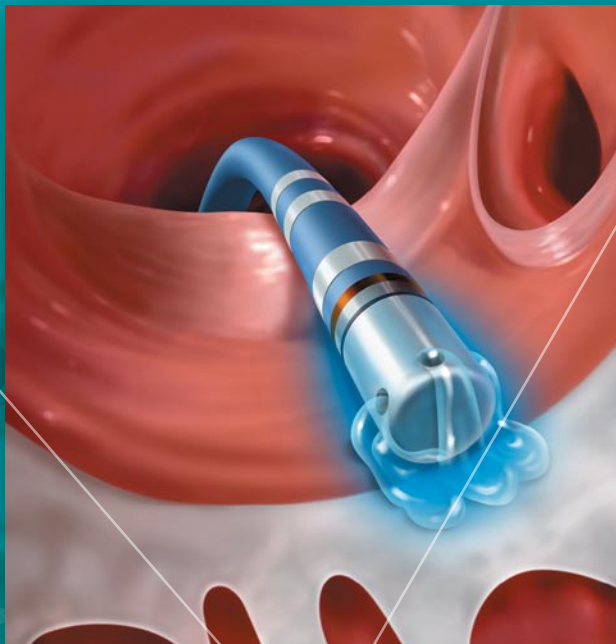


THERMOCOOL®

Irrigated Tip Catheter
And Integrated Ablation System

Ideas making a difference



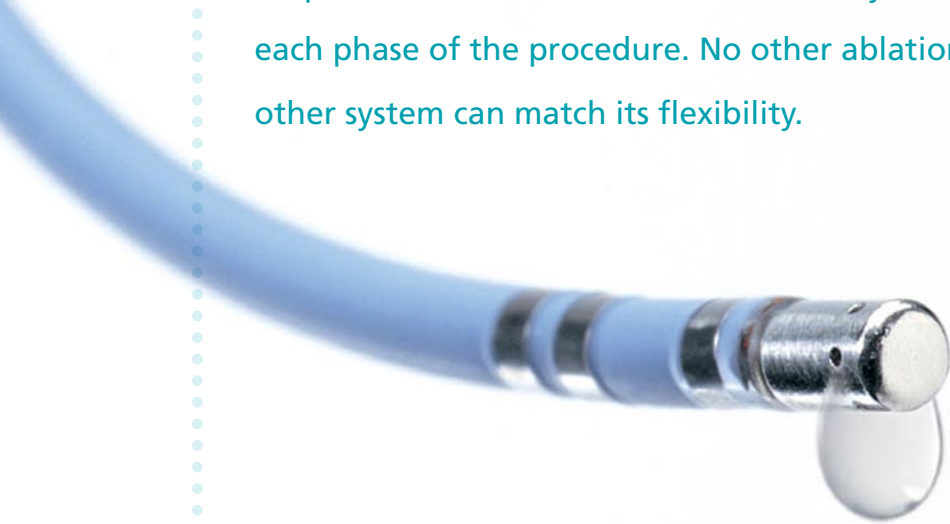
Open irrigation technology.
A new direction in power and control.

 **Biosense Webster®**
a *Johnson & Johnson* company



Create the lesion you need

The THERMOCOOL® Irrigated Tip Catheter and Integrated Ablation System is designed to improve your ability to create successful ablations with control and versatility. By controlling the power, you can create a lesion with the depth and breadth you need. And operation couldn't be simpler. One button activates the entire system—automatically performing safety checks at each phase of the procedure. No other ablation system gives you this ease of use, and no other system can match its flexibility.



THERMOCOOL® IRRIGATED TIP CATHETER

The THERMOCOOL® Catheter is the first power controlled, open-loop irrigated catheter. It is designed to maintain lower tip-to-tissue temperatures so you can deliver the power you need. This provides a range of significant benefits:

- > Reduces char and thrombus formation.¹
- > Allows you to apply the power needed to create a wider variety of lesion types and effectively monitor catheter tip cooling.
- > Active cooling permits delivery of constant, preset energy regardless of local blood flow cooling.
- > Controlled flow of cooling saline is designed to maintain safe tip-to-tissue temperature.
- > May reduce the number of RF applications needed.
- > Designed to provide shorter procedure times and reduced fluoroscopy.^{2,3}



COOLFLOW™ Pump

The COOLFLOW™ Pump delivers a constant flow of saline solution to the catheter tip to keep temperature lower while ablation energy is being delivered to the tissue. It is specifically designed to work seamlessly with the Stockert RF Generator and the THERMOCOOL® Catheter. Together, they comprise a totally integrated system.

