 million per annum.

We estimate medical therapy is effective in approximately 40% of patients, though, we note, it does not address anatomical discrepancies that may be a contributor to the overall condition. In addition, long term use of certain medications, such as antibiotics and steroids, can have a number of adverse side effects including antibiotic resistance, high blood pressure, and psychosis among others.

Biologics: Used in Asthma and Beginning to Gain Attention in Chronic Sinusitis

The US Food and Drug Administration (FDA) define biologics as substances derived from living organisms or produced by biotechnology methods. In recent years, biologics for the treatment of chronic sinusitis patients have received increased attention, as clinicians look for additional treatment options for this highly prevalent disease.

While biologics represent an addition to the treatment paradigm for chronic sinusitis patients, we believe the high, ongoing cost of the drug, could be a limiting factor moving forward.

We view three primary biologics as relevant in the treatment of chronic sinusitis patients, though, we note, there could be additional clinical studies beyond these products.

- **Xolair** is a monoclonal anti IgE (immunoglobulin E) antibody. The drug, marketed by Genentech and Novartis, has been FDA approved since June 2003 and is indicated for the treatment of moderate to severe persistent allergic asthma and chronic idiopathic urticaria (also known as 'hives'). We estimate the cost of Xolair to be more than \$1,000 per month.

In 2015, a systematic literature review showcased two clinical studies evaluating anti-IgE in chronic sinusitis patients. The data showed:

- A significant reduction in CT score ($p=0.04$),
 - A decrease in clinical polyp score, and
 - No significant difference related to quality of life as measured by Total Nasal Symptom Severity ($p<0.21$) and Sinonasal Outcome Test 20 (SNOT-20) ($p<0.60$).
- **Nucala (mepolizumab) and Cinqair (reslizumab)** are anti IL (interleukin) 5 biologics indicated for treatment of severe asthma. Nucala is marketed by GlaxoSmithKline, while Cinqair is marketed by Teva. We estimate the average cost of anti-IL 5 biologics to be more than \$2,000 per month.

In 2011, results from a 30 patient clinical trial evaluating mepolizumab were published. The clinical trial evaluated chronic sinusitis patients



with nasal polyps (n=20 (treatment group) and n=10 (control group)). The data showed:

- An improvement in nasal polyp score vs the control group (p=0.04 at 28 days, p=0.01 at 56 days, and p=0.05 at 84 days),
- An improvement of CT score at week 8.

In addition, a 2006 clinical trial evaluating reslizumab showed improved nasal polyp scores, though improvement was not seen in all patients.

- **Dupilumab** is an anti IL-4 and anti IL13 fully-human monoclonal antibody. The drug is being developed by Regeneron and Sanofi for a host of indications including chronic sinusitis with nasal polyps.

The companies announced positive Phase 2 top line data in 2014 and more recently published the full data set in the Journal of American Medical Association (JAMA) in February 2016. The clinical study showed a statistically significant improvement in the size of nasal polyps, which was the trial's primary endpoint. Statistically significant improvements were also observed in nasal air flow and patient reported symptoms such as sense of smell, post nasal drip, congestion, runny nose, and sleep disturbance. A Phase 3 trial is currently underway.

Functional Endoscopic Sinus Surgery (FESS)

Following multiple rounds of medication, we estimate that approximately 60% of patients remain symptomatic and may be optimal candidates for a more invasive treatment option.

Standard of Care

Functional endoscopic sinus surgery or FESS is the preferred surgical treatment option for chronic sinusitis patients. FESS is traditionally performed in a hospital operating room and involves the removal of the inflamed sinus tissue, as well as the underlying bone to open the nasal pathway and enlarge the sinus ostia. The surgeon can also perform additional procedures, if needed to treat nasal deformities or to gain access to the sinuses.

The three most common sinus surgery procedures include ethmoidectomy, maxillary antrostomy, and powered septoplasty with turbinoplasty.

- **Ethmoidectomy**, which aids in clearing the ethmoid sinuses. An ethmoidectomy occurs in all sinus surgery procedures.
- **Maxillary antrostomy**, which enables the maxillary sinuses to drain more efficiently and effectively.
- **Powered septoplasty with turbinoplasty**, which involves the clearing of breathing difficulties caused by a deviated septum, or a displaced nasal septum that causes one nasal passage to be smaller than the other, or enlarged turbinates, which clean and humidify the air as it transitions from the nose to the lungs.

When the surgical procedure is complete, the surgeon fills the nasal cavity with packing materials which aid in preventing surgical adhesions and controlling bleeding. In addition, patients often require at least one (if not multiple) follow up visits for debridement, whereby the surgeon removes damaged tissue from the body.



Some Drawbacks to Surgery Remain

While FESS is the standard of care in the surgical treatment of chronic sinusitis, it does carry a host of risks and selected drawbacks.

Figure 5: Selected Drawbacks, Traditional Sinus Surgery (FESS)

- ✘ Irreversible changes to the patient's underlying anatomy.
- ✘ Post operative pain and discomfort, including that of follow up debridement procedures.
- ✘ Recovery time of approximately 2-3 days.
- ✘ General anesthesia risks, such as excessive bleeding and intraorbital complications.
- ✘ Surgical complications, including eye swelling or blindness (though quite rare, occurring in approximately 1% of all FESS procedures).

Source: Company Data, Deutsche Bank

In addition, while sinus surgery is effective in the majority of patients, we estimate that approximately 10% of FESS patients will require revision surgery with more than 60% of patients experiencing recurrent symptoms within the first year of the FESS procedure.

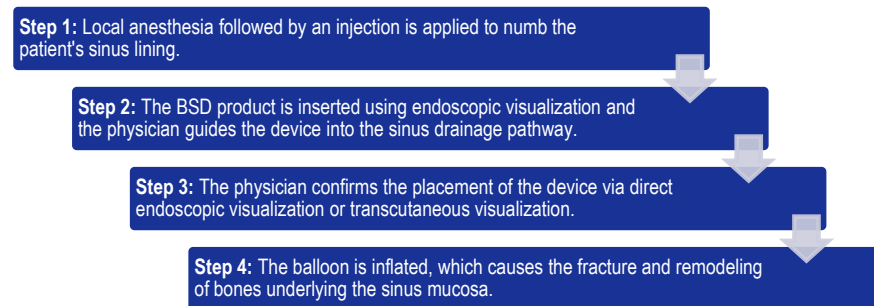
Balloon Sinus Dilation

The Minimally Invasive Alternative

Balloon sinus dilation was introduced in 2005 by Acclarent (acquired by Johnson & Johnson) as a minimally invasive alternative to functional endoscopic sinus surgery (FESS) in patients with chronic sinusitis.

Balloon sinus dilation can be used to treat the maxillary, frontal, and sphenoid sinuses but not the ethmoid sinuses. The procedure uses a balloon catheter to remodel and widen the sinus passageway and generally takes approximately one hour.

Figure 6: Procedure Overview, In Office Balloon Sinus Dilation



Source: Company Data, Deutsche Bank



From 'Open' to 'Minimally Invasive'

We view the shift from 'open' surgical procedures to minimally invasive surgical procedures as a key factor in driving growth in the chronic sinusitis market. While this shift has already started to occur, we believe it will accelerate over the coming years driven by the need to further reduce procedure related costs.

Underpenetrated Market with Opportunity to Expand

In 2015, we estimate there were approximately 550,000 adult functional endoscopic sinus surgery (FESS) procedures performed in the US. We believe 85% of current FESS procedures could be well suited for either standalone balloon sinus dilation or a hybrid procedure. In addition, we believe the availability of a minimally invasive alternative such as balloon sinus dilation will also benefit patients who are currently on the sidelines due to their unwillingness to undergo surgery; we estimate 85% of non surgical patients could be eligible for a standalone balloon sinus dilation procedure.

Altogether, this results in a total adult patient population of 627,000 in the US alone. However, at present, we view the patient population as approximately 20% penetrated with approximately 125,000 procedures.

Figure 7: Deutsche Bank US Adult Balloon Sinus Dilation Market Model, 2015 – 2021E

	2015	2016E	2017E	2018E	2019E	2020E	2021E
Adults							
Total ENT Adult Patient Population	1,229,444	1,255,235	1,292,361	1,329,983	1,396,026	1,434,869	1,474,227
<u>First Line Therapy - Medication</u>							
Patients Successfully Treated with Medication	491,778	502,094	516,944	531,993	558,410	573,948	589,691
%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%
Patients Unsuccessfully Treated with Medication	737,666	753,141	775,417	797,990	837,616	860,922	884,536
%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%
<u>Second Line Therapy - Surgery</u>							
Patients who Fail First Line Therapy and Opt Not to Have Surgery	185,259	189,145	194,739	200,408	210,360	216,213	222,144
%	25.1%	25.1%	25.1%	25.1%	25.1%	25.1%	25.1%
Patients who Undergo Sinus Surgery (FESS)	552,408	563,996	580,677	597,581	627,255	644,708	662,392
%	74.9%	74.9%	74.9%	74.9%	74.9%	74.9%	74.9%
<u>Balloon Sinuplasty Addressable Market</u>							
Sinus Surgery Patients Eligible for Standalone BSP	303,824	310,198	319,372	328,670	344,990	354,590	364,316
%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%
Non Surgery Patients Eligible for Standalone BSP	157,470	160,773	165,529	170,347	178,806	183,781	188,822
%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Sinus Surgery Patients Eligible for Hybrid BSP	165,722	169,199	174,203	179,274	188,177	193,412	198,718
%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
Total Addressable Adult Patient Population	627,016	640,170	659,104	678,291	711,973	731,783	751,856
<i>% of Addressable Market Penetrated</i>	<i>20%</i>	<i>21%</i>	<i>22%</i>	<i>23%</i>	<i>24%</i>	<i>26%</i>	<i>28%</i>
Current Addressable Adult Patient Population	125,403	134,436	145,003	156,007	170,874	190,264	210,520
Operating Room	87,782	92,492	95,992	99,376	102,695	106,548	110,523
% of total population	70%	68.8%	66.2%	63.7%	60.1%	56.0%	52.5%
% growth		5.4%	3.8%	3.5%	3.3%	3.8%	3.7%
In Office	37,621	41,944	49,011	56,631	68,179	83,716	99,997
% of total population	30%	31.2%	33.8%	36.3%	39.9%	44.0%	47.5%
% growth		11.5%	16.8%	15.5%	20.4%	22.8%	19.4%

Source: Company Data, Deutsche Bank



We estimate demand for total balloon sinus dilation procedures will increase to 28% in 2021. We believe increased penetration will be driven by continued clinical data supporting the use of the technology, as well as continued medical society and clinician support.

Increased Clinical Data Supports Expanded Balloon Penetration

Adequate clinical data supporting balloon sinus dilation has, in our view, only recently become available.

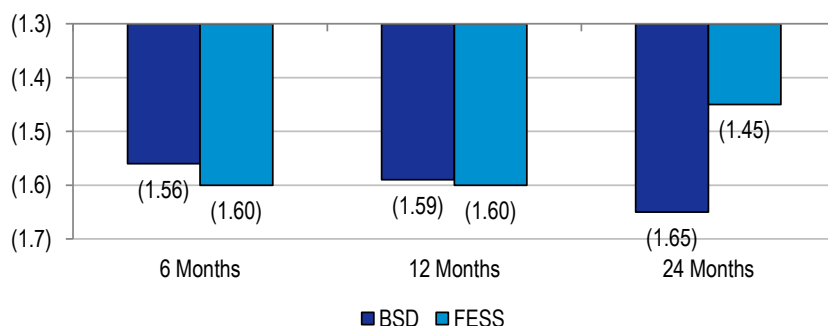
In the immediate period post FDA approval of balloon sinus dilation, a host of clinical studies were published showing high procedural success rates, quality of life and radiographic improvements, as well as low complication rates for balloon sinus dilation. However, these studies faced criticism from a number of physicians who believed the studies were poorly designed (lack of randomized clinical trials) and that the device needed proof of concept data in order to see wide spread use.

The **REMODEL clinical trial** was a multi center, prospective, open label, randomized controlled trial comparing balloon sinus dilation performed in the physician office setting to functional endoscopic sinus surgery (FESS) performed in the operating room for the treatment of chronic sinusitis.

While there were other clinical studies evaluating balloon sinus dilation, REMODEL was the only clinical trial that had enough statistical power to demonstrate advantages of balloon sinus dilation in comparison to traditional sinus surgery (FESS).

The REMODEL trial enrolled 135 adult patients with 61 patients in the FESS arm and 74 patients in the balloon dilation arm, with no significant differences in the two arms. The trial showed that balloon sinus dilation was non inferior to sinus surgery with comparable and significant long term symptom improvement.

Figure 8: Mean SNOT-20 Change from Baseline by Follow Up Period

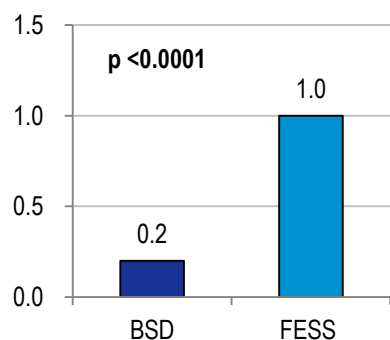


Note: 24 month data represents small sample of patients: n=15 for balloon sinus dilation arm and n=10 for sinus surgery arm.
 Source: Company Data, Deutsche Bank

At 12 months, the REMODEL trial also showed a better patient experience for balloon sinus dilation versus sinus surgery with fewer post operative debridements, less pain medication and faster recovery.

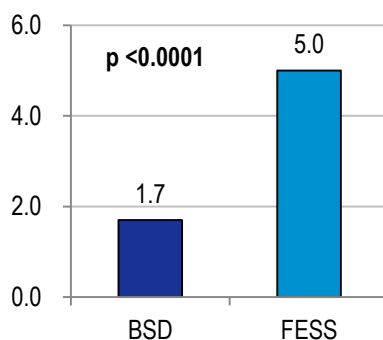


Figure 9: Mean Number of Debridements, 12 Months



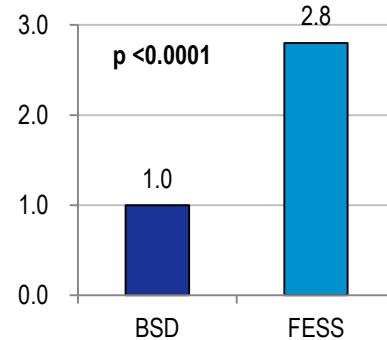
Source: Company Data, Deutsche Bank

Figure 10: Recovery Time, 12 Months



Source: Company Data, Deutsche Bank

Figure 11: Duration of Prescription Pain Medication(s), 12 Months



Source: Company Data, Deutsche Bank

The trial also showed that balloon sinus dilation delivers similar efficacy rates to that of sinus surgery in terms of symptom improvement, ostial patency, reduction of sinusitis episodes, and very low surgical revision rates.

