

Mediflex®



ENTrac® Retraction Systems: One Platform. Absolute Retraction.

Solutions for Trans Oral, Endoscopic, and Open Head & Neck Procedures

ENTrac[®] Stabilization Solutions



ENTrac for TORS



ENTrac for Thyroid



ENTrac for Parotid



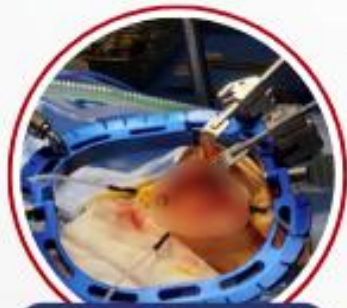
Flexible Scope Stabilization



Robotic Thyroid



Endoscope Stabilization



DynaTrac[®] Retractor



SureStay



Ear Speculum



**One Stabilization
Platform for ALL
your Surgical
Holding &
Positioning
Needs...**

Mediflex® Continues its R&D into Head & Neck

How did we arrive at ENTrac™? Mediflex continues a history of surgeon collaboration.

Dr. Suren Krishnan speaks to Daniel Adler about developing retractors for his Da Vinci Program (2017, Adelaide, Australia)

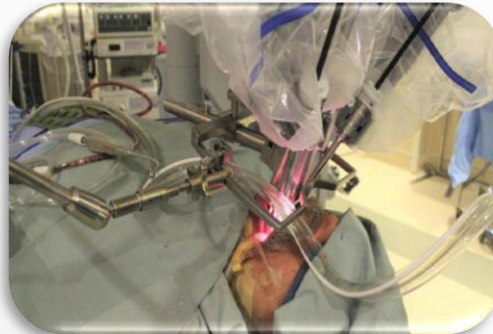
- ❖ Preliminary testing with Double Arm Holding Solution
 - ❖ One arm for upper jaw
 - ❖ One for lower jaw
 - ❖ Congruent retraction of Maxilla/Mandible required and to be improved upon



2017, Adelaide, Australia

Dr. Ichiro Tateya contacts Mediflex to help stabilize his FK retractor to prevent patient injury associated with colliding robotic arms (2021, Nagoya, Japan).

- ❖ Use 2x Mediflex 73000-SA to stabilize FK due to weight on patients' head
- ❖ To reduce patient injury when the robotic arms collide with the FK retractor
 - ❖ Tongue compression and jaw injuries
 - ❖ Mediflex introduces the concept of a ring retractor for TORS (2022)
 - ❖ Mediflex continues to develop several generations of design (2022-2025)
 - ❖ Continual process with development



2021, Nagoya, Japan

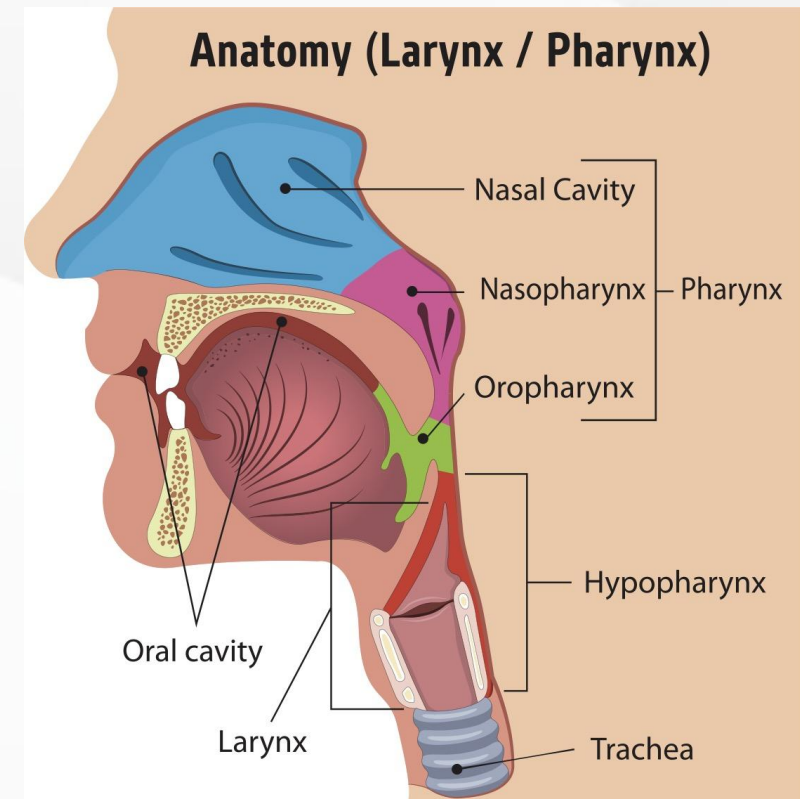
ENTrac® Who is it for?

Head & Neck Surgery (ENT) / Otolaryngology

1. **Fellowship-trained Head and Neck Surgical Oncologists** are the largest group, usually for cancer cases
(tonsil, tongue base, deep throat tumors)
2. **Apnea Surgeons** (also ENT-fellowship-trained) perform TORS tongue base/palate reduction for *Obstructive Sleep Apnea*
Often a distinct sub-population of ENT surgeons from the head-and-neck oncology group
3. **Oral and Maxillofacial Surgeons (OMFS)**
Especially in academic centers with combined ENT/OMFS head and neck programs

Most Common Procedures

1. **Tonsillectomy/Oropharynx resection**
Carcinoma/Malignant Tumors
2. **Tongue base reduction**
Obstructive Sleep Apnea
(non-oncologic — high volume at sleep-focused centers)
3. **Tongue base tumor resection**
Malignant Tumors
4. **Unknown primary tumor workup**
(Tongue) Tonsillectomy for diagnosis
5. **Supraglottic/hypopharyngeal resections or reefing**
Snoring remedy



ENTrac® Head & Neck Technologies

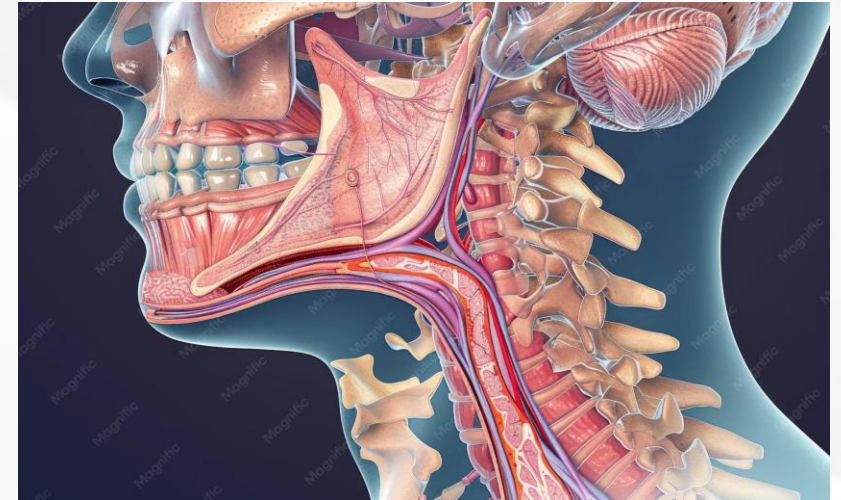
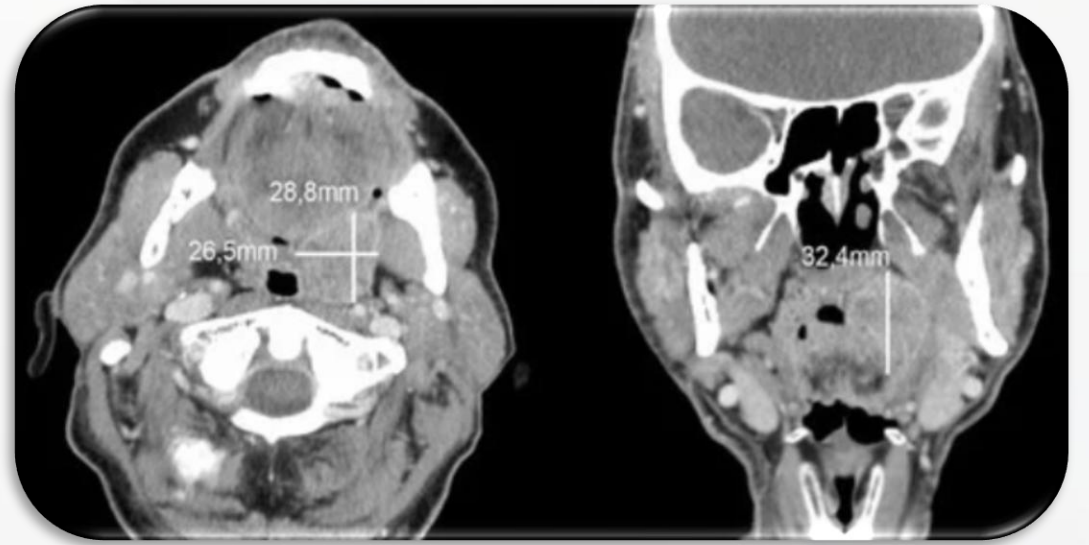
Advances in imaging, robotics, instrumentation, and artificial intelligence are quickly advancing surgeon capabilities in 'Head & Neck' procedures as part of Ear, Nose and Throat Procedures.

