Medtronic

FlexCath Cross™ Transseptal Solution

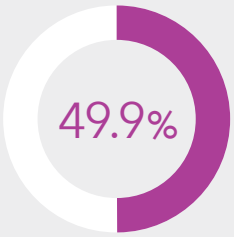
# Clinical evidence summary

## Three studies evaluated feasibility, safety, and time savings with the FlexCath Cross transseptal solution:

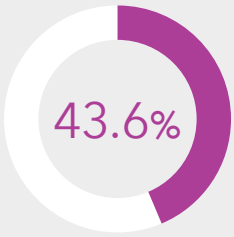
| | Rizzi, et al.[1] | Yap, et al.[2] | Yong Ji, et al.[3] |
|---|---|---|---|
| **Overview** | • Nonrandomized study<br>• Single center<br>• 40 patients<br>• AcQCross™ system vs. mechanical crossing with Abbott SL0™* sheath and dilator + BRK-1™* needle | • Retrospective study<br>• Single center<br>• 40 patients<br>• AcQCross system vs. RF crossing with Abbott SL1™* sheath and dilator + Bayliss NRG™* needle | • Retrospective analysis<br>• Single, high-volume ablation center<br>• 200 patients<br>• AcQCross system vs. mechanical crossing with Abbott SL0 sheath and dilator + BRK needle |
| **Results** | • Mean transseptal puncture (TSP) time was 3.6 ± 0.7 min in the AcQCross system group vs. 7.1 ± 0.6 min in the mechanical needle group, P < 0.01<br>• 49.9% relative reduction in the time for TSP with the AcQCross system vs. traditional mechanical needle<br>• No adverse events or peri- and postprocedural complications were noted | • Mean time for cryoballoon delivery to the left atrium was 15.5 ± 6.8 min in the AcQCross system group vs. 21.5 ± 7.4 min in NRG RF needle group, P = 0.01<br>• 27.9% relative reduction in time for cryoballoon delivery with the AcQCross system vs. NRG RF needle<br>• Procedure time was 49.7 ± 9.0 min in the AcQCross system group vs. 59.6 ± 8.1 min in the NRG RF needle group, P < 0.001<br>• 16.6% relative reduction in procedure time with the AcQCross system vs. NRG RF needle<br>• One temporary phrenic nerve injury in the AcQCross system group that resolved during the procedure | • Mean TSP time was 9.2 ± 9.5 min for the AcQCross system group vs. 16.3 ± 23.9 min for the mechanical needle group<br>• 43.6% relative reduction in the time for TSP with the AcQCross system vs. traditional mechanical needle<br>• No major safety issues were reported |

## The FlexCath Cross system is feasible[2] and safe[1-3] and demonstrated improvement in TSP[1,3] and procedure[2] time.

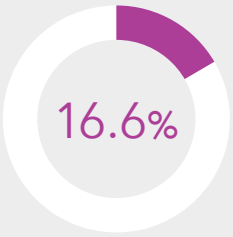
- No major safety issues were reported[1-3]
- FlexCath Cross system is more efficient and predictable in time to TS crossing[3]
- FlexCath Cross system improves efficiency in cryoballoon procedures by reducing the number of exchanges[2]




Relative reduction in **TSP time** with FlexCath Cross system vs. BRK-1[1]




Relative reduction in **TSP time** with FlexCath Cross system vs. BRK[3]




Relative reduction in **procedure time** with FlexCath Cross system vs. NRG[2]

# Bench testing to evaluate coring with RF

## Objective:

To evaluate the risk of coring with FlexCath Cross when RF energy is used

## Experimental setup:

- Swine heart attached to fixture
- Sample submerged in water bath
- FlexCath Cross needle actuated to its maximum exposure while simultaneously pushing the sharp tip into the fossa ovalis of the swine heart and "activating" the ES generator
  - Used "cut mode" at 20 W for approximately two seconds (two-time safety margin used)
- Visually inspected the FlexCath Cross and in the water bath for loose swine heart material debris
- Distal end of the FlexCath Cross was then placed in a glass beaker filled with distilled water and the guidewire was deployed through the distal end to capture any particulate into the beaker; the beaker was visually inspected


## Results:

No loose biological particulate or coring observed (n = 59)

- Visual inspection of the distal tip of the dilator and exposed needle after crossing under 10x magnification resulted in no observations of particulate matter
- Visual inspection after each crossing of the exposed needle before and after pushing a guidewire out of the distal end resulted in no observations of coring
- Each test unit was used to cross the fossa ovalis a total of five (5) times. Visual inspection of the distal tip (n = 29) after each crossing under 10x magnification resulted in no physical damage observed as a result of continued RF energy use as compared to the pre-test condition.

**References**

[1] Rizzi S, Pannone L, Monaco C, et al. First experience with a transseptal puncture using a novel transseptal crossing device with integrated dilator and needle. *J Interv Card Electrophysiol.* December 2022;65(3):731-737.

[2] Yap SC, Bhagwandien RE, Szili-Torok T. Use of a novel integrated dilator-needle system in cryoballoon procedures: a zero-exchange approach. *J Interv Card Electrophysiol.* November 2022;65(2):527-534.

[3] Yong Ji S, et al. Use of the Novel AcQCross Transseptal System Improves Procedural Efficiency Compared to Conventional Transseptal Puncture Technique. Presented at AF Symposium 2022.

**FlexCath Cross™ Transseptal Solution**

**Indications**

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. FlexCath Cross™ devices are FDA cleared. Not all FlexCath Cross devices are CE marked.

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free: 800.328.2518
Tel: +1.763.514.4000

**medtronic.com**



UC202400169 EN
09/2023

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