Figure 12: Additional Secondary and Safety Outcomes, 12 Months

	Balloon Sinus Dilation	FESS	p-value
Secondary Efficacy Outcomes (Recovery and Short Term)			
Patients discharged with nasal bleeding	32%	56%	0.009
Secondary outcomes (1 year)			
Change in number of sinusitis episodes per patient	-4.2	-3.7	Not statistically different
Ostial patency	>90%	>90%	Not statistically different
Mean reduction of activity impairment due to chronic sinusitis	68%	76%	Not statistically different
Mean reduction in overall work impairment due to chronic sinusitis	72%	80%	Not statistically different
Mean reduction in productivity loss	74%	78%	
Safety Outcomes			
Complications	0%	0%	Not statistically different
Revision Surgery Rate (1 Year)	1.4%	1.7%	Not statistically different

Source: Company Data, Deutsche Bank

Update to AAO-HNS Position Statement

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) revised its position statement related to balloon sinus dilation in mid September 2016. We view this revision as an incremental positive as we believe society support should aid in incremental physician adoption.

The revised position statement also adds recurrent acute sinusitis patients into the position statement, which we believe could increase the total addressable patient population in the long term.



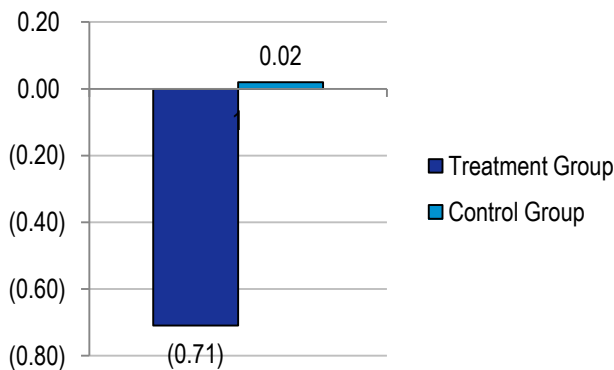
Future Drug Eluting Stents Could Replace Revision Surgical Procedures

The RESOLVE steroid eluting intranasal stent delivers mometasone fuorate over a 90 day period. The device is being designed as an in-office alternative treatment for patients with recurrent chronic sinusitis.

The device is currently being studied in a Phase 3 clinical trial, RESOLVE II, which is a prospective, randomized, blinded multi center clinical trial evaluating the use of the RESOLVE implant during a routine physician office visit. The study completed enrollment in June 2016, enrolling a total of 300 patients across 34 US centers. The trial’s endpoints include both patient reported outcomes and objective endoscopic outcomes. We expect top line data to be reported in late 2016 / early 2017.

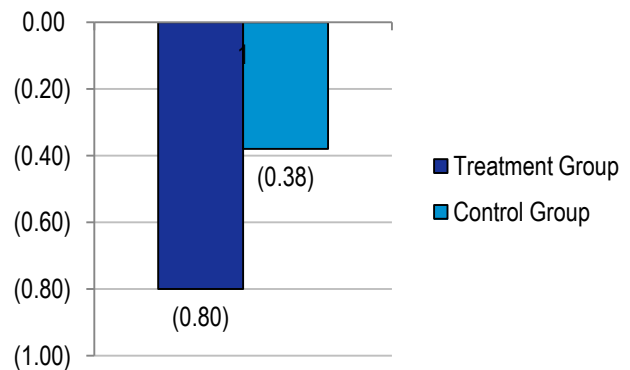
Long term results from the device’s Phase 2 study were published in June 2016. The data continues to show the benefits of RESOLVE, with statistically significant improvement in symptom scores, ethmoid sinus obstruction, and polyp grade versus the control arm. The data also showed that patients in the control arm were 3.6x more likely to remain indicated for a revision sinus surgery procedure.

Figure 13: Change in Bilateral Polyp Grade



Source: Company Data, Deutsche Bank

Figure 14: Change in Bilateral Polyp Grade, Grade 2 Patients or Higher



Source: Company Data, Deutsche Bank

Reducing Revision Surgery

If Phase 3 data is positive, we would estimate FDA approval of RESOLVE in 2018. We believe RESOLVE could cannibalize the number of revision sinus surgery procedures, and could also add those incremental patients who at present, choose not to undergo an additional sinus surgery procedure.

We estimate 64% of functional endoscopic sinus surgery (FESS) patients experience symptom recurrence within one year post procedure and 10% of FESS patients undergo a revision procedure.



From the Operating Room to the Office

As physicians and healthcare systems begin to look more closely at the cost of patient care, we believe an increasing number of otolaryngologists have started to shift selected chronic sinusitis procedures from the hospital operating room (OR) to the physician's office.

We view this shift as having a host of benefits for all parties involved: The physician, as he or she is paid more; the healthcare system, as it costs less; and the patient, with increased comfort in the physician's office. As patients become more involved in their healthcare decision making, we anticipate patient preference may also drive demand in the future.

Company strategies are shifting

Medical device manufacturers have become increasingly aware of the shift from hospital operating room based procedures to physician's office based procedures. As such, companies have begun to align their strategies and new product development to take advantage of this trend.

We View Entellus as the Clear 'Office' Market Leader for Balloons

We would estimate that Entellus leads the physician's office balloon sinus dilation market with its XprESS balloon sinus dilation system that looks and feels like a sinus seeker, a tool that is familiar amongst otolaryngologists. Primary competitors, Acclarent (Johnson & Johnson) and Medtronic's XoMed division have also started to invest in the physician's office space.

Surgical Tools and Instruments Vary

We estimate the in-office surgical tools and instruments market varies amongst a host of manufacturers as some physicians use the same surgical tools and instruments in the office that they use in the hospital operating room.

Companies have iterated on devices, however, with current tools being easier to use, disposable, smaller, and multi functional, such as combined suction and irrigation tools versus prior generations.

Current In-Office Penetration Varies, but Will Shift More in that Direction Over Time

We conducted a survey of 30 US based, board certified otolaryngologists. We asked our survey respondents to comment on the practice setting whereby they most often treat their adult chronic sinusitis patients, and whether that will shift going forward.

Our survey revealed that practice setting varies by type of chronic sinusitis procedure. In 2015, the majority of traditional, hybrid (functional endoscopic sinus surgery (FESS) in combination with balloon sinus dilation), and revision procedures were being performed in the operating room, while standalone balloon sinus dilation procedures were almost evenly split between operating room and the physician's office. In 2017, our survey estimates an overall shift towards the physician's office for all chronic sinusitis procedures.



We view our survey results as positive for a host of ENT medical supplies and devices manufacturers, particularly those that have a broad presence in the physician’s office and further enable the shift of procedures from the operating room to the office.

In balloon sinus dilation, specifically, our survey indicated less than 50% penetration, thus we see continued opportunity for penetration expansion. We believe there are a host of physicians who view the technology as an adjunct to functional endoscopic sinus surgery (FESS) versus a standalone procedure.

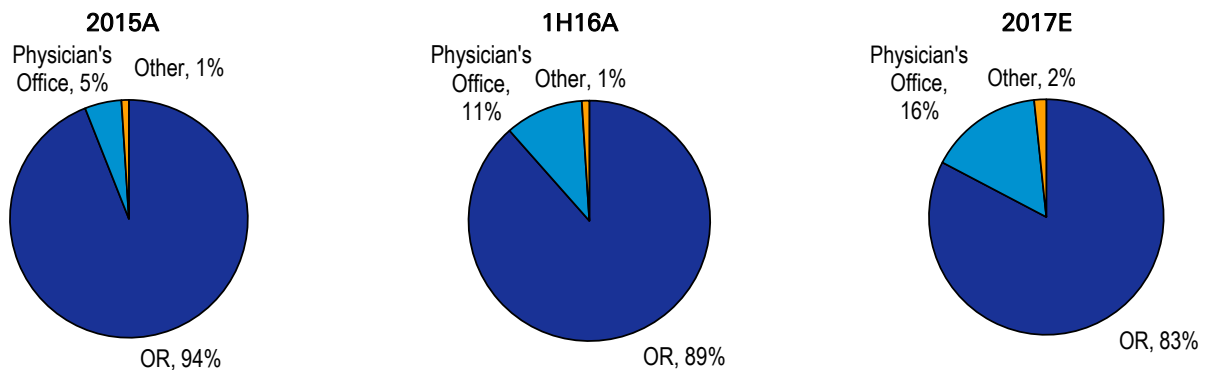
With almost a 90% operating room based procedure in 2017, we believe our survey results for revision functional endoscopic sinus surgery (FESS) procedures show a need for a less invasive treatment option that can be utilized in the physician’s office.

Traditional Sinus Surgery: Continued Skew towards the Operating Room

In 2015, our survey respondents, on average, performed 94% of their functional endoscopic sinus surgery (FESS) procedures in the operating room, with 5% in the physician’s office and 1% in “other” which was specified to be an ambulatory surgery center (ASC). We note, in 2015, more than half (n=17) of our survey respondents performed all (100%) of their FESS procedures in the operating room.

Our survey showed trends shifting with our survey respondents estimating procedures will shift from the operating room to other sites of care. In 2017, our survey respondents estimated, on average that 83% of their functional endoscopic sinus surgery (FESS) procedures would be performed in the operating room, with 16% performed in the physician’s office, and 2% performed in “other”. We note, in 2017, 13 of our survey respondents estimated that they would continue to perform all (100%) of their functional endoscopic sinus surgery (FESS) procedures in the operating room.

Figure 15: Percent of Traditional Sinus Surgery (FESS) Procedures Performed by Practice Setting, Average



Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents to comment on the rationale of their expected change in procedure setting for functional endoscopic sinus surgery (FESS) procedures. We highlight selected verbatim responses below, stratified by whether our respondents expect an overall increase, decrease, or no change in the percentage of procedures performed in the physician’s office from 2015 – 2017.



Figure 16: Procedure Setting Shifts, Traditional Sinus Surgery (FESS), Select Verbatim Responses

Increase in Physician's Office Procedures	Neutral	Decrease in Physician's Office Procedures
<p><i>"Better in office outcomes and reimbursement."</i></p> <p><i>"Increase in office."</i></p> <p><i>"More experience with in office procedures."</i></p> <p><i>"Sinus surgery is shifting towards the office setting."</i></p> <p><i>"I'm moving more and more to the office."</i></p> <p><i>"My group has budgeted to purchase office equipment 2017."</i></p> <p><i>"Increased marketing of clinic procedures."</i></p> <p><i>"I think I will be doing more office procedures in the future."</i></p> <p><i>"Better devices and less noted discomfort with specialized local anesthesia protocols for in office work."</i></p> <p><i>"More attempts at in office balloon sinuplasty."</i></p> <p><i>"Better equipment availability in office and comfort level."</i></p> <p><i>"I still find it difficult to have patients decide on the office setting."</i></p>	<p><i>"Not doing much in office currently."</i></p> <p><i>"My office setting is not conducive to in office procedures."</i></p> <p><i>"Recent affiliation with a surgery center."</i></p> <p><i>"No anticipated change."</i></p> <p><i>"I perform traditional sinus surgery in OR because that gives the best possible results and diminishes chances of requiring further surgery later."</i></p> <p><i>"Not set up or comfortable with FESS in the office."</i></p> <p><i>"Availability of office equipment."</i></p> <p><i>"Will not get reimbursed in the office."</i></p> <p><i>"No changes"</i></p> <p><i>"Would not perform traditional FESS in office due to bleeding risk."</i></p> <p><i>"Employed physician hospital."</i></p> <p><i>"Easier for me."</i></p> <p><i>"Again my numbers are usually very consistent year over year."</i></p> <p><i>"Equipment availability."</i></p> <p><i>"I always do traditional fess in OR."</i></p> <p><i>"I prefer operating room for traditional FESS."</i></p>	<p><i>"I expect volume of office procedures to remain stable or decrease as reimbursement has decreased by at least 20% per year past 2 years."</i></p>

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

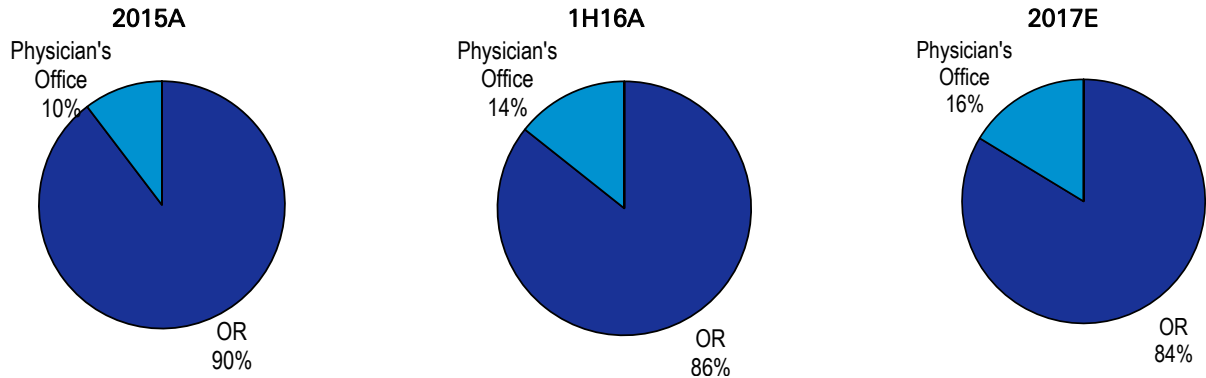
Hybrid Sinus Surgery Procedures: More in Office but at a Slow Rate

In 2015, our survey respondents, on average, performed 90% of their hybrid procedures in the operating room and 10% of procedures in the physician's office. In 2017, our survey respondents estimated, on average, that 84% of their hybrid procedures would be performed in the operating room and 16% in the physician's office.

We note, more than half of our survey respondents (n=20) indicated that they perform all (100%) of their hybrid procedures in the operating room. Further, in 2017, those same survey respondents estimated that they would continue to perform all of their hybrid procedures in the operating room.