Imaging: Modern imaging plays a central role in planning, executing, and verifying robotic head and neck procedures like TORS. Here's how it fits in at each stage:

CT and MRI are used to delineate the tumor's extent, depth of invasion, and relationship to critical structures (carotid artery, deep musculature, mandible). This helps surgeons decide:

PET-CT helps identify nodal disease and distant metastases, which is critical for staging and for planning the extent of neck dissection.

3D reconstruction / virtual surgical planning — developed using CT/MRI data to simulate the robotic approach, anticipate instrument angles, and assess whether the transoral corridor will allow adequate access (an important limiting factor in TORS, since visualization and instrument reach are constrained by mouth opening and pharyngeal anatomy).



ENTrac® Imaging Technologies

Intraoperative Imaging and Navigation Technologies

Image-guided Navigation Systems

Integrated with robotic platforms to overlay preoperative imaging onto the surgical field helps localize tumor margins in real time, especially to get clear visual boundaries.

Indocyanine Green (ICG) Fluorescence Imaging

Injected systemically or locally, can help identify vascular structures explore lymph node mapping during neck dissection, potentially reducing the extent of dissection needed.

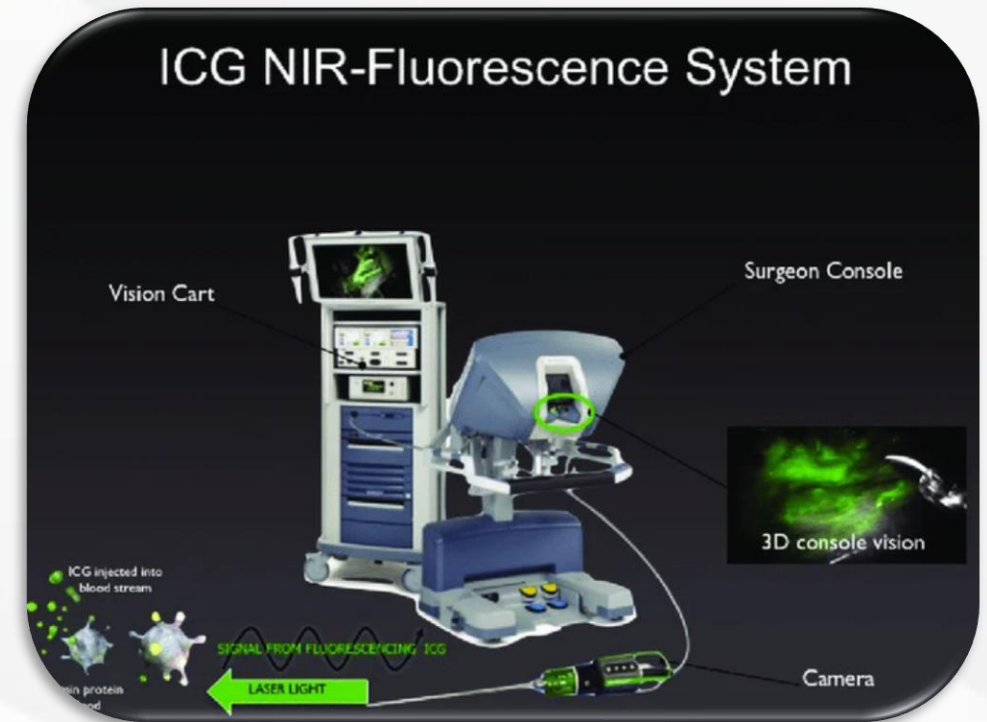
Intraoperative Ultrasound

Used in some centers, particularly for tongue base lesions.

Why This Matters for the Robotic Approach Specifically:

A key limitation of TORS is **loss of tactile feedback**- Surgeon can't 'feel' the tissue as in an open approach.

This makes pre- and intraoperative imaging so important, since visual and imaging information can compensate for the lack of 'touch'.



Da Vinci Firefly system: Surgeons can switch between standard white-light and the fluorescence overlay view, without removing instruments or pause the procedure.

The fluorescent signal highlights blood vessels, perfused tissue, or — in head and neck applications — potentially *sentinel lymph nodes* and other critical anatomy.

ENTrac® + RAS Technology

Robotic Assisted Surgery (RAS)

Surgical access and visualization with enhanced instrumentation.

Benefits:

Improved access to difficult anatomic locations

Robotic arms articulate in ways that traditional transoral instruments can't.

Magnified, 3D, high-definition visualization

Surgeons get a stereoscopic view with significant magnification, improving precision.

Tremor filtration and motion scaling

Natural hand tremor is filtered out.

Large hand movements are changed into smaller, more precise instrument movements.

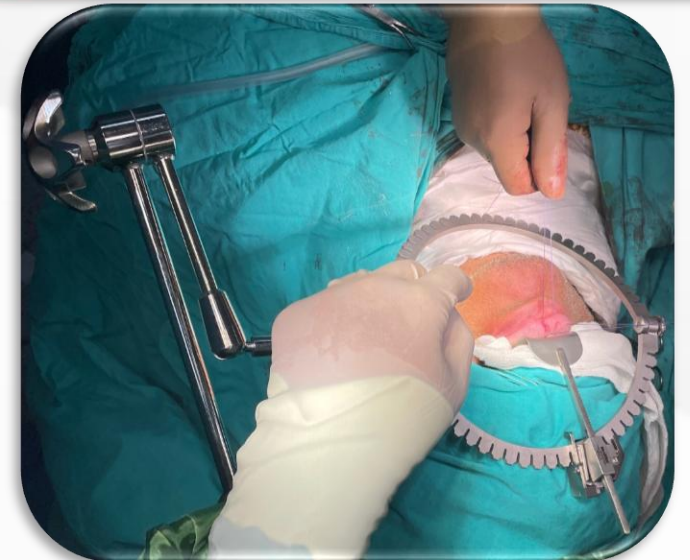
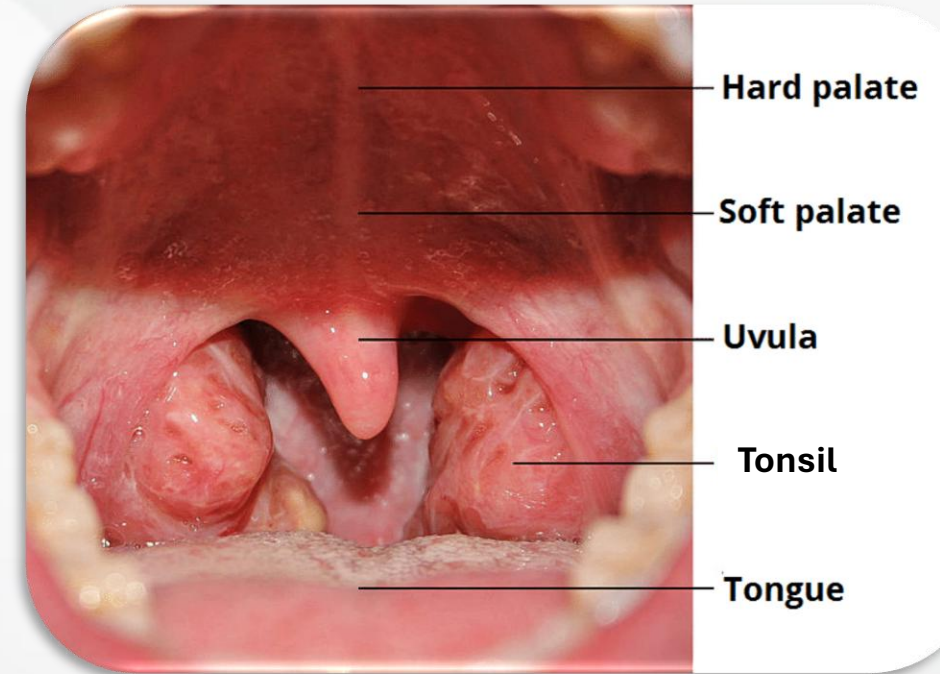
Wristed instrumentation

Instruments have multiple degrees of freedom, offering and improving unique dissection angles within a confined transoral space.

Open vs. TORS Approaches

Traditional approaches were associated with surgical and post-surgical complications in 10%–60% of cases, including problems with swallowing, jaw closure, and significant facial deformity.

TORS was designed to improve upon the above — and it largely has!



Challenges with Robotic/TORS Procedures

Loss of Tactile Feedback

This is probably the most frequently cited limitation. The surgeon can't palpate tissue to feel tumor margins, vessel pulsations, or tissue planes the way they could with a finger in open surgery. Surgeons have to rely almost entirely on visual cues and preoperative imaging to compensate.

Limited Instrument Selection

The range of TORS-specific instruments (graspers, electrosurgery, retractors) is limited

Suction and Bleeding Control

Robotic systems don't have integrated suction

Bleeding can obscure the visual field quickly; controlling it can be cumbersome as an assistant has to manage suction separately.

Lack of Haptic Alarms for Excessive Force

Without tactile feedback, a real risk of inadvertent tissue trauma exists.

The surgeon can apply more force than intended, since they can't 'feel' resistance.

Lack of Bedside Assistance

Aside from management of suction devices, bedside staff have a greatly reduced role due to the moving 'arms' being in the way of visualizing the operative site.



Challenges with TORS Procedures

Limited Mouth Opening

- ❖ Reduced mouth opening
- ❖ Short neck
- ❖ Limited lower jaw movement
- ❖ Head positioning can sometimes prevent TORS entirely. Stretching of head/neck is critical for exposure.