Ease of use

- > Switches between low and high flow automatically.
- > Highly visible flow rate display.
- > Fast purging.

Safety

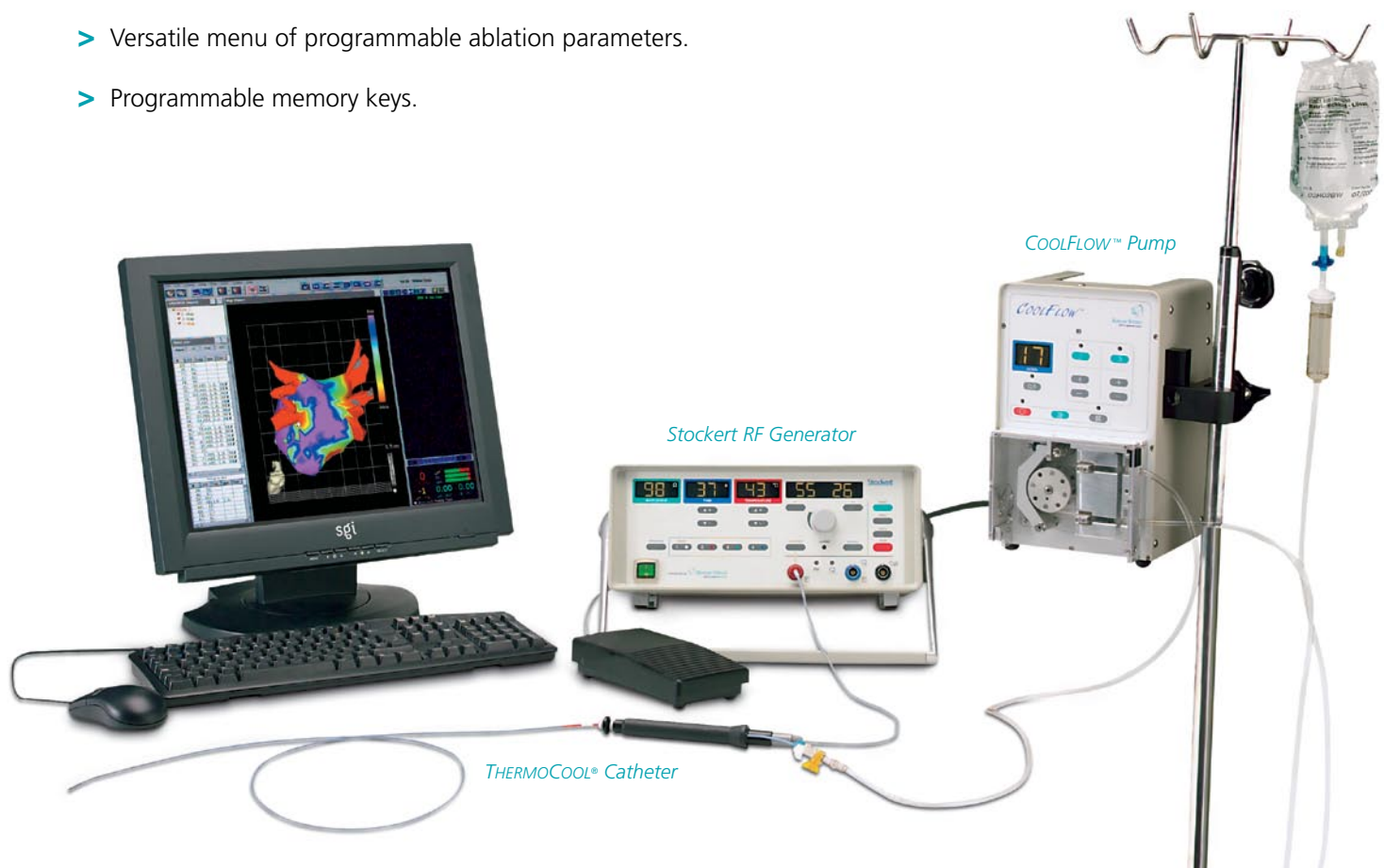
- > Dual bubble detector to minimize risk of air infusion.
- > Specially designed tubing to ensure correct loading.
- > High flow rate reminders.