Figure 17: Percent of Hybrid (Traditional Sinus Surgery and Balloon Sinus Dilation) Procedures Performed by Practice Setting, Average



Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents to comment on the rationale of their expected change in procedure setting for hybrid sinus surgery procedures. We highlight selected verbatim responses below stratified by whether our respondents see an overall increase, decrease, or no change in the number of hybrid sinus surgery procedures performed in the physician's office.



Figure 18: Hybrid Sinus Surgery Practice Setting Shifts, Select Verbatim Responses

Increase in Physician's Office Procedures	Neutral	Decrease in Physician's Office Procedures
<p><i>"Added comfort for in office."</i> <i>"Ability to do ethmoidectomy in office."</i> <i>"Patient toleration for more invasive procedures has been better than expected."</i></p>	<p><i>"Trends."</i> <i>"Hybrid in OR."</i> <i>"Only the hospital has the necessary tools for this complex surgery."</i> <i>"This needs to be done in OR."</i> <i>"No planned change in frequency."</i> <i>"No change."</i> <i>"More patient comfort."</i> <i>"Not prepared to do sinus procedures in the office."</i> <i>"Will not do traditional sinus surgery in the office due to risk of complications."</i> <i>"No reimbursement for office."</i> <i>"No change."</i> <i>"I don't see this changing to the office."</i> <i>"No changes anticipated for FESS – will not do in office."</i> <i>"No real change."</i> <i>"OR practice."</i> <i>"No change."</i> <i>"I rarely use the balloon in the OR. But I do see a big role for it in the office."</i> <i>"Not set up for FESS in office."</i> <i>"No change."</i> <i>"Would only do traditional surgery with or without balloon in OR."</i> <i>"No changes expected, I prefer any FESS procedure to be done in OR."</i> <i>"Not planning on doing traditional FESS in office."</i> <i>"No change. Practice saturated. Most patients need more work than what can be done logistically in office."</i> <i>"My patients ask for the OR."</i></p>	<p><i>"I am penalized for doing traditional sinus surgery in office. No reimbursement for the equipment that I need. Thus, I bring all these cases to operating room."</i></p>

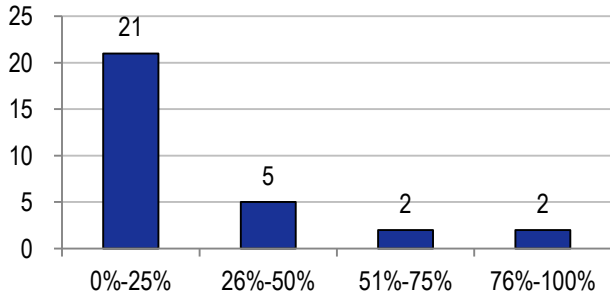
Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

We believe hybrid procedures prompt increased concern amongst physicians when shifting to the office, including the risk of excessive bleeding, as well as the need for general anesthesia.

We asked our survey respondents to comment on the percent of their hybrid sinus surgery procedures that they believe would be well suited for the physician's office. More than half of our respondents (n=21) noted that less than 25% of hybrid sinus surgery procedures could be performed in the physician's office.



Figure 19: Percent of Hybrid Procedures Conducive to the Physician’s Office, Number of Respondents

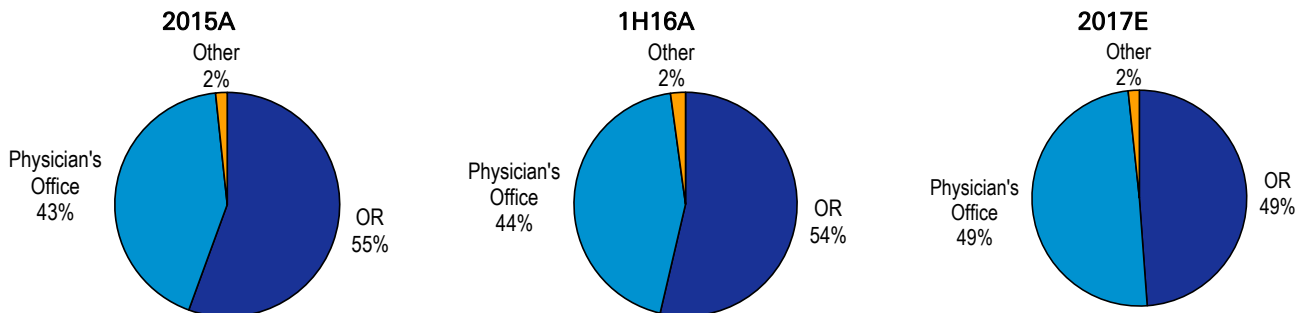


Source: Deutsche Bank 2016 Otolaryngologist Survey

Standalone Balloon Sinus Dilation: Many Procedures Already Office Based

In 2015, our survey respondents, on average, performed 55% of their standalone balloon sinus dilation procedures in the operating room and 43% of procedures in the physician’s office. In 2017, our survey respondents estimated, on average, that 49% of their standalone balloon sinus dilation procedures would be performed in the operating room and 49% in the physician’s office.

Figure 20: Percent of Standalone Balloon Sinus Dilation Procedures Performed by Practice Setting, Average



Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents to comment on the rationale of their expected change in procedure setting for standalone balloon sinus dilation procedures. We highlight selected verbatim responses below stratified by whether our respondents see an increase, decrease, or no change to the number of their standalone balloon sinus dilation procedures performed in the physician’s office setting.



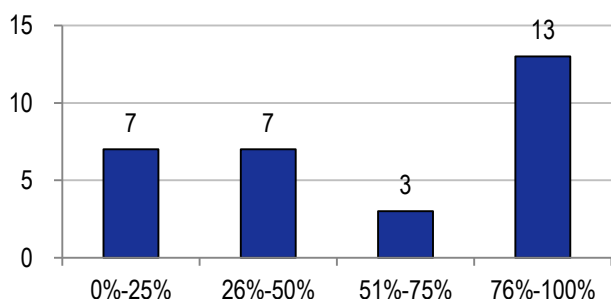
Figure 21: Standalone Balloon Sinus Dilation Practice Setting Shifts, Select Verbatim Responses

Increase in Physician's Office Procedures	Neutral
<p><i>"Better reimbursement."</i></p> <p><i>"Increase use of in office setting."</i></p> <p><i>"Sinus surgery is heading more in this direction with good outcome."</i></p> <p><i>"Patient comfort in OR."</i></p> <p><i>"More comfort with balloons."</i></p> <p><i>"I'm getting more comfortable in the office."</i></p> <p><i>"will have dedicated procedure room and marketing program."</i></p> <p><i>"More cost effective in office."</i></p> <p><i>"Doing standalone balloon cases in operating room is a complete loser for me. reimbursement is terrible. I only will perform standalone balloons in office, except for rare occassion (medically unstable patient for office, ICU patient)."</i></p> <p><i>"Patient toleration for more invasive procedures has been better than expected."</i></p> <p><i>"More likely to start performing in office procedures."</i></p> <p><i>"Will attempt more in office if acceptable."</i></p>	<p><i>"Trend."</i></p> <p><i>"No reason to perform in OR."</i></p> <p><i>"Rare in office procedure."</i></p> <p><i>"No change in operative setting plans."</i></p> <p><i>"Easy procedure to do in the office."</i></p> <p><i>"No significant change in indications."</i></p> <p><i>"No reimbursement for the office."</i></p> <p><i>"No changes anticipated for BSD alone."</i></p> <p><i>"OR based practice."</i></p> <p><i>"Typically office."</i></p> <p><i>"I only do stand alone balloon in the clinic."</i></p> <p><i>"No change. Use balloon for kids in OR."</i></p> <p><i>"No reason to do balloon alone in operating room for adults."</i></p>

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents to comment on the percent of their standalone balloon sinus dilation procedures that they believe would be well suited for the physician's office. 13 of our survey respondents believe more than 75% of standalone balloon sinus dilation procedures could be performed in the physician's office. 16 of our survey respondents believe more than 50% of standalone balloon sinus dilation procedures could be performed in the physician's office.

Figure 22: Percent of Standalone Balloon Sinus Dilation Procedures Conducive to the Physician's Office, Number of Respondents



Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents to comment on their rationale on the average percentage of balloon sinus dilation procedures conducive to the physician's. We list selected verbatim responses below.



Figure 23: Percent of Balloon Sinus Dilation Procedures Conductive to the Physician's Office, Verbatim Responses

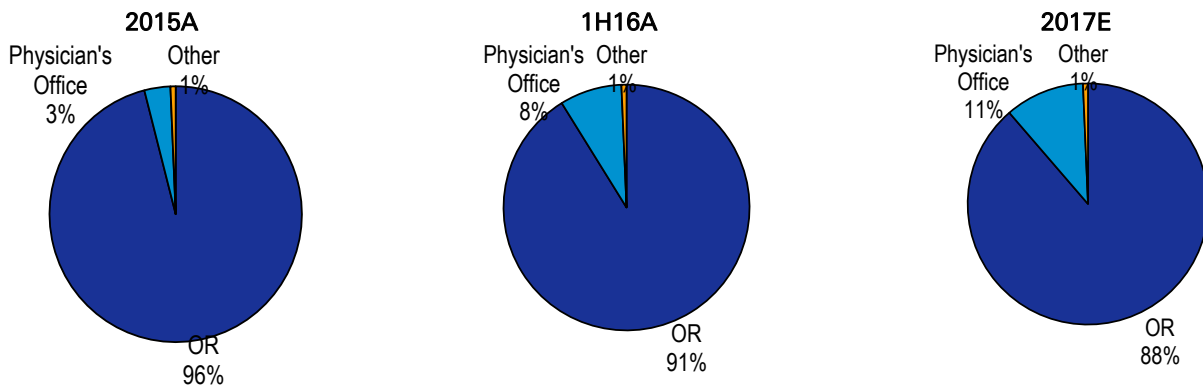
"Improved technique."
"Technology advancement helps."
"Work improved technique."
"Must be ideal candidate."
"In a properly equipped office this is a very viable option for most patients."
"A large proportion can be done in office."
"Simple cases with minimal disease with favorable anatomy."
"15% of frontal dilations cannot be accomplished in the office setting and physicians are not completing the procedures properly if attempted in that setting."
"More comfortable in the OR."
"Patient selection."
"Can be comfortably done with the patient awake."
"Don't have adequate staff/equipment if a complication arises."
"There are not a tremendous amount of isolated sinus cases to perform. Many are associated with a deviated septum about half (50%)."
"Most patients amenable with good anesthesia."
"Other than patient tolerance."
"Restricted to OR setting."
"Can be done in select patients."
"That is what I am able."
"The majority of my stand alone balloons are in the office."
"Unless there is a marked deviated septum this can be done in the office."
"Equipment availability."
"The only time i need to go to operating room for standalone balloon is for a very ill patient that is not medically cleared for office procedure or needs significant cardiovascular monitoring."
"Due to patient tolerance, anatomic factors, and ability to treat other aspects including turbinates and concha bullosa, I prefer to do majority of BSD in the OR."
"Almost all patients tolerate it relatively well alone."
"Primary issue is cost and patient tolerance."
"Minimal disease; straight forward."
"Anxiety is an issue for a subset of patients."

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

Revision Procedures: Shifting to the Office, but at a Slower Rate

In 2015, our survey respondents, on average, performed nearly all (96%) of their revision functional endoscopic sinus surgery (FESS) procedures in the operating room. In 2017, our survey respondents estimated that, on average, they would perform 88% of their revision FESS procedures in the operating room.

Figure 24: Percent of Revision Sinus Surgery Procedures Performed by Practice Setting, Average



Source: Deutsche Bank 2016 Otolaryngologist Survey



We asked our survey respondents to comment on the rationale of their expected change in procedure setting. We highlight the verbatim responses below stratified by whether physicians intend to increase the number of procedures performed in the physician's office.

Figure 25: Please discuss the rationale behind your anticipated volume changes

Increase in Physician's Office Procedures	Neutral	Decrease in Physician's Office Procedures
<p><i>"More comfortable with office procedures."</i></p> <p><i>"Sinus surgery shifting to office setting."</i></p> <p><i>"As before purchasing new equipment for 2017."</i></p> <p><i>"I have already started doing more office procedures such as polypectomy, balloons, etc compared to prior years."</i></p> <p><i>"Better tools available for revision."</i></p> <p><i>"Use of balloon to open up isolated stenotic ostia."</i></p> <p><i>"Typically complex and requiring more extensive work."</i></p>	<p><i>"Revision only in OR."</i></p> <p><i>"My office setting is not conducive to surgical procedures."</i></p> <p><i>"Operating room has more advanced equipments that I need."</i></p> <p><i>"No anticipated change."</i></p> <p><i>"My indications for revision surgery are many. Some patients require only minor intervention and therefore office based is probably indicated. On the other hand to perform a full revision the operating room is probably the safest approach."</i></p> <p><i>"All revisions are done preferably in the OR."</i></p> <p><i>"not set up in the office."</i></p> <p><i>"Difficulty in procedure."</i></p> <p><i>"Will not get reimbursed in the office."</i></p> <p><i>"No changes."</i></p> <p><i>"Will not be moving this to the office."</i></p> <p><i>"FESS would not be recommended in office."</i></p> <p><i>"Complex cases."</i></p> <p><i>"Wouldn't do that anywhere else."</i></p> <p><i>"Revision FESS in OR, safety concern and image guidance."</i></p> <p><i>"Usually these are more complicated cases requiring general anesthesia."</i></p> <p><i>"No change."</i></p> <p><i>"No change."</i></p> <p><i>"I prefer OR for FESS."</i></p> <p><i>"Usually require navigation."</i></p>	<p><i>"Trend for office."</i></p> <p><i>"Number of revision cases in office will remain stable or slightly decrease as reimbursement for office procedures is decreasing and making margins tighter."</i></p>

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey



Procedural Volume Should Continue to Increase

In 2015, we estimate there were approximately 29 million adults with chronic sinusitis in the US. We believe the number of adults with chronic sinusitis will increase slightly less than 1% per annum, which we believe is in line with broader US population growth.

Altogether, we believe the total otolaryngologist patient population should increase from 1.2 million in 2015 to approximately 1.5 million in 2021.