Working in a Confined Space

- ❖ The oral cavity and oropharynx are a tight, narrow 'box'.
- ❖ Instrument collision (clashing of the robotic arms) can be a real practical issue
- ❖ **Exposure-Dependent Feasibility**
Tongue base tumors can be hard to visualize and reach even with a robot.
This may require conversion to an open approach



Learning Curve

- ❖ TORS has a **significant learning curve and usually requires dedicated residency and training programs**
- ❖ Operative time, complication rates, and margin positivity can all be affected during a surgeon's early experience with the platform.
- ❖ Training requires not only *general robotic surgery skills* but *head-and-neck-specific judgment* about case selection

Difficulty Assessing Deep Margins

- ❖ Lack of tactile feedback and palpation causes judging the deep extent of a tumor to be harder than in open surgery. (especially base of tongue lesions)

Challenging Anatomy

- ❖ Very complex anatomy
 - ❖ Head
 - ❖ Neck
 - ❖ Lymphatic System
 - ❖ Vascular System
 - ❖ Maxo-facial
- ❖ Wide range of patient anatomy
 - ❖ Short, thick, obese anatomy

ENTrac® One Platform. Absolute Retraction.

A New Stabilization Platform Designed for:

❖ Trans Oral Robotic Surgery (TORS)

- ❖ Da Vinci Surgical (Intuitive)
 - ❖ Multi-Port approach
 - ❖ Single-Port approach

❖ Open Head & Neck procedures

- ❖ Mostly performed *before or after* TORS
 - ❖ (Bilateral) Neck dissection
 - ❖ Excision of lymph nodes/tumor
- ❖ Performed as a *separate procedure*
 - ❖ (Robotic) Thyroidectomy, Partial Thyroidectomy
 - ❖ Parotid Surgery
 - ❖ Several Malignant and Benign Tumors

Secondary Market

❖ Endoscopic Oral Surgery (Vocal Cords)

❖ Trans-Nasal/Skull Base Surgery

- ❖ Rigid Scope
- ❖ Flexible Scope



ENTrac® Benefits

ENTrac® is a *modular* platform based on our Mini-Bookler® technology, designed initially for open 'head & neck' surgery, with recent adaptations for endoscopic and Trans-Oral Robotics.

❖ Benefits:

❖ OR Table Mounted (StrongArm®)

- ❖ Does not rest on the patient's face, neck, or chest
- ❖ Ability to be assembled gradually instead of 'all at once'
- ❖ Reduces incidence of lower jaw dislocation

❖ Low Profile

- ❖ Robotic Arms *do not collide* with the retractor
- ❖ Lightweight

❖ Maximum Mouth Exposure

- ❖ Critical for procedural success

❖ Height-adjustable tongue blades

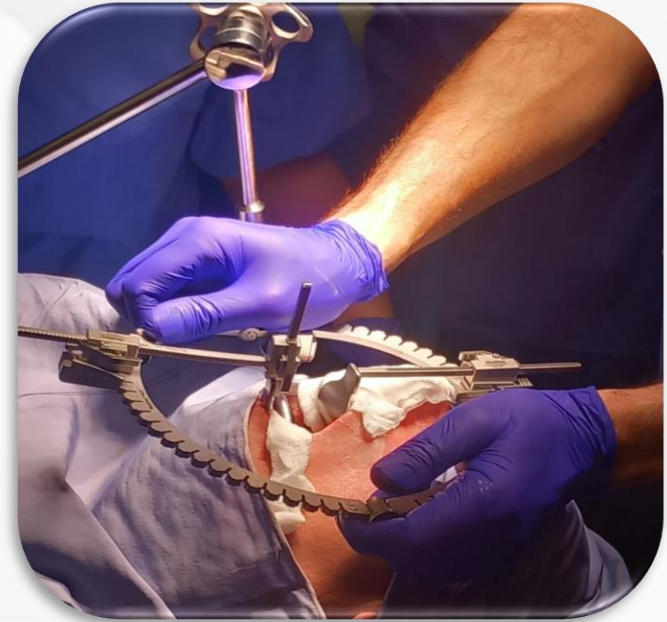
❖ Adaptable Maxilla stabilization for a wide range of patient anatomies

❖ Ability to offset Maxilla and tongue blades for unique patient anatomy and sizes

❖ Extremely competitive pricing for both low-volume and high-volume hospitals

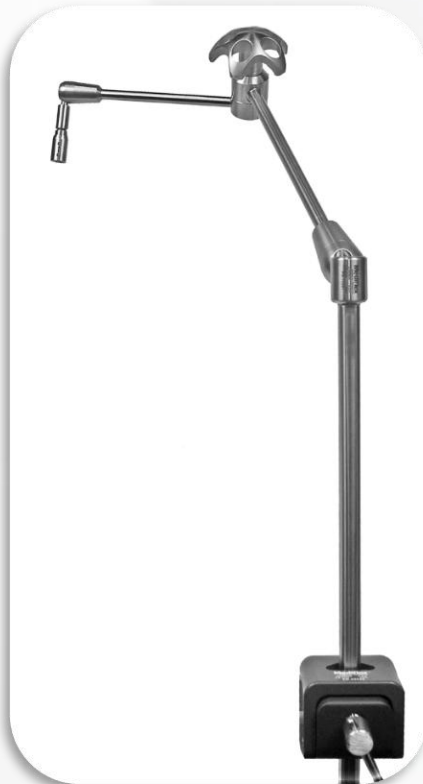
❖ Same kit can be used for open neck part of Robotic Assisted procedures

- ❖ Dissecting lymph nodes – Neck dissection
 - ❖ Change ring, change blades, add stays... and proceed.



ENTrac® Mounting Hardware

- ❖ For TORS, use StrongArm® 73000-SA (rail clamp included)



- ❖ Mini-Clasper
Attaches to **QC** fitting for holding a Mini-Bookler® Retractor Ring

72280



- ❖ While a FlexArm™ can be used for these procedures, it is better to simplify the setup for new surgeons who are not familiar with these types of devices. The fewer components, the better.

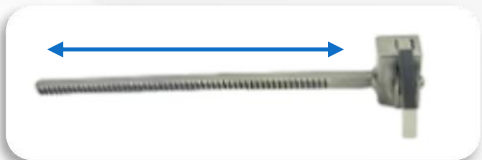


ENTrac® Retractor Componentry

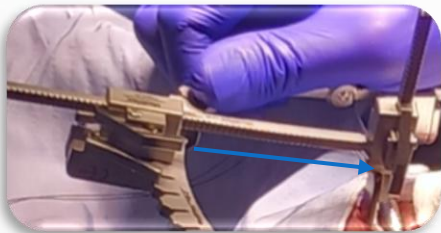
Rings



Ratchets



90° Elevating Ratchet



TORS Blades



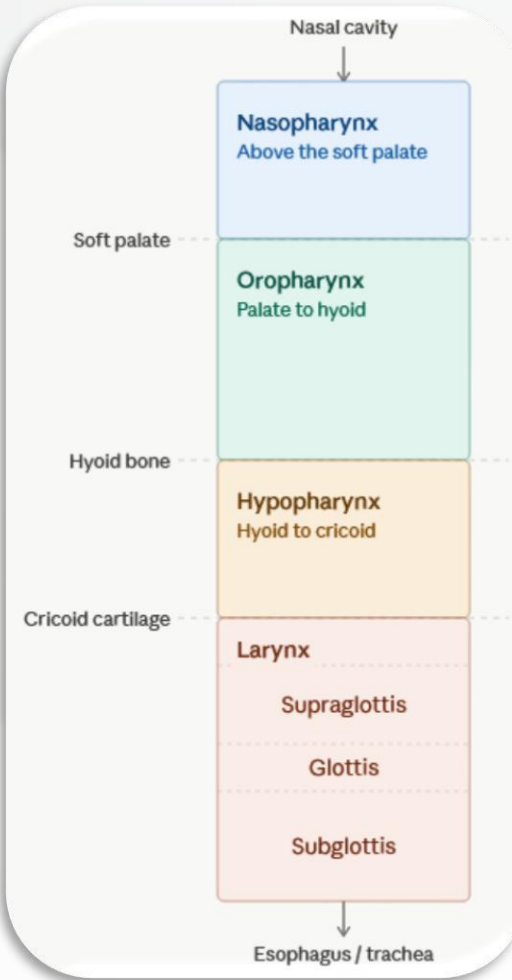
Upper Jaw Blade



S, M, L Tongue Blades



Left Right Tongue Blades



Deep Access Laryngeal Blade (new sizes being developed)

Mediflex®

PRODUCT KEY

A: 69099 	E: 72294-L 
B: 73000-SA 	F: 55009 
C: 72280 	G: 55013-IL  Other tongue blade options include: *55013-IL, 55014-IL, 55015-IL, 55016-IL, 55017-IL, 55018-IL
D: 55012 	H: 72284 



Attach the Rail Clamp (A) to the table rail and insert the vertical post of the StrongArm® (B), with the flat side facing the flat side of the Rail Clamp.

