



CADISS[®] SYSTEM

FOR MORE SELECTIVE DISSECTION

DEVICE DESCRIPTION
&
SCIENTIFIC INFORMATION

EFFICIENT,
SAFE AND
EASY
DISSECTION



THE AIM

CADISS® facilitates the tissue dissection by weakening adhesions between tissues.



THE SYSTEM

CADISS® enables topical application of the drug at the surgery site. Within seconds, the adhesion is weakened and separation is performed with the same instrument.



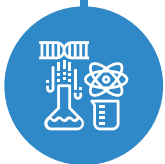
THE BENEFITS

- Reduce surgery side effects
- Reduce relapses
- Saves time
- Facilitates procedures



PROOF OF PRINCIPLE

Conclusive tests in 8 indications in ENT, neurosurgery, gynecology and gastroenterology with published results about 900 patients.



SAFETY

Absence of toxicity demonstrated, no side effects/no risks, registered as CE Class III, tested in many investigational clinical trials (13 published studies, 900 patients).

YOU HAVE TO SEPARATE TISSUES ?

CADISS® weakens the cleavage planes to facilitate the tissue separation

YES

01

IS YOUR INDICATION SUBJECT TO COMPLICATIONS?

CADISS® reduces the mechanical forces needed to separate tissues

02

IS YOUR INDICATION SUBJECT TO SIDE EFFECTS?

CADISS® protects healthy tissues during dissection

03

IS YOUR INDICATION SUBJECT TO RELAPSES?

CADISS® facilitates full withdrawal of pathological tissues

IF YOU ANSWERED YES TO ONE OF THESE QUESTIONS, CADISS® IS YOUR DISSECTION FACILITATOR AGENT

01 THE CADISS[®] SYSTEM

WHAT

Selective dissection

- Atraumatic tissue separation
- Dissection without cutting

HOW

Chemically assisted dissection

- Safe drug product
- Breaks disulfide bonds responsible for adhesences

WHERE

Many potential indications

- 2 approved indications
- 6 indications under investigation with published results

WHY

Efficiency

- Act in a few seconds
- Facilitates progression along cleavage planes

CHEMICALLY ASSISTED DISSECTION

Disulfide bonds, very frequent in fibrosis, are in large part responsible of the strength of adherence between tissues. Topical application of the drug Mesna breaks selectively these disulfide bonds, resulting in weakened adhesions. This CADISS[®] system was invented by a team of the University of Parma under the direction of Professor Carlo Zini.

SELECTIVE MECHANICAL DISSECTION WITHOUT CUTTING

CADISS[®] enables a selective dissection WITHOUT cutting by using the Mesna dispended through its surgical instruments. Therefore, surrounding organs are well preserved (nerves and veins).

02 THE ADDED VALUE OF THE CADISS® SYSTEM

Mechanical dissection is one of the methods used to separate non-infiltrating tissues when the use of non-selective cutting instruments such as electric laser knives should be avoided. The CADISS® system is unique, complementary to conventional techniques and offer many advantages to the surgeon and to the patient especially in case of risks of damaging organs, or facing relapses.

The surgeon benefits from an easier and safer surgical procedure. Moreover, by avoiding damages to healthy tissues, the patient has the advantage of a faster recovery and fewer side effects (bleedings, damages to nerves or surrounding organs). When it is critical to ensure complete withdrawal (e.g. tumors), full “en bloc” dissection is favored leading to less relapses.

Pre-clinical and clinical trials have shown that topical application of Mesna is well tolerated with clear positive effects:

Reduce surgery side effects caused by cutting instruments

Reduce relapses of non-infiltrating tumors

Facilitate clinical dissection and avoid complications

Reduce the dissection time

The method of chemically assisted dissection has been tested in preclinical and clinical investigational trials for over 20 years, and has been proven to be safe and effective. The essential requirements for CE Marking have been completed for the use of the CADISS® system in chronic otitis and epidural fibrosis indications. Additional indications are being developed.