Stockert RF Generator

The Stockert RF Generator utilizes the most advanced RF ablation technology to provide maximum control, exceptional safety, and unrivaled versatility.

Versatility and control

- > Stockert COOLFLOW™ Pump Interface.
- > Real-time impedance display.
- > Versatile menu of programmable ablation parameters.
- > Programmable memory keys.



Effective application of power*

- > Tip-to-tissue temperature is reduced by irrigation flow.
- > RF energy is efficiently delivered to tissue.



These ablations were created with a 4 mm catheter in temperature-control mode with limits set at 65°C at power settings of 20, 30, 40, and 50 watts for 60 seconds.

4 mm catheter, temperature control mode

Power settings	20	30	40	50
Average power output	7.5	6.5	5	5
Maximum temperature	65	65	65	65



These ablations were created with a THERMOCOOL® Catheter in power-control mode at power settings of 10, 15, 20, and 25 watts for 60 seconds.

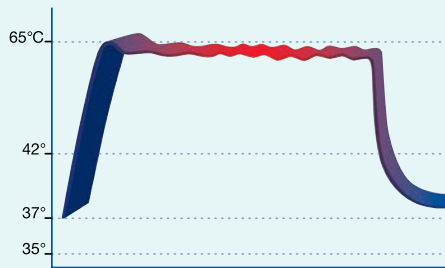
THERMOCOOL® Catheter, power control mode

Power settings	10	15	20	25
Average power output	9	13	19	23
Maximum temperature	35	39	42	41

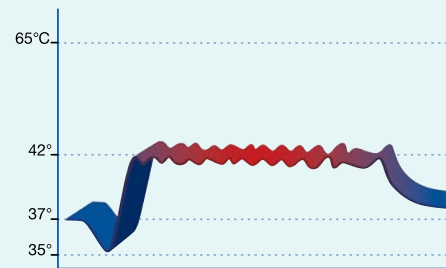
* Lesion examples *in vitro* with chicken breast meat in a wet lab setting. The exact lesion results cannot be translated directly to the *in vivo* experience.

Excellent safety features

- > Constant irrigation flow lowers tip-to-tissue temperatures and reduces the risk of charring or clotting.
- > Temperature sensor provides continuous monitoring of cooling effectiveness.



Standard 4 mm ablation catheter—Tip temperature rises to 65°C, which may cause coagulation and char formation.



THERMOCOOL® Ablation Catheter—Open, saline-irrigated catheter tip maintains a low temperature and lowers tip-to-tissue temperature, significantly reducing the risk of coagulation and char formation.

Big tip capability, small tip flexibility

The small, 3.5 mm tip of the THERMOCOOL® Catheter provides a number of advantages in ablations:

- > Provides high-quality signal resolution.
- > Creates consistent lesion sizes regardless of tip orientation.
- > Gives the physician maneuverability and flexibility.

Stockert COOLFLOW™ Pump Interface

The Stockert COOLFLOW™ Pump Interface operates as the “brains” of the system. The entire system is activated with a single touch and automatically switches between high and low flow as appropriate.

- > Fully-integrated system with enhanced safety features.
- > Generator interface provides reliable control for the entire process.

One-touch foot pedal automation so you can concentrate on the procedure.



Phase 0 Mapping

Phase 1 Pre-RF delay time

Phase 2 RF ablation

Phase 3 Post-RF delay time

Phase 4 Mapping



Pump should be set to low flow of 2 ml/min.

Pump is switched to high flow of 17-30 ml/min for 5 seconds.

Pump stays at high flow throughout ablation for 60 seconds.

Pump stays at high flow for an additional 5 seconds.

Pump switches back to low flow of 2 ml/min.



Safety Check: when pump is not switched to low flow and the generator senses the catheter has been inserted in the body, an alarm will go off (low flow check).

Safety Check: generator ensures that tip temperature has dropped by at least 2°C.

Generator starts delivering energy. Safety Check: RF energy delivery automatically stops if pump error is detected.

Generator automatically stops delivering energy.

Safety Check: built-in saline counter provides convenient fluid management.