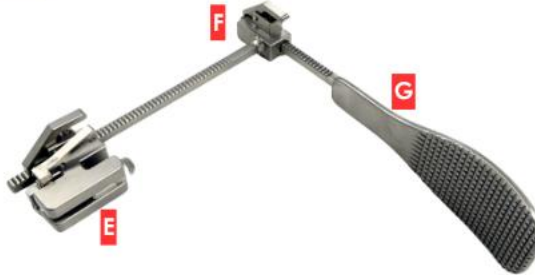


Attach the Clasper (C) into the Quick Connect fitting of the StrongArm. Attach the clasper (C) onto the ring (H), close to the knobs (I), on the same side of patient's maxilla side. The knobs on the ring need to align with the corners of the patient's mouth. Angle the mandible side of the ring upwards, slightly, and loosely tighten the ring to hold shape.



After protecting the teeth/gums – insert the maxilla blade (D) into the mouth and secure it with a tilt ratchet (E) onto the ring. Once attached, retract slightly to stabilize the ring setup.

4



Attach the Tongue Blade (G) into the extended ratchet (F). Insert the extended ratchet into the tilt ratchet (E).

5



Attach the Tongue Blade (G) into the mouth and fixate the tilt ratchet (F) onto the ring. Control the depth of the blade by moving it up and down on the extended ratchet. At the preferred depth, begin retracting the tongue and lower jaw.

6



Optimize the field of view as needed. Best use of the system is achieved when the angle of the ring is adjusted so as to be as close to the patient, without touching them, as possible. When all is set, lock the segmented knobs on the ring and ensure the strong arm is properly tightened.

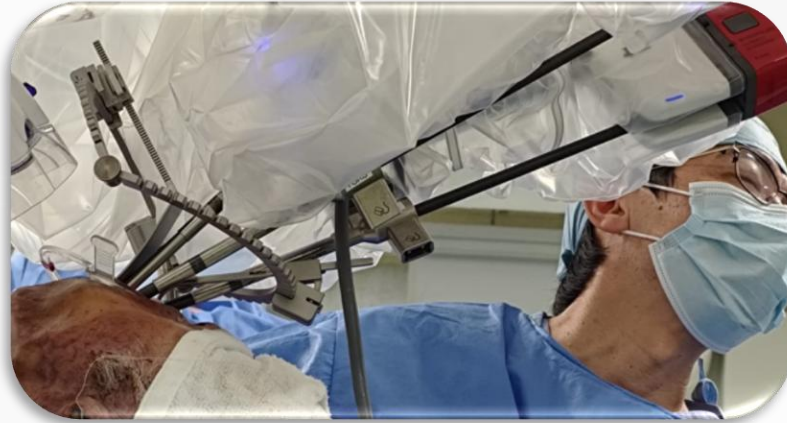
7



Follow the manufacturer's instructions for proper robot setup to avoid any collision with ENTrac®.

To break down the system, use this setup guide in reverse.

ENTrac® SETUP GUIDE for Laryngeal Procedures (deep access)



‘ENTrac™ Set Up’ with Multi-Port RAS



- ❖ Tips and Tricks
 - ❖ Massage and ‘stretch’ the neck
 - ❖ Relaxes muscles and tissue (Anesthesia relaxation drugs are also important)
 - ❖ Tilt head backwards to allow for direct visualization of the larynx
 - ❖ Keep center knobs of ring between mouth and nose (the shorter the head, the closer to the nose)



‘FK Set Up’ with Single-Port RAS

ENTrac® Case Report from Hospital Motol, Prague

- ❖ Dr. Michel Zadbrosky
 - ❖ Intuitive Proctor and thus very experienced
 - ❖ 'Top 5' in Europe
- ❖ All 3 cases were successful
 - ❖ 2 males, both large
 - ❖ 1 female, obese with challenging anatomy
 - ❖ All were tongue-based procedures (not deep)
- ❖ The first case took about 15 minutes to set up
 - ❖ The second and third cases were about 10 minutes to set up
- ❖ The up and down blade worked very well and allowed for easier set up than traditional 90-degree blades
 - ❖ The doctor used words like 'perfect' and easy to use
 - ❖ Noted that it was much less weight on the patient's head than the FK
- ❖ His partner also used the ENTrac System the next day for a parotid and said it cut down his procedure time with about 1/3
- ❖ Has not yet considered using RAS for laryngeal and deep access procedures
- ❖ He liked that the weight was light and stabilized by the Strong Arm rather than the patient



ENTrac® Case Report from Istanbul

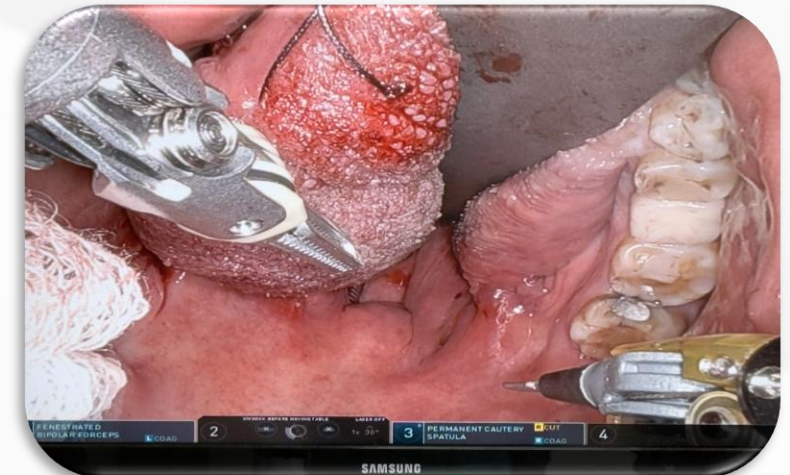
Excellent Trial

Surgeon: Prof. Dr. Murat Yener

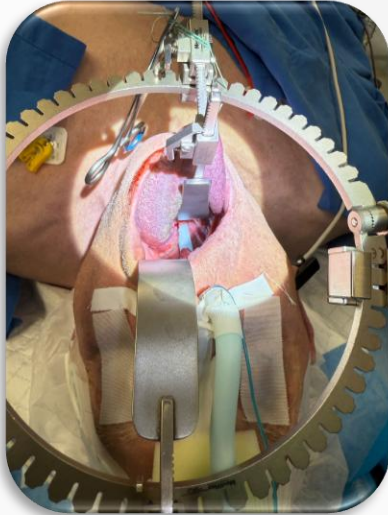
Procedure: Tongue Base Surgery

- ❖ The head was nicely tilted backwards
- ❖ Tongue suture in place
- ❖ Table low,
- ❖ Surgeon and assistant understanding the set-up as we/they practiced the day before
- ❖ Lower Jaw Ring part bent upward
- ❖ Resulting in access to the tongue base which was established in about 20 minutes.
- ❖ Normal Anatomy
- ❖ First time ENTrac® used in Turkiye

NOTE: This was the first time this surgeon used ENTrac®.



ENTrac® ‘Challenging’ Case Reports



Groningen, Netherlands

“First ‘failure’ of TORS set in UMC Groningen: Impossible to position due to strange anatomy of a *bilateral* tongue base tumor....”

We got the second case to work, but challenging anatomy still proved difficult.

This patient though, had irregular anatomy, and ENTrac allowed for the system to be set up offset



Trieste, Italy

“Wrong” trial
Unfortunately, a few issues arose in this trial in Italy:

- ❖ Surgeon and assistant had not practiced the day before, did not “understand” how to handle ratchets and angling of the ring
- ❖ The head was not tilted backwards at all
- ❖ No tongue suture in place
- ❖ Table high
- ❖ Lower Jaw Ring part bent downward instead of upward
- ❖ All resulting in over-retracting, thus bending the stem of the tongue blade, and still no proper access...



Japan



The correct set up

“The surgeon was unable to gain access to the deep larynx due to difficulty in setting up the ring. The angulation appears to have caused a problem.

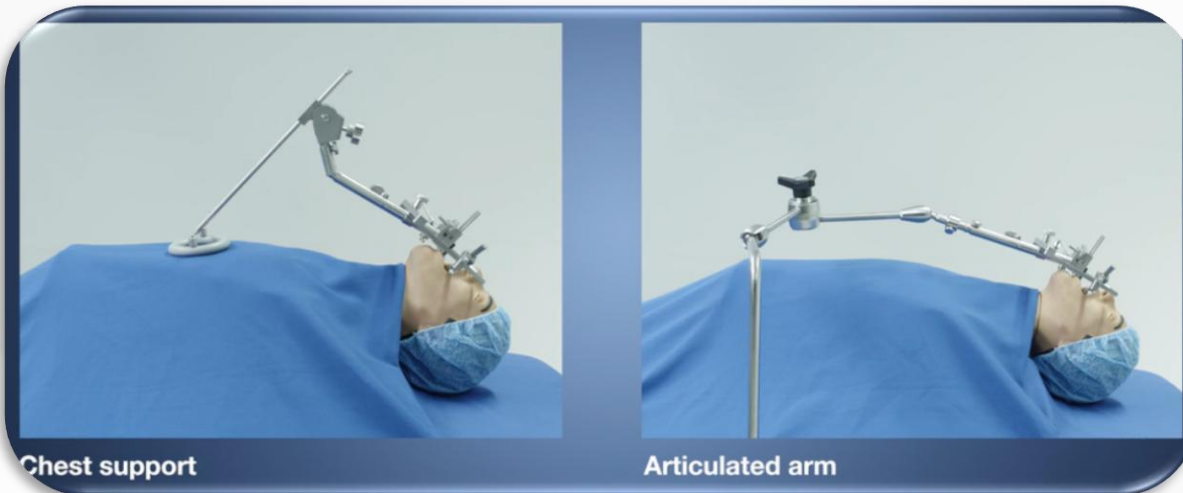
We had an easier time setting up during the next case by closely following the set-up instructions.”

