

CUSA® Clarity - Selectivity study

TissueSelect® mode increases control and selectivity to reduce the risks of damaging critical structures

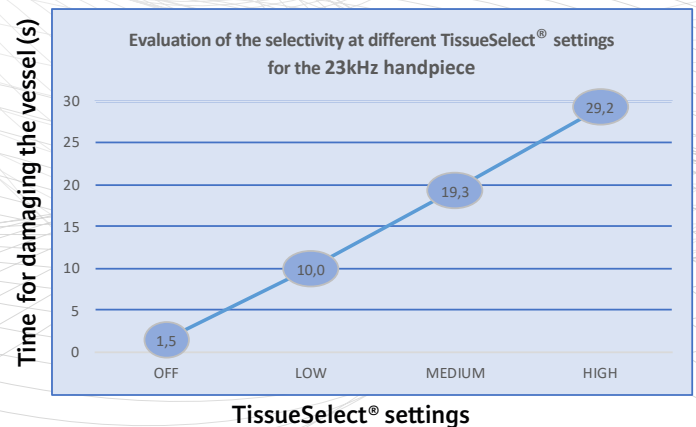
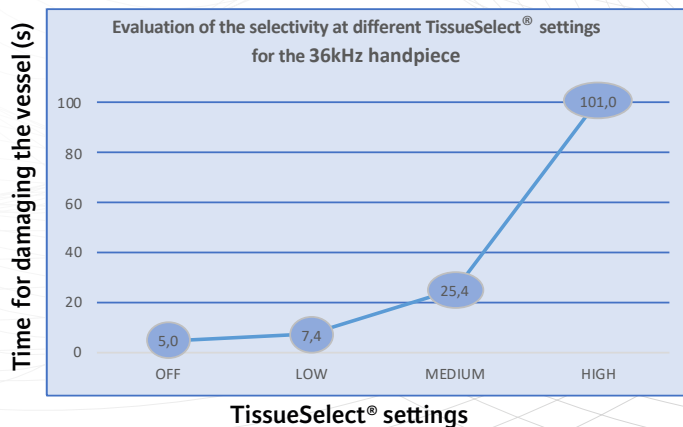
A study was conducted in partnership with Prof. Patrick Pessaux, in order to determine the impact of the TissueSelect® mode settings on the preservation of blood vessels. Professor Patrick Pessaux is the Head of the Hepato-Biliary and Pancreatic surgical Unit in the Department of Digestive and Endocrine Surgery at the University Hospital of Strasbourg, a Professor at the University of Medicine of Strasbourg, and a Researcher in the field of hepato-biliary and pancreatic diseases and of minimally invasive surgery at the IRCAD Institute of Strasbourg.

STUDY RESULTS

Selectivity is maximized when using TissueSelect® with both CUSA® Clarity handpieces

Thanks to the activation of TissueSelect® mode, the surgeon had more time to react before damaging the vessel.

A LOW TissueSelect® setting used for the 23kHz handpiece provided 6 times more time before damaging the vessel wall, compared with standard settings (off mode). Both 23 kHz and 36 kHz handpieces showed higher selectivity when TissueSelect® mode activated.



STUDY DESIGN

Objective: to assess the impact of TissueSelect® on vital structures

Material and Methods: 10 tests on one pig operated on with CUSA® Clarity using TissueSelect® mode set up from 0-Off to 4-Max

- First 5 tests were done with the 23kHz handpiece.
- The console set up was: Amplitude 40% from a maximum of 422μ, Irrigation 4mL/min and Suction at 40% from a maximum of 640mmHg.
- The following 5 tests were done with the 36kHz handpiece.
- The console set up was: Amplitude 60% from a maximum of 210μ, Irrigation 5mL/min and Suction at 55% from a maximum of 640mmHg.
- Video recording to calculate the time for damaging a blood vessel
- Surgery Process
 1. Liver resection to access a deep-seated vessel (using standard surgeon's settings)
 2. Localization and skeletonization of the blood vessel (Video starts when the vessel is skeletonized)
 3. CUSA handpiece tip **maintained on the vessel** until the vessel gets damaged
 4. Control of the hemostasis once the vessel is damaged

LIMITATIONS & DISCUSSION

- Pressure on the vein not strictly constant → The surgeon pushed harder when increasing the level of TissueSelect®
- Angle between tip and vein not strictly the same over the test
- Increased fragility of the vein over the test → Quick time for damage for the test N°10 (23 kHz – mode max). Therefore data not included for MAX mode.