Baseline temperature.

Temperature drops at least 2°C.

Temperature rises. Safety Check: generator automatically shuts off if tip temperature rises too high.

Temperature drops.

Temperature returns back to baseline.



No lesion.



No lesion.



Lesion forms continually while the generator is delivering energy.



Lesion continues to grow minimally.



No additional lesion growth.

NAVISTAR® THERMOCOOL® Catheter Specifications

CATALOG #	EUROPEAN ORDERING #	ELECTRODE SPACING	TIP ELECTRODE	SHAFT SIZE	CURVE TYPE	LENGTH	COLOR CODE
NI75TCBH	34H-17M	2-5-2 mm	3.5 mm	7.5F	B	115 cm	Red
NI75TCCH	34H-27M	2-5-2 mm	3.5 mm	7.5F	C	115 cm	Green
NI75TCDH	34H-37M	2-5-2 mm	3.5 mm	7.5F	D	115 cm	Blue
NI75TCFH	34H-57M	2-5-2 mm	3.5 mm	7.5F	F	115 cm	Orange
NI75TCJH	34H-J7M	2-5-2 mm	3.5 mm	7.5F	J	115 cm	Black

CELSIUS® THERMOCOOL® Catheter Specifications

CATALOG #	EUROPEAN ORDERING #	ELECTRODE SPACING	TIP ELECTRODE	SHAFT SIZE	CURVE TYPE	LENGTH	COLOR CODE
DI7TCBLRT	35Q-13R	2-5-2 mm	3.5 mm	7F	B	115 cm	Red
DI7TCDLRT	35Q-33R	2-5-2 mm	3.5 mm	7F	D	115 cm	Blue
DI7TCFLRT	35Q-53R	2-5-2 mm	3.5 mm	7F	F	115 cm	Orange
DI7TCLRT	35Q-73R	2-5-2 mm	3.5 mm	7F	J	115 cm	Black

Catheter Accessories

CATALOG #	EUROPEAN ORDERING #	PRODUCT DESCRIPTION	LENGTH (m)
C5MHNVMHS	39E-58M	Cable from Catheter to CARTO™ XP Patient Interface Unit	1.5
C5MHREFMHS	39E-59M	Cable from REFSTAR® External Reference Patch to CARTO™ XP Patient Interface Unit	1.5
C10MR10MSTKS	39E-43R	Cable from CARTO™ XP Patient Interface Unit to Stockert RF Generator Cable from CELSIUS® THERMOCOOL® Catheter to Stockert RF Generator	3.0
XRP6H	34N-01M	REFSTAR® External Reference Patch	

COOLFLOW™ PUMP and Accessories

CATALOG #	EUROPEAN ORDERING #	PRODUCT DESCRIPTION	LENGTH (m)
CFP002	N/A	COOLFLOW™ Pump consisting of: Pump, Power Cord, Stockert COOLFLOW™ Pump Interface Cable, Flow Rate Test Kit, Pole Clamp, User Manual	
N/A	CFP-001	COOLFLOW™ Pump consisting of: Pump, Power Cord, Pole Clamp, User Manual	
CFT001	CFT-001	COOLFLOW™ Pump Tubing	1.8
CFP006	CFP-006	Flow Rate Test Kit	

Stockert RF Generator and Accessories Ordering Information

CATALOG #	EUROPEAN ORDERING #	PRODUCT DESCRIPTION
S7001	39D-76X	Stockert RF Generator consisting of: Generator, Global Port, Power Cord, Grounding Cable, 3M Indifferent Patch Electrode Connection Cable, Serial Computer Cable, Optical Fiber Cable for Digital ECG/Computer, ECG Connection Cable
S7017	39D-60X	Stockert COOLFLOW™ Pump Interface Cable
S7019	39D-79X	Stockert RF Generator Remote Control consisting of: Remote, Power Cord, Remote Control Unit 10M Cable, User Manual



COOLFLOW™ Pump

Stockert RF Generator



THERMOCOOL® Irrigated Tip Catheter



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Caution: Federal US law restricts these devices to sale by or on the order of a physician. Please refer to the instructions for use accompanying each device before use. For healthcare professionals only. As part of Biosense Webster policy of continuous development, we reserve the right to change product specifications without prior notification.

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