ENTrac® Competition

The **original FK retractor** was developed by Dr. Feyh and Dr. Kastenbauer (Germany)

The retractor was not designed with robotic surgery in mind.

- ❖ The inventors found that conventional retractors, including the FK, did not provide the line-of-sight or range of motion needed for TORS specifically:
The frame provided insufficient access to the patient's mouth for the robotic tools.
- ❖ Therefore, modifications were made to the original FK, by Weinstein and O'Malley, for use with the Da Vinci system —
 - Renamed the FK-WO (Feyh-Kastenbauer Weinstein-O'Malley).Modifications included widening of the frame aperture for more instrument/camera room, plus new blades for supraglottic exposure.



Chest support

Articulated arm

Paper: **“Tongue base exposure during TORS without using a mouth prop”**
[Journal of Robotic Surgery](#)

“The FK has several interchangeable blades that allow for wide exposure of the oral cavity, oropharynx, hypopharynx, and larynx. This device is the most employed for TORS today. However, use of the F-K and other assorted tonsil retractors have the *disadvantage of introducing compression and distortion of the tongue* during TORS.

It may need to be re-positioned during TORS in order to achieve an adequate resection margin. In addition, it may limit the angle to which the robotic instruments are introduced into the mouth, a *factor that limits deeper exposure of the pharynx and larynx and may contribute to collisions during TORS*”

ENTrac[®] Competition (FK)

Industry Standard but **DISCONTINUED!**

- ❖ OEM Distributed by Olympus
 - ❖ Hospitals are looking for alternatives to start/continue their RAS programs
- ❖ Averaging around \$25-30,000 HLP
 - ❖ Mediflex considerably more economical
 - ❖ On average 40% less
- ❖ High profile - Robotic arm interference
- ❖ Tongue Compression Injuries
- ❖ Not able to perform open surgery
- ❖ Heavy (2x)
 - ❖ Weight distribution on chest or in holding arm
 - ❖ Mediflex solution is lighter and holds ring close
 - ❖ FK rests often on the patients chin
- ❖ High incidence of Jaw Luxation (TMJ)
Retractor is 'forced' into patients' mouth
 - ❖ Surgeons are more concerned with the opening of the mouth than internal force
 - ❖ *Can and has* resulted in patient injury



FK Retractor Inserted all at once



Weight resting on patient's head



Retractor being inserted 'blind'



Weight distribution utilizes patient's head/neck

ENTrac® Competition

'FK Like' Retractor

- ❖ Fentex Medical/German OEM's
- ❖ Asian manufacturers
 - ❖ Often violate 'FK' patents
- ❖ Very high profile
- ❖ Robotic arms can easily collide
- ❖ Not able to perform open surgery
- ❖ All the weight rests on the patient's face
 - ❖ Higher when they use a 'chest rest'
- ❖ High incidence of Jaw Luxation/TMJ
- ❖ Design takes up more real estate inside mouth



Challenging Access



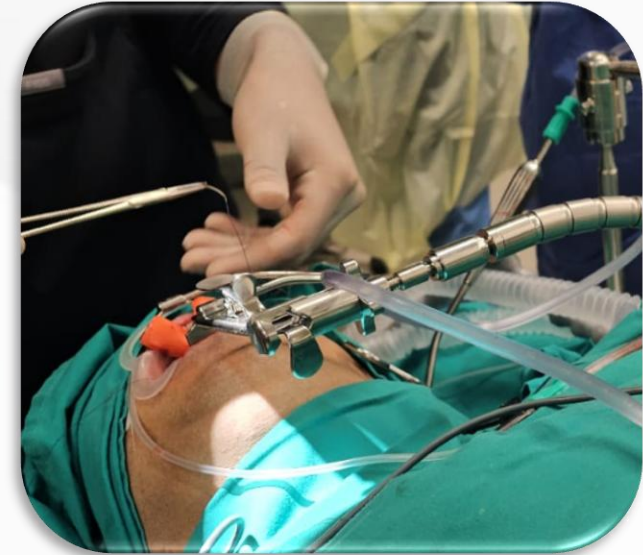
'Chest Rest' Set Up

Traditional Mouth Gags (Dingman)

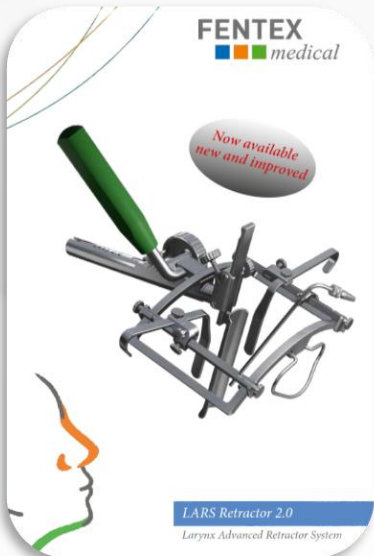
- ❖ Many suppliers
- ❖ Simple
- ❖ Poor mid-deep access
 - ❖ Require stabilization
 - ❖ Can be held by a Holding Arm



Traditional Mouth Gags

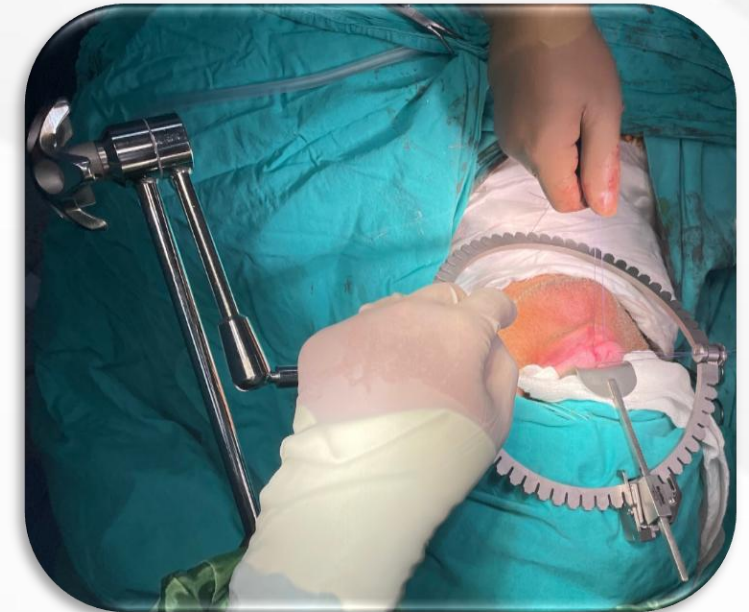
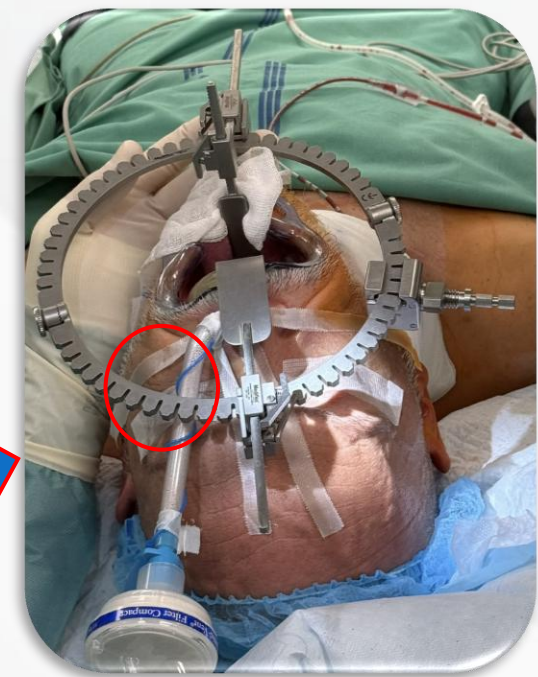