03 THE BENEFITS ON SPECIFIC PATHOLOGIES

ENT

PUBLICATION	MESNA / PLACEBO	RESULTS	CONCLUSION OF THE PUBLICATION
Kalcioglu MT et al. Effectiveness of Mesna on the success of cholesteatoma surgery. Am J. Otolaryngol. 2014; 35 (3): 357-6.	46 / 95	Relapses from 18% to 7%	"Mesna application on COM with cholesteatoma surgery can assist in the elimination of the disease and increase surgical success by facilitating the elevation of the epithelium via breaking the disulfide bonds, which may reduce the possibility of residual epithelium after surgery."
Vincenti V Et al. Chemically assisted dissection by means of Mesna in cholesteatoma surgery. Otol. Neurotol, 2014;35(10):1819-24.	108 / 106	Relapses from 25% to 11%	"Chemically assisted dissection by means of Mesna can be a safe, inexpensive, and effective support to further reduce the incidence of residual disease in cholesteatoma surgery." "This study showed that chemically assisted dissection by using Mesna represents a valid support in reducing the frequency of residual disease in cholesteatoma surgery."
Vincenti V Et al. Cochlear effects of intraoperative use of Mesna in cholesteatoma surgery. Acta Biomed. 2014;85(1):30-4.	55 / 51	Safety: No concern	"Intraoperative use of Mesna in middle ear surgery is safe and does not lead to ototoxic effects."
Zini C et al. Chemically-assisted dissection (C.A.D.I.S.S.) in surgery: a new method to separate pathologic from normal tissues and different anatomical layers from each other. Preliminary report, Italy, 1998.	n.a / n.a	Time from 5 to 4 hours	"The chemically assisted dissection of normal and pathological tissues during surgery, permits the surgeon to be more effective, quicker and less invasive . The intraoperative use of Mesna allows preservation of the integrity of anatomical cleavage layers and easier removal of pathological tissues. In our experience, this drug substance does not cause irritation on the live tissues and it does not have ototoxic effects ." "observe a decrease of surgical time , blood loss and length of post-operative hospitalization."

REVISION SPINE SURGERY

PUBLICATION	MESNA / PLACEBO	RESULTS	CONCLUSION OF THE PUBLICATION
Denaro V et al. Mesna for chemically assisted tissue dissection	15 / 15	Side effects (Dural Tears) from 27% to 7%	"In our hands, MESNA contributed significantly to reduce the operative complications , with a diminution of the surgical time and the grade of difficulty for the surgeon, confirming its ability as chemical dissector also for epidural fibrosis in revision lumbar spine surgery."
Casale M. Mesna for chemically assisted tissue dissection. Expert Opin Investig Drugs 2010;19(6): 699-707	n.a / n.a	Expert opinion	"In revision lumbar spine surgery, its use resulted in significantly easier surgery and reduction of postoperative complications . Given the high efficacy and favorable complications rate, future applications in the surgical field are expected to increase."

The main advantages cited by clinical studies are:

- "Facilitated procedures"
- "Safe and effective"
- "Fewer side effects"
- "Shorter procedures"
- "Reduced rate of relapses"

04 PRODUCT OFFERING FOR OPEN SURGERY PROCEDURES

The CADISS® System is based on the combination between mechanical dissectors and the topical application of the drug *Mesna* on the tissues to be separated. The combination between the mechanical dissection force and the delivery of the drug is achieved by the same instrument. The instruments differ according to the type of surgery, the configuration, and the accessibility of the tissues to be dissected.

They also depend on the surgeon's preferences. Indeed, two kits are available according to the surgeon's practices, uses and desires during a surgical procedure. Most instruments are reusable after cleaning and following recommended sterilization procedures. The kits contained the cartridge and the tubing are delivered sterile for single use.



CARTRIDGE

Stores the drug substance in **stable form**.

Reconstitutes the Drug Product **before surgery**.

TUBING & PUMPING

Delivers Drug Product to the Instrument

° **Manual kit:** pump integrated in the handle (controlled by hand)

° **Remote kit:** peristaltic pump cassette integrated in the tubing (controlled by foot)

IRRIGATED MECHANICAL INSTRUMENTS

Channel instrument with specific dissection shapes

° Delivers precisely the drug through the channel at the surgery site.