Figure 26: US Adult ENT Patient Population, 2015 – 2021E

	2015	2016E	2017E	2018E	2019E	2020E	2021E
Chronic Sinusitis Population - US							
Total US Population	322,755,353	325,231,193	327,726,025	330,239,994	332,773,248	335,325,935	337,898,203
% growth	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
Total US Adult Population	248,521,622	250,428,018	252,349,039	254,284,796	256,235,401	258,200,970	260,181,616
% adult	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%
US Adult Chronic Sinusitis Population	29,822,595	30,051,362	30,281,885	30,514,175	30,748,248	30,984,116	31,221,794
% prevalence of chronic sinusitis	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%
Physician Visits by Facility / Physician Type							
Primary Care Physician (PCP)	8,106,066	8,186,316	8,311,606	8,438,336	8,566,522	8,696,178	8,827,319
% of physician visits	65.9%	66.0%	66.5%	67.0%	67.5%	68.0%	68.5%
Otolaryngologist	2,794,191	2,852,807	2,937,184	3,022,688	3,172,786	3,261,067	3,350,515
% of physician visits	22.7%	23.0%	23.5%	24.0%	25.0%	25.5%	26.0%
Other	1,408,954	1,364,386	1,249,866	1,133,508	951,836	831,252	708,763
% of physician visits	11.4%	11.0%	10.0%	9.0%	7.5%	6.5%	5.5%
Total Physician Visits due to CS	12,309,212	12,403,509	12,498,656	12,594,532	12,691,144	12,788,497	12,886,597
% of adult population	41.3%	41.3%	41.3%	41.3%	41.3%	41.3%	41.3%
Repeat Visits to Ear, Nose, and Throat (ENT) Physician	1,564,747	1,597,572	1,644,823	1,692,705	1,776,760	1,826,197	1,876,289
%	56.0%	56.0%	56.0%	56.0%	56.0%	56.0%	56.0%
Total ENT Patient Population	1,229,444	1,255,235	1,292,361	1,329,983	1,396,026	1,434,869	1,474,227

Source: Company Data, Deutsche Bank

DB Survey Suggests Increasing Volume across Procedures

In our survey of 30 US based, board certified otolaryngologists, we asked respondents to comment on their current procedure volumes and expectations in the upcoming calendar year.

Our survey results estimate increases in all three primary functional endoscopic sinus surgery (FESS) procedures, which we believe bodes well for the industry, as a whole. Double digit increases are expected for standalone balloon sinus dilation, which we believe represents the relative 'newness' of the technology.

Traditional Sinus Surgery Volume +7% in 2016 and +9% in 2017

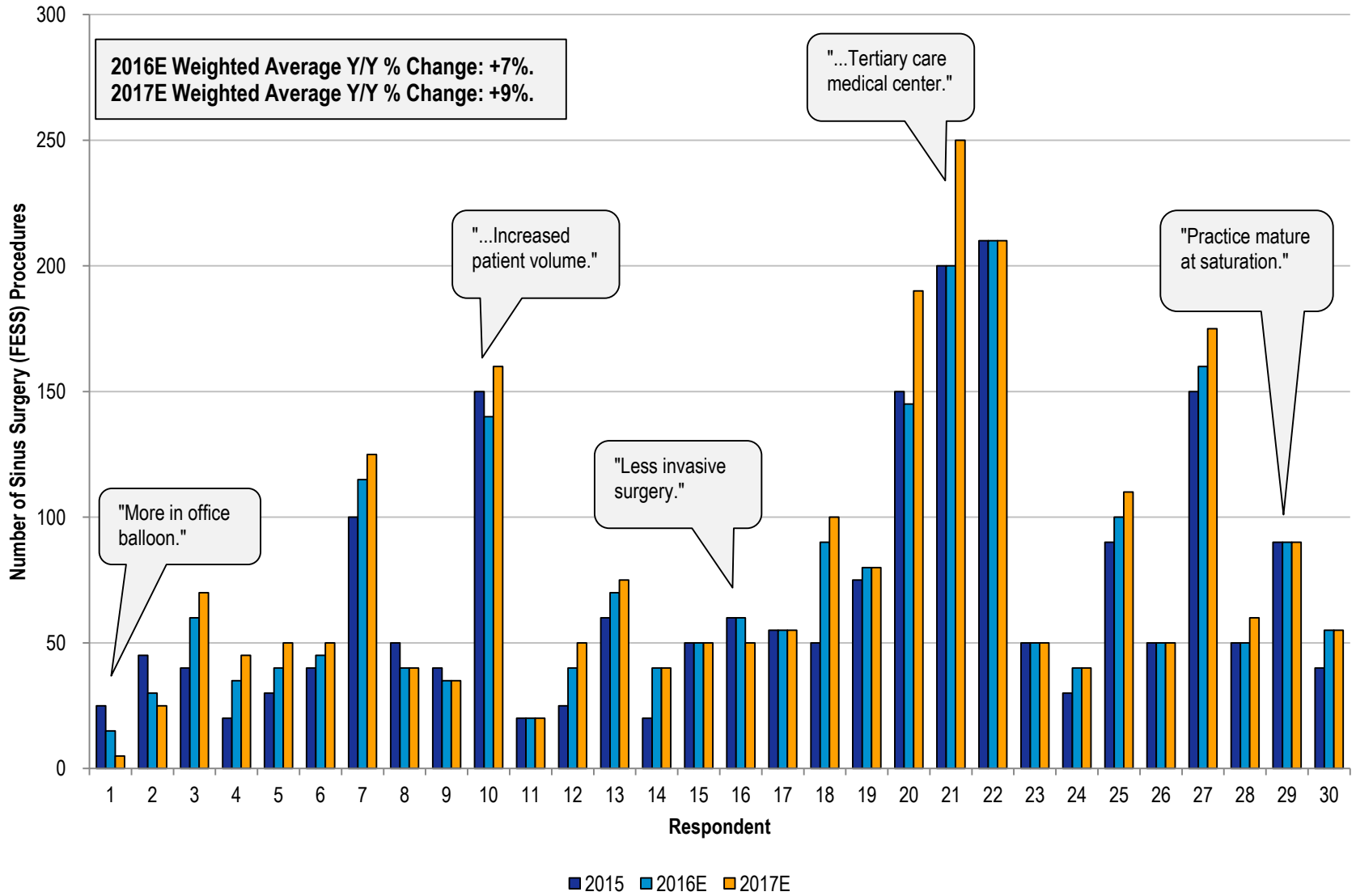
In calendar year 2016, the weighted average year over year change in traditional sinus surgery procedures was an increase of 7%. The majority of our survey respondents (n=14) anticipate their traditional sinus surgery procedure



volumes will increase over the prior year, though we note, 20% of our survey respondents (n=6) anticipate a decrease in their traditional sinus surgery procedure volumes versus the prior year.

In calendar year 2017, the weighted average year over year change in traditional sinus surgery procedures was an increase of 9%, which we note is accelerated from the expected 2016 rate. Similar to 2016, the majority of our survey respondents (n=14) anticipate their traditional sinus surgery procedure volumes will increase versus the prior year, while 10% (n=3) of our survey respondents anticipate a decrease versus the prior year. Approximately 43% of our survey respondents (n=13) anticipate volumes will remain stable in 2017 versus 2016.

Figure 27: Traditional Sinus Surgery (FESS) Procedure Volume, 2015 versus 2016E versus 2017E



Source: Deutsche Bank 2016 Otolaryngologist Survey





We asked our survey respondents to comment on their expected volume changes for traditional sinus surgery procedures. We highlight the verbatim responses below stratified by our respondent's view on overall change in sinus surgery procedure volume.

Figure 28: Please discuss the rationale behind your anticipated volume changes

Increase	Neutral	Decrease
<p><i>"More focus on sinus surgery."</i> <i>"Higher incidence of disease."</i> <i>"Ebb and flow of practice."</i> <i>"Increased number of referrals."</i> <i>"I am focusing more on sinus surgeries with increased marketing."</i> <i>"The health network has increased in patient volume."</i> <i>"Practice growth."</i> <i>"Practice building."</i> <i>"No changes."</i> <i>"No changes; I expect to maintain the current volumes I now experience."</i> <i>"Growing new practice."</i> <i>"Growing practice."</i> <i>"Increased marketing."</i> <i>"I perform revision FESS ~120/year, compared to primary fess (~80/year) based on my practice being at a tertiary care medical center."</i> <i>"Higher volume overall."</i> <i>"I have been growing my sinus surgical volume by 10% each year past 3 years."</i> <i>"My practice is becoming more specialized into rhinology and allergy than it has been in the past."</i> <i>"Greater population as well as retirement of partners."</i> <i>"Seeing more patients from other practices."</i></p>	<p><i>"No change."</i> <i>"Do not expect significant change."</i> <i>"My numbers have been consistent for many years."</i> <i>"Expected growth in market share."</i> <i>"I do not anticipate any significant changes in volume."</i> <i>"Practice mature at saturation."</i></p>	<p><i>"More in office balloon."</i> <i>"Volume related."</i> <i>"Better coverage for Balloon procedures with only one major insurer excluding balloons for hybrid."</i> <i>"Practice is focused on sinus and allergy so I expect similar case numbers from year to year. It is a conservative estimate."</i> <i>"Less invasive surgery, more conservative treatment."</i></p>

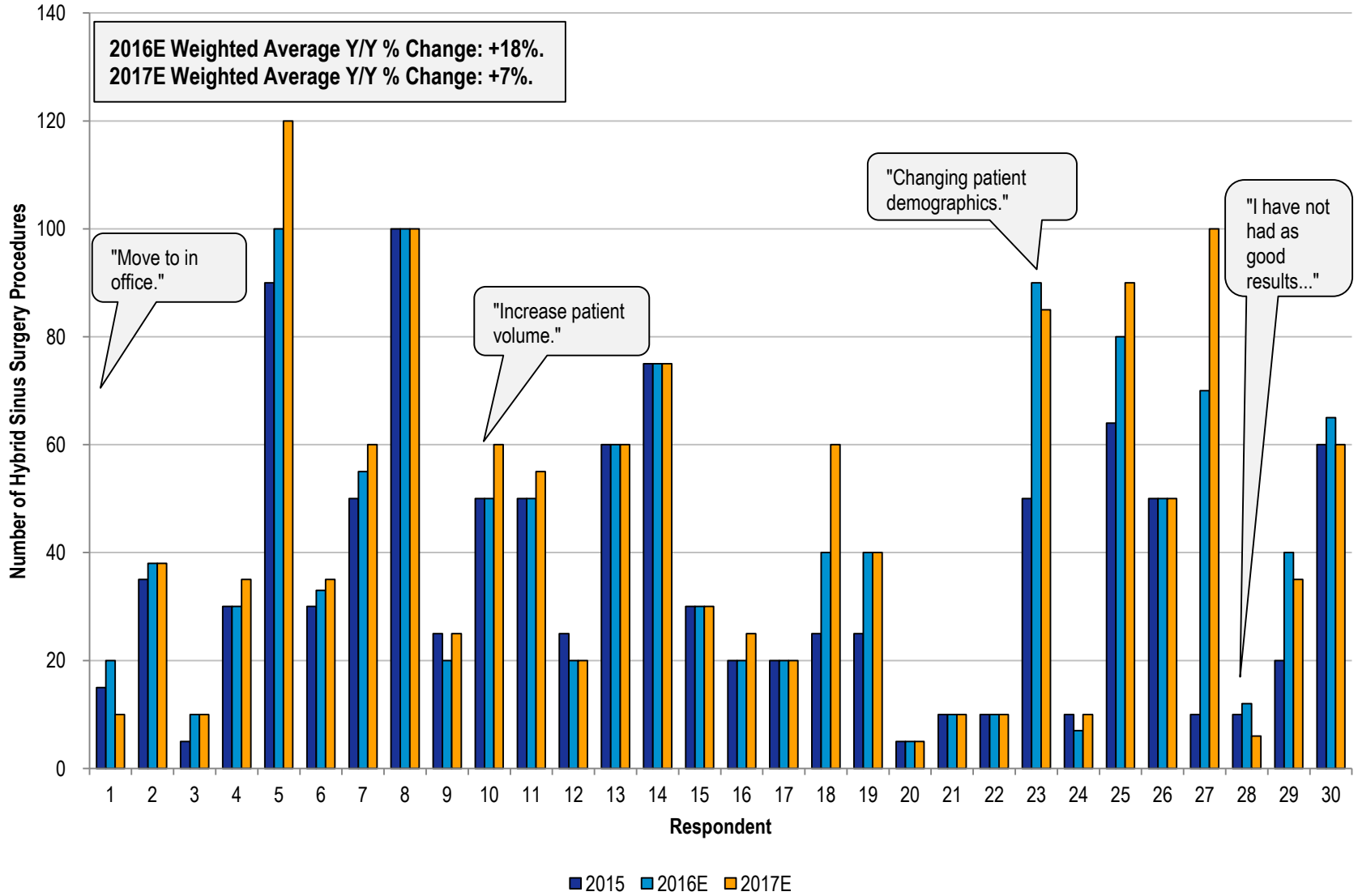
Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

Double Digit Increase in Hybrid Sinus Surgery Procedures in 2016 with High Single Digit Increase in 2017

In calendar year 2016, the weighted average year over year change in hybrid procedures (traditional sinus surgery in combination with balloon sinus dilation) was an increase of 18%. The majority of our survey respondents (n=15) anticipate an increase in procedure volumes in 2016 versus the prior year.

In calendar year 2017, the weighted average year over year change in hybrid procedures (traditional sinus surgery in combination with balloon sinus dilation) was an increase of 7%. We note, the majority of our survey respondents (n=13) anticipate no change in hybrid procedure volumes in 2017 versus 2016, while 12 of our survey respondents anticipate an increase in procedure volume. 5 of our survey respondents anticipate a decrease in their hybrid procedure volume in 2017 versus 2016.

Figure 29: Hybrid (Traditional Sinus Surgery in Combination with Balloon Sinus Dilation) Procedure Volume, 2015 versus 2016E versus 2017E



Source: Deutsche Bank 2016 Otolaryngologist Survey





We asked our survey respondents to comment on the rationale of their expected volume changes. We highlight selected verbatim responses below stratified by change in hybrid sinus surgery procedure volume.