Held by FlexArm

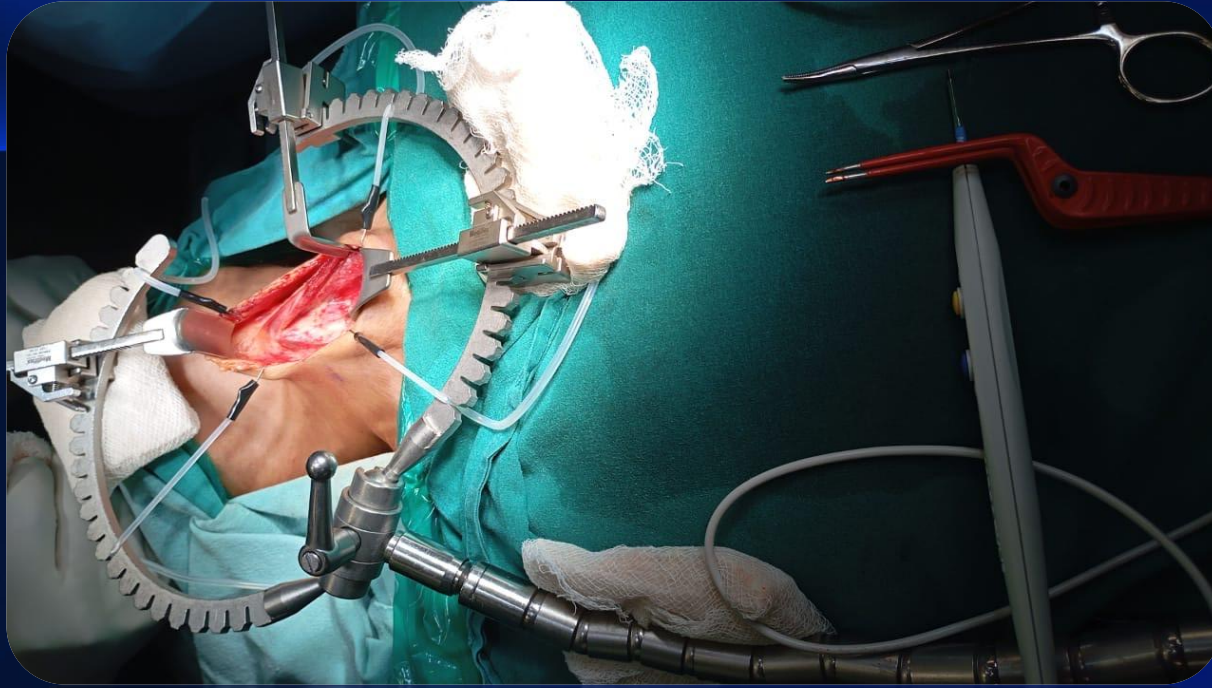


ENTrac® Set Up Tips and Tricks

- ❖ Managing Expectations: This is new technology for the surgeons
- ❖ Start with TORS 'easy cases': Shallow to Mid Access. No standard cases, no bilateral surgery.
- ❖ Dry demonstration is hard to replicate real-world factors, but essential in a successful case.
 - ❖ These types of surgeons are not trained on advanced retraction systems.
 - ❖ Practice set-up and handling of the set prior to surgery.
Get them *acquainted* with Ratchet positioning, Ring movement, untensioning blades before changing etc.
- ❖ Remember, breathing tube is set up on the opposite side of the 'point of attack.'*
 - ❖ 55012 upper jaw blade will go on the opposite side of the breathing tube to not interfere.
- ❖ Suggest to the Surgeon to tilt back and lower the neck! Anesthesia can help.
 - ❖ Loosens up the throat, neck and face to allow mouth to open wider.
- ❖ For average-sized heads, place the center of the ring between mouth and nose. For larger heads closer to the edges of the mouth. For smaller heads, closer to the nose.
- ❖ Don't be afraid to 'fail', surgeons do so as well: Not all patients are candidates for TORS.
Manage their expectations: ENTrac® is NOT a miracle. Huge variety in patient shapes, sizes, and anatomy.
- ❖ Surgeons do not see similar solutions, so do not be afraid to be confident and assertive in our proposed kits.
- ❖ Don't lock all until all is set: Flex the system inside the patient before locking rings and then the StrongArm®.



Mediflex®



ENTrac® Retraction Systems: One Platform. Absolute Retraction.

Open Surgery: Head and Neck

ENTrac® Mounting Hardware



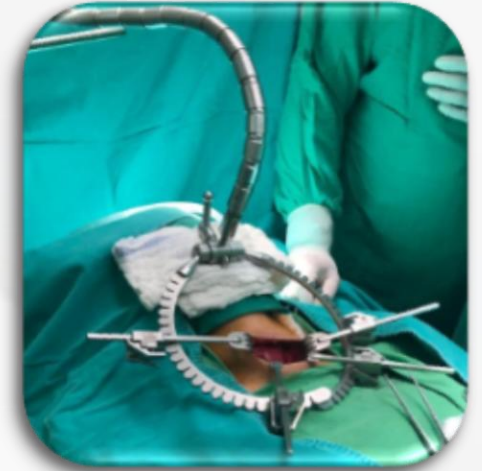
73000-SA

- ❖ For those surgeons who want maximum stability
- ❖ For dedicated kit for open surgery and TORS
 - ❖ Not for scope holding



99054-QCLR

- ❖ Ideal for surgeons performing MIS and Open
 - ❖ FlexArm™ to hold
 - ❖ Retractor
 - ❖ Rigid Scope
 - ❖ Flexible Scope



72280



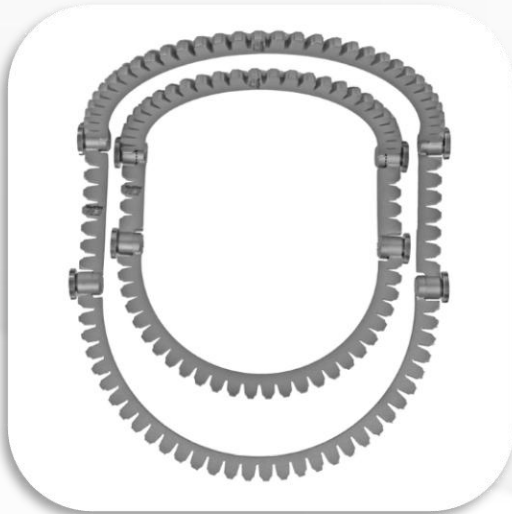
72295 (direct connection with no 72280)



- ❖ Mini-Clasper Attaches to QC fitting for holding a Mini-Bookler® Retractor Ring

ENTrac® Retractor Components

Rings



Tilt Ratchets



72294

Blades

Mini-Malleable – 9 sizes

Mini-Kelly – 15 sizes

Sharp Mini-Hook – 5 shapes

Blunt Mini-Hook – 5 shapes

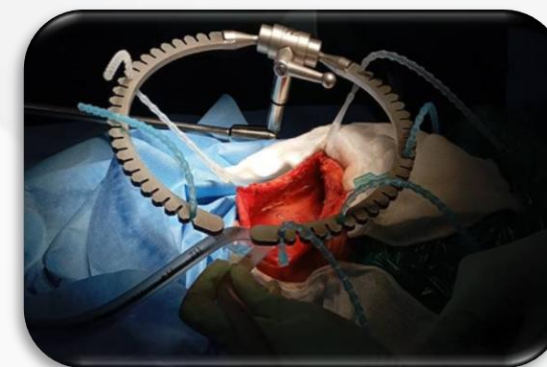
Mini-Senn-Miller – 1 size

Mini-Deaver – 3 sizes



ENTrac® + SureStay®

REF. NO.	DESCRIPTION
4105S-2	Elastic Beaded Stays, 5mm Sharp Hook, 2/Pk, 5Pks/Bx
4105S-2	Elastic Beaded Stays, 5mm Sharp Hook, 2/Pk, 5Pks/Bx
4107F-2	Elastic Beaded Stays, 7mm Two Finger Hook, 2/Pk, 5Pks/Bx
4112B-2	Elastic Beaded Stays, 12mm Blunt Hook, 2/Pk, 5Pks/Bx
412FB-2	Elastic Beaded Stays, 12mm Two Finger Blunt Hook, 2/Pk, 5Pks/Bx
4112B-50	Elastic Beaded Stays, 12mm Two Finger Blunt Hook, 50/c
4105B-50	Elastic Beaded Stays, 5mm Blunt Hook, 50/Cs
4105S-50	Elastic Beaded Stays, 5mm Sharp Hook, 50/Cs
4105B-2	Elastic Beaded Stays, 5mm Blunt Hook, 2/Pk, 5Pks/Bx



- ❖ Positive locking feature ensures position is always maintained
- ❖ Larger 'head' design allows for ease of gripping
- ❖ More secure and stronger than other brands
- ❖ Beaded design greatly reduces slippage when handling wet Stays
- ❖ Single and 2-finger hooks, sharp or blunt for superficial retraction
- ❖ Color-coded to identify sharp vs blunt configurations
- ❖ Sterile packaging options of 1 per pack (50 packs per box)
- ❖ Sterile packaging option of 2 per pack (5 packs per box)



ENTrac® + SureStay®

SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

DESIGNED FOR GRIP WHEN SURGEONS GLOVES ARE WET, ENSURING PROPER PLACEMENT.

CONFIDENT GRIP. ACCURATE PLACEMENT.
The textured beaded design provides superior grip—even in wet conditions—helping surgeons place stays exactly where they need them.

Engineered for Stability. Designed for Surgeons. **Mediflex®**

SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

HELPS SURGEONS IDENTIFY THE SHARPNESS OF THE NEEDLE WITHOUT REMOVING IT FROM THE TISSUE FOR REPOSITIONING.

VISUAL NEEDLE TIP IDENTIFICATION
The exposed needle tip allows surgeons to quickly confirm needle sharpness without removing the Stay—helping support efficient workflow and confident repositioning.

Engineered for Stability. Designed for Surgeons. **Mediflex®**

SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

STAYS THAT STAY PUT.

POSITIVE LOCKING FEATURE
Ensures the Stay stays exactly where you place it. No slippage. No repositioning. Just confidence.

Engineered for Stability. Designed for Surgeons. **Mediflex®**

SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

2X THE HOLDING STRENGTH. ZERO COMPROMISES.

POSITIVE LOCKING DESIGN
The beaded Stay securely locks behind the ring slot, delivering 2x the holding strength of competing systems.

No slipping. No unintended movement. Reliable retraction when it matters most.