THE MANUAL KIT

Disposable components



Ref. AU-0-002

combined with

THE INSTRUMENTS

Reusable components



THE REMOTE KIT

Disposable components



Ref. AU-0-001







combined with

PUMP & INSTRUMENTS

Reusable components

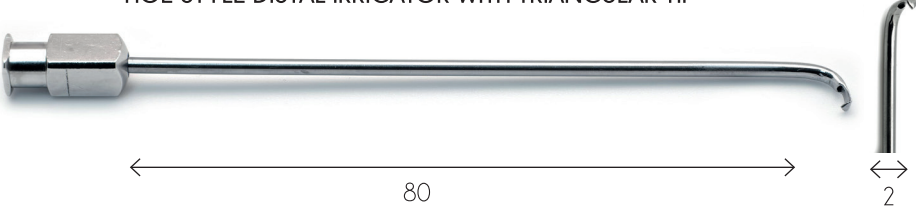
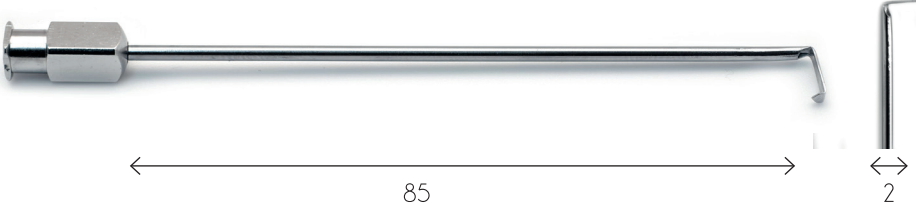
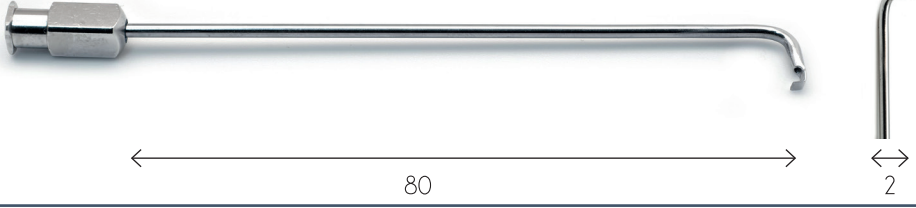


05 INSTRUMENTS CURRENTLY AVAILABLE

REF	INSTRUMENT	
AU - 4-002	 <p>← 80 →</p>	<p>DISK CANNULA</p> <p>↔ 2,8</p> <p>↔ 2,5</p>
AU - 4-003	 <p>← 80 →</p>	<p>CURVED PLATE</p> <p>↔ 3,3</p> <p>↔ 2,5</p>
AU - 4-004	 <p>← 80 →</p>	<p>JOSEPH PERIOSTEAL</p> <p>↔ 3,5</p> <p>↔ 2,5</p>
AU - 4-005	 <p>← 80 →</p>	<p>HOE-STYLE ELEVATOR</p> <p>↔ 1,5</p> <p>↔ 2</p>
AU - 4-010	 <p>← 93 →</p>	<p>SPATULA 7x4</p> <p>↔ 2,5</p>
AU - 4-014	 <p>← 80 →</p>	<p>DISK CANNULA - d2.8 1.2x0.6</p> <p>↔ 1,6</p> <p>↔ 2,5 ± 1</p>

06 INSTRUMENTS

AVAILABLE ON REQUEST

REF	INSTRUMENT
AU - 4-006	HOE STYLE DISTAL IRRIGATOR WITH TRIANGULAR TIP 
AU - 4-007	90° PROXIMAL IRRIGATOR WITH TRIANGULAR TIP 
AU - 4-008	90° DOUBLE PLATE CONTRA-ANGLE 10x10 

The showed instruments, specifically designed for open surgery procedures, are already launched on the market.

YOU NEED A SPECIFIC SHAPE
JUST CONTACT US

YOUR TAKE AWAY MESSAGES

- 1** CADISS® System facilitates your selective mechanical dissection without cutting or tearing tissues.
- 2** CADISS® System, new mode of action, weakens the adherence between tissues.
- 3** CADISS® System is easy to use and complement your existing surgery procedures.
- 4** CADISS® System is safe and preserves healthy tissues such as nerves and veins.

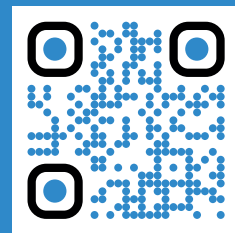


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COMPLEMENT TO SELECTIVE DISSECTION



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