Figure 30: Please discuss the rationale behind your anticipated volume changes

Increase	Neutral	Decrease
<p><i>"Trendsetters."</i> <i>"Availability of balloon."</i> <i>"Expect continued practice growth."</i> <i>"Increased referrals."</i> <i>"Sinus surgery is heading more in this direction with good outcome."</i> <i>"Increase patient volume."</i> <i>"Good results."</i> <i>"More patients asking for procedure."</i> <i>"Growing practice."</i> <i>"Changing patient demographics."</i> <i>"First, cases that I would previously would be done in office are going to operating room due to insurance restrictions. Second, my surgical volume has increased by 10% each year past 3 years."</i> <i>"Patient toleration for more invasive procedures has been better than expected. No one wants to go to the operating room for a procedure."</i></p>	<p><i>"Changes are minor just conservative estimates."</i> <i>"Practice building."</i> <i>"I don't see the estimated volume changing much."</i> <i>"No real changes in volume."</i> <i>"Trained."</i> <i>"Not much change here."</i> <i>"Very consistent practice."</i> <i>"Sporadic. sometimes will use for frontal if difficult and dont have navigation available."</i> <i>"No volume changes expected."</i> <i>"Less hours."</i></p>	<p><i>"Move to in office."</i> <i>"Able to do more in the office."</i> <i>"I have not had as good results for some patients with standalone procedure. Many of my patients have nasal polyposis."</i></p>

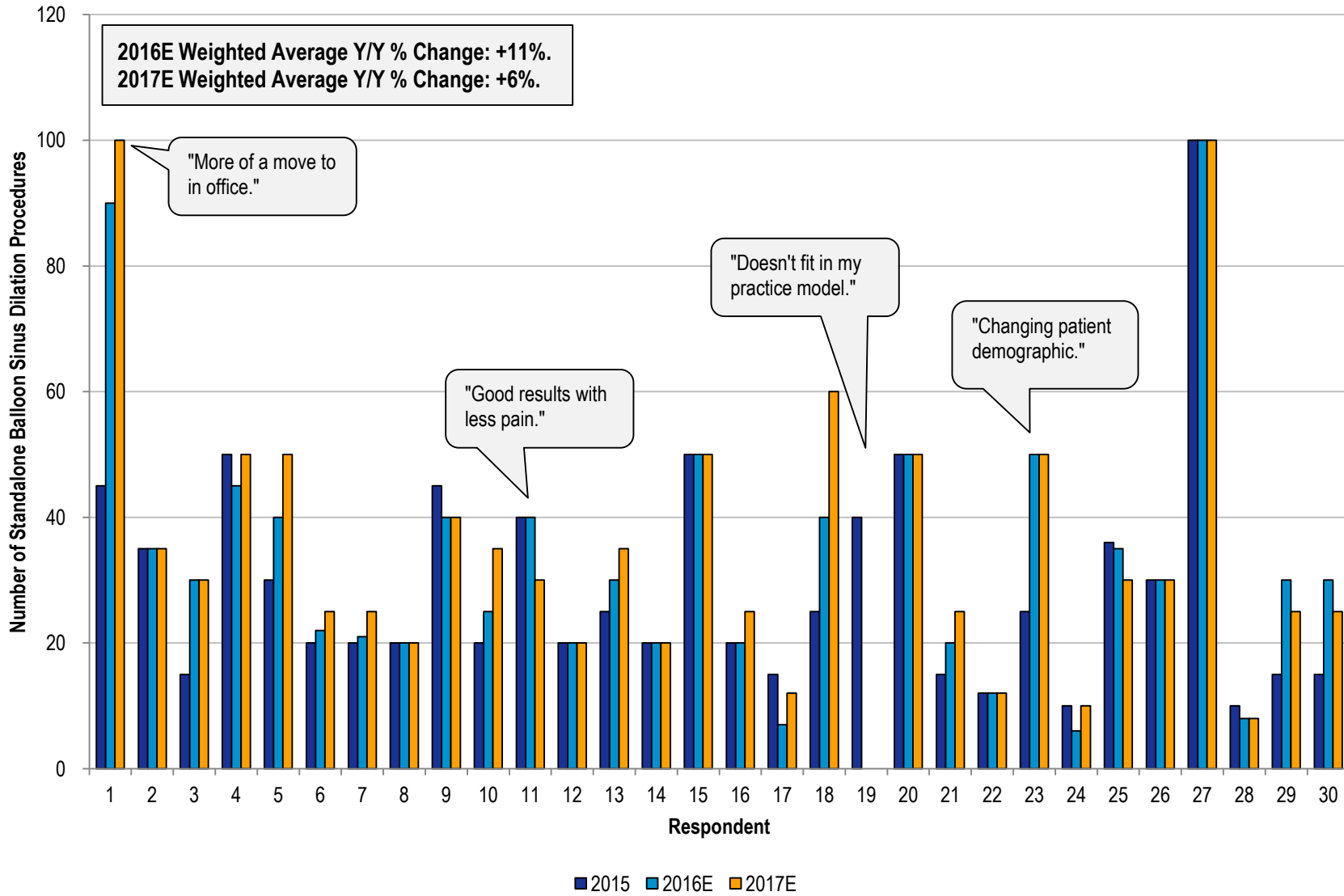
Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey

Double Digit Increase in Standalone Balloon Procedures in 2016 with Continued Increase in 2017

In calendar year 2016, the weighted average year over year change in standalone balloon sinus dilation procedures was an increase of 11%. The majority of our survey respondents (n=12) anticipate an increase year over year in their standalone balloon sinus dilation procedure volumes, while approximately 37% of our survey respondents (n=11) anticipate standalone balloon sinus dilation procedure volumes will remain stable versus the prior year. 7 of our survey respondents anticipate a decrease in standalone balloon sinus dilation procedure volumes.

In calendar year 2017, the weighted average year over year change in standalone balloon sinus dilation procedures was an increase of 6%. The majority of our survey respondents (n=14) anticipate standalone balloon sinus dilation procedures will remain stable versus the prior year, while 40% of our respondents (n=12) believe there will be an increase in standalone balloon sinus dilation procedure volume. 3 of our survey respondents anticipate a decrease in 2017 versus 2016.

Figure 31: Standalone Balloon Sinus Dilation Procedure Volume, 2015 versus 2016E versus 2017E



Source: Deutsche Bank 2016 Otolaryngologist Survey





We asked our survey respondents to comment on their expected volume changes for standalone balloon sinus dilation procedures. We highlight selected verbatim responses below stratified by our respondent's view on overall change in standalone balloon sinus dilation procedure volume.

Figure 32: Standalone Balloon Sinus Dilation Procedure Volume, Selected Verbatim Responses

Increase	Neutral	Decrease
<p><i>"More of a move to in office."</i> <i>"Changes to more in office balloon cases VS traditional surgery."</i> <i>"Expect continued practice growth."</i> <i>"Increased referrals."</i> <i>"Sinus surgery is heading more in this direction with good outcome."</i> <i>"Increase patient volume."</i> <i>"PRACTICE BUILDING."</i> <i>"More patients asking for procedure."</i> <i>"Growing practice."</i> <i>"Trained."</i> <i>"I think there is an increased role as I get more comfortable in the clinic using the balloon."</i> <i>"Changing patient demographics."</i></p>	<p><i>"Trends."</i> <i>"Increased disease incidence."</i> <i>"No change."</i> <i>"Practice growth."</i> <i>"No change."</i> <i>"Very consistent practice."</i> <i>"Hard to predict. Varies based on patient volume and insurance carrier."</i> <i>"Patient toleration for more invasive procedures has been better than expected."</i></p>	<p><i>"Changes are minor just conservative estimates."</i> <i>"Good results with less pain."</i> <i>"Will have dedicated procedure room."</i> <i>"Doesn't fit in my practice model."</i> <i>"The cost of balloons is high, while my reimbursement continues to decrease. Also, the largest payor in my region will not cover balloons despite our practice presenting data of how we have reduced cost for other insurance companies by doing appropriate cases in the office."</i> <i>"I have not had as good results for some patients with standalone procedure. Many of my patients have nasal polyposis."</i></p>

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey



New Technologies to Drive Further Growth

We believe new technologies that further enable the physician to recreate its operating room surgical suite in the physician’s office will garner increased attention. These technologies include: navigation, steroid eluting stents, and photodynamic therapy.

In addition, we continue to believe products that provide both clinical, as well as economic data should also garner high demand in the future.

Recreating the Surgical Suite in the Office via Image Guided Navigation

Image guided surgery combines surgical visualization and navigation capabilities and is used to aid the ENT physician in accurate device placement, primarily in the presence of complex anatomies.

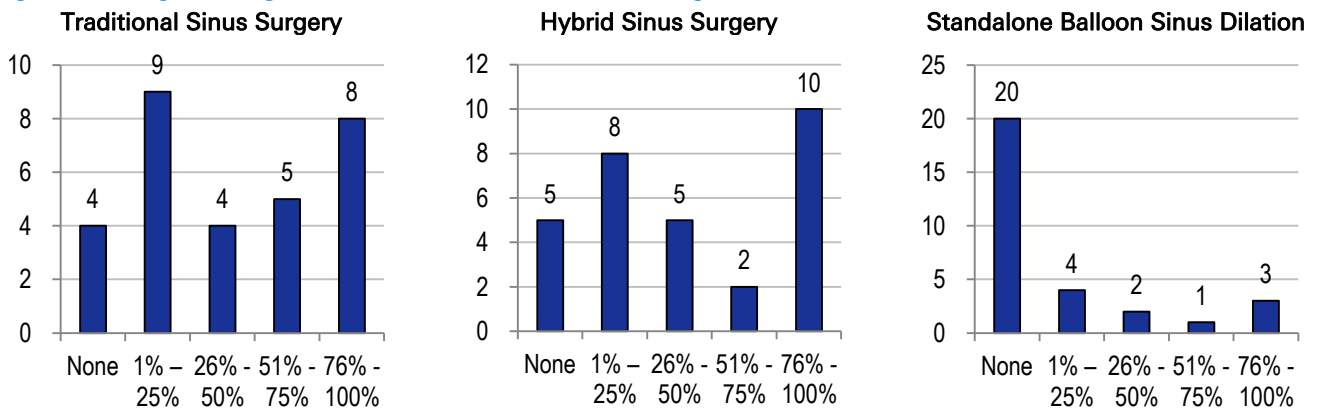
Two societies, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) and the American Rhinologic Society (ARS) have issued guidelines regarding the use of image guided surgery stating that it is only necessary in complex patient anatomies including procedures such as revision sinus surgery, distorted sinus anatomy, extensive sino-nasal polyposis, and benign and malignant sino-nasal neoplasms.

DB Survey Shows Overall Usage Varies by Procedure Type...

Image guided surgery is commonly used in ENT procedures that take place in the hospital operating room setting, however cost, space, and other factors limit the current use of the device in the physician’s office.

In our Deutsche Bank Otolaryngologist Survey, we asked our survey respondents to comment on their current usage of image guidance navigation systems; in both the operating room and physician’s office setting, as well as across procedure types.

Figure 33: Usage of Image Guidance Across All Practice Settings, Current



Source: Deutsche Bank 2016 Otolaryngologist Survey



Our survey showed that in traditional sinus surgery and hybrid sinus surgery procedures, image guidance is generally used more than 25% of the time. Usage in standalone balloon sinus dilation procedures, however, is currently scant. However, in speaking with physician experts, we believe that the option of having an image guidance system may increase the broader penetration of standalone balloon sinus dilation procedures, as some physicians are hesitant to use the balloon without exact confirmation of device placement.

Image guidance systems are a strong point for larger competitors in the ENT segment including Medtronic, Stryker, and Olympus.

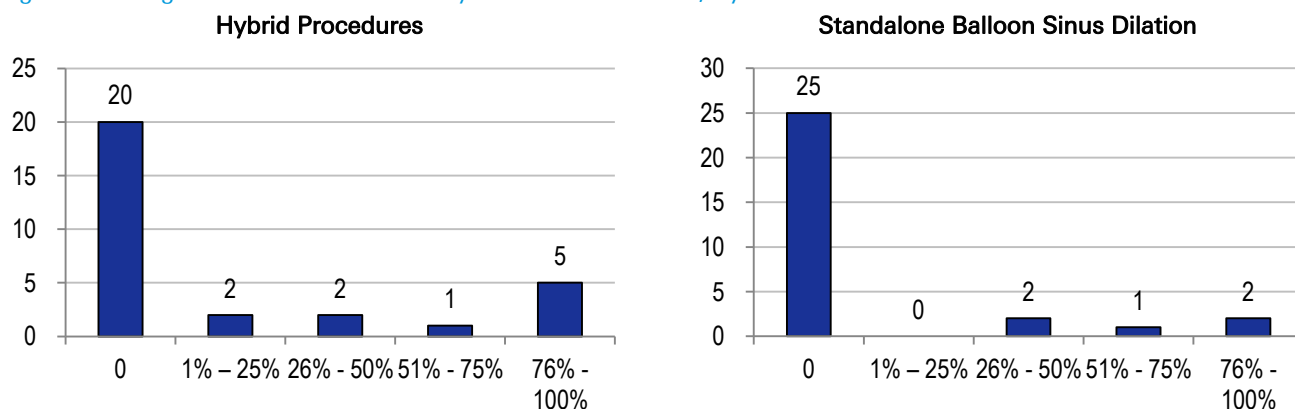
...With Very Limited Usage in the Physician's Office

Many physicians have steered away from using image guidance navigation systems for in office procedures due to the high initial cost of purchasing the device, as well as due to lack of adequate space for the device in the physician office.

In 2014, when Medtronic released its NuVent balloon sinus dilation device to be used in conjunction with its Fusion navigation system, it prompted the question of whether image guidance is necessary for standalone balloon sinus dilation or hybrid sinus surgery procedures.

Going further into image guidance, we asked our respondents of their usage of image guidance systems in the physician's office setting, specifically. The majority of our survey respondents (n=20 for hybrid sinus surgery procedures and n=25 for standalone balloon sinus dilation procedures) indicated that they did not use image guidance at all in the physician's office. We view these results as indicative of an opportunity for image guidance technology to further penetrate the physician's office.

Figure 34: Image Guidance Use in the Physician's Office ONLY, By Procedure



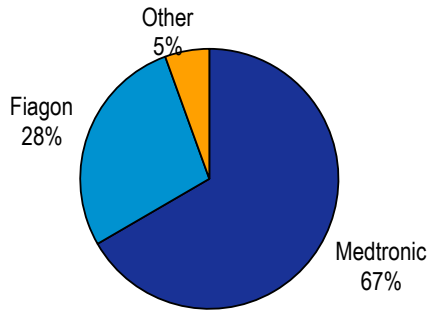
Source: Deutsche Bank 2016 Otolaryngologist Survey

We asked our survey respondents who use image guidance in the physician's office to comment on which manufacturer's system they use.