CUSA® Clarity
Ultrasonic surgical aspirator

Source : Pr Patrick Pessaux – Digestive and Hepatic surgery – IHU Strasbourg IRCAD – Research Institute against Digestive Cancer

CUSA® Clarity - Selectivity study

TISSUE SELECT® MODE: Increases control and selectivity to reduce the risks of damaging critical structures

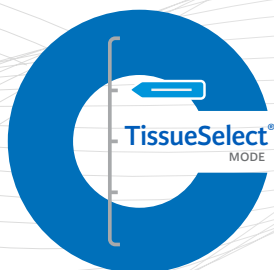
The **CUSA® Clarity System** is an ultrasonic surgical aspirator that allows a surgeon to remove tissue efficiently and selectively. It has four adjustable parameters: **Amplitude, Suction, Irrigation** and the unique **TissueSelect® mode**. They allow the surgeon to set up the tissue resection speed and the selectivity level.

Ultrasonic ablation differentiates between viscous/hydrated tissues and elastic/collagen-rich tissues by means of cavitation. **Cavitation** is the formation and collapse of bubbles, due to the movements of the Tip, that creates a chaotic stress field. This field fragments viscous/hydrated tissue more easily than elastic/collagen-rich tissue. **Cavitation** is linked directly to the **Amplitude**, and by consequence determines the impact on the tissue and the speed of resection.

The **TissueSelect® mode** is a unique feature to CUSA® and differentiates from the Amplitude. It increases selectivity to reduce the risks of damaging critical structures (vessels, pia matter, bile ducts), while limiting the decrease of the Amplitude, and thus the Cavitation effect, to maintain the speed of resection on viscous/hydrated tissue.

The **TissueSelect® mode** allows the surgeon to **optimize the combination of Speed and Selectivity**.

How does it work ?



Less shocks

+ Continuous energy is turned to **pulsed energy**, to reduce the number of strokes received by the tissue.



Rebound effect

+ The **adaptive power is reduced** to limit the additional energy delivered ordinarily to tougher structures.

Indications : The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable : Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery.

Contraindications : This ultrasonic aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

■ Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

■ Warning: Applicable laws restrict these products to sale by or on the order of a physician.

■ Consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

Products mentioned in this document are CE class I, Is, Ila, I Ib, III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

For more information or to place an order, please contact:

Sales & Marketing EMEA

Integra LifeSciences Services (France) SAS

Immeuble Séquoia 2 ■ 97 allée Alexandre Borodine

Parc technologique de la Porte des Alpes

69800 Saint Priest ■ FRANCE

Phone +33 (0)4 37 47 59 00 ■ Fax +33 (0)4 37 47 59 99

Integra Contact - Question, Information & Product Ordering

International: +33 (0) 437 47 59 50 ■ +33 (0) 437 47 59 25 (Fax) ■ csmea@integralife.com

France: +33 (0) 437 47 59 10 ■ +33 (0) 437 47 59 29 (Fax) ■ custsvcfrence@integralife.com

United Kingdom: +44 (0) 1264 312 725 ■ +44 (0) 1264 312 821 (Fax) ■ custsvc.uk@integralife.com

Ireland: +353 1800 901567 ■ +353 1822 5952 (Fax) ■ custsvcire@integralife.com

Germany: +49 (0) 2102 5535 6200 ■ +49 (0) 2102 5536 636 (Fax) ■ custsvcgermany@integralife.com

Austria: +43(0)720816067 ■ +43(0)19287201 ■ CustSvcAustria@integralife.com

Italy: +39 (0)2 577 89 21 ■ +39 (0)2 575 113 71 (Fax) ■ custsvcity@integralife.com

Belgium & Luxembourg: +32 (0)2 257 4130 ■ +32 (0)2 253 2466 (Fax) ■ custsvcbenelux@integralife.com

Netherlands: +31(0)852083167 ■ +31(0)207093627 ■ custsvcnetherlands@integralife.com

Switzerland: +41 (0)2 27 21 23 00 ■ +41 (0)2 27 21 23 99 (Fax) ■ custsvcsuisse@integralife.com

integralife.eu - integralife.com

Manufacturer:



Integra LifeSciences (Ireland) Ltd

IDA Business and Technology Park

Sragh, Tullamore,

County Offaly ■ IRELAND



2797

INTEGRA
LIMIT UNCERTAINTY

Integra and the Integra logo are registered trademarks of Integra LifeSciences Corporation in the United States and/or other countries. CUSA, CUSA Clarity and TissueSelect are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries. CUSA Quick Connect is a trademark of Integra LifeSciences Corporation or its subsidiaries. Document for use in Europe, Middle-East and Africa only. ©2020 Integra LifeSciences Corporation. All rights reserved. Last revision date: 02/2020 1328535-2-EN