Engineered for Stability. Designed for Surgeons. **Mediflex®**

SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

5mm Blunt, 12mm Blunt, 12mm Two Finger Blunt, 5mm Sharp, 7mm Two Finger Sharp

- Positive locking feature ensures position is always maintained
- Larger 'head' design allows for ease of gripping
- More secure and stronger than other brands
- Beaded design greatly reduces slippage when handling wet Stays
- Single and 2 finger hooks, sharp or blunt for superficial retraction
- Color coded to identify sharp vs blunt configurations
- Sterile packaging options of 1 or 2 Stays per pouch

REF. NO.	DESCRIPTION
41055-2	Elastic Beaded Stays, 5mm Sharp Hook, 2/Pk, 50Pcs/Bx
41055-50	Elastic Beaded Stays, 5mm Sharp Hook, 1/Pk, 50/bx
41058-2	Elastic Beaded Stays, 5mm Blunt Hook, 2/Pk, 50Pcs/Bx
41058-50	Elastic Beaded Stays, 5mm Blunt Hook, 1/Pk, 50/bx
41128-2	Elastic Beaded Stays, 12mm Blunt Hook, 2/Pk, 50Pcs/Bx
41128-50	Elastic Beaded Stays, 12mm Blunt Hook, 1/Pk, 50/bx
41075-2	Elastic Beaded Stays, 7mm Two Finger Sharp Hook, 2/Pk, 50Pcs/Bx
41278-2	Elastic Beaded Stays, 12mm Two Finger Blunt Hook, 2/Pk, 50Pcs/Bx
41278-50	Elastic Beaded Stays, 12mm Two Finger Blunt Hook, 1/Pk, 50/bx

ENTrac® Solutions for Head and Neck

Key Procedures

- ❖ Thyroidectomy, Parathyroidectomy
- ❖ Total, Subtotal Lobectomy
- ❖ Mandibulectomy
- ❖ Parotid Surgery
- ❖ Tumors

Challenges

- ❖ Small working space
 - ❖ More than 2 OR staff becomes very crowded very quickly
- ❖ Very complex anatomy
 - ❖ Head
 - ❖ Neck
 - ❖ Lymphatic System
 - ❖ Vascular System
 - ❖ Maxo-facial
 - ❖ Neuro
- ❖ Wide range of patient anatomy
 - ❖ Short, thick, obese anatomy
- ❖ Need for deep and superficial retraction
 - ❖ Relies on handheld positioning
 - ❖ Tremor
 - ❖ Workplace injuries



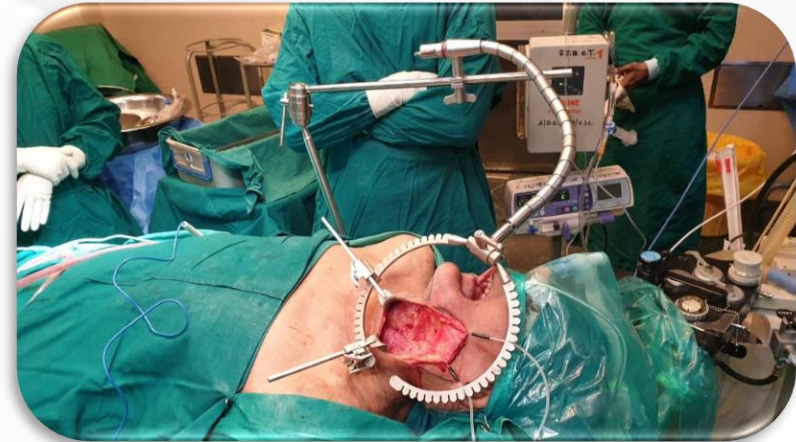
Adaptable to the most difficult of cases



Thyroidectomy



Hooks + Blades in Parotidectomy



Normally an assistance would need to stand behind the patient to assist with retraction for the entire case

ENTrac[®] Solutions for Head and Neck

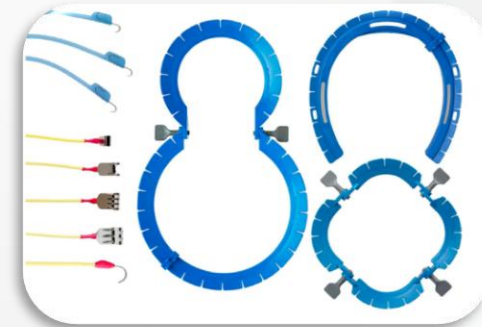


Competitor Challenges

- ❖ Only provide superficial retraction
 - ❖ Rely on hand-held retraction for deep tissue exposure
 - ❖ Crowded surgical site
- ❖ Lone Star is disposable and expensive
 - ❖ \$150-200 a procedure
 - ❖ Moves around
 - ❖ Not table mounted
- ❖ Legacy reusable retractor are considered insufficient
 - ❖ Not delicate or precise
 - ❖ Tissue trauma
 - ❖ Results in poor staff ergonomics
 - ❖ Only retract in one direction
 - ❖ One retract backwards and does not lift tissue
- ❖ Traditional competitors do not offer similar systems, only large access systems
 - ❖ Aspen
 - ❖ Omni-Tract
 - ❖ Thompson
 - ❖ Aesculap



Self-retaining/Handheld



Lone Star by Cooper Surgical



Joll-Friedman Retractor

FlexArm™ + ENTrac® Solutions for Head & Neck

Key Procedures

- ❖ Thyroidectomy, Parathyroidectomy (Open)
- ❖ Total-, Subtotal Lobectomy
- ❖ Neck Dissection (Lymph node removal)
 - ❖ Total
 - ❖ Partial
- ❖ Mandibulectomy
- ❖ Parotid surgery
- ❖ Tumors
- ❖ Laryngeal procedures
- ❖ Sleep Apnea procedures

Key Applications

- ❖ Holding Rigid Endoscope
 - ❖ Trans-Oral
 - ❖ Trans-nasal
 - ❖ Skull based procedures
- ❖ Holding Flexible Scope
 - ❖ Thyroid/Laryngeal
- ❖ Holding Retractor for open procedures

Benefits

- ❖ Reduction of handheld retraction
 - ❖ For deep and superficial retraction
- ❖ Attaches to bed so need to stabilize retractor with skin hooks/blades
- ❖ Free up space around the patient
- ❖ Improved ergonomics
- ❖ FlexArm™ allows for applications in MIS and Open procedures
- ❖ Stabilization of imaging in small areas
- ❖ Elimination of tremor
- ❖ Elimination of cognitive drift



Scope Holding



Robotic Access



Reinforcing a 'Chest Rest'

ENTrac[®] Stabilization Solutions



ENTrac for TORS



ENTrac for Thyroid



ENTrac for Parotid



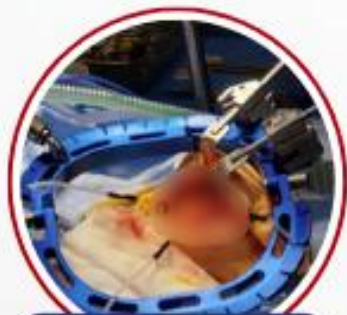
Flexible Scope Stabilization



Robotic Thyroid



Endoscope Stabilization



DynaTrac[®] Retractor



SureStay



Ear Speculum



**One Stabilization
Platform for ALL
your Surgical
Holding &
Positioning
Needs...**

QUESTION	ANSWER
I spoke to the surgeon and he says they are not starting their Trans oral RAS program till next year. Do you think there is anything else that would be of interest to them?	ENTrac® for TORS can also be utilized for video and endoscopic procedures. Whether they access the site with rigid instrumentation or robotic instrumentation, they will still need exposure and a stable surgical site to operate. It allows them to practice without the pressure of needing to dock the robot perfectly.
I did an inservice with my surgeon last week via tele-call but unfortunately the case did not go well. Do you think the surgeon should have struggled so much?	ENT surgeons are not used to using advanced retractor systems like other surgeons and need to 'hand-hold' a bit in the beginning to help them understand the technology. Having a dry setup is essential to clinical success with ENTrac®.
The doctor performing thyroid surgery claims that they have plenty of students who can help him retract. Why would they need a retractor then?	From our experience, there are at least 4 points of retraction in a thyroid case, sometimes up to 6, depending on the complexity of the procedure. It is a fairly small surgical incision (3-4cm), and there is not much room for multiple students to retract tissue in a gentle way without having tremor. Often, the student is standing in a position that does not allow them to watch the case and thus not learning. These procedures can routinely take over 1-2 hours to perform, making it very difficult for assistants not to tire and suffer ergonomically.
I just attended a head and neck open procedure and the surgeon was able to use 2 Weitliner retractor without any issue. He did rely on an assistant to retract deep tissue. Why would he feel that he does not need ENTrac®?	It is most likely that his patient was thin and had relatively easy anatomy to access. Many patients who suffer from a head & neck ailment are often obese, short and muscular anatomy that requires effective retraction to allow light to enter the cavity. In short, a surgeon can save a considerable amount of procedural time by having an effective retractor system that requires less intra-procedural readjustment by OR staff.

ENTrac® Sales Strategy & Messaging : Talk Track

Step 1: Start the Conversation

"Dr. [Last Name], are you currently using a self-retaining, table mounted or handheld retraction for establishing exposure in your head and neck procedures?" What about for your trans oral procedures?"

Let them talk. This invites a discussion without immediately pushing a product.

