



## Medical Device to Help Surgeons Locate Lost Surgical Items and Manage Miscounts in Patients

### Lost Surgical Items and Needle Miscounts are the Most Common “Never Event”



Miscounts can happen because surgeries often use dozens of instruments and hundreds of needles with multiple OR staff shift changes. While the adoption of RFID sponge detection systems has helped lower soft Retained Surgical Item (RSI) cases, OR teams still rely on counting and manual searches for needle and instrument RSI cases. It is estimated that 28% of lost surgical objects are never recovered, leaving the patient at risk for injury and the OR team and hospital at risk for liability lawsuits. One recent RSI case resulted in the death of the patient, a \$5 million lawsuit settlement and negative media coverage for the hospital.

**~3.6** lost object events per surgeon per year<sup>1</sup>

**~24** miscounts per OR nurse per year<sup>1</sup>

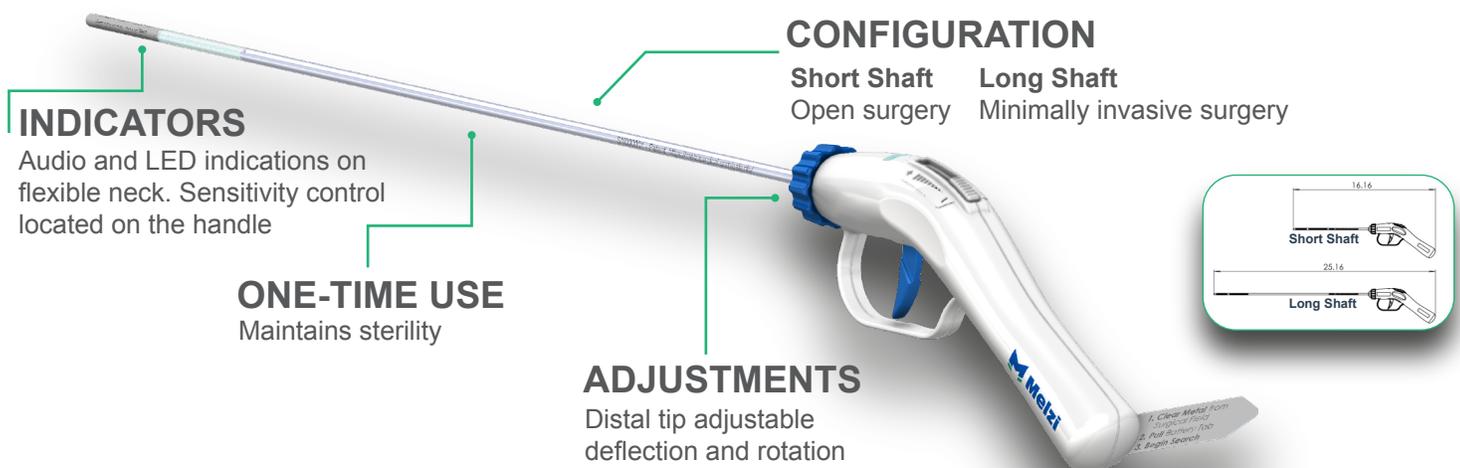
**28%** of lost object are NEVER recovered<sup>1</sup>

1: Company sponsored market research

2: North American Lost Sharp Events: 390,000. Retained Surgical Items: A Changing Landscape. Journal of Patient Safety, 2020, Weprin, et al.; 396k x 74% x 28% = 82,051, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4254476/>

### → A Solution: Melzi Sharps Finder

Shown to detect lost surgical items in-patient with a 95% reliability rate

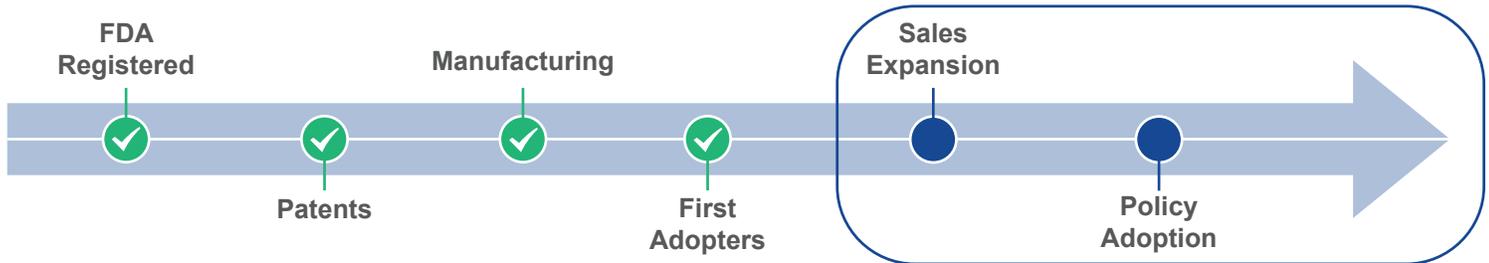


The Melzi Sharps Finder was designed by surgeons who understand how frustrating and time-consuming it can be to search for surgical needles and sharps. It uses a magnetometer in the tip to detect changes in the magnetic field when approaching a metal object. The long shaft version is designed for laparoscopic and robotic cases via a trocar. The short shaft version is ergonomically designed for open surgery. It gives audio and visual signals when a lost sharp is detected. It can detect needles as small as 7mm. OR teams reported finding lost needles in minutes with the Sharps Finder, where current protocol can take hours..



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## Executing on Commercial Launch



An X-Ray is used as current protocol in hospitals which is proven to be ineffective and add 60+ minutes to the surgery.

Sharps Finder is Capable of Detecting Needles Invisible to X-Ray (X-Ray Ineffective Below 15mm)

	LARGE			MEDIUM			SMALL				
NEEDLE SIZE	26mm	22mm	17mm	15mm	13mm	11mm	10mm	9mm	8mm	7mm	
X-RAY EFFECTIVENESS	Detectable			Decreased Detectability		Ineffective - DO NOT USE <sup>1</sup>					
SHARPS FINDER	Detectable <sup>2</sup>										

1: See Needle Algorithm, www.nothingleftbehind.org, Dr. Verna Gibbs, Surgeon/Clinical Affairs Prof. UCSF/San Francisco Veterans Affairs Medical Center

2: Out of the box 13mm, 17mm, and 26mm needles are detected at 95% reliability with 95% confidence, 9mm and 11mm needles with greater than 80% reliability @ 90% confidence, and 6mm needles with 70% reliability @ 90% confidence. Additionally, when magnetized by placing an individual needle on a magnetic instrument mat for 1 second (verified using Key Surgical MG-300-400R instrument mat ) all of the previously listed needle groups: 6mm, 9mm, 11mm, 13mm, 17mm and 26mm are detected at 95% reliability with 95% confidence.

## Commercialization Strategy

	Known Lost Sharp Event	Miscount Verification and Alternative to X-Ray	Routine Check in Every Surgery
SURGERY TYPE	Minimally invasive and open surgeries	Minimally invasive and open surgeries	Open surgeries
USE CASE APPLICATION	Faster, more reliable tool to identify lost sharp items "Fire Extinguisher" model	Provides alternative to X-Ray, which is known to be ineffective with smaller needles	Solution for hospital to eliminate the number 1 Never Event
SYSTEM DEPLOYMENT	Off the shelf unit deployed	Subscription service with commitment to use in every miscount situation	Subscription service with commitment to use in every open surgery using 10 needles or more