Our survey results revealed that Medtronic holds the highest market share within the segment. We note, the company launched its Fusion Compact, a reduced size version of its Fusion navigation system, in early 2016. Other players include Fiagon, BrainLab. Johnson & Johnson (Acclarent) is also working on its first image guided system for ENT procedures. The system will build upon the company's Biosense Webster navigation platform and a launch is expected in 2017.



Figure 35: Image Guidance Use by Manufacturer, Physician's Office



Source: Deutsche Bank 2016 Otolaryngologist Survey

Cost could be a Gating Factor in Increased Usage

We asked our survey respondents to comment more broadly on the importance of image guidance systems in the physician's office. We highlight selected verbatim responses below and note, cost, was often cited as a reason for lack of use.

Figure 36: Please discuss your view on the importance of image guided navigation systems in the physician's office setting, Verbatim Responses

"Useful."
 "Can do more."
 "Not as critical."
 "May be a good adjunct in some patients."
 "I have no experience with such a system."
 "Important but too expensive."
 "I feel it is less important that in OR as I do more complex cases in OR."
 "Not sure if necessary, don't think its necessary just equipment companies trying to sell."
 "Too expensive."
 "Not important."
 "I would only use this in the sphenoid sinus where transillumination is not possible."
 "Way too costly."
 "Too costly and cannot get reimbursed for the technology."
 "Don't use image guidance except for the balloon."
 "Too costly."
 "Seems redundant if your OR has one."
 "Too complex for office procedures."
 "No value."
 "Excellent."
 "I've begun to change my thinking about this. I do think there would be a role. I'm looking forward to trying the Fiagon system at my hospital soon."
 "Make it easier to use the balloon especially for sphenoid sinus."
 "If available, would be helpful."
 "I do not feel it is important. Feel comfortable with transillumination. Sounds like it costs more."
 "At this point, I have no need for this. I am not being reimbursed for adding this technology. The cost is too expensive. If a patient needs image guidance, they are going to operating room."
 "Not sure how useful it would be for my practice, since I do not perform any type of FESS in the office."
 "I like the image guidance, but not only to exclusion of transillumination."
 "As I perform the vast majority of sinus cases in OR, I would not think it would be important until in-office procedures became more profitable and easier in my particular situation."
 "Depends on whether sinus surgery becomes better reimbursed in the office. Could be very important for the future."
 "Not available in my practice - would use [in the] OR."

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey



Steroid Eluting Intranasal Implants

Steroid eluting intranasal implants combine the spacing properties of nasal packing materials and aid in keeping the sinus cavity open post procedure, and the anti inflammatory and scar reduction properties of associated with steroids. Intersect ENT is currently the only provider of steroid eluting intranasal stents. Its current product offerings, PROPEL and PROPEL mini, are indicated for use post functional endoscopic sinus surgery (FESS) and clinical data has shown that the use of the device improves the efficacy of a FESS procedure, thereby reducing the need for a revision procedure.

While no direct competitors exist, oral steroids represent an alternative and have established clinical benefits post sinus surgery. However, some physicians avoid prescribing oral steroids due to the potential side effects. In addition, there are certain sub populations (such as diabetics) that cannot tolerate the use of oral steroids.

PROPEL / PROPEL Mini: 20% of Respondents Do Not Use

In our Deutsche Bank Otolaryngologist Survey, we tried to gauge overall usage and penetration of Intersect ENT's PROPEL and PROPEL mini and asked our survey respondents to comment on their usage of PROPEL / PROPEL mini.

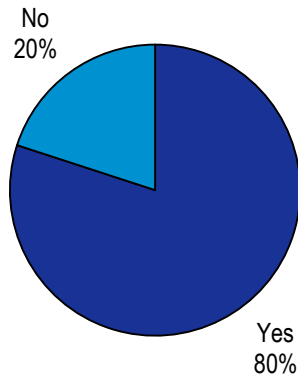
20% (n=6) of our survey respondents indicated that they did not use PROPEL / PROPEL mini, with cost and device availability often cited as factors.

80% of survey respondents use the device. For our respondents that used the device, we asked them of their reasons in using the device given its higher upfront cost. The most often cited reason was better patient outcomes (n=18), with respondents largely commenting on reduced polyps and prior positive experience. Superior clinical data was also cited frequently (n=14) among survey respondents who use Propel / Propel mini, as well as "other" which included unclear advantage, familiarity, and outpatient setting.

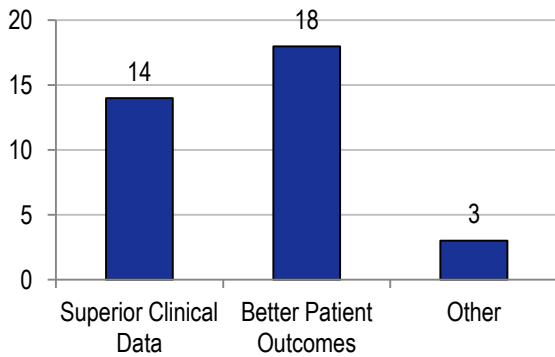


Figure 37: PROPEL / PROPEL mini Usage

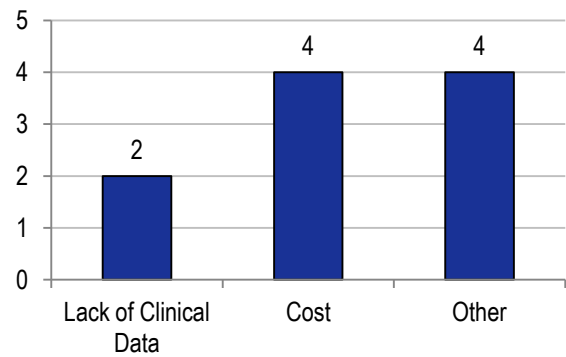
PROPEL / PROPEL mini Current Usage



If Survey Respondents Currently Use PROPEL / PROPEL mini:



If Survey Respondents DO NOT Currently Use PROPEL / PROPEL mini:



Source: Deutsche Bank 2016 Otolaryngologist Survey

When our survey respondents who used the device cited better patient outcomes, they often commented on reduced inflammation and faster healing. We highlight selected verbatim responses below.



Figure 38: PROPEL / PROPEL mini, Selected Verbatim Responses

"Perhaps."
"Reduced inflammation and polyps."
"Mechanical and chemical barriers."
"Unfortunately, cannot get reimbursement when used in conjunction with balloons."
"I like the idea of slow release of steroid."
"Less scarring."
"Personal experience."
"Agree."
"Shown in studies."
"Good personal exp."
"Fewer polyps post op."
"Much better healing with Propel, less likelihood for recurrence and need for revision surgery."
"Proposed less frequent revision."
"Clinically faster healing."
"Substantiated with experience."
"Less polyps."

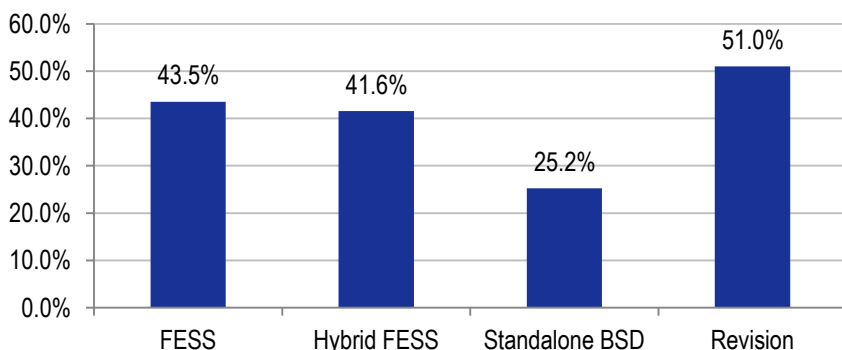
Note: Responses edited for typos, grammar, and misspellings.
Source: Deutsche Bank 2016 Otolaryngologist Survey

Large Opportunity Could Be in Revision Patients

In our Deutsche Bank Otolaryngologist Survey, we asked our survey respondents to comment on their use of oral steroids post sinus surgery and balloon sinus dilation procedures.

Our survey revealed that oral steroids are, on average, prescribed in 50% or less of chronic sinusitis procedures with standalone balloon sinus dilation procedures having the lowest occurrence and revision sinus surgery procedures having the highest occurrence.

Figure 39: Oral Steroid Prescription Post Operative, Average



Source: Deutsche Bank 2016 Otolaryngologist Survey

With our survey indicating limited oral steroid use following standalone balloon sinus dilation likely due to the lower amount of inflammation and scarring versus a sinus surgery procedure, we are cautious around the uptake of a steroid eluting intranasal stent (Intersect ENT's NOVA). However, we believe our survey results indicate the potential of a large opportunity for revision sinus surgery patients who often have more inflammation and scarring (Intersect ENT's RESOLVE).



Figure 40: Please discuss the rationale behind your usage of oral steroids in FESS and standalone balloon sinus dilation procedures, Verbatim Responses

Traditional Sinus Surgery (FESS)	Standalone Balloon Sinus Dilation
<i>"Cut down on inflammation."</i>	<i>"Cut down on inflammation."</i>
<i>"More swelling."</i>	<i>"[BSD results in] less swelling."</i>
<i>"I like to give steroids for most sinus cases to reduce inflammation."</i>	<i>"I like to give steroids for most sinus cases to reduce inflammation."</i>
<i>"Rarely use"</i>	<i>"Rarely use."</i>
<i>"I choose steroids on a case by case assessment."</i>	<i>"I choose steroids on a case by case assessment."</i>
<i>"I find it very helpful to prescribe steroid preop."</i>	<i>"I do not use steroid just for dilation."</i>
<i>"I rarely use postop oral steroids & only for severe polyp patients."</i>	<i>"I rarely use postop oral steroids & only for severe polyp patients."</i>
<i>"I don't use oral steroid after surgery."</i>	<i>"I don't use oral steroid after surgery."</i>
<i>"I think steroids overall play a minor role in FESS patients unless in patients with extensive polypoid disease."</i>	<i>"I have not seen a major improvement whether I use steroids or not and since steroids are not without complications I prefer not to use."</i>
<i>"Do not like oral steroids."</i>	<i>"Do not like oral steroids."</i>
<i>"Noted polyps."</i>	<i>"Noted inflammation"</i>
<i>"Prevent post operative inflammation."</i>	<i>"No need to prevent post procedural scarring [in balloon sinus dilation]."</i>
<i>"Usually not needed."</i>	<i>"Usually not needed."</i>
<i>"Only for the more difficult patient."</i>	<i>"Only for the more difficult patient."</i>
<i>"Steroid use depends on amount of inflammation noted on clinical exam preop."</i>	<i>"Less likely to have inflammatory disease than candidates for traditional FESS."</i>
<i>"Polyps."</i>	<i>"Rare to perform [standalone balloon sinus dilation] with polyps."</i>
<i>"Reduce post operative inflammation."</i>	<i>"Reduce post operative inflammation."</i>
<i>"Mostly polyp cases."</i>	<i>"Polyp cases."</i>
<i>"Steroids help with fess scarring especially when with polyps."</i>	<i>"Don't use."</i>
<i>"I generally use a short course of prednisone after sinus surgery (2 weeks)."</i>	<i>"I rarely use steroids after balloon dilation (I generally feel that balloons are best for cases with scar tissue, rather than recurrent polyps)."</i>
<i>"Usually these cases involve polyps or fungal sinusitis."</i>	<i>"Less involved cases."</i>
<i>"If medically indicated."</i>	<i>"If medically indicated."</i>
<i>"Rarely use steroids unless polyp change develop."</i>	<i>"Rarely use steroids unless polyp change develop."</i>
<i>"Unless medical contraindication to steroids,exceptionally rare that i do not use oral steroids. [They] reduce swelling, congestion, pain, and scarring following surgery."</i>	<i>"Sphenoid or maxillary i may not use oral steroids, any case with frontals always use steroids."</i>
<i>"If there is significant risk for scarring or adhesions."</i>	<i>"If I am concerned for inflammation."</i>
<i>"If polyps yes, or if there is a large volume of post op inflammation, yes."</i>	<i>"Helps aid recover and maintain patency."</i>
<i>"I have moved away from oral steroids with use of Propel stent."</i>	<i>"Depending on which sinuses are dilated, I may prescribe oral steroids."</i>
<i>"Not necessary with good technique."</i>	<i>"No polyposis."</i>
<i>"Usually eosinophilic polyposis."</i>	

Note: Responses edited for typos, grammar, and misspellings.
 Source: Deutsche Bank 2016 Otolaryngologist Survey



Competitive Landscape

We divide the ENT device market into two broad categories: surgical tools and instruments which can be used for a host of disorders including chronic sinusitis and balloon sinus dilation. We estimate the combined market is more than \$1 billion and features a wide array of competitors. We note, while there are some companies who compete in both the surgical tools and instruments and balloon sinus dilation sub segments (Medtronic and Entellus, primarily, and to a lesser extent Smith & Nephew), most have capabilities in either one or the other.

Medtronic (Xomed): Strong Presence

Medtronic's Xomed division, is a large competitor in the broader ENT market. We estimate the company holds a leading position in the surgical tools and instruments segment of the ENT device market, with smaller market share in the balloon sinus dilation market.

- **NovaShield** is a chitosan-based nasal packing and stent designed for use following traditional sinus surgery (FESS) procedures. The device has hemostatic properties that controls bleeding and also provides tissue separation and acts as a space occupying packing material.
- **MeroGel and MeroPack** are hyaluronic acid based nasal packing materials. MeroGel nasal packing is a bioresorbable woven fleece that is used in either its dry or wet form following traditional sinus surgery (FESS) procedures. In the dry state, MeroGel aids in the control of bleeding, while in its wet state, the device turns into a gel that dissolves in 2 weeks. MeroPack is a combination dressing that is designed for post procedural hemostasis and wound healing. The device is slowly absorbed within 2 weeks.
- The company also offers traditional nasal packing materials, which is sold under the **MeroCel** brand.

Medtronic entered the balloon sinus dilation space with the August 2014 launch of its NuVent EM balloon sinus dilation system. The system features balloon sinus seekers that are pre-calibrated for surgical navigation with Medtronic's Fusion ENT Navigation System during balloon sinus dilation enabling physicians to locate and move tissue, bone or cartilage around sinus drainage pathways.

We estimate Medtronic holds less than 10% market share in the US balloon sinus dilation market, with a skew towards the operating room practice setting. We believe the company has used its strength in sinus surgery to gain traction in balloon sinus dilation, though the requirement to use the company's Fusion navigation system may present challenges as more procedures shift outside of the operating room and into the physician's office. We note, Medtronic has reduced the size of its initial Fusion device with the launch of Fusion Compact earlier this year.