Step 2: Identify Their Pain Points (Sample Probing Questions)

"Does your current retractor system accommodate both disposable hook Stays for superficial retraction and scaled-down blades for deeper retraction?"

"Are you currently performing RAS TORS, and if so, are you happy with your access and exposure?"

"Are you using self-retaining retractors for head and neck access, and do you require supplemental hand-held retraction?"

"Does your facility currently have an FK retractor, and if so, did you know that it is discontinued?"

"If you could perform head & neck incision cases without an assistant for hand-held retraction, could they be performing productive tasks?... Do you think you'd have improved workflow if you could work without an assistant?"

"Are you interested in a platform that could assist in your open, endoscopic and robotic ENT procedures?"

Take note of their responses — you'll tailor your ENTrac® pitch accordingly.

Step 3: Introduce Mediflex® as the Solution

"Mediflex® has developed a novel retractor line specifically designed for Trans-Oral Robotics Surgeries (TORS) and open head and neck procedures – that improves surgeon visualization and access for a wide range of patient anatomy."

ENTrac® Resources & Assets

- Recommended sales approach
- Key talking points / elevator pitch
- Suggested questions to uncover customer needs

Mediflex® **FAQ GUIDE**
ENTrac® Retraction Systems

Q: When setting up the Bookler, how and where do you recommend setting up the field post?

A: When placing the Field Post, we generally advise to set it up opposite of the primary surgeon to reduce surgeon obstruction. The surgeon has the option of either placing the field post directly on the bed rail or over 2 layers of drapes (never directly on the bed). Some surgeons can also make a hole in the drape and will treat the field post as being partially non-sterile.

Q: The surgeon expressed some concern about the fit of the ratchets lying on the patient and leaving marks. Is there anything I can recommend?

A: Generally speaking, the ring, ratchet, and blades should be just above the skin so that there is limited contact. Some surgeons will put towels/gauze/cottons between the bottom of the fit ratchet and the skin to reduce leaving behind marks on the patient.

Q: We sold a system last year to a female surgeon but she is complaining that it is difficult to bend our malleable blades. Do you have any recommendations?

A: For surgeons who have trouble bending malleable blades, we have our blade bending tool part number 72007 which slides onto the field post and allows the surgeon to angulate the blades to the desired shape using one hand. Malleable blades are designed with a certain rigidity to ensure tissue and organs are retracted effectively while being able to change shape.

Q: I need to market the Bookler Adolescent System to a pediatric surgeon but he said that it is too large for his patients. I thought this set was for pediatric?

A: Pediatric represents a wide range of patient sizes from neonatal to toddler to adolescent to young adult. If the surgeon is operating on children under a certain weight, we would recommend the Mini-Bookler system to him. There are more post-birth defects that require surgical intervention for newborns, generally speaking, than with more mature children.

Q: I have a vascular surgeon interested in the Bookler but there is some concern that the largest ring will not let him work from the abdomen down into the groin.

A: We would simply advise to add an extra set of straight ring segments, angulating the ring, giving the surgeon the exposure he needs.

www.mediflex.com **info@mediflex.com** **1-800-362-4624** **300 Gibbs Road, Ithaca, NY 14850**

Mediflex®
ENTrac®
RETRACTION SYSTEMS

Why Choose Mediflex® ENTrac® Retraction Systems?

- Adapts to all patient sizes
- Stable table-mounted surgical access
- Lightweight design for robotic procedures
- Versatile retractor and blade options

Elevate Your Surgical Retraction

CONTACT US

to learn how our ENTrac® Systems can enhance exposure and streamline your surgical workflow

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One Platform. Absolute Retraction.

Mediflex® **CLINICAL SPOTLIGHT**
ENTrac® Retraction Systems

ENTrac® is the only retraction system on the market designed for both TORS and open Head and Neck procedures, where precise positioning and fine adjustability can make the difference between adequate and exceptional exposure. From superficial to mid and deep exposure, its modular design allows the system to be used in a wide variety of procedure from thyroidectomies and parotidectomies, to robotic assisted and endoscopic assisted procedures.

TRANSORAL ROBOTIC SURGERY (TORS)

- Radical Tonsillectomy (Transoral Robotic Radical Tonsillectomy)
- Partial Glossectomy (Base of Tongue Resection)
- Uvulotomies
- Soft Palate Resection
- Tongue Base Reduction for OSA
- Laryngeal/Hypopharyngeal Procedures
- Supraglottic Partial Laryngotomy
- Hypopharyngeal Tumor Resection

HEAD AND NECK

- Parotidectomy
- Parathyroidectomy / Thyroidectomy
- Tumor Excision
- Mandibulotomy
- Glossectomy
- Laryngectomy
- Maxillectomy

Mediflex® **TALK TRACK**
ENTrac® Retraction Systems

Use this guide to start conversations with surgeons performing open abdominal or pelvic cases and to introduce how the Mediflex® Bookler® System uses their pain points.

Step 1: Break the ice - open with empathy

"Dr. _____, when you are performing open surgery, what is your preferred retractor setup for creating exposure? What type of incisions are looking for retraction?"

Step 2: Identify the pain points

Blades and Ratchets

Q: Have you ever had your fit ratchets fall off the ring into the non-sterile field?

A: Mediflex® offers a line of fit ratchets that when onto the ring without need a staple providing counter retraction. This is especially important in any general set up where the ring is not parallel to the bed/post.

Q: Do you currently have all of the necessary Bookler Blades needed for all of your procedures?

A: Mediflex® has over 80 different blade patterns with many specialty procedures patterns.

Hospital budgetary concerns

Q: Is your hospital looking to save money while still purchasing a high quality product?

A: Mediflex® Bookler® Systems are 15-40% less than major competitors and proudly made in the USA.

Procedure time

Q: Are you interested in reducing your set up time with less components required?

A: The Mediflex® Strong Arm Plus allows for a quicker set up with less parts.

A: Mediflex® blades are all one-piece, reducing setup, cleaning, and sterilization time.

Step 3: Introduce Mediflex® as the solution

"We've heard these concerns from many surgeons, and we have listened to them. We have created a durable, dynamic retraction platform that is engineered with the highest quality materials, within the lowest budget."

System benefits to the above questions are as follows:

Step 4: Invite engagement

"Would you be open to a quick in-service or hands-on demo? (I'd love to show you how Mediflex® compares to your current setup -- and how it could simplify your next procedure."

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SureStay® Beaded Surgical Stays
For use with DynaTrac® & Mini-Bookler® Systems

• Positive locking feature ensures position is always maintained
• Larger "head" design allows for ease of gripping
• More secure and stronger than other brands
• Beaded design greatly reduces slippage when handling wet Stays
• Single and 2 finger hooks, sharp or blunt for superficial retraction
• Color coded to identify sharp vs blunt configurations
• Sterile packaging options at 5 Stay/2 Stays per package

Part No.	DESCRIPTION
72001	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72002	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72003	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72004	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72005	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72006	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72007	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72008	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72009	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72010	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"

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ENTrac® Retraction Systems

One Platform. Absolute Retraction. Designed for Versatility.

Mediflex®

Mini-Bookler® **ENT / THYROID**
Table Mounted Retractor Systems

The Mini-Bookler® product line offers miniaturized Bookler® components to enable optimal exposure in ENT/Thyroid surgery - with uncompromised field access in head and neck procedures.

• Adjustable Split Ring to accommodate any size patient
• Table mounted stabilization creates a static operative site
• Extensive offering of retractor blades for deep tissue retraction and exotic Stays for superficial retraction
• Reduces the need for hand-held retraction resulting in fewer personnel and potential work place injuries
• Procedural systems and individual component availability
• Proprietary design, manufactured in the USA

Bookler® vs. Mini-Bookler® Blades

Mediflex®

Mini-Bookler® **ENT / THYROID**
Table Mounted Retractor Systems

Applications for Mini-Bookler® Retractor System for ENT/Thyroid surgery include:
Parotidectomy • Para/Thyroidectomy • Endotracheotomy
Tumor Excision • Neck Dissection • Bypass

Surgical benefits of the Mini-Bookler® Retraction System

- Novel stabilization systems adapt to the most challenging patient positioning
- Split Ring frame is adjustable to surgical site requirements
- Creates more working space of the surgical site with fewer bodies being required

Mini-Bookler® ENT/Thyroid Basic System

Part No.	DESCRIPTION
72011	Mini-Bookler® Adjustable Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72012	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72013	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72014	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72015	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72016	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72017	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"
72018	Mini-Bookler® Split Ring, 17" Split Ring, 1/4" x 1/4" x 1/4"

Complete your Mini-Bookler® Retraction System with a Mediflex® Holding System and Surgical Stays

Holding and Positioning Systems

Part No.	DESCRIPTION
72019	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72020	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72021	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72022	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72023	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72024	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72025	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72026	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72027	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72028	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72029	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"
72030	Mediflex® Holding System, 17" Split Ring, 1/4" x 1/4" x 1/4"

Disposable Surgical Basic Stays

Part No.	DESCRIPTION
72031	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72032	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72033	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72034	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72035	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72036	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72037	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72038	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"
72039	Beaded Beaded Stay, Sharp Bead Head, 1/4" x 1/4" x 1/4"
72040	Beaded Beaded Stay, Blunt Bead Head, 1/4" x 1/4" x 1/4"

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