Johnson & Johnson (Acclarent): #1 in Balloon Sinus Dilation

Acclarent pioneered the balloon sinus dilation market via its introduction of the device in 2005. Johnson & Johnson acquired Acclarent in January 2010 for \$785 million.

Figure 41: MeroPack



Source: Image Courtesy of Medtronic

Figure 42: NuVent EM



Source: Image Courtesy of Medtronic



Acclarent launched three next generation balloon dilation systems in 2016.

- **RELIEVA SCOUT Multi Sinus Dilation System** is a low profile balloon dilation system that features an extendable, illuminated ball tip to confirm device placement. The device was launched in July 2016.
- **RELIEVA SpinPlus** builds off the company's initial RELIEVA Spin device and also features integrated irrigation. The device was launched in March 2016 and is available in 5mm and 6mm diameter sizes. We estimate the Spin / SpinPlus family of products represents the majority of Acclarent's sales mix.
- **AERA Eustachian Tube Balloon Dilation System** received FDA approval on September 16, 2016 and was launched in the US on September 19, 2016. The device represents a new treatment approach for Eustachian tube disorder, which has historically been difficult to treat.

Figure 43: RELIEVA SCOUT



We estimate Acclarent holds the leading market position in the balloon sinus dilation market, with its market share skewed more towards the operating room versus the in office setting (we estimate approximately 20% of Acclarent's balloon sinus dilation sales are into the physician office).

The company has experienced some loss of market share in recent years driven by, in our view, competitive pressures (Entellus first launched its balloon sinus dilation device in 2014) as well as a lack of focus (the company restructured the division in 2014 and experienced some sales force disruption).

Looking forward, Johnson & Johnson appears to be investing in the business as evidenced by the three new product launches thus far in 2016. In addition, the company plans to expand its penetration into functional endoscopic sinus surgery (FESS) via consumables and navigation. Acclarent anticipates launching a navigation platform in 2017, which will be the Acclarent's first image guided system for the ENT space. In addition, Acclarent also appears to be focusing on expanding its presence in the in office balloon sinus dilation space, as more procedures continue to shift from the operating room to the physician's office.

Smith & Nephew (ArthroCare): Strong in FESS; Minimal Presence in Balloons

Smith & Nephew acquired its ENT business via its 2013 acquisition of Arthrocare. We estimate the business is approximately \$100 million in sales growing in the double digit teens range driven by an expanded geographical reach and the launch of new products.

The ENT portfolio includes an array of surgical tools and instruments, as well as nasal dressing and implants. In addition, Smith & Nephew also markets the Ventera balloon sinus dilation system in US (FDA cleared in 2013) and OUS markets (launched in Europe in July 2015), though we estimate the company has minimal market share in balloon sinus dilation.

In addition, in July 2015, Smith & Nephew announced a partnership with Scopis, a German developer and manufacturer of surgical navigation systems and became the sole distributor of Scopis' target guided surgery system in the UK, Ireland, and Belgium to be used in support of ENT surgeons.



Some have viewed the ENT business as a potential divestiture candidate for Smith & Nephew, however, management recently commented that it is pleased with the performance of its ENT business and has no intention to divest of it at this stage.

Stryker

Stryker is a player in the surgical segment of the ENT market and offers a portfolio of surgical tools and instruments for functional endoscopic sinus surgery (FESS). Included in that portfolio are bioresorbable packing materials, such as Nasopore for the nasal cavity.

Nasopore is a bioresorbable nasal dressing, which is used as a temporary wound dressing in the sinunasal cavity. The dressing provides compression at the treatment site and fully absorbs with a few days.

Olympus

Olympus is a player in the surgical segment of the ENT market and offers imaging solutions, as well as debridors for sinus surgery procedures. We estimate the company's sinus surgery business is less than \$100 million, though Olympus has commented that it is focused on increasing its penetration in FESS procedures.

SinuSys: A "Slow" Approach to Balloon Sinus Dilation

SinuSys, a private company based in Palo Alto, California, markets its Vent-Os sinus dilation system in the US and OUS markets. The system differs from traditional balloon sinus dilation products as it provides low pressure, gradual dilation which the company believes is more suitable for maximum patient tolerability. We note, traditional balloon sinus dilation products use rapid, high pressure inflation.

In July 2016, the company broadened its product portfolio via the receipt of FDA 510(k) clearance of its Vent-Os system in the frontal and sphenoid sinuses, which complements the company's original maxillary sinus indication.

Sinopsys (Private)

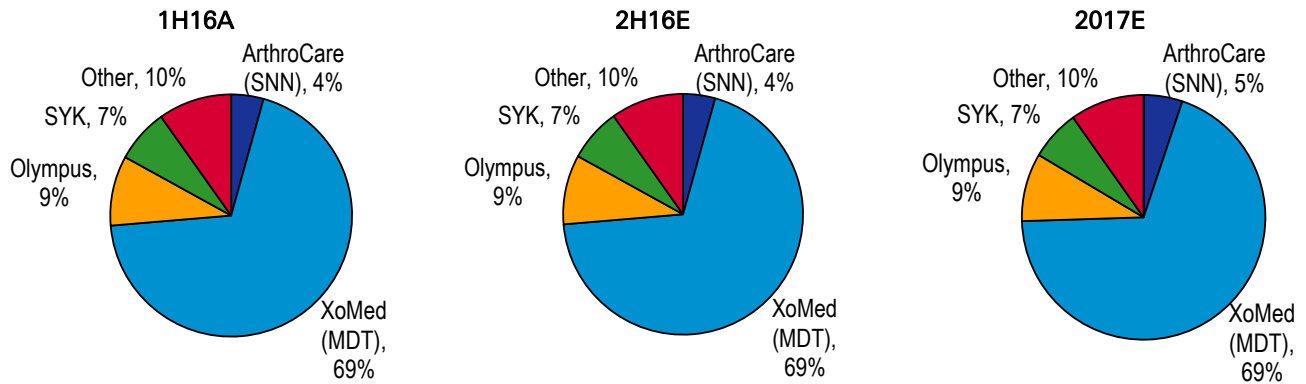
Sinopsys has developed the SinopSys lacrimal stent, which aims to shift the tear duct to drain into the sinuses in an effort to relieve chronic sinusitis. The procedure is percutaneous, reversible and provides direct access to the ethmoid sinus for local saline irrigation as well as potential delivery for other therapeutic agents.

DB Survey Shows Surgical Market Shares Sticky

Medtronic, with its extensive presence in the operating room, holds a commanding market share lead with our survey anticipating that share will hold steady in 2017.



Figure 44: Sinus Surgery Tools and Instruments Market Shares, Current and Expected



Source: Deutsche Bank 2016 Otolaryngologist Survey

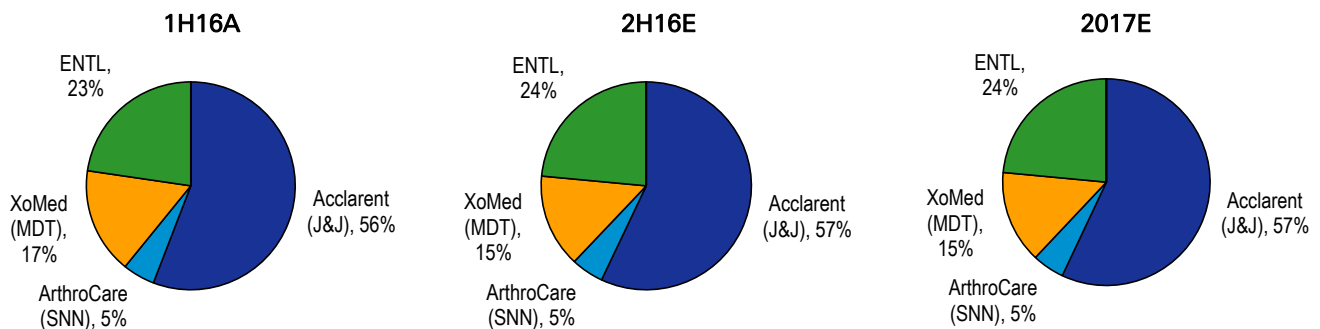
DB Survey Shows Acclarent Continues to Lead in Balloons

Johnson & Johnson’s Acclarent division pioneered the balloon sinus dilation market in 2005 and as such, is the market leader in the space. While the company has lost market share in recent years, our survey results show that its current share appears to be holding steady.

Our survey results indicate that some of Acclarent’s regained market share may be from Medtronic, with Entellus Medical and Smith & Nephew’s market shares holding steady.

In 2016, Acclarent has launched three new devices- Relieva SpinPlus, Relieva multi sinus, and the Aera Eustachian tube dilation device. We believe these new product launches may allow the company to regain some of its lost market share.

Figure 45: Balloon Sinus Dilation Market Shares, Current and Expected



Source: Deutsche Bank 2016 Otolaryngologist Survey



Reimbursement Dynamics

Chronic sinusitis procedures (functional endoscopic sinus surgery (FESS), as well as balloon sinus dilation) are primarily performed in the hospital outpatient or physician's office setting. Therefore, reimbursement is primarily dictated by private payors or the Centers for Medicaid and Medicare Services (CMS).

Sinus Surgery Reimbursement is Well Established...

Sinus Surgery Reimbursement, on Average, Has Increased

In the hospital outpatient setting, reimbursement for functional endoscopic sinus surgery (FESS) is positive and has increased, on average, at an approximately 5% CAGR from 2010 – 2015.

Figure 46: Average Medicare National Payment Amounts, Hospital Outpatient Prospective Payment System (HOPPS)

HCPCS		2010	2011	2012	2013	2014	2015
Code	Procedure Description						
31254	Partial ethmoidectomy	\$1,973	\$2,131	\$2,125	\$2,027	\$1,880	\$2,009
31255	Total ethmoidectomy	\$1,973	\$2,131	\$2,125	\$2,027	\$3,052	\$3,070
31256	Maxillary Antrostomy	\$1,973	\$2,131	\$2,125	\$2,027	\$1,880	\$2,009
31267	Maxillary Antrostomy with removal of tissue	\$1,973	\$2,131	\$2,125	\$2,027	\$1,880	\$2,009
31276	Frontal sinus exploration	\$1,973	\$2,131	\$2,125	\$2,027	\$3,052	\$3,070
31287	Sphenoidectomy	\$1,973	\$2,131	\$2,125	\$2,027	\$3,052	\$3,070
31288	Sphenoidectomy with removal of tissue	\$1,973	\$2,131	\$2,125	\$2,027	\$3,052	\$3,070

Source: Centers for Medicare and Medicaid Services (CMS), Deutsche Bank

We list the Centers for Medicare and Medicaid Services (CMS) 2016 average national payment amounts for traditional sinus surgery (FESS) procedures in the hospital outpatient setting and ambulatory surgical center below.

Figure 47: Average National Payment Amounts, Hospital Outpatient, Final 2016

APC Code	HCPCS Code	Description	Hospital Outpatient	Ambulatory Surgical Center
5155	31254	Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)	\$3,066	\$1,715
5155	31255	Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)	\$3,066	\$1,715
5154	31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy	\$1,992	\$1,114
5155	31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of maxillary sinus tissue	\$3,066	\$1,715
5155	31276	Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of frontal sinus t	\$3,066	\$1,715
5155	31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy	\$3,066	\$1,715
5155	31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of sphenoid sinus tissue	\$3,066	\$1,715

Source: Centers for Medicare and Medicaid Services (CMS), Deutsche Bank

Functional endoscopic sinus surgery (FESS) procedures in the hospital outpatient setting are reimbursed based on the number of sinuses treated per procedure. Sinuses are reimbursed on an individual and unilateral basis, thus the initial sinus is reimbursed at 100% of the reimbursement rate, while CMS attaches a -50 modifier to the bilateral sinus and all additional sinuses.

We estimate that an average of 4 – 6 sinuses are treated per procedure. We list an illustrative Medicare reimbursement amount for a 6 sinus procedure in the hospital outpatient setting below.



Figure 48: Illustrative Average National Payment Amount – 6 Sinus Procedure, Hospital Outpatient, Final 2016

Anterior ethmoidectomy	\$3,066
+ Posterior ethmoidectomy	\$1,533
+ Right maxillary sinus	\$1,533
+ Left maxillary sinus	\$1,533
+ Right frontal sinus	\$1,533
+ Left frontal sinus	\$1,533
Total Medicare reimbursement	\$10,733

Source: Centers for Medicare and Medicaid Services (CMS), Deutsche Bank

Proposed 2017 Medicare Changes Could Drive More Procedures in Office

The Centers for Medicare and Medicaid Services (CMS) released its proposed hospital outpatient prospective payment (HOPP) rule and physician fee schedule for 2017 in June 2016. Within the rule, CMS has proposed that APC codes 5153, 5154, and 5155 become comprehensive APCs as an effort to increase the agency's efforts to pay healthcare providers for quality versus quantify of care. We note that this is in line with practices we have seen in other areas such as the recent proposed cardiac care bundling program.

A comprehensive APC packages payment for services and supplies rather than providing separate multiple payments for each individual service. The package eliminates any additional reimbursement for adjunctive services and supplies used during the delivery of the primary service.

Thus, these codes have a higher payment versus the 2016 rate to reflect an increase in the overall cost of the procedure and the elimination of separate payment for multiple procedures.

Figure 49: Proposed 2017 APC Payment Changes

Description	Status Indicator		Relative Weight			Payment Rate		
	Final 2016	Proposed 2017	Final 2016	Proposed 2017	% Change	Final 2016	Proposed 2017	% Change
Level 2 Airway Endoscopy	T	T	5.088	4.847	-4.7%	\$375	\$363	-3.2%
Level 3 Airway Endoscopy	T	J1	14.073	16.879	19.9%	\$1,038	\$1,264	21.9%
Level 4 Airway Endoscopy	T	J1	27.018	32.083	18.7%	\$1,992	\$2,403	20.7%
Level 5 Airway Endoscopy	T	J1	41.594	57.735	38.8%	\$3,066	\$4,325	41.0%

Source: Centers for Medicaid and Medicare Services (CMS), Deutsche Bank

If the reimbursement change is implemented as proposed, it would impact a number of procedures that take place within the hospital operating room setting, including both sinus surgery, as well as balloon sinus dilation. The proposal imposes a maximum reimbursement amount for procedures, which as proposed is \$4,325 for functional endoscopic sinus surgery (FESS) and balloon sinus dilation procedures, which compares to current reimbursement of a 6-sinus procedure of approximately \$10,733.

We anticipate all ENT players would feel price pressure as it relates to procedures performed in the operating room if the proposed ruling were to go into effect. However, we estimate this dynamic could drive physicians to increase the amount of their sinus procedures in the physician's office setting,



which we believe would be a positive for Entellus given its focus in the physician's office and also for Intersect ENT long term (2019 and beyond if reimbursement for steroid eluting intranasal stents in the physician's office is established).

The comment period to the proposal closed September 6, 2016. We expect the final rule to be released in 4Q16 (we expect late October / early November).

Balloon Sinus Dilation: Reimbursement Generally Established

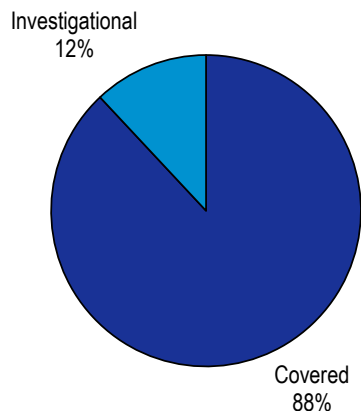
Reimbursement codes for balloon sinus dilation came into effect in 2011, six years following initial device approval. We view reimbursement for balloon sinus dilation as largely established in both the hospital operating room and physician's office setting, with minor work remaining.

Hospital Outpatient Setting: Nearly 100% Covered

When balloon sinus dilation is performed in combination with functional endoscopic sinus surgery (FESS), the device is characterized as a surgical supply and is reimbursed as part of the total FESS procedure with no device specific reimbursement. We estimate the average cost of a balloon sinus dilation device to be approximately \$1,500 on average.

We estimate that 88% of total covered lives have positive coverage decisions for hybrid procedures.

Figure 50: Insurance Coverage, Hybrid (Functional Endoscopic Sinus Surgery (FESS) in combination with Balloon Sinus Dilation) Procedures



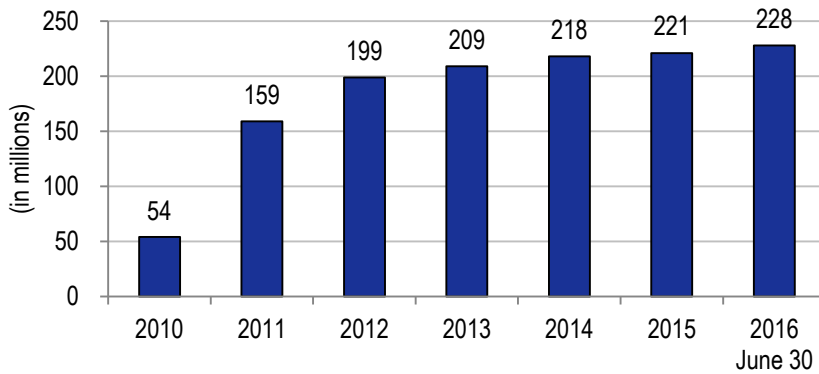
Source: Company Data, Deutsche Bank

Physician's Office Setting: Close, but Not Completely There

In the physician office setting, the number of lives covered for standalone balloon sinus dilation has consistently grown with 54 million covered lives in 2010 to approximately 228 million covered lives as of June 30, 2016.



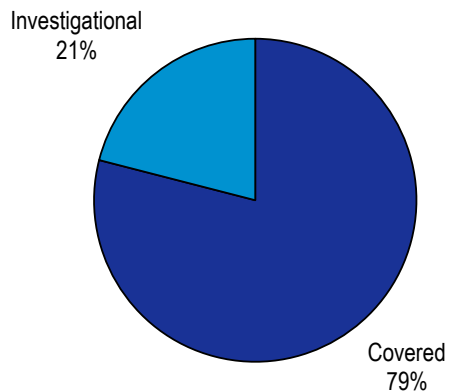
Figure 51: Growth in Payer Coverage, Standalone Balloon Sinus Dilation



Source: Company Data, Deutsche Bank

We believe that positive coverage will continue to be adopted driven by increasing clinical data showing that standalone balloon sinus dilation is a safe and effective procedure and a viable alternative to traditional sinus surgery or FESS. In addition, we believe that continued successful procedures and positive patient outcomes will further lead physicians to highlight their respective experiences with payors.

Figure 52: Insurance Coverage, Standalone Balloon Sinus Dilation



Source: Company Data, Deutsche Bank

The majority of the large payors now have positive coverage decisions in place for standalone balloon sinus dilation, including United Healthcare, Aetna, Cigna, Humana, Kaiser, TRICARE, Health Net.

Anthem / WellPoint remains the only large payor that has a non coverage decision on standalone balloon sinus dilation procedures. We estimate Anthem / WellPoint accounts for approximately 30 million covered lives.

Economic Benefit for All

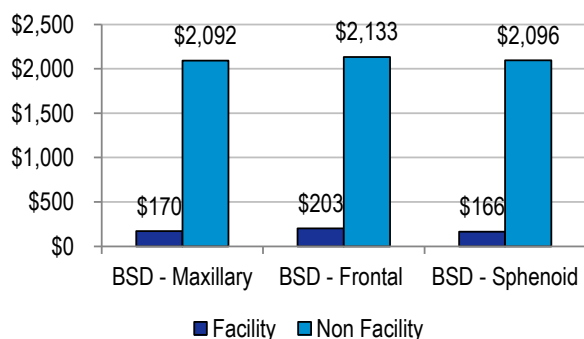
The Medicare Physician Fee Schedule reimburses physician services and is composed of three items- physician work, practice expense, and malpractice / liability insurance. Generally, each item is assigned a relative value unit (RVU) which is specific to the specified procedure and the total RVU is multiplied by the conversion factor to determine the physician payment.



The Centers for Medicare and Medicaid Services (CMS) released its 2017 Medicare Physician Fee Schedule proposed rule in July 2016. The comment period ended in early September and we estimate a final rule will be released in late October or early November 2016.

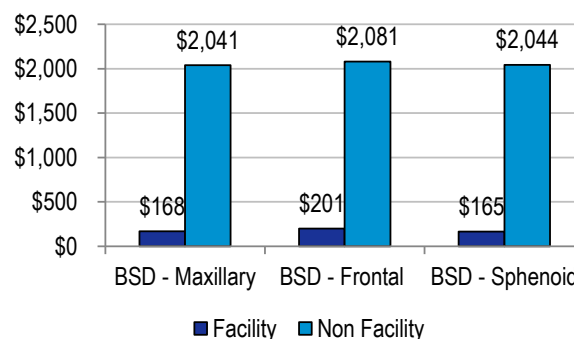
Based on the proposed rule, we estimate that physician payments related to balloon sinus dilation procedures will see a small decrease (primarily driven by a lower overall conversion factor in 2017). That being said, there remains considerable benefit to the physician in performing balloon sinus dilation in the office setting versus the hospital operating room. We note, CMS defines a “facility” as hospital, ambulatory surgery centers (ASC’s), and skilled nursing facilities (SNF’s).

Figure 53: Average Physician Payment, Final 2016



Source: Centers for Medicare and Medicaid Services (CMS), Deutsche Bank

Figure 54: Average Physician Payment, Proposed 2017



Source: Centers for Medicare and Medicaid Services (CMS), Deutsche Bank

Payors: Average Cost to Medicare Reduced in the Office

In addition to benefits to the physician due to a higher payment rate, there are also benefits to the broader healthcare system in shifting patients from traditional sinus surgery to in office balloon sinus dilation.

Balloon sinus dilation procedures are reimbursed based on the number of sinuses treated per procedure. Sinuses are reimbursed on an individual and unilateral basis, thus the initial sinus is reimbursed at 100% of the reimbursement rate, while CMS attaches a -50 modifier to the bilateral sinus and all additional sinuses.

A physician performing bilateral maxillary sinus dilation in the office with a nasal endoscopy exam for follow up is \$3,356 using 2016 Medicare reimbursement rates. In contrast, if the same patient were instead treated in an ambulatory surgery center (ASC) by way of sinus surgery with a follow up debridement, it would cost Medicare approximately 50% more. Furthermore, the same procedure in a hospital outpatient department would cost Medicare more than 100% of the cost of in office balloon sinus dilation.

Figure 55: 2016 Medicare National Average Payment Rates, BSD vs FESS

	In Office Balloon Sinus Dilation	Hospital FESS	ASC FESS	% vs BSD	
				Hospital	ASC
Maxillary Sinuses	\$3,356	\$7,980	\$5,075	138%	51%
Maxillary and Frontal Sinuses	\$4,987	\$11,830	\$7,574	137%	52%
Maxillary, Frontal, and Sphenoid Sinuses:	\$6,590	\$15,323	\$9,715	133%	47%

Source: Company Data, Deutsche Bank



The Stock Opportunity

We are initiating coverage of two pure play ear, nose, and throat (ENT) medical supplies and devices companies that we believe take advantage of these key industry themes, though company specific factors prevent us from being positive on both names.

Please see our individual initiation reports dated 10/06/16.

We View ENTL as Best Positioned

Multiple Levers for 20%+ Sales Growth

We are initiating coverage of Entellus Medical with a Buy rating and a \$26 price target. We view Entellus as a key player in the ENT space with sustainable double digit sales growth and high gross margins expected over the coming years driven primarily by two factors: the shift from operating room based procedures to physician's office based procedures and the shift from functional endoscopic sinus surgery (FESS) to balloon sinus dilation, a minimally invasive alternative.

Entellus Medical completed its initial public offering in January 2015 at \$17 per share. ENTL shares peaked in April 2015 following strong 4Q14 results and the appointment of Bob White as CEO, though contracted along with the broader small cap universe in 2015.

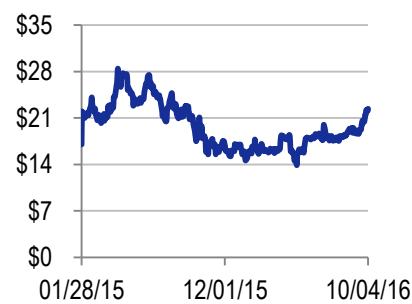
While year to date (through October 4, 2016), ENTL shares are up approximately 33% (versus Russell 2000 up 9%), we see room for multiple expansion closer to other high growth medical supplies and devices peers, which we believe should be driven by continued execution as the company delivers on expectations.

Valuation and Risks

Given the early stage of the company, our valuation framework is based on a peer group EV / sales metric. Using a 5.0x multiple, we derive an enterprise value of \$466 million or \$26 per share. We believe this multiple is fair as it gives credit to the company's sustainable near and midterm 20%+ growth potential, while balancing the risk of increased competition.

We view increased competition as the biggest risk for ENTL shares as the company competes against JNJ, MDT, and SNN who are much larger in size. Other risks include: product failures / adverse events, market contraction, sales force disruption, and additional capital raises.

Figure 56: Share Price Performance, ENTL



Source: Thomson Reuters



XENT: Shares Fairly Valued Given Near Term Risks

We are initiating coverage of Intersect ENT (ticker: XENT) with a Hold rating and a \$17 price target. We believe Intersect ENT has a differentiated product platform with its steroid eluting intranasal stents, however, overhang from recent sales force disruptions, as well as reimbursement headwinds as the company enters the physician's office segment of the market, keep us on the sidelines for now.

Intersect ENT completed its initial public offering (IPO) in July 2014 at \$11 per share and completed a secondary offering in June 2015 at \$25 per share. Shares continued to climb and reached an all time high on July 23, 2015, however shares declined following disappointing 3Q15 results in November 2015. Shares rebounded shortly thereafter, but declined again after the company reported disappointing 1Q16 results in May 2016.

Year to date (through October 4, 2016), XENT shares are down approximately 27% (versus Russell 2000 up 9%). While the company put up solid 2Q16 results, beating Street expectations, we believe recent execution challenges warrant a lower multiple.

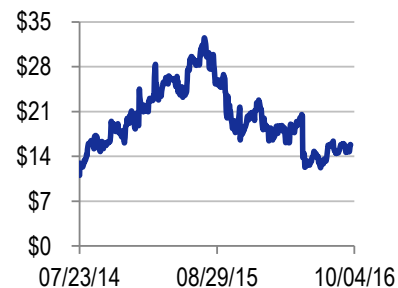
In addition, while pipeline products, NOVA and RESOLVE, should enter the model beginning in 2017, we believe there will be limited uptake until reimbursement is more broadly established which we do not expect to occur until at least 2019. Thus, while valuation seems favorable given the company's growth rate (20%+) and long term potential, near term risks keep us on the sideline.

Valuation and Risks

Our 12 month price target of \$17 is based on a weighted average 3.4x EV / 2017E sales multiple based on a sum of the parts (SOTP) analysis. This is at a discount to the high growth peer group, which we believe is warranted given near term execution risk and reimbursement headwinds while also giving credit to the company's pipeline. Thus, all in, we derive an equity value of \$514M or \$17 per share.

Upside Risks: Increased territory manager productivity, favorable reimbursement coverage, faster than expected penetration of PROPEL mini in the frontal sinuses, accelerated FDA approvals, positive clinical trial data, international expansion, and M&A. Downside risks include: Decreased territory manager productivity, negative reimbursement decisions, OR FESS market contraction, additional capital raises, and pipeline failures and / or delays.

Figure 57: Share Price Performance, XENT



Source: Thomson Reuters



Appendix 1

Important Disclosures

Additional information available upon request

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Equity rating key

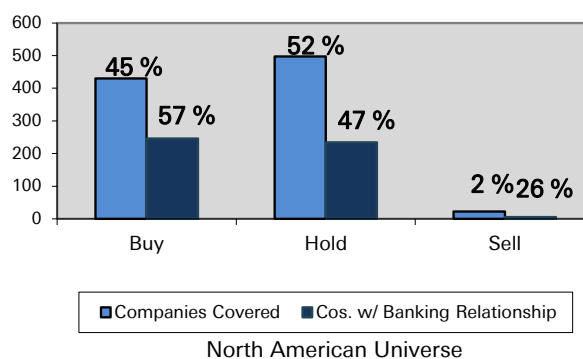
Buy: Based on a current 12-month view of total share-holder return (TSR = percentage change in share price from current price to projected target price plus projected dividend yield), we recommend that investors buy the stock.

Sell: Based on a current 12-month view of total share-holder return, we recommend that investors sell the stock

Hold: We take a neutral view on the stock 12-months out and, based on this time horizon, do not recommend either a Buy or Sell.

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